KRUSE | LAW

MLAW PHILIPP KRUSE, ATTORNEY AT LAW, LL.M.

LEGAL STAFF
DR. IUR. MARKUS ZOLLINGER, ATTORNEY AT LAW
MLAW DANIEL LIECHTI

DEEPL TRANSLATION

REGISTERED MAIL

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Zurich, 14 July 2022
PK / MZ

Criminal complaint

Dear Madam Prosecutor, Dear Mr. Prosecutor,

in the matter of

Indicators 1-37, according to separate list,

hereinafter: the **complainants**,

all represented by
Philipp Kruse, Advocate, LL.M.,
Talstrasse 20, 8001 Zurich,
Markus Zollinger, Attorney-at-Law, Dr. iur., Talstrasse 20, 8001 Zurich,

and

Private Claimants 1-6, as per separate list,

hereinafter: the **private claimant**,

all represented by
Philipp Kruse, Advocate, LL.M.,
Talstrasse 20, 8001 Zurich,
Markus Zollinger, Attorney-at-Law, Dr. iur., Talstrasse 20, 8001 Zurich,

against

1. **[...]** Swissmedic,
   Swiss Agency for Therapeutic Products, Hallerstrasse 7, 3012 Bern,
2. **[...]** Swissmedic,
   Swiss Agency for Therapeutic Products, Hallerstrasse 7, 3012 Bern,
3. **[...]** Swissmedic,
   Swiss Agency for Therapeutic Products, Hallerstrasse 7, 3012 Bern,

and against

4. **[...]** Insel Group,
   Inselspital, University Hospital Bern, Freiburgstrasse 18, 3010 Bern,
5. **[...]** Insel Group,
   Inselspital, University Hospital Bern, Freiburgstrasse 18, 3010 Bern,
6. **[...]** Insel Group,
   Inselspital, University Hospital Bern, Freiburgstrasse 18, 3010 Bern,
7. **[...]**
   Insel Group,
   Inselspital, University Hospital Bern, Freiburgstrasse 18, 3010 Bern,
8. **[...]**
   Insel Group,
   Inselspital, University Hospital Bern, Freiburgstrasse 18, 3010 Bern,

hereinafter: the **defendants**

regarding
the urgent suspicion

**multiple (possibly) intentional, possibly negligent
violation of the duty of care under the law on medicinal products
(Art. 86 para. 1 lit. a and para. 2 lit. a HMG; possibly para. 4),**

**multiple (possibly) intentional, possibly negligent
violation of the obligation to report medicinal products
(Art. 87 para. 1 lit. c HMG; possibly para. 3),**

**multiple (possibly) intentional, possibly negligent
violation of the prohibition on advertising of medicinal products
(Art. 87 para. 1 lit. b HMG; possibly para. 3),**

**multiple (possibly) intentional, possibly negligent, homicide (
Art. 111 StGB; possibly Art. 117 StGB),**

**of multiple punishable (eventual) intentional abortion
(Art. 118 para. 2 SCC),**

**multiple serious (possibly) intentional bodily harm,
possibly negligent bodily injury
(Art. 122 SCC; possibly Art. 125 para. 1 and para. 2 SCC),**

multiple endangerment of life (Art. 129 StGB),

**multiple (possibly) intentional, possibly negligent, endangerment by genetically modified or pathogenic organisms
(Art. 230bis para. 1, possibly para. 2, StGB),**

the punishable preparatory acts under Art. 260bis para. 1 lit. a-c SCC,

**multiple (possibly) intentional, possibly negligent
forgery of documents in
office (Art. 317 no. 1, possibly no. 2, SCC),**

we submit to you the following

Criminal complaint

under the position of the following

Applications

1. A criminal investigation should be opened against the defendants.
   If necessary, the authorisation procedure should first be initiated against the defendants, whereby urgent protective measures should be taken immediately.

2. The criminal investigation was to be extended to include any other persons involved in the crime.

3. The coercive measures necessary to establish the facts of the case were to be ordered and the documents, dossiers, e-mails, internal notes, minutes of conversations, etc. that served to establish the facts were to be seized.

4. In particular, all marketing authorisation documents (modules 1-5) of Spikevax (Moderna) and Comirnaty (Pfizer/BioNTech) were to be seized for the purpose of establishing the facts.

5. All mRNA "vaccines" and batch samples in Switzerland, and possibly all those at the manufacturers' and cantonal vaccination centres, are to be seized, confiscated and randomly tested by batch by at least two independent experts in accordance with Art. 182 et seqq. StPO for their ingredients according to a standardised test protocol.

6. The evidence of all unusual deaths in Switzerland since December 2020, in which corresponding tissue samples were seized by the Institutes of Forensic Medicine following post-mortem examinations, should be seized and examined according to a standardised test protocol.

7. In view of the health problems of the victims, any hearings of the victims were to be conducted by means of a one-time video conference, while respecting the rights of participation of the accused persons.

8. The private plaintiff's right to participate in all investigative actions must be preserved.

9. The accused should be punished appropriately.

10. All with costs and compensation consequences at the expense of the accused.

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«Executive Summary»

1 37 complainants and six private plaintiffs directly harmed by mRNA "vaccinations" (all according to the rubric) file the present criminal complaint to protect their own health and out of justified concern for the health of their fellow human beings.

2 We are dealing here with the **greatest danger caused by medicinal products and already occurred injury to human health, which has ever occurred in Switzerland:** The approval and administration of the largely ineffective mRNA "vaccines" pose a far greater danger than the pathogen SARS-CoV-2, against which these "vaccines" are supposed to protect.

3 Swissmedic is primarily responsible for this risk: by law, it has the central function of protecting the health of the Swiss population. To this end, it must ensure on the one hand that only high-quality, safe and effective therapeutic products are placed on the market. On the other hand, it must protect consumers of therapeutic products from deception (Art. 1 HMG). The persons authorised to act on behalf of Swissmedic repeatedly and to a considerable extent failed to comply with these obligations, which is why they are under urgent suspicion of having committed an offence since December 2020 until today,

- repeatedly breached the **duty of care under the law on medicinal products** (Art. 86 para. 1 lit. a HMG in conjunction with Art. 3 HMG [general duty of care] and Art. 7 HMG [duty of care of the manufacturer]) in the course of the marketing authorisation and batch testing, which is deemed to be manufacturing according to the case **law of the Federal Supreme** Court. Art. 3 HMG [general duty of care] and Art. 7 HMG [duty of care of the manufacturer]), in that
  - they have granted "temporary" authorisation within the meaning of Art. 9a HMG for the mRNA "vaccines" despite the lack of sufficient evidence of efficacy and safety and despite massive risk signals,
  - they massively undercut the already very low safety precautions that are decisive for the procedure according to Art. 9a HMG and thus created risks to public health that had never been posed by a medicinal product before,
  - they have not only permanently withheld elementary information on the minimal to no protective effect of the mRNA "vaccines" as well as on the actual risk of side effects from the population and the medical profession, but have also systematically misled them,
- not having fulfilled the duty of post-marketing surveillance (so-called "pharmacovigilance") in a risk-adequate manner, but rather having permanently violated the **obliga-**

tion to report under the law on medicinal products (Art. 87 para. 1 lit. c HMG) in a serious manner,

- having seriously violated the **prohibition on advertising medicinal products under the Therapeutic Products** Act (Art. 87 para. 1 lit. b HMG),
- to have fulfilled the corresponding **offences in** the case of a "success" (death, bodily injury).

4 The breaches of due diligence complained of here essentially consist in the fact that the authorised persons acting on behalf of Swissmedic (and in principle also the notified physicians) were already aware of countless risk factors from **December 2020** onwards, each of which, taken in isolation, would have prevented the granting of the "temporary" authorisation (or the administration of the corresponding mRNA injections) until the relevant risk factors had been clarified in detail and eliminated under normal circumstances. The following should be emphasised at this point (for further risk factors see N 840):

- At the end of 2020, the mRNA technology - which has so far only been used (unsuccessfully!) as **gene therapy for** cancer patients - was to be used for the first time **on a healthy general population as** a precautionary measure (i.e. for prophylaxis). Compared to all other properly or "temporarily" approved medicines, the approval of this mRNA technology for healthy people is an absolute **abnormality**.
- **Animal studies** - a mandatory requirement for a proper authorisation and a central safety element - had not been carried out at all or not in an adequate manner.
- The **human trials on which the "temporary" approvals were based at the end of 2020 had** run for just **two months** (instead of the usual 12-24 months), thus lacking any long-term data on safety and efficacy.
- The manufacturers Pfizer/BioNTech and Moderna had **largely deprived these approval studies of** their **informative value** shortly after the start of the study by **disbanding** the **control groups.** Accordingly, it is impossible that the manufacturers will ever - and certainly not by the end of 2022, which they are legally obliged to do - be able to provide **complete clinical documentation for the** purpose of converting the "temporary" approval into a regular approval.
- It is already clear from the approval documents that **toxic, potentially mutagenic and carcinogenic impurities** are present in the mRNA "vaccines" with nitrosamine, benzene (benzene) and bacterial DNA.
- The mRNA "vaccines" also contain new, untested ingredients that have never been approved in humans before: **toxic lipid nanoparticles**. These are potentially **carcinogenic**, can potentially **impair fertility** and **harm the child in the womb.**
- A **possible risk in pregnancies** was known to Swissmedic, but was simply ignored.

- These pivotal clinical trials had already revealed clear risk signals such as **evidence of increased morbidity in the vaccine group.**
- By the end of 2020, there were already indications of possible **late effects of the mRNA "vaccines" such as neurodegenerative diseases or autoimmune diseases.**

5 Despite these and numerous other risk-increasing circumstances, the initial authorisation of the mRNA "vaccines" was "rushed through" by Swissmedic: In only 63 calendar days, the applications for authorisation were "reviewed" (an ordinary procedure would take 330 days, a procedure for "temporary" authorisation usually 140 days) and important - mandatory - milestones were simply omitted. As a result, this "time-limited" authorisation in the sense of Art. 9a HMG means nothing other than that the entire Swiss population **was** and **is** participating without their knowledge in the **largest clinical experiment that has ever been conducted in Switzerland** (and at the same time worldwide).

6 Without adequately addressing this risk (created by the "time-limited" authorisation), Swissmedic proceeded unflinchingly in **June 2021 to** extend authorisations to adolescents aged 12 and over. And this despite the fact that, in addition to all the previous risk-increasing and therefore legally relevant facts, by mid-June 2021 it was known, among other things (for further risk factors, see in detail below N 847) were known,

- that **no sufficient proof of efficacy of the mRNA "vaccines" for adolescents** had been provided in the approval studies,
- that the dose approved for adolescents was **half** (Comirnaty) or **five times** (Spikevax) **higher than the recommended dose**, thus posing a completely unnecessary risk to adolescents,
- that by February 2021 alone - i.e. within just a few months - a total of **42,086 side effects and 1,200 deaths** had been reported with Comirnaty, which should have led to the **immediate termination of the study,**
- that according to global adverse event reports, by June 2021 the **alert level of 50 deaths** had been **exceeded by a factor of over 150.**

7 Even these alarm signals did not prompt Swissmedic to seriously question the path taken. Instead, at the end of 2021, Swissmedic took the step of extending the authorisations to a third dose ("booster") and to children from the age of five years, although by this time it was known, among other things (for details of **many** other risk factors, see N 852) were also known,

- that **data** had been **falsified** within the framework of the **Comirnaty approval study,**

- that the **toxic spike protein** produced in the body of the vaccinated person is present in the body for longer - than originally stated by Swissmedic and manufacturers - and thus leads to a variety of severe side effects (up to and including death),
- that **Pfizer/BioNTech** had presented an alarming interim report ("PSUR") at the end of August 2021, according to which **46 cases** had been **fatal in the clinical trials** and **5,115 cases (1.6%)** had been **fatal in the** so-called **"post-marketing phase",**
- that **71 deaths** were recorded in children in Switzerland, the EU and the USA for Comirnaty and Spikevax alone, which means that the absolute **alarm value of 50 deaths - which would have to lead to the immediate suspension of any approval of medicines - was clearly exceeded in** this target group alone, which is in no way endangered by SARS-CoV-2,
- that only in the USA and the EU **more than 2,000 premature and stillbirths had** already been reported after mRNA injections,
- that teenagers are **six times more** likely to have **heart problems (myocarditis) caused by COVID "vaccines"** than they are to have severe COVID disease,
- that the mRNA "vaccines" (Comirnaty and Spikevax) had received **68 times the number of reports of serious adverse events** and **20 times the number of deaths per million doses administered by the** end of 2021 compared to the flu vaccines.

8 Instead of finally pausing and carrying out a detailed analysis of the decisions taken, Swissmedic continued to uphold all "temporary" authorisations in 2022, even though it was known, in addition to all previous risk and legally relevant facts (for further risk factors, see in detail below N 854),

- that worldwide (Switzerland, EU, USA) almost four million side effects had already been reported for all COVID "vaccines" by May 2021, with Comirnaty and Spikevax alone accounting for **over 1.7 million side effects** - of which **473,128 were serious** side effects and **20,381 deaths,** meaning that the **alert value of 50 deaths had been exceeded** worldwide by **over 400 times** at that time,
- that despite Swissmedic's pronouncements that the mRNA "vaccines" had no effect on pregnancy, by May 2022, **2,177 stillbirths had** already been reported **after Comirnaty injection** and **810 stillbirths after Spikevax injection** - not counting underreporting - in the EU and the USA alone, although in 2022 the manufacturers still openly admitted that **- due to a lack of appropriate studies - "the safety profile of the vaccine in pregnant or breastfeeding women** is **not known",**
- that according to a study on male fertility published in June 2022, the **sperm concentration 150 days after the 2nd "vaccination" was still 15.9% below the initial val-**

ue, which means that not only female but also male fertility is potentially negatively affected by the "vaccination",

- that in the course of several autopsies in 2022, important proof of the **lethal mode of action of the spike protein** had been provided, according to which the spike protein production caused by mRNA appears to be the causal cause of vascular lesions and (fatal) myocarditis suffered as a result,
- that with **V-AIDS,** a long-suspected and now increasingly detected serious side effect has made itself felt, which results in **damage to the immune system, which** can lead not only to the increased occurrence of autoimmune diseases and cancer, but above all to the increased occurrence of infectious diseases,
- that by 1 March 2022, at least **128 peer-reviewed publications on heart problems, 223 peer-reviewed publications on life-threatening coagulation disorders (thromboses, etc.) and 7 peer-reviewed publications on possible deaths as a result of the COVID "vaccinations"** had appeared.

9 With the "temporary" authorisation of the mRNA "vaccines", Swissmedic therefore took an **unprecedented and steadily increasing risk,** which could at best only be justified by the fact that it could have averted a threat (from SARS-CoV-2) that had never existed before and which could outweigh the risk associated with the mRNA "vaccines". This is obviously not the case. There is and never was a "life-threatening or disabling" disease with "COVID-19" - *the* main condition of the "temporary" authorisation - which would have threatened the entire population:

- In Switzerland, neither for 2020 nor for 2021 was there an overall mortality rate that (taking demographics into account) would have exceeded the maximum values of the 10 previous years.
- At no time since the outbreak of the "Corona crisis" have hospitals throughout Switzerland been overloaded. The **intensive care units,** for example, have always had a **maximum capacity utilisation of 80%** nationwide - despite the politically forced reduction of beds during the ongoing "pandemic" (!), which indicates actual **normal operation.**
- Globally, the lethality of SARS-CoV-2 for 2020 was **0.15%-0.20% (IFR), equivalent to** that of moderate influenza.
- Adolescents and children with a mortality rate of **0.002% (IFR)** have never been at significant risk from SARS-CoV-2 - to date, there has never been a single official case in Switzerland where children have been proven to have died from COVID-19.
- At the time of the "booster" approval at the end of 2021, it was also obvious that the entire population was no longer particularly threatened by SARS-CoV-2 due to the

prevailing **"delta variant"**: the lethality was still around **0.01-0.02% (IFR)** worldwide, which corresponded to a **mild flu.**

- With the emergence of the "Omikron variant", the lethality worldwide was only **0.001-0.002% (IFR). "Omicron"** is thus **at least 50 times less dangerous than normal flu for** the population as a whole.

10 According to the above, Swissmedic has authorised a highly experimental and dangerous medicinal product against a disease that poses no greater threat(s) to the population as a whole than influenza. As the last "lifeline", Swissmedic would only have to prove that the somewhat higher risk target population of elderly and pre-sick people would have been at least somewhat effectively protected against SARS-CoV-2. But this is in no way the case either. The "vaccination" clearly fails to achieve the necessary "great" effectiveness:

- The "vaccinations" would have to protect against serious (fatal or disabling) diseases. However, in the registration studies (which are still ongoing), it was primarily investigated whether the "vaccinations" protect against headaches, coughs, fever and other trivial events in combination with a positive PCR test result.
- The reported efficacy rates of up to 100% only refer to such **minor events** and are based on calculations that do not reflect reality in any way: Rather, an effectiveness in **the low single-digit percentage range** is to be assumed - if at all.
- **Not a single study has even come close to proving protection against severe disease:** the few cases investigated are in the realm of statistical chance.
- "Vaccinations" would have to "immunise" in the long term - which has not been demonstrated in a single study concerning mRNA "vaccines".
- Obviously, the mRNA "vaccines" fail to have the necessary lasting effect, otherwise no "boosters" would be propagated, which were planned from the beginning.
- In addition, since spring 2022, a worldwide trend has been apparent according to which the vaccinated are much more seriously ill than the unvaccinated: the **worldwide figures for hospitalisations and deaths are now led by those who have been vaccinated several times.** The "effectiveness" is therefore presumably negative.

11 Swissmedic has thus authorised a medicinal product on the Swiss market whose **risk-benefit profile** is **devastatingly negative. The** plan to authorise mRNA "vaccines" for all adults in Switzerland from December 2020 must be qualified as a **project with maximum, unprecedented risk content.** At the same time, the **lack of efficacy of** the mRNA "vaccines" was apparent from the outset - and has become increasingly obvious as time has gone on. An unprecedented risk, which in the meantime has already been impressively realised in a multitude of serious side effects, was and is therefore offset by a barely

measurable benefit. This consideration alone must lead to the compelling conclusion that the mRNA "vaccines" should never have been authorised and that the authorisations that were nevertheless granted represent a **massive breach of the duty of care on the part of Swissmedic.**

12 At the same time, Swissmedic did not take **sufficient risk-reducing measures** to minimise the risk to the general population posed by these mRNA "vaccines", which were authorised against the law and against recognised rules of good manufacturing practice. **In particular, Swissmedic failed to (1) ensure rigorous product monitoring and (2) provide transparent information to the public, and instead prominently disseminated misleading or outright false information:**

- Swissmedic was content with a purely passive reporting system within the framework of market surveillance, which can in no way be considered adequate in terms of risk for such a **novel medicinal product** that is **burdened with considerable** risks and is still at the stage of human trials (clinical phase III), and which is obviously inadequate. **Rather, the mRNA "vaccines" should have been subjected to active monitoring (pharmacovigilance) - as under study conditions - from the very beginning.**
- However, Swissmedic does not even enforce the passive reporting system in a legally sufficient manner: In Switzerland, compared with other EU countries, **only about 10% of all adverse drug reactions** are **reported at all.** This **massive under-reporting** makes it impossible for Swissmedic and the public to recognise the full extent of the devastating consequences.
- On 19 December 2020, Swissmedic announced in the media regarding the authorisation of Comirnaty: "This is the world's first authorisation in an **ordinary** procedure". This statement is simply false and represents a **misleading lie,** which many people still mistakenly believe to be true today - after all, this announcement can still be viewed on the Swissmedic homepage.
- In the technical information for Comirnaty, Swissmedic published in December 2020 that "no vaccine-related effects on female fertility, pregnancy, embryo-fetal development or the development of the offspring have been observed". This is in stark **contrast to the results of studies** and warnings issued by the manufacturer and expert committees, which were available to Swissmedic.
- Probably as early as the end of 2020, Swissmedic posted an **"FAQ"** on its own website directed at the population, which **contained countless misleading pieces of information** that Swissmedic was able to recognise as clear misinformation based on the data already available internally at the end of 2020.

- Moreover, it was already clear to Swissmedic by the end of 2020 that the animal studies on toxicity and pharmacokinetics were completely inadequate or even absent, although they did contain initial risk signals (such as indications of accumulation of the toxic lipid nanoparticles [LNP]). Despite this, Swissmedic announced, **without any evidence, by concealing the risk signals and thus in a misleading manner,** that it was **"not to be expected" that** components of the vaccine could be mutagenic and/or carcinogenic, or that there were **"no indications" of an** accumulation of LNP.
- On 7 May 2021, Swissmedic announced in a media release that there were **"no international indications" of an increased rate of deaths** after mRNA injection - which, in view of the **high reporting rates of 17.1-32.1 deaths per million doses administered** worldwide up to that time, once again constituted **misleading and dangerous misinformation to the public.**
- Despite explicit reference by the manufacturers to missing data ("missing information") concerning the **older, pre-diseased population,** Swissmedic did **not include a corresponding warning in the Comirnaty product information at the** end of 2021, whereupon the "booster" - in disregard of precisely this missing study data - was even recommended as a priority for this age group.
- On 10 December 2021, Swissmedic announced on its website a "High clinical efficacy in younger children" - which is diametrically **opposed to the study results. Swissmedic thus exposed the very least threatened population group to the risk of serious side effects and deaths without need and in an absolutely misleading manner.**
- In its "Vigilance News" of May 2022, Swissmedic **omitted** elementary **findings from the clinical trials**, **such as serious side effects and deaths,** thus **misleading experts.**
- The **specialist and patient information** - the basis of information for the treating doctors - is **completely inadequate with regard to contra-indications and frequent side effects:** For example, there is no reference to thromboembolic events (**thromboses** etc.), although this serious, in the worst case fatal danger (pulmonary embolisms, heart and brain strokes) has already been proven in detail in hundreds of studies worldwide and is evident from the worldwide reports on side effects.

13 This list is also not exhaustive (for further misleading information see N 845, 849, 853 and 855). The result is the picture of a **population that has not been sufficiently informed in any respect, and has even been misled, and which,** on the basis of false assumptions, has been subjected to a **completely new and dangerous gene therapy without any significant protective effect.** To this day, many people are probably unaware that

they are participating in a **worldwide human experiment.** Swissmedic (and the partly compliant doctors) knew better, or at least should have known better. All of them have long been and still are under an obligation not to allow this disastrous experiment in the first place or to do everything possible to stop it immediately.

14 Accordingly, the criminal liability of the **doctors in charge and vaccinating** the patients (in this case: the defendants of the Insel Group) must also be examined, in particular if they did not provide any or completely insufficient information to the patients prior to the application **(Art. 86 para. 1 lit. a HMG in conjunction with Art. 26 HMG) of the** mRNA "vaccines". Based on the documents available so far, it can be stated that either **no information was provided at** all or that at best only five minutes of information was documented, which is simply not sufficient in view of the complexity of the mRNA "vaccines". Without informed consent, the "vaccination" was hastily carried out, causing bodily harm or even death, which means that **offences under the Criminal Code must** also be examined. Furthermore, a **violation of the ban on advertising medicinal products** (Art. 87 para. 1 lit. b HMG) must also be examined in the case of the **medical profession,** insofar as misleading information was and is disseminated (as on the Insel Group website). In view of the massive underreporting, there is also an urgent suspicion that a large number of doctors have violated their duty of care in the area of **reporting obligations under the law on medicinal products** (Art. 87 para. 1 lit. c HMG).

15 With their grossly negligent behaviour, the Swissmedic officials (and the doctors who share responsibility) have already accepted damage to public health that goes far beyond the alleged threat posed by SARS-CoV-2. But this is obviously still not enough: Swissmedic has prepared everything in specially issued guidelines to massively increase the damage already done. According to the new guidelines, Swissmedic **intends to tolerate all conceivable manipulations (exchange of serotypes, strains, etc.) of these "vaccines" based on the illegal "temporary" initial authorisations of the mRNA "vaccines", in order to then be able to immediately authorise these modified mRNA "vaccines" - which represent completely new products and would have to go through a proper procedure - without any safety mechanisms such as preclinical and clinical studies.**

16 This planned procedure - based exclusively on emergency law - is not only in the most elementary breach of all the principles of therapeutic products law, but also of mandatory international law: according to Art. 7 and Art. 4, paras. 1 and 2 of the International Covenant on Civil and Political Rights (SR 0.103.2), no one may be subjected to medical or scientific trials without their voluntary consent - not even in the case of a public emergency. Thus, if Swissmedic actually intended to authorise **new medicines under the guise**

of a "pandemic" without any studies and without compulsory warnings - which were comprehensible and transparently communicated to everyone - the corresponding "authorisation" would lead to yet another **human experiment**, to which no one could validly consent for lack of sufficient information. This was a **blatant violation of mandatory international law, which must be prevented as a matter of urgency.**

17 Without immediate intervention at all relevant levels, the health risks and damage caused by the mRNA injections already administered and those still planned will continue to increase - without any significant positive benefit being achieved. To protect people living in Switzerland from the dangerous and largely ineffective mRNA injections, the **urgent coercive measures (house search at Swissmedic; seizure of the mRNA "vaccines")** must therefore be **taken immediately.** In addition, it must be effectively ensured that the **misled population** is **informed of the** facts of the case as soon as possible. For this reason, the undersigned lawyers reserve the right to **publish the present criminal complaint together with its enclosures in order to protect the public.**

Preliminary remark on the file regulations

18 All **publicly available sources** are listed in footnotes. For the purpose of preserving evidence, all sources other than legal literature (e.g. Basler Kommentar), Swiss case law (e.g. BGE) and legislation (e.g. embassies, ordinances) were saved digitally and are listed in a separate **list of sources** (e.g. scientific literature, Swissmedic publications), which in turn is offered as evidence.

BO: Supplement **1:** "Source list criminal complaint", 14.07.2022

19 **Evidence that is not publicly accessible (e.**g. correspondence, additional modules of the criminal complaint, named source lists) is offered as evidence in the continuous text ("offers of evidence", "BO") and listed in the list of evidence.

20 The additional modules of the criminal complaint include:

BO: Supplement **2:** "List of complainants", 14.07.2022

BO: Supplement **3:** "List and documentation of private plaintiffs", 14.07.2022

BO: Supplement **4:** "Evidence Report", 14.07.2022

BO: Supplement **5:** "Analysis 15 deaths", 14.07.2022

21 The aforementioned enclosures 2-5 in turn contain separate lists of sources and evidence, each according to the same model (public / non-public). **All four documents (enclosures 2-5) are an integral part of the present criminal complaint.**

22 All documents of the present criminal complaint (including the only digitally secured sources) are offered on a data DVD as additional evidence:

BO: Supplement **6:** "Data DVD Sources", 14.07.2022

Justification

A. FORMAL / PROCEDURAL

I. Legitimation

23 The legal representative of the private plaintiffs and complainants is duly authorised: The legitimation is based on the enclosed lists and documentation **(Annexes 2 and 3),** each with further documentary evidence.

II. Local jurisdiction

24 An offence is deemed to have been committed where the offender carries it out or remains inactive in breach of duty and where the success has occurred (Art. 8 para. 1 SCC; in some cases in conjunction with Art. 104 SCC). The authorities of that place are responsible for prosecution and adjudication (Art. 31 para. 1 Criminal Procedure Code).

1. Concerning Swissmedic

25 According to the extract from the commercial register, the Swiss Agency for Therapeutic Products Swissmedic has its registered office at Hallerstrasse 7, 3012 Bern.[1]

26 [...].

27 [...].

28 [...].

29 If Swissmedic has granted a "temporary authorisation" to COVID "vaccines" in breach of its duty of care under the law on medicinal products, and if Swissmedic maintains an inadequate reporting system which endangers the health of a large number of people or has already done so, the acts of defendants 1-3 accused in this regard are deemed to have been committed in 3012 Bern.

2. Concerning "Island Group

30 According to the extract from the commercial register, "Insel Gruppe AG" has its registered office at Freiburgstrasse 18, 3010 Bern.[2]

31 [...].

32 [...].

33 [...].

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1 Commercial Register Office of the Canton of Bern, "Internetauszug Swissmedic", 09.06.2022, https://be.chregister.ch/cr-portal/auszug/auszug.xhtml?uid=CHE-108.952.985.

2 Commercial Register Office of the Canton of Bern, "Internetauszug Insel Gruppe AG", 09.06.2022, https://be.chregister.ch/cr-portal/auszug/auszug.xhtml?uid=CHE-433.951.246.

34

[...].[3]

[...
][4]

[...[.[5]

[...].

35 If the "Insel Group" has used COVID "vaccines" on humans in breach of the duty of care under the law on therapeutic products, has reported side effects to Swissmedic in an inadequate manner and if the "Insel Group" has endangered or already injured the health of a large number of people in the careless use of the mRNA "vaccines", the offences of defendants 4-8 in this regard are deemed to have been committed in 3010 Bern and/or at Friedbühlstrasse 15 in 3008 Bern (location of the Inselspital vaccination centre).

III. Subject matter jurisdiction

36 If criminal provisions of the Therapeutic Products Act are to be examined, it must be determined whether the federal or cantonal prosecution authorities have subject-matter jurisdiction in accordance with the "split" jurisdiction provided for in Art. 90 HMG.

37 In the present case, the reported violation of the obligation to notify constitutes an offence under Art. 87 para. 1 lit. c HMG. However, there is also a strong suspicion of other - more serious - offences under the Therapeutic Products Act within the meaning of Art. 86 TPA. Swissmedic is primarily responsible for the testing and authorisation of new medicinal products (medicines) and for granting licences to companies that manufacture medicinal products or wish to trade in them (Art. 5, 9 ff., 18 f. and 28 f. TPA). Swissmedic thus controls the production of medicinal products as bulk goods.[6] Pursuant to Art. 58 para. 3 TPA

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3 [...].

4 [...].

5 [...].

6 BURRI, in: Eicker (ed.), Swissmedic, Heilmittelgesetz und Strafverfahren - Gesetzeskonkurrenzen, Zuständigkeitskonflikte und Information der Öffentlichkeit, Bern 2017, p. 147.

(HMG; SR 821.21), the Institute (Swissmedic) is also responsible for monitoring the safety of therapeutic products, which would in principle mean that the Confederation would be responsible for prosecution under Art. 90 TPA.

38 However, in the case of more serious threats of punishment under the StGB, the cantonal prosecution authority is responsible. If an offence under Art. 87 para. 1 lit. c HMG were to be assumed, the offences also alleged under the StGB would clearly take precedence and the cantonal prosecution authorities would have jurisdiction. The same would also apply if one of the offences in Art. 86 Para. 1-3 HMG were relevant: The HMG offences are only consumed by Art. 230bis Para. 1 StGB, which is also being raised here, due to the higher minimum penalty of one year's imprisonment and because of the same protected legal interests.[7] In addition, there are the offences of homicide and bodily harm under the StGB, which are also asserted here and which are in real competition with the HMG offences.[8] This means that the cantonal criminal authorities are competent.

39

[...].[9]

IV. Sufficient and urgent suspicion

40 According to Art. 309 para. 1 lit. a Criminal Procedure Code (StPO), a "reasonable suspicion" is sufficient to open an investigation, which can arise from a criminal complaint. **The principles of fair trial and legality require that an investigation be opened in**

7 BURRI, in: Eicker (ed.), Swissmedic, Heilmittelgesetz und Strafverfahren - Gesetzeskonkurrenzen, Zuständigkeitskonflikte und Information der Öffentlichkeit, Bern 2017, p. 150 FN 24.

8 BURRI, in: Eicker (ed.), Swissmedic, Heilmittelgesetz und Strafverfahren - Gesetzeskonkurrenzen, Zuständigkeitskonflikte und Information der Öffentlichkeit, Bern 2017, p. 150 FN 24; SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 8 f., N 116. Cf. also Dispatch on a Federal Act on Medicinal Products and Medical Devices (Heilmittelgesetz, HMG) of 1 June 1999, BBl 1999 III 3562.

9

[...].

case of doubt. If the requirements of Art. 309 para. 1 CCP are met, the investigation must be opened **immediately.**[10]

41 The **opening of a criminal investigation** requires the existence of a concrete or **sufficient suspicion of a** criminal offence, i.e. the necessary factual indications of a criminal offence must be of a concrete nature. The suspicion is concrete if there is a **certain probability that the offender will** be **convicted.** The totality of the factual indications must permit the plausible prognosis that the accused will be convicted with some probability.[11] According to Federal Supreme Court case law, suspicion of a crime is considered sufficient if **detailed allegations in the criminal complaint do not appear to be completely implausible or without any doubt unfounded** - especially if the criminal complaint is filed by a lawyer who is aware of the implications of such a step and does not take it lightly and without reason.[12]

42 If there is a **substantial probability of a subsequent conviction** because there are substantial factual indications pointing to the commission of a criminal offence, then there is an **urgent suspicion of the offence,** which is a prerequisite for **ordering coercive measures** within the meaning of Art. 196 Criminal Procedure Code.[13]

43 In the following material part, an overwhelming number of factual indications are presented, each of which is sufficient to open a criminal investigation (probable cause). Since the evidence and circumstantial evidence is already presented in such a condensed manner, there is a considerable likelihood of a subsequent conviction (**strong suspicion**), **at least with regard to the reported HMG offences and the negligence offences of the StGB,** which is why coercive measures are to be ordered immediately.

V. Authorisation procedure (Swissmedic)

44 Swissmedic is an institute under public law which, in accordance with its purpose, fulfils the tasks assigned to it by law and assigned to it by the Federal Council within the framework of its performance mandate. [14]

45 According to Art. 1 para. 1 LCA (SR 170.32), all persons to whom the exercise of a public office of the Confederation is entrusted are subject to the Responsibility Act, namely the members and substitutes of authorities (and commissions) of the Confederation that are

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10 BOSSHARD / LANDSHUT, in: Donatsch et. al. [eds.], Kommentar StPO, 3rd ed., Zurich 2020, Art. 309 N 10a.

11 BOSSHARD / LANDSHUT, in: Donatsch et. al [eds], Kommentar StPO, 3rd ed, Zurich 2020, Art. 309 N 25.

12 Thus BGE 106 IV 413 E. 4a p. 418 f.

13 BOSSHARD / LANDSHUT, in: Donatsch et. al [eds], Kommentar StPO, 3rd ed, Zurich 2020, Art. 309 N 27.

14 Commercial Register Office of the Canton of Bern, FN 1.

outside (the federal courts and) the federal administration (lit. d), as well as all other persons insofar as they are directly entrusted with tasks of the Confederation under public law (lit. f). Persons 1-3 (Swissmedic) are thus likely to be subject to the protection of the Responsibility Act.

46 Art. 15 para. 1 VG provides that the prosecution of civil servants for criminal offences relating to their official activity or position, with the exception of offences in road traffic, requires the authorisation of the FDJP. The authorisation must be obtained by the cantonal prosecution authorities "without delay" at the beginning of criminal proceedings, and **urgent protective measures must be taken in parallel** (Art. 15 para. 2 VG). However, a delayed authorisation does not result in the nullity of the criminal judgment if it is obtained at the beginning of the proceedings before the higher cantonal instance and the latter is entitled to full legal and factual cognition (BGE 139 IV 161 E. 2.5 p. 166 f.).

47 If an offence and the legal requirements for prosecution appear to be fulfilled, the authorisation may only be refused in minor cases and if the offence appears to be sufficiently punishable under all circumstances by a disciplinary measure taken by the offending party (Art. 15 para. 3 VG). A "minor case" was assumed for an offence of up to approximately CHF 500 (BGE 139 IV 161 E. 2.3 f. p. 165). The present allegations are far more serious and clearly do not constitute a minor case. Since - as shown below - various elements of the offence appear to be fulfilled and the other requirements for prosecution are met, the authorisation must be granted by the FDJP. An appeal must be lodged against any refusal of authorisation (Art. 15 para. 5 and para. 5bis VG). **In addition, urgent measures - in particular house searches to be carried out (N 73 ff.) - must be carried out in parallel and thus without delay.**

VI. Victim interviews

48 Only those who have the capacity to act (Art. 106 para. 1 Code of Criminal Procedure), i.e. who are physically and mentally able to follow the proceedings, have the capacity to stand trial. As a rule, serious illnesses are likely to negate the ability to stand trial and be heard.[15] Should the prosecuting authority deem it necessary to hear victims in addition to the material evidence (such as patient files) in order to establish the facts of the case, any victim hearings must be conducted by video conference in the event of health problems (Art. 144 Criminal Procedure Code; Art. 78 para. 6 Criminal Procedure Code).[16] The public prosecutor's office must ensure that the person to be interviewed is not exposed to any influence by third parties during the video conference.[17] A right of participation modified in

15 WEHRENBERG, in: BSK StGB, 4th ed., Basel 2019, Art. 114 StPO N 7.
16 See HÄRING, in: BSK StGB, 4th ed., Basel 2019, Art. 144 StPO N 6.
17 GODENZI, in: Donatsch et al. [eds.], Kommentar StPO, Art. 144 N 4.

this way depending on the situation is permissible: The requirements of Art. 144 Code of Criminal Procedure form the basis for the partial restriction of the physical right to participate in audiovisual hearings. The parties' rights of participation are sufficiently safeguarded if they can attend the audiovisual hearing and have the opportunity to ask supplementary questions (via video conference).[18]

49 Taking into account the respective state of health of the victims, it must also be ensured that they do not have to testify more than once if possible, but that a single video conference takes place per victim while safeguarding the participation rights of the accused persons (analogous to Art. 155 para. 1 and Art. 154 para. 4 lit. b and c Criminal Procedure Code). This is subject to cases of urgent preservation of evidence (such as imminent total incapacity to stand trial), whereby the rights of participation of the accused persons may be granted after the fact, depending on the state of health of the victims. If the presentation of the facts of the case is based on statements by respondents or witnesses, the rights of participation of the accused person must be safeguarded (Art. 147 ff. Code of Criminal Procedure). An incriminating (witness) statement is admissible if the accused has had reasonable and sufficient opportunity at least once during the proceedings to cast doubt on the statements and to ask questions of the person incriminating him or her (BGE 133 I 33 E. 3.1; Federal Supreme Court judgment 6B_492/2015 of 2 December 2015 E. 1.2.1; Federal Supreme Court judgment 6B_183/2013 of 10 June 2013 E. 1.3). In addition, it should be noted that evidence that criminal authorities have collected in violation of validity provisions (such as Art. 147 para. 4 Criminal Procedure Code) may nevertheless be utilised, provided that its utilisation is indispensable for the investigation of serious criminal offences (generally crimes, such as Art. 111 Criminal Code) (Art. 141 para. 2 Criminal Procedure Code).[19]

VII. Private plaintiff

1. Constitution

50 The aggrieved persons 1-6 listed according to the heading constitute themselves as private plaintiffs within the meaning of Art. 118 StPO .

51 Any necessary criminal charges are equivalent to this constituent declaration (Art. 118 para. 2 Code of Criminal Procedure).

18 On the whole, HÄRING, in: BSK StGB, 4th ed., Basel 2019, Art. 144 StPO N 10a

19 GLESS, in: BSK StPO, 2nd ed., Basel 2014, Art. 141 StPO N 67, N 72.

1.1. Constitution as a criminal prosecution

52 The private prosecution expressly demands the prosecution and punishment of the persons responsible for the offences (Art. 119 para. 2 lit. a Criminal Procedure Code).

53 As a criminal plaintiff, the private plaintiff has full party status (Art. 104 para. 1 lit. b Code of Criminal Procedure).

1.2. Constitution as a civil claimant

54 Moreover, the private plaintiff also constitutes itself as a civil plaintiff and examines the assertion of claims under private law by way of adhesion (Art. 119 para. 2 lit. b Code of Criminal Procedure).

55 A quantification of the civil claim is expressly reserved (Art. 123 Code of Criminal Procedure).

2. Brief explanation of the injured party's position

56 The detailed justification of the position of the aggrieved party, including evidence (offers of proof), is provided in the separate document "List and Documentation of Private Claimants" (Annex **3**) .

57 At this point, it should be noted for the sake of form that the private plaintiffs named were directly violated in their rights by the offences denounced (Art. 115 para. 1 Criminal Procedure Code); in detail:

2.1. Private plaintiff 1

58 Private plaintiff 1, who was approximately 45 years old during the relevant period, received an mRNA injection from Moderna in April 2021.

59 Within 5-15 minutes of this injection, Private Plaintiff 1 suffered a Grade III anaphylactic shock and survived only thanks to immediate emergency admission to hospital and intensive medical care there. Her "vaccinating" family doctor was aware that Private Plaintiff 1 had already suffered Grade III anaphylactic shock twice after ingesting peanuts. To this day, the private plaintiff continues to suffer from various physical ailments. She was exempted from further mRNA injections, as they are life-threatening for her.

2.2. Private plaintiff 2

60 Private Plaintiff 2, who was 43 and 44 years old respectively during the relevant period, received two injections of "Moderna" in May and June 2021 and the "booster" of "Moderna" in December 2021.

61 After the second mRNA injection, strong reactions occurred for the first time (pain), but these were not yet associated with the injection. Shortly after receiving the "booster", the pain then worsened considerably (back and legs). The joints were swollen and the private plaintiff 2 could no longer move, which led to an emergency admission to hospital by the family doctor on 19 December 2021.

62 In February 2022, the evaluation of a blood test revealed a reactivation of viruses (adenoviruses, Epstein-Barr virus **[EBV],** herpes simplex virus). The state of health continued to deteriorate until in March 2022 the skin turned blue/purple and the private plaintiff had to go to hospital as an emergency. Various examinations and treatments were carried out at the hospital; the private plaintiff was discharged on 01 April 2022.

2.3. Private plaintiff 3

63 The private plaintiff 3, who was 47 years old during the relevant period, received an injection of Moderna in August 2021. From the second day after the mRNA injection, migraine-like headaches and increased pressure in the head occurred, which was accompanied by latent fatigue.

64 About a week after the mRNA injection, tachycardia (heart palpitations) occurred for the first time (which had been successfully treated a few years earlier). About 10 days later, atheromas appeared in the armpit area (sebaceous cyst) and about one month after the "vaccination", circular hair loss occurred. In addition, there was an unexplained weight gain and the menstrual cycle was completely derailed (cramp-like pain in the middle of the cycle, previously unknown heavy menstrual bleeding).

2.4. Private plaintiff 4

65 Private Plaintiff 4, who was 27 years old during the relevant period, received mRNA injections from Pfizer/BioNTech in June and July 2021.

66 About 1-1½ h after the second "vaccination", private plaintiff 4 became increasingly worse (dizziness, feeling of weakness, fever > 40 degrees, chest pain, shortness of breath, fainting several times). Despite several examinations and a stay in rehabilitation, Private Claimant 4's state of health continued to deteriorate. In December 2021, a possible reacti-

vation of the Epstein-Barr virus **(EBV) was** diagnosed, among other things. In March 2022, an allergy to polysorbate 80 was diagnosed and based on this, a "booster vaccination" was explicitly not recommended.

2.5. Private plaintiffs' association 5

67 The 20-year-old daughter of private plaintiff 5 received the mRNA injection from "Moderna" twice in 2021 and the one from "Pfizer" once in 2022 ("off-label").

68 Subsequently, the "vaccination" presumably led to an activation of the Epstein-Barr virus **(EBV;** possibly also to an activation of blood clotting) in the previously healthy young woman, whereupon the 20-year-old died of a ruptured spleen (possibly also of a pulmonary embolism) on 1 April 2022 after a rapid deterioration and very short treatment in hospital. After the Institute of Forensic Medicine had determined a natural cause of death after a superficial autopsy, had flatly denied any connection with the "vaccinations" and had not investigated the same in any way, **the public prosecutor's office ordered a supplementation and improvement of the forensic medical report at the end of June 2022 at the request of the private plaintiff.**

2.6. Private plaintiff 6

69 Private plaintiff 6, who was 17 years old during the relevant period, received mRNA injections from Pfizer / BioNTech in January and March 2021,

70 Immediately after the first injection, very severe headaches, pain in the limbs and high fever began; Private Plaintiff 6 had reported the severe headaches before the 2nd injection. In July 2021, Private Plaintiff 6 developed acute severe spasms in the form of twitching, uncontrolled movements and uncontrolled eye-twisting. The eye-twisting has not subsided till date. Her blood values are strongly outside the normal range.

VIII. Inspection of the files of private plaintiffs

71 The aggrieved complainants constituted as private plaintiffs must be granted access to the files at the latest in accordance with Art. 101 para. 1 Code of Criminal Procedure (Art. 104 para. 1 lit. b Code of Criminal Procedure).

72 If experts are to be appointed, the private plaintiff shall request prior access to the file and the opportunity to comment within the meaning of Art. 184 para. 3 Code of Criminal Procedure. In any case, however, access to the file must be granted in accordance with Art.

188 and Art. 189 SCC, including all files and documents on which any expert opinion commissioned is based.[20]

IX. Seizures (and confiscations)

73 According to Art. 263 para. 1 CCP, objects belonging to an accused person or a third party may be seized if the objects and assets are likely to be used as evidence (lit. a) or are to be confiscated (lit. d; in particular, security confiscation under Art. 69 SCC). **Urgent protective measures must be taken in parallel with any proceedings for authorisation** (art. 15 para. 2 VG; see above N 46). Coercive security measures are permissible, for example, if the mere request for disclosure would frustrate the purpose of the measure (Art. 265 para. 4 Code of Criminal Procedure).[21] Since in the present case there is a risk that the mere request to hand over the evidence listed below will lead to acts of thwarting on the part of the defendants, and since on the basis of the present explanations there is a considerable danger to public health, the preservation of evidence described below must take place predominantly within the framework of **house searches** (Art. 244 para. 2 lit. b and c Criminal Procedure Code).

1. Securing approval documents (application 4)

74 As also at the back (N 264 ff.), there is practically no publicly available regulatory documentation concerning the approval of the mRNA "vaccine" from Spikevax (Moderna). This is in open contrast to Comirnaty - but only because Pfizer (or the US regulatory authority FDA) was forced by US lawyers to hand over the documents.[22] Since the corresponding court order, thousands of pages have been gradually released to the public since around the beginning of 2022, whereby the FDA (or Pfizer) had originally wanted to keep this data (approx. 451,000 pages) under lock and key until 2076 (!) and is now, despite the court order, continuing to try by all means to delay the release.[23]

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20 DONATSCH, in: Donatsch/Lieber/Summers/Wohlers [eds.], Kommentar zur Schweizerischen Strafprozessordnung, 3rd ed., Zurich/Basel/Geneva 2020, Art. 189 N 3.

21 BGE 143 IV 270 E. 7.5 S. 283

22 Civil Action No. 4:21-cv-01058-P, Public health and medical professionals for transparency against food and drug administration, 15.11.2021, https://www.sirillp.com/wp-content/uploads/2021/11/020-Second-Joint-Status-Report-8989f1fed17e2d919391d8df1978006e.pdf.

23 On the whole: SIRI, "FDA Doubles Down: Asks Federal Judge to Grant it Until at Least the Year 2096 to Fully Release Pfizer's COVID-19 Vaccine Data", 08.12.2021, https://aaronsiri.substack.com/p/fda-doubles-down-asks-federal-judge?s=r; SIRI, "FDA Asks the Court to Delay First 55,000 Page Production Until May and Pfizer Moves to Intervene in the Lawsuit", 26.01.2022, https://aaronsiri.substack.com/p/fda-asks-the-court-to-delay-first?s=r.

75 The same picture can be seen in Germany, but the competent authorities (especially the Paul Ehrlich Institute [PEI]) have so far failed to respond to legal requests, either completely or at least materially, without even a rudimentary explanation. Although the requested authorities have even admitted that they have the requested documents, their release has so far been refused and delayed with ever new excuses.

BO:	Supplement **7:**	Request University of L. to Paul Ehrlich Institute, "Subject: Our request according to §1 IFG of 3.3.2022 [...]", 13.04.2022
BO:	Supplement **8:**	Law firm R.: "Inquiry by Professors Prof. Dr. M. et al. [...]", 14.04.2022
BO:	Supplement **9:**	Law firm R.: "Inquiry of Professors Prof. Dr. M. et al. [...] - My letter of 13 April 2022", 29.04.2022

76 In Switzerland, too, no data from the registration documents have been published so far. As explained below (N 815), Swissmedic has not even published the **batch release protocols** since September 2021 for unknown reasons**.**

77 This **complete lack of transparency** is incomprehensible and downright unacceptable in view of the mRNA "vaccines" that are still in the experimental phase. In addition, the relevant authorisation documents (incl. batch release protocols) are indispensable for assessing the criminal liability of the persons acting on behalf of Swissmedic as well as other perpetrators. Even from the few Comirnaty documents available, **serious irregularities and indications of information suppressed from the public on the part of Swissmedic** emerge. There is not a single rational or legal reason not to publish this elementary data - unless there is something to hide, which the first leaks and the forced - not even remotely complete - release of the Pfizer documents unfortunately suggest in no uncertain terms (for more on these, see N 172, N 185 f., N 192 ff., N 271 ff., N 274 ff., N 279 ff., N 334 f., N 336).

78 In favour of **Proposal 4,** all Spikevax marketing authorisation documents, including batch release protocols, must therefore be seized and confiscated as part of the evidence gathering process. Since the competent foreign authorities such as the FDA (USA) and the PEI (Germany) oppose the rapid release of the Comirnaty documents, these should also be seized from Swissmedic in accordance with Art. 263 para. 1 lit. a Criminal Procedure Code. With regard to Proposal 5 concerning Module 3 (Quality), the following must be ensured in particular:

a. Methods of analysis and control of all ingredients, including the active ingredient, lipid nanoparticles, and the finished product.

b. Manufacturing and testing protocols for the individual manufacturing steps of the active substance, the lipid nanoparticles and the finished product.

c. Release specifications of the finished product.

d. Batch release protocols of all batches released by Swissmedic.

e. Certificates of analysis from the manufacturers of the active substance, excipients and finished medicinal product.

f. Excipient Master Files for excipients not listed in the European Pharmacopoeia

g. Control methods for the analysis of mRNA for purity and identity.

h. Control methods for the analysis of the amount of mRNA contained in the finished medicinal product.

i. Control methods for analysis for mRNA concentration determination and distribution when using multi-dose containers.

j. Control methods to ensure that no proteins other than the spike protein are formed in the body.

k. Studies on the pharmacokinetics of the ingredients and their biodegradation products.

l. Toxicity, genotoxicity and carcinogenicity studies of all components.

2. Securing "vaccines" and batch samples (Motion 5)

79 In favour of **Motion 5,** all mRNA "vaccines" (Comirnaty; Spikevax) throughout Switzerland - at least those stored at the official "vaccination centres", the Swiss army and the manufacturer Moderna - including batch samples are to be seized and confiscated on the following (alternative) grounds:

BO: Supplement **10:** "List of addresses of vaccination centres CH", 01.04.2022

2.1. Seizure as evidence

80 The mRNA "vaccines" are to be confiscated as evidence so that they can finally and for the first time be subjected to a high-quality independent official examination with regard to the ingredients. In particular, the mRNA "vaccines" on the market are to be compared with the batch samples[24] that must be provided and retained on the occasion of the batch release (see N 813 ff.).

[24] On this retention obligation, see DUPASQUIER/BOEHM, BSK HMG, 2nd ed., Basel 2022, Art. 7 N 11.

2.2. Seizure for the purpose of confiscation

81 According to Art. 69 SCC, objects are to be confiscated *without regard to the criminal liability of a specific person if they have* served or were intended for the commission of a criminal offence or have been produced by a criminal offence if these objects endanger the safety of people, morality or public order.

82 Confiscation by way of security presupposes an offence that is objectively and subjectively constituent and unlawful. However, the decision on confiscation is independent of the decision concluding the criminal proceedings, even if it is not a convicting decision; this is because **confiscation is possible without regard to the criminal liability of a specific person** and therefore does not require criminal proceedings to be conducted against a specific person. Nor does the presumption of innocence preclude confiscation.[25]

83 The danger of a (further) criminal use of the object can result from its nature as well as only from the expected use by its owner. Accordingly, the prosecution authorities have to make a prognosis as to whether it is sufficiently probable that the object in the hands of the offender will endanger the safety of people, morality or public order in the future.[26] The requirements for endangering are not too high: public order can already be endangered by counterfeit objects.[27]

84 Already by way of introduction (front N 1 ff.) and in detail at the back (e.g. N 155 ff. , N 165 ff.), it is shown that the mRNA "vaccines" are toxic, potentially carcinogenic and possibly even mutagenic, while they are in no way effective in protecting against SARS-CoV-2. The mRNA "vaccines" therefore pose an unjustifiable major threat to human health safety, which is why they must be withdrawn from circulation immediately in order to protect public health.

3. Seizure of evidence of performed autopsies (Motion 6)

85 As at the back (N 313 ff.), there is a massive under-reporting of deaths presumed to be directly related to the mRNA "vaccines" due to autopsies not being performed or not being performed with sufficient specificity. This makes it considerably more difficult to prove a direct causal link between "vaccination" and "death".

86 The analysis of the 15 deaths (Annex **5**), which are at least chronologically closely related to mRNA "vaccinations", shows that in at least some cases, evidence of first autopsies

25 BGE 117 IV 233 E. 3 p. 237; HUG, in: Donatsch [ed.], op. cit., Art. 69 N 5.
26 BGE 116 IV 117 E. 2a p. 119 f.; HUG, in: Donatsch [ed.], op. cit., Art. 69 N 7.
27 BGE 101 IV 36 E. III.7. p. 41; BGE 89 IV 62 E. 2d p. 70.

must still be available, as these must be preserved for at least six months beyond the time of the preparation of the expert opinion.

87 In favour of **Motion 6, the** evidence must therefore be seized immediately (for seizure pursuant to Art. 263 para. 1 lit. a Code of Criminal Procedure) at least with regard to the deaths on 02.01.2022, 03.01.2022 and 16.01.2022, and moreover with regard to the deaths on 12.02.2021, 13.02.2021, 13.02.2021, 15.02.2021 and 09.06.2021. Furthermore, the competent public prosecutor's office is requested to immediately order the competent police to investigate further deaths of a similar nature and to seize the corresponding evidence.

X. Appointment of experts

88 Within the meaning of Art. 182 et seq. StPO, the following expert examinations are to be carried out and corresponding experts are to be appointed:

1. "Vaccines": Examination by means of test protocol (application 5)

89 **If Motion 5 is** approved, the seized mRNA "vaccines" must be subjected to an independent and thorough review.

90 Primarily, all quality controls (allegedly) carried out by the manufacturers must be checked on the basis of the manufacturing and testing protocols of the manufacturers themselves. Accordingly, the securing of the corresponding protocols for Module 3, as requested in Proposal 4, is of central importance. In addition, the mRNA "vaccines" must be checked for declared and undeclared ingredients in order to be able to identify all the ingredients contained per "vaccine" and batch. Without precise knowledge of all ingredients, it will not be possible to provide the right medical help to the numerous people in Switzerland who have already been affected by vaccine side effects.

2. Post-mortem examinations: Second examination on the basis of examination protocols (Proposal 6)

91 In favour of **Proposal 6, the** following investigations shall be carried out in particular:

2.1. Standardised protocol Prof. Burkhardt

92 A second examination is to be carried out on the basis of the recovered evidence. The re-examination must be carried out on the basis of a protocol which not only superficially searches for the obvious final causes of death (such as organ damage and haemorrhages), but which also investigates the causal cause of these final causes of death - e.g. vas-

cular damage caused by toxic ingredients of the vaccine or components produced by it (in particular spike protein).

BO: Supplement **11:** Autopsy protocol Prof. Dr. A. Burkhardt, "Notes and recommendations for conducting post-mortem examination (autopsy) of persons deceased in connection with COVID vaccination", 17 March 2022

93 If the institutes of forensic medicine are technically or for other reasons not able to do so, the institutes must report this immediately and give reasons. **The private plaintiff offers to call in and make available at its own expense appropriate experts (in particular pathologists) who will carry out the examination at the institute under the supervision of the competent institute.**

2.2. Addition to the protocol: qPCR and DNA sequencing

94 As an essential characteristic of all Corona "vaccines", the manufacturers had stated that the mRNA components remain at the injection site and that they do not spread in the body and organs. In recent months, however, this has been proven to be clearly false information (for more details see N 185 ff. , cf. also N 265 ff.). If parts of the "vaccine" mRNA are found in the tissue of various organs of the deceased, this indicates an unintended mode of action of the mRNA therapy and the existence of a corresponding causal connection with the death of the deceased. RNA viruses and mRNA also have the - in itself "undesirable" - potential to integrate into human DNA (for more on this see N 148 ff.), which also needs to be investigated.

95 In addition to the "Burkhardt autopsy protocol", the following (cumulative or alternative) examinations are therefore to be carried out to strictly prove a causal connection between mRNA therapy and cause of death.

96 If the institutes of forensic medicine are technically or for other reasons unable to carry out subsequent examinations, the institutes are to report this immediately and give reasons. **The private plaintiff offers to call in appropriate experts (including biomedical experts and bioinformaticians) at its own expense, who will conduct the examination under the supervision of the competent institute.**

2.2.1. Test by means of qPCR

97 For a (rapid and inexpensive) analysis of the tissue samples using PCR procedures, proceed as follows:[28]

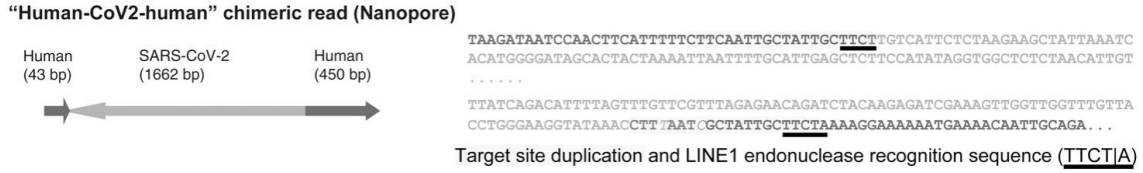
[28] The information is provided analogously to the "Burkhardt autopsy protocol" in English.

- Extract DNA using standard protocol measures (order e.g. here*:* https://www.qiagen.com).
- Use state of the art primers to detect spike mRNA sequence in tissue DNA (order e.g. here: *https:*//www.sigmaaldrich.com/).
- Design primers based on WHO Pfizer mRNA sequence to produce 100 bp amplicon to amplify spike mRNA specific DNA using qPCR.
- Negative control: tissue from non-infected, non-vaccinated individual.
- Positive control: RNA vaccine vial, reverse transcribed to cDNA.

2.2.2. DNA sequencing

98 For an analysis of the tissue samples by means of DNA sequencing (which is more complex and cost-intensive due to the necessary evaluation), proceed as follows:[29]

- Extract DNA using standard protocol measures (order e.g. here*:* https://www.qiagen.com).
- The PNAS publication addresses integration with long read sequencing methods using Nanopore (send e.g. here: *https:*//www.baseclear.com/).
- This process is non targeted and sequenced reads can be aligned to the human genome to check for integration using target site duplication evidence of LINE1 recognition site:



B. MATERIAL S

I. Protection of health as the primary goal: Therapeutic Products Act

1. Applicable legal norms; Protected legal interest

99 The acts in question concern the protection of public health and consumer confidence in authorised medicinal products. Public health (including life) is one of the most important police assets in Switzerland. Its protection is ensured in the Constitution and in various federal laws with numerous standards. The protection of public health against *risks in connection with medicinal products* falls within the competence of the Confederation pur-

29 The information is provided analogously to the "Burkhardt autopsy protocol" in English.

suant to Art. 118 para. 2 lit. a of the Federal Constitution and was concretised as follows with the Therapeutic Products Act, including penal sanctions that directly serve its implementation or health protection as a whole:

1.1. Therapeutic Products Act

100 With the Therapeutic Products Act (SR 812.21; Federal Act on Medicinal Products and Medical Devices), the Confederation concretises its competence in accordance with Art. 118 para. 2 of the Federal Constitution and clearly defines the purpose and the associated areas of responsibility of the competent authorities at the beginning of the Act:

> "The purpose of this Act is to ensure, for the protection of human and animal health, that only high quality, safe and effective remedies are placed on the market."

101 Art. 1 para. 2 HMG further states the purpose:

> "[This law] shall also:
>
> a. Protect consumers of therapeutic products from deception;
> b. contribute to ensuring that therapeutic products placed on the market are used appropriately and moderately for their intended purpose;
> c. contribute to the provision of a safe and orderly supply of therapeutic products, including the necessary professional information and advice, throughout the country.

102 In the enforcement of this Act, in particular in the issuing of ordinances and in the application in individual cases, special attention must also be paid to the *efficiency and independence of the Swiss Therapeutic Products Control Authority* (Art. 1 para. 3 lit. a HMG).

103 The purpose article of the HMG already makes it clear that the legislator wanted to protect public health from medicinal products of poor quality, lacking efficacy and above all lacking safety as well as from deceptive information. The authorisation of unsafe, ineffective or risky remedies was to be excluded, as well as deceptive information on the remedies and inadequate expert information.

104 The above-mentioned basic features of the Federal Therapeutic Products Act are not the only basis for the criminal law assessment of the conduct reported, but they are an important one. The following summary of the legally relevant facts shows that, in addition to the special offences reported here, the persons reported have clearly, repeatedly and permanently disregarded all the essential fundamental objectives of the Therapeutic Products Act cited above in a criminally relevant manner.

1.2. Penal provisions on health protection

1.2.1. Penal sanctions of the HMG

105 The Therapeutic Products Act itself already contains criminal law norms that serve the realisation and ultimate enforcement of the purposes of the Therapeutic Products Act: Thus, the norms of Art. 86 et seq. TPA are intended to ensure that only high-quality, safe and effective medicinal products are placed on the market (Art. 1 para. 1 TPA).[30]

1.2.1.1 Basic standard: abstract endangerment offence

106 The basic provision of Art. 86 para. 1 HMG is even designed as an **abstract endangerment offence**: A mere abstract endangerment of human health is therefore sufficient for criminal liability.[31]

107 The protection of legal interests has therefore been brought forward to the maximum by the legislator: There is no need for an actual violation of the legal interest of health, or even a concrete threat to it. The **mere performance of certain acts that are deemed to be dangerous is declared punishable.**[32] The abstract endangerment is presumed in the case of actions under the offence and does not have to be proven as an additional element of the objective offence in the individual case.[33] According to the Federal Supreme Court, any violation of the HMG even implies an abstract danger to human health.[34]

108 In view of the high goal of protecting human health, the legislator has therefore chosen the most severe of all available types of offence by structuring Art. 86 para. 1 HMG as an abstract endangerment offence.

1.2.1.2 Qualification: Concrete endangering offence

109 If the health of people is not only endangered in the abstract, but already in a concrete way, Art. 86 para. 2 lit. a HMG provides for a massive increase of the threatened sanction to ten years imprisonment.

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30 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, before 8th chapter N 17; on this also Dispatch on a Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, HMG) of 1 June 1999, BBl 1999 III 3453 ff., 3456 f..

31 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 4, N 10; cf. also JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 20 ff.

32 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 8 p. 106 f.

33 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 4, N 19.

34 Federal Supreme Court ruling 6B_1354/2017 of 14 June 2018, E 1.3: "The provisions of the Therapeutic Products Act serve to protect human and animal health (cf. Art. 1 para. 1 HMG). If such a regulation is violated, an abstract danger to human and animal health must be assumed. Further consideration of possible health hazards is not necessary".

110 Such a concrete endangerment exists if the **probability or near possibility of an injury to the health of people is created or increased**.[35] The concrete endangerment of people as a qualifying criterion means that **"proof of an actual endangerment of** the **health of at least one person** must be **provided"**; the mere possibility or presumption of an endangerment is not sufficient. In contrast to the offences of injury, however, a threat to the protected legal interest is sufficient - an injury is not required.[36]

111 If, in addition to a violation of a relevant provision of the law on medicinal products (para. 1), there is a concrete health risk to a single person (para. 2), the offender is already threatened with many years of imprisonment as the most severe of all possible sanctions.

1.2.2. Further punitive sanctions to protect health

112 Art. 230bis StGB - endangerment by genetically modified or pathogenic organisms - also protects the legal interests of life and limb.[37] As with Art. 86 para. 2 HMG, the mere **concrete endangerment of** an individual person is sufficient.[38] If there is no concrete danger, the **abstract endangerment offences of** the Gene Technology Act (GTG; SR 814.91) and the Environmental Protection Act (USG; SR 814.01) are relevant, which also serve to protect human health.[39] For example, anyone who handles genetically modified organisms (as intended) in such a way as to endanger humans in the abstract is liable to a custodial sentence (Art. 35 para. 1 lit. a **GTG in** conjunction with Art. 6 para. 3 lit. f and para. 1 lit. a GTG). The same applies to anyone who places pathogenic organisms (as intended) on the market and thereby endangers people in the abstract (Art. 60 para. 1 lit. i **USG** in conjunction with Art. 29d para. 1 and Art. 6 para. 3 lit. f and para. 1 lit. a GTG). Art. 29d para. 1 and Art. 29a para. 1 lit. a USG). It is also a criminal offence to place genetically modified organisms on the market without labelling them as such for the recipient (Art. 35 para. 1 lit. g GTG).

113 Like the criminal provisions of the HMG, the **offences of violation of the StGB** also protect human health - namely in the form of the protection of life itself (Art. 111 ff. StGB)[40]

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35 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 100; JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 21; DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 8 p. 106.

36 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 4, cf. also N 100; BGE 135 IV 37 E. 2.4.1 p. 40.

37 ACKERMANN / SCHRÖDER BLÄUER, in: BSK StGB, 4th ed., Basel 2019, Art. 230bis StGB N 3.

38 ACKERMANN / SCHRÖDER BLÄUER, in: BSK StGB, 4th ed., Basel 2019, Art. 230bis StGB N 4 f.

39 Cf. ACKERMANN / SCHRÖDER BLÄUER, in: BSK StGB, 4th ed., Basel 2019, Art. 230bis StGB N 50; Wohlers / Godenzi / Schlegel, Handkommentar StGB, 4th ed., Bern 2020, Art. 230bis StGB N 4.

40 SCHWARZENEGGER / STÖSSEL, in: BSK StGB, 4th ed., Basel 2019, Vor Art. 111 StGB N 1.

and the protection of physical and health integrity (Art. 122 ff. StGB).[41] In the case of the latter, the effective violation of human health is required for the commission of the offence.

1.3. Other national and international standards for the protection of public health

114 In addition to the norms of the Therapeutic Products Act and its implementing provisions, as well as sanctions for the protection of health that are subject to criminal sanctions, a large number of norms exist at national and international level for the purpose of protecting human health. A presentation that is even remotely comprehensive would go beyond the scope of the present report. Where necessary, the relevant norms are used below to interpret the relevant penal norms.

2. Principles and maxims for the protection of public health

115 The standard of review for health protection is always whether government action - whether in the form of executive orders or direct application of the law - ensures that therapeutic products are of high quality, **safe** and effective. [42]

2.1. Precautionary principle

116 The top priority and **decisive factor** in all ordinary and special ("temporary" or "simplified") authorisation procedures is **always "that safety is guaranteed".**[43]

117 Thus, both a regular authorisation (Art. 9, Art. 10 ff. HMG) and a temporary authorisation (Art. 9a HMG) are possible from the outset only if the **protection of health and life is guaranteed.**[44] This means that a refusal of authorisation is not only possible if there is a concrete risk to the health of the user. Rather, it is sufficient if a preparation poses a "not insignificant potential danger to public health" in the sense of an abstract danger, which is to be eliminated as far as possible in the sense of the **precautionary principle under the law on medicinal products.**[45] This precautionary principle under medicinal products law is concretised in Art. 3 para. 1 HMG:[46] According to this, anyone who handles medicinal products must take all measures that are necessary according to the state of the art in science and technology so that the health of humans and animals is not endangered (on the **duty of care under medicinal products law, see in** detail N 824 ff.).

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41 ROTH / BERKEMEIER, in: BSK StGB, 4th ed., Basel 2019, Vor Art. 122 StGB N 6.
42 RICHLI, BSK HMG, 2nd ed., Basel 2022, Art. 81 N 17.
43 Message HMG, 3501; cf. RICHLI, BSK HMG, 2nd ed., Basel 2022, Art. 81 N 17.
44 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 9a N 5.
45 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 10 N 8.
46 JAISLI / SCHUMACHER-BAUSCH, BSK HMG, 2nd edition, Basel 2022, Art. 3 N 3.

2.2. Effectiveness of government action

118 If the standard of review for all actions under the law on medicinal products is to be based on the purpose of Art. 1 HMG, it follows that the protective purpose of the law - protection of public health - requires that the entire situation be considered from the perspective of its effect. Compliance with formal regulations does not in itself provide sufficient certainty for ensuring health protection. All circumstances must be considered as a whole with regard **to their effect on health protection** according to the respective state of science and general life experience. Accordingly, state action must be effective with regard to the highest legal interest - human health (**principle of effectiveness)** and must not be exhausted in a formalistic way of acting. Therefore, there cannot and must not be a "service by the book" in the area of health protection, especially since state actions have a direct impact on people's health.[47]

2.3. Risk-based management of specific risk factors

119 "Anyone who handles therapeutic products must take all measures that are necessary according to the state of the art in science and technology to ensure that the health of humans and animals is not endangered". Art. 3 para. 1 HMG explicitly describes the principle and the standard of care for the handling of therapeutic products, which already follows inevitably from the principles and maxims for the protection of public health set out above: It is the central task of the supreme licensing authority to focus its attention from the outset on the type and number of risk factors of which it becomes aware in connection with the authorisation of medicinal products, and to take effective measures to exclude these risks. [48]

120 Classic risk factors in connection with drug approvals are, for example:

1) Novelty of the ingredients,
2) Novelty of the manufacturing process,
3) Novelty of the disease to be controlled,
4) Lack of experience of the manufacturing companies in the production of similar medicinal products,
5) approvals without the usual clinical trials,
6) particular time pressure, for example in the form of political-media pressure.

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47 Cf. on the effectiveness of state measures HÄFELIN / MÜLLER / UHLMANN, Allgemeines Verwaltungsrecht, 8th ed., Zurich / St. Gallen 2020, N 1579.

48 For more information on the duty of care under medicinal product law according to Art. 3 HMG, see N 825 ff.

121 The less certainty and certainty that can be gained in the approval process, the higher the hurdles must be for approval, or - in the case of approval despite risk factors - the more effective and close-meshed must be

1) the prior information of the consumer about these risks; and
2) The early detection of side effects must be ensured.

122 Large uncertainties of a substance at the time of authorisation therefore necessarily mean, without exception: maximum care with regard to risk/benefit information for consumers and maximum care with regard to effective recording and publication of side effects ("best effort yardstick"). Otherwise, public health cannot be protected from risks that were underestimated at the time of authorisation, that were still unknown at that time or that only materialised after the authorisation of the substances concerned.

II. Circle of perpetrators

123 In principle, anyone can be considered a perpetrator of the above-mentioned penal provisions on health protection - but certainly those persons who appear to be the bearers of the violated duties of care.[49] In particular, anyone who **manufactures** medicinal products in violation of Art. 3 HMG (general duty of care) (Swissmedic is regarded as the manufacturer, particularly in the context of batch testing)[50] or **uses them** (use of the medicinal product on patients by doctors) is liable to prosecution under Art. 86 para. 1 lit. a HMG.

124 Both the natural persons of Swissmedic and the "Insel Gruppe" who have been notified therefore come into consideration as potential perpetrators. Accordingly, the legal status and the associated framework conditions of the organisations mentioned should be briefly discussed:

1. Manufacturer - Swissmedic

125 As at the back (N 813 ff.), Swissmedic is considered to be a manufacturer within the meaning of the Therapeutic Products Act due to its duty to check batches, which makes it the addressee of the sanction standards formulated in Art. 86 TPA and the corresponding duties of care in Art. 3 TPA and Art. 7 TPA.

49 Cf. SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 86.
50 For more details see N 813 ff.

1.1. Organisation of the licensing authority

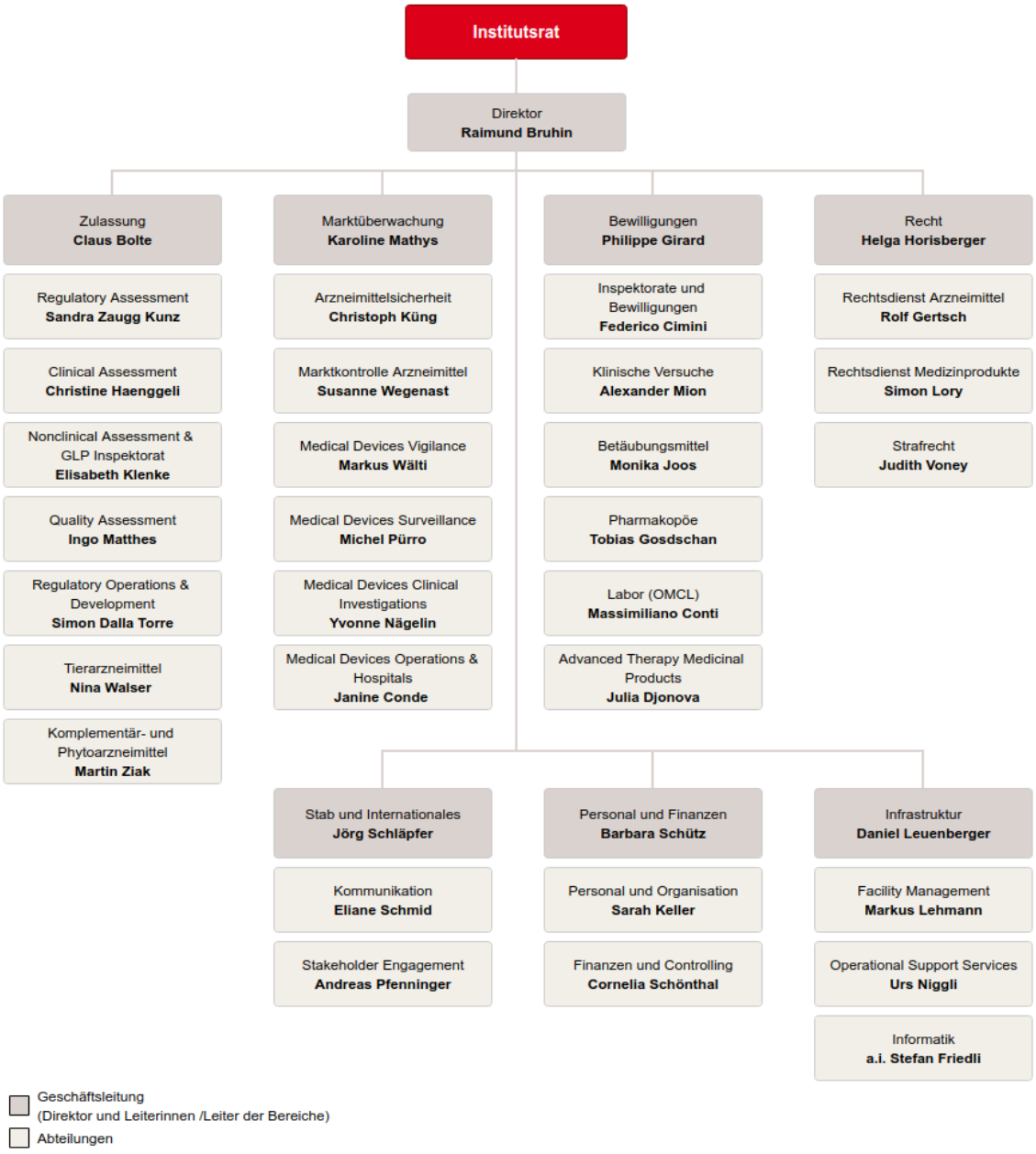
126 Swissmedic, the Swiss authorisation and supervisory authority for medicinal products and medical devices (therapeutic products), is a federal institution under public law with its own legal personality. It is independent in its organisation and management and keeps its own accounts.[51]

127 Swissmedic was founded in 2002[52] and is currently organised as follows:[53]

51 Swissmedic, "Strategic objectives 2019 to 2022", 24.10.2018, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/direktion/strategischeziele2019-2022.pdf.download.pdf/strategischeziele2019-2022.pdf, p. 1.

52 General Secretariat FDHA, "Bundesrat genehm genehm den neuen Leistungsauftrag an Swissmedic", 24.11.2010, https://www.admin.ch/gov/de/start/dokumentation/medienmitteilungen.msg-id-36375.html.

53 Swissmedic, "Organisation chart as of May 2022", https://www.swissmedic.ch/swissmedic/de/home/ueber-uns/organisation.html.



128 Swissmedic states that it is in regular contact with international partner authorities with regard to the safety of medicinal products and that it considers this exchange to be particularly important when new safety risks are suspected.[54]

54 Swissmedic, "On the trail of pharmacovigilance", 03/2021, https://www.swissmedic.ch/swissmedic/de/home/ueber-uns/publikationen/visible/swissmedic-visible-april-2021.spa.v3.app/de/arzneimittelsicherheit.html.

1.2. Performance mandate or "strategic objectives" of Swissmedic

129 According to Art. 69 HMG, Swissmedic must fulfil the tasks assigned to it under the Therapeutic Products Act and other federal laws. In order to fulfil these tasks, the Federal Council approves the **strategic objectives of** the **Agency for** a period of four years on the **proposal of the Agency Council** (Art. 70 para. 1 TPA). This norm is new and has only been in force since 1 January 2019. Previously, the Federal Council had issued a performance mandate (with a performance agreement) to Swissmedic.[55] The Federal Council did not provide a more detailed justification for this change of instrument in its dispatch on the revision of the HMG.[56] **However, the change to these "strategic objectives" obviously shifted the balance of power between Swissmedic and the Federal Council:** whereas the Federal Council previously controlled the Agency by means of a unilateral, sovereign performance mandate, it now only has approval powers.[57] Swissmedic has set itself the following "strategic priorities" for the period 2019-2022:[58]

130 Under the introductory "programmatic focal points", Swissmedic states that it operates in a "field of tension between potentially conflicting interests": on the one hand, **protection against risks that may emanate from therapeutic products. On the other hand,** consumers and patients expect **rapid access to safe and effective therapeutic products.** In addition, the **therapeutic products industry** also had **"a legitimate interest in competitive framework conditions".** Against this background, a **"competent and independent control of therapeutic products" is** indispensable both for the safety of patients and for Switzerland as a pharmaceutical and medical technology location.

