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Evidence Report (ER)

regarding

Risks and efficacy of mRNA gene therapies
and the danger of SARS-CoV-2

Table of contents

Table of contents

A. INTRODUCTION

1 The subject of the present study is the temporary approvals of the two mRNA-COVID "vaccines" from Pfizer/BioNTech (Comirnaty®, market share 37%) and Moderna (Spikevax®, market share 62.6%)[1] that are primarily used in Switzerland.

2 First, the authorisation decisions of Swissmedic are presented in chronological order.

3 Subsequently, the **mRNA vaccines** are **examined for their risks and efficacy.** The structure in the corresponding section follows the structure of the main document - but one hierarchy level/title level higher, in order to have an additional title level available for further explanations. Subsequently, the **hazardousness of Sars-Cov2 is** examined according to the same pattern.

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1 Swissmedic, "Suspected adverse reactions to Covid-19 vaccinations in Switzerland - 23rd update", 11.03.2022 (Comirnaty / Moderna), *https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/covid-19-vaccines-safety-update-13.html.*

4 Finally, some of the **publicity announcements made by** Swissmedic are examined for **their truthfulness.**

B. ADMISSION DECISIONS: CHRONOLOGY AND ANOMALIES

5 The authorisation decisions of Swissmedic for the period from 19 December 2020 to 10 December 2021 are presented below in chronological order:

I. Adult "vaccinations" (from 19.12.2020)

1. Pfizer / BioNTech (Comirnaty®)

1.1. Misleading announcement of the admission

6 On 19 December 2020, Swissmedic announced the *temporary* authorisation for the first COVID-19 vaccine (mRNA) in Switzerland in a thoroughly misleading manner - using the *term "*ordinary procedure", although it is the procedure under Art. 9a HMG:[2]

> "**Pfizer/BioNTech vaccine approved in rolling review after careful consideration of benefits and risks**".
>
> Swissmedic has approved the Pfizer/BioNTech vaccine. According to the data evaluated by the Swiss Agency for Therapeutic Products, vaccine protection is over 90 per cent seven days after the second vaccination. This is the world's first authorisation in an ordinary procedure.
>
> Persons aged 16 years and older can be vaccinated against the novel coronavirus (SARS-CoV-2), following the official federal vaccination recommendations. For optimal vaccination protection, two intramuscularly administered vaccinations at least 21 days apart are recommended. According to the study data evaluated by Swissmedic, vaccination protection is over 90 per cent in adults seven days after the second administration. [...].
>
> Safety: focus on side effects
>
> As with all medicinal products that are new to the market, Swissmedic is closely monitoring the safety of the vaccine and will take immediate action, if necessary, should any safety signals appear. The most frequent

[2] Swissmedic, "Swissmedic grants authorisation for the first Covid 19 vaccine in Switzerland", 19.12.2020, https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/covid-19-impfstoff_erstzulassung.html.

side effects documented in the registration studies are comparable to those following a flu vaccination.

Swissmedic operates a special online system (ElViS) for healthcare professionals to report suspected adverse effects. Recipients of vaccines are advised to contact their vaccination centre, hospital, doctor or pharmacist if they experience severe or unusual symptoms after vaccination.

Linked to the authorisation, Swissmedic continues to require the authorisation holder to collect continuous information on the safety, efficacy and quality of its vaccine."

1.2. Violations of the intended approval procedure

7 Pfizer submitted the application for the temporary marketing authorisation on 16 October 2020. Swissmedic already granted the temporary marketing authorisation by letter dated 19 December 2020 (Annex **2**, p. 2).

BO: Supplement **2:** Marketing authorisation decision Comirnaty from Pfizer incl. minutes of the HMEC meeting of 18.12.2020, Swissmedic, 19.12.2020

8 **Swissmedic thus "examined" the application in a processing time of just 45 working days (corresponding to 63 calendar days).** How a thorough examination of all documents and a "careful consideration of benefits and risks" could be even remotely possible in this short time is already extremely questionable. This is only possible against the background of the fact that the very short processing period of 140 calendar days, which is usually envisaged even for a time-limited authorisation, was once again massively undercut.[3]

9 In addition, it is clear from the same letter of authorisation from Swissmedic to Pfizer that the answers to the "List of questions" ("LoQ") with regard to 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. According to the guideline "*Deadlines for HMV4 licence applications*" of 28 February 2022, not all types of applications have to go through all stages of the procedure and milestones. If **no questions** arise from the assessment I, then the milestone "LoQ" may be skipped according to "Swissmedic". In the present case, however, it is clear from the letter of authorisation from Swissmedic to Pfizer that **there were serious ambiguities** and **thus unanswered questions with** regard to

3 The various admission procedures are described in detail in the criminal complaint.

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.[4]

2. Moderna (Spikevax®)

10 On 12 January 2021, Swissmedic announced the approval of Moderna's COVID-19 mRNA vaccine:[5]

> "Swissmedic has today granted a temporary marketing authorisation in Switzerland to Moderna's mRNA platform-based vaccine (COVID-19 mRNA Vaccine Moderna) following a careful review of all submitted safety, efficacy and quality data. This means that a second Covid-19 vaccine meets the high requirements for safety, efficacy and quality and can be used in Switzerland with immediate effect. The approval studies showed a high efficacy of 94 percent 14 days after the second vaccination.
>
> Swissmedic today granted a temporary marketing authorisation to Moderna's Covid-19 vaccine after the independent expert panel HMEC (Human Medicines Expert Committee) supported Swissmedic's assessment of the risk-benefit balance at an extraordinary meeting in addition to the internal review. [...]
>
> Moderna's Covid-19 vaccine may be administered to persons 18 years of age and older in accordance with the drug information and official federal vaccination recommendations. The vaccination consists of two doses, which trained medical personnel administer intramuscularly to vaccinated persons at intervals of one month. According to clinical studies, vaccinated persons are reliably protected 14 days after the second dose.
>
> Based on the current data, Swissmedic recommends adhering to the vaccination interval and not postponing the second vaccination dose, as stated in the product information. In addition, different vaccines should not be combined, as no data on the interchangeability of Covid-19 vaccines are available. [...]

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4 Swissmedic, "Wegleitung Fristen Zulassungsgesuche HMV4", 15.06.2022, p. 5 and 11, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/zulassung/zl_hmv_iv/zl000_00_014d_wlfristenzulassungsgesuche.pdf.download.pdf/zl000_00_014d_wlfristenzulassungsgesuch.pdf.

5 Swissmedic, "Swissmedic grants authorisation for Moderna's Covid-19 vaccine", 12.01.2021, https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/zulassung-covid-19-impfstoff-moderna.html.

> As with all medicinal products that are new to the market, Swissmedic closely monitors the safety of vaccines. The most frequently documented adverse reactions are comparable to those following a flu vaccination. Linked to the authorisation, Swissmedic continues to require the authorisation holder to collect continuous information on the safety, efficacy and quality of its vaccine.
>
> The other applications for authorisation of pandemic vaccines will continue to be assessed in a rolling procedure, using all resources with high priority. Swissmedic will decide on further authorisations for pandemic vaccines as soon as sufficient data are available. Swissmedic also exchanges information on this with partner authorities at short intervals."

11 Moderna submitted the application for the temporary authorisation on 9 November 2020. Swissmedic granted the temporary authorisation by letter dated 12 January 2021 (Annex **3**, p. 1). This **also** results in **a processing time of exactly 45 working days**, which also calls into question whether this marketing authorisation dossier could also be seriously and soundly assessed.

BO: Supplement **3:** Authorisation decision COVID-19 Vaccine from Moderna, Swissmedic, 12.01.2021

II. "Vaccination" of young people aged 12 and over (from 04.06.2021)

1. Pfizer / BioNTech (Comirnaty®)

12 On 4 June 2021, Swissmedic approved the extension of the indication for "Comirnaty®" for 12- to 15-year-olds. The application submitted by Pfizer on 7 May 2021 had been "carefully examined" in an "accelerated rolling procedure".[6]

2. Moderna (Spikevax®)

13 On 9 August 2021, Swissmedic approved the indication extension of the Spikevax® vaccine for 12- to 17-year-olds. The application submitted by Moderna Switzerland GmbH on 11 June 2021 had been "carefully examined" in an "accelerated rolling procedure".[7]

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6 Swissmedic, "Covid-19 vaccine from Pfizer/BioNTech released in Switzerland for adolescents", 04.06.2021, https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/covid-19-impfstoff-pfizer-biontech-fuer-jugendliche.html.

7 Swissmedic, "Swissmedic approves indication extension of Spikevax vaccine for 12 to 17-year-olds", 09.08.2021, https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/indikationserweiterung-spikevax-impfstoff.html.

III. "Booster" "Vaccination" (from 26.10.2021)

1. Pfizer / BioNTech (Comirnaty®)

14 On 26 October 2021, Swissmedic approved the **booster vaccination** from Pfizer/BioNTech (Comirnaty®) for "persons at particular risk". **With Comirnaty®, the booster "vaccination" takes place at least 6 months after the second dose with the same dose as the first two vaccinations**. **This third vaccination "could potentially maintain protection against Covid-19 disease in older people or those at risk"**.

15 Immunocompromised **individuals or patients with suppressed immune responses** (for example, organ transplant recipients or cancer patients) who have built up little or no immune response against SARS-CoV-2 coronavirus after two vaccinations could be **given a third identical dose at least 28 days after the second.**[8]

16 On 23 November 2021, Swissmedic approved the booster vaccination with Comirnaty® for all adults aged 16 and over. For persons at particular risk, the booster would remain possible from the age of 12, as envisaged in the Swissmedic decision of 26 October 2021. Swissmedic stated, among other things:[9]

> "Swissmedic made this decision based, among other things, on a study with 10,000 participants aged 16-87 years. The interim results of this study have not revealed any indications of new risk aspects for the vaccine. The basic immunisation with Comirnaty is carried out with two doses of 0.3 ml at intervals of three weeks. The booster vaccination now approved at least six months later can further maintain protection against covid 19 disease. "

2. Moderna (Spikevax®)

17 On 26 October 2021, Swissmedic approved the **third "vaccination"** of **Spikevax®** for "**persons particularly at risk**". For Spikevax®, **half** the **dosage** was to be used for the booster.

18 **Immunocompromised individuals or patients with suppressed immune responses** (for example, organ transplant recipients or cancer patients) who have built up little or no

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8 Swissmedic, "Covid-19 vaccines from Moderna and Pfizer/BioNTech: Swissmedic approves third vaccination for certain population groups", 26.10.2021, https://www.admin.ch/gov/de/start/dokumentation/medienmitteilungen.msg-id-85591.html.

9 Swissmedic, " Pfizer/BioNTech's Covid-19 vaccine: Swissmedic approves extension of booster vaccination (booster dose) to all persons aged 16 years and older", 23.11.2021, https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/covid-19-impfstoff-pfizer-biontech-boosterdosis.html.

immune response against SARS-CoV-2 coronavirus after two vaccinations could be given a **third dose at** the **same dosage at least 28 days after the second.**[10]

19 On 26 November 2021, Swissmedic approved booster vaccination with Moderna's Covid-19 vaccine for all adults aged 18 and over. For persons at particular risk, the booster would remain possible from the age of 12, as envisaged in the decision of 26 October 2021. Swissmedic also stated:[11]

> "This week, the marketing authorisation holder Moderna Switzerland GmbH submitted further data on the booster vaccination of its Covid-19 vaccine (Spikevax®). Swissmedic evaluated the benefits and risks of booster vaccination for the general adult population and adapted the medicinal product information. "
>
> "The basic immunisation with Spikevax is done with two doses of 0.5 ml each, one month apart. For a booster vaccination at least 6 months after the second vaccination, half the dose (0.25 ml) is administered. Immune response data from ongoing clinical trials indicate that booster vaccination may re-enhance the body's immune response, which declines over time. "
>
> "Marketing authorisation holders must continue to provide continuous information on the safety, efficacy and quality of their preparations. Swissmedic continues to closely monitor the benefits and risks of all vaccines for the prevention of coronavirus disease in Switzerland and internationally. "

IV. Child "vaccinations" from 5 years (from 10.12.2021)

1. Pfizer / BioNTech (Comirnaty®)

20 On 10 December 2021, Swissmedic announced that it had "carefully reviewed all data on the requested indication extension of Pfizer/BioNTech's Covid-19 vaccine (Comirnaty®)". The clinical study results had shown that the vaccination was "safe and effective" for children, which is why in Switzerland children aged five years and older "can be vaccinated

10 Swissmedic, FN 8.

11 Swissmedic, "Swissmedic authorises booster vaccination (booster dose) with Moderna's Covid-19 vaccine for adults aged 18 years and over", 26.11.2021, https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/auffrischimpfung-boosterdosis-impfstoff-moderna-ab-18-jahren.html.

against the novel coronavirus (SARS-CoV-2) in accordance with the updated vaccination recommendations of the Confederation". Swissmedic went on to say:[12]

> "**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."

2. Moderna (Spikevax®)

21 On 13 May 2022, Swissmedic approved the indication extension of Spikevax® for use in children aged 6 to 11 years. Children from 6 years of age are to receive half the dose (50 micrograms) twice every 4 weeks compared to adults and adolescents from 12 years of age.

> "The main study in children aged 6 to 11 years showed that the immune response to the SARS-CoV-2 virus triggered by the vaccine was comparable to that in young adults. The most commonly reported side effects, such as pain, redness or swelling at the injection site, fatigue, headache, chills or nausea, were similar to those reported in adolescents and young adults. Fever was more common in children, while muscle and joint pain was less common than in adolescents and adults. The adverse effects were usually mild to moderate and lasted a few days.
>
> Vaccination can especially benefit children with pre-existing conditions who are at increased risk of severe covid 19 disease. Children aged 6 to 11 years receive half the vaccine dose (50 instead of 100 micrograms) compared to older children at intervals of four weeks.
>
> The safety, efficacy and quality of all Covid 19 vaccines used will continue to be closely monitored in children and adults worldwide, both through

12 Swissmedic, "Swissmedic approves Pfizer/BioNTech's Covid-19 vaccine for children aged 5 to 11 years", 10.12.2021, https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/covid-19-impfstoff-pfizer-biontec-kinder-5-11-jahren-genehmigt.html.

spontaneous reporting (pharmacovigilance system) and in ongoing and additional clinical trials."[13]

C. MRNA "VACCINES": RISKS AND EFFICACY

I. State of knowledge at the end of 2020 (first registrations adults)

1. Risks

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

22 Swissmedic classifies mRNA preparations as "vaccinations" and therefore describes them as "immunological medicinal products" within the meaning of Art. 2 lit. b AMBV, without adequately addressing 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), mRNA preparations are potentially **classified as gene therapies.**[14] 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:[15]

> "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."

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13 Swissmedic, "Moderna's Covid-19 vaccine licensed in Switzerland for children aged 6-11 years", 13.5.2022, https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/covid-19-impfstoff-moderna-fuer-kinder-6-11-jahren-zugelassen.html.

14 United States Securities and Exchange Commission (SEC), "Form F1 registration statement under the Securities Act of 1933, BioNTech SE", 09.09.2019, https://www.sec.gov/Archives/edgar/data/1776985/000119312519241112/d635330df1.htm, p. 7 ("**Some of our product candidates are classified as gene therapies by the U.S. Food and Drug Administration and the European Medicines Agency.** Even though our mRNA product candidates are designed to have a different mechanism of action from gene therapies, the association of our product candidates with gene therapies could result in increased regulatory burdens, impair the reputation of our product candidates, or negatively impact our platform or our business."), p. 35 ("Some of our product candidates are classified as gene therapies by the FDA and the EMA").

15 Medinside, "mRNA preparations equal gene therapy - what's it all about? ", 28.01.2022, https://www.medinside.ch/de/post/mrna-praeparate-gleich-gentherapie-was-hat-es-damit-auf-sich.

23 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.[16] However, the **mRNA "vaccinations"** discussed here have a **fundamentally different mechanism of action. This consists of getting our <u>own healthy</u> 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". These are then transported to the surface of the cell and recognised by the immune cells.[17]

24 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**[18] , because no relevant efficacy could be proven .[19] 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, the following is still completely unexplored: [20]

- 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

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16 BGV, "The Principle of Vaccination", 01.07.2022, https://www.bgv-impfen.de/prinzip-der-impfung.html.

17 See SCNAT, "How do mRNA vaccines work? ", 01.07.2022, https://naturwissenschaften.ch/covid19-vaccination-explained/mrna_vaccines/wie_funktioniert_ein_mrna_impfstoff_.

18 RND, "Immunologist Steve Pascolo: We have a lot of experience with mRNA vaccines", 10.03.2021, https://www.rnd.de/gesundheit/immunologe-steve-pascolo-wir-haben-viel-erfahrung-mit-mrna-impfstoffen-BDWQSKCWVJDGFGKL54UHQ2ZPV4.html.

19 Gesundheitsindustrie BW, "Hope for mRNA vaccines despite dampeners", 26.06.2017, https://www.gesundheitsindustrie-bw.de/fachbeitrag/aktuell/hoffnung-fuer-mrna-impfstoffe-trotz-daempfer: "Patients survived no longer after injection of mRNA molecules coding for six tumour-associated antigens than after placebo vaccination. ".

20 See in particular N 138 ff, N 145 ff, N 151 ff. and N 299 ff.

- 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.

25 In fact, the mRNA therapies or mRNA "vaccines" for flu prevention were still in the realm of animal studies (preclinical phase)[21] at the end of 2019 - far from proper approval. As such, they belong to the category of vaccines against a disease for which there has never been a suitable vaccine (category "*unprecedented*") - as is also the case with HIV and malaria.[22] **The development of such "unprecedented" vaccines takes an average of 12.5 years.** They have an estimated chance of just 5% of successfully surviving clinical phase II. Once they have survived this, the chance of successfully completing the registration studies and market approval is 40%.[23]

26 Manufacturers such as BioNTech therefore announced as late as September 2019 that they expected that **such gene therapy** might **"never"** be **approved.**[24] BioNTech stated that it was a "clinical-stage biopharmaceutical company" and did not have any pharmaceutical products approved for commercial sale. Since its inception, the company has suffered "significant losses" and it is expected that "significant losses will continue to be incurred for the foreseeable future". This is because "no mRNA immunotherapy has yet

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21 United States Securities and Exchange Commission (SEC), "Form F1 registration statement under the Securities Act of 1933, BioNTech SE", 09.09.2019, https://www.sec.gov/Archives/edgar/data/1776985/000119312519241112/d635330df1.htm. Overview of the phases in which the drug candidates are located: p. 132; There is also talk of mRNA therapies for "up to 10 further indications", which are to be developed with Pfizer as a cooperation partner, among others.

22 SENNEFF/NIGH, "Worse Than the Disease? Reviewing Some Possible Unintended Consequences of the mRNA Vaccines Against COVID-19", 10.05.2021, *https://dpbh.nv.gov/uploadedFiles/dpbhnvgov/content/Boards/BOH/Meetings/2021/SENEFF~1.PDF.*

23 YOUNG et al. , "Developing New Health Technologies for Neglected Diseases: A Pipeline Portfolio Review and Cost Model", 19.02.2020, *https://doi.org/10.12688/gatesopenres.12817.2.*

24 United States Securities and Exchange Commission (SEC), FN 21, p. 6: "We are a clinical-stage biopharmaceutical company with no pharmaceutical products approved for commercial sale. "; "We have incurred significant losses since our inception and we anticipate that we will continue to incur significant losses for the foreseeable future."; "No mRNA immunotherapy has been approved, and **none may ever be approved,** in this new potential category of therapeutics. mRNA drug development has substantial clinical development and regulatory risks due to the novel and unprecedented nature of this new category of therapeutics."; "Some of our product candidates are **classified as gene therapies** by the U.S. Food and Drug Administration and the European Medicines Agency. Even though our mRNA product candidates are designed to have a different mechanism of action from gene therapies, the association of our product candidates with gene therapies could result in increased regulatory burdens, impair the reputation of our product candidates, or negatively impact our platform or our business"; "Our product candidates may not work as intended, may cause undesirable side effects or may have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any. "

been approved" and it is possible that "no mRNA immunotherapy will ever be approved". For example, some of the product candidates have been classified as "gene therapy" in the USA and the EU, which could lead to an increased regulatory burden. Furthermore, some product candidates might not work as intended and "cause undesirable side effects".

27 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.).[25]

28 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 pharmacokinetics of the mRNA and that of the spike proteins were unclear: Neither was it clear from initial studies how the modified (intentionally delayed degradation rate) mRNA 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 genotoxicity and carcinogenicity studies** have been **conducted. Whether mRNA therapy can lead to (irreversible) damage to the genetic material or to cancer was thus completely unknown.**

29 The complete novelty and partial lack of clarity of the mode of action would, under normal circumstances, make it imperative to carry out all the necessary studies, at best even additional clinical trials. The fact that this was not possible within the framework of the approval procedure (described below) of the so-called "time-limited" approval, or that it was deliberately waived, must be assessed as a considerable risk factor.

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25 United States Securities and Exchange Commission (SEC), "FORM 10-Q, Quarterly report of moderna Inc. ", 30.06.2020, p. 69, https://www.sec.gov/Archives/edgar/data/1682852/000168285220000017/mrna-20200630.htm: "Currently, mRNA is considered a **gene therapy product** by the FDA. [...] In addition, because no product in which mRNA is the primary active ingredient has been approved, the **regulatory pathway for approval is uncertain.** The number and design of the clinical trials and preclinical studies required for the approval of these types of medicines have not been established, may be different from those required for gene therapy products, or may require safety testing like gene therapy products. Moreover, the length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one pharmaceutical product to the next, and may be difficult to predict".

1.2. Prohibited use of GMOs on humans?

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

1.2.1. FOEN classifies mRNA "vaccine" as GMO

31 The Federal Office for the Environment (FOEN) stated:[26]

> "The mRNA represents genetic material, as it physically - like DNA - consists of nucleic acids and is functionally indispensable for protein synthesis. The synthesis of a specific protein [spike protein in the mRNA vaccines against Covid-19] as well as the specific immune response against a certain antigen of this protein represent biological activities.
>
> However, the "naked" mRNA alone should (...) in the present case [mRNA vaccination] not be capable of eliciting this biological activity, as it is not cell-passable (enough).
>
> However, the mRNA acquires this ability through its packaging in a lipid shell of specific components. The resulting nanoparticle has the necessary cell permeability to be able to carry out the biological activities described.
>
> **Therefore, mRNA vaccines are biologically active genetic material and therefore they are legally equivalent to an organism."**

32 According to the FOEN, the combination of the mRNA with the lipid nanoparticles leads to the assumption of a genetically modified organism (GMO). If this assessment is confirmed, a "temporary authorisation" should not have been granted at any time.

1.2.2. Fundamental right to non-artificially modified genetic material

33 The integrity of the human genome is absolutely protected by various constitutional articles: In particular, according to **Art. 119 para. 2 lit. a BV, "all [...] interventions in the genetic material of human germ cells and embryos [...] are inadmissible". The** genetic material of human germ cells and embryos therefore enjoys unconditional protection against interventions, whereby it is a **directly effective prohibition norm**.[27] It is even

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26 Medinside, FN 15.

27 BIAGGINI, BV Kommentar, 2nd ed. Zurich 2017, Art. 119 N 12.

said to be a **"fundamental right to genetic material that has not been artificially altered"**.[28]

34 Now, embryos are not directly "vaccinated" - but this is also not a prerequisite for the application of this absolute prohibition: Artificial intervention in human DNA is also compulsorily prohibited via the reproductive route, which is why precursor cells, from which sperm or eggs develop in humans, are also included.[29]

1.2.3. Strict regulatory requirements for GMOs and CRISPR/Cas9

35 The use of genetically modified organisms (GMOs) is therefore subject to strict regulation.[30] In brief, GMOs are entities (incl. mixtures, etc.) that are capable of reproducing or **transferring genetic material** and have been produced and modified in a way "that does **not occur under natural conditions** through cross-breeding or natural recombination**".**

36 If such a GMO is present, massively stricter requirements are placed on a marketing authorisation: In Art. 12 para. 5 lit. c and e VAM, "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.

37 In order to qualify something as a GMO, it is sufficient that even individual gene sequences are modified: According to a ruling of the European Court of Justice, organisms obtained by mutagenesis (i.e. without the use of foreign genes) are also to be classified as genetically modified, whereby the focus is primarily on the **process of modification** and less on the result itself.[31] Therefore, it was ruled that the use of the new CRISPR/Cas9

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28 Thus REUSSER / SCHWEIZER, BV Kommentar SG, 3rd edition, Zurich 2014, Art. 119 N 23.

29 REUSSER / SCHWEIZER, BV Kommentar SG, 3rd edition, Zurich 2014, Art. 119 N 23.

30 See in particular: Art. 5 para. 1 and para. 2 Gene Technology Act (GTG; SR 814.91); Art. 7 para. 5ter Environmental Protection Act (USG; SR 814.01); Art. 22 of the Ordinance on Clinical Trials with the Exception of Clinical Trials of Medical Devices (Ordinance on Clinical Trials; KlinV; SR 810.305); Art. 3 para. 1 lit. a, lit. d and Annex 1 No. 1 of the Ordinance on the Handling of Organisms in the Environment (Release Ordinance, FrSV; SR 814.911).

31 Judgment of 25. 7. 2018, C-528/16, EU:C:218: 583, N 30, N 32 et seq, N 38.

technology also leads to the creation of genetically modified organisms.[32] This decision was justified in particular with the **precautionary principle.**[33]

38 In the CRISPR/Cas9 technology mentioned above, DNA sequences are - to put it simply - "cut out" and replaced with genetically modified DNA sequences. The procedure thus involves a **direct intervention in the DNA.**

1.2.4. Manufacturing process and intended effect of the mRNA active substances

39 The intended mode of action of mRNA is different: mRNA active substances are supposed to offer a platform for transient, human protein synthesis in order to specifically treat diseases. In this context, mRNA is considered transient - i.e. "temporary" - because (rapid) degradation takes place and thus a change in human DNA is supposedly not possible.[34] For this reason, mRNA agents - unlike CRISPR/Cas9 - did not fall under the strict regulatory requirements of GMOs. However, the potential for DNA integration - and thus stable protein synthesis in the human body - was not analysed deeply enough: **If it should turn out that mRNA ultimately does have the potential to permanently alter human DNA, the regulatory advantage currently enjoyed by mRNA "vaccines" would no longer be justified in any way.** This potential will be examined on the basis of the following explanations of the production process and the altered mode of action of the artificially produced mRNA.

40 The mRNA vaccines are produced according to the following very simplified procedure:[35]

- After analysing the viral gene sequences associated with SARS-CoV-2, researchers selected the spike protein gene as a vaccine candidate. The corresponding gene sequence leads to the production of a functional spike protein in the human host cell, which is transported to the cell surface and thus makes the cell a target that is recognised and attacked by the immune system.
- Based on this finding, the spike protein gene was synthesised and inserted into a plasmid, a small, circular piece of DNA.

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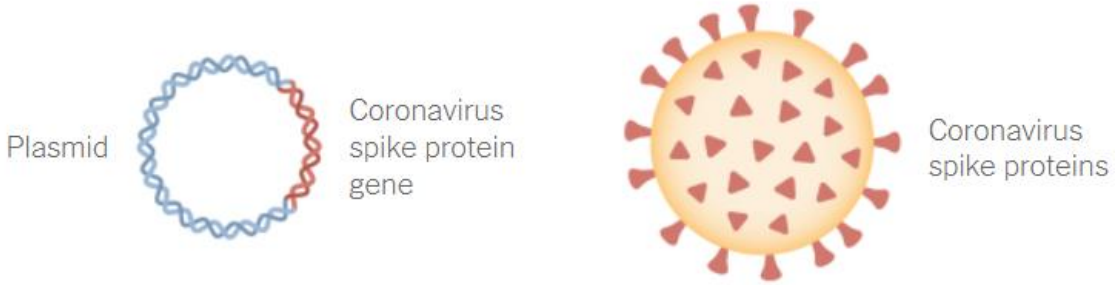
32 ACKERMANN / SCHRÖDER BLÄUER, in: BSK StGB, 4th ed., Basel 2019, Art. 230bis StGB N 9.

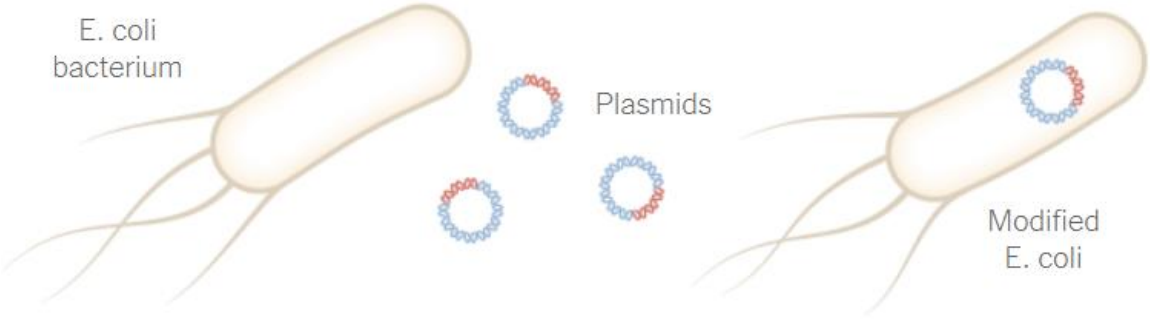
33 WAGNER PFEIFER, Umweltrecht - Besondere Regelungsbereiche, 2nd edition, 2021, Zurich/St. Gallen, N 391.

34 PARDI et al, "mRNA vaccines - a new era in vaccinology", 12.01.2018, https://www.nature.com/articles/nrd.2017.243.

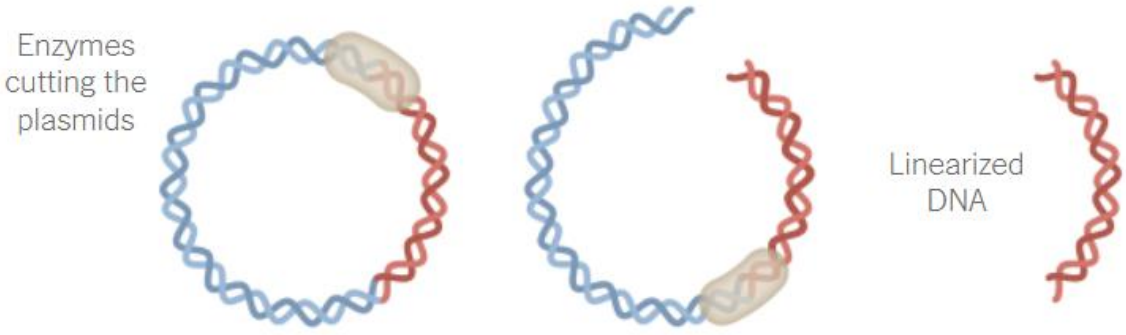
35 For the whole (incl. following graphics): The new york times, "How Pfizer Makes Its Covid-19 Vaccine", 28.04.2021, https://www.nytimes.com/interactive/2021/health/pfizer-coronavirus-vaccine.html; NIH, "COVID-19 mRNA Vaccine Production", 31.08.2021, https://www.genome.gov/about-genomics/fact-sheets/COVID-19-mRNA-Vaccine-Production; See also: SOUSA ROSA et al, "mRNA vaccines manufacturing: challenges and bottlenecks", 24.03.2021, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7987532/;* PARDI *et al, FN* 34*.*



- These artificially produced plasmids are then introduced into modified E. coli bacteria.



- In a warm environment, the bacteria (and thus the plasmids they contain) are massively multiplied in a 300-litre nutrient broth. During the phase of fastest growth, the number of bacterial cells, and thus of plasmid DNA molecules, doubles every 20 minutes.
- Once this fermentation is complete, chemicals are added to the bacterial broth to break down the bacteria and release the plasmids from their cells.
- The mixture is then purified and the plasmids checked for quality.
- Enzymes are then added to the mixture, which cut the round plasmids so that the spike protein gene sequence is separated out (linearisation).

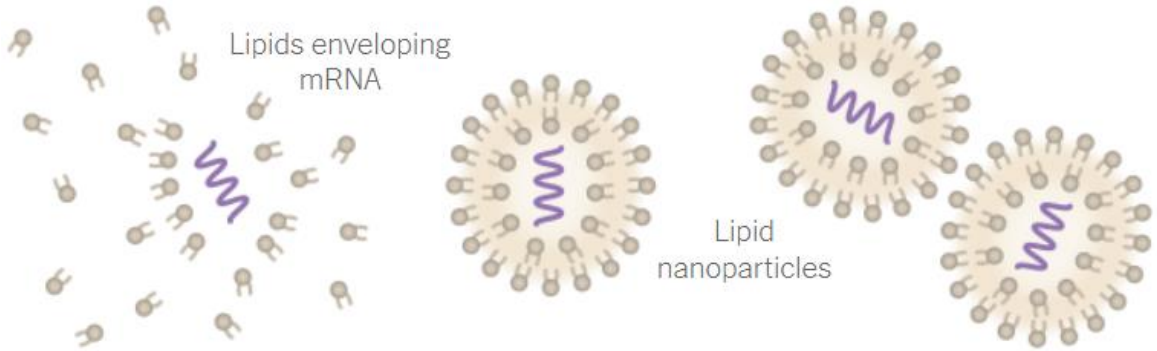


- Finally, all remaining bacteria and plasmid fragments are filtered out - only the purified spike protein gene sequence (DNA) may remain.

- This DNA sequence is then mixed with RNA polymerase enzymes and RNA building blocks called nucleotides. Over several hours, enzymes break down the DNA templates and transcribe them into mRNA strands. Among other things, **modified nucleotides** such as 1-methylpseudouridine are used: the naturally occurring uridine in RNA is replaced by artificial pseudouridine to increase protection against nucleases (which degrade RNA) and thus make the RNA more stable. [36]

- This mixture must also be filtered afterwards to remove **unwanted DNA**, enzymes or other impurities.
- In a separate process, **lipids** (fat-like molecules) are produced and mixed with ethanol.
- Finally, the mRNA strands and the lipids are mixed together. When the lipids come into contact with the naked strands of mRNA, they attract each other due to opposite electrical charges. This results in the mRNA being coated by several layers of lipids ("nanolipid particles"), which are supposed to protect the mRNA and facilitate its entry into human cells.

36 MORAIS et al, "The Critical Contribution of Pseudouridine to mRNA COVID-19 Vaccines", 04.11.2021, https://www.frontiersin.org/articles/10.3389/fcell.2021.789427/full; Scinexx, "The Trick is in the Details", 08.10.2021, *https://www.scinexx.de/dossierartikel/die-tuecke-liegt-im-detail/.*



- This newly prepared mixture is filtered again to remove the ethanol, then concentrated and filtered again to remove any remaining impurities.
- The "vaccine" is then filled into vials.

41 When this "vaccine" is finally injected into the body, the following can be observed:

- the "vaccine" enters muscle cells via injection into the muscles and also reaches the bloodstream[37] and the lymphatic system.[38]
- Muscle cells, endothelial cells of blood vessels, blood cells and dendritic cells in human lymphoid tissue take up the mRNA and produce the functional spike protein.
- Immune cells induce an immune response and produce antibodies against the foreign spike protein.

1.2.5. Stabilised mRNA - sustained expression of the toxic spike protein

42 Natural mRNA is - as described above - transient and therefore degrades quickly. However, in the production process - as also shown - an **artificially stabilised mRNA is used** (modified capping of the 5'-end[39] and replacement of the naturally occurring uridine by pseudouridine). All these measures serve to increase the stability of the artificial mRNA. This is "beneficial" in the case of mRNA "vaccination", as otherwise the immune system would sound the alarm to break down non-proprietary RNA in the body.[40] In one

37 FERTIG et al, "Vaccine mRNA Can Be Detected in Blood at 15 Days Post-Vaccination", 28.06.2022, https://www.mdpi.com/2227-9059/10/7/1538/htm.

38 RÖLTGEN et al, "Immune imprinting, breadth of variant recognition, and germinal centre response in human SARS-CoV-2 infection and vaccination", 25 Jan 2022, https://pubmed.ncbi.nlm.nih.gov/35148837/; PALMER et al, "On the use of the Pfizer and the Moderna COVID-19 mRNA vaccines in children and adolescents", 03 May 2022, https://doctors4covidethics.org/on-the-use-of-the-pfizer-and-the-moderna-covid-19-mrna-vaccines-in-children-and-adolescents/.

39 VAN DÜLMEN et al, "Chemo-Enzymatic Modification of the 5′ Cap Maintains Translation and Increases Immunogenic Properties of mRNA", 22.03.2021, https://onlinelibrary.wiley.com/doi/full/10.1002/anie.202100352.

40 ANDRIES et al, "N1-methylpseudouridine-incorporated mRNA outperforms pseudouridine-incorporated mRNA by providing enhanced protein expression and reduced immunogenicity

study, it was effectively shown that Curevac's mRNA vaccine (CVnCoV), which uses unmodified RNA, was much less effective than Moderna and Pfizer BioNTech's mRNA vaccines, which use pseudouridine.[41]

43 The aim of this modification of the mRNA is to bring it safely into the cell and thus be able to produce as much spike protein as possible.

44 Normally, the brain is reliably protected from harmful substances by the "blood-brain barrier".[42] The problematic consequences of overcoming the blood-brain barrier of the spike protein were already known at the end of 2020.[43] The damaging potential of too long an expression was therefore already clearly recognisable - and was subsequently confirmed several times (see below N 299 ff. and N 525 ff.).

1.2.6. Reverse transcription of mRNA to DNA : Swissmedic saw the potential

45 On the other hand, the artificial stabilisation leads to the mRNA staying in cells longer than under natural circumstances - and possibly getting to places where it should not. Thus, an accumulation of lipid nanoparticles in the reproductive organs (high concentrations were measured in the ovaries in particular) was discovered (see N 146). Thus, it cannot be ruled out that mRNA could also reach the gametes in the same way and remain there longer than planned. This could have the effect that an **- unintentional - effect of the mRNA on the human DNA in the germ cells could take place.**

46 As early as 1997, the existence of DNA sequences originating from an RNA virus that was not a retrovirus was demonstrated in mammals (mice). It was already concluded at that time that these DNA copies of the viral RNA genome must have originated by means of reverse transcription by cellular enzymes.[44] The molecular mechanism was elucidated in detail by scientists from the same laboratory in 2009.[45]

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in mammalian cell lines and mice", 10.11.2015, https://www.sciencedirect.com/science/article/abs/pii/S0168365915300948?via%3Dihub; NELSON et al, "Impact of mRNA chemistry and manufacturing process on innate immune activation", 24.06.2020, https://www.science.org/doi/10.1126/sciadv.aaz6893.

41 MORAIS et al, "The Critical Contribution of Pseudouridine to mRNA COVID-19 Vaccines", 04.11.2021, https://www.frontiersin.org/articles/10.3389/fcell.2021.789427/full.

42 Apotheken-Umschau, "The Blood-Brain Barrier," 03 Jan. 2019, https://www.apotheken-umschau.de/mein-koerper/gehirn-und-gedaechtnis/die-blut-hirn-schranke-721023.html.

43 RHEA et al, "The S1 protein of SARS-CoV-2 crosses the blood-brain barrier in mice", 16 Dec 2020, https://www.nature.com/articles/s41593-020-00771-8.

44 KLENERMAN et al, "A non-retroviral RNA virus persists in DNA form", 20.11.1997, https://pubmed.ncbi.nlm.nih.gov/9384383/.

45 GEUKING et al, "Recombination of retrotransposon and exogenous RNA virus results in non-retroviral cDNA integration", 16.01.2009, *https://pubmed.ncbi.nlm.nih.gov/19150848/* .

47 In subsequent years, several studies were published that demonstrated that integration of RNA sequences from non-retroviruses into the mammalian genome is possible.[46] While all the observations cited here refer to sequences derived from RNA viruses, there is no reason to exclude that other RNA sequences, such as those of mRNA vaccines, would be subject to the same mechanism.

48 As early as December 2020, a study was published as a preprint that showed that viral RNA from SARS-CoV-2 could be integrated into the human genome in a roundabout way via "reverse transcription".[47]

49 Swissmedic was aware of this study at the time of granting the temporary marketing authorisations for the COVID "vaccines" and addressed it in the marketing authorisation decision of 21 January 2021 to Moderna, freely translated as follows (Annex **3**, p. 12):

> "***Swissmedic agrees that the risk of reverse transcription of modified mRNA*** *by LINE-1 encoded RT (reverse transcriptase)* ***and subsequent integration into the genome is very low****. Swissmedic recommends Moderna to address the risk of reverse transcriptases (LINE-1, HIV) being able to convert modified mRNA into DNA.* "

50 Although **Swissmedic recognised** the **emerging risk of integration of the vaccine RNA into the human genome** as existing in principle, it did not demand any further studies on this problem, accepted the lack of essential genotoxicity studies and also did not formulate it as a condition for the granting of the temporary authorisation that it had to be ruled out with certainty in animal studies that the modified mRNA of the COVID "vaccines" could be integrated into the genome.

51 Contrary to the concerns expressed, Swissmedic subsequently even approved the following statement in the expert information for Comirnaty® ("Genotoxicity/caricinogenicity" section), which was absolutely contrary to the data already available at the time and to its own conclusion: "***In particular, it can be assumed that the mRNA does not enter the cell nucleus or interact with the genome****.* "

BO: Supplement **4:** Specialised information Comirnaty, Swissmedicinfo, 12.2020

52 This passage was deleted in the course - reasons for this are not officially known - and can no longer be found in the current technical information.[48]

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46 PALMER et al, "On the use of the Pfizer and the Moderna COVID-19 mRNA vaccines in children and adolescents", 03.05.2022, https://doctors4covidethics.org/on-the-use-of-the-pfizer-and-the-moderna-covid-19-mrna-vaccines-in-children-and-adolescents/.

47 ZHANG et al, 'SARS-CoV-2 RNA reverse-transcribed and integrated into the human genome', 13 Dec 2020, *https://www.biorxiv.org/content/10.1101/2020.12.12.422516v1* .

53 In February 2022, another study was published which, based on in vitro studies, proved that the mRNA contained in the Pfizer/BioNTech vaccine can be reverse transcribed into DNA within a few hours in human liver cells.[49]

1.2.7. Incorporation of mRNA into human DNA theoretically possible

54 Contrary to the general statement by "Swissmedic", an incorporation of mRNA into human DNA is quite conceivable as follows:

- The spike proteins can possibly negatively influence and promote cancer.[50]
- Cancers can lead to a reactivation of so-called "jumping" LINE-1 genes.[51] These are normally "switched off" to prevent mutations. However, if they are "activated", they can multiply in the human genome. Since 17% of our human genome consists of these repetitive and frequently occurring LINE-1 genes, the activity of individual LINE-1 genes cannot be ruled out from the outset[52] - activity is therefore also possible in (previously) healthy people.
- To enter DNA, mRNA must first reach the cell nucleus, where the human genome is located. Gene sequences have been discovered in RNA molecules that help natural and artificially-produced RNA molecules into the cell nucleus. One such example - among many others (!) - is the SIRLOIN sequence, a 42 nucleotide-long gene sequence flanked by 2 "CCTCCC".

SIRLOIN: CGCCTCCCGGGTTCAAGCGATTCTCCTGCCTCAGCCTCCCGA

- In the regulatory end sequence (called 3'UTR) of the mRNA-Pfizer gene sequence, there is a very similar 48 nucleotide-long piece flanked by "CCTCC(C)". This se-

48 Swissmedicinfo, "Fachinformation Comirnaty", status 04.2022, https://www.swissmedicinfo.ch/ShowText.aspx?textType=FI&lang=DE&authNr=68225.

49 ALDÉN et al, "Intracellular reverse transcription of Pfizer BioNTech COVID-19 mRNA vaccine BNT162b2 in vitro in human liver cell line", 25 Feb 2022, *https://www.mdpi.com/1467-3045/44/3/73/htm* .

50 SINGH/SINGH, "S2 Subunit of SARS-nCoV-2 Interacts with Tumour Suppressor Protein p53 and BRCA: an In Silico Study", 30.06.2020, https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC7324311/.

51 ZHANG et al, "New Understanding of the Relevant Role of LINE-1 Retrotransposition in Human Disease and Immune Modulation", 07.08.2020, https://www.frontiersin.org/articles/10.3389/fcell.2020.00657/full.

52 XIAO-JIE et al, "LINE-1 in cancer: multifaceted functions and potential clinical implications", 03.09.2015, https://www.nature.com/articles/gim2015119; PAUL et al, "Coprs inactivation leads to a derepression of LINE1 transposons in spermatocytes", 19.12.2018, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6325579/.

quence has, in principle, the potential to funnel the artificial mRNA into the human nucleus, which increases the probability of DNA integration into the human genome.[53]

CCTGAAGGGCTGTTGTAGCTGTGGCAGCTGCTGCAAGTTCGACGAGGACGATTCTGAGCCCG
TGCTGAAGGGCGTGAAACTGCACTACACATGATGACTCGAGCTGGTACTGCATGCACGCAAT
GCTAGCTGCCCCTTTCCCGTCCTGGGTACCCCGAGTCTCCCCCGACCTCGGGTCCCAGGTAT
GCTCCCACCTCCACCTGCCCCACTCACCACCTCTGCTAGTTCCAGACACCTCCCAAGCACGC
AGCAATGCAGCTCAAAACGCTTAGCCTAGCCACACCCCCACGGGAAACAGCAGTGATTAACC
TTTAGCAATAAACGAAAGTTTAACTAAGCTATACTAACCCCAGGGTTGGTCAATTTCGTGCC
AGCCACACCCTGGAGCTAGCAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAGCATATGACTAA
AAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAA
AAAAAA

55 A **potential danger of the mRNA "vaccines" for the reproductive organs** - in the sense of an alteration of the human DNA in the germ cells - and on the potential offspring can therefore not be excluded. This circumstance **should have been urgently investigated in (preclinical and) clinical studies - but this did not happen.**

1.2.8. Possible consequences of mRNA integration: cancer and/or genetic damage

56 The **integration of new segments into the DNA via mRNA can have a variety of consequences: [54]**

57 The insertion can occur within a gene and disrupt it. This can lead to the loss of important cellular gene products (proteins) and thus potentially to the development of diseases, including cancer. The occurrence of malignancies through DNA integration and activation of cancer-promoting genes (oncogenes) has been demonstrated in clinical trials using a retroviral vector for the genetic treatment of children with SCID-X1 (severe combined immunodeficiency).[55] These **malignancies usually do not manifest until several years after completion of treatment. Therefore, thorough long-term studies on possible genotoxic effects of chromosomal integration are absolutely necessary in the preclinical and clinical phases for a benefit-risk analysis**. This applies not only to retroviral vectors, but to any recombinant nucleic acid that can insert itself into the chromosomes of the cell.[56]

58 The integration of the spike protein gene into the host cell could lead to a permanent expression of this antigen and thus trigger a chronic autoimmune-like disease.

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53 LUBELSKY/ULITSKY, "Sequences enriched in Alu repeats drive nuclear localization of long RNAs in human cells," Jan. 24, 2018, https://www.nature.com/articles/nature25757; https://www.nature.com/articles/nature25757.

54 PALMER et al., FN 46.

55 STAAL et al, "Sola dosis facit venenum. Leukemia in gene therapy trials: a question of vector-sinserts and dosage?", 22.10.2008, https://pubmed.ncbi.nlm.nih.gov/18769449/.

56 PALMER et al, FN 46.

1.2.9. Conclusion: Potential of mRNA to modify DNA

59 A *targeted* integration (insertion) of DNA into the human genome is not possible - unlike with CRISPR/Cas9. The random factor is simply too high for this: possibly - if at all - only part of the mRNA sequence is transcribed into DNA. Once this - randomly dependent - transcription has taken place, it is also impossible to determine at which exact point in the genome the DNA is to be integrated. Therefore, at best, a random transcription of the mRNA into DNA and subsequent, likewise random, integration into the human genome is conceivable.

60 At the time of the granting of the temporary authorisation, the data on the danger and potential effects of the applied vaccine mRNA on the human genome were fully known. Nevertheless, this possible effect of the mRNA in the COVID "vaccines" was not even researched within the framework of preclinical studies (animal studies or in vitro studies) or - as far as can be seen - no such data have been published to date. It **can therefore not be ruled out that the mRNA substances have the potential to permanently (hereditarily) modify the DNA of humans.** If this were the case, the use of mRNA would violate mandatory constitutional provisions. Moreover, the potential to modify the DNA of a single human being without inheriting this modified DNA is already sufficient as a condition for which the strict authorisation requirements applicable to GMOs (incl. CRISPR/Cas9) would have had to be compulsorily fulfilled. 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.

61 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" that can hardly be calculated, but an **absolute criterion for exclusion from any authorisation.**

1.3. New, not yet tested ingredients: Toxic lipid nanoparticles

1.3.1. Functionality of lipid nanoparticles (LNP)

62 To protect the mRNA in the COVID "vaccines" from degradation and to facilitate its uptake into the body's cells, it is "packaged" in a shell of fats (lipid nanoparticles, LNP). The LNP consist of a mixture of phospholipids, cholesterol, PEGylated lipids and cationic (positively charged) or ionisable lipids. The phospholipids and cholesterol have structural and stabi-

lising functions, while the PEGylated lipids support prolonged circulation. The cationic/ionisable lipids serve to allow the complexation of the negatively charged mRNA molecules and the exit of the mRNA from the endosome into the cytosol for translation.[57]

63 Depending on how LNP are constructed on the surface, they behave differently. According to Uğur Şahin, CEO of BioNTech, the LPNs for Comirnaty® were deliberately chosen to **favour migration from muscle cells into lymph nodes**.[58]

1.3.2. Missing data on the degradation of ALC-0159 and ALC-0315 (Comirnaty®)

64 ALC-0315 and ALC-0159 are two non-natural lipids contained in Comirnaty® lipid nanoparticles (LNP). ALC-0315 is weakly basic and positively charged (cationic) in the protonated state, ALC-0159 contains a polyethylene glycol (PEG) element.

65 Pharmacokinetic studies with the LNP used in Comirnaty® in rats and mice show that the labelled lipids appeared in the blood plasma after a very short time. The highest plasma level was reached already two hours after injection (add N 146).[59]

66 The lipid **ALC-0315 accumulated in high concentrations in the liver, spleen and ovaries and was degraded only slowly**. Even after 6 weeks, some of the compound was still detected in the liver. It cannot be excluded that these synthetic lipids are redistributed from the liver to other organs where they may be stored for a longer period of time.[60]

67 The registration dossier, chapter "*Non Clinical* Overview"[61] shows that while the concentration of the two lipids (ALC-0315 and ALC-0159) in the blood plasma decreased relatively quickly, **the degradation of ALC-0315 in the liver was very slow :**

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57 NDEUPEN et al, "The mRNA-LNP platform's lipid nanoparticle component used in preclinical vaccine studies is highly inflammatory", preprint dated 23/07/2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7941620/.

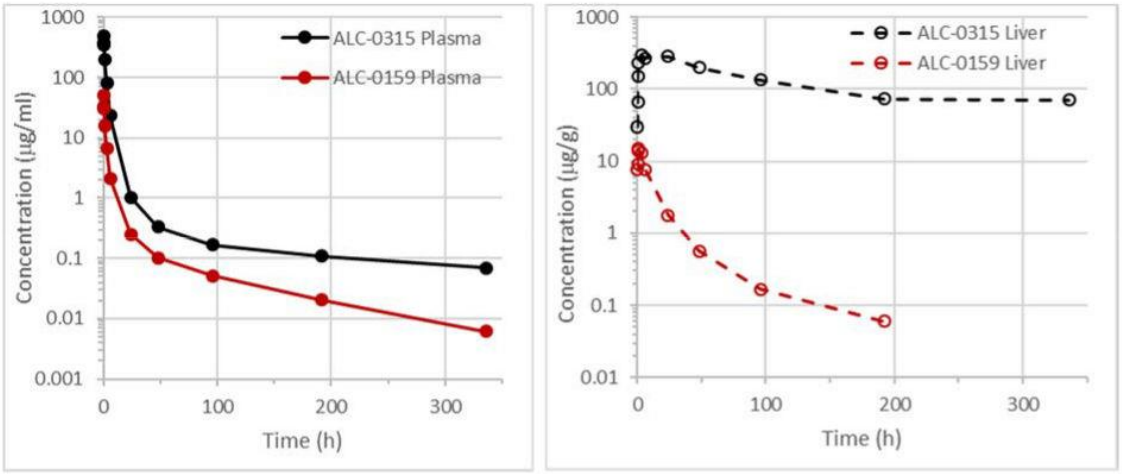
58 Wiener Zeitung, "Part of Covid-19 vaccine could come from Austria", 02.09.2020, *https://www.wienerzeitung.at/nachrichten/wissen/forschung/2073592-Teil-von-Covid-19-Vakzine-koennte-aus-Oesterreich-kommen.html.*

59 Pfizer confidential translated, "SARS-CoV-2 mRNA vaccine (BNT162, PF-07302048)", 22.07.2021, https://archive.org/details/pfizer-confidential-translated/page/n7/mode/2up.

60 PALMER/BHAKDI, "The Pfizer mRNA vaccine: pharmacokinetics and toxicity", 23.07.2021, *https://doctors4covidethics.org/wp-content/uploads/2021/07/Pfizer-pharmacokinetics-and-toxicity.pdf; Internet Archive*, "Pfizer-confidential-translated", 22.07.2022, https://archive.org/details/pfizer-confidential-translated/page/n3/mode/2up.

61 BNT162b2, "Module 2.4. Nonclinical Overview", para. 2.4.3., 08.02.2021, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf.

Figure 2.4.3-1. Plasma and Liver Concentrations of ALC-0315 and ALC-0159 in Wistar Han Rats After IV Administration of LNPs Containing Surrogate Luciferase RNA at 1 mg/kg



68 Since the lipids were not detectable in the urine and 50% for ALC-159 and only 1% for ALC-0315 in the faeces, the rest must have been metabolised. Some of the metabolites could be detected.

69 In summary, these preclinical data suggest that LNP and **ALC-0315 in** particular **accumulate in the liver**. The metabolic degradation of this lipid was slow and the concentration was still at a high level at the end of the study after 12.5 days.

70 Although this data had also been submitted to Swissmedic by Pfizer in the authorisation dossier, Swissmedic publicly claimed to the LNP:[62]

> "These are very unstable fat droplets that break down quickly in the body.
> "
>
> "There is no evidence that they accumulate in tissues or organs over time.
> "

71 This is to be qualified as a deliberate false statement, which is intended to cover up the dangerousness of the lipid components.

72 ALC-0315 in particular has not been sufficiently studied from a chemical point of view. It contains two chiral (asymmetric) centres, which means that different enantiomers and diastereomers (in simple terms, mirror-image forms) can be present from the same product. However, these forms can have significantly different toxicological properties, as the example of thalidomide (Contergan®) clearly demonstrated. The mutagenic properties

62 Medinside, "Swissmedic: 'These excipients are not a risk to humans'", 20.01.2022, https://www.medinside.ch/de/post/swissmedic-diese-hilfsstoffe-sind-kein-risiko-fuer-den-menschen.

were only caused by one of the two enantiomers, the other was harmless.[63] It is not clear or not defined which of these forms is used or whether, which is more likely due to the synthesis strategy, a mixture of these compounds is used. In the context of an accumulation of this substance in the liver and slow metabolisation, a thorough clarification of the toxicity, carcinogenicity and mutagenicity of these substances would have been urgently required before authorisation. Even if, on the basis of plausibility considerations, a hazard from these substances should not appear likely, these questions should have been answered before the temporary authorisation was granted. It is irresponsible to clarify human toxicity in vivo only after administration to billions of people.

73 Pfizer assumes that the distribution of the spike protein, which is encoded by the mRNA, is directly dependent on the LNP distribution and that the results presented from the animal studies are representative of the vaccine:

> "The biodistribution of the antigen (spike protein) encoded by the RNA component of BNT162b2 (Comirnaty®) is expected to be dependent on LNP distribution, and the results presented are representative of the vaccine ... . "[64]

74 This leads to the conclusion that the spike proteins are produced in the blood as well as in various organs. This has since been confirmed by pathological examinations (see N 525).

1.3.3. Toxicity of LNP proven

75 **The use of LNPs in humans has been considered critical for years because of their toxicity and associated dangerous side effects,** especially when administered repeatedly over a long period of time. Katalin Karikó, senior vice-president of BioNTech, therefore officially took the view, at least until recently, that mRNA therapies are better suited for diseases with short-term treatment, as "*toxicities caused by the carrier material*" are less likely.[65]

76 In the scientific literature, the toxicity of positively charged LNP, as also used in the COVID "vaccines" (ALC-0315 for Comirnaty®, SM-102 for Spikevax®), has long been known.[66] The damaging influence on DNA through DNA strand breaks was already shown in animal studies in 2015.[67]

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63 Scinexx, "Ein Spiegelbild mit tragischen Folgen Contergan und seine (Neben-)Wirkung", 30.05.2000, https://www.scinexx.de/dossierartikel/ein-spiegelbild-mit-tragischen-folgen/.

64 BNT162b2, "Module 2.4. Nonclinical Overview", para. 2.4.3.4., 08.02.2021, https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf.

65 Statnews, "Ego, ambition, and turmoil: Inside one of biotech's most secretive startups", 13.09.2016, https://www.statnews.com/2016/09/13/moderna-therapeutics-biotech-mrna/.

66 PALMER/BHAKDI, "The Pfizer mRNA vaccine: pharmacokinetics and toxicity", 23.07.2021, https://doctors4covidethics.org/wp-content/uploads/2021/07/Pfizer-pharmacokinetics-and-

77 A study by Tel Aviv University already showed in 2010 that positively charged LNP drastically (up to 75 times) increase inflammatory markers (e.g. interleukins, interferons) in mice.[68]

78 These early observations were confirmed in a July 2021 study: The mice inoculated with LNP quickly showed visible signs of inflammation. 80 % of the mice that received the highest doses of LNP administered through the nose died, probably due to the massive inflammatory reactions triggered in the lungs. The scientists concluded: "*Similar to skin inoculation, intranasal administration of LNP leads to massive inflammation. Moreover, the inflammatory properties of LNP are not site-specific and show a rapid rate of diffusion, dispersion and distribution in (other) tissues.* " The researchers pointed out that it was very likely that intramuscular injection of LNP would trigger similar inflammatory reactions in the muscle.[69]

79 The product information for Comirnaty® and Spikevax® shows that such inflammatory reactions were also observed in preclinical studies:

> *"Rats given Comirnaty® intramuscularly ... showed mild oedema and erythema at the injection site, enlargement of local lymph nodes and spleen, and an increase in leukocytes (including basophils and eosinophils), suggestive of an inflammatory reaction, ... "*[70]
>
> "Intramuscular application of Spikevax® (and other Moderna mRNA research vaccines) with the same formulation, up to 4 doses every 2 weeks to rats at dose levels ranging from 9 to 150 mcg/dose, resulted in transient erythema and oedema at the injection site, an increase in body temperature and a general systemic inflammatory response. "[71]

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toxicity.pdf; 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.

67 BRAM KNUDSEN et al, "In vivo toxicity of cationic micelles and liposomes", 08.07.2014, https://www.sciencedirect.com/science/article/pii/S1549963414004274?via%3Dihub.

68 KEDMI et al, "The systemic toxicity of positively charged lipid nanoparticles and the role of toll-like receptor 4 in immune activation", 11.06.2010, https://www.sciencedirect.com/science/article/abs/pii/S0142961210006459.

69 NDEUPEN et al., FN 57.

70 Swissmedicinfo, FN 48.

71 Swissmedicinfo, "Fachinformation Spikevax", status 05.2022 https://www.swissmedicinfo.ch/ShowText.aspx?textType=FI&lang=DE&authNr=68267.

1.3.4. Hazardousness and lack of suitability of ALC-0159 and ALC-0315 (Comirnaty®) for human use

80 A German legal opinion by Beate Bahner, a specialist lawyer for medical law, shows that the two novel lipids ALC-0159 and ALC-0315, which are used for the first time in a medicinal product, were not approved for use in humans until 8 December 2021, according to the manufacturer's information, but only for research purposes:[72]

ALC-0159 is a PEGylated lipid which has been used to form lipid nanoparticles for delivery of RNA. ALC-0159 is one of the components in the BNT162b2 vaccine against SARS-CoV-2 in addition to ALC-0315, DSPC, and cholesterol. This product is for research use only and not for human use.

ALC-0315 is an ionizable lipid which has been used to form lipid nanoparticles for delivery of RNA. ALC-0315 is one of the components in the BNT162b2 vaccine against SARS-CoV-2 in addition to ALC-0159, DSPC, and cholesterol. This product is for research use only and not for human use.

81 The statement "*not for human use*" on the homepage of Echelon Biosciences, which supplies the lipid components, was removed by the company a few days later. The statements remaining on the homepage are now only "*for research only*".[73] However, this means the same thing, namely that the **substances are not suitable as ingredients of a medicinal product for use in or on humans.**

82 In the aforementioned legal opinion and in the *EMA*'s *assessment report, it is* evident that the marketing authorisation holder Pfizer/BioNTech has not yet submitted any documents and data for ALC-0159 and ALC-0315 *to* prove the perfect quality and thus the suitability and safety of these excipients for use in the medicinal product Comirnaty®, although these were explicitly requested by the *EMA*.[74]

83 The lipid components are not listed as excipients in either the European or the Swiss Pharmacopoeia.[75] At the request of Swissmedic, active substances and excipients not

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72 BAHNER, "Legal opinion on criminal liability", 27.12.2021, https://www.docdroid.net/NjG3dS1/rechtsgutachten-rain-bahner-strafbarkeit-nach-95-amg-durch-impfung-pdf; Internet Archive, "ALC-0315", 08.12.2021, *https://web.archive.org/web/20211208053009/https://www.echelon-inc.com/product/alc-0315/* ; Internet Archive, "ALC-0159", 08 Dec. 2021, https://web.archive.org/web/20211208072146/https://www.echelon-inc.com/product/alc-0159/.

73 Echelon Biosciences, "ALC-0315," 6/16/2022, https://www.echelon-inc.com/product/alc-0315/; Echelon Biosciences, "ALC-0159," 6/16/2022, https://www.echelon-inc.com/product/alc-0159/.

74 BAHNER, "Legal opinion on criminal liability", 27.12.2021, *https://www.docdroid.net/NjG3dS1/rechtsgutachten-rain-bahner-strafbarkeit-nach-95-amg-durch-impfung-pdf;* European medicines agency , "Assessment report on the annual renewal of the conditional marketing authorisation", 2021, *https://www.ema.europa.eu/en/documents/variation-report/comirnaty-h-c-5735-r-0046-epar-assessment-report-renewal_en.pdf.*

75 BAHNER, "Legal opinion on criminal liability", 27.12.2021, https://www.docdroid.net/NjG3dS1/rechtsgutachten-rain-bahner-strafbarkeit-nach-95-amg-durch-impfung-pdf; Swissmedic, "Pharmacopoea Helvetica online", 16.06.2022, *https://www.swissmedic.ch/swissmedic/de/home/legal/pharmacopoea/pharmacopoea-helvetica0/pharmacopoea-helvetica-online.html.*

included in the pharmacopoeia may be used in medicinal products if quality and safety are adequately documented in the marketing authorisation documentation.

BO: Supplement **5:** E-mail response regarding pharmacopoeia, Swissmedic, 06.01.2022

84 This is demonstrably not the case for ALC-0159 and ALC-0315. The correspondence between Swissmedic and Pfizer shows that the most relevant documents on quality and safety, in particular on possible impurities (see N 98 ff.) on the lipid nanoparticle (LNP) components ALC-0159 and ALC-0315 had not been submitted to Swissmedic and that Swissmedic had objected to this.

85 According to statements made in a public interview in January 2022, in which Swissmedic was asked about risks in connection with ALC-0159 and ALC-0315, its spokesperson replied that, on the basis of the data submitted and examined in the authorisation procedure, it had come to the conclusion that the new excipients mentioned and the impurities they may contain in traces "do not pose a risk to humans in the quantities used in Comirnaty®". Swissmedic's assessment is contrary to that of the *EMA,* which at the same time was still complaining about risks in connection with the new excipients and special requirements that had not been fulfilled.[76] Since the documents relevant to answering the questions regarding the safety of the LNP components were not available to the *EMA at* that time, it can be assumed that these documents had also not been submitted to Swissmedic.

1.3.5. Hazardousness and lack of suitability of SM-102 (Spikevax®) for human use

86 The cationic lipid used in Spikevax® is SM-102, which, according to the Swissmedic approval letter, is supplied to Moderna by the company *Corden Pharma.*

87 No specific information on SM-102 can be found on the *website of Corden Pharma,* but it can be found on the *website of* an alternative supplier, the Cayman company. There it is stated that SM-102 is not suitable for use on humans or animals and may only be used for research purposes:[77]

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76 Medinside, "Swissmedic: These excipients are not a risk to humans", 20.01.2022, https://www.medinside.ch/de/post/swissmedic-diese-hilfsstoffe-sind-kein-risiko-fuer-den-menschen.

77 Cayman chemical, "SM-102", 16.06.2022, https://www.caymanchem.com/product/33474/sm-102; Cayman chemical, "SM-102 for Research Use Only (RUO)", 19.05.2021, https://www.caymanchem.com/news/sm-102-statement.

Product Description

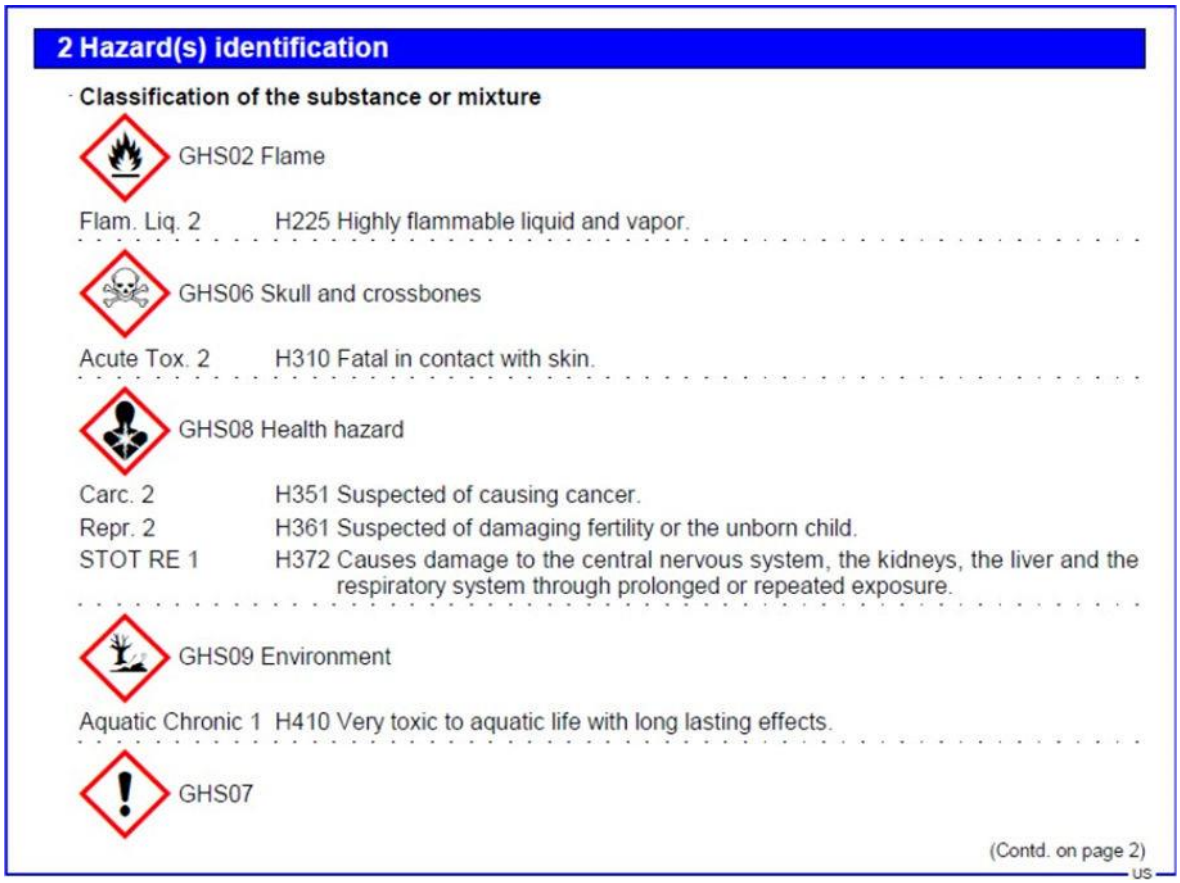
SM-102 is an ionizable amino lipid that has been used in combination with other lipids in the formation of lipid nanoparticles (LNPs).[1] Administration of luciferase mRNA in SM-102-containing LNPs induces hepatic luciferase expression in mice. Formulations containing SM-102 have been used in the development of LNPs for delivery of mRNA-based vaccines.