131 Swissmedic then formulates a total of seven "task and company-related objectives". Of these, three are directed towards **international harmonisation for the purpose of reducing costs (objective 1), support for authorisation decisions by foreign authorities (objective 2)** and **acceleration of authorisation procedures with orientation towards the fastest authorities (objective 6).** Swissmedic states in this regard:

> "Harmonised international standards are an important basis for reducing the burden on authorities [...]" (Goal 1)
>
> "[...] Swissmedic intends to rely [...] on the assessment results of other recognised authorities wherever the minimum material requirements are met" ("reliance")". (Goal 2)

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55 RICHLI / MEYER, BSK HMG, 2nd ed., Basel 2022, Art. 70 N 3. See also Swissmedic, "Strategische Ziele", 30.09.2019, *https://www.swissmedic.ch/swissmedic/de/home/ueber-uns/swissmedic--schweizerisches-heilmittelinstitut/strategy.html.*

56 RICHLI / MEYER, BSK HMG, 2nd ed., Basel 2022, Art. 70 N 4.

57 RICHLI / MEYER, BSK HMG, 2nd ed., Basel 2022, Art. 70 N 5 f.

58 Swissmedic, FN 51.

> "Swissmedic will shorten the duration of relevant procedures by an average of 10 per cent while maintaining quality by speeding up time-critical processes. In the area of authorisation procedures, it will be guided by the fastest authorities." (Goal 6)

132 None of these three goals - nor any of the four[59] not mentioned in detail here - is designed to ensure the most careful and thorough examination possible in Switzerland for the best possible handling of the risk associated with the authorisation of medicinal products. **Everything is aimed at speeding up the procedure and adopting foreign (authorisation) decisions as unchecked as possible** - entirely in the interests of the pharmaceutical industry. On the other hand, protection against risks and thus the main purpose of the law on therapeutic products - the protection of human health - is only addressed under the heading of "programmatic priorities". Even there, this elementary point is not particularly emphasised, but immediately blurred with the (alleged) interests of consumers and the (immanent) interests of the pharmaceutical industry in fast and uncomplicated marketing authorisations.

133 Whether Swissmedic can fulfil the main purpose of therapeutic products law - the protection of human health in the sense of the explicit legal bases and legal principles set out above (see N 99 ff.) - can be fulfilled at all, seems extremely questionable. However, this question does not need to be assessed conclusively here, as Swissmedic must be measured against the (authorisation) decisions actually taken: These must satisfy the legal requirements at all times - an autonomous "discharge" of the legal obligations by way of conflicting or at least weakening formulations of objectives is not possible in accordance with the principle of legality, as this would violate the principles of delegation in accordance with the practice of the Federal Supreme Court: a legislative delegation with regard to important or fundamental provisions by the Federal Council is not possible.[60] Increasing the autonomy of an administrative unit can and must never lead to circumvention of the principle of legality (Art. 5 para. 1; 164 para. 1 FC). [61]

2. Users - the example of the Inselspital in Bern

134 Anyone who uses medicinal products is also an addressee of the sanction standards formulated in Art. 86 HMG. In this case, the duties of care according to Art. 26 HMG are

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59 The other goals concern communication with the public (Goal 3), exchange with national decision-makers in the health sector (Goal 4), digitalisation (Goal 5) and strengthening regulatory systems in other countries (Goal 7).

60 BGE 141 II 169 E. 3.2.

61 Cf. on the principle of legality and effect-oriented administrative management HÄFELIN / MÜLLER / UHLMANN, Allgemeines Verwaltungsrecht, 8th edition, Zurich / St. Gallen 2020, N 1584 and N 1586 f.

particularly relevant, i.e. the duties of care in prescribing, dispensing and use. The central duty here is to fully inform the patient before the intervention (see in detail N 857 ff.).

135 The "Insel Group" operates a "COVID Vaccination Centre" on the premises of the Inselspital Bern.[62] Under the title "Every vaccination counts", "initial vaccinations", "booster vaccinations", "child vaccinations from 5 to 11 years" and other "COVID vaccinations" have been offered there since 2021.[63] Accordingly, the officers acting for the "Insel Gruppe" are responsible for ensuring that the vaccinated persons are informed in accordance with the law on therapeutic products.

136 In the present case, at least the private plaintiff 2 received two mRNA injections at the "Insel vaccination centre" - and this, given the current state of knowledge, without sufficient clarification, which means that the defendants acting for the "Insel group" belong to the potential group of perpetrators.

III. Means of Crime - mRNA "Vaccines"

137 All statements made in this section are based in full on the **evidence report** enclosed with this criminal complaint **(Supplement 4),** which contains further discussions and lists the relevant supporting documents. The title structure in this section of the criminal complaint and the attached evidence report (section "mRNA "vaccines": risks and efficacy") correspond in terms of content, but are shifted by one level (e.g.: Title level "**1st** state of knowledge at the end of 2020" of the criminal complaint corresponds to title level "**I. State** of knowledge at the end of 2020" of the evidence report). **Accordingly, reference is made to the detailed evidence report in its entirety for proof and for more in-depth explanations below.**

138 All the above-mentioned penal provisions with the purpose of protecting health have mRNA "vaccines" in common in this case. In this regard, the licensing authority Swissmedic had different levels of information on the substances to be licensed at different times. In view of the legal bases and legal principles set out above (see N 99 ff.), of particular interest for the present criminal proceedings is all the information that contains indications of risks to public health, i.e. indications of (as already partly listed in N 120 listed above):

1) Novelty of the ingredients,

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62 INSEL GRUPPE, "Situationsplan Inselspital", 03.2022, https://www.insel.ch/fileadmin/Inselspital/Bilder/Patienten_und_Besucher/Corona/Situationsplan-Impfzentrum-Inselcampus.pdf.

63 ISLAND GROUP, "Every vaccination counts", 20.06.2022, https://www.insel.ch/de/patienten-und-besucher/coronavirus/covid-impfzentrum-auf-dem-inselcampus.

2) Novelty of the manufacturing process,
3) Novelty of the disease to be controlled,
4) Lack of experience of the manufacturing companies in the production of similar medicinal products,
5) approvals without the usual clinical trials,
6) Results from empirical studies available worldwide,
7) Results from adverse event reports available worldwide,
8) Any other information that comes to the attention of the Institute.

139 Furthermore, all actions by Swissmedic and the persons involved that have had the effect of increasing or reducing these risks to public health are of interest.

140 Against this background, the following facts are to be classified as legally relevant for the present criminal proceedings (in each case according to their temporal availability at the moment of the respective admission) and to be assessed accordingly:

1. Swissmedic's state of knowledge at the end of 2020 (first authorisations for adults)

141 When the mRNA "vaccines" were first authorised in December 2020 (and January 2021), Swissmedic was already aware of the following circumstances with regard to the risk-benefit profile:

1.1. Risks

1.1.1. New, as yet unproven mode of action: Gene therapy

142 Swissmedic classifies the mRNA preparations as "vaccinations" and therefore describes them as "immunological medicinal products" within the meaning of Art. 2 lit. b AMBV (SR 812.212.1), without going into the special mode of action of these preparations. Both on the part of the manufacturers and on the part of the licensing authorities of the USA (FDA) and the EU (EMA), the mRNA preparations are **potentially classified as gene therapies.** Even in public, individual representatives of the pharmaceutical industry openly present these preparations as what they are: A gene therapy. For example, Stefan OELRICH, member of the executive board of Bayer AG and head of the drug division of the chemical and pharmaceutical company, stated in October 2021:

> "The mRNA vaccinations are an **example of cell and gene therapy.** If we had done a public poll two years ago asking who would be willing to take gene or cell therapy and have it injected into their body, probably 95

per cent of people would have rejected it. This pandemic has opened a lot of people's eyes to innovation in a way that wasn't possible before."

143 In established vaccinations used so far, a harmless amount of a killed or attenuated pathogen (active vaccination) or antibodies (passive vaccination) are directly introduced into the body. In the case of active vaccination, our immune system recognises the pathogen as foreign based on the specific recognition features it carries on its surface and activates the immune defence system to produce specific antibodies and memory cells that render the pathogen harmless. The immune system is thus "trained" by recognising **foreign** recognition features of a pathogen, reacting to them and being able to quickly destroy the pathogen in a subsequent encounter. However, the **mRNA "vaccinations"** discussed here have a **fundamentally different mechanism of action. This consists of getting our own healthy body cells to produce the foreign recognition feature (spike protein) and attach it to their cell surface**. In this way, our own healthy body cells "disguise" themselves and appear to our immune system as foreign. The blueprint for this foreign feature (the spike protein) is injected into the body via a genetically artificially stabilised mRNA. The mRNA then forces the body's own cells to produce this foreign recognition feature, the "spike protein". This is then transported to the surface of the cell and recognised by the immune cells.

144 This special mode of operation has so far only been tried out on seriously ill patients in individual cases. No comparable pharmaceutical product had so far received market approval for use in healthy - non-pre-diseased - populations. Until then, the novel mRNA technology had **only** been used on a trial basis in **individual cases in cancer patients** - i.e. severely pre-diseased people. But even there, this technology had **not yet** led to **any resounding success** because no relevant efficacy could be proven. In the area of a broadly effective, prophylactic application, on the other hand, this special mode of operation is still completely new. Thus, until today, it is still completely unexplored:

- which body cells end up being involved in the production of the spike protein;
- how long the production will last and in what quality and quantity, and
- how large the proportion of the population is that does not tolerate the large-scale administration of mRNA injections or the body's own production of new substances in the intended way without side effects.

145 In fact, the mRNA therapies or mRNA "vaccines" for flu prevention were still at the stage of animal studies (preclinical phase) at the end of 2019 - far from proper approval. No comparable pharmaceutical product had received market approval for use in healthy - not pre-diseased - populations by then. Manufacturers such as BioNTech therefore an-

nounced as late as September 2019 that they expected that **such a gene therapy** might **"never"** be **approved.** Moderna followed with a similar statement only on 30 June 2020: mRNA is considered a **gene therapy product for which the approval path** is **uncertain in** view of its complete novelty (no previous marketing authorisation, unclear study requirements, etc.).

146 Just a few months later - in December 2020 - Swissmedic approved these same mRNA therapies for the precautionary treatment of SARS-CoV-2 on the market. But little had changed compared to 2019 - let alone June 2020 - and a large number of parameters were still unknown. Both the absorption of the applied mRNA and that of the spike proteins in the body (so-called pharmacokinetics) were unclear: Neither was it clear from initial studies how the modified mRNA (deliberately delayed degradation rate) would degrade compared to the natural mRNA, nor was the effect of the production of the spike proteins stimulated by the mRNA in any way adequately researched. As if these were not already enough uncertainties, **no studies** were **carried out to exclude possible toxic effects (genotoxicity studies) nor to exclude possible carcinogenic effects (carcinogenicity studies). Whether mRNA therapy can lead to (irreversible) damage to the genetic material or to cancer was therefore completely unknown.**

147 A medicinal product that is based on a method that has never been used on a healthy population and for which all relevant parameters are still largely unexplored must necessarily be regarded as dangerous until its safety has been proven. In view of the high standard of care pursuant to Art. 3 para. 1 HMG, the complete novelty and partial lack of clarity of the mode of action would make it imperative that all necessary preclinical and clinical studies be carried out in a sound manner. The fact that this was not possible within the framework of the authorisation procedure (described below) for the so-called "time-limited" authorisation, or that it was deliberately dispensed with, must be assessed as a considerable risk factor of which the competent authority was aware.

1.1.2. Prohibited use of GMOs on humans?

148 Moreover, there are indications that the mRNA "vaccines" are not "only" a "gene therapy", but even genetically modified organisms (GMOs).

149 For example, the Federal Office for the Environment (FOEN) classified the mRNA "vaccine" as a genetically modified organism (GMO) due to the combination of the mRNA with the lipid nanoparticles. If one bases this assessment on the substance at hand, a "temporary authorisation" should not have been granted at any time:

150 GMOs are entities (incl. mixtures, etc.) that are capable of reproducing or **transferring genetic material** and have been produced or modified "in a way that does **not occur under natural conditions** through cross-breeding or natural recombination**".** If such a GMO is present, massively increased requirements are placed on an authorisation, to which reference is made at the end (N 551 ff. , N 565, N 569, 599 f., N 750 ff.) and which cannot be fulfilled in any way with a temporary authorisation. If the genetic material were to be transferred into human **germ cells, this** would violate the integrity of the human genome, which is **absolutely protected under Article 119(2)(a) of the Federal Constitution: "all [...] interventions in the genome of human germ cells and embryos are impermissible".** It is sufficient that even individual gene sequences are directly modified, as is the case with **CRISPR/Cas9 technology**, in which specific DNA sequences are "cut out" and replaced precisely by genetically modified DNA sequences.

151 The intended mode of action of the mRNA "vaccines" does not, on the face of it, involve any direct intervention in the DNA. However, **various studies were** already **available at the** end of 2020 that **showed a so-called "reverse transcription" of mRNA into DNA in human cells.** The mRNA in the "vaccines" was modified in this way (in particular: Replacement of uridine by pseudouridine, modified capping of the 5'-end) that it "survives" longer in the body and is protected from degradation by enzymes ("ribonucleases") and from the immune system. The aim of this artificial adaptation of the mRNA is to bring it safely into the cells so that as much spike protein as possible can be synthesised. The danger from the "spike protein" was assessed by Swissmedic as "low" because a "minimal systemic exposure after intramuscular application" was to be expected. It was already known by the end of 2020 that a **sustained expression of the toxic spike protein on** the one hand certainly **increases** the **potential for possible side effects** (**such as cancer)** (on the toxicity of the spike protein and the corresponding consequences, see in detail behind N 172, N 185 ff., N 265 ff.). On the other hand, the artificial modification leads to the mRNA staying in the body longer than under natural circumstances - and possibly reaching places where it should not, such as the reproductive organs, which has been found in animal experiments. In the enclosed evidence report, it is explained in detail that in this way an **- unintentional - effect of the mRNA on the human DNA in the germ cells could take place.**

152 Swissmedic was already aware of this problem in principle at the end of 2020. As a precautionary measure, it stated in a letter to Moderna that the **risk of integration into the genome** was **considered to be "very low".** However, in a completely incomprehensible manner, Swissmedic did not insist on the performance of studies that would have ruled out this risk. Swissmedic did not even draw the public's attention to the - albeit at

best "very slight" - danger, but rather blurred this fact. Contrary to the data available at the time, Swissmedic stated in the first version of the Comirnaty expert information (section "Genotoxicity/caricinogenicity"): **"In particular, it can be assumed that the mRNA does not enter the cell nucleus or interact with the genome.** This passage was **deleted in** subsequent versions - reasons for this are not officially known.

153 **Whether the mRNA substances have the potential to permanently (hereditarily) modify human DNA can therefore not be ruled out.** If this were the case, the use of mRNA would violate mandatory constitutional provisions. Moreover, only the potential to modify the DNA of a single human being is sufficient for the strict authorisation requirements that apply to GMOs (incl. CRISPR/Cas9) to have been mandatory. The modification of the DNA of a single human being - and even more so the potential for permanent, heritable modification of the human genome - would probably mean the immediate end of mRNA research, as it would no longer have any regulatory advantages over CRISPR/Cas9.

154 In view of these serious uncertainties, an authorisation that has nevertheless been granted is a violation of the **precautionary principle** under medicinal product law: The **potentially gene-changing effect of mRNA substances** - the **potentially permanent, irreversible alteration of the human genome** - is not merely a "risk factor" that can hardly be calculated, but an **absolute criterion for exclusion from any marketing authorisation. This fact was also known to the approval authority at the time of the first approval in December 2020.**

1.1.3. New, not yet tested ingredients: Toxic Lipid nanoparticles

155 To protect the mRNA in the COVID "vaccines" from degradation and facilitate its uptake into the body's cells, it is "packaged" in a shell of fats (lipid nanoparticles, LNP). The use of **LNP** in humans has been considered **critical for years** because of their **toxicity** and associated dangerous side effects**.**

156 Nevertheless, the COVID "vaccines" used LNP and especially the problematic components ALC-0159 and ALC-0315 (Comirnaty) or SM-102 (Spikevax).

157 The original claims of the manufacturing company ("This product is for research use only and not for human use.") for Pfizer/BioNTech concerning ALC-0315 and ALC-0159 were replaced in autumn 2021 by "for research use only" without any scientifically indicated reason. In the end, of course, this means exactly the same: **Not intended for use in humans.**

158 The actual toxicity of these LNP components can also be seen in the "Safety Data Sheet" of a manufacturer of SM-102 , which is also no longer available to the public. There, as of 11 April 2021, it was still expressly stated:

- H310 **Danger to life** by skin contact
- H351 Suspected of causing **cancer**
- H361 Suspected of **damaging fertility** or the unborn child
- H372 **Causes damage to the central nervous system, kidneys, liver and respiratory system through prolonged or repeated exposure.**

GHS06 Skull and crossbones

Acute Tox. 2	H310 Fatal in contact with skin.

GHS08 Health hazard

Carc. 2	H351 Suspected of causing cancer.
Repr. 2	H361 Suspected of damaging fertility or the unborn child.
STOT RE 1	H372 Causes damage to the central nervous system, the kidneys, the liver and the respiratory system through prolonged or repeated exposure.

159 As of 15 September 2021, this then suddenly read as follows:

GHS06 Skull and crossbones

Acute Tox. 3	H301 Toxic if swallowed.
Acute Tox. 3	H331 Toxic if inhaled.

GHS08 Health hazard

Carc. 1A	H350 May cause cancer.

160 And already a few months later, the next adjustment took place on 7 June 2022:

· **Classification of the substance or mixture**

GHS02 Flame

Flam. Liq. 2	H225 Highly flammable liquid and vapor.

GHS07

Acute Tox. 4	H302 Harmful if swallowed.
Skin Irrit. 2	H315 Causes skin irritation.
Eye Irrit. 2A	H319 Causes serious eye irritation.

161 All hazard warnings had been successively downgraded by the manufacturer: Accordingly, "**Danger to life in case** of skin contact" first became "**Toxic if** swallowed or inhaled" and finally "**Harmful** if swallowed". The second highest toxicity level (Acute Tox. 2) was downgraded to level 3 (Acute Tox. 3) and finally to level 4 (Acute Tox. 4).

162 In addition, the presumed carcinogenicity and proven damage to vital organs, the presumed impairment of fertility, including damage to the child in the womb, was initially changed to a simple "may cause cancer", before this reference was completely removed as of June 2022. Here, too, it remains completely unclear where this sudden re-declaration came from. Unless one takes into account that these very ingredients were approved "for a limited period" within the framework of the vaccine approvals and that corresponding warnings about these isolated ingredients could be critical for a longer-term approval after arousing public interest or could reduce the willingness to vaccinate.

163 For the sake of good order, it should be noted that these warnings apply "only" to the isolated concentrate of SM-102 - and not to the admixture in the mRNA "vaccines". "The dose makes the poison". However, one would at least expect that in view of the officially reported toxicity of LNP, corresponding studies would have been carried out by the "vaccine" manufacturers. The opposite is the case: Up to the time of the first approval of the mRNA "vaccines", **no studies whatsoever were carried out on the genotoxicity and carcinogenicity of the novel "vaccine" substances. In the** technical information it was even stated placatingly - without any scientific basis - that **no mutagenic or carcinogenic effects were to be expected. This** was justified, among other things, by the fact that the risk "due to the **minimal systemic exposure after intramuscular application**" would be assessed as "low". The latter is blatant misinformation: it is already clear from the authorisation dossier that the **degradation of ALC-0315 in the liver,** for example, was **very slow.**

164 Here, too, the first-time use of ingredients already known for their toxic effects should, under normal circumstances, make it imperative that all necessary studies be carried out. In addition, it would be mandatory to provide transparent information about the unclear - and even identified - risks. The fact that this was waived in the context of the so-called "time-limited" authorisation is to be assessed as a considerable risk factor, which was known to the authorisation authority.

1.1.4. Toxic, mutagenic and carcinogenic impurities

165 The requirements for ordinary admission and those for "temporary" admission are discussed in the back (N 493 ff.) are explained in detail: What these forms of authorisa-

tion have in common is that the absolute most basic requirements for **quality** must always be guaranteed. This means that at least the criteria of **stability and purity** must be guaranteed. However, it is precisely in the area of purity that considerable deficiencies have been identified:

1.1.4.1 Contamination with nitrosamine and benzene

166 The authorisation documents show that Swissmedic had found toxic "impurities" in the mRNA "vaccines": for example, nitrosamine (Pfizer) and benzene (Moderna) were contained in the "vaccines".

167 **Nitrosamine is highly toxic even in the smallest concentrations, is one of the most carcinogenic substances of all and is mutagenic. Benzene has been proven to be toxic, carcinogenic and mutagenic.** It is stored in the brain, bone marrow and fatty tissue.

168 Such dangerous ingredients have no place in a "vaccine" - not even in the form of "impurities". Before granting authorisation, Swissmedic should therefore have requested further documentation, if only to be able to approximately assess the presence and concentration of the toxic substances and thus the risk. Instead, Swissmedic was content with simply requesting additional data while at the same time granting authorisation.

1.1.4.2 Contamination with bacterial DNA: Potential for DNA damage?

169 The enclosed evidence report clearly describes the manufacturing process of the mRNA "vaccines" and shows when and how the manufacturers must take measures to remove the DNA produced during manufacture in purification steps with the aim of preventing these undesirable "contaminants" from being found in the finished medicinal product. Nevertheless, the **mRNA "vaccines"** were **contaminated with DNA from bacterial cells (E. coli) according to the authorisation letters from Swissmedic for the attention of the manufacturers.** This should not happen under any circumstances and indicates an improper and not yet fully developed manufacturing process.

170 Both the European Medicines Agency (EMA) and Swissmedic had identified such impurities. Swissmedic therefore requested Moderna in the authorisation letter to comment on the impurities found and to address this problem. Generous deadlines were set - for example until 30 June 2021 - without it being known whether this problem has been remedied in any way.

171 This frivolous approach is also in no way comprehensible: The DNA contained in the vaccine as an impurity can be **integrated into the genome of the host cells** and thus

cause potentially harmful mutations. Bacterial DNA also promotes non-specific inflammation. Such DNA sequences have no place in a "vaccine" - nevertheless, authorisation was granted. Here, too, Swissmedic took on an **increased risk** known to it with the "temporary" authorisation - without investigating the identified deficiencies in a sufficiently compelling manner and without demanding immediate adjustments to the manufacturing process.

1.1.5. Increased risk for pregnant women

1.1.5.1 Animal study: double the number of pre-implantation losses and malformations

172 Pregnant women were excluded from participation in the phase III trials for both Comirnaty and Spikevax. The "Human Medicines Experts Committee (HMEC)" commissioned by Swissmedic accordingly stated unequivocally at the end of 2020: "Pregnancy should be listed under **'precautions'. At present, there is** little data in pregnant women, and preclinical studies have identified a **possible risk in pregnancies** ." From the only study conducted in this regard, as far as can be seen (a study conducted by Pfizer in female rats), there was a **twofold increase in pre-implantation losses** (9.77%, compared to 4.09% in the control group), and **malformations** were found in the foetuses. Both indicate a toxic effect of the "vaccines" - presumably caused by the toxic LNP they contain and the spike protein, which is also toxic (for more on this see N 265 ff.) - on the embryo or the developing placenta. However, such striking negative results did not lead either the manufacturer or Swissmedic to take further investigative action that could have ruled out the risk found in animals in the case of human pregnancies; on the contrary, Pfizer itself pointed out that **"no data on the placental transmission of BNT162b2 [Comirnaty]** are **available"**. In addition, the study was extremely sparse: only 21 litters were examined in rats.

1.1.5.2 British Health Authority and WHO: No recommendation for pregnant women

173 A conclusive assessment of the risks to pregnancy in animals - let alone in humans - was in no way possible on this basis. Even the WHO therefore did not recommend vaccination of pregnant women in a general way in February 2021. And the British health authority had already correctly stated as of 8 December 2020 in the British drug information,

- that the **influence on fertility** is **not known,**
- that **Pfizer's vaccination** could **not** be **recommended for use during pregnancy,**
- that pregnancy must be ruled out before vaccination and

- Women of childbearing age should avoid pregnancy for at least two months after the second dose.

1.1.5.3 Australian health authority also ignores warnings

174 Similar to Switzerland, in Australia the assessor of the preclinical data recommended that Comirnaty should only be approved for pregnant women under a risk warning that animal studies were inadequate or lacking. As in Switzerland, the Australian regulatory authority ignored this warning and stated that animal studies did not indicate any direct or indirect adverse effects on pregnancy, embryonic/fetal development, birth or postnatal development.

1.1.5.4 Interim conclusion

175 Thus, as early as December 2020, Swissmedic knew that **a possible risk in pregnancies** had been identified in **preclinical studies.** Swissmedic also failed to adequately address this risk in any way - and even **concealed it** - which is described in more detail below N 704 ff. below.

1.1.6. Unprecedented short "development time

176 As previously stated (N 145), mRNA therapies were still in the preclinical phase (animal trials) at the end of 2019. Only when these are successfully completed can we proceed to in-depth trials on humans (clinical phase), which take well over a year in total. And only if these trials are all positive can the path of the one-year ordinary approval procedure be taken.[64] Under normal circumstances, the **development and approval of an unprecedented mRNA "vaccine" for the prevention of influenza** would therefore still have **taken at least two years in the very best case** - in view of the many unknown parameters, probably many years more. Thus, the Pfizer / BioNTech "phase III" study, for which 12-month results must normally be available for proper approval and 24-month results are available at the time of approval, will run at least until 8 February 2024.[65]

177 In the present case, the mRNA "vaccines" were "developed" in just one year - and approved in the same year. The temporary approvals of the COVID "vaccines" were initially granted on the basis of **"phase I/II/III" studies**, in which the study participants were observed for a median of **only two months** .

64 In detail behind N 497 ff., esp. N 522 ff.
65 In addition at the back N 519.

178 The fact that such a completely new medicinal product with a novel mode of action and novel substances has been brought onto the market in such a short time is to be assessed as a serious risk factor, if not as an actual alarm signal.

1.1.7. Missing, incomplete, alarming and sabotaged studies

179 In addition, even in the case of an emergency authorisation - as the so-called "temporary" authorisation within the meaning of Art. 9a HMG *de facto* represents (see below N 584 ff.) - the **most fundamental information on safety must be** available, which can only be provided on the basis of (fully) conducted **animal studies** and at least **initial meaningful tests in humans in the** context of dose-finding (phase I studies). These minimum requirements - which are far below those of a "regular authorisation" - were also not met in the present case:

1.1.7.1 Missing and incomplete animal studies on toxicity

180 As far as can be seen from the publicly available information, just three toxicity studies were available at the time of the initial approval of Comirnaty:

181 One of these is the animal study on developmental and reproductive toxicity mentioned earlier (N 172) on developmental and reproductive toxicity, in which only female rats were examined. In the other two studies, male rats were also examined - but not with regard to reproductive capacity. The indispensable **data that could have proven the safety of the use of mRNA "vaccines" in young males of reproductive age were thus completely lacking by the end of 2020.**

182 A waiver of mandatory further studies was justified with a reference to a WHO recommendation from 2005, which is in no way permissible: This "recommendation" dates from a time when only conventional vaccines were used and the application of experimental mRNA gene therapies in humans was at best a distant prospect. The application of this guideline can thus not be objectively justified. However, even if the invocation of this outdated guideline were to be considered admissible, the WHO itself explicitly states the following:

> "For **example, for** a product for which there is **no previous non-clinical and clinical experience, non-clinical testing is** likely to be **more extensive** than for vaccines that are already licensed and used in humans."

183 The WHO guideline thus does not give a "free pass" to the omission of elementary studies to ensure the most basic safety of mRNA "vaccines" approved for the first time and tested on humans for the first time - quite the opposite: on the contrary, it demands that non-

clinical tests tend to be even more extensive than under normal circumstances. The **renunciation of the most elementary animal studies thus represents a massive and obvious increase in risk.**

184 The supreme licensing authority thus lacked any reliable basis and evidence to publicly claim in the expert information that "it is not to be expected" that components of the vaccine could be harmful to genetic material and/or carcinogenic (on this misleading communication to the public, see N 726 f.).

1.1.7.2 Missing and suppressed animal studies on pharmacokinetics

185 According to their own official statements, the manufacturers have also refrained from obtaining animal studies on pharmacokinetics (the totality of all processes to which a medicinal product is subject in the body) with reference to the WHO guideline mentioned above. Instead of imposing corresponding conditions or taking its own precautions to check the risk, Swissmedic states, for example, in the Spikevax expert information, succinctly and without any evidence: "No assessment of the pharmacokinetic properties is required for vaccines". This is also in open contradiction to the requirement of HMEC, which demanded an investigation of the **effects of the spike protein** on the tissue at least as a condition for authorisation. **However, a corresponding study was apparently never requested by Swissmedic:** At least nothing can be found on this in the technical information of Comirnaty and Spikevax to date.

186 In the absence of corresponding information in the product information, it would therefore also be assumed that no pharmacokinetic studies had been carried out at all. But this is obviously not the case: According to the Pfizer documents, which have now been released, such studies were indeed carried out to a very limited extent. According to Pfizer, the results are even representative for the mRNA "vaccine" - nevertheless, the **results are not disclosed in the Comirnaty technical information.** And the results are quite explosive: the one pharmacokinetic study in rats showed an increased **accumulation of the toxic lipid nanoparticles (LNP) in the** liver, spleen, but also in other organs such as the ovaries, where high concentrations had been found. **Even after these early study results were available, it was thus obvious that the COVID "vaccines" did not remain at the injection site at all, but were distributed throughout the body.**

187 Here, too, Swissmedic claimed publicly, without any evidence and contrary to the study available to Swissmedic, **"[that the LNPs] are excreted within a few days. There is no evidence that they accumulate in tissues or organs over a longer period of time."**

This is blatant misinformation on the part of Swissmedic, to which we will return briefly at the end of N 728 briefly at the end.

188 The same applies to the **pharmacokinetics of the** mode of action of **mRNA.** Only because of the unnatural modifications mentioned above (N 151) mentioned above (N) (in particular: Replacement of uridine by pseudouridine, modified capping of the 5'-end), appropriate studies were imperative. Swissmedic had even recognised this and criticised Pfizer in the authorisation letter of 19 December 2020: **"Swissmedic urgently recommends analysing the kinetics of the modified mRNA in vitro and in vivo in detail."** Whether Swissmedic has ever requested these studies in a legally sufficient manner is unknown. However, in view of the lack of references in the expert information, it must be assumed that here, too, **no sufficient measures** had been **taken to ensure the safety of the medicinal product.**

1.1.7.3 Risk signals in initial tests on humans

189 The basic prerequisite for studies with humans (clinical trials) are completed animal studies. Although the latter were not available, "clinical trials" of the so-called "phase I", "phase II" and "phase III" were started simultaneously for the COVID "vaccines". Normally, each of these phases lasts from several months (Phase I) to several years (especially Phase III), with the next phase only being initiated after the successful completion of each phase (for more details see N 511 ff.). In December 2020, however, only data on a **two-month investigation phase of** a "telescoped" "phase I/II/III" study was available. This alone represents a massive increase in risk: This so-called "telescoping" carries the risk that time-delayed side effects will only be detected after the vaccine has already been widely used. **Without long-term studies in humans, any kind of approval is a real blind flight.**

190 Now, such a blind flight could at best be dared if the first clinical data did not indicate any problems in human application. But the opposite was the case: the registration studies of Comirnaty and Spikevax showed **indications of increased morbidity in the vaccine group**. There were **3042 more serious events in the** Spikevax **vaccine group than in the placebo group (3985 cases versus 913 cases). In the case** of Comirnaty - with unfortunately only incomplete data - approx. 90-100 more serious events occurred in the vaccine group than in the placebo group (approx. 240 cases versus approx. 139 cases).

191 There was thus also a **risk signal** here, according to which the "vaccines" could do more harm than good to people's health.

1.1.7.4 Unblinding of Phase III studies

192 The aforementioned approval studies by Pfizer and Moderna ("Phase I/II/III") were planned, set up and initiated as "placebo-controlled, randomised and observer-blinded" studies (so-called "double-blind studies") in line with standard practice. However, as early as December 2020 - i.e. still at the time of the limited initial approvals - all study participants were offered the opportunity to switch from the placebo to the vaccine group "for ethical reasons". Citing "ethical reasons" for such a ***de facto discontinuation of the* approval studies** was and is not justified in view of the massive risk potential identified, the demonstrable lack of efficacy of the mRNA "vaccines" (see N 201 ff.) and the overall absolutely negligible danger of SARS-CoV-2 (N 479 ff.) is obviously not justified in any way.

193 Approximately 93.5% - 98% of the study participants made use of this "offer" (by June 2021 at the latest). The control groups thus "shrank" to a size of approx. 2-6.5% of all study participants, with which the **studies were largely "unblinded"** and thus degraded from so-called "double-arm" approval studies to mere observational studies. This means that the **only two human studies that should have (and could have) proven the safety and efficacy of the mRNA "vaccines" according to the recognised rules for clinical trials were downright sabotaged by both manufacturers themselves without corresponding intervention on the part of the regulatory authorities.**

194 Irritatingly, Swissmedic was already aware at the time of the initial authorisations in December 2020 and January 2021 that the manufacturers had unblinded the studies - but more on this later (N 691 ff.) under "Acts of misconduct".

1.1.8. First indications of possible late effects

195 At the time of the first registrations in December 2020, it was only possible to speculate about potential (further) late effects due to a lack of corresponding data (no long-term studies in humans). Nevertheless, **blood diseases, neurodegenerative diseases or autoimmune diseases** (especially ADE) have already been discussed in detail. In this initial situation, the manufacturers, such as Pfizer, had apparently exempted themselves from any liability and stated in the leaked "vaccine" contracts with Brazil that "the efficacy and long-term effects of the vaccine are not yet known and that there **may be adverse effects of the vaccine that are not yet known"**.

196 This is another clear alarm signal, which under normal circumstances would at least have made it imperative to carry out all the necessary animal studies. The failure to do so must once again be seen as a considerable risk factor.

1.1.9. Epidemiologically motivated measure for total population

197 In contrast to all previous medicines, which were approved in the so-called time-limited approval procedure, the mRNA "vaccines" are medicines that should potentially be given to all inhabitants of the whole of Switzerland (from a certain age). This circumstance also leads to a massive **increase in the risk profile** - after all, if the "vaccination strategy" is unsuccessful, it is not only people who are already ill and close to death who are **affected,** but the **entire - fundamentally healthy - population, including children,** who - as shown below (N 474 ff.) - would not have had to expect any significant disadvantages even without this substance. Thus, any risk of "vaccination" side effects, however small, has a negative net benefit for this population group, which Swissmedic was aware of. The licensing authority should therefore have taken special care to exclude all vaccine-related risks for this large population group (Art. 3 para. 1 HMG).

1.1.10. Ongoing phase III study, human trial in general population

198 As previously stated, the temporary approvals were granted in December 2020 based on provisional 2-month data from the pivotal studies. The studies have not yet been completed and are expected to continue until at least 2024.[66] The otherwise usual test procedures with animals were - as far as can be seen from the released Pfizer documents - carried out to a symbolic extent at best.

199 In the present case, it has been shown that no meaningful clinical studies are available for the new "vaccines", in particular no studies on a larger and representative group of people that would have gone beyond an observation period of a few months. The protection of public health within the meaning of Art. 1 and Art. 3 para. 1 HMG is not based on formal criteria, but is to be assessed according to the respective actual effects of certain facts (effect principle; see above N 118). It should therefore be noted that **since the date of the first authorisation in December 2020,** all mRNA "vaccines" are **de facto still in the clinical trial phase.** This legally relevant fact will be referred to again and again in the present criminal complaint.

200 Every person who is administered the mRNA "vaccines" is thus *de facto a* participant in the **largest clinical experiment ever conducted by mankind.** However, only those who have explicitly consented to participate in a clinical trial after being adequately informed about the foreseeable risks and burdens ("*informed consent*"; Art. 16 HFG [SR 810.30]; Art. 7 ff. KlinV [SR 810.305]) can participate in a clinical trial. This includes in particular all facts relevant to the decision, such as the circumstance of missing studies and corre-

66 In addition at the back N 519.

spondingly still unknown possible side effects (on the requirements for informed consent see N 859 ff.). In the absence of appropriate communication in the sense of complete and transparent information, very few vaccinated persons are (or were) aware of these facts relevant to the decision (for more on Swissmedic's misleading communication, see N 701 ff.).

1.2. Effectiveness

201 In December 2020, the mRNA "vaccines" thus presented themselves as medicinal products with a risk profile that is unparalleled in the history of Swiss legislation on therapeutic products. This massive risk could only be compensated by an almost miraculous efficacy, which is also unparalleled. At the very least, however - according to Art. 9a para. 1 lit. b HMG - a **"major"** therapeutic benefit would have to be expected. This was and is by no means the case:

1.2.1. Minimal therapeutic benefit for mere trivial events

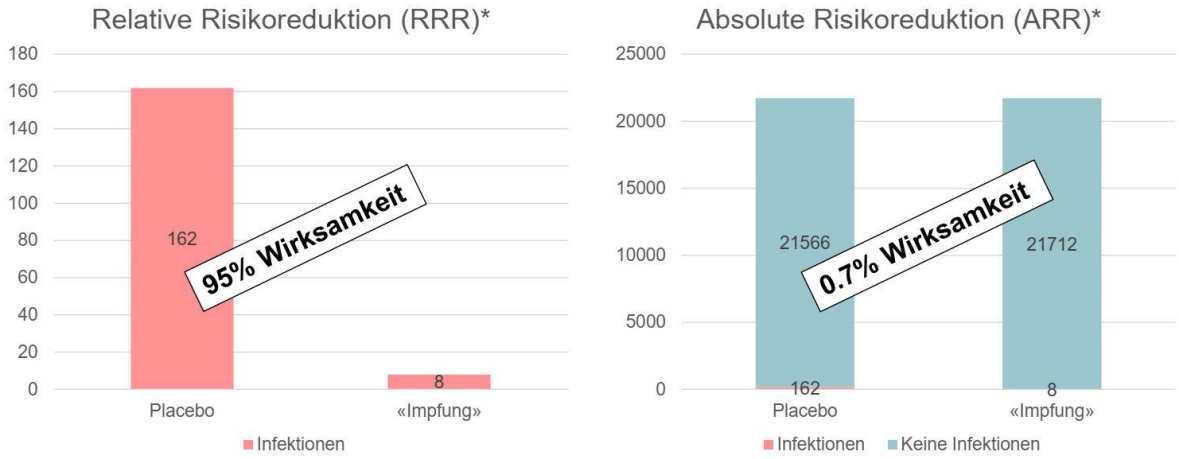
202 According to Art. 9a para. 1 HMG, a medicinal product can only be authorised "for a limited period" if it can be used to treat a life-threatening or disabling disease. This would have to be proven in (clinical) approval studies.

203 This was obviously not the case: The so-called "**primary efficacy endpoint"** chosen in the Pfizer and Moderna **pivotal** studies was selected in such a way that primarily mild "COVID diseases" were recorded - defined on the basis of a positive PCR test plus one or two symptoms such as fever, cough, shortness of breath, cold, sore throat, headache, pain in the limbs, loss of smell/taste, nausea, vomiting or diarrhoea. **With such a study design, only minor events are recorded - and precisely not the fatal or disabling events required by law.**

204 Officially, Pfizer and Moderna reported a high efficacy of 95% and 94.1% respectively for these criteria. Again: This allegedly high "efficacy" refers to primarily mild symptoms that are in no way life-threatening or disabling. **The "efficacy" calculated in relation to the aforementioned minor events is thus from the outset not a sufficient basis for an authorisation according to Art. 9a HMG.**

205 In addition, this unrealistically high efficacy of almost 100% was communicated using a non-transparent, scientifically questionable methodology based on the calculation of the relative risk reduction (RRR), which is to be demonstrated using the example of Comirnaty ("efficacy 95%"): In the Pfizer study, a "confirmed COVID disease" occurred in only **8** (=0.04%) of 21,720 subjects in the vaccine group and in only **162** (=0.74%) of 21,728 sub-

jects in the placebo group. Thus, if a total of 170 cases (8 plus 162) occurred, a total of 162 cases were formally "prevented" in the vaccine group. From this ratio (162 "prevented" cases out of a total of 170 cases) Pfizer then deduced that there was a **95% efficacy** (162 ./. 170), which in science is called Relative Risk Reduction (RRR). Of course, this does not mean that 95% of the more than 40,000 study participants were "successfully" protected from disease: In absolute numbers, **only 162 people out of the more than 40,000 study participants were "protected" from disease.** Presenting the effectiveness only on the basis of the RRR - without putting it in the context of the overall figures (which are presented on the basis of the ARR; more on this in a moment) - thus leads to a **complete distortion of reality,** which is illustrated by the following graph:



* Datenbasis: Pfizer-Zulassungsstudie Phase I/II/III (Comirnaty®); Placebogruppe 21'728 Teilnehmer; «Impfgruppe» 21'720 Teilnehmer

206 It is unscientific and dubious that the manufacturers operate on these factual bases only with information on the RRR - but at the same time do not provide any information on the ARR: it has **been known for over 20 years that the presentation of the RRR without simultaneous disclosure of the ARR and the underlying figures distorts the efficacy data**. Announcements and publications presented in a correspondingly distorted - in the end: massively embellished - manner serve the sole purpose of promoting sales, which even qualifies them as advertising.

207 Correctly, the efficacy should therefore also have been calculated from the beginning on the basis of the **absolute risk reduction (ARR)** and disclosed in relevant documents such as the drug texts: If 162 out of 21,728 people **(= 0.74%)** fell ill with COVID-19 in the Pfizer study with placebo and only 8 out of 21,720 people **(= 0.04%) with the** "vaccine", **the absolute risk reduction (ARR) with Comirnaty is just 0.70%** (0.74% minus 0.04%). The same applies to Moderna: the ARR of **Spikevax is just 1.2%.** Such values are definitely far from a "great" therapeutic benefit.

208 The RRR is not an inadmissible calculation method per se. What is relevant, however - as just explained - is the context. If, instead of just 170 people, several thousand or only several hundred people out of more than 40,000 study participants had been identified as having the disease, then representative efficacy values could certainly be calculated on the basis of the RRR. And this is where **another deception on the part of the manufacturers** comes into play:

209 The allegedly high efficacy of **95%** for Pfizer was calculated on the basis of data that had been **falsified by "adjustments".** Thus, not only 8 but 1,594 "symptomatic COVID cases" occurred in the Pfizer vaccine group, and not only 162 but 1,816 in the placebo group, as officially declared. For inexplicable and undisclosed reasons, however, no PCR test was carried out on these 3,410 cases, despite their symptoms, and the corresponding cases were "sorted out" without further ado. To put it bluntly: **In this way, any conceivable and "desired" result can be manipulated.** If these "sorted out" cases are included, however, even after the **"relative risk reduction" (RRR),** an **"effectiveness" of just 12-19% results.** This is also far from a "major" therapeutic benefit, which is mandatory for the applicability of Art. 9a HMG.

1.2.2. No proven therapeutic benefit for "severe" diseases

210 "Severe" COVID diseases - i.e. those that could fulfil the requirements of a life-threatening or disabling disease - were incomprehensibly only studied in a secondary manner. For these, Pfizer still reported an efficacy of 66.4%. Moderna claimed that only in the placebo group 30 to 185 severe cases occurred, whereas in the vaccine group not a single case occurred - but refrained from stating an efficacy in percent (which according to the RRR calculation method would be an incredible 100%) for severe cases.

211 Pfizer calculated the 66.4% again using the "relative risk reduction" (RRR). In the vaccine group, "severe" COVID disease occurred in only **1** (=0.005%; rounded) of 21,720 subjects and in the placebo group in only **3** (=0.01%; rounded) of 21,728 subjects. **With a total of 4 cases out of over 40,000 study participants, this is obviously in the realm of statistical chance. To conclude from these 4 cases that there is an efficacy of 66.4% is simply dubious, unscientific and misleading.** The same would apply to the 100% efficacy of Moderna determined by the RRR method.

212 Here, too, the efficacy should have been calculated from the beginning on the basis of the **absolute risk reduction (ARR):** With Comirnaty this would be just **0.0092%** (0.0138% minus 0.0046%), with Spikevax it would be **0.2%**.

213 Such values, which are not even in the percentage range, are far from a **"major"** therapeutic benefit, which would have to be given for life-threatening or disabling diseases according to Art. 9a HMG.

1.2.3. No protection against transmission

214 It is only worth mentioning that the manufacturers themselves never claimed that the mRNA "vaccines" could prevent the transmission of SARS-CoV-2 . Rather, Pfizer, for example, stated: **"the question of prevention of virus transmission remains unanswered"**. Nevertheless, Swissmedic misleadingly announced information to the contrary for the attention of the public, according to which "current data" would show that "the possibility of transmission of the coronavirus to other persons after complete vaccination is low".

1.3. Interim result at the end of 2020: Maximum risk, minimum effectiveness

215 As of December 2020, the regulatory authority had for the first time received approval for a medicinal product which, in **all relevant aspects of the approval procedure,** exhibited **considerable to maximum risk factors** - at best even one or more absolute exclusion criteria - such as had probably never existed before in the history of the Institute. First and foremost, the completely novel basic principle of "gene therapy" for preventive purposes, i.e. the manipulation of the body's own functions in a healthy overall population, with the aim of shifting the production of the spike protein into the human body. At the time of the end of 2020, Swissmedic had no confirmed empirical data on the mode of action and the effects of this new technology in a healthy population. In particular, Swissmedic had no reliable empirical data on the question of which organs would ultimately carry out this production process and, above all, in what quality, in what quantity and over how long a period of time, although it is precisely the correct quality and the individually correct dosage of medicinal products that are mandatory prerequisites for any successful treatment.

216 At the same time, the **efficacy of the mRNA preparations** had not been **proven in any way - there could be no question of a "major therapeutic benefit" for the treatment of a fatal or disabling disease.** The basic requirements for an emergency authorisation according to Art. 9a HMG ("temporary authorisation") were therefore already obviously not fulfilled at that time.

217 Accordingly, Swissmedic would have been obliged to **choose** an **authorisation procedure that took maximum account of these risks and uncertainties.** Nevertheless, Swissmedic granted the "temporary" authorisation - without first requesting the relevant

documentation on the identified risks as a mandatory condition for the authorisation. The authorisation authority thus authorised completely new medicinal products with an exceptionally unfavourable risk profile without having itself thoroughly convinced itself of the required quality, safety and efficacy of the "vaccine" (including the new endogenous production technology).

218 With this decision**, Swissmedic took the path of maximum risk - in violation of Art. 9a and Art. 3 para. 1 HMG.** However, if this path of inadmissible risk was chosen, the institute was at least obliged to **exercise all possible care to contain and minimise the inadmissible risk that had been created.** Risks which are not yet conclusively known at the time of the granting of the licence and which are therefore not controllable must be compensated for with effective countermeasures: Anyone who approves a high-risk product must subsequently exercise the utmost care and transparency in informing the public, users and patients. This means: **comprehensive information about all conceivable risks and side effects - with a clear indication that it is a high-risk product in the experimental stage.** In addition, the use of the high-risk product must be closely monitored - with **active monitoring of unintended side effects throughout Switzerland, which could only have been achieved by means of clear instruction and control of the users to report side effects nationwide. It would** have been imperative to provide the necessary personnel for this, for example within the framework of a special safety task force - if necessary, with the deduction of personnel in other departments.

219 As will unfortunately be shown by the following explanations, Swissmedic did not comply in any way with the mandatory obligation to contain the risks, but instead made the desolate situation worse and worse with each new extension of the authorisation, with each misleading orientation of the public and with the failure to monitor the side effects:

2. Swissmedic knowledge status mid-2021 (authorisation adolescents)

220 Six months later, in June 2021, Swissmedic extended the authorisation of the mRNA "vaccines" to adolescents aged 12 and over, although in the meantime further facts were added that further worsened the risk-benefit profile of the experimental substances:

2.1. Risks

2.1.1. High-risk unit dose, especially for adolescents

221 For all adults and adolescents from 12 years of age, a single dose was approved for the basic immunisation with both "vaccines", which meant that an absolutely **unnecessary and long since proven risk had been** taken.

222 It was already clear from a dose-finding study - which had to be part of the marketing authorisation dossier - by Pfizer/BioNTech that younger study participants (18-55-year-olds) generated side effects more frequently and to a more severe extent than older study participants (65-85-year-olds) at all doses investigated (10µg, 20µg, 30µg). According to the study, a dosage of **20 micrograms (µg)** would have been **"appropriate" for** 18- to 55-year-olds for Comirnaty - nevertheless, **30 µg mRNA** was approved for **Comirnaty** and **100 µg mRNA for Spikevax** - i.e. a **fivefold higher value** - across the board.

2.1.2. Comirnaty: 42,086 adverse events and 1200 deaths by February 2021

223 Pfizer/BioNTech allegedly submitted a "*Post Marketing Pharmacovigilance Report*" to the regulatory authorities in April/May 2021. The report, which summarised the data from the time of marketing authorisation to 28 February 2021 - a mere 2 ½ months - already contained the sheer number of **suspicious reports of 42,086 side effects and 1,200 deaths in** connection with the "vaccination". These figures alone were already highly alarming and should have - as far as the back N 239 ff. and N 243 f. below - would have led to an **immediate ban on vaccination in** earlier times.

224 Interestingly, the occurrence of severe allergic reactions and disease exacerbations due to vaccination (vaccine *associated enhanced disease,* "*VAED"*) including exacerbations of respiratory infections (*vaccine associated enhanced respiratory disease,* "*VAERD"*) was mentioned in the report under the heading "*Safety concerns".* This risk has been known for a long time and was already discussed at the time of approval. Similar Corona vaccines against SARS and MERS never made it to market approval in the past, partly because of these safety problems. Studies in animals had shown that **extremely severe courses of disease and deaths occurred in vaccinated persons** - via *antibody-dependent enhancement* (*ADE*) - **as soon as vaccinated persons were exposed to the virus.**

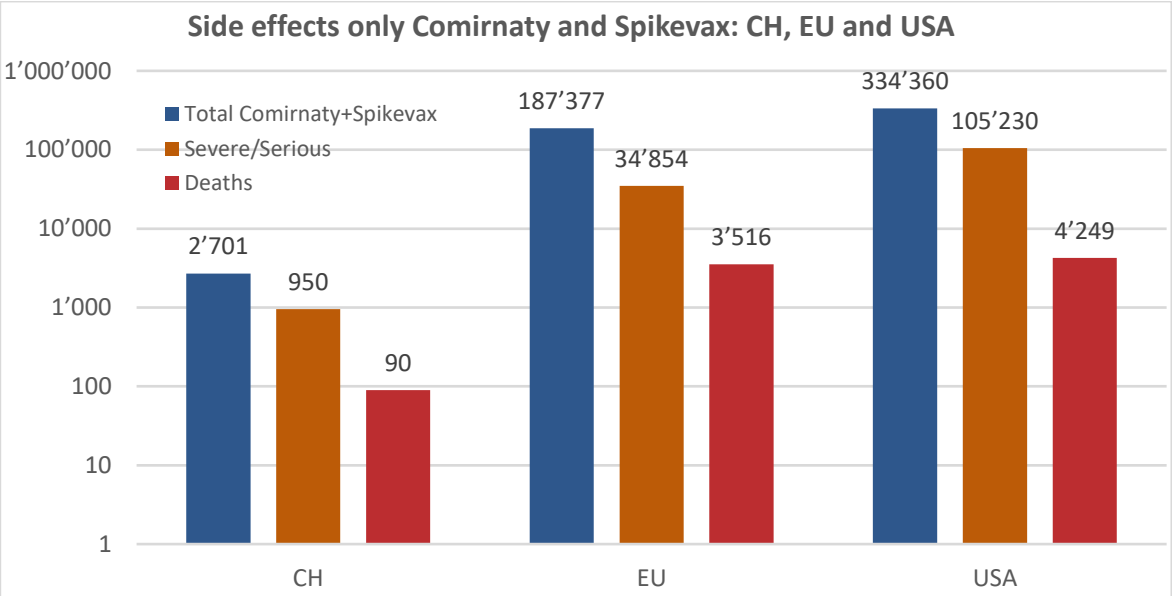
225 Swissmedic thus accepted a risk that turned the actual objective, namely to ensure protection against severe infection by SARS-CoV-2, into its opposite: The substances carried the risk of a worsening of the course compared to persons without injection. That

at least an attempt would have been made to somehow counter this massive risk - if at all possible - is not evident and is dealt with below (on the acts, see below N 715 ff. and 723 ff.).

2.1.3. Worldwide reports of side effects until June 2021

2.1.3.1 Side effects with Comirnaty and Spikevax (absolute numbers)

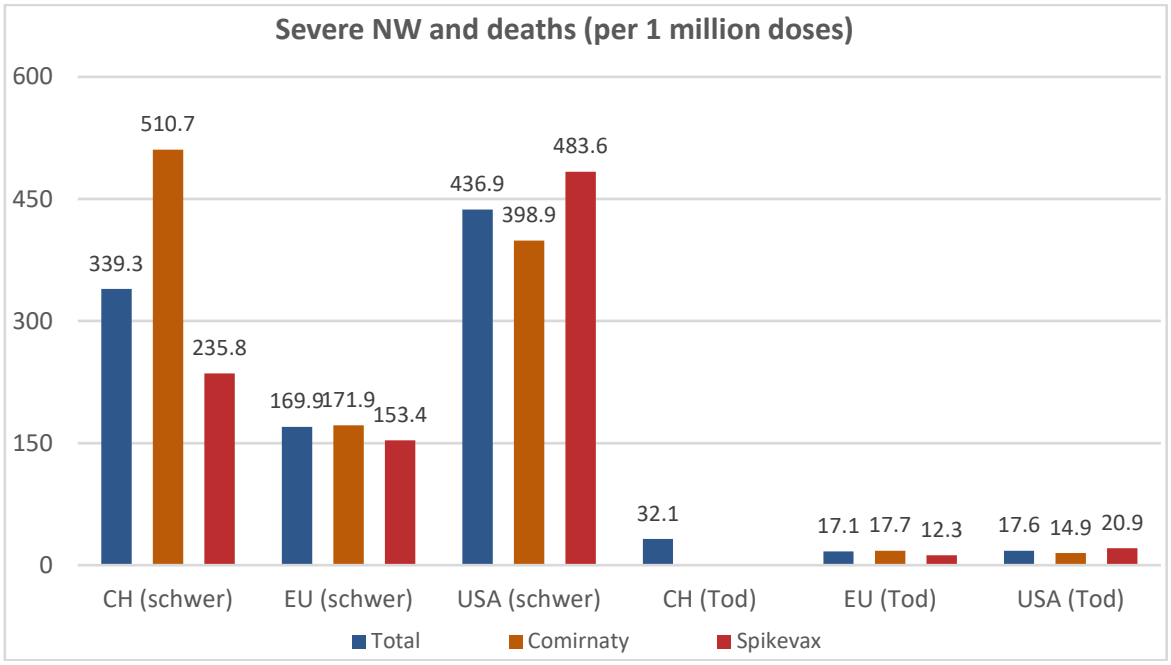
226 By 04 June 2021 in Switzerland, and by 05 June 2022 in the EU and the USA, a total of **524,438 adverse reactions had** been reported for Comirnaty and Spikevax - including **141,034 serious** adverse reactions and **7,855 deaths:**



227 As described below (N 243 f.), studies used to be immediately discontinued or marketing authorisations withdrawn if only about 50 deaths (suspected cases) occurred worldwide. **In June 2021, this alarm value had already been almost doubled in Switzerland alone - and exceeded 150 times worldwide.**

2.1.3.2 Side effects with Comirnaty and Spikevax (per 1 million "vaccine doses")

228 The number of serious adverse events and fatalities for Spikevax and Comirnaty **per million doses administered as** of **June 2021** was as follows:



229 As shown below (N 245), the risk profile of all COVID "vaccines" is devastating compared to influenza vaccines, for example:

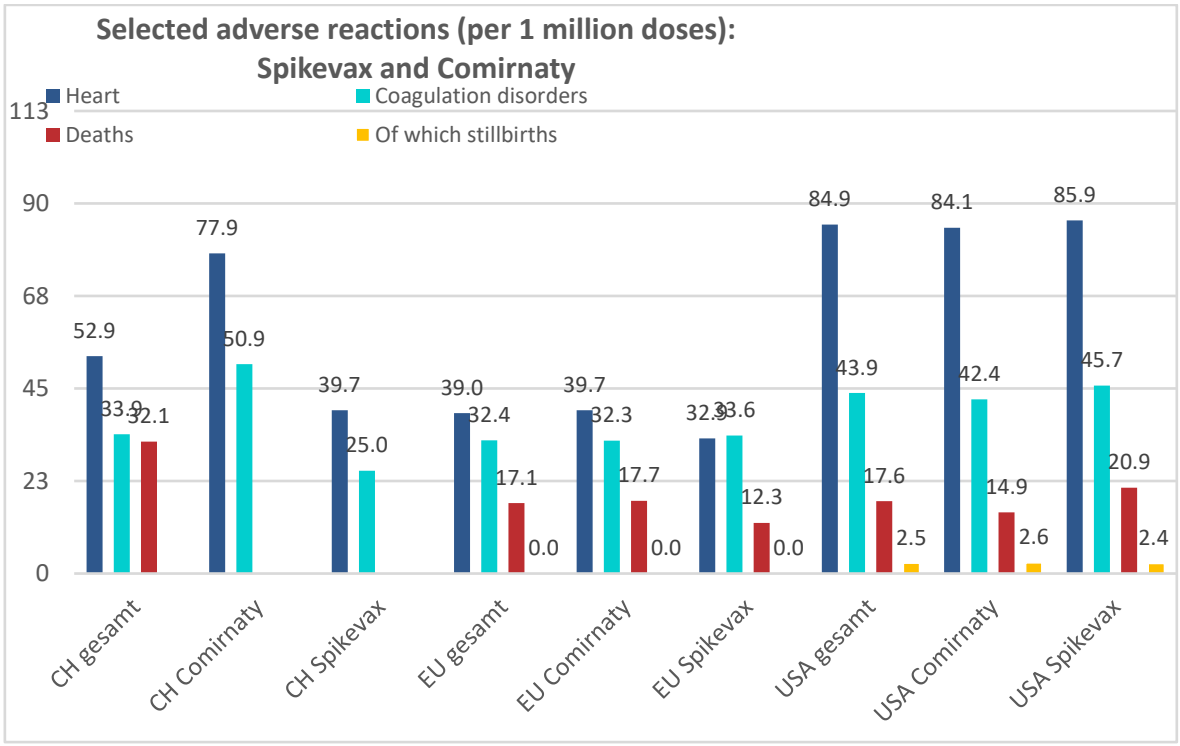
230 Unfortunately, a comparison of the **serious side effects** is admittedly difficult due to different counting methods (in particular the different recording of all serious side effects or only those with permanent damage or hospitalisation). But the picture is abundantly clear: while **0.28 to 3.3** serious side effects per 1 million doses are reported for flu vaccinations, the figure for **Comirnaty / Spikevax is 169.9 to 436.9** as of June 2021 **- that is at least 50 times the number of serious side effects.**

231 The comparison is simpler due to the same counting method for deaths: While **0.38 to 0.63** deaths per 1 million doses are reported for influenza vaccines, the figure for **Comirnaty / Spikevax is 12.1 to 27.8 - at least 20 times the number of reported deaths.**

232 All these are not marginal, tolerable deviations in the lower percentage range, but deviations that are alarming in every respect. Accordingly, it was already openly recognisable in June 2021 that the **"temporary" approvals** were **devastatingly wrong decisions.**

2.1.3.3 Selected side effects: Heart, thromboses, deaths, stillbirths

233 A more detailed analysis of all adverse event reports for Comirnaty and Spikevax - broken down by symptoms such as heart (myocarditis etc.), coagulation disorders (thromboses etc.) as well as deaths and stillbirths - gives the following picture **per 1 million "vaccine doses"** as of **June 2021:**



234 The side effect reports concerning the **heart (myocarditis/pericarditis** etc.) at that time were 32.9 to 85.9 per 1 million "vaccine doses" worldwide, which according to the definition (MedDRA system organ classes) were **"very rare" side effects,** since less than 1 case per 10,000 doses occurred - and this already without taking into account the massive underreporting. Swissmedic's technical information at the time made completely inadequate reference to this risk, which was already known at the time (see N 715 ff.).

235 Even then, the reports of coagulation disorders were worrying, ranging from 25 to 50.9 cases per 1 million doses worldwide. The official data were thus already at that time in a range that was clearly comparable, measurable and estimable. The number of cases per 10,000 was 0.25 to 0.509, which meant that the **coagulation disorders** were **already** classified **as "very rare" side effects (<1/10,000) in June 2021. This** considerable risk was not adequately addressed in any way in Swissmedic's specialist information at the time (see N 715 ff.).

236 **The high number of deaths reported in Switzerland of** 32.1 per 1 million doses is very striking: such high values were never reached later - except approximately in the USA as of 14 May 2022 (see N 384) have never been reached again.

237 Even then, data from the USA showed that there was an **increase in stillbirths.** The increased risk potential for pregnant women (see N 172 ff.) had already materialised.

2.1.4. Alarm signal deaths and severe side effects

238 As before (N 226 ff.), the reports of side effects - especially serious side effects and deaths - concerning Comirnaty and Spikevax alone had already reached absolutely alarming levels in June 2021. It is explained below that such alarm signals in earlier times would have long since led to an immediate "stopping of the exercise":

2.1.4.1 Pandemrix: 5000 serious side effects worldwide

239 After the WHO had declared a "swine flu pandemic" in June 2009 for the H1N1 virus (which is largely harmless because it causes mostly harmless cases), the Pandemrix vaccine from Glaxo Smith Kline (GSK), among others, was probably already approved in Switzerland in October 2009 within the framework of a "temporary authorisation" (the precursor to the "temporary approval"). Swissmedic needed one month longer than the EMA for this. But there was a good reason for this: **Swissmedic decided (unlike the EMA) not to grant authorisation for pregnant women, children/adolescents under 18 years of age and adults over 60 years of age - because it had simply received too little information from GSK for a full authorisation.** *Swissmedic was criticised for this, but this* **caution - in keeping with Art. 1 and Art. 3 para. 1 HMG -** *should pay off for the Swiss population.*

240 *The subsequent vaccination campaign turned into a real disaster worldwide: in just a few months, a* total of 5'069 serious adverse events *were* reported for **Pandemrix (72 cases *I* million doses administered) by** 31 March 2010. Although politicians and regulatory authorities knew about the lack of threat posed by the H1N1 virus and the serious side effects associated with Pandemrix, the population was not educated and the vaccination campaign continued unperturbed. In the *end*, of the *approximately 30 million people vaccinated in Europe, more than 1,300 people (mainly children)* suffered **narcolepsy in** *connection with Pandemrix* **(43 cases per million doses administered).** Thanks to Swissmedic's correct refusal to authorise the vaccine for children, **Switzerland** was **largely spared these consequences.**

241 The supposed "pandemic" was declared over by the WHO around 12 August 2010, which also made the failed vaccination campaign obsolete and discontinued it. The legal proceedings against GSK concerning vaccine damage are apparently still pending.

242 As a result, the **swine flu vaccination campaign was stopped with a few thousand - reported - serious side effects worldwide.** This value had long since been exceeded **several times in** June 2021 - another serious alarm signal.

2.1.4.2 Withdrawal of medicines: 50 deaths or life-threatening incidents

243 In 2001, the company Bayer withdrew the cholesterol-lowering drug Lipobay. This was after **52 deaths had** occurred in connection with the use of Lipobay and muscle weakness. Something similar happened in 2004: Merck withdrew the anti-inflammatory Vioxx , which was **suspected of having** caused **41 heart attacks** worldwide. Moreover, in a ruling in 2008, the Federal Supreme Court stated that "discontinuation criteria" had been defined in a clinical trial, according to which the trial would have been "discontinued after the first **50 patients" in the** event of findings on the "harmfulness of the therapeutic procedure".

244 In the past, the worldwide occurrence of approximately 50 fatal or life-threatening incidents - including merely suspected cases - had already led to a suspension of approval or discontinuation of studies. This alarming value had already been **exceeded more than 100 times in** June 2021. In addition, the above-mentioned drugs were only used to treat people who were already ill - mRNA "vaccines", on the other hand, are used prophylactically in a healthy population, which means that a lethal risk from the drug is much more serious.

2.1.4.3 Comparison of COVID "vaccines" *with flu vaccine*

245 In Switzerland, there is only very insufficient data on the side effects of influenza vaccines, which is why a direct comparison with the mRNA "vaccines" is difficult. Accordingly, data from the EU and the USA must be used. The corresponding sources are presented in detail in the evidence report. A comparison of **serious side effects** (side effects that are fatal or life-threatening, require hospitalisation or lead to significant or permanent damage) **and deaths** can be seen in the following overview (data in cases per million vaccine doses administered):

Table 1: Serious adverse reactions (per million vaccine doses)

	Flu	Pandemrix	COVID "vaccines
Switzerland	--	--	**250**
EN	0.28	--	**47.8**[67]
EU	1.8	72	**278**
USA	3.3	--	**96**[68]

Table 2: Deaths (per million vaccine doses)

	Flu	Pandemrix	COVID "vaccines
Switzerland	--	--	**12.1-15.2**
EN	0.38	--	**15.6**

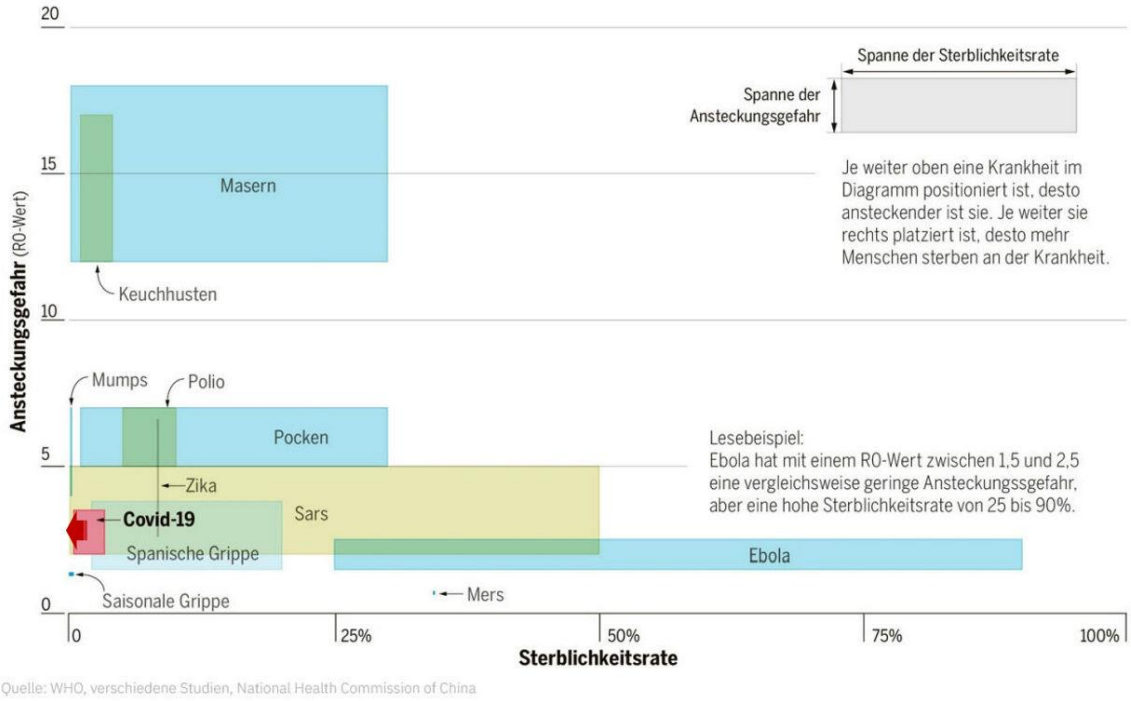
67 Side effects with *permanent* damage.
68 Side effects associated with *hospitalisation*.

EU	0.63	--	**12.1-12.9**
USA	0.41	--	**19.6-27.8**

246 *Even if the figures collected are subject to greater fluctuation depending on their origin and due to a non-uniform definition of "severe side effects", the findings are clear: the COVID "vaccines" already show an absolutely devastating balance after just over one year of use. The* **number of *severe side effects*** *per million doses vaccinated is* ***more than 30 times*** **higher, the number of deaths even 20-50 times higher than with flu vaccines (per million doses "vaccinated" in each case).** Any (medium- and) long-term side effects of the *COVID "vaccines" are not even taken into account here, depending on the circumstances - in contrast to the other vaccines described.*

2.1.4.4 Comparison of COVID "vaccines" with measles vaccines

247 A comparison of the *COVID "vaccines"* designed for Sars-Cov-2 *with the measles vaccines is not meaningful in view of the lethality of the two diseases to be "combated":* ***measles has a high lethality of up to 30%,*** *while Covid-19 has a lethality of just 0.15% (alpha variant), or even only 0.002% (omicron variant) (see N* 480 *ff. and N* 487 *f.). However,* ***measles*** *is not only many times more deadly, it is also* ***many times more contagious:***



Quelle: WHO, verschiedene Studien, National Health Commission of China

248 A comparison of the side effect reports in VAERS and EudraVigilance also reveals that the **risk of a side effect after COVID "vaccination"** is **13 times higher in the USA and as much as 72 times higher in the EU area than for measles vaccination.**

249 The comparison with measles vaccines is also *absolutely devastating* for the *COVID "vaccines": They are supposed to "fight" a far less dangerous disease - at the same time they generate massively more side effects. The "omens" should be the other way round: More side effects than with the measles vaccine would only be tolerable if a much more dangerous disease than measles were "fought" with it.*

2.1.5. First studies: connection between COVID "vaccination" and side effects

250 All these reported side effects were not in a "vacuum": there was already a strong suspicion at the time that they were **directly causally related to the COVID "vaccines"**:

251 For example, by 4 June 2021, at least **5 peer-reviewed publications on heart problems, 44 peer-reviewed publications on life-threatening coagulation disorders (thromboses, etc.) and one peer-reviewed publication on possible deaths as a result of COVID "vaccinations" had** already appeared**.**

252 **All these studies showed an alarmingly high number of side effects even in the first few months of the COVID "vaccination". All these studies were peer-reviewed and publicly available - thus also to Swissmedic - and were highly relevant in terms of the protection of public health within the meaning of Art. 3 para. 1 HMG.**

2.2. Effectiveness

2.2.1. Efficacy data in adults

253 As far as can be seen, the official effectiveness data concerning adult persons had not changed by this time compared to the time of the first approval in December 2020 (see above N 201 ff.).

2.2.2. Efficacy claims in adolescents

2.2.2.1 Minimal therapeutic benefit for mere trivial events

254 As was already the case with adults, primarily **minor events** were also investigated in adolescents, which - as already mentioned - precisely do **not** represent a **"life-threatening or disabling disease" in the sense of Art. 9a HMG.** Here, too, no proof of a "major" therapeutic benefit could be provided from the outset.

255 Once again, the distorting calculation method of the RRR was used to "calculate" an almost implausible efficacy: For Comirnaty, **100% efficacy** was announced in adolescents aged 12-15 years, because a "confirmed COVID disease" (i.e. a trivial event) had oc-

curred in **16** of 1129 subjects (prevalence 1.4%) in the placebo group vs. in **0** of 1131 subjects in the vaccination group. A similar picture emerged for Spikevax: In the product information, an efficacy of **93.**3% (-100%) was published, whereby depending on one of the two case definitions used, **7 versus 1** (or 4 versus 0) "confirmed COVID illnesses" (minor events) were reported in the placebo versus vaccine group in the 3,732 study participants. Again, these figures do not mean that up to 100% of the total of 2,260 or 3,732 study participants were "successfully" protected from disease. In addition, 16 and 8 cases, respectively, out of several thousand study participants, are obviously in the realm of statistical chance.) **To conclude an effectiveness of up to 100% from these few cases is dubious, unscientific and misleading.**

2.2.2.2 No data for "severe" diseases

256 "Severe" COVID diseases - i.e. those that could fulfil the requirements of a life-threatening or disabling disease within the meaning of Art. 9a HMG - could not be investigated at all. This was for a very simple reason: **neither in the registration study of Comirnaty nor of Spikevax were "severe COVID diseases" reported for adolescents aged 12 and over.**

257 Although not a single adolescent was seriously ill with corona in the approval studies, a **"temporary" approval** was **granted for "protection" against corona, which adolescents obviously do not need.** Due to the lack of corresponding data, it cannot even begin to be proven that the vaccination would have the potential to effectively protect adolescents from a serious (life-threatening or disabling) disease.

2.2.3. Infection with SARS-CoV-2 reliably protects against re-infection

258 At the time of the approval of the COVID vaccinations for children and adolescents aged 12 years and older, it was already apparent that a previous illness reliably protects against a new infection: In a large-scale American study of 15 March 2021 with more than 150,000 patients, it was shown that having had the disease protected against a recurrence of symptomatic disease with an "efficacy" of 84.5%. This early study joins a total of **at least 37 publications and pre-print publications that have** also come to the conclusion that a previous illness produces a broad and long-lasting immune response or protects at least as well or even better against a COVID illness than the "vaccination".

259 Exposing young people to the risk of an experimental "vaccination", although they were in no way endangered by the disease to be "fought" and, moreover, are even more reliably

protected after infection than after "vaccination", was already recognisable as a clear wrong decision in June 2021.

2.3. Interim result (mid-2021): High risk already realised

260 The high risk potential of the "vaccines", already shown at the time of initial approval in December 2020, had been realised in the most impressive way by June 2021: thousands of people died in close connection with the administration of the mRNA "vaccines", tens of thousands suffered severe side effects.

261 Instead of reacting immediately and finally removing the toxic, presumably carcinogenic and potentially mutagenic medicines from the market, their authorisation was extended in a further risk-increasing manner - by now also allowing adolescents to be "vaccinated" with the same demonstrably dangerous substances in the same high - potentially lethal - dose, although the basic requirement for a temporary authorisation in the sense of Art. 9a HMG - a life-threatening or disabling disease - was not proven by the manufacturers in any case for the placebo group of adolescents over 12 years of age.

262 The prerequisites for a temporary authorisation of the COVID vaccines in the privileged examination procedure according to Art. 9a HMG were thus obviously not met for this age group.

3. Swissmedic's state of knowledge at the end of 2021 ("Booster" and children)

263 On 26 October 2021, Swissmedic approved a third dose of the mRNA "vaccines" ("booster") and extended the scope of application on 10 December 2021 to children aged 5 years and older. Again, this was done in the knowledge of further facts that further worsened the risk-benefit profile of the experimental medicinal products:

3.1. Risks

264 For the sake of clarity, it should be noted that the violations at Comirnaty are only highlighted below because **no such information** is **publicly available on Spikevax due to the lack of publication of the corresponding reports.** It is imperative that this circumstance be corrected, which is why the corresponding requests for evidence are made at the beginning.

3.1.1. Toxic effect of the spike protein

265 Already before (N 155 ff.), it was shown that the lipid nanoparticles (LNP) contained in the mRNA "vaccines" - contrary to official statements - did not remain at the injection site, but were distributed throughout the body and accumulated in various organs. But it was not only the LNP that had been examined in a completely inadequate way for their toxicity. The same applies to the effect of the spike protein on the human body:

266 The amount of spike protein effectively produced in the body of the individual "vaccinated" is - as far as can be seen - completely unknown: Data on this is still completely lacking, as no pharmacokinetic studies on humans have been conducted in this regard. This circumstance is completely untenable in view of the proven toxic effect of the spike protein:

267 Several studies from 2021 (and 2022) **still** detected **the spike protein in the entire human body two to four months after the "vaccination".** Thus, there could and can be no question of a "short-term" application. This overlong presence in the body has numerous devastating consequences:

268 **Every cell in the body that expresses the spike protein thus becomes a target for the immune system over a longer period of time.** Animal studies showed as early as April 2021 that the spike **protein causes vascular damage, which** in turn can lead to cardiovascular events such as heart attacks, strokes, etc. However, due to its mode of action, the spike protein not only causes vascular damage in all kinds of organs (the immune system attacks the cells that form the spike protein) - it is also able to activate blood platelets directly. Both lead to increased blood clotting and thus to **blood clots.** This explains the side effects reported thousands of times with the start of the "vaccination campaign", such as **heart attacks, strokes, pulmonary embolisms, thromboses,** etc.

269 The **overlong presence of the toxic spike protein, which is in no way intended, therefore presumably leads to a large number of serious side effects (up to and including death). It is not** evident that Swissmedic has in any way effectively countered this obvious risk, which can hardly be controlled in the absence of detailed studies.

270 What cannot be explained is why the manufacturers chose the spike protein of all things for "vaccine production": Apart from the spike protein, there would have been various other suitable **- less harmful - surface proteins that** could have been used for this purpose as less aggressive alternatives.

3.1.2. Comirnaty: Revealed falsifications in the registration studies

271 Previously, it was explained in detail that the registration studies were sabotaged by "unblinding" on the part of the manufacturers. But it did not stop there:

272 According to a publication of 2 November 2021 in the renowned *British Medical Journal,* the phase 3 study by Pfizer/BioNTech was not conducted at various study centres in accordance with the rules of *"Good Clinical Practice (GCP)"* (Art. 5 para. 1 lit. a AMZV): Among other things, the contract research organisation *Ventavia* reported **protocol deviations, falsification of data, poor laboratory management, incorrect storage of the vaccine vials and untrained study staff.**

273 *In view of these serious violations of the GCP, the* **data integrity of the Pfizer/BioNTech pivotal study can hardly be guaranteed.** *Normally, such findings would force marketing authorisation holders and regulatory authorities to conduct extensive investigations and to recall the medicinal product concerned until the results of the investigation were available. The fact that this has not happened to date must once again be seen as a massive increase in risk, of which Swissmedic must have been aware.*

3.1.3. Comirnaty: Fake death reports, more deaths in vaccination group

274 In July 2021, Pfizer reported 15 deaths in the vaccine group versus 14 deaths in the placebo group in the 6-month report. The deaths were not "COVID deaths" but "all cause mortality". The number of deaths in the category "all cause mortality" has always been considered a sensitive marker for the safety of a drug, which is why even low numbers are relevant.

275 Most alarmingly, the number of deaths reported was apparently wrong, as even the FDA noted: Instead of 14 deaths, **17 deaths were** recorded in **the placebo group** and instead of 15, **21 deaths were** recorded in **the vaccine group.** In another analysis of the same reported figures, the *Canadian COVID Care Alliance* ("CCCA") came to a similar conclusion: there were actually **14 deaths in the placebo group,** but a full **20 deaths in the vaccine group**.

276 This unacceptably **euphemistic deviation "in favour" of the vaccine group**, obviously made by Pfizer itself, should once again have raised considerable doubts among the competent authorities about the trustworthiness of the company, the data it provided and ultimately the safety of the mRNA vaccine.

3.1.4. Comirnaty: More (serious) events in vaccination group

277 In the aforementioned analysis, the *Canadian COVID Care Alliance* ("CCCA") uncovered another explosive fact: In the vaccine group, a total of 5,241 *adverse events occurred,* whereas in the placebo group only 1,311 *adverse events occurred for* which a connection with the study medication was established. For ***serious*** *adverse events,* the number of cases was 262 (vaccine group) vs. 150 (placebo group).

278 In the **vaccine group, four times more *adverse events* and almost two times more *serious adverse events occurred as a*** result of the medication. This is also a real exclusion signal as far as the safety of the mRNA "vaccines" is concerned.

3.1.5. Comirnaty: Alarming Interim Report ("PSUR")

279 The manufacturers were obliged by the regulatory authorities to submit interim reports, so-called *Periodic Safety Update reports* ("PSUR"). The first PSUR from Pfizer was published as part of the Pfizer Leaks; Moderna also lacks corresponding publicly available information. The Pfizer PSUR covers the observation period from 19 December 2020 to 18 June 2021, was finalised on 19 August 2021 and had to be submitted to the regulatory authorities as of that date. This interim report again contains a **large number of additional risk-increasing facts:**

3.1.5.1 Excessive number of deaths

280 Of 702 serious events that occurred in the **clinical trials, 46 cases (6.6%)** ended **fatally**. Also studied were 327,827 cases from the so-called **"postmarketing phase"**: of these, 100,808 (30.8%) were classified as serious, with **5,115 cases (1.6%)** ending **fatally.**

281 As before (N 243 f.), in earlier times 50 deaths had already sufficed for an immediate suspension of approval. Why this is now handled differently with mRNA "vaccines" is in no way comprehensible.

3.1.5.2 Older people with previous illnesses are particularly at risk - but again there is a lack of data

282 Due to 23 deaths - which only occurred in the first weeks after approval (until 14 January 2021) in Norwegian old people's homes - the Norwegian regulatory authority adjusted its vaccination recommendations: **Caution should be exercised when vaccinating frail elderly people** and decisions should be made on a case-by-case basis.

283 Once again, the completely inadequate data situation becomes apparent: In the Comirnaty registration trial, only 804 (4.4%) of the study participants were in the vaccine group ≥ 75 years. Also, only 21% of the study participants had a concomitant disease. Comirnaty was therefore studied in a predominantly younger and healthy population. The studies concerning the safety of the older and previously ill population are thus absolutely insufficient, which even the manufacturers openly admit: **Pfizer itself classified the use of Comirnaty in frail patients with concomitant diseases (cardiovascular or neurological diseases, diabetes, chronic obstructive pulmonary disease [COPD]) as "missing information".**

284 Despite this, the "booster" was authorised precisely for the elderly population as a matter of priority without any warning (on Swissmedic's actions, see N 712 f.).

3.1.5.3 Side effects hastily classified as "signals that do not pose risks

285 Another striking aspect of PSUR No. 1 is that Pfizer had classified various side effects, such as **thrombosis** or **herpes zoster,** as **"signals that do not represent risks".** This was already in obvious contradiction to the actually reported side effects in mid-2021: **According to the EMA, thromboses** were among the **most frequently reported serious suspected cases.** Swissmedic itself had also recognised herpes zoster as a potential safety signal, according to 92 reported cases. Swissmedic had thus certainly recognised that**, contrary to the assessments of the manufacturers, thromboses or herpes zoster could certainly be classified as "signals representing risks".**

3.1.5.4 Interim conclusion

286 All these alarm signals should have led to a far-reaching investigation and a "stop to the practice" in view of the central object of protection according to Art. 1 and Art. 3 Para. 1 HMG - public health. At the very least, however, the licensing authority would have had to impose mandatory conditions and corrective measures on the manufacturers. Above all, however, there was the greatest reason to finally take effective measures for the protection of public health to effectively recognise the risk signals - in particular in the form of rigorous market surveillance.

3.1.6. Spikevax: 2 out of 149 (1.3%) of the study participants suffered pericarditis

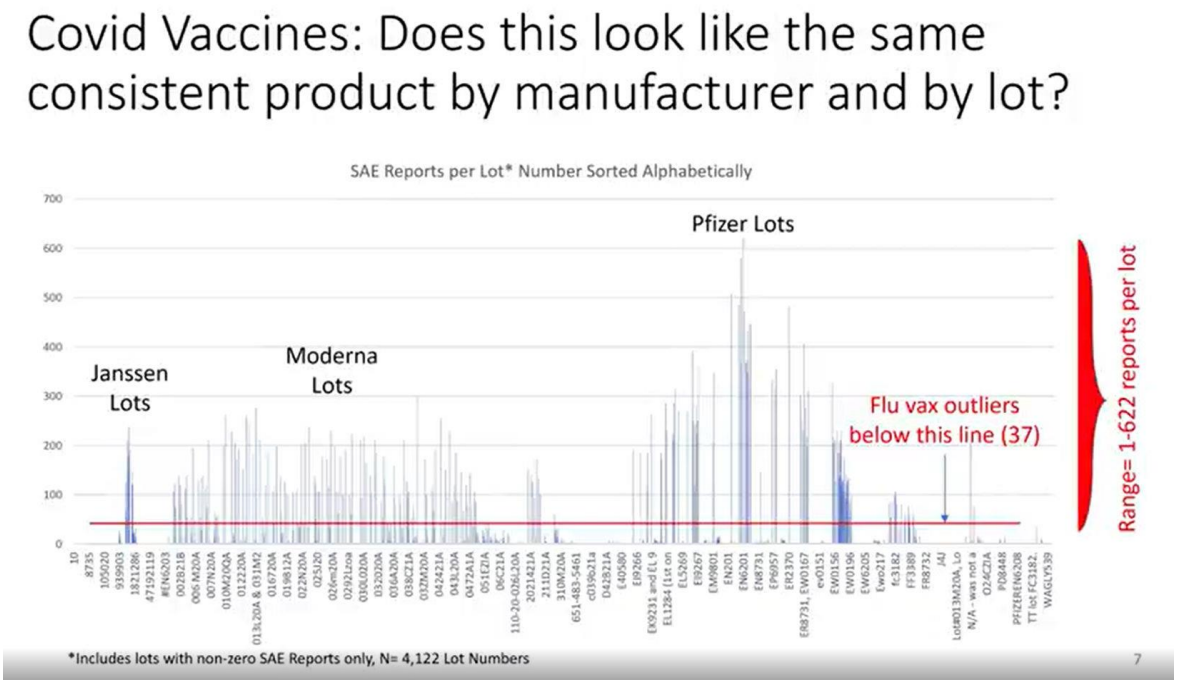
287 According to Swissmedic's technical information, "only limited data are available on booster vaccination with Spikevax". One figure, however, makes one sit up and take notice: In **2 of 149 (1.3%) participants, pericarditis was observed in temporal connec-**

tion with the administration of the booster vaccination, which would be classified as a **"frequent" side effect.** However, the study is so weak that no clear conclusions can be drawn from it, as these cases are in the realm of statistical chance.

3.1.7. Significant variability in adverse events per "vaccination batch"?

288 With regard to the following remarks, it should be expressly noted that these are not results from peer-reviewed or even properly published studies. However, the findings appear to be so important that they should at least be taken as an *initial indication of* possible irregularities and must give rise to further investigations.

289 In December 2021, US researchers published results showing that the **individual vaccine batches were responsible for the occurrence of severe side effects to a highly variable extent.**

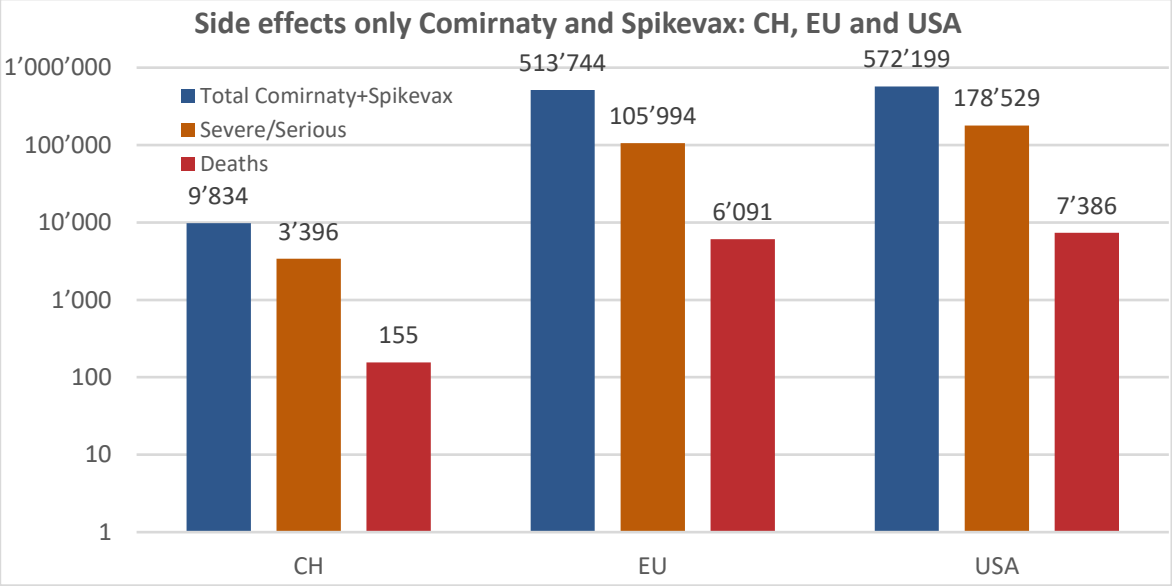


290 They had made this finding based on an evaluation of the adverse events registered in the US *VAERS* database. Although in principle factors such as different reporting behaviour at different sites, incorrect transport or incorrect storage could have contributed to these differences, the overall differences are so serious that they point to **uneven production in** the COVID "vaccines" and thus to a **serious quality problem.**

3.1.8. Worldwide reports of side effects continue to rise massively

3.1.8.1 Side effects with Comirnaty and Spikevax (absolute numbers)

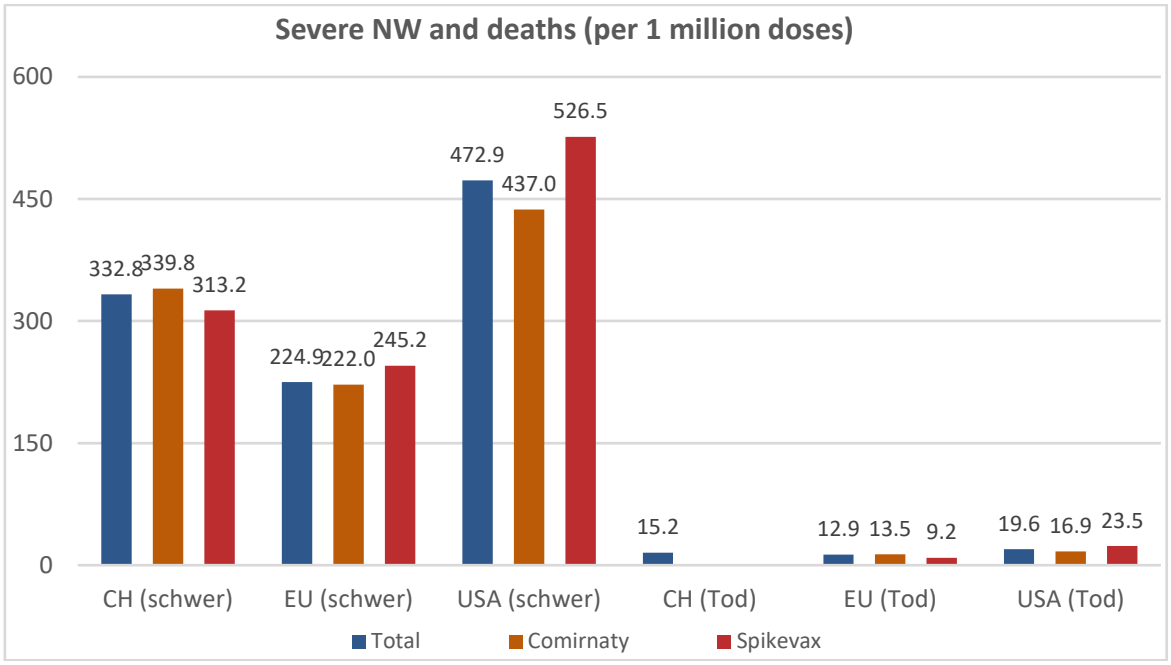
291 By 05 November 2021 in Switzerland, and by 30 October 2021 in the EU and the USA, a total of **1,095,777 adverse reactions had** been reported for Comirnaty and Spikevax - including **287,919 serious** adverse reactions and **13,632 deaths**:



292 The **alarm value of 50 deaths was thus massively exceeded with 13,632 deaths - more than <u>250 times</u>.**

3.1.8.2 Side effects with Comirnaty and Spikevax (per 1 million "vaccine doses")

293 The number of serious adverse reactions and deaths for Spikevax and Comirnaty **per million doses administered at** the beginning of **November 2021 was** as follows:



294 As shown previously (N 245), the risk profile of all COVID "vaccines" is devastating compared to influenza vaccines, for example:

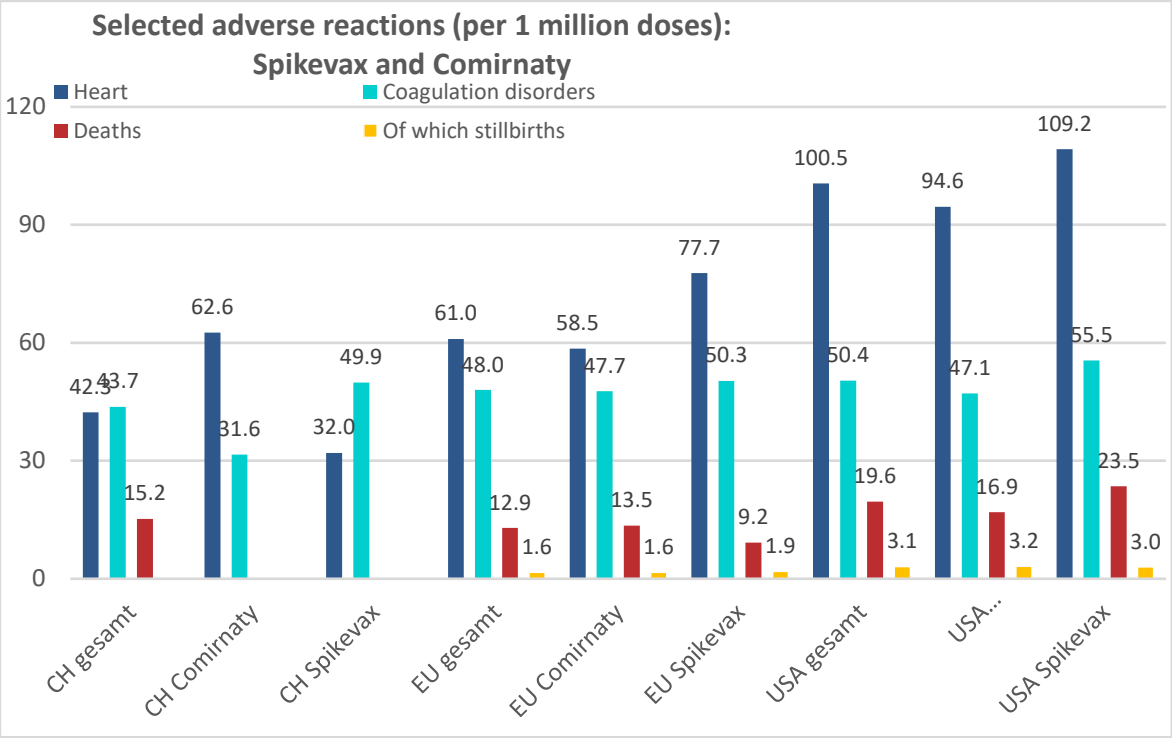
295 The comparison with the influenza vaccinations is similar to the previous one (N 230), whereby a slight "increase" is even recognisable: **Comirnaty / Spikevax show at least 68 times the number of severe side effects compared to the flu vaccination.**

296 Compared to the flu vaccines, **Comirnaty / Spikevax continue to record at least 20 times the number of reported deaths.**

297 All these are not marginal, tolerable deviations in the lower percentage range, but deviations that are alarming in every respect. In November 2021, it once again became openly apparent to everyone that the **"temporary" approvals** were **devastatingly wrong decisions**.

3.1.8.3 Selected side effects: Heart, thromboses, deaths, stillbirths

298 A more detailed analysis of all adverse event reports for Comirnaty and Spikevax - broken down by symptoms such as heart (myocarditis etc.), coagulation disorders (thromboses etc.) as well as deaths and stillbirths - gives the following picture **per 1 million "vaccine doses"** as of **November 2021:**



299 What is already striking here is the tendency towards **comparatively higher reporting rates** concerning "heart" and the double to triple higher reporting rates concerning deaths **in the USA.** Whether these differences are population- or reporting-related would have to be investigated in more detail. Under no circumstances, however, should strikingly higher reporting rates in the USA and also in individual countries of the EU be ignored by a Swiss regulatory authority - on the contrary: in view of its mandate to protect public health, these figures are just as important as the figures in Switzerland, since the same "vaccine" substances are involved in all countries.

300 As early as November 2021, the side effect reports in the USA concerning the **heart (myocarditis/pericarditis** etc.) were 94.6 (Comirnaty) to 109.2 (Spikevax) per 1 million vaccine doses. At least in the case of Spikevax, these were **"rarely" occurring side effects** according to the definition (MedDRA system organ classes) (Comirnaty: still just under "very rare") - and this already without taking into account the massive underreporting. However, Swissmedic's expert information does not reflect this considerable risk (see N 715 ff.).

301 Even then, the reports of coagulation disorders were worrying, ranging from 31.6 to 55.5 cases per 1 million doses worldwide. The official data were thus in a range that could clearly be compared, measured and estimated. The number of cases per 10,000 was 0.316 to 0.555, which means that the **coagulation disorders** were classified **as "very**

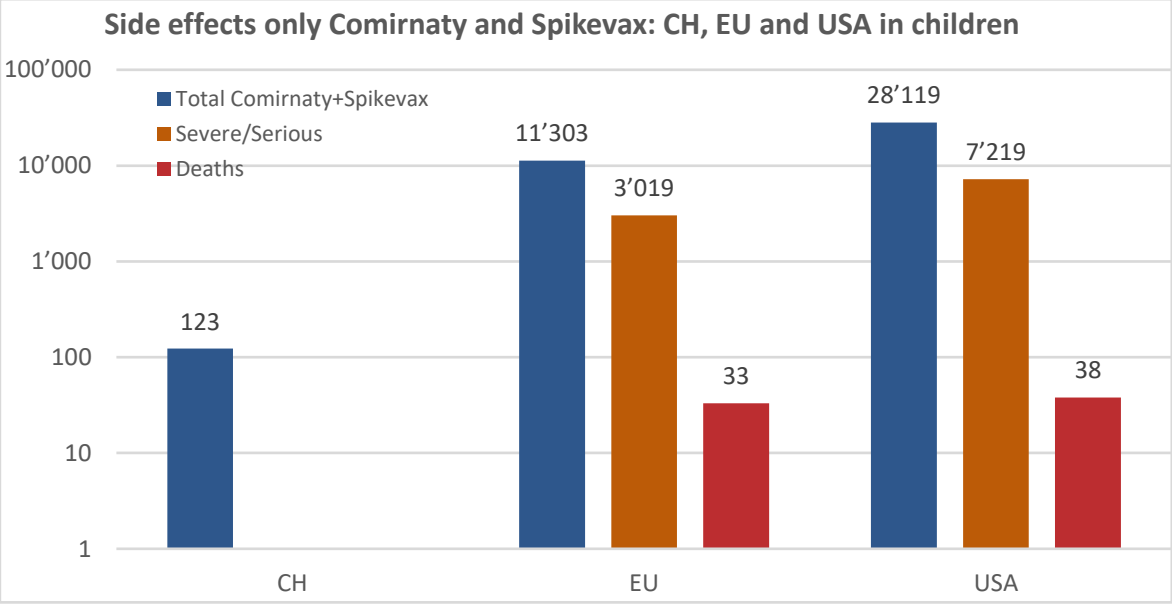
rare" side effects (<1/10,000). However, Swissmedic's expert information does not reflect this considerable risk (see N 715 ff).

302 Very striking are the **death reports in** Switzerland, which are suddenly only half as high at 15.2 (previously: 32.1) per 1 million doses. In addition to fewer actual deaths, possible reasons for this could be the increased number of "preliminary examinations" carried out by Swissmedic (see N 312) or a change in reporting behaviour (see N 313 ff.).

303 With regard to **stillbirths,** on the other hand, an increase was recorded in the USA in the same period, and stillbirths are now also listed in the EU. In Switzerland - at the time of our work - there is no corresponding information. On the basis of the international data, it has in the meantime become evident that the presumed increased risk potential for pregnant women (see N 172 ff.) had already been impressively realised.

3.1.8.4 In particular: Side effects in children

304 By 17 December 2021 in Switzerland, and by 11 December 2022 in the EU and the USA, a total of **39,545 adverse reactions had** been reported for Comirnaty and Spikevax in **children** (including adolescents) - of which **10,238 were serious** and **71 were deaths:**



305 Only in the case of children was the **alert value of 50 deaths clearly exceeded at** the time of the extension of the authorisation from 5 years of age in December 2021. If one considers that not a single child in Switzerland had demonstrably died from "COVID-19", there was no justification for the extension of the authorisation that was nevertheless carried out.

3.1.8.5 Interim conclusion

306 As an interim conclusion, it can be stated that nationally and internationally, **the reported adverse** drug **reactions had reached an unprecedented level by the end of 2021** - and this despite the fact that, due to the purely passive reporting system, massive underreporting can be assumed in all countries:

3.1.9. Massive underreporting in general

307 The worldwide passive reporting systems have one thing in common: the reports are in no way automated and systematic. Rather, reporting depends on the knowledge and awareness that an observation could be a side effect and on the will of those involved to take on the effort of reporting in the first place. This leads to massive under-reporting:

3.1.9.1 Studies on (worldwide) under-reporting: Only 6% reporting rate

308 As early as 1991, it was estimated that with passive reporting systems, only about 5% of all adverse drug reactions are reported at all. A peer-reviewed study from 2012 confirmed this assessment: 37 studies on the topic of under-reporting of adverse drug reactions from 12 countries were analysed. The study found that **only 6% of all effectively occurring adverse drug reactions were reported.**

309 **The problem of worldwide under-reporting in passive reporting systems has therefore long been a general concern.**

3.1.9.2 USA: Under 3% of all adverse reactions reported

310 This is also confirmed by analyses from individual countries: In the USA, for example, according to a Harvard study from 2010, just 1% of all side effects are reported to the vaccine side effect database VAERS. For the mRNA "vaccines", recent studies came to a similar conclusion: due to under-reporting, **all registered serious adverse reaction reports** would have to be **multiplied by at least a factor of 41 in order to reflect reality** (which corresponds to an effective coverage of 2.43%).

3.1.9.3 Switzerland: Reporting rate is 50% of the reporting rate of Germany

311 A comparison of Switzerland with Germany also leads to the conclusion that the reporting rate here is likely to be even worse than in Germany: While in Germany a reporting rate of 1.7/1000 vaccine doses can be observed, the **reporting rate in Switzerland is only 0.8/1000 vaccine doses, i.e. half.**

312 One possible reason for this massive underreporting in Switzerland could be that Swissmedic states that it carries out a "preliminary check". Other countries also check the reports for their meaningfulness - but nevertheless publish the total number of reports. **Swissmedic only publishes suspected cases of adverse drug reactions that it has authorised after the preliminary assessment.** In the interests of transparent communication, it is in no way comprehensible why Swissmedic does not also disclose the total number of suspected adverse drug reactions.

3.1.10. Underreporting of deaths: No "vaccination" deaths without autopsies

3.1.10.1 International warnings and calls to perform more autopsies

313 Another serious problem of under-reporting is the widespread **lack of autopsies:** From May to August 2021, professors across Europe had already warned that there was a large number of unreported cases regarding a causal connection of the COVID "vaccination" with deaths that had occurred in a temporal context. Accordingly, they demanded that a post-mortem examination be obligatory for deaths in a temporal connection with the vaccination.

314 The demand was not heard: for example, by **the end of September 2021, fewer than ten people** who had died in a temporal connection with the vaccination had been **autopsied at the University Hospital Zurich.**

3.1.10.2 Own investigation: Too few and ineffective autopsies

315 A specially conducted "analysis of 15 deaths" **(Annex 5)** in the periods from February 2021 to June 2021, and December 2021 to mid-January 2022 (plus two further deaths outside these periods) confirms this misguided approach:

316 In a total of five deaths during the two periods mentioned, in which **explicit references** to "vaccinations" were made by the police (e.g. "vaccinated the day before", "vaccinated 10 days ago"), no post-mortem examination was ordered by the responsible public prosecutor's office. Moreover, it is particularly disturbing that in two cases it was even stated that the **"cause of death was unclear"** and **in one case a post-mortem examination** was **not ordered by the public prosecutor, contrary to the assessment of the cantonal medical officer.**

317 It is also incomprehensible why, outside of the above-mentioned periods, no indications of COVID "vaccinations" were placed by the police, although in at least two cases (September 2021 and April 2022) it is known on the basis of their own investigations that the de-

ceased had been "vaccinated". **The police investigation of the vaccination status is an indispensable prerequisite for the decision to perform a post-mortem examination.** It is imperative that this clarification be carried out systematically. On the contrary, however, it is unfortunately to be noted that this clarification is being omitted - the abrupt refraining from reporting "vaccination" indications on the part of the police from 9 June 2021 and from 16 January 2022 onwards can hardly be explained otherwise, despite two deaths with "vaccinated" persons according to these data.

318 Of the 15 unusual deaths, a post-mortem examination was ordered in eight to nine cases. Only one autopsy result of a 20-year-old woman is known in more detail: The result of the post-mortem examination was "bleeding to the inside in case of rupture of the spleen" after infection with Epstein-Barr virus (EBV). More than 90 percent of people become infected with EBV in the course of their lives, which usually runs without symptoms and usually without consequences. Life-threatening complications such as respiratory distress or rupture of the spleen are rare. If such a rare event occurs, the chance of survival is 85-95%. In the very young patient, an accumulation of unfortunate circumstances must therefore have contributed to her effectively dying from this diagnosis. The connection between a frequent occurrence of EBV infections and the COVID "vaccinations" has meanwhile been proven in several publications.

319 It is explosive that the young woman had **already** received **two injections of Spikevax in** 2021 **and a "booster" with Comirnaty in spring 2022**. **This circumstance was neither clarified by the police nor by the public prosecutor's office, nor was it examined by forensic medicine.** Instead, the expert opinion of the institute of forensic medicine stated in a brief note that from a forensic medical point of view there was "no connection". In addition, it was added: "Furthermore, it remains to be noted that with the high COVID-19 vaccination rate in the catchment area of the [institute], in the case of a causal connection between COVID-19 vaccinations and splenic ruptures, an increase in such splenic ruptures would have to be ascertained, which, however, is not the case.

320 In summary: There is a strong suspicion that **the police and the public prosecutor's office omit relevant indications of "vaccinations" and thus of a possible connection between "vaccinations" and deaths, which means that in many cases there are no forensic medical examinations at all. And in the few forensic medical examinations that are nevertheless carried out, a causal connection is not even clarified, because this is considered implausible from the outset due to the few cases admitted.** This is obviously a case of the cat biting its own tail. It could not be more obvious how the investigation and proof of possible connections is - intentionally or unintentionally - prevented.

321 The competent prosecution authorities would have every reason to conduct autopsies: **Various causes of death (namely poisoning, etc.) cannot be uncovered without a post-mortem examination.** Accordingly, if a demonstrably toxic, experimental and in no way properly licensed substance was injected into the body of a deceased person, **this must necessarily entail a post-mortem examination to clarify the exact cause of death.** In the case just described (above N 318 f.), a **supplement to and improvement of the forensic medical report** was **ordered at the request of the private plaintiff (**N 68).

3.1.11. Children and adolescents: No risk of disease, massive "vaccination" risk

322 **Children and adolescents are demonstrably not at risk from SARS-CoV-2** (for more details see N 479 ff., especially N 483 and N 485 f.), a "life-threatening or disabling disease" for the entire target population of minors thus obviously does not exist. Nevertheless, the "vaccines" were approved worldwide - with absolutely unacceptable consequences for the youngest and weakest members of our society:

3.1.11.1 Deaths among children and adolescents

323 Previously (N 304 f.) it was explained that at the time of the extension of the authorisation from 5 years, the **alert value of 50 deaths was clearly exceeded.**

324 According to the report of the German *Paul Ehrlich Institute* (*PEI*), **8 children and adolescents** died in Germany as of 31 December 2021 at **intervals of 2 days to 5 months in connection with the COVID "vaccination". In 6 of these 8 cases, a causal connection with the vaccination could not be disproved until today.** This means: Children who were demonstrably in no way at risk from SARS-CoV-2 died and are therefore presumably dying as a result of the **mRNA therapy.**

3.1.11.2 Appropriate reaction to an alarm signal: Admission stop already with 15 cases with side effects

325 **The fact that these deaths - in view of the lack of danger of SARS-CoV-2 for minors - have not long since led to the immediate withdrawal of worldwide approvals is in no way comprehensible.**

326 A comparison: In July 1999, the American *Centers for Disease Control and Prevention* (CDC) recommended that the approval of the rotavirus vaccine for infants be stopped. This was preceded by just **15 reports** to VAERS of intestinal obstructions (these can in principle be life-threatening, but usually heal without complications if treated early) in vac-

cinated infants. At the same time, rotavirus, which causes vomiting and severe watery diarrhoea, is responsible for 20-40 deaths and more than 50,000 hospitalisations annually in the USA alone.

327 **15 Reports of mostly reversible side effects had thus led to the immediate suspension of approval,** although the disease to be treated (rotavirus) may be potentially serious for the target population and associated with hospitalisation. With the mRNA vaccinations, it is just the opposite: even deaths in the target population as a result of "vaccination" did not lead to an immediate suspension of approval, although the target population is not threatened with a life-threatening or disabling disease and the effectiveness of the "vaccinations" is not proven in any way.

3.1.11.3 Interim conclusion: Alarm values long since exceeded

328 Although **children and adolescents** are **demonstrably not at risk from SARS-CoV-2** and although the **number of vaccine-related deaths (and side effects) worldwide** had **long since reached critical levels in this age group alone**, and these had probably been far exceeded, Swissmedic gave the go-ahead for the children's "vaccinations" and played down the consequences of myocarditis/pericarditis (for Swissmedic's actions, see N 708 ff. and N 716 ff.). An immediate revocation of the temporary authorisation - at least for children - would have been the only correct consequence in order to meet the strict requirements of the Swiss Therapeutic Products Act (in particular Art. 1; 3 para. 1 and 9a HMG) for the protection of public health.

329 The consequences of myocarditis/pericarditis are discussed in more detail below:

3.1.12. Alarm signal: myocarditis

330 As before (N 298 ff.), myocarditis is generally one of the frequently reported suspected cases of adverse drug reactions. However, the frequency in children and adolescents is particularly striking: Here, a total of 1822 cases of **myocarditis/pericarditis** officially occurred in the EU area by the beginning of 2022, making it the **second most serious adverse reaction** and the sixth most fatal. The *VAERS database* reported 579 cases for the 12-17 age group as of 31 December 2021. An earlier analysis of *VAERS data* from August 2021 concluded that the rates for **myocarditis associated with** COVID "vaccination" after the second dose in 12-15-year-old and 16-17-year-old male adolescents were a **high 162.2 and 93.0 cases per million doses administered, respectively.**

331 In severe cases, the fatal outcome is a matter of time: the **damage to the heart muscle is permanent** and leads to a massively increased mortality of those affected in the follow-

ing years. **Based on earlier studies, it must therefore be expected that between 7% and 55% of the young people affected could die before the age of 30.** These possible deaths are therefore not yet reflected in the statistics. However, it should be noted that there is currently no clear picture of whether and, if so, to what extent "vaccine" myocarditis differs from "classic" myocarditis, such as that caused by viruses. This, too, would have to be investigated in detail - until a difference is proven, it must therefore be assumed that the (fatal) consequences of "vaccine" myocarditis correspond to those of "classic" myocarditis.

332 This massive danger from "vaccination" is out of all proportion to the "danger" posed to young people by SARS-CoV-2 (see below N 483). Accordingly, an August 2021 study concluded that **teenagers are six times more likely to suffer heart problems caused by the COVID "vaccine" than they are to develop severe COVID disease. In particular, it should be noted that to date there is no evidence that myocarditis/pericarditis poses an equally relevant risk to unvaccinated adolescents. Such proof would have had to be provided by the manufacturers.**

333 In view of this devastating risk-benefit balance, Swissmedic announced in August 2021 that **"there could at least possibly be a causal relationship between COVID-19 mRNA vaccines and myocarditis or pericarditis".** In October 2021, various countries (such as Sweden, Norway and Finland) at least suspended the use of Spikevax for young adults - but instead recommended Comirnaty as a second dose in under-30s.

3.1.13. Pregnant women: Inadequate risk management and realised risk

3.1.13.1 Still missing data

334 As before (N 172 ff.), the sparsely performed animal studies pointed to possible malformations, which made the blind approval for pregnant women a high-risk project. One would expect that this major risk would be adequately addressed. But the opposite was the case:

335 As late as the end of 2021, Pfizer submitted a consent form dated 15 December 2021 to participants in a Comirnaty study with the following passage: **"The effects of the COVID-19 vaccine on sperm, pregnancy, a foetus or a nursing child are not known."**

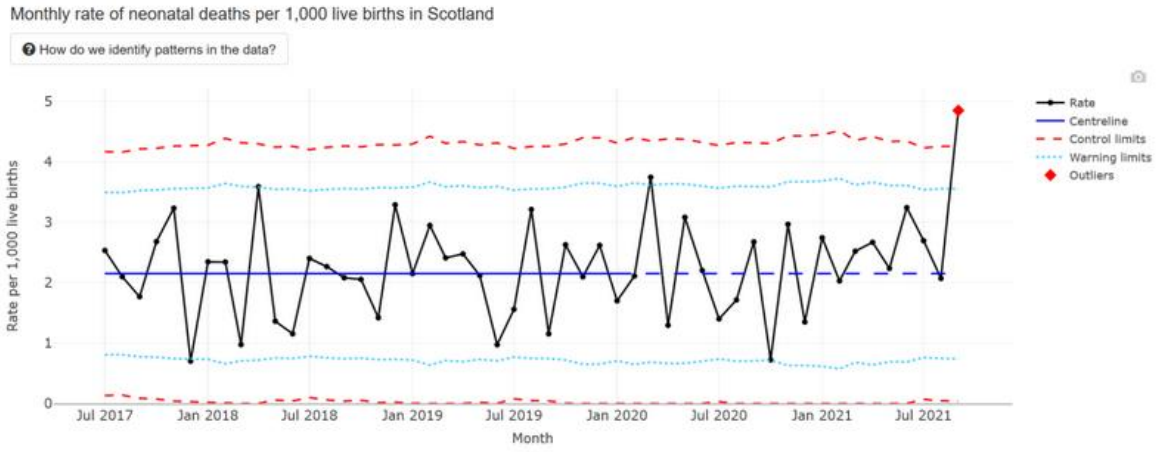
3.1.13.2 Manufacturer's data: Multiple stillbirths in pregnant women

336 However, there was not a complete lack of data: Pfizer disclosed in the "*Post Marketing Pharmacovigilance Report*" that in the first 2.5 months after market approval alone, ad-

verse reactions in connection with Comirnaty were listed in 270 pregnant women: **23 cases involved miscarriage,** two cases involved premature birth with subsequent death of the child, two cases involved intrauterine death (death of the child in utero), in five cases the outcome of the case was pending, and in 238 cases "no information" was available.

3.1.13.3 England: Massive increase in neonatal mortality

337 In England, there was a sudden increase in neonatal mortality in September 2021. There were 4.9 stillbirths per 1000 births - a hugely high figure not seen since the late 1980s.



3.1.13.4 Breastfeeding mothers: Spike protein and LNP in breast milk?

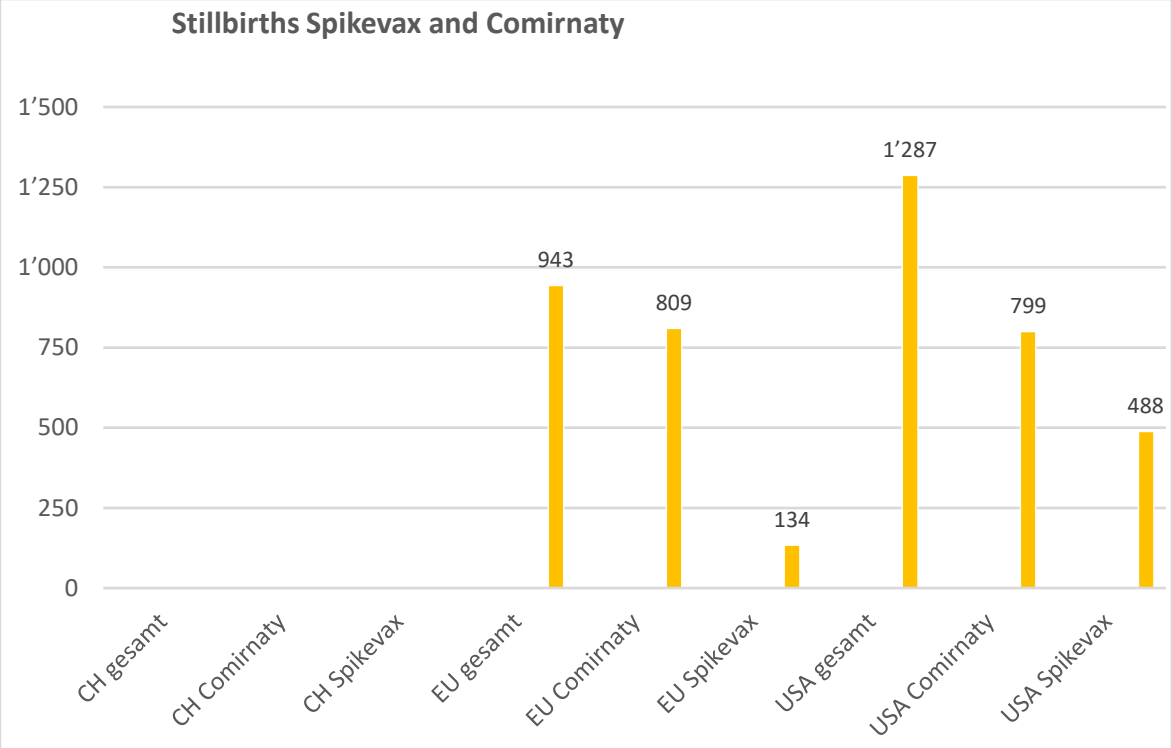
338 In addition, there is another problem: components of the mRNA "vaccines" are probably not only passed on to unborn babies in the womb, but presumably also to infants via breast milk. There is a strong suspicion that the toxic spike protein and toxic lipid nanoparticles (LNP) pose a risk to newborns breastfed by vaccinated mothers. A study with just eight mothers, which should have disproved such a transfer by means of breast milk, is not very valid due to the small number of participants as well as improper storage of the breast milk. This risk is also real and legally relevant, which is why it should have been adequately addressed long ago.

3.1.13.5 Utah: Miscarriages up 12 per cent after fertility treatment

339 A report by the *Health Independence Alliance showed that* at a large fertility clinic in Utah, the miscarriage rate rose from 28 to 40 per cent since the introduction of the COVID "vaccination", an absolute increase of 12 per cent.

3.1.13.6 Thousands of premature and stillbirths worldwide

340 As of 11 December 2021, **over 2,000 miscarriages** related to the mRNA "vaccines" Spikevax and Comirnaty have already been reported in the EU and the USA:



341 As far as can be seen, there are no figures for Switzerland. Already at the time of publication of this data, it must have been clear to the licensing authority that these figures only represented the "tip of the iceberg". On the one hand, due to the massive underreporting (see below N 397 ff.), on the other hand due to the fact that pregnancies usually last nine months, which inevitably goes hand in hand with a delayed reporting rate.

3.1.14. Correlation of "suspected cases" with Corona "vaccinations".

3.1.14.1 Disproportionate increase in side effects

342 There were already many indications at the end of 2021 that the many suspected cases reported were deaths and severe damage effectively caused by the mRNA "vaccines". In advance, of course, purely on the basis of the unprecedented number of cases - which in reality are likely to be many times higher due to massive under-reporting.

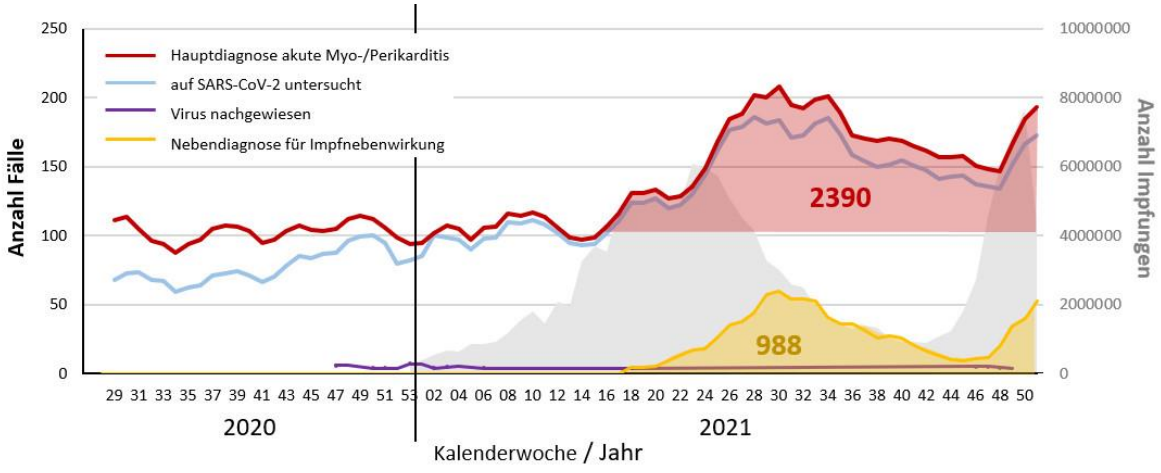
3.1.14.2 Close temporal connection between "vaccinations" and reports of side effects

343 Comprehensive studies have shown that there is also a **close temporal relationship** between the administration of the mRNA "vaccines" and the side effects that occurred. An analysis of more than 7.8 million adverse reaction reports (from 1.6 million affected people) from the *EUDRA-VIGILANCE* and *VAERS database from* October 2020-October 2021 showed **that in 77.6-89.1% of cases, serious adverse reactions occurred within seven days of "vaccination" .**

344 Another study, which took into account *EUDRA-VIGILANCE data* up to 29 August 2021, came to a similar conclusion: **of 13,801 reported deaths, 61% occurred in the first two days after "vaccination".** Most of the serious side effects (such as cardiac arrest and thrombotic events) also occurred early - usually in the first four to five days after the "vaccination". This is also confirmed by a study from Israel: not only was there a **25% increase in emergency calls for cardiac arrest in the 16-39 year old population from** January to May 2021, this increase also **correlated** significantly with the **rates of the first and second vaccination doses** for this age group - but not with the COVID infection rates.

3.1.14.3 Time-delayed connection between "vaccination" and hospitalisations

345 An analysis carried out in Germany also revealed that there is a temporal, but slightly delayed, relationship between administered mRNA "vaccines" and hospitalisations for myo/pericarditis:



346 The increases in myo/pericarditis cases fall in those calendar weeks in which most vaccine doses against COVID-19 (grey shaded area) were administered: On the one hand, in summer 2021 during the (first and) second vaccinations and then in autumn 2021 during the "booster". However, it should be noted that the number of cases remains

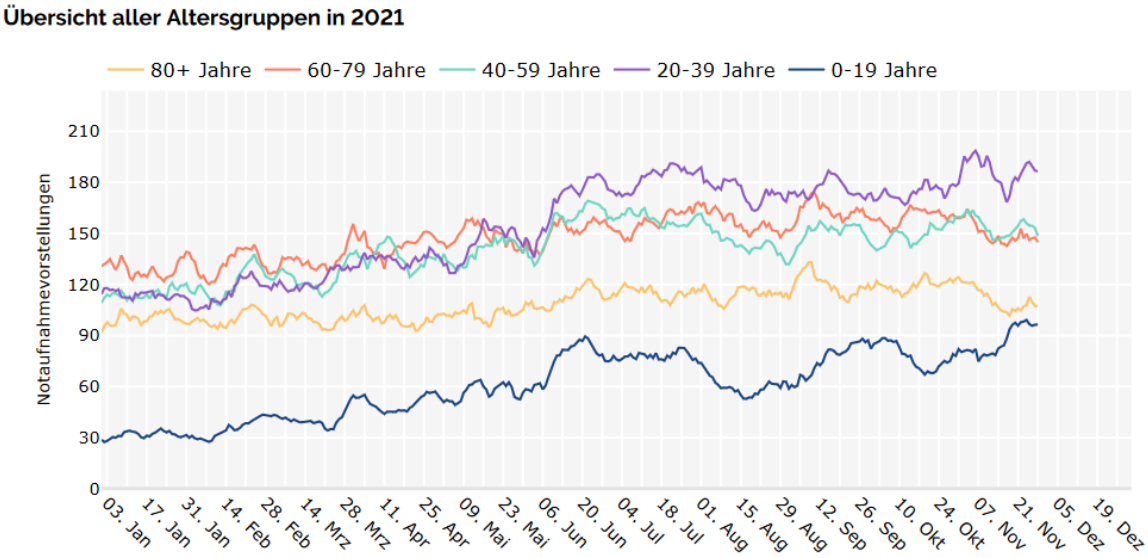
strongly elevated even weeks after the number of "vaccinations" has decreased in late summer. This **long-lasting increase in myo/pericarditis case numbers strengthens the suspicion that the side effects can also occur weeks after the "vaccination"**.

3.1.14.4 Further evidence of temporal correlation in mortality and hospitalisations

347 In 2021, there was increasing evidence worldwide of a temporal connection between "vaccination" and side effects. In New Zealand, for example, it was reported that the **general mortality rate in the over-60s correlated with the administration of the COVID "vaccination" in this age group. In** addition, US life insurers reported that the **mortality rate of non-COVID-related deaths among people of working age 18-64 years** had **increased by 40% compared to the pre-pandemic period.**

348 In Germany, **weekly emergency hospital admissions** increased **by a factor of 11** (481 vs. 43 cases/week) at the beginning of 2021, and **intensive care treatments by a factor of 9** (55 vs. 6 cases/week) compared to the previous period of 2019-2020. Similar findings were made with regard to children: The time course of the occurrence of suspected reports of all adverse effects related to COVID "vaccines" in adolescents aged 12 years and older in the *EudraVigilance database* clearly correlates with the granting of marketing authorisation for the "vaccines" for this age group by the EMA (Comirnaty end of May 2021, Spikevax July 2021). This was also shown by the RKI's "Emergency Department Situation Report": according to this, **emergency admissions to hospitals in** the 0-19 age group had **more than doubled as** of 1 December 2021 compared to January 2021.

349 The graphical overview shows that for all age groups of the German population, a significant increase in emergency admissions was observed in direct temporal relation to the maximum number of vaccine doses administered, i.e. in summer and late summer 2021:



3.1.14.5 Australia: Compensation for myocarditis and other side effects

350 In December 2021, the Australian government acknowledged in principle the existence of a causal link between the mRNA "vaccines" and side effects such as severe allergic reactions, **myocarditis/pericarditis** or even Guillain-Barré syndrome.

3.1.14.6 Many other studies that indicate a connection

351 By 26 October 2021, many more studies had been added to those listed previously (N 251), which indicate a connection between the COVID vaccines and side effects, many more studies were added: A total of at least **85 peer-reviewed publications on heart problems, 130 peer-reviewed publications on life-threatening coagulation disorders (thromboses, etc.) and 4 peer-reviewed publications on possible deaths as a result of the COVID vaccines.**

352 In view of this flood of scientific studies, no one could seriously claim from this point onwards at the latest that the mRNA "vaccines" were not at least under urgent suspicion of causing serious side effects, even death.

353 All this information was available to the Swiss Agency for Therapeutic Products, Swissmedic. They were and are of particular legal significance for the fulfilment of its basic legal mandate - the protection of public health against harmful medicinal products - which is why these facts must also be assumed to be known by Swissmedic.

3.2. Effectiveness

3.2.1. First and second vaccinations: Updated and missing data

3.2.1.1 Minimal therapeutic benefit for mere trivial events

354 Based on extremely reduced 6-month data (data from only 7% of the study participants were actually available over a period of 6 months), it was stated in the NEJM (New England Journal of Medicine) on 4 November 2021 regarding **Comirnaty** that the **efficacy**, although not 95% as originally stated, was still a high **91.3%.** This calculation was again made according to the RRR method, which - as before (N 205 ff.) - is in no way able to accurately represent the effective efficacy.

355 By the end of 2021, there was apparently still no new efficacy data on Spikevax at all, which is very surprising after one year of "authorisation": these must always be kept up to date with the latest scientific findings (Art. 28 VAM) and data on efficacy (as well as risks) must be submitted continuously by the authorisation holders, especially in the "rolling authorisation procedure", and reviewed by Swissmedic.

3.2.1.2 No proven therapeutic benefit for "severe" diseases

356 While the efficacy of **Comirnaty for** minor events is said to have decreased according to official data, an efficacy of 96.7% was published for "severe" diseases instead of the originally stated efficacy of 66.4%. This already seems paradoxical without consulting the underlying data: Why the efficacy of Comirnaty should have worsened for "confirmed COVID diseases" but significantly improved for "severe COVID diseases" cannot be rationally explained. The efficacy figure of 96.7% also lacks any scientific basis: according to "6-month data", **30** "severe COVID cases" were reported for the vaccine group **1** and for the placebo group, from which the **96.7%** result according to RRR. As already stated before: **With a total of 31 cases out of originally more than 40,000 study participants, one is obviously in the realm of statistical chance. To conclude an efficacy of 96.7% from these 31 cases is dubious, unscientific and misleading.** The relevant absolute risk reduction (**ARR**) is only **0.1%.**

357 No new data were available for Spikevax under this heading until the end of 2021.

3.2.1.3 International studies: manufacturers' efficacy claims untenable

358 The fact that the manufacturers' claims have little in common with reality was impressively demonstrated in the course of 2021: mRNA therapy neither protected against infection with SARS-CoV-2, nor did it save people from severe courses of the disease.

359 Accordingly, several studies came to the conclusion, even using the RRR, that the alleged almost 100% **efficacy** dropped to 64% after a short time and was finally a **meagre 23%**. The originally propagated "years-long" or even "decades-long" protection also quickly proved to be complete misinformation, which became obvious only because of the alleged "necessity" of "booster vaccinations".

3.2.1.4 Interim conclusion: Pure fantasy figures of the manufacturers

360 The allegedly high efficacy of the COVID "vaccinations" finds no support whatsoever in the registration studies and the observations carried out based on them.

361 According to international studies, the effectiveness of the COVID "vaccinations" also tended towards zero after a short time. Analogous to conventional vaccines, it would be expected that a long-lasting immunisation would be achieved after one or two vaccinations - the alleged need for "boosters", however, obviously shows that a lasting immunising effect can never be achieved with the COVID "vaccinations", which fundamentally questions their effectiveness.

3.2.2. " Booster": lack of or insufficiently proven effectiveness

3.2.2.1 "Booster" planned from the beginning

362 It was originally publicly communicated to the population that with "two pricks" the immunisation against SARS-CoV-2 would be sufficient (and one would thereby regain freedom). In fact and truth, the "booster" was already planned covertly at the time of the initial authorisations. This is what Swissmedic wrote to Moderna in the **authorisation order of 21 January 2021**:

> **"Moderna is considering additional booster doses of** mRNA-1273 with ongoing clinical trials to investigate safety and immunogenicity endpoints. As at this stage the **duration of protection and the possible need for booster doses are not known**, Swissmedic asks Moderna to keep Swissmedic informed by submitting amended protocols."

363 How, under these circumstances, a high and implicitly sustainable efficacy could ever have been communicated to the public with a clear conscience is in no way comprehensible: **Communicating an efficacy of almost 100% to the medical profession and the population (which the average addressee, in layman's terms, equates with a reliable and long-lasting protective effect as with conventional vaccines), but secretly knowing about the lack of protection duration, is simply irresponsible and incompatible with the legal protection mandate of a licensing authority.**

3.2.2.2 Data situation "Booster": Insufficient studies and misleading calculations

364 In the case of **Comirnaty, the** efficacy of the booster vaccination was investigated within the framework of three studies. Studies 1 and 2 are in no way able to meet the requirements normally placed on efficacy studies: The first study included just 23 study participants, the second was conducted retrospectively using database analyses. This leaves study 3: In this placebo-controlled study, the incidence of confirmed COVID-19 cases was investigated in about 10,000 participants aged 16 years and older who had occurred in the period of at least 7 days after the booster vaccination until the data cut-off date on 5 October 2021, which corresponds to a **very short follow-up period of 2.5 months. The** number of "confirmed COVID cases" was - as in the pivotal studies - in the low percentage range: in the vaccine group, **6** out of 4,695 **(0.1%)** and in the placebo group, **123** out of 4,671 **(2.6%)** study participants experienced such symptoms. Again, based on these low numbers, a relative efficacy (RRR) of 95% was proclaimed, **but the absolute risk reduction (ARR) was only 2.5%.** Moreover, this study lacked any significance with regard to the "vaccination" protection for the time after the observation period of 2.5 months.

365 The data situation for **Spikevax** is even more meagre: according to the product information, "only limited data are available on booster vaccination with Spikevax". For example, a study with **just 198 study participants was** apparently intended to provide proof of efficacy. **Due to the very small number of participants, none of the submitted studies even formally meets the most basic requirements for a marketing authorisation according to the Swiss HMG.**

3.2.2.3 "Third dose" for immunosuppressed persons: No relevant proof of efficacy

366 For both COVID "vaccines", a third dose in two small trials (101 and 120 participants, respectively) did not lead to increased antibody levels in a not insignificant proportion (32% Comirnaty; 45% Spikevax) of those immunosuppressed as a result of organ transplantation. For both "vaccines" it is not known whether and to what extent an increase in antibodies to SARS-CoV-2 is associated with the prevention of (severe) COVID disease.

367 The data situation for immunocompromised persons is so unclear that this is even expressed in the Spikevax expert information: "The additional dose **could** increase protection in at least **some** patients". For both COVID "vaccines", Swissmedic's expert information also states: "The **efficacy, safety** and immunogenicity of the vaccine have **not** been **studied** in immunocompromised persons, including persons under immunosuppressive treatment.**" This is** also an obvious **warning signal: instead of simply approving the "vaccination" in the absence of any data, Swissmedic should have demanded mandatory studies.**

368 Furthermore, it is irritating that Spikevax only recommends half the dosage (0.25ml corresponding to 50µg mRNA) for the booster for the general population compared to the first and second vaccinations, while the full dosage (0.5ml corresponding to 100µg mRNA) is recommended for immunocompromised persons, whereas Comirnaty uses the same dosage for the basic immunisation, booster vaccination and the third dose for immunocompromised persons. These divergent dosing concepts are inconsistent and incomprehensible from a scientific and medical point of view.

369 In view of all these inconsistencies and gaps in information, the authorisation of the third "vaccination" for immunosuppressed persons, which was granted nonetheless, lacks any basis (on the actions of Swissmedic see N 714).

3.2.3. Children 5 years and older: Lack of efficacy COVID "vaccination".

3.2.3.1 Minimal therapeutic benefit for mere trivial events

370 In the Comirnaty pivotal trial, **3** out of 1517 (0.2%) 5-11 year olds in the vaccine group and **16** out of 751 (2.1%) in the placebo group had "confirmed COVID". The absolute risk reduction (ARR) was just 1.9%. For proof of a "major therapeutic benefit", clearer figures would have to be expected.

3.2.3.2 No data for "severe" diseases

371 "Severe" COVID diseases - i.e. those that could fulfil the requirements of a life-threatening or disabling disease - could not be investigated at all. This is for a very simple reason: In the **5-11 year olds - as in the adolescents from 12 years of age - no "severe COVID diseases" occurred in the registration studies.**

372 Thus, although not a single child was seriously ill with corona in the approval studies, a **"temporary" approval** was **granted for "protection" against corona, which children obviously do not need.** Due to the lack of corresponding data, it cannot be proven that

the vaccination has the potential to effectively protect children from a severe (life-threatening or disabling) disease. The proof of a major therapeutic benefit for the prevention of a serious or disabling disease within the meaning of Art. 9a para. 1 HMG was therefore not even rudimentarily provided for the age group of children between 5 and 12 years.

3.2.4. Infection with SARS-CoV-2 protects against re-infection (continued)

373 In addition to the previously listed (N 258), **at least another 24 publications and pre-print publications** came to the conclusion by about the end of 2021 that a **disease that has been passed through produces a broad and long-lasting immune response** or protects at least as well or even better against a COVID disease than "vaccination".

3.3. Interim result (end 2021): High risk, no effectiveness

374 The devastating development, which had already become apparent in mid-June 2021, continued until the end of 2021: tens of thousands of people died in close connection with the administration of the mRNA "vaccines", hundreds of thousands - indeed several million - suffered severe side effects.

375 At the same time, the manufacturers - as shown above - were in no way able to provide the necessary proof for the effectiveness of their "vaccines". On the contrary, they continued to use calculation methods that have nothing whatsoever in common with reality and must even be described as deception. In the absence of suitable proof of effectiveness, they manipulated data or had them manipulated by commissioned research institutions. And they also commissioned these very same research institutions for future studies. The globally networked regulatory authorities were aware of all this.

376 However, instead of reacting and finally removing from the market these medicines, which have been proven to be ineffective, but are now associated with a long list of side effects and deaths, some of which are extremely serious, and which are potentially damaging to genetic material, their approval has been extended in a way that increases the risk even further - in that by the end of 2021, children and the entire population are now also to be "vaccinated" a third time.

4. Swissmedic knowledge status as of 2022 ("Omicron variant")

377 In 2022, too, all temporary authorisations for mRNA "vaccines" were maintained unchanged, although various further incriminating facts should have long since led to the immediate revocation of the authorisation (Art. 16c HMG):

4.1. General motor risks

4.1.1. Worldwide reports of side effects at all-time highs

378 With all of the following figures, it should be remembered - once again - that these are the officially reported adverse events. These figures are subject to massive **underreporting** due to the passive reporting systems**, which** is why the **effective figures are** probably at **least five to ten times higher** (front N 307 ff.; rear N 397 ff.). But even without this correction, the officially reported figures are highly alarming - **and above all, they are generally** alarming**:**

4.1.1.1 Side effects of all "COVID vaccines

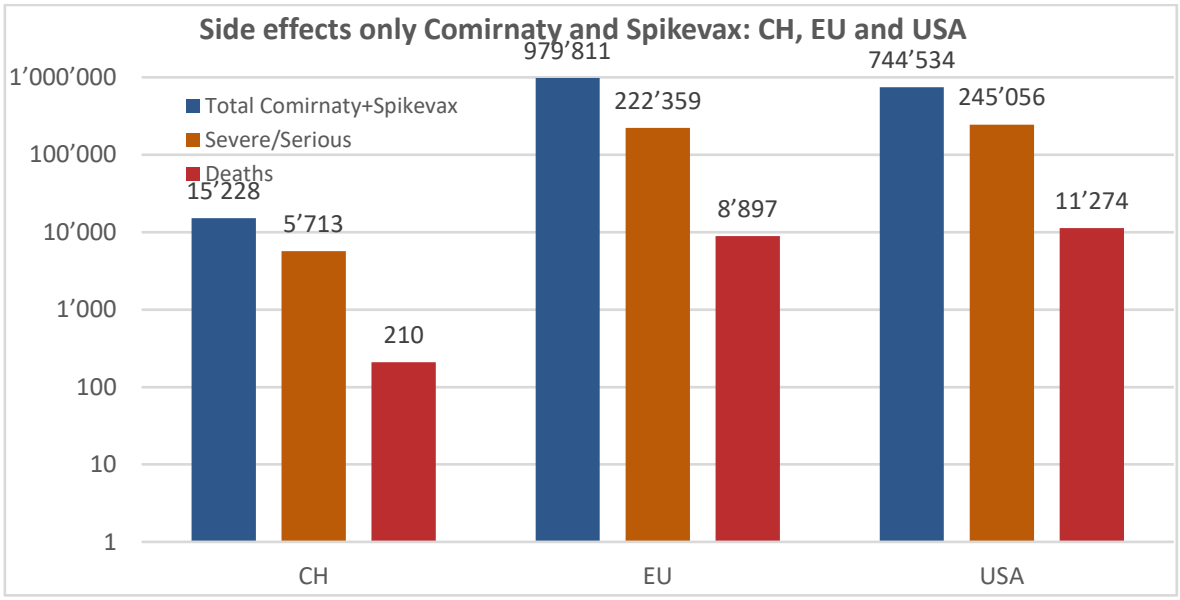
379 Regarding all "COVID vaccines" (i.e. including "COVID-19 Vaccine Janssen" or "COVID-19 Vaccine AstraZeneca"), **1.8 million suspected adverse events** were reported **across Europe** as of 06 May 2022, 586,363 of which were classified as serious and **24,619 deaths were** registered in connection with a COVID "vaccination".

380 In the **USA, 2.1 million suspected** adverse events, 155,633 hospitalisations and **27,968 deaths** related to COVID vaccination were reported for all "COVID vaccines" as of 06 May 2022.

381 Worldwide, reports of side effects have thus reached an unprecedented - and absolutely alarming - high. As a reminder: In earlier times, drug approvals were withdrawn or corresponding studies were discontinued if only around **50 deaths (**suspected cases) were detected (front N 243 f.). **This alarm value has been exceeded <u>thousands of times.</u>**

4.1.1.2 Side effects with Comirnaty and Spikevax (absolute numbers)

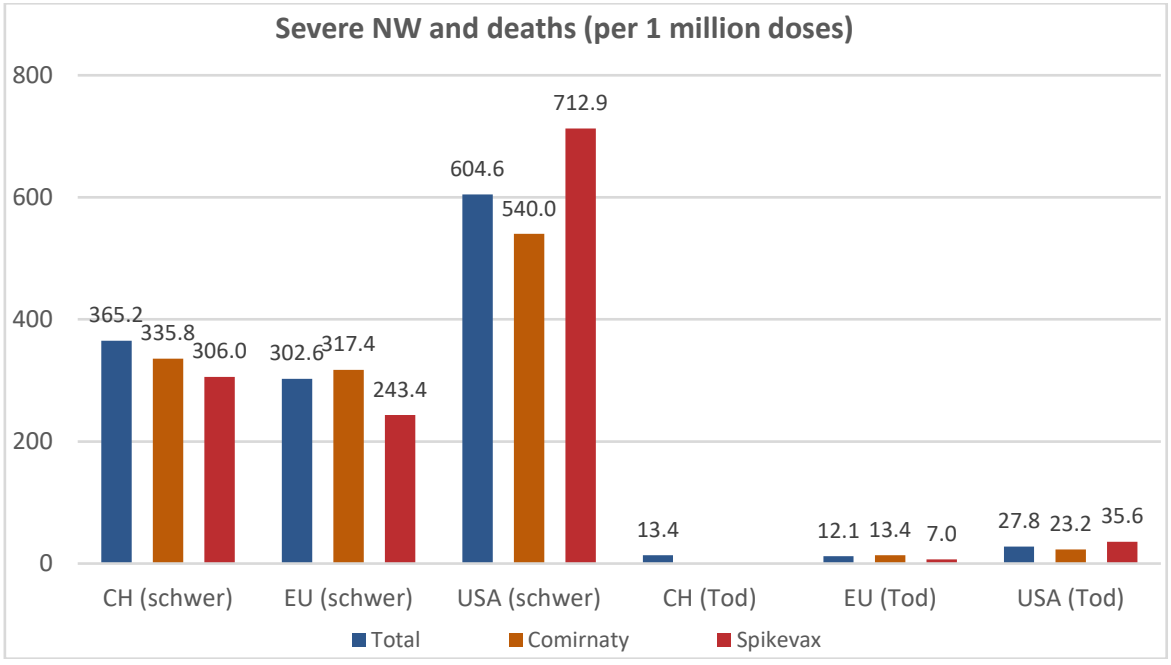
382 The two "vaccines" of Comirnaty and Spikevax investigated here make a significant contribution to the aforementioned disastrous record. By 06 May 2022 in Switzerland, and by 14 May 2022 in the EU and the USA, a total of **1,739,573 adverse reactions had been** reported for Comirnaty and Spikevax - of which **473,128 were serious** and **20,381 deaths:**



383 Here, too, the **alarm value of 50 deaths has been massively exceeded - by a factor of 400.**

4.1.1.3 Side effects with Comirnaty and Spikevax (per 1 million "vaccine doses")

384 The number of serious and fatal adverse events for Spikevax and Comirnaty **per 1 million doses administered as** of **May 2022** is as follows:



385 As shown previously (N 245), the risk profile of all COVID "vaccines" is devastating compared to influenza vaccines, for example:

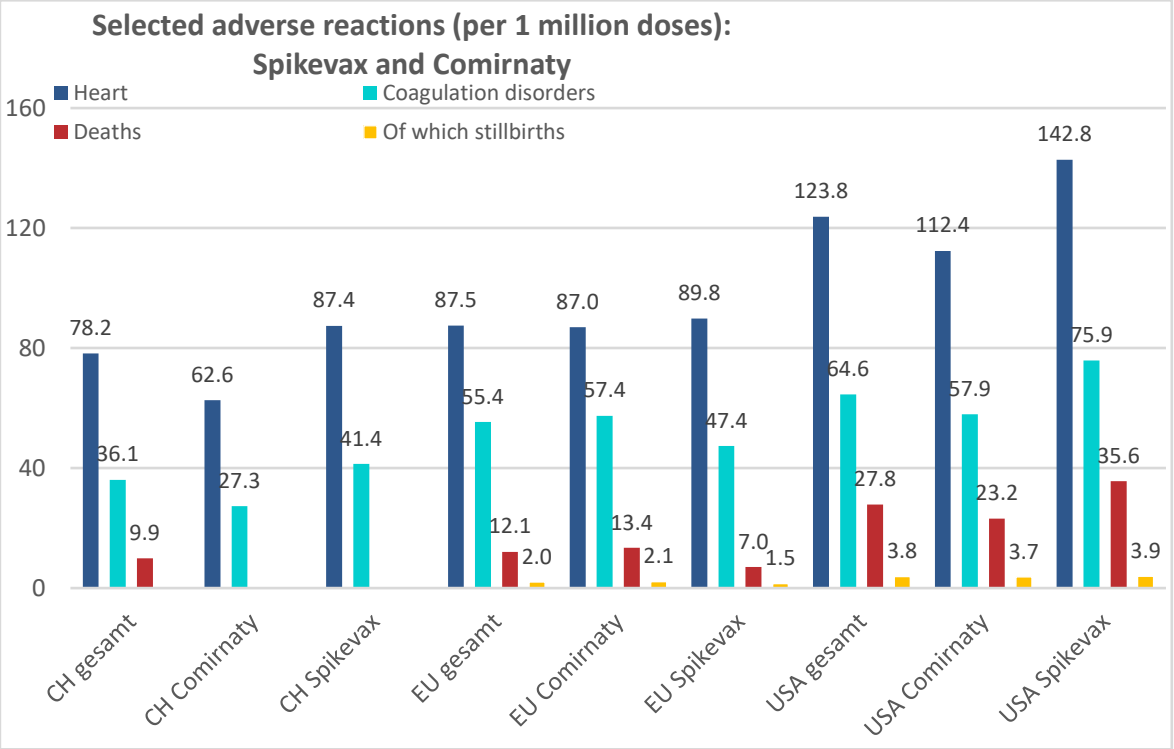
386 A comparison of the **serious side effects** is unfortunately difficult due to the different counting methods (in particular the different recording of all serious side effects or only those with permanent damage or hospitalisation). But the picture is abundantly clear: while **0.28 to 3.3** serious side effects per 1 million doses are reported for influenza vaccines, the figure for **Comirnaty / Spikevax as of the beginning of May 2022 is 302.6 to 604.6 cases - at least 100 times the number of serious side effects**.

387 The comparison is simpler due to the same counting method for deaths: While **0.38 to 0.63** deaths per 1 million doses are reported for influenza vaccines, the figure for **Comirnaty / Spikevax as of the beginning of May 2022 is 12.1 to 27.8 cases - at least 20 times the number of reported deaths.**

388 All these are not marginal, tolerable deviations in the lower percentage range, but deviations that are alarming in every respect. **No medicinal product - really not a single one - should be on the market even one day longer with this devastating result.**

4.1.1.4 Selected side effects: Heart, thromboses, deaths, stillbirths

389 A more detailed analysis of all side effect reports on Comirnaty and Spikevax - broken down by symptoms such as heart (myocarditis etc.), coagulation disorders (thromboses etc.) as well as deaths and stillbirths - gives the following picture **per 1 million "vaccine doses"** as of **May 2022:**



390 The **comparatively higher reporting rates** concerning "heart" and the double to triple higher reporting rates concerning deaths **in the USA are** striking. Whether these differences are due to population or reporting would have to be investigated in more detail.

391 However, if the side effect reports in the USA concerning the **heart (myocarditis/pericarditis** etc.) are 112.4 (Comirnaty) to 142.8 (Spikevax), then according to the definition (MedDRA system organ classes) these are **"rare" side effects** (not: "very rare"), as more than 1 case per 10,000 doses occurs - and this already without taking into account the massive underreporting.

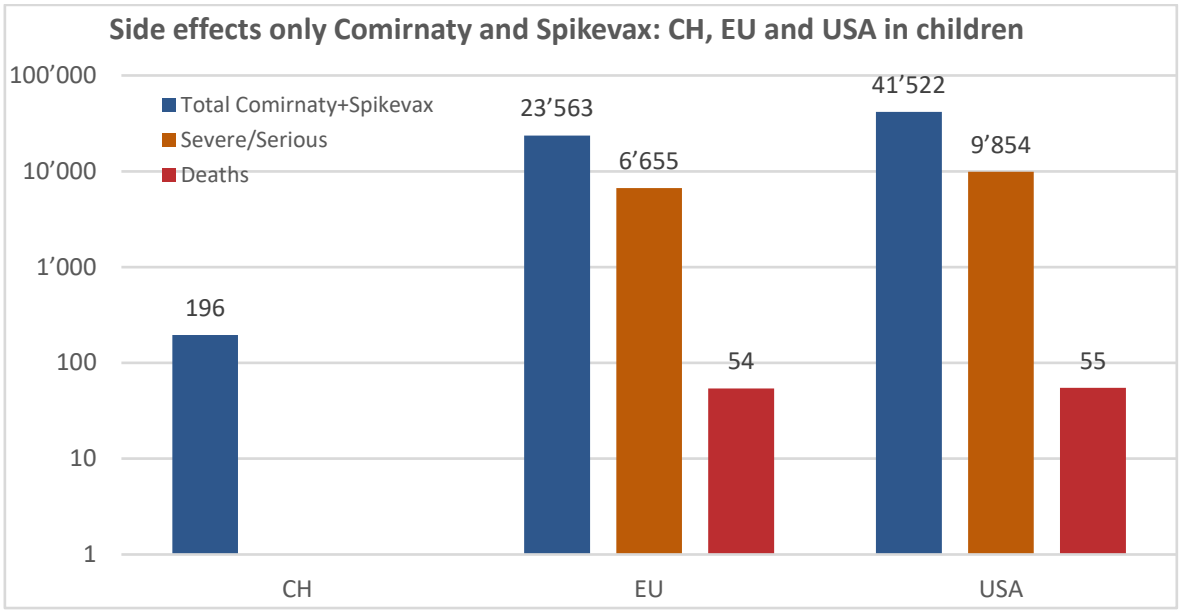
392 The strikingly higher reporting rates in the USA and also in individual countries of the EU are also of particular importance for a Swiss licensing authority with regard to the protection of public health. After all, we are dealing with one and the same "vaccine" substances in all countries. However, Swissmedic's technical information does not take these risk signals from abroad into account in any way (see N 715 ff.).

393 Also worrying are the reports of coagulation disorders, which range from 27.3 to 75.9 cases per 1 million doses worldwide. The official data are thus in a range that can clearly be compared, measured and estimated. The number of cases per 10,000 is 0.273 to 0.759, which means that **coagulation disorders can** be classified **as "very rare" side effects (<1/10,000).** However, Swissmedic's expert information does not adequately reflect this risk (see N 715 ff.).

394 On the reported stillbirths, in detail at the back N 410.

4.1.1.5 In particular: Side effects in children

395 By 06 May 2022 in Switzerland, and by 14 May 2022 in the EU and the USA, a total of **65,281 adverse reactions had** been reported for Comirnaty and Spikevax in **children** (including adolescents) - of which **16,509 were serious** adverse reactions and **109 were deaths:**



396 This means that the **alarm value of 50 deaths** has already been **doubled for** children alone**.** If one considers that not a single previously healthy child in Switzerland has demonstrably died due to "COVID-19", the risk of death through "vaccination" is disproportionate to the "risk of death" through an infection with SARS-CoV-2.

4.1.2. Massive underreporting impressively confirmed

397 The circumstance of massive underreporting, which was already known at the end of 2021 (see N 307 ff.) was once again impressively confirmed by corresponding studies in 2022:

4.1.2.1 EU: only 20% of all adverse reactions are reported

398 For the EU, there are significant differences in reporting discipline between member states for the year 2021. An in-depth, Europe-wide country comparison of these data by an association of over 80 renowned (German) scientists and professors revealed that **at least 80% of suspected cases** are **not reported to EudraVigilance.**

4.1.2.2 Germany: Only 20% of all side effects are reported

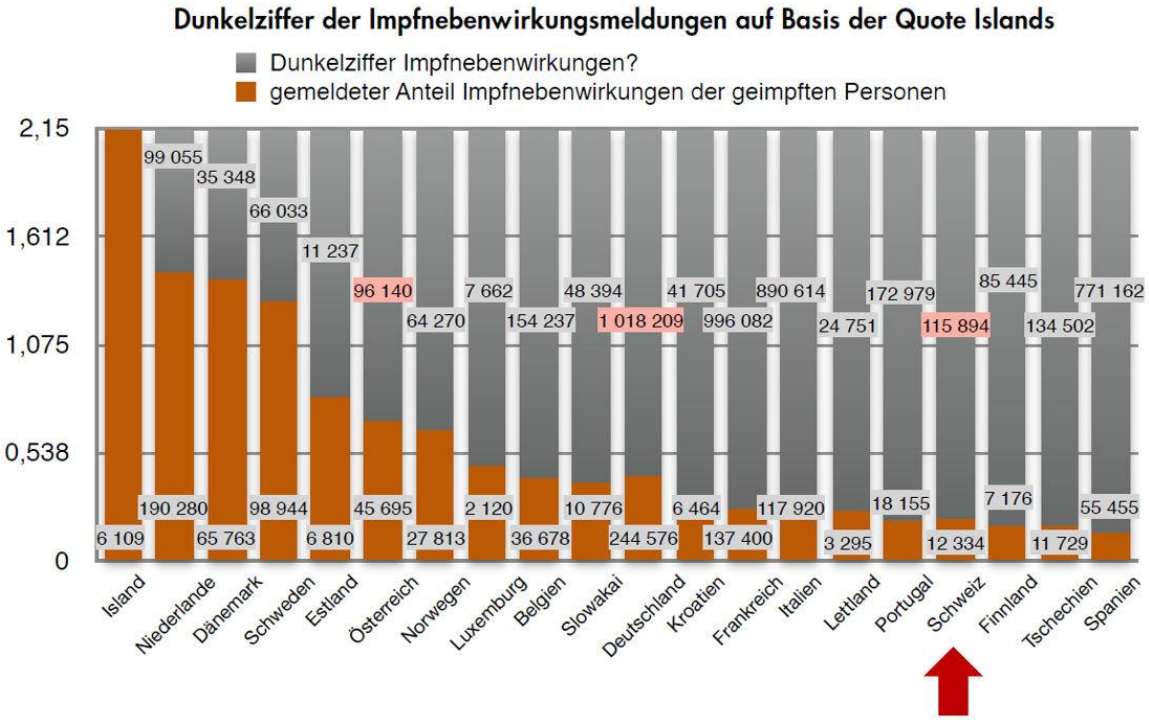
399 According to the above analysis, Germany is exactly in line with the EU average: According to this, only about 20% of all side effects are reported at all in Germany.