Read our statement on SM-102 for research use only

WARNING This product is **not** for human or veterinary use.

88 The "*Safety Data Sheet*" of SM-102 was adapted and downgraded in terms of hazard when the novel lipids came under media criticism:

89 As of 11 April 2021, the document still looked as follows:



2 Hazard(s) identification

· **Classification of the substance or mixture**

GHS02 Flame

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

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.

GHS09 Environment

Aquatic Chronic 1 H410 Very toxic to aquatic life with long lasting effects.

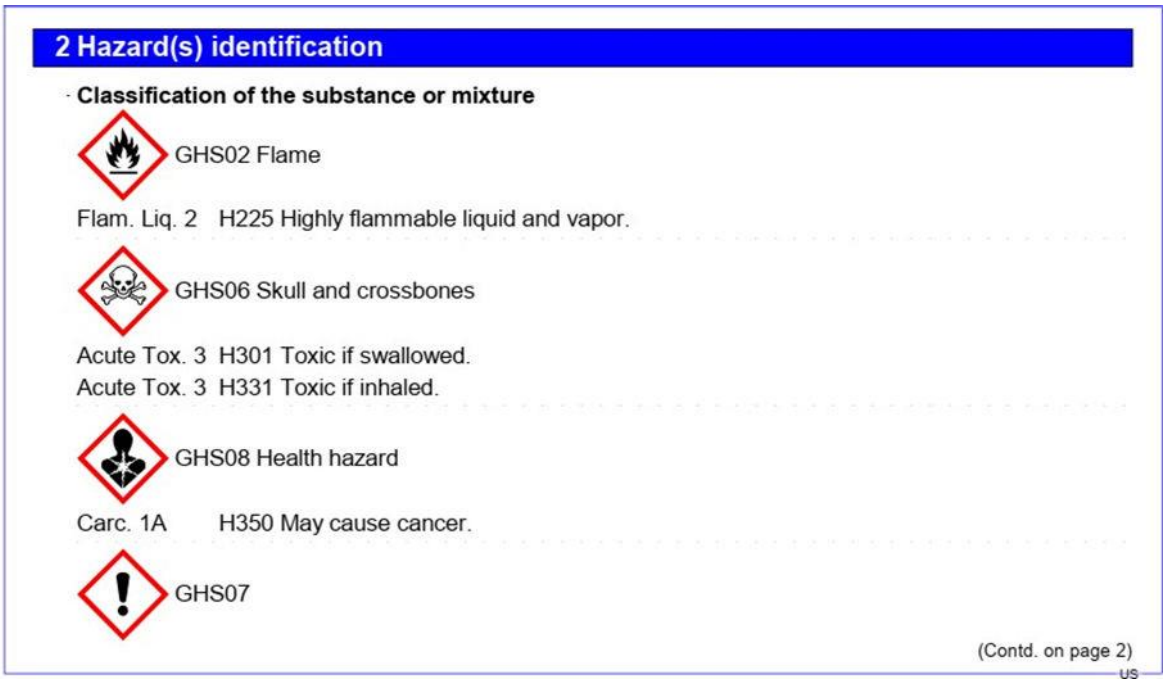
GHS07

(Contd. on page 2)

US

BO: Supplement **6:** Safety data sheet, Cayman chemical, 11.04.2021

90 As of 15 September 2021 then suddenly like this:[78]



2 Hazard(s) identification

· **Classification of the substance or mixture**

GHS02 Flame

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

GHS06 Skull and crossbones

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

GHS08 Health hazard

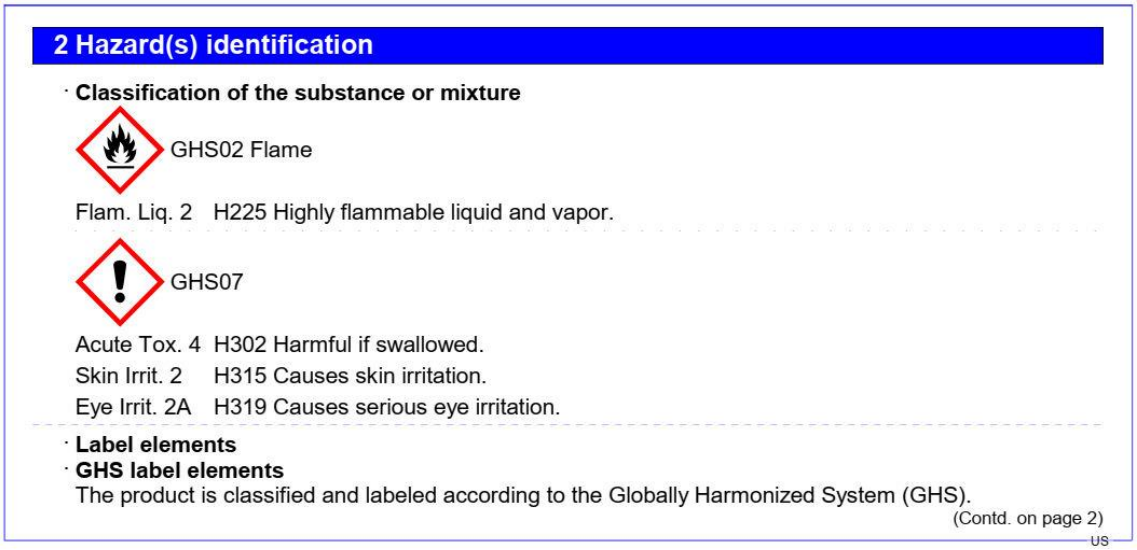
Carc. 1A H350 May cause cancer.

GHS07

(Contd. on page 2)

US

91 And already a few months later, the next adjustment took place on 7 June 2022:[79]



2 Hazard(s) identification

· **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.

· **Label elements**
· **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).

(Contd. on page 2)

US

92 All hazard warnings had been successively downgraded: Thus, "**Danger to life in case** of skin contact" first became "**Toxic if** swallowed or inhaled" and finally "**Harmful** if swal-

78 Internet Archive, "Safety Data Sheet", 15.09.2021, *https://web.archive.org/web/20211120001839/https://cdn.caymanchem.com/cdn/msds/33474m.pdf* .

79 Internet Archive, "Safety Data Sheet", 07.06.2022, https://web.archive.org/web/20220626094044/https://cdn.caymanchem.com/cdn/msds/33474m.pdf. *https://web.archive.org/web/20211120001839/https:/cdn.caymanchem.com/cdn/msds/33474m.pdf.*

lowed". The second highest toxicity level (Acute Tox. 2) was downgraded to level 3 (Acute Tox. 3) and finally to level 4 (Acute Tox. 4).

93 In addition, from

- "H351 May probably cause cancer",
- "H361 Suspected of damaging fertility or harming the unborn child" and
- "H372 Causes damage to the central nervous system, kidneys, liver and respiratory system through prolonged or repeated exposure".

In September 2021, the warning still read "Could cause cancer" before disappearing altogether as of June 2022.

94 It is clear from the authorisation letter that Swissmedic objected to various points regarding the quality and suitability of SM-102 before granting the temporary authorisation.

95 Swissmedic also requested that Moderna provide documentation on the following points by 1 July 2021:

> "More data on the tests purity and assay of SM-102. The limits of the tests purity and assay should be further tightened accordingly. "
>
> "Impurities should be specified and limits should be implemented. "
>
> "A discussion on fate and purge of the impurities should be submitted. "

96 Swissmedic also requested additional documentation on potentially toxic impurities. (Supplement **3**, p. 7 f.)

97 It is unknown to the complainants whether the requested documents in this context have been submitted by the marketing authorisation holder in the meantime.

1.4. Toxic, mutagenic and carcinogenic impurities

1.4.1. Contamination with nitrosamine and benzene

98 The authorisation letters also show that "Swissmedic" had found toxic "impurities" in the mRNA "vaccines": **Benzene** (in the case of Moderna) and **nitrosamine** (in the case of Pfizer and Moderna) were contained in the "vaccines".

99 In the marketing authorisation notice, Swissmedic requested Moderna to submit documents on the following points, among others, by 1 July 2021 (Annex **3**, p. 7 f.):

> "The control strategy for **benzene** should be submitted."

> "A risk evaluation on the potential presence of **nitrosamine impurities** ...should be submitted. The risk evaluation will have to be adequately documented and, if applicable, supported by confirmatory testing in case a possible risk of presence of nitrosamines has been identified".

100 In its letter of 19.12.2021, Swissmedic requests Pfizer to submit missing documents on the following points "before 1 February 2022" (Supplement **2**, p. 6):

> "A risk assessment (for ALC-0159 and ALC-0315) on the possible presence of impurities with **nitrosamine** shall ... be submitted. The risk assessment shall be adequately documented and, if a possible risk to the presence of nitrosamines has been identified, supplemented with data from confirmatory testing."

101 **Nitrosamine is highly toxic even in the smallest concentrations, is one of the most carcinogenic substances of all and is mutagenic.** [80]

102 **Benzene has been proven to be toxic, carcinogenic and mutagenic.** It is stored in the brain, bone marrow and fatty tissue.[81]

103 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.**

1.4.2. Contamination with bacterial DNA: Potential for DNA damage?

104 As described above (see N 40), manufacturers must take measures to remove the DNA produced during manufacture in purification steps, with the aim of preventing these undesirable "contaminations" from being found in the finished medicinal product. Nevertheless, the mRNA "vaccines" were contaminated with DNA from bacterial cells (E. coli). This should not happen under any circumstances and indicates improper production.

105 The *assessment report of* Comirnaty®[82] of 19 February 2021 also shows that the *EMA* found the measures for removing the DNA contaminations to be insufficiently presented:

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80 ECGBI, "Nitrosamines", 16.06.2022, https://www.eggbi.eu/forschung-und-lehre/zudiesemthema/nitrosamine/.

81 LANUV, "Noxen-Informationssystem für den ÖGD", 05.2012, https://www.nis.nrw.de/publik/1/wirk.html.

"The robustness of the DNase digestion step is not considered comprehensively demonstrated."

106 *The EMA* asked Pfizer/BioNTech to "re-evaluate" the specifications for DNA contamination.

107 Swissmedic also classified the DNA contaminations in Spikevax® as critical in the letter of authorisation to Moderna and explicitly requested the marketing authorisation holder to tighten the specifications for DNA residues left in the vaccine solution from the manufacturing process ("residual DNA templates") by 30 June 2021 (Annex **3**, p. 4).

108 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.[83] Such DNA sequences simply have no place in a "vaccine" - nevertheless, approval was granted.

1.5. Increased risk for pregnant women

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

109 The *Human Medicines Experts Committee* (*HMEC*) mandated by Swissmedic summarised in the meeting minutes of 18.12.2020 on the item "Pregnancy" for Comirnaty®: "***Pregnancy should be listed under "Precautions"****. At the moment there is little data in pregnant women and* ***preclinical studies have identified a possible risk in pregnancies****.* " (Supplement **2**, p. 16).

110 Swissmedic itself also concluded in the authorisation letter, loosely translated: "*The ongoing and proposed additional pharmacovigilance activities are considered sufficient to further characterise the important ...* ***missing information "use in pregnancy and lactation***" to *further characterise* ..." (Supplement **2**, p. 11).

111 The excerpt from a "DART study" ("Developmental and Reproductive Toxicology Study), which Pfizer conducted in rats, supports the possible risk in pregnancy identified by *HMEC*: "*There was an* ***increase (~2x)*** *in* ***preimplantation losses*** *(9.77%, compared to 4.09% in the control group). ... Among the fetuses (out of a total of n=21 mothers/litters)****,*** *there was a very low incidence of* ***gastroschisis*** *(defect of the anterior abdominal wall)****, oral/jaw malformations, right aortic arch and cervical vertebral anomalies***. " Thus, malformations occurred in principle. The incidence was assessed by Pfizer as "very low"

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82 European medicines agency, "Assessment report comirnaty", 19.02.2021, p. 16f. and 40, https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf.

83 PALMER et al, FN 46.

and "within the usual range". This classification cannot be conclusively classified due to the unavailability of raw data.

112 The observed preimplantation loss indicated toxicity at a very early stage of development, either to the embryo or the developing placenta. This could be caused by a high expression of spike proteins, but also by toxic lipids.[84] Pfizer itself pointed out in the cited report of the DART study that it had not been investigated whether the "vaccine" could pass the placenta: "*It is noted that there is currently no available data on the placental transfer of BNT162b2*."

113 It is incomprehensible that the question of the potential harmfulness of the "vaccine" to the unborn child was not investigated more closely and extensively by the marketing authorisation holder, despite indications of implantation difficulties or increased miscarriage rates and observed malformations with the reference that these rates were "within the normal range", based on only n=21 litters. The fact that Swissmedic did not request any further preclinical data on this issue, in the knowledge that the vaccine was to be administered to all pregnant women in the course of their pregnancy, shows that Swissmedic did not act in the interests and for the protection of the Swiss population.

BO: Supplement **7:** E-mail response regarding comirnaty fertility trials, Pfizer, 07.01.2021

114 According to the minutes of the *HMEC meeting of* 18.12.2020, there were no comments on the part of Swissmedic on the content of the minutes, i.e. Swissmedic had agreed with *HMEC*'s assessment (Annex **2**, p. 16).

115 It is surprising how Swissmedic was able to agree to or approve the following contents in the section on "*Pregnancy, lactation*" and "*Developmental toxicity" for the* specialist information for Comirnaty® (Annex **4**): "*There is only limited experience of the use of Comirnaty® in pregnant women. Animal studies do not indicate direct or indirect adverse effects related to pregnancy, embryonic/fetal development, parturition or postnatal development*" and "***No vaccine-related effects on female fertility, pregnancy or embryo-fetal development or on the development of the offspring have been observed***. "

116 These statements are contrary to the findings and recommendations of the *HMEC* commissioned by Swissmedic.

117 The *HMEC* recommended that the temporary marketing authorisation be approved, with the condition, among others, that the topic of "*pregnancy*" and the lack of data in this context be included in the "*Precautions*" section of the SmPC (Supplement **2**, p. 16).

84 PALMER/BHAKDI, "The Pfizer mRNA vaccine: pharmacokinetics and toxicity", 23.07.2021, https://doctors4covidethics.org/wp-content/uploads/2021/07/Pfizer-pharmacokinetics-and-toxicity.pdf.

118 **This was demonstrably not implemented by Swissmedic. A** corresponding note was not included in the aforementioned section of the SmPC (Annex **4**).

119 Pregnant women were excluded from participation in the phase 3 trials of both Comirnaty® and Spikevax®.[85]

1.5.2. British Health Authority and WHO: No recommendation for pregnant women

120 Based on the data available at the time of the marketing authorisation, **the UK health authority explicitly stated in the** drug information "*Information for Healthcare Professionals on Pfizer/BioNTech COVID-19 vaccine*"[86] of 8 December 2020, which was published on the occasion of the emergency marketing authorisation of Comirnaty®**, that the Pfizer vaccine cannot be recommended for use during pregnancy, that pregnancy should be excluded prior to vaccination and women of childbearing age should avoid pregnancy for at least two months after the second dose, and that the effect on fertility is unknown:**

> **4.6 Fertility, pregnancy and lactation**
>
> **Pregnancy**
> There are no or limited amount of data from the use of COVID-19 mRNA Vaccine BNT162b2. Animal reproductive toxicity studies have not been completed. COVID-19 mRNA Vaccine BNT162b2 is not recommended during pregnancy.
>
> For women of childbearing age, pregnancy should be excluded before vaccination. In addition, women of childbearing age should be advised to avoid pregnancy for at least 2 months after their second dose.
>
> **Breast-feeding**
> It is unknown whether COVID-19 mRNA vaccine BNT162b2 is excreted in human milk. A risk to the newborns/infants cannot be excluded. COVID-19 mRNA Vaccine BNT162b2 should not be used during breast-feeding.
>
> **Fertility**
> It is unknown whether COVID-19 mRNA vaccine BNT162b2 has an impact on fertility.

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85 Pfizer, "A phase 1/2/3, placebo-controlled, randomized, observer-blind, dose-finding study to evaluate the safety, tolerability, immunogenicity, and efficacy of SARS-CoV-2 RNA vaccine candidates against Covid-19 in healthy individuals", 11.2020, https://cdn.pfizer.com/pfizercom/2020-11/C4591001_Clinical_Protocol_Nov2020.pdf; Internet archive, "clinical study protocol", 20.08.2020, *https://web.archive.org/web/20220325130049/https://www.modernatx.com/sites/default/files/mRNA-1273-P301-Protocol.pdf* .

86 Internet Archive, "Information for Healthcare Professionals on Pfizer/BioNTech COVID-19 vaccine", *08.12.2020,* https://web.archive.org/web/20201208152320/https:/www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-healthcare-professionals-on-pfizerbiontech-covid-19-vaccine.

121 Similarly, **in a factsheet from February 2021**[87] , the ***WHO pointed out that*** **vaccination is generally not recommended for pregnant women** and should only be carried out in exceptional cases (e.g. among health workers who are at high risk):

Special conditions and groups

Condition/group	SAGE recommendation
Pregnancy	• Vaccination is not recommended unless the benefit of vaccinating a pregnant woman outweighs the risks (e.g. health workers at high risk of exposure).

122 In contrast to these present recommendations, the first available summary of product characteristics for Comirnaty® approved by Swissmedic did not advise against vaccination of pregnant women, but kept open the possibility in the event that "benefits outweigh the risk to mother and foetus" (Supplement **4**, "Pregnancy, lactation"):

Die Verabreichung von Comirnaty in der Schwangerschaft sollte nur in Betracht gezogen werden, wenn die möglichen Vorteile die potenziellen Risiken für Mutter und Fötus überwiegen.

123 Based on the data available at that time (and to date), which unequivocally pointed to an existing risk to the foetus, it seems completely incomprehensible that Swissmedic left this option open and hereby delegated responsibility to treating physicians.

1.5.3. Australian health authority also ignores warnings

124 The Australian Health Authority reviewer of the preclinical study data of Comirnaty® also concluded that it showed an increased risk for pregnant women. He recommended pregnancy category B2[88] :

Increased incidence of supernumerary lumbar ribs in rat fetuses was noted in the fertility and developmental study with the proposed vaccine. Pregnancy category B2 is considered acceptable.

125 This recommendation was also implemented to the contrary in the subsequently published drug information, the reference to the risks was deleted instead and Comirnaty® was given pregnancy category B1[89] :

87 WHO, "Fact sheet for health workers: Comirnaty", 02.2021, https://apps.who.int/iris/bitstream/handle/10665/339681/WHO-EURO-2021-1964-41715-57093-eng.pdf?sequence=1&isAllowed=y.

88 Therapeutic goods administration, "Delegate's Overview and Request for ACV's Advice", 11.01.2021, p. 8 and 27, https://www.tga.gov.au/sites/default/files/foi-2389-01.pdf.

89 Therapeutic goods administration, "Australian product information - cominarty", 25.01.2021, p. 7, https://www.tga.gov.au/sites/default/files/auspar-bnt162b2-mrna-210125-pi.pdf.

Use in pregnancy - Pregnancy Category B1

There is limited experience with use of COMIRNATY in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/fetal development, parturition or post-natal development (see Effects on fertility). Administration of COMIRNATY in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus.

126 Although animal studies indicated an increased risk, Comirnaty® was thus assigned to a pregnancy category, which is normally reserved for drugs that have been shown in animal studies not to carry an increased risk[90] :

Category B1

Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed.

Studies in animals have not shown evidence of an increased occurrence of fetal damage.

Category B2

Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed.

Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of fetal damage.

127 The approach is analogous to that of Swissmedic: the authority deliberately ignored risk signals from the preclinical studies and willfully did not implement precautionary measures.

1.5.4. Interim conclusion

128 As early as December 2020, Swissmedic knew that **a possible risk to pregnancies** had been identified in **preclinical studies. Swissmedic** did not adequately address this risk either - indeed, like the Australian regulatory authority**,** it even **concealed it.**

1.6. Unprecedented short "development time

129 The temporary approvals of the COVID "vaccines" were granted based on **"phase I/II/III" studies in** which the study participants had been observed for a median of **only two months.**[91]

90 Therapeutic goods administration, "Australian categorisation system for prescribing medicines in pregnancy", 04.05.2011, https://www.tga.gov.au/australian-categorisation-system-prescribing-medicines-pregnancy.

1.7. Missing, incomplete, alarming and sabotaged studies

1.7.1. Missing and incomplete animal studies on toxicity

130 The individual steps in the development of a medicinal product and, in particular, the investigations necessary and customary in the preclinical phase to prove its safety are described in detail in the criminal complaint (section "Swissmedic's offence"): A medicinal product is considered dangerous until its safety has been proven. In this context, only drug candidates that have passed all the investigations in the preclinical phase, i.e. that have sufficiently demonstrated their safety in animals in vivo, may enter the next development phase with studies in humans (clinical trials).

131 According to *Module 2.4 "Non clinical overview", Table 2.4.4.1 (p.22)*[92] *(this module was also submitted to Swissmedic as part of the marketing authorisation dossier),* just three toxicity studies were conducted for Comirnaty® :

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91 POLACK et al, "Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine", 31 Dec 2020, *https://www.nejm.org/doi/10.1056/NEJMoa2034577?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed* ; BADEN et al, "Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine", 04.02.2021, *https://www.nejm.org/doi/pdf/10.1056/NEJMoa2035389?articleTools=true* .

92 BNT162b2, FN 61.

Table 2.4.4-1. Overview of Toxicity Testing Program

Study[a]	Study (Sponsor) No.	Group/ Dose, µg RNA	Total Volume (µL)[b]	No. of Animals/ Group	Study Status
Repeat-Dose Toxicity					
17-Day, 2 or 3 Dose (1 Dose/Week) IM Toxicity With a 3 Week Recovery Phase in Rats[c,d]	38166	Control[e], 0	200[f]	15/sex	Completed
		BNT162b2 (V8)[i], 100	200[f]	15/sex	
17-Day, 3 Dose (1 Dose/Week) IM Toxicity With a 3 Week Recovery Phase in Rats[g]	20GR142	Saline[h], 0	60	15/sex	Completed
		BNT162b2 (V9)[i], 30	60	15/sex	
Developmental and Reproductive Toxicity					
Combined Fertility and Developmental Study (Including Teratogenicity and Postnatal Investigations) by the IM route in Rats[j]	20256434 (RN9391 R58)	Saline[h], 0	60	44 F	Completed
		BNT162b2 (V9)[i], 30	60	44 F	

a. All studies are GLP-compliant and were conducted in an OECD mutual acceptance of data-compliant member state.
b. Doses were administered as 1 application at 1 site unless otherwise indicated.
c. Study also evaluated the BNT162a1, BNT162b1, and BNT162c1 vaccine candidates.
d. QW x 3 (Days 1, 8, 15) for BNT162a1, BNT162b1, and BNT162b2 (V8); QW x 2 (Days 1, 8) for BNT162c1.
e. Phosphate buffered saline, 300 mM sucrose.
f. One application (100 µL) at 2 sites for a total dose volume of 200 µL.
g. Study also evaluated BNT162b3.
h. Sterile saline (0.9% NaCl).
i. BNT162b2 (V8) and BNT162b2 (V9) both encode the same amino acid sequence of the spike protein antigen with two prefusion conformation-stabilizing amino acids in the stalk.
j. Study also evaluated BNT162b1 and BNT162b3.

132 Two studies were general toxicity studies in which the tolerability of the "vaccine" formulation was investigated in male and female rats. The third study was a reproductive study (*DART study*) in which the hazard of the "vaccine" was investigated in female pregnant rats. This *DART study* had, as already explained (see N 111), this DART study showed an increased risk for offspring and thus also for pregnancy in humans.

133 The influence of the "vaccine" on the fertility of male rats has not been investigated. Thus, there is still a lack of data,[93] , which would have proven the safety of the use of COVID "vaccines" in young males of reproductive age .

134 In the case of the COVID "vaccines", important preclinical in vivo studies were officially dispensed with, citing the *WHO guideline* ("*WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION",* 2005) .[94]

93 See the notes at the back N 522 f. concerning an analysis of 220 sperm samples.

135 The invocation of this *WHO guideline* is in no way justifiable from a factual-scientific point of view: it dates from 2005, i.e. from a time when the application of experimental mRNA gene therapies in humans was at best a distant prospect. How such a completely outdated document can serve as a basis for not raising, but even lowering the safety requirements for the first approval of mRNA "vaccines" for a healthy world population is completely incomprehensible.

136 In addition, even these ***WHO recommendations*** explicitly state that **preclinical "*in vivo*" studies** ("*non-clinical testings*") **should in principle be more detailed for "novel vaccines":**

> "The need for and extent of non-clinical testing will depend on the product being tested. **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.** ... Early communication between the vaccine manufacturer and the competent national regulatory authority to agree on the requirements and nature of the non-clinical testing is recommended."[95]

The *WHO guideline* thus does not give a "free pass" to omit elementary studies to ensure the most basic safety - quite the contrary. In view of the lack of clinical experience regarding mRNA "vaccines", "Swissmedic" would have been obliged - entirely in accordance with its own mission statement and Art. 1 HMG - to ensure "that the authorised therapeutic products are of impeccable quality, effective and safe. "[96] However, there are no indications in Swissmedic's authorisation letters to Pfizer (Annex **2**) and Moderna (Annex **3**) that Swissmedic would have taken serious measures to request the preclinical studies in order to be able to adequately assess and eliminate the risks when used in humans.

1.7.2. Missing and suppressed animal studies on pharmacokinetics

137 Pharmacokinetics describes the totality of all processes to which a drug is subject in the body. The distribution, retention and degradation of medicinal products in the body in animals and humans must normally be carefully and compulsorily investigated before the start of clinical trials with humans, for example by means of labelling with radioactive sub-

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94 WHO, "WHO expert committee on biological standardization " , 2005, *http://apps.who.int/iris/bitstream/handle/10665/43094/WHO_TRS_927_eng.pdf;jsessionid=64155AFF93B13895E1A78876139255A7?sequence=1*, p. 31 ff.

95 WHO, FN 94, S. 33.

96 Swissmedic, "Leitbild", 16.06.2022, https://www.swissmedic.ch/swissmedic/de/home/ueber-uns/swissmedic--schweizerisches-heilmittelinstitut/leitbild.html.

stances (for the studies and documents that must be submitted in the various authorisation procedures, see detailed criminal complaint, section "Swissmedic offence").

1.7.2.1 Lack of pharmacokinetics studies especially on spike protein

138 With reference to the currently valid *WHO guidelines* ("*WHO EXPERT COMMITTEE ON BIOLOGICAL STANDARDIZATION*", 2005)[97] , no pharmacokinetic studies were officially carried out for the COVID "vaccines", as this was "not considered necessary" according to the guidelines for vaccines.

139 Attention has already been drawn to the lack of timeliness of the *WHO guidelines* and the delegation of responsibility regarding the requirement to provide preclinical data to the national regulatory authority for unproven vaccines (see N 135 f.).

140 In the expert information of both mRNA-COVID "vaccines" approved in Switzerland, no data are available to date under the heading "*Pharmacokinetics"*; under the headings *absorption, distribution, metabolism and elimination there is the* note "*not applicable*", in the expert information of Spikevax® with the additional note "No *assessment of pharmacokinetic properties is required for vaccines*".[98]

141 Since the COVID "vaccines" demonstrably do not meet the criteria for a vaccine, and since they are completely novel gene therapies that have never been approved for use in humans in this form, Swissmedic, as an independent regulatory authority that sets high qualitative and ethical standards for itself and its work, should of course have demanded well-founded pharmacokinetic data to protect the Swiss population.

142 **In particular, the pharmacokinetics of the mRNA, the spike protein produced and the lipid nanoparticles (LNP) should have been investigated in detail**. The risks of the mRNA and the LNP surrounding it were already known at the time of the approval of the basic immunisation (see N 64 ff.). The danger of the spike proteins only became apparent in the course of the vaccination, which is why they were not mentioned later (see N 299 ff. and N 525 ff.) will be dealt with in detail.

143 It should be noted that ***HMEC*** **explicitly required** that the **expression of the spike protein in the tissues "*should be further investigated*" as a condition for granting the temporary approval** (Supplement **2**, p. 15).

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97 BioNTech, "Investigator's brochure BNT162/PF-07302048", 12.08.2020, p. 34, https://www.tga.gov.au/sites/default/files/foi-2183-09.pdf; WHO, FN 94.

98 Swissmedicinfo, FN 48 and 71.

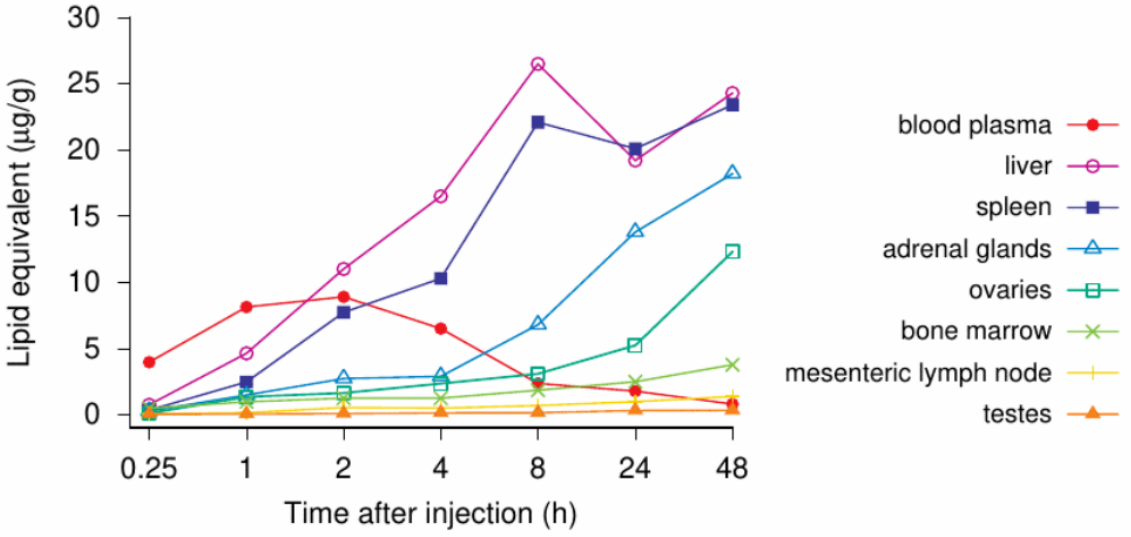
144 Due to the complete lack of information on this subject in the expert information of Comirnaty® and Spikevax® (section "Pharmacokinetics ")[99] , it must be assumed that no such data have been requested and submitted for the spike protein to date.

1.7.2.2 Swissmedic ignores pharmacokinetic studies conducted by Pfizer

145 Officially, therefore, no pharmacokinetic data are available for the COVID "vaccines" according to the specialist information approved by Swissmedic. The registration documents for Comirnaty®, module 2.4 "*Non clinical overview*",[100] , which have now been published internationally, show that this information is not true. The manufacturer had indeed conducted several preclinical pharmacokinetic studies with components of the final vaccine formulation prior to approval. **According to Pfizer and BioNTech, which market the "vaccine" worldwide in cooperation,** the results of these **studies are considered to be representative for the mRNA vaccine, but**[101] **has been completely concealed in the product information to date.** This is in no way comprehensible, as the results of these studies are extremely explosive:

146 The results of a pharmacokinetics study with a model vaccine (the mRNA coded for luciferase and not for the SARS-CoV-2 spike protein, but the LNP had the same chemical composition as Comirnaty®) in rats - which Pfizer submitted to the Japanese regulatory authority in 2020 for emergency approval[102] -, show that the **LNP** used in the vaccines (the cholesterol contained was radioactively labelled) was rapidly absorbed from the muscle tissue into the bloodstream after application to the muscle. The highest plasma level was reached two hours after injection. After the blood plasma level decreased, activity increased in various organs, including the brain. The most rapid and highest increase was observed in the liver and spleen, and **accumulation** occurred in other organs, including high concentrations in the ovaries:[103]

99 Swissmedicinfo, FN 48 and 71.
100 BNT162b2, FN 61.
101 BNT162b2, "Module 2.4. Nonclinical Overview", para. 2.4.3.4, 08.02.2021, *https://phmpt.org/wp-content/uploads/2022/03/125742_S1_M2_24_nonclinical-overview.pdf.*
102 PALMER/BHAKDI, FN 84.
103 Pfizer confidential translated, FN 59Graphic representation according to PALMER/BHAKDI, FN 84, S. 6.



147 The reported measurements were stopped after 48h, although the concentrations were still increasing in various organs (adrenal gland, bone marrow, liver, lymph nodes, ovaries) at this time.

148 Even after these study results were available, it was obvious that the COVID "vaccines" did not remain at the injection site, but were distributed throughout the body .

149 The observations are in line with much earlier studies on this topic: The distribution of LNP in the body was already studied in mice in 2014 using radioactive labelling. This also showed that the LNP were distributed throughout the body and accumulated in specific organs such as the liver, spleen, adrenal glands and the seminal vesicle wall.[104]

150 Until there is a clear refutation, it must also be assumed that the production of the spike protein takes place in all tissues in which the LNP accumulate with the mRNA they contain.

1.7.2.3 Missing data on the degradation of the modified mRNA

151 The mRNA (messenger RNA) used in the COVID "vaccines" is a modified RNA in which the naturally occurring uridine is replaced by pseudo-uridine in order to prolong the half-life. It is known that the degradation of the (m)RNA can be circumvented or at least delayed by an additional targeted modification at the ends of the (m)RNA strands that do not belong to the protein code. For this purpose, the mRNA strands of the COVID "vaccines" have special "end caps" at the 5` end and modified base sequences at the opposite end

104 CHRISTENSEN et al, "Biodistribution and Metabolism Studies of Lipid Nanoparticle-Formulated Internally [3H]-Labelled siRNA in Mice", 03.01.2014, https://dmd.aspetjournals.org/content/42/3/431.long.

piece, the poly-tail-A. The 3-UTR section following this "tail", a part of the mRNA that is also not read out for protein production, is also modified.[105]

152 Consequently, it can be assumed that the **modified mRNA** used in the COVID "vaccines" is **degraded with a significant delay** compared to naturally occurring (m)RNA.

153 In the authorisation decision for Spikevax®, Swissmedic writes: (Supplement **3**; p. 9):

> "No report on the ADME (absorption, distribution, metabolism, elimination) of the modified mRNA was provided. Data from cell-based experiments were summarised in which no difference in mRNA half-life was observed between unmodified mRNA and the same sequences fully substituted with N1 pseudo-uridine. These data will be submitted to Swissmedic as soon as possible in a full report. "

154 In the case of the mRNA used in the vaccines, as already explained, not only was uridine replaced by pseudouridine, but the capping of the 5'-end was also modified.

155 It is not clear from the authorisation decision whether Swissmedic has taken this fact into account. Swissmedic should have specifically requested studies that not only compare the modification with regard to uridine-pseudouridine, but also with regard to modified capping of the 5'-end, or generally examine in detail the delayed degradation of the mRNA used in the COVID "vaccines".

156 In the letter of authorisation to Pfizer, Swissmedic also criticises the fact that no pharmacokinetic studies were carried out with the vaccine mRNA (Supplement **2**, p. 7):

> "Swissmedic strongly recommends analysing the kinetics of the modified mRNA in vitro and in vivo in detail. "

157 **Measures to demand this data have obviously been omitted to date.**

158 Since the labelling of (m)RNA with radioactive iodine and consequently the tracking of the distribution of this labelled m(RNA) in the body can be carried out relatively easily,[106] it is in no way comprehensible why such data were not proactively submitted by the marketing authorisation holders and why they were not requested by Swissmedic.

159 The mRNA encodes the spike protein, which has been shown to be toxic (see N 299 ff. and N 525 ff.). From this point of view, it is absolutely essential to know how long the

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105 Scinexx, "The trick is in the detail", 08.10.2021, *https://www.scinexx.de/dossierartikel/die-tuecke-liegt-im-detail/.*

106 PIATYSZEK et al, "Iodo-gen-mediated radioiodination of nucleic acids", 01.08.1988, https://pubmed.ncbi.nlm.nih.gov/3189783/.

modified mRNA circulates in the body and how long spike proteins can be produced as a result.

1.7.2.4 Interim conclusion

160 Contrary to the declaration in the technical information of the COVID "vaccines", pharmacokinetic studies in animals were indeed carried out, at least for Comirnaty®, which are also part of the international marketing authorisation dossier Module 2.4 "Non clinical overview", which was marked by the FDA with "Approved On: 08-Feb-2021". It can be assumed that this information was also available to Swissmedic shortly afterwards at the latest.

161 The pharmacokinetics studies showed that components of Comirnaty® accumulate in individual organs. To date, the extent to which the accumulation of the vaccine components in the ovaries is associated with impaired fertility has not been investigated. By supporting a concealment of the explosive data on pharmacokinetics and not arranging for these to be made available to the medical profession in the professional information, Swissmedic has once again actively contributed to the trivialisation of COVID "vaccines" and failed to protect the population from the emerging risks.

1.7.3. Risk signals in initial tests on humans

162 In December 2020, data on just one **two-month study phase of** a "telescoped" "phase I/II/III" study was available. This alone represents a massive increase in risk: **Telescoping** carries the risk that time-delayed side effects will only be detected after the vaccine has already been widely used.[107]

1.7.3.1 Swissmedic: "Vaccines" are "safe

163 In the original publications of the 2-month data of the registration studies of Comirnaty® and Spikevax® it is summarised that the safety is comparable to other vaccines and that mostly short-term mild to moderate side effects such as headache, fatigue and pain at the injection site occurred[108] or severe side effects were reported only rarely and equally often in the vaccine and placebo groups .[109]

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107 ARVAY, "Genetic vaccines against COVID-19: hope or risk?", 01.07.2020, https://saez.ch/article/doi/saez.2020.18982.

108 POLACK et al, "Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine", 31 Dec 2020, *https://www.nejm.org/doi/10.1056/NEJMoa2034577?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.*

109 BADEN et al, "Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine", 04.02.2021, *https://www.nejm.org/doi/pdf/10.1056/NEJMoa2035389?articleTools=true.*

164 In its communications on the temporary authorisations granted, Swissmedic blindly endorsed the manufacturers' assessment that the COVID "vaccines" were safe. If Swissmedic had taken the time to analyse the relevant data in more detail, it would have had to come to a different conclusion:

1.7.3.2 Analysis of the registration studies: Increased morbidity in vaccination group

165 A more well-founded analysis published in August 2021[110] of the original publications of the 2-month data of Comirnaty® and Spikevax® including the associated appendices came to a different conclusion than the manufacturers - namely using alternative criteria for the assessment of "adverse effects":

166 In many areas of medicine, e.g. oncology, the use of disease-specific endpoints (e.g. deaths from cancer) in pivotal trials has been abandoned because they are not very meaningful. Instead, they have been replaced by "all-cause mortality or morbidity". Data from the pivotal clinical trials of COVID "vaccines" were re-analysed based on this finding, with "severe all-cause morbidity" including "COVID disease".

167 Total serious morbidity" was calculated by summing all serious events reported in the pivotal trials. Serious events were defined as both "severe COVID disease" and all other serious adverse events in the vaccine and placebo groups, respectively. In this analysis, the reduction of "severe COVID disease" is weighted the same as adverse events of equal severity.

168 The results demonstrate that **none of the "COVID vaccines" provide any health benefit because they are** associated with **a statistically significant increase in "serious all-cause morbidity" compared to placebo:**

1.7.3.3 Spikevax®: 3042 additional serious events in vaccination group

169 In the **vaccine group**, according to this same analysis (N165), there were 11 cases of "confirmed COVID disease", no cases of "severe COVID disease" and **3985 cases of severe adverse events**. In the placebo group, 185 cases of "confirmed COVID disease" and 30 cases of "severe COVID disease" were recorded. Only one of these cases required admission to an intensive care unit. There were **913 serious adverse events** reported in the **placebo group**. Two deaths were reported in the vaccine group and three in the placebo group.

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110 CLASSEN, "US Covid-19 Vaccines proven to cause more harm than good based on pivotal clinical trial data analysed using the proper scientifit endpoint, 'all cause severe morebidity'", 2021, https://www.scivisionpub.com/pdfs/us-covid19-vaccines-proven-to-cause-more-harm-than-good-based-on-pivotal-clinical-trial-data-analyzed-using-the-proper-scientific--1811.pdf.

170 Overall, **3042 more serious events** occurred **with Spikevax® in the vaccine group than in the** placebo **group.**

1.7.3.4 Comirnaty®: 90 additional serious events in vaccination group

171 Pfizer's data were only incompletely disclosed and do not allow any conclusive statements to be made.

172 Overall, however, 90 more serious adverse events occurred in the vaccine group than in the placebo group in the analysis of unsolicited events.

1.7.3.5 Interim conclusion "registration studies

173 Because the COVID "vaccines" have been shown to be associated with no benefit, but generated significantly more severe side effects in the vaccine groups of the pivotal trials than in the placebo groups, the authors concluded that **administering these "vaccines" definitely harms the health of the population**.

174 Since the 2-month data on which this analysis was based was the basis for granting the temporary authorisation and was thus available to Swissmedic in full before the authorisation was granted, it is not comprehensible how Swissmedic came to the conclusion that the COVID "vaccines" were safe on the basis of these figures and granted the authorisation on the basis of this assessment.

1.7.4. Unblinding of Phase III studies

1.7.4.1 Controlled registration studies mandatory

175 Marketing authorisation studies for medicinal products usually have to be conducted in a "controlled" manner, i.e. in comparison to placebo or a standard therapy.[111] Even if exceptions have been made for vaccines in the past and vaccines have exceptionally been approved based on observational studies instead of prospective randomised trials,[112] in the case of a medicinal product approved as a "vaccine" with a completely novel mRNA technology for the protection of the population, it would be essential to dispense with such exceptions in order to be able to soundly assess efficacy and safety.

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111 Pharmazeutische Zeitung, "Wie Humanarzneimittel geprüft werden", 25.07.2011, https://www.pharmazeutische-zeitung.de/ausgabe-302011/wie-humanarzneimittel-geprueft-werden/.

112 Swissmedicinfo, "Fachinformation Boostrix Polio", as of 12.2021, https://www.swissmedicinfo.ch/ShowText.aspx?textType=FI&lang=DE&authNr=00681.

1.7.4.2 Unblinding by the manufacturers

176 The temporary approvals of the COVID "vaccines" from Moderna and Pfizer were initially granted based on interim data from two months of phase 3 trials, the results of which were later published (see N 194 ff. and 205 ff.). The phase 3 trials were planned, set up and initiated as "placebo-controlled randomised observer-blinded trials". As early as December 2020, however, all study participants were offered the opportunity to switch from the placebo to the vaccine group "for ethical reasons". In the phase 3 study of Spikevax®, 98% of the study participants made use of this "offer"; Pfizer/BioNTech did not provide any concrete figures on the number of study participants who switched to the vaccine upon request.[113] The "Periodic Safety Update Report" ("*PSUR*") No. 1 of Comirnaty® shows that only 1202 study participants (6.5% of all study participants in the original placebo group of the pivotal study) remained in the placebo group until June 2021 (Supplement **8**, p. 3):

> Cumulatively, it is estimated that 53,499 subjects have participated in BNT162b2 sponsor-initiated clinical trials worldwide, with 46,577 subjects exposed to BNT162b2, 30 subjects exposed to BNT162a1, 411 exposed to BNT162b1, 96 subjects each exposed to BNT162b3 and BNT162c2. There were 330 subjects exposed to BNT162b2s01, 4757 exposed to blinded therapy and 1202 to placebo.

177 Thus, both registration studies of the COVID "vaccines" were *de facto* unblinded[114] and degraded to mere observational studies.

BO: Supplement **8:** Periodic Safety Update Report #1 for COVID-19-mRNA-vaccine BNT162b2, 19.08.2021

1.7.4.3 No justification for unblinding

178 Due to the lack of efficacy of the COVID "vaccines" (see below N 194 ff. and 205 ff.), unblinding cannot be justified on "ethical grounds". On the contrary, and in view of the serious risks of the COVID "vaccines" (see front N 22 et seq., at the back N 219 ff. and N 504 ff.) as an arbitrary **cover-up tactic by destroying the control group**.

179 Pharmacologist, toxicologist and immunologist Prof. Dr. Stefan Hockertz questions the real reasons for unblinding: "*The control group exists (usually) exactly as long as the*

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113 DOSHI, "Covid-19 vaccines: In the rush for regulatory approval, do we need more data?", 18.05.2021, https://www.bmj.com/content/373/bmj.n1244.

114 Canadian Covid Care Alliance, "More harm than good", 16.12.2021, *https://www.canadiancovidcarealliance.org/wp-content/uploads/2021/12/The-COVID-19-Inoculations-More-Harm-Than-Good-REV-Dec-16-2021.pdf* ; DOSHI, "Covid-19 vaccines: In the rush for regulatory approval, do we need more date? ", 18.05.2021, *https://www.bmj.com/content/373/bmj.n1244* ; FDA, "Statistical Review Comirnaty", 18.05.2021, https://www.fda.gov/media/152255/download.

study runs. If the control group is removed, the study is considered to be terminated, as comparisons between the treated and non-treated group are no longer possible. If I take away the comparison aspect, I can always claim that the 85 heart attacks in 1,000 people are just so common now. " According to Hockertz, the control group is also usually kept for follow-up beyond the study in order to be able to filter out serious side effects in the treated group.[115]

1.8. First indications of possible late effects

180 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. Nevertheless, **blood diseases**, **neurodegenerative diseases** or **autoimmune diseases** had already been discussed in detail.[116] In this initial situation, the manufacturers, such as Pfizer, had exempted themselves from any liability and held on to the supply contracts concluded with the governments for several years:

> "O Comprador ainda reconhece que a eficácia e os efeitos a longo prazo da Vacina ainda não são conhecidos e que pode haver efeitos adversos da Vacina que não são conhecidos atualmente."[117]
>
> Loosely translated:
>
> "The purchaser further acknowledges 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 currently known."

181 Swissmedic had to be aware of these circumstances from the beginning (December 2020) and, based on the publications listed below, at the latest at the time of the authorisation extension for adolescents (June 2021), as the Institute boasts of its international networking and corresponding knowledge procurement. [118]

1.9. Conclusion

182 Overall, Swissmedic failed to request data from the marketing authorisation holders that sufficiently clarified emerging risks. Elementary questions regarding the safety of the

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115 REITSCHUSTER, "Das Rätsel um die Auflösung der Impfkontrollgruppen", 26.01.2022, https://reitschuster.de/post/das-raetsel-um-die-aufloesung-der-impfkontrollgruppen/.

116 FAZ, "A spectre for Corona vaccination", 09.09.2020, https://www.faz.net/aktuell/wissen/impfstoff-nebenwirkung-ade-ein-schrecken-fuer-die-corona-impfung-16944897.html; SENNEFF/NIGH, FN 22YAHI et al, "Infection-enhancing anti-SARS-CoV-2 antibodies recognise both the original Wuhan/D614G strain and Delta variants. A potential risk for mass vaccination?", 16.08.2021, https://www.journalofinfection.com/action/showPdf?pii=S0163-4453%2821%2900392-3.

117 Ministério da saúde, "Contrato Nº 52/2021", 18.03.2021, para. 5.5, https://d37iydjzbdkvr9.cloudfront.net/arquivos/2021/05/12/contrato-pfizer.pdf.

118 See the statements in the criminal complaint concerning Swissmedic's performance mandate and "strategic objectives".

COVID "vaccines" were demonstrably not clarified before the temporary authorisation was granted:

183 To date, it has not been ruled out that the mRNA administered by means of "vaccination" is integrated into the human genome via detours, although studies have shown that this cannot be ruled out.

184 To date, marketing authorisation holders have not submitted any data showing how long and where the applied mRNA, the LNP incl. their components and the toxic spike proteins produced circulate in the body after the "vaccination" and what consequences this is associated with.

185 The data on the novel LNP components ALC-0159, ALC-0315 and SM-102 with regard to quality, safety and suitability for use in humans was completely inadequate, at least at the time of approval.

186 With regard to the use of the COVID "vaccines", risks were already clearly apparent in the preclinical studies, which had been recognised by *HMEC.* Swissmedic deliberately failed to make adequate reference to these risks in the drug texts, contrary to the advice of *HMEC.*

187 From this, it must be concluded that Swissmedic did not adequately protect the Swiss population, and in particular vulnerable groups such as pregnant women and their unborn children, from emerging risks, but rather exposed them to emerging risks with their eyes open.

188 Since it was already apparent from dose-finding studies that the widespread use of a single dose was fraught with risks and that younger people (18 to 55-year-olds) were more likely to suffer severe side effects at the same dose, Swissmedic should not have approved a single dose for all adults. Since it also became apparent in the first five months after authorisation that the side effect reports internationally and also in Switzerland were more severe than officially communicated in the 2-month data of the authorisation studies, Swissmedic should not have accepted the extension of the indication and the further extended use of the single dose in the now also younger population group of 12-year-olds and over.

2. Effectiveness

2.1. Minimal therapeutic benefit for mere trivial events

2.1.1. Primary objective: protection against mere petty incidents

189 According to the Swissmedic guidance "Temporary authorisation for human medicinal products HMV4"[119] , the following points must be fulfilled so that a major therapeutic benefit can be "convincingly" demonstrated: The selected study endpoints must be clinically relevant. This means that survival rates - or scientifically validated and recognised *surrogate markers* for survival or prevention of severe disability in the target population - must be available.[120] Furthermore, the events assigned to the study endpoint must occur sufficiently frequently to allow an assessment of the effect size.[121] Finally, causality between treatment and clinical effect must be evident. The prevention or treatment of the disease must relevantly reduce the risk of disability or threat to life.[122]

190 This means: The primary target must be set and proof must be provided that the target population is **saved from death or severe disability** thanks to vaccination. This requirement was obviously not met:

191 The study endpoint (=primary efficacy endpoint) chosen in the pivotal studies by Pfizer and Moderna is **not clinically relevant,** as they mainly **recorded** mild "confirmed COVID disease" and thus **trivial events:**

192 According to the study protocols[123] of the two mRNA vaccines used in Switzerland, the primary efficacy endpoint examines the effectiveness regarding the prevention of a "confirmed COVID disease" that occurs at the earliest seven days after the 2nd dose (Comirnaty®) or at the earliest 14 days after the 2nd dose (Spikevax®). **A "confirmed COVID disease" is defined as the occurrence of at least 1-2 symptoms such as fever, cough, shortness of breath, cold, sore throat, headache, pain in the limbs, loss of smell/taste, nausea, vomiting or diarrhoea in combination with a positive PCR test.**

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119 Swissmedic, "Wegleitung Befristete Zulassung Humanarzneimittel HMV4", status 01.04.2022, p. 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.

120 See Swissmedic, FN 119.

121 See Swissmedic, FN 119.

122 See Swissmedic, FN 119.

123 Pfizer and Internet archive, FN 85.

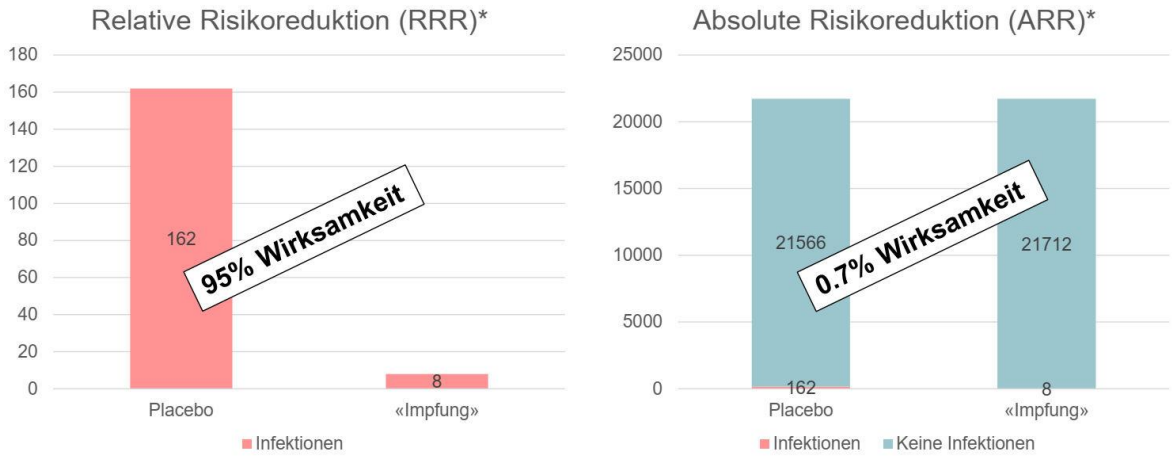
193 The defined symptoms in themselves do not suggest an immediately life-threatening or disabling disease. To make matters worse, one (!) of these symptoms in combination with a positive PCR test[124] should be sufficient to define a "COVID disease". This target **obviously covers mild courses of disease and not life-threatening diseases.**

2.1.2. Comirnaty®: Primary target not achieved

2.1.2.1 Lack of efficacy in "confirmed COVID disease".

194 In the registration trial of Comirnaty®, for which the temporary approval was granted based on the 2-month interim data, a "confirmed COVID disease" occurred in only **8** of 21,720 (=0.04%) in the vaccine group and in only **162** of 21,728 (=0.74%) in the placebo group.[125] According to these - very low - figures, 20 times more people would have fallen ill in the placebo group than in the vaccine group. Due to the fact that COVID diseases already occurred in less than 1% of the study participants in the registration study, the necessity of a "vaccination" or therapy already had to be questioned at this point.

195 A high **efficacy of** Comirnaty® of **95%** was proclaimed by "inflating" the demonstrably small effect by using the "relative risk reduction" (RRR):[126]



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

196 The RRR for the Pfizer/BioNTech vaccine is actually 95%, because out of a total of 170 events, a full 162 events were formally "prevented" in the vaccine group (with only 8 events). However, this does not mean that 95 out of 100 vaccinated people were protected out of a total of over 40,000 study participants. Rather, **141 persons must be vac-**

124 On the unsuitability of the PCR test in relation to establishing a disease diagnosis at the rear N 661 ff.
125 POLACK et al., FN 108.
126 POLACK et al., FN 108.

cinated in order to prevent a single "confirmed COVID disease", which is likely to be mainly mild courses of the disease.[127] Therefore, the absolute risk reduction (ARR) should be used: Under placebo, 162 of 21,728 people **(= 0.74%) contracted** COVID-19, and under the vaccine, only 8 of 21,720 people **(= 0.04%)** contracted COVID-19. **The absolute risk reduction (ARR) was therefore only 0.70%** (0.74% minus 0.04%).[128]

197 **Without contextual information or without details of the underlying case numbers, the relative risk reduction RRR cannot be interpreted validly.** [129]

198 Various studies have been conducted on the interpretation of numerical information from studies and how this depends on the presentation of the information. Technically, this is known as 'framing' and **the effects of framing were examined in a systematic review of twelve studies published up to 1998.**[130] **An impressive RRR was one of the factors that** doctors rated most positively and **that made them most receptive** to **implementing a method** or prescribing a medicine. **RRR may have a disproportionate influence on** physicians' **perceptions of treatment benefit**. Similarly, an analysis[131] , which examined the behaviour of 182 members of 13 health authorities, concluded that the willingness to fund a 'health programme' was significantly influenced by the way the data was presented. **When the results of** the "health programmes" **were expressed as RRR, significantly higher approval ratings were generated compared to other methods**, such as when **the results were shown using ARR**. Similarly, a **study of 235 physicians** showed that they tended to **prescribe therapy significantly more often when the results had** been **presented to** them **using RRR rather than ARR.**[132] **It was thus known more than 20 years ago that presenting the RRR without ARR and underlying figures distorts efficacy data. Articles that only publish an RRR without ARR discredit themselves as non-professional publications by this fact alone. Since they have been proven to promote sales, they are not to be classified as information, but as advertising.**

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127 MONTASTRUC et al, "Efficacy of COVID-19 vaccines: Several modes of expression should be presented in scientific publications", 11.07.2021, https://onlinelibrary.wiley.com/doi/full/10.1111/fcp.12715.

128 POLACK et al. and BADEN et al. 91.

129 Ärzteblatt, "Fake News in der Medizin: Relatives Risiko", 06.09.2021, https://www.aerzteblatt.de/archiv/221054/Fake-News-in-der-Medizin-Relatives-Risiko.

130 MCGETTIGAN, "The Effects of Information Framing on the Practices of Physicians", 10.1999, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1496755/.

131 FAHEY, "Evidence-based purchasing: understanding results of clinical trials and systematic reviews", 21.10.1995, https://pubmed.ncbi.nlm.nih.gov/7580661/.

132 FORROW, "Absolutely relative: How research results are summarised can affect treatment decisions", 01.02.1992, *https://www.amjmed.com/article/0002-9343(92)90100-P/pdf*.

199 **In extreme cases, an apparently impressively high efficacy can be feigned with case numbers that are in the range of statistical chance by using the RRR.** This has been consistently done with the case numbers of the COVID "vaccines". Most impressive is the claim that Comirnaty® prevents severe COVID disease with an efficacy of 64%. This calculation is based on 1 case of severe COVID disease in the vaccine group and 3 such cases in the placebo group (see below N 209 f.). With more than 40,000 study participants, these figures have neither mathematical nor scientific significance, but are, on the contrary, in the realm of statistical chance. If there had been 1 case of severe COVID in the placebo group and 0 in the vaccine group, an efficacy of 100% could even be proclaimed on the basis of this calculation method, which is exactly what was done for children and adolescents (see N 291).

200 A well-founded analysis[133] by the "*Canadian COVID Care Alliance*", an association of 500 Canadian scientists and physicians, shows that the officially reported case numbers in the 2-month analysis are questionable and subject to error: According to an **FDA briefing document dated 10 December 2020**[134] , not only 8 but a full **1,594 "symptomatic COVID illnesses"** occurred in the vaccine group, as officially declared, and not only 162 in the placebo group, as officially declared, but **1,816. For inexplicable and undisclosed reasons, however, no PCR test was carried out on these 3410 cases despite their symptoms, and the corresponding cases were simply "sorted out"** ("suspected but unconfirmed cases"). Why, for example, in the vaccine group, out of a total of 1,602 symptomatic cases, a whole 1,594 were summarily not taken into account and only 8 were reported, is in no way comprehensible (the same applies, of course, to the placebo group). The data must therefore be classified as extremely unreliable.

201 Based on the 1816 vs. 1594 **"suspected but unconfirmed" cases, the** relative risk reduction (RRR, **"efficacy"**) would be **12%**. If the numbers of "confirmed COVID cases" and the "suspected cases" were added up, this would result in a total of 1978 (placebo group) versus 1602 (vaccine group) - which would correspond to a **relative risk reduction (RRR, "efficacy") of only 19%**. Such figures would definitely no longer fulfil the international requirement for approval - and would certainly never have met the criteria for a temporary approval.

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133 Canadian Covid Care Alliance, "More harm than good", 16.12.2021, *https://www.canadiancovidcarealliance.org/wp-content/uploads/2021/12/The-COVID-19-Inoculations-More-Harm-Than-Good-REV-Dec-16-2021.pdf.*

134 FDA, "Briefing Document Pfizer-BioNTech COVID-19 Vaccine," 10 Dec 2020, https://www.fda.gov/media/144245/download.

2.1.2.2 Acknowledgement on the part of Swissmedic

202 Swissmedic was already aware of the inadequate data situation and the lack of evidence regarding the efficacy of the "COVID vaccines" before the temporary authorisations were granted. This is evident from Swissmedic's comments in the letter of authorisation of 19 December 2020 to Pfizer, in which it requested, among other things, further data to prove immunity of vaccinated persons (Annex **2**, pp. 9 and 11):

> "The ongoing and proposed additional pharmacovigilance activities are considered sufficient to further characterise the important potential risks of "Vaccine-associated enhanced diseases (VAED), including "Vaccine-associated enhanced respiratory diseases (VAERD)", as well as the **missing information** "Use during pregnancy and lactation" and **"Vaccine efficacy"."**
>
> "The company should commit to developing a **plan to analyse the immunogenicity of the** BNT162b2 **COVID-19 vaccine in vaccinated individuals.**"

203 Swissmedic thus acknowledged that *de facto* no data had been submitted that adequately demonstrated efficacy at the time of authorisation. Accordingly, in the technical information for Comirnaty® (Annex **4**), it is stated cautiously and using the subjunctive form under the heading "*Properties/effects*":

> "**The vaccine** triggers both the production of neutralising antibodies and a cellular immune response against the spike (S) protein, and in this way **could contribute to protection against COVID-19.**"

204 According to Art. 9a para. 1 lit. b HMG in conjunction with Art. 18 lit. c VAZV, a vaccine **must be expected to provide a major therapeutic benefit.** Art. 18 lit. c VAZV, a **major therapeutic benefit must** be **expected from a vaccine**. A "could", a possible, hypothetical benefit that might occur with a lot of luck, is obviously not sufficient for this. Why Swissmedic nevertheless granted a temporary authorisation is therefore incomprehensible.

2.1.3. Spikevax®: Lack of efficacy in "confirmed COVID disease".

205 With Spikevax®, the number of "confirmed COVID cases" was **11** out of 14,134 (=0.08%; vaccine group) vs. **185** out of 14,073 (=1.3%; placebo group).[135] Despite the "rampant pandemic", a "confirmed COVID disease" thus occurred in only about 1% of the study

135 BADEN et al., FN 109.

participants - here, too, the efficacy calculations were therefore based on vanishingly small case numbers.

206 As with Pfizer, Moderna was claimed to have a high efficacy of 94.1% based on relative risk reduction (RRR).[136] In absolute terms, **however,** the risk reduction **(ARR) of Spikevax® was just 1.2%**.[137] This means that 91 people need to be vaccinated to prevent a single "confirmed COVID disease" with a mild course.[138]

207 Due to the very similar study design, it cannot be ruled out that the case numbers of Spikevax® are also subject to error in a similar way to Comirnaty® , because a PCR test was not carried out in all suspected cases (see above N 200). Subject to error, the corresponding study data - unlike those of Pfizer - have not yet been publicly published by Moderna.

2.2. No proven therapeutic benefit for "severe" diseases

2.2.1. Secondary target: Protection against "severe" COVID diseases

208 According to the study protocols[139] , the efficacy of the COVID vaccines with regard to "severe COVID disease" is only examined in a secondary efficacy endpoint. For a "severe COVID disease", at least one of the following criteria must be fulfilled:

- Clinical signs at rest indicative of severe systemic disease (≥30 breaths per minute, HR ≥125 beats per minute, O_2 saturation ≤93%);
- Respiratory failure;
- Signs of shock;
- Significant acute renal, hepatic or neurological dysfunction;
- Admission to an intensive care unit;
- Death.

The case numbers for "confirmed" and "severe COVID disease" are linked to the presence of a positive PCR test result. The shortcomings and unsuitability of the PCR test for the detection of disease activity have been demonstrated in detail.

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136 Internet Archive, "Moderna Announces Primary Efficacy Analysis in Phase 3 COVE Study for Its COVID-19 Vaccine Candidate and Filing Today with U.S. FDA for Emergency Use Authorization," Nov. 30, 2020, https://web.archive.org/web/20211223072507/https://investors.modernatx.com/news/news-details/2020/Moderna-Announces-Primary-Efficacy-Analysis-in-Phase-3-COVE-Study-for-Its-COVID-19-Vaccine-Candidate-and-Filing-Today-with-U-S--FDA-for-Emergency-Use-Authorization-11-30-2020/default.aspx.

137 POLACK et al. and BADEN et al. 91.

138 MONTASTRUC et al., FN 127.

139 Pfizer and Internet archive, FN 85.

2.2.2. Comirnaty®: Lack of efficacy in "severe COVID disease".

209 For "severe COVID diseases", an efficacy of 66.4% is proclaimed for Comirnaty® for adults in the technical information released by Swissmedic as of December 2021[140] , because **1 case occurred in the** vaccine group (n=21,720), corresponding to a prevalence of 0.0046% in the vaccine group (n=21,720) and **3 cases** in the placebo group (n=21,728), corresponding to a prevalence of 0.0138% (Supplement **4,** "Efficacy against COVID-19 with severe course"), which corresponded to an absolute risk reduction (ARR) of just 0.0092%.[141]

210 Considering the total of over 40,000 study participants, these numbers of "severe COVID cases" are within the realm of statistical chance**, and it is frivolous, unscientific and misleading to claim, based on only 4 cases, that the vaccine reduces severe courses with an efficacy of 66.4%.** Nevertheless, Swissmedic blindly accepted this misleading result of 66.4% and also agreed to the public publication in the technical information.

2.2.3. Spikevax®: Lack of efficacy in "severe COVID disease".

211 According to the original publication in the *New England Journal of Medicine* (*NEJM*), Spikevax® resulted in 30 "severe COVID events" in the placebo group (n=15,210), corresponding to a prevalence of 0.2%, and no severe events in the vaccine group (n=15,210).[142] Thus, the absolute risk reduction (**ARR**) for **severe courses of Spikevax® was** just **0.2%**.

2.3. No protection against transmission

212 Incidentally, it should also be mentioned that Swissmedic had already stated in the authorisation letter to Pfizer of 19.12.2020 that no data were available to show that transmission of the virus was prevented by the "vaccination": "[...] *the prevention of viral transmission remains unanswered*. Swissmedic demands: "*The company should commit or develop a plan to analyse the immunogenicity from BNT172b2 COVID-19 vaccine in vaccinated subjects*. "(Supplement **2**, p. 8 f.)

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140 Internet archive, "Fachinformation Comirnaty", as at 12.2021, https://web.archive.org/web/20220112044218/https://www.swissmedicinfo.ch/ShowText.aspx?textType=FI&lang=DE&authNr=68225.