400 This high number of unreported cases was recently confirmed by an analysis of German health insurance data: According to a corresponding extrapolation, about 2.5-3 million Germans affected by side effects must have been in treatment in 2021. This is **ten times**

more than the Paul Ehrlich Institute (PEI) officially reports based on spontaneous reports.

4.1.2.3 Switzerland: Only 10% of all side effects are reported

401 As already stated above (N 311), the reporting rate in Switzerland was already half that of Germany in mid-2021. In 2022, Swissmedic's reporting rate improved only marginally and was 0.97 suspected cases/1000 vaccine doses in May 2022. In comparison with the EU countries, Switzerland ranked only 17th in the reporting of adverse events: the **percentage reporting rate in Switzerland was just 10% of the reporting rate in Iceland, which can be easily seen from the following graphical processing of the official figures:**



4.1.3. Manufacturers: disclosure of major risks in production and distribution

402 As in 2019, Pfizer and BioNTech stated in their annual reports published in early 2022 that they may not be able to demonstrate sufficient efficacy or safety of their COVID "vaccine" to obtain permanent regulatory approval.

403 These warnings are absolutely justified: The fact that the requirements for a conversion into an ordinary authorisation are obviously not fulfilled is explained at the end (N 633 ff., esp. N 674 ff.) is explained in detail.

4.1.4. Children and young people massively harmed - courts against "vaccination

404 As already mentioned before (N 395 f.), by May 2022, over 100 suspected cases of deceased children had already been reported from the EU and the USA regarding Comirnaty and Spikevax alone - not including underreporting.

405 The side effect reports concerning infants of "vaccinated" mothers are particularly worrying: The risk of transmission through breast milk was already recognised at the end of 2021 (front N 338) - nevertheless, the human experiment was continued. In Switzerland, 7 cases of adverse reactions to infants were reported by May 2022. In the **EU, out of 168 infant deaths, a full 24 deaths were attributable to infants up to four weeks old**.

406 These data are obviously unpleasant for the responsible authorities: While, for example, the German Paul Ehrlich Institute had still provided detailed information about deaths among children and adolescents in the safety report as of the end of 2021 (there were 8 death reports), such information can no longer be found in the current safety report from 2022. In the meantime (mid-2022), the number should certainly have exceeded the previous value of 10 death reports - which means that **the number of deaths due to "vaccination" exceeds the official number of deaths in connection with "COVID-19" (**approx. 10) **in Germany. The** cost-benefit ratio is thus conspicuously negative in the case of children and adolescents: under no circumstances is it permissible to kill the same number or even more people with a drug than people die from the supposedly preventable disease.

The mRNA "vaccines" are therefore in no way compatible with the best interests of the child. This had already been recognised at the beginning of 2022 by courts in Germany and Italy as well as by the Florida Health Authority (USA). Their verdict: **The risk clearly outweighs the benefit, which is why "childhood vaccinations" should be dispensed with.**

4.1.5. Pregnant women: worrying number of miscarriages

4.1.5.1 Still missing data - stalling tactics of the manufacturers

407 One year after approval, the manufacturers of Comirnaty and Spikevax still had to admit to the regulatory authorities in early 2022 that **"the safety profile of the vaccine in pregnant or breastfeeding women** is **not known ".**

408 This was because the pregnant women had been excluded from the clinical registration trial (see above). 172). As a replacement, studies with pregnant women were started in

February 2021. As far as can be seen, the corresponding results are still not available. In any case, it is questionable whether these studies can deliver useful results at all, since the contract research institute *Ventavia* was again commissioned for one of these core studies. In other words, exactly the same institute that had obviously already falsified data in the approval studies (see N 272).

409 This **delaying tactic by the manufacturers in** such a sensitive area is in no way compatible with an ongoing approval procedure. Particularly in view of the fact that reports of premature births and stillbirths had long since accumulated worldwide by the end of 2021 and unfortunately increased considerably again in 2022, it is questionable on what empirical data basis Swissmedic could still justify the authorisation of the COVID "vaccines" for pregnant women in particular:

4.1.5.2 Worldwide reports of stillbirths massively increased

410 Already before (N 389), it was shown graphically that for Comirnaty and Spikevax in the EU and the USA **2-3.8 stillbirths per 1 million vaccine doses** were recorded. In absolute numbers, this is already **2,177 stillbirths for Comirnaty and 810 stillbirths for Spikevax in** the EU and the USA - not including underreporting. This is only until May 2022 - in view of the nine-month delay (duration of pregnancy), these downright alarming figures are probably only the tip of the iceberg.

4.1.5.3 Austrian midwives sound the alarm: increased miscarriages

411 The fact that **many birth complications and deaths are not reported** is also shown by an appeal from over 200 concerned Austrian midwives at the beginning of 2022. There would be a **high incidence of miscarriages, premature labour, early premature rupture of the membranes, vaginal bleeding, premature births, growth retardation and eclampsia (seizures), which would** not be investigated further.

4.1.5.4 Interim conclusion

412 The several thousand officially reported stillbirths worldwide alone are a grave alarm signal - the urgent consequence should be an immediate ban on the licensing of these drugs.

4.1.6. Male fertility: Decrease in sperm concentration by 15.9

413 A study on male fertility published in June 2022, which was conducted on 220 sperm samples, concluded that sperm concentration, motility and sperm count had not normal-

ised even 150 days after vaccination: **150 days after the 2nd "vaccination", sperm concentration was still 15.9% below the baseline value.**

414 This, too, is a massive alarm signal, which the licensing authority is aware of: the approval of the mRNA "vaccines" was nevertheless granted in an incomprehensible manner without a single investigation of the effects on (male) reproductive capacity (for more details see N 180 ff.). This circumstance should obviously have been investigated.

4.1.7. Lethal mode of action of the spike protein

415 The toxicity of the spike protein has been described previously (N 265 ff.) has been explained in detail.

416 In 2022, pathologists detected the spike protein in organs such as the liver, spleen and brain of people who had died after COVID vaccination - in some cases **up to four months after the "vaccination". In** addition, it was shown that **vascular damage in 12 out of 15 deceased persons** was due to the spike protein. In at least one of these cases, the spike **protein production** stimulated by the mRNA "vaccines" was **the causal cause of vascular lesions and myocarditis suffered as a result.**

417 **The spike protein is therefore not "only" toxic and potentially harmful. In 12 out of 15 cases investigated, it led causally to death.**

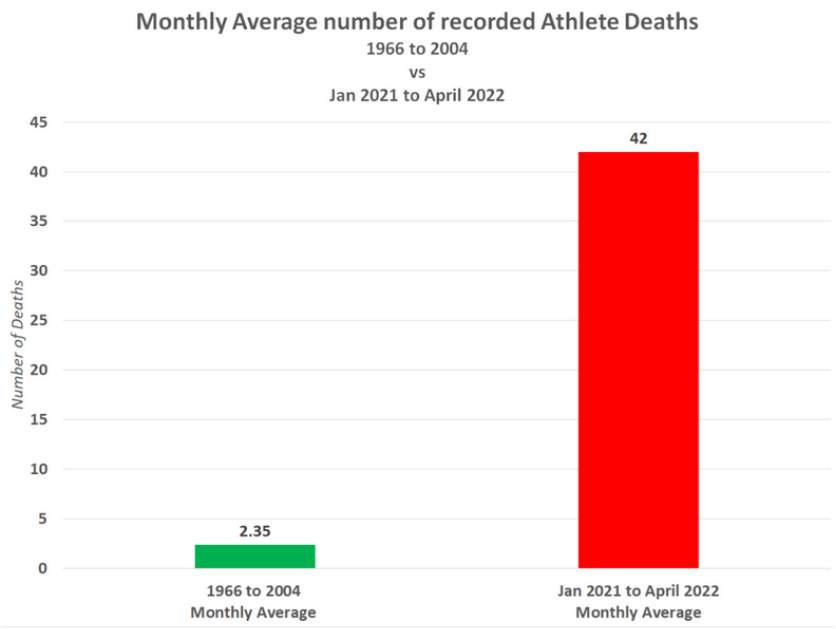
4.1.8. Alarm signal: Myocarditis (continued)

418 Already in 2021, the danger from myocarditis - which can lead to death - was evident (front N 330 ff.) and was further aggravated by additional reports of side effects (see above N 389 ff.) as well as further studies, reports and data in 2022:

419 In particular, a large-scale Scandinavian analysis of over 23 million people concluded in April 2022 that COVID "vaccinations" significantly increased the risk of myocarditis across all age groups. Among 16-24 year old men, there was a **5-fold increased risk after Comirnaty** and a **15-fold increased risk after Spikevax.** However, as already shown graphically (N 389) - it is not only Spikevax that is responsible for the high number of myocarditis cases: In the USA, 77.6% of the cases are accounted for by Comirnaty, which, however, has a market share of "only" about 60%.

420 In an Israeli study, the false claim that myocarditis can also be a consequence of COVID disease was also impressively refuted: By means of database analysis, the **entries of over 750,000 "unvaccinated" persons were used to determine that myocarditis does not occur more frequently after COVID disease than without the disease**.

421 Worldwide, reports about the connection between "vaccination" and myocarditis are increasing: even in a study conducted for the CDC and FDA, scientists came to the conclusion that **the upper limit of the expected myocarditis rates** had been **significantly exceeded, especially in young men and women.** This is also evident worldwide in the many young athletes who collapse "suddenly and unexpectedly" (on the playing field). Since the start of the vaccination campaign at the beginning of 2021 until 24 June 2022, 14,013 medical incidents and "sudden deaths" have been recorded internationally among professional and amateur athletes. The average age of these cases was 40 years. This is clearly not something that would have always existed, but an entirely new development. For example, the number of athletes who died suddenly has apparently increased massively compared to previous years:



422 In view of this worrying development, the Japanese Ministry of Health had already **acknowledged** the **increasing rate of heart muscle inflammation in the vaccinated population in** January 2022 and forbade discriminating against people who rejected the COVID "vaccines". Finally, in June 2022, a Japanese cardiovascular surgeon reported **numerous complications** and some **deaths in** "vaccinated" patients in the medical journal Virology Journal: Numerous **post-operative infections** in vaccinated patients after open-heart surgery could not have been **controlled** even after several weeks of antibiotic therapy. He therefore called for an immediate stop to "booster vaccinations". This, too, is a serious indication: the "vaccines" not only lead to myocarditis and other consequences, they apparently also stand in the way of rapid recovery after curative interventions.

4.1.9. Alarm signal: V-AIDS

423 In June 2022, the German law firm *Rogert & Ulbrich Rechtsanwälte in Partnerschaft mbB, which* specialises in the legal processing of vaccination damage, drew the public's attention to what they believed to be a widespread phenomenon that experts agreed was due to vaccination with COVID "vaccines": damage to the immune system, which had already been described in various publications in the specialist literature as "**Vaccine-Acquired** Immune Deficiency Syndrome" (so-called **V-AIDS**). In these publications it was concluded that

- the COVID "vaccines" damage the immune system's communication system by suppressing the messenger interferon 1, and the mRNA "vaccines" can thus make vaccinated people more susceptible to infectious diseases and cancer.
- the spike proteins lead to "syncytia formation", where many human cells fuse to form a large cell and the lymphocytes, which are important for immune defence, are damaged in the process, so that lymphocytopenia can develop.
- the COVID "vaccines" can deactivate the function of the natural T-killer cells and thus disable the recognition of viruses and cancer cells by the immune system.

424 The law firm had already noticed in a number of individual cases that autoimmune diseases had been diagnosed following vaccination. In the blood tests that had been commissioned, the corresponding markers, which indicate damage to the immune system, were demonstrably altered.

425 The phenomenon of V-AIDS is therefore of fatal importance because damage to the immune system is known to lead not only to the increased incidence of autoimmune diseases and cancer, but above all to the increased incidence of infectious diseases. In this context, it is relevant that according to the statistics of numerous countries, COVID hospitalisations and deaths are driven by the vaccinated, which further supports the thesis of V-AIDS. Thus, there is increasing evidence pointing to a negative cost-benefit ratio of COVID vaccination. These indications are further strengthened by impressive official data from Israel and the US army:

4.1.10. More data on the dangerousness of the "vaccines": Israel, US Army

426 In February 2022, the Israeli Ministry of Health published the results of a study according to which **66% of Israeli citizens who had received a booster vaccination suffered from side effects.** This evaluation in itself is cause for great concern, as it directly calls into question the cost-benefit ratio.

427 In the USA, an analysis of the **US military's medical epidemiology database (*DMED*)** showed an **increase of 270% in heart attacks**, **460% in pulmonary embolisms, 1000% in nerve diseases, 490% in breast cancer, 290% in facial nerve palsies, 290% in Guillain-Barré syndrome (a severe neurological disease with paralysis), and a further 10% in the number of people who have been vaccinated** since the start of the COVID "vaccination campaign", **breast cancer by 490%,** facial **paralysis by 290%**, **Guillain-Barré syndrome** (a severe neurological condition with paralysis usually starting in both legs) by **550%** and **miscarriages by 280%** compared to the five-year average. These figures only became public thanks to the US lawyer Renz, who was then accused of "misinformation" and defamed by the US government. Thanks to this active monitoring and recording system of the health status of all soldiers within the US Army, it is now clear and beyond reasonable doubt to the general public: **the negative effects of the COVID vaccinations far outweigh the claimed benefits of the COVID vaccination in this basically healthy group of people (active soldiers) who are not significantly endangered by SARS-CoV-2**.

4.1.11. Numerous other studies that indicate a causal relationship

428 By 1 March 2022, the previously (N 251, N 351), which indicate a connection between the COVID vaccines and side effects, many more studies were added: A total of at least **128 peer-reviewed publications on heart problems, 223 peer-reviewed publications on life-threatening coagulation disorders (thromboses, etc.) and 7 peer-reviewed publications on possible deaths as a result of the COVID vaccines.**

429 In view of this flood of scientific studies, no one could seriously claim that the mRNA "vaccines" were not at least suspected of causing serious side effects, including death. Insofar as these side effects have occurred and continue to occur in people who do not belong to the risk group (endangered by SARS-CoV-2), a negative net benefit of the COVID-19 "vaccines" is thus easily proven.

4.2. Effectiveness

4.2.1. Omicron variant: Rapid decrease in (relative) efficacy (RRR)

430 German, Swedish, Canadian and US studies came to the conclusion that the mRNA "vaccines" would have had a certain initial protection against "Omikron" as well - but that this protection decreased strongly after a few months. **Relative efficacies of 23%-59%** were calculated. In children, according to the US study, this even dropped relatively quickly to 12-51%. Once again: The RRR method - as explained in detail above (N 205 f.), the

RRR method leads to completely distorted data in the case of only a few proven infections. The absolute risk reduction (ARR) is thus likely to be in the low single-digit percentage range. The mRNA "vaccines" thus offered no "major therapeutic benefit" from the outset - they were simply unsuitable for protection against "omicron" under the title of Art. 9a HMG.

431 This soon became apparent: in Germany, the RKI officially stated as of 28 April 2022:

> "What **is striking is the significant drop in the calculated vaccine effectiveness of** both the basic immunisation and the booster vaccination against symptomatic infection in all age groups since the beginning of 2022, i.e. with dominance of the omicron variant."

432 The corresponding official graphs even showed that the **vaccine effectiveness in the** groups of 5-59 year-olds had **been at zero since at least the end of March 2022.** However, instead of providing further information about the non-existent vaccination effectiveness, the RKI discontinued all information in this regard as of 5 May 2022. No comprehensible reasons for withholding this data were given and obviously do not exist. Once again, this shows the **complete lack of transparency of the responsible authorities,** who are legally obliged to inform the population in full about all risks and (non-)effects of the experimental mRNA "vaccines".

4.2.2. No protection against transmission and infection

433 Neither the manufacturers nor the regulatory authorities have ever been able to prove that the mRNA "vaccines" protect against transmission and infection, as has been shown repeatedly. On the contrary: in their reports to the EMA in November 2021 and March 2022 - i.e. after more than a year of "vaccination campaign" - the manufacturers themselves stated that it was still **not known to what extent the vaccination prevents further transmission.** A study published in January 2022 also showed that there was **no significant difference in the transmission of circulating variants of SARS-CoV-2 between vaccinated and unvaccinated people.**

434 Once again, the manufacturers' claims are glossed over: it is well known that a "vaccination" does not prevent further transmission. This has once again been impressively confirmed by cases of double and triple "vaccinated" people. Accordingly, even the RKI had to admit that the vaccination protection decreases over time and the probability of becoming PCR-positive despite vaccination increases. And Prof. A. Radbruch (immunologist and vice-president of the Federation of European Immunological Societies [EFIS]) stated une-

quivocally in March 2022 that the **viral load of infected vaccinated persons** is **high** and the **protection from vaccination is only short-term.**

4.2.3. Recovered people better protected against re-infection than vaccinated people (continued)

435 Already by the end of 2021 (front N 373), more than 60 publications have shown that **a previous illness reliably protected against re-infection and that the immunity acquired in this way is superior to vaccination**.

436 As a result of further studies, it was already noted in December 2021 that the antibody diversity was greater in those who had recovered than in those who had been vaccinated. In April 2022, a large-scale retrospective observational study by scientists at Oxford University also found that vaccinated **persons had a 13-fold higher risk of re-infection** and a **7-fold higher risk of a new symptomatic illness with "delta"** than unvaccinated persons. There is no clearer evidence than these findings from scientists at one of the world's most prestigious universities that COVID-19 "vaccinations" **weaken the natural immune system instead of strengthening it** - and thus do exactly the opposite of what they were intended to do. This observational study thus joins the many legally relevant facts and evidence showing that the "vaccines" are, on balance, a danger to public health.

437 This data situation, which was devastating for the "vaccination" strategy, then led to the decision, at least in the USA, to put natural and vaccine-acquired immunity against COVID-19 on an equal legal footing in Tennessee (USA).

4.2.4. Poor recording of "vaccination breakthroughs

438 In Switzerland, so-called "vaccination breakthroughs" - i.e. a lack of efficacy - are not adequately recorded: Since the end of October 2021, only deaths and hospitalisations are to be recorded - all other cases are excluded. But not even these two categories (deaths and hospitalisations) are strictly recorded:

439 Thus, it has already been stated above (N 313 ff.) that **deaths** are in no way sufficiently recorded.

440 There are also massive gaps in **hospitalisations**: some hospitals had not even begun to systematically record vaccination status until late summer 2021 *at the earliest.* Others started at the end of November 2021 at the earliest, sometimes only recording the certificate (and thus the "vaccination status") "if clinically relevant". Such orders do not ensure that the "vaccination status" is systematically recorded. As a result of this **lax practice,** as

of 31 January 2022, the **vaccination status** was still **officially unknown for 20% of** hospitalisations in connection with a COVID disease.

441 Without strict recording of "vaccine breakthroughs", accurate analyses of the efficacy of the mRNA "vaccines" are made much more difficult - which is simply unacceptable given that they are still in ongoing clinical trials.

4.2.5. Do vaccinated people contract and die more often from COVID than unvaccinated people?

4.2.5.1 International trends

442 There is growing evidence worldwide that the "vaccinated" fall ill with COVID more often than the "unvaccinated" and more often have to be treated in hospital or even die. As far as can be seen, no conclusive studies are yet available, but a clear *correlation can be* seen:

443 In his analysis ("preprint") of 145 countries, K. BEATTIE OF the University of Alberta concluded that the **"vaccines"** would **lead to higher rates of COVID infections (USA: +38%) and COVID-related deaths (USA: +31%).** In May 2022, *Walgreens,* one of the largest *US* pharmacy chains and provider of PCR testing at over 5,000 locations, published data showing that **double and triple vaccinated people** had **the highest rates of positive SARS-CoV-2 test results.**

444 In *England,* **72.5% of patients hospitalised for COVID** were already **"vaccinated" by the** end of December 2021. By March 2022, this trend had become impressively clear from the death figures: **9 out of 10 COVID deaths were in the vaccinated population and 4 out of 5 COVID deaths were in the triple-vaccinated population.** If one were to carry out an effectiveness analysis on the basis of relative risk reduction (RRR), this would result in an **effectiveness** (RRR) of **minus 80% with** regard to the prevention of COVID **hospitalisations** and **an effectiveness** (RRR) of **minus 92% with regard to COVID deaths.**

445 *Scotland* reports a similar **story***:* vaccinated patients already accounted for 73% of COVID hospital admissions by the end of 2021 - **vaccinated patients accounted for 83% of deaths.**

446 Also in *Canada,* **97.7% of those who died of COVID** were **fully "vaccinated" or "boosted" at** the end of April 2022.

447 In *Israel,* Prof. Jacob Giris, head of the COVID department at Ichilov Hospital in Tel Aviv, reported at the beginning of February 2022 that **70-80% of hospitalised patients with severe COVID had been "vaccinated" three times. The** "vaccination" definitely has no significance in terms of preventing severe COVID courses. In addition, the European mortality monitor *EuroMomo* shows that **Israel** had **the highest excess mortality for Q1 2022** since the beginning of the Corona crisis - and this despite the circulation of the harmless "Omikron variant".

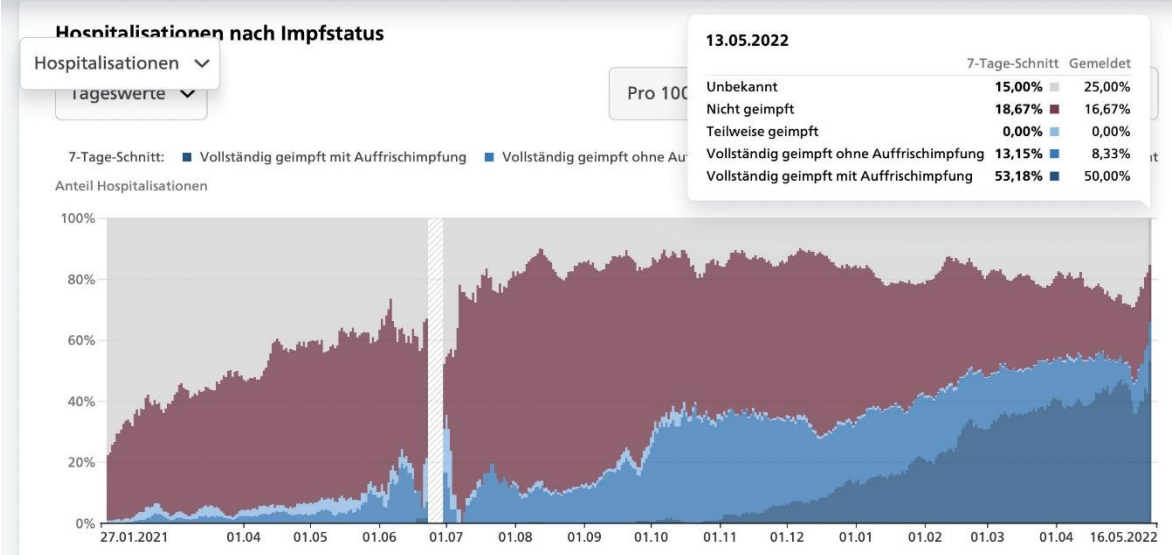
448 The data from "Zero COVID" Australia, which has a very high "vaccination coverage" rate of 85%, is also alarming: from around April 2020 to the end of 2021 - i.e. within just under two years - only 2,253 COVID deaths were officially reported. From 1 January 2022 to 8 May 2022 - i.e. in about four months - an additional 5,263 COVID deaths were suddenly reported. **Despite the demonstrably harmless "Omikron variant" and despite (or rather because of) the high vaccination coverage rate, 70% of all COVID deaths occurred during this short period.**

449 The situation is similar in "Zero COVID" *New Zealand*: there, too, **deaths have risen massively and sharply since spring 2022,** even though (or rather because) 95% of the population over 12 years of age was fully vaccinated.

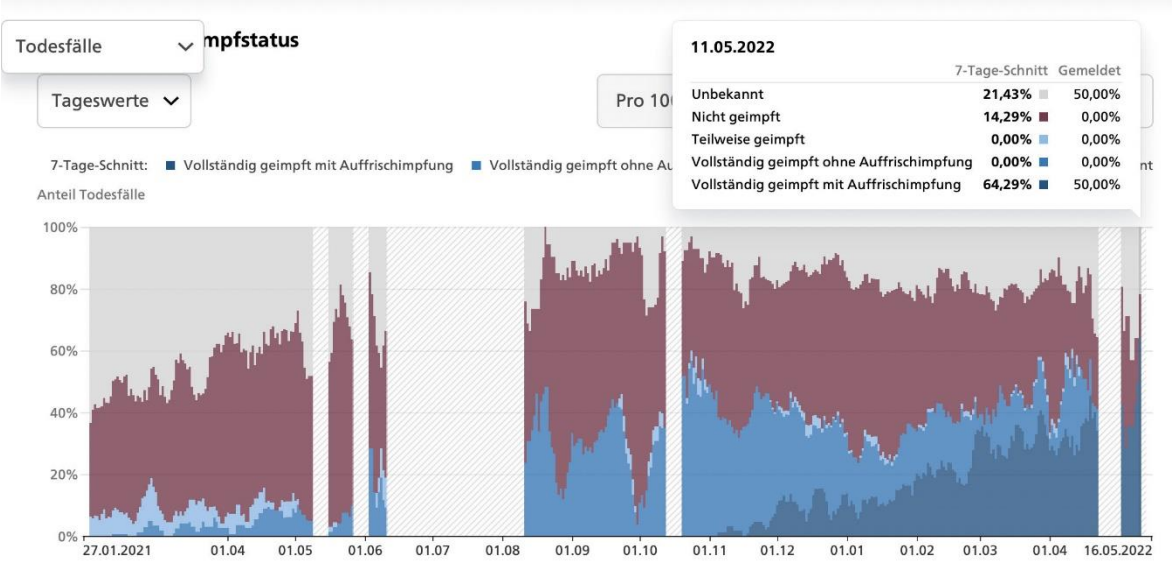
450 *Portugal* and *Malta are* also experiencing a similar trend: With "vaccination coverage" rates of over 80%, these countries have seen a **significant increase in reported COVID deaths** since January 2022.

4.2.5.2 Same pattern in Switzerland

451 Unfortunately, Switzerland is also following this international trend: While 42.7% of COVID hospitalised patients were vaccinated at the beginning of 2022, **66.3% of COVID hospitalised patients** had already been **vaccinated by** mid-May 2022**.** Only 19.6% were unvaccinated, and the vaccination status of 27.8% was "unknown" - this high number of unreported cases is simply unacceptable (see N 438 ff.).

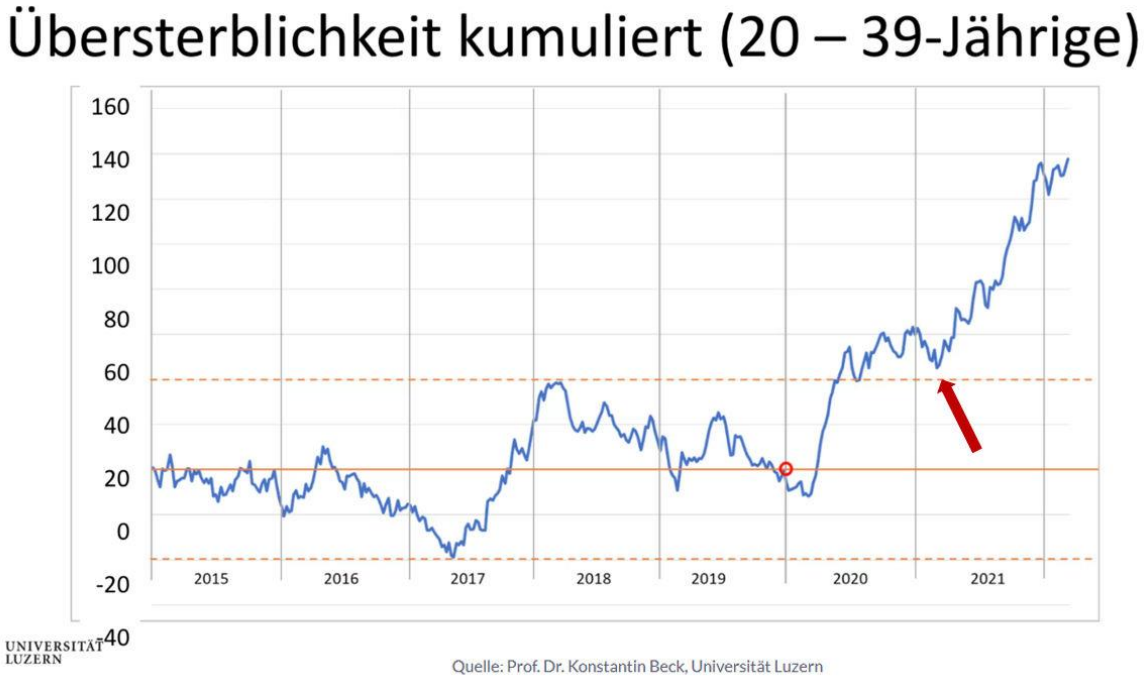


452 But not only do the "vaccinated" now make up the majority of those hospitalised for COVID, they also seem to die more frequently: as of 11 May 2022, 64.3% of those who officially died of COVID were triple vaccinated.



453 In addition, a study published in June 2022 by Konstantin BECK, Professor of Insurance Economics at the University of Lucerne, who had analysed the mortality data of the Confederation, according to age categories, shows a persistently strong increase in deaths for the age group 40-64 years from April 2021:

454 The same picture emerges among 20-39 year-olds:



455 An increase can also be seen in the age group 0-19 years, although less pronounced. The less pronounced increase in the 0-19 age group could be explained by the lower vaccination coverage rate in this age group.

456 Even if these data alone cannot prove causality, they do show a worrying and impressive correlation between the start of "vaccination coverage" of the respective age group and rising excess mortality, which urgently needs to be clarified.

4.2.5.3 Interim conclusion

457 Both international and Swiss figures unequivocally demonstrate that COVID illnesses and associated hospitalisations and deaths are driven by the multiply vaccinated.

458 **If vaccination were effective and if it successfully prevented (severe) SARS-CoV-2 COVID courses, nationally and internationally COVID hospitalisations would have to be consistently cited from unvaccinated persons**. A final assessment is not yet possible. Analyses are currently being conducted in various countries on this - presumed - correlation between vaccination and death rates.

4.3. Intermediate outcome (from 2022): Increased death rates, negative effectiveness

459 The devastating development, which had already become apparent in 2021, continued in 2022. Alarm values for deaths are exceeded thousands of times - and this despite massive underreporting. Initial studies have shown that the spike protein causes human deaths. Children are dying from the mRNA "vaccines" - the risk obviously exceeds the benefit. The mRNA "vaccines" continue to be given to pregnant women, although not a single study on the effects in pregnant women has been successfully completed. The sad consequence of this is that thousands of stillbirths have occurred worldwide - stillbirths that, like many other deaths, could have been prevented. Based on the latest data worldwide, there is strong evidence that vaccinated women die more often from COVID than unvaccinated women. The effectiveness of the mRNA "vaccines" is thus not only tending towards zero - it is probably even negative.

4.4. Outlook: Use of self-replicating mRNA "vaccines"?

460 Despite the obvious failure of the mRNA "vaccines" and without waiting for the final results of the approval studies, the mRNA technology was further advanced in the background: In the future, it is possible that not only non-replicating but even **"self-replicating mRNA"** (sa mRNA) will be used, as in the currently marketed "vaccines". These have the **ability to replicate independently in the human body.** Should a waiver of pharmacokinetic data also be envisaged for these "vaccines", this would be highly worrying, since predic-

tions on the amount and duration of mRNA production in the human body are hardly possible with self-replicating mRNA.

461 Vaccines with self-amplifying mRNA have already been tested since 2015 in animal trials for various infectious diseases such as Ebola, HIV, malaria, influenza rabies and Zika, and for rabies and SARS-CoV-2 in initial trials in humans.

462 Results of a phase 1 trial of a self-amplifying mRNA-COVID "vaccine" for SARS-CoV-2 were published in the Lancet on 13 January 2022:

463 The "vaccine" was administered twice to 192 volunteers in six different doses at an interval of four weeks. The generated immunity and side effects were subsequently observed over a period of eight weeks: The "vaccine" was deemed safe based on **six serious and 25 moderate adverse events,** all of which were classified as - allegedly - "not associated with the vaccine", but the generated immunity was deemed insufficient, which is why optimisations to the formulation were deemed necessary.

5. Conclusion (as of mid-2022): Increasing maximum risk without appropriate safety precautions

464 The mRNA "vaccines" show the objective peculiarities described above in detail, which became known to Swissmedic in increasing detail from summer 2020 onwards. Both individually and collectively, these point unmistakably to particular risks to public health. In view of their impact on the entire population of Switzerland, the project to authorise mRNA "vaccines" in Switzerland for all adults from December 2020 must be qualified as a **project with an increasing, unprecedented risk character** for public health, for the following reasons:

465 Even before the first market approval in December 2020, the Swiss regulatory authority was aware that, for the first time in the history of therapeutic products, a completely new technology was to be applied to the broad and healthy population: The mRNA technology, officially classified as a gene "therapy" in the USA and the EU. This transfers the **production process of the actual active substance (spike protein) into the human body.** Swissmedic was aware that there was insufficient empirical data available in this context to show that this endogenous production of the spike protein was controllable in terms of: (i.) duration; (ii.) location; (iii.) quality; (iv.) quantity; and (v.) effect and tolerability in humans. Thus, however, the basic principles that are mandatory for any drug treatment and also for any drug approval were and still are missing.

466 The **lack of proof of efficacy with** regard to these mRNA "vaccines" was openly evident from the outset from the manufacturer studies presented. The lack of efficacy has also

continued to manifest itself over time in the form of numerous official statistics and scientific evaluations of the same. Equally obvious was the **accumulation of serious side effects** (which were becoming more and more evident worldwide): from the weakening of the immune system, to heart problems, cancer and autoimmune diseases, to "vaccine" related "sudden and unexpected" deaths on an unprecedentedly high scale.

467 In the course of time, the data and facts proving the lack of efficacy and the accumulation of serious side effects have steadily increased to an almost overwhelming extent. A **risk to public health that has** never before been accepted by a Swiss authority and is steadily **increasing is** thus offset by a benefit to public health that has by no means been sufficiently proven.

468 The numerous legally relevant facts and evidence summarised herewith and proven in the enclosed evidence report, taken as a whole, prove beyond any reasonable doubt that the "vaccine" substances, on balance, pose a **continuously and increasingly increasing risk to public health.**

469 Furthermore, at the time of the first authorisation in December 2020, the authorisation authority was aware that the studies submitted by the manufacturers to demonstrate efficacy and safety (both with regard to experiments with animals and those with humans) were completely inadequate in terms of quality and quantity in every respect - even for the purposes of a temporary authorisation. Swissmedic and the persons notified were thus aware beyond any doubt at the time of December 2020 that the granting of the temporary authorisation for the entire population of Switzerland was **tantamount to an actual human experiment.** Nevertheless, the authority refrained from actively informing the public about this legally relevant fact (which is absolutely necessary for an informed vaccination decision) and from ensuring proactive monitoring of the side effects (see below N 686 ff.).

470 Consideration of this increasingly overwhelming body of data must lead to the compelling conclusion that the mRNA "vaccines" should never have been approved and that - in order to prevent further harm to the population - they must be withdrawn from circulation immediately.

471 However, should this risk - purely hypothetically and contrary to all the facts described so far - nevertheless be considered acceptable, then the assumption of the same can only be considered permissible under two alternative circumstances at best:

472 Either Swissmedic and all those involved in the administration of the experimental substances would have to **exercise maximum care and caution with regard to the** protection of public health enshrined in law. This includes, for example, the duty to (1) inform the medical profession, the public and patients/consumers transparently and comprehen-

sively about the particular risk-benefit situation and (2) to take measures to ensure that all unintended side effects are recorded as fully as possible and to be able to stop the experiment immediately if risks come to light. This is discussed below (N 493 ff., especially N 527 ff. and N 683 ff.).

473 Or, as a special circumstance, there is such a serious dangerous situation that the taking of such a maximum risk could only be outweighed for a short time and only if the highest safety precautions were taken :

IV. Circumstances of the crime - " Dangerous situation WHO pandemic "

474 All statements made in this section are based in their entirety on the **evidence report** enclosed with this criminal complaint **(Annex 4),** which contains further discussions and lists the relevant supporting documents. The title structure in this section of the criminal complaint and the enclosed evidence report (section "WHO pandemic risk situation") correspond in terms of content, but are shifted by one level (e.g.: Title level "**2.** State of knowledge at the beginning of the crisis " of the criminal complaint corresponds to title level "**II.** State of knowledge at the beginning of the crisis" of the evidence report). **Accordingly, reference is made to the detailed evidence report in its entirety for proof and in order to deepen the following explanations.**

475 All approvals of the mRNA "vaccines" are under the impression of the "COVID pandemic": The aim of the mRNA "vaccinations" is to "combat" the so-called SARS-CoV-2 virus by immunising the population against it and, in particular, to prevent severe courses of the disease.

476 First of all, the (alleged) origin and the (alleged) detection of SARS-CoV-2 will be discussed in a short excursus. A conclusive classification does not have to be made here, as it is then explained in detail - assuming that SARS-CoV-2 is indeed the cause of the "COVID diseases" - that **SARS-CoV-2 has never posed** and does not pose **a life-threatening or disabling danger to the entire population** (target population).

1. Excursus: Origin and detection of SARS-CoV-2

477 The first "proof" of SARS-CoV-2 was already provided on 10 January 2020 by a working group led by Prof. ZHANG in Shanghai. However, the "detection" is based purely on computer models or bioinformatics (shown below in simplified form): Lung fluid was taken from a single human being and - **without purification/centrifugation/sedimentation etc. of the** same - RNA pieces of arbitrary length contained therein were assembled on the basis of overlaps and "aligned" with two known gene sequences of corona viruses using two

different (again arbitrarily chosen) "assemblers". In other words, a **"genome framework"** was **assembled** on the computer from a large number of unrelated short gene sequences by means of **"overlaps" using** specific software algorithms **and the "gene sequence" of SARS-CoV-2 was finally constructed using two known corona viruses (and specific PCR primers).** As a result, no precisely determined viral gene sequence was effectively isolated.

478 Whether strict proof - the detection of an isolate - of SARS-CoV-2 has been provided to date does not need to be conclusively clarified in the present case. In the following, it is therefore assumed that SARS-CoV-2 has been detected as a virus and as such causes the disease "COVID-19" .

2. State of knowledge at the beginning of the crisis (early 2020)

479 At the beginning of the crisis, the **lethality of SARS-CoV-2 was** assumed to be high to very high - demonstrably too high:

- In June/July 2020, an infection fatality rate (IFR) of **8%** (group aged 70-79) and even **14.8%** (group aged 80 and over) was calculated for China;
- In July 2020, however, a lethality rate of "only" **0.6% was** calculated for the total population in Switzerland;
- in July 2020, the CDC assumed a total population death rate of **0.5-0.65%;**
- In August, the WHO put the lethality of the total global population at **0.5 -1%.**

3. State of knowledge at first adult registrations (end 2020)

480 Shortly afterwards, these figures were massively corrected downwards: In October 2020, Prof. IOANNIDIS calculated a global lethality of just **0.15%-0.20%**; for people under 70 years of age, only **0.03-0.04%.**

481 It was therefore already clear at this early stage that the **"dangerousness" of SARS-CoV-2 roughly corresponds to that of a moderate flu:** according to the WHO, the lethality of seasonal influenza (flu) is normally below 0.1%. In the USA, the CDC calculated a lethality of **0.1355% for the** entire population for the last (moderate) flu wave of 2017-2018.

482 **There was therefore no question of a life-threatening or disabling disease for the entire adult population at the time of the first temporary authorisation. If** at all, the "vaccinations" would only have been considered for the somewhat more endangered persons over 70 years of age.

4. State of knowledge with indication extension to adolescents (June 2021)

483 The lack of threat posed by SARS-CoV-2 to the Swiss population as a whole - and to young people in particular - was already evident in June 2021:

- For the "pandemic year" 2020, **no excess mortality** was observed in Switzerland; the year 2020 ranked "5th" in comparison to the 10 previous years - there were thus a total of 4 years from 2010 with higher mortality than in 2020.
- The global lethality (IFR) was again revised downwards by Prof. IOANNIDIS IN March 2021 and set at **0.15%**. The CDC also adjusted its estimates downwards. **For adolescents, the IFR was already at that time only 0.002% - they were therefore in no way threatened by SARS-CoV-2.**
- Despite repeatedly predicted horror scenarios, there was **no overloading of Swiss hospitals in** the winter of 2020/2021**:** even at the "peak" of the crisis (December 2020), intensive care units were **never over 80% full throughout Switzerland** - despite politically forced bed reductions during the ongoing "pandemic" (!), which indicates actual **normal operation.**
- The PCR test used to determine the "case numbers" has long since been scientifically exposed as unsuitable for diagnosing the disease. In particular, testing symptomless people leads to a large number of "false positive" results, which completely distorts the overall picture of the threat situation. The "high number of cases" was thus already to be regarded as an irrelevant criterion in itself in June 2021.

5. Knowledge status at the end of 2021 ("Booster" / children)

484 The alleged threat posed by SARS-CoV-2 to the Swiss population as a whole was once again shown to be non-existent at the time the "booster" was approved:

- In the calendar year 2021, not only was there no excess mortality, the year 2021 even showed an **under-mortality of -5,983 people** compared to previous years. If SARS-CoV-2 had been so dangerous, the opposite would definitely have been expected.
- Already in July 2021, the lethality with the **"delta variant" was** ten times lower compared to the alpha/beta variant and was still about **0.01-0.02% (IFR),** which corresponds to a **mild flu.**
- Although the number of hospital beds was further reduced, the utilisation of the intensive care units never exceeded 80% in 2021. In addition, the officially reported **COVID patients accounted** for **only about 10% of all hospitalisations, and significantly less during various periods.**

485 With regard to the "vaccination" for children, the following should also be pointed out:

- From the beginning of the "pandemic", the children were never threatened with a **lethality that** would have exceeded **0.0027%.** Children as the "target population" were thus never threatened with death by SARS-CoV-2. In the official statistics of the FOPH and the Federal Statistical Office, four children are officially reported as having died from or with Corona by the beginning of 2022. To date, however, despite relevant requests for evidence in over a dozen court cases brought by the lawyer co-signing this report, the authorities have not yet provided evidence in a single case **as to** how many children in Switzerland have actually died or been hospitalised **predominantly as a result of infection with SARS-CoV-2.** [69]
- According to "Pediatrics Switzerland", "Long COVID" and "PIMS" do not pose a danger to children themselves, which means that there has never been a threat of an invalidating disease.
- In September 2021, Paediatrics Switzerland also clarified that children - contrary to what is repeatedly claimed - are not "superspreaders", or that the direction of infection even primarily runs from adults to children and not from children to adults.

486 **The risk for children to seriously contract COVID-19 tended towards zero at any time.** Accordingly, the requirement of Art. 9a para. 1 subpara. 1 HMG i.V.m. Art. 18 lit. a VAZV, according to which the risk of serious disability or possible death must apply to all patients covered by the target population - i.e. all children - was obviously not fulfilled at any time.

6. State of knowledge as of 2022

487 With the "Delta" variant of 2021 at the latest, there was no longer a disease threatening the entire population. The basic prerequisite of a life-threatening or disabling disease had obviously long since ceased to exist - indeed, it had not existed from the very beginning.

488 With the "Omikron" variant, this realisation was once again confirmed in all clarity:

- In the calendar year 2021, too, no significant excess mortality was discernible - rather, the figures were within the usual range.
- The lethality of the **"Omikron variant"** was still about **0.001-0.002% (IFR). "Omicron"** is thus significantly **- at least 50 times - less dangerous than normal influenza for** the population **as a** whole.

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69 This delay in providing evidence by the authorities is all the more relevant as the authorities are burdened with the burden of proof in proceedings to review the constitutionality of encroachments on fundamental rights within the meaning of Art. 36 of the Federal Constitution and encroachments on fundamental rights, particularly with regard to children (special protection of fundamental rights Art. 11 of the Federal Constitution), are to be qualified as unconstitutional without proven necessity due to a violation of the principle of proportionality.

- The situation in the area of (intensive care) hospital beds continued to develop within the range of the completely normal in winter 2021/22. In addition, from autumn 2021 at the latest, there was a **massive manipulation of the "case numbers" in the hospitals: around 50% (!)** of the cases reported by the FOPH as "COVID-19 hospitalisations" were in fact not causally hospitalised because of a SARS-CoV-2 infection. On the basis of this manipulation of figures, an **unprecedented smear campaign** against the **unvaccinated ("epidemic of the unvaccinated")** took place, which was "blamed" for an - effectively unprecedented - overload of the hospital system.
- The unsuitability of the PCR test described above had become evident by the end of 2021: the "laboratory-confirmed cases" had long since decoupled from the "laboratory-confirmed deaths". **The criterion of "number of cases" was therefore never suitable for effectively identifying a danger situation that needed to be combated.**
- From 2022 onwards, there was also increasing evidence from studies that **"Long COVID" and "PIMS" do not** pose any risk to the unvaccinated (especially not to children), but that on the contrary, these symptoms are **much more likely to occur in the vaccinated.**

7. Conclusion

489 At the beginning of the "crisis" - i.e. in the spring of 2020 - SARS-CoV-2 did not pose a threat to the population as a whole that would exceed the level of a moderate flu. Only elderly people aged 70 and over were affected by a higher mortality rate. Children were not at risk at any time.

490 With the Delta variant, the overall "dangerousness" of SARS-CoV-2 was reduced to the level of mild flu, and with the Omicron variant, SARS-CoV-2 was about 50 times less lethal than normal flu.

491 At no time did excess mortality occur. At no time were hospitals in Switzerland operating at more than 80% capacity.

492 **SARS-CoV-2 thus did not in any way represent a life-threatening or disabling disease for the entire adult population from the time of the "temporary" approval of the experimental mRNA therapies.**

V. Swissmedic offence - authorisation as a source of danger; no adequate protective measures

493 Vaccines are classified as medicinal products ("immunological medicinal products") according to Art. 2 lit. b AMBV. They are used "to produce active or passive immunity or to

diagnose a state of immunity" and, according to Art. 1 HMG, may only be authorised in Switzerland for the protection of human and animal health if they are effective, safe and of high quality. Or to put it another way: the benefit-risk assessment by the authorisation authority Swissmedic must be clearly positive. The smaller the expected benefit of a medicinal product, the more carefully potential risks must be analysed and the suspected cases of undesirable side effect reports associated with the medicinal product observed after a marketing authorisation. Risks and benefits must be weighted differently depending on the target population: In the case of a medicinal product used for advanced cancer, more and also more severe side effects may be accepted than in the case of a medicinal product which - as in the current case of the COVID "vaccinations" - is to be administered to a primarily healthy population including children only for **preventive protection.**

494 On the basis of the foregoing, it is clear that the **mRNA "vaccines" are medicinal products with a maximum risk profile and minimal to hardly any efficacy.** Circumstances that would nevertheless justify an authorisation with such a devastating cost-benefit profile did not exist at any time.

495 Nevertheless, Swissmedic granted a so-called "temporary" authorisation for the mRNA "vaccines" for the first time in December 2020 and subsequently extended it several times. In the following, we will therefore examine what the characteristics and requirements of the "time-limited authorisation" are and whether these have been fulfilled. In order to be able to better locate the "time-limited" authorisation in the system of the various authorisation procedures under medicinal products law, the ordinary authorisation procedure is described in detail below and then differentiated from the "simplified" and the "time-limited" authorisation procedures.

496 It will become clear that **with the "temporary" authorisation of a medicinal product, practically all the ordinary safety mechanisms under medicinal product law can be circumvented.** And even more: Even the few remaining safety requirements of the "time-limited" authorisation procedure - which Swissmedic even imposed on itself - have been ignored by Swissmedic with regard to mRNA "vaccines" and distorted beyond recognition:

1. Usual admission procedure: Ordinary admission

497 In Switzerland, medicinal products are normally authorised "ordinarily" on the basis of Art. 9, 10, 11 and 16 HMG as well as the corresponding implementing provisions .[70]

[70] In particular, Ordinance on Medicinal Products (VAM; SR 812.212.21) and Ordinance of the Swiss Agency for Therapeutic Products on the Requirements for the Authorisation of Medicinal Products (Medicinal Products Authorisation Ordinance; AMZV; SR 812.212.22).

1.1. Application for approval with complete data set

1.1.1. Development of a medicinal product up to marketing authorisation

498 **The development of a drug and especially a vaccine takes an average of ten to twenty years. It** regularly takes **more than 13 years from the** idea to the approved drug.[71] During this time, scientists from different disciplines, chemists, biologists, physicians and pharmacists, work closely together. If all the tests during the development phase have been successful, the manufacturer can apply for approval from the competent authorities by submitting all the results documenting preclinical and clinical development and manufacturing as a **"marketing authorisation dossier".**

499 The success rate for the approval of a new drug is very low: **out of 10,000 drug candidates, only one actually reaches the market in the end.** Reasons for stopping the development of a new drug are often insufficient efficacy or serious side effects.[72]

1.1.2. International standardisation by means of CTD (modules 1-5)

500 An application for a marketing authorisation for a medicinal product for human use with a new active substance must be submitted to the competent regulatory authority with an internationally uniformly defined structure in **5 modules**, in the so-called **"CTD" format** ("Common Technical Document" format). This is to ensure that an applicant does not have to compile the application documents anew for each approval authority and that the comparability of the applications is also made possible. The CTD format was also implemented in Switzerland in 2003. The modules are structured as follows:[73]

- Module 1 contains administrative information and varies depending on the country. It contains, among other things, a comprehensive table of contents of the entire dossier, regionally and administratively important information, various forms, as well as infor-

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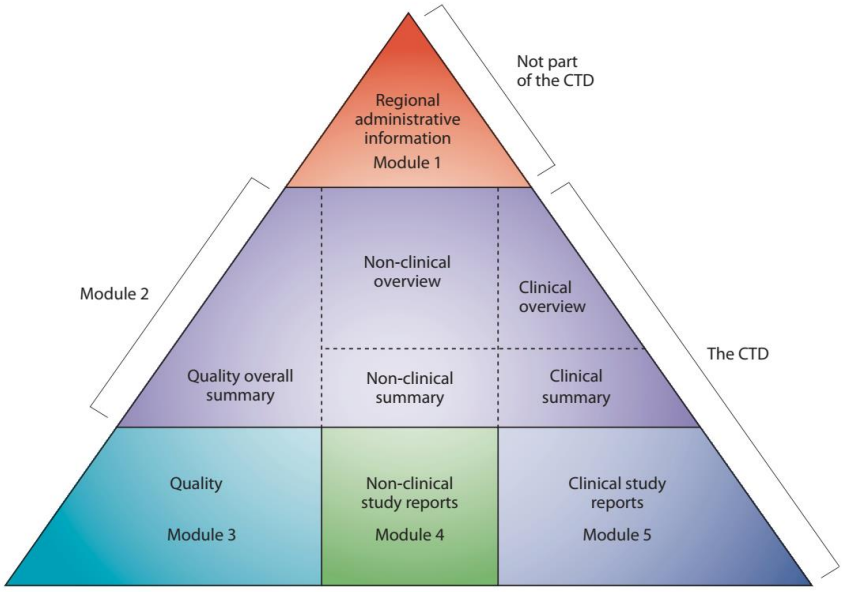
71 vfa. Die forschenden Pharma-Unternehmen, "Klinische Studien zur Erprobung neuer Medikamente", 28.12.2016, https://www.vfa.de/de/arzneimittel-forschung/so-funktioniert-pharmaforschung/klinische-studien-uebersicht.html.

72 Infovac, "Development of Vaccines", 04.10.2021, https://www.infovac.ch/de/faq/entwicklung-von-impfstoffen; Interpharma, "Marketing Authorisation and Market Introduction", 09.06.2022, https://www.interpharma.ch/themen/fuhrend-in-forschung-entwicklung/der-weg-eines-medikaments/zulassung-und-markteinfuehrung-phase-iv/.

73 ICH (The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use), "M4: The Common Technical Document", 09.06.2022, https://www.ich.org/page/ctd. See SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 10 f.; JORDAN, "An overview of the Common Technical Document (CTD) regulatory dossier", 2014, *https://journal.emwa.org/regulatory-writing-basics/an-overview-of-the-common-technical-document-ctd-regulatory-dossier/article/1693/2047480614z2e000000000207.pdf.*

mation on the use of the medicinal product such as drug texts (summary of product characteristics, patient information).

- Module 2 provides an overview of modules 3-5.
- **Module 3 deals with** pharmaceutical **quality. The** chemical, pharmaceutical and biological information on the medicinal product can be found here - i.e. information on the manufacturing process, the control, characterisation and specifications of the drug substance, the excipients and the finished medicinal product, among other things.
- **Module 4** deals with the **safety of** the medicinal product and contains all reports on the **preclinical investigations** (investigations "in vivo" on animals or "in vitro"). Among other things, the results of the investigation of the pharmacology of the medicinal product (pharmacokinetics, pharmacodynamics) and the studies which analysed the safety of the medicinal product in "toxicity studies" can be found here.
- **Module 5** concerns the **efficacy of** the medicinal product and contains the study reports of the **clinical** trials conducted in humans.



The CTD triangle. The Common Technical Document is organized into five modules. Module 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.

1.1.3. Legal regulation in the HMG

501 According to Art. 11 HMG, the application for marketing authorisation must "contain all information and documents essential for the assessment". Accordingly, a **complete marketing authorisation dossier** must be submitted, containing at least (Art. 11 Para. 1 and Para. 2 lit. a Nos. **1-6** HMG):[74]

74 Cf. SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, before Art. 8-17 N 16.

1) the production method, composition, quality and shelf life [Module 2/3],
2) the results of the physical, chemical, galenical and biological or microbiological tests, **[Module 3].**
3) the results of pharmacological, toxicological, **[Module 4]** and clinical trials **[Module 5],** including any results from trials in special populations,
4) the curative effects and the undesirable effects **[Module 5]**,
5) the labelling, the information on the medicinal product and the method of dispensing and use [Module 1],
6) an assessment of the risks and, where necessary, a plan for their systematic identification, clarification and prevention (pharmacovigilance plan) [Module 1],
7) the paediatric investigation plan according to Article 54a HMG [Module 1].

502 In the case of medicinal products with a new active ingredient, a large number of documents must be submitted containing all known properties of the preparation, the **results of years of research in the context of preclinical and clinical trials**, the complete patient and technical information including packaging samples as well as **risk assessment plans** and test concepts.[75]

1.2. Main criteria: Quality, safety and efficacy

503 If a medicinal product is **authorised for the first time**, in addition to the analytical and technical information on the manufacturing process (quality; module 3), the findings from the pharmacological-toxic (animal studies; module 4) and clinical (human trials; module 5) tests must also be available with regard to the desired and undesired effects of the preparation. This information is mandatory in order to prove efficacy in the sense of a statistically recorded positive therapeutic effect of a preparation. The clinical trials on humans are central to this: In particular, they provide information on tolerability in humans, on the nature of the effect and on undesirable effects.[76]

504 Based on these documents, an **evaluation of the benefit-risk ratio has** to be carried out, which is associated with considerable evaluation questions. With regard to efficacy, a medicinal product must be both of **high quality** (extensive achievement of the therapeutic objective) and **quantitatively effective** (high probability of efficacy). The **risks** are to be assessed according to the severity and the probability of occurrence or the frequency and severity of the adverse effects. In this context, it also plays a role whether or not **warning symptoms** are observed prior to the occurrence of the adverse drug reactions.[77] Adverse

75 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 8.
76 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 16.
77 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 17.

drug reactions also include a lack of effect, which must be known for reasons of drug safety.[78] **Underestimated interactions of a** pharmacokinetic or pharmacodynamic nature with other medicinal products or with food and stimulants also fall under adverse drug reactions.[79] In particular, the following must be observed:

1.2.1. Quality: stability and purity

505 The documentation of the physical, chemical, galenic and biological or microbiological tests concerns the composition, manufacturing process, control of the starting materials, the intermediate products and the finished product, furthermore the shelf life tests (Art. 11 para. 2 lit. a No**. 1** HMG; Art. 3 para. 1 AMZV; **"Module 3"**). Appropriate analytical studies must demonstrate that the **quality of the preparation,** i.e. the degree of purity, composition and galenic properties, remain **constant** during production.[80] In addition to stability, proof must also be provided that there are **no impurities.**[81]

506 It is not excluded that reference can be made to individual analysis data of another medicinal product. However, according to the Federal Supreme Court, it is excluded to make a general reference to the documents concerning another preparation for the quality assessment of a medicinal product, even if the composition is largely identical.[82]

1.2.2. First safety features: Preclinical phase (animal studies)

507 The safety of a medicinal product is a relative characteristic: any undesirable effects must be compared with the therapeutic effects related to the indication, resulting in a favourable risk-benefit ratio. [83]

508 A medicinal product must necessarily be considered dangerous until its safety has been demonstrated. Possible harmfulness and thus potential adverse effects are first determined on the basis of pharmacological and toxicological tests within the framework of **animal experiments** or validated alternative models (Art. 11 Para. 2 lit. a **No. 2** HMG; Art. 4 Para. 1 AMZV; **"Module 4"**). The drug candidate is investigated **"in vitro"** (e.g. **cell cultures**), as well as **"in vivo" in animals.** This involves pharmacological questions, e.g.

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78 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 14, cf. also N 29a.
79 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 14.
80 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 28; cf. Swissmedic, "Wegleitung Zulassung Humanarzneimittel mit neuer aktiver Substanz HMV4", 15.09.2021, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/zulassung/zl_hmv_iv/zl101_00_005d_vwlnleitungfuerdiezulassungvonhumanarzneimittelnmi.pdf.download.pdf/zl101_00_005d_wlzulassungHumanneuerwirkstoff.pdf.
81 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 10.
82 Judgement 2A.16/2005 of the Federal Supreme Court of 04.08.2005, E. 2.2.
83 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 10 N 12.

what happens to the drug or its components in cells or in a whole organism and what reactions are triggered. Furthermore, it is investigated exactly how long the effect lasts and which dose is necessary for the desired effect.

509 According to Art. 4 para. 2 AMZV, the corresponding documentation must include in particular documentation on **pharmacodynamics** (i.e. the relationships between the circulatory concentration of the active substance and the resulting effects on the organism), **pharmacokinetics** (i.e. the relationships between the dosage of an active substance and the resulting concentration in the blood, urine, body tissue and at the site of action), **toxicology (i.e.** tolerance in the organism) and **ecotoxicity** (i.e. tolerance in the environment). **These animal studies should already enable an initial benefit-risk analysis**[84] - although only rudimentary indications of possible (curative) effects in humans can be taken from these preclinical studies.

510 **Many drug candidates already fail these toxicity tests.** Only those drug candidates that pass all safety tests are allowed to enter the next development phase with studies in humans (clinical trials).[85]

1.2.3. Safety and efficacy: Clinical phases I-III

511 To prove the effect in humans, **clinical studies in humans** are also required, which provide information on clinical pharmacology and pharmacokinetic and pharmacodynamic interactions (Art. 11 para. 2 lit. a **No. 2** HMG; Art. 5 AMZV; **"Module 5"**).

512 Clinical trials involving therapeutic products on humans are regulated in Art. 53 ff. HMG, the Human Research Act (HFG; SR 810.30) and the Ordinance on Clinical Trials (KlinV; SR 810.305). The definition in Art. 2 lit. a KlinV shows that it is a **"research project with persons"**, i.e. a "method-guided search for generalisable findings" (Art. 3 lit. a HFG). This means that scientifically recognised **procedures, especially systematic and verifiable ones, must be** used and the validity of the findings must extend beyond the context of the research project.[86] Research involving human subjects must comply with the international rules of Good Clinical Practice ("GCP") (Art. 10 para. 1 HRA; Art. 5 para. 1 and Annex 1 No. 2 ClinO), whereby reference is made to the Guideline on Good Clinical Practice of the International Conference on Harmonisation as amended on 9 November 2016 (ICH Guideline).

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84 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 30.

85 Netdoktor, "Arzneimittelzulassung", 10.08.2020, https://www.netdoktor.ch/medikamente/arzneimittelzulassung/.

86 SCHNEIDER, BSK HMG, 2nd ed., Basel 2022, Art. 53 N 3b.

513 Clinical testing on humans (**module 5**) with medicinal products is only justified if in animal experiments (preclinical; **module 4**) cumulatively[87]

1) direct or at least indirect evidence for the desired pharmacological efficacy of an active substance has been found,
2) The speed and pathways of drug absorption into and excretion from the organism (pharmacokinetics) were investigated,
3) no undesirable side effects have occurred in the range of the pharmacologically effective normal doses, and
4) dangerous or even lethal toxic organ and/or system damage has only been observed with overdoses that are many times higher than the normal doses.

514 If the aforementioned premises are fulfilled, the **three phases of the clinical trial** can be started, which build on each other:[88]

1.2.3.1 Phase I: Safety (dose-finding study)

515 In **phase I, the** tolerable dose and thus the **tolerability of** a test substance is tested for the first time in a small group of healthy volunteers (usually 60-80, regularly less than 100 subjects) **(dose finding).** In up to 30 successive tests, phase I checks whether the predictions from the animal experiments are confirmed about how quickly the active substance enters the blood, how long it remains there, how it is metabolised in the body and how quickly and by what route it leaves the body again. In order to minimise the risk for the test persons, new active substances may initially only be tested in a dose that is far below the dose that will later be contained in the drug. The dose is then gradually increased. If there are problems, the treatment of the volunteers is stopped immediately. If it becomes apparent that an active ingredient causes unacceptable side effects in the concentrations needed for treatment, the entire development programme is discontinued. If, on the other hand, the drug is tolerated, the clinical trial can be continued.[89]

1.2.3.2 Phase II: First signs of efficacy (first study in sick people)

516 In **phase II, the** first trials are conducted with a small number of patients (usually 100-500 patients). This involves more detailed surveys on the occurrence of undesirable **side effects**. The main goal, however, is to be **able to prove the efficacy and therapeutic benefit of a test substance statistically and thus in a generally valid way for the first**

87 SCHNEIDER, BSK HMG, 2nd ed., Basel 2022, Art. 53 N 9.
88 Netdoctor, FN 85.
89 SCHNEIDER, BSK HMG, 2nd ed., Basel 2022, Art. 53 N 10 ff; vfa. The research-based pharmaceutical companies, FN 71.

time. This proof can only be provided in participating persons who suffer from the disease to be treated.[90] In the case of **vaccine candidates,** the **immune response in healthy people** is **observed over several months in phase II**, but in particular common side effects are also to be identified.

1.2.3.3 Phase III: Safety and efficacy: (double-blind study)

517 In **phase III, the** same is tested as in phase II, only with considerably more (**several 1,000 to several 10,000**) **study participants** and over an even longer period of time. Here, the clinical trials that **are decisive for approval are** carried out as so-called **randomised controlled trials (**RCT), which is considered the so-called "gold standard": one group receives a placebo, the other the drug to be tested, with patients being randomly assigned to the groups.[91] This is to prevent hopes, fears or sceptical attitudes of doctors and patients from influencing the outcome of the treatment and thus reducing the significance.

518 The purpose of these comprehensive "registration studies" is to **find out whether the vaccine** really does provide **lasting protection against the disease** against which it was developed and, above all, **whether it is safe**. Only in such large-scale phase III studies, in which many study participants are observed over a sufficiently long period of time - normally **several years** - can rare side effects that only occur in the medium or long term be detected. Vaccination against a disease is only recommended if its benefit *far* outweighs the risk of adverse effects.[92]

1.2.3.4 Duration of clinical phases I-III

519 **As a rule, each of the phases I-III should last at least one year, usually longer.**[93] Corresponding time specifications can hardly be found in the relevant literature or in the public domain. For phase I (dose finding), a few months may suffice, while phase II usually lasts up to one year. For phase III, a period of well over a year is usually estimated - which is also evident in the present "phase I/II/III" study by Pfizer, which will last until 2024 and for which more than three years are planned.[94]

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90 SCHNEIDER, BSK HMG, 2nd ed., Basel 2022, Art. 53 N 10 ff; vfa. The research-based pharmaceutical companies, FN 71.

91 SCHNEIDER, BSK HMG, 2nd ed., Basel 2022, Art. 53 N 10 ff; vfa. The research-based pharmaceutical companies, FN 71.

92 Infovac, FN 72.

93 vfa. The research-based pharmaceutical companies, FN 71.

94 NIH, "Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals", 30.04.2020, https://clinicaltrials.gov/ct2/show/NCT04368728.

1.2.4. Appraisal: Safety and efficacy only after completion of phase III

520 Solid proof of the safety of a medicinal product can therefore only be provided after all preclinical animal studies and the clinical studies in humans (phases I-III) have been carried out.[95] Adverse drug reactions must be determined in particular on the basis of **clinical studies** and truthfully documented with information on frequency and severity (Art. 11 para. 2 lit. a Nos. **2 and 3** HMG; Art. 5 AMZV; **"Module 5"**). The **occurrence of adverse drug reactions is not a general reason for exclusion from marketing authorisation.** Even severe, life-threatening side effects are not *per se a* reason for rejecting an application. However, they must be taken into account as a central aspect in the evaluation of the risk-benefit ratio. [96]

521 The results of clinical trials serve on the one hand to determine the tolerability of a medicinal product and its side effects and interactions, and on the other hand to **assess its efficacy.**[97] Accordingly, the intended medical effects of the medicinal product for the detection, prevention or treatment of a specific disease, as determined in clinical trials, must be stated in the marketing authorisation application.[98] The so-called therapeutic efficacy is required. It **must be proven on** the basis of the (clinical) studies conducted that **the desired therapeutic, diagnostic or preventive effect is achieved in relation to the indication**.[99] **The mere presentation of the pharmacological effects determined on the basis of animal experiments is not sufficient.**[100] Where proof of efficacy cannot be provided stringently, a statistical evaluation of the documented tests in the sense of a probability statement may suffice. However, the efficacy determined in this way must be derivable with **sufficient probability** according to recognised scientific rules.[101]

1.3. Authorisation procedure and overall duration of the procedure

522 In order to **apply for a marketing authorisation for a medicinal product, in** addition to the **documents on the quality of a medicinal product** and the **preclinical studies, the complete "phase II" study results and the 12-month data of the "phase III" studies are** normally submitted in the marketing authorisation dossier for review.

523 The complete application is then subjected to a **comprehensive examination by** Swissmedic with regard to the manufacturing method, composition, quality and shelf life,

95 Cf. SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 10 N 13.
96 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 37.
97 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 33.
98 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 35.
99 BGE 143 V 95 E. 3.2 p. 99 f.
100 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 15.
101 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 10 N 16; cf. ruling C-5649/2015 of the FAC of 24.07.2018, E. 5.3.

as well as the desired and undesired effects, based on the criteria in accordance with Art. 10 HMG.[102] This examination within the framework of the ordinary authorisation procedure takes around **330 calendar days**.[103] Accordingly, the 24-month data of the **"phase III" studies** are normally available at the time of the granted marketing authorisation, which additionally rounds off the picture with regard to efficacy and safety. For the clinical studies alone (i.e. without the preclinical animal studies), including the approval procedure, **at least two years** must be estimated.

1.4. Approval, requirements and conditions

524 As a rule, an ordinary marketing authorisation is granted for five years (Art. 16 Para. 2 Sentence 1 HMG).

525 Each marketing authorisation can be linked to requirements and conditions (Art. 16 para. 1 sentence 2 HMG). Possible conditions mentioned by the legislator include the obligation to further evaluate a preparation (clarifications on interactions, undesirable effects, regulations for special patient groups or on dosage)[104] or the ban on advertising a specific medicinal product to specialists and the general public[105] . Swissmedic thus has a certain discretion to refuse authorisation in a specific case or to grant authorisation subject to conditions. **However, "serious deficiencies" in terms of safety or efficacy cannot be remedied by imposing conditions**[106] - and the authorisation must therefore be refused.

526 The results of the studies that the medicinal product underwent in the preclinical and clinical phases can be viewed in the medicinal product information approved by Swissmedic (summary of product characteristics or patient information), which is published for each medicinal product on *www.swissmedicinfo.ch.*

1.5. "Phase IV": Market surveillance

527 Relatively **rare side effects** - those that occur on average less than **once in 1,000 people treated** ("rare"; ≥1/10,000 to <1/1,000) - are **often not detected in the pre-marketing studies.** At the beginning of the career of a - properly approved - drug, a good dose of mistrust is therefore indicated.[107] In the run-up to the approval decision, rare serious ad-

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102 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, before Art. 8-17 N 15.

103 Swissmedic, "Wegleitung Fristen Zulassungsgesuche HMV4", 01.06.2022, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/zulassung/zl_hmv_iv/zl000_00_014d_wlfristenzulassungsgesuche.pdf.download.pdf/zl000_00_014d_wlfristenzulassungsgesuch.pdf, p. 10.

104 Message HMG, 3504.

105 Message Revision HMG, 107.

106 SCHMID / UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 16 N 15.

107 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 18.

verse drug reactions can hardly be detected because the controlled clinical trials are only conducted with a relatively small number of subjects and patients.[108] Despite these (pre-clinical and) clinical trials, which are carried out extensively prior to proper approval, many side effects will therefore only become apparent after the drug has been approved, when the number of patients treated multiplies, which is why there is still a need for thorough market and thus risk monitoring even after proper approval.[109]

1.5.1. Risk Management Plan (and PSUR/PBRER)

528 There is already an obligation to submit a pharmacovigilance plan in the marketing authorisation application (in "Module 1") in accordance with Art. 11 Para. 2 lit. a No. 5 HMG (Art. 4 VAM). This requirement was newly introduced with the revision of the HMG as of 1 January 2019 - as a **reaction to serious incidents in the past in which risks** were **identified too late. The** aim is therefore to identify and name risk factors at an early stage in order to monitor them in detail after market authorisation.[110] The risk management plan must fulfil the requirements of Good Vigilance Practice ("GVP") according to Annex 3 VAM and includes a summary assessment of the important known risks, important possible risks and risks that have not yet been sufficiently investigated, as well as a plan describing the follow-up of these risks and the measures to ensure the safe use of the medicinal product (Art. 5a para. 1 AMZV).

529 Following approval of the marketing authorisation application, the marketing authorisation holder is obliged to submit a summary of the risk management plan to the Institute (Art. 5a para. 2 AMZV). This is then published publicly by Swissmedic as a supplement to the available expert and patient information.[111]

530 A risk management plan must be submitted in the ordinary procedure according to Art. 11 HMG for first authorisation applications for medicinal products containing at least one new active substance (Art. 4 para. 1 lit. a VAM). In addition, according to Swissmedic, it follows from Art. 11 HMG that a **risk management plan is** also mandatory for all applications for authorisation of medicinal products that do not qualify for a simplified authorisation procedure (Art. 14 HMG, Art. 12 para. 5 VAZV): i.e. for "**vaccines**, sera and toxins", "medicinal

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108 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 18.
109 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 36.
110 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 14 and N 47 ff; Swissmedic, "Wegleitung RMP ICH E2E Informationen Einreichung HAM", 01.03.2022, *https://www.swissmedic.ch/dam/swissmedic/de/dokumente/marktueberwachung/mu/MU_HMV4/mu103_10_001d_wlrmpiche2einformationeneinreichunghmv4.pdf.download.pdf/MU103_10_001d_WL_RMP_ICH_E2E_Informationen_Einreichung_HMV4.pdf*, p. 1.
111 Swissmedic, (FN 110), S. 1.

products containing genetically modified organisms" and for "advanced therapy medicinal products based on gene transfer methods (gene therapy medicinal products)".[112]

531 As part of the subsequent market surveillance, the marketing authorisation holder of a medicinal product with a new active substance must submit (at least) **annually and without being requested to do so an updated report on the safety and risk-benefit balance of** the medicinal product (so-called **PSUR** or PBRER) (Art. 60 para. 1 VAM).[113] In the event of a significant change in risks or the emergence of new risks, an updated pharmacovigilance plan must also be submitted.[114]

532 Based on this data, among other things, Swissmedic must carry out a continuous review of the benefit-risk profile of medicinal products (Art. 16c HMG [review of authorisation] in conjunction with Art. 14 VAM).[115] In doing so, the Institute may of course not rely solely on the manufacturer's data: The obligation for subsequent market surveillance by the licensing authority is comprehensive in order to guarantee quality, efficacy and safety, which obliges it to maintain a close-meshed reporting and monitoring system that goes beyond mere manufacturer data:

1.5.2. Obligation to report

533 The obligation to notify according to Art. 59 Para. 1-3 HMG is an important instrument of ex post market surveillance by the authorities.[116] As previously explained (N 527), the subsequent market surveillance of medicinal products authorised for the first time (properly) serves to detect **rare adverse reactions that** could not have been detected during the preclinical and clinical studies. The obligation to report is thus one of the cornerstones for ensuring the protection of human (and animal) health (Art. 1 para. 1 HMG).[117]

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112 Swissmedic, (FN 110), S. 3.

113 For periodicity see: Art. 60 para. 2 VAM in conjunction with. Annex 3 VAM with reference to the periodic report on the safety of medicinal products and the risk-benefit balance: ICH Guideline E2C (R2) as amended on 17 December 2012; Swissmedic, "Wegleitung PSUR PBRER Information Einreichung HAM", 01.04.2022, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/marktueberwachung/mu/MU_HMV4/mu103_10_002d_wlpsurpberinformationeinreichunghmv4.pdf.download.pdf/MU103_10_002d_WL_PSUR_PBRER_Information_Einreichung_HMV4.pdf.

114 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 53.

115 Swissmedic, "Wegleitung Arzneimittelsignale HAM", 01.02.2022, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/marktueberwachung/mu/MU_HMV4/mu101_20_001d_wlarzneimittelsignalehmv4.pdf.download.pdf/MU101_20_001d_WL_Arzneimittelsignale_HMV4.pdf, p. 4.

116 Message on a Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, HMG) of 1 June 1999, BBl 1999 III 3453 ff., 3540; SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 87 N 19b.

117 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 1 N 12 and N 14 with explicit reference to the reporting obligations under Art. 58 ff. HMG.

1.5.2.1 Duties of Swissmedic

534 According to Art. 58 para. 3 sentence 1 HMG, the Institute (Swissmedic) is responsible for monitoring the safety of therapeutic products. To this end, it collects notifications in accordance with Article 59 TPA, evaluates them and takes the necessary administrative measures. Ensuring the safety of therapeutic products within the framework of **ex-post market surveillance is** therefore just as much a core area of the Institute's activities as the area of authorisation. The **Institute is obliged to identify and clarify risks as early as possible in order** to immediately take the necessary measures to ensure **the safety of medicinal products**. [118]

535 To this end, those who place medicinal products on the market must ensure a functioning reporting system (Art. 59 para. 1 sentence 1 HMG).[119] In addition, quality defects (Art. 59 para. 2 HMG) and serious and unknown adverse reactions (Art. 59 para. 3 HMG) must be reported. The Institute, in turn, is obliged by Art. 59 para. 1-3 in conjunction with Art. 58 para. 3 HMG to effectively enforce a **functioning reporting system** that **ensures the early detection of potential risks.** The Institute's responsibility for monitoring safety includes not only the reporting system pursuant to Art. 58 para. 3 sentence 2 HMG, i.e. for example that within the framework of pharmacovigilance and good vigilance practice (monitoring of the risks of undesirable effects in connection with the use of medicinal products: Art. 61-66 VAM and Annex 3 VAM). According to the wording, meaning and purpose of Art. 58 Para. 3 Sentence 1, the **Institute's responsibility** is to be understood as a **comprehensive obligation within the framework of monitoring the safety of therapeutic products**. [120]

536 In reality, the **reporting system** "set up" by Swissmedic is of a **purely passive nature:** it is based on observed suspicious cases, for which spontaneous notifications are (or would have to be) made by notifiers to Swissmedic, which then have to be checked and evaluated by the latter.[121] It is therefore all the more important to **enforce this reporting obligation.** This is also a mandatory prerequisite for the **targeted issuing of administrative measures in** accordance with Art. 66 para. 2 HMG: According to this, the Institute is obliged, for example, to order "the distribution and dispensing of medicinal products [...] and the immediate recall of medicinal products from the market or the dissemination of harm-preventing behavioural recommendations" (lit. e), to seize "medicinal products that

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118 Message on a Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, HMG) of 1 June 1999, BBl 1999 III 3453 ff, 3539; EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 58 N 16, Art. 59 N 2.

119 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 87 N 19b.

120 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 58 N 15.

121 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 4.

are hazardous to health or do not comply with the provisions of this Act" (lit. d) or to suspend or revoke "authorisations and licences" (lit. b). However, these means can only be used to achieve the purpose if the Institute ensures that it has the necessary information for this purpose. **Without the effective implementation of the legal obligation to enforce a functioning reporting system, all efforts to ensure effective ex post market surveillance for the protection of health will come to nothing**. This refers to the relationship between efficacy and safety (cf. Art. 10 Para. 1 lit. a and Art. 11 Para. 2 lit. a Nos. 3 and 5 HMG). According to Art. 10 HMG, quality, safety and efficacy are prerequisites for authorisation. **The potential benefit of a preparation must always exceed its potential risk.** If this **requirement** is **no longer met** due to new findings on the safety of the medicinal product, **the marketing authorisation must be revoked** or suspended (Art. 16, 16a and 16c HMG). [122]

537 Swissmedic is therefore responsible, within the framework of ex post market surveillance, for the **situation-appropriate - comprehensive and functioning - monitoring of therapeutic product safety** and **rigorous enforcement of the obligation to notify.**

1.5.2.2 Obligations of the manufacturers

538 The subject matter of the manufacturers' obligation to report is very broad and in principle is not restricted at all at the legislative level.[123] Manufacturers must report **all undesirable effects** and events that could endanger or impair the health of patients (Art. 59 para. 1 lit. b HMG).

1.5.2.3 Obligations of medical personnel (medical profession)

539 Medical personnel, on the other hand, only have to report **serious and previously unknown adverse reactions**: According to Art. 59 para. 3 HMG, they must report serious or previously unknown adverse effects and occurrences, observations of other serious or previously unknown facts, and quality defects to the Institute (Swissmedic).

540 Observations of **serious adverse drug reactions/facts must therefore be reported in any case,**[124] which is also stated accordingly in Art. 63 para. 1 lit. a and lit. d VAM. Serious adverse drug reactions or observations of serious facts must be reported within 15 days (Art. 63 para. 3 sentence 1 VAM). A serious adverse reaction exists if it is "**fatal or life-threatening**, requires **inpatient treatment** or prolongation of inpatient treatment, re-

122 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 58 N 16.
123 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 23, cf. also N 29 as well as N 12a/b.
124 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 58 N 16, N 44.

sults in **permanent or serious disability or invalidity,** or is a congenital anomaly or **birth defect**".[125]

541 Previously **unknown adverse effects**, on the other hand, must be reported irrespective of their severity (Art. 63 para. 1 lit. b VAM). Previously "unknown" or "new" adverse drug reactions are those that are **not or not sufficiently mentioned in the product information.**[126] Such events must be reported within 60 days (Art. 63 para. 3 VAM).

542 According to Art. 59 para. 5 HMG, the reports according to paras. 1-3 must be submitted in accordance with the recognised rules of good vigilance practice. Accordingly, the reports under Art. 59 HMG should and must be submitted electronically in a standardised form and entered into the corresponding database (e.g. via the Electronic Vigilance Reporting Portal ElVis).[127]

1.5.2.4 Threshold for mandatory reporting: degree of certainty

543 The extent of the adverse reactions to be reported (all or "only" serious and new ones), depending on the addressee of the reporting obligation, must **be distinguished from** the **degree of certainty at which the reporting obligation applies:** Is certain knowledge required or is the mere suspicion that an adverse reaction could be present sufficient?

544 The Dispatch and doctrine are unanimous in this respect: the starting point for the reporting system is the **mere suspicion of** undesirable effects.[128] The Dispatch states unequivocally in this regard:

> "The time and scope of the obligation to report depends on the degree of health risk and the already existing level of knowledge about adverse effects and incidents of the therapeutic product. The greater the health hazard and the less known the adverse effect or incident is, the sooner the event must be reported".[129]

545 A report must already be made if a signal is merely **suspected.**[130] A concrete danger to public health is not necessary: **Even an abstract risk obliges the notification and re-**

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125 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 18a (cf. also N 40a); with reference to Art. 1 No. 12 of Directive 2001/83/EC and analogously ICH Harmonised E2D Tripartite Guidline No. 2.3.

126 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 41.

127 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 3.

128 Message on a Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, HMG) of 1 June 1999, BBl 1999 III 3453 ff, 3540; EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 3, N 24.

129 Dispatch on a Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of 1 June 1999, BBl 1999 III 3453 ff., 3540.

130 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 4.

view of the safety of medicinal products on the market. Thus, any possible, relevant deterioration of the benefit-risk profile entails the legal obligations of Art. 59 HMG.[131]

1.5.3. International cooperation

546 The most **complete** possible **collection and evaluation of all relevant data** is an indispensable prerequisite for implementation in the sense of improving drug safety. To this end, there is an international exchange of data with the participation of Switzerland (access by Switzerland to the "WHO Programme for International Drug Monitoring [PIDM]"; "EMA Eudra Vigilance System").[132]

1.5.4. Special labelling obligation (black triangle) and advertising ban

547 Drug texts and also promotional materials of **medicinal products with new active substances for** which there is a **lack of information regarding** their **risks** because they have not yet been used under real conditions and therefore rare allergic reactions, side effects or long-term effects have not yet been adequately recorded must be marked with a **black triangle.**[133] Correctly, the technical information of the **mRNA "vaccines" is** marked with such a **black triangle.**[134]

548 Furthermore, there is a **ban on advertising to the general public with** regard to mRNA "vaccines" available only on prescription (for more details see N 922 ff.).

1.5.5. Conditions and withdrawal of approval

549 According to Art. 66 HMG, Swissmedic has various options for intervening and imposing sanctions in the event of defects being identified: Swissmedic can, for example, issue complaints and set an appropriate deadline for restoring the lawful state of affairs. For example, it can require the manufacturer to draw attention to newly discovered side effects in the text of the medicinal product. It can also impose **restrictions on use**: If rare

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131 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 3, N 41.

132 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 5.

133 Swissmedic, "Medicinal product advertising: representation of the black triangle for medicinal products
Under Additional Surveillance", 11.2019, *https://www.swissmedic.ch/dam/swissmedic/de/dokumente/marktueberwachung/werbung/darstellung-schwarzen-dreiecks.pdf.download.pdf/schwarzes-Dreieck.pdf.*

134 Swissmedicinfo, "Fachinformation Comirnaty", as of 04.2022, https://www.swissmedicinfo.ch/ShowText.aspx?textType=FI&lang=DE&authNr=68225;
Swissmedicinfo, "Fachinformation Spikevax", as of 05.2022 https://www.swissmedicinfo.ch/ShowText.aspx?textType=FI&lang=DE&authNr=68267.

but serious side effects have been observed in certain patient groups, the authority can order that the medicinal product may no longer be used in these patient groups.[135]

550 In addition, Swissmedic can suspend or revoke marketing authorisations if, over time, **unacceptable risks have become** apparent as a result of their use. Sometimes the **manufacturer** also **voluntarily withdraws** such a medicinal product **from the market.**

1.6. Additional requirements for GMOs and gene therapeutics

1.6.1. Special authorisation requirements

551 Genetically engineered medicinal products, medicinal products containing genetically modified organisms (GMOs) and gene therapy medicinal products are not explicitly mentioned in the HMG.[136] In Art. 12 Para. 5 lit. c and e VAZV, "medicinal products containing genetically modified organisms" and "advanced therapy medicinal products based on gene transfer methods **(gene therapy medicinal products)" are excluded from the simplified authorisation procedure.** And according to Art. 6 VAM, for "medicinal products containing GMOs" it is stated that in addition to the requirements of the HMG, these must also meet those of Art. 28 FrSV (Release Ordinance; SR 814.911). An application for authorisation in accordance with Art. 28 lit. a-i FrSV must contain, among other things, a **comprehensive technical dossier,** results of previous studies in a contained system with the same organisms concerning hazards or adverse effects on humans, **authorisations for experimental releases** and for placing on the market, a monitoring plan, a proposal for **labelling** (Art. 10 FrSV), **information for recipients** (Art. 5 FrSV) and proof that the obligations to ensure safety have been fulfilled.

1.6.2. Special labelling requirements

552 In addition, there is a declaration obligation for medicinal products consisting of GMOs or containing such organisms. The type of GMO and genetic modification must also be stated in the product information (Art. 27 para. 1 and 2 VAM).

553 Active ingredients and processing aids derived from GMOs must be declared in accordance with the regulations on the labelling of genetically modified foods (Art. 27 Para. 3 VAM). According to Art. 8 para. 1, 2 and 6 VGVL[137] , foodstuffs, ingredients and pro-

135 Netdoktor, FN 85; Interpharma, FN 72.

136 So also SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 63, cf. also Art. 10 N 29 ff.

137 Ordinance of the FDHA on genetically modified food (SR 817.022.51).

cessing aids that are GMO products must be labelled with the words **"genetically modified".**

1.7. Summary and assessment

554 The ordinary authorisation procedure is dominated in its entirety by the guidelines of Art. 1 para. 1 HMG: With its high requirements for the necessary **quality tests, in-depth animal studies** and **long-term studies in humans,** and the in-depth **one-year review phase by the Institute (Swissmedic), it ensures** that only high-quality, safe and effective therapeutic products are placed on the market. The omission of necessary intermediate steps or the replacement of fundamental studies by other information is absolutely inadmissible. If a medicinal product fails even one of the necessary intermediate steps, market access is denied in order to protect the population.

2. Special approval procedures

2.1. Overview

555 The following description is limited to the second form of authorisation, which has been regulated in detail at the legislative level: The simplified marketing authorisation (Art. 14 HMG). The focus of the analysis is on answering the question of the areas in which **significant reductions** can be identified in **comparison with the ordinary authorisation procedure** and how these are **compensated for by alternative measures.** Subsequently, the "temporary authorisation" form of authorisation chosen by Swissmedic, which is a special form of simplified authorisation, is presented.

556 In addition to the three procedures described above (ordinary, simplified, time-limited), there are many other (sub)types of procedure, such as the accelerated authorisation procedure (Art. 7 VAM), the procedure with prior notification,[138] the "off-label use" (Art. 3 and Art. 26 HMG) or "unlicensed use" (Art. 20 para. 1 HMG in conjunction with Art. 48 f. AMBV). These will not be discussed further below (among other things, due to a lack of sufficient comparability of the differences in the areas of quality, safety and efficacy).

138 A "special offer from Swissmedic", according to Swissmedic, "Wegleitung Verfahren mit Voranmeldung HMV4", 01.03.2021, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/zulassung/zl_hmv_iv/zl101_00_013d_wlerlaeuterungenzumverfahrenmitvoranmeldungvmva.pdf.download.pdf/zl101_00_013d_mberlaeuterungenzumverfahrenmitvoranmeldungvmva.pdf, p. 2.

2.2. Simplified authorisation (Art. 14 f. HMG)

557 According to Art. 14 para. 1 HMG, Swissmedic may provide for simplified authorisation procedures for certain categories of medicinal products. This applies, for example, to the following categories:

- Medicinal products with **known** active substances, **"generics"** (**lit. a**; Art. 12 ff. VAZV [SR 812.212.23]);
- Medicinal products that have been **authorised for** at least **10 years in** at least one **EU or EFTA** country, **"well-established use"** (**lit. a^{bis}** ; Art. 14a para. 1 lit. a HMG), or
- important medicinal products for rare diseases, so-called **"orphan drugs"** (lit. f.; Art. 4-8 and 24-26 VAZV).

558 The simplifications granted can be of a material (fee reduction) or documentary nature - in particular in the form of **reductions in the requirements for the marketing authorisation dossier to be submitted. For** example, only simplified proof of efficacy and tolerability can be provided.[139] In addition, a **pharmacovigilance plan** can be **dispensed with**.[140]

559 Such a curtailment of the ordinary authorisation procedure fundamentally means an **increase in risk.** Therefore, Art. 14 para. 1 HMG requires that the requirements for **quality, safety and efficacy** must be **guaranteed elsewhere.**[141] This necessary balance can be achieved, for example, by requiring that **other documentation be** submitted (known active substances and/or active substances already authorised in the EU) or that **use only be** considered at all in **narrowly defined cases** ("orphan drugs").

2.2.1. "Known active substances" (Art. 14 para. 1 lit. a HMG): "Generic medicinal products".

560 According to Art. 14 para. 1 lit. a HMG, "medicinal products with known active substances" can be authorised in a simplified manner. This primarily includes so-called **"generic**

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139 SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 3.

140 Swissmedic, "Wegleitung Zulassung nach Art. 14 Abs. 1 Bst. a^{bis} -quater HMG HMV4", 28.02.2022, *https://www.swissmedic.ch/dam/swissmedic/de/dokumente/zulassung/zl_hmv_iv/zl000_00_022d_wlzulassungart14abs1bstabis-quaterhmg.pdf.download.pdf/zl000_00_022d_wlzulassungart14abs1bstabisquaterhmg.pdf*, Ziff. 5.5; cf. also Swissmedic, "Wegleitung Orphan Drug HMV4", 01.03.2021; *https://www.swissmedic.ch/dam/swissmedic/en/dokumente/zulassung/zl_hmv_iv/zl100_00_002d_wleorphandrugs.pdf.download.pdf/ZL100_00_002d_WL%20Orphan%20Drug.pdf*; see also: Art. 12-14 VAZV, which do not mention the pharmacovigilance plan; Art. 14a para. 1 lit a HMG, which refers to Art. 11 para. 1 and 2 letter a items 1-4 (but not item 5 [pharmacovigilance plan]). Cf. also SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14a N 7.

141 Message HMG 1999, p. 3470; SCHMID / UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 3.

medicinal products".[142] They are characterised by the same active substance, the same pharmaceutical form, the same route of administration, the same dosage and the same indications (cf. Art. 4 para. 1 lit. asepties HMG). The simplified marketing authorisation in such cases is justified by the fact that comprehensive documentation or complete marketing authorisation documents of an existing reference medicinal product can be used.[143]

2.2.1.1 Refrain from animal and human studies

561 Accordingly, the pharmacological and toxicological tests (preclinical; **animal studies**) can be **waived for** "generic medicinal products" if "sufficient evidence is available in the published literature" (Art. 13 para. 2 VAZV).[144]

562 Proof of safety and therapeutic efficacy (comprehensive **clinical studies** phases I-III; human trials) can also be provided by alternative means, whereby Art. 14 para. 1 VAZV indicates corresponding possibilities. Essentially, it is a matter of proving **that the findings already obtained in the studies of the reference medicinal product can be transferred with sufficient certainty to the generic medicinal product to be newly authorised.**[145]

563 The previously described - costly and lengthy - studies of modules 4 and 5 can thus be completely dispensed with by relying on established data. In other words, the **increased risk of missing studies is replaced by consolidated and seamlessly transferable scientific findings.**

2.2.1.2 No application for vaccines

564 However, an important exception to the simplified authorisation procedure for medicinal products with known active substances is explicitly stated in Art. 12 Para. 5 lit. a VAZV: **"Simplified authorisation cannot be granted: Vaccines, serums and toxins".** Even for vaccines with known active substances, a simplified authorisation is therefore out of the question, since the **necessary risk balance can obviously not be provided. This applies all the more to the novel and toxic mRNA "vaccines": A simplified authorisation of these would not be in conformity with the law under any circumstances**.

142 SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 11.
143 SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 14 f.
144 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 31.
145 SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 16.

2.2.1.3 No application for GMOs and gene therapies

565 Art. 12 para. 5 lit. c and e of the Ordinance on the simplified marketing authorisation procedure for medicinal products with known active substances contains a further important exception: Medicinal products containing genetically modified organisms (GMOs) and advanced therapy medicinal products based on gene transfer methods (gene therapy medicinal products) are excluded from the simplified authorisation procedure.

2.2.2. "EU/EFTA" medicinal products (Art. 14 para. 1 lit. a^{bis} HMG): "well-established use".

566 According to Art. 14 para. 1 lit. a^{bis} HMG, there is also a simplified marketing authorisation for "medicinal products whose active substances are used in a medicinal product which, at the time the application is submitted, has demonstrably been authorised as a medicinal product for at least 10 years in at least one country of the EU or EFTA and which is comparable in terms of indications, dosage and method of application". This is the so-called **"well-established use"**,[146] , i.e. a marketing authorisation based on proven use. The prerequisite, in addition to a **10-year period of use, is** comparability: this is given if the medicinal products "can be regarded **as 'essentially** the **same' in** terms of their **safety and efficacy,** irrespective of the differences between them".[147]

2.2.2.1 Refrain from animal and human studies

567 The facilitations granted essentially correspond to those of the "known active substances": According to Art. 14a para. 1 lit a HMG, the "results of pharmacological, toxicological and clinical trials" (Art. 11 para. 2 lit a no. 2 HMG) can be replaced by a compilation of equivalent scientific evidence. It is necessary that sufficient evidence of the safety and efficacy of the medicinal product is available in the published specialist literature (Art. 17b para. 1 VAZV).[148]

568 **Bibliographic evidence therefore replaces the costly and lengthy studies of modules 4 and 5. This increase in risk is compensated for by the preceding 10 years of successful application in humans.**

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146 SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 18.
147 SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 18. Cf. also Art. 17a lit. b VAZV.
148 SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14a N 7.

2.2.2.2 Application to vaccines and GMOs / gene therapeutics

569 This risk compensation - the 10-year use in humans - is apparently weighted so highly that Art. 14 para. 1 lit. a^{bis} HMG is applicable to all groups of medicinal products - i.e. also to **vaccines and GMOs / gene therapy medicinal products**.[149] This means that for GMOs and gene therapy medicinal products, the simplified procedure is available for medicinal products that have been used in humans for many years in the EU/EFTA.

2.2.3. "Orphan use" (Art. 14 para. 1 lit. f HMG)

570 According to Art. 14 para. 1 lit. f HMG (Art. 4-8 VAZV; Art. 24-26 VAZV), "important medicinal products for rare diseases" can also be granted a simplified authorisation. These are medicinal products for diseases that are so rare ("orphan diseases") that it is not worthwhile for the manufacturers to conduct research in view of the comprehensive ordinary authorisation procedure (so-called "**orphan use"**).[150] The purpose of the simplified authorisation in this area is therefore to increase the chance that medicines for rare diseases will nevertheless come onto the market and that research will be carried out in this area.[151]

2.2.3.1 Obtaining "Orphan Drug Status" (ODS)

571 In order for a medicinal product to be recognised as an "orphan drug" for the first time, the manufacturer must prove on the basis of documents (specialist literature, database information, etc.) (Art. 4 Para. 1 and 2 VAZV in conjunction with Art. 4 Para. 1 lit. $^{adecies\ No}$**. 1** HMG) that

- it serves to detect, prevent or treat a **life-threatening or chronically disabling disease,**
- which, at the time the application is submitted, **affects no more than five out of ten thousand people in Switzerland.**

572 This is **close to the content of Art. 9a HMG,** which may also only be used for life-threatening or disabling diseases. Accordingly, the doctrine postulates that an authorisation of "orphan drugs" is also possible within the framework of the "time-limited authorisation" (if the conditions are met).[152]

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149 SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 23.
150 BGE 139 V 375 E. 4.4. S. 378
151 SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 52.
152 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 9a N 6; SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 52 *in fine*.

573 Recognition is also possible if the medicinal product or its active substance has already been **granted** the **status of an** important medicinal product for rare diseases by **another country** with comparable medicinal product control within the meaning of Art. 13 HMG (Art. 4 Para. 1 VAZV in conjunction with Art. 4 Para. 1 lit. adecies No. **2** HMG).

2.2.3.2 Monetary incentives and procedural assistance

574 Once orphan drug status (ODS) is confirmed, monetary (and scientific) incentives and procedural support come into play:

- Waiver of government flat fees for new registrations.[153]
- Extended document protection of fifteen years.[154]
- Possibility of preliminary clarifications by Swissmedic prior to submission of a marketing authorisation application, which concern all relevant elements of a marketing authorisation (quality, safety and efficacy, according to Art. 3-6 AMZV and Modules 3-5).[155]

575 In addition, the medicinal product can be granted a simplified authorisation (Art. 24 para. 1 VAZV), whereby the authorisation procedure (Art. 24-26 VAZV) is basically based on the procedural regulations for known active substances (simplified authorisation)[156] or on those concerning new active substances (full authorisation) .[157][158] This means that proof of quality, safety and efficacy must be provided for the authorisation.[159] However, there are some significant exceptions:

2.2.3.3 Refrain from animal and human studies

576 According to Art. 26 para. 1 VAZV, the rarity of the disease and the associated **difficulty in conducting clinical trials pursuant to Art. 5 AMZV** is taken into account "appropriately" by Swissmedic with regard to the requirements for scientific documentation for authorisation. The more difficult conduct of trials consists in particular in the limited number

153 See Art. 65 para. 6 in conjunction with Art. 9 lit. Art. 9 lit. a and b GebV-Swissmedic (SR 912.214.5); SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 52.
154 Art. 11b para. 4 HMG.
155 Art. 25 VAZV; SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 52.
156 Swissmedic, "Wegleitung Zulassung Humanarzneimittelmit bekannter Wirkstoff HMV4", 01.03.2021, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/zulassung/zl_hmv_iv/zl101_00_007d_wlanleitungzulassungvonhumanarzneimittelnmitbekann.pdf.download.pdf/ZL101_00_007d_WL%20Zulassung%20Humanarzneimittel%20mit%20bekanntem%20Wirkstoff.pdf, Ziff. 4
157 Swissmedic, (FN 80), point 4.
158 Swissmedic, "Wegleitung Orphan Drug HMV4" (FN 140), section 7.1.
159 SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 58.

of patients. In "justified" cases, this means that **complete study reports are not required,** although results published elsewhere must be provided.[160]

577 In its guidance, Swissmedic even states that the problem of rarity is also taken into account in the "assessment of **preclinical**" data. Accordingly, the study reports on the pharmacological and toxicological tests (animal tests) according to Art. 4 AMVZ would also be affected.[161]

578 In addition, if the medicinal product has already been authorised by another country with comparable medicinal product control, the applicant may submit to Swissmedic the documentation on quality, toxicology and clinic that formed the basis for authorisation in the third country (Art. 26 para. 2 VAZV).

2.2.3.4 Risk equalisation: Very limited scope of application

579 Accordingly, medicinal products can be marketed under the title of "orphan use" if they have new active substances whose efficacy and safety have not been verified to the same extent in animal trials (preclinical) or human trials (clinical) as would be the case in the ordinary procedure. Where there is no foreign authorisation, risk compensation as a result of years of use in humans is ruled out. Also, if a new active substance is available, risk compensation by comparison with studies on known active substances is not guaranteed to the same extent as is the case with generics. **The relevant risk reduction therefore consists in the fact that "orphan drugs" may be used in a maximum of 0.05% (corresponding to 4320 persons) of the total Swiss population.**[162]

2.2.3.5 Use with vaccines?

580 Whether vaccines could also be recognised as "orphan drugs" is not explicitly regulated. However, two circumstances speak against this: If vaccines are already expressly excluded for safety reasons in the case of known active substances (Art. 14 Para. 1 lit. a HMG; generics), this must also be the case *a fortiori for* vaccines that may be completely new. Moreover, vaccines are intended to immunise against infectious diseases that affect tens of thousands of people, which means that it is precisely not a "rare" disease that is to be combated. A **simplified authorisation of vaccines under the title "orphan use" must therefore be ruled out from the outset.**

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160 Swissmedic, "Wegleitung Orphan Drug HMV4" (FN 140), point 7.2.

161 See Swissmedic, FN 160.

162 "Five out of ten thousand people" corresponding to 0.05%; total population Switzerland currently at approx. 8,637,000.

2.2.3.6 Application in gene therapies

581 At least the factual situation in the field of gene therapeutics is different: Worldwide, the first gene therapies have already been recognised as "orphan drugs". Gene therapy drugs are usually administered for rare hereditary diseases only once at a young age, in the hope that this treatment will be sufficient for the patient's entire life.[163]

2.2.4. Interim conclusion

582 In all the simplified authorisation procedures examined, the animal and human studies (modules 4 and 5) that are mandatory in the ordinary procedure can be dispensed with. This waiver results in an increase in risk, which is counteracted with various compensatory measures depending on the medicinal product. The missing studies are replaced in this way

- through consolidated and seamlessly **transferable scientific knowledge** with a restriction of authorised medicinal products (known active substances; generics) or
- knowledge gained through **more than 10 years of application in humans** ("well-established-use") or
- by **limiting the use to** a small target population ("orphan use").

583 Since none of these criteria is applicable to the mRNA gene therapy to be assessed here, or to SARS-CoV-2, the simplified procedure with the associated facilitations was and is not available for the approval of this new type of "vaccine" against SARS-CoV-2.

2.3. "Temporary authorisation" (Art. 9a HMG; Art. 18 - 22 VAZV)

584 In regulatory terms, the "temporary authorisation" was separated from the ordinary and simplified authorisation by the legislator and ordinance and specifically regulated in Art. 9a

163 KERPEL-FRONIUS, "Development and Use of Gene Therapy Orphan Drugs-Ethical Needs for a Broader Cooperation Between the Pharmaceutical Industry and Society", 23.12.2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7785873/; HUTTON, "Adverum Biotechnologies gets Orphan Drug Designation from FDA for gene therapy candidate", 06.01.2022, https://www.ophthalmologytimes.com/view/adverum-biotechnologies-gets-orphan-drug-designation-from-fda-for-gene-therapy-candidate; PARK, "Gene Therapy Candidate Designated Orphan Drug for Buerger Disease", 20.10.2021, https://www.empr.com/home/news/drugs-in-the-pipeline/gene-therapy-candidate-designated-orphan-drug-for-buerger-disease/.

HMG, concretised and supplemented in Art. 18 - 22 VAZV [164][165] and presented in a guideline from Swissmedic. [166]

585 According to Art. 9a HMG, a "medicinal product for diseases that are **life-threatening or result in disability**" can be **authorised "for a limited period" in a "simplified" procedure** - if this is compatible with the protection of health, a major therapeutic benefit can be expected and no alternatives are available.

586 As can be seen from the legal definition, the *term "*temporary authorisation" chosen by the legislator has no meaning whatsoever to describe the special features of this specially regulated authorisation procedure. Due to the characteristics described below, this specific form of authorisation is rather a special authorisation, *de facto an* actual emergency authorisation.

2.3.1. Narrow scope: pre-existing life-threatening diseases

2.3.1.1 History of origins

587 Art. 9a HMG emerged from the former Art. 9 para. 4 aHMG. This read:

> "The Institute may **grant temporary authorisation** for the distribution or dispensing of unauthorised medicinal products for **life-threatening** diseases if this is compatible with the protection of health, if a major therapeutic benefit can be expected from their use and if no comparable medicinal product is available."

588 According to the 1999 dispatch, this original norm was created in response to a motion "in the interest of patients with life-threatening diseases", "which wanted to allow the use of unregistered medicines in public hospitals under strict medical control".[167] And further: "It should be possible to make **promising new medicines for life-threatening diseases available to** patients **without a marketing authorisation.** Since the submission of a complete application for a marketing authorisation is a time-consuming and costly activity, it should be possible to authorise distribution and dispensing under the above-mentioned

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164 Ordinance of the Swiss Agency for Therapeutic Products on the simplified authorisation of medicinal products and the authorisation of medicinal products in the notification procedure (VAZV; SR 812.212.23).

165 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 9a N 17.

166 See also Swissmedic, "Wegleitung Befristete Zulassung Humanarzneimittel HMV4", Status: 01.01.2022, *https://www.swissmedic.ch/dam/swissmedic/de/dokumente/zulassung/zl_hmv_iv/zl109_00_001d_wl_befristete_zl_ham_hmv4_ab_010121.pdf.download.pdf/ZL109_00_001d_WL_Befristete_Zulassung_Humanarzneimittel_HMV4.pdf* , p. 4 ff.

167 Message HMG 1999, p. 3470.

conditions. [...] These **exceptional authorisations** are intended for the use of a medicinal product **for individual patients,** for a specific group of patients or for patients who cannot take part in ongoing studies".[168]

589 In the dispatch on the new Art. 9a HMG, the extension to invalidating diseases was justified on the grounds that, with regard to the benefit/risk assessment, "it is hardly possible to distinguish between life-threatening diseases and those leading to invalidity".[169] In fact, however, an **adjustment to the legal situation in the EU took** place here.[170] In addition, "for reasons of consistency", the "temporary authorisation" became a "temporary authorisation", which could be granted on the basis of "simplified requirements". This is because **placing on the market "for an indefinite number of patients" is** terminologically not an "authorisation" but a "**marketing** authorisation". [171]

590 The **originally** narrowly envisaged scope of application of the "temporary authorisation" - as an **exception for individual patients without a regular marketing authorisation** - was thus largely emptied of its meaning with the supposedly simple transfer to Art. 9a HMG: **Suddenly there was talk of a broadly effective "authorisation". The** temporary authorisation, on the other hand - which materially corresponds much more to the old Art. 9 para. 4 aHMG - was newly accommodated in Art. 9b HMG.

591 Under the guise of a mere reformulation, a new type of "simplified" or "time-limited authorisation" was created, which came into force as Art. 9a HMG on 1 January 2019. At the same time, it was still stated that "temporary authorisations according to Art. 9a" could only be granted for a "shorter duration" due to their **"exceptional character".**[172]

2.3.1.2 Reason Prerequisite: "Life-threatening, disabling illness".

592 According to Art. 9a HMG, the possibility for a temporary authorisation in a simplified procedure is only open to medicinal products that are to be used against life-threatening or incapacitating diseases, if this is compatible with the protection of health (lit. a), if a major therapeutic benefit is expected from the corresponding medicinal product (lit. b) and if no authorised, alternative and equivalent medicinal product is available in Switzerland (lit. c).[173]

593 The overriding aim of the temporary marketing authorisation is to make a medicinal product available immediately and pragmatically for a **life-threatening, disabling dis-**

168 Message HMG 1999, p. 3496 f. (emphasis added).
169 Message HMG 2012, p. 62.
170 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, before Art. 8-17 N 42b.
171 Message HMG 2012, p. 62 f.
172 Message HMG 2012, p. 70.
173 For all requirements, see in detail below N 584 ff., N 619 ff.

ease for which no therapeutic options are available on the market and which is expected to be of great benefit based on initial provisional data. The doctrine therefore states that Art. 9a HMG would regulate so-called **"compassionate use".**[174] This is defined in the EU as follows:

> "[...] 'compassionate use' means that a [...] medicinal product is made available for humane considerations to a group of patients **suffering from a debilitating chronic or serious illness** or **whose illness is considered life-threatening** and who cannot be satisfactorily treated with an authorised medicinal product".

594 The subject of compassionate use - and thus also of Art. 9a HMG - must therefore be **diseases from which patients are already suffering. The** application of compassionate use to diseases that are possibly just beginning or possibly threatening - i.e. **for prophylaxis in people who are actually healthy - is definitely not provided for in principle.**

595 This finding is in line with the case law of the Federal Supreme Court: According to this case law, the **risk of severe disability or possible death** must apply to all patients included in the target population and must **not** appear to be **a mere possibility.** Rather, it must be **seriously expected to materialise** due to the concrete circumstances.[175]

2.3.1.3 Application of Art. 9a HMG also for vaccines (for prophylaxis)?

596 This narrow scope of application of Art. 9a HMG was obviously in Swissmedic's way. Barely three months after the entry into force of the new Art. 9a HMG (1 January 2019), Swissmedic felt compelled to publish the following on its website in March 2019: [176]

> "**Temporary authorisations also possible for vaccines (i.e. for prophylaxis)?**
>
> Yes
>
> A-154
>
> Last updated 20.03.2019"

597 From the point of view of the manufacturers of the mRNA "vaccines" and the licensing authority, this "clarification" was certainly "necessary" in order to be prepared for the

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174 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Vor Art. 8-17 N 42a, Art. 9a N 4.

175 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 9a N 20; Federal Supreme Court ruling 8BC_523/2106 of 27.10.2016, E. 5.2.1.

176 Swissmedic, "Temporary authorisations also possible for vaccines", 20 March 2019, https://www.swissmedic.ch/swissmedic/de/home/news/specials/hmv4-ambvmedicrime-info/tpa-revision-faq/fragen-infoanlass-1/a-154.html.

"COVID pandemic" that was declared just under a year later. The basis for this clarification, however, is in open contradiction to the legal foundations: **Both from the history of the origin of Art. 9a HMG and from the meaning of "compassionate use", a prophylactic use of mRNA "vaccines" in a healthy population is ruled out from the outset.**

598 The fact that clear norms for the protection of public health according to the principle of legality and the principles of delegation derived from it by the Federal Supreme Court cannot under any circumstances be softened or repealed by the competent administrative authority on its own authority has already been stated above (N 133). Swissmedic can therefore under no circumstances evade the legal requirements imposed on the protection of public health by means of a simple reference on its own website.

2.3.1.4 Application of Art. 9a HMG for gene therapeutics / GMOs?

599 Neither the law nor the ordinance explicitly state whether Art. 9a HMG can also be applied to gene therapy products / GMOs.

600 Analogous to the (non-)regulation of "orphan use", the conclusion would therefore have to be drawn that at least gene therapeutics would have to be authorised. However, in the case of broad application - as is erroneously practised with Art. 9a HMG - precisely the elementary protective element of "orphan use" is missing. In addition, the strict regulatory requirements described above apply to GMOs. Any circumvention of these via Art. 9a HMG would clearly contradict the intentions of the legislator as outlined above.

2.3.1.5 Effective scope of application of Art. 9a HMG: pre-existing diseases

601 This absolutely unusual - and inadmissible - extension of the scope of application of Art. 9a HMG to gene therapeutics / GMOs is also demonstrated by the fact of how Art. 9a HMG (or the predecessor norm of Art. 9 para. 4 aHMG) had been applied in practice before the "Corona pandemic":

602 According to the Basel Commentary, at one time (presumably before December 2020) "only four medicinal products authorised for a limited period" were listed on Swissmedic's website on the publication list pursuant to Art. 22 para. 1 VAZV.[177]

603 In the meantime - as of February 2022 - there are already 20 medicinal products on this list of "*temporarily authorised medicinal products against life-threatening* diseases"[178] , in addition to the COVID "vaccines", which are used as antidotes for snakebites (2 medicinal

177 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 9a N 8.

178 Swissmedic, "Temporarily authorised medicinal products for life-threatening diseases", 02.2022, https://www.swissmedic.ch/swissmedic/de/home/services/listen_neu.html.

products) or for excessive blood thinning (1 medicinal product) or as therapy for severe osteoporosis (1 medicinal product). for excessive blood thinning (1 drug) or as therapy for severe osteoporosis (1 drug), cancer (13 drugs), a severe form of muscular atrophy in young children up to 2 years of age (1 drug) and for the therapy of a COVID disease (2 drugs).

604 It is striking that the **COVID "vaccines"** are **an absolute exception on this list: They** were and are the only medicines approved for a limited period of time that were and are used **preventively** and against the basically **healthy general population.** And this for a disease with a **very high survival rate of approx. 99.85%** (for more details see N 479 ff.). The other medicines, on the other hand, are used to treat individual patients who are already seriously ill and whose chances of survival (cancer, snakebite) have already been massively reduced.

605 An exception for the "prophylactic" use in humans within the framework of a "temporary authorisation" was probably only the swine flu vaccine Pandemrix, whose hasty approval in 2009 had caused immense suffering worldwide due to unforeseen side effects (see above N 239 ff.). Why this serious mistake had to be repeated in 2020 and why this wrong decision is still being adhered to is simply incomprehensible.

2.3.2. Massively divergent regulatory requirements: Forecasts instead of facts

606 Due to the independent standardisation in Art. 9a HMG (as well as Art. 18 - 22 VAZV), the "time-limited authorisation" differs massively in regulatory terms from the previously discussed ordinary and simplified forms of authorisation. Whereas in the case of the simplified marketing authorisations described above, the law and ordinance explicitly define which central elements of the ordinary marketing authorisation can be dispensed with, this is precisely not the case with the time-limited marketing authorisation. Accordingly, it is virtually impossible to show the difference between the ordinary and temporary authorisation procedures directly on the basis of the legal and ordinance norms.

607 Whereas in the **ordinary and simplified procedure clear requirements are set for the documents to be submitted (quality tests, animal studies, clinical studies)**, such information is completely missing in the provisions of the law and ordinances for "temporary authorisation". **As a "substitute" for the hard facts, forecasts are sometimes used for the "temporary authorisation":** A cost-benefit analysis is not carried out conclusively, but in the hope that the criterion of **efficacy in** particular will be proven strictly in the **future. The** legislator and ordinance-makers attempted to take this into account with various test criteria, all of which must be fulfilled *cumulatively* at the time of initial authorisation:

- Pre-existing life-threatening or disabling disease
  (Art. 9a para. 1 **subpara. 1** HMG in conjunction with Art. 18 lit. a VAZV)
- Compatibility with the protection of health
  (9a para. 1 lit. a HMG)
- Great therapeutic benefit **can be expected**
  (Art. 9a para. 1 **lit. b** HMG in conjunction with Art. 18 lit. c VAZV)
- Lack of alternative treatment
  (Art. 9a para. 1 **lit. c** HMG in conjunction with Art. 18 lit. b VAZV)
- Subsequent delivery of complete (study) data **probably** possible
  (Art. 9a HMG in conjunction with Art. 18 **lit. d** VAZV)
- Temporal urgency
  (Art. 9a HMG in conjunction with Art. 18 **lit. e** VAZV)

608 It follows from this: Even if, according to the will of the legislator, some compromises can be made with regard to the criterion of **efficacy,** the other core criteria of Art. 1 HMG - **quality and most fundamental safety** - of a medicinal product to be authorised must **always** be **proven.**

2.3.3. Massively shortened procedure duration; Incomplete data

609 In order to be able to help patients in life-threatening situations quickly, the procedure for **"temporary approval"** takes just **140 calendar days.**[179] In addition, there is an additional massive acceleration due to the fact that the temporary approval can also be granted on the basis of **limited data and corresponding studies that have not yet been conducted**. [180]

610 According to Swissmedic, the following documents, among others, must therefore be submitted:[181]

- complete data in relation to pharmaceutical quality (module 3),
- complete preclinical data (animal studies; module 4),
- available relevant top-line results of ongoing studies as supporting information,

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179 Swissmedic, FN 103.

180 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, before Art. 8-17 N 42a.

181 Swissmedic, "Wegleitung Befristete Zulassung Humanarzneimittel HMV4", Status: 01.01.2022, Ziff. 5.5., *https://www*.swissmedic.ch/dam/swissmedic/de/dokumente/zulassung/zl_hmv_iv/zl109_00_001d_wl_befristete_zl_ham_hmv4_ab_010121.pdf.download.pdf/ZL109_00_001d_WL_Befristete_Zulassung_Humanarzneimittel_HMV4.pdf.; Swissmedic, Info-Veranstaltung zur Revision des Heilmittelgesetzes "Befristete Zulassung", 25.10.2018, *https://www.swissmedic.ch/dam/swissmedic/de/dokumente/stab/veranstaltung/hmg/befristetezulassung.pdf.download.pdf/09_Befristete%20Zulassung_J%C3%B6rg%20Schl%C3%A4pfer.pdf.*

- Draft risk management plan (RMP).

611 "Top-line results" represent the results of the phase II trials. Since these do not have to be available in full (but only "available relevant" results), two conclusions must be drawn from this: On the one hand, **definitive study results for clinical phases II and III are not available in the case of a "time-limited authorisation" - in deviation from the regular authorisation procedure.** On the other hand, however, according to this, at least the results of the completed clinical phase I trial (dose finding) must be submitted as the absolute minimum standard (most basic safety).

612 The **clinical documentation** (Module 5) on the efficacy and safety of the COVID "vaccines" is accordingly **largely incomplete.** A "temporary authorisation" can therefore be granted by **omitting the most elementary safety precautions** - namely the broad testing of a medicinal product on healthy and sick people, usually over several years (phase II/III studies).

613 **Compensation for this massive increase in risk** therefore consists in principle only in the fact that **"temporary authorisation" is only permissible for diseases that are life-threatening for the entire target population or result in disability** (Art. 9a para. 1 HMG). Unlike in the cases of simplified authorisation, in which corresponding study protocols or literature can be provided due to known active substances and years of use in humans, such empirical values are lacking for medicinal products authorised for the first time under the title of Art. 9a TPA. A risk reduction as in the case of "orphan use" - i.e. a very limited application in a few people - is also ruled out.

614 As a **further risk compensation,** the restriction that gives the authorisation its name also comes into play, according to which the "time-limited" authorisation can only be granted for a **maximum of two years** with special conditions. During this period, results of the ongoing approval study must be submitted on an ongoing basis in a "rolling procedure" so that the "time-limited" approval can be converted into a regular approval based on **complete clinical documentation after two years at the latest** (Art. 21 VAZV)[182] - or else it must be suspended immediately. However, this **time limit does not effectively reduce the risk** - the experimental substances are already being used on humans without restriction during this period.

615 Effective compensation for the increased risks associated with the time-limited authorisation in order to protect public health can therefore only be achieved in two areas: (i.) Particularly **careful information of the patient about all risks** and about all aspects of the benefit/risk ratio; (ii.) **Particularly careful and effective pharmacovigilance,** which al-

182 Swissmedic, "Wegleitung Befristete Zulassung Humanarzneimittel HMV4", FN 181.

lows any undesirable side effects to be identified immediately so that the time-limited authorisation can be revoked immediately in the event of a negative benefit/risk ratio.

2.3.4. Careful weighing of interests and only restrained application

616 The limited data situation is accompanied by possible health risks, which must be weighed against the potential health benefits of using the preparation in question.[183] The balancing of interests to be undertaken thus touches on the right to life and the rights of self-determination of the individual patient (Art. 10 para. 2 BV) on the one hand, and on the public interest in protection against potentially unsafe or ineffective medicinal products (Art. 118 para. 1 BV; Art. 1 HMG) and the associated right to physical integrity of the individual (Art. 10 para. 2 BV) on the other. [184]

617 If a regular authorisation procedure is waived in favour of a temporary authorisation, the patient is exposed to a risk due to the incomplete documentation on efficacy and safety, as it may become apparent in the course of treatment that the medicinal product is not effective after all or is associated with serious side effects. **Consequently, a temporary authorisation can only be justified if the expected benefit and the potential harm resulting from withholding the therapy are very great.** In such a case, due diligence requirements must be weighted very highly and potential risks must be carefully and comprehensively monitored in parallel - both in the phase III trial, which has not yet been completed, and among users in the real world - so that safety signals can be detected immediately and measures can be taken against them if necessary.

618 Not least because of these imponderables, the possibility of **"compassionate use"** (or Art. 9a HMG) should **only be used with restraint** according to Federal Supreme Court case law, as otherwise the purpose of the general authorisation requirement could be undermined.[185]

3. "Temporary approval" for mRNA "vaccines".

3.1. Massive deviations from the planned approval procedure

619 As explained above, Art. 9a HMG deviates considerably from the requirements of the ordinary authorisation procedure. The application of the standards of the "temporary authorisation" is already accompanied by a considerable increase in risk.

183 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 9a N 2.
184 Similarly SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 9a N 3.
185 Judgement 2A.469/2003 of 06.09.2004, E. 3.3.

620 In the present case, the situation was aggravated by the fact that Swissmedic had not even complied with the requirements of Art. 9a HMG (and the corresponding implementing provisions), but had once again fallen significantly short of them:

3.1.1. Massively reduced processing time

621 Pfizer had submitted the application for the "temporary authorisation" on 16 October 2020, whereupon Swissmedic had already granted the temporary authorisation by letter dated 19 December 2020. **According to the letter, Swissmedic "reviewed" the application in a processing time of just 45 working days (corresponding to 63 calendar days).**

622 The same applies to Moderna: the application for the "temporary authorisation" was submitted on 9 November 2020. Swissmedic granted the temporary authorisation by letter dated 12 January 2021. This **also** results in a **processing time of exactly 45 working days.**

623 Both represent a massive undercutting of their own specifications (processing in 140 calendar days), and it is obvious that this has once again massively increased the risk in a completely unnecessary way.

3.1.2. Omission of answers to elementary questions ("List of Questions")

624 In addition, it is clear from Swissmedic's letter of authorisation to Pfizer that the answers to the "List of questions" ("LoQ") regarding preclinical, quality and clinical aspects were not yet available from Pfizer at the time of authorisation. This is also a clear violation of the authorisation procedure that Swissmedic has imposed on itself: the answer to the "LoQ" is listed as a prerequisite for the preliminary decision and, accordingly, for the subsequent "temporary authorisation".

625 According to the guideline "*Deadlines for marketing authorisation applications HMV4*" of 28 February 2022, not all types of application have to go through all stages of the procedure and milestones. If **no questions** arise from the assessment, then the "LoQ" milestone may be skipped according to Swissmedic. In the present case, however, it is clear from Swissmedic's letter of authorisation to Pfizer that **there were serious ambiguities** and **thus unanswered questions with** regard to quality, pre-clinic and clinic **. The** granting of the temporary authorisation without waiting for the answers to the open questions ("LoQ") is clearly contrary to the requirements that Swissmedic has imposed on itself.

3.1.3. Abandonment of elementary studies on quality and safety

626 As previously stated, for a "temporary authorisation", the documents for module 3 (**quality**), module 4 (**safety**; preclinical/animal studies) and from module 5 at least one phase I study are mandatory.

627 At the time of the first approval of the mRNA "vaccines", not even these minimal requirements were met. Thus, it follows from the foregoing that

- purity (module 3) was obviously not guaranteed in view of various impurities (N 165 ff.) and
- no or insufficient animal studies (module 4) - namely on pharmacokinetics and toxicology - had been carried out (see above N 179 ff.).

628 After all, two-month data from telescoped phase I/II/III studies were submitted. However, these data and the corresponding evaluations - as previously shown in detail (see for example N 271 ff. and N 202 ff.) - had either been falsified or prepared in a scientifically untenable manner. Accordingly, the requirements for Phase I were formally fulfilled - but materially the studies all failed.

629 The necessary draft of a risk management plan (RMP) was also formally submitted - but the risks already recognisable there (e.g. in pregnant women) were in no way adequately addressed on the part of Swissmedic (cf. on this already above N 172 ff., N 334 ff.); cf. also below N 704 ff.).

3.2. Comparison of the methods and interim conclusion

630 As explained above, a direct comparison of the temporary authorisation on the one hand and the regular/simplified authorisation on the other is relatively difficult due to the legislative requirements. However, such a comparison can be made on the basis of the key points identified above (such as necessary studies, procedure, etc.). It becomes obvious that the "temporary" authorisation of mRNA "vaccines" fails in practically all areas examined:

Necessary studies for **admission application**	Ord.	**Temporary**		Simplified		
		mRNA	9a	Bek.	EU	Orph.
Module 3 *(Quality)*						
Stability	YES	(?)	YES	YES	YES	YES
Purity	YES	NO	YES	YES	YES	YES
Module 4 *(Preclinic)*						
Pharmacology	YES	NO	YES	NO*	NO*	NO*
Toxicology	YES	NO	YES	NO*	NO*	NO*
Module 5: (Clinic)						

Phase I (usually 2-4 months)	YES	YES	YES	NO*	NO*	NO*
Phase II (usually 1 year)	YES	NO	YES	NO*	NO*	NO*
Phase III (min. 1 year)	YES	NO	NO	NO*	NO*	NO*
Admission modalities						
Process flow						
Duration in calendar days	330	63	140	--	--	210
Answer "LoQ	YES	NO	YES	--	--	--
Medicines **excluded for**:						
Vaccines	NO	NO	(NO.)	YES	NO	(YES)
Gene therapy and GMOs	NO	NO	(YES)	YES	NO	NO
Population-wide application	NO	NO	YES*	NO	NO	YES
Mandatory "conditions						
"Risk Management Plan" & PSUR	YES	YES	YES	NO	NO	NO
NO*: Under replacement of studies by literature, alternative studies, previous approvals						
YES*: only in the case of life-threatening or disabling disease in the target population.						

631 The various temporary authorisations repeatedly granted for mRNA "vaccines" thus deviate from the regular authorisation in all essential safety aspects. Indeed, they do not even fulfil the reduced requirements of a simplified authorisation and even fall short of the minimum requirements for a "temporary authorisation" according to Art. 9a HMG. As explained in detail above,

- there are at least indications of irregularities with regard to stability (see above N 288 ff.),
- the purity was obviously not given in view of the impurities (front N 165 ff.),
- no sufficient preclinical studies are available (front N 179 ff.),
- the clinical trials were only conducted in a completely blinded fashion for just over two months and were subsequently sabotaged by unblinding (front N 189 ff., N 192 ff.),
- the procedure for "temporary" authorisation was carried out in a rush and in undercutting its own specifications (N 619 ff.),
- in an already risky procedure, additional risky substances (vaccines, gene therapy, possibly even GMOs) were approved for use on a healthy population (see above N 142 ff., N 148 ff.), and
- In the past, reports from manufacturers (e.g. by means of PSUR) were ignored by Swissmedic and withheld from the public (see above N 279 ff.; cf. also N 734 ff.).

632 The mRNA "vaccines" fulfil - in the absence of data available elsewhere - at best only the requirements for stability (but see above N 288 ff.). Otherwise, the manufacturers were unable to provide any studies in their applications for marketing authorisation that would satisfy the requirements for elementary modules 3 and 4 (as well as 5). With this **blatant omission of the most elementary data on safety and efficacy, the greatest possible**

of all risks was taken. To make matters worse, the planned duration of the procedure was once again massively undercut and important intermediate steps were simply omitted, contrary to the authors' own specifications. The risk is further increased by the fact that the mRNA "vaccines" are used for mere prophylaxis in a basically healthy population and that there is also the suspicion that they represent genetically modified organisms.

3.3. Examination of the legal requirements for "temporary admission

633 Now, as previously explained, "temporary authorisation" is not primarily defined on the basis of the specifications of ordinary/simplified authorisation, but follows its own rules to a certain extent by working with **forecasts.**

634 For this reason, the mRNA approvals will be examined below on the basis of the formal requirements of the legislator and the ordinance. All of the following criteria must be fulfilled **cumulatively** for a legally compliant "temporary authorisation". Effectively, however, none of these criteria was and is ever fulfilled:

3.3.1. Life-threatening or disabling illness?

635 According to Art. 9a para. 1 **subpara. 1** HMG i.V.m. Art. 18 lit. a VAZV, the medicinal product must be used for life-threatening or disabling diseases. As previously (N 592 ff.), this **risk** must be **seriously expected to materialise in the entire target population**. According to the traditional view, it must therefore be a matter of **pre-existing diseases that pose an** immediate life-threatening or disabling risk for the entire population - authorisation for mere prophylaxis is therefore ruled out from the outset.

636 SARS-CoV-2 never posed a greater risk to the general population - which is the target population of COVID "vaccinations" - than seasonal moderate influenza (foregoing N 479 ff.). Already with the delta variant, SARS-CoV-2 corresponded to a mild flu (front N 484), with the "Omikron" variant the **lethality of SARS-CoV-2** was **even 50-fold lower than that of seasonal flu (fron** N 487 f.). For children and adolescents, there was no danger at any time: with a lethality of 0.0027%, their "COVID-19 risk" tended towards zero from the beginning. **COVID-19 was thus never a disease from the outset that would lead to severe disability, severe suffering with possible fatal consequences or death in the short term in a relevant part of the target population. The** first criterion for the temporary approval of the COVID "vaccines" was thus never fulfilled. **Accordingly, the trial could already be terminated at this point: The "temporary" approval was simply unlawful due to the lack of a fatal or disabling disease.**

637 However, even if COVID-19 were similarly lethal or slightly more lethal than severe influenza, a lethality of e.g. 0.15-0.2% would never - really never - be sufficient to assume a life-threatening (or disabling) disease for the entire population. Assuming such a danger with such a low lethality would have the consequence that a "temporary authorisation" could always be applied for all conceivable infectious diseases. **The purpose of the regular authorisation requirement would be permanently undermined.** However, this is precisely what must not happen under any circumstances according to the case law of the Federal Supreme Court. In addition, there is the circumstance that, according to the traditional view, a temporary authorisation was **never** intended for **prophylaxis,** but only in the case of diseases from which the individual patient was already suffering and therefore threatened with death (or severe invalidity). This basic requirement of compassionate use was abandoned by Swissmedic in 2019 without any comprehensible reasons - although such a requirement can be derived neither from the legislative process nor from European regulation. **The "temporary" authorisation of mRNA "vaccines" under the impression of a non-threatening disease that has been tested proves to be a Trojan horse for undermining and eroding the most central safety mechanisms of medicinal product law.** This undermining is already evident in the fact that the **number of medicines authorised for a "limited period"** has **risen exponentially from 4 to over 30 (!) since the "pandemic" was declared.** This development is absolutely devastating for patient safety and must be stopped immediately.

3.3.2. Compatibility with health protection?

638 According to Art. 9a para. 1 **lit. a** HMG, the use of the medicinal product must be compatible with the protection of health. This means that the medicinal product must meet the **most basic safety standards** - which is normally checked in detail on the basis of animal and human trials (see above N 507 ff.). As previously (N 179 ff.), such trials were waived to an alarming extent prior to the "temporary" marketing authorisations. In addition, there is a multitude of other **risks** which made the **incompatibility of the mRNA "vaccines" with human health clear from** the outset:

3.3.2.1 Identifiable risks at the time of initial registration en end of 2020

639 At the time of the first registrations at the **end of 2020,** a large number of risks were already openly identifiable. These had already been identified previously (N 141 ff.) and are discussed in detail below (N 840 ff.) in the context of the alleged breaches of due diligence. In order to avoid repetition, reference is made to the corresponding statements and only key points are referred to below:

640 By the end of 2020, gene therapy was already a new mode of action that had never been tested on a healthy population. In addition, the mRNA "vaccines" contained toxic lipid nanoparticles and toxic, potentially mutagenic and carcinogenic impurities were already detected at that time. The mere presence of these alarm signals (there were many more) should have led to the authorisation documents being evaluated particularly carefully with regard to these identifiable risks and linked to conditions. But this is exactly what did not happen: Instead, the first approvals were rushed through (see N 621 ff.), omitting important milestones (N 624 f.) and the internally identified risks were not communicated to the public or were communicated in an absolutely trivialising manner (see in particular N 701 ff.).

3.3.2.2 Additional identifiable risks mid-2021

641 Unfortunately, things continued in the same vein even after the first "temporary" approvals. By mid-2021, various risks had already materialised and new ones were even added: these had already been identified previously (N 220 ff.) and are described in detail below (N 847 ff.) in the context of the alleged breaches of due diligence. In order to avoid repetition, reference is made to the corresponding statements.

642 At this point, it should only be emphasised that by June 2021, a total of 524,438 side effects had already been reported in Switzerland, the EU and the USA for Comirnaty and Spikevax alone - of which 141,034 were serious side effects and 7,855 deaths. The **alert value of** 50 deaths had thus already been **exceeded** worldwide by a factor of **more than 150 at** that time **- which should have led to an immediate suspension of marketing authorisation.**

3.3.2.3 Additional identifiable risks at the end of 2021

643 Although the reported side effects had already exceeded every known level by June 2021 and thousands of people had already died as a result of the mRNA "vaccines" or were suffering from severe side effects, there was no "stopping of the exercise". Rather, procedures continued in the same style. By the end of 2021, various risks had once again become evident and **alarm signals** - such as **reports of falsified studies and massive under-reporting of side-effects - were sent to** those **responsible at Swissmedic**. These had already been mentioned previously (N 264 ff.) and are discussed in detail below (N 852 ff.) in the context of the alleged breaches of the duty of care. In order to avoid repetitions, reference is made to the corresponding statements.

644 By the end of 2021, the correlation between mRNA "vaccinations" and severe side effects, including death, was so obvious that **causality** could be assumed: **mRNA "vaccines" almost certainly lead to severe side effects, including death.** And this was not in individual cases, but in such an **overwhelming number of cases as had never occurred since systematic records of side effects began.**

3.3.2.4 Additional identifiable risks from 2022

645 How, against this background, the vaccination campaign could have been continued at all is in no way comprehensible. Even when "Omikron" was used to "fight" a pathogen that is 50 times less deadly than a normal flu, the demonstrably toxic, disabling and deadly mRNA preparations were not taken off the market. Rather, the huge mountain of risks piled up even more. These have already been reported before (N 378 ff.) and are discussed in detail below (N 854 ff.) in the context of the alleged breaches of due diligence. In order to avoid repetitions, reference is made to the corresponding statements.

3.3.2.5 Conclusion

646 In view of the novel therapy, the potential health risks were already very high at the time of authorisation. A temporary authorisation should therefore never have been granted from the outset, also for this reason.

647 However, at the latest when the risks had manifested themselves openly in June 2021 and then in an overwhelming manner at the end of 2021 in the form of the most serious side effects, including death, on a worrying and unprecedented scale, any initial, extended and maintained authorisation was in no way compatible with the protection of public health.

3.3.3. Great therapeutic benefit?

648 According to Art. 9a para. 1 **lit. b** HMG in conjunction with Art. 18 lit. c VAZV. Art. 18 lit. c VAZV, a major therapeutic benefit must be expected from the use of the medicinal product authorised for a limited period. So far, a clear definition of this term has been provided neither in the text of the ordinance, nor in Swissmedic's explanations, nor in case law.

649 The concept of major therapeutic benefit is linked to that of **efficacy** within the meaning of Art. 10 para. 1 lit. a HMG. A medicinal product is effective if it produces the intended therapeutic, diagnostic or preventive effect in relation to the indication. The proof of efficacy must be provided according to scientific methods. The applicant must therefore demonstrate in a clinically and scientifically convincing manner that the medicinal product has the

desired effect in the target population. The assessment of clinical relevance is based on the respective clinical picture and the associated clinical and scientific practice.[186]

3.3.3.1 Basic requirement: vaccines must immunise

650 According to Art. 2 lit. b AMBV, vaccines are "medicinal products used to produce active or passive immunity". Accordingly, the WHO definition is that vaccines use the body's natural defences "to build up resistance to certain infections and to strengthen the immune system".[187] Even this central basic function - immunity against an infection - is obviously not fulfilled by the COVID "vaccines": neither do they immunise, nor do they protect against disease, nor do they protect against a severe course of disease or even death (on this in detail, see N 354 ff., N 433 ff.).

651 Even if an increase in antibodies ("*surrogate markers*") has been shown in studies and this can be interpreted purely formally as "immunisation", to date neither in registration studies nor in other prospective studies based on hard clinical endpoints (e.g. reduction of COVID diseases or COVID hospitalisations; cf. on this above N 442 ff.) that an increase in antibodies correlates with a resulting protection of vaccinated persons and that the COVID "vaccinations" are associated with a benefit in this respect.

3.3.3.2 Therapeutic benefit unclear from the outset

652 However, the lack of therapeutic benefit did not only manifest itself in the course of the use of COVID "vaccinations", but was already sufficiently recognisable at the time of the first limited approval, as has been shown in detail: The study endpoint (= primary efficacy endpoint) selected in the approval studies by Pfizer and Moderna was **clinically irrelevant from** the outset, as they mainly **recorded** mild "confirmed COVID diseases" and thus **trivial events that** burden neither the individual nor the health care system. In addition, the events assigned to the study endpoints did not occur with sufficient frequency: "confirmed COVID diseases" occurred in only about 1%, "severe COVID diseases" in just ≤0.2% of the study participants.

653 The mRNA "vaccines" were thus not suitable from the outset for protection against fatal or disabling diseases. And even against these minor events, the mRNA "vaccines" provided

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186 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 9a N 28.

187 WHO, "Vaccines and immunization: What is vaccination?", 30.08.2021, *https://www.who.int/news-room/questions-and-answers/item/vaccines-and-immunization-what-is-vaccination* : "Vaccination is a simple, safe, and effective way of protecting people against harmful diseases, before they come into contact with them. It uses your body's natural defenses to build resistance to specific infections and makes your immune system stronger."

minimal protection at best - when it came to protection against "severe COVID diseases", they failed completely (front N 201 ff.).

654 Subsequent studies have also never been able to demonstrate a benefit that would have even come close to deserving the predicate "major". In particular, the approval studies of the "COVID vaccines" had not shown any relevant efficacy either for a booster vaccination, a 3rd dose in immunosuppressed persons, or in children from 5 years of age at the time of the approvals (N 362 ff. , N 370 ff.). In 2022, there was increasing evidence worldwide that vaccinated people were more likely to contract and die from COVID than unvaccinated people - which would even mean that the efficacy would be negative (front N 442 ff.).

3.3.3.3 Conclusion

655 No *major* clinical benefit was to be expected from the COVID "vaccines" at any time, which means that this condition of the temporary approval is also not fulfilled.

3.3.4. Lack of alternative treatment?

656 According to Art. 9a para. 1 **lit. c** HMG in conjunction with Art. 18 lit. b VAZV. Art. 18 lit. b VAZV, no authorised, alternative and equivalent medicinal product may be available in Switzerland.

3.3.4.1 Cost-benefit ratio

657 Where another treatment approach already exists, the lack of a treatment alternative is generally to be affirmed where the new therapy in question has a significantly better cost-benefit ratio.[188] With regard to the reimbursement of medicinal products in individual cases (Art. 71 a ff KVV [SR 832.102]), the Federal Supreme Court held, for example, that a high therapeutic benefit presupposes a favourable therapeutic benefit-cost ratio, in the sense that "the higher the costs, the greater the therapeutic benefit must be expected".[189] It went on to say:[190]

> "Only by comparing different cost-benefit ratios can it be decided whether a particular cost-benefit ratio is favourable or unfavourable. If there are no significant differences between two alternative treatment methods from a medical point of view, the more cost-effective and thus more economical

188 Cf. SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 9a N 25.
189 BGE 143 V 130 E. 11.2 S. 136.
190 BGE 142 V 26 E. 5.2.1 P. 35.

> application is to be chosen. However, if a certain treatment method has advantages over other applications from a diagnostic or therapeutic point of view (including lower risks, fewer complications, more favourable prognosis regarding side effects and late effects), this may justify the assumption of the costs of this more expensive application or this must be taken into account when comparing the prices of medicinal products."

658 Unlike in health insurance law, however, a therapy alternative cannot be disregarded because it is more inconvenient or more expensive and therefore does not have a favourable cost-benefit risk. There is no room for cost-related considerations in the context of the authorisation procedures under therapeutic products law.[191] In the present case, "costs" are therefore not to be understood "monetarily", but in the sense of side effects and other risks associated with the use of the medicinal product. **The expected benefit of a vaccine would therefore have to outweigh the benefit of other treatment methods.**

659 Accordingly, Swissmedic also states in its guidance "Temporary authorisation for human medicinal products HMV4"[192] that, on the basis of the clinical documentation submitted, "it must be possible to assess, without evaluating the detailed data, that the therapeutic benefit clinically relevant exceeds the benefit of the previously authorised therapy/standard therapy (basis for comparison)". The basis for comparison was, among other things, "all therapies with authorised medicinal products available in Switzerland at the time of submission of the application [...]".

3.3.4.2 Costs/benefits of COVID "vaccines

660 If - as in the present case - the use of COVID "vaccines" is associated with side effects of unprecedented magnitude, and thus with a **very high risk** (see above N 638 ff.), the COVID "vaccines" would have to have an enormous advantage over other methods in order to compensate for these immense "costs".

661 This is obviously not the case: not only do the COVID "vaccines" not even begin to contribute to sustainable immunisation, they also do not protect against infection, transmission and disease. They are largely **ineffective in** "combating" SARS-CoV-2 and thus useless (see N 648 ff. with further references). In contrast, several alternative drugs and treatment protocols with high efficacy exist, one of which is discussed below as an example:

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191 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 9a N 26.

192 Swissmedic, "Wegleitung Befristete Zulassung Humanarzneimittel HMV4", (FN 181), S. 5.

3.3.4.3 Ivermectin as a low-cost, safe and effective alternative

662 For the treatment of SARS-CoV-2, early drug treatment protocols such as that of the *FLCCC*, in which ivermectin is used among other things, have already existed since around mid-2020, or at the latest since the start of the vaccination campaign. [193]The strong antiviral activity of ivermectin against SARS-CoV-2 *in vitro* was already demonstrated in June 2020.[194] Since then, the **efficacy of ivermectin against COVID-19 has been demonstrated in 67 studies,** 31 of which were prospective randomised trials (RCT= gold standard of studies). A meta-analysis including data from 3406 patients from 24 RCTs concluded that ivermectin reduces the risk of death and reduces severe courses when used early.[195]

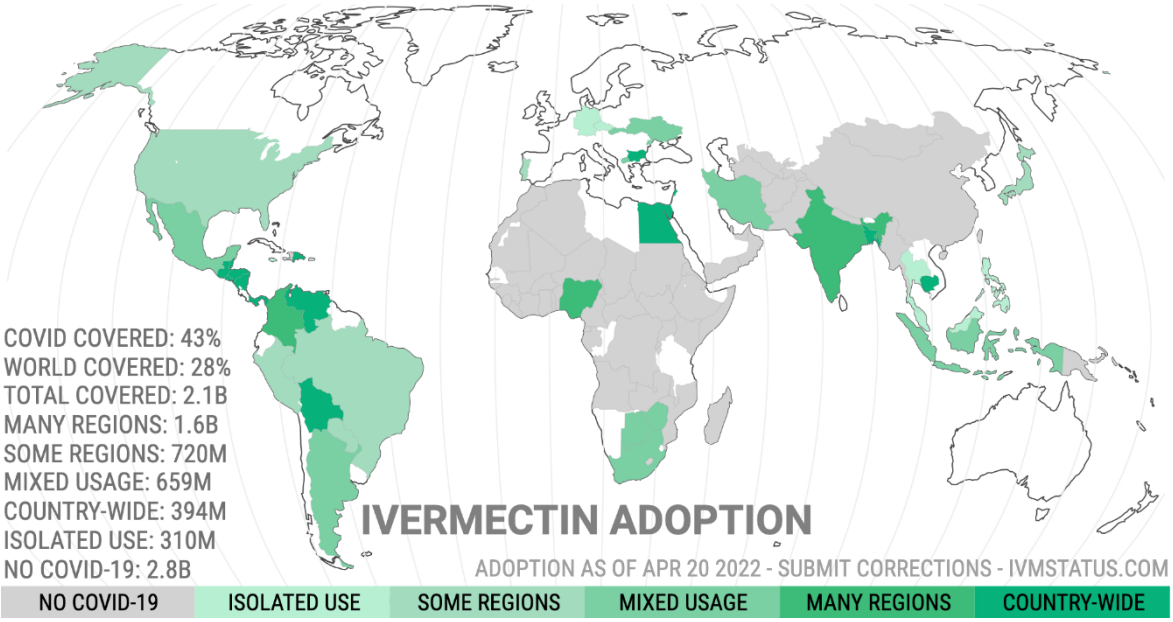
663 Currently, **ivermectin is used successfully in more than 20 countries for the treatment of COVID-19:** In Europe, for example, it is approved in Portugal, Germany, the Czech Republic, Slovakia, Ukraine and Macedonia on a restricted basis ("isolated use"; "some regions"). **In Bulgaria - an EU member state - ivermectin has already been used country-wide for the treatment of SARS-CoV-2 since 15 January 2021.**[196]

193 See for example: Front Line COVID-19 Critical Care Alliance, "Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19", 16.01.2021, https://covid19criticalcare.com/wp-content/uploads/2020/11/FLCCC-Ivermectin-in-the-prophylaxis-and-treatment-of-COVID-19.pdf; Front Line COVID-19 Critical Care Alliance, "Prevention and Treatment Protocols for COVID-19", 10.06.2022, https://covid19criticalcare.com/covid-19-protocols/; WHO, "WHO advises that ivermectin only be used to treat COVID-19 within clinical trials", 31.03.2021, https://www.who.int/news-room/feature-stories/detail/who-advises-that-ivermectin-only-be-used-to-treat-covid-19-within-clinical-trials.

194 CALY et al, "The FDA-approved drug ivermectin inhibits the replication of SARS-CoV-2 in vitro", 03.04.2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7129059/.

195 BRYANT/LAWRIE et al, "Ivermectin for Prevention and Treatment of COVID-19 Infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines", 21 Jun 2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8248252/; HOFT, "There Are Now 365 Studies that Prove the Efficacy of Ivermectin and HCQ in Treating COVID-19 - Will Anyone Confront Fauci and The Medical Elites on Their Deception?", 25 Nov 2021, https://www.thegatewaypundit.com/2021/11/now-365-studies-prove-efficacy-ivermectin-hcq-treating-covid-19-will-anyone-confront-fauci-medical-elites-deception/.

196 Ivmstatus, "Global ivermectin adoption for COVID-19", 10.06.2022, https://ivmstatus.com.



664 Nevertheless, Merck, the manufacturer of ivermectin, claims that the efficacy of ivermectin has allegedly not been proven.[197] Meanwhile, evidence has emerged that the study on which these claims are primarily based was manipulated.[198]

665 Merck's denial of efficacy can only be explained by the fact that it has submitted marketing authorisation applications in various countries, including Switzerland, for molnupiravir, which is expected to be very expensive and is to be used to treat COVID-19. While the production costs for a therapeutic dose of molnupiravir are USD 17.80, it is expected to cost USD 712.00 for the patient in the USA. Merck is thus demanding a 40-fold price premium.[199] Preclinical studies indicate that Molnupiravir can even damage the genetic material.[200] How, with this data, an approval of Molnupiravir can be seriously considered, while the same is denied to the safe drug Ivermectin, which has been tried and tested for decades, is in no way comprehensible.

666 In complete contrast to the COVID "vaccinations", there is therefore strong evidence for the high efficacy and safety, even harmlessness, of ivermectin - and this at the latest from the approval of ivermectin in the EU country Bulgaria in January 2021. **Accordingly, the**

197 Merck, "Merck Statement on Ivermectin use During the COVID-19 Pandemic", 04.02.2021, https://www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/.

198 WORLD COUNCIL FOR HEALTH, "Scientific Misconduct Uncovered in the TOGETHER Ivermectin Trial", 12.6.2022, https://worldcouncilforhealth.org/news/2022/06/together-trial/75890/.

199 SCHEPIS, "Serious deficiencies in the registration trial of the Corona vaccine. Where are the consequences?", 04.11.2021, https://www.nebelspalter.ch/gravierende-maengel-bei-zulassungsstudie-des-corona-impfstoffes-wo-bleiben-die-konsequenzen.

200 ZHOU et al, "β-D-N4-hydroxycytidine Inhibits SARS-CoV-2 Through Lethal Mutagenesis But Is Also Mutagenic To Mammalian Cells", 07.05.2021, https://academic.oup.com/jid/article/224/3/415/6272009.

approval in Switzerland should have been suggested by Swissmedic in accordance with the duty to minimise risk, applied for by Merck and quickly approved by Swissmedic within the framework of the simplified approval procedure (Art. 14 HMG). Instead, Swissmedic claims in an almost grotesque manner that there is "no scientific evidence" of the efficacy of ivermectin - only to then publicly warn against the use of the drug, which is defamed as a mere "dewormer", on the basis of this allegedly non-existent evidence.[201] If Swissmedic warns against allegedly ineffective medicines, it should have issued such a warning about the obviously ineffective and, moreover, lethal COVID "vaccines" long ago.

3.3.4.4 More alternatives

667 Based on international recommendations, **remdesivir, dexamethasone (**a cortisone) and **heparin for** blood thinning were also used in Swiss hospitals **as early as 2020 for the treatment of COVID patients** with severe courses.[202] Remdesivir (Veklury) was given a temporary marketing authorisation on 25 November 2020 for the treatment of COVID patients.[203] Treatment recommendations have expanded over time to include toculizumab, monoclonal antibodies and 'convalescent plasma therapy', depending on the clinic present in each case.[204]

668 Olumiant was approved in August 2021, Ronapreve in December 2021 and Xevudy (temporary) and Regkirona (temporary) in January 2022 for the treatment of COVID-19.[205] With the active substances molnupiravir, toculizumab, favipiravir, nirmatrelvir/ritonavir (paxlovid) and tixagevimab/cilgavimab, five further potential medicinal products for the treatment of COVID-19 were in the assessment procedure at Swissmedic as of May 2022.[206]

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201 Swissmedic, "Swissmedic warns: Do not buy medicines to treat or prevent COVID-19 infection on the internet", 02.11.2021, https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/marktueberwachung/arzneimittel-aus-dem-internet/drug-safety-current-threats/vorbeugung-covid-19.html.

202 USZ, "Revised Therapy Recommendations for Nephrological Patients with Detected SARS-CoV-2 Infection, with Special Consideration of Immunosuppression Adjustment", 12.2020, https://www.usz.ch/app/uploads/2021/03/Therapieempfehlungen-COVID-22.12.20.pdf.

203 Swissmedic, "Stand Zulassungen zur Bekämpfung von COVID-19", as of 10.06.2022, https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/stand-zl-bekaempfung-covid-19.html.

204 USZ, "Coronavirus SARS-CoV-2 and COVID-19: Treatment", 10.06.2022, https://www.usz.ch/fachbereich/infektiologie/angebot/coronavirus-sars-cov-2-und-covid-19-behandlung/.

205 Swissmedic, FN 203.

206 Swissmedic, FN 203.

669 If the current and future therapeutics have a better cost-benefit ratio compared to the COVID "vaccines", there is no longer any basis for a temporary approval of the COVID "vaccines" for "prophylactic" administration to a largely harmless target population.

3.3.4.5 Federal Council undermines requirement of lack of alternative treatment

670 A highly questionable development also emerged towards the end of 2021: With the ordinance of 27 October 2021, the Federal Council inserted a rule that came into force on 28 October 2021, which simply undermines the - legal (!) - requirement of no alternative treatment (Art. 21 para. 5 COVID-19 Ordinance 3):

> "By way of derogation from Article 9a paragraph 1 letter c of the Therapeutic Products Act of 15 December 2000, temporary marketing authorisations may be granted even if an authorised, alternative and equivalent medicinal product is available in Switzerland, provided that the marketing authorisations serve to ensure the supply of medicinal products for the prevention and control of coronavirus in Switzerland."

671 For its highly questionable approach, the Federal Council is probably invoking Art. 3 para. 2 lit. c COVID-19 Act (SR 818.102), with which Parliament authorised it to provide for exemptions from the authorisation requirement for medicinal products or to adapt the authorisation requirements or the authorisation procedure. **However, the fact that the Federal Council is undermining the requirement for alternative treatment methods speaks volumes: Obviously, such alternatives exist and would have been approved long ago instead of the experimental, dangerous and useless mRNA "vaccinations".**

3.3.4.6 Conclusion

672 There would thus have been very good reasons to at least consider the approval of ivermectin as well as other promising (drug) early treatment protocols for SARS-CoV-2, instead of relying completely unilaterally on the experimental and dangerous COVID "vaccination" as the only "game-changer".

673 The requirement of a lack of treatment alternatives was already not fulfilled in December 2020. In view of the lack of efficacy and safety of the COVID "vaccines" and the alternative therapies that are becoming increasingly available as the disease progresses, the priority adherence to the mRNA "vaccines" also violates this condition of "temporary" approval.

3.3.5. Subsequent delivery of complete data?

674 Furthermore, according to Art. 9a HMG in conjunction with Art. 18 lit. Art. 18 **lit. d** VAZV, the applicant must presumably be in a position to subsequently provide the required data in terms of the 2nd or 3rd section of the AMZV. This means that the studies required for a regular authorisation must be submitted within two years at the latest (cf. Art. 21 para. 1 VAZV) after the temporary authorisation.[207]

675 As previously shown in detail, the manufacturers have unblinded (sabotaged) their own approval studies. Without a comparator arm (placebo group), the starting position for the temporary marketing authorisation granted has fundamentally changed and the conditions for converting the temporary marketing authorisations into a full marketing authorisation are no longer met. The marketing authorisation holders will not be able to present data comparing efficacy and safety over a period longer than a few months between vaccine and placebo. In addition, there were protocol deviations, falsification of data and other irregularities. All this was already known to the regulatory authorities at the beginning of 2021 and it was openly apparent that the manufacturers would not be able to provide the necessary studies.

676 In addition, the manufacturers keep postponing the end of the phase III trials - currently until 2024 - but they should be in a position to deliver the final data after two years, i.e. by the end of 2022. They will obviously miss this target as well. This mandatory requirement of the "time-limited" approval is thus obviously not fulfilled either.

3.3.6. Temporal urgency?

677 Finally, according to Art. 9a HMG in conjunction with Art. 18 lit. Lastly, according to Art. 9a HMG in conjunction with Art. 18 lit. **e** VAZV, the collection of all necessary data and the processing and evaluation of the data according to Art. 11 lit. d HMG (ordinary marketing authorisation) would have to take so long that irreversible damage would occur or be exacerbated or that this would be associated with severe suffering for the patient.

678 It is not to be expected that the collection of all necessary data within the framework of an ordinary approval procedure would have been associated with the occurrence of irreversible damage or with severe suffering in patients suffering from SARS-CoV-2. Thus, it was stated in advance (N 635 ff.) that at no time was there a life-threatening or disabling disease threatening the entire target population. A danger existed at most for older people, who could have been adequately protected in other ways. In particular, alternative treatment methods would have existed practically from the beginning of the Corona crisis - i.e.

207 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 9a N 35.

as early as the mid-2020s - which could have been approved quickly and with a side effect profile that had already been known for many years (see above N 656 ff.).

679 Waiting until all the data required for an ordinary procedure were available would not have been associated with any disadvantage for COVID patients, nor with the occurrence of irreversible damage or severe suffering, so that this condition of the temporary authorisation is also not fulfilled.