141 For number of study participants, see POLACK et al, "Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine", 31.12.2020, https://www.nejm.org/doi/10.1056/NEJMoa2034577?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.

142 BADEN et al., FN 109.

213 Nevertheless, Swissmedic published the following answer to the question "Can I transmit COVID-19 if I am vaccinated?" on its own website:

> "Current data show that the possibility of transmission of coronavirus to others after full vaccination is low. "

214 Where Swissmedic wants to get this information from remains completely unclear.

2.4. Overall conclusion "lack of effectiveness

215 The two COVID "vaccines" Comirnaty® and Spikevax® were clearly not expected to have any major therapeutic benefit at the time of approval: not only was the data situation completely insufficient, even on the basis of the available data it could not be concluded that the approval could have effectively combated a life-threatening or disabling disease.

216 The approval studies of the "COVID vaccines" have shown only negligible efficacy with regard to mild courses ("confirmed COVID diseases") and no relevant efficacy at all with regard to "severe COVID diseases" in both adults and adolescents aged 12 years and older already at the time of the approvals and until today. **A vaccine that predominantly reduces minor events neither contributes to a relief of the health care system nor protects against life-threatening or disabling diseases.**

217 The proof that a major therapeutic benefit could be expected from the vaccines according to Art. 9a para. 1 lit. b HMG i.V.m. Art. 18 lit. c VAZV was therefore not provided in any way and the time-limited authorisation was therefore inadmissible from the outset.

218 Moreover, this lack of effectiveness did not change when the manufacturers submitted further data in 2021 (see N 438 ff., N 452 ff., N 456 ff., N 461, N 462).

II. State of knowledge in mid-2021 (admission of young people)

1. Risks

1.1. High-risk unit dose, especially for adolescents

219 For all adults and adolescents aged 12 years and older, a unit dose has been approved for basic immunisation: For Comirnaty® 0.3ml corresponding to 30 µg mRNA and for Spikevax® 0.5ml corresponding to 100 µg mRNA.

220 A dose-finding study for the Pfizer/BioNTech "vaccine" published in the *New England Journal of Medicine* (*NEJM*) on 17 December 2020 already showed that younger study participants (18-55-year-olds) generated side effects more frequently and to a more se-

vere extent than older study participants (65-85-year-olds) at all doses investigated (10µg, 20µg, 30µg). The frequency and severity of side effects was dose-dependent.[143]

221 Experts publicly criticised[144] that the results of this study had not been taken into account for the further development of the "vaccines" and accused the licence holders that it was wrong to use the same dose of the COVID "vaccines" for all adults aged 12 years and older, because the (serious) side effects, which began to appear immediately after approval, were directly attributable to the problem of the unit dose, among other things. According to the study, a dosage of 20 micrograms for Comirnaty® would have been appropriate for 18- to 55-year-olds, and 30 micrograms per injection, possibly even more, for 65- to 85-year-olds.

222 According to Klaus Stöhr, epidemiologist and long-time head of the WHO and Novartis vaccination programme, and virologist Alexander Kekulé, the vaccine doses should have been administered in an age-adapted manner from the beginning, or at the latest after observing the side effect rates. Susanne Wagner, biotech expert, consultant in drug development and specialist in the test plans of new drugs with 30 years of experience in high-tech research, also took a hard line with regulatory authorities and marketing authorisation holders: "**One should have reacted immediately and reduced the dose already after the first deaths of younger people after the first indications of the sometimes severe side effects such as heart muscle inflammation or strokes.** "

223 As recently as May 2021, the **German Society for General and Family Medicine** had clearly expressed its **opposition to vaccinating children and adolescents** due to the lack of individual and societal benefits and the lack of medium- and long-term data on safety.[145]

224 It must be assumed that the dose-finding study referred to was part of the authorisation dossier and that Swissmedic was aware of these results. It is incomprehensible that Swissmedic did not question the unit doses at any point.

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143 WALSH et al, "Safety and Immunogenicity of Two RNA-Based Covid-19 Vaccine Candidates," Dec. 17, 2020, https://www.nejm.org/doi/full/10.1056/NEJMoa2027906.

144 Welt, "Findings that fundamentally contradict German vaccination practice", 06.04.2022, https://www.welt.de/politik/deutschland/plus238021185/Biontech-Der-Haken-bei-der-Einheitsdosis-des-Corona-Impfstoffs.html.

145 Degam, "Statement COVID-19 vaccinations in children and adolescents", 26.05.2021, *https://www.degam.de/files/Inhalte/Degam-Inhalte/Ueber_uns/Positionspapiere/20210526_COVID-19_Impfungen_bei_Kindern_und_Jugendlichen_Err.pdf.*

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

225 The Pfizer/BioNTech "*Post Marketing Pharmacovigilance Report*" with data on the first 2.5 months after marketing approval[146] , which was submitted to all authorities worldwide - presumably in April/May 2021 - was published by the FDA together with various other documents as part of a court-ordered release schedule resulting from an emergency *Freedom of Information Act (FOIA)* request by *Public Health and Medical Professionals for Transparency* (PHMPT).[147] The report, which summarised data from the date of marketing approval to 28 February 2021, contained **42,086 suspected adverse events** and **1223 suspected deaths related to the "vaccination"** (p.7):

Table 1. General Overview: Selected Characteristics of All Cases Received During the Reporting Interval

Characteristics		Relevant cases (N=42086)
Gender:	Female	29914
	Male	9182
	No Data	2990
Age range (years): 0.01 -107 years Mean = 50.9 years n = 34952	≤ 17 18-30 31-50 51-64 65-74 ≥ 75 Unknown	175[a] 4953 13886 7884 3098 5214 6876
Case outcome:	Recovered/Recovering	19582
	Recovered with sequelae	520
	Not recovered at the time of report	11361
	Fatal	1223
	Unknown	9400

a. in 46 cases reported age was <16-year-old and in 34 cases <12-year-old.

226 Reported cases included **1403 cases of cardiovascular side effects** (including 130 heart attacks and 91 cases of heart failure), **1050 cases of immune-mediated - resp. There were 1050 cases of immune-mediated or autoimmune diseases**, **501 cases of neurological diseases** [including 204 seizures, 95 cases of epilepsy, **449 cases of facial** paralysis], **275 strokes, 298 cases of herpes zoster disease/reactivation, 151 cases of thromboembolic events (**including **86 cases of thrombosis** and **60 cases of pulmo-**

146 Pfizer, "Cumulative analysis of post-authorization adverse event reports of PF-07302048 (BNT162B2) received through 02/28/2021," 04/30/2021, https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf; Canadian Covid Care Alliance, FN 133.

147 SIRI / GLIMSTAD, "Freedom of information act request, expedited processing requested", 27.08.2021, https://phmpt.org/wp-content/uploads/2021/10/IR0546-FDA-Pfizer-Approval-FINAL.pdf; United States District Court for the northern district of Texas fort worth division, No. 4:21-cv-1058-P, "Order", 06.01.2022, https://phmpt.org/wp-content/uploads/2022/01/ORDER_2022_01_06.pdf; see also The Defender, "FDA releases 10'000 more Pfizer vaccine documents. What will they reveal?", 04.03.2022, *https://childrenshealthdefense.org/defender/fda-releases-pfizer-vaccine-documents/.*

nary embolism), 24 cases of Guillain Barré syndrome and **10 cases of reactivation of multiple sclerosis**. The connection of the occurrence of all these side effects with the COVID "vaccines" was confirmed in the course by the suspected cases and publications of side effects registered in the international databases (see below N 237 ff. , N 285 ff., N 433 ff., N 479 ff., N 551 ff, 767 ff., N 775 ff.).

227 In the "*Safety concerns*" section, reference was made, among other things, to the occurrence of severe allergic reactions and exacerbations of disease due to "vaccination" (vaccine *associated enhanced disease*, "*VAED"*) incl. exacerbations of respiratory infections (*vaccine associated enhanced respiratory disease,* "*VAERD"*). This danger has been known for a long time. Similar Corona vaccines against SARS and MERS had never made it to market approval in the past, partly because of these safety problems. The studies had shown that extremely severe courses and deaths occurred in vaccinated persons - via *antibody-dependent enhancement* (*ADE*) - as soon as vaccinated persons were exposed to the virus.[148] This risk was already mentioned in the protocol of the registration trial of the Pfizer/BioNTech vaccine under point "*8.2.4 Surveillance of Events That Could Represent Enhanced COVID-19 and Phase 2/3 Stopping Rule*".[149]

228 Swissmedic was also aware of the potential risk of *VAED* and *VAERD* at the time of authorisation: "*The ongoing and proposed additional pharmacovigilance activities are considered sufficient to further characterise the important potential risks of VAED, VAERD*....". (Supplement **2**, p. 11).

1.3. Worldwide reports of side effects until June 2021

1.3.1. Preliminary remark: Sources used and methods of presentation

229 All subsequent graphical presentations (also corresponding graphical presentations in later sections concerning the end of 2021 and 2022) on worldwide reports of side effects and doses administered are based on data from the following sources in particular:

- Switzerland: SWISSMEDIC, Suspicious reports of adverse effects of Covid-19 vaccinations in Switzerland.[150]

148 CARDOZO/VEAZEY, "Informed consent disclosure to vaccine trial subjects of risk of COVID-19 vaccines worsening clinical disease", 28.10.2020, *https://onlinelibrary.wiley.com/doi/10.1111/ijcp.13795.*

149 Pfizer, "A phase 1/2/3, placebo-controlled, randomized, observer-blind, dose-finding study to evaluate the safety, tolerability, immunogenicity, and efficacy of SARS-CoV-2 RNA vaccine candidates against Covid-19 in healthy individuals", 11.2020, https://cdn.pfizer.com/pfizercom/2020-11/C4591001_Clinical_Protocol_Nov2020.pdf.

150 Swissmedic, "Periodic Report on Suspected Vaccine Reactions Associated with Covid-19 Vaccines", 04.05.2021,

- EU: EudraVigilance (side effects)[151] and ECDC (number of COVID "vaccinations").[152]
- USA: VAERS (side effects)[153] and CDC (number of COVID "vaccinations").[154]

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https://www.swissmedic.ch/dam/swissmedic/de/dokumente/marktueberwachung/uaw/swissmedic-covid-19-pharmacovigilancereport20210504.pdf.download.pdf/Swissmedic-Covid-19-PharmacovigilanceReport20210504.pdf; Swissmedic, "Adverse reactions to Covid-19 vaccines in Switzerland - Update", 07.05.2021, *https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/nebenwirkungen-covid-19-impfungen-update-5.html*; Swissmedic, "Adverse reactions to Covid-19 vaccinations in Switzerland - Update", 04.06.2021 (Comirnaty / Moderna), https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/covid-19-vaccines-safety-update.html; Swissmedic, "Suspected adverse reactions to Covid-19 vaccinations in Switzerland - Update", 24.09.2021 (Comirnaty / Moderna), *https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/covid-19-vaccines-safety-update-6.html*; Swissmedic, "Suspected adverse reactions to Covid-19 vaccinations in Switzerland - Update", 05.11.2021 (Comirnaty / Moderna), https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/covid-19-vaccines-safety-update-8.html; Swissmedic, "Suspected adverse reactions to Covid-19 vaccinations in Switzerland - 20th update", 17.12.2021 (Comirnaty / Moderna), *https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/covid-19-vaccines-safety-update-10.html*; Swissmedic, "Suspected adverse reactions to Covid-19 vaccinations in Switzerland - 24th update", 08.04.2022 (Comirnaty / Moderna), https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/covid-19-vaccines-safety-update-14.html; Swissmedic, "Suspected adverse reactions to Covid-19 vaccinations in Switzerland - 25th update", 06.05.2022 (Comirnaty / Moderna), https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/covid-19-vaccines-safety-update-15.html.

151 EudraVigilance, "European Database of Reported Suspected Drug Side Effects", 22.06.2022, https://www.adrreports.eu/de/index.html; EudraVigilance, "Covid-19 MRNA Vaccine Moderna [CX-02441]", "Covid-19 MRNA Vaccine Pfizer-Biontech [Tozinameran]", 22.06.2022, *https://www.adrreports.eu/en/search_subst.html#*; EudraVigilance, "COVID-19 MRNA VACCINE MODERNA [CX-02441] - Individual Cases by Age Group (Graphic)", 23.06.2022; EudraVigilance, "COVID-19 MRNA Vaccine Moderna [CX-02441] - Individual Cases by Age Group (Table)", 23.06.2022; EudraVigilance, "Covid-19 MRNA Vaccine Moderna [CX-02441] - Individual Cases by Geographic Origin (Graphic)", 23.06.2022; EudraVigilance, "Covid-19 MRNA Vaccine Moderna [CX-02441] - Individual Cases by Geographic Origin (Table)", 23.06.2022; EudraVigilance, "Covid-19 MRNA Vaccine Pfizer-Biontech [Tozinameran] - Individual Cases by Age Group (Graphic)", 23.06.2022; EudraVigilance, "Covid-19 MRNA Vaccine Pfizer-Biontech [Tozinameran] - Individual Cases by Age Group (Table)", 23.06.2022; EudraVigilance, "Covid-19 MRNA Vaccine Pfizer-Biontech [Tozinameran] - Individual Cases by Geographic Origin (Graphic)", 23.06.2022; EudraVigilance, "Covid-19 MRNA Vaccine Pfizer-Biontech [Tozinameran] - Individual Cases by Geographic Origin (Table)", 23.06.2022.

152 ECDC, "Data on COVID-19 vaccination in the EU EEA", 22.06.2022, https://www.ecdc.europa.eu/en/publications-data/data-covid-19-vaccination-eu-eea; ECDC, "Data on COVID-19 vaccination - Data Download in XLSX", 22.06.2022, https://opendata.ecdc.europa.eu/covid19/vaccine_tracker/xlsx/data.xlsx.

153 VAERS, "Vaccine Adverse Event Reporting System", 22.06.2022, https://vaers.hhs.gov/data.html; VAERS, "Data Sets", 22.06.2022, https://vaers.hhs.gov/data/datasets.html: VAERS, "Data 2020", 22.06.2022, https://vaers.hhs.gov/eSubDownload/index.jsp?fn=2020VAERSData.zip; VAERS, "Data 2021", 22.06.2022, https://vaers.hhs.gov/eSubDownload/index.jsp?fn=2021VAERSData.zip; VAERS, "Data 2022", 22.06.2022, https://vaers.hhs.gov/eSubDownload/index.jsp?fn=2022VAERSData.zip.

154 CDC (Centers for Disease Control and Prevention), "COVID-19 Vaccinations in the United States," 6/22/2022, https://data.cdc.gov/Vaccinations/COVID-19-Vaccinations-in-the-United-

230 Swissmedic publishes periodic "updates" on adverse reaction reports; there is no public access to the corresponding raw data. The situation is different with EudraVigilance and VAERS: in the respective web interfaces, it is possible to download the individual adverse reaction cases from the databases in a table, the "Line Listing Report". Both the periodic "updates" from Swissmedic and the American and European databases form the starting point for the data presented below. The following tables and graphs therefore only reflect the content of the available public data from the regulatory authorities - the accuracy of this data is the responsibility of the regulatory authorities. However, the data consulted are compiled and summarised below in a different way than is done by the competent (regulatory) authorities.

231 The following calculations of side effects per 1 million "vaccine doses" have already taken into account the fact that there is a **delay in reporting: In** the EU, for example, the national authorities must report serious cases within 15 days, [155] the remaining side effects within 90 days.[156] Following this delay in reporting, the "vaccination rates" for the calculation of the side effects per 1 million vaccine doses were calculated on the basis of the status 6 weeks previously.

232 It should also be taken into account that the worldwide reporting systems are purely **"passive systems":** There is no active recording of adverse drug reactions by the regulatory authorities. Rather, they rely on reports from manufacturers, physicians or even patients. If these reports are not submitted, no side effects are officially reported. This leads to **massive underreporting** (see N 353 ff.). In the following analyses, the officially reported figures are nevertheless presented, i.e. without taking underreporting into account.

States-Jurisdi/unsk-b7fc; CDC, "COVID-19 Vaccinations in the United States Jurisdiction (Export-ZIP)," 6/22/2022, https://data.cdc.gov/api/views/unsk-b7fc/rows.csv?accessType=DOWNLOAD&bom=true&format=true&delimiter=%3B.

155 See, for example, Art. 104 Para. 2, Art. 105 Para. 2 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, Official Journal L 311 of 28/11/2001 P. 0067 - 0128, https://eur-lex.europa.eu/legal-content/DE/TXT/HTML/?uri=CELEX:32001L0083&from=en.

156 At least in Germany according to § 62 para. 3 of the German Medicines Act (AMG; Arzneimittelgesetz in der Fassung der Bekanntmachung vom 12. Dezember 2005 [BGBl. I p. 3394], which was last amended by Article 3 of the Act of 27 September 2021 [BGBl. I p. 4530]): "The competent higher federal authority shall electronically transmit every suspected case of a serious adverse reaction reported to it and occurring in Germany within 15 days and every suspected case of a non-serious adverse reaction reported to it and occurring in Germany within 90 days to the database pursuant to Article 24 of Regulation (EC) No. 726/2004 (EudraVigilance database). "

1.3.2. Data basis

233 Based on the periodic "updates" from Swissmedic (until 04.06.2021) and the American and European databases (until 05.06.2021), the number of adverse reactions (all, serious/serious/serious, deaths) is as follows:[157]

	CH	Children (CH)	EU	Children (EU)	USA	Children (USA)
Comirnaty	1.120		164.221	244	160.538	5.433
Ernst Comirnaty	492		31.361	65	52.936	1.582
Deaths Comirnaty			3.235	1	1.984	7
Spikevax	1.538		23.156	30	173.822	3.783
Ernst Spikevax	433		3.493	8	52.294	124
Deaths Spikevax			281	0	2.265	2
Total Comirnaty+ Spikevax	2.701	8	187	274	334	9
Severe/ Ernst	950		35	73	105	126
Deaths	90		284	1	4	9
Vaccination doses Comirnaty	963.372		182.428.545		132.721.153	
Vaccine doses Spikevax	1.836.628		22.764.689		108.142.826	
Comirnaty+ Spikevax / Mio	964,6		913,2		1.388,2	
Severe/ Ernst / 1Mio	339,3		169,9		436,9	
Deaths / million	32,1		17,1		17,6	

234 The following figures were reported in the areas of heart (Cardiac disorders), coagulation disorders and consequences (Blood and lymphatic system disorders) and deaths overall:

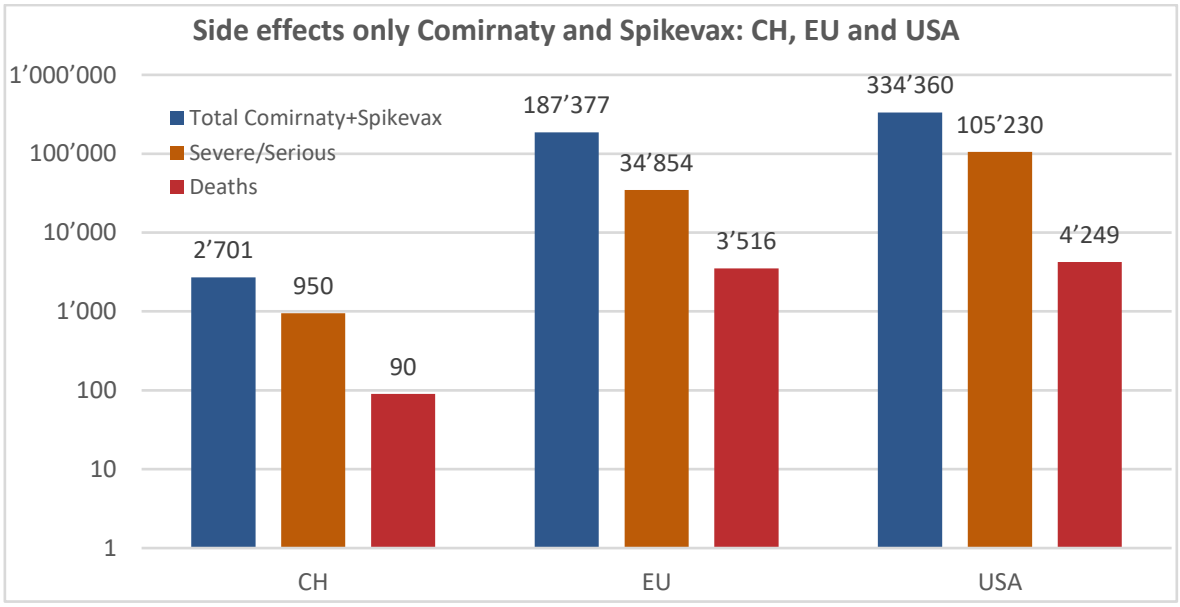
	CH total	CH Comir-naty	CH Spike-vax	EU total	EU Comir-naty	EU Spike-vax	USA total	USA Comir-naty	USA Spike-vax
Heart	148	75	73	757	7.244	750	20	11.158	9.292
Coagulation disorders	95	49	46	772	5.886	766	11	5.633	4.943
Deaths Comirnaty	90			284	3.235	281	4	1.984	2.265
Stillbirths				1	1	0	604	346	258

157 Due to late reporting, the vaccine doses are backdated: 07.05.21 (CH), 24.04.21 (EU), 01.05.21 (USA).

	CH total	CH Comir-naty	CH Spike-vax	EU total	EU Comir-naty	EU Spike-vax	USA total	USA Comir-naty	USA Spike-vax
per 1 Mio									
Heart	52,9	77,9	39,7	39,0	39,7	32,9	84,9	84,1	85,9
Coagulation disorders	33,9	50,9	25,0	32,4	32,3	33,6	43,9	42,4	45,7
Deaths Comirnaty	32,1			17,1	17,7	12,3	17,6	14,9	20,9
Stillbirths				0,0	0,0	0,0	2,5	2,6	2,4

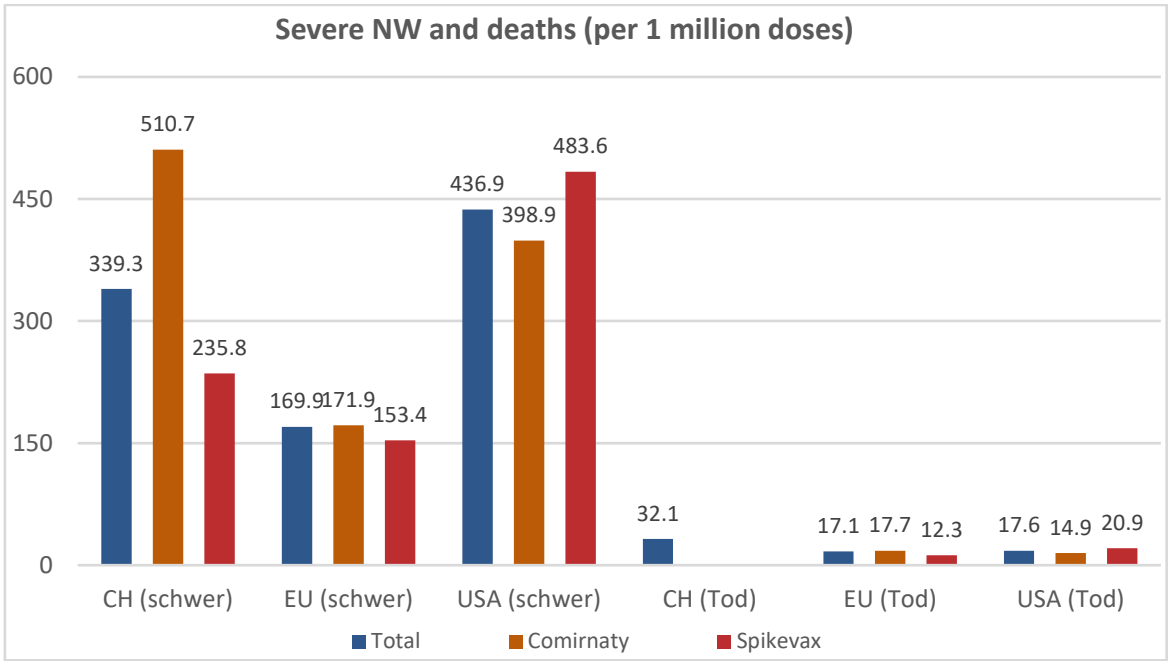
1.3.3. Side effects with Comirnaty® and Spikevax® (absolute numbers)

235 By 04.06.2021 in Switzerland, by 05.06.2022 in the EU and the USA, a total of **524,438 adverse reactions had** been reported for Comirnaty® and Spikevax® - of which **141,034 were serious and 7,855 were deaths:**



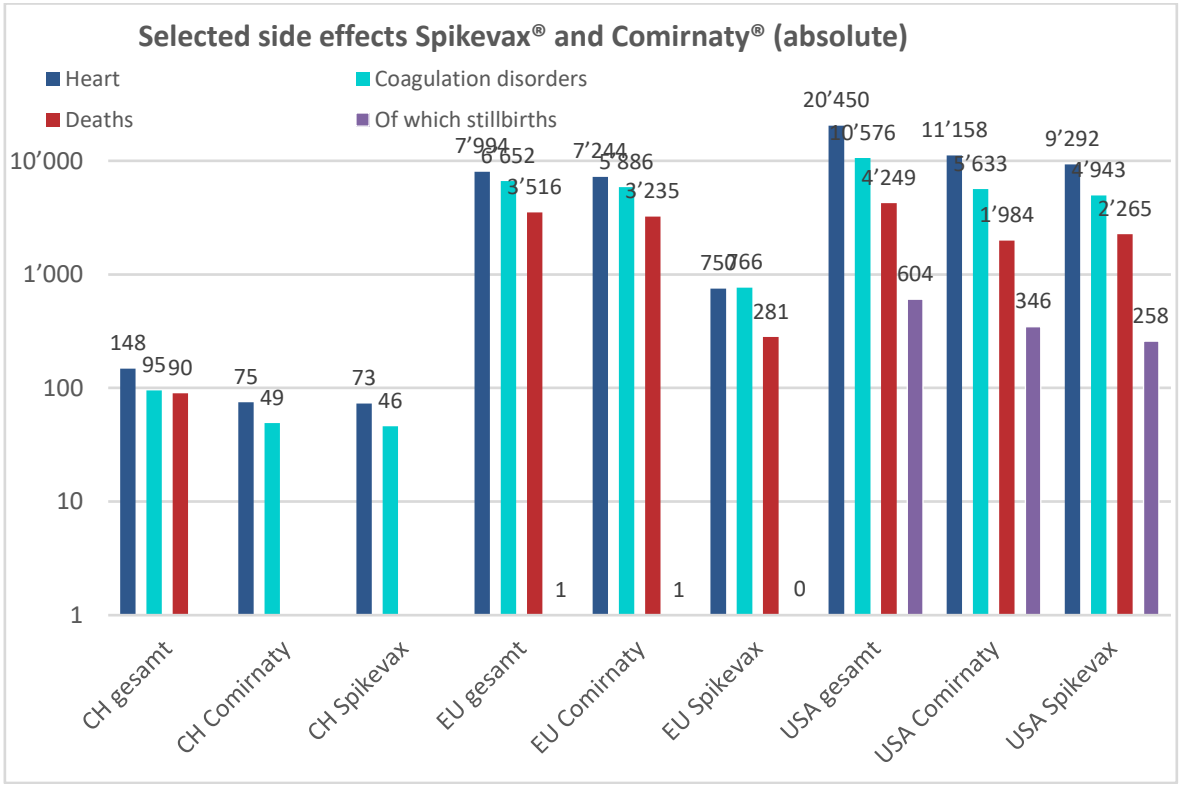
1.3.4. Side effects with Comirnaty® and Spikevax® (per 1 million "vaccine doses")

236 The number of serious and fatal adverse events for Spikevax® and Comirnaty® **per 1 million doses administered as** of **June 2021** was as follows:

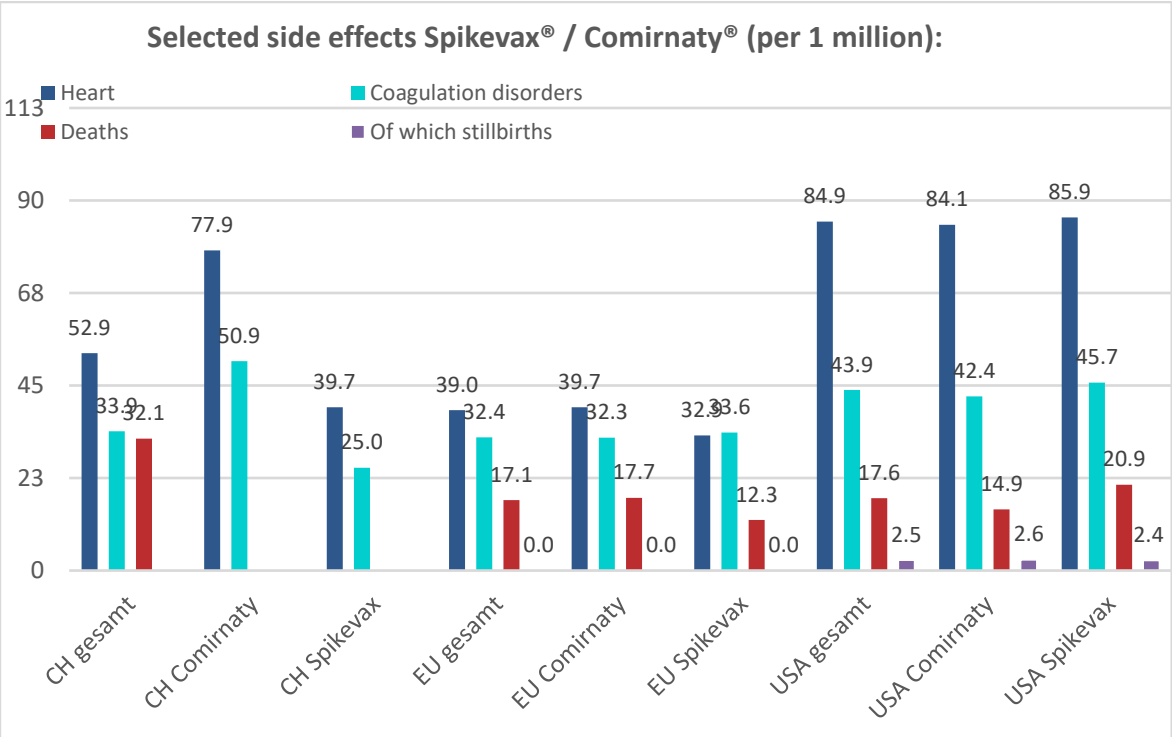


1.3.5. Selected side effects: Heart, thromboses, deaths, stillbirths

237 A more detailed analysis of all adverse reaction 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 in **absolute figures** as of **June 2021:**



238 **Per 1 million "vaccine doses"** this gives the following picture:



239 The side effect reports concerning the **heart (myocarditis/pericarditis** etc.) at that time were 32.9 to 85.9 worldwide, which according to the definition (MedDRA system organ classes) were **"very rare" side effects,** as less than 1 case per 10,000 doses occurred.

240 Even then, the reports of coagulation disorders were worrying, ranging from 25 to 50.9 cases per 1 million doses worldwide. Even at that time, the official data was already in a range that was clearly comparable, measurable and estimable. The number of cases per 10,000 is 0.25 to 0.509, which means that the **coagulation disorders were already to** be classified **as "very rare" side effects (<1/10,000) in June 2021.**

241 **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 in the USA as of 14 May 2022 (see N 483) have never been reached again.

242 Even then, data from the USA showed that there was an **increase in stillbirths.**

1.4. Alarm signal deaths and severe side effects

243 In the past, it was repeatedly shown that licensing authorities worldwide reacted only with delay to safety signals. In the following, it is explained that alarm signals - as they currently exist - would have long since led to an immediate "exercise termination" in earlier times:

1.4.1. *Pandemrix*® : 5000 serious side effects worldwide

1.4.1.1 "Temporary authorisation" by Swissmedic

244 *After the WHO declared a "swine flu pandemic" for the H1N1 virus in June 2009, the vaccines Pandemrix® from Glaxo Smith* Kline (GSK) *and Focetria® from Novartis were already authorised in Switzerland in October 2009. The authorisations were granted quickly,*[158] *presumably on the basis of Art. 9 para. 4 of the old HMG ("temporary authorisation"),*[159] *i.e. on the basis of the predecessor norm of Art. 9a HMG ("temporary authorisation"). The authorisation for Focetria® was granted for adults and children from six months of age. Regarding Pandemrix®, Swissmedic - in contrast to the EMA*[160] *- decided against a marketing authorisation for pregnant women, children/adolescents under 18 years of age and adults over 60 years of age.*[161] *Two weeks later, a third H1N1 vaccine - Celtura®, also from Novartis - was approved for adults and children aged 3 years and older.*[162]

245 *Swissmedic was criticised at the time because it took about a month longer to obtain authorisation for Pandemrix® than the EMA, for example. However, Swissmedic had obviously exercised the necessary care at the time: it had simply received too little information from GSK that would have enabled a complete release of Pandemrix® for all*

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158 Cf. Swissmedic: "Swissmedic very well prepared for the authorisation of pandemic vaccines", 24.07.2009: "Finally, in urgent and very critical health cases, Swissmedic can also issue a temporary authorisation for the distribution of the new vaccines in accordance with Art. 9 para. 4 HMG (Therapeutic Products Act). This provision allows Swissmedic to eliminate an acute supply bottleneck in extraordinary situations. Application of the article would be justified if the vaccines had to be administered immediately, for example to counteract an uncontrolled spread of the pandemic or to protect particularly vulnerable sections of the population", https://www.admin.ch/gov/de/start/dokumentation/medienmitteilungen.msg-id-28231.html.

159 Art. 9a para. 4 aHMG (in force until the new Art. 9a HMG comes into force on 1 January 2019), read as follows: "The Institute may authorise the distribution or dispensing of unauthorised medicinal products for life-threatening diseases for a limited period of time 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. "; See also: Swissmedic, "Revision des Heilmittelgesetzes - Anpassungen des Verordnungsrechts", 04.12.2018, https://www.swissmedic.ch/swissmedic/de/home/news/specials/hmv4-ambvmedicrime-info.html.

160 European medicines agency, "Assessment report Comirnaty", 25.11.2021, https://www.ema.europa.eu/en/documents/variation-report/comirnaty-h-c-5735-x-0077-epar-assessment-report-extension_en.pdf; European medicines agency, "Arzneimittelinformation Pandemrix", 20.05.2008, pp. 3 and 5, https://www.ema.europa.eu/en/documents/other/pandemrix-summary-product-characteristics_de.pdf.

161 Swissmedic, "Swissmedic grants authorisation for pandemic vaccines", 30.10.2009, https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/archiv/swissmedic-erteilt-zulassung-fuer-pandemie-impfstoffe.html.

162 Swissmedic, "Swissmedic grants authorisation for Celtura", 13.11.2009, https://www.swissmedic.ch/swissmedic/de/home/news/mitteilungen/archiv/swissmedic-erteilt-zulassung-fuer-celtura.html.

population groups.[163] *This indicated caution paid off in favour of the health of the Swiss population, as will be explained below.*

1.4.1.2 Vaccination campaign Switzerland

246 *The Confederation undertook to vaccinate eighty per cent of the population twice. Accordingly, it purchased eight million doses from GSK (Pandemrix®) and five million doses from Novartis for a total of CHF 82 million. The vaccination campaign started in November 2009, although it was already clear at that time that H1N1 mainly generated high numbers of cases with mild courses of disease. In the months that followed, only a small part of the population was vaccinated: a total of only 3 million vaccine doses were used, 8 million were destroyed and the rest donated to poor countries.*[164]

1.4.1.3 Concealment of first side effects

247 Shortly after the approval of Pandemrix®, reports of adverse events began to accumulate: As early as November 2009, GSK had received 1,138 reports of suspected cases of serious adverse events for Pandemrix® (corresponding to 76 cases / million doses administered). By mid-December 2009, there were already 3280 reports of serious adverse events (68 cases / million doses administered). The last report on 31 March 2010 showed 5,069 serious adverse events for **Pandemrix® (72 cases / million doses administered).** Common adverse events included allergic shock, facial paralysis, convulsions, vascular inflammation and brain inflammation. **Neither GSK nor the health authorities published this information** - and it is not clear whether the significantly higher side effect rates of Pandemrix® compared to the other H1N1 vaccines were investigated. Neither GSK nor the regulatory authorities have answered corresponding enquiries on this topic to date. [165]

248 It is particularly shocking that German politicians must have been aware of the problems with Pandemrix® as early as November 2009 - the Chancellor and ministers apparently did not have themselves immunised with Pandemrix® but with an alternative H1N1 vaccine. Nevertheless, the vaccination campaign with Pandemrix® for the general population was allowed to continue. The then chairman of the Drug Commission of the German Medical Profession, Wolf-Dieter Ludwig, expressed himself accordingly sharply: *"We are unhappy about this vaccination campaign [...]. The health authorities fell for a campaign of*

163 WOZ, FN 163.
164 WOZ, FN 163.
165 DOSHI, "Pandemrix vaccine: why was the public not told of early warning signs? ", 20.09.2018, https://www.bmj.com/content/362/bmj.k3948.

the pharmaceutical companies who simply wanted to make money with a supposed threat. "[166]

1.4.1.4 Other side effect: narcolepsy (sleeping sickness)

249 The first side effects mentioned were soon joined by another: Narcolepsy. In three renowned sleep laboratories in Canada, the USA and France, it was recognised after the approval of Pandemrix® that cases of narcolepsy (sleeping sickness) increased significantly. In the year following swine flu, the three institutions together registered a threefold increase in new patients in the regions they studied.[167] Sweden and Finland also noted a similar increase in children and adolescents.[168]

250 Narcolepsy is a neurological disease that, once contracted, remains lifelong. It is a disorder of sleep-wake regulation, the centres of which are located in the brainstem and midbrain. It can cause significant professional, family and personal problems, as the symptoms usually severely affect the lifestyle of those affected.[169]

251 The cases of narcolepsy were finally attributed in several studies to Pandemrix® - more precisely: the effect-enhancing critical adjuvant AS03 contained in the vaccine - as a probable causal *agent.*[170]

252 Of the approximately 30 million vaccinated people in Europe, more than 1300 people developed narcolepsy in connection with Pandemrix®.[171] In Switzerland, by contrast, only nine cases of narcolepsy were reported in connection with Pandemrix®. This relatively low

166 Der Spiegel, "Chancellor and ministers to receive special vaccine", 17.10.2009, *https://www.spiegel.de/wissenschaft/medizin/schutz-vor-schweinegrippe-kanzlerin-und-minister-sollen-speziellen-impfstoff-erhalten-a-655764.html.*

167 WOZ, FN 163.

168 ECDC, "Narcolepsy in association with pandemic influenza vaccination", 09.2012, *https://www.ecdc.europa.eu/sites/default/files/media/en/publications/Publications/Vaesco%20report%20FINAL%20with%20cover.pdf.*

169 SNaG, "What is narcolepsy? ", 17.06.2022, https://www.narcolepsy.ch/de-ch/ueber-narkolepsie/was-ist-narkolepsie.

170 PARTINEN et al, "Increased Incidence and Clinical Picture of Childhood Narcolepsy following the 2009 H1N1 Pandemic Vaccination Campaign in Finland", 28.03.2012, https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC3314680/; NOHYNEK et al., "AS03 Adjuvanted AH1N1 Vaccine Associated with an Abrupt Increase in the Incidence of Childhood Narcolepsy in Finland", 28.03.2012, https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC3314666/; MILLER et al, "Risk of narcolepsy in children and young people receiving AS03 adjuvanted pandemic A/H1N1 2009 influenza vaccine: retrospective analysis", 26.02.2013, https://www.bmj.com/content/346/bmj.f794.long; see also WOZ, FN 163.

171 Science, "Why a pandemic flu shot caused narcolepsy", 01.07.2015, https://www.science.org/content/article/why-pandemic-flu-shot-caused-narcolepsy; see also: Der Spiegel, "Manufacturer of swine flu vaccine ignored risks", 21.09.2018, https://www.spiegel.de/gesundheit/diagnose/schweinegrippe-impfstoff-pandemrix-risiken-wurden-ignoriert-a-1229144.html.

rate is probably due to the fact that Swissmedic had only authorised Pandemrix® for adults: most cases of narcolepsy break out between the ages of ten and twenty.[172]

1.4.1.5 Total side effects and conclusion

253 The supposed "pandemic" was declared over by the WHO on 10 August 2010,[173] whereby the failed vaccination campaign also became obsolete and was not continued.

254 In Switzerland, more than 80% of the adverse reaction reports ultimately concerned Pandemrix®; however, thanks to the intervention of Swissmedic, Switzerland got off relatively lightly.[174] Worldwide, however, the number of suspected cases of serious side effects in connection with Pandemrix® is said to have totalled over 5,000 by 2018. Due to the well-known underreporting, this number is likely to reflect a maximum of 10% of the actual cases.[175] Despite all this data and obvious causal links, GSK and the European Medicines Agency (EMA) still do not consider it proven that the cases can be traced back to Pandemrix® - corresponding legal proceedings are apparently still ongoing.[176]

255 Although it became apparent early on that the "swine flu" was much milder than predicted, the vaccination campaign was continued undeterred to the detriment of people despite the side effects that were also known early on (but not officially published).[177] A clean "risk-benefit analysis" could thus obviously not take place, at least at the European level.

1.4.2. Withdrawal of medicines: 50 deaths or life-threatening incidents

256 In 2001, the company Bayer withdrew the cholesterol-lowering drug Lipobay® because of 52 deaths worldwide that had occurred in a temporal connection with the intake of Lipobay® and a muscle weakness.[178]

257 The company Merck withdrew the anti-inflammatory Vioxx® in 2004 because it was shown to be associated with an increased risk of cardiovascular disease: among 20,742

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172 WOZ, FN 163.

173 Internet Archive, "H1N1 in post-pandemic period", 26.08.2010, https://web.archive.org/web/20100826004505/https://www.who.int/mediacentre/news/statements/2010/h1n1_vpc_20100810/en/index.html.

174 WOZ, FN 163.

175 Der Spiegel, "Manufacturer of swine flu vaccine ignored risks", 21.09.2018, https://www.spiegel.de/gesundheit/diagnose/schweinegrippe-impfstoff-pandemrix-risiken-wurden-ignoriert-a-1229144.html.

176 Der Spiegel, FN 175.

177 Cf. Der Spiegel, FN 175.

178 FAZ, "52 deaths admitted after Lipobay ingestion", 13.08.2001, *https://www.faz.net/aktuell/wirtschaft/bayer-52-todesfaelle-nach-lipobay-einnahme-eingeraeumt-129872.html;* Finanz und Wirtschaft, "*Bayer does not form provisions*", 18.08.2001, https://www.fuw.ch/article/bayer-bildet-keine-rckstellungen.

patients observed, a total of 52 heart attacks had occurred, 41 of whom had taken Vioxx®. A study by the University of Bern concluded that this risk was already provable in 2000.[179]

258 Moreover, in a ruling in 2008, the Federal Supreme Court stated that "termination criteria" had been defined in a clinical trial, according to which the trial would have been "terminated after the first **50 patients" in the** event of findings on the "harmfulness of the therapeutic procedure".[180]

1.4.3. Comparison of COVID "vaccines" with flu vaccine

1.4.3.1 Switzerland: Little meaningful data available

259 In Switzerland, three vaccines are currently used for immunisation against influenza in adults and children: Influvac Tetra®, Fluarix Tetra® and Vaxigrip Tetra®.[181] While the corresponding technical information on www.swissmedicinfo.ch lists the usual mild to moderate side effects for vaccinations (e.g. headache, pain at the injection site, muscle pain, chills, fever) based on the results of the clinical studies, there are also severe side effects such as Guillain-Barr, based on the reports from the post-marketing phase with "unknown frequency".These include Guillain-Barré syndrome (a form of polyneuropathy in which muscle weakness occurs), facial nerve palsy, vasculitis or optic neuritis (inflammation of the optic nerve).

260 In 2014 and 2015, Swissmedic reported a total of 296 and 278 suspected cases of adverse reactions to vaccinations. Over 100 of the total of 278 suspected cases of adverse reactions to vaccination were attributable to influenza vaccination; 20% of these cases were classified as serious. One case of facial paralysis and one death were reported in connection with influenza vaccination. As no reliable data are available on the number of vaccinations administered in Switzerland, no conclusions can be drawn on reporting or side effect rates.[182]

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179 University of Bern, "Risks of Vioxx were already apparent in 2000", 05.11.2004, *https://www.unibe.ch/aktuell/medien/media_relations/archiv/news/2004/041105vioxx/index_ger.html.*

180 BGE 134 IV 175, E. 4.3. P. 182.

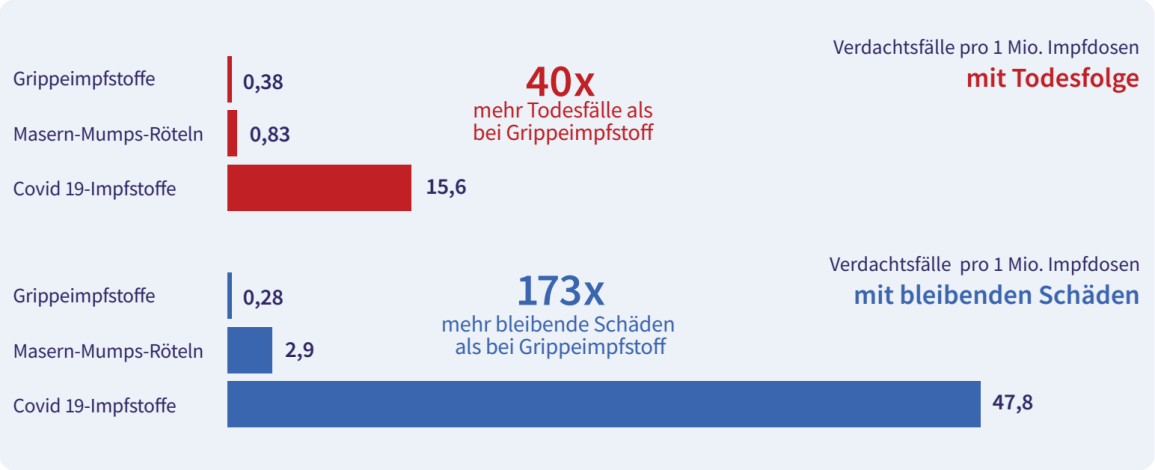
181 Vaccine Against Influenza, "Influenza Vaccine Information", as of 05.2022, *https://impfengegengrippe.ch/de-ch/impfung/impfstoffe.html.*

182 Swissmedic, " Summary of adverse events reported in Switzerland following vaccinations in 2015", 14.09.2016, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/marktueberwachung/vigilance/zusammenfassung_zudeninderschweizgemeldetenunerwuenschtenereigni.pdf.download.pdf/zusammenfassung_zudeninderschweizgemeldetenunerwuenschtenereigni.pdf.

261 As of May 2021, Swissmedic reported 1,953 evaluated suspected cases of adverse reactions to 2.8 million doses of COVID "vaccines", of which 701 cases were classified as serious.[183] This results in a rate of **250 serious adverse reactions per 1 million doses administered.**

1.4.3.2 Germany: COVID "vaccines" 40 times deadlier than flu vaccines

262 The adverse reaction reports collected by the ***Paul Ehrlich Institute* (*PEI*) in Germany** show that the **death rate for the COVID "vaccines" is 40 times** higher (15.6 per million doses administered) **than for the flu vaccine** (0.4 per million doses administered). The **probability of an adverse reaction with permanent damage is 173 times greater for** COVID "vaccines" (47.8 per million doses administered) **than for influenza vaccination** (0.3 per million doses administered):[184]



1.4.3.3 EU: COVID "vaccines" 21 times deadlier than flu vaccines

263 Based on European data from the **EUDRA vigilance, the likelihood of death is 21 times** greater than with flu vaccination (COVID "vaccines": 13 deaths per million doses administered, flu vaccination 0.63 deaths per million doses administered).[185]

264 **The rate for a serious adverse reaction associated with** a **COVID "vaccination"** is **278 per million doses administered .**[186]

183 Swissmedic, FN 571.
184 WIGES, "Vaccination side effects", 29.06.2022, https://wiges.org/impfnebenwirkungen/.
185 WIGES, FN 184.
186 7Arguments, "A COVID-19 vaccine requirement is unconstitutional", 09.03.2022, https://7argumente.de/; 7Arguments, "Annex 4: Recorded and unrecorded side effects of COVID-19 vaccines", 08.03.2022, https://7argumente.de/download/922/.

1.4.3.4 USA: COVID "vaccines" 51 times deadlier than flu vaccines

265 **American figures** from the ***VAERS database*** also show the same worrying trend:

266 An analysis that included *VAERS data* up to 5.3.2022 reported 1274 deaths (0.41 per 1 million doses given) for the flu vaccine since 1990 and 11,312 deaths (21 per 1 million doses given) for the COVID "vaccine". The **risk of dying as a result of a side effect** is thus **51 times higher for the COVID "vaccines"** than for the flu vaccination.[187]

267 Similarly, for the same reporting period, 52,162 (96 per million doses administered) adverse events associated with hospitalisation were recorded for the COVID "vaccines" and 10,194 (3.3 per million doses administered) for the influenza vaccine. The risk of **hospitalisation due to an adverse reaction** is thus **29 times greater for the COVID "vaccines" than for the influenza vaccination**.[188]

1.4.3.5 *Comparison: Massively increased risk of mRNA- "Vaccines".*

268 Based on the previously described **serious side effects** (side effects that are fatal or life-threatening, require hospitalisation or lead to significant or permanent damage)[189] **and deaths,** the following overview results (data in cases per million vaccine doses administered):

Table 1: Serious side effects

	Flu[190]	Pandemrix®[191]	COVID "vaccines[192]
Switzerland	--	--	**250[193]**
EN[194]	0.28	--	**47.8[195]**
EU	1.8	72	**278**
USA	3.3	--	**96[196]**

Table 2: Deaths

	Flu[197]	Pandemrix®[198]	COVID "vaccines[199]

187 WIGES, FN 184.
188 WIGES, FN 184.
189 AkDÄ, "Reporting side effects, a guide for doctors", 03.2019, p. 10, https://www.akdae.de/arzneimitteltherapie/lf/uaw.
190 Front N 263 (EU) and 266 (USA).
191 Front N 247 (EU).
192 Front N 263 (EU) and N 266 (USA).
193 Front N 261 (CH).
194 Front N 262 (EN)
195 Side effects with *permanent* damage.
196 Side effects associated with *hospitalisation*.
197 Front N 263 (EU) and N 266 (USA).
198 Cf. above N 244 ff.

Switzerland	--	--	**12.1-15.2**
EN[200]	0.38	--	**15.6**
EU	0.63	--	**12.1-12.9**
USA	0.41	--	**19.6-27.8**

269 Even if the figures collected are subject to considerable fluctuations depending on their origin and as a result of non-uniform definitions of "severe side effects", the findings are clear: the COVID "vaccines" already have an absolutely devastating record after just over one year of use. For every million doses vaccinated, the **number of severe side effects is over 30 times higher, and the number of deaths even 20-50 times higher than with influenza vaccines.** Any (medium- and) long-term side effects of the COVID "vaccines" are not even included here - in contrast to the other vaccines discussed.

270 In view of these figures, it is in no way comprehensible how Swissmedic can continue to answer the question "1. Are Covid-19 vaccines safe?" ("FAQ") on its own website for citizens seeking information. ("FAQ"), Swissmedic can claim: "So far, there are no indications of lasting negative health effects.[201]

1.4.4. Comparison of COVID "vaccines" with measles vaccines

1.4.4.1 Measles: Massively higher (infection) and mortality rates

271 Measles is a viral infectious disease that can lead to severe complications, permanent disabilities and in rare cases even death. In about 10% of cases, measles leads to complications, some of them serious (7-9% middle ear infection, 1-6% pneumonia, 0.6% febrile convulsions, 0.1% encephalitis), which make hospitalisation necessary. Despite the best medical care in Europe, the disease is fatal in one in about 3,000 cases, which is why immunisation by vaccination is recommended worldwide.[202] The FOPH recommends two basic immunisations at the age of 9 and 12 months with a combined measles-mumps-rubella vaccine.[203]

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199 Rear N 343 and 486 (Switzerland / EU / USA; each only concerning Comirnaty and Spikevax); see also N 266 (USA).

200 Front N 262 (EN)

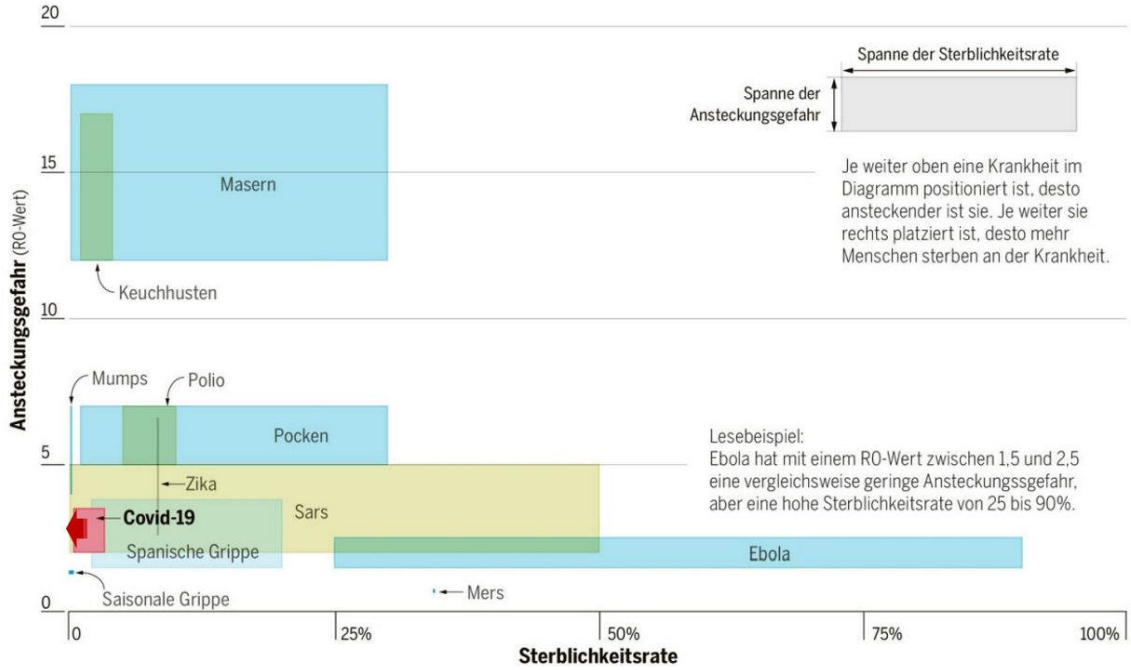
201 Swissmedic, "FAQ on Covid-19 vaccines", 23.06.2022, https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/faq-covid.html.

202 BAG, "Vaccinate against measles and don't miss a thing", 10.2013, https://www.infovac.ch/docs/public/masern-rougeole-mumps-oreillons-roteln-rubeole/4-masern-zuhause-bleiben.pdf.

203 BAG, "Adaptation of recommendations for the prevention of measles, mumps and rubella (MMR)", 25.03.2019, https://www.bag.admin.ch/dam/bag/de/dokumente/mt/i-und-b/richtlinien-empfehlungen/neue-empfehlungen-2019/mmr-impfung.pdf.download.pdf/mmr-impfung-de.pdf.

272 As explained in detail in various places (see N 633 ff., N 648 ff., N 687 ff., N 706 ff., N 722 ff.), COVID is not normally a severe disease that leads to serious complications, permanent disabilities or death, neither in adults nor in children. COVID is at most as dangerous as a moderately severe wave of influenza, for which vaccination has so far only been recommended for high-risk patients and health professionals.[204]

273 As early as March 2020, an article in the Tagesanzeiger illustrated that SARS-CoV-2 is significantly less dangerous and also less contagious than measles and most other infectious diseases:[205]

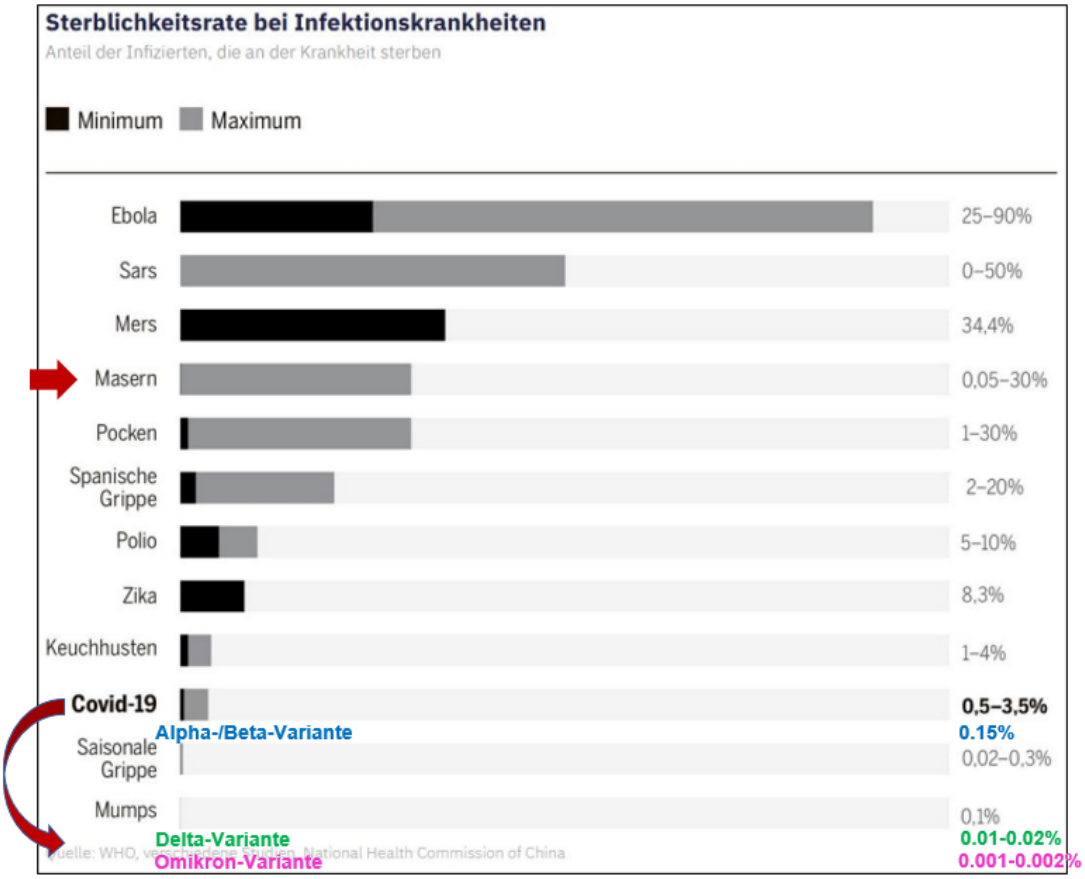


Quelle: WHO, verschiedene Studien, National Health Commission of China

274 The mortality rate for COVID published in the Tagesanzeiger was demonstrably overestimated:

204 Infovac, "Flu", 01.06.2022, https://www.infovac.ch/de/impfunge/nach-krankheiten-geordnet/grippe.

205 Tagesanzeiger, "So gefährlich ist das neue Coronavirus im Vergleich", 25.03.2020, https://interaktiv.tagesanzeiger.ch/2020/wuhan-coronavirus-im-vergleich/?nosome.



275 As early as March 2020, Anthony Fauci himself had compared the dangerousness of COVID to a severe flu.[206] Subsequent variants became increasingly less dangerous and the mortality rate, as discussed in the above text passages and supplemented in the above figure, was corrected significantly downwards.

276 **Based on these data, a comparison of SARS-CoV-2 with measles makes no sense, as the two diseases are not comparable in terms of severity or risk of infection**. Nor **is it medically justifiable to support a broad vaccination recommendation for COVID by referring to the recommended measles vaccination**.

1.4.4.2 Risk potential of the two vaccines

277 The risks associated with measles vaccination are not comparable to those of the COVID "vaccines". The vaccine side effects recorded and evaluated in a detailed international

206 FAUCI, "Covid-19 - Navigating the Uncharted", 26.03.2020, https://www.nejm.org/doi/full/10.1056/nejme2002387.

pharmacovigilance report[207] by the organisation "World Council for Health" show that the **COVID "vaccines"** are **many times more dangerous than the measles vaccine**:

278 In the WHO's "Vigi-Access" database, 6,231 adverse reactions have been recorded for measles vaccines since 1968 as of May 2022, i.e. in 54 years. In contrast, there are 3,777,652 registered side effects for the COVID "vaccines" in a period of 1.5 years:

Table 2: Other Vaccine Adverse Event Data on VigiAccess

Vaccine	Total Number of Adverse Event Reports on VigiAccess as of May 2022	Percentage of 1 year olds who have been immunized globally	Data Collected Since
Tuberculosis Vaccine	37335	88%	1968
Polio Vaccine	123732	86%	1968
Diphtheria Vaccine	1914	85%	1979
Tetanus Vaccine	15381	85%	1968
Pertussis Vaccine	2259	85%	1972
Hepatitis B Vaccine	106761	85%	1984
H. Influenza B Vaccine	90044	72%	1986
Measles Vaccine	6231	71%	1968
Rubella Vaccine	2640	71%	1971
Covid-19 Vaccine	3777652	65.7%***	2020

*** Percentage of current world population ***

279 In the American **VAERS system** , 77,954 adverse reactions (**259 adverse reactions/1 million vaccinated persons**) were registered for the **measles-mumps-rubella vaccine in** 301 million vaccinated persons, and 856,340 adverse reactions (**3,358 adverse reactions/1 million vaccinated persons**) were registered for the **COVID "vaccines" in** 255 **million vaccinated persons:**

Table 3: Contextual Data of Covid-19 Vaccine and Measles, Mumps, Rubella Vaccine on VAERS

# of	Covid-19 Vaccine	Measles/Mumps/Rubella
Approximate Number of Individuals Vaccinated	255000000	301000000
Total number of Adverse Event Reports on VAERS	856340	77954

280 In the **EudraVigilance system** , 48,913 adverse reactions (**72.7 adverse reactions/1 million vaccinated persons**) were registered for the **measles vaccine in** 673.2 million vaccinated persons, and 1,800,000 adverse reactions (**5269.3 adverse reactions/1 mil-**

207 World Council for Health, "Covid-19 Vaccine Pharmacovigilance Report", 16.06.2022, https://worldcouncilforhealth.org/resources/covid-19-vaccine-pharmacovigilance-report/.

lion vaccinated persons) were registered for the **COVID "vaccines" in** 341.6 **million vaccinated persons:**

Table 4: Contextual Data of Covid-19 and Measles Vaccine: EudraVigilance

# of	Covid-19 Vaccine	Measles Vaccine
Approximate Number of Individuals Vaccinated	341628772	673200000
Total number of Adverse Event Reports on EudraVigilance	1800000	48913

281 **The risk of an adverse reaction is thus 13 times higher for the COVID "vaccines", based on the VAERS data from the USA, and 72 times higher based on the Eudra-Vigilance data, than for the measles vaccines** .

282 **To base the necessity of a COVID "vaccination" as an analogue on the recommendation of the measles vaccination thus lacks any basis not only medically but also ethically.**

1.5. First studies: connection between mRNA "vaccination" and side effects

283 The following are worldwide **peer-reviewed publications** published up to 4 June 2021.

284 The list is then published (at the back N 433 ff. and at the back N 551 ff.) for the worldwide publications until 26 October 2021 and 1 March 2022 respectively.

285 Despite the following **5 publications on heart problems, 44 publications on life-threatening coagulation disorders (thromboses, etc.) and one publication on possible fatal consequences of the COVID "vaccinations", the** "vaccinations" for adolescents were approved in June 2021, although it was already obvious at that time that adolescents were in no way threatened by SARS-CoV-2.[208] How "Swissmedic" could come to a positive "cost-benefit ratio" under these circumstances is therefore in no way comprehensible.