3.4. Overall conclusion: Conditions of the "temporary admissions" never fulfilled

680 Thus, of the six cumulative conditions of the temporary approvals, not a single one is fulfilled any more. Even worse: at **the time of the first time-limited authorisations, not a single cumulative requirement was fulfilled.** With a lot of "goodwill", it could be argued that in December 2020, at best, no alternative treatment methods existed yet and that older people in particular were exposed to an increased risk, which is why a certain urgency existed at best for a short time. But even then, the temporary authorisations fail completely in the remaining three conditions **(not compatible with the protection of health; no major therapeutic benefit; no subsequent delivery of complete data).**

681 Moreover, it was previously shown in detail that the authorisation of the mRNA "vaccines" deviates from the ordinary and even the simplified authorisation in all essential safety aspects. The approval of the mRNA "vaccines" was thus **accompanied by** a **blatant omission of the most elementary safety and efficacy tests, thus** taking the **greatest possible of all risks.**

682 **The conditions for the ("temporary") authorisations of the COVID "vaccines" were thus never met - the granting and maintenance of the same by Swissmedic is simply unlawful.**

4. Mandatory duty to minimise risk: vigilance and education

683 Some of the statements made in this section are **supplements to the information previously provided in this criminal complaint**, **to which explicit reference is made in each case**.

684 Other explanations are based on the **evidence report** attached to this criminal complaint **(Annex 4),** which contains further discussions where appropriate and lists the relevant supporting documents. The title structure in this section of the criminal complaint and the attached evidence report (section "Mandatory duty to minimise risk: vigilance and education") correspond in content, but are shifted by two levels (e.g.: Title level "**4.1** Control of

risks ["Pharmacovigilance"]" of the criminal complaint corresponds to title level "**I.** Control of risks ["Pharmacovigilance"] in the evidence report).

685 The last resort for risk minimisation would therefore be risk management after authorisation, which is beyond all doubt - but even there, Swissmedic does not meet the most basic requirements with its massive under-reporting of side effects and a misleading information strategy vis-à-vis the public:

4.1. Control of risks ("pharmacovigilance")

4.1.1. No active monitoring

686 To date, Swissmedic has limited itself to a purely passive reporting system, which is in no way designed for emergency authorisations: the passive reporting system is designed for medicinal products that have been thoroughly tested on humans, in order to be able to detect rare side effects that may have been overlooked in studies (see N 533 ff.).

687 However, the mRNA "vaccines" are - as explained in detail - highly experimental as **gene therapy for prophylactic use on an overall population that is healthy in itself** and are **not backed up by a single (long-term) study on humans.** Rather, they are still in the first clinical phase, which is expected to last until (at least) 2024. The starting position for the "temporarily" authorised mRNA therapies is therefore in no way comparable to that of new medicinal products with a full marketing authorisation. On the contrary, Swissmedic has created an **unprecedented risk with the** authorisation of mRNA therapies and has repeatedly renewed it despite constantly increasing evidence regarding the lack of efficacy and unprecedented side effects, which would have to be **compensated for by substitute measures to minimise the risk.**

688 In view of the fact that the mRNA "vaccinations" are still in the clinical phase and in view of the fact that a medicinal product with a (in this context: preventive use for the healthy general public), the mRNA **"vaccinations" should have been subjected to active pharmacovigilance - as is mandatory under study conditions - from the very beginning**. However, this was never done.

4.1.2. Massive underreporting in Switzerland - complete passivity at Swissmedic

689 The fact that the passive reporting system is not even close to being able to capture the massive risk potential is also shown by the underreporting that has already been pointed out several times: In Switzerland, **at best 10% of all side effects** are **reported - an untenable number of unreported cases.**

690 If Swissmedic had wanted to adhere to the passive reporting system, it should have done everything in its power to ensure that the doctors involved at least fulfilled their passive reporting obligations with the best possible care. However, the opposite is the case: there is no evidence that Swissmedic ever urged the doctors subject to the reporting obligation to comply strictly with the reporting obligation. Nor is it apparent that administrative or criminal proceedings have been initiated against doctors who fail to report. On the other hand, in the course of their work as lawyers, the present undersigned lawyers are regularly told by hospital staff that it is virtually impossible to persuade the doctors on duty - even in very clear cases - to investigate a possible connection between Covid "vaccinations" and unusual clinical pictures (heart muscle inflammations; thromboses; permanent inflammations etc.) at the request of affected (often young) patients. Instead of investigating such cases, the principle is applied "that what cannot be, must not be".

BO: Interviewing the hospital staff on duty

4.1.3. Swissmedic approves unblinding of registration studies

691 By the end of 2020 - i.e. at the time of the first approvals - the manufacturers had already almost completely unblinded the "phase III" studies that are mandatory for approval, which is tantamount to a ***de facto discontinuation*** (front N 192 ff.).

692 Swissmedic was already aware of this fact at the time of the initial authorisations. Swissmedic wrote to Moderna in the authorisation decision of 12 January 2020:

> "The open-ended questions on duration of protection will depend heavily on a non-blinded control group. ... This question could alternatively be answered with a household contact study."

693 And to Pfizer, Swissmedic wrote in the authorisation decision of 18 December 2020:

> "It is reasonable to assume that once vaccination is available, it will not be possible to maintain a control group. A study with an alternative study design, e.g. a blinded crossover design or any study design that can circumvent this problem, is strongly recommended".

694 The fact that Swissmedic describes the dissolution of the control group as "reasonable" is simply untenable. Every new medicinal product must be tested for safety and efficacy in a double-blind study. The waiving of this elementary requirement is simply not justifiable in any way - certainly not with the terse "assumption" that a control group cannot be maintained.

695 The unblinding of the "phase 3" studies and the accompanying obvious refusal of the manufacturers to provide solid data for the final assessment of the safety and efficacy of the mRNA "vaccines" appears downright brazen. The fact that Swissmedic accepted such an attitude of refusal must once again be classified as an almost obvious breach of duty against the background of the clear legal duty of care within the meaning of Art. 3 para. 1 HMG. Here, too, Swissmedic manifested a complete absence of will, or at least pure inability, to effectively verify the safety and efficacy of the "temporarily" authorised mRNA "vaccines".

4.1.4. Ignored messages from the manufacturers

696 As has already been pointed out in several places (above N 192 ff., N 279 ff. , N 336), the manufacturers themselves had reported massive side effects and other serious anomalies (such as the **unblinding of the approval studies) to** the international **approval** authorities and thus also to Swissmedic. None of this had prompted Swissmedic to demand the most elementary safety standards, or even to suspend the "time-limited" authorisations, which was actually mandatory.

697 And even more serious: The corresponding reports were not only ignored by Swissmedic, they were also not communicated to the public in any way - or if they were communicated, they were presented in a glossy manner (on this, see below N 715 ff.).

4.1.5. Ignored third party studies

698 Swissmedic ignored not only the warnings of the manufacturers, but also those of third parties who had studied the risk-benefit profile of the mRNA "vaccines" in detail. Swissmedic even ignored the fact that Pfizer falsified data in the approval studies - a fact that should have led to the immediate suspension of the approval.

699 All this bounced off Swissmedic repeatedly and over a period of now more than 18 months. For example, Swissmedic was still holding on incoherently to the well-founded criticism of the *Canadian COVID Care Alliance* ("*CCCA*") regarding Comirnaty's 6-month data on 1 February 2022:

> "As you can see, the assessment, evaluation and ultimately the decision on the authorisation and life cycle of medicinal products in general and of COVID-19 relevant medicinal products in particular is in good and the only legitimate hands at Swissmedic to ensure the safety, efficacy and quality of these therapeutic products for patients."

700 Without exception, well-founded indications of serious alarm signals are brushed aside without any substantive discussion - and the *de facto* emergency approvals are maintained without any visible measures for risk reduction.

4.2. Completely insufficient education of patients and the medical profession

701 In addition, communication to the public is misleading in every respect:

4.2.1. Admission in an "ordinary procedure"?

702 On 19 December 2020, Swissmedic made the following announcement regarding the authorisation of Comirnaty: "This is the world's first authorisation in an **ordinary** procedure". This wording gave the impression to users and patients that the authorisation of mRNA "vaccines" was a regular and proven process that did not deviate from the usual norm. The corresponding entry on Swissmedic's homepage can still be accessed even in 2022.

703 However, as has been shown in detail, the authorisation of Comirnaty has nothing remotely in common with an "ordinary" procedure: not a single one of the mandatory requirements that must be met for an ordinary authorisation (regulated in Art. 11 TPA) was fulfilled as of 19 December 2020 - and they are still not fulfilled today. Swissmedic even fell short of the minimum requirements that apply to the "temporary" authorisation under Art. 9a HMG - an actual emergency authorisation. Under these circumstances, **to publicly announce that the authorisation would have been granted in an "ordinary" procedure, although the relevant requirements had been undercut to the maximum extent possible, is simply untenable and a brazen misleading of the population.** In view of the time span of more than 18 months (Swissmedic should have deleted this entry long ago), this misinformation can no longer be dismissed as a mere error. Rather, it is a case of deliberate misinformation, indeed an **outright lie,** which many people must mistakenly believe to be true to this day - after all, this notification is still publicly available. Many people are still unaware that they are participating in an actual human experiment.

4.2.2. Approval for pregnant and breastfeeding women

704 In the technical information for Comirnaty, Swissmedic published in December 2020 that **"no vaccine-related effects on female fertility, pregnancy or embryo-fetal development or on the development of the offspring have** been **observed**" . In doing so, Swissmedic passed the risk-benefit analysis on to the users and patients: "Administration

of Comirnaty in pregnancy should only be considered if the possible benefits outweigh the potential risks to the mother and foetus".

705 These public references are in stark contrast to the information that Swissmedic already had internally at the time (see in detail N 172 ff. and N 334 ff.) - but was not communicated to the public in a completely incomprehensible manner.

706 The **withholding of key information** - such as problems identified in animal studies, the lack of clinical studies and a corresponding complete lack of risk profile - makes **a mockery of the already inadmissible shifting of risk assessment onto users and patients.** By authorising the "vaccines" for pregnant women without explicit warnings, Swissmedic created the illusion that administration to pregnant women was harmless. In this way, the licensing authority caused pregnant women to consent to the "vaccination" without full knowledge of the relevant risks, thereby accepting the harm to expectant mothers and their foetuses.

707 Finally, the overall demonstrably trivialising, misleading and incorrect wording in the Swiss Medicinal Product Information of Comirnaty, approved by Swissmedic, paved the way for a vaccination recommendation in Switzerland - initially only for pregnant women with chronic diseases from May 2021 and for all pregnant women from the 2nd trimester onwards from September 2021. **Swissmedic thus enabled the widespread use of a toxic, carcinogenic and potentially mutagenic substance in one of the most vulnerable patient groups, although there was no proof of safety for pregnant women either at the time the authorisation was granted or to *date* - indeed, on the contrary, considerable risks had to be expected and still have to be expected with its use.**

4.2.3. Admission for children and adolescents

708 The marketing authorisations for children and adolescents are in flagrant violation of Art. 9a HMG, which has been shown in detail; in particular:

- Children and adolescents are not in any way at risk from SARS-CoV-2 (front N 483, N 484 ff.).
- In children and adolescents, mRNA "vaccines" have only been shown to be of minimal benefit for minor illnesses and of no benefit at all for severe illnesses (front N 254 ff. , N 370 ff.).
- At the same time, all alarm values - serious and fatal side effects - have long since been exceeded in children and adolescents (front N 304 f., N 322 ff.).

709 Nevertheless, Swissmedic was still communicating on 10 December 2021 in a complete distortion and embellishment of all the facts:

"**High clinical efficacy in younger children**

The ongoing pivotal trial with over 1,500 participants shows that the COVID-19 vaccine can virtually completely prevent severe disease progression caused by the SARS-CoV-2 virus in 5 to 11 year olds. Side effects tended to be less common than in adolescents and adults. These included pain at the injection site and fatigue, and in rarer cases headache, joint pain or fever. They usually lasted only a short time and were slightly more frequent after the second dose."

710 A "practically complete" - i.e. 100% - effectiveness against severe diseases is **diametrically opposed to the study results.** And the described **mild side effects** are a **massive understatement in** view of the devastating side effect profile.

711 In view of the virtually total lack of benefit of the mRNA "vaccines", Swissmedic exposed this youngest and least threatened population group by SARS-CoV-2 to the risk of severe side effects and deaths without need and in an absolutely misleading manner.

4.2.4. Admission for elderly and pre-diseased people

712 A completely neglected and misled population group are also elderly and pre-diseased people: In this regard, Pfizer itself had admitted that **no information ("missing information")** was available on the effect of the mRNA "vaccines" on this target group. Nevertheless, Swissmedic approved the "booster" ("booster vaccination") in this knowledge. **With regard to the problem of the complete lack of information, there is no corresponding warning in the Swiss Comirnaty product information to date.** It is simply irresponsible to grant a marketing authorisation under the title of Art. 9a HMG when there is a complete lack of data, and this is in open contradiction to the duty of care under the law on medicinal products (Art. 3 para. 1 HMG). It is obvious here that Swissmedic has carried out the benefit/risk assessment required under Art. 9a TPA without the necessary information.

713 It is particularly shocking that the FOPH (and the Federal Commission for Vaccination Matters; EKIF), based on this unlawful authorisation by Swissmedic, classifies precisely this age group - i.e. persons over 75 years of age and persons with chronic diseases - as **"Target group 1**" and recommends "vaccination" as a priority. Swissmedic should have corrected such misguided communication long ago - but is now contributing to the massive misleading of this population group by maintaining its own unlawful authorisation and its own silence.

4.2.5. Approval for immunosuppressed persons

714 The data presented to substantiate the efficacy of a "3rd dose in immunocompromised patients" is - as previously explained in detail (N 366 ff.) - is completely insufficient. It is therefore in no way comprehensible how Swissmedic could approve an authorisation and thus expose vulnerable immunocompromised patients to the high risks of gene-based "vaccination" - and this at full dosage - without any relevant benefit (and obviously not even safety) having been proven.

4.2.6. Misleading technical information for mRNA "vaccines

715 It has already been stated on several occasions that the information provided by Swissmedic in the expert information regarding **side effects did** not correspond to the latest state of knowledge ("Adverse effects" section) and that the medical profession and patients had not been adequately informed of **hazards** ("Contraindications" and "Warnings and precautions" sections). This should be addressed in the following:

4.2.6.1 Completely inadequate warning of myocarditis side effect

716 The warning about side effects concerning the **heart (myocarditis/pericarditis** etc.) is much too timid in view of the high reporting values from the USA - i.e. already without taking into account the massive underreporting: Contrary to what is stated in the product information under "Warnings and precautions", these are not "very rare" but already **"rare" side effects** (front N 391). Taking into account the massive underreporting (in the USA, less than 3% of all side effects are reported), we would already be in the range of occasional side effects - which means that for every 1,000 "vaccine doses", more than one person would be affected by myocarditis. In view of these figures, the fact that the side effect "heart disease" is **still listed as "unknown" (!) under "frequency" in** both technical information sheets[208] must be classified as blatant misleading.

4.2.6.2 Complete lack of warning about the side effect of herpes zoster

717 In the case of Comirnaty, there is still no indication of **herpes zoster (shingles),** although this potentially serious side effect occurs more frequently than **side effects** (such as nausea or arthralgia [joint pain]) that are already officially **qualified as frequent (≥1/100 to <1/10).** Swissmedic had already recognised herpes zoster as a potential side effect in

208 Swissmedicinfo, "Fachinformation Comirnaty", as of 04.2022, https://www.swissmedicinfo.ch/ShowText.aspx?textType=FI&lang=DE&authNr=68225; Swissmedicinfo, "Fachinformation Spikevax", as of 05.2022 https://www.swissmedicinfo.ch/ShowText.aspx?textType=FI&lang=DE&authNr=68267.

June 2021. In May 2022, herpes zoster was ranked 7th in Comirnaty's "Ranking of the 15 most common adverse reactions" published by Swissmedic. Despite this, Swissmedic has not yet decided to explicitly list herpes zoster as a potential adverse reaction in Comirnaty's product information.

4.2.6.3 Complete lack of evidence of thromboembolic side effects

718 There are no indications of **thromboembolic side effects** (such as thromboses, strokes, pulmonary embolisms), although according to EU data, thromboembolic events are among the top seven causes of serious to fatal cases, and even far **ahead of myocarditis**. In addition, according to the worldwide reports on adverse drug reactions - even without taking into account the massive underreporting - thromboembolic events have long since qualified as **"very rare"** and thus mandatory to be listed (front N 235, N 301 and N 393). The fact that the mRNA "vaccines" lead to **blood thickening** and **thrombosis is,** moreover, generally known from hundreds of international studies on life-threatening coagulation disorders (front N 428). The inclusion of this side effect is therefore long overdue.

4.2.6.4 Patients with increased tendency to clot: "Contraindications" and "Warnings and precautions" completely inadequate

719 As just stated, Comirnaty and Spikevax have been shown to be associated with an increased risk of thromboembolic events. As a consequence, **both medicinal products should not be administered to patients with an increased pre-existing risk of blood clots** (listing of the risk in this case under the heading "Contraindications") or should only be **administered with** caution or under supervision (e.g. monitoring of certain coagulation parameters such as D-dimers).

720 However, the contra-indication **of** an **increased tendency to coagulate** is simply not listed in the product information for Spikevax and Comirnaty.[209] **There is no risk indication of an increased tendency to clot ("too thick blood").** On the contrary: In both expert information, under the heading "Warnings and precautions", reference is made to potential risks in connection with an increased tendency to bleed (thrombocytopenia, haemophilia, etc.) - i.e. "too thin blood".

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209 Swissmedicinfo, "Fachinformation Comirnaty", as of 04.2022, https://www.swissmedicinfo.ch/ShowText.aspx?textType=FI&lang=DE&authNr=68225; Swissmedicinfo, "Fachinformation Spikevax", as of 05.2022 https://www.swissmedicinfo.ch/ShowText.aspx?textType=FI&lang=DE&authNr=68267.

4.2.6.5 Further omissions

721 The **concealment of all these facts, which are as relevant in legal terms as they are in terms of risk, in** its expert information for the attention of the Swiss public constitutes a **serious breach of due diligence within the** meaning of Art. 3 para. 1 HMG on the part of Swissmedic to the detriment of public health.

722 This list of missing and euphemistically presented side effects and warnings could be added to at will - for which, however, more detailed investigations and analyses are necessary.

4.2.7. Further omissions and appeasements by Swissmedic

723 The following list of misleading communications is also in no way to be considered exhaustive:

4.2.7.1 Swissmedic: "Vaccines" are "safe

724 Swissmedic announced various misinformation on the occasion of each "limited" authorisation (including indication extensions): For example, completely misleading efficacy data were presented to the public by the manufacturers without any contextual information, and reference was made to mostly short-term mild to moderate side effects (ignoring serious side effects) - even claiming that the side effects were "comparable to those after a flu vaccination".

725 Moreover, it was placatingly stated that Swissmedic would "continue to closely monitor the benefits and risks of all vaccines for the prevention of coronavirus disease in Switzerland and internationally", and even that the "safety of the vaccine" would be closely monitored and "if necessary, immediate measures" would be taken "should safety signals appear". Swissmedic has not kept any of these promises.

4.2.7.2 Swissmedic: Probably no hereditary genetic damage/carcinogenic effect

726 In the technical information, Swissmedic publicly claimed that it was **"not to be expected" that** components of the vaccine could be mutagenic **and/or carcinogenic. Swissmedic** made this claim without **sufficient studies having been carried out at all.** In doing so, Swissmedic - once again - disregarded HMEC's advice that "reproductive, genotoxicity and neurotoxicity studies were lacking and should be provided later". Despite this clear recommendation, Swissmedic contented itself with requesting preclinical toxicity studies with regard to reproduction and development, which - as previously (N 180 ff.) - were completely insufficient.

727 By acting in this way, Swissmedic not only breached its duty to demand the mandatory animal studies. Instead of publicly propagating a presumed harmlessness in a misleading manner, Swissmedic should have pointed out that the animal studies on the mutagenic and carcinogenic effects had in no way been adequately carried out and requested. However, this - or correspondingly clear specialist information for the attention of the public - would have been imperative in order to protect public health from the risks in the absence of studies within the meaning of Art. 1 and Art. 3 para. 1 HMG.

4.2.7.3 Swissmedic: "No evidence of accumulation of the LNP".

728 As previously explained (N 187), Swissmedic claimed publicly, without any evidence and even contrary to the presumably internally available study, **"[that the LNPs] are excreted within a few days. There is no evidence that they accumulate in tissues or organs over a longer period of time." This is** also blatant misinformation on the part of Swissmedic.

4.2.7.4 Swissmedic: "No proven fatalities".

729 As of 7 May 2021, Swissmedic stated:

> "Despite a temporal association, according to current knowledge, diseases that occur independently of the vaccinations, such as infections, cardiovascular events or diseases of the lungs and respiratory tract, led to death. **Currently, there is also no international evidence that the two mRNA vaccines lead to an increased rate of deaths."**

730 This, too, can only be qualified as **deliberate misinformation: At** that time, Swissmedic must have already known, based on the "*Post Marketing Pharmacovigilance Report*" by Pfizer/BioNTech (approx. April/May 2021), that from the time of marketing authorisation until 28 February 2021 - i.e. in just 2 ½ months - **1,200 deaths had** already been recorded in connection with the vaccination.

731 Even at the end of November 2021 - when a total of **13,632 deaths had** already been reported worldwide in relation to Comirnaty and Spikevax alone - Swissmedic stated that "despite a temporal association, there was no concrete evidence in any case that the vaccination was the cause of the death".[210] What Swissmedic based this statement on remained completely open.

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210 Swissmedic, "Suspected adverse reactions to COVID-19 vaccinations in Switzerland", 26.11.2021, https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/covid-19-vaccines-safety-update-9.html.

732 To date, Swissmedic appears to be denying any causal link between the mRNA "vaccinations" and the reported deaths, without any evidence.

4.2.7.5 Swissmedic plays down side effects

733 As of 7 May 2021, however, Swissmedic had not only played down possible deaths, but side effects per se. Swissmedic announced that the reports to date "confirmed the side effect profile known from the authorisation studies" and that "the known positive benefit-risk ratio of the two mRNA vaccines used would not change" - in view of the side effect reports already known at that time (see above N 223 f.; cf. also N 226 ff.) a **blatant misinformation.**

4.2.7.6 Swissmedic disseminates false information in "Vigilance-News

734 With its journal "Vigilance News", Swissmedic addresses healthcare professionals and regularly informs them about news on the topic of "drug safety". In the May 2022 issue, Swissmedic announced that "at the beginning of the vaccination campaign with the COVID 19 vaccines, **some non-serious and very frequent adverse** events following vaccination, so-called AEFIs (Adverse Events Following Immunisation), were already known on the basis of observations in controlled clinical trials".

735 In view of the facts presented above, this represents a **blatant trivialisation and blatant misinformation: The** PSUR, which already commented on these clinical trials at the end of 2021, revealed that 702 suspected cases of **side effects from clinical trials** had been classified as **serious** and that **46 (6.6%)** of these were **fatal** (see above N 279 ff.). The statement of 702 serious and 46 fatal side effects is in irresolvable contradiction to Swissmedic's trivialising statement that only a few "non-serious" events had been detected. Once again, Swissmedic's presentation represents deliberate misinformation, which makes it impossible to form a correct will and effective consent ("informed consent") to "vaccination".

736 Swissmedic even reported further, stating: "**For other signals, there are only a few examples in the literature...**". Which literature Swissmedic is referring to here remains unclear. In view of the overwhelming number of hundreds of peer-reviewed studies (N 251, N 351 and N 428) on only three topics (thromboses, heart attacks, deaths) - thus excluding many other studies on various other side effects - this is also **blatantly misinformed**.

4.2.8. "FAQ" on Swissmedic website

737 Swissmedic publishes *questions and answers about COVID-19 "vaccinations"* ("*FAQ about COVID-19 vaccines*") on its own website for the general public and has apparently been disseminating absolutely misleading information there since 2020. None of the questions are answered correctly. To illustrate a selection of questions, the corresponding answers from Swissmedic, together with the correction, are compared below:[211]

4.2.8.1 Question 1: Are the COVID vaccines safe?

738 Swissmedic's response: "The vaccines against COVID-19 were thoroughly tested during their development and then carefully reviewed by Swissmedic experts. Only vaccines that have been proven to be safe, effective and of high quality are licensed in Switzerland. So far, there are no indications of lasting negative consequences for health."

739 Correct answer: "All 'time-limited' approved mRNA "vaccines" are ineffective and unsafe; even the quality has been insufficiently proven. The 'time-limited' approval is based on absolutely insufficient and incomplete data. In addition, there have been unprecedented reports of side effects and deaths associated with COVID "vaccines" worldwide. "

4.2.8.2 Question 2: Do the vaccines work?

740 Swissmedic's response: "Only vaccines with proven efficacy are licensed in Switzerland. The vaccine manufacturers have carried out preclinical and clinical studies on efficacy and safety. The results of the clinical trials showed a protection against severe COVID-19 disease of 94 per cent or more. According to the data, elderly people and people with chronic disease are also well protected against an outbreak or severe course of the disease."

741 Correct answer: "The mRNA gene therapies were approved in Switzerland without their effectiveness ever having been proven. The officially stated 94% efficacy is based on completely biased calculation methods and on falsified study documents. To date, no solid prospective randomised study has shown that the COVID 'vaccines' reduce severe courses to a relevant extent. The data on older people and people with chronic diseases is absolutely insufficient, which is why there is no basis for approval. To date, the COVID 'vaccines' have not demonstrated any relevant efficacy, neither in registration studies nor in '*real world evidence*'. On the contrary, recent developments even show that people who have received the mRNA therapies have a reduced immune defence and are increasingly leading the figures for hospitalisations and deaths. "

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211 In the evidence report, the supporting documents for the correct answers are listed and/or referenced under the same title ("'FAQ' on Swissmedic website").

4.2.8.3 Question 4: Isn't it healthier if I go through the disease to gain immunity?

742 Answer from Swissmedic: "No, on the contrary. The course of an infection is very individual and unpredictable. Vaccination mobilises the body's natural defences and thus prevents, in particular, severe courses of disease that can cause lasting damage to health. Vaccination works together with the body and its natural defences; the body learns about the virus and subsequently knows how to protect itself from a disease outbreak in the event of a future infection."

743 Correct answer: "Yes, absolutely - as long as they take precautions. Figures from various countries show that the mRNA 'vaccines' make people more susceptible to COVID-19-related illnesses, hospitalisations and deaths. Numerous studies also show that the immunity generated by a COVID illness is broader and longer-lasting than after a 'vaccination'. In the meantime, various studies and recommendations have been published, for example by the FLCCC, which propagates the intake of high doses of vitamin D3, vitamin C and zinc. "

4.2.8.4 Question 8: Do mRNA vaccines change my DNA?

744 Answer from Swissmedic: "No, the messenger RNA transmits the information about the surface properties of the virus to your cells. This enables the body to prepare the immune response, which is later retrieved for the defence in the event of renewed contact. The mRNA does not enter the protected cell nucleus where your genetic material is located and consequently does not interact with your DNA at any time."

745 Correct answer: "The mode of action of modified mRNA has not yet been investigated in humans in any long-term study, which is why this question cannot be answered conclusively at present. We consider the risk to be 'very small', which is what we stated in the approval letter to Moderna. However, studies have shown that under certain conditions it is possible to insert RNA into DNA (so-called 'reverse transcription/insertion'). However, additional research is still needed to answer this question conclusively, so this risk cannot be ruled out for the time being. "

4.2.8.5 Question 12: What vaccination reactions should I expect?

746 Answer from Swissmedic: "Common side effects include: Reactions at the injection site such as pain, redness and swelling; headache, tiredness; muscle and joint pain; general symptoms such as chills, feeling of fever or fever."

747 Correct answer: "In addition to rather mild side effects such as redness, headache and fever, they must expect serious side effects such as severe allergic reactions of all kinds,

shingles, enlarged lymph nodes, thrombosis, facial paralysis, myocarditis/pericarditis and in very rare cases even death. "

4.2.8.6 Question 13: I am pregnant or would like to become pregnant soon. Can the vaccination affect my fertility?

748 Answer from Swissmedic: " The vaccine has no effect on your body's ability to become pregnant. It also has no influence on the future development of the placenta or the course of a future pregnancy. Furthermore, the vaccination also has no negative effects on you or your child if you are breastfeeding."

749 Correct answer: "Animal studies have identified a possible risk in pregnancies. The panel advising us, HMEC, therefore already advised us at the end of 2020 that we should list pregnancy under 'precautions'. Even at the end of 2021, the safety profile in pregnant and breastfeeding women was still completely unknown. To date, thousands of premature and stillbirths related to mRNA 'vaccinations' have been reported worldwide. "

4.2.9. mRNA as GMO/genetherapeutics: Special labelling requirements?

750 As explained at the beginning, the mRNA "vaccines" basically have the potential to have a gene-modifying effect. Even if this were not the case, however, they must at least be classified as gene therapy products in the sense described above. In the sense of the **precautionary principle** and the **protection of consumers from deception** (Art. 1 para. 2 lit. a HMG), it would therefore be **urgently indicated if this unsafe status** were **declared accordingly and communicated to the public in a comprehensible manner.**

751 This is obviously not the case. This is what Comirnaty's professional and patient information says:

> "Tozinameranum (single-stranded messenger RNA [mRNA] with 5'-cap structure, produced by cell-free in vitro transcription with corresponding DNA templates and coding for the spike [S] protein of the SARS-CoV-2 virus).
>
> The product contains non-replicating nucleoside-modified mRNA."
>
> [...]
>
> "Comirnaty is a concentrate for the preparation of an injection dispersion containing the active ingredient tozinameran, a COVID-19 mRNA vaccine (nucleoside-modified)."

752 And the Spikevax patient information leaflet says:

> "Single-stranded 5'-capped mRNA produced in a cell-free in vitro transcription from the corresponding DNA templates and encoding the viral spike(S) protein of SARS-CoV-2. The mRNA is embedded in lipid nanoparticles."
>
> "COVID-19 mRNA vaccine (nucleoside-modified)".
>
> [...]
>
> "The active ingredient in Spikevax is mRNA encoding the SARS-CoV-2 spike protein. The mRNA is embedded in SM-102 lipid nanoparticles."

753 The indications "in vitro transcription" and "nucleoside-modified" or "nucleoside-modified" suggest some kind of modification. For the normal addressee, however, this in no way implies that it could be a product with **"genetically modifying" potential. The** mere fact that the **mRNA "vaccines" are in fact novel gene therapies, which have never been used with this particular mechanism of action for purely preventive purposes for a previously healthy population,** is in no way sufficiently recognisable to the average addressee.

754 In particular, it is not evident that fundamental basic information, which in principle should always be known for every remedy before it is taken, remains entirely in limbo with this special technology. As already mentioned above (N 143 f.), it can by no means be said with certainty when the substances in question are administered:

- which body cells are ultimately involved in the production of the spike protein,
- exactly how long the production lasts in the human body,
- in which quality and in which quantity this spike protein is produced by the body and
- how large the proportion of the population is in which these mRNA injections (administered "to everyone", so to speak) or the body's own production of the spike protein cause negative side effects.

755 The exact knowledge and controllability of these parameters would usually be an essential prerequisite for targeted drug treatment, but cannot be guaranteed in any way with this type of "vaccine".

5. Planned complete abolition of the Therapeutic Products Act: Complete abandonment of clinical trials?

756 With Art. 3 para. 2 lit. c COVID-19 Act, Parliament has authorised the Federal Council to provide for exemptions from the authorisation requirement for medicinal products or to adapt the authorisation requirements or the authorisation procedure. However, this is only

for the purpose of "ensuring an adequate supply of the population with important medical goods".

757 It already follows from this wording that an exception to the licensing requirements is only possible if the supply of the population cannot be ensured otherwise. As previously stated (N 656 ff.), there are already a large number of treatment alternatives for COVID-19 disease - there is therefore simply no room for the approval of a prophylactic gene therapy to "combat" SARS-CoV-2 by omitting the most elementary safety mechanisms.

758 Art. 3 para. 2 lit. c of the Covid 19 Act is based exclusively on the idea of protecting public health. In no way did the legislator intend to authorise the Federal Council to dispense with basic protective measures such as preclinical and clinical studies in the context of the authorisation of medicinal products and with the consideration of all other risk-relevant facts. The provision does not constitute a free pass to the Federal Council to approve any mRNA gene therapy unchecked under the pretext of fighting a pandemic and without further risk/benefit analysis, disregarding the most essential pillars of the Therapeutic Products Act - on the contrary: even according to the Covid 19 Act, the Federal Council is obliged to observe the principles of subsidiarity, effectiveness and proportionality. It must direct its strategy towards the mildest and shortest possible restriction [...] (Art. 1 para. 2bis Covid-19 Act). Accordingly, the Federal Council was in no way authorised to arbitrarily abandon the mandate under medicinal products law pursuant to Art. 1 HMG to protect public health from ineffective medicinal products or from unsafe medicinal products.

759 However, based on Art. 3 para. 2 lit. c COVID-19 Act, the Federal Council then provided for various exceptions to the authorisation requirements for medicinal products in **COVID-19 Ordinance 3 of 19 June 2020** (SR 818.101.24) - for example in Art. 21 para. 2, which is quite likely to jeopardise the protection of public health against unsafe medicinal products:

> "Amendments to the marketing authorisation of a medicinal product authorised in Switzerland with an active substance in accordance with **Annex 4 Number 1 [No. 41: "COVID-19 vaccines"], on the** basis of which the medicinal product **may be** used for the treatment of COVID-19 patients in Switzerland, **may be implemented immediately after submission of a corresponding application for amendment until Swissmedic reaches a decision.** Swissmedic may, on the basis **of a benefit/risk analysis,** authorise deviations from the applicable provisions of medicinal products legislation in the case of variations to the marketing authorisation

of medicinal products containing an active substance in accordance with Annex 4 Number 1."

760 Here too, however, the Federal Council explicitly adheres to the above basic order with regard to public health by repeating the principle **according to which Swissmedic must carry out a benefit/risk analysis prior to each authorisation.** Since Swissmedic has for years been the supreme authority with the technical and factual competence to correctly identify risks under medicinal products law and to take the appropriate precautions, the Federal Council ordinance in question does not change Swissmedic's legal obligations to protect public health from ineffective and unsafe medicinal products.

761 However, based on the Federal Council ordinance, Swissmedic then provided for various changes in the corresponding guidance for "Authorisation procedures for COVID-19 medicinal products in the event of a pandemic HMV4"[212] since May 2021 - among other things:

- Amendments dated 15 May 2021:
  - Chapter 5: Clarification of the minimum requirements for the submission of applications with active substances listed in Annexes 4 and 5 of COVID-19 Regulation 3.
  - New chapter 8 [currently: chapter 9]: "Adaptation of vaccines to new SARS-CoV-2 variants".
  - New Annex 1: Consideration of modified strains in licensed vaccines in the current SARS-CoV-2 pandemic.
- Changes from 01 May 2022:
  - Chapter 5: Clarifications on the procedure for applications under Art. 21 paras. 1-2 COVID-19 Ordinance 3.

762 On 1 May 2022, Swissmedic announced, together with the above-mentioned amendments ("clarifications"), that it would continue to "prioritise" and "expedite appropriately to the pandemic situation" marketing authorisation applications for medicinal products "intended for the prevention and treatment of a pandemic disease (e.g. COVID-19)", so that effective and safe medicinal products would be available to patients as soon as possible. [213]

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212 Swissmedic, 01.05.2022, "Wegleitung Zulassungsverfahren für COVID-19 Arzneimittel im Pandemiefall HMV4", https://www.swissmedic.ch/dam/swissmedic/de/dokumente/zulassung/zl_hmv_iv/zl000_00_044d_wl_zulassungsverfahren_covid-19.pdf.download.pdf/ZL000_00_044d_WL_Zulassungsverfahren_f%C3%BCr_Covid_19_Arzneimittel_im_Pandemiefall.pdf.

213 Swissmedic, 01.05.2022 "Anpassung der Wegleitung Zulassungsverfahren für COVID-19 Arzneimittel im Pandemiefall HMV4", https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/authorisations/informationen/anpassung-wl-covid-19-im-pandemiefall.html.

763 In view of the fatal experiences to date with mRNA therapies authorised on a "temporary" basis, the changes to the Swissmedic pathways envisaged since May 2021 read as **instructions for the continued "authorisation" of untested medicinal products and thus for the continued violation of the most fundamental legal obligations of protection and due diligence with regard to public health:**

764 Since 15 May 2021, marketing authorisation extensions, **type II variations (such as indication extensions and new dosage recommendations)** can be implemented immediately after submission of a corresponding variation application *(chapter 5, p. 4).* This regulation presumably came into effect for the first time for the indication extensions to adolescents on 4 June 2021 and subsequently for the "booster" and children's marketing authorisations.

765 Also since 15 May 2021, however, Swissmedic has also stated that "for reasons of public health and for scientific considerations" it would **not** consider **"an updated coronavirus vaccine to be a completely new product"**, which is why it would **waive the "requirement for lengthy, comprehensive clinical trials"** *(Chapter 9.1, p. 7)*. In doing so, it unceremoniously reclassifies such "updates" - i.e. actually completely new products - as "type II changes" *(chapter 9.2, p. 8):*

> "Changes related to the **replacement** or addition of a serotype, **strain**, antigen or coding region, or a combination of serotypes, strains, antigens or coding regions, of a human coronavirus vaccine shall be **classified** as a **type II change.** "

766 In Annex 1 (p. 11, point 3), Swissmedic states (emphasis added):

> **"Under a more restrictive interpretation, regulators would consider an adaptation of an approved vaccine to a new strain as a new product and require new clinical trials to demonstrate safety, immunogenicity and efficacy**. This would result in a significant delay before such a new version of the vaccine would be ready for distribution, as the time-limiting step is the collection of efficacy data because it requires spontaneous infections and a comparison group."

767 Swissmedic itself thus admits that under normal circumstances, such fundamental manipulations to a "vaccine" would necessarily make it a new product that would have to undergo a complete authorisation procedure. So now, **based on the already massively accelerated time-limited initial approvals of the mRNA "vaccines",** it wants to **allow all conceivable manipulations of these "vaccines" in order to then be able to inject these modified mRNA "vaccines" directly into humans without any safety mecha-**

nisms such as preclinical and clinical studies. This is a deliberate and continued acceptance of unmanageable risks to public health.

768 In the knowledge of the increasing risk factors described in detail in the first part of the criminal complaint and documented in the evidence report, and in the knowledge of the lack of positive proof of the efficacy of the COVID-19 "vaccines", Swissmedic is, at the latest with the publication of these information leaflets, making a **fundamental departure from all the basic safeguards for the protection of public health that are essential in this context** (including Art. 1, Art. 3 para. 2 and Art. 9a TPA). Swissmedic is hereby arbitrarily terminating its main legal mandate within the meaning of Art. 1 TPA - without, of course, being authorised to do so by the legislator.

769 On 18 June 2022, **Ugur Sahin** - CEO of BioNTech - himself confirmed that the planned approach of Swissmedic just outlined is by no means made up out of thin air: **He** blatantly **demands (!) that the worldwide regulatory authorities completely abandon clinical trials for "vaccine adaptations".**[214] In doing so, he is demanding nothing other than the undermining of the very last elementary safety mechanisms of the law on therapeutic products - and Swissmedic is quite obviously prepared to comply with this devastating - criminal - demand: On 24 June 2022, Swissmedic announced that Moderna had submitted an application to extend the marketing authorisation for a Corona vaccine against Omikron.[215] Ibid Swissmedic seriously holds:

> "Swissmedic examines applications for the extension of marketing authorisations on a rolling basis. Applicants **do not** have to submit a **complete dossier to** Swissmedic with the initial submission of the application. Instead, they submit the **first available data packages** and submit a plan with deadlines for the subsequent submission of further data packages. Data submitted so far, which are now being reviewed, include studies from **laboratory studies (preclinical)** and **initial manufacturing and quality data (CMC).** "

770 It can be concluded from this that Swissmedic is implementing the plan that has been drawn up and is actually complying with the manufacturers' demands for a complete **waiver of clinical trials** without further ado. However, it can even be concluded from the

214 FINANCIAL TIMES, "BioNTech chief calls for speedy ruling on covid vaccines that target latest strains", 18.06.2022; WIESBADENER KURIER, "Coronavirus: BioNTech chief switches to alert mode", 21.06.2022.

215 SWISSMEDIC, "Moderna submits application to extend marketing authorisation for a Corona vaccine against Omicron", 24.06.2022, https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/moderna-zulassungserweiterung-impfstoff-corona-omikron.html.

media release that **complete documentation on quality and preclinical studies is not even available.** This means that the most fundamental data is missing. It is simply impossible for Swissmedic to carry out an examination of quality, safety and even efficacy that complies with the law on medicinal products, given this absolutely inadequate data situation.

771 Moreover, this planned procedure, which is not based on any suitable legal foundation, not only violates all principles of medical law in the most elementary way, but also violates mandatory international law: The legal obligations that Switzerland must fulfil in the context of "pandemics" (i.e. "PHEIC" ["Public Health Emergency of International Concern"] declared by the WHO General Secretariat) are defined by the International Health Regulations (IHR; SR 0.818.103). Art. 3 para. 1 IHR explicitly stipulates that states must uphold the fundamental rights of citizens even in times of pandemic :

> "These provisions shall be implemented with full respect for human dignity, human rights and fundamental freedoms."

772 It follows from Art. 3 para. 4 and from Art. 57 para. 1, 2nd sentence IIA that the legal obligations of States under IIA do not in any way limit the legal obligations under other international agreements:

> "The IIAs shall not affect the rights and obligations of States Parties under other instruments of international law."

773 Thus, the UN Covenant on Civil and Political Rights is also applicable (SR 0.103.2). Art. 7 of the Covenant stipulates:

> "No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, **no one shall be subjected to medical or scientific experimentation without his or her voluntary consent.** "

774 This provision also applies in times of emergency, which follows quite explicitly from Art. 4 para. 1 and para. 2 of the aforementioned UN Covenant:

> "In the event of a public emergency which threatens the life of the nation and which is officially proclaimed [...]"
>
> "By virtue of the foregoing provision [*1], Articles 6, 7, 8 (paragraphs 1 and 2), 11, 15, 16 and 18 shall not be set aside [...]."

775 This means that **the absolute ban on human trials without informed consent also applies in these special situations.** If Swissmedic were to actually intend to authorise

novel medicinal products under the guise of a "pandemic" without any studies and without compulsory warnings that are comprehensible to everyone and communicated transparently, the corresponding "authorisation" would lead to a human experiment to which no one can give valid consent due to the lack of sufficient information. With such an intended procedure, Art. 7 of the UN Covenant is obviously undermined.

6. Result

776 The responsible persons at Swissmedic were and are aware that Swissmedic is the **supreme responsible authority in** Switzerland on the basis of the legal competences and obligations to protect public health (against ineffective and harmful therapeutic products as well as against false information) outlined above. By virtue of special legislation on therapeutic products, Swissmedic has the actual key role in Switzerland in the areas of authorisation, placing on the market and subsequent market surveillance of therapeutic products, and it bears responsibility for the accuracy of the related product information.

777 For this reason, politicians, officials, courts, the media and citizens rely to a particular extent on the information and assessment provided by Swissmedic when it comes to the quality, efficacy and safety of new medicinal products. They attach a very special credibility and truth value to the decisions and public communication of this authorisation authority and its representatives.

778 The responsible persons at the licensing authority were also aware that the market authorisations of the mRNA "vaccines" and the associated official information from Swissmedic are relevant to decision-making for the individual benefit/risk analysis and therefore play a very decisive role for Switzerland as a whole.

779 **Despite this, Swissmedic has consistently, repeatedly and deliberately violated fundamental therapeutic product protection standards and duties of care that** serve to protect public health. In particular, despite the absence of all the essential requirements for a temporary authorisation under Art. 9a HMG - neither formally nor materially - it granted such an authorisation. It did not in any way adequately and effectively take into account the risks and dangers to public health that this created, in accordance with the high standard of care set out in Art. 3 para. 1 HMG:

780 Swissmedic has permanently and regularly ignored essential information on the lack of efficacy and the lack of safety and concealed it from the public. For example, it misled the public about the true nature of the authorisations in question by presenting them on its homepage as the "world's first authorisation in the ordinary procedure" and repeatedly and permanently emphasising that the substances in question had been tested for their effica-

cy and safety with the conscientiousness required by law and met the strict standards of Article 1 of the Therapeutic Products Act.

781 Swissmedic has consistently suppressed, concealed and covered up virtually all significant evidence of lack of efficacy and lack of safety from the public, thereby permanently and repeatedly misleading Swiss politicians and the public about the extent of the actual and impending risks of the mRNA "vaccines".

782 At the same time, at no time since the first authorisation was granted in December 2020 has Swissmedic effectively ensured that it has obtained an accurate picture of the ever-increasing undesirable side effects. It has either completely dispensed with stringent requirements for manufacturers, or it has failed to enforce them, or to revoke the temporary authorisation if the requirements are not met. Nor has it ensured that undesirable side effects are recorded effectively and as promptly as possible, and that they are published (active market surveillance or pharmacovigilance).

783 In order to avoid repetition, a **recapitulation of the violations of duties under the law on remedies will not be given here,** as this will be done in detail at the **end of N 838 ff. in** detail.

784 With the persistent, repeated and serious violations of the most fundamental duties of care under the law on therapeutic products and norms for the protection of public health, Swissmedic is not only in breach of Swiss law, but there is also the **suspicion** that, in view of the ongoing human experiment and the lack of a possibility to consent to the same due to the misleading nature of the experiment, there is a **violation of international law -** in particular Article 7 of the UN Covenant on Civil and Political Rights. This stipulates that **no one may be subjected to medical or scientific experiments without their voluntary consent - not even in "emergency situations".**

VI. Act of the medical profession - vaccination without sufficient information

785 Above (N 56 ff.), the facts concerning the private plaintiff were already briefly presented.

786 The detailed facts and the corresponding actions of the medical profession (and also of Swissmedic) in relation to the private plaintiffs can be found in Annex **3** (**"List and documentation of private plaintiffs"),** which is attached to this criminal complaint and still needs to be supplemented and expanded.

1. Classification COVID "vaccines": Medicinal product category B

787 When deciding on the marketing authorisation application, Swissmedic assigns the medicinal product to a dispensing category (Art. 40 para. 1 VAM). According to Swiss-

medic's list of "Temporarily authorised medicinal products for human use against life-threatening diseases"[216] , all mRNA "vaccines" are assigned to the "dispensing category medicinal products" B. According to Art. 42 VAM, a medicinal product is assigned to the **category of medicinal products subject to prescription (dispensing category B) if,** among other things, it is recommended against diseases for the treatment of which a **medical diagnosis or monitoring is required (lit.** a), it contains active substances or preparations of active substances whose effects and undesirable effects still require more detailed research (lit. d) and its dispensing requires **specialist advice from** a medical **professional** (lit. f).

788 Pursuant to Art. 24 of the HMG (elaborated by the Federal Council in Art. 45 of the VAM), exemptions from the medical prescription requirement are also provided for, which means that **pharmacists** may also dispense certain human medicinal products in dispensing category B.[217] The mRNA "vaccines" do not appear to meet the requirements set out in Art. 45 VAM. Accordingly, the canton of Zurich, for example, has explicitly regulated as of 17 February 2021 in § 24 para. 3 lit. e MedBV (LS 811.11) that pharmacists may provide "vaccinations against COVID-19" to persons aged 16 and over with the authorisation of the Directorate of Health without a medical prescription. Of course, this delegation to pharmacists does not release them from compliance with the above-mentioned other requirements (diagnosis, monitoring, expert advice) that are imposed on prescription-only category B medicinal products.

2. Case groups

789 In the following, the private plaintiffs are assigned to individual case groups on the basis of the explanations in the "Private Plaintiff Documentation":

2.1. Case group 1: Curative information, non-observed contra-indications

2.1.1. "Vaccination" by general practitioners (and in individual vaccination centres)

790 Insofar as the private plaintiffs received the mRNA injections from their **general practitioners** (and at most in individual vaccination centres), there is at least minimal documentation available of a brief - approximately five-minute - explanation (written information and declaration of consent).

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216 Swissmedic, "Temporarily authorised medicinal products for human use against life-threatening diseases", 31.05.2022, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/internetlisten/befristete_ham.xlsx.download.xlsx/Befristet_zugelassene_Arzneimittel%20HAM.xlsx.

217 See BÜRGI, BSK HMG, 2nd ed., Basel 2022, Art. 24 N 14a f. on this innovation.

791 **However, none of the private plaintiffs was - according to the current state of knowledge - sufficiently informed about**

- that their health is in no way significantly endangered without a COVID "vaccination" due to SARS-CoV-2, and that there were and are perfectly valid alternatives for the prevention or treatment of a severe illness due to infection with SARS-CoV-2,
- that the authorisations of the COVID-19 "vaccines" are by no means ordinary authorisations within the meaning of Art. 9, 10, 11 and 16 HMG, but only so-called "temporary authorisations" within the meaning of Art. 9a HMG,
- that these marketing authorisations were granted on the basis of **incomplete clinical data,** according to the technical and patient information,
- that there was a limited (unblinded) study population and a massively shortened study duration,
- that due to a complete lack of long-term studies, not all risks and side effects were known and are still not known,
- that this is an experimental "vaccine" which is still in the testing phase of human trials (clinical phase III trials).

792 This important information alone (for a detailed discussion of the entire scope of the duty to inform, see N 859 ff.) concerns essential risk factors and is simply indispensable for a free decision to vaccinate. Without their knowledge and individual consideration, any consent is based on an error of fact.

793 In principle, the following private plaintiffs fall into this group - subject to completion of the "documentation private plaintiff":

- Private plaintiff 1,
- (Private plaintiff 3),
- Private plaintiff 6.

2.1.2. "Vaccination" by pharmacists

794 As explained above, "COVID vaccinations" could apparently also be carried out by pharmacists according to cantonal regulations - **in compliance with all the requirements (in particular diagnosis, monitoring, specialist advice) that are imposed on prescription-only category B medicines.** In a corresponding leaflet "Vaccination in pharmacies"[218] , the Cantonal Therapeutic Products Control of the Canton of Zurich states

218 Canton of Zurich, Cantonal Therapeutic Products Control, leaflet "Vaccination in pharmacies - target group: public pharmacies", as of 1 March 2021, https://www.zh.ch/content/dam/zhweb/bilder-dokumen-

that questionnaires are provided to clarify the necessity of the "vaccination", which are to be filed in a **patient documentation. In** addition, it is expressly stated in section 4.5 "Patient **consent**":

> "Consent" is understood to be the agreement communicated by patients that they wish to be vaccinated at the pharmacy.
>
> Consent is lawful if the following conditions are met:
>
> a. The patient is capable of judgement.
>
> b. The patient has been **fully informed** about:
>
> - Type or effect of the vaccination, number of injections as well as advantages and disadvantages of vaccination (e.g. side effects or tolerance).
>
> - Alternatives to vaccination (natural diseases, drug treatment)
>
> - Procedure in the event of side effects
>
> - Costs of vaccination (assumption of costs, amount)
>
> To safeguard the pharmacist, it is advisable to confirm this consent by means of a signature."

795 In this absolutely minimal "clarification" - should it really have taken place in this way - any reference to the fact that the mRNA "vaccines" were only approved on the basis of **incomplete clinical data** and are still at the stage of human trials is therefore also missing here.

796 No private plaintiffs currently fall into this group - error and completion of the "documentation private plaintiff" reserved - yet.

2.2. Case group 2: Absence of any vaccination history

797 Insofar as the private plaintiffs received the mRNA injections in **"vaccination centres", it** is mostly to be noted that in these cases any documentation on the vaccination history is missing. There is not even any evidence that information was provided, let alone a declaration of consent. Individual vaccination centres were only able to provide bare "vaccination documentation", which only comments on the injection data and the mRNA "vaccines" administered.

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te/themen/gesundheit/gesundheitsberufe/pharmazie/MKB_40708_Impfen_in_Apotheken_D.pdf

798 In principle, the following private plaintiffs fall into this group - subject to completion of the "documentation private plaintiff":

- Private plaintiff 2,
- (Private plaintiff 3),
- Private plaintiff 4,
- Private plaintiff 5.

3. Insel Gruppe: Misleading information

799 The spreading of misleading false information aggravates the mostly completely inadequate education. For example, the Insel Group is still spreading "facts about COVID vaccination" in a six-page brochure on its website under "Every vaccination counts"[219] in June 2022,[220] which - as explained in detail above - have long since been refuted:

800 Under #2 "fertility" is stated without any evidence:

> "There are no effects on fertility as a result of vaccination. [...] The vaccination also has no influence on the future development of the placenta or the course of a future pregnancy."

801 Under #3 "Long-term safety of the vaccines" it is stated despite all the serious side effects up to and including death that have already occurred:

> "Late effects of mRNA vaccines are not to be expected. [...] Serious adverse reactions to vaccination are very rare from experience and have historically occurred within one to two months after vaccination. This period has already been carefully checked with the approval studies. [...] Any side effects are carefully analysed and checked. No long-term consequences are known so far. "

802 Under #6 "Risk vs. benefit of vaccination:" is once again presented in complete negation of thousands of death reports and millions of reported side effects:

> "The benefits of vaccination massively outweigh potential risks. [...] If serious side effects were to occur, this would be known by now with such a high number of vaccinated people. [...] The mRNA vaccines offer robust

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219 Island Group, "Every vaccination counts", 05.04.2022, 15.06.2022, 20.06.2022, 27.06.2022, https://www.insel.ch/de/patienten-und-besucher/coronavirus/covid-impfzentrum-auf-dem-inselcampus.

220 Island Group, "Facts around COVID vaccination", 09.09.2021, https://www.insel.ch/fileadmin/Inselspital/Bilder/Patienten_und_Besucher/Corona/Fakten_COVID-Impfung_Insel_Gruppe.pdf.

> protection against both severe disease progression and long-term sequelae. "

803 Further statements under #1 "DNA" ("Our genes are not changed by the mRNA vaccine"), #4 "Speed of development of the vaccine" and #5 "Virus variants" also lack any critical appreciation of the mRNA "vaccines" and contain only euphemistic and trivialising "facts".

C. LEGAL

804 In the following examination, the criminal provisions of the TPA are presented in the first section: First, the abstract and concrete endangerment offences of Art. 86 HMG concerning the authorisation of therapeutic products, followed by the offence of Art. 87 HMG concerning the supervision of therapeutic products. Only in the second section do the endangering offences of the SCC follow, and finally in the third section the (more serious) penal provisions of the SCC, all of which are structured as offences of success. The fourth section then deals with the punishable preparatory acts.

I. Penal provisions HMG

805 The penal sanctions of Chapter 8 of the HMG serve to realise the central concerns of the protection of human (and animal) health and the protection against deception.[221] Among other things, they are intended to ensure that only high-quality, safe and effective medicinal products are placed on the market (Art. 1 para. 1 HMG).[222]

806 The dispatch elaborates on the key role of Swissmedic in the areas of authorisation, placing on the market and subsequent market surveillance of therapeutic products:

> "In order to be able to guarantee that only high-quality, safe and effective therapeutic products are placed on the market, an efficient, independent and binding control of therapeutic products for the whole of Switzerland is indispensable".[223]

> "With the creation of a Swiss Institute for Therapeutic Products, the existing forces with their knowledge and experience are to be effectively bundled. [...]. The Institute is primarily responsible for the authorisation and manufacturing authorisation of medicinal products and, in cooperation

221 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Pre 8th chapter N 16.

222 In this regard, Dispatch on a Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of 1 June 1999, BBl 1999 III 3453 et seq., 3456 et seq.

223 Dispatch on a Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of 1 June 1999, BBl 1999 III 3484.

with the cantons, for the subsequent market surveillance of therapeutic products."[224]

"However, safe use also includes ensuring that, as far as possible, no harm is caused by therapeutic products. This is achieved by evaluating the risk-benefit ratio at the time of authorisation, the dosage regulations and information on undesirable interactions with other medicinal products or foodstuffs or in the case of certain genetic dispositions. Information on adverse effects also provides indications in which cases medicinal products should not be used or should be used with particular caution."[225]

1. Violation of due diligence obligations (Art. 86 para. 1 lit. a HMG)

1.1. Offences and crimes against the HMG

1.1.1. Basic offence: abstract endangerment (misdemeanour)

807 According to Art. 86 para. 1 lit. a HMG, anyone who intentionally **manufactures,** places on the market, **uses,** prescribes, imports, exports or trades abroad in medicinal products without the required authorisation or licence, in contravention of the requirements and conditions attached to an authorisation or licence, or in **contravention of the duties of care laid down in Articles 3, 7,** 21, 22, **26,** 29 and 42, is liable to a custodial sentence not exceeding three years or to a monetary penalty.

1.1.2. Qualification: Concrete danger (crime)

808 According to Art. 86 para. 2 lit. a HMG, anyone who knows or must assume that conduct contrary to the duty of care within the meaning of Art. 1 para. 1 lit. a HMG **concretely endangers the** health of people is liable to a custodial sentence not exceeding ten years, which may be combined with a monetary penalty, or to a monetary penalty.

1.2. Basic objective offence (Art. 86 para. 1 lit. a HMG)

809 With regard to **Swissmedic,** the offence variant of **manufacture in** violation of the duties of care set out in Art. 3 HMG and Art. 7 HMG must be examined in particular.

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224 Dispatch on a Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of 1 June 1999, BBl 1999 III 3467.

225 Dispatch on a Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of 1 June 1999, BBl 1999 III 3484.

810 With regard to **doctors, the** offence variant of **use in** violation of the duty of care stipulated in Art. 26 HMG is examined in particular.

1.2.1. Object of crime: medicinal products

811 Medicinal products are products of chemical or biological origin that are intended or advertised to have a medicinal effect on the human organism, in particular for the prevention or treatment of diseases (Art. 4 para. 1 lit. a HMG). In Art. 2 lit. b AMBV, immunological medicinal products are defined as medicinal products "which are used to produce active or passive immunity or to diagnose a state of immunity, in particular vaccines".

812 The COVID "vaccines" are intended as ready-to-use products with a medical - immunological - effect for the prevention of a disease due to infection with SARS-CoV-2,[226] whereby they constitute medicinal products within the meaning of the HMG.

1.2.2. Swissmedic: Crime variant "Manufacture "

813 The offences punishable by law are described in Art. 86 Para. 1 lit. a HMG, whereby Swissmedic is primarily interested in the offence variant of "manufacture":

1.2.2.1 Concerning batches manufactured in Switzerland (Moderna: Spikevax)

814 Manufacture" is defined as "all operations involved in the production of medicinal products, from the procurement of starting materials to processing, packaging, storage and delivery of the final product, as well as quality controls and releases" (Art. 4 para. 1 lit. c HMG). **Batch release** also falls under this.[227] According to the Federal Supreme Court, it is **part of the manufacturing process:**[228] "La libération des lots fait partie du processus de fabrication".[229] If the manufacture of a medicinal product requires special measures, in particular to ensure safety - protection of the legal interest of health -,[230] a release must be obtained from the Swiss Agency for Therapeutic Products for each batch before distribution, according to Art. 17 HMG. According to Art. 18 para. 1 lit. b of the Ordinance of the Swiss Agency for Therapeutic Products on the Requirements for the Authorisation of Me-

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226 On the definition of medicinal product, see EGGENBERGER/KESSELRING, BSK HMG, 2nd ed., Basel 2022, Art. 4 N 8 ff, especially N 22 with specific reference to vaccinations as medicinal products.

227 For the term batch, see Art. 2 lit. h AMBV: "a homogeneous and defined quantity of starting material, medicinal product or packaging material produced in one operation or in a series of operations".

228 EGGENBERGER/KESSELRING, BSK HMG, 2nd ed., Basel 2022, Art. 4 N 159.

229 Federal Supreme Court ruling 2F_17/2019 of 29 December 2019, E. 3.2; see also Federal Supreme Court ruling 2C_600/2018 of 13 May 2019, E. 11.2.

230 BECK / BRAUN, BSK HMG, 2nd ed., Basel 2022, Art. 17 N 10.

dicinal Products (Ordinance on the Authorisation of Medicinal Products, AMZV; SR 812.212.22), "vaccines" are subject to batch release. The assessment of a batch is usually carried out by the OMCL within 30 days after submission of the manufacturer's batch documentation and the samples by the marketing authorisation holder.[231] If the quality requirements are fulfilled, Swissmedic (or its Official Medicines Control Laboratory [OMCL]) issues the batch release and a certificate to the marketing authorisation holder (Art. 21 para. 1 AMZV). [232]

815 Swissmedic granted Lonza an operating licence[233] for a new production site ("Ibex Solutions", Valais) for the manufacture of Moderna's COVID-19 active ingredient in Switzerland at the beginning of January 2021 and finally on 15 March 2021.[234] Subsequently, Lonza manufactured the mRNA active ingredient Spikevax for Switzerland and for all of Europe.[235] The batches released by Swissmedic were published publicly until September 2021.[236] After that, Swissmedic discontinued publication without giving any reasons.[237] At the same time, the batch releases from January 2021 to August 2021, which had apparently been published publicly until then, were retroactively taken offline.[238] Since around May/June 2022, Swissmedic no longer publishes the batch releases on its own website, but refers to the "Open Government Data" website[239] - without, however, publishing the batch releases for the "COVID-19 vaccines" there.[240]

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231 Swissmedic, Laboratories Division (OMCL) "Behördliche Chargenfreigabe von Impfstoffen und Blutprodukten", Status 16.06.2021, *https://www.swissmedic.ch/dam/swissmedic/de/dokumente/bewilligungen/labor_omcl/23_vz_03_d_behoerdlichechargenfreigabe.pdf.download.pdf/23_vz_03_d_behoerdlichechargenfreigabe.pdf*, p. 4; BECK / BRAUN, BSK HMG, 2nd ed., Basel 2022, Art. 17 N 19.

232 BECK / BRAUN, BSK HMG, 2nd ed., Basel 2022, Art. 17 N 14 f.

233 See Art. 3 ff., Art. 39 ff. AMBV.

234 Swissmedic, "Swissmedic grants Lonza in Visp a further operating licence for the production of COVID-19 active substances", 15.03.2021, https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/lonza-weitere-betriebsbewilligung-produktion-covid-19-ws.html.

235 Huszno, "Moderna - COVID-19 vaccine produced in Switzerland", 14.04.2021, https://houseofswitzerland.org/de/swissstories/wissenschaft-bildung/moderna-der-schweiz-hergestellter-covid-19-impfstoff.

236 Until September 2021 to be found at: Swissmedic, "Released batches, COVID-19 vaccines", 06.05.2022, https://www.swissmedic.ch/swissmedic/de/home/services/omcl-lab/freigegebene_chargen.html.

237 Swissmedic, "Batch releases: COVID-19 vaccines", 14.09.2021: "The public publication of the released batches has been discontinued as of September 2021. Authorised persons should contact notification@swissmedic.ch for information", https://www.swissmedic.ch/dam/swissmedic/de/dokumente/bewilligungen/labor_omcl/chargenfreigaben_covid-19_impfstoffe.pdf.download.pdf/Freigaben_Covid-19_Impfstoffe.pdf.

238 Swissmedic, "Batch releases July 2021 - Screenshot document properties" (last modified 16 September 2021 at 08:39:58), cf. Swissmedic, "Released batches 2021 - Screenshot last modified 01.02.2022", https://www.swissmedic.ch/swissmedic/de/home/services/omcl-lab/freigegebene_chargen/2021.html.

239 Swissmedic, "Freigegebene Chargen", 10.06.2022, https://www.swissmedic.ch/swissmedic/de/home/services/omcl-

816 **Swissmedic is responsible for the release of the vaccine batches manufactured in Switzerland, has evidently also granted the corresponding releases and is still granting them. The competent persons acting on behalf of Swissmedic thus fulfil the offence of "manufacturing" within the meaning of Art. 86 para. 1 lit. a HMG, insofar as the batches of the mRNA "vaccine" from Spikevax (Moderna) manufactured in Switzerland are concerned.**

1.2.2.2 Regarding imported batches (probably Pfizer: Comirnaty): MRA recognition ?

817 The production sites of the Comirnaty (Pfizer) batches intended for Switzerland are not known in detail to the complainants. At least in Switzerland - subject to error and the release of the batch release protocols (see above N 79 f.) - there does not seem to be one. Accordingly, it must be assumed that Comirnaty is manufactured entirely abroad and imported into Switzerland.

818 Insofar as the **production of** the imported Comirnaty batches took place **in the EU**, a direct batch release by Swissmedic is no longer necessary: According to Art. 17 para. 1 sentence 2 HMG, "international agreements on the recognition of batch releases" are reserved. One such agreement is the bilateral agreement between the Swiss Confederation and the EU/EEA on mutual recognition in relation to conformity assessment (MRA) of 21 June 1999. This provides for mutual recognition of official batch release for products that have been industrially manufactured in Switzerland or in the EU (Chapter 15 and Explanatory Notes to Chapter 15),[241] the so-called MRA recognition procedure.

819 According to this, Swissmedic can also issue the batch release certificate (Art. 21 para. 1 AMZV) on the basis of a batch release from an EU authority, provided that the industrial production of the preparation has taken place in the EU/EEA area (Art. 21 para. 2 AMZV).[242] This means that for medicinal products which are subject to official batch release in Switzerland and at least in one EU state and which have already been tested and released by an OMCL of an EU member state, no additional sample testing is carried out by the OMCL and the batch release of the EU OMCL is fully recognised if these medicinal products are to be placed on the Swiss market. **According to the agreement, only one notification of the batch is made by the marketing authorisation holder to the OMCL.** Within 7 working days of receipt of the necessary documents (Marketing Infor-

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lab/freigegebene_chargen.html. Cf. shortly before: Swissmedic, "Freigegebene Chargen", 06.05.2022.

240 Opendata.swiss, "Released batches", 01.05.2022, https://opendata.swiss/de/dataset/freigegebene-chargen.

241 Agreement between the Swiss Confederation and the European Community on mutual recognition in relation to conformity assessment (SR 0.946.526.81).

242 BECK / BRAUN, BSK HMG, 2nd ed., Basel 2022, Art. 17 N 14b.

mation Form, MIF, copy of the EU Batch Release Certificate and, if applicable, a Certificate of Analysis) by the OMCL, the marketing authorisation holder receives confirmation by e-mail that the batch can be distributed in Switzerland. [243]

820 The **MRA recognition therefore substitutes the actual batch testing.** Like the batch test, however, the MRA recognition procedure is the indispensable prerequisite for the authorisation of the mRNA "vaccines" to be imported onto the Swiss market. The batch release - or in this case: the MRA recognition - does not replace the authorisation of a medicinal product according to Art. 16 ff. HMG.[244] In individual cases, official batch release can also be a condition of a marketing authorisation decision.[245] If Swissmedic had sufficient reason to withdraw the marketing authorisation granted to Pfizer/BioNTech for Comirnaty in the context of the MRA recognition of a batch, then no MRA recognition of the batch should have taken place.

821 The opposite view would have the consequence that the manufacturer's status would depend in a random way on where a medicinal product is produced: If it is produced within Switzerland or outside the EU, Swissmedic is the "manufacturer" - if it is produced within the EU, Swissmedic could attempt to evade responsibility as the manufacturer. This would open the door to circumvention of the safety mechanisms under medicines law. For the Swiss market, however, Swissmedic is **the "gatekeeper" envisaged by the legislator: by delegating elementary supervisory and testing duties such as batch testing to a foreign authority, Swissmedic cannot absolve itself of its own responsibility.**

822 **As the final and highest supervisory authority, Swissmedic also remains responsible for the release of vaccine batches not manufactured in Switzerland.** Thus, the competent persons acting on behalf of Swissmedic also fulfil the definition of "manufacturing" within the meaning of Art. 86 para. 1 lit. a HMG with regard to Comirnaty (Pfizer/BioNTech).

1.2.2.1 Supplementary: "Importation" and "Placing on the market

823 If - contrary to the case law of the Federal Supreme Court - the view is taken that **Swissmedic is** not considered to be a "manufacturer", then the other offence variants of "import" and "placing on the market" in particular would have to be examined in detail.

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243 Swissmedic, Laboratory Division (OMCL) "Behördliche Chargenfreigabe von Impfstoffen und Blutprodukten", Status 16.06.2021, *https://www.swissmedic.ch/dam/swissmedic/de/dokumente/bewilligungen/labor_omcl/23_vz_03_d_behoerdlichechargenfreigabe.pdf.download.pdf/23_vz_03_d_behoerdlichechargenfreigabe.pdf*, p. 4 f.; BECK / BRAUN, BSK HMG, 2nd ed., Basel 2022, Art. 17 N 11, N 14b, N 29 ff.

244 BECK / BRAUN, BSK HMG, 2nd ed., Basel 2022, Art. 17 N 3.

245 BECK / BRAUN, BSK HMG, 2nd ed., Basel 2022, Art. 17 N 3.

1.2.3. Swissmedic: "Due diligence obligations under Art. 3 and Art. 7 HMG" offence variant

824 The duties of due diligence that are subject to penalties are also defined in Art. 86 para. 1 lit. a of the TPA, whereby the duties of due diligence under Art. 3 of the TPA (general duty of due diligence) and Art. 7 of the TPA (duty of due diligence for manufacture) are of primary interest to Swissmedic. In principle, the duties of care contained in the implementing provisions issued on the basis of the TPA are also covered. The **duties that are** punishable are those that are **intended to prevent hazards to human health.**[246] In principle, anyone can be a perpetrator; even **limited actions (division of labour) are sufficient** as contributions to the offence and are to be included in the offence.[247] However, insofar as specific (due diligence) duties are involved, only the bearers of these duties can be considered as perpetrators.[248] The duties of care are breached if they are not fulfilled in **full and on time.**[249]

1.2.3.1 Art. 3 HMG - (general) duty of care

825 Anyone handling medicinal products must take all measures required by the state of the art in science and technology to ensure that the health of humans and animals is not endangered (Art. 3 para. 1 HMG).

826 In particular, authorities such as Swissmedic as the authorisation and supervisory authority are also considered as addressees of the general duty of care.[250]

827 Art. 3 is the general duty of care standard. The general clause of Art. 3 HMG only applies if (1) when handling a therapeutic product (2) a duty of care required by the current state of science and technology has been breached and (3) as a result, i.e. adequately causally, the health of a person has been endangered in a concrete or abstract manner.[251] Increased requirements are to be placed on the violation of the required or conceivable duties of care - similar to the application of the risk phrase[252] . It is not sufficient that a lack of due diligence is immediately inferred from an actual health risk.[253]

828 The handling of medicinal products should not pose a health risk to humans, which already follows from Art. 1 HMG.[254] Safety is at the centre of this: this is not only striven

246 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 27.
247 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 84, N 86.
248 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 86.
249 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 29.
250 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 37b.
251 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 59a/60.
252 To this at the back N 1035 ff.
253 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd edition, Basel 2022, Art. 3 N 74.
254 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd edition, Basel 2022, Art. 3 N 13.

for in Art. 1 and 3 of the HMG, but is declared an explicit requirement for the authorisation of medicinal products in Art. 3 para. 1 HMG.[255] Absolute safety cannot be achieved and therefore cannot be demanded.[256] When dealing with therapeutic products, however, there is an **obligation to minimise risk,** which requires that appropriate risk analyses are carried out.[257] The **risk profile of a therapeutic product must therefore** be **reviewed on an ongoing basis.** This must be done by systematically weighing and assessing the risks and benefits of a remedy. The efficacy must be put in relation to the risks and undesirable effects, whereby in individual cases the **benefits must outweigh the disadvantages.**[258] Only when this assessment results in an **acceptable risk of** the medicinal product may it be **described as "safe" within the** meaning of the HMG.[259] As long as the benefits exceed the risks in the individual case, a risk to health is acceptable and does not constitute a breach of due diligence.[260]

829 Accordingly, the core of the risk analysis required under Art. 3 HMG is the **regular, systematic, forward-looking search for hazards.**[261] This means that the requirements for the duty of care are based on the **current** state of science and technology - and not, for example, on the state at the time of the initial authorisation of the medicinal product.[262] The current **findings of theoretical science and** the current empirical **values of practice are to** be taken into account.[263] **And this also means that this search for hazards must be actively pursued**. Swissmedic must therefore not wait until other state agencies or a manufacturer or another authorisation authority abroad approach Swissmedic and present it with evidence of an overriding risk.

830 In keeping with the principle of proportionality, all measures must therefore be taken proactively to avoid a health hazard, if and to the extent that they are necessary to protect public health.[264] In particular, this also means that information on undesirable side effects must be provided **transparently in** the specialist (Art. 13 and Annex 4 AMZV) and patient information (Art. 14 and Annex 5 AMZV).[265] If this is not done, justified safety expectations are violated and **existing residual risks** are concealed. [266]

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255 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd edition, Basel 2022, Art. 3 N 14.
256 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd edition, Basel 2022, Art. 3 N 14.
257 Dispatch on a Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of 1 June 1999, BBl 1999 III 3453 ff, p. 3487.
258 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 17, cf. also N 24.
259 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd edition, Basel 2022, Art. 3 N 18.
260 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd edition, Basel 2022, Art. 3 N 24.
261 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 56 f.
262 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd edition, Basel 2022, Art. 3 N 42.
263 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd edition, Basel 2022, Art. 3 N 43.
264 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 50 ff.
265 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd edition, Basel 2022, Art. 3 N 14.
266 Cf. JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 54 f.

831 **However, if essential information on the lack of efficacy or the lack of safety of mRNA "vaccinations" is withheld from the public or is not communicated with the required clarity, then each individual** benefit/risk assessment **based on this erroneous information** and ultimately the resulting and each individual **consent to "vaccination" must be considered ineffective if** it would have been withheld with full knowledge of all the facts.[267]

832 The standard of care for the information on medicinal products is specified in more detail in Art. 28 VAM, among others, in concretisation of the general duty of care of Art. 3 HMG: According to this, the marketing authorisation holder is obliged to adapt the **information on** the **medicinal product to** the **current state of science and technology as well as to new events** and assessments on an ongoing basis and without being asked to do so.[268] If, for example, the risk assessment has changed after marketing authorisation, this must necessarily lead to an adjustment of the information on the medicinal product: Under normal circumstances - i.e. for properly authorised medicinal products - the inclusion of newly discovered adverse reactions is mandatory in Switzerland and the EU if a causal relationship between the administration of the medicinal product and the adverse reaction can at least be reasonably assumed ("Adverse Drug Reaction" [ADR]).[269] The **requirement of a presumption of causality** makes perfect sense in the area of properly authorised or simplified authorised medicinal products, as these have been tested on humans for many years and many side effects could already be determined before authorisation. However, the situation is completely different in the case of **mRNA "vaccines" that have been approved for a limited period of time on the** basis of completely insufficient data and a complete lack of long-term human trials: **The search could essentially only begin after approval. Under these circumstances, the principle of prudence dictates that all side effects that have occurred be recorded in a particularly strict manner and reported to the public.**

833 The borderline to just permissible passivity in the area of the recording and publication of adverse drug reactions is crossed at the latest when there is **a risk of misleading the public:** if experience, findings and assessments in practical implementation show that, for example, a statement in a medicinal product information is misunderstood by experts, the marketing authorisation holder, together with the **Institute,** must **immediately ensure** that clarity is created by **eliminating the risk of misleading the public through necessary clarifications**. [270]

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267 See on information and consent in detail below N 859 ff. and N 1118 ff.
268 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 11.
269 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 10.
270 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 65, Art. 32 N 35.

1.2.3.2 Art. 7 (Requirements for production)

834 Art. 86 para. 1 lit. a HMG explicitly refers to Art. 7 HMG. In Art. 7 para. 1 HMG and in Art. 4 of the Medicinal Products Licensing Ordinance (AMBV), the general standard of care for the **manufacture of a medicinal product is** specified in more detail.[271] According to Art. 7 para. 1 HMG, medicinal products and pharmaceutical excipients whose manufacture requires a licence must be manufactured in accordance with the recognised rules of good manufacturing practice (Art. 7 para. 1 HMG).

835 Accordingly, the legislator refrains from regulating this special field on its own and limits itself to declaring technical standards as legally binding.[272] The rules of good manufacturing practice are concretised accordingly at ordinance level (AMBV) with reference to the European directives. Despite these further references, the Federal Supreme Court assumes that the **HMG thus satisfies the requirement for certainty**.[273] In view of the target group of the TPA - qualified persons from the therapeutic products sector - the doctrine also assumes that the requirement of certainty has been satisfied. This is especially true in view of the fact that "the complexity of the regulation of therapeutic products is due to the complexity of the subject matter and that there are no reasonable alternatives to the currently practised method of graduated legislation in the area of therapeutic products".[274]

836 The rules of good manufacturing practice contain regulations that must be ensured throughout the entire manufacturing process and can basically be divided into nine categories: **Quality assurance system,** sufficient and qualified personnel, suitable premises and equipment, documentation obligation, clearly defined production processes, independent **quality control,** clear contract design, complaint and recall system, self-inspection.[275] Although these rules are formally related first and foremost to **quality**, according to the Federal Supreme Court, the other elements of **safety and efficacy mandated** by Art. 1 HMG must of course also be guaranteed at all times.[276]

837 The elements of quality assurance and quality control mentioned above are particularly important here: the manufacturer must effectively ensure that the medicinal products are of the required quality (as well as safety and efficacy) for use.[277] This includes minimising the risk of errors in order to **avoid impurities**, cross-contamination and, in general, effects

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271 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd edition, Basel 2022, Art. 3 N 61.
272 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd edition, Basel 2022, Art. 3 N 48.
273 Federal Supreme Court ruling 6B_600/2020 of 07.09.2020, E. 5.6.
274 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 17.
275 DUPASQUIER/BOEHM, BSK HMG, 2nd ed., Basel 2022, Art. 7 N 5 ff.
276 Judgement 2C_424/2018 of the BGer of 05.03.2019, E. 3.3., E. 3.5.1; on this DUPASQUIER/BOEHM, BSK HMG, 2nd ed., Basel 2022, Art. 7 N 5.
277 DUPASQUIER/BOEHM, BSK HMG, 2nd ed., Basel 2022, Art. 7 N 6.

affecting the quality of the product.[278] As part of the **quality control process, it** must be ensured that the necessary tests are carried out, for example as part of the **release procedure,** and that **no products are released for delivery until their quality (and safety and efficacy) has been assessed as satisfactory. Samples of each batch of** a starting material or a finished product must be **kept for** a certain period of time.[279] Swissmedic thus has the key role in the area of quality control within the framework of batch release: without its release, the products do not reach the market.

1.2.4. Swissmedic: Due diligence obligations under the Therapeutic Products Act violated several times

838 Accordingly, Swissmedic is obliged under Art. 3 HMG and Art. 7 HMG to review the risk-benefit profile continuously, comprehensively and in a timely manner for each authorisation of mRNA "vaccines" and the batch releases granted on the basis of this as part of the manufacturing process. In doing so, Swissmedic is required to search for hazards regularly, systematically and with foresight. The benefit of the "vaccines" must always outweigh the risk incurred, with a mandatory obligation to minimise the risk. For each batch release, it must therefore be ensured that the quality and safety requirements are at least met - and that the medicinal product is ideally also effective. In addition, Swissmedic is required to inform the public transparently at all times, in particular about side effects and contra-indications, in accordance with the current state of theoretical science and empirical values in practice; misleading reports must be removed and clarified immediately.

839 Swissmedic violated each and every one of these due diligence obligations of Art. 3 and 7 HMG:

1.2.4.1 Breaches of duty on first registrations adults (end 2020)

840 At the end of 2020 and beginning of 2021, Swissmedic granted the "temporary" marketing authorisation for Comirnaty and Spikevax respectively for all adults aged 18 and over ("first and second vaccinations") in a fast-track procedure: The applications for approval were "reviewed" **in only 63 calendar days**. An ordinary procedure would take 330 days, a procedure for "temporary authorisation" usually 140 days, **whereby in the omission of all possible safety mechanisms** ("List of Questions", waiving of elementary studies on quality and safety) a **maximum deviation from an ordinary authorisation procedure** was made (see above N 619 ff.). This is how Swissmedic handled the **matter,** although

278 DUPASQUIER/BOEHM, BSK HMG, 2nd ed., Basel 2022, Art. 7 N 8 with reference to ruling 2A.156/2004 of the Federal Supreme Court of 25.03.2004, E. 2.2, and ruling C-3214/2009 of the Federal Administrative Court of 10.06.2010.

279 DUPASQUIER/BOEHM, BSK HMG, 2nd ed., Basel 2022, Art. 7 N 11.

the following **risk-increasing and therefore legally relevant facts** were already known to the licensing authority at the time, or must have been known beyond reasonable doubt, namely:

- that the technology in question was a novel mRNA technology, also known as **gene therapy**, which until now had only been used in individual cases in cancer patients, i.e. only in severely pre-diseased people and only on an experimental basis. Even in the context of this use, no relevant efficacy has been demonstrated to date, and no pharmaceutical product with mRNA technology has ever received marketing authorisation for purely prophylactic use in healthy population groups (see N 142 ff.).
- that mRNA "vaccines" for healthy people therefore represented an absolute **abnormality in** comparison to all other medicinal products that had previously been authorised properly or "for a limited period" (see above N 587 ff., esp. N 596 ff.),
- that the present new mRNA technology is characterised by the fact that the production process of the actual active substance (the spike protein) is transferred to the human body, whereby **this active substance would not be produced itself without this intervention, and no sufficient empirical data were available which made this endogenous production of the spike protein and its novel mode of action in the body appear to be controllable with** regard to: (1) duration of production (2) location in the body (organs affected); (3) quality; (4) quantity of production as well as with regard to (5) the efficacy and safety of the active substance produced for the otherwise healthy population (above N 143 f.; cf. also N 750 ff.),
- that this medicinal product, in the absence of evidence of an immunising effect, can in no way be qualified as a vaccination in the conventional sense (see above N 354 ff., N 433 ff., N 650 f.),
- that, due to the lack of controllability of the dosage and quality of this medicinal product and due to the lack of sufficient evidence of a significant protective effect against infection with SARS-CoV-2, the most essential requirements for a general marketing authorisation for prevention for a healthy population were clearly not fulfilled, neither for a proper (see above N 497 ff., esp. N 630) nor for a "temporary authorisation" (N 584 ff., N 619 ff., esp. N 633 ff.),
- that to date the suspicion that this medicinal product could even be a **genetically modified organism has** by no means been sufficiently dispelled with certainty (see N 148 ff.), which should never have been approved within the framework of a "limited authorisation" (N 551 ff., N 599 f.),
- that the mRNA "vaccines" with the **toxic lipid nanoparticles** (LNP) contain new ingredients that have not yet been tested and have not previously been approved in

humans, which**, according to the manufacturer's description,** can presumably cause cancer, presumably impair fertility and harm the child in the womb - and damage the central nervous system, kidneys, liver and respiratory system with prolonged or repeated exposure (front N 155 ff.),

- that despite this unresolved suspicion of the presence of a genetically modified organism and **the** reported toxic properties of LNP, **no animal studies on genotoxicity and carcinogenicity** had been carried out (N 180 ff.),
- that the mRNA "vaccines" with nitrosamine, benzene and bacterial DNA contained **toxic, mutagenic and carcinogenic impurities** (front N 165 ff.), which, until proven otherwise, gives rise to the urgent suspicion that the **quality** (Module 3: including purity) of the "vaccines" is already insufficient (N 505 ff.),
- that preclinical studies (animal studies) had identified a **possible risk in pregnancies** (twofold increase in pre-implantation losses, malformations), which is why the Human Medicines Experts Committee (HMEC) commissioned by Swissmedic at the end of 2020 urgently advised that "Pregnancy" be listed under **"Precautions" in the** product information (front N 172 ff.), which Swissmedic subsequently failed to do,
- that in animal studies on pharmacokinetics, an accumulation of toxic lipid nanoparticles (LNP) had been found in the liver, spleen and other organs such as the ovaries (front N 185 ff.),
- that marketing authorisations for novel medicinal products are normally only granted on the basis of clinical trials with an observation period of 24 months, but that the study participants in the mRNA "vaccines" were only observed for a **mere two months in the** clinical approval trials (see N 176 ff.; for the proper development of a drug see N 498 ff.),
- that in these same clinical approval studies there were already clear risk signals such as **indications of increased morbidity in the vaccination group** (front N 189 ff.),
- that these very same **clinical approval studies** had been unblinded by the manufacturers, thus de facto aborted and thus themselves **sabotaged** (see above N 192 ff.), which, in the absence of a control group, made it highly improbable - if not downright impossible by the manufacturer - that useful and complete data would ever be available, which, however, would be a mandatory prerequisite for a time-limited authorisation (ff. N 674 ff.),
- that there were already indications of possible **late effects such as blood diseases, neurodegenerative diseases or autoimmune diseases** (especially ADE) at the end of 2020 (front N 195 ff.),
- that the studies submitted by the manufacturers (both studies with animals and those with humans) were completely insufficient in qualitative and quantitative terms to be

able to provide sufficient proof of a significant protective effect and safety (front N 179 ff.),

- that against the background of the facts listed above, a release of the mRNA "vaccines" for the entire population by means of a "limited" authorisation within the meaning of Art. 9a HMG in December 2020 would mean nothing other than that the Swiss population **would** participate without their knowledge in the largest clinical experiment **ever conducted in Switzerland** (and at the same time worldwide) (see above N 198 f.),
- that Swissmedic, with the "temporary" authorisation of the mRNA "vaccines", consequently took an **unprecedented risk for the** public health of the entire population aged 18 and over, which could at best only be justified by the fact that it could have averted an unprecedented immediate and maximum threat (from SARS-CoV-2) for this very population, for which there were no other healing and prevention options at the time of authorisation,
- However, at no time did "COVID-19" pose a "life-threatening or disabling" disease or threat to the general public as a whole, which would have been *the* main prerequisite for a "temporary approval", since the worldwide lethality of SARS-CoV-2 of **0.15%-0.20% (IFR)** already corresponded to that of moderate influenza at the end of 2020, and no mortality rate for any age group in Switzerland was significantly higher than the maxima of the last 10 years (see N 480 ff.).

841 Swissmedic thus authorised a highly experimental and dangerous medicinal product against a disease that did not pose a significant threat to the population as a whole. Therefore, and in view of the very manageable threat situation in connection with SARS-CoV-2, which can be very well controlled with alternative methods of prevention and treatment, a "gene therapy" with the maximum risk potential summarised above, which has not yet been sufficiently tested on humans, should never have been authorised.

842 As the last "lifeline", Swissmedic was left with only the evidence that a "major therapeutic benefit" for protection against SARS-CoV-2 could have been expected for the somewhat higher-risk target population of elderly and pre-sick people". But this was clearly not the case either, as it was already known in December 2020,

- that the "vaccinations" should protect against serious (fatal or disabling) diseases - but in the (still ongoing, but sabotaged) approval studies it was primarily investigated whether the "vaccinations" protect against headaches and other trivial incidents (see N 202 f.),
- that the reported efficacy figures of up to 100% only referred to **minor events** and were based on calculations that in no way reflect reality, which is why - if at all - an **ef-**

ficacy in the low single-digit percentage range had to be assumed (see above N 204 ff.),

- that the **proof of protection against severe disease had not been even approximately provided in a single study,** especially since the few cases investigated were in the realm of statistical chance (front N 210 ff.),
- that "vaccinations" must "immunise" in the long term (front N 650), which, however, in view of the "booster vaccinations" planned from the beginning (front N 362) and the large-scale occurrence of so-called "vaccination breakthroughs", this was an unattainable goal.

843 Swissmedic has thus authorised a medicinal product on the Swiss market whose **risk-benefit profile** was **devastatingly negative from the outset.** Against this background, the plan to authorise mRNA "vaccines" for all adults in Switzerland from December 2020 must be qualified as a **project with maximum, unprecedented risk content,** whereby the **lack of protective effect of the** mRNA "vaccines" was apparent from the outset. A risk that had never been taken before was therefore offset by a benefit that was not measurable or barely measurable - especially since there was clearly no sufficiently threatening disease for the population as a whole.

844 This consideration alone should have led to the compelling conclusion that the mRNA "vaccines" should not be authorised, which is why the authorisations that were nevertheless granted *per se* represent a **massive breach of the duty of care on the part of Swissmedic** and created considerable new dangers for public health in Switzerland, which would not have threatened the vast majority of the population without this authorisation of the mRNA substances, or through SARS-CoV-2 alone.

845 At the same time, however, Swissmedic did not take **any sufficiently risk-reducing measures** to minimise the risk to the general population posed by these mRNA "vaccines", which were authorised against the law and against the recognised rules of good manufacturing practice. In **particular, Swissmedic failed (1) to provide transparent information to the population and (2) to ensure rigorous monitoring:**

- In the context of market surveillance, Swissmedic was content with a purely passive reporting system (see above N 686 ff.), which in the case of a completely new active substance, which is still in the phase of the first human trials ever, can in no way be considered adequate in terms of risk, or is simply insufficient - especially as the problem of "underreporting" in passive reporting systems has been known for a long time (see N 307 ff.; above N 689 f.). **Instead, the mRNA "vaccines"** should **have been subjected to active pharmacovigilance - as under study conditions - from the**

very beginning (on the requirements for a functioning reporting system see above N 534 ff.; on the violation of the reporting obligations, see N 901 ff. , esp. N 911).

- On 19 December 2020, Swissmedic announced in the media regarding the authorisation of Comirnaty: "This is the world's first authorisation in an **ordinary** procedure". To publicly announce that the authorisation had been granted in an "ordinary" procedure, although the requirements for an ordinary authorisation had been undercut to the maximum extent possible, is simply untenable and a **brazen misleading of the population.** Since this misinformation comes from the supreme control and licensing authority itself, the resulting misleading effect on the will formation of large parts of the population is particularly great. In view of the true facts, it is an **outright lie,** which many people mistakenly believe to be true to this day - after all, this communication is still publicly available (front N 702 f.).
- It was already clear to Swissmedic at the time of the initial authorisations that the manufacturers had *de facto* broken off and sabotaged their own authorisation studies by dissolving the control groups (unblinding of the clinical studies) (front N 192 ff.; ff. 691 ff.). The manufacturers will obviously not be in a position to ever provide complete data (see above N 674). The waiver of this elementary requirement is simply not justifiable in any way, and Swissmedic's approval of this illegal procedure constitutes a serious violation of Art. 9a TPA (and Art. 3 TPA).
- In the technical information for Comirnaty, Swissmedic published in December 2020 that "no vaccine-related effects on female fertility, pregnancy or embryo-fetal development or on the development of the offspring have been observed" (front N 704 f.), which is in stark **contradiction to the study results of** the manufacturers and to explicit warnings issued by its own expert panel. Swissmedic has thus even thrown well-founded **manufacturer and expert warnings to the** wind.
- Moreover, it was already clear to Swissmedic by the end of 2020 that the animal studies on toxicity and pharmacokinetics were completely inadequate or even completely lacking, although they did contain initial risk signals (such as indications of accumulation of toxic lipid nanoparticles [LNP]). Despite this, Swissmedic prematurely announced**, without any evidence, in a misleading** and publicity-effective **manner,** that components of the vaccine could **"not be expected" to be mutagenic** and/or carcinogenic, or that there were **"no indications" of an** accumulation of LNP (see above N 180 ff., N 185 ff., N 726 f., N 728).
- Furthermore, Swissmedic posted an **"FAQ"** on its own website directed at the population, which **contained countless misleading pieces of information** that Swissmedic was able to recognise as clear misinformation on the basis of the data already available internally at the end of 2020 (see N 737 ff.).

846 The data situation as of the end of 2020 is based primarily on the information provided by Swissmedic for publicity purposes and Pfizer's marketing authorisation documents, which have been published only very sparsely to date; as far as can be seen, Moderna's marketing authorisation documents are not available to the public in any form. The present list of serious violations of due diligence obligations under the law on medicinal products is therefore likely to be considerably extended once all marketing authorisation documents have been secured and evaluated (on the corresponding application, see N 74 ff.) will be considerably longer. Even without this additional information, however, there is clearly a strong suspicion that **the persons acting on behalf of Swissmedic** had **already grossly breached their duties of care by the end of 2020,** thereby enabling the health of an increasingly large proportion of the population to be endangered.

1.2.4.2 Breaches of duty in case of extension to juveniles (June 2021)

847 Without effectively counteracting the breaches of due diligence described above - i.e. without eliminating them or compensating for them through appropriate measures (information of the population; monitoring) - Swissmedic took the step in June 2021 of extending the authorisations to adolescents aged 12 and over. And this despite the fact that, in addition to all the previous risk-increasing and therefore legally relevant facts, it was known until mid-June 2021,

- that the approval was given for adolescents, although this target population with a mortality of **0.002% (IFR) was** never at significant risk from SARS-CoV-2 (and also the mortality data from Switzerland provided no evidence of an exceptional threat from SARS-CoV-2 to this very population group; N 483),
- that in the approval studies, in view of the complete lack of "danger" of SARS-CoV-2, accordingly not **a single young person was seriously ill with Corona, with the** result that the **"vaccinations" could not fulfil the legal purpose from the outset** (because there was no protection against "life-threatening or disabling illness") and any approval for young people was therefore unlawful (see above N 256 f.),
- that the efficacy data of up to 93% provided by the manufacturer again only referred to **minor events** and were based on figures that were in the realm of statistical coincidence, which makes any efficacy calculation based on them dubious, unscientific and misleading (see N 254 f.) - and thus once again showed that these medicines, due to their lack of immunising effect, should never have been qualified and approved as vaccination in the conventional sense,

- that the dose approved for adolescents was **half** (Comirnaty) or **five times (**Spikevax) **higher than the recommended dose** (front N 221 f.), once again posing a completely unnecessary risk to adolescents,
- that in the case of Comirnaty alone, by February 2021 - i.e. within a few months - a total of **42,086 side effects and 1,200 deaths** had been reported (front N 223 f.), which in earlier times (approx. 5,000 serious side effects or approx. 50 deaths) would have led to the **immediate withdrawal of** the corresponding drug or the **immediate termination of the study** (front N 243 f.),
- that by June 2021 the worldwide reports of side effects (524,438) and deaths (7,855) had already reached a level (front N 226 f.), at which the **aforementioned alarm value of 50 deaths** - which would have to lead to the immediate termination of the study or withdrawal of approval - had already been **exceeded by a factor of over 150,**
- that at least 50 **peer-reviewed** studies had already shown a link between the mRNA "vaccines" and serious side effects such as heart problems, thrombosis and death (front N 250 f.).

848 The high risk potential of the "vaccines", which had already been identified at the time of their initial approval in December 2020, **had been** realised in the most impressive way by June 2021, with **all alarm levels being exceeded:** thousands of people died in close connection with the administration of the mRNA "vaccines", tens of thousands suffered severe side effects. This development was not only reflected in absolute numbers but was also very strikingly reflected in the alarmingly large increase in the rates of severe side effects and deaths **per million doses administered by** June 2021 (front N 228 ff.).

849 Despite this serious development, Swissmedic again failed to provide the public with **unambiguous and truthful information** on the **risk factors that were** already known from the outset and those that have been added since December 2020, and **even published misleading information once again:**

- On 7 May 2021, Swissmedic issued a media release stating that there were **"no international indications" of an increased rate of deaths** after mRNA injection - which, in view of the **high reporting rates of 17.1-32.1 deaths per million doses administered** worldwide (front N 228), this once again constituted **blatantly misleading information to the public (front** N 729 ff.).
- In the same press release, Swissmedic also stated that as a result of the suspicious reports "a clearer picture of the safety of the vaccines" was available and that nothing had changed in the "known positive benefit-risk ratio" (front N 733). These empty assertions have nothing in common with the reality of the escalating reports of side ef-

fects - once again, it is a consistently **whitewashing, untrue and misleading representation of the actual situation.**

850 Instead of immediately removing the toxic, presumably carcinogenic and potentially mutagenic drugs from the market, their **authorisation** was **extended in a further risk-increasing and misleading way** - by spreading false information and allowing young people who were in no way threatened by SARS-CoV-2 to be "vaccinated" with the same demonstrably dangerous substances in the same high - potentially lethal - dose.

851 Accordingly, there is also a strong suspicion in mid-2021 that **the officers acting on behalf of Swissmedic** had **grossly breached their duties of care.**

1.2.4.3 Breaches of duty in case of admission "Booster" / children (end 2021)

852 Without finally effectively countering the breaches of due diligence described above, Swissmedic took the step at the end of 2021 of extending the authorisations to a third dose ("booster") and to children from the age of five. And this despite the fact that, in addition to all the previously listed risk-increasing and therefore legally relevant facts, it was known until the end of 2021,

- that the **presence and mode of action of the toxic spike protein** in the human body, **which cannot be controlled in** terms of time, quantity and quality, presumably leads to a large number of serious side effects (including death) (foregoing N 265 ff.),
- that the rules of *"Good Clinical Practice (GCP)"* were violated several times in the Comirnaty pivotal **study**, and that **data** were even **falsified,** which means that the data integrity of the Pfizer/BioNTech pivotal study can hardly be guaranteed (see N 271 ff.),
- that **Pfizer/BioNTech** had **even falsified death reports in order** to hide the fact that **more deaths** occurred in **the vaccine group** than in the placebo group (front N 274 ff.),
- that in Comirnaty, **four times more adverse events** and almost two times more serious adverse events occurred in the **vaccine group as a** result of the medication than in the placebo group (front N 277 ff.),
- that **Pfizer/BioNTech** had presented an alarming interim report ("PSUR") at the end of August 2021, according to which **46 cases** had ended **fatally in the clinical trials** and **5,115 cases (1.6%)** had ended **fatally in the** so-called **"post-marketing phase"** (front N 280),

- that **Pfizer/BioNTech** in this same interim report ("PSUR") concerning the effect of the "vaccination" on frail patients with concomitant diseases explicitly pointed out the complete lack of data ("missing information") (see N 282 ff.),
- that **Pfizer/BioNTech** stated in this same interim report ("PSUR"), contrary to all the data already available at that time on reported side effects, that reports of **thromboses** or **herpes zoster,** for example, would not represent risk signals (front N 285),
- that the data on the "booster" with Spikevax is extremely thin, but the few data already revealed the severe and potentially **frequent side effect of pericarditis** (front N 287),
- that, according to initial investigations, the individual vaccine batches were responsible for the occurrence of serious side effects to a highly variable extent, which indicates **uneven production and** thus a **serious quality problem** (N 288 ff.), and which is highly alarming, as quality must be strictly guaranteed as an absolutely mandatory element of any marketing authorisation (ff. N 505 ff.; ff. 584 ff., esp. N 610),
- that in Switzerland, the EU and the USA a total of **1,095,777 adverse reactions** - including **287,919 serious** adverse reactions and **13,632 deaths - had** already been reported for Comirnaty and Spikevax alone, which meant that the absolute **alert value of 50 deaths** had already been **exceeded by a factor of 250 (**see N 291 ff.),
- that **71 deaths** were recorded in children in Switzerland, the EU and the USA for Comirnaty and Spikevax alone (front N 304 f.), which means that in this target group alone - which is in no way endangered by SARS-CoV-2 - the absolute **alarm value of 50 deaths - which would have to lead to the immediate suspension of any approval of medicinal products - was clearly exceeded,**
- that the mRNA "vaccines" (Comirnaty and Spikevax) had received **68 times the number of reports of serious adverse events** and **20 times the number of deaths per million doses administered by the** end of 2021 compared to influenza vaccines (front N 293 ff.),
- that a **massive underreporting of adverse drug reactions** was observed worldwide (N 307 ff.) and that the reporting rate in Switzerland was conspicuously low only in comparison with Germany (ff. N 311 f.),
- that worldwide massive underreporting has been criticised, especially in deaths, which is due to the widespread **lack of autopsies** and the premature exclusion of a connection between mRNA injection and death (foregoing N 313 ff.),
- that even at the end of 2021, manufacturers were still unable to provide usable data on the tolerability of mRNA "vaccines" in pregnant women, while by the end of 2021 **over 2,000 premature and stillbirths had** already been reported after mRNA injection only in the USA and the EU (front N 334 ff. , esp. N 340),

- that several studies and in the meantime a total of well over 200 **peer-reviewed** studies had shown a connection between the mRNA "vaccines" and severe side effects such as heart problems, thromboses and death (front 342 ff.),
- that, in contrast, in view of insufficient studies and misleading calculations, the protective effect of the "booster" and the "3rd dose in immunocompromised persons" had not been proven in any way (above N 362 ff.; N 714),
- that in **children and adolescents, in the** complete absence of threat from SARS-CoV-2 (anterior N 483, N 484 ff.), with virtually non-existent efficacy of mRNA "vaccines" (N 254 ff., N 370 ff.) and with **more than 50 deaths reported** worldwide as a result of mRNA injection (N 322 ff.; cf. also N 304 f.) in this age group alone, a risk/benefit assessment obviously had to turn out negative,
- that, moreover, teenagers are **six times more** likely to suffer from **heart problems (myocarditis) caused by COVID "vaccines"** than they are to develop a severe course of COVID (N 330 ff.), so that for this reason too, a risk/benefit assessment obviously had to be negative.

853 Under no circumstances was there even the slightest justification for the extensions of the authorisations as of the end of 2021. On the contrary, **Swissmedic should finally have immediately revoked all "time-limited" authorisations for mRNA "vaccines".** However, this did not happen - instead, **Swissmedic once again published misleading information in order to conceal its own wrong decisions from the public:**

- On 10 December 2021, Swissmedic communicated, in a complete distortion and embellishment of all facts, a **"high clinical efficacy in younger children",** whereby severe courses of disease would be "practically completely" prevented (front N 708 ff.). A "practically complete" - i.e. 100% - effectiveness against severe diseases is **diametrically opposed to the study results. Swissmedic thus exposed the very least threatened population group to the risk of serious side effects and deaths without need and in an absolutely misleading manner.**
- Despite explicit reference by the manufacturers to missing data ("missing information") concerning the **elderly, pre-diseased population,** Swissmedic did **not include a corresponding warning in the Comirnaty summary of product characteristics,** whereupon the "booster" was even recommended with priority for this age group. The suppression of this elementary information in the expert information and the toleration of the priority recommendation of the "Booster" for the elderly population once again represents an open violation of the duty of care under the law on medicinal products (Art. 3 para. 1 HMG) on the part of Swissmedic (see above N 712 f.).

- By the end of 2021, **cardiac problems (myocarditis/pericarditis) were** already to be classified and reported at least as **"rarely" occurring side effects, coagulation disorders (**thromboses etc.) as **"very rare"** side effects (front N 298). **Herpes zoster** has also long been recognised as a potential risk signal (front N 285). Nevertheless, Swissmedic warned completely inadequately about the serious side effect of myocarditis (front N 716) and dispensed with any warning of herpes zoster as a side effect (front N 717). In addition, there was still no mention of any thromboembolic side effects (coagulation disorders; front N 718) and also any warnings to patients with an increased tendency to clot (front N 719 f.). These suppressed facts also represent a considerable danger for patients and thus a serious violation of the duty of care under the law on medicinal products.
- Finally, it can be assumed that due to the completely inadequate passive reporting system and the accompanying massive underreporting (see N 307 ff., N 397 ff.), a large number of other side effects have not been and are not being recognised or not recognised sufficiently.

1.2.4.4 Breaches of duty from 2022

854 In 2022, Swissmedic also maintained all "temporary" authorisations, although in addition to all the previous risk and legally relevant facts were known,

- that with the **"Omikron variant",** the lethality of SARS-CoV-2 was only about **0.001-0.002% (IFR),** which means that "Omikron" is significantly - namely at least **50 times - less dangerous for the** overall population **than normal influenza** and **definitely does not** represent **a life-threatening or incapacitating disease** (see N 487 f.), which would justify an emergency authorisation according to Art. 9a HMG,
- that despite a **massive manipulation of the COVID "case numbers" in the hospitals, which** became public, there was never an overload of the hospital system and also in the calendar year 2021 no **significant over-mortality** was discernible (front N 487 f.), which once again confirmed that SARS-CoV-2 is largely harmless,
- that worldwide (Switzerland, EU, USA) almost four million side effects had already been reported for all COVID "vaccines" by May 2021, with Comirnaty and Spikevax alone accounting for **over 1.7 million side effects** - of which **473,128 were serious** side effects and **20,381 deaths** (front N 378 ff.), which at that time **exceeded the alert value of 50 deaths** worldwide **by a factor of more than 400,**
- that the mRNA "vaccines" (Comirnaty and Spikevax) had received **100 times the number of reports of serious adverse events** and **20 times the number of deaths** per million doses administered compared to influenza vaccines (front N 385 ff.),

- that several studies have shown that in the EU at best 20% of all side effects, and in Switzerland probably **only 10% of all side effects are reported at all** (see above N 397 ff.), which **means that Swissmedic allows the public to be massively misled about the true extent of side effects,**
- that the **manufacturers** reiterated in their 2021 **annual reports** that they may **not be able to demonstrate sufficient efficacy or safety of their COVID "vaccine" to** obtain permanent regulatory approval (front N 402 f.),
- that by May 2022 the **number of** suspected cases of (very young) children killed by mRNA "vaccines" will continue to accumulate worldwide, and **in Germany it can even be assumed that, despite underreporting, the number of deaths among children due to "vaccination" will exceed the official statistics of deaths according to "COVID-19"** (see N 404 ff.),
- that despite Swissmedic's pronouncements that the mRNA "vaccines" had no effect on pregnancy, by May 2022, **2,177 stillbirths with Comirnaty** and **810 stillbirths with Spikevax** - not including underreporting - had already been reported in the EU and the USA alone, with the manufacturers still openly admitting in 2022 that **- due to a lack of appropriate studies - "the safety profile of the vaccine in pregnant or breast-feeding women** is **not known"** (front N 407 ff.),
- that according to a study on male fertility published in June 2022, the **sperm concentration 150 days after the 2nd "vaccination" was still 15.9% below the initial value** (front N 413 ff.), which means that not only female but also male fertility is potentially negatively affected by the "vaccination",
- that in the course of several autopsies in 2022, an important proof of the **lethal mode of action of the spike protein** had been provided, according to which the spike protein production caused by mRNA appears to be the causal cause of vascular lesions and a (lethal) myocarditis suffered as a result (in front N 415),
- that the cases of **myocarditis** per million "inoculated" doses continued to increase in 2022 and reached such high values that both Comirnaty and Spikevax are "rare" side effects (not: "very rare") - again not including underreporting (front N 716 with reference to N 391),
- that in particular in 16-24-year-old men, according to a large-scale Scandinavian study from April 2022, there is a 5-fold increased risk of myocarditis after "vaccination" with Comirnaty and a 15-fold increased risk of myocarditis after "vaccination" with Spikevax (front N 419),
- that with **V-AIDS** a long-suspected and now since 2022 occurring serious side effect has made itself felt, which results in **damage to the immune system, which** can lead

not only to the increased occurrence of autoimmune diseases and cancer, but above all to the increased occurrence of infectious diseases (front N 423 ff.),

- that reports of side effects and devastating health consequences are pouring in worldwide: for example, **66% of Israelis who had received a booster vaccination suffered from side effects -** and in the US military a massive **increase of 270% in heart attacks**, **460% in pulmonary embolisms**, **1000% in nerve diseases**, **490% in breast cancer, 290% in** facial **paresis**, **550% in Guillain-Barré syndrome** and 280% in **miscarriages was** recorded (N 426 ff.),
- that by 1 March 2022, a total of at least **128 peer-reviewed publications on heart problems, 223 peer-reviewed publications on life-threatening coagulation disorders (thromboses, etc.) and seven peer-reviewed publications on possible deaths as a result of COVID "vaccinations" had** already appeared (front N 428 f.),
- that the **mRNA "vaccines" are obviously of no use against the "Omikron" variant either,** as can be seen from the fact that the **"vaccinated" are** visibly **filling hospitals** worldwide (including in Switzerland) and **leading the reports of deaths** - if the "vaccination" were actually effective and if it successfully prevented (severe to fatal) COVID courses, then a completely different result would definitely be expected and nationally and internationally the COVID hospitalisations/deaths would have to be led by the unvaccinated (see N 430 ff.).

855 **The revocation of all "temporary" authorisations for mRNA "vaccines" was thus long overdue.** However, this still did not happen - instead, **Swissmedic once again published new misleading information and maintained the misleading information already published in order to continue to conceal its own wrong decisions from the public:**

- Thus, Swissmedic ignored not only warnings from the manufacturers, but also from third parties who had examined the benefit-risk profile of the mRNA "vaccines" in detail and pointed out, for example, the falsification of data at Pfizer (see N 698 ff.).
- Swissmedic also maintained the "vaccination recommendation" for pregnant women without even having sufficient evidence of safety and in the knowledge that reports of stillbirths were increasing worldwide.
- In addition, as late as May 2022, Swissmedic disseminated the information in its "Vigilance News" for the attention of the medical profession that "**some non-serious and very frequent adverse events"** had occurred in controlled clinical trials, which in view of the **46 (6.6%) fatal** "adverse events" was blatantly misleading (front N 734 f.).
- On the same page, Swissmedic also disseminated the information that "**only a few examples" of other signals** (side effects) could be found in the **literature**, which in

view of the overwhelming number of hundreds of peer-reviewed studies, which continue to increase every week, on only three topics (thromboses, heart attacks, deaths) - i.e. excluding many other studies on various other side effects - **represents blatant misinformation** (see N 734 f.).

- In addition, Swissmedic announced on 24 June 2022 that it wanted to "review" Moderna's application for the "extension of authorisation" for a Corona vaccine against "Omikron" without a complete dossier **(without clinical trials, without complete preclinical studies)** (foregoing N 756 ff.). Swissmedic presents this process as an absolutely normal procedure - which it is in no way, since it **fundamentally deviates from all principles of therapeutic products law** - and **thus continues to give the public the illusion of a "courant normal", which has in no way been the case since the end of 2020.**

1.2.4.5 Result

856 As already summarised in detail above (N 464 ff.), the plan to authorise mRNA "vaccines" for all adults in Switzerland from December 2020 must be qualified as a **project with an increasing, unprecedented risk character** for public health. Swissmedic had several opportunities to take corrective action after the first wrong decision was taken at the end of 2020 - but none of these opportunities were taken and the risk and the damage done to public health was massively increased with each authorisation extension.

1.2.5. Medical profession: offence variant "application" (duty to inform)

857 With regard to the medical profession, the punishable acts ("use") and duties of care are also described in Art. 86 para. 1 lit. a HMG, whereby in this case the duties of care according to Art. 26 HMG (duties of care in prescribing, dispensing and use) are of particular interest.

1.2.5.1 Notion of "levy" includes application

858 The term "dispensing" covers the last stage, i.e. the transfer or handing over of a ready-to-use medicinal product to the end user. The prescription of a medicinal product itself is not yet considered as dispensing; only the execution of a prescription leads to the actual dispensing of the medicinal product. The term "dispensing" also includes the **use of the medicinal product by third parties** (Art. 4 para. 1 lit. f HMG).[280] The persons responsible for

280 Message HMG, p. 3491; BÜRGI, BSK HMG, 2nd ed., Basel 2022, Art. 24 N 5, Art. 26 N 6.

injecting the mRNA "vaccines" into the patient (**physicians**) therefore fulfil the definition of "use" within the meaning of Art. 86 para. 1 lit. a HMG.

1.2.5.2 Art. 26 - Requirements for dispensing (application): Duty to inform

859 With regard to the duties of care to be fulfilled, the requirements described above (N 824) (avoidance of hazards to human health; limited actions sufficient; fully timely fulfilment) apply equally and analogously to the medical profession.

860 When prescribing, **dispensing and using** medicinal products, the recognised rules of medical and pharmaceutical science must be observed (Art. 26 para. 1 HMG). **Before each dispensing** (and use) of a medicinal product for human use that is subject to prescription, a person authorised to prescribe and dispense must in **principle issue a prescription to the** patient (Art. 26 para. 4 HMG). A medicinal product may only be prescribed (and used) if the **patient's state of health is known** (Art. 26 para. 2 HMG).

861 In the interest of drug safety and **patient protection,** the dispensing system of the Therapeutic Products Act is based on **specialist counselling** by means of appropriate instructions within the framework of prescribing and dispensing.[281] The patient must therefore be informed individually and during a consultation: Information forms or the summary of product characteristics can at best have a supporting function and serve as a basis for the discussion, but they cannot replace the personal discussion and the individual information.[282] The medical prescription of the medicinal product must therefore be made in full knowledge of the patient's **vital data**, state of health, any **allergies**, **drug intolerances** and the **potential for interaction** with other active substances from medicinal products or food.[283] From the physician's duty of care in general and within the framework of the recognised rules of medical science, there also follows a **duty to sufficiently inform the** patient before the intervention.[284] The doctor must inform the patient about the correct therapeutic behaviour in the context of a treatment and must draw attention to known dangers (so-called **precautionary information**).[285] In particular, information must be provided not only about frequently occurring risks, but also about rare risks, provided they are known and can have serious consequences.[286]

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281 BGE 142 II 80 E. 2.2 p. 87; BÜRGI, BSK HMG, 2nd ed., Basel 2022, Art. 26 N 6.
282 HOFMANN, 'COVID-19 vaccination: information and capacity to judge', FMH Recht 2021, pp. 158-159, p. 159.
283 BGE 142 II 80 E. 2.1 p. 86; cf. EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 14.
284 Cf. BGE 134 IV 175 E. 4.1. p. 180; also BÜRGI, BSK HMG, 2nd ed., Basel 2022, Art. 26 N 9.
285 BGE 116 II 519 E. 3b p. 521; judgement 4C.229/2000 of the BGer of 27.11.2000 E. 3a/aa.
286 HOFMANN, 'COVID-19 vaccination: information and capacity to judge', FMH Recht 2021, pp. 158-159, p. 159.

862 **Prescription medicines** such as those in dispensing category B (COVID "vaccines") are in principle available[287] only after consultation **with a doctor** and on the basis of a **consultation** and **examination by a** competent doctor. The doctor must make a decision based **on** knowledge of all preparations available on the market with the same indication and knowledge of their positive and negative effects - and primarily **on the basis of the specialist information. The** safety expectation of a prescription drug is therefore based on that of the prescribing doctor and not on that of the patient.[288] In the case of prescription medicines, the doctor has to weigh up the **opportunities and risks of** the various products available on the market on the basis of the expert information with regard to the specific application and **discuss** these **with his patient.**[289] Accordingly, the physician's explanation of all aspects that are important for the patient and that are (only) listed in the product information is elementary. The **duty to inform lies with the doctor,** who cannot exonerate himself by requiring his patient to inform himself or to read the medical instructions on the package leaflet of the medicinal product.[290] In addition, the patient must also be informed about any risks that are not yet included in the expert information but have been scientifically proven.[291]

863 The requirement of comprehensive information must be given particular weight if little is known scientifically about the use of a medicinal product: If a **therapy** still has a **purely experimental character** due to the lack of scientifically proven findings, the **pre-invasive obligations to provide information and to weigh up the risks** must be **fulfilled with particular care.**[292] This prerequisite obviously applies to the completely new mRNA therapies: they do not represent a common form of therapy in any way - certainly not for prophylactic and experimental use in an overall population that is healthy in itself. They have never been tested on humans on a broad scale before and are still in the stage of human trials, which is warned against at least in part - but openly recognisable to experts - in the expert information (front N 547 [black triangle], N 791 [incomplete clinical data]). Accordingly, the references in the expert information to a **limited study population** - if the patient to be vaccinated belongs to this **population** - and a possibly **shortened study duration** or other **special circumstances must be** mentioned **in the approval proce-**

287 For the possible exceptions, according to which a prescription incl. administration is also possible by pharmacists, see above N 788.

288 Cf. ruling 4A_365/2014 of the Federal Supreme Court of 5 January 2015, E. 5, with reference to ruling LB130045-O/U of the Supreme Court of the Canton of Zurich of 7 May 2014, p. 18 f.

289 Federal Supreme Court ruling 4A_365/2014 of 5 January 2015, E. 9.2.

290 Judgement 4C.229/2000 of the Federal Supreme Court of 27.11.2000, E. 3a/bb.

291 HOFMANN, 'COVID-19 vaccination: information and capacity to judge', FMH Recht 2021, pp. 158-159, p. 159.

292 Cf. BGE 134 IV 175 E. 4.1 f. p. 180.

dure. The patient must also be informed that **not all risks and side effects are known** if this is the case due to the **lack of long-term studies.**[293] This additional obligation to provide information is particularly relevant in the case of so-called **"off-label use", i.e.** the prescription and administration of a medicinal product outside its marketing authorisation: information must be provided about this circumstance itself and also about the associated consequences such as the lack of cost coverage by the health insurance fund (Art. 71a ff KV) and the threat of the manufacturer's product liability lapsing.[294]

864 The patient must therefore be informed about the nature and risks of the proposed "vaccination" in such a way that he or she can give informed consent.[295] The content of the information must be based on the technical information accompanying the vaccine. At the very least, the patient must be **informed** about all **side effects, contraindications, incompatibilities and other warnings** contained in the product information **- and in particular about the incompleteness of the clinical data** .

865 In view of the novelty of the mRNA "vaccines" and the still ongoing "rolling" approval procedure, **every doctor** was also **obliged to provide very careful and detailed information.** Accordingly, the patient also had to be informed that not all risks and side effects are yet known due to the lack of studies, i.e. that the expert information is not complete and is constantly being supplemented due to newer findings.

1.2.6. Medical profession: Various breaches of the duty of care under the law on therapeutic products

866 As in front (N 866 ff.), the duties of care (in particular the duty to inform) were fulfilled to varying degrees depending on the location or the medical professional responsible for the "vaccination". Accordingly, an attempt is made to group cases:

1.2.6.1 Case group 1 - Curative information, non-observed contra-indications

867 With regard to case group 1 (above N 790 f.), it should be noted that a five-minute explanation is hardly ever sufficient in view of the established complexity of the mRNA "vaccines". As already explained above (N 791), as far as can be seen, no private plaintiff was adequately informed about the existence of a "time-limited" authorisation in the sense of Art. 9a HMG with the associated **incomplete data situation**. No information was provided about the fact that this is an experimental "vaccine" which is still in the **test phase**

293 HOFMANN, 'COVID-19 vaccination: information and capacity to judge', FMH Recht 2021, pp. 158-159, p. 159.
294 Cf. BÜRGI, BSK HMG, 2nd ed., Basel 2022, Art. 26 N 9.
295 HOFMANN, 'COVID-19 vaccination: information and capacity to judge', FMH Recht 2021, pp. 158-159, p. 159.

of human trials (clinical phase III trials). There was also no information about the **lack of long-term studies** and the associated **uncertainty about possible side effects.** However, it was mandatory to provide information about all these circumstances - especially because the doctor had specialised knowledge after consulting the expert information, which he had to communicate to the patient. Moreover, nothing is known about the fact that the private plaintiffs would have been correctly informed about the fact that their health is in no way significantly endangered without a COVID "vaccination" due to SARS-CoV-2, and what **valid alternatives** there were and are for the prevention, respectively for the treatment of the disease. In addition, the **warnings and side effects** already **contained in the product information** should at least have been explained. However, in view of the publicly available data on risks and side effects, it was clearly not enough to limit oneself to the information contained in the summary of product characteristics: it was therefore also imperative to inform the public that the **worldwide reports of side effects** had already reached a level by mid-2021 that - as far as can be seen - had never been the case before for a single medicinal product.

868 A consideration of the "vaccination" of a person willing to be vaccinated therefore had to be made in detail after complete information about the most elementary principles of the "temporary" approval such as the incomplete clinical data situation as well as all possible - even theoretically possible - side effects and in relation to the underlying diseases, risk factors and existing medication. Without compliance with these mandatory elements, there is therefore primarily insufficient information in these cases.

869 Secondarily, it must also be examined whether the acting family doctor should have recognised contra-indications based on the medical history and should have advised his patient against the "vaccination", or even refused it. These clarifications had to be made particularly carefully in view of the fact that the "vaccines" are still in the experimental phase. Where contra-indications arose on the basis of the specialist and patient information provided by Swissmedic, the general practitioner was obliged to carry out further clarifications.

870 On the basis of the documents available so far, there is an urgent suspicion that in the cases mentioned above (front N 790 f.), **no clarification had taken place that would meet the necessary requirements in the sense of the above explanations** (above N 859 ff.)**.**

1.2.6.2 Case group 2 - Absence of any vaccination history".

871 With regard to case group 2 (front N 797), it is to be noted that **an education was not documented in any way.** Until proven otherwise, it must therefore be assumed that in the cases mentioned above, no information was provided. **Without information, however, any administration of a prescription-only medicinal product is simply unlawful. The** examination of further actions of the responsible medical profession (or of a pharmacist who may be responsible) is therefore basically unnecessary in these cases.

1.2.7. Factual "success"?

872 As discussed at the outset (above N 106 f.), the basic provision of Art. 86 para. 1 lit. a HMG is an abstract endangerment offence - a constituent "success" is therefore not necessary. The abstract endangerment is presumed due to the aforementioned constituent action and does not have to be proven as an additional element of the objective offence in the individual case.

1.3. Qualification (Art. 86 para. 2 lit. a HMG)

873 According to Art. 86 para. 2 lit. a HMG, a qualified penalty is imposed for manufacture (Swissmedic) or use (medical profession) in breach of the duty of care, provided that the health of humans has been specifically endangered. As discussed above (N 109 ff.), proof must be provided that at **least one person's health was** actually **endangered**.

874 Only the front (N 58 ff.) were not only specifically endangered in their health by the mRNA "vaccines" approved by Swissmedic and administered to doctors, but were even injured.

875 There is therefore an urgent suspicion that the defendants have concretely endangered the health of people.

1.4. Causality between action and success

1.4.1. Connection between HMG action and health hazard

876 There must be a legally relevant causal connection between the handling (manufacture / use) of a medicinal product and the abstract (para. 1) or concrete (para. 2) health hazard. The consequence of this causality requirement is that only those duties of care that could actually lead (para. 1) or have led (para. 2) to a health hazard fall under Art. 3 HMG. In the case of omission of legally required actions, the omission in question must have been

adequately causal for the occurrence of the health hazard to be assessed.[296] The same applies mutatis mutandis to Art. 7 HMG and Art. 26 HMG.

1.4.2. Causality theories

1.4.2.1 Active action: "conditio sine qua non "

877 According to the theory of conditions or equivalence, a cause is any condition that cannot be eliminated without the success being lost *("conditio sine qua non").* Causality is thus given without regard to the nature of the offender's action, if this only already constituted *a* condition for the success that occurred (so-called natural causality). Neither the number nor the weight of possible (co-)causes is important.[297]

1.4.2.2 Passive behaviour: Hypothetical causal link

878 In the case of passive conduct - i.e. in the case of an offence of omission - the hypothetical causal connection must be determined. According to the majority and the case law of the Federal Supreme Court, this assessment must be made according to the so-called theory of probability: The necessary connection is given if the required action could not be added without the success most probably ceasing to exist.[298]

1.4.3. Causality at Swissmedic

879 The aforementioned breaches of duty by Swissmedic cannot be disregarded without removing the abstract and concrete health risks described above: The incorrect choice of procedure for the "temporary authorisation" alone, and in particular the completely incorrect determination of the cost-benefit ratio, constitute the central prerequisite for the authorisation of the dangerous and useless mRNA "vaccines" in Switzerland, as a result of which the health of a large number of people was endangered in both abstract and concrete terms. The same applies to the actions of the multiple extensions and maintenance of the authorisations.

880 If the maintenance of the authorisation were to be seen as a rather passive behaviour, then a corresponding hypothetical causal connection would also exist: If Swissmedic had intervened and correctly revoked the illegal authorisations, further damage would have been obviously, or at least most probably, averted.

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296 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 53; cf. also BGE 135 IV 37 E. 2.4.1 p. 40.
297 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 8 p. 103 f.
298 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 pp. 325 f.

881 The actions (and also the omissions) of the persons responsible at Swissmedic are thus by far the most important cause of the occurrence of the abstract and concrete health hazards.

1.4.4. Causality in the medical profession

882 The same applies in principle to the medical profession: careful anamnesis and thorough patient education are central to preventing health hazards.

883 If the **medical history** had been taken correctly - especially in the case of previously exposed patients - the doctor acting correctly would have recognised the various general motor risks associated with the mRNA injection and those contained in the specialist information, compared them with the low actual risk from a SARS-CoV-2 infection in the respective individual case, dispensed with an mRNA injection and thus prevented a (concrete) health risk (for the time being).

884 If, in addition, the **patients** had been **informed** correctly, taking into account all the facts essential for their personal risk/benefit assessment (lack of data on efficacy and safety; experimental stage of clinical phase III; approval only "limited in time"; publicly available data on risks and side effects strikingly negative, etc.), the patients would have recognised with a high degree of probability, taking into account their personal circumstances, that an mRNA injection would by no means reliably improve the protection of their health against severe courses of COVID-19 infection. Due to the numerous risk and uncertainty factors and with correct information about the actual - rather weak - threat from SARS-CoV-2 (incl. about the prevention and treatment alternatives available in this context), a different picture would have emerged in the end - when weighing all circumstances in the context of an individual benefit/risk analysis - and many of the patients concerned would probably have refrained from the mRNA "vaccination".

1.5. Subjective facts

885 On the distinction between contingent intent and negligence, cf. below N 1062.

1.5.1. Preliminary assessment concerning Swissmedic

1.5.1.1 With regard to the basic offence (para. 1 lit. a)

886 Subjectively, intent, at least contingent intent, is required. [299]

[299] SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 92.

887 At the latest from the appearance of the thousands of adverse reactions worldwide since spring 2021, it was apparent to the notifiers acting at Swissmedic that all the risk signals that were already apparent at the end of 2020 had manifested themselves in an open manner. From spring 2021 at the latest, the notifiers could therefore no longer be confident that a possible "success" in the sense of a hazard would not occur - it had clearly already occurred. In view of the already overwhelming evidence - without having the complete authorisation documents at their disposal - the existence of the abstract health hazard must have been so obvious to them that the **willingness to simply accept this hazard can only reasonably** be interpreted as **its acceptance**.

888 However, it was previously explained in detail that Swissmedic had already had information internally at the end of 2020 that was extremely worrying. Swissmedic had simply brushed aside all these alarm signals and had not communicated them publicly in any way. There are therefore already strong indications of a willingness on the part of those notified to have willingly and knowingly accepted health risks for a very large number of people as early as the end of 2020.

889 There is therefore an urgent suspicion that those acting on behalf of Swissmedic had already accepted an abstract health risk to a very large part of the Swiss population by the end of 2020, but at the latest from spring 2021 (approx. June 2021). Based on the seizures and confiscations to be made, the investigation must also examine what additional internal knowledge Swissmedic already had at an earlier point in time.

1.5.1.2 With regard to qualification (para. 2 lit. a)

890 Here, too, intent, or at least contingent intent, is required. The intent must include at least the concrete endangerment of the health of **at least one person.**[300]

891 With regard to qualification, the above applies in principle. Depending on the evaluation of further documents - in particular the complete authorisation documents - an acceptance in favour of the defendants can be assumed from June 2021 at the earliest. However, by this time at the latest, the international data situation was almost overwhelming and thousands of concrete health hazards had to be assumed.

1.5.1.3 Possibly: Negligent commission?

892 According to Art. 86 para. 4 HMG, the negligent commission of an offence is also punishable.

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300 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 94, N 100 (and N 4.).

893 According to the above, there is hardly any room for a merely negligent commission of the offence, at best still at the time of the first admissions at the end of 2020 or the beginning of 2021. Due to the large amount of incriminating material already available as of December 2020 (as proof of the contingent intent as of December 2020), it is to be expected that this urgent suspicion of contingent intent will also be substantiated after the requested investigative measures have been carried out, whereby new, exculpatory evidence would have to be taken into account ex officio (cf. Art. 6 para. 2 CCP).

1.5.2. Preliminary assessment concerning the medical profession

894 In principle, a similar temporal progression is to be assumed for the "vaccinating" medical profession: The more overwhelming the evidence, the more likely it is to assume intent instead of negligence. What the doctors knew or should have known is to be investigated in the course of the criminal proceedings to be opened.

1.6. Justification reason: consent?

895 It should be noted in advance that the location of the examination of consent is dogmatically controversial: some doctrines consider consent to be a feature that excludes the offence, while others examine consent under the heading of unlawfulness.[301] In the present case, consent is examined - admittedly dogmatically uncleanly separated - both in the area of the offence (breach of the duty of care due to lack of information) and under the heading of justification.

896 A more detailed description of the issue of consent is given in the offence of (negligent) grievous bodily harm (see below N 1118 ff.).

897 In the Basel Commentary on the Therapeutic Products Act, the view is expressed that under Art. 86 HMG, the consent of the (abstractly or concretely) endangered person should in principle be considered as a ground for justification.[302] **However, consent is only permissible where the person giving consent may dispose of the good alone** - which is only possible in the case of offences against the individual (i.e. in particular Art. 111 ff. StGB).[303] The individual cannot validly dispose of legal goods of the general public.[304] How an individual can consent to an offence that endangers the common good of the **health of all people in an** abstract or concrete way (for more on this see N 105 ff.) is not comprehensible. The validity of the consent of an individual - let alone a somehow

301 In detail NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, Vor Art. 14 N 10 ff.
302 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 95.
303 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, Vor Art. 14 N 18.
304 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, Vor Art. 14 N 25.

fictitious consent of the "general public" - to the actions of **Swissmedic** under Art. 86 HMG is therefore ruled out. The objectively ascertainable breaches of the duty of care committed by Swissmedic, as described in detail above (see N 838 ff.).

898 Regarding the criminal liability of the **medical profession, it** should be noted that a valid consent would already exclude the constituent elements of the offence: If there was a sufficiently informed consent, the persons "vaccinating" would not have acted carelessly. Previously (N 859 ff, N 866 ff.), it has already been explained in detail that there is a lack of sufficient information, which means that valid consent is ruled out.

1.7. Grounds for exclusion of guilt

899 No grounds for exclusion of guilt are apparent.

1.8. Conclusion

900 There is strong suspicion that the persons who have been notified and the other perpetrators, who have yet to be identified, have committed a criminal offence under Art. 86 para. 1 lit. a and para. 2 lit. a HMG (possibly also Art. 86 para. 4 HMG).

2. Violation of reporting obligations (Art. 87 para. 1 lit. c HMG)

901 According to Art. 87 para. 1 lit. c HMG, anyone who intentionally violates reporting obligations under the Therapeutic Products Act is liable to a fine of up to CHF 50,000.00.

902 Art. 87 para. 1 lit. c HMG includes, in particular, reporting obligations under Art. 59 paras. 1-3 HMG.[305] These have been discussed in detail above (N 533 ff.).

2.1. Objective facts

2.1.1. Circle of perpetrators

903 The circle of perpetrators is open ("who"): It is a matter of reporting obligations that must be fulfilled by anyone who carries out his or her own activities with therapeutic products and thereby possibly creates a dangerous situation. [306]

2.1.1.1 Swissmedic

904 As before (N 534 ff.), Swissmedic is responsible within the framework of ex post market surveillance for the **- comprehensive and functioning - monitoring of therapeutic**

305 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 87 N 18.
306 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 87 N 19.

product safety and **strict enforcement of the obligation to notify in accordance with the situation.** If the Institute breaches this duty, it creates a risk situation for public health, which means that the persons acting on behalf of the Institute belong to the potential group of offenders with regard to the breach of notification obligations within the meaning of Art. 87 para. 1 lit. c TPA in conjunction with Art. 59 para. 1-3 TPA. Art. 59 para. 1-3 HMG in conjunction with Art. 58 para. 3 HMG. Art. 58 para. 3 HMG.

2.1.1.2 Medical profession

905 As before (N 539 ff.), medical professionals (doctors) are obliged to report all **serious** side effects as well as all **unknown** side effects not listed in the product information. Doctors are therefore among the potential perpetrators of violations of reporting obligations within the meaning of Art. 87 para. 1 lit. c HMG in conjunction with Art. 59 para. 3 HMG. Art. 59 para. 3 HMG.

2.1.2. Object of crime: medicines

906 With regard to the medicinal products mentioned in Art. 59 Para. 1-3 HMG, the legal definitions according to HMG apply.[307] The only definition of interest here is that of "medicinal products" pursuant to Art. 2 para. 1 lit. a in conjunction with Art. 4 para. 1 lit. a HMG. Art. 4 para. 1 lit. a HMG, which have already been described above (N 811 f.): The mRNA "vaccines" are medicinal products within the meaning of the HMG.

2.1.3. Offence: Violation of the obligation to notify

2.1.3.1 On the part of Swissmedic

907 At no time did Swissmedic fulfil its obligations to install a **situation-appropriate - comprehensive and functioning - monitoring of therapeutic product safety** and **strict enforcement of the reporting obligation:**

908 The passive reporting systems are not sufficient for an active substance that is still in the phase of the first human trial ever, and which from the beginning had so strikingly many and such strikingly serious risk characteristics (front N 141 ff. and N 840 ff.), is simply insufficient. With the mRNA "vaccinations", Swissmedic has for the first time ever approved a gene therapy for prophylaxis in an otherwise healthy population "for a limited period" (i.e. on the basis of completely insufficient data) - and has taken the greatest possible risk. In this initial situation, **the mRNA "vaccines"** should have been **subjected to**

307 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 87 N 19.

active pharmacovigilance - similar to study conditions - from the very beginning (see N 845 with further references).

909 To make matters worse, Swissmedic does not even enforce the passive reporting system nearly enough: In Switzerland, **only about 10% of all adverse drug reactions** are **reported at all,** which represents a **massive underreporting** (ff. N 307 ff., N 397 ff., N 689 f.). Swissmedic obviously does not require those required to report to adhere to strict reporting discipline, or does not do so to any sufficient extent - which would be absolutely necessary in the present situation with the novel mRNA "vaccines". This **massive underreporting** makes it impossible for Swissmedic (and the public) to recognise the full extent of the devastating consequences in order to take appropriate safety measures (such as the mandatory adaptation of the expert information).

910 There is therefore an urgent suspicion that Swissmedic has breached its duty of care in the area of reporting obligations under the law on medicinal products on several occasions and, above all, on an ongoing basis.

911 If the reporting system does not meet the legal requirements of Art. 59 SCC or if, as a result, the information on medicinal products is not adapted in time, **criminal liability under Art. 86 para. 1 lit. a** (or even para. 2) may also apply if there is a **health risk.**[308] Accordingly, the violated reporting obligations have already been mentioned above (N 845).

2.1.3.2 On the part of the medical profession (medical personnel)

912 The medical profession is obliged to report even **mere suspicions** (N 543 ff.) **of serious or new side effects.**

913 It can be concluded from the massive underreporting in Switzerland alone that the medical profession fulfils this reporting obligation in a completely inadequate manner.

914 This is exemplified by the case of private plaintiff 3: none of the doctors treating her felt obliged to submit a report to Swissmedic, despite the obligation to do so. In the end, she even had to submit the report herself.

915 Accordingly, there is an urgent suspicion that a large number of doctors have violated their duties of care in the area of reporting obligations under the law on medicinal products.

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308 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 31a.

2.2. Subjective facts

2.2.1. Intent

916 Subjectively, the facts of Art. 87 para. 1 lit. c HMG require intent, whereby contingent intent is sufficient.[309] On the distinction between contingent intent and negligence, cf. below N 1062.

917 In view of the obvious under-reporting of the side effects, which was tolerated for months, it must be assumed that all those involved accepted the corresponding consequences. The corresponding suspicion must be substantiated (or dismissed) within the framework of the criminal proceedings to be conducted.

2.2.2. Negligence

918 If no intent can be proven, it should be noted that negligent acts are also covered by Art. 87 para. 3 HMG.[310]

2.3. Forms of participation

919 Furthermore, it should be noted that - despite the mere fact of an offence (cf. Art. 105 para. 2 SCC) - attempt and aiding and abetting are also punishable (Art. 87 para. 4 HMG).[311]

2.4. Grounds for justification and exclusion of guilt

920 No grounds for justification and exclusion of guilt are apparent.

2.5. Conclusion

921 There is strong suspicion that the persons who have been notified and the other perpetrators, who have yet to be identified, have committed a criminal offence under Art. 87 para. 1 lit. c HMG.

3. Violation of the advertising ban (Art. 87 para. 1 lit. b HMG)

922 According to Art. 87 para. 1 lit. b HMG, anyone who violates the provisions on the advertising of medicinal products is liable to a fine of up to CHF 50,000.00.

309 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 87 N 39.
310 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 87 N 44.
311 SUTER / PIELES, BSK HMG, 2nd edition, Basel 2022, Art. 87 N 46 et seq.

3.1. Objective facts

3.1.1. Circle of offenders: Swissmedic and Insel Group

923 The circle of offenders is openly formulated ("who"). According to Art. 31 para. 3 HMG, the object of protection of the provisions on the advertising of medicinal products is health and protection against deception or misleading. It is a violation of the provisions on the advertising of medicinal products by anyone who

- does not comply with the limits of permissible advertising in specialist advertising in accordance with Art. 32 Para. 1 HMG and Art. 3-13 Medicinal Products Advertising Ordinance (AWV; SR 812.212.5) or
- in advertising to the public does not comply with the limits of permissible advertising according to Art. 32 Para. 1 and 2 HMG as well as Art. 14-22 and Art. 23 Para. 1 AWV.[312]

924 Accordingly, everyone is an addressee of this provision - including those acting on behalf of Swissmedic and the Insel Group.

3.1.2. Object of crime: medicinal products

925 The mRNA "vaccines" are medicinal products within the meaning of the HMG (front N 906).

3.1.3. Offences

3.1.3.1 Prohibited advertising to the public

926 **Advertising to the general public** is only permitted for non-prescription medicinal products in categories C, D and E (Art. 31 para. 1 lit. b HMG; Art. 14 AWV). Since **mRNA "vaccines" belong** to category B (available only on prescription; see N 787 f.), they are subject to a **strict ban on advertising to the general public.** Advertising to the general public according to Art. 15 AWV includes advertisements in newspapers, brochures or posters (lit. a) and also advertising via electronic media (lit. c). The ban on advertising to the general public thus also applies to prescription medicinal products on the **internet**. [313]

927 Advertising of medicinal products is defined as all information, marketing and incentive measures aimed at promoting the prescription, dispensing, sale, consumption or use of medicinal products (Art. 2 lit. a AWV). The essential criterion here is the intention to pro-

312 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 87 N 14.
313 JAISLI / SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 31 N 82, Art. 32 N 43a.

mote sales: this includes **all sales-promoting measures that are** likely to infringe one of the health-policy interests (e.g. **protection against deception** or **protection against inappropriate use of medicinal products**).[314] According to Swiss case law, an activity qualifies as medicinal product advertising if a large number of persons are influenced by certain measures or if **incentives are created that are intended to lead these persons to change their consumption behaviour.**[315] Even the mere provision of information on the possible uses of medicinal products constitutes advertising if it is intended and suitable to influence consumer behaviour.[316] Advertising does not have to refer directly to a medicinal product: It is also sufficient if it is clear and unambiguous to an averagely educated and interested advertising addressee, based on his or her prior knowledge or further information, which specific medicinal product is being advertised.[317] In this context, a distinction must be made between medicinal product advertising and medicinal product information: If the active ingredients **are** upgraded compared to other effective active ingredients or if further active ingredients **are** neglected and/or **undesirable side effects are concealed, such an approach is contrary to the prohibition of advertising to the general public.**[318] Such unbalanced and incomplete information cannot meet the requirements for permissible information of a general nature within the meaning of Art. 1 para. 2 lit. c AWV.[319] Moreover, it was probably misleading advertising anyway:

3.1.3.2 Misleading trade advertising

928 By contrast, **specialised advertising** - i.e. advertising in specialised journals or via electronic media (Art. 4 lit. a and c AWV) - is also permitted for category B medicinal products (Art. 31 para. 1 lit. a HMG). The statements made in specialised advertising must be **accurate, balanced, factually correct and verifiable**; in addition, the statements must **not** be **misleading** (Art. 5 para. 3 AWV; cf. also Art. 32 para. 1 lit. a HMG). Misleading is defined as the pretence or suppression of facts.[320]

314 JAISLI / SCHUMACHER-BAUSCH, BSK HMG, 2nd edition, Basel 2022, Art. 31 N 21a.
315 FAC ruling C-5490/2015 of 28 March 2017, E. 6.4.1; FAC ruling C-3090/2014 of 4 March 2016, E. 4.3.4.
316 Judgment C-5490/2015 of 28 March 2017, E. 6.4.1.
317 JAISLI / SCHUMACHER-BAUSCH, BSK HMG, 2nd edition, Basel 2022, Art. 31 N 21b.
318 JAISLI / SCHUMACHER-BAUSCH, BSK HMG, 2nd edition, Basel 2022, Art. 31 N 33.
319 JAISLI / SCHUMACHER-BAUSCH, BSK HMG, 2nd edition, Basel 2022, Art. 31 N 33.
320 JAISLI / SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 32 N 11, cf. also Art. 31 N 49.

3.1.4. Offences committed by Swissmedic

3.1.4.1 Prohibited advertising to the public

929 As before (N 737 ff.), since the beginning of the "vaccination campaign" **Swissmedic has** maintained a **"FAQ"** on its own website, which is directed at the entire population. This contains blatantly false information ("So far there are no indications of lasting negative health consequences"; false quality information; false efficacy information; false risk information), lacks sufficient risk information on serious side effects and the special nature of the present procedure, which undermines almost all safety mechanisms. Swissmedic thus presents the mRNA "vaccines" in a completely unbalanced, even misleading manner. In addition, Swissmedic has published **media releases** (including the one of 19 December 2020 on its homepage with the reference to an allegedly "ordinary" authorisation procedure) with false content and maintains these publications to this day.

930 Swissmedic thus gives the public the impression that mRNA "vaccines" are safe and largely free of side effects, which is **likely to induce consumers (misled in this way) to change their consumption behaviour - to take a regular "vaccination".**

3.1.4.2 Misleading trade advertising

931 As previously explained (N 734 ff.), **Swissmedic does** not shy away from spreading **blatant trivialisations and blatant misinformation in** its own specialist publications such as "Vigilance-News". By suppressing the fact that 702 serious and even 46 fatal side effects had occurred in the clinical trials, and by suppressing the fact that hundreds of peer-reviewed studies worldwide must indicate the devastating side effect profile of the mRNA "vaccines", **Swissmedic is therefore deliberately misleading even the specialist public**.

3.1.5. Offences committed by the Island Group: Prohibited advertising to the public

932 As before (N 799 ff.), the Insel Gruppe also publishes information on its own website on the basis of which the mRNA "vaccines" are presented in a completely unbalanced, even misleading manner. In this way, the Insel Gruppe also conveys the impression to the public willing to be vaccinated that the mRNA "vaccines" are safe and largely free of side effects, in order to induce the (misled) consumer to change his consumption behaviour - to take a regular "vaccination".

3.2. Subjective facts

3.2.1. Intent

933 Subjectively, the facts of Art. 87 para. 1 lit. b HMG require intent, whereby contingent intent is sufficient.[321] For the distinction between contingent intent and negligence, see N 1062.

934 In particular, in view of the whitewashing and downright misleading advertising of the mRNA "vaccines" to **the** public on **Swissmedic'**s own website from **December 2020 until the present time** (i.e. over 18 months) and the completely misleading advertising to specialists even in 2022, there is considerable suspicion that those acting on behalf of **Swissmedic** at least took the risk of violating advertising bans under medicinal product law. The suspicion must be substantiated (or dismissed) within the framework of the criminal proceedings to be conducted.

935 The same applies with regard to advertising to the public concerning the advertisers acting on behalf of the **Insel Group.**

3.2.2. Negligence

936 If no intent can be proven, it should be noted that negligent acts are also covered by Art. 87 para. 3 HMG.[322]

3.3. Forms of participation

937 Furthermore, it should be noted that - despite the mere fact of an offence (cf. Art. 105 para. 2 SCC) - attempt and aiding and abetting are also punishable (Art. 87 para. 4 HMG).[323]

3.4. Grounds for justification and exclusion of guilt

938 No grounds for justification and exclusion of guilt are apparent.

3.5. Conclusion

939 There is strong suspicion that the persons who have been notified and the other perpetrators, who have yet to be identified, have committed a criminal offence under Art. 87 para. 1 lit. b HMG.

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321 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 31 N 21a.
322 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 87 N 44.
323 SUTER / PIELES, BSK HMG, 2nd edition, Basel 2022, Art. 87 N 46 et seq.

II. Endangering offences of the StGB

940 Due to the close factual relationship to the provisions of the HMG and the fact that they are designed as endangering offences, the following section first deals with Art. 230bis SCC (concrete endangering offence), Art. 317 SCC (abstract endangering offence) and Art. 129 SCC (concrete endangering offence). In the next section, the successful offences of the StGB are presented.

1. Endangerment by GMOs or pathogenic organisms (Art. 230bis StGB)

941 According to Art. 230bis Para. 1 lit. a SCC, anyone who intentionally releases genetically modified or pathogenic organisms is liable to prosecution if he knows or must know that he is endangering the life and limb of humans by these actions. According to para. 2, the commission of a negligent act is also punishable.

1.1. Objective facts

1.1.1. Means of crime

1.1.1.1 Genetically modified organisms

942 In the substantive part, it was explained in detail that mRNA "vaccines" are "gene therapy" (the body's own production of a spike protein of unknown quality and quantity, over an unknown period of time, forced by mRNA substances, which cannot be produced by the human body itself without this intervention; foregoing N 142 ff.), or even genetically modified organisms (GMOs) (N 148 ff.).

943 In particular, it was explained that a transcription of mRNA into DNA (so-called "reverse transcription") could not yet be ruled out due to a lack of corresponding studies (see above N 151 ff.). In the enclosed evidence report it is also explained in detail, with reference to initial studies, how and where such an incorporation of the "vaccine" mRNA into human DNA could take place.

944 Accordingly, there is an urgent suspicion that the mRNA "vaccines" could be genetically modified organisms within the meaning of Art. 230bis para. 1 lit. a StGB.

1.1.1.2 Pathogenic organisms

945 It must also be examined whether pathogenic organisms could also be involved, should pathogenicity be proven:

946 Organisms are pathogenic if they can cause diseases (Art. 7 para. 5quater USG). Pathogenicity results from the abstract potential of the introduced organism to cause transmissible diseases. The diseases must be triggered by the biological action of the micro-organism in the host, in that the organisms multiply or form toxic substances that cause the host to become ill.[324]

947 In the material part, it was explained in detail how mRNA "vaccines" stimulate the production of the toxic, presumably carcinogenic and mutagenic spike protein. If people are deliberately made ill with them, there is also an urgent suspicion here that the mRNA "vaccines" could be pathogenic organisms within the meaning of Art. 230bis para. 1 lit. a StGB.

1.1.1.3 Further requirements for the means of crime?

948 Furthermore, due to the wording of the law, no special requirements are to be placed on organisms as means of committing an offence according to Art. 230bis . In particular, it is not required that the organism itself must already have a certain minimum degree of dangerousness. Rather, the potential for harm and thus the criminally relevant danger results from the respective conduct that constitutes the offence. The result of the endangerment can certainly result from the handling of an organism that is already dangerous in itself. However, it is also conceivable that only the corresponding conduct - for example, the release of a pathogenic organism in a certain quantity or into a certain environment - causes the danger, whereas the organism itself would not be dangerous in the criminal law sense if used in a different way.[325]

1.1.2. Offence

949 The offence of release under Art. 230bis SCC covers both the experimental release and the placing on the market of the organisms.[326] **Authorised release is also an offence.**[327] Initially, however, an "unauthorised release" was still required as an offence. [328,329] Any

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324 ACKERMANN / SCHRÖDER BLÄUER, in: BSK StGB, 4th ed., Basel 2019, Art. 230bis StGB N 10.

325 ACKERMANN / SCHRÖDER BLÄUER, in: BSK StGB, 4th ed., Basel 2019, Art. 230bis StGB N 11.

326 WBK-S, Minutes of the meeting of 2/3 April 2001, 79 f.; cf. also BARBEZAT, ZStrR 2011, 378. In the GTG as well as in the USG, a distinction is made between these types of release, cf. Art. 11 and 12 GTG, Art. 29c and 29d USG.

327 Supplementary report II of the administration of 27. 3. 2001, para. 3, WBK-S, minutes of the meeting of 2/3. 4. 2001, annex.

328 Cf. for example WBK-S, minutes of the meeting of 14.12.2000, 4; report of the administration of 16.1.2001, para. 3.1; WBK-S, minutes of the meeting of 22.1.2001, 21, 23; supplementary report of the administration of 16.2.2001, para. 3, WBK-S, minutes of the meeting of 19./20.2.2001, annex; WBK-S, minutes of the meeting of 19./20.2.2001, 5 ff.

"handling of organisms in the environment", i.e. outside of "closed systems", is considered a "release".[330]

950 The mRNA "vaccines" have already been used on millions of people in Switzerland on the basis of a "temporary" authorisation by Swissmedic - in breach of fundamental legal duties of care - and have thus been placed on the market.

1.1.3. Factual "success "

951 Art. 230[bis] para. 1 lit. a SCC presupposes a threat to life and limb as a constituent element of the offence.

952 A **concrete** danger is required. The probability of the occurrence of damage is decisive. A concrete danger exists if, according to the usual course of events, there is the probability or the near possibility of a violation of the protected legal interest. A particularly close, acute risk of injury is required.[331] In this context, it is sufficient to establish the common danger that an individual person has been concretely endangered, but only if he or she is not individually determined from the outset in the sense of the theory of representation, but is selected by chance.[332]

953 As a result, the same concrete danger is required as under Art. 86 para. 2 lit. a HMG. This is - as previously (N 873 ff.) - is given.

1.2. Subjective facts

1.2.1. Intent

954 Intent is required, whereby contingent intent is sufficient. The contingent intent must also include the endangerment: The offender must have recognised that an endangerment could possibly occur and he must have accepted such an endangerment.[333]

955 As previously explained, Swissmedic was already aware of the possibility of mRNA integration into the human genome at the end of 2020; the regulatory authority described this possibility as "very low" (front N 152). This "very low" risk did not subsequently prompt

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329 On the whole, ACKERMANN / SCHRÖDER BLÄUER, in: BSK StGB, 4th ed., Basel 2019, Art. 230[bis] StGB N 14; gl. M. BARBEZAT, ZStrR 2011, 378; a. M. PK3-Trechsel/Coninx, Art. 230[bis] N 4.

330 ACKERMANN / SCHRÖDER BLÄUER, in: BSK StGB, 4th ed., Basel 2019, Art. 230[bis] StGB N 13.

331 ACKERMANN / SCHRÖDER BLÄUER, in: BSK StGB, 4th ed., Basel 2019, Art. 230[bis] StGB N 18, N 23.

332 ACKERMANN / SCHRÖDER BLÄUER, in: BSK StGB, 4th ed., Basel 2019, Art. 230[bis] StGB N 18, N 24.

333 ACKERMANN / SCHRÖDER BLÄUER, in: BSK StGB, 4th ed., Basel 2019, Art. 230[bis] StGB N 31 et seq.

Swissmedic to take any safety measures, so that a possible realisation of this risk was obviously accepted.

1.2.2. Negligence

956 If it is not possible to prove intent, it should be noted that Art. 230bis para. 2 SCC also covers negligent commission of the offence.

1.3. Grounds for justification and exclusion of guilt

957 No grounds for justification and exclusion of guilt are apparent.

1.4. Conclusion

958 There is at least sufficient suspicion that the persons who have been charged and the other perpetrators, who have yet to be identified, have committed offences under Article 230bis para. 1, or possibly para. 2, SCC.

2. Forgery of documents in office (Art. 317 SCC)

959 According to Art. 317 No. 1 SCC, anyone who, as a public official or person of public faith, deliberately forges or falsifies a document commits forgery in office. If the offender acts negligently, the penalty is a fine (Art. 317 No. 2 SCC). Forgery of documents is an abstract endangering offence.[334] .

2.1. Objective facts

2.1.1. Circle of perpetrators

960 Civil servants are deemed to be officials and employees of a public administration and the administration of justice as well as persons who provisionally hold an office or are provisionally employed by a public administration or the administration of justice or temporarily exercise official functions (Art. 110 para. 3 SCC). The decisive factor is the characteristic of the function in the service of the public.[335]

961 In their functions, the authorised officers (Swissmedic) fulfil a public service mandate, which means that they are considered public officials within the meaning of the Criminal Code.

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334 BGE 129 IV 53 E. 3.2 P. 58.
335 BGE 135 IV 201.

2.1.2. Offence

962 The offences under Art. 317 para. 1 SCC correspond to the forgery of documents under Art. 251 para. 1 SCC[336] Only writings that are intended and suitable to prove a fact of legal significance are considered to be documents (Art. 110 para. 4 SCC). Facts are legally significant if they alone or in conjunction with other facts bring about the creation, preservation, establishment, alteration, transfer or cancellation of a right or an obligation.[337] False certification is the **creation of** a genuine but **untrue document,** i.e. where the real facts and the facts contained in the document do not coincide. The truth of the declaration is protected: a deed is true if its content gives rise to ideas which, according to the public's perception, correspond to reality. It is untrue if the facts it expresses did not occur at all or occurred in a different way.[338] False certification requires a qualified written lie. According to the case law of the Federal Supreme Court, this is assumed to be the case if the document has an **increased credibility** and the addressee therefore places a special trust in it: What is necessary are generally valid objective guarantees that ensure the truth of the statement.[339] False certification is also possible by omission.[340]

963 As before (N 715 ff.), those responsible at Swissmedic have omitted elementary safety information from both the technical and patient information for the mRNA "vaccines": for example, there is a lack of compelling information regarding the occurrence and frequency of side effects (frequency of myocarditis, occurrence of herpes zoster and thrombosis) or compelling information regarding contraindications (people with pre-existing blood thickening; pregnant women). These contents are legally relevant: for a not inconsiderable part of the population, these are factors influencing the decision, which, depending on personal predisposition, can lead to the rejection of a declaration of consent.

964 In this context, the specialist and patient information, both of which are standardised by law, have increased credibility: they express that the "vaccines" authorised for a "limited period" meet the requirements for high-quality, safe and effective therapeutic products (Art. 1 HMG).

965 Swissmedic has therefore created and published untrue documents with the expert and patient information on Comirnaty and Spikevax.

336 BGE 117 IV 286 E. 6b p. 290 f.
337 BGE 113 IV 77 E. 3a , with further references.
338 BSK-StGB, BOOG, N 66 to Art. 251.
339 BGE 132 IV 12 E. 8.1 p. 14 f.; 129 IV 130 E. 2.1 p. 133 f.
340 Judgement 6P.76/2004 of the Federal Supreme Court of 01.10.2004, E. 6.4

2.1.3. No "offence success" necessary

966 As an abstract endangering offence, the offence is already completed when the false documents are put into circulation.[341] It is not necessary that a person is actually deceived.[342]

2.2. Subjective facts

967 Intent is given if the perpetrator knowingly, in his capacity as a public official, untruthfully states legally significant facts in a writing that he knows is suitable or intended to prove those facts.[343] In addition, the perpetrator must act with the **intent to deceive in legal dealings.** The intention to deceive results from the perpetrator's intention to use the documents as genuine.[344] The perpetrator must have the intention to deceive in legal transactions or at least accept it. [345]

968 Those responsible at Swissmedic deliberately allowed and still allow the specialist and patient information with the untrue content to be published in order to enable and maintain the approval of the mRNA "vaccines" and to promote their administration. And this despite the fact that they have long known or should have known that the cost-benefit profile for the average population in general (for more details see N 838 ff.) is clearly to the disadvantage of the mRNA "vaccines" and that they should therefore have been withdrawn from the market long ago. They therefore know about the untruthfulness of the content and nevertheless want to convey the safety of the "vaccines" to the general public, thereby acting with intent to deceive.