1.5.1. Heart problems (myocarditis etc.): 5 publications

286 By **4 June 2021,** the following **5 peer-reviewed publications** had appeared in which an association between the occurrence of heart problems (myocarditis, myopericarditis, pericarditis, perimyocarditis, etc.) and the COVID "vaccinations" was proven (or at least a significant suspicion in this respect was shown):

- GATTI et al, Influenza Vaccination and Myo-Pericarditis in Patients Receiving Immune Checkpoint, 04.01.2021, https://pubmed.ncbi.nlm.nih.gov/33406694/

208 Rear N 642 ff.

- CALDERON-COLMENERO et al , Acute myocarditis after administration of BNT162b2 vaccine against COVID-19, 01.03.2021, *https://www.revespcardiol.org/en-linkresolver-acute-myocarditis-after-administration-bnt162b2-S188558572100133X*
- BOIVIN et al. , Premature myocardial infarction or side effect of COVID-19 vaccine, 02.03.2021, https://pubmed.ncbi.nlm.nih.gov/33824804/
- AMMIRATI et al. , Temporal relationship between the second dose of BNT162b2 mRNA Covid-19 vaccine and cardiac involvement in a patient with previous SARS-COV-2 infection, 31.03.*2021, https://www.sciencedirect.com/science/article/pii/S2352906721000622*
- MOUCH et al , Myocarditis following COVID-19 mRNA vaccination, 28.05.2021, *https://pubmed.ncbi.nlm.nih.gov/34092429/*

1.5.2. Coagulation disorders etc. (thromboses, cerebral strokes etc.): 44 publications

287 By **4 June 2021, 44 peer-reviewed publications had been** published in which a connection between the occurrence of coagulation disorders including associated consequences (thromboses, strokes, etc.) and COVID "vaccinations" was proven (or at least a considerable suspicion in this regard was shown):

- ZUR-WYROZUMSKA, CAd26.COV2-S vaccination may reveal hereditary thrombophilia: massive cerebral venous sinus thrombosis in a young man with normal platelet count, 28.01.2021, https://pubmed.ncbi.nlm.nih.gov/34632750/
- LORENTE, Idiopathic Ipsilateral External Jugular Vein Thrombophlebitis After Coronavirus Disease (COVID-19) Vaccination, Feb. 24, 2021, https://pubmed.ncbi.nlm.nih.gov/33624509/
- PANOVSKA-STAVRIDIS et al. , A rare case of the superior ophthalmic vein thrombosis and thrombocytopenia following ChAdOx1 nCoV-19 vaccination against SARS-CoV-2, 01.03*.2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8265377/pdf/mjhid-13-1-e2021048.pdf*
- LEE et al , Thrombocytopenia following Pfizer and Moderna SARS-CoV-2 vaccination, 09.03.2021, https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8014568/
- MALAYALA et al , Purpuric rash and thrombocytopenia after mRNA-1273 (Modern) COVID-19 vaccine, 25.03.2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7996471/
- CARLI et al. , Deep venous thrombosis (DVT) occurring shortly after second dose of SARS-CoV-2 mRNA vaccine, 01.04.2021, https://pubmed.ncbi.nlm.nih.gov/33687691/
- HELMS et al. , Severe and refractory immune thrombocytopenia occurring after SARS-CoV-2 vaccination, 06.04.2021, https://pubmed.ncbi.nlm.nih.gov/33854395/

- AGOSTINO et al. , A rare case of cerebral venous thrombosis and disseminated intravascular coagulation temporally associated with administration of COVID-19 vaccine, 08.04.2021, https://pubmed.ncbi.nlm.nih.gov/33917902/
- FRANCHINI et al , Cerebral venous thrombosis and thrombocytopenia after COVID-19 vaccination, 08.04.2021, https://pubmed.ncbi.nlm.nih.gov/33878469/
- GREINACHER et al. , Thrombotic thrombocytopenia after vaccination with ChAdOx1 nCov-19, 09.04.2021, https://www.nejm.org/doi/full/10.1056/NEJMoa2104840?query=recirc_curatedRelated_article
- WOLF et al. , Thrombocytopenia and intracranial venous sinus thrombosis after exposure to the "AstraZeneca COVID-19 vaccine", 09.04.2021, https://pubmed.ncbi.nlm.nih.gov/33918932/
- CASTELLI et al. , Cerebral venous sinus thrombosis associated with thrombocytopenia after COVID-19 vaccination, 12.04.2021, https://pubmed.ncbi.nlm.nih.gov/33845870/
- MEHTA et al , Cerebral venous sinus thrombosis and thrombocytopenia after COVID-19 vaccination: report of two cases in the United Kingdom, 20.04.2021, https://www.sciencedirect.com/science/article/pii/S088915912100163X
- HAAKONSEN et al. , Deep venous thrombosis more than two weeks after COVID-19 vaccination, 28.04.2021, https://pubmed.ncbi.nlm.nih.gov/33928773/
- PORRES-AGUILAR et al. , COVID-19 vaccine-induced immune-immune thrombotic thrombocytopenia: an emerging cause of splanchnic vein thrombosis, 30.04.2021, https://www.sciencedirect.com/science/article/pii/S1665268121000557
- WELSH et al. , Thrombocytopenia, including immune thrombocytopenia after receiving COVID-19 mRNA vaccines reported to the Vaccine Adverse Event Reporting System (VAERS), 30.04.*2021, https://www.sciencedirect.com/science/article/pii/S0264410X21005247*
- BAYAS et al. , Bilateral superior ophthalmic vein thrombosis, ischemic stroke and immune thrombocytopenia after vaccination with ChAdOx1 nCoV-19, 01.05.2021, https://pubmed.ncbi.nlm.nih.gov/33864750/
- TARAWNEH et al , Immune thrombocytopenia in a 22-year-old post Covid-19 vaccine, 01.05.2021, https://pubmed.ncbi.nlm.nih.gov/33476455/
- TAJSTRA et al. , Acute thrombosis of the coronary tree after vaccination against COVID-19, 03.05.2021, https://www.sciencedirect.com/science/article/pii/S1936879821003988
- YOCUM et al. , Thrombotic thrombocytopenic purpura after vaccination with Ad26.COV2-S, 04.05.2021, https://pubmed.ncbi.nlm.nih.gov/33980419/

- IDOGUN et al. , Newly diagnosed idiopathic thrombocytopenia after COVID-19 vaccine administration, 05.05.2021, https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8176657/
- POTTEGÅRD et al. , Arterial events, venous thromboembolism, thrombocytopenia and bleeding after vaccination with Oxford-AstraZeneca ChAdOx1-S in Denmark and Norway: population-based cohort study, 05.05.2021, https://pubmed.ncbi.nlm.nih.gov/33952445/
- WORKING GROUP, Diagnostic-therapeutic recommendations of the ad-hoc FACME expert working group on the management of cerebral venous thrombosis related to COVID-19 vaccination, 06.05.2021, https://www.sciencedirect.com/science/article/pii/S0213485321000839
- CICCONE et al. , The importance of recognizing cerebral venous thrombosis following anti-COVID-19 vaccination, 10.05.2021, https://pubmed.ncbi.nlm.nih.gov/34001390/
- JAMME et al , Fatal cerebral venous sinus thrombosis after COVID-19 vaccination, 13.05.2021, https://pubmed.ncbi.nlm.nih.gov/33983464/
- JONES et al , Limb ischemia and pulmonary artery thrombosis after ChAdOx1 nCoV-19 vaccine (Oxford-AstraZeneca): a case of vaccine-induced immune thrombotic thrombocytopenia, 14.05.2021, https://pubmed.ncbi.nlm.nih.gov/33990339/
- DOUXFILS et al. , Hypothesis behind the very rare cases of thrombosis with thrombocytopenia syndrome after SARS-CoV-2 vaccination, 15.05.2021, https://www.sciencedirect.com/science/article/pii/S0049384821003315
- GUPTA et al , Covid-19 vaccine-induced thrombosis and thrombocytopenia: a commentary on an important and practical clinical dilemma, 18.05*.2021, https://www.sciencedirect.com/science/article/pii/S0033062021000505*
- GRAS-CHAMPEL et al. , Atypical thrombosis associated with the vaccine VaxZevria® (AstraZeneca): data from the French network of regional pharmacovigilance centres, 19.05.2021, https://pubmed.ncbi.nlm.nih.gov/34083026/
- MCGONAGLE et al , Mechanisms of immunothrombosis in vaccine-induced thrombotic thrombocytopenia (VITT) compared to natural SARS-CoV-2 infection, 19.05.2021, https://www.sciencedirect.com/science/article/pii/S0896841121000706
- ALTHAUS et al. , Procoagulant antibody-mediated procoagulant platelets in immune thrombotic thrombocytopenia associated with SARS-CoV-2 vaccination, 20.05.2021, https://pubmed.ncbi.nlm.nih.gov/34011137/
- POMARA et al , Post-mortem findings in vaccine-induced thrombotic thrombocytopenia (covid-19), 20.05*.2021, https://haematologica.org/article/view/haematol.2021.279075*
- GRAF et al. , Immediate high-dose intravenous immunoglobulins followed by direct treatment with thrombin inhibitors is crucial for survival in vaccine-induced immune

thrombotic thrombocytopenia Sars-Covid-19-vector adenoviral VITT with venous thrombosis of the cerebral sinus and portal vein, 22.05.2021, https://pubmed.ncbi.nlm.nih.gov/34023956/

- GEERAERTS et al. , Vaccine-induced cerebral venous thrombosis and thrombocytopenia. Oxford- AstraZeneca COVID-19: a missed opportunity for rapid return on experience, 24.05.2021, https://www.sciencedirect.com/science/article/pii/S235255682100093X
- CATTANEO, Thrombosis with thrombocytopenia syndrome associated with COVID-19 viral vector vaccines, 25.05*.2021, https://www.sciencedirect.com/science/article/pii/S0953620521001904*
- DIAS et al , Cerebral venous thrombosis after BNT162b2 mRNA SARS-CoV-2 vaccine, 25.05*.2021, https://www.sciencedirect.com/science/article/pii/S1052305721003098*
- LONG et al. , Thrombosis with thrombocytopenia syndrome associated with COVID-19 vaccines, 25.05.2021, https://www.sciencedirect.com/science/article/pii/S0735675721004381
- RZYMSKI et al. , Thrombotic thrombocytopenia after vaccination with COVID-19: in search of the underlying mechanism, 27.05.2021, https://pubmed.ncbi.nlm.nih.gov/34071883/
- DHOOT et al. , Thrombocytopenia and splanchnic thrombosis after vaccination with Ad26.COV2.S successfully treated with transjugular intrahepatic portosystemic shunt and thrombectomy, 31.05.2021, https://onlinelibrary.wiley.com/doi/10.1002/ajh.26258
- FUEYO-RODRIGUEZ et al , Secondary immune thrombocytopenia putatively attributable to COVID-19 vaccination, 31.05.2021, https://casereports.bmj.com/content/14/5/e242220.abstract
- GANZEL et al , Immune thrombocytopenia following Pfizer-BioNTech BNT162b2 mRNA COVID-19 vaccine, 01.06.2021, https://pubmed.ncbi.nlm.nih.gov/34155844/
- GRESELE et al. , Management of cerebral and splanchnic vein thrombosis associated with thrombocytopenia in subjects previously vaccinated with Vaxzevria (AstraZeneca): position statement of the Italian Society for the Study of Hemostasis and Thrombosis (SISET), 01.06.2021, https://pubmed.ncbi.nlm.nih.gov/33871350/
- JEFFREY et al , Idiopathic thrombocytopenic purpura and the Modern Covid-19 vaccine, 01.06.2021, *https://www.annemergmed.com/article/S0196-0644(21)00122-0/fulltext*
- SCHULTZ et al. , Thrombosis and thrombocytopenia after vaccination with ChAdOx1 nCoV-19, 03.06.2021, https://www.nejm.org/doi/full/10.1056/NEJMoa2104882?query=recirc_curatedRelated_article

1.5.3. Deaths: 1 publication

288 By **4 June 2021,** the following **peer-reviewed publication** had been published, in which a connection between the death of two vaccinated persons and the COVID "vaccinations" post mortem was proven (or at least a significant suspicion in this respect was shown):

- POMARA et al , COVID-19 Vaccine and Death: Causality Algorithm According to the WHO Eligibility Diagnosis, 26.05.2021, https://pubmed.ncbi.nlm.nih.gov/34073536/

289 The authors called for an autopsy to be declared mandatory for all deaths occurring in a temporal association with COVID "vaccination".

2. Effectiveness

2.1. Efficacy data in adults

290 As far as can be seen, there had been no changes in the official efficacy data for adults up to this point.

2.2. Efficacy claims in adolescents

2.2.1. Minimal therapeutic benefit for mere trivial events

291 For Comirnaty®, **100% efficacy** was announced for "confirmed COVID disease" in adolescents 12-15 years of age, because **16** of 1129 subjects (prevalence 1.4%) in the placebo group vs. **0** of 1131 subjects in the vaccination group had "confirmed COVID disease". [209]

292 For Spikevax®, an **efficacy of 93.3-100%** for "confirmed COVID disease" in adolescents aged 12 years and older was proclaimed in the SmPC because, depending on one of the two case definitions used, **4 versus 0** or **7 versus 1** "confirmed COVID disease" was reported in the placebo versus vaccine group in the 3732 study participants.[210] In the original publication, 4 cases of "confirmed COVID disease" were reported for Spikevax® in the placebo group and none in the vaccine group.[211]

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209 FRENCK et al, "Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents," 27 May 2021, https://www.nejm.org/doi/pdf/10.1056/NEJMoa2107456?articleTools=; Internet archive, FN 140.

210 Internet archive, "Fachinformation Spikevax", status 09.2021, https://web.archive.org/web/20211022194442/https://www.swissmedicinfo.ch/ShowText.aspx?textType=FI&lang=DE&authNr=68267.

211 ALI et al, "Evaluation of mRNA-1273 SARS-CoV-2 Vaccine in Adolescents", 09.12.2021, https://www.nejm.org/doi/full/10.1056/nejmoa2109522.

293 The proclaimed effectiveness of 93.3-100% is again based on the use of relative risk reduction, which is not meaningful without contextual information (see N 196 ff.). In addition, this allegedly high efficacy relates exclusively to non-severe COVID cases.

294 Since severe COVID courses in children are extremely rare (see N 688 f.), the number of participants in this study was too small ("underpowered") to be able to draw any conclusions in this regard.

2.2.2. No data for "severe" diseases

295 Neither the pivotal study of Comirnaty® nor Spikevax® reported "severe COVID disease" for adolescents 12 years and older.[212]

296 The proof that the "vaccination" could protect adolescents from a life-threatening or disabling disease is not provided in this way either, since no corresponding events occurred at all, but this is a compulsory prerequisite for a temporary authorisation (above N 189 ff.).

297 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 young people from a serious (life-threatening or disabling) disease.

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

298 Already at the time of the approval of the COVID "vaccinations" for children and adolescents aged 12 years and older, it became apparent that a previous illness reliably protects against a renewed infection: In a large-scale American study with over 150,000 patients, published on 15 March 2021, it was shown that having had the disease protected against a recurrence of symptomatic disease with an "efficacy" of 84.5%.[213] This early study joins a total of **at least 37 publications and pre-print publications that have** also concluded up to this point that having been through the disease produces a broad and long-lasting immune response or protects against COVID disease at least as well or even better than "vaccination" (for a continuation of the list, see back N 478):

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212 FRENCK et al, "Safety, Immunogenicity, and Efficacy of the BNT162b2 Covid-19 Vaccine in Adolescents," 27 May 2021, https://www.nejm.org/doi/pdf/10.1056/NEJMoa2107456?articleTools=. See also source(s) in ALI et al, FN. 211.

213 SHEEHAN et al , "Reinfection Rates among Patients who Previously Tested Positive for COVID-19: a Retrospective Cohort Study", 15 Mar 2021, https://academic.oup.com/cid/article/73/10/1882/6170939?login=false.

- JUNO et al. , Humoral and circulating follicular helper T cell responses in recovered patients with COVID-19, 13.07.2020, https://www.nature.com/articles/s41591-020-0995-0
- LE BERT et al , SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected controls, 15.07.*2020, https://www.nature.com/articles/s41586-020-2550-z*
- HOULIHAN et al , Pandemic peak SARS-CoV-2 infection and seroconversion rates in London frontline health-care workers, 25.07.2020, *https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31484-7/fulltext*
- COLLINS, Immune T Cells May Offer Lasting Protection Against COVID-19, 28.07.*2020, https://directorsblog.nih.gov/2020/07/28/immune-t-cells-may-offer-lasting-protection-against-covid-19/*
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- RIPPERGER et al , Orthogonal SARS-CoV-2 serological assays enable surveillance of low-prevalence communities and reveal durable humoral immunity, 17.11.2020, *https://www.cell.com/immunity/fulltext/S1074-7613(20)30445-3*
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- HARTLEY et al , Rapid generation of durable B cell memory to SARS-CoV-2 spike and nucleocapsid proteins in COVID-19 and convalescence, 22 Dec 2020, https://www.science.org/doi/10.1126/sciimmunol.abf8891
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- DAN et al. , Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection, 06.01.2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7919858/pdf/abf4063.pdf
- RODDA et al , Functional SARS-CoV-2-specific immune memory persists after mild COVID-19, Jan 07, 2021, *https://www.cell.com/cell/fulltext/S0092-8674(20)31565-8?_returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS0092867420315658%3Fshowall%3Dtrue*
- DAN et al. , Lasting immunity found after recovery from COVID-19, 26.01.2021, https://www.nih.gov/news-events/nih-research-matters/lasting-immunity-found-after-recovery-covid-19#main-content
- PILZ et al. , SARS-CoV-2 re-infection risk in Austria, 13.02.2021, https://onlinelibrary.wiley.com/doi/full/10.1111/eci.13520
- LE BERT et al. , Highly functional virus-specific cellular immune response in asymptomatic SARS-CoV-2 infection, 01.03.*2021, https://rupress.org/jem/article/218/5/e20202617/211835/Highly-functional-virus-specific-cellular-immune*
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- WANG et al , Exposure to SARS-CoV-2 generates T-cell memory in the absence of a detectable viral infection, 19.03.2021, https://www.nature.com/articles/s41467-021-22036-z
- CAMARA et al. , Differential effects of the second SARS-CoV-2 mRNA vaccine dose on T cell immunity in naïve and COVID-19 recovered individuals, 22.03.*2021, https://www.biorxiv.org/content/10.1101/2021.03.22.436441v1*

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- JANE Hall et al , SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre prospective cohort study, 17.04.2021, *https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00675-9/fulltext*
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- TURNER et al. , SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans, 24.05.2021, https://www.nature.com/articles/s41586-021-03647-4
- CALLAWAY, Had COVID? You'll probably make antibodies for a lifetime, 26.05.2021, https://www.nature.com/articles/d41586-021-01442-9
- VITALE et al. , Assessment of SARS-CoV-2 Reinfection 1 Year After Primary Infection in a Population in Lombardy, Italy, 28.05.2021, https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2780557

III. State of knowledge at the end of 2021 (approvals "Booster" and children)

1. Risks

1.1. Toxic effect of the spike protein s

299 By the end of 2020, the preclinical pharmacokinetic studies had already 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 (front N 146 ff.). But it was not only the LNP that was examined in a completely inadequate manner with regard to its toxicity. The same applies to the effect of the spike protein on the human body:

300 After administration of the COVID "vaccination", the spike protein is produced in the cytosol of the cell based on the "blueprint" of the mRNA, which subsequently triggers the immune response at the cell surface.[214] How high the effectively produced amount of spike proteins is 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 have been carried out in this regard (see N 138 ff.). It can therefore not be ruled out that the amount of spike proteins produced after a "vaccination" is subject to a high inter-individual variability, which is likely to result in a very different susceptibility to side effects in this context. In view of the toxic effect of the spike protein described below, this is an untenable situation:

301 Severe COVID diseases are often accompanied by **pathological activation of blood coagulation.**[215] The **central role of the spike protein in this complication** was already recognised by the end of 2020.[216] At least two different mechanisms exist for triggering blood clotting[217] :

302 1. when the spike protein is expressed in vascular endothelial cells - the innermost cell layer of blood vessels - an immune response to the spike protein can destroy these cells. The resulting vascular lesion activates blood clotting. Cytotoxic T cells, but also antibodies that trigger the complement system and other immune effector mechanisms can be involved in this immune reaction.

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214 SCNAT, FN 17.

215 CAMPBELL et al, "Comparison of the coagulopathies associated with COVID-19 and sepsis", 18.05.2021, https://pubmed.ncbi.nlm.nih.gov/34027292/.

216 FRYDMAN et al , "The Potential Role of Coagulation Factor Xa in the Pathophysiology of COVID-19:A Role for Anticoagulants as Multimodal Therapeutic Agents", 07.10.2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7541169/.

217 PALMER et al. , FN 46.

303 2.spike protein molecules can be cleaved and one of the products (the S1 fragment) can be released from the cell. S1 fragments that are formed in the bloodstream or enter it after being synthesised elsewhere in the body can bind directly to blood platelets (thrombocytes) and activate them. This in turn triggers blood clotting.

304 The second mechanism is significant because it does not require an immune response and can therefore be triggered immediately even in individuals who do not yet have immunity. The first mechanism is most effective in individuals who already have immunity to the spike protein, either due to infection with the virus or a previous "vaccination". It is important to note that the underlying mechanism of cell damage also works in other tissues - **any cell in the body that expresses the spike protein thus becomes a target for the immune system**.

305 **Toxic effects of the spike protein have been documented both in COVID sufferers and in the "vaccinated".**[218] Accordingly, knowledge of how long and where these toxic spike protein molecules produced by the mRNA "vaccinations" reside in the human body is central to assessing the safety of the drug. In this context, a study published in *Circulation Research as of* April 2021 showed that the **isolated spike protein** (in the study, the effects were examined in hamsters with a pseudovirus that was coated with spike proteins) **cause vascular damage, which in turn** can **lead to cardiovascular events such as heart attacks, strokes, etc.** [219]

306 Even at that time, these results unmistakably indicated that there was probably a causal relationship between mRNA "vaccinations" and heart problems, which in reality also manifested itself openly: for example, according to the **"**Emergency Department Situation Report"[220] from the Robert Koch Institute (RKI), **from spring 2021 - i.e. with the start of the "vaccination campaign" - a significant and sustained increase in** patients who had to visit a hospital emergency department as a result of a **cardiological illness was** observed:

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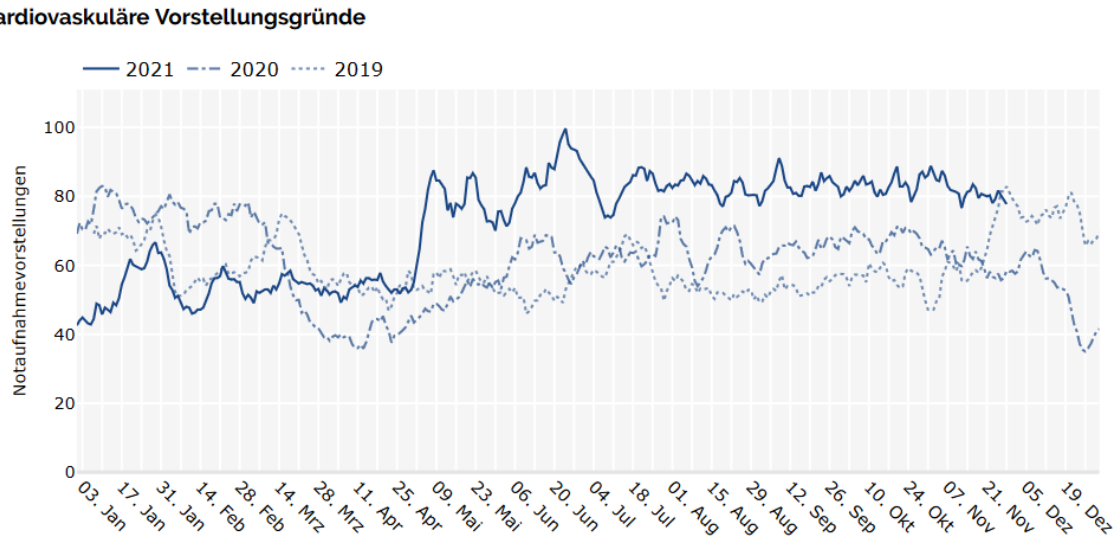
218 LEVY, "Canceling the spike protein", 18.10.2021, http://orthomolecular.org/resources/omns/v17n24.shtml.

219 Salk, "The novel coronavirus' spike protein plays additional key role in illness", 30.04.2021, https://www.salk.edu/news-release/the-novel-coronavirus-spike-protein-plays-additional-key-role-in-illness/?s=09; LEI et al, "SARS-CoV-2 spike protein impairs endothelial function via downregulation of ACE 2", 31.03.2021, https://www.ahajournals.org/doi/10.1161/CIRCRESAHA.121.318902.

220 RKI, "Emergency Department Situation Report", 01.12.2021, *https://edoc.rki.de/bitstream/handle/176904/9043/SitRep_de_2021-12-01.pdf?sequence=1&isAllowed=y.*



307 In children and adolescents, as well as in adults, cardiovascular events such as acute heart disease/heart attack, bleeding/disruption of blood clotting and thrombosis/embolism and strokes are among the frequent serious adverse effects associated with COVID "vaccination" according to *EMA* data (Supplement **9**, p. 224 f.).

BO: Supplement **9:** Daily report of serious adverse reactions to COVID-19 vaccinations, as of 01.04.2022

308 Contrary to the official euphemistic pronouncements, it can by no means be assumed that there was only "minimal systemic exposure"[221] of the mRNA "vaccines" at the injection site in the human body: Rather, the spike protein produced by the mRNA "vaccines" could be detected in plasma.[222] And **the exposure throughout the body is long-lasting:** the results of a study published in the *Journal of Immunology in* October 2021 showed that the spike protein produced by Comirnaty® could be detected in exosomes in the plasma of vaccinated individuals for **over 4 months**.[223] The continued expression of the toxic spike protein - further studies detected this up to 8 weeks after the "vaccination" - obviously increases the potential of possible side effects. [224]

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221 On this point, see N 793 ff.

222 OGATA et al, "Circulating severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine antigen detected in the plasma of mRNA-1273 vaccine recipients", 20 May 2021, *https://academic.oup.com/cid/article/74/4/715/6279075?login=false.*

223 BANSAL et al, "Cutting Edge:Circulating Exosomes with COVID spike protein are induced by BNT162b2 (Pfizer-BioNTech) Vaccination prior to development of antibodies: a novel mechanism for immune activation by mRNA vaccines", 15.10.2021, *https://www.jimmunol.org/content/early/2021/10/11/jimmunol.2100637*Doctors for COVID ethics, "Long-term persistence of the SARS-CoV-2 spike protein:evidence and implications", 21.12.2021, https://doctors4covidethics.org/long-term-persistence-of-the-sars-cov-2-spike-protein-evidence-and-implications-2/.

224 RÖLTGEN et al, "Immune imprinting, breadth of variant recognition, and germinal centre response in human SARS-CoV-2 infection and vaccination", 25.01.2022, https://pubmed.ncbi.nlm.nih.gov/35148837/.

309 In view of these data, it seems incomprehensible why vaccine manufacturers have unanimously decided to develop an mRNA "vaccine" with which the blueprint for the toxic spike protein is injected without first mitigating its toxicity, e.g. by means of mutagenesis, and not the blueprint for one of the other suitable - less harmful - surface proteins .[225]

1.2. Comirnaty®: Revealed falsifications in the registration studies

310 According to Art. 5 Para. 1 lit. a AMZV (= 2nd section "Medicinal products for human *use*"), the marketing authorisation documentation on the clinical trial must prove "that the investigations on humans have been carried out according to the recognised rules of good practice of clinical trials", i.e. according to the rules of *"Good Clinical Practice (GCP)".*

311 A publication of 2 November 2021 in the renowned *British Medical Journal* reveals that the phase 3 trial of the Pfizer/BioNTech vaccine was not conducted in a *GCP-compliant manner* at American study centres supervised by the contract research organisation *Ventavia*. Reports include **protocol deviations, falsification of data, poor laboratory management, incorrect storage of vaccine vials and untrained study staff. In** addition, data from study participants were unblinded prematurely, leading to falsification of the results and rendering them completely useless. Overall, the incidents and deficiencies uncovered are considered significant.[226]

312 *Based on this publication, not only the data integrity of the Pfizer/BioNTech pivotal study itself, but also the integrity of the marketing authorisation per se must be questioned. The registration studies of Comirnaty® were demonstrably not carried out according to the rules of GCP, as required by Art. 5 AMZV, among others. Normally, such findings would force marketing authorisation holders and marketing authorisation authorities to conduct extensive investigations and would result in a recall of the medicinal product concerned until the results of the investigations were available. Despite being aware of this publication, Swissmedic has not reacted to date and continues to maintain the positive benefit-risk ratio.*

BO: Supplement **10:** E-mail response regarding serious deficiencies in the conduct of phase 3 studies of Pfizer mRNA vaccines: Consequences?, Swissmedic, 04.11.2021

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225 Pharmazeutische Zeitung, "That's what makes SARS-CoV-2", 03.06.2020, https://www.pharmazeutische-zeitung.de/das-macht-sars-cov-2-aus-117916/.

226 THACKER, "Covid-19: Researcher blows the whistle on data integrity issues in Pfizers's vaccine trial", 02.11.2021, https://www.bmj.com/content/375/bmj.n2635.

1.3. Comirnaty®: Falsified death reports, more deaths in vaccination group

313 In the 6-month report ("Data Cut-Off" mid-March 2021), of which a first preprint version was available online on 28 July 2021[227] and which was officially published in the *New England Journal of Medicine* (*NEJM) on* 4 November 2021[228] , Pfizer reported 15 deaths in the vaccine group versus 14 deaths in the placebo group. These were not "COVID deaths" but "all cause mortality". It should be emphasised that one study participant in the vaccine group died of COVID pneumonia. The *FDA document* "*Summary Basis for Regulatory Actions*" of 8 November 2021 proved (p.23) that the death figures reported by Pfizer were incorrect: Instead of 14 deaths, 17 deaths were recorded in the placebo group, and in the vaccine group it was 21 instead of 15:[229]

> From Dose 1 through the March 13, 2021 data cutoff date, there were a total of 38 deaths, 21 in the COMIRNATY group and 17 in the placebo group. None of the deaths were considered related to vaccination.

314 The "error" does not inspire much confidence in the data and its quality and makes the claim that the deaths have nothing to do with the "vaccination" seem less credible.[230] The case numbers of deaths were small, but nevertheless raise eyebrows, since "all cause mortality" has always been considered a sensitive marker for the safety of a drug.

315 A well-founded analysis by the *Canadian COVID Care Alliance* ("*CCCA"*) also revealed the following:[231] In addition to the 15 (vaccine group) and 14 (placebo group) deaths officially reported in the 6-month data, there were 5 further deaths which were also reported hidden in the 6-month report: *"...3 participants in the BNT162b2 group and 2 in the original placebo group who received BNT162b2 after unblinding died*".[232] **In total, 23 study participants who had received the vaccine and 14 study participants who had received placebo officially died.** These figures still differed from those in the FDA document "*Summary Basis for Regulatory Actions*"[233] , which once again indicated that the marketing authorisation holder was not working properly.

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227 THOMAS et al, "Six Month Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine", preprint dated 28/07/2021, https://www.medrxiv.org/content/10.1101/2021.07.28.21261159v1.

228 THOMAS et al, "Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months", 04 Nov 2021, https://www.nejm.org/doi/full/10.1056/nejmoa2110345, especially "Supplementary appendix", Table S4.

229 FDA, "Summary Basis for Regulatory Action", 08.11.2021, https://www.fda.gov/media/151733/download.

230 BERENSON, "More people died in the key clinical trial for Pfizer's Covid vaccine than the company publicly reported", 16.11.2021, *https://alexberenson.substack.com/p/more-people-died-in-the-key-clinical?r=73uzx&utm_campaign=post&utm_medium=web&utm_source=&s=r.*

231 Canadian Covid Care Alliance, FN 133.

232 THOMAS et al, "Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine through 6 Months," 04 Nov 2021, https://www.nejm.org/doi/full/10.1056/nejmoa2110345.

233 FDA, FN 229.

316 Nine of the "vaccine"-associated deaths and five of the deaths in the placebo group were attributed to cardiovascular events.

317 Swissmedic was sent this analysis, which clearly and well-foundedly questioned the positive benefit-risk profile of Comirnaty®, on 04.01.2022 with a request for a statement. In a reply letter dated 01.02.2022, Swissmedic did not address the data in any way, but instead implied incoherently: "*As you can see, the assessment, evaluation and ultimately decision on the authorisation and life cycle of medicinal products in general and of Covid-19 relevant medicinal products in particular is in good hands at Swissmedic and the only legitimate hands under therapeutic products law to ensure the safety, efficacy and quality of these therapeutic products for patients.* "

BO: Supplement **11:** E-mail regarding analysis of the Pfizer study by the Canadian Covid Care Alliance, EpiLunar Partners AG, 04.01.2022

BO: Supplement **12:** E-mail response regarding analysis of the Pfizer study by the Canadian Covid Care Alliance, Swissmedic, 01.02.2022

1.4. Comirnaty®: More (serious) events in vaccination group

318 In the well-founded analysis of the *Canadian COVID Care Alliance* ("*CCCA*")[234] it was also found that the **6-month data of the** registration studies of the COVID "vaccine" from Pfizer/BioNTech, clearly **showed that the "vaccination" is not associated with any benefit, but with great harm**: In the vaccine group, 5241 adverse events occurred, in the placebo group 1311, for which a connection with the study medication was established ("related"). For serious adverse events, the number of cases was 262 (vaccine group) vs. 150 (placebo group).

319 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 clear warning signal regarding the safety of the mRNA "vaccines".

1.5. Comirnaty®: Alarming Interim Report ("PSUR")

320 **Swissmedic** explicitly **requested Pfizer** (Annex **2**, p. 8) **and Moderna** (Annex **3**, p. 9) **in the marketing authorisation letters to** submit a summary of the *Risk Management Plan no later than* 60 days after the granting of the temporary marketing authorisation, to monitor safety signals with the highest priority, to report these monthly and to **submit all** Periodic ***Safety Update Reports*** ("*PSUR*") **submitted to the EMA to** Swissmedic.

234 Canadian Covid Care Alliance, FN 133.

PSUR No. 1 of Comirnaty® summarised the findings and data on the safety of the "vaccine" over the period 19 December 2020 to 18 June 2021.

BO: Supplement **8:** Periodic Safety Update Report #1 for COVID-19-mRNA-vaccine BNT162b2, 19.08.2021

The report was finalised by Pfizer on 19 August 2021. It can be assumed that the document was also submitted to Swissmedic for review immediately afterwards, as this was explicitly requested by the authorities.

1.5.1. Excessive number of deaths

321 For the observation period, 702 case reports of adverse events from clinical trials and 327,827 case reports of adverse events from the postmarketing phase were listed. All 702 events (100%) that occurred in clinical trials and 100,808/327,827 of the postmarketing events (30.8%) were classified as serious. **46 cases** (**6.6%**) **from the clinical trials and 5069 cases (1.5%) from the postmarketing phase ended fatally** (p.31):

Table 5. Selected Case Characteristics - All Cases Received during the Reporting Interval

Characteristics		All No. of Cases	CT [a,b] No. of Cases	PM No. of Cases
No. of Cases		327,827	702	327,125
Gender	Female	233,948	329	233,619
	Male	75,340	371	74,969
	Unknown/No Data	18539	2	18,537
Case Seriousness	Serious	100,808	702	100,106
	Non-serious	227,019	0	227,019
Case Outcome	Resolved/Resolving	172,162	540	171,622
	Resolved with sequelae	3319	41	3278
	Not resolved	76,960	72	76,888
	Fatal	5115	46	5069
	Unknown	70,271	3	70,268

a. BioNTech is the Sponsor of all Clinical Trials; for the following Clinical Trials (C4591001, C4591005, C4591015, C4591017, C4591020), Pfizer acts as lead development party and for the Clinical Trials (BNT162-03, BNT162-06), BioNTech Third Party act as lead development party.
b. Includes 12 cases from BioNTech and Fosun sponsored Interventional Studies.

322 In the document, the safety signals presented below became particularly visible in connection with Comirnaty®:

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

323 On **14 January 2021,** a report of **23 deaths following COVID "vaccination" in elderly frail Norwegian patients was** published and quickly attracted international interest. At

that time, 43,740 people had been vaccinated against COVID-19 in Norway, a large proportion of whom were nursing home residents. The Norwegian Medicines Agency reported that common adverse effects of the vaccine, such as fever, nausea and diarrhoea, may have contributed to the fatal outcomes in some of these people.[235]

324 According to *PSUR* No.1 (p.3), these incidents led the **Norwegian licensing authority to update its** vaccination **recommendations**, indicating that **caution should be exercised when vaccinating frail elderly people and that decisions should be made on a case-by-case basis:**

> On 15 January 2021, following fatal events involving elderly patients vaccinated with BNT162b2 in Norway, the Norwegian Agency updated their guidance for vaccination, advising that caution and case-by-case judgement should be used when vaccinating frail, elderly subjects.

325 Up to now, there has been no corresponding warning on this subject in the Swiss product information for Comirnaty®.[236]

326 It is noteworthy that the **data situation for elderly and frail people was poor from the beginning**: while it was assumed that 85% of the people for whom COVID-19 could pose a serious threat were over 75 years of age, in the registration trial of Comirnaty® only 804 (4.4%) of the study participants in the vaccine group were ≥ 75 years of age. Although 95% of all people who died of COVID had at least one, on average four, comorbidities, only 21% of the study participants had a comorbidity.[237] Comirnaty® was thus tested in a much healthier and unrepresentative population in the registration studies. For incomprehensible reasons, this point was not criticised anywhere by Swissmedic.

327 Swissmedic does not make any vaccination recommendations itself and refers in its *FAQ to* the vaccination recommendations of the FOPH. There, vaccination of persons over 75 years of age and persons with chronic diseases ("target group 1") was recommended as a priority from the beginning (and still is).[238] This is despite the fact that the **use of Comirnaty®** in *PSUR* No. 1 (p. 5) **in frail patients with concomitant diseases (cardiovascular or neurological diseases, diabetes, chronic obstructive pulmonary disease**

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235 DSRU, "Deaths following COVID-19 vaccination in frail and elderly people in Norway: A Living Pharmacovigilance Evidence Review by the DSRU", 10.02.2021, *https://www.dsru.org/deaths-following-covid-19-vaccination-in-frail-and-elderly-people-in-norway/.*

236 Swissmedicinfo, FN 48.

237 Canadian Covid Care Alliance, FN 133.

238 Swissmedic, FN 201; BAG/EKIF, "Vaccination recommendation for mRNA vaccines against Covid-19", as of 23.05.2022, https://web.archive.org/web/20210414185954if_/https://www.bag.admin.ch/dam/bag/de/dokumente/mt/k-und-i/aktuelle-ausbrueche-pandemien/2019-nCoV/impfempfehlung-covid-19.pdf.download.pdf/Impfempfehlung%20f%C3%BCr%20mRNA-Impfstoffe%20gegen%20Covid-19.pdf.

[COPD]) was **classified as "missing information" .** Despite being aware of this information, Swissmedic took no action.

BO: Supplement **8:** Periodic Safety Update Report #1 for COVID-19-mRNA-vaccine BNT162b2, 19.08.2021

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

328 Various events that had been reported as suspected adverse events in connection with the administration of Comirnaty® were classified in *PSUR No. 1* as "Signals to be determined not to be risks " (p.4):

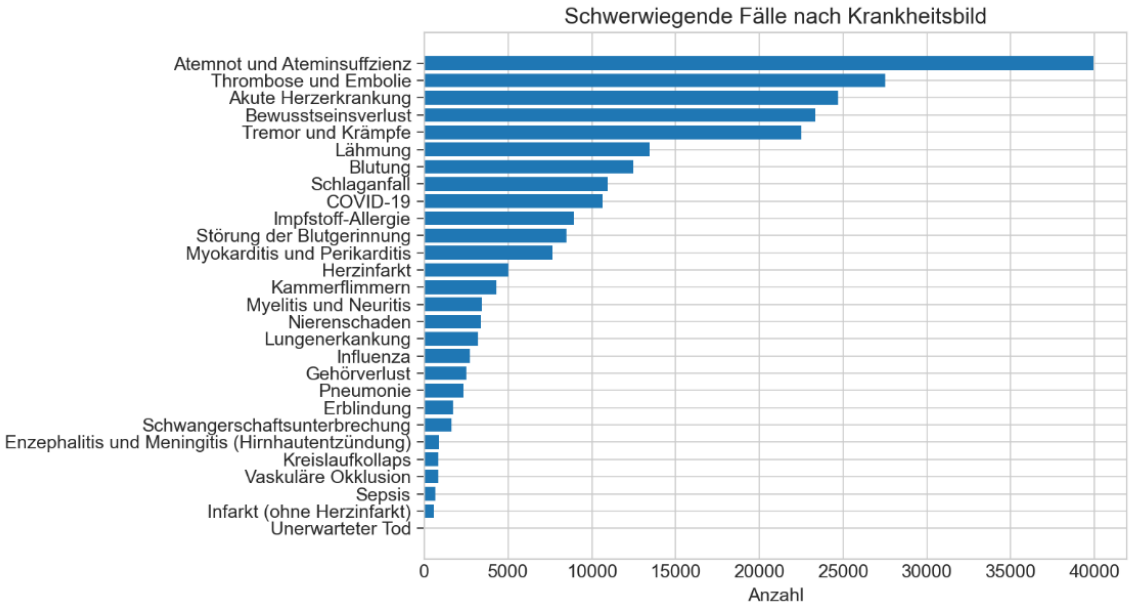
- Signals determined not to be risks:

  Seizure, Thromboembolic events, Delayed skin reaction, Delayed syncope, Eye pain and eye swelling, Herpes zoster including ophthalmic herpes zoster, Appendicitis, Hearing loss and tinnitus, Extensive swelling of the limbs, Reaction associated with dermal fillers, Injection site pruritis, Insomnia, Overdose, Deaths (including elderly or frail individuals), Facial nerve palsy.

329 **Facial paresis"** (facial **paralysis**), **"insomnia"** and **"extensive swelling of the vaccinated limb" were officially listed as adverse effects in the Comirnaty® package leaflet** during the course.[239]

330 In the statistics published by the EMA on suspected adverse reactions, it was already apparent in September 2021, i.e. at the time when Swissmedic submitted *PSUR No. 1* for review, that, among other things, **thromboses and embolisms were** among the most **frequently reported serious suspected adverse reactions** and that **seizures** and a **loss of hearing** were **clearly recognisable** as **safety signals** (Annex **13**, p. 25):

239 Swissmedicinfo, FN 48.



BO: Supplement **13:** Daily report of serious adverse reactions to COVID 19 vaccinations, as of 17.09.2021

1.5.4. Interim conclusion

331 All these indications made it obvious that the data and assessments submitted by Pfizer were not very reliable and that, as a result, the regulatory authority should have acted independently and proactively in order to detect safety signals for the protection of the population itself at an early stage and to be able to initiate appropriate measures adequately.

1.5.5. Conclusion Swissmedic's consideration of the data from PSUR No.1

332 Swissmedic obviously did not take into account the data and findings of *PSUR* No. 1 for its benefit-risk assessment of Comirnaty®, did not initiate an update of the SmPC with regard to important findings, and has actively withheld this important information from the medical profession and the public to date. Swissmedic downplayed the side effects that occurred and concealed the fact that a relevant proportion of the suspected cases of side effects reported in *PSUR No. 1 were* associated with a high morbidity and mortality rate.

333 Although Swissmedic was aware of the inadequate data situation for older people and patients with concomitant diseases and was informed about the deaths in this context, it neither informed the public about this nor suggested that the *ECIF* adjust the vaccination recommendation.

334 While Swissmedic's classification that more than a third of the suspected cases of adverse events were "serious" coincided with the data of *PSUR* No.1, the regulatory authority offi-

cially consistently negated a causal relationship of deaths that occurred in a temporal association with the COVID "vaccination". This was done with the reference that "despite a temporal association, there was no concrete evidence in any case that the vaccination was the cause of the death".[240] More detailed information (e.g. figures and results of post-mortem examinations carried out) showing the reader in a comprehensible way how this conclusion was derived has not been disclosed to date.

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

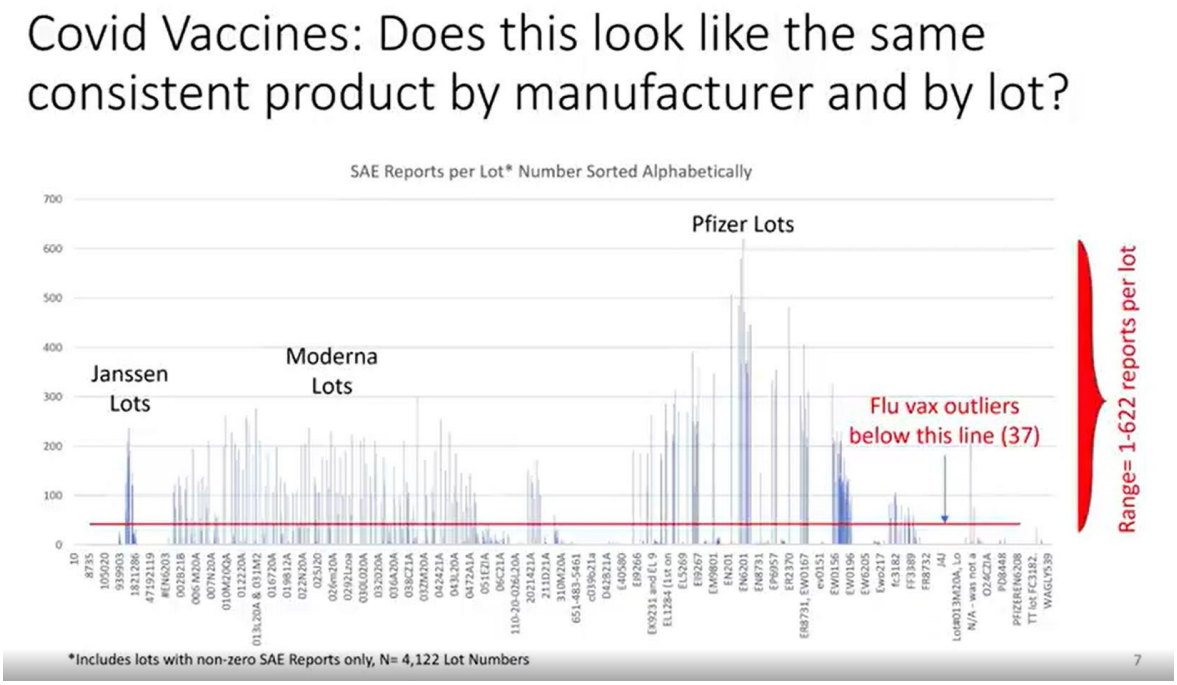
335 According to the product information, "only limited data are available on booster vaccination with Spikevax®".[241] One figure, however, makes one sit up and take notice: In **2 of 167 ("safety set") or 2 of 149 ("per protocol set") study participants, pericarditis was observed in connection with the administration of the booster vaccination,** which corresponds to an **incidence of 1.2% and 1.3%, respectively,** and would thus be classified as **"frequent".** However, the study is so weak that no clear conclusions can be drawn from it, as these case numbers are in the realm of statistical chance.

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

336 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.

337 In December 2021, the first results were published by researchers who found, on the basis of the side effects registered in the US *VAERS* database, that the individual vaccine batches were responsible for the occurrence of severe side effects to a highly variable extent :[242]

240 Swissmedic, FN 1.
241 Swissmedicinfo, FN 71.
242 Team Enigma, "Covid Vax Variability Between Lots - Independent Research by International Team", 15.12.2021, https://www.bitchute.com/video/4HllyBmOEJeY/.



338 While in a study of 22,000 batches of influenza vaccine, 5 or fewer severe adverse events ("SAEs") occurred in almost all batches and this value was exceeded in only two batches (22 SAEs and 37 SAEs), the COVID "vaccine batches" were subject to significant fluctuations.[243]

339 To date, these investigations have been kept quiet in the public media. Even if, in principle, factors such as different reporting behaviour at different locations, where different batches were used, incorrect transport or incorrect storage could have contributed to these differences, the differences are so serious overall that they point to **uneven production in** the COVID "vaccines" and thus to a **serious quality problem.**

1.8. Worldwide reports of side effects continue to rise massively

1.8.1. Data basis

340 Based on the periodic "updates" from Swissmedic (until 05.11.2021) and the American and European databases (until 30.10.2021), the number of adverse reactions (all, serious/serious/serious, deaths) is as follows:[244]

	CH	Children (CH)	EU	Children (EU)	USA	Children (USA)

243 Front Team Enigma, FN 242.

244 Due to late reporting, vaccine doses are backdated: 24.09.21 (CH), 18.09.21 (EU), 02.10.21 (USA).

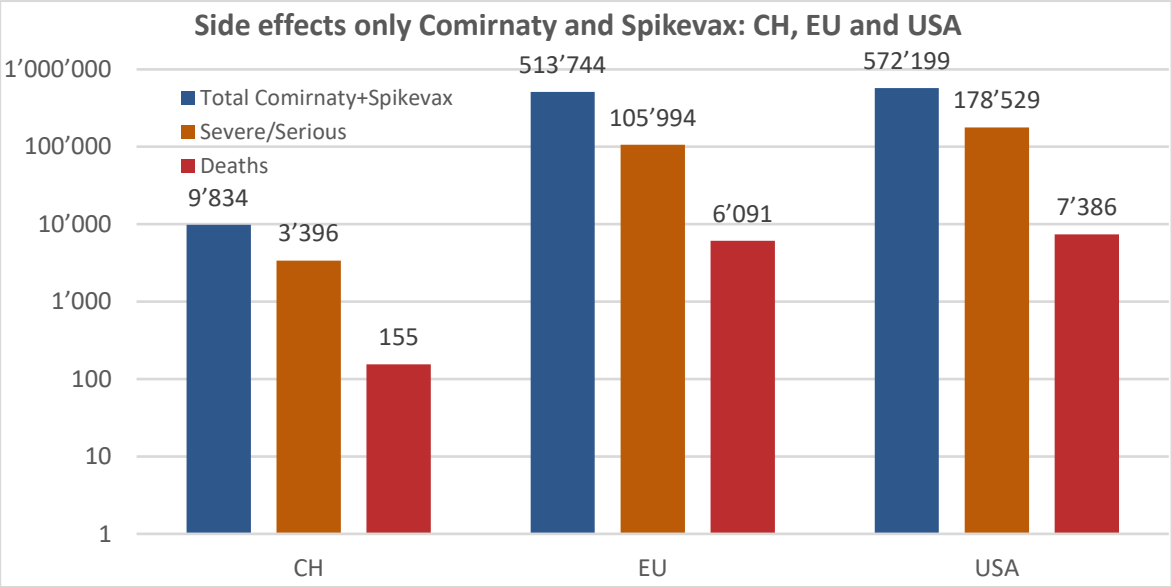
	CH	Children (CH)	EU	Children (EU)	USA	Children (USA)
Comirnaty	2.835		418.935	7.898	279.637	16.606
Ernst Comirnaty	1.173		91.233	2.114	98.769	5.644
Deaths Comirnaty			5.540	24	3.828	29
Spikevax	6.777		94.809	824	292.562	6.224
Ernst Spikevax	2.115		14.761	186	79.760	237
Deaths Spikevax			551	1	3.558	4
Total Comirnaty+ Spikevax	9.834	88	514	832	572	23
Severe/ Ernst	3.396		106	188	179	243
Deaths	155		557	25	7	33
Vaccination doses Comirnaty	3.452.353		410.979.487		226.033.301	
Vaccine doses Spikevax	6.752.039		60.209.914		151.481.614	
Comirnaty+ Spikevax / Mio	963,7		1.090,3		1.515,7	
Severe/ Ernst / 1Mio	332,8		224,9		472,9	
Deaths / million	15,2		12,9		19,6	

341 The following figures were reported in the areas of heart (Cardiac disorders), coagulation disorders and consequences (Blood and lymphatic system disorders) and deaths overall:

	CH total	CH Comir-naty	CH Spike-vax	EU total	EU Comir-naty	EU Spike-vax	USA total	USA Comir-naty	USA Spike-vax
Heart	432	216	216	29	24.059	4.679	38	21.393	16.537
Coagulation disorders	446	109	337	23	19.602	3.030	19	10.636	8.404
Deaths Comirnaty	155			557	5.540	551	7	3.828	3.558
Stillbirths				772	659	113	1182	720	462
per 1 Mio									
Heart	42,3	62,6	32,0	61,0	58,5	77,7	100,5	94,6	109,2
Coagulation disorders	43,7	31,6	49,9	48,0	47,7	50,3	50,4	47,1	55,5
Deaths Comirnaty	15,2			12,9	13,5	9,2	19,6	16,9	23,5
Stillbirths				1,6	1,6	1,9	3,1	3,2	3,0

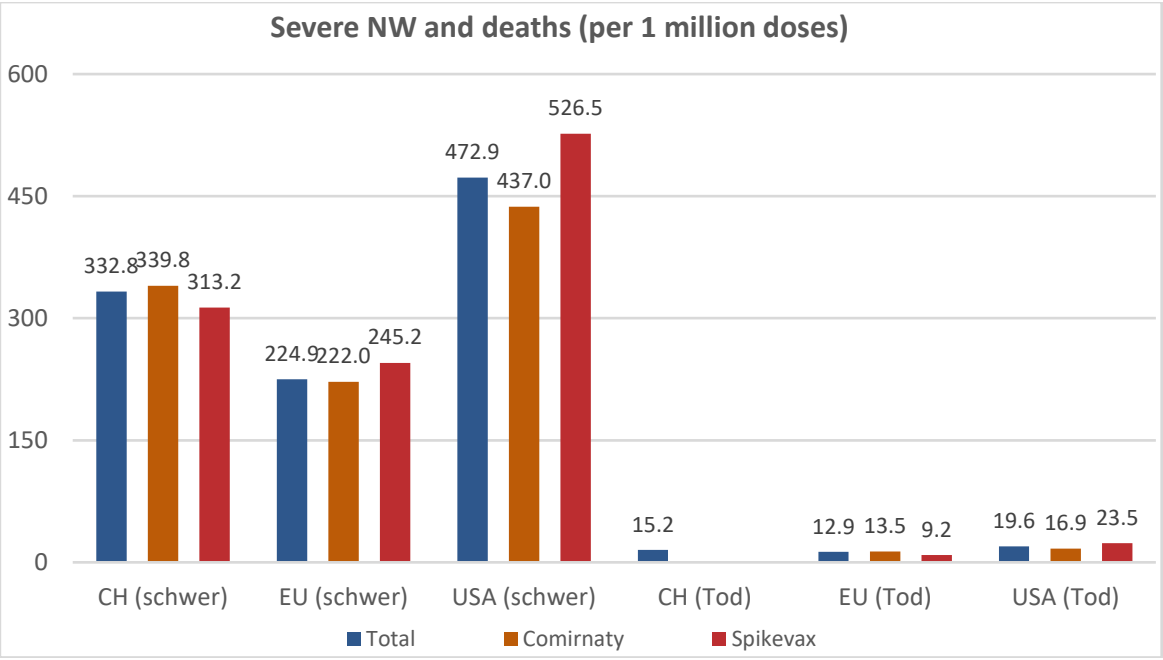
1.8.2. Side effects with Comirnaty® and Spikevax® (absolute numbers)

342 By 05.11.2021 in Switzerland, by 30.10.2021 in the EU and the USA, a total of **1,095,777 adverse reactions had** been reported for Comirnaty® and Spikevax® - of which **287,919 were serious** adverse reactions and **13,632 deaths:**



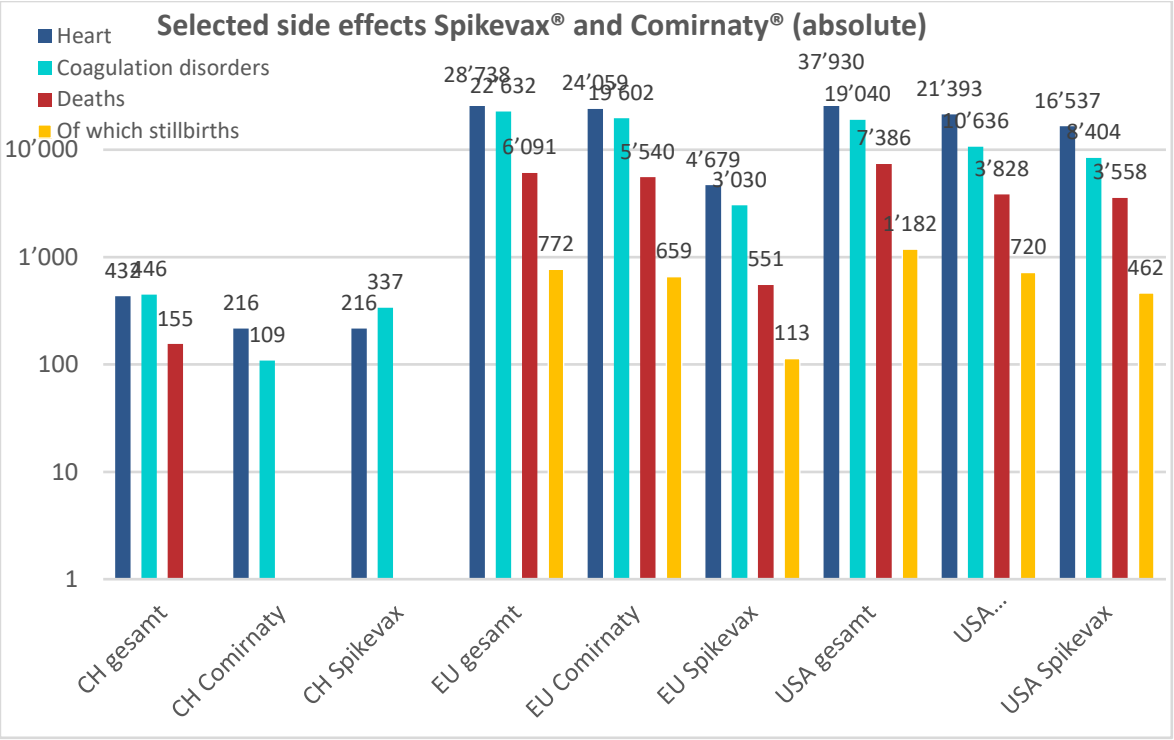
1.8.3. Side effects with Comirnaty® and Spikevax® (per 1 million "vaccine doses")

343 The number of serious adverse reactions and deaths for Spikevax® and Comirnaty® **per 1 million doses administered** at the beginning of **November 2021** was as follows:

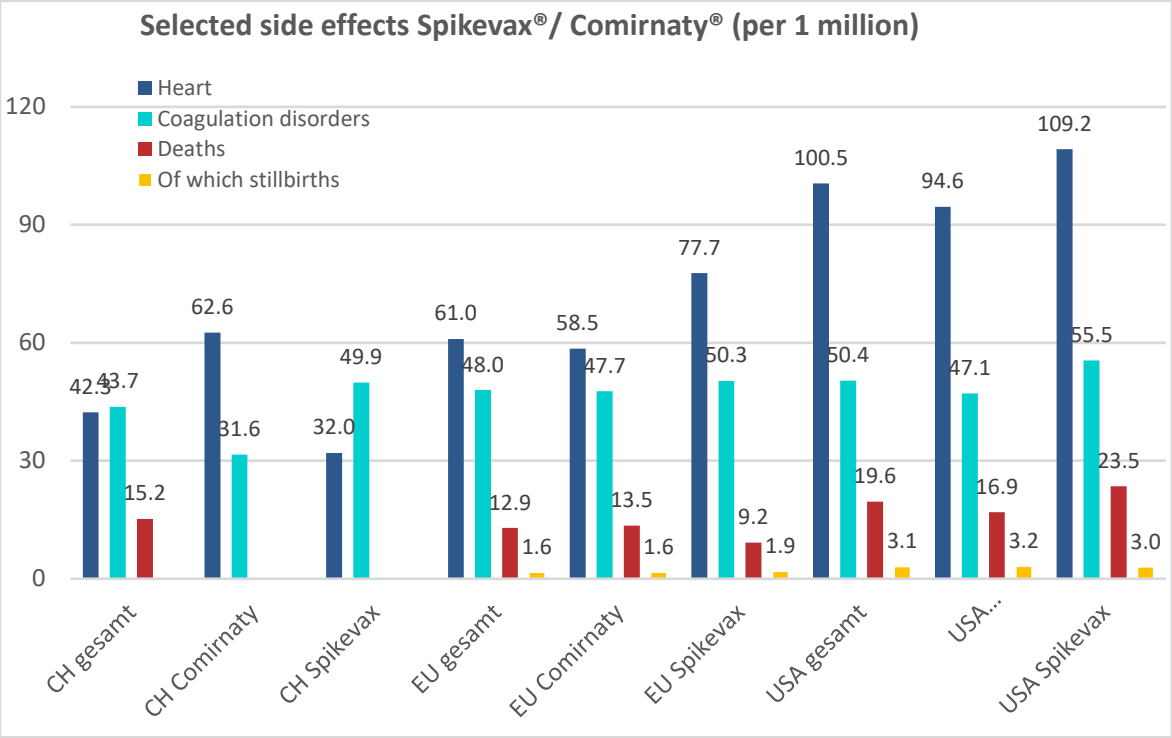


1.8.4. Selected side effects: Heart, thromboses, deaths, stillbirths

344 A more detailed analysis of all adverse reaction 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 in **absolute figures** as of **November 2021:**



345 **Per 1 million "vaccine doses"** this gives the following picture:



346 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 due to population or reporting would have to be investigated more closely.

347 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 injections. According to the definition (MedDRA system organ classes), at least in the case of Spikevax® these were **"rarely" occurring side effects** (Comirnaty®: still just under "very rare").

348 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 can 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** to be classified **as "very rare" side effects (<1/10,000).**

349 Very striking are the suddenly only half as many **deaths reported in** Switzerland of 15.2 (previously: 32.1) per 1 million doses.

350 Regarding **stillbirths, there has been an** increase in the USA and stillbirths are now also listed in the EU. In Switzerland, there is no corresponding information on this - error excepted.

1.8.5. In particular: Side effects in children

1.8.5.1 Data basis

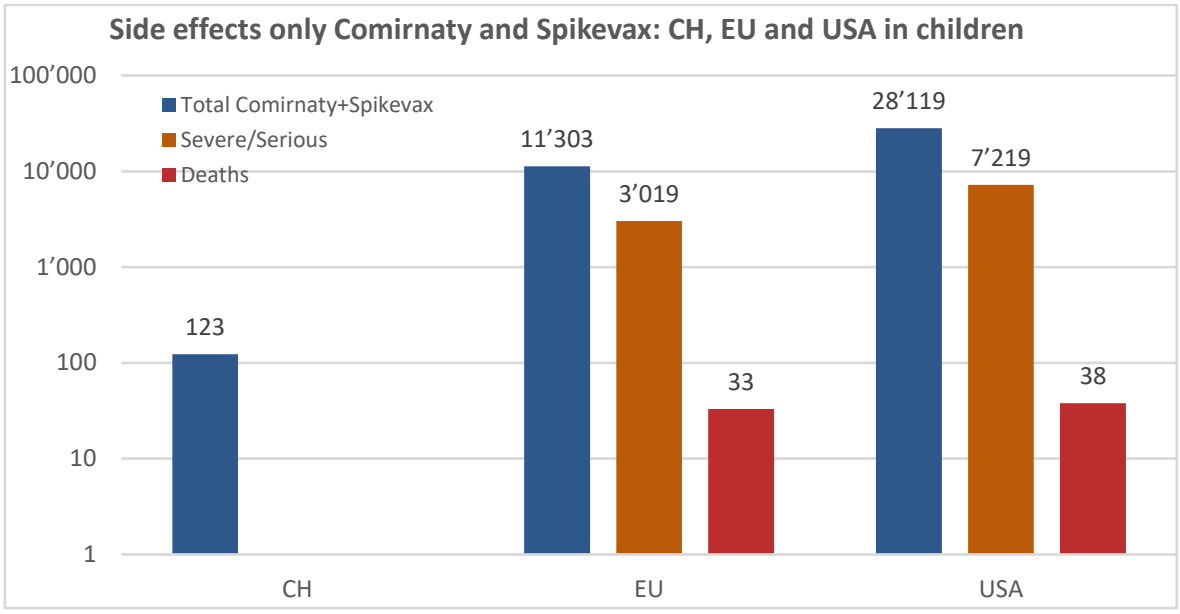
351 Based on the periodic "updates" from Swissmedic (until 17.12.2021) and the American and European databases (until 11.12.2021), the number of adverse reactions (all, serious/serious/serious, deaths) is as follows:[245]

	CH	Children (CH)	EU	Children (EU)	USA	Children (USA)
Comirnaty	3.121		494.009	10.258	306.219	21.895
Ernst Comirnaty	1.334		108.872	2.783	109.594	6.982
Deaths Comirnaty			6.107	32	4.280	34
Spikevax	7.403		112.045	1.045	317.619	6.224
Ernst Spikevax	2.431		17.609	236	87.279	237
Deaths Spikevax			604	1	3.932	4
Total Comirnaty+ Spikevax	10.842	123	606	11	624	28
Severe/ Ernst	3.927		126	239	197	244
Deaths	178		610	33	8	38
Vaccination doses Comirnaty	3.824.485		410.979.487		253.826.942	
Vaccine doses Spikevax	7.291.217		60.209.914		151.481.614	
Comirnaty+ Spikevax / Mio	975,4		1.286,2		1.539,2	
Severe/ Ernst / 1Mio	353,3		268,4		485,7	
Deaths / million	16,0		14,2		20,3	

1.8.5.2 Children: Side effects with Comirnaty® and Spikevax® (absolute numbers)

352 By 17.12.2021 in Switzerland, by 11.12.2022 in the EU and the USA, a total of **39,545 adverse reactions** were reported for Comirnaty® and Spikevax® in **children** (incl. adolescents) - of which **10,238 were serious** adverse reactions and **71 were deaths:**

245 Due to late reporting, vaccine doses are backdated: 05.11.2021 (CH), 30.10.21 (EU), 13.11.21 (USA).



1.9. Massive underreporting in general

353 The worldwide passive reporting systems have one thing in common: the reports are in no way automated and systematic. Rather, reporting is dependent on the knowledge and awareness of those involved that an observation could be a side effect and their willingness to take on the effort of reporting in the first place. This leads to massive underreporting - typical estimates of the reporting rate are between 1% and 10%:

1.9.1. Studies on (worldwide) undercoverage

354 A review of 37 studies came to a median of 6% capture rate.[246] LASEK et al. estimate that a maximum of 5% of serious adverse events are reported in spontaneous reporting systems.[247]

1.9.2. USA: Under 3% of all adverse reactions reported

355 According to a Harvard study, less than 1% of all adverse reactions are reported to the vaccine adverse reaction database *VAERS.*[248]

246 HAZELL/SHAKIR, "Under-reporting of adverse drug reactions: a systematic review", 20.11.2021, https://doi.org/10.2165/00002018-200629050-00003.

247 LASEK/TIADEN, "Erfassung unerwünschter Arzneimittelwirkungen", 31.01.1991, https://www.aerzteblatt.de/archiv/97564/Erfassung-unerwuenschter-Arzneimittelwirkungen.

248 LAZARUS et al, "Electronic support for public health-vaccine adverse event reporting system", 2010, https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf; LAZARUS et al , "Electronic Support for Public Health: validated case finding and reporting for notifiable diseases using electronic medical data", 01.01.2009, https://doi.org/10.1197/jamia.M2848.

356 Based on a CDC-approved methodology, an "*under reporting factor*" ("*URF*") of at least 41 was calculated for the most serious/obvious events reported to *VAERS.* **This means that all registered adverse event reports must be multiplied by at least a factor of 41 to reflect reality** (which corresponds to an effective coverage of 2.43%).[249]

1.9.3. Switzerland: Reporting rate is 50% of the reporting rate of Germany

357 **Swissmedic** listed 2,944 "evaluated reports of adverse vaccination reactions" on its website as of **15.06.2021.** In 35.4% of the cases, the adverse reactions were classified as serious. With 6,120,202 vaccine doses administered as of 13.6.2021, this resulted in a **reporting rate of 0.5/1000 vaccine doses**. In comparison, the ***PEI*** reported 49,961 "suspected cases of adverse reactions or vaccine complications" for Germany by 30.4.2021, corresponding to a **reporting rate of 1.7/1000 vaccine doses**. Standardised to 1000 vaccine doses administered, Swissmedic thus reported only one third of the adverse reactions reported by the *PEI.*[250]

358 The rate of "evaluated reports of suspected adverse reactions to Covid 19 vaccines" published by Swissmedic improved only marginally during the course of the study: As of **14.12.2021, Swissmedic** listed 10,842 "suspected cases of evaluated reports of adverse reactions to vaccines" on its website for 12,856,178 vaccine doses administered. This again resulted in a **reporting rate of only 0.8/1000 vaccine doses, about half that of the *PEI***, which reported a **reporting rate of 1.6 suspected cases/1000 vaccine doses for** all COVID "vaccines" together as of **30.11.2021**.[251]

359 Based on the comparison with the *PEI* figures, it must be assumed that **the figures published by Swissmedic must be multiplied by a factor of at least 2 to reflect the true number of suspected adverse reaction reports received**.

360 In the course of the study, it became apparent that both Switzerland and Germany, in comparison with other EU countries, were afflicted with a very high number of unreported

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249 KIRSCH, "How to verify for yourself that over 150,000 americans have been killed by the COVID vaccines", 05.01.2022, https://stevekirsch.substack.com/p/how-to-verify-for-yourself-that-over.

250 Aletheia, "Open letter to Swissmedic", 08.07.2021, https://aletheia-scimed.ch/IMG/pdf/2021-07-08_offener_brief_an_swissmedic_sofortige_sistierung_covid-19_impfstoffe_webversion-2.pdf.

251 Swissmedic, "Suspected adverse reactions to Covid-19 vaccinations in Switzerland - 20th update", 17.12.2021, https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/covid-19-vaccines-safety-update-10.html; Paul Ehrlich Institute, "Safety report", 23.12.2021, https://www.pei.de/SharedDocs/Downloads/DE/newsroom/dossiers/sicherheitsberichte/sicherheitsbericht-27-12-20-bis-30-11-21.pdf?__blob=publicationFile&v=7.

adverse drug reactions and that the figures published by Swissmedic must even be multiplied by a factor of 10 in order to reflect reality (see N 500 ff.).

361 One possible reason for this massive under-reporting in Switzerland could be a "pre-screening" of the reports by Swissmedic: While the *PEI* stated that it considers "open communication" to be important for a high vaccination acceptance and consequently reports continuously on all suspected cases of adverse reactions or vaccination complications reported in Germany in connection with the "vaccination" against COVID-19[252] , Swissmedic makes a "pre-selection" and only publishes suspected cases of adverse reactions that it has "evaluated".

362 In terms of transparent communication, it is incomprehensible why Swissmedic does not also disclose the totality of suspected cases of adverse reactions.

363 Swissmedic's approach does not inspire much confidence, but rather the impression that the public is being deprived of side effects to a relevant extent.

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

1.10.1. International warnings and calls to perform more autopsies

364 Another serious problem of under-reporting is the widespread **lack of autopsies:** In August 2021, the chief pathologist of the Heidelberg University Hospital, Prof. Peter Schirmacher, warned that there was a large number of unreported cases regarding a causal connection of the COVID "vaccination" with deaths occurring in a temporal context. In the autopsy network of Baden-Württemberg, which he heads, 33 persons who had died in a temporal connection with the COVID "vaccination" were autopsied. A causal connection was proven in 5 deceased persons (15%). According to Schirmacher, there is a responsibility to investigate unclear deaths related to COVID "vaccination". In March 2022, he again criticised and again denounced that a connection between the COVID "vaccination" and unclear deaths was still predominantly not recognised. In the meantime, Schirmacher said, his investigations had shown that in 30 per cent of people who died unex-

252 Paul-Ehrlich-Institut, "FAQ Coronavirus", 20.06.2022, *https://www.pei.de/DE/newsroom/dossier/coronavirus/coronavirus-inhalt.html;jsessionid=D5386F926502221D2C84C9F61EAFCEF1.intranet212?nn=169730&cms_pos=6*.

pectedly and shortly after vaccination, a direct connection to the vaccination could be proven.[253]

365 The Zurich professor of pathology, Zsuzsanna Varga, also regretted that so few autopsies were performed. **At the University Hospital Zurich, fewer than ten people who** had died in a temporal connection with the "vaccination" had **been autopsied** by the **end of September 2021**. [254]

366 Various Italian professors demanded as early as May 2021 that a post-mortem examination be obligatory for deaths in a temporal connection with the "vaccination".[255]

1.10.2. Own investigation: Too few and ineffective autopsies

367 A specially conducted analysis of 15 deaths 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.

368 The corresponding surveys and results are contained in Criminal Complaint, Supplement **5** (analysis of 15 deaths).

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

1.11.1. Deaths among children and adolescents

369 As previously stated (N 352), **71 child deaths** were recorded in the EU and the USA by the end of 2021.

370 As of 14.1.2022, Swissmedic reported 11,467 suspected cases of evaluated adverse reactions for the year 2021. In 1400 cases, the age of the person concerned was not known. In 138 (1.2%) cases, children and adolescents under 18 years of age were affected. In 7 cases, infants or young children aged 28 days to 23 months were involved. Information on the severity of adverse reactions in children and adolescents was not available in the Swissmedic report.[256]

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253 Rhein-Neckar-Zeitung, "Are many vaccination deaths not even recognised? ", 19.03.2022, https://www.rnz.de/politik/hintergrund_artikel,-corona-werden-viele-impftote-gar-nicht-erkannt-plus-podcast-_arid,846085.html.

254 Observer, "More autopsies wanted", 07.10.2021, https://www.beobachter.ch/gesundheit/medizin-krankheit/mogliche-todesfalle-wegen-covid-19-impfung-mehr-obduktionen-erwunscht.

255 POMARA et al, "COVID-19 Vaccine and Death: Causality Algorithm According to the WHO Eligibility Diagnosis", 26.05.2021, https://www.mdpi.com/2075-4418/11/6/955/htm.

256 Swissmedic, "Suspected adverse reactions to Covid-19 vaccinations in Switzerland - 21st update", 14.01.2022 (Comirnaty / Moderna),

371 According to the report of the German *Paul Ehrlich Institute* (*PEI*), 3,732 suspected cases of adverse reactions in children and adolescents were recorded in Germany as of 31.12.2021. **8 (0.2%) of the affected children and adolescents died between 2 days and 5 months in connection with the COVID "vaccination". In 6 of these 8 cases, a causal relationship with the "vaccination" could not be disproved to date. In** 147 children/adolescents, myocarditis/pericarditis occurred, in 6 children/adolescents Guillaume-Barré syndrome (a form of polyneuropathy in which muscle weakness occurs) , 22 cases related to facial paresis (facial paralysis) . In the 5-11 age group, 398 suspected cases of adverse reactions related to COVID "vaccination" were reported, 5 of which were classified as serious. 20 cases of adverse reactions involved breastfed infants in whom adverse reactions associated with maternal "vaccination" had been observed.[257]

1.11.2. Appropriate reaction to an alarm signal: Stop of marketing authorisation already with 15 cases of side effects

372 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.

373 A comparison: In July 1999, the *CDC* recommended that health care providers and parents suspend the use of the rotavirus vaccine for infants. This action was based on reports to *VAERS of* bowel obstructions in 15 infants who had received the rotavirus vaccine. At that time, the manufacturer voluntarily stopped further distribution of the vaccine in consultation with the *FDA.* Rotavirus poses a significant health burden to children. There are 20-40 deaths and more than 50,000 hospitalisations annually in the US due to severe diarrhoea and dehydration caused by rotavirus. [258]

374 When comparing the benefit-risk profile of the rotavirus vaccine with the COVID "vaccine", where to date no relevant benefit has ever been proven for any of the age groups, it seems downright grotesque that the COVID "vaccines" have not been withdrawn from the market in the face of an immense number of reported side effects and observed deaths of

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https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/covid-19-vaccines-safety-update-11.html.

257 Paul Ehrlich Institute, "Safety Report", 07.02.2022, https://www.pei.de/SharedDocs/Downloads/DE/newsroom/dossiers/sicherheitsberichte/sicherheitsbericht-27-12-20-bis-31-12-21.pdf?__blob=publicationFile&v=5.

258 CDC, "Withdrawal of rotavirus vaccine recommendation", 05.11.1999, https://www.cdc.gov/mmwr/preview/mmwrhtml/mm4843a5.htm.

children and adolescents, and that authorities such as Swissmedic continue to cling to a "positive benefit-risk profile" like a prayer mill.[259]

1.12. Alarm signal: myocarditis

1.12.1. Myocarditis common and severe side effect

375 Since myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the pericardium) are two of the most frequently reported side effects in connection with COVID vaccination, the current data on these will be discussed separately in detail in this chapter.

376 In most databases, myocarditis and pericarditis are reported in aggregate. In the following, the focus is on myocarditis because it is usually more severe than pericarditis.

377 The typical symptoms of acute myocarditis can include chest pain, malaise, breathing difficulties, fatigue, palpitations (too fast/irregular heartbeat) and cardiac arrhythmias up to unconsciousness and cardiogenic shock in severe cases. However, the clinical symptoms of myocarditis are very variable and can even resemble an acute myocardial infarction. [260]

378 Myocarditis can lead to severe impairment of heart function, require hospitalisation, artificial heart pumps or even heart transplants, and can be fatal.[261]

379 Severe myocarditis weakens the heart so that the rest of the body is no longer supplied with sufficient blood. Clots can form in the heart, leading to a stroke or heart attack. **Sudden cardiac death** is one of the known complications of the disease**.**[262]

380 The mortality rate can be over 20% in 6.5 years.[263] Damage due to myocarditis to the heart is usually permanent, and the three- to five-year survival rate after myocarditis has historically ranged from 56% to 83%.[264]

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259 Swissmedic, "Suspected adverse reactions to Covid-19 vaccinations in Switzerland - Update", 05.11.2021, *https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/covid-19-vaccines-safety-update-8.html.*

260 Swissmedic, "Investigation of reports of myocarditis associated with mRNA vaccines against Covid-19", 04.06.2021, *https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/untersuchung-berichten-ueber-myokarditiden-zusammenhang-mrna-impfstoffe.html.*

261 Statnews, "If Covid-19 vaccines can cause heart inflammation, caution should be warranted in those at risk", 29.06.2021, https://www.statnews.com/2021/06/29/myocarditis-covid-19-vaccine-connection-caution-needed-for-those-at-risk/.

262 KANG/AN, "Viral myocarditis," 05.01.2022, https://www.ncbi.nlm.nih.gov/books/NBK459259/; Canadian Covid Care Alliance, FN 133.

263 GREEN et al, "Long-term follow-up after viral myocarditis established by endomyocardial biopsy:Predictors of mortality", 02.02.2011, https://jcmr-online.biomedcentral.com/articles/10.1186/1532-429X-13-S1-M7.

381 Patients with acute fulminant myocarditis (characterised by severe left ventricular systolic dysfunction requiring drug therapy or mechanical circulatory support) who survive the acute stage have a survival rate of 93 % at 11 years, whereas patients with acute non-fulminant myocarditis (left ventricular systolic dysfunction but otherwise haemodynamically stable) have a survival rate of only 45 % at 11 years. **This could mean that between 7% and 55% of young people damaged by COVID-19 "vaccines" today may not survive into their late 20s or early 30s. Some may not even make it to their early 20s.**[265]

382 Myocarditis is one of the most frequently reported suspected adverse events according to *EUDRA-VIGILANCE* data. Among suspected cases of serious adverse events, myocarditis/pericarditis ranked 7th overall, 4th among cases requiring hospitalisation, 11th among life-threatening adverse events and 12th among cases with permanent damage. **Among children and adolescents,** myocarditis/pericarditis ranked **2nd among serious adverse events and 6th among adverse events with a fatal outcome**. Up to 11.02.2022, 21'759 cases of myocarditis were registered in the EU. Of these, 16,272 cases occurred in the most affected age group of 18-64 years and 1822 in the age group of 12-17 years. 99% of the cases were classified as serious, 216 cases (**1%**) were **fatal**. **72% of** the cases were reported in **connection with the administration of the Pfizer/BioNtech vaccine** (Supplement **14,** pp. 24, 26-28, 34, 137 f.).

BO: Supplement **14:** Daily report of serious side effects of COVID-19 vaccinations, as of 11.02.2022

1.12.2. Investigations and measures

383 A study published as a preprint on 08/09/2021 (and in the *European Journal of Clinical Investigation* on 14/02/2022 with a **changed first author and new title**) concluded that teenagers were six times more likely to have heart problems caused by the COVID "vaccine" than they were to have severe COVID disease.[266]

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264 DENNERT et al, "Acute viral myocarditis", 09.07.2008, https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC2519249/.

265 AMMIRATI et al, "Fulminant versus acute nonfulminant myocarditis in patients with left ventricular systolic dysfunction," 23 July 2019, https://pubmed.ncbi.nlm.nih.gov/31319912/.

266 HØEG et al, "SARS-CoV-2 mRNA Vaccination-Associated Myocarditis in Children Ages 12-17: A Stratified National Database Analysis", preprint 08/09/2021, https://www.medrxiv.org/content/10.1101/2021.08.30.21262866v1; KRUG, "BNT162b2 Vaccine-Associated Myo/Pericarditis in Adolescents: A Stratified Risk-Benefit Analysis", 14/02/2022, https://onlinelibrary.wiley.com/doi/10.1111/eci.13759.

384 On 29/09/2021, ONTARIO PUBLIC HEALTH recommended that young men 18-24 years of age not be vaccinated with Spikevax® due to an increased risk of suffering myocarditis or pericarditis.[267]

385 Sweden, Norway and Finland also suspended the use of Spikevax® for young adults on 07.10.2021 for the same reason. The pause "for precautionary reasons" in Sweden and Finland affected everyone born in 1991 or later. In Finland, those under 30 were offered Comirnaty® as a second dose. In Norway, the authorities suspended the use of Spikevax® in under-18s and advised that they be offered Comirnaty® instead.[268]

386 In a "*Dear Healthcare Professional Communication*" ("*DHPC*") to be sent by the marketing authorisation holders in August 2021, *Swissmedic stated*: "*Swissmedic has reviewed all available data and has come to the conclusion that there could at least possibly be a causal relationship between COVID-19 mRNA vaccines and myocarditis and pericarditis. The 'Warnings and precautions' and 'Adverse effects' sections of the SmPCs will be updated accordingly. "*Healthcare professionals should advise vaccinated individuals to seek immediate medical advice and assistance in the event of chest pain, shortness of breath or palpitations, according to the instructions issued by the marketing authorisation holder and Swissmedic. According to Swissmedic, it can be assumed that the course of myocarditis and pericarditis after "vaccination" is "similar to the course of myocarditis and pericarditis in general".[269]

387 The vaccination recommendation by the Swiss Federal Vaccination Commission (EKIF) was adapted to the effect that persons under 30 years of age were preferentially recommended basic immunisation with Comirnaty® (Supplement **15**, p. 4, 35 ff.).

BO: Supplement **15:** Vaccination recommendation for mRNA vaccines against Covid-19, BAG/EKIF, Status 21.01.2022

388 Nowhere in the *DHPC did* Swissmedic refer to the danger and potential long-term consequences of myocarditis/pericarditis. In November 2021, Swissmedic published a

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267 Public Health Ontario, "Myocarditis and pericarditis following vaccination with COVID-19 mRNA vaccines in Ontario: December 13, 2020 to November 21, 2021," Jan. 27, 2022, *https://www.publichealthontario.ca/-/media/documents/ncov/epi/covid-19-myocarditis-pericarditis-vaccines-epi.pdf?sc_lang=en.*

268 PATERLINI, "Covid-19: Sweden, Norway, and Finland suspend use of Moderna vaccine in young people "as a precaution", 11.10.2021, *https://www.bmj.com/content/375/bmj.n2477.*

269 Swissmedic, "DHPC - mRNA vaccines against COVID-19 (COVID_19 Vaccine Moderna and Comirnaty)", 13.08.2021, *https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/marktueberwachung/health-professional-communication--hpc-/dhpc-mrna-impfstoffe-gegen-covid-19.html.*

report[270] on the 95 myocarditis cases that had been recorded in the National Pharmacovigilance Database up to 13.8.2021 in connection with the COVID "vaccination". Although all 95 cases had been classified by the notifiers as "serious", 7 cases even as "life-threatening", the myocarditis required hospitalisation in 86 cases and one case ended fatally, Swissmedic emphasised that the clinical course after drug treatment was mostly "mild". Swissmedic pointed out that although the majority of cases concerned Spikevax®, a comparison based on spontaneous reports was methodologically questionable, as it could not be ruled out that the higher reporting rate for Spikevax® was only due to the fact that more Spikevax® (market share up to 15.12.2021 64%) than Comirnaty® (market share up to 15.12.2021 36%) had been used in Switzerland up to that time. [271] According to Swissmedic, possible differences in the risk of myocarditis in connection with the vaccines used should definitely be investigated on the basis of data from larger populations and clinical studies.

389 By 3.11. 2021, Swissmedic reported 199 suspected cases of myocarditis and/or pericarditis from 11,137,489 vaccine doses administered in Switzerland, of which 35 cases were related to Comirnaty® and 157 to Spikevax® (in 7 cases the vaccine was not known). This resulted in an incidence rate of 1.8 cases/100,000 doses of myocarditis/pericarditis overall and a rate of 0.3 cases/100,000 doses for Comirnaty® and 1.4 cases/100,000 doses for Spikevax®.[272] A comparison with the figures reported from Canada as of 12.11.2021, 1.9 cases/100,000 doses administered for Comirnaty® and 3.0 cases/100,000 doses administered for Spikevax® again indicates massive underreporting by Swissmedic, the figures from Canada are higher by a factor of 2 to 6 . The rates of myocarditis/pericarditis after the second vaccine dose reported from Canada specifically for men aged 18-29 years were as high as 15.9 cases/100,000 doses administered for Spikevax® and 2.6/100,000 doses administered for Comirnaty®. [273]

390 An analysis of *VAERS data* from February 2022, analysing data from January-June 2021, also concluded that COVID "vaccination" was associated with a high risk of myocarditis in

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270 Swissmedic, "Vigilance News", 11.2021, *https://www.swissmedic.ch/dam/swissmedic/en/dokumente/marktueberwachung/vigilance/vigilance-news-november2021.pdf.download.pdf/ENG_Vigilance-News-Edition_27_2021%2011%2029.pdf.*

271 Swissmedic and Paul Ehrlich Institute, FN 251.

272 Swissmedic, FN 259.

273 PHAC, "An advisory committee statement (ACS) national advisory committee on immunization", 03.12.2021, https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/rapid-response-recommendation-use-covid-19-vaccines-individuals-aged-12-years-older-myocarditis-pericarditis-reported-following-mrna-vaccines/rapid-response-recommendation-use-covid-19-vaccines-individuals-aged-12-years-older-myocarditis-pericarditis-reported-following-mrna-vaccines.pdf.

12-17 year olds: Rates of myocarditis associated with COVID "vaccination" after the second dose were 162.2 (12 to 15 years) and 93.0 (16-17 years) in male adolescents and young men, and 13.0 and 12.5 per million doses administered in female adolescents and young women. The rate of cardiac adverse events for healthy 12- to 15-year-olds was 2.6-4.3 times higher than their 120-day COVID-19 hospitalisation risk. 95% of myocarditis cases registered in the *VAERS database* were associated with hospitalisation.[274]

391 In a statement issued in July 2021, the AMERICAN HEART ASSOCIATION classified the lifelong effects of myocarditis on morbidity and mortality in children and adolescents as "significant" and drew attention to the fact that those affected should not participate in competitive sports while inflammation is present. A long-term ECG is recommended before returning to competitive sports.[275]

392 In Orange County, California, new ECG screenings became mandatory for the 2021/2022 school year for high school students who wanted to participate in sports programmes to identify athletes who were at risk for sudden cardiac arrest.[276]

393 *Myocarditis, as explained at the beginning of the chapter, can* lead *to* cardiogenic shock, cardiac arrhythmias or cardiac arrest in *severe cases.* In 2021, sudden deaths of *FIFA-registered* footballers during a match increased by a factor of five compared to previous years: While 2001-2020 saw an average of 4.2 footballers per year die as a result of sudden cardiac death/unexplained sudden death, 21 such cases were documented for January-November 2021.[277]

1.12.3. Swissmedic measures on myocarditis/pericarditis insufficient

394 The data presented above show that Swissmedic's communication on the subject of myocarditis/pericarditis was trivialising and the true risks and long-term damage were concealed.

395 Considering the fact that **71.2% of the 15,148 cases of myocarditis/pericarditis recorded in *EUDRA-VIGILANCE* as of April 2022 occurred after injections of Comirnaty®** (Supplement **16**, p. 155), that as a result of adjusted recommendations regarding the non-use of Spikevax® in certain age groups, no decrease in the number of cases

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274 KRUG, "BNT162b2 Vaccine-Associated Myo/Pericarditis in Adolescents: A Stratified Risk-Benefit Analysis," Feb. 14, 2022, https://onlinelibrary.wiley.com/doi/10.1111/eci.13759.

275 LAW et al, "Diagnosis and Management of Myocarditis in Children, A Scientific Statement From the American Heart Association", 07.07.2021, *https://www.ahajournals.org/doi/10.1161/CIR.0000000000001001.*

276 OCPS, "sports physicals", 20.06.2022, *https://www.ocps.net/departments/athletics/sports_physicals.*

277 CONNOLLY/SHIR-RAZ, "5-fold increase in sudden cardiac deaths of FIFA players in 2021", 15.11.2021, https://stephenc.substack.com/p/5-fold-increase-in-sudden-cardiac?s=r.

was observed, but on the contrary an overall increase in new cases from summer 2021 onwards, and that Swissmedic itself had ascertained that the emerging higher risk for Spikevax® could be falsified as a result of higher sales and that new studies were needed to investigate the risk profile of the COVID "vaccines", it is incomprehensible why no such extensive investigations were initiated and the COVID "vaccination" was not completely suspended until results were available in younger people. This is especially true since the risk-benefit profile of the "vaccination" was even more clearly negative for the younger age group than for the population as a whole due to the lack of danger posed by SARS-CoV-2.

BO: Supplement **16:** Daily report of serious side effects of COVID-19 vaccinations, as of 22.04.2022

1.13. Pregnant women: Inadequate risk management and realised risk

1.13.1. Still missing data

396 In an *informed* **consent form dated 15.12.2021**, in which Pfizer/BioNTech informed potential study participants about the details of a study to examine the effect of additional doses of vaccine, as well as about the benefits and risks of Comirnaty® in general, it was officially declared that risks in connection with fertility, pregnancy or during breastfeeding could not be ruled out: **"*The effects of the COVID-19 vaccine on sperm, a pregnancy, a fetus or a nursing child are not known. "*** (S. 10).

BO: Supplement **17:** Cincinnati Children's Hospital medical centre, Informed Consent Form (Sub Study C), 14.12.2021

1.13.2. Manufacturer's data: Multiple stillbirths in pregnant women

397 In the Pfizer/BioNTech "*Post Marketing Pharmacovigilance Report*" with data on the first 2.5 months after marketing authorisation[278] , which was submitted to all authorities worldwide and also to Swissmedic - presumably in April/May 2021 - adverse reactions in connection with Comirnaty® were listed for the post-marketing phase in 270 pregnant women. In **23 cases, this involved an abortion, in** two cases a premature birth with subsequent death of the child, in two cases an 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:

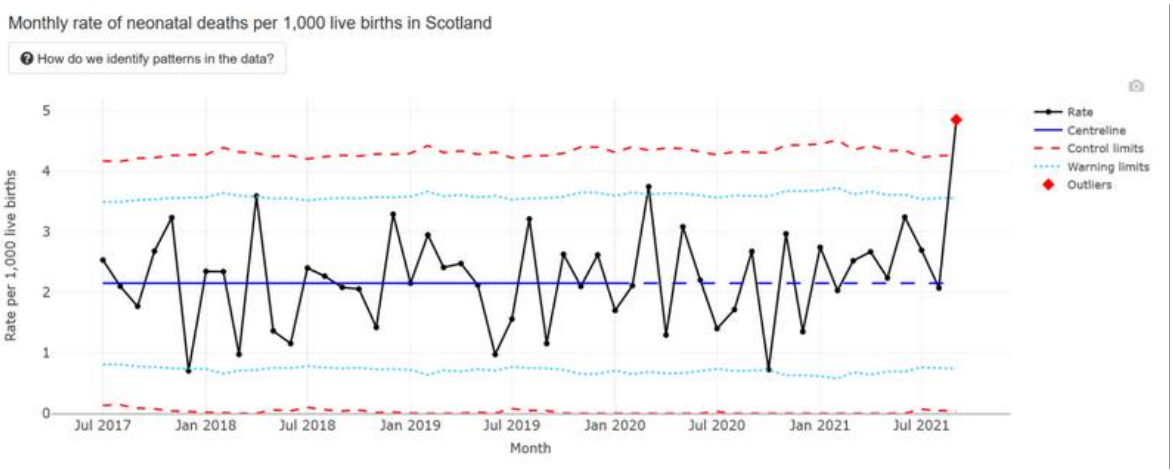
278 Pfizer, "Cumulative analysis of post-authorization adverse event reports of PF-07302048 (BNT162B2) received through 02/28/2021," 04/30/2021, *https://phmpt.org/wp-content/uploads/2021/11/5.3.6-postmarketing-experience.pdf.*

Pregnancy cases: 274 cases including:

- 270 mother cases and 4 foetus/baby cases representing 270 unique pregnancies (the 4 foetus/baby cases were linked to 3 mother cases; 1 mother case involved twins).
- Pregnancy outcomes for the 270 pregnancies were reported as spontaneous abortion (23), outcome pending (5), premature birth with neonatal death, spontaneous abortion with intrauterine death (2 each), spontaneous abortion with neonatal death, and normal outcome (1 each). No outcome was provided for 238 pregnancies (note that 2 different outcomes were reported for each twin, and both were counted).

1.13.3. England: Massive increase in neonatal mortality

398 Figures from *Public Health Scotland* show that 21 babies died within 28 days of birth in September 2021, pushing the neonatal mortality rate above an upper warning limit, known as the 'control limit', for the first time in at least four years:[279]



399 Although the rate has fluctuated from month to month, in September 2021 it was 4.9 stillbirths per 1000 births, a level last seen in the late 1980s.

400 *Public Health Scotland* said that the fact that the upper control limit was exceeded "suggested that there was a higher likelihood of factors beyond random variation contributing to the number of deaths that occurred".

1.13.4. Breastfeeding mothers: Spike protein and LNP in breast milk?

401 The spike protein can pose a risk to pregnant women and their unborn children, as well as to newborns who are breastfed by vaccinated mothers. Due to the physiological properties, it must be assumed that both the mRNA-containing lipid nanoparticles (LNP) and spike proteins already produced by the mother can pass into the breast milk.[280]

279 BBC, "Investigation into spike in newborn baby deaths in Scotland", 19.11.2021, https://www.bbc.com/news/uk-scotland-59347464.

280 PALMER/BHAKDI, FN 84.

402 A study that claimed to show that no vaccine mRNA could be detected in the breast milk of 8 breastfeeding mothers by means of PCR and that consequently no spike proteins were transferred through the breast milk must be regarded as not very valid. The authors themselves admitted that the storage of the breast milk might have negatively influenced the stability of the mRNA.[281]

403 The transfer of vaccine mRNA from Comirnaty® into breast milk was demonstrated in another study.[282]

1.13.1. Utah: Miscarriages up 12 per cent after fertility treatment

404 A report by the *Health Independence Alliance* shows 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.[283]

1.13.2. Thousands of premature and stillbirths worldwide

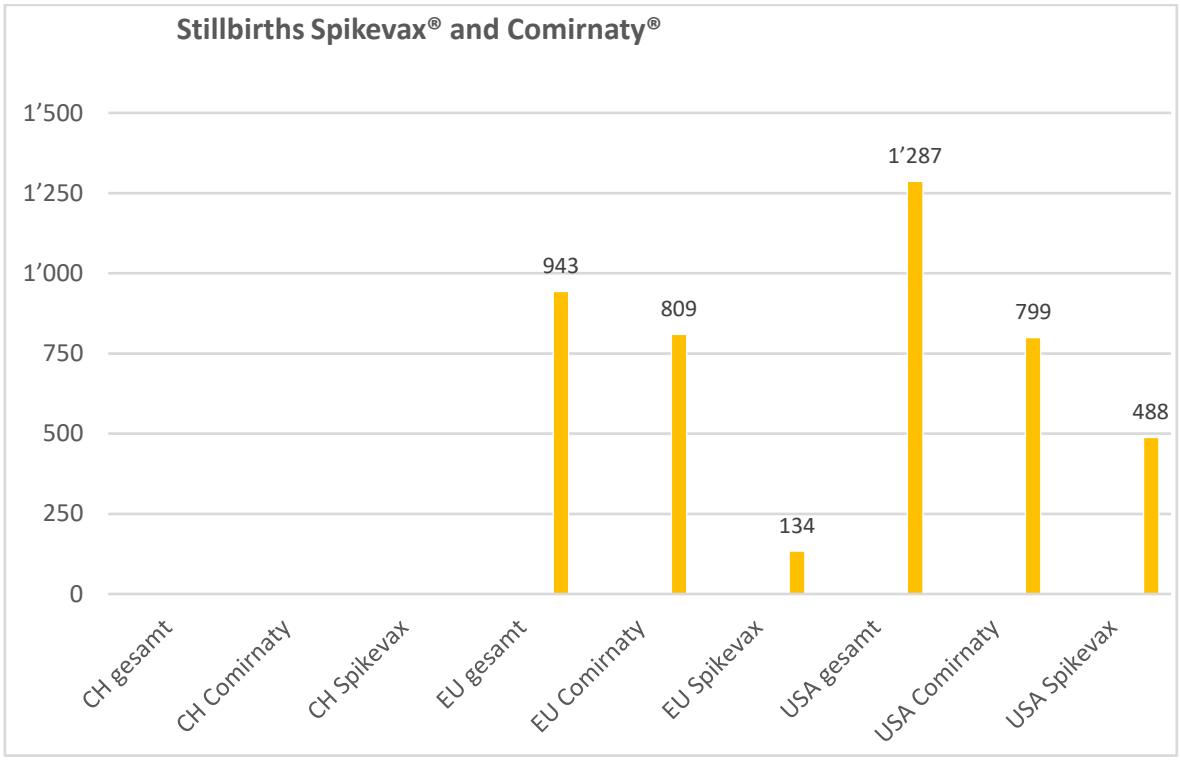
405 By 11.12.2021, **over 2,000 miscarriages** have already been reported in the EU and the USA in connection with the mRNA "vaccines" Spikevax® and Comirnaty® alone:[284]

281 GOLAN et al, "Evaluation of messenger RNA from Covid-19 BTN162b2 and mRNA-1273 vaccines in human milk", 06.07.2021, https://jamanetwork.com/journals/jamapediatrics/fullarticle/2781679.

282 LOW et a., "BNT162b2 vaccination induces SARS-CoV-2 specific antibody secretion into human milk with minimal transfer of vaccine mRNA", preprint dated 29.4.2021, https://www.medrxiv.org/content/10.1101/2021.04.27.21256151v1.

283 Health Independence Alliance, "Covid Vaccination Victims-UTAH," 09.11.2021, https://drive.google.com/file/d/1yyLIeQtptpKQGyI7oav8nCaK81wskrW0/view.

284 See already the graphic in front N 344.



406 As far as can be seen, there are no figures for Switzerland.

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

1.14.1. Disproportionate increase in side effects

407 With regard to the relevance and weighting of the data presented on side effects, the objection is often raised that these are merely "suspected cases" of side effects for which no causal connection with the COVID vaccines has been proven.

408 Proving a causal relationship between a vaccination and a vaccination incident is difficult and costly. A causality of adverse event and vaccination can be proven in two ways: Either an adverse event occurs much more frequently in vaccinated individuals than in comparable unvaccinated individuals (for example, sinus vein thrombosis following COVID "vaccinations" with AstraZeneca's vaccine), or a mechanism can be demonstrated that likely caused the vaccination response.[285] Proving causality of rare side effects can take years.

409 The disproportionate increase in adverse events just mentioned is already a strong indication of a close causal connection between the COVID "vaccinations" and the report-

[285] REMMEL, "Why is it so hard to investigate the rare side effects of COVID vaccines?", 01.04.2021, https://www.nature.com/articles/d41586-021-00880-9.

ed adverse events. Taking into account the fact of massive underreporting, this considerable suspicion becomes even stronger.

1.14.2. Close temporal connection between "vaccinations" and reports of side effects

1.14.2.1 Various messages show connection

410 The close temporal correlations shown below are a clear indication that deaths, hospitalisations in intensive care and various (serious) adverse events can be attributed to the COVID "vaccinations":

411 The increase in "all cause mortality" from Q1 2021 in the over 60s in New Zealand correlated temporally with the administration of the COVID "vaccine" to this age group.[286]

412 An analysis of more than 7.8 million adverse reaction reports from the *EUDRA-VIGILANCE* and *VAERS database from* October 2020 to October 2021 showed that in 77.6-89.1% of cases, serious adverse reactions occurred within seven days of "vaccination".[287]

413 A study published in the prestigious journal *Nature,* which analysed Israeli ambulance service data from 2019 to 2021, found a 25% increase for emergency calls related to cardiac arrest or acute coronary syndrome in the 16- to 39-year-old population for the period from January to May 2021. The number of weekly emergency calls correlated significantly with first and second dose vaccination rates for this age group, but not with Covid infection rates .[288]

1.14.2.2 August 2021: Analysis of EU data

414 An analysis[289] of *EUDRA-VIGILANCE data* from December 2021 *(*https://www.adrreports.eu, database deadline week 34 2021 [29.08.2021]) showed that most serious adverse events occurred in the first 4 days, and deaths and spontaneous abortions even in the first 2 days after administration of the "vaccination".

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286 HATCHARD, "Relationship between Covid-19 vaccination and all cause mortality", 17.12.2021, https://hatchardreport.com/relationship-between-covid-19-vaccination-and-all-cause-mortality/.

287 MONTANO, "Frequency and associations of adverse reactions of COVID-19 vaccines reported to pharmacovigilance systems in the European union and the united states", 03.02.2022, https://www.frontiersin.org/articles/10.3389/fpubh.2021.756633/full.

288 SUN et al, "Increased emergency cardiovascular events among under-40 population in Israel during vaccine rollout and third COVID-19 wave", 28.04.2022, https://www.nature.com/articles/s41598-022-10928-z#Sec14.

289 ZIMMER et al, "Data Suggesting that the Significant Number of Serious Adverse Events and Deaths Following Administration of the New COVID-19 Vaccines Has a Causal Link to Vaccination," 12.2021; https://www.researchgate.net/publication/357403474.

415 This underlines the acute toxicity of the administered COVID "vaccines" and cannot be reduced to an expected background morbidity compared to an unvaccinated population in an observation period of 14 or 30 days after "vaccination". In the latter case, the events would have to occur equally distributed over the observation period.

416 An excerpt of the serious side effects examined in this analysis is presented below:

417 Regarding **deaths, a** total of 13,801 suspected death events were reported after administration of the COVID "vaccines". Of these, 3635 (26.3%) were reported with a time of occurrence of this adverse event. 61% of vaccinated persons who died and for whom the time of death was known died in the first two days after "vaccination". The majority of deaths involved persons over 64 years of age, but 23% of cases also involved younger persons between 18 and 64 years of age.

418 A total of 2035 suspected cases of **cardiac** arrest and sudden death were reported following administration of COVID vaccines. Of these, 519 (26%) were timed. For Comirnaty®, 87%, and for Spikevax®, 76% of cases occurred in the first two days after "vaccination". 24% of the events involved younger patients aged 18-64 years.

419 The majority of **thromboembolic events** (more than 50%) occurred up to day 5 after "vaccination".

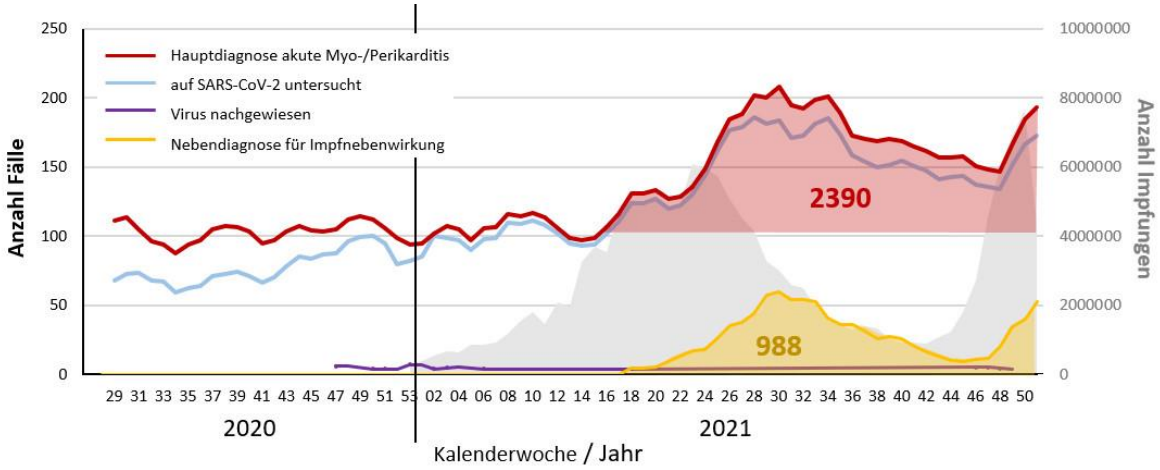
420 A total of 1276 suspected cases of **spontaneous abortions** after administration of the vaccines were reported up to 29.8.2021. Time data were available for about 20% of the events**. The median of spontaneous abortions was on day 1 for Spikevax® and on day 3 after "vaccination" for Comirnaty®.**

1.14.2.3 Interim conclusion

421 Due to the clear very close temporal correlation in the occurrence of the investigated severe suspected cases of vaccination side effects in the large majority of affected patients, a causal relationship is extremely likely.

1.14.3. Time-delayed connection between "vaccination" and hospitalisations

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



423 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 can be seen 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 the number of myo/pericarditis cases strengthens the suspicion that the side effects can also become clinically manifest weeks after the "vaccination"**.

1.14.4. Further evidence of temporal correlation in mortality and hospitalisations

1.14.4.1 Adults

424 A large-scale study analysing data from 145 countries concluded in November 2021 that COVID "vaccines" were associated with higher rates of COVID infections and COVID-related deaths. Specifically, in the USA, the vaccines were associated with a 38% increase in COVID cases and a 31% increase in COVID-related deaths. The author concluded that these findings should encourage policymakers to make decisions based on data rather than narrative.[290]

425 The CEO of *One America* life insurance company reported at a press conference organised by the Indiana Chamber of Commerce on 30 December 2021 that the **mortality rate among people of working age** 18-64 had **increased by 40% compared to the pre-pandemic period** and that all life insurance companies were currently observing among

290 BEATTIE, "Worldwide Bayesian Causal Impact Analysis of Vaccine Administration on Deaths and Cases Associated with COVID-19: A BigData Analysis of 145 Countries," preprint, Nov. 15, 2021, *https://www.researchgate.net/publication/356248984_Worldwide_Bayesian_Causal_Impact_Analysis_of_Vaccine_Administration_on_Deaths_and_Cases_Associated_with_COVID-19_A_BigData_Analysis_of_145_Countries.*

their policyholders the highest mortality rates they had ever seen in the history of this industry. **Most of the death claims submitted were not classified as COVID-19 deaths.** Similarly, the company reported a significant increase in disability claims. The president of the *Indiana Hospital Association* confirmed that these observations were consistent with figures at hospitals in the state. **Hospital admissions in the state were higher than before the introduction of the COVID-19 vaccine a year earlier and even higher than in the five years before that,** he said.[291]

426 An analysis of German hospital billing data published in February 2022 clearly showed how the number of inpatient treated vaccine side effects had jumped at the beginning of 2021. **The mean value of all weekly hospitalisations with diagnosed vaccine side effects in 2021 was a factor of 11** (481 vs. 43 cases/week), and **for intensive care treatments with diagnosed vaccine side effects a factor of 9** (55 vs. 6 cases/week) **higher than the mean value for the period 2019 to 2020**. Due to the nature of this data, it was clear that these were serious symptomatology cases, as otherwise no inpatient hospitalisations would have been required.[292]

1.14.4.2 Children and young people

427 The time course of the occurrence of suspected reports of all adverse effects associated with COVID "vaccines" in adolescents aged 12 years and older in the *EudraVigilance database,* taking into account a subsequent slight delay in the start of vaccination in EU countries, clearly correlated with the granting of marketing authorisation for the vaccines for this age group by the *EMA* (Comirnaty® end of May 2021, Spikevax® July 2021). [293]The ten most common serious adverse reactions in children and adolescents included: Myocarditis, respiratory distress, cardiac arrhythmias, convulsions, paralysis, blood clotting disorders, bleeding, tremors, brain disorders and thrombosis (Supplement **18**, p. 33).

BO: Supplement **18:** Daily report of serious adverse reactions to COVID 19 vaccinations, as of 25.03.2022

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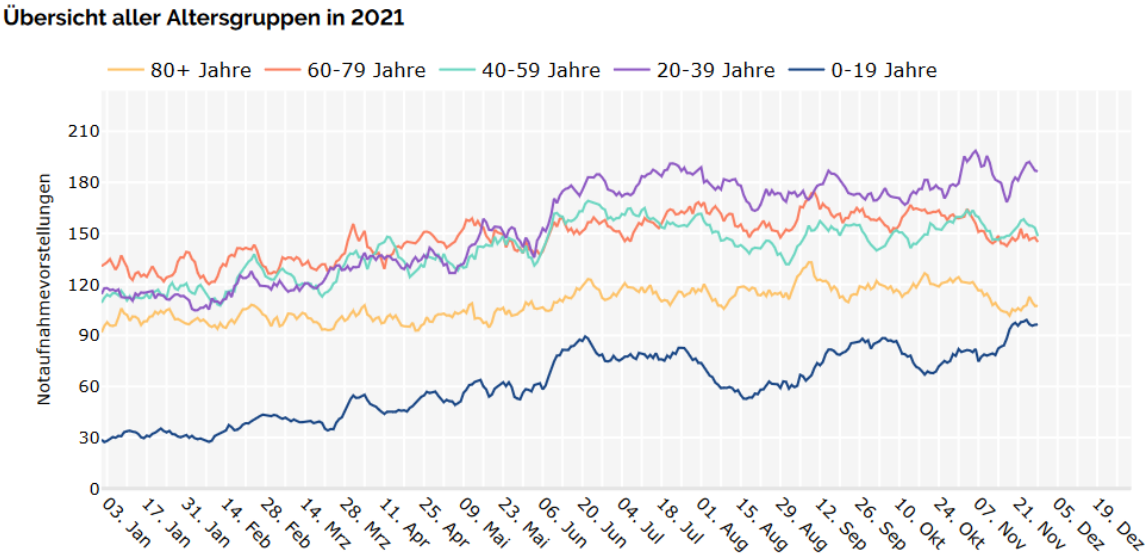
291 The centre square, "Indiana life insurance CEO says deaths are up 40% among people ages 18-64", 01.01.2022, *https://www.thecentersquare.com/indiana/indiana-life-insurance-ceo-says-deaths-are-up-40-among-people-ages-18-64/article_71473b12-6b1e-11ec-8641-5b2c06725e2c.html.*

292 Corona Data Analysis, "Hospital Billing Data: Vaccination Adverse Events 2019 to 2021", 26.02.2022, *https://coronadatenanalyse.de/krankenhaus-abrechnungsdaten-impfnebenwirkungen-2019-bis-2021/.*

293 vfa, "Covid-19 vaccination for children and adolescents", 11.03.2022, https://www.vfa.de/de/arzneimittel-forschung/coronavirus/covid-19-impfung-fuer-kinder-und-jugendliche.

428 According to the *RKI*'s "Emergency Department Situation Report", admissions to an emergency department in the 0-19 age group had more than doubled as of 01.12.2021 compared to January 2021:[294]



1.14.5. Australia: Compensation for myocarditis and other side effects

429 In December 2021, the Australian Government launched an Indemnity *Scheme which* allowed vaccinated people to claim compensation in the event of the occurrence of an adverse reaction listed in the approved product information, for Comirnaty® and Spikevax® an allergic reaction or myocarditis/pericarditis :[295]

430 The connection of the listed side effects with the COVID "vaccines" was thus indirectly acknowledged.

1.14.6. Many other studies that indicate a connection

431 In continuation of the worldwide studies until 4 June 2021 (front N 285 ff.), reference is made to the following additional studies published **until 26 October 2021.**

432 The list is then published at the back (N 552 ff.) for the worldwide studies until 1 March 2022.

294 RKI, FN 220.

295 Australian Government, "COVID-19 vaccine claims scheme", "Who can get it", 24.05.2022, https://www.servicesaustralia.gov.au/who-can-get-support-under-covid-19-vaccine-claims-scheme?context=55953; Australian Government, "COVID-19 vaccine claims scheme", "What costs you can claim", 24.05.2022, https://www.servicesaustralia.gov.au/what-costs-you-can-claim-under-covid-19-vaccine-claims-scheme?context=55953.

433 The "booster vaccinations" were approved on 26 October 2021 and the children's "vaccinations" on 10 December 2021, even though **85 studies on heart problems were** already **available at** the time of the former **and 130 studies on life-threatening coagulation disorders (e.g. thromboses, pulmonary embolisms, strokes) and four studies had already** pointed to **possible fatal consequences of the COVID "vaccinations".** Moreover, it was already obvious at that time that children were in no way threatened by SARS-CoV-2[296] and that the COVID "vaccinations" were largely ineffective.[297] How "Swissmedic" could still come to a positive "benefit-risk ratio" under these circumstances is in no way comprehensible.

1.14.6.1 Heart problems (myocarditis etc.): 85 publications

434 By **26 October 2021,** the following additional **85 peer-reviewed publications** had appeared in which a connection between the occurrence of heart diseases (myocarditis, pericarditis, etc.) and the COVID "vaccinations" was proven (or at least a significant suspicion in this regard was shown):

- VIDULA et al , Myocarditis and other cardiovascular complications of mRNA-based COVID-19 vaccines, 10.06.2021, https://pubmed.ncbi.nlm.nih.gov/34277198/
- SINGH et al , COVID-19 mRNA vaccination and myocarditis, 14.06.*2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8276934/pdf/2681-1-23129-1-10-20210611.pdf*
- HABIB et al. , Acute myocarditis after administration of BNT162b2 vaccine, 16.06.*2021, https://www.sciencedirect.com/science/article/pii/S2214250921001530*
- MUTHUKUMAR et al. , In-depth evaluation of a case of presumed myocarditis after the second dose of COVID-19 mRNA vaccine, 16.06.2021, https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.121.056038
- SHAW et al. , Possible association between COVID-19 vaccine and myocarditis: clinical and CMR findings, 16.06.2021, https://www.sciencedirect.com/science/article/pii/S1936878X2100485X
- MANSOUR et al , Acute myocarditis after a second dose of COVID-19 mRNA vaccine: report of two cases, 18.06.2021, *https://www.clinicalimaging.org/article/S0899-7071(21)00265-5/fulltext*
- MINOCHA et al , Recurrence of acute myocarditis temporally associated with receipt of coronavirus mRNA disease vaccine 2019 (COVID-19) in a male adolescent, 22 Jun 2021, https://www.sciencedirect.com/science/article/pii/S002234762100617X

296 Rear N 687 ff.
297 Rear N 437 ff.

- KERNEIS et al , COVID-19 vaccines and myocarditis, 26.06.2021, https://pubmed.ncbi.nlm.nih.gov/34246566/
- NEVET, Acute myocarditis associated with anti-COVID-19 vaccination, 28.06.*2021, https://ecevr.org/DOIx.php?id=10.7774/cevr.2021.10.2.196*
- MONTGOMERY et al. , Myocarditis following immunization with COVID-19 mRNA vaccines in members of the US military, 29.06.2021, https://jamanetwork.com/journals/jamacardiology/fullarticle/2781601
- WATKINS et al , Myocarditis following vaccination with BNT162b2 in a healthy male, 29.06.2021, https://www.sciencedirect.com/science/article/pii/S0735675721005362
- CEREDA et al. , Acute myocarditis after the second dose of SARS-CoV-2 vaccine: serendipity or causal relationship, 01.07.2021, https://pubmed.ncbi.nlm.nih.gov/34236331/
- SCHAUER et al. , Myopericarditis after Pfizer mRNA COVID-19 vaccination in adolescents, 03.07.2021, https://www.sciencedirect.com/science/article/pii/S002234762100665X
- GARGANO et al. , Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices, 09.07.2021, https://pubmed.ncbi.nlm.nih.gov/34237049/
- NASSAR et al , COVID-19 vaccine-induced myocarditis: a case report with review of the literature, 10.07.2021, https://www.sciencedirect.com/science/article/pii/S1871402121002253
- LARSON et al. , Acute myocardial infarction within 24 hours after COVID-19 vaccination: is Kounis syndrome Clinical and histopathologic spectrum of delayed adverse skin reactions after COVID-19 vaccination, 12.07.2021, https://pubmed.ncbi.nlm.nih.gov/34292611/
- ABRAHAM et al , Myocarditis / pericarditis associated with COVID-19 vaccine, 16.07.2021, https://science.gc.ca/eic/site/063.nsf/eng/h_98291.html
- RAMÍREZ-GARCÍA et al , Pericarditis after administration of BNT162b2 mRNA COVID-19 mRNA vaccine, 16.07.*2021, https://www.sciencedirect.com/science/article/pii/S1885585721002218*
- DAS et al. , Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination: What Do We Know So Far? , 18.07.2021, https://pubmed.ncbi.nlm.nih.gov/34356586/
- BOZKURT et al , Myocarditis with covid-19 mRNA vaccines, 20.07.2021, https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.121.056135
- STAREKOVA et al. , Myocarditis associated with vaccination with COVID-19 mRNA, 20.07.*2021, https://pubs.rsna.org/doi/10.1148/radiol.2021211430*

- MCLEAN et al , Myopericarditis in a previously healthy adolescent male after COVID-19 vaccination: Case report, 21.07.2021, https://pubmed.ncbi.nlm.nih.gov/34133825/
- KHOGALI et al. , Unusual presentation of acute pericarditis after vaccination against SARS-COV-2 mRNA-1237 Modern, 23.07.2021, https://pubmed.ncbi.nlm.nih.gov/34447639/
- WILLIAMS et al , Acute myocarditis after SARS-CoV-2 vaccination in a 24-year-old man, 24.07.*2021, https://www.sciencedirect.com/science/article/pii/S2589790X21001931*
- SINGER et al , Risk of Myocarditis from COVID-19 Infection in People Under Age 20: A Population-Based Analysis, 27.07.2021, https://pubmed.ncbi.nlm.nih.gov/34341797/
- TANO et al , Perimyocarditis in adolescents after Pfizer-BioNTech COVID-19 vaccination, 28.07.2021, https://academic.oup.com/jpids/article/10/10/962/6329543
- LONG, Important information on myopericarditis after vaccination with Pfizer COVID-19 mRNA in adolescents, 29.07.2021, https://www.sciencedirect.com/science/article/pii/S0022347621007496
- DAS et al , Myopericarditis after vaccination with COVID-19 mRNA in adolescents 12 to 18 years of age, 30.07.2021, https://www.sciencedirect.com/science/article/pii/S0022347621007368
- CHAMLING et al. , Occurrence of acute infarct-like myocarditis after COVID-19 vaccination: just an accidental coincidence or rather a vaccination-associated autoimmune myocarditis? , 31.07.2021, https://pubmed.ncbi.nlm.nih.gov/34333695/
- PEPE et al. , Myocarditis, pericarditis and cardiomyopathy after COVID-19 vaccination, 31.07.2021, https://www.sciencedirect.com/science/article/pii/S1443950621011562
- ALBERT et al , Myocarditis following COVID-19 vaccination, 01.08.2021, https://pubmed.ncbi.nlm.nih.gov/34025885/
- PATRIGNANI et al. , Acute myocarditis after Comirnaty (Pfizer) vaccination in a healthy male with previous SARS-CoV-2 infection, 02.08.2021, https://www.sciencedirect.com/science/article/pii/S1930043321005549
- HASNIE et al. , Perimyocarditis following first dose of the mRNA-1273 SARS-CoV-2 (Moderna) vaccine in a healthy young male: a case report, 04.08.2021, https://pubmed.ncbi.nlm.nih.gov/34348657/
- TAILOR et al. , Case report: acute myocarditis after second dose of mRNA-1273 SARS-CoV-2 mRNA vaccine, 04.08.2021, https://academic.oup.com/ehjcr/article/5/8/ytab319/6339567
- LUK et al. , Myocarditis and pericarditis after vaccination with COVID-19 mRNA: practical considerations for care providers, 08.08.2021, *https://www.sciencedirect.com/science/article/pii/S0828282X21006243*

- KING et al. , Myocarditis after SARS-CoV-2 mRNA vaccination, a case series, 09.08.2021, https://pubmed.ncbi.nlm.nih.gov/34396358/
- UMEI et al , Recurrence of myopericarditis following mRNA COVID-19 vaccination in a male adolescent, 09.08.2021, https://pubmed.ncbi.nlm.nih.gov/34904134/
- VOLLMANN et al. , Acute perimyocarditis after the first dose of COVID-19 mRNA vaccine, 09.08.2021, https://pubmed.ncbi.nlm.nih.gov/34515024/
- DIONNE et al , Association of myocarditis with COVID-19 messenger RNA vaccine BNT162b2 in a case series of children, 10.08.2021, https://jamanetwork.com/journals/jamacardiology/fullarticle/2783052
- ROSNER et al. , Myocarditis temporally associated with COVID-19 vaccination, 10.08.2021, https://www.ahajournals.org/doi/pdf/10.1161/CIRCULATIONAHA.121.055891
- KIM et al. , Cardiac imaging of acute myocarditis after vaccination with COVID-19 mRNA, 16.08.2021, https://pubmed.ncbi.nlm.nih.gov/34402228/
- LAZAROS et al. , The new COVID-19 mRNA vaccine platform and myocarditis: clues to the possible underlying mechanism, 16.08.2021, https://pubmed.ncbi.nlm.nih.gov/34312010/
- PARK et al. , Epidemiology and clinical features of myocarditis/pericarditis before the introduction of COVID-19 mRNA vaccine in Korean children: a multicenter study, 16.08.2021, https://pubmed.ncbi.nlm.nih.gov/34402230/
- SULEMANKHIL et al. , Temporal association between COVID-19 vaccine Ad26.COV2.S and acute myocarditis: case report and review of the literature, 16.08.2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8364889/pdf/main.pdf
- ABBATE et al , Fulminant myocarditis and systemic hyper inflammation temporally associated with BNT162b2 COVID-19 mRNA vaccination in two patients, 18 Aug 2021, https://www.sciencedirect.com/science/article/pii/S0167527321012286
- LI et al , Intravenous injection of coronavirus disease 2019 (COVID-19) mRNA vaccine can induce acute myopericarditis in a mouse model, Aug 18, 2021, https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab707/6353927?s=09&login=true
- HAN et al. , Be alert to the risk of adverse cardiovascular events after COVID-19 vaccination, 24.08*.2021, https://www.xiahepublishing.com/m/2472-0712/ERHM-2021-00033*
- KNOWLTON, Insights from a murine model of COVID-19 mRNA vaccine-induced myopericarditis: could accidental intravenous injection of a vaccine induce myopericarditis, 28 Aug 2021, https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab741/6359059

- IOANNOU, Myocarditis should be considered in those with a troponin rise and unobstructed coronary arteries following Pfizer-BioNTech COVID-19 vaccination, 31.08.2021, https://pubmed.ncbi.nlm.nih.gov/34463755/
- LEE et al. , Reply to "Letter to the editor: Myocarditis should be considered in those with a troponin rise and unobstructed coronary arteries following PfizerBioNTech COVID-19 vaccination, 31.08.2021, https://pubmed.ncbi.nlm.nih.gov/34463770/
- BARSHA et al. , A case of acute encephalopathy and non-ST-segment elevation myocardial infarction after vaccination with mRNA-1273: possible adverse effect, 01.09.2021, https://pubmed.ncbi.nlm.nih.gov/34703815/
- CALCATERRA et al. , COVID 19 vaccine for adolescents. Concern for myocarditis and pericarditis, 01.09.2021, https://www.mdpi.com/2036-7503/13/3/61
- DICKEY et al. , A series of patients with myocarditis after vaccination against SARS-CoV-2 with mRNA-1279 and BNT162b2, 01.09.2021, *https://www.sciencedirect.com/science/article/pii/S1936878X21004861*
- VISKIN et al. , Myocarditis associated with COVID-19 vaccination: echocardiographic, cardiac CT, and MRI findings, 01.09.2021, https://pubmed.ncbi.nlm.nih.gov/34428917/
- WONG et al. , Clinical Guidance for Young People with Myocarditis and Pericarditis after Vaccination with COVID-19 mRNA, 01.09.2021, https://cps.ca/en/documents/position/clinical-guidance-for-youth-with-myocarditis-and-pericarditis
- MARSHALL et al , Symptomatic Acute Myocarditis in 7 Adolescents after Pfizer-BioNTech COVID-19 Vaccination, 03.09*.2021, https://publications.aap.org/pediatrics/article/148/3/e2021052478/179728/Symptomatic-Acute-Myocarditis-in-7-Adolescents*
- LEVIN et al , Myocarditis after COVID-19 vaccination: a case series, 04.09*.2021, https://www.sciencedirect.com/science/article/pii/S0264410X21011725?via%253Dihub*
- UJUETA et al , Lymphohistocytic myocarditis after vaccination with COVID-19 Ad26.COV2.S viral vector, 07.09*.2021, https://www.sciencedirect.com/science/article/pii/S2352906721001573*
- HØEG et al. , Myocarditis associated with SARS-CoV-2 mRNA vaccination in children aged 12 to 17 years: stratified analysis of a national database, 08.09*.2021, https://www.medrxiv.org/content/10.1101/2021.08.30.21262866v1*
- PATEL et al , Cardiovascular magnetic resonance imaging findings in young adult patients with acute myocarditis after COVID-19 mRNA vaccination: a case series, 09.09*.2021, https://jcmr-online.biomedcentral.com/articles/10.1186/s12968-021-00795-4*

- GAUTAM et al , A Late Presentation of COVID-19 Vaccine-Induced Myocarditis, 11.09.2021, https://pubmed.ncbi.nlm.nih.gov/34660088/
- BARDA et al , Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting, Sep 16, 2021, https://www.nejm.org/doi/full/10.1056/NEJMoa2110475
- UAPRASERT et al. , Prevalence of thrombocytopenia, antiplatelet factor 4 antibodies, and elevated D- dimer in Thais after vaccination with ChAdOx1 nCoV-19, 18.09.2021, https://pubmed.ncbi.nlm.nih.gov/34568726/
- AMBATI et al , Acute myopericarditis after COVID-19 vaccination in adolescents, 20.09.2021, https://pubmed.ncbi.nlm.nih.gov/34589238/
- KAUL et al , Myocarditis after COVID-19 vaccination, 20.09*.2021, https://www.sciencedirect.com/science/article/pii/S2352906721001603*
- HENDREN et al. , Severe myocarditis associated with COVID-19 vaccine: zebra or unicorn? , 21.09.2021, *https://www.internationaljournalofcardiology.com/article/S0167-5273(21)01477-7/fulltext*
- KOIZUMI et al , Myocarditis after COVID-19 mRNA vaccines, 21.09.2021, *https://pubmed.ncbi.nlm.nih.gov/34546329/*
- ASHAARI et al. , Case report: symptomatic pericarditis post COVID-19 vaccination, 24.09.2021, https://pubmed.ncbi.nlm.nih.gov/34693198/
- AYE et al , Acute myocardial infarction and myocarditis after COVID-19 vaccination, 29.09.2021, https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8522388/
- VERMA et al. , Myocarditis following immunization with Covid-19 mRNA, 30.09.2021, https://www.nejm.org/doi/full/10.1056/NEJMc2109975
- D'ANGELO et al. , Myocarditis after SARS-CoV-2 vaccination: a vaccine-induced reaction? , 01.10.2021, https://pubmed.ncbi.nlm.nih.gov/34118375/
- ISAAK et al , Myocarditis Following COVID-19 Vaccination, 01.10.2021, https://pubmed.ncbi.nlm.nih.gov/34342500/
- KWAN et al , mRNA COVID vaccine and myocarditis in adolescents, 01.10.2021, https://pubmed.ncbi.nlm.nih.gov/34393110/
- SNAPIRI et al , Transient cardiac injury in adolescents receiving the BNT162b2 mRNA COVID-19 vaccine, 01.10*.2021, https://journals.lww.com/pidj/Fulltext/2021/10000/Transient_Cardiac_Injury_in_Adolescents_Receiving.1.aspx*
- SUNG et al , Acute myocardial infarction within 24 hours after COVID-19 vaccination, 01.10.2021, https://pubmed.ncbi.nlm.nih.gov/34364657/
- MAKI et al , Biventricular systolic dysfunction in acute myocarditis after SARS-CoV-2 mRNA-1273 vaccination, 03.10.2021, https://pubmed.ncbi.nlm.nih.gov/34601566/

- MEVORACH et al , Myocarditis following BNT162b2 mRNA Covid-19 mRNA vaccine in Israel, 06.10.2021, https://pubmed.ncbi.nlm.nih.gov/34614328/
- KIM et al , Report of a case of myopericarditis after vaccination with BNT162b2 COVID-19 mRNA in a young Korean male, 11.10.2021, https://pubmed.ncbi.nlm.nih.gov/34636504/
- ALANIA-TORRES et al. , Case report: probable myocarditis after Covid-19 mRNA vaccine in a patient with arrhythmogenic left ventricular cardiomyopathy, 12.10.2021, https://pubmed.ncbi.nlm.nih.gov/34712717/
- HAJJO et al , Shedding light on post-vaccination myocarditis and pericarditis in COVID-19 and non-COVID-19 vaccine recipients, 15.10.2021, https://pubmed.ncbi.nlm.nih.gov/34696294/
- SALAH et al , COVID-19 vaccine and myocarditis, 15.10.2021, https://pubmed.ncbi.nlm.nih.gov/34399967/
- Choi et al , Myocarditis-induced sudden death after BNT162b2 COVID-19 mRNA vaccination in Korea: case report focusing on histopathological findings, 18 Oct 2021, https://pubmed.ncbi.nlm.nih.gov/34664804/
- MIQDAD et al , Acute myocarditis after administration of the second dose of BNT162b2 COVID-19 vaccine, 18.10.2021, https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8599115/
- ONDERKO et al , Myocarditis in the setting of a recent COVID-19 vaccination, 19.10.2021, https://pubmed.ncbi.nlm.nih.gov/34712497/
- SCHMITT et al. , Acute myocarditis after COVID-19 vaccination: a case report, 19.10.2021, https://www.sciencedirect.com/science/article/pii/S0248866321007098

1.14.6.2 Coagulation disorders etc. (thromboses, cerebral strokes etc.): 130 publications

435 By **26 October 2021,** the following additional **130 peer-reviewed publications** had appeared in which a connection between the occurrence of coagulation disorders and associated consequences (thromboses, pulmonary embolisms, strokes, etc.) and the COVID "vaccinations" was proven (or at least a significant suspicion in this regard was shown):

- BIKDELI et al. , Cerebral venous sinus thrombosis in the U.S. population after SARS-CoV-2 vaccination with adenovirus and after COVID-19, 08.06.2021, https://www.sciencedirect.com/science/article/pii/S0735109721051949
- ÖCAL et al , Portal vein thrombosis associated with ChAdOx1 nCov-19 vaccine, 08.06.2021, *https://www.thelancet.com/journals/langas/article/PIIS2468-1253(21)00197-7/fulltext*

- ZAKARIA et al. , Cerebral venous sinus thrombosis 2 weeks after first dose of SARS-CoV-2 mRNA vaccine, 08.06.2021, https://pubmed.ncbi.nlm.nih.gov/34101024/
- BOURGUIGNON et al. , Immunoglobulin adjuvant for vaccine-induced immune thrombotic thrombocytopenia, 09.06.2021, https://pubmed.ncbi.nlm.nih.gov/34107198/
- SIMPSON et al , First dose of ChAdOx1 and BNT162b2 COVID-19 vaccines and thrombocytopenic, thromboembolic, and hemorrhagic events in Scotland, 09.06.2021, https://www.nature.com/articles/s41591-021-01408-4
- WARKENTIN et al. , Spontaneous HIT syndrome: knee replacement, infection and parallels with vaccine-induced immune thrombotic thrombocytopenia, 09.06.2021, https://pubmed.ncbi.nlm.nih.gov/34144250/
- CINES et al , Thrombotic immune thrombocytopenia induced by SARS-CoV-2 vaccine, 10.06.2021, https://www.nejm.org/doi/full/10.1056/nejme2106315
- AL-MAQBALI et al, 59-year-old woman with extensive deep venous thrombosis and pulmonary thromboembolism 7 days after a first dose of Pfizer-BioNTech BNT162b2 mRNA vaccine COVID-19, 12.06.2021, https://pubmed.ncbi.nlm.nih.gov/34117206/
- HUH et al. , Predicted and observed incidence of thromboembolic events among Koreans vaccinated with the ChAdOx1 nCoV-19 vaccine, 12.06.2021, https://pubmed.ncbi.nlm.nih.gov/34254476/
- HWANG et al. , Comparison of vaccine-induced thrombotic episodes between ChAdOx1 nCoV-19 and Ad26.COV.2.S vaccines, 15.06.2021, https://pubmed.ncbi.nlm.nih.gov/34139631/
- MARCHANDOT et al. , Procoagulant microparticles: a possible link between vaccine-induced immune thrombocytopenia (VITT) and cerebral sinus venous thrombosis, 15.06.2021, https://pubmed.ncbi.nlm.nih.gov/34129181/
- KRAJEWSKI et al. , Immune thrombocytopenic purpura associated with COVID-19 mRNA vaccine Pfizer- BioNTech BNT16B2b2, 16.06.2021, https://pubmed.ncbi.nlm.nih.gov/34077572/
- SØRENSEN et al. , A case of multiple thrombocytopenia and thrombosis following vaccination with ChAdOx1 nCoV-19 against SARS-CoV-2, 17.06.2021, https://pubmed.ncbi.nlm.nih.gov/34137813/
- TSILINGIRIS et al , Vaccine-induced thrombotic thrombocytopenia: the dark chapter of a success story, 18.06.2021, https://www.sciencedirect.com/science/article/pii/S2589936821000256
- LAVIN et al. , Vaccine-induced immune thrombotic immune thrombocytopenia (VITT): a new clinicopathologic entity with heterogeneous clinical presentations, 22.06.2021, https://pubmed.ncbi.nlm.nih.gov/34159588/

- SEE et al. , US case reports of cerebral venous sinus thrombosis with thrombocytopenia after vaccination with Ad26.COV2.S (against covid-19), 22.06.2021, https://pubmed.ncbi.nlm.nih.gov/33929487/
- CARI et al. , Blood clots and bleeding episodes after BNT162b2 and ChAdOx1 nCoV-19 vaccination: analysis of European data, 23.06.2021, https://www.sciencedirect.com/science/article/pii/S0896841121000937
- DUTTA et al. , Cerebral venous sinus thrombosis negative for anti-PF4 antibody without thrombocytopenia after immunization with COVID-19 vaccine in a non-comorbid elderly Indian male treated with conventional heparin-warfarin based anticoagulation, 24.06.2021, https://www.sciencedirect.com/science/article/pii/S1871402121002046
- GESSLER et al. , Neurosurgical considerations with respect to decompressive craniectomy for intracerebral hemorrhage after SARS-CoV-2 vaccination in vaccine-induced thrombotic thrombocytopenia-VITT, 24.06.*2021, https://pubmed.ncbi.nlm.nih.gov/34202817/*
- CRISTOFARO et al. , Vaccine-induced thrombotic thrombocytopenia, a rare but severe case of friendly fire in the battle against the COVID-19 pandemic: What pathogenesis? , 29.06*.2021, https://www.sciencedirect.com/science/article/pii/S0953620521002314*
- CLIFF-PATEL et al. , Renal vein thrombosis and pulmonary embolism secondary to vaccine-induced thrombotic immune thrombocytopenia (VITT), 30.06.2021, https://pubmed.ncbi.nlm.nih.gov/34268278/
- BLAUENFELDT et al. , Thrombocytopenia with acute ischemic stroke and hemorrhage in a patient recently vaccinated with an adenoviral vector-based COVID-19 vaccine, 01.07.2021, https://pubmed.ncbi.nlm.nih.gov/33877737/
- CICCONE, Cerebral venous thrombosis induced by SARS-CoV-2 vaccine, 01.07.2021, https://pubmed.ncbi.nlm.nih.gov/34090750/
- COOPER et al , Severe immune thrombocytopenic purpura after SARS-CoV-2 vaccine, 01.07.2021, https://pubmed.ncbi.nlm.nih.gov/34754937/
- CUKER, Thrombosis with thrombocytopenia syndrome after COVID-19 immunization, 01.07*.2021, https://www.hematologyandoncology.net/files/2021/07/ho0721Cuker-1.pdf*
- FURIE et al. , Diagnosis and treatment of cerebral venous sinus thrombosis with vaccine-induced immune-immune thrombotic thrombocytopenia, 01.07.2021, https://pubmed.ncbi.nlm.nih.gov/33914590/
- SMADJA et al. , COVID-19 vaccination: information on the occurrence of arterial and venous thrombosis using data from VigiBase, 01.07.2021, https://pubmed.ncbi.nlm.nih.gov/33863748/

- SØRVOLL et al. , An observational study to identify the prevalence of thrombocytopenia and anti-PF4 / polyanion antibodies in Norwegian health care workers after COVID-19 vaccination, 01.07.2021, https://pubmed.ncbi.nlm.nih.gov/33909350/
- TURI et al. , A case of vaccine-induced immune-immune thrombotic thrombocytopenia with massive arteriovenous thrombosis, 01.07.2021, https://pubmed.ncbi.nlm.nih.gov/34059191/
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1.14.6.3 Deaths: 4 publications

436 By **26 October 2021, the** following **4 peer-reviewed publications** had also **been** published in which a connection between the death of vaccinated persons (incl. stillbirths) and COVID "vaccinations" was proven (or at least a significant suspicion in this regard was shown):

- SHIMABUKURO et al , Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons, 17.06.2021, https://www.nejm.org/doi/full/10.1056/NEJMoa2104983
- EHRLICH et al. , Biopsy-proven lymphocytic myocarditis after first COVID-19 mRNA vaccination in a 40-year-old man: case report, 06.09.2021, https://pubmed.ncbi.nlm.nih.gov/34487236/
- SCHNEIDER et al. , Postmortem investigation of fatalities following vaccination with COVID-19 vaccines, 30.09.2021, *https://pubmed.ncbi.nlm.nih.gov/34591186/*
- WATCHMAKER et al , Brain death in a vaccinated patient with COVID-19 infection, 11.10.2021, https://pubmed.ncbi.nlm.nih.gov/34656887/

2. Effectiveness

2.1. First and second vaccinations: Updated and missing data

437 As already mentioned above (N 189 ff., N 291 ff.), the information on the efficacy of the interim results in the approval studies was based on very thin, flawed data and, moreover, was presented in a distorting manner by stating the relative risk reduction. This did not change even after almost a year - on the contrary:

2.1.1. Minimal therapeutic benefit for mere trivial events

2.1.1.1 Pfizer: Lack of efficacy in "confirmed COVID disease".

438 In the *NEJM* (*New England Journal of Medicine*) "6-month data" published on 4 November 2022, based on 81 cases in the vaccine group versus 873 cases in the placebo group, a reduced but still high efficacy **of 91.3%** compared to the **initial efficacy of 95%** was officially reported.[298] Again, the efficacy was inflated by using the RRR (see N 196 ff.). The fact that the case numbers reported in the approval studies are generally unreliable and erroneous because, among other things, in the vaccine and placebo groups no PCR test was carried out at all in > 1500 cases each of symptomatic diseases for inexplicable reasons has already been explained in detail (see N 200 f.).