2.3. Grounds for justification and exclusion of guilt

969 No grounds for justification and exclusion of guilt are apparent.

2.4. Privilege: Negligence

970 Possibly, a negligent commission of the offence is to be examined in the sense of Art. 317 para. 2 SCC.

341 BGE 113 IV 77 E. 4 P. 82.
342 BGE 121 IV 216 E. 4 p. 223 with reference.
343 BGE 100 IV 182.
344 BGE 135 IV 198, unpublished E. 9.4
345 BGE 100 IV 180 E. 3a p. 182.

2.5. Conclusion

971 There is a strong suspicion that the persons who have been notified and the other perpetrators, who have yet to be identified, have committed a criminal offence under Art. 317 para. 1 SCC, or possibly under para. 2.

3. Endangering life (Art. 129 StGB)

972 According to 129 StGB, anyone who unscrupulously puts a person's life in immediate danger is liable to prosecution.

973 The legal interest covered by Art. 129 SCC is life (not health). Because this must actually be put in immediate danger, it is a concrete endangerment offence.[346]

3.1. Objective facts

974 It is necessary to cause a concrete, immediate danger to the life of another person. The latter must be specifically identifiable, or it must at least be a clearly defined group of persons.[347] Not every, but only an immediate danger to life is sufficient. This is the case if, according to the "usual course of events, there is the probability or the near possibility of injury to the protected legal interest".[348] In road traffic, this imminent possibility may be that there is a "high probability" of a serious accident with potentially fatal consequences.[349]

975 In the present case, at least the case of private plaintiff 1 is on record, who suffered a grade III anaphylactic shock immediately after the mRNA injection and only survived thanks to immediate hospitalisation. Due to the anaphylactic shock grade III she had already suffered (twice) after ingesting peanuts, the (very) near possibility of a fatal consequence of the injection was definitely present and had manifested itself accordingly. In view of the numerous reports on side effects of potentially fatal cases of myocarditis and other serious side effects, the number of people specifically threatened is likely to increase many times over.

976 The objective elements of the offence are thus likely to be fulfilled in a large number of cases without further ado.

346 MAEDER, in: BSK StGB, 4th ed., Basel 2019, Art. 129 StGB N 6 and N 12.
347 MAEDER, in: BSK StGB, 4th ed., Basel 2019, Art. 129 StGB N 8 and N 10.
348 BGE 133 IV 1, E. 5.1 P. 8; BGE 94 IV 60, P. 62.
349 MAEDER, in: BSK StGB, 4th ed., Basel 2019, Art. 129 StGB N 21.

3.2. Subjective facts

977 It is more difficult to prove the subjective element of the offence, as this requires both direct intent and unscrupulousness:

3.2.1. Direct intent

978 Art. 129 SCC requires direct intent, contingent intent with regard to the endangerment is not sufficient according to doctrine, materials and case law of the Federal Supreme Court.[350]

979 To take up the example of private plaintiff 1: According to the current state of knowledge, her "vaccinating" family doctor was aware that she had already suffered grade III anaphylactic shocks twice after ingesting peanuts. The knowledge side was therefore undoubtedly present. However, whether the family doctor also wanted to endanger the private plaintiff 1's life is to be determined.

980 The same applies to those acting on behalf of Swissmedic: they must have been aware of the possible lethal risks. The volitional side, on the other hand, must be determined. The same applies to those acting on behalf of the "Insel Gruppe".

3.2.2. Unscrupulousness

981 However, not only direct intent is required, but also "unscrupulousness". Accordingly, there must be a qualified degree of reproachability - such as a particular lack of inhibition and recklessness on the part of the perpetrator, a danger that lacks any consideration for the lives of other people.[351]

982 Such proof would probably first have to be provided by "vaccinating" doctors, who had acted virtually "on a piecework basis" and by omitting all basic safety mechanisms (in particular a complete lack of information). The same applies to those acting on behalf of Swissmedic and the "Insel Group".

3.3. Grounds for justification and exclusion of guilt

983 With regard to the justification of consent, it should be noted that the principle of "volenti non fit iniuria" does not apply to Art. 129 SCC: the unscrupulous offender - and only the unscrupulous offender is punishable under Art. 129 SCC - cannot exculpate himself by

350 MAEDER, in: BSK StGB, 4th ed., Basel 2019, Art. 129 StGB N 57, inter alia with reference to BGE 133 IV 1 E. 5.1 p. 8.
351 MAEDER, in: BSK StGB, 4th ed., Basel 2019, Art. 129 StGB N 51.

referring to the consent of the victim.[352] The justification of consent is moreover dealt with in detail below (N 1118 ff.) (cf. also N 1051).

984 Nor are any grounds for exclusion of guilt apparent.

3.4. Conclusion

985 There is at least sufficient suspicion within the meaning of Article 309 paragraph 1 letter a of the Code of Criminal Procedure that the persons who have been charged and the other perpetrators, who are still to be investigated, have committed a criminal offence under Article 129 of the Criminal Code.

III. Success offences of the StGB

1. Attribution of offences

986 The offences brought to court in this case have in common that - as far as can be seen - they were not committed directly by the acting defendants in a leading function, but by medical staff in vaccination centres, pharmacies or general practitioners' practices.

987 For a corresponding accusation against the defendants who do not "inoculate" themselves, an attribution of the "consequence of the offence" is therefore required, which can, for example, take place on the basis of the non-genuine offence of omission (inter alia in the form of the principal's liability) or - if a corresponding accusation can be substantiated - on the basis of indirect perpetration.

1.1. False injunctions (and principal's liability)

988 For the criminal liability of those acting on behalf of Swissmedic, the imputation takes place via the non-genuine offence of omission, since according to Art. 11 SCC a guarantor position exists according to the law or from the creation of a danger.

989 The same applies in principle to authorised persons in a management function outside Swissmedic who are responsible for "vaccinating" staff. In this case, particular attention must be paid to the instructions given to the "vaccinating" staff and to the precautionary and safety measures taken in the area of the mandatory clarification. In this case, the responsibility is not directly attributed via Art. 11 SCC, but via the principal's liability, which is also a non-genuine offence of omission.

352 MAEDER, in: BSK StGB, 4th ed., Basel 2019, Art. 129 StGB N 54.

1.1.1. Non-genuine offence of omission: Guarantor status

990 A felony or misdemeanour may also be committed by failing to act in accordance with one's duty (Art. 11 para. 1 SCC). According to Art. 11 para. 2, anyone who fails to prevent the endangerment or violation of a legal right protected by criminal law, although he is obliged to do so by virtue of his legal position, namely on the basis of:

- a. of the law;
- b. of a contract;
- c. a voluntarily entered into risk community; or
- d. the creation of a hazard.

991 A person who remains inactive in breach of his or her duty is only liable to prosecution on the basis of the corresponding offence if, according to the circumstances of the offence, he or she can be accused of the same offence as if he or she had committed the offence by an active act (Art. 11 para. 3 SCC).

1.1.1.1 Guarantor obligation

992 Bringing about the constituent success by means of omission is only equivalent to an active act if someone has a duty to act accordingly on the basis of a special legal position.[353] There are two basic types of guarantor status. The duty may relate to

- that someone has to avert all dangers and damages threatening certain legal interests of individual persons (duty of care or duty to protect) or
- that the person concerned has to keep a certain source of danger under control so that damage to legal interests of any bearer is avoided (duty to safeguard or supervise).[354]

993 According to Art. 11 para. 2 lit. a SCC, **guarantor obligations** can arise from **the law.** Whether a statutory duty qualifies as a guarantor's duty must be determined on the basis of criminal law evaluations. Relevant norms are, for example, legal duties on the basis of which a person is required to **monitor a source of danger** (business owner's liability Art. 55 CO; animal owner's liability Art. 56 CO; work owner's liability Art. 58 CO). Similarly, a **guarantor's position** may arise from **official and professional duties**:[355] For example, the Anti-Money Laundering Act and the FINMA guidelines establish a guarantor's position,

353 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 p. 310.
354 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 p. 310.
355 On the whole DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 pp. 312 ff.

which is why a financial intermediary may be guilty of money laundering by omission.[356] The **penal provisions of Art. 86 f. HMG (in conjunction with the due diligence obligations of Art. 3 and Art. 7 HMG)** oblige the persons acting on behalf of Swissmedic to ensure, in order to protect the health of the Swiss population, that only high-quality, safe and effective therapeutic products are placed on the market. In other words, they are responsible for one of the highest goods - human health. In doing so, they must strictly monitor all possible sources of danger emanating from medicinal products and contain them in the interests of risk minimisation. The officers acting on behalf of Swissmedic are thus in a **position of guarantor** (concretised in law by Art. 3 para. 1 HMG, among other things) with **regard to the physical and health integrity of people** - the very legal interests that are also protected by the success offences of Art. 111 ff. StGB[357] and Art. 122 ff. StGB .[358]

994 According to Art. 11 para. 2 lit. d SCC, the person who has **created or increased dangers to a legal interest is** also obliged to ensure that these dangers do not materialise. In this context, it is possible that conduct qualifies as an omission due to its social significance if certain activities (i.e. active doing) are associated with it. **A guarantor's duty exists even if a risk was created in a permissible manner and in compliance with the prescribed safety regulations.**[359]

1.1.1.2 Concrete danger situation and power of action

995 Insofar as non-genuine offences of omission are considered to be offences of success, the duty to intervene presupposes that a **concrete situation of danger** has arisen with regard to the legal interests to be protected, i.e. that there is a threat of the occurrence of the constituent element of the offence.[360]

996 Only this triggers the duty to intervene in favour of endangered legal interests. The person failing to **act** must therefore have the **power to** avert the danger.[361]

1.1.1.3 Occurrence of success and causal connection

997 Insofar as offences of non-genuine omission are to be assessed as offences of success, the objective elements of the offence presuppose the occurrence of the **constituent** element of the offence.[362]

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356 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 p. 315 with reference to BGE 136 IV 188.
357 SCHWARZENEGGER / STÖSSEL, in: BSK StGB, 4th ed., Basel 2019, Vor Art. 111 StGB N 1.
358 ROTH / BERKEMEIER, in: BSK StGB, 4th ed., Basel 2019, Vor Art. 122 StGB N 6.
359 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 pp. 319 f.
360 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 p. 324.
361 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 pp. 324 f.

998 There must be a causal connection between the occurrence of this success and the omission. In the case of non-genuine offences of omission, the **hypothetical causal connection must be** determined. According to the majority and the case law of the Federal Supreme Court, this assessment must be made according to the so-called theory of probability: The necessary connection is given if the required action could not be added without the success most likely being lost.

1.1.1.4 Swissmedic: Notified as breaching duty, inactive guarantors

999 From their position at Swissmedic alone, the defendants held a position of guarantor for the protection of the health of the Swiss population, which arises directly from, among other things, the main purpose of this authority as described in Art. 1 HMG and Art. 3 para. 1 HMG. The serious violation of their duty of care under the law on medicinal products already created a concrete risk situation by authorising a substance for use by the general healthy population, the risk/benefit profile of which was downright devastatingly negative due to the risk factors comprehensively described in the facts of the case.

1000 Moreover, by completely failing to take the necessary and adequate measures to contain the danger created - such as (1) transparent and clear information to the public and also to the medical profession about the relevant risk factors mentioned; (2) strict enforcement of the reporting obligations and (3) revocation of the authorisations - the officials acting on behalf of Swissmedic have exacerbated the already existing danger to the legal interest of human integrity.

1001 This dangerous situation was openly recognisable to the defendants from June 2021 at the latest (see above N 847 ff.), whereby the power to prevent the "successes" that occurred, such as serious bodily injuries and killings, lay entirely with the defendants.

1002 If they had compensated in time for the - uniquely large - risk created by the "temporary" authorisation, they should have actively ensured through the following:

1) Risk-adequate and risk-focused requirements for the manufacturers and effective enforcement of the same; in particular with regard to supplementing the incomplete application documentation (complete declaration of all ingredients; proof of the quality of the manufacturing process; proof of methodologically correctly conducted and correctly conducted clinical studies, etc.);
2) risk-adequate education of the population and the medical profession about the true extent of the risks and side effects;

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362 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 pp. 325.

3) a risk-adequate, effective system for the timely and, as far as possible, complete and prompt recording and reporting of serious and as yet unknown side effects in particular;
4) risk-adequate monitoring of all publicly available information on risks and side effects of the approved substances;
5) an immediate suspension or revocation of the "temporary" authorisations as soon as there is reason to worry that the benefit/risk ratio is no longer clearly positive.

1.1.2. Principal's liability

1.1.2.1 Control competence concerning typical operational hazards

1003 If the principal himself is *actively* involved in an offence, the following questions do not arise. However, if a principal remains inactive - i.e. if there is potentially a non-genuine *offence of omission* - it is disputed in case law and doctrine under which conditions a guarantor's duty can be assumed due to the principal's position:

1004 There seems to be widespread agreement that a principal cannot be held responsible for all offences committed in his business.[363] Rather, it is necessary that the offences are related to the **dangers typical for the business** and that these offences are committed by persons in whose **control competence** the corresponding area of responsibility falls.[364]

1005 If a company is exposed to typical operational hazards, the principal is responsible for controlling and, if necessary, minimising them. Under the heading of principal's liability, this means that the principal, Swissmedic, must - in addition to ensuring appropriate organisation - also be responsible for the existence and implementation of a **safety concept where** necessary. In addition to the senior managers, the persons who are responsible for the control or minimisation of typical operational hazards in accordance with the organisational structure of the company, or who should have ordered the safety precautions in accordance with the relevant specifications, are also considered to be guarantors for the existence, content and implementation of the safety plan.[365]

1006 The principal may and - if he wants to fulfil his management duties in larger companies - must delegate tasks. In general, the **delegation** - provided it is permissible or valid and the recipient of the delegation actually takes it up - results in a far-reaching exemption

363 See BGE 105 IV 176 Regeste, E. 4a p. 176 f.
364 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, Art. 11 N 104. See also DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 35 pp. 381 f. with reference to BGE 105 IV 176 f. and BGE 96 IV 155, 173 ff.
365 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 35 p. 383.

from liability under civil and thus also criminal law.[366] The prerequisite for this exemption from liability is essentially that the delegator cannot be accused of having acted in breach of duty in selecting (cura in eligendo), informing (cura in instruendo) and supervising (cura in custodiendo) the recipient of the delegation.[367]

1.1.2.2 Swissmedic: Notified as breaching duty, inactive guarantors

1007 The guarantor status of the officials acting on behalf of Swissmedic already results from their legal duty to protect the health of the Swiss population (see above N 992 ff.). Alternatively, a guarantor's position also arises from the liability of the principal: Unintended side effects of medicinal products that occur primarily because marketing authorisations were granted unjustifiably or because the public was not adequately informed of the risks or because risk-adequate pharmacovigilance was not carried out are to be regarded as "hazards typical of the business", which must be recognised and excluded as far as possible and proactively by the authorised persons acting on behalf of Swissmedic by means of risk-adequate measures or at least minimised as far as possible. The notifying parties clearly did not meet these minimum requirements, which is why their guarantor status also arises from their principal's liability.

1.1.2.3 Senior medical staff

1008 The senior medical staff in the present case is obliged to counteract typical operational dangers with appropriate safety concepts. Within the framework of the investigation, it must be determined what concrete precautions have been taken, in particular to ensure that patients are fully informed. If the corresponding precautions are inadequate - for which the sometimes completely missing documentation is a first indication - and are not only due to behaviour contrary to duty of the "vaccinating" staff, then according to the duty of guarantee, complicity of the senior medical staff is indicated.

1.1.3. Deliberate or negligent omission

1009 The offender must know or at least be aware of the possibility that the actual conditions of his guarantor status exist. Likewise, he must realise that the danger has occurred, that he has the possibility to eliminate it and that if he continues to stand by, the success of the offence could occur.[368] In addition, the offender must have at least accepted all of this.[369]

366 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 35 p. 384.
367 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 35 pp. 384; SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 89.
368 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 pp. 327 f.

1010 If the offender fails to recognise one or more of these circumstances, his conduct is to be assessed according to the rules of **factual error.** In particular, a **negligent offence of success** comes into consideration.[370]

1.1.3.1 Swissmedic: Persons notified acted with suspected contingent intent

1011 The officials at Swissmedic were and are well aware of their role as guarantors of the health of the Swiss population, as they refer in their mission statement to their function of ensuring safe and effective therapeutic products (front N 130). However, in view of the overwhelming facts, those responsible must have realised by June 2021 at the latest that they had made a serious mistake in approving the mRNA "vaccines". Added to this is the withholding of warnings and the dissemination of various misinformation (see N 701 ff.), which indicates at least a possible intentional act.

1.1.3.2 Senior medical staff

1012 In view of the misleading information provided by Swissmedic, it is not readily apparent to what extent the senior medical staff were aware of the extent of misconduct in the area of mRNA authorisations. However, it must also have been clear to the senior medical staff that, in view of the low mortality rates, SARS-CoV-2 was in no way a life-threatening or disabling disease for the population as a whole. This basic prerequisite is already missing, which means that a "temporary authorisation" should never have been granted, which the senior medical staff must also have known. In addition, if the investigation should show that not even the most basic organisational safety precautions had been taken on the part of the senior medical staff with regard to a completely transparent and documented explanation, not only would an appeal to the three curae be out of the question - the serious breach of duty would also indicate acceptance of the corresponding consequences.

1.2. Indirect perpetration?

1013 In view of the massively misleading public statements made by Swissmedic, the question also arises as to whether there could be indirect perpetration:

1014 An indirect perpetrator is one who uses another person as an "unwilling or at least unintentional tool to carry out the intended criminal act" (BGE 101 IV 306 p. 310 E. 8b).

1015 The indirect perpetrator puts the person in front of him ("intermediary") into an error that excludes his intent or exploits an already existing misconception of this kind in order to

369 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 p. 329; BGE 105 IV 176 Regeste, E. 4b p. 177 f.

370 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 p. 328.

make him realise the objective facts of the offence or at least individual elements of it. It must be an error of fact.[371] According to Art. 13 para. 1 SCC, an error of fact exists if the offender acts "in an erroneous conception of the facts". The error may relate, for example, to the means used by the offender. As an example: someone puts a substance into the drinking water whose harmful effect on health he does not know.[372]

1016 For his part, the **person in front** can at most be held responsible for **negligently** bringing about a result that he caused (see Art. 13 para. 2 SCC), namely if he acted under the influence of an error caused by the "person behind" and this must be charged to him as imprudence in breach of duty. Otherwise, the "tool" remains unpunished. [373]

1017 If the leading and also the "vaccinating" doctors were therefore misled by Swissmedic's misleading information, there may at best be indirect perpetration.

1.3. Other forms of offence

1018 If the person in front (e.g. the "inoculating" staff) commits the act at least with contingent intent (which means that there is no indirect perpetration), either aiding and abetting or complicity must be examined. [374]

1019 An accomplice is anyone who intentionally and significantly cooperates with other perpetrators in the commission, planning or execution of an offence, so that he or she stands as the main participant (BGE 130 IV 58 p. 66 E. 9.2.1). An aider and abettor is a person who intentionally assists in the commission of a felony or misdemeanour (Art. 25 SCC).

1020 In addition, if there is corresponding intent, incitement could also be relevant (Art. 24 para. 1 SCC).

1021 More detailed explanations will not be given here, as it will only be possible to determine who acted intentionally and who negligently at what point in time on the basis of the investigation to be carried out.

2. Negligent homicide (Art. 117 StGB)

1022 Anyone who negligently causes the death of a person is punished under Art. 117 SCC.

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371 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 15 p. 189.
372 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 10 p. 129.
373 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 15 p. 188 f.
374 FORSTER, BSK StGB, 4th ed., Basel 2019, Vor Art. 24 N 30, cf. also N 35.

2.1. Bringing about the success required by the offence

2.1.1. Offence: Causing death

1023 Any kind of causing the death of a living person is sufficient as an act, whereby the perpetrator can use any means. For the fulfilment of this success-oriented offence, the acceleration of the occurrence of death is sufficient. Killing by false omission is also covered.[375]

1024 Based on international surveys and studies, there are numerous indications that mRNA "vaccinations" have led to deaths (front N 251, N 351, N 415 ff. and N 428). The deaths of people in Switzerland are potentially caused or accelerated by the fact that **Swissmedic has** authorised the mRNA "vaccines" in accordance with Art. 9a HMG and has repeatedly extended or not revoked their authorisation - with completely neglected monitoring and misleading information to the public - and that the mRNA "vaccines" have been and are being administered by the **medical profession.**

2.1.2. Success according to the facts

1025 With the occurrence of death, involuntary manslaughter is completed.

1026 Even if Swissmedic denies this for Switzerland (see N 729 ff.), it seems rather unlikely that none of the 210 suspected deaths reported in Switzerland to date (N 382) due to mRNA "vaccination" could be substantiated. As already explained several times and in detail (N 845 with further references), Swissmedic has not taken adequate account of the special risks associated with mRNA "vaccines" when designing the monitoring of these substances. This complete passivity in the area of pharmacovigilance - with the reliance on a completely inadequate passive reporting system resulting in massive underreporting - is already a clear indication that Swissmedic is not willing to ensure complete transparency.

1027 As far as can be seen, Swissmedic has not made any recognisable efforts to date to work towards the consistent performance of professional autopsies in the area of suspected cases of mRNA injections resulting in death - for example by means of corresponding publicity publications or direct recommendations for the attention of the public prosecutor's offices and forensic medicine institutes. This is exemplified by the specific case of private plaintiff 5, in which a post-mortem examination had taken place that was in no way adequate (see N 67 f., N 315 ff.): Limiting the examination to obvious final causes of death

375 SCHWARZENEGGER, BSK StGB, 4th ed., Basel 2019, Art. 111 N 4.

(such as organ damage and haemorrhages) is simply not sufficient to determine vascular damage caused by the mRNA "vaccines", which then lead to the final causes of death.

2.1.3. Causality

1028 In the case of success offences, the question arises as to whether the actor has caused the success in its concrete form. According to the theory of conditions or equivalence, a cause is any condition that cannot be disregarded without the success ceasing to exist *("conditio sine qua non").* In the case of passive behaviour by omission, a hypothetical causal connection comes into consideration, as previously defined (N 878 and N 998). Causality is thus given without regard to the nature of the offender's act if it only already constituted *a* condition for the success that occurred (so-called natural causality). Neither the number nor the weight of possible (co-)causes is important.[376]

1029 The authorisation of mRNA "vaccines" by those acting on behalf of Swissmedic is the central prerequisite for their use by the medical profession in Switzerland. The authorisation, its repeated maintenance, the omission of any risk-adequate measures to avert danger as well as the "vaccination actions" that have taken place cannot be disregarded without the "success" in the sense of the harmful "vaccination" side effects being omitted. The actions (and omissions) of the responsible persons thus represent one - probably by far the most important - cause of the "vaccination damage" that has occurred.

2.2. Disregard of a duty of care

1030 A person commits a negligent act if he or she fails to consider the consequences of his or her conduct due to imprudence in breach of his or her duty or if he or she fails to take them into account. Imprudence is contrary to duty if the offender fails to observe the caution to which he is obliged under the circumstances and according to his personal circumstances (Art. 12 para. 3 SCC).

1031 It must first be examined whether an unlawful risk was "objectively" created by the breach of duty, and then whether this breach of duty is "subjectively" reproachable under the specific circumstances and personal circumstances of the perpetrator.

376 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 8 p. 103 f.

2.2.1. Creation of an unauthorised risk

2.2.1.1 Violation of general-abstract norm

1032 Where special standards require certain conduct, the degree of care to be observed shall be determined primarily by these regulations.[377]

1033 General-abstract norms dealing with risky behaviour are often found in special laws in the form of abstract endangering offences. Accordingly, the maximum permissible risk is at least indirectly defined in these. If an offence occurs, there is a certain probability that the duty of care according to Art. 12 para. 3 SCC has been disregarded if the special law norm is disregarded.[378]

1034 As in front (N 838 ff.), there is a strong suspicion that the defendants have violated several duties of care (and standardised endangering offences) of the HMG and have thus disregarded the maximum permissible risk. In addition, there are weighty indications (see N 873 ff.) that this risk has materialised in the form of the violation of the physical integrity of a large number of people , i.e. a constituent "success" has occurred. There is therefore a considerable probability that the due diligence required under Art. 12 para. 3 SCC was not exercised.

2.2.1.2 General hazard rate and permitted risk

1035 If a general, abstract standardised duty has not been breached, the general principle of danger or the requirement of "neminem laedere" can also be used as a subsidiary basis.[379] According to this, the person who carries out a dangerous act must do everything reasonable to ensure that the danger does not lead to a violation of the legal interests of others.[380] In doing so, the actors must ensure that any unnecessary increase in risk is avoided and that the limits of the permissible (maximum permissible) risk are not exceeded.[381] The decisive factor here is which risks for legal interests protected by criminal law may be accepted in a certain area of conduct (high-risk versus low-risk activities) according to general opinion.[382]

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377 BGE 140 II 7 E. 3.4 S. 10.

378 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 32 pp. 348 f.

379 BGE 140 II 7 E. 3.4 p. 10; BGE 121 IV 14 f.; DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 32 pp. 349 and p. 351.

380 BGE 135 IV 64; DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 32 pp. 351.

381 BGE 140 II 7 E. 3.4 p. 10; DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 32 pp. 343.

382 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 32 pp. 354.

1036 If, contrary to expectations, the actions of the defendants can in any way be classified as just still subject to due diligence, based on the vast number of legal norms on the level of laws and ordinances as well as further recommendations, the following should be pointed out:

1037 In the present case, activities such as the authorisation of medicinal products are to be examined, which are not per se in breach of duty, but which involve a certain risk to the legal interests of others. In this context, any regulation and documentation cannot obscure the fact that the core question is whether, with the initial and ongoing approval of mRNA "vaccinations", those responsible created an unacceptable risk that led to the injury of people's health. As explained in detail above, the benefit of the "vaccines" tends towards zero (N 201 ff., N 253 ff., N 354 f.), while at the same time the risks that can already be ascertained dwarf anything that has gone before and the medium to long-term consequences cannot be assessed in any way due to the lack of any studies (N 141 et seq. and N 840 ff.; N 220 ff. and N 847 ff.; N 264 ff. and N 852 ff.; N 378 ff. and N 854 ff.). In addition, the officials acting on behalf of Swissmedic have not taken account of this already alarming risk situation through their own actions (such as insufficient requirements vis-à-vis the manufacturers, misleading information for the public and the medical profession, completely inadequate monitoring, etc.; see above N 683 ff.) even worse. In this initial situation, it is obvious that the defendants have not done everything reasonable and are still not doing anything to protect the endangered and already violated legal interests with due care.

2.2.1.3 Insertion: Principle of trust

1038 In the present case, the respondents could invoke the principle of trust. According to the principle of trust, everyone may assume that their fellow citizens will behave dutifully. This applies in particular to cooperation based on the division of labour. However, there are important restrictions: If someone is obliged to supervise another person, or if several persons cooperate within the framework of a multiple security system, none of the cooperating persons can exonerate themselves by having trusted in the dutiful conduct of the other participants. In addition, if there are concrete indications of negligent behaviour on the part of another person, special precautionary measures are required of the person behaving correctly. This means that in such a case, the assessment of the duty of care must be based on a lower risk than the maximum permissible risk.[383]

383 On the whole DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 32 pp. 352 f.

1039 The officers acting on behalf of **Swissmedic** cannot therefore claim to have relied on the fact that the manufacturers would behave in accordance with their duty of care. On the contrary: as managers of the supervisory authority, it is precisely part of their fundamental duty to supervise the manufacturers. In view of the complete novelty of the mRNA "vaccines" and the numerous alarm signals that have arisen (N 141 ff. and N 840 ff.; N 220 ff. and N 847 ff.; N 264 ff. and N 852 ff.; N 378 ff. and N 854 ff.), the defendants were also required to exercise particular diligence in connection with the authorisation and monitoring of the COVID "vaccines".

1040 The same applies to the **medical profession:** insofar as the doctors complied with Swissmedic's requirements and fulfilled all their obligations to provide information, the question also arises here as to whether they - despite the misleading information from Swissmedic - should not have known better as professionals. The international studies on side effects (see N 251, N 351 and N 428) and the obvious lack of a "pandemic" (N 474 ff.) had to give rise to justified doubts in every doctor's mind as to the accuracy of Swissmedic's information. Accordingly, they could not blindly trust Swissmedic's specifications, but would have had to carry out their own clarifications.

2.2.2. Attribution of the success

1041 According to the foregoing, there is an urgent suspicion that the defendants exceeded the maximum permissible risk and thereby created a hazardous situation resulting in injury. However, in order to justify a breach of the duty of care, this created risk must have been both *foreseeable* and *avoidable for the* persons acting, whereby the due diligence to be exercised is measured according to an objective-individual standard.[384]

2.2.2.1 Foreseeability: Social adequacy

1042 The sequence of events leading to success must be foreseeable for the specific offender at least in its essential features[385] - including any special knowledge.[386] In order to answer the question whether the danger of the occurrence of success was foreseeable for the perpetrator, the standard of adequacy applies; this means that his conduct must be suitable, according to the usual course of events and the experiences of life, to bring about or at least favour a success like the one that occurred.[387] Whether an act within the meaning of the **theory of adequacy** is suitable according to the ordinary course of events and the

384 BGE 140 II 7 E. 3.4 S. 10
385 BGE 129 IV 282 E. 2.1 P. 284.
386 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 32 pp. 355 f.
387 BGE 129 IV 282 E. 2.1 p. 284 f.; BGE 121 IV 10 E. 3 p. 15; DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 32 p. 353.

general experience of life to bring about or favour a success of the kind that occurred must be decided *ex ante, i.e.* from the time of the act; because the subsequent (better) knowledge of the context cannot decide whether an act was permitted or prohibited at the time it was performed.[388]

1043 As previously shown in detail (N 838 ff.), the officials acting on behalf of **Swissmedic** had different data at their disposal at different times - or, in view of their position, should have had them at their disposal. As time went on, knowledge of the lack of danger posed by COVID-19 solidified, and it became increasingly apparent that the mRNA "vaccinations" were not only not as effective as promised, but that the risk associated with the authorisation was beyond anything that had ever been assumed in the case of previous medicinal product authorisations. At the same time, at the time of the first "limited" authorisation in December 2020 - but at the latest at the time of the "limited" authorisation for adolescents from 12 years of age in June 2021 - there were already so many warnings which were known or must have been known to the notifying parties that these "limited" authorisations should never have been granted. Accordingly, it was already recognisable to the notifying parties - particularly due to their specialist knowledge - that the approval of the experimental gene therapy contained a considerable risk potential which, in view of the low lethality in the overall population due to COVID-19, was disproportionate to the expected benefit. As specialists, they had to recognise that the approval of such a "vaccine" lay outside the still permissible risk and was capable of massively damaging the physical integrity of the vaccinated people. The foreseeability of the occurrence of success was thus given. The conduct of the defendants was, according to the usual course of events and the experience of life (at that time), at least likely to favour a success such as the one that occurred. Accordingly, the defendants should have geared their conduct to the known risk.

1044 The same applies to the **medical profession** - albeit with a slight time lag: by June 2021 at the latest, the side effects occurring in excess were obvious to everyone and thus also to doctors (see N 220 ff. and N 847 ff.). The same applies to the lack of danger of SARS-CoV-2 and the (largely) uselessness of the mRNA "vaccinations". Those who were still "vaccinating" from this point on had to know accordingly about the devastating risk-benefit ratio with the potential for fatal effects - even if they strictly adhered to Swissmedic's guidelines. Independently of this, those cases must be assessed in which elementary obligations to provide medical history and information had been violated (see above N 859 ff.): Anyone who, as a doctor (or pharmacist), did not clarify and inform properly, created a danger in every case that could adequately and causally lead to homicide.

388 BGE 135 IV 56 E. 2.2 P. 65.

2.2.2.2 Avoidability: Individual ability to fulfil duty

1045 For the occurrence of the success to be attributable to the offender's conduct in breach of duty, its foreseeability alone is not sufficient. A further prerequisite is that the success was also individually avoidable: A course of events is only controllable if the perpetrator has the ability to eliminate the danger associated with his or her conduct - be it by taking appropriate precautions or also by refraining from the risky action.[389] In this context, a hypothetical causal course is examined and it is examined whether the success would not have occurred if the perpetrator had acted dutifully, whereby this is to be answered by evaluating all circumstances known *ex post.* The success is to be attributed to the offender if his conduct was the cause of the success at least with a high degree of probability or with probability bordering on certainty.[390] It must be taken into account that in emergency situations and in the case of temporal urgency of an intervention, depending on the circumstances, it cannot always be demanded that of various possible measures, the one that appears to be the most objectively expedient upon retrospective consideration is taken.[391]

1046 With regard to the officials acting on behalf of **Swissmedic, it** should be noted that in December 2020 there was considerable media and political pressure for approval of the experimental mRNA "vaccines". However, under no circumstances must the licensing authority buckle under media or political pressure, but must strictly comply with the law and ensure that "only high-quality, safe and effective medicinal products are placed on the market" (Art. 1 para. 1 HMG) in order to protect the health of people in this country. Nor can the defendants seriously argue that there was an actual emergency situation or even urgency in terms of time: As already explained in detail (above N 479 ff.), there was in no way a mortal danger, at least with regard to the population as a whole. If at all, it was persons over the age of 70 who were threatened. With dutiful behaviour, the damage to physical integrity caused by the "vaccinations" could therefore have been prevented completely unnecessarily. This possibility of preventing harm was readily available to the Notified Bodies, as they are the gatekeepers in Switzerland with regard to the authorisation (and monitoring) of medicinal products. The fact that the authorities nevertheless decided otherwise can only be attributed to political pressure or other - in no way medico-epidemiologically indicated - motives.

1047 With regard to the **medical profession, a** distinction must be made once again: Insofar as obligations to provide medical history and information were violated, the corresponding

389 STRATENWERTH, AT I, 4th edition, Bern 2011, § 16 N 10
390 BGE 140 II 7 E. 3.5 S. 11; BGE 135 IV 56 E. 2.1 S. 65.
391 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 32 pp. 344.

conduct was easily avoidable. Nor was there any "temporal urgency" or even an "emergency situation" that would have prevented at least the most elementary duties of care from being complied with in the context of clarification. It was possible and also reasonable for every doctor practising in Switzerland to present and explain to his or her own patient in the specific consultation all the essential general motor facts as the basis for an informed decision on the benefit/risk assessment. In this respect, the medical profession, by virtue of its special professional competence and its obligation to serve the well-being of its patients, can be expected to think independently, even if in individual cases this results in a decision that deviates from the generally prevailing schematised-general vaccination recommendation of Swissmedic (and other administrative units). By refraining from the obviously risky action in the form of "vaccination" with an experimental gene therapy, every "vaccinating" doctor (and also the doctor propagating the "vaccination" in a management function) could have prevented the successful outcome.

2.2.2.1 Insertion: no serious contributory negligence of third parties

1048 In the present case, the defendants could still argue that all vaccinated persons had "consented" to the "vaccination" and the possible side effects associated with it. However, the adequacy of the cause to be assessed for the success is only to be denied if quite exceptional circumstances, such as the contributory negligence of a third party or material or construction errors, are added as contributory causes, which could not be expected in the first place and which are so serious that they appear to be the most probable and direct cause of the success and thus push all other contributory factors - namely the behaviour of the defendants - into the background.[392] It would be necessary for a person affected to endanger his or her legal interests of health and physical integrity in such a self-responsible manner that this would correspond to actual self-harm.[393] The decisive factor here is whether it would have been possible and reasonable for the potential perpetrator to inform the person concerned about the risks of his actions. Both presuppose superior abilities to reduce risk - in particular superior expert knowledge regarding the dangers in question.[394] The criminal liability of the perpetrator promoting the self-harm for the success that has occurred therefore begins if the victim, for example due to his inexperience or youth, does not recognise the danger, if the perpetrator, due to superior expert knowledge, understands the risk better than the person endangering himself or if he has a guarantor position in favour of the victim.[395]

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392 BGE 135 IV 56 E. 2.2 P. 65.
393 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 32 pp. 358.
394 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 32 pp. 359.
395 BGE 125 IV 189 E. 3a p. 194.

1049 With the authorisation, the inadequate to non-existent monitoring and the associated maintenance of the authorisation, as well as the misleading public communication, the authorised persons acting on behalf of **Swissmedic have been the** main reason why people in Switzerland have had themselves "vaccinated" against COVID-19. However, the notifiers did not stop at mere authorisation decisions: They "informed" the population (including doctors and medical personnel) publicly about the alleged harmlessness and the allegedly high effectiveness of the "vaccinations" - and this in a blatantly misleading manner (see N 715 ff.). At the same time, the defendants had specific expert knowledge (on the additional guarantor position see N 992 ff.) and would therefore have had the duty to transparently inform those willing to be vaccinated - which they did not do. Against this background, any "consent" on the part of the injured is completely eclipsed. The same applies in principle to intermediate actions by the medical profession, insofar as they acted in accordance with Swissmedic's recommendations and provided sufficient information. There are thus simply no "exceptional" circumstances in the sense of self-inflicted or third-party culpability that could be discerned that would cause the actions of the defendants to recede into the background. The most probable and direct cause of the vaccination damage appears to be Swissmedic's authorisation decisions, for which the defendants share responsibility.

1050 With regard to the medical profession, a distinction must once again be made between those doctors who strictly adhered to Swissmedic's requirements and fulfilled all their obligations to provide information, and those doctors who largely or even entirely failed to provide medical histories and information in breach of their duties. The former can - up to a certain point - claim to have been misinformed by Swissmedic, although here too they must allow their specialist knowledge to be taken into account. The latter, through their own gross misconduct (breach of the obligations to provide medical history and information), have contributed to the cause in such a weighty manner that an appeal to third-party fault is no longer possible from the outset.

2.3. Justification: Consent ?

1051 Consent to one's own killing is not legally possible: Art. 114 SCC declares the killing of another person punishable, even if the person concerned seriously and insistently requests it.[396]

396 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, Vor Art. 14 N 27.

2.4. Grounds for exclusion of guilt

1052 No grounds for exclusion of guilt are apparent.

2.5. Conclusion

1053 There is an urgent suspicion that the persons who have been reported and the further perpetrators, who have yet to be identified, have committed multiple offences under Art. 117 SCC for the period from December 2020 - at the latest from June 2021.

3. Intentional homicide (Art. 111 StGB) and murder (Art. 112 StGB)

1054 Anyone who intentionally kills a person is liable to prosecution under the basic offence of Art. 111 SCC. Intentional homicide may also be committed by an indirect perpetrator.[397]

1055 If qualifying elements of the offence are present, the offence of murder under Art. 112 SCC must be examined.

3.1. Objective basic offence (Art. 111 StGB)

3.1.1. Bringing about the success required by the offence

1056 With regard to the act of committing the offence, the result of the offence and natural causality, reference is made to above (N 1023 ff.).

3.1.2. Excursus: Objective attribution

1057 In the event that the very far-reaching attribution of success via natural causality would appear to be unreasonable, the examination of objective attribution would be appropriate.[398] A success is objectively attributable if the perpetrator has created a legally relevant danger that is realised in the constituent success.[399]

1058 The objective imputability of the success is lacking, for example, if the success is not or is no longer covered by the *scope of protection of the norm that* the offender has violated by his act.[400] Like the penal provisions of the HMG, which serve to protect human health (Art. 1 HMG), the offences of violation of the StGB also protect human health - namely in the form of the protection of life itself (Art. 111 ff. StGB)[401] as well as the protection of physical

397 TRECHSEL / FINGERHUTH, in: Trechsel / Pieth [eds], Schweizerisches Strafgesetzbuch, Praxiskommentar, 2nd ed, Zurich / St Gallen 2013, Art. 111 N 1.
398 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 7 p. 88.
399 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 7 p. 88.
400 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 7 p. 88 f.
401 SCHWARZENEGGER / STÖSSEL, in: BSK StGB, 4th ed., Basel 2019, Vor Art. 111 StGB N 1.

and health integrity (Art. 122 ff. StGB).[402] With the approval and administration of the COVID "vaccinations", those responsible have created precisely the legally relevant danger which has materialised in the constituent success of the violation of human health.

1059 However, the scope of protection of a norm ends where the victim's *own responsibility* begins: Self-responsible, conscious self-harm by people capable of judgement and informed therefore generally leads to the limitation of the attribution of success.[403] However, if the person involved in creating the risk has *superior knowledge* compared to the victim, the principle of personal responsibility must be carefully examined.[404] Thus, also under the title of objective imputation, the elements of "guarantor status" and "third-party fault" come into play,[405] as they have previously been under the titles of injunctive relief (N 992 ff.) and negligence offences (N 1048 ff.). Both a position of guarantor and superior knowledge on the part of the defendant were affirmed. A limitation of the attribution of success is therefore not appropriate.

3.2. Subjective facts

1060 Homicide under Art. 111 SCC must be committed intentionally, although contingent intent is sufficient.

1061 A person commits a felony or misdemeanour intentionally if he or she carries out the act with knowledge and will (Art. 12 para. 2 sentence 1 SCC). In addition to knowledge of the real possibility of committing the offence, intent also requires the will to carry out the offence. The offender must decide against the legally protected good. This will is given in the sense of **direct intent if the realisation** of the elements of the offence is the actual goal of the offender's action or appears to him as a necessary prerequisite for achieving his goal. The same applies if the realisation of the elements of the offence is a necessary secondary consequence for the offender, even if he is indifferent or even undesirable to it.[406]

1062 A person acts with **contingent intent if he or she** considers the realisation of the offence possible and accepts it (Art. 12 para. 2 sentence 2 SCC). Both those who act with contingent intent and those who act with conscious negligence are aware of the possibility of the occurrence of success. However, there are differences in the element of will. The perpetrator who acts with deliberate negligence trusts (due to imprudence in breach of duty)

402 ROTH / BERKEMEIER, in: BSK StGB, 4th ed., Basel 2019, Vor Art. 122 StGB N 6.
403 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 7 p. 89.
404 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 7 p. 89.
405 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 7 p. 90, inter alia with reference to BGE 125 IV 189 E. 3a p. 194 (betr. *fahrlässige* Körperverletzung).
406 BGE 130 IV 58 E. 8.2 p. 60 f.

that the success he foresaw as possible will not occur.[407] Contingent intent, on the other hand, is given if the offender considers the occurrence of the success or the realisation of the offence to be possible, but nevertheless acts because he accepts the success in the event of its occurrence, accepts it, even if it is undesirable to him. The court may infer the will from the knowledge of the offender if the occurrence of the success imposed itself on the offender as so probable that the willingness to accept it as a consequence can reasonably only be interpreted as an approving acceptance of the success.[408] Among the external circumstances from which the conclusion can be drawn that the offender accepted the realisation of the offence, case law also includes the magnitude of the risk of the realisation of the offence known to the offender and the seriousness of the breach of the duty of care. The greater the probability of the realisation of the offence and the more serious the breach of the duty of care, the closer it is to the factual conclusion that the offender has accepted the realisation of the offence.[409]

3.2.1. Concerning first and second "vaccinations

1063 As previously explained in detail (N 840), the persons acting on behalf of **Swissmedic were** already in gross breach of their duty of due diligence under the law on medicinal products by the end of 2020. In particular, their internal knowledge - based only on the few documents currently available - differed flagrantly from the information communicated to the outside world, which points to the existence of contingent intent. It is therefore imperative that the criminal investigation determine what other documents (authorisation documents, mail communication, internal memos, etc.) Swissmedic had at its disposal.

1064 The case is probably different here in the area of the **medical profession**: in view of the widespread misinformation from Swissmedic and the still missing publicly accessible data on side effects, it is hardly possible to prove a corresponding contingent intent on the part of a doctor.

3.2.2. Further approvals as of June 2021 and as of autumn 2021

1065 At least as of June 2021, it was obvious to those acting on behalf of **Swissmedic** that they had authorised a medicinal product for the prophylactic treatment of a hardly life-threatening or disabling disease, which is neither effective nor safe. Accordingly, they knew that not a single one of the requirements for a "temporary authorisation" had (ever) been met. Under these circumstances, the knowledge of the defendants leads to the ur-

407 BGE 143 V 285 E. 4.2.2 S. 291.
408 BGE 137 IV 1 p. 4 E. 4.2.3; cf. also BGE 130 IV 58 E. 8.3 p. 61.
409 BGE 130 IV 58 E. 8.4 P. 62.

gent suspicion that the occurrence of completely avoidable side effects, including the unnecessary death of vaccinated persons, had to impose itself on them as so probable that their actions to the contrary can only reasonably be interpreted as acceptance of this very "success".

1066 The same applies to the **medical profession**, although here a corresponding contingent intent can only be assumed from autumn 2021 (approval of booster and child "vaccinations"): At that time at the latest, it was openly recognisable to every independently thinking and informed doctor that SARS-CoV-2 is a disease that is not dangerous for the general population, that the mRNA "vaccinations" do not immunise sufficiently in any way in view of the "necessity" of "boosters" and that the reports of side effects had reached an unprecedented number worldwide. To continue to "vaccinate" in the face of this overwhelming evidence can only be interpreted as accepting the most serious consequences.

3.2.3. From the predominance of the "omicron" variant

1067 By 2022 at the latest, SARS-CoV-2 with "Omikron" had lost all danger for the entire target population of the mRNA "vaccinations". At the same time, worldwide reports of side effects reached new highs. In addition, the lack of efficacy of the mRNA "vaccinations" was demonstrated by the fact that even triple-vaccinated people repeatedly fell ill with "COVID-19" (front N 442 ff.). The mRNA "vaccinations" are therefore - since 2022 at the latest, obvious to everyone - useless and, moreover, dangerous to the point of being fatal.

1068 Under these circumstances, the knowledge of the defendants gives rise to the urgent suspicion that the occurrence of completely avoidable side effects, including the unnecessary death of vaccinated persons, had to impose itself on them as so probable that their actions to the contrary can only reasonably be interpreted as acceptance of this very "success". In view of the overwhelming facts, this absolutely irresponsible action must even be considered as **direct intent.**

3.3. Qualification: Murder (Art. 112 StGB)

1069 Murder first requires an intentional killing, whereby contingent intent is sufficient;[410] accordingly, reference is made to the preceding explanations (above N 1062).

1070 If, in addition, the perpetrator acts in a particularly unscrupulous manner, in particular if his motive, the purpose of the act or the manner of execution are particularly reprehensible, the qualifying characteristics of murder under Art. 112 SCC are present.

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410 BGE 112 IV 65 E. 3b; SCHWARZENEGGER, in: BSK StGB, 4th ed., Basel 2019, Art. 112 StGB N 26.

1071 The use of poison, for example, is considered to be a particularly reprehensible manner of execution: However, this alone should not be sufficient to assume particular unscrupulousness.[411] The use of poison is particularly reprehensible if it is used in an insidious manner. Insidiousness exists if the perpetrator first gains the victim's trust in order to then kill him by taking advantage of his guilelessness.[412] For example, it was qualified as murder when poison was administered under the pretext of caring.[413]

1072 The mRNA "vaccines" lead to the body's own production of the so-called spike protein, which has a pathogenic - i.e. disease-causing - effect that can, in the worst case, lead to death (see in detail N 265 ff., N 415 ff.). In addition, there are the toxic, potentially carcinogenic and mutagenic lipid nanoparticles (LNP), which can also cause devastating damage to the body (see N 155 ff.). In addition, toxic, carcinogenic and mutagenic impurities in the form of benzene and nitrosamine have been found in the mRNA "vaccines" (N 165 ff.) - such substances simply have no place in a "vaccine". Despite all these circumstances known to them, those responsible at **Swissmedic** praised the "vaccinations" as "safe" (N 715 ff., especially N 724 and N 738), without pointing out the possible fatal consequences in a single place that was comprehensible and easily visible to patients (cf. N 737 ff. and N 729 ff.). In this way they created false confidence in the dangerous "vaccination" among those affected, which they exploited against their better knowledge in view of the overwhelming facts.

3.4. Grounds for justification and exclusion of guilt

1073 No grounds for justification and exclusion of guilt are apparent.

1074 In particular, valid consent to one's own killing is not possible (anterior N 1051).

3.5. Conclusion

1075 At the very least, there is sufficient suspicion that the persons notified, acting on behalf of **Swissmedic,** and the other perpetrators, who have yet to be identified, have committed multiple offences under Art. 111 SCC, or possibly under Art. 112 SCC.

1076 In addition, there is a strong suspicion that the doctors who were prosecuted and the other perpetrators, who have yet to be identified, have committed multiple offences under Article 111 of the Criminal Code.

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411 SCHWARZENEGGER, in: BSK StGB, 4th ed., Basel 2019, Art. 112 StGB N 23.

412 TRECHSEL / FINGERHUTH in: in: Trechsel / Pieth [eds], Schweizerisches Strafgesetzbuch, Praxiskommentar, 2nd ed, Zurich / St Gallen 2013, Art. 112 N 21.

413 BGE 77 IV 57 E. 3 p. 64: "[...] the use of poison speaks for their insidiousness. ".

4. Criminal abortion (Art. 118 StGB)

1077 According to Art. 118 para. 2 SCC, anyone who terminates a pregnancy without the consent of the pregnant woman is liable to a custodial sentence of one year to ten years.

4.1. Objective facts

4.1.1. Offence: termination of pregnancy

1078 The act consists in terminating the pregnancy.[414] This includes any killing of an embryo or foetus between nidation and the onset of labour. [415]

1079 Both acts that lead to the premature separation of the fruit and subsequently to its death and the killing of the fruit in the mother's womb are constituent elements of the offence. [416]

1080 Induced premature births are also punishable: Both induced premature births in the early and middle stages of pregnancy (non-viable foetuses) and in the late stage of pregnancy (foetuses that are basically viable) are punishable if the perpetrator's (contingent) intention was directed towards killing the nascens.[417]

4.1.1.1 Offences committed by Swissmedic

1081 As guarantor (front N 990 ff.), Swissmedic was and is obliged to prevent damage such as premature births and miscarriages in connection with mRNA "vaccinations". Instead, Swissmedic committed the following serious breaches of its duty of care:

1082 At the end of 2020 and the beginning of 2021, respectively, Swissmedic granted Comirnaty and Spikevax the "temporary" marketing authorisation for pregnant women as well and stated in the technical information for Comirnaty that "no vaccine-related effects on female fertility, pregnancy or embryo-fetal development or on the development of the offspring have been observed" (front N 704 ff.), although it was already known at that time,

- that the lipid nanoparticles SM-102 contained in Spikevax can probably impair fertility and harm the child in the womb (front N 155 ff.) and
- that a possible risk in pregnancies (twofold increase in pre-implantation losses, malformations) had been found in preclinical studies (animal studies) (front N 172 ff.).

1083 Even at the end of 2021, Swissmedic maintained the still completely trivialising and misleading texts in the expert information ("Animal studies do not indicate any direct or

414 SCHWARZENEGGER / HEIMGARTNER, BSK StGB, 4th ed., Basel 2019, Art. 118 N 16.
415 SCHWARZENEGGER / HEIMGARTNER, BSK StGB, 4th ed., Basel 2019, Art. 118 N 4.
416 SCHWARZENEGGER / HEIMGARTNER, BSK StGB, 4th ed., Basel 2019, Art. 118 N 4.
417 SCHWARZENEGGER / HEIMGARTNER, BSK StGB, 4th ed., Basel 2019, Art. 118 N 4.

indirect adverse effects with regard to pregnancy, embryonic/fetal development, birth or postnatal development"; Spikevax: Comirnaty: "Animal studies do not indicate any direct or indirect adverse effects with regard to pregnancy, embryonic/fetal development, birth or postnatal development"), although it was additionally clear at the time,

- that according to the manufacturers, the effects of the mRNA "vaccines" on pregnancy, the foetus or a child to be breastfed were not known (front N 334 f.),
- that more than 2,000 miscarriages or premature births have already been reported worldwide (ff. N 336 ff., esp. N 340),
- that numerous complications and deaths of newborns breastfed by recently vaccinated mothers have already been registered worldwide (front N 338).

1084 In the course of 2022, Swissmedic also maintained the still completely trivialising and misleading texts in the expert information, although it was now also additionally clear,

- that the safety profile of the "vaccine" in pregnant or breastfeeding women was still not known and that a manufacturer had again commissioned the necessary studies from a research institute known for falsifying data (front N 407 ff.),
- that only up to May 2022, **2-3.8 stillbirths per 1 million vaccine doses** were recorded for Comirnaty and Spikevax in the EU and the USA.

1085 In addition, despite all these circumstances, Swissmedic has apparently been publishing a false and completely misleading text on its own website ("FAQ") for the attention of the public since the beginning of the "vaccination campaign" (front N 748: "The vaccine has no effect on your body's ability to become pregnant. It also has no influence on the future development of the placenta or the course of a future pregnancy. Furthermore, the vaccination also has no negative effects on you or your child if you are breastfeeding.") - and has still not removed this text.

1086 By allowing the "vaccination" of pregnant women with the mRNA "vaccines" and, in addition, disseminating false and misleading information instead of expressly warning of the presumed - and now proven - danger, the persons acting on behalf of the licensing authority helped to cause a huge number of abortions in Switzerland.

4.1.1.2 Acts of the medical profession

1087 Corresponding offences by the medical profession should also be investigated.

4.1.2. Lack of consent

1088 An abortion induced under Article 118 para. 2 SCC must take place without the consent of the pregnant woman.[418] The validity of the consent is determined by the general requirements for the consent of the injured person (see in detail N 1118 ff.), which presupposes complete information (see in detail N 859 ff.). First of all, the pregnant woman must be capable of judgement, i.e. she must be able to correctly assess the purpose and scope of the medical intervention. Consent must be free from defects of will, i.e. the pregnant woman must have full knowledge of the nature and scope of the intervention (without coercion, threat or deception). Consent may be communicated explicitly or impliedly, but the perpetrator must have knowledge of it before the execution of the act begins.[419]

1089 In view of the misleading information provided by Swissmedic regarding the alleged harmlessness of mRNA "vaccinations" during pregnancy and breastfeeding, there is a deception that is relevant to legal interests, which means that any declarations of consent are afflicted with a serious lack of will. Under these circumstances, no valid consent is conceivable - unless an individual doctor had provided correct and comprehensive information beyond the specialist information.

1090 In addition, there is the considerable pressure exerted on people to be "vaccinated" by 3G and the 2G certificate obligation. Without "vaccination", there was a threat of drastic consequences ranging from social ostracism to job loss with corresponding existential fears. Even under this impression of latent coercion to "vaccinate", no pregnant woman could give valid consent at all.

4.1.3. Success according to the facts

1091 The constituent success consists in the killing of the embryo or foetus.[420]

1092 As explained above, international reports indicate that mRNA "vaccinations" are probably linked to unwanted abortions. There is therefore an urgent suspicion that such cases have also occurred in Switzerland.

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418 SCHWARZENEGGER / HEIMGARTNER, BSK StGB, 4th ed., Basel 2019, Art. 118 N 17.

419 On the whole SCHWARZENEGGER / HEIMGARTNER, BSK StGB, 4th ed., Basel 2019, Art. 118 N 5

420 SCHWARZENEGGER / HEIMGARTNER, BSK StGB, 4th ed., Basel 2019, Art. 118 N 19 i.V.m. N 10.

4.1.4. Causality (and objective attribution)

1093 The approval and administration of the mRNA "vaccines" represent one - probably by far the most important - cause for the vaccine damage that occurred (see above N 1028 f.), which are also objectively attributable to the perpetrators (see N 1057 ff.).

4.2. Subjective facts

1094 The subjective element of the offence requires (contingent) intent. The perpetrator must know or at least accept that he will perform the abortion against the pregnant woman's will.[421] In addition, he must at least accept that his action may lead to an unwanted abortion (cf. above N 1080).

1095 **Swissmedic** was already spreading false information against its better judgement at the end of 2020 (front N 1081 ff.). In view of this circumstance, there is an urgent suspicion that the defendants, with their actions, had at least taken into account the possibility of unwanted abortions in vaccinated pregnant women already at the time of the first authorisation of the COVID "vaccines" in December 2020 - but at the latest from the end of 2021.

1096 A corresponding intent can also be determined among the **medical profession.**

4.3. Grounds for justification and exclusion of guilt

1097 No grounds for justification and exclusion of guilt are apparent.

1098 In particular, there are no consents (front N 1088 ff.)

4.4. Competitions

If a pregnancy is brought about by killing the pregnant woman herself, the offender is to be punished under Art. 111-113 and Art. 118 para. 2 SCC (genuine competition).[422]

4.5. Conclusion

1099 There is an urgent suspicion that the persons who have been reported and the other perpetrators, who have yet to be identified, have committed multiple offences under Art. 118 para. 2 SCC.

421 SCHWARZENEGGER / HEIMGARTNER, BSK StGB, 4th ed., Basel 2019, Art. 118 N 20.
422 SCHWARZENEGGER / HEIMGARTNER, BSK StGB, 4th ed., Basel 2019, Art. 118 N 19, N 32.

5. Intentional and negligent (grievous) bodily harm

1100 If the COVID "vaccination" has not (yet) led to the death of the vaccinated person, bodily injury offences must be examined. The following explanations are limited to official offences:

5.1. Negligent grievous bodily harm (Art. 125 StGB)

1101 According to Art. 125 Para. 1 in conjunction with Para. para. 2 SCC, anyone who negligently causes serious bodily harm or damage to the health of a person is liable to prosecution.

5.1.1. Bringing about the success required by the offence

5.1.1.1 Offence

1102 Bodily injury can be committed both by active action and by failure to act in breach of one's duty (on the non-genuine offences of omission see N 988 ff.).

1103 Based on the reports to Swissmedic (see N 223 ff., N 226 ff., N 291 ff., N 378 ff.) as well as on the basis of international surveys and studies (see N 251, N 351 and N 428), there are numerous indications that the COVID "vaccinations" have led to significant violations of bodily integrity. The fact that **Swissmedic** has authorised the mRNA "vaccines" in accordance with Art. 9a HMG and has repeatedly extended or not revoked their authorisation - with completely neglected monitoring and misleading information to the public - and that the mRNA "vaccines" have been and are being administered by the **medical profession**, means that people's bodily integrity has been and is being violated.

5.1.1.2 Success in terms of the offence: grievous bodily harm

1104 The bodily injury is serious if it corresponds to the objective facts of Art. 122 SCC.[423] According to Art. 122 SCC, grievous bodily harm exists, among other things, if there was either a *life-threatening* injury (para. 1), an *important organ of* a human being was mutilated or rendered useless (para. 2) or if a human being was rendered *permanently incapacitated or infirm* (para. 3).

1105 The *danger to life* required by law must be immediate. It is not sufficient that the injury is somewhat dangerous and that the possibility of death is close at hand, as may be the case, for example, with a broken leg. One may only speak of life-threatening bodily injury

423 BGE 109 IV 18 E. 2a p. 18 f.

if the injury has led to a condition in which the possibility of death has become so dense that it has become a serious and urgent probability.[424] A danger to life of short duration is sufficient.[425]

1106 *A* kidney, *an* eye or *an* ear are already considered *important organs*;[426] even more so, the heart or brain also belong to the important organs. Organs are already mutilated or rendered useless if their function is permanently impaired, such as in the case of a stiffened elbow.[427] A permanent but only minor restriction of function is not sufficient.[428]

1107 *Permanent incapacity to work or frailty* only exists in the case of irreversible impairment of health. Frailty means a state of permanent illness or permanent impairment of health such as poisoning. In practice, this variant is to be read with the *general clause of para. 3* ("other serious damage to the body or physical or mental health").[429] In particular, the duration of the hospital stay, the (full or partial) incapacity for work, as well as the degree and duration of the invalidity and the pain suffered are to be taken into account.[430]

5.1.1.3 "Tat success" using the example of myocarditis

1108 Only the cases of myocarditis already reach the necessary severity level in all previously listed variants without further ado:

1109 There is simply no such thing as "mild" myocarditis. Myocarditis can lead to cardiogenic shock, cardiac arrhythmias or cardiac arrest (anterior N 330 ff., N 418 ff.) and thus lead to immediate death. There is therefore a serious risk of death from the COVID "vaccinations".

1110 But even those who survive this first immanent danger of death in the acute phase of myocarditis remain scarred for life: The survival rate after myocarditis drops massively - the damage to the heart muscle is permanent and leads to a massively increased mortality of those affected in the following years (on this in detail in front N 330 ff.). The heart as a vital organ of the human body is therefore damaged to a serious - life-threatening - and permanent extent.

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424 BGE 109 IV 18 E. 2c p. 20.
425 BGE 91 IV 193 E. 2 P. 194.
426 TRECHSEL / FINGERHUTH, in: Trechsel / Pieth [eds], Schweizerisches Strafgesetzbuch, Praxiskommentar, 2nd ed, Zurich / St Gallen 2013, Art. 122 N 5.
427 TRECHSEL / FINGERHUTH, in: Trechsel / Pieth [eds], Schweizerisches Strafgesetzbuch, Praxiskommentar, 2nd ed, Zurich / St Gallen 2013, Art. 122 N 6.
428 BGE 129 IV 1 E. 3.2 p. 3 (fanned and bipartite urinary stream).
429 TRECHSEL / FINGERHUTH, in: Trechsel / Pieth [eds], Schweizerisches Strafgesetzbuch, Praxiskommentar, 2nd ed, Zurich / St Gallen 2013, Art. 122 N 7.
430 TRECHSEL / FINGERHUTH, in: Trechsel / Pieth [eds], Schweizerisches Strafgesetzbuch, Praxiskommentar, 2nd ed, Zurich / St Gallen 2013, Art. 122 N 9.

1111 This is of course accompanied by an irreversible severe impairment of health.

5.1.1.4 "Success of the offence" using the example of further cases

1112 The necessary degree of severity is also likely to be reached in other cases: For example, in the case of irreparable autoimmune diseases or severe cerebral strokes (cf. in detail N 195 ff., N 423 ff.).

1113 In the present case, several private plaintiffs have suffered such serious damage that their ability to work will probably be impaired for the rest of their lives.

1114 The complainants reserve the right to bring and present further cases of aggrieved private plaintiffs in detail in the course of the present criminal proceedings.

5.1.1.5 Causality

1115 The causality *("conditio sine qua non")* between authorisation and administration on the one hand and vaccination side effects on the other is given (N 1028 f.).

5.1.2. Disregard of a duty of care

5.1.2.1 Creation of an unauthorised risk

1116 With the approval, lack of sufficient monitoring and administration of the mRNA "vaccines", an unauthorised risk was created, which has materialised in the violation of the physical integrity of a large number of people (see in detail N 1032 ff.).

5.1.2.2 Attribution of the success

1117 The risk created was both foreseeable and avoidable for those acting (see in detail N 1041 ff.).

5.1.3. Justification: Consent

1118 In principle, consent is to be examined as a ground for justification (for the dogmatic classification see above N 895).

1119 Consent is not expressly standardised in the Penal Code. However, it is generally recognised and also standardised under civil law (Art. 28 para. 2 of the Civil Code) that

the consent of the person entitled to legal protection excludes the wrongfulness of the act ("volenti non fit iniuria").[431] Consent is only valid under three cumulative conditions:[432]

- the person giving consent must be allowed to **dispose of the legal object;**
- the consent must be given in full **knowledge of the facts and before the act;**
- consent must be given **voluntarily.**

5.1.3.1 Power of disposal: Consent to grievous bodily harm permissible?

1120 With regard to the possibility of consent in cases of serious bodily injury, some scholars are of the opinion that this is only possible if the acceptance of the injury serves a moral, ethically recognised purpose (such as organ donation).[433] However, this restriction of the freedom of disposition cannot be substantiated (exceptions reserved): The decisive factors are capacity of understanding and voluntariness. Therefore, according to the correct view, consent to serious bodily harm can be given in principle.[434] The Federal Supreme Court and the prevailing opinion assume that a medical "curative intervention" is always a physical injury that requires the consent of the injured person.[435] Because medical interventions in bodily integrity can be severe and permanent, there are particularly high requirements for consent, especially with regard to information:[436]

5.1.3.2 Knowledge of the facts: Prior and complete clarification

1121 The person giving consent must know what he or she is doing; at least **capacity of judgement** is therefore mandatory.[437] In the case of violation of absolute legal rights, the patient's prior consent is central: he or she must be adequately informed about the intended intervention. The requirement of the patient's consent and the associated **right to information are** based on the patient's general right of personality and serve to protect both the freedom of will and the patient's right to self-determination and physical integrity.[438] **Prior, proper and complete information** about the intervention and its possible consequences is necessary. The decisive factor is whether and to what extent the patient, as a

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431 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, Vor Art. 14 N 8.
432 Cf. NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, Vor Art. 14 N 23.
433 ROTH / BERKEMEYER, BSK StGB, 4th ed., Basel 2019, before Art. 122 N 21; TRECHSEL / FINGERHUTH, in: Trechsel / Pieth [eds.], Schweizerisches Strafgesetzbuch, Praxiskommentar, 2nd ed., Zurich / St. Gallen 2013, before Art. 122 N 8.
434 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, Vor Art. 14 N 31-33.
435 BGE 99 IV 208 (concerning injection), confirmed in BGE 124 IV 258 E. 2 p. 260; ROTH / BERKEMEYER, BSK StGB, 4th ed., Basel 2019, before Art. 122 N 21, N 26; NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, before Art. 14 N 51.
436 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, Vor Art. 14 N 31-33.
437 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, Vor Art. 14 N 34 f.
438 BGE 115 Ib 180 /81, BGE 114 Ia 358 E. 6, BGE 112 II 128, BGE 108 II 61 ff. E. 2 and 3.

layperson, understands and is able to comprehend the medical information and thus the scope of the intended intervention.[439] The exclusion of wrongfulness only extends as far as the consent. What the person giving consent does not know, does not recognise and does not foresee, he or she cannot validly permit.[440]

5.1.3.3 Voluntariness

1122 Consent must be freely given and must not suffer from any relevant defects of will.[441] The relevant will may be missing or distorted in the following cases in particular:

1123 Lack of voluntariness exists in particular in cases of direct **threat and coercion.** Forced" consent is not consent.[442]

1124 If the person concerned is **deceived, the** decisive factor is whether the deception relates to the legal interest in question and affects the content, scope or extent of the consent. If the deception is relevant to the legal interest, no valid consent is given.[443] Accordingly, **partial truths** can also be used to deceive if they give the impression that the whole truth is involved.[444] Deception by omission is also possible, especially if a mistake is not remedied. However, this is only possible if there is a **guarantor's duty to rectify the error.** A qualified legal obligation to act is necessary.[445]

5.1.3.4 Burden of proof on the attending physician

1125 The doctor has to prove that the patient has been properly informed and has given his consent as a justification.[446] The requirements for documentation and the scope of information have been discussed above (N 859 ff.) have been shown in detail. From the point of view of probative value, it is therefore not sufficient to make a general note in the medical record that the patient was informed about the planned intervention and the possible complications. Rather, the information must be fully documented in the medical record and, in particular, it must be briefly noted which aspects of the specialist information were explained.[447]

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439 ROTH / BERKEMEYER, BSK StGB, 4th ed., Basel 2019, Vor Art. 122 N 21, N 24.
440 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, Vor Art. 14 N 40.
441 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, Vor Art. 14 N 47.
442 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, Vor Art. 14 N 42.
443 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, Vor Art. 14 N 45.
444 Cf. MAEDER / NIGGLI, BSK StGB, 4th ed., Basel 2019, Art. 146 N 50.
445 Cf. MAEDER / NIGGLI, BSK StGB, 4th ed., Basel 2019, Art. 146 N 56-58.
446 BGE 115 Ib 181, 113 Ib 425.
447 HOFMANN, 'COVID-19 vaccination: information and capacity to judge', FMH Recht 2021, pp. 158-159, p. 159.

5.1.3.5 Swissmedic: Deceptive information makes valid consent impossible

1126 Any appeal by Swissmedic to justifiable consent by the "vaccinated" would be misguided: With its misleading information policy, Swissmedic has largely made it impossible for the "vaccinated" to have been fully and transparently informed. The deception about the safety and efficacy of the "vaccination" is decisive - given the full state of knowledge, hardly anyone willing to be vaccinated would have consented to become part of a world-first human experiment with an ineffective and dangerous to lethal drug.

5.1.3.6 Medical profession: Incomplete information makes valid consent impossible

1127 As explained in detail above (N 866 ff.), various doctors violated their most fundamental duties of information and due diligence under the law on therapeutic products. In none of the cases described is there sufficient information, which means that there is no valid consent.

5.1.4. Grounds for exclusion of guilt

1128 No grounds for exclusion of guilt are apparent.

5.1.5. Conclusion

1129 There is a strong suspicion that the persons who have been charged and the other perpetrators, who have yet to be identified, have committed multiple offences under Art. 125 para. 1 in conjunction with Art. 125 para. 2 SCC. para. 2 of the Penal Code.

5.2. Intentional grievous bodily harm (Art. 122 StGB)

1130 According to Art. 122 SCC, anyone who intentionally causes serious bodily harm or damage to a person's health is liable to prosecution.

5.2.1. Objective facts

1131 For the fulfilled elements of the offence of grievous bodily harm, see in detail above N 1104 ff.

5.2.2. Subjective facts

1132 Concerning a present contingent intent from June 2021 at the latest and possibly even direct intent from 2022 at the latest of the defendants, see in detail above N 1063 ff.

5.2.3. Grounds for justification and exclusion of guilt

1133 On the lack of justification of consent, see in detail above N 1118 ff.

1134 No grounds for exclusion of guilt are apparent either.

5.2.4. Conclusion

1135 There is at least sufficient suspicion that the persons charged and the other perpetrators, who have yet to be identified, have committed multiple offences under Art. 122 SCC from June 2021 at the latest.

5.3. Qualified simple bodily injury (art. 123 no. 1 / 2 StGB)

1136 According to Art. 123 No. 1 Para. 1 in conjunction with. No. 2, paras. 1 and 2 SCC, anyone who intentionally harms a person's body or health in a way other than that specified in Art. 122 SCC and uses poison is liable to prosecution.

5.3.1. Objective facts

5.3.1.1 Basic offence

1137 Art. 123 No. 1 para. 1 SCC covers all bodily injuries that are not yet considered serious within the meaning of Art. 122 SCC, but are also no longer considered mere assaults within the meaning of Art. 126 SCC.[448] Physical integrity is impaired in the sense of bodily injury if internal or external injuries or damage are inflicted that require at least some treatment and healing time, such as broken bones, concussions or bruises with haematomas.[449] In addition, there are disturbances of well-being that are equivalent to an actual pathological condition, which is the case, for example, when considerable pain is caused.[450]

1138 Already before (N 1108, N 1112), it was established that in a large number of cases, serious bodily injury is to be assumed; these cases thus also fulfil the basic offence of simple bodily injury without further ado.

1139 In addition, there were already all the simple bodily injuries that had been unnecessarily inflicted on people in the form of "frequent side effects": Reactions at the injection site such as pain, redness and swelling, muscle and joint pain and chills/fever. In addition, all

448 ROTH / BERKEMEIER, BSK StGB, 4th ed., Basel 2019, Art. 123 N 3.
449 ROTH / BERKEMEIER, BSK StGB, 4th ed., Basel 2019, Art. 123 N 4.
450 ROTH / BERKEMEIER, BSK StGB, 4th ed., Basel 2019, Art. 123 N 5.

other bodily injuries that do not yet reach the level of serious bodily injury are also covered.

5.3.1.2 Qualification: Use of poison

1140 No. 2 of Art. 123 SCC qualifies the particularly dangerous or reprehensible action by waiving the application requirement while maintaining the threat of punishment.[451] The explicitly mentioned "poison" is a substance that is intended or suitable to harm the human body. This includes medicines, toxins, viruses and bacteria.[452]

1141 As previously (N 1072), the mRNA "vaccines" are toxins.

5.3.2. Subjective facts

1142 Regarding a present contingent intent from June 2021 at the latest and even direct intent from 2022 at the latest of the defendants, see in detail N 1067 ff.

5.3.3. Grounds for justification and exclusion of guilt

1143 On the lack of justification of consent, see in detail above N 1118 ff.

1144 No grounds for exclusion of guilt are apparent either.

5.3.4. Conclusion

1145 There is a strong suspicion that the persons charged and the other perpetrators, who have yet to be identified, have committed multiple offences under Art. 123 No. 1 para. 1 in conjunction with No. 2 paras. and 2 SCC from June 2021 at the latest. No. 2 paras. 1 and 2 SCC.

IV. Criminal preparatory acts (Art. 260bis StGB)

1146 According to Art. 260bis para. 1 lit. a-c SCC, anyone who takes concrete technical or organisational precautions in a planned manner, the nature and extent of which show that they are preparing to carry out an intentional killing (Art. 111 SCC), murder (Art. 112 SCC) or grievous bodily harm (Art. 122 SCC) is punished.

1. Objective facts

1147 Preparatory acts under criminal law are understood to be preparations that are intended to enable or facilitate a subsequent offence. Preparatory acts are **planned** if several and

451 ROTH / BERKEMEIER, BSK StGB, 4th ed., Basel 2019, Art. 123 N 11 f.
452 ROTH / BERKEMEIER, BSK StGB, 4th ed., Basel 2019, Art. 123 N 14.

interrelated acts are directed towards a common goal, namely the preparation of the offence. The preparation must be carried out systematically and over a certain period of time. The preparations are **concrete** if they are recognisably related to one of the offences mentioned (homicide, bodily harm, etc.). Sufficiently concrete are preparatory acts which, according to the usual course of events and general experience of life, appear suitable for the realisation of the offences in question. **Organisational** measures are measures that are taken to ensure that the plan of the offence runs smoothly. From a **temporal** point of view, the preparations must be so far advanced in terms of their nature and scope that it can reasonably be assumed that the perpetrator will continue to pursue his thus manifested intention to commit the offence without further ado in the direction of carrying out the offence. However, the perpetrator does not have to be in the immediate process of committing the offence.[453]

1148 As in front (N 712 ff.), since May 2021 at the latest, Swissmedic has been pursuing a plan to completely undermine all safety mechanisms of therapeutic products legislation: Swissmedic has prepared everything in its own regulations to completely dispense with clinical trials for an "updated coronavirus vaccine". Based on the already massively accelerated "time-limited" initial authorisations of the mRNA "vaccines", **Swissmedic** thus wants to permit all conceivable manipulations of these "vaccines" in order to then be able to inject these modified mRNA "vaccines" directly into humans without any safety mechanisms such as preclinical and clinical studies. It is thus quite obviously complying with manufacturers' demands and**, according to the latest media release of 24 June 2022, is already examining the first corresponding application from Moderna - without clinical studies being available and apparently also on the basis of completely inadequate data on quality and safety.** This no longer has anything to do with guaranteeing the safety of medicinal products - an authorisation would even violate the absolute ban on human trials without "informed consent" if the absolutely non-transparent information of the public continues. In view of all the experiences since the end of 2020 with the useless, risky to lethal mRNA "vaccines", Swissmedic's approach, which has been planned for a long time and is now already being implemented, is obviously likely to cause further deaths and bodily harm.

2. Subjective facts

1149 The preparatory acts must be done intentionally; contingent intent is <u>not</u> sufficient. There must be the intention to realise one of the listed offences.[454]

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453 On the whole ENGLER, BSK StGB, 4th ed., Basel 2019, Art. 260bis N 1-9.

454 On the whole ENGLER, BSK StGB, 4th ed., Basel 2019, Art. 260bis N 12.

1150 In view of the large number of previously (N 141 ff. and N 840 ff.; N 220 ff. and N 847 ff.; N 264 ff. and N 852 ff.; N 378 ff. and N 854 ff.) and the unswerving continuation of the useless and dangerous "vaccination campaign", there is a strong suspicion that the persons responsible at Swissmedic have either long since lost their minds - or are pursuing deeply malicious intentions. It will be necessary to determine which of the two variants applies on the basis of the documents to be seized and the interrogations to be carried out.

3. Grounds for justification and exclusion of guilt

1151 No grounds for justification and exclusion of guilt are apparent.

4. Conclusion

1152 There is an urgent suspicion that the persons denounced and the further perpetrators, who have yet to be identified, are planning to take specific technical or organisational precautions to carry out an intentional killing (Art. 111 SCC), murder (Art. 112 SCC) or grievous bodily harm (Art. 122 SCC).

End

In conclusion, we kindly ask you to consider our submissions favourably and to approve the applications made at the beginning.

With kind regards

Lawyer Ph. Kruse, LL.M. Lawyer Dr. M. Zollinger

List of supplements Criminal complaint

Supplement **1:** "Source list criminal complaint", 14.07.2022

Supplement **2:** "List of complainants", 14.07.2022

Supplement **3:** "List and documentation of private plaintiffs", 14.07.2022

Supplement **4:** "Evidence Report", 14.07.2022

Supplement **5:** "Analysis 15 deaths", 14.07.2022

Supplement **6:** "Data DVD Sources", 14.07.2022

Supplement **7:** Request University of L. to Paul Ehrlich Institute, "Subject: Our request according to §1 IFG of 3.3.2022 [...]", 13.04.2022

Supplement **8:** Law firm R.: "Inquiry by Professors Prof. Dr. M. et al. [...]", 14.04.2022

Supplement **9:** Law firm R.: "Inquiry of Professors Prof. Dr. M. et al. [...] - My letter of 13 April 2022", 29.04.2022

Supplement **10:** "List of addresses of vaccination centres CH", 01.04.2022

Supplement **11:** Autopsy protocol Prof. Dr. A. Burkhardt, "Notes and recommendations for conducting post-mortem examination (autopsy) of persons deceased in connection with COVID vaccination", 17 March 2022