298 THOMAS et al, FN 232.

439 It should be noted that only about 7% of the study participants really had data for six months. For 51% of the study participants, only data on a follow-up of four to significantly less than six months after the second dose were available, which calls into question the official designation "6-month data".

2.1.1.2 Moderna: No updated data available

440 As already mentioned above (N 205 f.), the data on the efficacy of Spikevax® in the 2-month analyses of the registration studies were based on very thin data and were also distorted (RRR).

441 The endpoint events ("confirmed COVID conditions" and "severe COVID conditions") in the most recent Spikevax® SmPC available in May 2022 (as of January 2022) still corresponded to the 2-month data and have not been updated to date.[299] This is astonishing in the context of a "rolling marketing authorisation procedure", since the marketing authorisation study of Spikevax® was initiated in July 2020 and Swissmedic had requested in the marketing authorisation letter to Moderna that interim results of ongoing studies be submitted (Supplement **3**, p. 9). According to Art. 28 of the Ordinance on Medicinal Products (OMP), the marketing authorisation holder is obliged to adapt the information on the medicinal product to the current state of science and technology and to new events and assessments on an ongoing basis and without being asked to do so.

2.1.2. No proven therapeutic benefit for "severe" diseases

442 The lack of efficacy of the COVID "vaccinations" for severe COVID diseases, which had already been shown in the 2-month data of the approval studies, was also confirmed on the basis of the 6-month data - even if the manufacturers once again misleadingly announced the opposite:

2.1.2.1 Pfizer: Lack of efficacy in "severe COVID disease".

443 The unscientific and false presentation of efficacy with regard to "severe COVID diseases" supported by Swissmedic once again becomes obvious when looking at the updated summary of product characteristics for Comirnaty®[300] , published in the *New England Journal of Medicine* (*NEJM*)[301] with regard to "6-month data":

299 Swissmedicinfo, FN 71.
300 Swissmedicinfo, FN 48.
301 THOMAS et al, FN 232.

444 The originally declared efficacy of 66.4%[302] (2-month data) concerning the prevention of severe courses of disease is now said to have risen to "95-100%", because according to "6-month data", 30 **"severe COVID diseases"** were reported for the vaccine group 1 and for the placebo group. From this, an efficacy of 96.7% is derived - again based on the relative risk reduction (RRR). However, the relevant absolute risk reduction (**ARR**) is only **0.1%**. Against this background, the **updated efficacy data on the prevention of "severe COVID diseases" in the** product information must once again be classified as **unscientific and misleading.**

445 Why the efficacy of Comirnaty® should have worsened in the "confirmed COVID diseases" but significantly improved in the "severe COVID diseases" is not rationally explainable.

2.1.2.2 Moderna: No updated data available

446 No new data were available on Spikevax® under this title until the end of 2021.

2.1.3. International studies: manufacturers' efficacy claims untenable

447 Already a few months after the first temporary approval of the COVID "vaccines", studies were published which openly questioned the allegedly high efficacy of over 90%.

2.1.3.1 Effectiveness falls to 23

448 A large-scale study in California, where 869 samples of nasal swabs were examined from June to August 2021, showed that the viral load, measured by the Ct value, was comparable in "vaccinated" and "unvaccinated" persons infected with SARS-Cov-2. More than 20 % of the "vaccinated" persons who tested positive had a high viral load (Ct values <20).[303]

449 In July 2021, an Israeli study concluded that the "vaccine" only protected 64% against COVID infections.[304] In September 2021, a Swedish study determined that the - alleged - protection by Comirnaty® was still "a meagre 23%". [305]

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302 Internet archive, FN 140.

303 ACHARYA et al, "No Significant Difference in Viral Load Between Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Groups Infected with SARS-CoV-2 Delta Variant", preprint 05.10.2021, https://www.medrxiv.org/content/10.1101/2021.09.28.21264262v2.

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305 MDR, "Swedish study - Hardly any protection against infection after half a year - how long do the individual Corona vaccines work? ", 15.11.2021, https://www.mdr.de/brisant/corona-impfstoff-wirksamkeit-100.html.

2.1.3.2 Myth of "years of protection

450 The media painted an equally false picture with regard to the duration of the - alleged - immunisation by the "COVID vaccines": In June 2021, they talked about "years of protection after vaccination", which would practically rule out the need for a "booster".[306] In August 2021, they even went one better: "Immunity against Corona probably lasts for decades!" was the headline in the German newspaper "Bild".[307] And in December 2021, BioNTech founder Uğur Şahin announced that it "makes sense to offer a booster after only three months".[308] The turnaround from decades of protection (which obviously never existed) to a (supposed) three-month protection thus took place within a few months. In March 2022, the Federal Council was even planning the fourth "vaccination".[309]

2.2. "Booster": lack of or insufficiently proven efficacy

2.2.1. "Booster" planned from the beginning

451 **Even before the COVID "vaccines" were licensed in** December 2020, it **became apparent that** the basic immunisation with two doses of vaccine would not be sufficient and **the licence holders** were **planning booster vaccinations.** In the letter *"Zulassungsverfügung"* dated 21.01.2021, Swissmedic wrote to Moderna: "*Moderna is considering additional booster doses of mRNA-1273 with ongoing clinical trials to assess safety and immunogenicity endpoints. Given that at this point the duration of protection and the potential need for boosting doses is unknown, Swissmedic would like Moderna to keep Swissmedic informed through submission of protocol amendments and SAPs.* " (Annex **3**, p. 12) .

306 Picture, "Hammer study on Moderna and Biontech - Years of protection after vaccination!", 29.06.2021, https://www.bild.de/ratgeber/gesundheit/gesundheit/hammer-studie-aus-den-usa-forscher-sicher-jahrelanger-schutz-nach-diesen-beiden-76908882.bild.html.

307 Bild, "Immunologist gives hope - Immunity against Corona probably lasts decades! ", 06.08.2021, https://www.bild.de/bild-plus/ratgeber/2021/ratgeber/immunologe-immunitaet-gegen-corona-haelt-wahrscheinlich-jahrzehntelang-77295636.

308 FAZ, "Biontech founder Uğur Şahin - 'Sensible to offer a booster after just three months'", 09.12.2021, https://www.faz.net/aktuell/gesellschaft/gesundheit/coronavirus/booster-ugur-sahin-fuer-corona-auffrischung-nach-drei-monaten-17676684.html.

309 20Minuten, "Bundesrat plans fourth vaccination - Another booster vaccination to become topical in autumn at the latest", 31.03.2022, https://www.20min.ch/story/massnahmen-weg-bundesrat-plant-vierte-impfung-956907760824.

2.2.2. Data situation "Booster": Insufficient studies and misleading calculations

2.2.2.1 Pfizer: Comirnaty®

452 For Comirnaty®, the efficacy of a booster vaccination was investigated in three studies:

453 In study 1, an ongoing randomised trial administered a "booster" approximately 8 months after the 2nd dose in 11 study participants aged 18-55 years and in 12 study participants aged 65-85 years. It was shown that antibody levels increased significantly 4 weeks after the booster. Data on the longer-term course of antibody levels are missing. This study also did not investigate whether the increase in antibodies was associated with fewer (severe) COVID diseases in the course. It is incomprehensible why the course of the antibody levels was only examined in a total of 23 study participants.[310]

454 Study 2 was a retrospective analysis of an Israeli health database that examined the data of 1,137,804 people (>60 years) over a period of four weeks (30 July to 31 August 2021). The number of "COVID cases" 12 days after the "booster" was lower by a factor of 11, and the number of severe "COVID cases" was lower by a factor of 19 in the boostered than in the dually vaccinated.[311] The study period of just four weeks in this study is, of course, clearly too short for a conclusive assessment of the effectiveness of a booster vaccination. Retrospective observational studies like this health database analysis are prone to systematic bias. They can lead to erroneous results. Whenever possible, a question should therefore be investigated by means of a prospective randomised trial. It is absolutely unusual to grant marketing authorisations based on database analyses.[312]

455 Study 3 was a placebo-controlled trial that investigated the incidence of confirmed COVID-19 cases in approximately 10,000 participants aged 16 years and older who had occurred between at least 7 days after booster vaccination and the data cut-off date of 5 October 2021, which corresponds to a median follow-up time of 2.5 months. In the vaccine group, 6/4,695 (0.1%) and in the placebo group, 123/4,671 (2.6%) study participants experienced "confirmed COVID disease". Based on these figures, a (relative) efficacy of 95% is proclaimed in the product information, while the absolute risk reduction is only 2.5%.[313]

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310 FALSEY et al, "SARS-CoV-2 Neutralization with BNT162b2 Vaccine Dose 3", 21 Oct 2021, https://www.nejm.org/doi/10.1056/NEJMc2113468?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.

311 BAR-ON et al, "Protection of BNT162b2 Vaccine booster against Covid-19 in Israel", 15.09.2021, https://www.nejm.org/doi/10.1056/NEJMoa2114255?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.

312 Ärzteblatt, "Avoiding biased results in observational studies", 09.10.2009, https://www.aerzteblatt.de/archiv/66222/Vermeidung-verzerrter-Ergebnisse-in-Beobachtungsstudien.

313 Swissmedicinfo, FN 48.

2.2.2.2 Moderna: Spikevax®

456 For Spikevax®, the efficacy of booster vaccination was investigated in an ongoing randomised trial: 149/198 study participants received a single booster dose at least 6 months after the 2nd dose, which was shown to be "immunogenic and non-inferior" to the immunogenicity evidenced on day 57 after the 2nd dose of basic immunisation on day 29 after its administration.[314]

457 **It was not investigated whether the antibody levels were maintained in the longer term and whether there were also fewer (severe) COVID cases in the course after the booster vaccination compared to double vaccinated or unvaccinated persons.**

458 The data presented to prove the effectiveness of a booster vaccination for the mRNA vaccines must be regarded as completely inadequate overall. It is not comprehensible how Swissmedic could grant an authorisation for the "booster" vaccinations based on these data.

2.2.2.3 Interim conclusion: Approval of the "booster" irresponsible

459 The fact that Swissmedic approved the authorisation of the "booster" on the basis of this completely insufficient data seems abstruse in view of the risks that were known with the COVID "vaccines" at the time of this indication extension. This is especially true since the "booster" was to be administered preventively to all (healthy) persons aged 16 and over (Comirnaty®) or 18 and over (Spikevax®) and to all "particularly at risk" persons aged 12 and over[315] for a disease which, at the time of the extension of the indication, clearly posed less of a risk to the majority of this target group than it did at the beginning of the pandemic (see N 633 ff., N 648 ff., N 670 ff.). It must be assumed that the risk of side effects multiplies with each additional dose.[316]

460 By deliberately authorising the repeated doses of COVID "vaccines" despite serious safety signals now emerging worldwide, Swissmedic has failed in its legal duty to protect the Swiss population from risks associated with medicinal products.

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314 Internet archive, "Fachinformation Spikevax", status 11.2021, https://web.archive.org/web/20220112130026/https://www.swissmedicinfo.ch/ShowText.aspx?textType=FI&lang=DE&authNr=68267.

315 Internet archive, FN 314Internet archive, FN 140.

316 Doctors for COVID Ethics, "The danger of booster shots and COVID-19 "vaccines": boosting blood clots and leaky vessels", 17.09.2021, https://doctors4covidethics.org/boosting-blood-clots-and-leaky-vessels-the-dangers-of-covid-19-vaccines-and-booster-shots/.

2.2.3. "3rd dose immunosuppressed": no relevant proof of efficacy provided

2.2.3.1 Pfizer: Comirnaty®

461 The data basis for the 3rd dose in immunocompromised patients for Comirnaty® is a retrospective observational study in France with 101 immunocompromised organ transplanted patients, which showed that after the 2nd dose 40% of the patients examined had antibodies (AK) against SARS-CoV-2, four weeks after the 3rd dose this proportion increased only slightly and was then 68%. No information is available on whether the AK levels remained stable beyond four weeks.[317]

2.2.3.2 Moderna: Spikevax®

462 In the case of Spikevax®, a randomised trial of 120 immunosuppressed organ transplant patients investigated how antibody levels developed when a 3rd dose (n=60) versus a placebo solution (n=60) was administered. A "significant" increase in SARS-CoV-2 antibody levels occurred four weeks after the 3rd dose in only 55% of those in the vaccine group and 17.5% of those in the placebo group.[318] The methodology of a detection technique that also shows an antibody increase in 17.5% of the study participants in the placebo group seems questionable after all.

2.2.3.3 Summary on the efficacy of a 3rd dose in immunocompromised patients

463 For both COVID "vaccines", a 3rd dose did not lead to increased antibody levels in a significant proportion of organ transplant recipients (32% Comirnaty® 45% Spikevax®). 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. In the phase 3 trials, immunosuppressive therapy was an exclusion criterion for participation in the study.[319]

464 The uncertain data on efficacy in immunocompromised *patients* was noted in the SmPC of Spikevax® with the following sentence: "*Although there is no direct evidence that the ability to produce antibodies in these patients protects against severe COVID-19 disease, it is believed that the additional dose may increase protection in at least some patients. "*[320]

317 KAMAR et al, "Three doses of mRNA Covid-19 Vaccine in solid-organ transplant recipients",12.08.2021, https://www.nejm.org/doi/10.1056/NEJMc2108861?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.
318 FN 314.
319 Pfizer and Internet archive, FN 85.
320 Internet archive, FN 314.

465 The current Spikevax® and Comirnaty® product information still contains the following note regarding the lack of evidence of efficacy in immunocompromised individuals: "*The efficacy, safety and immunogenicity of the vaccine have not been studied in immunocompromised individuals, including those receiving immunosuppressive treatment. The efficacy of the vaccine may be reduced in immunosuppressed individuals. "*[321]

466 The Medicines and Healthcare products Regulatory Agency (M*HRA*) explicitly advised *immunocompromised* persons to use physical *precautions* even after the third dose, as the immunity generated by the "vaccination" was insufficient: "*If you are immunocompromised and receive an additional dose of mRNA Vaccine BNT162b2, it may still not provide full immunity to COVID-19 and you should continue to maintain physical precautions to help prevent COVID-19*".[322]

467 The data presented to substantiate the efficacy of a "3rd dose in immunocompromised patients" must be considered overall as unsound and insufficient. It is incomprehensible how Swissmedic could approve an authorisation and thus expose vulnerable organ transplanted and immunosuppressed patients for other reasons to the risks of gene-based "vaccination" without any relevant benefit having obviously been demonstrated.

2.2.3.4 Inconsistent dosing booster and 3rd dose Comirnaty® versus Spikevax®.

468 For Comirnaty®, the same dosage (0.3ml corresponding to 30µg mRNA) is recommended for the booster vaccination and the 3rd dose in immunocompromised persons as for the basic immunisation.[323]

469 With Spikevax®, the basic immunisation is carried out with 0.5ml (corresponding to 100µg mRNA). For the booster vaccination half the dosage (0.25ml corresponding to 50µg mRNA) is recommended, for the 3rd dose in immunosuppressed persons the full dosage (0.5ml corresponding to 100µg mRNA).[324]

470 These divergent dosing concepts for the booster vaccination or the third dose for immunosuppressed persons for the two COVID "vaccines" are inconsistent and incomprehensible from a scientific and medical point of view.

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321 Swissmedicinfo, FN 71; Swissmedicinfo, FN 48.

322 MHRA, "Information for UK recipients on Pfizer/BioNTech COVID-19 vaccine (Regulation 174)", 24.05.2022, https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19/information-for-uk-recipients-on-pfizerbiontech-covid-19-vaccine.

323 Internet archive, FN 140.

324 Internet archive, FN 314.

2.2.3.5 Interim conclusion

471 The data situation for booster vaccination and the 3rd dose in immunosuppressed persons is altogether thin and not very convincing. No relevant efficacy was demonstrated for any of the target groups investigated. The fact that Swissmedic approved the rapid authorisation of the 3rd dose in immunosuppressed persons based on this completely insufficient data situation seems grotesque in view of the risks known with the COVID "vaccines" at the time of this indication extension.

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

2.3.1. Minimal therapeutic benefit for mere trivial events

472 In the pivotal trial of Comirnaty®, which investigated efficacy in children aged 5-11 years, "confirmed COVID disease" occurred in 3/1517 (0.2%) children in the vaccine group and in 16/751 (2.1%) children in the placebo group.[325] From these figures, an absolute risk reduction (ARR) of 1.9% was derived. This showed that 53 children had to be vaccinated, i.e. exposed to the risk of an immature mRNA "vaccine" ("*NNTV*", "*number needed to vaccine*"), in order to prevent a trivial event such as a sore throat or headache in combination with a positive PCR test.

2.3.2. No data for "severe" diseases

473 In the 5 to 11-year-olds, as in the adolescents aged 12 and older, no "severe COVID diseases" occurred in the registration studies.[326] The COVID-19 "vaccination" from Pfizer/BioNTech has thus not been able to show any efficacy against severe disease. This fact that no severe "COVID illnesses" occur in children in the phase 3 trial reflects the reality, where likewise hardly any severe disease courses are observed in connection with illness with the SARS-CoV-2 virus.

474 Swissmedic's statement in its communication "*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*" (N 20) was once again taken out of a vacuum and grossly misleading, as the pivotal trial did not contain any data to support such a conclusion.

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325 WALTER et al, "Evaluation of the BNT162b2 Covid-19 Vaccine in Children 5 to 11 Years of Age", 06.01.2022, https://www.nejm.org/doi/10.1056/NEJMoa2116298?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.

326 See already source(s) in ALI et al., FN 211; FRENCK et al., FN 212 and WALTER et al., FN 325.

2.3.3. Conclusion

475 The pivotal studies of Comirnaty® have not shown relevant efficacy in children aged 5 to 11 years. Since data as early as 2020 demonstrated that children do not become severely ill with COVID, generate long-lasting immunity in the event of disease, and do not expose adults to an increased risk of disease or hospitalisation in the event of infection (posterior N 687 ff.), it was already obvious before the temporary approval was granted that the COVID "vaccination" cannot be associated with any benefit for children.

476 A detailed statement by three authors from Wageningen University in Holland, Johns Hopkins University in Baltimore and Oxford University in England, submitted for publication on 16.2.2022, concluded that **COVID "vaccination" of healthy children** could **not** be **justified on ethical grounds** because the **risks outweighed** the minimal benefits.[327]

477 The conditions for a temporary approval of Comirnaty® were thus not fulfilled, even in purely formal terms. Since serious risks with serious events and deaths in connection with the use of COVID "vaccines" in adolescents aged 12 years and older were already apparent in the suspected cases of side effects recorded worldwide before the approval for children aged 5 to 11 years was granted (see above N 352, N 369 ff., N 427 f.), Swissmedic deliberately and willingly exposed children aged 5 and over to a high risk by authorising Comirnaty® , since the "vaccination" has been proven not to be beneficial, but only harmful.

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

478 In addition to the previously listed (N 298), **at least another 24 publications and preprint 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":

- LYSKI et al. , SARS-CoV-2 specific memory B-cells from individuals with diverse disease severities recognise SARS-CoV-2 variants of concern, 03.06.*2021, https://www.medrxiv.org/content/10.1101/2021.05.28.21258025v1.full*
- NIELSEN et al , SARS-CoV-2 elicits robust adaptive immune responses regardless of disease severity, 04.06.2021, *https://www.thelancet.com/journals/ebiom/article/PIIS2352-3964(21)00203-6/fulltext*

327 KRAAIJEVELD et al, "Against COVID-19 vaccination of healthy children", 16.02.2022, https://onlinelibrary.wiley.com/doi/epdf/10.1111/bioe.13015.

- LAFON et al , Potent SARS-CoV-2-Specific T Cell Immunity and Low Anaphylatoxin Levels Correlate With Mild Disease Progression in COVID-19 Patients, Jun 14, *2021, https://www.frontiersin.org/articles/10.3389/fimmu.2021.684014/full#B14*
- WANG et al. , Naturally enhanced neutralizing breadth against SARS-CoV-2 one year after infection, 14.06.2021, https://www.nature.com/articles/s41586-021-03696-9
- JUNG et al. , SARS-CoV-2-specific T cell memory is sustained in COVID-19 convalescent patients for 10 months with successful development of stem cell-like memory T cells, 30.06.2021, https://www.nature.com/articles/s41467-021-24377-1?utm_source=other&utm_medium=other&utm_content=null&utm_campaign=JRCN_1_LW01_CN_natureOA_article_paid_XMOL
- LETIZIA et al , SARS-CoV-2 seropositivity and subsequent infection risk in healthy young adults: a prospective cohort study, 01.07.2021, *https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(21)00158-2/fulltext*
- WEI et al. , Anti-spike antibody response to natural SARS-CoV-2 infection in the general population, 05.07.*2021, https://www.medrxiv.org/content/10.1101/2021.07.02.21259897v1*
- KOJIMA et al. , Incidence of severe acute respiratory syndrome coronavirus-2 infection among previously infected or vaccinated employees, 08.07.2021, *https://www.medrxiv.org/content/10.1101/2021.07.03.21259976v2.full.pdf+html*
- PETERSEN et al , SARS-CoV-2 Natural Antibody Response Persists for at Least 12 Months in a Nationwide Study From the Faroe Islands, 15.07.2021, https://academic.oup.com/ofid/article/8/8/ofab378/6322055?login=false
- SURESHCHANDRA et al , Single cell profiling of T and B cell repertoires following SARS-CoV-2 mRNA vaccine, 15.07.*2021, https://www.biorxiv.org/content/10.1101/2021.07.14.452381v1*
- MISHRA et al. , Natural immunity against COVID-19 significantly reduces the risk of reinfection: findings from a cohort of sero-survey participants, 19.07.*2021, https://www.medrxiv.org/content/10.1101/2021.07.19.21260302v1*
- COHEN et al. , Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells, 20.07.2021, *https://www.cell.com/cell-reports-medicine/fulltext/S2666-3791(21)00203-2#%20*
- RANK et al. , One Year after Mild COVID-19: The Majority of Patients Maintain Specific Immunity, But One in Four Still Suffer from Long-Term Symptoms, 27.07.2021, https://pubmed.ncbi.nlm.nih.gov/34362088/
- CHO et al , Antibody Evolution after SARS-CoV-2 mRNA Vaccination, 29.07.*2021, https://www.biorxiv.org/content/10.1101/2021.07.29.454333v1*

- DEHGANI-MOBARAKI et al. , Longitudinal observation of antibody responses for 14 months after SARS-CoV-2 infection, 31.07.2021, https://www.sciencedirect.com/science/article/pii/S1521661621001510
- WANG et al. , Ultrapotent antibodies against diverse and highly transmissible SARS-CoV-2 variants, 13.08.2021, https://www.science.org/doi/full/10.1126/science.abh1766
- GAZIT et al. , Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections, 25.08.2021, *https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.full.pdf+html*
- WADMAN, Having SARS-CoV-2 once confers much greater immunity than a vaccine-but vaccination remains vital, 26.08.2021, https://www.science.org/content/article/having-sars-cov-2-once-confers-much-greater-immunity-vaccine-vaccination-remains-vital
- CHIVESE et al , The prevalence of adaptive immunity to COVID-19 and reinfection after recovery - a comprehensive systematic review and meta-analysis of 12 011 447 individuals, 17.09.2021, *https://www.medrxiv.org/content/10.1101/2021.09.03.21263103v3.full.pdf+html*
- SHENAI et al. , Equivalency of Protection from Natural Immunity in COVID-19 Recovered Versus Fully Vaccinated Persons: A Systematic Review and Pooled Analysis, 21.09*.2021, https://www.medrxiv.org/content/10.1101/2021.09.12.21263461v1*
- HAVERI et al. , Persistence of neutralizing antibodies a year after SARS-CoV-2 infection in humans, 27.09*.2021, https://onlinelibrary.wiley.com/doi/10.1002/eji.202149535*
- ZHANG et al , One-year sustained cellular and humoral immunities in coronavirus disease 2019 (COVID-19) convalescents, 05 Oct 2021, https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab884/6381561?login=false#.YWGhCytQ_Hc.twitter
- ISRAEL et al. , Large-scale study of antibody titer decay following BNT162b2 mRNA vaccine or SARS-CoV-2 infection, 31.12.2021, https://www.mdpi.com/2076-393X/10/1/64
- SHRESTHA et al , Necessity of Coronavirus Disease 2019 (COVID-19) Vaccination in Persons Who Have Already Had COVID-19, 13 Jan 2022, https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciac022/6507165?login=false

IV. State of knowledge as of 2022 ("Omicron variant")

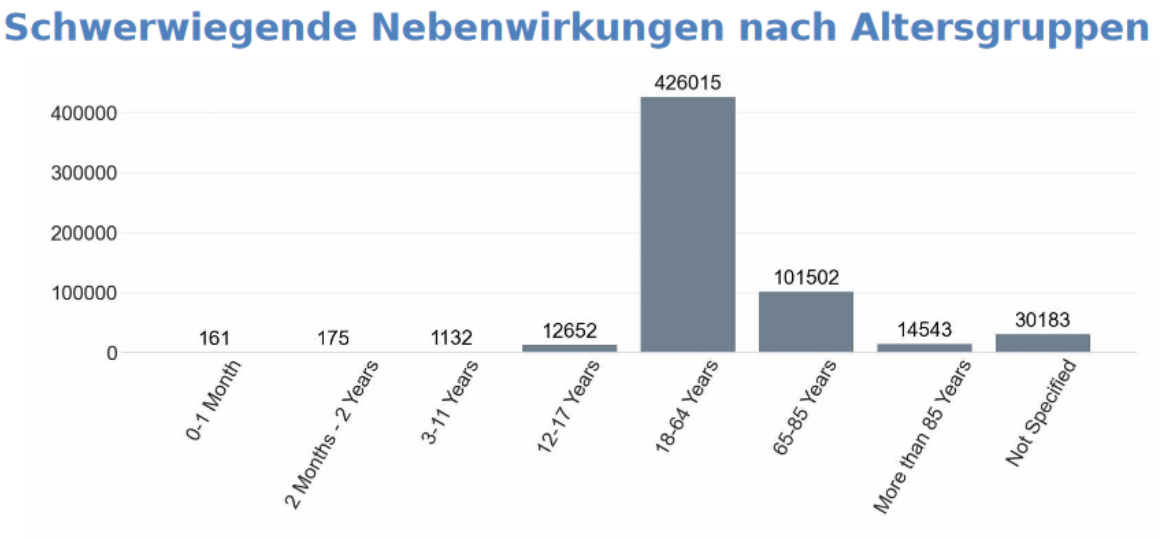
1. General motor risks

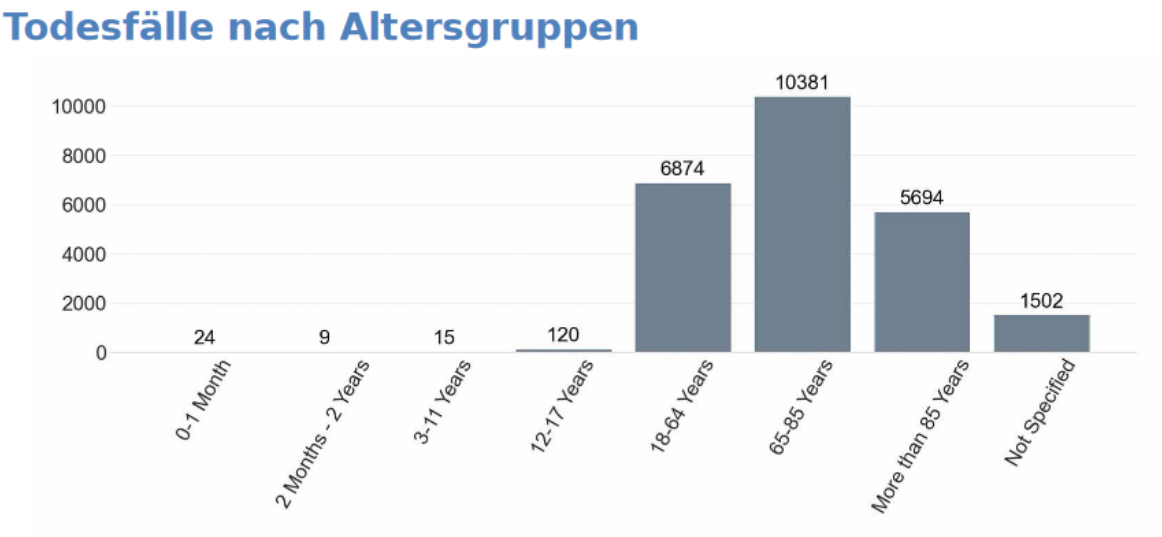
1.1. Worldwide reports of side effects at all-time highs

1.1.1. Side effects of all COVID-19 "vaccines

1.1.1.1 EU region: 24,619 deaths, 1.8 million adverse event reports

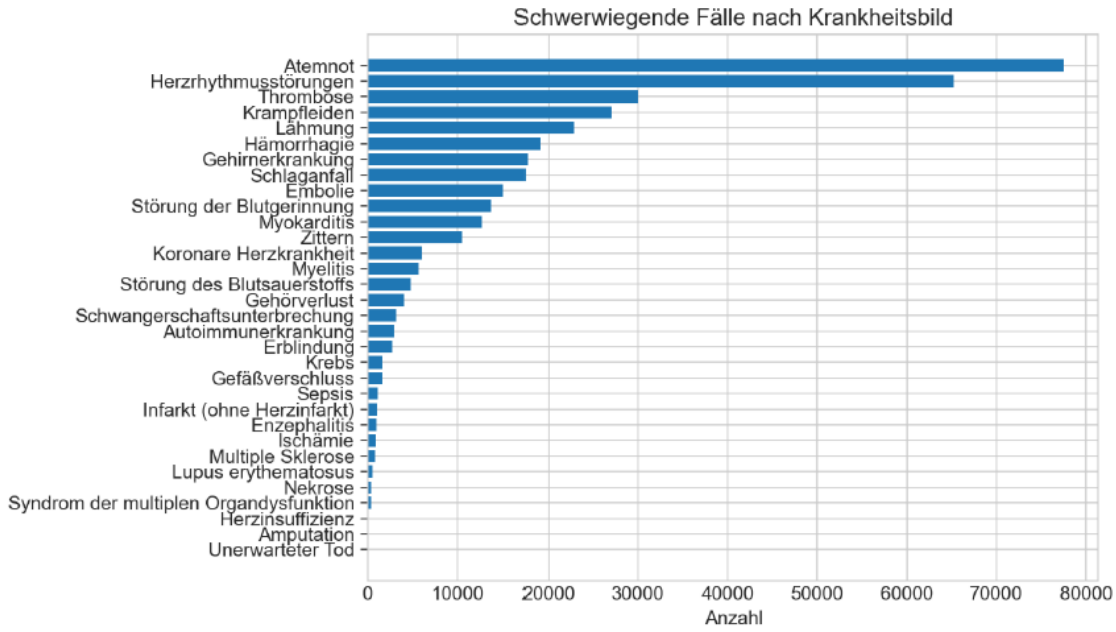
479 As of 6.5.2022, **1.8 million suspected adverse events** were reported by the *EMA,* 586,363 of which were classified as serious, and **24,619 deaths were** registered in connection with a COVID "vaccination". 168 deaths occurred in children and adolescents under 18 years of age, 6874 deaths in 18 to 64 year olds, 16'075 in over 64 year olds. In 1502 cases, no information on age was available (Supplement **18**, pp. 9, 11, 13, 17):





BO: Supplement **19:** Daily report of serious adverse reactions to COVID 19 vaccinations, as of 06.05.2022

480 **Common serious side effects** included **respiratory distress, cardiac arrhythmias, thrombosis, convulsions, paralysis, bleeding, brain disorders, strokes, embolisms, blood clotting disorders, myocarditis, tremors, coronary heart disease, myelitis** (inflammation of the spinal cord), **hearing loss**, **blindness**, **autoimmune diseases, cancer and abortions** (Supplement **19**, p. 25):



BO: Supplement **19:** Daily report of serious adverse reactions to COVID 19 vaccinations, Status 06.05.2022

1.1.1.2 USA: 27,968 deaths, 2.1 million adverse event reports

481 The US database "*Open VAERS*" creates and maintains its own database with records that are regularly downloaded from the official VAERS *website.* Large differences were observed between the numbers of adverse events reported by the official VAERS *website* and the *Open VAERS website,* which were attributed, among other things, to the fact that a relevant proportion of records were deleted from the *VAERS website.*[328]

482 *Open VAERS* reported **2.1 million suspected** adverse **events**, 155,633 hospitalisations and **27,968 deaths** related to COVID-19 "vaccination" as of 6/5/2022.[329]

1.1.2. Data basis

483 Based on the periodic "updates" from Swissmedic (until 06.05.2022) and the American and European databases (until 14.05.2022), the number of adverse reactions (all, serious/serious/serious, deaths) is as follows:[330]

328 VAERS ANALYSIS, "Are VAERS records for Covid-19 Vaccines being deleted every week???", 10.06.2021, https://vaersanalysis.info/2021/06/10/are-vaers-records-being-deleted-every-week/.

329 OPEN VAERS, as of 10.06.2022, https://openvaers.com/; cf. above VAERS, FN. 153.

330 Due to late reporting, the vaccine doses are backdated: 04.04.2022 (CH), 02.04.22 (EU), 16.04.21 (USA).

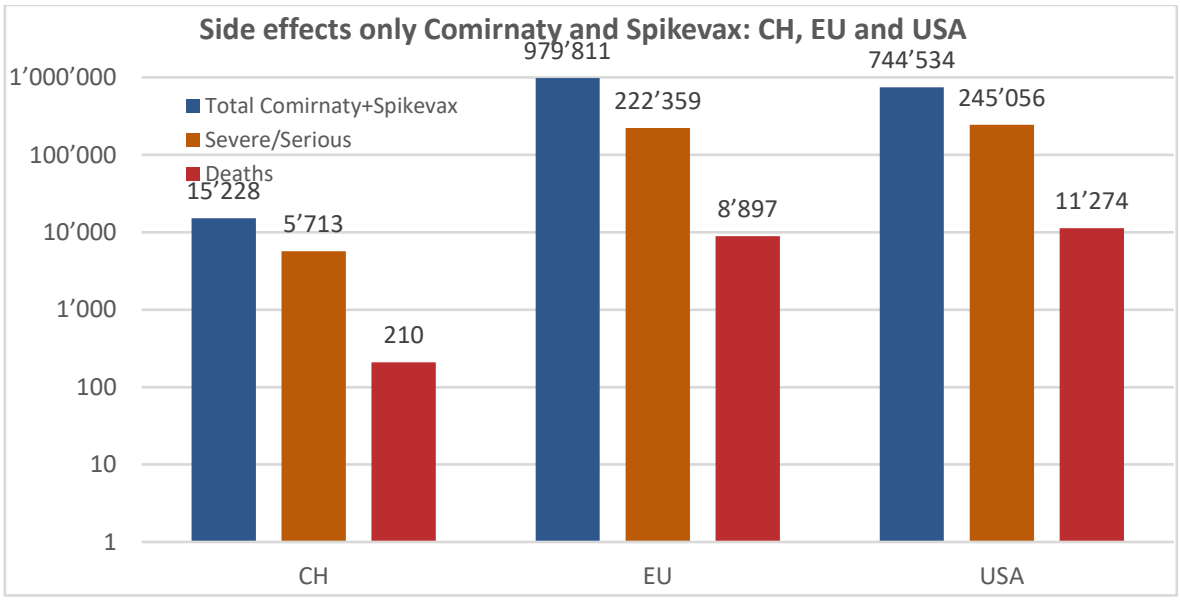
	CH	Children (CH)	EU	Children (EU)	USA	Children (USA)
Comirnaty	3.843		769.604	21.800	374.598	33.216
Ernst Comirnaty	1.957		186.592	6.251	137.059	9.519
Deaths Comirnaty			7.871	50	5.888	47
Spikevax	8.564		210.207	1.763	369.936	8.306
Ernst Spikevax	3.003		35.767	404	107.997	335
Deaths Spikevax			1.026	4	5.386	8
Total Comirnaty+ Spikevax	15.228	196	980	24	745	42
Severe/ Ernst	5.713		222	410	245	345
Deaths	210		9	54	11	55
Vaccination doses Comirnaty	5.828.328		587.964.352		253.826.942	
Vaccine doses Spikevax	9.813.888		146.934.492		151.481.614	
Comirnaty+ Spikevax / Mio	973,5		1.333,3		1.837,0	
Severe/ Ernst / 1Mio	365,2		302,6		604,6	
Deaths / million	13,4		12,1		27,8	

484 The following figures were reported in the areas of heart (Cardiac disorders), coagulation disorders and consequences (Blood and lymphatic system disorders) and deaths overall:

	CH total	CH Comir-naty	CH Spike-vax	EU total	EU Comir-naty	EU Spike-vax	USA total	USA Comir-naty	USA Spike-vax
Heart	1223	365	858	64	51.127	13.192	50	28.527	21.631
Coagulation disorders	565	159	406	41	33.753	6.969	26	14.689	11.494
Deaths Comirnaty	155			9	7.871	1.026	11	5.888	5.386
Stillbirths				220	1.234	219	1534	943	591
per 1 Mio									
Heart	78,2	62,6	87,4	87,5	87,0	89,8	123,8	112,4	142,8
Coagulation disorders	36,1	27,3	41,4	55,4	57,4	47,4	64,6	57,9	75,9
Deaths Comirnaty	9,9			12,1	13,4	7,0	27,8	23,2	35,6
Stillbirths				2,0	2,1	1,5	3,8	3,7	3,9

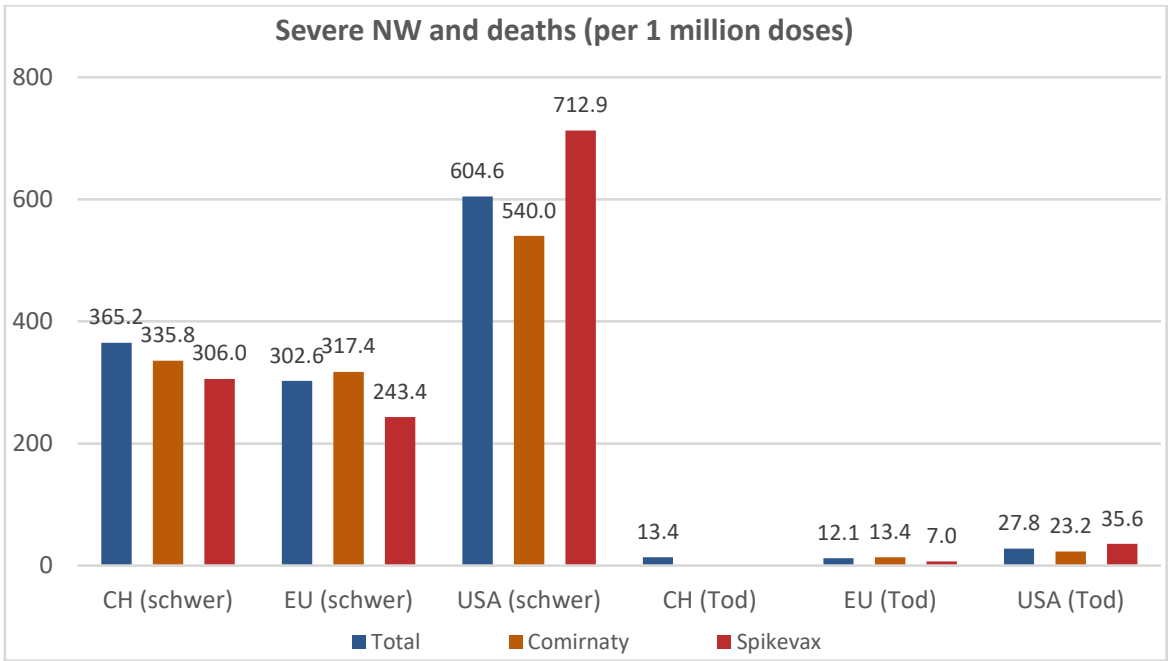
1.1.3. Side effects with Comirnaty® and Spikevax® (absolute numbers)

485 By 06.05.2022 in Switzerland, by 14.05.2022 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 were deaths:**



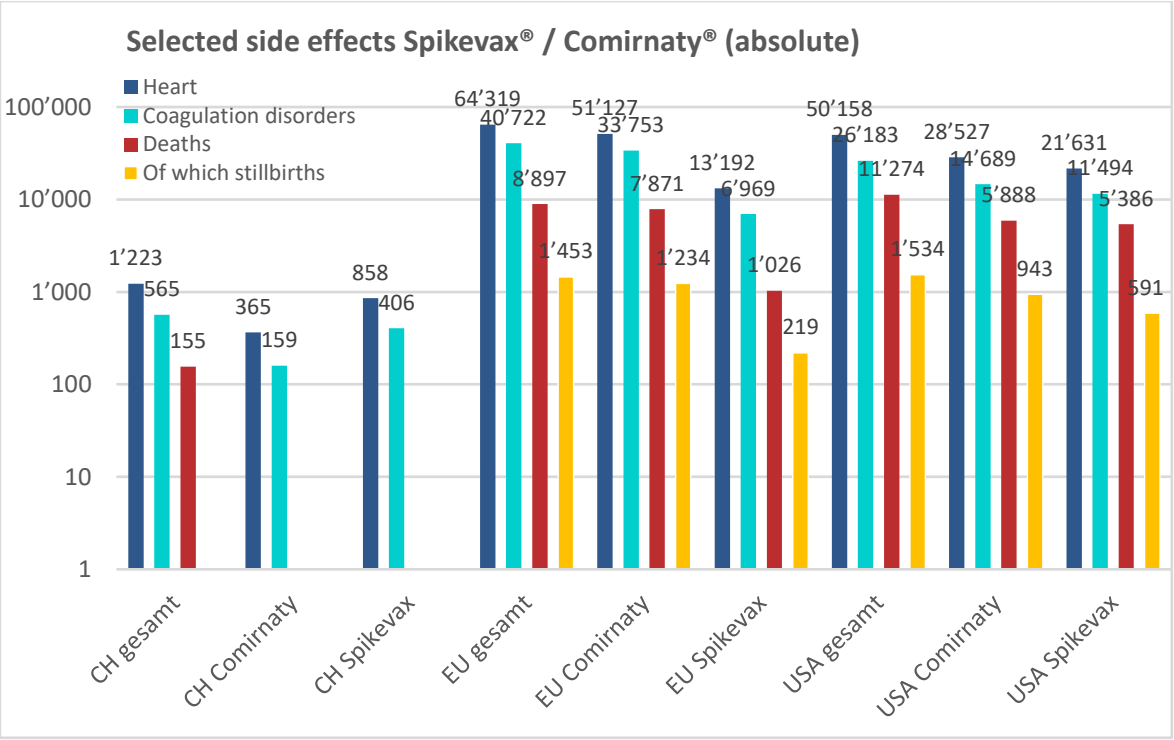
1.1.4. Side effects with Comirnaty® and Spikevax® (per 1 million "vaccine doses")

486 The number of serious adverse reactions and those resulting in death for Spikevax® and Comirnaty® **per 1 million doses administered as** of **May 2022** is as follows:

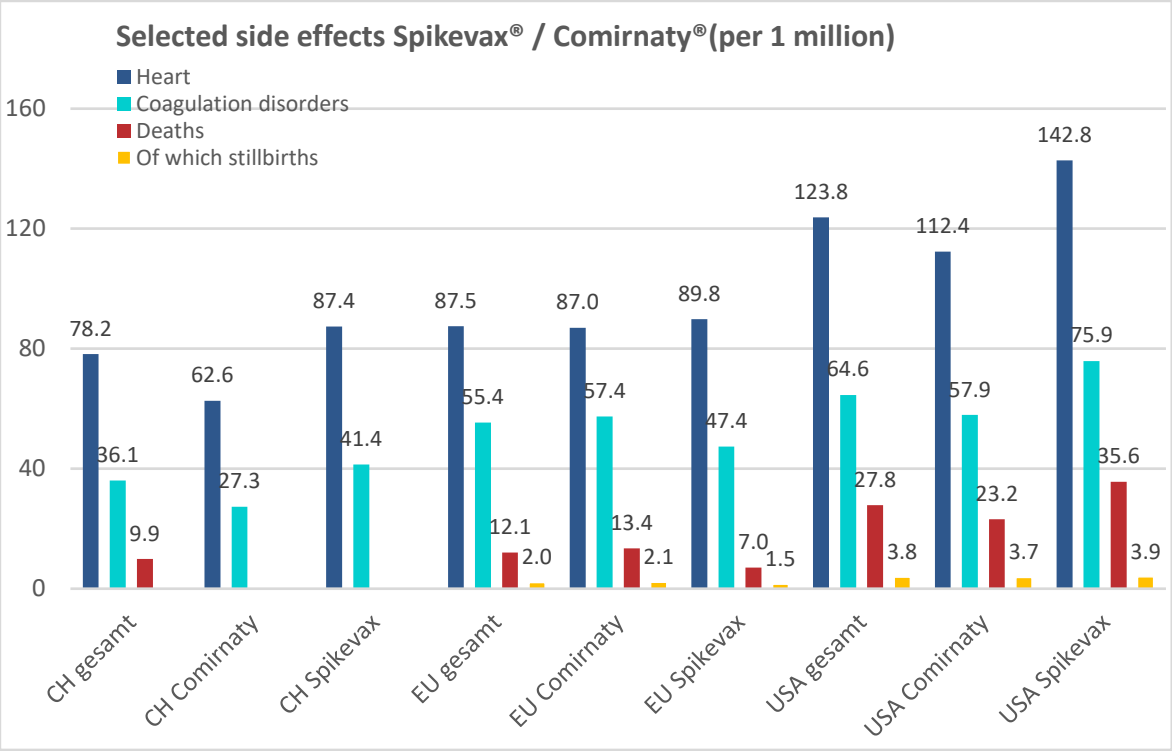


1.1.5. Selected side effects: Heart, thromboses, deaths, stillbirths

487 A more detailed analysis of all adverse reaction 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 in **absolute figures** as of **May 2022:**



488 **Per 1 million "vaccine doses"** this gives the following picture:



489 **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 more closely.

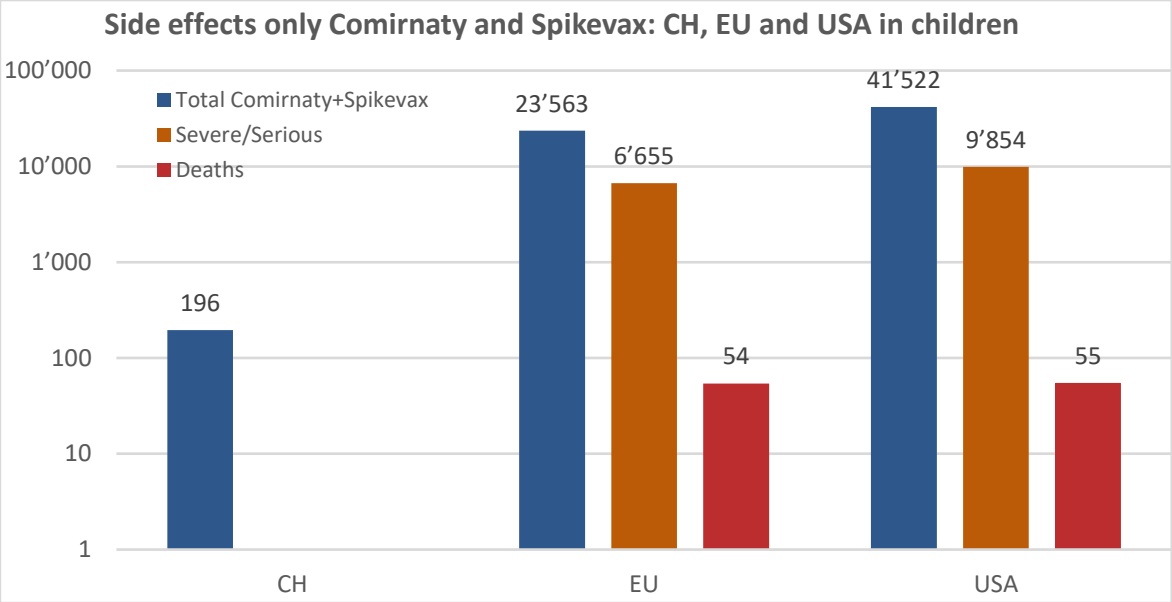
490 However, if the side effect reports in the USA concerning the **heart (myocarditis/pericarditis** etc.) are 112.4 (Comirnaty®) to 142.8 (Spikevax®), these are **"rare" side effects** (not: "very rare") according to the definition (MedDRA system organ classes), as more than 1 case per 10,000 doses occurs.

491 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).**

492 Regarding **stillbirths,** a further increase has been recorded in the USA and in the EU, both in absolute numbers and per 1 million "vaccine doses". In Switzerland - subject to error - there is still no corresponding information on this.

1.1.6. In particular: Side effects in children

493 By 06.05.2022 in Switzerland, by 14.05.2022 in the EU and the USA, a total of **65,281 adverse reactions** had been reported for Comirnaty® and Spikevax® in **children** (incl. adolescents) - of which **16,509 were serious** adverse reactions and **109 were deaths:**

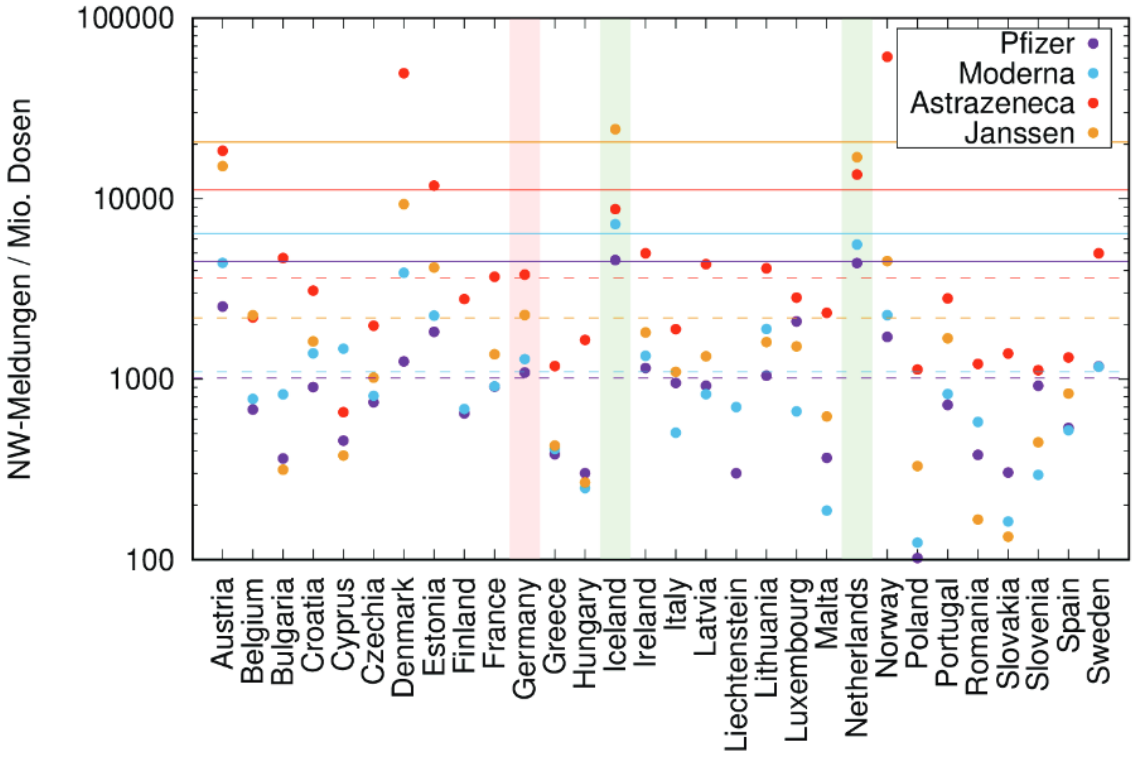


1.2. Massive underreporting impressively confirmed

1.2.1. EU: only 20% of all adverse reactions are reported

494 In the EU, there are large differences in the reporting of adverse reactions between the individual countries, with fluctuations in the reported incidence of adverse reactions of up to a factor of 100:[331]

331 7arguments, "COVID-19 vaccination requirement is unconstitutional", 09.03.2022, p. 32, *https://7argumente.de/download/910/.*



495 The vertical axis in the figure above is scaled logarithmically. The dashed lines represent the EU average, the solid lines show the respective mean values of the two countries with the highest reported case numbers, the Netherlands and Iceland. Assuming that these two countries actually report all suspected adverse drug reactions to the *Eudravigilance database*, it can be deduced for the EU average that only 20% of suspected cases are reported.

496 If one also assumes a realistic under-reporting of suspected cases of side effects in the Netherlands and Iceland, the number of unreported cases is significantly higher.

1.2.2. Germany: Only 20% of all side effects are reported

497 For Germany, even Charité researchers admitted an under-reporting of at least 70%.[332] Based on the above comparison with the European countries[333] , it must be assumed that in Germany, as in the EU countries as a whole, only 20% of vaccination adverse events are reported, which corresponds to 11th place in the EU ranking (Supplement **20**, p. 45).

BO: Supplement **20:** Strong facts: Switzerland, as of 13.04.2022

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332 Focus, "Charité researchers: 'At least 70 percent under-reporting of vaccination side effects'", 01.04.2022, https://www.focus.de/gesundheit/news/charite-forscher-harald-matthes-im-interview-mindestens-70-prozent-untererfassung-bei-den-impfnebenwirkungen_id_76570926.html.

333 7arguments, FN 331.

498 This high number of unreported cases was impressively confirmed in a well-founded analysis of insured persons' data published in February 2022 by the German company health insurance fund *BKK,* which arrived at considerably higher figures for side effects than the *Paul Ehrlich Institute* (*PEI*): From the beginning of the year to mid-July 2021 (corresponding to 7.5 months), 216,695 insured persons were treated for side effects caused by vaccines, based on an analysis of 10.9 million *BKK* insured persons , according to the *BKK*. Extrapolated to the entire - still ongoing - application phase of the COVID "vaccines" and to all of Germany, this would result in about 2.5 to 3 million people affected by side effects. [334]This is **ten times more than the Paul Ehrlich Institute (PEI) officially reports on the basis of spontaneous reports .**[335] *After only a little more than a year of vaccination campaigns, these figures are several times higher than what can be observed with established vaccines (for more details see N 262 f., N 266 ff., N 277 ff.). For this reason alone, the dangerous COVID "vaccination campaign" should be stopped immediately and the temporary approvals should be suspended.*

499 The *BKK ProVita* board member, Andreas Schöfbeck, who was dismissed without notice shortly afterwards, denounced in DIE WELT at the end of February 2022 that the *BKK* figures were a "clear warning signal"; they showed that a "danger to human life" could not be ruled out.[336] In a letter to the *PEI,* Schöfbeck demanded a well-founded analysis on the true data situation regarding the safety of COVID vaccines.[337] The discussion of the BKK analysis in public and with the *PEI* was immediately stopped.[338]

1.2.3. Switzerland: Only 10% of all side effects are reported

500 It was already shown above (N 358), it was shown that Swissmedic's reporting rate of 0.8 suspected cases/1000 vaccine doses at the end of 2021 was half as high as the *PEI*'s reporting rate of 1.6 suspected cases/1000 vaccine doses in Germany. Swissmedic's re-

334 Berliner Zeitung, "Impffolgen: Krankenkasse BKK schreibt Brief an Paul-Ehrlich-Institut", 24.02.2022, *https://www.berliner-zeitung.de/news/impffolgen-krankenkasse-bkk-schreibt-brief-an-paul-ehrlich-institut-li.213676.*

335 World, "More vaccine side effects than previously known", 25.02.2022, https://www.welt.de/politik/deutschland/plus237106177/Coronavirus-Impf-Nebenwirkungen-deutlich-mehr-als-bisher-bekannt.html.

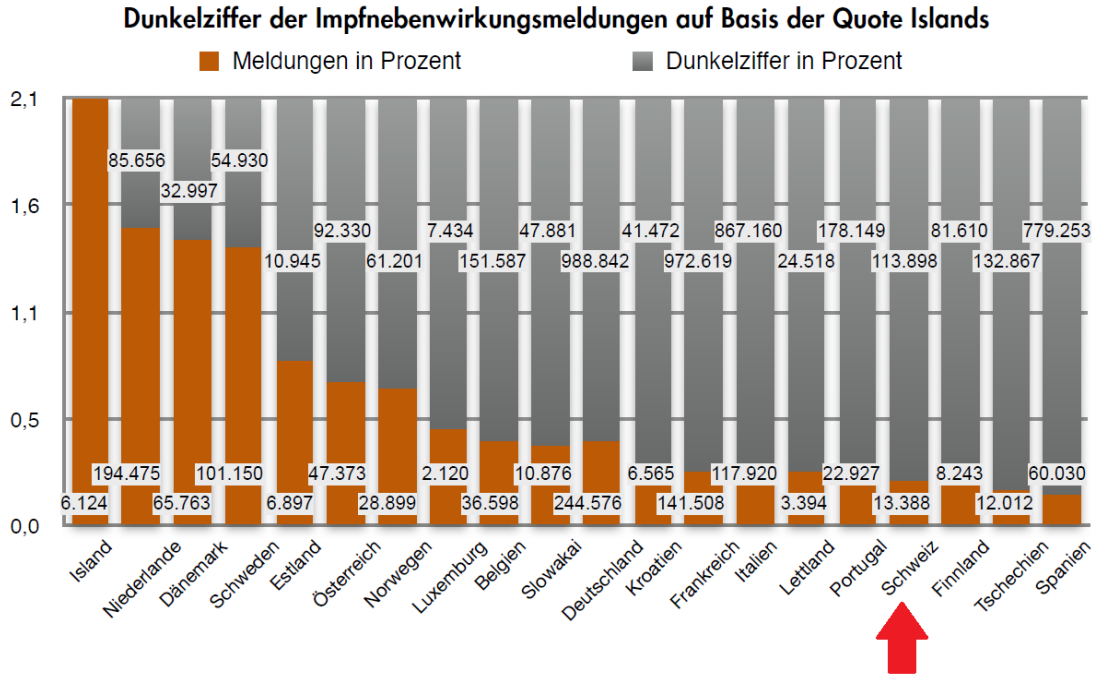
336 World, FN 335.

337 Berliner Zeitung, FN 334.

338 Berliner Zeitung, "Kritik an Zahlen von Nebenwirkungen: BKK boss dismissed without notice", 01.03.2022, *https://www.berliner-zeitung.de/gesundheit-oekologie/nach-brandbrief-bkk-provita-vorstand-soll-fristlos-entlassen-worden-sein-li.214733.*

porting rate improved only marginally over the course of time and was 0.97 suspected cases/1000 vaccine doses in May 2022.[339]

501 In comparison with the EU countries, **Switzerland** ranked only **17th in** the reporting of adverse drug reactions**. The percentage reporting rate in Switzerland was** just **10% of the reporting rate in Iceland (**Supplement **20**, p. 45**):**



BO: Supplement **20:** Strong Facts: Switzerland, as of 13.04.2022

502 It follows from these figures that the **figures reported by Swissmedic on suspected cases of adverse** drug **reactions must be multiplied by a factor of at least 10 to reflect reality.**

503 If it is assumed that the vaccine batches used in the EU and Switzerland are comparable, it would be expected that a comparable number of side effects would occur in the individual countries.

1.3. Producers: Disclosure of major risks in production and distribution

504 As early as September 2019, BioNTech disclosed major concerns about the mRNA vaccines to the U.S. *Securities and Exchange Commission* (*SEC*). In particular, concerns were highlighted that product candidates might not work as intended or might cause undesirable side effects (front N 26).

339 Swissmedic, "Suspected adverse reactions to Covid-19 vaccinations in Switzerland - 25th update", 06.05.2022, https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/covid-19-vaccines-safety-update-15.html.

505 The updated report BioNTech filed with the SEC in April 2022 for the past fiscal year 2021 also indicated that BioNTech continued to have significant concerns about its COVID "vaccines" and mRNA therapies. The company admitted that it may not be able to demonstrate sufficient efficacy or safety of its COVID "vaccine" and/or variant-specific formulations to obtain permanent regulatory approval:

> *"We may not be able to demonstrate sufficient efficacy or safety of our COVID-19 vaccine and/or variant-specific formulations to obtain permanent regulatory approval in the United States, the United Kingdom, the European Union, or other countries where it has been authorised for emergency use or granted conditional marketing approval.*
>
> *Significant adverse events may occur during our clinical trials or even after receiving regulatory approval, which could delay or terminate clinical trials, delay or prevent regulatory approval or market acceptance of any of our product candidates.*
>
> *mRNA drug development has substantial clinical development and regulatory risks due to limited regulatory experience with mRNA immunotherapies.*
>
> *Our future revenues from sales of our COVID-19 vaccine depend on numerous factors, including:*
>
> *the durability of immune response generated by our COVID-19 vaccine, which has not yet been demonstrated in clinical trials;*
>
> *our ability to receive full regulatory approvals, where we currently have emergency use authorisations or equivalents;*
>
> *the safety profile of our COVID-19 vaccine, including if previously unknown side effects or increased incidence or severity of known side effects as compared to those seen during clinical trials are identified with our COVID-19 vaccine with widespread global use after approval ... "*
>
> *We may not be able to demonstrate sufficient efficacy or safety of our COVID-19 vaccine to obtain permanent regulatory approval in jurisdictions where it has been authorised for emergency use or granted conditional marketing approval."*[340]

340 BIONTECH, "SEC Filing Form 20F BioNTech," Mar. 30, 2022, pp. 5, 6 and 11, https://investors.biontech.de/node/11931/html#ic5e06a05a31d4c4491031d3208cef8c2_2806 .

506 In its report on the financial year 2021 to the *SEC of* 24 February 2022, Pfizer also rated the risk as high that the temporary or emergency approval of COVID drugs including Comirnaty® could not be converted into a permanent approval:

> *"We may not be able to receive or maintain favourable recommendations by technical or advisory committees, such as the ACIP or any FDA Advisory Committee that may be convened to review our applications such as EUAs, NDAs or BLAs, which may impact the potential marketing and use of our products. Further, claims and concerns that may arise regarding the safety and efficacy of in-line products and product candidatescan negatively impact product sales, and potentially lead to product recalls or withdrawals, including regulator-directed risk evaluations, and/or consumer fraud, product liability and other litigation and claims. Further regulatory agency requirements may result in a more challenging, expensive and lengthy regulatory approval process than anticipated due to requests for, among other things, additional or more extensive clinical trials prior to granting approval, or increased post-approval requirements. For these and other reasons discussed in this Risk Factors section, we may not obtain the approvals we expect within the timeframe we anticipate, or at all."*[341]

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

1.4.1. Hundreds of deaths among (young) children and adolescents worldwide

507 Regarding the following reporting data, it should be pointed out again that all these cases must be interpreted against the background that the numbers of severe adverse events must be multiplied by a factor of at least 41 to reflect reality (front N 355 f.) and that the use of the rotavirus vaccine was suspended in 1999 because of 15 cases of intestinal obstruction in infants (front N 373).

1.4.1.1 Swissmedic: 7 infants affected by vaccination side effects

508 According to Swissmedic, 196 (1.3%) of the 15,228 adverse reaction reports evaluated as of 6.5.2022 in connection with a COVID "vaccination" concerned children and adolescents

341 PFIZER, "SEC Filing Form 10K Pfizer," 2/22/2022, p. 17, https://s28.q4cdn.com/781576035/files/doc_financials/2021/ar/PFE-2021-Form-10K-FINAL.pdf.

under 18 years of age. **7 infants** aged between 28 days and 23 months were affected by a **suspected case of a vaccination side effect**, which indicates the problem in connection with a possible transmission of vaccine components from the nursing mother to the child (see above N 401). Information on the severity of the side effects or on any deaths in connection with the "vaccination" in children and adolescents can be found in vain in the Swissmedic report.[342]

1.4.1.2 EU: 168 deaths, of which 24 infant deaths

509 Of the **1.8 million suspected adverse events** reported to the ***EMA*** as of 6.5.2022, **33,159** (1.9%) cases **involved children and adolescents under 18 years of age, of** which **14,120 cases (42.6%) were** classified as **serious** and **168 cases were fatal**. **Twenty-four deaths involved infants up to four weeks of age and 9 cases involved infants under two years of age**, which again supports the thesis of transmission of dangerous vaccine components by vaccinated mothers (Supplement **19**, pp. 9 f. , 12, 17).

BO: Supplement **19:** Daily report of serious adverse reactions to COVID 19 vaccinations, Status 06.05.2022

1.4.1.3 Germany: More children die from "vaccination" than from "Covid-19

510 In its safety report of 4.5.2022[343] for children and adolescents, the **German *Paul Ehrlich Institute*** reported a total of **5,862 suspected cases of side effects in** connection with the COVID "vaccinations". 61 cases concerned adverse reaction reports from infants of vaccinated mothers. Whereas in the report of 31.12.2021[344] the Institute had still provided detailed information on eight pages about the cases of side effects in children and adolescents and had reported, among other things, 8 deaths in a temporal connection with the "vaccination", the reporting for children and adolescents had shrunk to two pages in May 2022. Data on deaths among children and adolescents were completely missing. **If the prevalence remained the same (0.2%), the number of deaths among children and adolescents should have increased to at least 11 cases**. By February 2022, 10 children and adolescents had officially died of COVID in Germany, although in 3 cases it was unclear whether SARS-CoV-2 was actually the cause of death.[345] **Thus, as of May 2022, more children and adolescents are likely to have died in Germany in connection**

342 Swissmedic, FN 339.

343 Paul Ehrlich Institute, "Safety Report", 04.05.2022, https://www.pei.de/SharedDocs/Downloads/DE/newsroom/dossiers/sicherheitsberichte/sicherheitsbericht-27-12-20-bis-31-03-22.pdf?__blob=publicationFile&v=5.

344 Paul Ehrlich Institute, FN 257.

345 B.Z. , "So many children really died of Corona", 15.02.2022, https://www.bz-berlin.de/deutschland/so-viele-kinder-starben-wirklich-an-corona.

with the "vaccination" than in connection with a COVID disease, taking into account the known underreporting.

1.4.1.4 USA: 112 deaths among children and adolescents

511 As of 20.05.2022, **48,583 suspected cases of adverse drug reactions in children and adolescents** aged 5 to 17 years were reported in the American ***VAERS database.*** 3,862 cases were associated with hospitalisation, in 1315 cases myocarditis was diagnosed, in 207 cases facial paralysis. 605 cases were classified as life-threatening. 112 deaths related to COVID "vaccination" were reported.[346]

1.4.2. First court/authority decisions: best interests of the child violated

512 In a decision of 13.01.2022, the district court of Weilheim (D), after considering the latest data, concludes that the **risks of a COVID "vaccination" clearly outweigh the benefits for children** and that the "**vaccination"** is therefore **not in the best interests of the child.**[347]

513 A court in Pistoia, Italy, also concluded on 04.03.2022, based on the scientific data, that **COVID "vaccination" was not indicated in children** because the **risks outweighed the benefits.**[348]

514 On 07.03.2022, the **Florida Department of Health, USA,** advised against vaccinating **healthy children** against the coronavirus after an analysis of the currently available data because the **risks outweighed the benefits.**[349]

1.5. Pregnant women: worrying number of miscarriages

1.5.1. Still missing data - stalling tactics of the manufacturers

515 For Comirnaty® and Spikevax®, the **missing data for pregnant women in** the *Risk Management Plans of* February and March 2022*,* which contained data until the end of

346 VAERS, "COVID Vaccine reports in Children", 20.05.2022, https://web.archive.org/web/20220601002115/https://openvaers.com/covid-data/child-summaries.

347 Weilheim Local Court, "Beschluss 2 F 538/21", 13.01.2022, *https://www.vaterlos.eu/wp-content/uploads/2022/02/20220113-Familiengericht-Weilheim-2-F-538-21-anonymisiert.pdf.*

348 Tribunale di Pistoria, V.G. 2022, 04.03.2022, https://2020news.de/wp-content/uploads/2022/03/Trib.-Pistoia-4.3.2022.pdf; see also 2020 News, "Judge in Italy rejects child vaccination", 09.03.2022, *https://2020news.de/richterin-in-italien-lehnt-kinderimpfung-ab/.*

349 Tampa bay times, "Florida says healthy kids shouldn't get COVID vaccine, contradicting CDC", 07.03.2022, https://www.tampabay.com/news/florida-politics/2022/03/07/healthy-children-shouldnt-get-coronavirus-vaccine-florida-health-department-says/.

2021 and which were also submitted to Swissmedic, *were still* addressed as **"missing information".**[350] For Comirnaty® it was stated there on p. 105:

> *Missing Information: Use in Pregnancy and while breast feeding*
>
> *Risk-benefit impact*
>
> ***The safety profile of the vaccine is not known in pregnant or breast-feeding women*** *due to their initial exclusion from the pivotal clinical study, however one clinical study of the safety and immunogenicity of the COVID-19 vaccine in pregnant women is ongoing (C4591015); and 2 non-interventional studies (C4591009 and C4591011) to assess whether sub-cohorts of interest, such as pregnant women, experience increased risk of safety events of interest following receipt of the COVID-19 vaccine are approved.*
>
> *It is important to obtain long term follow-up on women who were pregnant at or around the time of vaccination so that any potential negative consequences to the pregnancy can be assessed and weighed against the effects of maternal COVID-19 on the pregnancy.*

516 According to the *Risk Management Plan, the* efficacy and safety of the COVID "vaccines" in pregnant women should be investigated in a prospective randomised trial (C4591015, *clinicaltrials.gov identifier* NCT04754594). The trial started in February 2021 and is scheduled to end in August 2022. It will probably take several months before the final evaluated results are available.[351]

517 The extent to which this study will provide correct data is questionable, since Pfizer again hired the contract research organisation *Ventavia for* this study. Only recently, serious deficiencies were reported at study centres supervised by *Ventavia, which were* involved in the implementation of the registration study of the Pfizer/BioNTech vaccine (front 311 f.).[352]

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350 Moderna, "EU risk management plan for Spikevax", 01.03.2022, https://www.ema.europa.eu/en/documents/rmp-summary/spikevax-previously-covid-19-vaccine-moderna-epar-risk-management-plan_en.pdf; Pfizer, "Comirnaty (COVID-19 mRNA vaccine) risk management plan", 02.02.2022, https://www.ema.europa.eu/en/documents/rmp-summary/comirnaty-epar-risk-management-plan_en.pdf.

351 BioNTech, "Study to evaluate the safety, tolerability, and immunogenicity of SARS CoV-2 RNA vaccine candidate (BNT162b2) against COVID-19 in healthy pregnant women 18 years of age and older", 15.02.2021, https://clinicaltrials.gov/ct2/show/NCT04754594.

352 Reitschuster, "Brisant: Serious flaws in BioNTech/Pfizer pivotal trial", 19.01.2022, https://reitschuster.de/post/brisant-gravierende-maengel-in-der-zulassungsstudie-von-

1.5.2. Worldwide reports of stillbirths massively increased

518 Already before (N 488) 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 observed.

519 In the ***EMA***'s suspected adverse reaction report of 6.5.2022, abortions ("pregnancy interruptions") were reported in 17th place among "serious cases" and in 15th place among cases with permanent damage (Supplement **19**, pp. 25, 28).

BO: Supplement **19:** Daily report of serious adverse reactions to COVID 19 vaccinations, Status 06.05.2022

1.5.3. Austrian midwives sound the alarm: increased miscarriages

520 In January 2022, 217 concerned midwives wrote an **"open letter" to the Austrian Board of Midwives,** reporting professional observations in connection with the COVID "vaccination" in pregnant women, which were often not followed up. They reported, among other things, **frequent miscarriages, premature labour, premature rupture of the membranes, vaginal bleeding, premature births, growth retardation and eclampsia (seizures).** Regarding COVID courses in pregnant women, they stated that they were mainly aware of mild to moderate cases and requested that severe courses in pregnant women and associated risk factors should be systematically collected and published. [353]

1.5.4. Interim conclusion

521 These most recent and highly alarming international figures, in addition to those already shown at earlier times, confirm what the preclinical data had already indicated: COVID "vaccination" is associated with a major risk for pregnant women and their unborn babies. To date, Swissmedic has not reacted to the deaths of unborn children reported worldwide and has not taken any measures to ensure that the marketing authorisation holders adequately reflect this risk in the drug texts. On the contrary, the risks were covered up in the drug texts (see N 109 ff.). Similarly, although Swissmedic was informed again by March 2022 at the latest, based on the information in the **Risk Management Plan,** that the recommendation to vaccinate pregnant women was not based on solid data, it did not intervene with the *ECIF to* reverse the recommendation of COVID "vaccination" in pregnant women. **Based on all these points, it must be concluded that Swissmedic is directly**

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biontech-pfizer/; THACKER, "Covid-19:Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial", 02.11.2021, https://www.bmj.com/content/375/bmj.n2635.

353 Wochenblick, "Can't take it any longer: 217 midwives are loudly against gene injections", 10.01.2022, https://www.wochenblick.at/allgemein/koennen-das-nicht-laenger-hinnehmen-217-hebammen-sind-laut-gegen-gen-spritzen/.

complicit in all vaccination complications in pregnant women and in particular in unborn child deaths.

1.6. Male fertility: Decrease in sperm concentration by 15.9

522 A study that analysed the influence of Comirnaty® on the sperm in 220 samples came to the official conclusion that any impairment of sperm concentration and quality by the mRNA injection was reversible and that all parameters had normalised 150 days after "inoculation" (time T3). A look at the underlying data showed that this was precisely not the case:[354]

Table 2: Percentage and absolute change[1] compared to T0 as reference measured by repeated measures analysis (total samples)

		Change[1]	95%CI		p-value
Semen volume	T0[2]	Ref			
	T1	10%	-3.9%	25.8%	
	T2	-4.5%	-14.7%	7%	0.214
	T3	9%	-6.3%	26.8%	
Sperm concentration	T0	Ref			
	T1	-14.5%	-27.9%	1.4%	
	T2	**-15.4%**	**-25.5%**	**-3.9%**	**0.044**
	T3	-15.9%	-30.3%	1.7%	
Sperm motility	T0	Ref			
	T1	2.7	-1	6.6	
	T2	-1.9	-4.9	1.7	0.058
	T3	-4.1	-8.2	0.1	
Total Motile Count	T0	Ref			
	T1	-2%	-19.9%	20.1%	
	T2	**-22.1%**	**-35%**	**-6.6%**	**0.027**
	T3	-19.4%	-35.4%	0.6%	

[1] Volume, concentration, and TMC are presented as *percentage* change compared to T0 while motility change is presented as *absolute* change.

[2]T0 – pre-vaccination baseline control; T1, T2, and T3 – short, intermediate, and long-term evaluations after 15-45, 75-150, and over 150 days after vaccination date, respectively.

523 Sperm concentration, motility and sperm count had not normalised 150 days after "vaccination". **150 days after the 2nd "vaccination", the sperm concentration was still**

354 GAT, "Covid-19 vaccination BNT162b2 temporarily impairs semen concentration and total motile count among semen donors", 17.06.2022, https://onlinelibrary.wiley.com/doi/10.1111/andr.13209.

15.9% below the baseline value. On the contrary, sperm motility had again significantly deteriorated compared to the measurement after the 2nd "vaccination".

1.7. Lethal mode of action of the spike protein

524 On the harmfulness of the spike protein already discussed in detail in N 299 ff.

525 At the beginning of 2022, vascular damage was meanwhile revealed in the course of pathological examinations in 12 of 15 persons who died in connection with "vaccination". The spike protein induced by the "vaccination" was reliably detected in the vessels of a person who died 4 months after the "vaccination" and who had vascular lesions and also vaccine-induced myocarditis. The detection was achieved by an antibody specific for the spike protein using conventional immunohistochemistry on the tissue sections.[355] The spike protein was also documented in other organs such as the liver, spleen and brain in persons who died after COVID "vaccination".[356] In a 77-year-old man who died three weeks after his third COVID "vaccination", an autopsy in the brain revealed multifocal necrotising encephalitis with massive inflammatory lymphocyte infiltrates. In addition, the heart showed signs of severe myocarditis. The SARS-CoV-2 spike protein was also detected in the tissues of the affected organs by immunohistochemical staining. Based on these immunohistochemical findings, the inflammatory changes in the patient's brain tissue are likely to be due to immunological processes. At the same time, the absence of SARS-CoV-2 nucleocapsid protein was documented, suggesting that the detected spike protein is not associated with a SARS-CoV-2 infection. If such an infection were the cause of the spike protein, then the SARS-CoV-2 nucleocapsid protein would also be present. Consequently, the confirmed presence of the spike protein had to be attributed to the earlier "vaccination" with Comirnaty® that the deceased patient had received. [357]

1.8. Alarm signal: Myocarditis (continued)

526 The danger of myocarditis - which can lead to death - was already evident in 2021 and was unfortunately confirmed by further studies in 2022:

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355 Pathology Conference, "Pathology of Vaccine Deaths and Vaccine Damage: After the Evidence First", 11.03.2022, https://pathologie-konferenz.de.

356 Doctors for COVID Ethics, Symposium, "Expectations fulfilled: the scientific evidence- Prof. Arne Burkhardt with Prof. Sucharit Bhakdi", 20.02.2022, *https://doctors4covidethics.org/video-replays-d4ce-symposium-iii-session-i/.*

357 MÖRZ, "A Case Report: Multifocal Necrotizing Encephalitis and MYOCARDITIS after BNT162b2 MRNA Vaccination against Covid-19", 22.06.2022, https://www.preprints.org/manuscript/202206.0308/v1.

1.8.1. Study from Scandinavia: Massively increased risk of myocarditis

527 For **myocarditis in particular,** a large-scale Scandinavian study[358] , which analysed data from 23.1 million people from Denmark, Finland, Norway and Sweden and was published in April 2022 in the renowned *JAMA Cardiology, concluded that the* **risk of myocarditis** was **significantly increased** after COVID "vaccination". It calculated 4 to 7 (compared to an unvaccinated population) additional events in 28 days per 100,000 vaccinated after Comirnaty® and 9 to 28 additional events per 100,000 vaccinated after Spikevax®. Dr Rickard Ljung, professor and physician at the Swedish Medicines Agency and one of the authors of the study, explained that these additional events corresponded to a **5-fold increased risk after Comirnaty®** and a **15-fold increased risk after Spikevax® in** men aged 16 to 24 years.[359] In order to be able to make reliable statements on the myocarditis risk of the individual "vaccines", the market shares of the individual countries would of course have to be taken into account.

1.8.2. Canada: Expected myocardial infarction rates significantly exceeded

528 That even the figures from Canada, especially for Comirnaty®, were set too low was shown by a study published in the *JAMA Network in* January 2022, conducted by scientists for the CDC, the FDA and various other organisations. It examined *VAERS entries from* December 2020 to August 2021: "*Rates of myocarditis were highest after the second dose of vaccine in male adolescents aged 12 to 15 years (70.7 per million doses of Comirnaty® vaccine administered), male adolescents aged 16 to 17 years (105.9 per million doses of Comirnaty® administered), and young men aged 18 to 24 years (52.4 and 56.3 per million doses of Comirnaty® and Spikevax® vaccine, respectively)*. " 96% of individuals (784/813) required hospitalisation. Even though the risk of myocarditis after COVID "vaccination" was higher overall in (young) men than in (young) women, the upper limit of the expected myocarditis rates was also clearly exceeded in women under 30 years of age after the second vaccination with Comirnaty® and with Spikevax®.[360]

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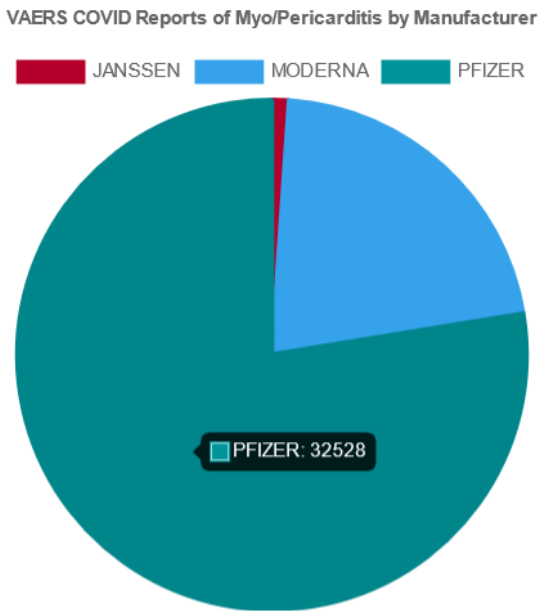
358 KARLSTAD et al, "SARS-CoV-2 Vaccination and Myocarditis in a Nordic Cohort Study of 23 Million Residents", 20.04.2022, https://jamanetwork.com/journals/jamacardiology/article-abstract/2791253.

359 Report24, "Study: Risk of heart inflammation in vaccinated people several times higher than in unvaccinated people", 26.04.2022, https://report24.news/studie-risiko-fuer-herzentzuendung-bei-impflingen-um-ein-vielfaches-hoeher-als-bei-ungeimpften/.

360 OSTER et al, "Myocarditis cases reported after mRNA-based COVID-19 vaccination in the US from December 2020 to august 2021", 25 Jan 2022, *https://jamanetwork.com/journals/jama/fullarticle/2788346.*

1.8.3. USA: Comirnaty® leads in absolute numbers of myocarditis cases

529 As of 10/06/2022, **77.6%** (32,528 cases) of all **myocarditis/pericarditis reports** (41,938 cases) in the US reported **by VAERS** involved **Comirnaty®:**[361]



530 The market share of Comirnaty® in the US was around 60% as of June 2022.[362]

1.8.4. Japan: Ministry of Health recognises rising rate of myocarditis

531 The *Japanese Ministry of Health* acknowledged in January 2022 the increasing rate of heart muscle inflammation in the vaccinated population and prohibited discriminating against people who refused the COVID "vaccine". It was estimated that by 14/11/2021, out of one million men who had been vaccinated with the Moderna vaccine, 81.8 men aged 10-19 years and 48.8 men aged 20-29 years had been affected by such adverse events. For those who had been vaccinated with Comirnaty®, the figures were 15.7 and 13.3 per million doses administered, respectively. Japanese hospitals should be required by law to report in detail incidents in which symptoms occurred within 28 days of "vaccination".[363]

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361 Open VAERS, "Myocarditis&Pericarditis", 10.06.2022, https://openvaers.com/covid-data/myo-pericarditis.

362 CDC, "COVID-19 Vaccinations in the United States," 6/21/2022, https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total.

363 Australian national review, "Japan drops all vaxxine mandates, places myocarditis warning on label", 06.01.2022, https://www.australiannationalreview.com/health/japan-drops-all-vaxxine-mandates-places-myocarditis-warning-on-label/.

1.8.5. Japanese heart surgeon calls for immediate admission ban

532 On 5 June 2022, the medical journal *Virology Journal* published a "Letter to the Editor" in which Japanese cardiovascular surgeon Kenji Yamamoto reported numerous complications and some deaths in vaccinated patients that occurred in his own Department of Cardiovascular Surgery at Okamura Memorial Hospital. Dr Yamamoto's biggest concern was the harmful effects of the COVID "vaccines" on the immune system. He reported numerous post-operative infections in vaccinated patients after open-heart surgery, which could not be controlled even after several weeks of antibiotic therapy. He demanded that the administration of further booster vaccinations be stopped immediately for the safety of the patients.[364]

1.8.6. Sudden and unexpected medical incidents and deaths in athletes

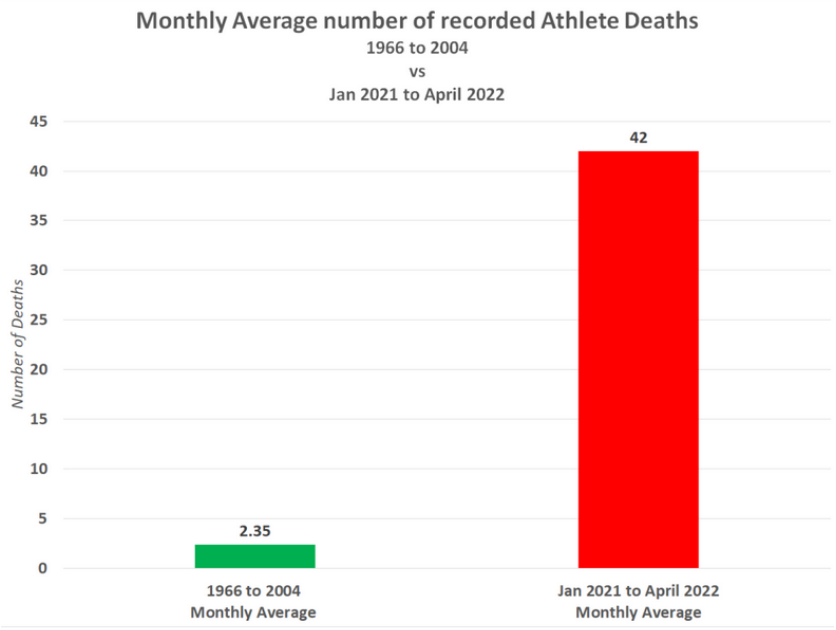
533 According to a study published in 2006 by the Department of Paediatric Cardiology at the University Hospital of Lausanne, from 1966 to 2004, 1,101 cases of sudden cardiac death were recorded worldwide in athletes under the age of 35, which corresponds to a rate of 2.35 deaths per month.[365]

534 This compares to 673 athlete deaths documented from January 2021 to April 2022, and 715 by 4 June 2022, a rate of 42 deaths per month, a factor of 18 increase on previous years:[366]

364 YAMAMOTO, "Adverse effects of COVID-19 vaccines and measures to prevent them", 05.06.2022, https://virologyj.biomedcentral.com/articles/10.1186/s12985-022-01831-0.

365 BILLE et al, "Sudden cardiac death in athletes: the Lausanne Recommendations", 01.12.2006, https://pubmed.ncbi.nlm.nih.gov/17143117/.

366 Real Science, "1090 Athlete Cardiac Arrests, Serious Issues, 715 Dead, After COVID Injection," 6/13/2022, https://goodsciencing.com/covid/athletes-suffer-cardiac-arrest-die-after-covid-shot/.



535 Since the start of the vaccination campaign at the beginning of 2021 until 24.06.2022, 14'013 medical incidents and "sudden deaths" were recorded internationally among professional and amateur athletes. The average age of these cases was 40 years .[367]

536 Since the majority of athletes are fully vaccinated, it must be assumed that these incidents are directly related to the COVID "vaccinations" due to the close temporal correlation of the jump in the number of cases with the worldwide start of vaccination.

537 In February 2022, the Austrian Federal Ministry recommended physical rest for three days after the COVID "vaccination", as well as general abstinence from sports for one week. In case of exhaustion, fatigue or fever within 3 weeks after the "vaccination", physical exertion and competitive sports should be completely avoided.[368] The causal connection between potential medical incidents and the "vaccination" was thus indirectly acknowledged.

538 As cases of "sudden and unexpected death" were increasing worldwide at an unprecedented rate and were arguably becoming less and less concealable to the public, "sudden adult death syndrome" ("SADS") was introduced in June 2022 as an umbrella term for unexpected deaths in young people. People under the age of 40, even if they felt fit and

367 Sudden and Unexpected, "Athletes, Coaches and Spectators of Sporting Events", as of 24.06.2022, https://ploetzlich-und-unerwartet.net/.

368 Ministry of Social Affairs, "General Questions", 20.05.2022, https://www.sozialministerium.at/Corona-Schutzimpfung/Corona-Schutzimpfung---Haeufig-gestellte-Fragen/Corona-Schutzimpfung-%E2%80%93-Haeufig-gestellte-Fragen---Allgemeine-Fragen.html#impfung-spezieller-personengruppen.%20-%3E%20pdf.

young, were urged to have their hearts checked urgently to see if they were at increased risk of SADS.[369]

539 While publicly a connection of SADS with COVID "vaccination" has been denied until now, international studies showed that a significant increase in cardiovascular emergencies (see N 306 ff.) and an observed excess mortality (posterior N 592 f. and N 611 ff.) all correlated with COVID vaccination campaigns.

540 The occurrence of myocarditis associated with COVID "vaccination" is much more common than is publicly admitted (see N 382 ff., N 434 ff., N 480, N 487 ff, 526 ff., 552 ff.). Sudden cardiac death is a known complication of myocarditis (N 379).

541 All this data points unmistakably to a correlation of the unprecedented number of cases of "SADS" with the COVID "vaccination" since the start of the vaccination campaign.

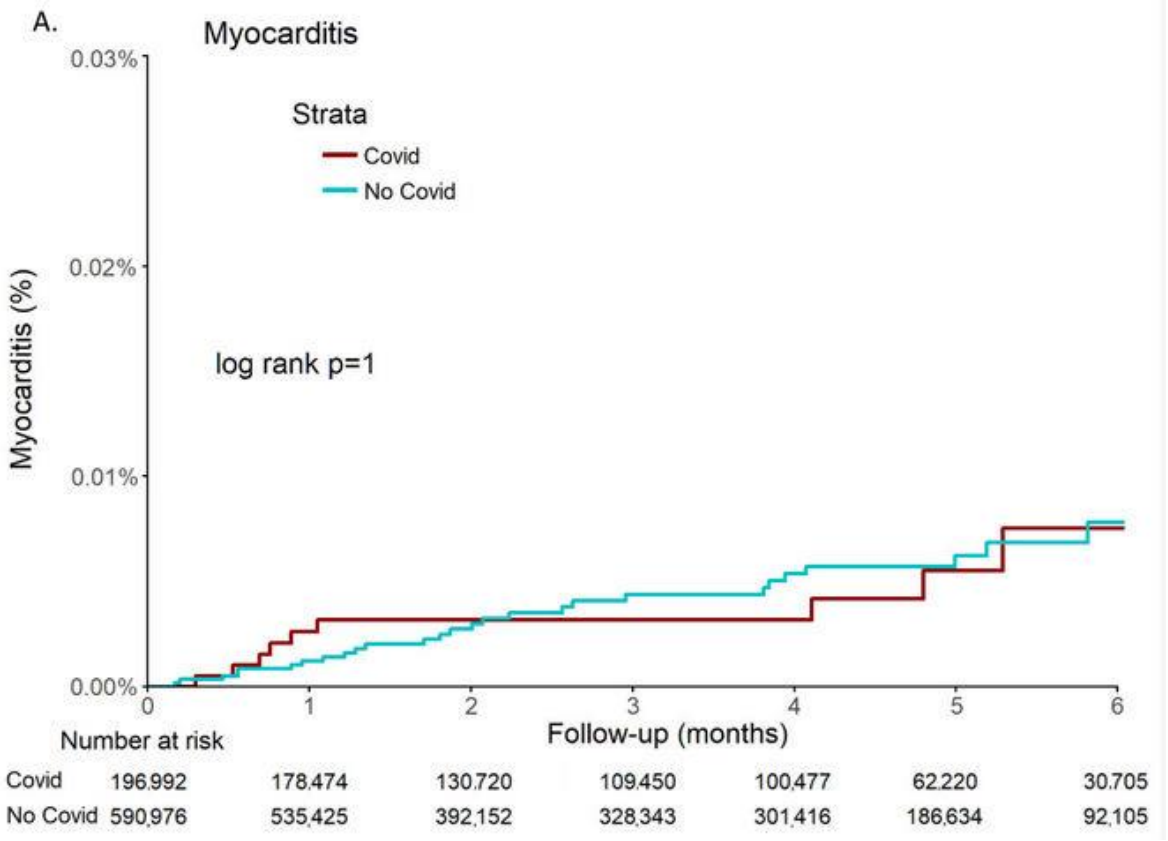
1.8.7. Myocarditis not a consequence of COVID disease

542 With regard to the risk-benefit analysis, the authorities like to argue that the risk of myocarditis after COVID "vaccination" is similar to that after COVID disease.[370] This thesis was refuted in April 2022 by a large Israeli database analysis[371] : In the group of around 197,000 people suffering from COVID (positive PCR test in the period from 07.03.2020 to 31.01.2021), myocarditis did not occur more frequently than in a comparison group (n=590,976):

369 New Zealand Herald, "What is Sads? Healthy young people dying from Sudden Adult Death Syndrome", 07.06.2022, https://www.nzherald.co.nz/lifestyle/what-is-sads-healthy-young-people-dying-from-sudden-adult-death-syndrome/TIOAK4SYPF5LFSKP5QZCVG23IM/.

370 BAG/EKIF, "Vaccination recommendation for mRNA vaccines against Covid-19", as of 23.05.2022, p. 37 ff, https://web.archive.org/web/20210414185954if_/https://www.bag.admin.ch/dam/bag/de/dokumente/mt/k-und-i/aktuelle-ausbrueche-pandemien/2019-nCoV/impfempfehlung-covid-19.pdf.download.pdf/Impfempfehlung%20f%C3%BCr%20mRNA-Impfstoffe%20gegen%20Covid-19.pdf.

371 TUVALI et al, "The Incidence of Myocarditis and Pericarditis in Post COVID-19 Unvaccinated Patients-A Large Population-Based Study", 15 Apr 2022, https://www.mdpi.com/2077-0383/11/8/2219/htm.



543 Individuals who had received a COVID "vaccination" were excluded from this analysis.

1.9. Alarm signal: V-AIDS

544 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" (V-AIDS).[372] The publications had come to the conclusion that

- the COVID "vaccines" damage the immune system's communication system by suppressing the messenger interferon 1 and can thus make those vaccinated with mRNA "vaccines" more susceptible to infectious diseases and cancer.[373]

372 Focus Online, "What is V-Aids after vaccination? How is V-Aids diagnosed? ", 16.06.2022, https://www.focus.de/presseportal/was-ist-v-aids-nach-einer-impfung-wie-wird-v-aids-diagnostiziert_id_107968934.html.

373 SENEFF, "Innate immune suppression by SARS-CoV-2 mRNA vaccinations: The role of G-quadruplexes, exosomes, and MicroRNAs", 15.04.2022,

- the spike protein causes "syncytia formation", whereby 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.[374]
- 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.[375]

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

546 Damage to the immune system is known to lead not only to increased incidence of autoimmune diseases and cancer, but also to increased incidence of infectious diseases. Current international figures show that internationally COVID hospitalisations and deaths due to such diseases mainly affect vaccinated people (N 581 ff.), which further supports the thesis of V-AIDS.

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

1.10.1. Israel: 66% of those boostered had side effects

547 The results of a survey by Israel*'s Center for Disease* Control, published in February 2022 by the Israeli Ministry of Health, showed that **66% of Israelis who had received a booster vaccination suffered from side effects that were** mild to severe. Almost half of the 2049 respondents said they had difficulty performing daily activities as a result. The most common side effect in women was menstrual irregularities.[376]

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https://www.sciencedirect.com/science/article/pii/S027869152200206X; IVANOVA, "SARS-CoV-2 mRNA vaccine elicits a potent adaptive immune response in the absence of IFN-mediated inflammation observed in COVID-19", 21.04.2021, https://pubmed.ncbi.nlm.nih.gov/33907755/; LIU, "Comprehensive investigations revealed consistent pathophysiological alterations after vaccination with COVID-19 vaccines", 26.10.2021, https://www.nature.com/articles/s41421-021-00329-3.

374 ZHANG, "SARS-CoV-2 spike protein dictates syncytium-mediated lymphocyte elimination," 20 Apr. 2021, https://www.nature.com/articles/s41418-021-00782-3.

375 LIU, "Comprehensive investigations revealed consistent pathophysiological alterations after vaccination with COVID-19 vaccines", 26.10.2021, https://www.nature.com/articles/s41421-021-00329-3.

376 DAVAR, "10% of women reported menstrual disorders (ISR / EN)", 10.02.2022, https://en.davar1.co.il/360784/; see also: Lifesitenews "Two-thirds of Israelis report having adverse reaction to COVID booster shots: survey", 01.03.2022, https://www.lifesitenews.com/news/two-thirds-of-israelis-report-having-adverse-reaction-to-covid-booster-shots-survey/.

1.10.2. US military: Massive increase in side effects

548 In a high-profile hearing in the United States Senate on 24 January 2022, lawyer Tom Renz reported on data from a **US military medical epidemiology database (*DMED***) made available to him by whistleblowers, showing the extent to which the US Department of Defence had information about apparent side effects of COVID "vaccinations". Renz testified that this data was also available to the US health authority *CDC,* which would mean that the government was telling the public the untruth. Renz spoke of corruption. [377] The government shortly afterwards classified the data as "misinformation" and publicly defamed Tom Renz.[378]

549 Figures from this *DMED* showed a **270% increase in heart attacks**, **460% increase in pulmonary embolisms**, **1000% increase in nerve disease**, **490% increase in breast cancer, 290% increase in** facial **paresis**, **550% increase in Guillain-Barré syndrome** (a severe neurological condition with paralysis usually starting in both legs) and **280% increase in miscarriages** compared to the five-year average since the COVID vaccination campaign started. [379]

1.11. Numerous other studies that indicate a causal relationship

550 In continuation of the worldwide studies until 4 June 2021 (front N 285 ff.) and until 26 October 2021 (front N 433 ff.), reference is made to the following additional studies published **until 1 March 2022.**

551 In the entire period from 1 January 2020 to 1 March 2022, there are **at least 358 peer-reviewed publications that** prove or at least suggest an association between COVID "vaccinations" and acute **heart problems (128 studies),** life-threatening **thromboembolic events (223 studies)** and **deaths (7 studies).** At the latest with the emergence of the Omikron variant, which rapidly displaced all other variants still circulating at that time, there was no longer any life-threatening or disabling danger from Sars-CoV-2 for the entire target population (see N 707). Moreover, it had long been clear that the COVID "vaccinations" were largely ineffective (N 437 ff, N 556 ff.) Nevertheless, the temporary author-

377 Alschner Klartext, "The whistleblowers are military officers of very high rank", 08.02.2022, *https://alschner-klartext.de/2022/02/08/die-whistleblower-sind-militaers-von-sehr-hohem-rang/.*

378 The Washington Post, "One lawyer's rise shows how vaccine misinformation can fuel fundraising and far-right celebrity", 20.09.2021, https://www.washingtonpost.com/investigations/2021/09/20/vaccine-lawsuits-thomas-renz-covid/.

379 Renz Law, "Renz Whistleblowers DMED DATA reveals incredibly disturbing spikes in vaccine injuries across the board", 03.02.2022, *https://renz-law.com/attorney-tom-renz-whistleblowers-dmed-defense-medical-epidemiology-database-reveals-incredibly-disturbing-spikes-in-diseases-infertility-injuries-across-the-board-after-the-military-was-forced-to/.*

isations were allowed to continue unchanged in view of their obvious harmfulness, instead of finally being suspended and referred to the ordinary procedure. How "Swissmedic" could still come to a positive "cost-benefit ratio" under these circumstances is in no way comprehensible.

1.11.1. Heart problems (myocarditis etc.): 38 publications

552 By **1 March 2022,** the following additional **38 peer-reviewed publications** had appeared in which a connection between the occurrence of heart problems (myocarditis, myopericarditis, pericarditis, perimyocarditis, etc.) and the COVID "vaccinations" was proven (or at least a significant suspicion in this regard was shown):

- CHELALA et al. , Myocarditis findings on cardiac magnetic resonance imaging after vaccination with COVID-19 mRNA in adolescents, 27.10.2021, https://pubmed.ncbi.nlm.nih.gov/34704459/
- LI et al. , Myocarditis and pericarditis after COVID-19 vaccination: inequalities in age and vaccine types, 28.10*.2021, https://www.mdpi.com/2075-4426/11/11/1106*
- LAZAROS et al. , A case series of acute pericarditis after vaccination with COVID-19 in the context of recent reports from Europe and the United States, 29.10.2021, https://pubmed.ncbi.nlm.nih.gov/34635376/
- LIM et al. , Case report: acute fulminant myocarditis and cardiogenic shock after messenger RNA coronavirus vaccination in 2019 requiring extracorporeal cardiopulmonary resuscitation, 29.10.2021, https://pubmed.ncbi.nlm.nih.gov/34778411/
- ISTAMPOULOUOGLOU et al. , Myocarditis and pericarditis in association with COVID-19 mRNA vaccination: cases from a regional pharmacovigilance centre, 30.10.2021, https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8587334/
- FACETTI et al. , Acute myocarditis in a young adult two days after vaccination with Pfizer, 01.11.2021, https://pubmed.ncbi.nlm.nih.gov/34709227/
- JAIN et al , Myocarditis associated with COVID-19 vaccination in adolescents, 01.11*.2021, https://publications.aap.org/pediatrics/article/148/5/e2021053427/181357*
- JOOB et al , Acute myocarditis after 2019 coronavirus disease vaccination, 01 Nov 2021, https://pubmed.ncbi.nlm.nih.gov/34734821/
- PEREZ et al , Myocarditis after 2019 coronavirus disease mRNA vaccine: a case series and determination of incidence rate, 03 Nov 2021, https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab926/6420408
- SHIYOVICH et al , Myocarditis following COVID-19 vaccination: MRI study, 05.11.2021, https://pubmed.ncbi.nlm.nih.gov/34739045/

- KANETA et al , Young male with myocarditis after mRNA-1273 coronavirus disease-2019 (COVID-19) mRNA vaccination, 06.11.2021, https://pubmed.ncbi.nlm.nih.gov/34744118/
- BOURSIER et al , Ga-DOTATOC digital PET images of inflammatory cell infiltrates in myocarditis after vaccination with COVID-19, 08.11.2021, https://pubmed.ncbi.nlm.nih.gov/34746968/
- SHEN et al. , Acute pericarditis and cardiac tamponade after vaccination with Covid-19, 08.11.2021, https://pubmed.ncbi.nlm.nih.gov/34749492/
- JHAVERI et al , Weighing the Risks of Perimyocarditis With the Benefits of SARS-CoV-2 mRNA Vaccination in Adolescents, 11 Nov 2021, https://pubmed.ncbi.nlm.nih.gov/34270752/
- FOLTRAN et al , Myocarditis and pericarditis in adolescents after the first and second doses of COVID-19 mRNA vaccines, 16.11.2021, https://pubmed.ncbi.nlm.nih.gov/34849667/
- HO et al. , A review of COVID-19 vaccination and the reported cardiac manifestations, 19.11.2021, https://pubmed.ncbi.nlm.nih.gov/34808708/
- TINOCO et al , Perimyocarditis after vaccination with COVID-19, 24.11.2021, https://pubmed.ncbi.nlm.nih.gov/34866957/
- CHUA et al. , Epidemiology of acute myocarditis/pericarditis in Hong Kong adolescents after co-vaccination, 28.11.2021, https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab989/6445179?login=true
- KADWALWALA et al. , Multimodality imaging and histopathology in a young man presenting with fulminant lymphocytic myocarditis and cardiogenic shock after vaccination with mRNA-1273, 30.11.2021, https://pubmed.ncbi.nlm.nih.gov/34848416/
- AZIR et al. , STEMI mimicry: focal myocarditis in an adolescent patient after COVID-19 mRNA vaccination, 01.12.2021, https://pubmed.ncbi.nlm.nih.gov/34756746/
- CARI et al. , Cardiovascular, neurological, and pulmonary events after vaccination with BNT162b2, ChAdOx1 nCoV-19, and Ad26.COV2.S vaccines: an analysis of European data, 01.12.2021, https://pubmed.ncbi.nlm.nih.gov/34710832/
- DEB et al. , Acute myocardial injury after COVID-19 vaccination: a case report and review of current evidence from the Vaccine Adverse Event Reporting System database, 01.12.2021, https://pubmed.ncbi.nlm.nih.gov/34219532/
- KOUNIS et al , Hypersensitivity Myocarditis and COVID-19 Vaccines, 01.12.2021, https://pubmed.ncbi.nlm.nih.gov/34856634/
- WITBERG et al , Myocarditis after Covid-19 vaccination in a large healthcare organization, 02.12.2021, https://www.nejm.org/doi/10.1056/NEJMoa2110737

- NAGASAKA et al. , Acute myocarditis associated with COVID-19 vaccination: report of a case, 03.12.2021, https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8639400/
- MAEDA et al , Acute myocarditis defined after vaccination with 2019 mRNA of coronavirus disease, 04.12.2021, https://pubmed.ncbi.nlm.nih.gov/34866122/
- BUCHAN et al. , Epidemiology of myocarditis and pericarditis following mRNA vaccines in Ontario, Canada: by vaccine product, schedule, and interval, 05.12.*2021, https://www.medrxiv.org/content/10.1101/2021.12.02.21267156v1*
- PATONE et al , Risks of myocarditis, pericarditis, and cardiac arrhythmias associated with COVID-19 vaccination or SARS-CoV-2 infection, 14.12.2021, https://pubmed.ncbi.nlm.nih.gov/34907393/
- GELLAD, Myocarditis after vaccination against covid-19, 16.12.2021, https://pubmed.ncbi.nlm.nih.gov/34916217/
- FAZLOLLAHI et al , Cardiac complications following mRNA COVID-19 vaccines: A systematic review of case reports and case series, 17.12.2021, https://pubmed.ncbi.nlm.nih.gov/34921468/
- Clarke et al. , Should T2 mapping be used in cases of recurrent myocarditis to differentiate between the acute inflammation and chronic scar? , 18.12.2021, https://pubmed.ncbi.nlm.nih.gov/34933012/
- IOANNOU, T2 mapping should be utilised in cases of suspected myocarditis to confirm an acute inflammatory process, 21.12.2021, https://academic.oup.com/qjmed/advance-article/doi/10.1093/qjmed/hcab326/6472386?login=true
- KOHLI et al , mRNA Coronavirus-19 Vaccine-Associated Myopericarditis in Adolescents: A Survey Study, 22 Dec 2021, https://pubmed.ncbi.nlm.nih.gov/34952008/
- TAKEDA et al , Eosinophilic Myocarditis Following Coronavirus Disease 2019 (COVID-19) Vaccination, 25 Dec 2021, https://pubmed.ncbi.nlm.nih.gov/34955479/
- NYGAARD et al. , Population-based Incidence of Myopericarditis After COVID-19 Vaccination in Danish Adolescents, 01.01.2022, https://pubmed.ncbi.nlm.nih.gov/34889875/
- TRUONG et al. , Clinical suspicion of myocarditis temporally related to COVID-19 vaccination in adolescents and young adults, 01.02.*2022, https://www.ahajournals.org/doi/full/10.1161/CIRCULATIONAHA.121.056583?rfr_dat=cr_pub%2520%25200pubmed&url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org*
- MURAKAMI et al. , Myocarditis following vaccination with COVID-19 messenger RNA: a Japanese case series, 15.02.2022, https://pubmed.ncbi.nlm.nih.gov/34840235/

- CHOUCHANA et al , Features of Inflammatory Heart Reactions Following mRNA COVID-19 Vaccination at a Global Level, 01.03.2022, https://pubmed.ncbi.nlm.nih.gov/34860360/

1.11.2. Coagulation disorders etc. (thromboses, cerebral strokes etc.): 49 publications

553 By **1 March 2022,** the following **49 peer-reviewed publications had been** published in which a connection between the occurrence of increased blood clotting including the associated consequences (thromboses, strokes, etc.) and the COVID "vaccinations" was proven (or at least a considerable suspicion in this regard was shown):

- CHANG et al. , Vaccine-associated thrombocytopenia and thrombosis: venous endotheliopathy leading to combined venous micro-macrothrombosis, 26.10.2021, https://pubmed.ncbi.nlm.nih.gov/34833382/
- MARAMATTOM et al. , Cerebral venous sinus thrombosis following vaccination with ChAdOx1: the first case of definite thrombosis with thrombocytopenia syndrome in India, 27.10.2021, https://pubmed.ncbi.nlm.nih.gov/34706921/
- AL-MAYHANI et al. , Ischemic stroke as a presenting feature of immune thrombotic thrombocytopenia induced by ChAdOx1-nCoV-19 vaccination, 01.11.2021, https://pubmed.ncbi.nlm.nih.gov/34035134/
- BENNETT et al , Newly diagnosed immune thrombocytopenia in a pregnant patient after coronavirus disease 2019 vaccination, 01 Nov 2021, https://pubmed.ncbi.nlm.nih.gov/34420249/
- BONATO et al. , Massive cerebral venous thrombosis due to vaccine-induced immune thrombotic thrombocytopenia, 01.11.2021, https://pubmed.ncbi.nlm.nih.gov/34261296/
- CHEN et al , Palmar digital vein thrombosis after Oxford-AstraZeneca COVID-19 vaccination, 01 Nov 2021, https://pubmed.ncbi.nlm.nih.gov/34473841/
- HUNDELSHAUSEN et al. , Vaccine-induced immune thrombotic immune thrombocytopenia (VITT): targeting pathologic mechanisms with Bruton's tyrosine kinase inhibitors, 01.11.2021, https://pubmed.ncbi.nlm.nih.gov/33851389/
- KENDA et al. , Treatment of acute ischemic stroke associated with ChAdOx1 nCoV-19 vaccine- induced immune thrombotic thrombocytopenia, 01.11.2021, https://pubmed.ncbi.nlm.nih.gov/34461442/
- KRZYWICKA et al. , Cerebral venous sinus thrombosis following vaccination against SARS-CoV-2: an analysis of cases reported to the European Medicines Agency, 01.11.2021, https://pubmed.ncbi.nlm.nih.gov/34293217/
- KUTER, Exacerbation of immune thrombocytopenia after COVID-19 vaccination, 01.11.2021, https://pubmed.ncbi.nlm.nih.gov/34075578/

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- SIMSEK et al. , Massive cerebral venous thrombosis and venous basin infarction as late complications of COVID-19: a case report, 01.11.2021, https://pubmed.ncbi.nlm.nih.gov/34373991/
- SU et al. , Case report: vaccine-induced immune thrombotic thrombocytopenia in a patient with pancreatic cancer after vaccination with messenger RNA-1273, 01.11.2021, https://pubmed.ncbi.nlm.nih.gov/34790684/
- KIM et al. , Case report of immune thrombocytopenia after vaccination with ChAdOx1 nCoV-19, 08.11.2021, https://pubmed.ncbi.nlm.nih.gov/34751013/
- BALDI et al. , Thrombotic events after COVID-19 vaccination in over 50 years of age: results of a population-based study in Italy, 10.11.2021, https://pubmed.ncbi.nlm.nih.gov/34835237/
- SALEH et al. , Case study of thrombosis and thrombocytopenia syndrome after administration of the AstraZeneca COVID-19 vaccine, 12.11.2021, https://pubmed.ncbi.nlm.nih.gov/34781321/
- CLEAVER et al. , Endovascular treatment for vaccine-induced cerebral venous sinus thrombosis and thrombocytopenia after vaccination with ChAdOx1 nCoV-19: report of three cases, 15.11.2021, https://pubmed.ncbi.nlm.nih.gov/34782400/
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- GREINACHER et al. , Information on ChAdOx1 nCoV-19 vaccine-induced immune-mediated thrombotic thrombocytopenia, 02.12.2021, https://pubmed.ncbi.nlm.nih.gov/34587242/
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- KUZUMI et al. , Genital necrosis with cutaneous thrombosis following vaccination with COVID-19 mRNA, 01.03.2022, https://pubmed.ncbi.nlm.nih.gov/34839563/

1.11.3. Deaths: 2 studies

554 By **1 March 2022** (or by the end of 2021)**, the** following **2 peer-reviewed publications** had also appeared in which a connection between the death of vaccinated persons and the COVID "vaccinations" was proven (or at least a considerable suspicion in this respect was shown):

- STASSI et al , An Insight into the Role of Postmortem Immunohistochemistry in the Comprehension of the Inflammatory Pathophysiology of COVID-19 Disease and Vaccine-Related Thrombotic Adverse Events: A Narrative Review, 06.11.2021, https://pubmed.ncbi.nlm.nih.gov/34769454/
- SESSA et al , Autopsy Findings and Causality Relationship between Death and COVID-19 Vaccination: A Systematic Review, 15.12.2021, https://www.ncbi.nlm.nih.gov/pubmed/34945172

2. Effectiveness

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

555 With regard to the specific efficacy of COVID "vaccination" in the Omikron variant in particular, it should be noted in advance that this variant differed much more from the original Wuhan strain in terms of virus genetics than the Beta and Delta variants.[380] It is therefore not surprising that the (relative) effectiveness (RRR) against infection of the Omikron variant decreased significantly directly after the "vaccination":

2.1.1. Danish study: Relative efficacy of 37%-55%.

556 A Danish cohort study analysing data from 5,767 people with omicron concluded in December 2021 that Comirnaty® was only 55% effective against omicron and Spikevax® was 37% effective against omicron for people vaccinated shortly before they became ill, and that this effectiveness declined significantly further within 5 months.[381]

2.1.2. Swedish study: Relative efficacy of 23-59%.

557 A large-scale retrospective Swedish study examining registry data from 1.6 million vaccinated and unvaccinated persons, concluded in February 2022 that the relative effi-

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380 7arguments, "COVID-19 vaccination requirement is unconstitutional", 09.03.2022, p. 10, *https://7argumente.de/download/910/.*

381 HOLM HANSEN et al, "Vaccine effectiveness against SARS-CoV-2 infection with the Omicron or Delta variants following a two-dose or booster BNT162b2 or mRNA-1273 vaccination series: A Danish cohort study", preprint dated 23/12/2021, *https://www.medrxiv.org/content/10.1101/2021.12.20.21267966v3.full.pdf+html*.

cacy of COVID "vaccinations", both in terms of preventing COVID disease of any severity and in terms of severe disease progression, declined dramatically over time: six months after the second injection, Comirnaty® was calculated to have an efficacy of just 23%, Spikevax® 59%.[382]

2.1.3. US study: Relative efficacy in children rapidly decreased to 12-51%.

558 As part of a cohort study, researchers from the New York State Department of Health (*NYSDH*) determined the effectiveness of the mRNA vaccine Comirnaty® against COVID-19 and against COVID-19-related hospitalisations in **children in the two age groups 5 to 11-year-olds and 12 to 17-year-olds in** New York State and published the results in February 2022. They analysed two vaccination databases, as well as one database each on reportable COVID-19 test results and hospitalisations. The study period was from 13 December 2021 to 30 January 2022. In the fully vaccinated cohort of **5 to 11 year olds** (365,502 children), the effectiveness of the vaccine against COVID-19 declined rapidly: in the week of 13 December 2021, **effectiveness was 68 per cent; six weeks later, it was only 12 per cent.** In the group of fully vaccinated 12-17 year olds (852,384 children), **effectiveness dropped from 66 per cent to 51 per cent** over the same period. In terms of **Corona-related hospitalisations, efficacy among children** aged five to 11 years dropped from **100 per cent in the** week of 13 December 2021 to **48 per cent in** the week of 24 January, and among 12-17 year olds, **the figures dropped from 85 per cent to 73 per cent**. [383] In this publication, efficacy was once again presented based only on relative risk reduction. Information on underlying case numbers is missing.

2.1.4. Canada: Relative effectiveness at a maximum of 36

559 Based on a database analysis published as a preprint in January 2022, which included 16,087 positive Omikron cases, a "vaccination" efficacy of just 36% was calculated for the state of Ontario, Canada, for the Omikron variant and symptomatic diseases occurring in connection with it. There was no efficacy 180 days after the second vaccination.[384]

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382 NORDSTRÖM et al, "Risk of infection, hospitalisation, and death up to 9 months after a second dose of COVID-19 vaccine: a retrospective, total population cohort study in Sweden", 04.02.2022, https://www.sciencedirect.com/science/article/pii/S0140673622000897?ref=cra_js_challenge&fr=RR-1.

383 DORABAWILA et al, "Effectiveness of the BNT162b2 vaccine among children 5-11 and 12-17 years in New York after the Emergence of the Omicron Variant," Preprint, Feb. 28, 2022, https://www.medrxiv.org/content/10.1101/2022.02.25.22271454v1.

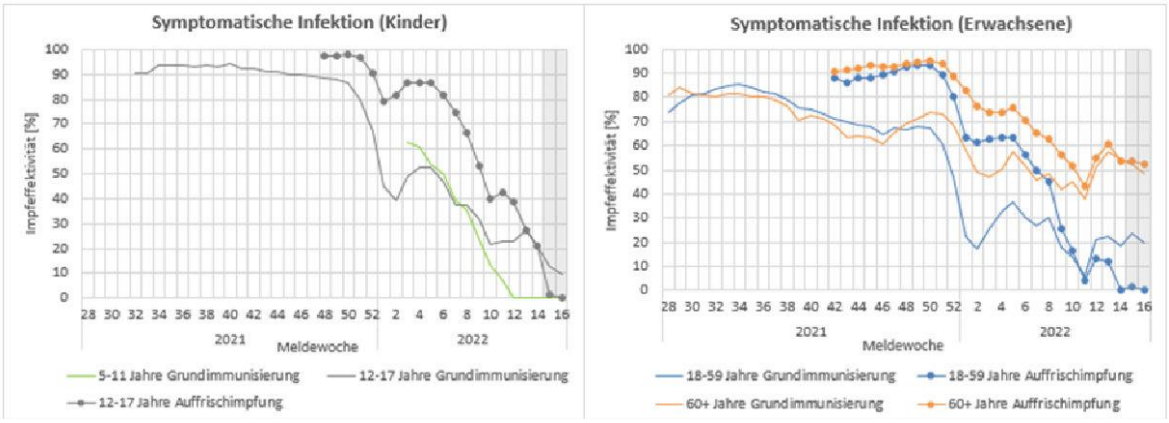
384 BUCHAN et al, "Effectiveness of COVID-19 vaccines against Omicron or Delta symptomatic infection and severe outcomes ", preprint dated 28 Jan 2022, https://www.medrxiv.org/content/10.1101/2021.12.30.21268565v2.

2.1.5. Germany: Vaccine effectiveness close to 0% at the end of March 2022

560 The German *RKI* admitted in its weekly report of 28 April 2022:[385]

> "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 Omikron variant. This development is also shown by the incidences of symptomatic COVID-19 cases according to vaccination status. Since the beginning of the year, the calculated vaccine effectiveness against hospitalisation has also been declining: this development is most evident for the basic vaccination and in the age groups <60 years and less pronounced for the booster vaccination and in the age group 60 years and older. In other countries, too, with the predominance of the omicron variant, a reduced effectiveness of COVID-19 "vaccination" compared to the delta variant, and a further decline over time, was observed mainly against symptomatic infection. Particularly low vaccine efficacies are shown for basic immunisation in children between 5 and 11 years of age. "

561 Graphs in the weekly report showed that **vaccine effectiveness in** terms of symptomatic infections has been at zero since at least the end of March 2022 in the group of 5 to 11-year-olds with "basic immunisation" (double vaccination) and in 12 to 59-year-olds with "booster vaccination":



562 In a roundabout way and with incomprehensible arguments, the *RKI* concluded that the "vaccination" nevertheless generated good protection against severe courses and hospi-

385 RKI, "RKI Weekly Situation Report on Coronavirus Disease-2019 (COVID-19)", 28.04.2022, p.30/31, https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Situationsberichte/Wochenbericht/Wochenbericht_2022-04-28.pdf?__blob=publicationFile.

talisations. This has since been clearly refuted by "real-world evidence" from various countries (see N 582 ff.).

563 **In the report of 5 May 2022, the *RKI* informed shortly afterwards that it would no longer publish data on vaccination efficacy**: "As of today, Thursday, the RKI's COVID-19 weekly report will no longer include regular information on the efficacy of COVID-19 vaccination."[386]

2.2. No protection against transmission and infection

564 **The "*Assessment reports*" of** Comirnaty® and Spikevax®[387] issued by the ***EMA in*** November 2021 and March 2022 explicitly stated that the effect of the "vaccination" on the spread of the SARS-CoV-2 virus in the population was not known:

> **"It is currently unknown if vaccination provides protection against asymptomatic infection,** and to what extent vaccination prevents further transmission. The efficacy against transmission would be of great interest to predict the impact of the vaccine against SARS-CoV-2 circulation, particularly among the paediatric population. ... The duration of protection is unknown in children and adolescents, as well as among adults. "(Assessment report Comirnaty®, p. 40)
>
> "The efficacy of the vaccine in preventing SARS-CoV-2 shedding and transmission, in particular from individuals with asymptomatic infection, can only be evaluated post-authorisation in epidemiological or specific clinical studies". (Assessment report Spikevax®, p. 145/147)

565 A commentary published in January 2022 in the renowned journal *The Lancet,* referring to a prospective study in England, emphasised that the effect of COVID "vaccination" on the transmissibility of SARS-CoV-2 "remains to be clarified". The study, which examined 8,145 samples from September 2020 to September 2021, showed that **no significant**

386 RKI, "RKI Weekly Situation Report on Coronavirus Disease-2019 (COVID-19)", 05.05.2022, p. 4, https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Situationsberichte/Wochenbericht/Wochenbericht_2022-05-05.pdf?__blob=publicationFile.

387 European medicines agency, "Assessment report Comirnaty", 25.11.2021, p. 40, https://www.ema.europa.eu/en/documents/variation-report/comirnaty-h-c-5735-x-0077-epar-assessment-report-extension_en.pdf; European medicines agency, "Assessment report Spikevax", 11.03.2021, p. 146 f., *https://www.ema.europa.eu/en/documents/assessment-report/spikevax-previously-covid-19-vaccine-moderna-epar-public-assessment-report_en.pdf.*

difference was observed in the transmission of circulating variants of SARS-CoV-2 between vaccinated and unvaccinated individuals.[388]

566 The German *Robert Koch Institute* (*RKI*) announced in March 2022 that it must be assumed that people would become PCR-positive after contact with SARS-CoV-2 despite vaccination, could also excrete viruses and be infectious. These people could either develop symptoms of a disease or no symptoms at all. In addition, the vaccine protection would diminish over time, and the probability of becoming PCR-positive despite vaccination would increase. The vaccine efficacy after basic immunisation is "significantly reduced" compared to Omikron.[389]

567 Prof. Andreas Radbruch, immunologist and vice-president of the Federation of European Immunological Societies (*EFIS*) and member of the Leopoldina as well as the Berlin-Brandenburg Academy of Sciences, wrote on 21.03.2022 in a statement to the German Bundestag that the **viral load of infected vaccinated persons** is **high** and the **protection from vaccination is only short-term.**[390]

2.3. Those who have recovered are better protected against a recurrence of COVID than those who have been vaccinated.

568 By the end of 2021, more than 60 publications had already proven that **a previous illness reliably protected against re-infection and that the immunity acquired in this way** was **superior to a "vaccination"** (see above N 298 ff. and N 478 ff.).

569 In December 2021, it was known that the antibody diversity in particular was also greater in those who had recovered than in those who had been vaccinated.[391]

570 In the course of the study, it became apparent that this protection was not broken in those who had recovered, even by new virus mutations. In the case of infection with the delta strain, the same absolute risk reduction (both for a renewed positive PCR test and for symptomatic disease) was found after pre-infection with alpha as in the case of infection with alpha after alpha. **Of 50,327 patients who tested positive before 31 December**

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388 FRANCO-PAREDES, "Transmissibility of SARS-CoV-2 among fully vaccinated individuals", 01.01.2022, *https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00768-4/fulltext.*

389 RKI, "Vaccination Effectiveness", as of 18.3.2022, https://web.archive.org/web/20220320013601/https://www.rki.de/SharedDocs/FAQ/COVID-Impfen/FAQ_Liste_Wirksamkeit.html.

390 RADBRUCH, "Stellungnahme an den Deutschen Bundestag", 21.03.2022, https://www.bundestag.de/resource/blob/885544/603140227998e5482d2fb207eedbc13a/20_14_0017-27-_Prof-Dr-Andreas-Radbusch_Impfpflicht-data.pdf.

391 Pharmazeutische Zeitung, "Antibody formation differs in recovered and vaccinated persons", 13.12.2021, *https://www.pharmazeutische-zeitung.de/antikoerperbildung-bei-genesenen-und-geimpften-unterschiedlich-130191/.*

2020, reinfection with the Delta variant was observed in only 40 cases (0.08%). The duration of immunity was at least 13 months. [392]

571 A large-scale retrospective observational study in which Oxford University researchers analysed data generated over the period June to August 2021 from 124,500 people in Israel concluded in April 2022 that vaccinated people had a 13-fold higher risk of re-infection and a 7-fold higher risk of re-symptomatic disease with "delta" than recovered unvaccinated people.[393]

572 On 11 April 2022, in Tennessee, USA, **legislation to legally equalise natural and "vaccine" acquired immunity to COVID-19** was **passed overwhelmingly** by the lower house of the legislature on the grounds that "immune protection acquired through prior COVID-19 infection is at least as protective against COVID-19 as a COVID-19 vaccine". There was therefore "no rational reason to treat persons who have undergone a previous COVID-19 infection differently from persons who have received a COVID-19 vaccine", it concluded.[394]

2.4. Poor recording of "vaccination breakthroughs"

573 "Vaccination breakthroughs" have been recorded in Switzerland since the end of October 2021 only for hospitalised persons and deaths.[395] But even this recording was obviously done in a completely inadequate manner:

574 Some hospitals had not even begun to systematically record vaccination status until late summer 2021 *at the earliest.* The Cantonal Hospital of St. Gallen confirmed on request that the vaccination status of hospitalised persons had not been systematically recorded until 23 August 2021.

BO: Supplement **21:** E-mail response regarding vaccination status, Cantonal Hospital St. Gallen, 23.08.2021

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392 KIM et al, "Duration of Severe Acute Respiratory Syndrome Coronavirus 2 Natural Immunity and Protection Against the Delta Variant: A Retrospective Cohort Study", 03.12.2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8690283/.

393 GAZIT et al, "SARS-CoV-2 Naturally Acquired Immunity vs. Vaccine-induced Immunity, Reinfections versus Breakthrough Infections: a Retrospective Cohort Study", 05.04.2022, *https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciac262/6563799?login=false.*

394 State of Tennessee, "Public Chapter No. 930, House Bill No. 1871", 11.04.2022, https://publications.tnsosfiles.com/acts/112/pub/pc0930.pdf.

395 Observer, "BAG does not consistently record vaccination breakthroughs", 02.12.2021, https://www.beobachter.ch/burger-verwaltung/chaos-in-der-statistik-bag-erfasst-impfdurchbruche-nicht-konsequent.

575 The complainants also have internal instructions from other hospitals, according to which the written official orders for the systematic recording of the "vaccination status" did not even take place until November 2021 (USZH).

BO: Supplement **22:** University Hospital Zurich (USZ), "Internal information, recording vaccination status in KISIM", 30.11.2021

576 At other hospitals, even at that late stage, no directive had apparently been issued on mandatory recording: The Lucerne Cantonal Hospital, for example, stated that the certificate (and thus the "vaccination status") should only be recorded "if clinically relevant".

BO: Supplement **23:** Lucerne Cantonal Hospital, LUKiS News, recording certificate 'if clinically relevant', 27.11.2021

577 This fact was also investigated by *Medinside in* an investigative report of 24 November 2021: According to a corresponding survey, the **vaccination status in Swiss hospitals** was **only** recorded on **the basis of patient surveys and** not by means of a reliable method - such as recording the COVID certificate.[396]

578 **On the subject of "lack of efficacy"**, as which a **"vaccination breakthrough" is to** be classified, Swissmedic communicated on its website:[397]

⇓ Wann ist «lack of efficacy / loss of drug effect / drug ineffective» als Einzelmeldung meldepflichtig?

«Lack of efficacy» per se ist in der Schweiz nicht meldepflichtig. Swissmedic empfiehlt jedoch die Meldung aller Fälle von «lack of efficacy», insbesondere dann, wenn mit klinisch relevanten Folgeerscheinungen zu rechnen ist (z. B. bei Impfstoffen, Kontrazeptiva, Antibiotika oder Medikamenten zur Behandlung von lebensbedrohlichen Erkrankungen). Alle gemeldeten Fälle werden in die nationale Datenbank aufgenommen und anschliessend an die WHO Datenbank weitergeleitet.

Häufungen von «lack of efficacy» Fällen müssen gemäss HMG Art. 59 gemeldet werden.

396 Medinside, "How accurate are the figures on vaccinated people in hospitals?", 24.11.2021, *https://www.medinside.ch/de/post/wie-genau-sind-die-zahlen-ueber-geimpfte-in-den-spitaelern.*

397 Swissmedic, "Frequently asked questions and answers: General pharmacovigilance", 14.01.2015, https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/marktueberwachung/pharmacovigilance/haeufige-fragen-und-antworten/haeufige-fragen-und-antworten--allgemeine-pharmakovigilanz.html.

579 In view of these recommendations and the inadequate data on the efficacy of the COVID "vaccines", it seems completely incomprehensible that Swissmedic did not take measures from the outset to ensure reliable recording of the vaccination status of those tested positive for SARS-CoV-2, and in particular of those hospitalised for COVID, when according to the approval criteria COVID is officially a life-threatening disease and consequences in the event of a lack of efficacy are therefore to be classified as serious.[398] By spring 2022, the vaccination status of about 20% of those hospitalised for COVID was still unknown (N 2.5.2.1ff.).

580 Already in the **"*Post Marketing Pharmacovigilance-Report*"**[399] by Pfizer/BioNTech with data on the first 2.5 months after market approval, **1665 cases with missing effect after administration of Comirnaty®** (788 cases after the 1st injection, 139 cases after the 2nd injection, in 722 cases no data were available) had been reported:

Lack of efficacy cases

- Number of cases: 1665[b] (3.9 % of the total PM dataset) of which 1100 were medically confirmed and 565 non medically confirmed;

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

581 On 10.01.2022, Pfizer CEO A. Bourla himself admitted that two doses of the "COVID vaccine were "limited, if effective at all" against "current mutants". A booster, however, would offer "acceptable protection".[400] That this is not so, but that the "vaccination" on the contrary makes people more susceptible to contracting COVID or dying from it, is shown very impressively by the data presented below.

2.5.1. International trends

582 Numerous studies from various countries made it increasingly clear from autumn 2021 onwards that the "vaccination" did not help, but on the contrary the vaccination rate correlated positively with COVID infections and associated illnesses and deaths.[401] The "vaccination" seems to make "vaccinated" people more susceptible to severe courses associated with the Omikron variant.

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398 Observer, FN 395.

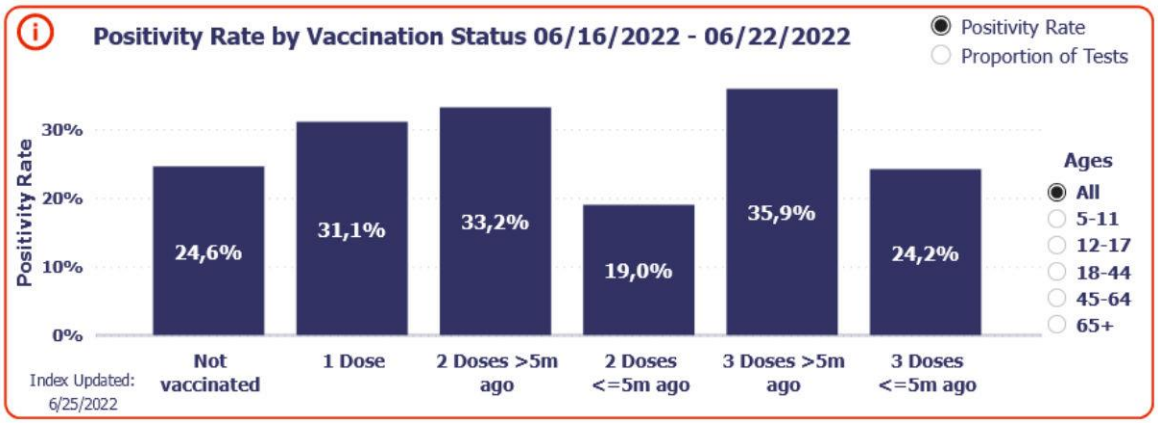
399 Pfizer, FN 278.

400 Science files, "Pfizer CEO: 2 times Comirnaty does not protect, 3 times is only slightly better", 12.01.2022, https://sciencefiles.org/2022/01/12/pfizer-ceo-2-mal-comirnaty-schuetzt-nicht-3-mal-ist-nur-wenig-besser/.

401 KIRSCH, "The more we vaccinate, the higher the number of cases", 14.12.2021, https://stevekirsch.substack.com/p/the-more-we-vaccinate-the-higher.

2.5.1.1 USA

583 *Walgreens*, one of the largest US pharmacy chains, which in partnership with *Aegis Sciences Coorperation* offers PCR testing at over 5,000 locations in the US and Puerto Rico, released data showing that as of 10 May 2022 (over 5 months ago), double and triple vaccinated individuals had the highest rates of positive SARS-CoV-2 test results:[402]



2.5.1.2 England

584 As of 29 December 2021, according to the *UK Health Authority Agency*, unvaccinated patients accounted for 25.3% of COVID hospitalisations in England, once-vaccinated patients accounted for 6.1%, twice-vaccinated patients accounted for 43.2%, and triple-vaccinated patients accounted for 23.2%. Overall, **72.5% of patients hospitalised for COVID** were **"vaccinated"**:[403]

Table 3. Number of Omicron cases admitted or transferred to hospital at the end of presentation to emergency care by vaccination status, England. Data to 29 December 2021

Vaccination status	Count (n)	Percentage (%)
Unlinked*	18	2.2
Not vaccinated	206	25.3
Received one dose (1 to 20 days before specimen date)	1	0.1
Received one dose, ≥21 days before specimen date	49	6.0
Second dose ≥14 days before specimen date	352	43.2
Third dose or Booster ≥14 days before specimen date	189	23.2

* Individuals whose NHS numbers were unavailable to link to the National Immunisation Management System.

585 The trend that triple-vaccinated people led hospitalisations and deaths related to COVID disease was further clarified during the course:

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402 Walgreens, "Walgreens COVID-19 Index," 6/22/2022, https://www.walgreens.com/businesssolutions/covid-19-index.jsp.

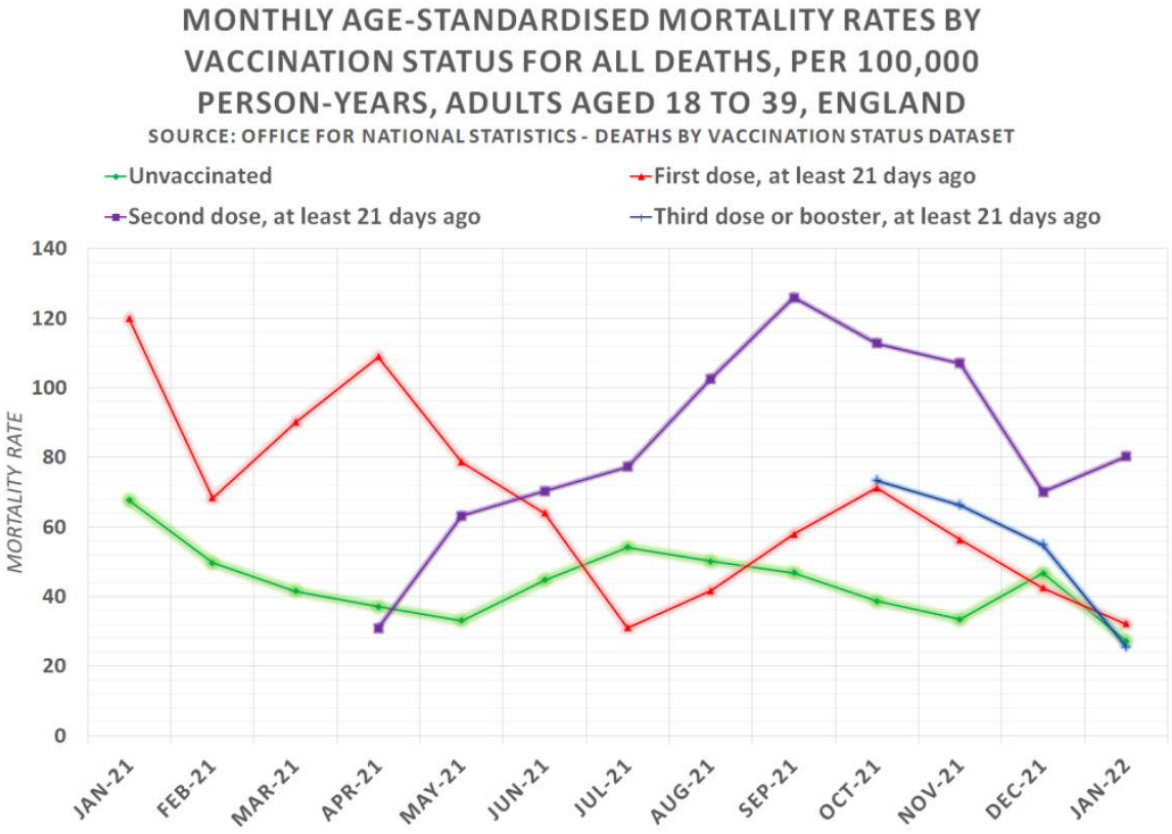
403 UK Health Security Agency, "SARS-CoV-2 variants of concern and variants under investigation in England", 31.12.2021, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1045619/Technical-Briefing-31-Dec-2021-Omicron_severity_update.pdf.

586 In the period from 28 February to 27 March 2022, 10,326 COVID hospitalisations were recorded, according to the *UK Health Authority Agency.* Triple vaccinated individuals accounted for 6,750 (65.4%), (1 to 3 times) vaccinated individuals accounted for a total of 8,261 (80.0%) and the non-vaccinated population accounted for only 2,065 (20.0%) of the cases. A total of 4,057 COVID deaths were recorded for the period mentioned, of which 3,054 (75.2%) were in the triple-vaccinated population, 3,736 (92%) deaths were in the (1-3 times) vaccinated population as a whole, and only 321 (7.9%) were in the non-vaccinated population. [404] **This meant that 9 out of 10 COVID deaths were attributable to the vaccinated population and 4 out of 5 COVID deaths were attributable to the triple-vaccinated population.** If one were to calculate the effectiveness of the COVID "vaccines" based on these official figures from England, analogous to how the "high" effectiveness is communicated based on the registration studies by means 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**.

587 Figures from the *Office for National Statistics* (*ONS*), a recognised statistical institute of England, which compiled national mortality data by vaccination status, showed that COVID "vaccination" was associated with a significantly increased risk of mortality:[405]

404 UK Health Security Agency, "COVID-19 vaccine surveillance report, Week 13", 31.03.3022, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1066759/Vaccine-surveillance-report-week-13.pdf.

405 ONS, "Deaths by vaccination status, England", 16.05.2022, Excel File "Deaths occurring between 1.1.2021 and 31.3.2022", https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/datasets/deathsbyvaccinationstatusengland; Graphic from The Exposé, "Doctors 'baffled' by sudden uptick in "Sudden Adult Death Syndrome" despite Government data proving COVID Vaccine is to blame", 09.06.2022, https://expose-news.com/2022/06/09/covid-vaccine-causing-sudden-adult-death-syndrome/.



2.5.1.3 Scotland

588 A report by ***Public Health Scotland*** published on 22/12/2021 showed that "unvaccinated" patients accounted for only 27% of **COVID hospital admissions** between 20/11/2021 and 17/12/2021, while **"vaccinated" patients** accounted for **73%**. It was further shown that between 13/11/2021 and 10/12/2021, there were 63 "COVID deaths" among "unvaccinated", 13 deaths among "partially vaccinated", 251 deaths among "double vaccinated" and 35 deaths among "triple vaccinated". This meant that only 17% of **deaths between 13/11/2021 and 10/12/2021 were among** "unvaccinated" and **83% were among "vaccinated"**.[406]

2.5.1.4 Canada

589 As of 10 April 2022, 15,775 COVID deaths have been reported by *Health Canada* since recording began, and 16,002 as of 17 April 2022.[407] This resulted in a total of 227 COVID deaths for the week of 10 April to 17 April 2022. Of these 227 cases, 160 people (70.4%)

406 Public health Scotland, "COVID-19 statistical report", 22.12.2021, https://publichealthscotland.scot/publications/covid-19-statistical-report/covid-19-statistical-report-22-december-2021/.

407 YAKIWCHUK, "99.6% of Deaths in Vaccinated - 70% Boosted", 05.05.2022, https://sheldonyakiwchuk.substack.com/p/996-of-deaths-in-vaccinated-70-boosted?s=r.

were fully vaccinated and boosted, and 62 (27.3%) people were fully **vaccinated, meaning that a** total of 222 (**97.7%**) people **who died of COVID were fully vaccinated or boosted**. In comparison, a single COVID death involved an unvaccinated person:

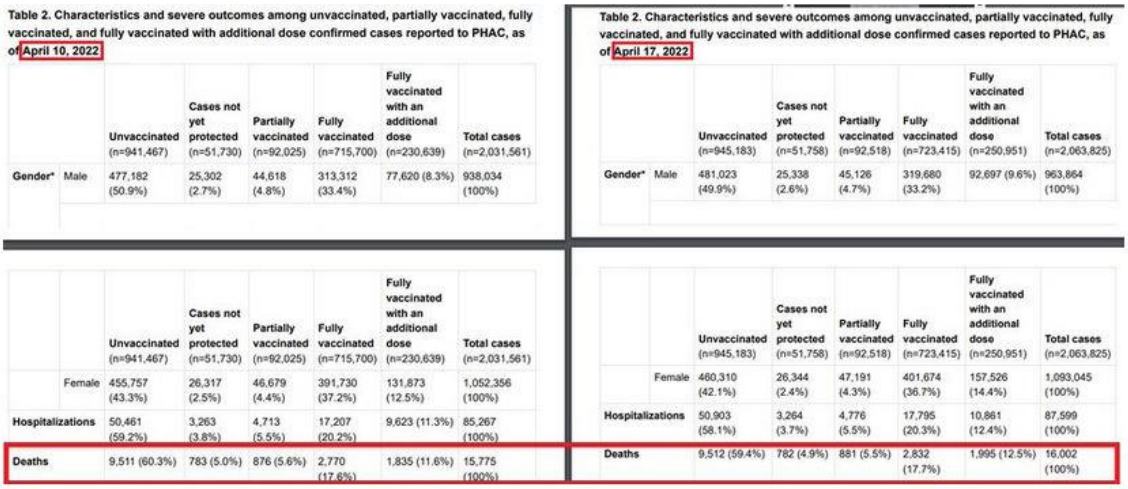


Table 2. Characteristics and severe outcomes among unvaccinated, partially vaccinated, fully vaccinated, and fully vaccinated with additional dose confirmed cases reported to PHAC, as of April 10, 2022

		Unvaccinated (n=941,467)	Cases not yet protected (n=51,730)	Partially vaccinated (n=92,025)	Fully vaccinated (n=715,700)	Fully vaccinated with an additional dose (n=230,639)	Total cases (n=2,031,561)
Gender*	Male	477,182 (50.9%)	25,302 (2.7%)	44,618 (4.8%)	313,312 (33.4%)	77,620 (8.3%)	938,034 (100%)
	Female	455,757 (43.3%)	26,317 (2.5%)	46,679 (4.4%)	391,730 (37.2%)	131,873 (12.5%)	1,052,356 (100%)
Hospitalizations		50,461 (59.2%)	3,263 (3.8%)	4,713 (5.5%)	17,207 (20.2%)	9,623 (11.3%)	85,267 (100%)
Deaths		9,511 (60.3%)	783 (5.0%)	876 (5.6%)	2,770 (17.6%)	1,835 (11.6%)	15,775 (100%)

Table 2. Characteristics and severe outcomes among unvaccinated, partially vaccinated, fully vaccinated, and fully vaccinated with additional dose confirmed cases reported to PHAC, as of April 17, 2022

		Unvaccinated (n=945,183)	Cases not yet protected (n=51,758)	Partially vaccinated (n=92,518)	Fully vaccinated (n=723,415)	Fully vaccinated with an additional dose (n=250,951)	Total cases (n=2,063,825)
Gender*	Male	481,023 (49.9%)	25,338 (2.6%)	45,126 (4.7%)	319,680 (33.2%)	92,697 (9.6%)	963,864 (100%)
	Female	460,310 (42.1%)	26,344 (2.4%)	47,191 (4.3%)	401,674 (36.7%)	157,526 (14.4%)	1,093,045 (100%)
Hospitalizations		50,903 (58.1%)	3,264 (3.7%)	4,776 (5.5%)	17,795 (20.3%)	10,861 (12.4%)	87,599 (100%)
Deaths		9,512 (59.4%)	782 (4.9%)	881 (5.5%)	2,832 (17.7%)	1,995 (12.5%)	16,002 (100%)

590 When interpreting these figures, it is important to bear in mind that the recording of cases began on 14 December 2020 and thus a large proportion of COVID cases from the "unvaccinated" were included in the statistics at the beginning, reflecting the high rate of "unvaccinated status" of the overall population at that time.

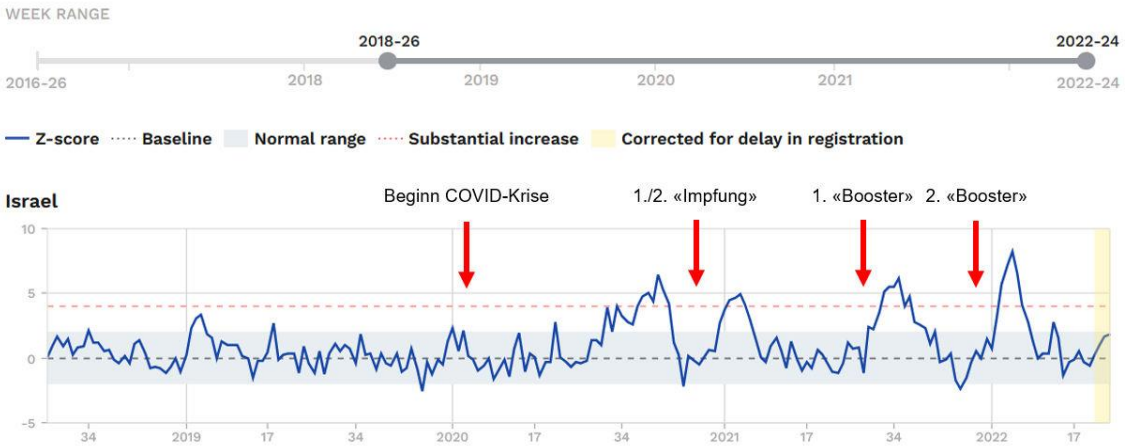
2.5.1.5 Israel

591 Prof. Jacob Giris, head of the COVID department at Ichilov Hospital in Tel Aviv, announced in an interview at the beginning of February 2022 that 70-80% of hospitalised patients with severe COVID were triple-vaccinated and that "vaccination" thus definitely had no significance in terms of preventing severe COVID courses.[408]

592 The European mortality monitor *EuroMomo* reported the highest excess mortality for Israel for Q1 2022 since the beginning of the Corona crisis.[409] While the data from Israel did not yet document proven causality, it did document a worryingly impressive correlation between injections and overall mortality that urgently needs to be clarified:

408 Israel National News, "'80% of serious COVID cases are fully vaccinated' says Ichilov hospital director", 03.02.2022, https://www.israelnationalnews.com/news/321674.

409 Euromomo, "Graphs an maps", 23.06.2022, *https://www.euromomo.eu/graphs-and-maps* (graph supplemented by time of "vaccine doses" administered).



593 Since the demonstrably harmless Omikron variant was circulating at the time, it is more obvious to attribute this excess mortality to the high vaccination coverage and not to COVID.

2.5.1.6 Australia

594 According to the New South Wales Health Authority report, as of 16 April 2022**, 45% of all COVID hospitalised people** had been **vaccinated 3 times, 26% twice, 2% once,** and 27% were unvaccinated or patients where vaccination status was unknown:[410]

Table 1. Vaccination status of people with a COVID-19 diagnosis in the previous 14 days who were admitted to hospital in the week ending 16 April 2022, NSW

Vaccination status	Admitted to hospital (but not to ICU) (%)	Admitted to ICU (%)	Total
Three or more doses	432 (45%)	35 (37%)	467 (45%)
Two doses	249 (26%)	27 (29%)	276 (26%)
One dose	19 (2%)	0 (0%)	19 (2%)
No dose/Unknown	253 (27%)	32 (34%)	285 (27%)
Total	953 (100%)	94 (100%)	1047 (100%)

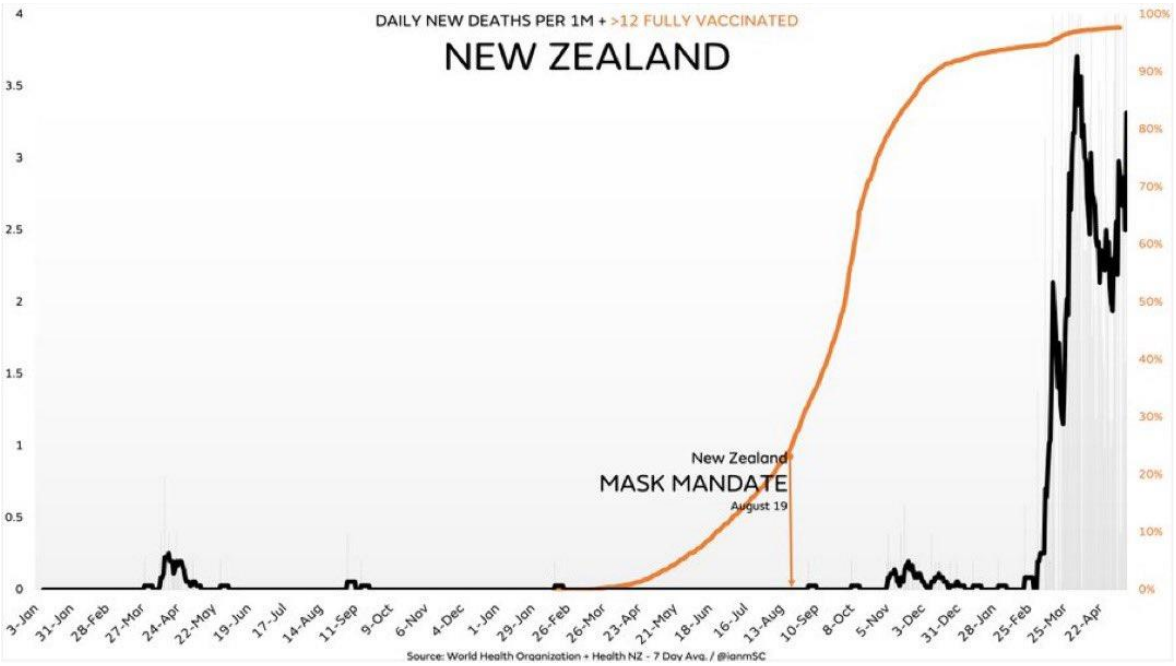
595 From the start of the pandemic to 31 December 2021, a total of 2,253 COVID deaths were reported in Australia, according to *Our World in Data.* From 01 January to 08 May 2022, this total number of COVID deaths had skyrocketed by 5,263 cases to 7,516. This means that **despite proven harmless Omikron variant and high vaccination coverage** (as of 9.5.2022, 85% of the Australian population had at least double vaccination), **70% of all COVID deaths** occurred **from January to April 2022.** [411]

410 New South Wales Health, "NSW Covid-19 weekly data overview", 16.04.2022, https://www.health.nsw.gov.au/Infectious/covid-19/Documents/weekly-covid-overview-20220416.pdf.

411 The Sidney Morning Herald, "We're living with COVID but more of us are dying than ever", 07.05.2022, https://www.smh.com.au/national/we-re-living-with-covid-but-more-of-us-are-dying-than-ever-20220429-p5ah7y.html.

2.5.1.7 New Zealand

596 Another development that would in no way be expected with an effective vaccine against SARS-CoV-2 is the fact that in "Zero-COVID" New Zealand, **deaths have risen massively and sharply since spring 2022, even though 95% of the population over 12 years of age was fully vaccinated:**



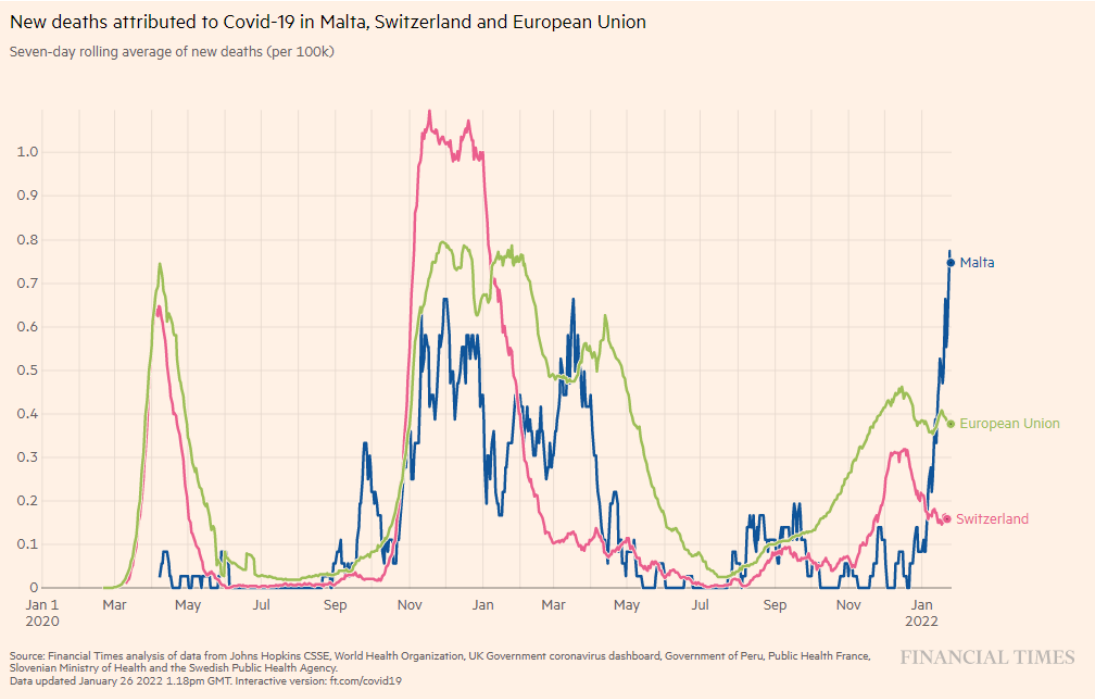
597 By May 2022, a private database in New Zealand had registered over 450 deaths in a temporal connection with the COVID "vaccination" with the associated detailed information. Of these, just 160 cases were recorded in the official New Zealand adverse event database *CARM*, with only three cases acknowledged to be causally related to the "vaccination". The majority of the 450 deaths involved young people, including children, who died suddenly and unexpectedly without pre-existing conditions. In an open letter on 24 May 2022, *New Zealand Doctors Speaking Out with Science* ("NZDSOS") called on the government to investigate the details of these deaths and release information.[412]

2.5.1.8 Malta

Malta recorded one of the highest vaccination coverage rates worldwide (vaccination rate per

412 NZDSOS, "Deaths Following C-19 Vaccination", 24.05.2022, https://nzdsos.com/2022/05/24/deaths-following-c-19-vaccination/.

15.1.2022: Malta 85.3%, EU 70.3%, Switzerland, 67.5%[413]) in January 2022 the highest COVID death rate since the beginning of the Corona crisis:

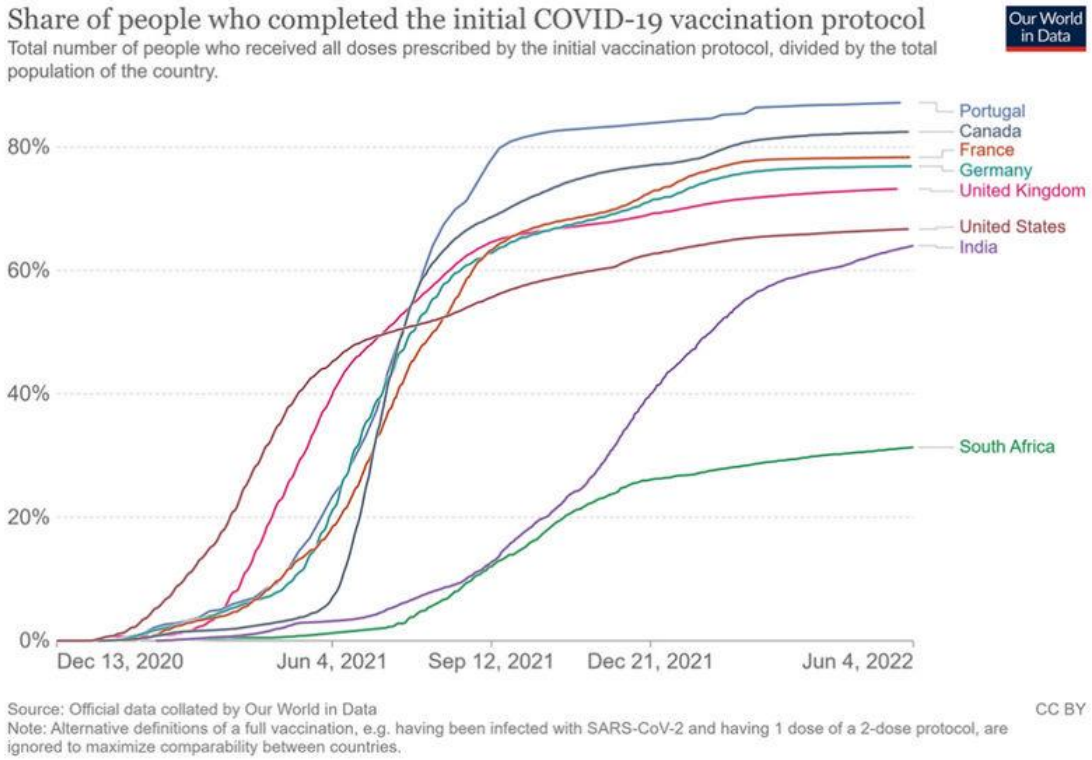


2.5.1.9 Portugal-South Africa comparison

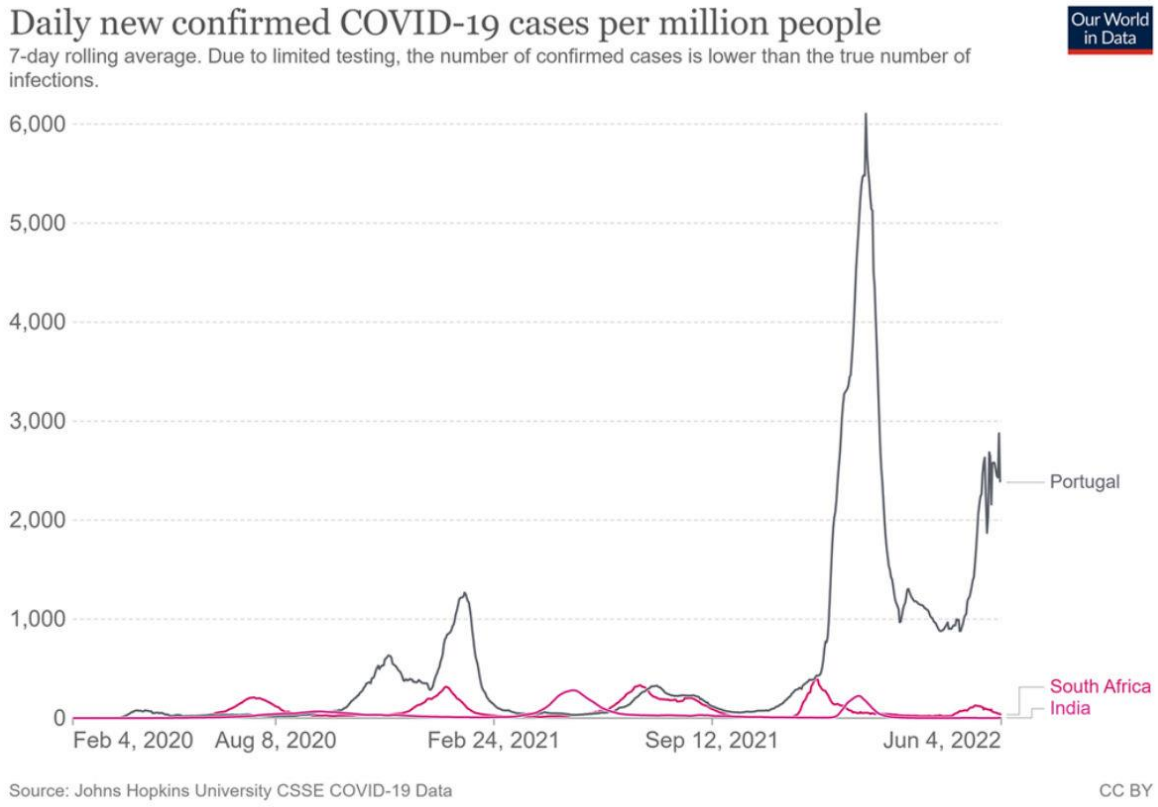
598 According to the platform "Our world in data " , Portugal was one of the countries with the highest vaccination coverage rate as of June 2022, while South Africa was one of the countries with the lowest:[414]

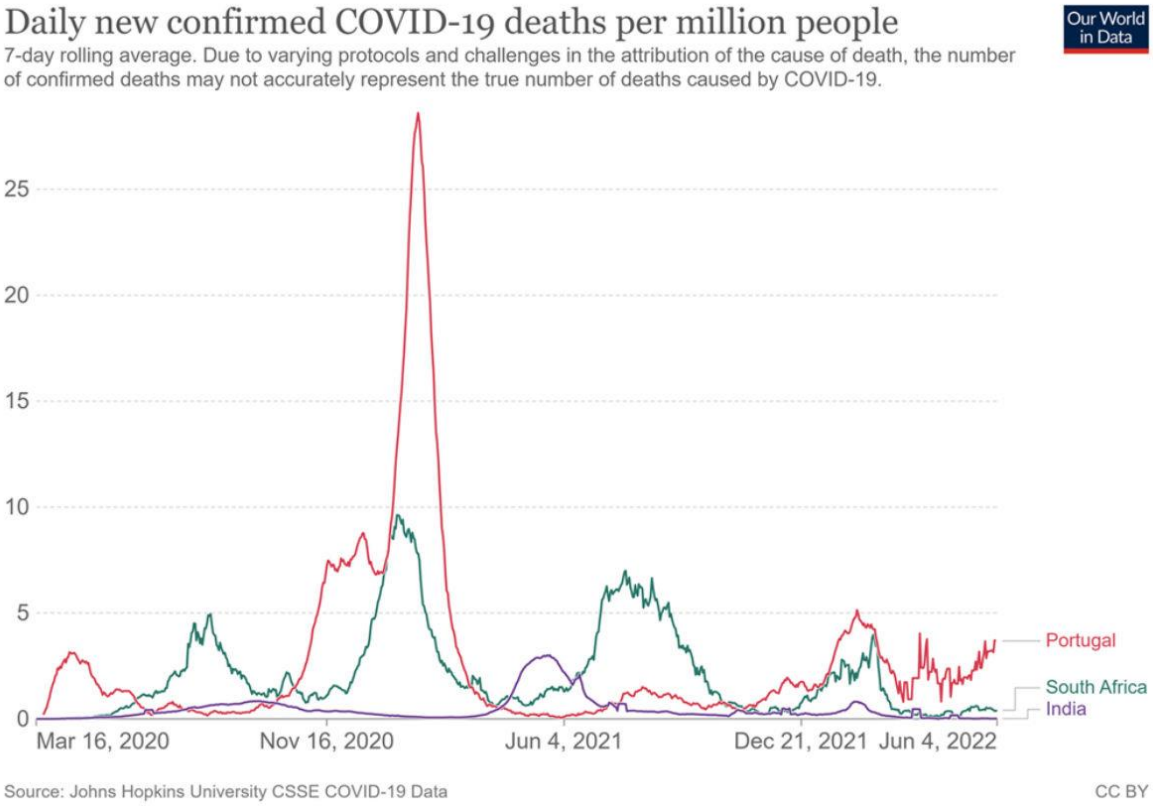
413 Euronews, "EU countries compared: who vaccinates faster against Covid-19?", 17.01.2022, https://de.euronews.com/my-europe/2021/11/09/eu-lander-im-vergleich-wer-impft-schneller-gegen-covid-19.

414 Our world in data, "Explore the global situation", 23.06.2022, https://ourworldindata.org/coronavirus#explore-the-global-situation.



599 When comparing these two countries, it is easy to see at first glance that South Africa performs significantly better in terms of both reported COVID cases and COVID deaths:





2.5.1.10 Denmark

600 According to an investigation, at a private event on the Faroe Islands in early December 2021, 21 out of 33 participants, all healthcare workers, contracted the coronavirus and became symptomatically ill. All 21 people were triple vaccinated.[415]

2.5.2. Same pattern in Switzerland

2.5.2.1 66.3% of COVID hospitalised are "vaccinated

601 In Switzerland, COVID hospitalisations have been officially driven by a constant increase in the number of vaccinated persons since the beginning of 2022 at the latest[416] :

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415 HELMSDAL et al, "Omicron outbreak at a private gathering in the Faroe Islands, infecting 21 of 33 triple-vaccinated healthcare workers", 03.02.2022, https://academic.oup.com/cid/advance-article-abstract/doi/10.1093/cid/ciac089/6520882?redirectedFrom=fulltext&login=false.

416 BAG, "Cases by vaccination status, hospitalisations", 23.06.2022, https://www.covid19.admin.ch/de/vaccination/status?vaccStatusDevRel=relative; BAG, "Cases by vaccination status, deaths", 23.06.2022, https://www.covid19.admin.ch/de/vaccination/status?vaccStatusDevRel=relative&indicator=death.

602 As of **31.1.2022, 42.7% of COVID hospitalised persons** were **vaccinated** (21.2% with a booster vaccination), 36.4% were unvaccinated, and the vaccination status was "unknown" for 20.1%.

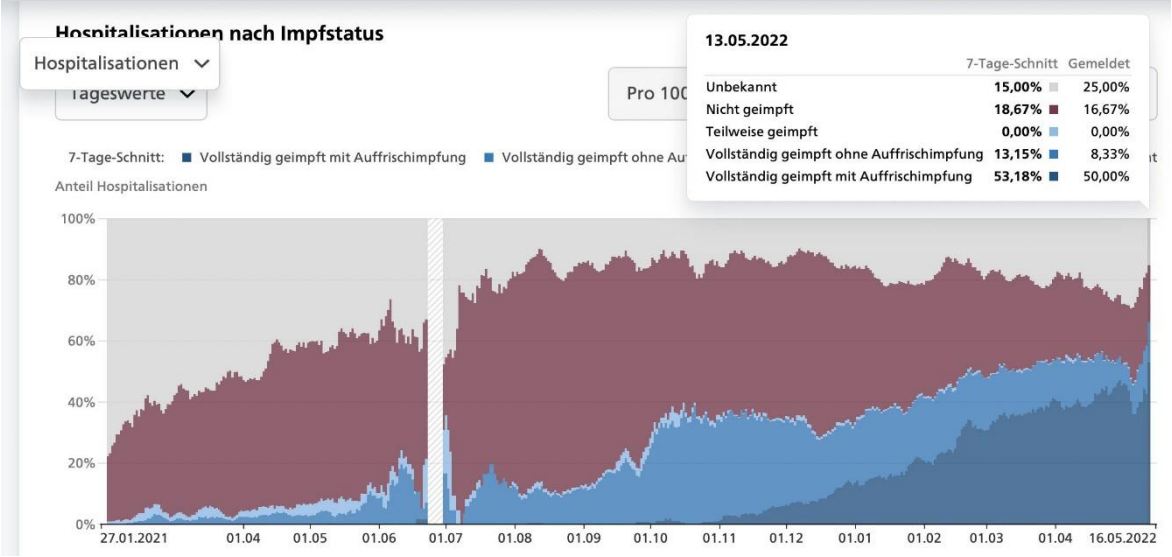
603 As of **28.2.2022, 49% of** COVID **hospitalised** were **vaccinated** (31.3% with a booster), 32.9% were unvaccinated, and the vaccination status was "unknown" for 18%.

604 As of **15.3.2022, 49.8% of hospitalised** patients were **vaccinated** (**35.3% with a booster vaccination**), 31.8% were unvaccinated, and the vaccination status was "unknown" for 18.3%.

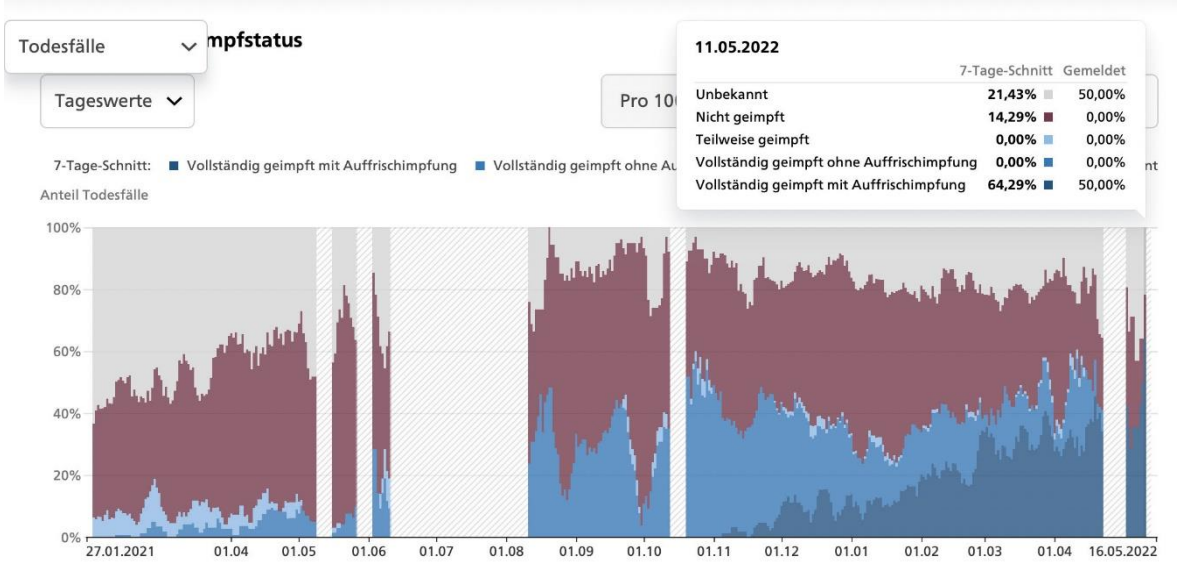
605 As of **31.3.2022, 52.6% of COVID hospitalised** persons were **vaccinated** (41.1% with a booster vaccination), 29.3% were unvaccinated, and the vaccination status was "unknown" for 18.1%.

606 As of **2.5.2022, 52.6% of COVID hospitalised** persons were still **vaccinated** (45.5% with a booster vaccination), 19.6% were unvaccinated, and the vaccination status was "unknown" for 27.8%.

607 As of **13.5.2022, 66.3% of COVID hospitalised** were **vaccinated** (53.2% with a booster vaccination), 18.7% unvaccinated, and for 15.0% the vaccination status was "unknown":



608 Far more alarming: As of 11.5.2022, 64.3% of those who died of COVID were triple vaccinated:



609 Even if the absolute case numbers of COVID hospitalisations and deaths corresponding to the seasonality of the coronaviruses from the end of March 2022 in Switzerland became too small to be able to make statistically relevant statements: If the "vaccination" were really the promised "game changer", these figures would definitely have to look different.

610 It is often argued that the high coverage rate of hospitalisations and deaths associated with COVID simply reflects the high coverage rate of the population and is not, of course, an indication of ineffectiveness. Even if this were correct, consider how regulatory authorities, physicians and patients would react if it turned out that more than 50% of those hospitalised for pulmonary embolism or stroke had taken a drug to thin the blood, i.e. to prevent these events. Of course, if prevention is really effective, it can be expected to be highly successful in preventing the disease for which it is used, and people for whom this prevention has been used will certainly not have to be hospitalised with a severe course.

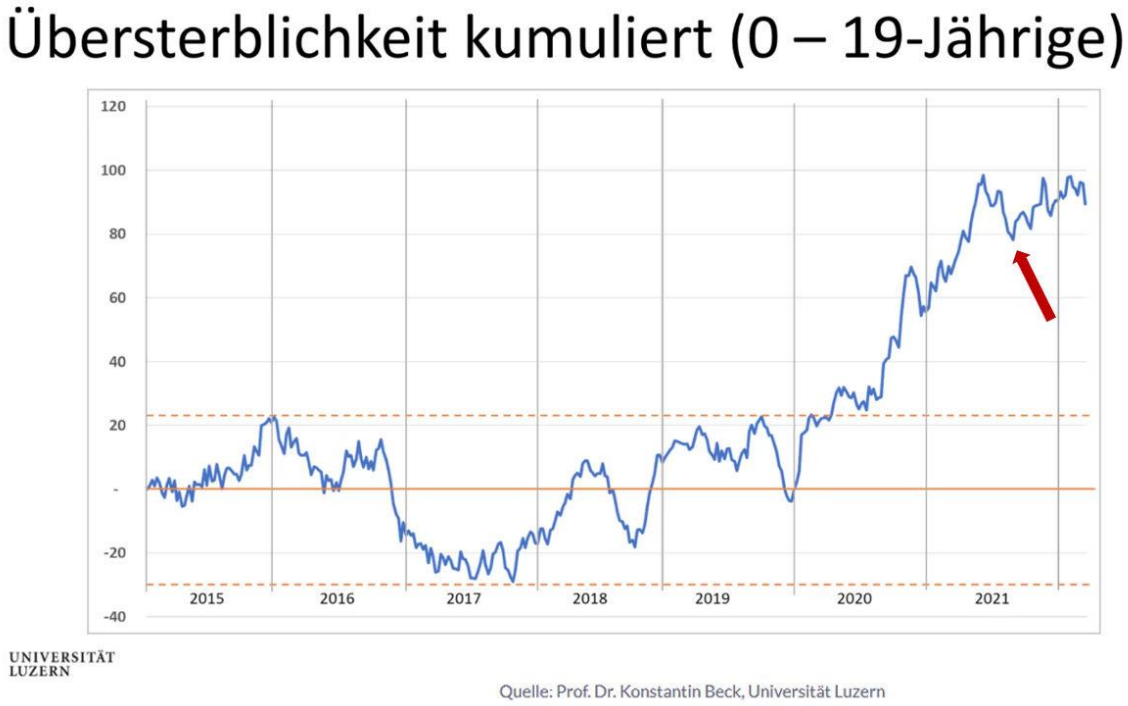
2.5.2.2 From the start of the "vaccination campaign": excess mortality in Switzerland

611 A study published in June 2022 by Constantin Beck, Professor of Insurance Economics at the University of Lucerne, who had analysed the federal government's mortality data by age category, shows a sustained sharp increase in deaths for the 40-64 age group from April 2021 :[417]

417 Nebelspalter, "Unaccountable deaths among younger people", 21.06.2022, https://www.nebelspalter.ch/corona-nicht-erklaerbare-todesfaelle-bei-juengeren?code=-2028810339.

612 Also at 20-39-year-olds

613 and for 0-19 year olds



614 a similar trend was observed.

615 The increases in the mortality curves correlate with the expansion of the "vaccination": After the approval of the COVID "vaccinations" from December 2020, the vaccination campaign first started at the beginning of 2021 for older persons and "risk patients" with pre-existing diseases, and from May 2021 the "vaccination" was then also available for younger healthy persons from 16 years of age.[418] For children and adolescents aged 12 and older, the COVID "vaccination" was approved in June 2021.[419]

616 The less pronounced increase among 0-19 year-olds could be explained by the lower vaccination coverage rate in this age group .

617 Although these data do not yet prove causality, they do show a worryingly impressive correlation between the start of vaccination coverage in the respective age group and rising excess mortality, which urgently needs to be clarified.

2.5.1. Interim conclusion

618 Both international and Swiss figures unequivocally show that COVID illnesses and associated hospitalisations and deaths mainly affect the multiply vaccinated.

418 Canton Fribourg, "COVID-19 vaccination available from 8 May for all persons aged 16 and over", 05.05.2021, https://www.fr.ch/de/covid19/news/covid-19-impfung-ab-8-mai-fuer-alle-personen-ab-16-jahren-moeglich.

419 For the individual authorisation decisions, see N 6 ff.

619 If the "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. We will continue to monitor this development and call on Swissmedic to do the same.

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

620 Neither in the registration studies, nor according to the available international and national data and observations, have the "vaccinations" shown any relevant efficacy against "COVID disease", "COVID hospitalisation" or deaths associated with "COVID infection".

621 On the contrary, the "vaccinations" are even associated with negative efficacy. Although Omicron, at least for the unvaccinated, has been shown to be less dangerous than previously circulating variants and as a typical influenza disease, COVID hospitalisations and deaths due to COVID continued to rise, especially driven by the (multiply) vaccinated in 2022. From the data available to date, it must be concluded that the COVID "vaccines" do not strengthen the immune system, but on the contrary make vaccinated persons more susceptible to illness and hospitalisation in connection with a "COVID illness". This applies to both the basic immunisation and the booster "vaccinations".

622 **The data suggest that "vaccination" has thus lost all justification, as it does not protect vaccinated people, but on the contrary makes them more susceptible to the virus.**

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

623 Despite the proven failure of the COVID "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[420] , as in the currently marketed "vaccines", but even "self-replicating mRNA" (sa mRNA) will be used. These have the ability to replicate independently in the human body. [421]Should a waiver of pharmacokinetic data also be envisaged for these "vaccines", this would be highly worrying, since predictions on the quantity and duration of mRNA production in the human body are hardly possible with self-replicating mRNA.

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420 Swissmedicinfo, FN 48.

421 BLAKNEY, "An Update on Self-Amplifying mRNA Vaccine Development," Jan. 28, 2021, https://www.mdpi.com/2076-393X/9/2/97.

624 Vaccines with sa 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. [422]

625 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:

626 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. [423]

D. DANGER SITUATION "WHO PANDEMIC

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

627 On 10 January 2020, a research group led by Prof. ZHANG in Shanghai published a sequence sequence on a website accessible to virologists, which is supposed to represent the genetic material of the virus later named SARS-CoV-2. This sequence was published in the scientific journal Nature on 3 February 2020[424] and became decisive for all further research.

628 In their publication, WU / ZHANG et al. describe that no virus was isolated, nor were any cell cultures, but very short pieces of RNA were sequenced from the lungfluid of a single patient as follows:

629 The very short pieces were aligned to two given gene sequences of known corona viruses using the so-called "de novo assembly" method - a method for "optimally aligning sequences to a reference genome"[425] . WU / ZHANG et al. used a coronavirus associated with humans and one associated with bats as templates. This fact alone entails the considerable risk that the numerous gene sequences will ultimately be assembled into what is (supposedly) already known - in this case a coronavirus. In this "alignment", a long gene se-

422 BLAKNEY, FN 421.

423 POLLOCK, "Safety and immunogenicity of a self-amplifying RNA vaccine against COVID-19: COVAC1, a phase I, dose-ranging trial", 13/01/2022, *https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(21)00543-5/fulltext*.

424 WU et al, "A new coronavirus associated with human respiratory disease in China", 03.02.2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7094943/.

425 Bioinformatics Wiki, "Sequence alignment", 26.09.2021, http://wiki.bioinfo.nat.tu-bs.de/3_Alignments.

quence is **calculated on the** computer using certain software algorithms from a large number of unrelated short gene sequences **and assembled on the basis of "overlaps".**

630 In addition, WU / ZHANG et al. **generated two completely different final results** by **using two assemblers**. They decided to use the longer contiguous sequence because "it covers almost the entire viral genome" of the two reference genomes. This longer sequence was found with the programme "Megahit" and amounted to 30,474 nucleotides, while the other programme "Trinity" generated a longest contig of 11,760 nucleotides from the same data set. Conversely, Trinity produced significantly more contiguous pieces of sequence, namely 1,329,960 pieces, than Megahit (384,096). **The "discovery" - rather: the calculation - of a new virus genome that is as complete as possible thus depends decisively on the choice of the "right" assembler.**[426] Among other things, it cannot be ruled out that the "discovery" of SARS-CoV-2 mutations (via sequencing) is nothing more than the results of different assemblers or simply of laboratory errors.[427]

631 As a result, no precisely determined viral gene sequence was found. Rather, a variety of human and microbial RNA from the lungs of a single person was "aligned" with two known DNA corona viruses and **computationally** assembled into an entire genome.

632 However, whether strict proof - the detection of an isolate - of SARS-CoV-2 has been provided to date is not to be conclusively clarified at this point. 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".

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

633 Two key parameters can be used to assess the risk of an infectious disease: The **case fatality** rate (***CFR***) and the **infection** fatality rate (***IFR***). The ***CFR* is less meaningful** and is calculated as the **number of deaths per known case**, while the ***IFR*** calculates the total number **of deaths per infected person**.

634 The ***CFR*** is **many times higher than *IFR,*** since in normal cases the vast majority of infection cases remain undetected. As a ratio between detected and actual infections, the *WHO* recommends a factor of 20, the American CDC a factor of 10.[428] Conversely, this means that the ***CFR*** must be **divided by 10 or 20 to calculate the *IFR.***

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426 ISLAM et al, "Choice of assemblers has a critical impact on de novo assembly of SARS-CoV-2 genome and characterizing variants", 05.04.2021, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8083570/.*

427 DE MAIO et al, "Issues with SARS-CoV-2 sequencing data", 14.05.2020, https://virological.org/t/issues-with-sars-cov-2-sequencing-data/473.

428 AP News, "WHO: 10% of world's people may have been infected with virus," 05.10.2020, https://apnews.com/article/virus-outbreak-united-nations-health-ap-top-news-international-

635 At the beginning of the Corona crisis, estimates of the lethality of SARS-CoV-2 were massively exaggerated: For example, as late as June/July 2020, a mortality rate (Infection Fatality Rate; IFR) of 8% (group aged 70 to 79) and even 14.8% (group aged over 80) was calculated for China.[429] However, these initial figures did not last long: In Switzerland, with regard to the total population, an IFR of 0.64% (Geneva)[430] and 0.6% (Zurich)[431] was soon assumed, whereby it was already apparent at that time that the population aged 65 and over in nursing homes was primarily affected: Of a total of 286 deceased persons, 268 were over 65 years of age, of which 134 lived in nursing homes. [432]

636 In an assessment of 4 August 2020, the WHO referred to these previous studies (including the above-mentioned Swiss studies) and assumed a lethality rate of 0.5 -1% for the total global population.[433] In its "COVID-19 Pandemic Planning Scenarios" of July 2020, the CDC also assumed a mortality rate of 0.5-0.65% for the total population.[434]

637 **Anthony Fauci,** in an editorial in the *New England Journal of Medicine* (*NEJM*) of 26 March 2020 at the beginning of the **pandemic, had assumed** a ***CFR of* only 1-2%** (corresponding to an *IFR of* 0.1-0.2%) and concluded that the figures suggested that the clinical consequences of COVID-19 would ultimately be comparable to those of severe seasonal ***influenza***: "***This suggests that the overall clinical consequences of COVID-19 may ultimately be more akin to those of a severe seasonal influenza ... or a pandemic influenza.*** " [435]

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news-54a3a5869c9ae4ee623497691e796083; CDC, "Dr. Robert R. Redfield Statement on SARS-CoV-2 infections," 22.07.2020, https://www.cdc.gov/media/releases/2020/s0722-SARS-CoV-2-infections.html.

429 AXFORS/IOANNIDIS, "Infection fatality rate of COVID-19 in community-dwelling populations with emphasis on the elderly: An overview", preprint of 13.07.2021, p. 13, https://www.medrxiv.org/content/10.1101/2021.07.08.21260210v1.full.pdf.

430 PEREZ-SAEZ et al, "Serology-informed estimates of SARS-CoV-2 infection fatality risk in Geneva, Switzerland", 14.07.2020, *https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30584-3/fulltext*.

431 EMMENEGGER et al, "Early peak and rapid decline of SARS-CoV-2 seroprevalence in a Swiss metropolitan region", preprint of 07.08.2020, N 224 f., https://www.medrxiv.org/content/10.1101/2020.05.31.20118554v4.full.pdf.

432 PEREZ-SAEZ et al, FN 430.

433 WHO, "Estimating mortality from COVID-19", 04.08.2020, https://www.who.int/news-room/commentaries/detail/estimating-mortality-from-covid-19.

434 CDC, "COVID-19 Pandemic Planning Scenarios," update as of 10.07.2020, https://archive.vn/w2xC7#selection-1507.0-1507.36.

435 FAUCI et al, "Covid-19 - Navigating the Uncharted", 26.03.2020, https://www.nejm.org/doi/full/10.1056/nejme2002387.

III. State of knowledge at first adult approvals (end 2020)

638 Shortly afterwards, these initial figures were (once again) massively relativised with regard to the total population: In a study from October 2020, a global lethality of just 0.15% to 0.20% was determined; for people under 70 years of age, only 0.03 to 0.04%. [436]

639 In addition, as of November 2020, studies were available according to which SARS-CoV-2 **was** already **endemic in** Italy in September 2019 and in France in **November 2019, without any clustered disease activity being observed clinically.**[437] If this applies to Italy and France, SARS-CoV-2 should therefore already have "raged" throughout Europe (but in all probability in neighbouring Switzerland) by the end of 2019 - without this having led to any measures, activism and temporary approvals of medicines.

640 According to the WHO, the mortality rate for seasonal influenza (flu) is usually less than 0.1%[438] - even though the WHO later removed this figure from its current website for unknown reasons.[439] In the USA, the death rate during the (last moderate) flu wave from 2017 to 2018 was estimated by the CDC at 0.1355%.[440] It was therefore already known at the time of the first temporary approvals for adults that the mortality of COVID-19 was approximately in the range of a (moderate) seasonal flu. **There was therefore no question of a life-threatening or disabling disease for the entire adult population at the time of the first temporary approval.** If at all, the "vaccinations" would only have been considered for the somewhat more endangered persons over 70 years of age.

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436 IOANNIDIS, "Global perspective of COVID-19 epidemiology for a full-cycle pandemic", 06.10.2020, https://onlinelibrary.wiley.com/doi/epdf/10.1111/eci.13423.

437 APOLONE et al. , "Unexpected detection of SARS-CoV-2 antibodies in the prepandemic period in Italy", 11.11.2020, https://journals.sagepub.com/doi/full/10.1177/0300891620974755; CARRAT et al. , "Evidence of early circulation of SARS-CoV-2 in France: findings from the population-based 'CONSTANCES' cohort", 06.02.2021, https://link.springer.com/article/10.1007/s10654-020-00716-2.

438 "For seasonal influenza, mortality is usually well below 0.1%. ", Internet Archive, "Coronavirus disease (COVID-19): Similarities and differences with influenza, 17.03.2020, https://web.archive.org/web/20201022054325/https:/www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/coronavirus-disease-covid-19-similarities-and-differences-with-influenza.

439 WHO, Coronavirus disease (COVID-19): Similarities and differences with influenza, 30.09.2021, https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/coronavirus-disease-covid-19-similarities-and-differences-with-influenza.

440 Specifically, an estimated 61,000 deaths out of an estimated 45 million people with the disease: CDC, "Past Seasons Estimated Influenza Disease Burden", 01.10.2020, https://www.cdc.gov/flu/about/burden/past-seasons.html.

641 Incidentally, such a low mortality rate would not be able to fulfil the old WHO definition of a "pandemic" at all, since an "enormous number of dead and sick" was required for this[441] . This requirement was deleted without replacement in May 2009 for no apparent reason.[442]

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

1. No (significant) overall excess mortality

642 By the end of December 2020, it was already evident from the official figures of the Federal Statistical Office that there was no relevant excess mortality in 2020 compared to previous years in the area of the total population.[443]

643 However, older people were definitely affected. The FSO stated about the excess mortality of the over-65s until the end of 2021:[444]

> "In the period following the second wave of Covid-19-related deaths, from week 7/2021 (since 15/2/2021) to week 13/2021, a number of deaths was reported that is usually only seen in summer, the period with the lowest seasonal mortality. Compared to the expected number, about 996 fewer people died during these seven weeks. This is likely related to the fact that of the approximately 10 311 people who died in the first and second waves of Covid-19-related excess mortality, **some were nearing the end of their lives even without Covid-19 and had probably lost only a few weeks or months of their lives due to Covid-19.** It will not be possible to draw up an overall balance of deaths as a result of Covid-19 until the epidemic in Switzerland has been concluded."

644 Interestingly, this very reference "disappeared" from the website in 2022.[445] There is no evidence that the original assessment was in any way wrong.

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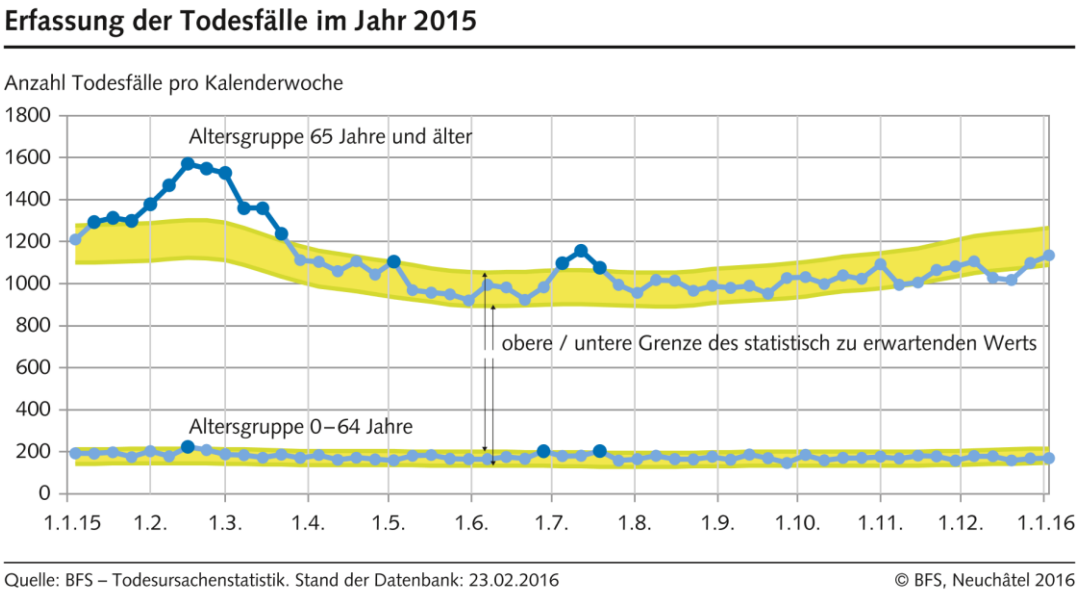
441 "An influenza pandemic occurs when a new influenza virus appears against which the human population has no immunity, resulting in epidemics worldwide with enormous numbers of deaths and illness": Internet archive, "Epidemic and Pandemic Alert and Response (EPR) ", 29.04.2009, https://web.archive.org/web/20090429090600/http:/www.who.int/csr/disease/influenza/pandemic/en/index.html.

442 "An influenza pandemic may occur when a new influenza virus appears against which the human population has no immunity": Internet archive, "Epidemic and Pandemic Alert and Response (EPR)", 09.05.2009, https://web.archive.org/web/20090509013608/http:/www.who.int/csr/disease/influenza/pandemic/en/index.html.

443 Aletheia, "Covid-19 - Infection situation, burden on hospitals in Switzerland week 50", 24.12.2020, https://aletheia-scimed.ch/IMG/pdf/eingabe_br_schweiz_24-12-2020.pdf.

444 Internet archive, "Mortality, Causes of Death" (emphasis added), 13.12.2021, https://web.archive.org/web/20211213102752/https:/www.bfs.admin.ch/bfs/de/home/statistiken/gesundheit/gesundheitszustand/sterblichkeit-todesursachen.html.

645 A comparison with previous years, such as 2015, reveals that there are always seasonal periods with excess mortality - especially among the over-65s:[446]



646 Overall, with regard to excess mortality, there was nothing in 2020 that would have in any way "broken the mould" of previous years: rather, 2020 was in the middle of the field in comparison to the ten previous years in terms of mortality ("Rank" 5 of 12, Supplement **20,** p. 11).

BO: Supplement **20:** Strong Facts: Switzerland, as of 13.04.2022

647 If SARS-CoV-2 had been the feared (century) "pandemic", the data on overall mortality would definitely have been many times worse, dwarfing all previous years (and decades). This is clearly not the case.

2. Still lower IFR regarding SARS-CoV-2

648 Only a few months after the first approvals - as early as March 2021 - corresponding study data were available, according to which the best estimate of the global infection mortality rate (IFR) for the population as a whole is 0.15% and less than 0.05% for those under 70

445 Swiss Federal Statistical Office, "Mortality, causes of death", 23.06.2022, https://www.bfs.admin.ch/bfs/de/home/statistiken/gesundheit/gesundheitszustand/sterblichkeit-todesursachen.html.

446 Swiss Federal Statistical Office, "Weekly Deaths 2015", 23.02.2016, https://www.bfs.admin.ch/bfs/de/home/statistiken/gesundheit/gesundheitszustand/sterblichkeit-todesursachen.assetdetail.317264.html.

years of age.[447] The results from October 2020 were thus not only confirmed, but even a slightly lower lethality was calculated.

649 The CDC also assumed massively lower values in more recent scenarios from March 2021:[448]

Parameter	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5: Current Best Estimate
R_0*	2.0		4.0		2.5
Infection fatality ratio (Estimated number of deaths per 1,000,000 infections)†	0–17 years old: 6 18–49 years old: 150 50–64 years old: 1,800 65+ years old: 26,000		0–17 years old: 80 18–49 years old: 1,700 50–64 years old: 20,000 65+ years old: 270,000		0–17 years old: 20 18–49 years old: 500 50–64 years old: 6,000 65+ years old: 90,000

650 If the above figures are converted to a lethality rate in %, it becomes apparent that the CDC also saw the elderly population as being primarily threatened by SARS-CoV-2:

Age	Scenario 1/2	Scenario 3/4	Scenario 5
00-17	0.0006%	0.008%	0.002%
18-49	0.015%	0.17%	0.05%
50-64	0.18%	2%	0.6%
65+	2.6%	27%	9%

651 In all scenarios, a possible **lethality** for (children and) **adolescents was** therefore already **calculated** at that time, **which tends towards zero.**

652 On the one hand, there was **no legal basis for the extension of the indication to adolescents** from 12 years of age in June 2021 due to the lack of a corresponding threat - on the other hand, the temporary authorisations as a whole should have been suspended immediately and referred to the ordinary procedure at the latest from this point in time.

3. No overloading of hospitals

653 Also, based on the general Swiss bed occupancy figures[449] and the specific figures on the utilisation of Swiss intensive care beds[450] , it was already readily apparent in spring 2021

447 IOANNIDIS, "Reconciling estimates of global spread and infection fatality rates of COVID-19: An overview of systematic evaluations", 14.03.2021, https://onlinelibrary.wiley.com/doi/epdf/10.1111/eci.13554; OKE et al., "Global Covid-19 Case Fatality Rates", 17.03.2020, https://www.cebm.net/covid-19/global-covid-19-case-fatality-rates/.

448 CDC, "COVID-19 Pandemic Planning Scenarios," update, 19 Mar 2021, https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html.

449 FOPH, "Total hospital capacity", 23.06.2022, https://www.covid19.admin.ch/de/hosp-capacity/total.

that there had never been any dangerous overcrowding. Despite repeatedly forecast horror scenarios[451] , even at the peak of November 2020, triage had never taken place in the hospitals and intensive care beds were available at all times.[452] And when Switzerland was then sent into the second lockdown on 18 December 2020 because of allegedly "imminent overloading of the healthcare system", the bed utilisation rate overall and for intensive care beds was only around 75%.[453]

3.1. Chronic overload in winter; nevertheless too low capacity utilisation

654 It should be noted that Switzerland has 950 to 1000 certified intensive care beds at normal times, with a typical annual average occupancy rate of around 75 per cent.[454] The occupancy rate has always been subject to seasonal fluctuations with a peak in the winter months, as was also observed in 2020/2021.[455] In principle, intensive care units regularly reach their capacity limits. As early as 2007, the heads of the adult intensive care units of the CHUV (Lausanne) and HUG (Geneva) reminded us of the major difference between intensive care units and other clinical departments:

> "The first ones have to manage multiple flows with almost all hospital services, which is not the case for the latter, who only have one flow line with

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450 Health Geography and Policy Group, "Near-real time beds/ventilators occupancy in intensive care units ICU in Switzerland during the COVID-10 pandemic", 23.06.2022, www.icumonitoring.ch.

451 SRF, "Capacities in hospitals will not be enough", 30.10.2020, https://www.srf.ch/news/schweiz/bund-und-kantone-informieren-taskforce-chef-kapazitaeten-in-spitaelern-werden-nicht-reichen; NZZ, "Fürchtet euch! Why the constant prophecies of doom regarding intensive care beds are counterproductive" , 19.11.2020, https://www.nzz.ch/schweiz/intensivbetten-staendige-warnungen-sind-kontraproduktiv-ld.1587836.

452 NZZ, "Hospitals are the eye of the needle in the pandemic. Were they ever overloaded? And why have they cut places? " ("despite the bottlenecks, no hospital has introduced explicit patient triage"), 27.07.2021, https://www.nzz.ch/schweiz/spitaeler-in-der-coronakrise-waren-sie-je-ueberlastet-ld.1636298; cf. also SRF, "Triage decision should apply to the whole of Switzerland" ("there are still enough places available"; "according to Pargger, just under half of the 900 or so certified intensive care places are currently occupied by Corona patients, but in fact around 1200 places are ready for use. ") , 06.11.2020, https://www.srf.ch/news/schweiz/coronavirus-in-der-schweiz-triage-entscheid-soll-fuer-die-ganze-schweiz-gelten.

453 Aletheia, FN 443; Juristen Komitee, "Declaration by Swiss lawyers: 2G certificate obligation is unconstitutional", 24.12.2021, *https://juristen-komitee.ch/wp-content/uploads/2021/12/2021-12-24_Deklaration-2G-DE.pdf; Ostschweiz, "Fröhliche Zahlenknobelei oder Reise nach Jerusalem?", 04.05.2021,* https://www.dieostschweiz.ch/artikel/froehliche-zahlenknobelei-oder-reise-nach-jerusalem-a3g33v7.

454 Medinside, "Statistics on intensive care beds cause confusion", 30.07.2020, *https://www.medinside.ch/de/post/statistiken-zu-intensivbetten-sorgen-fuer-verwirrung.*

455 Health Geography and Policy Group, "Near-real time beds/ventilators occupancy in intensive care units ICU in Switzerland during the COVID-10 pandemic", 23.06.2022, "National trends" chart, www.icumonitoring.ch.

> intensive care. This difficulty is exacerbated by the very limited number of intensive care units, compared to the intermediaire units and patient units: in a modern hospital, the proportion of intensive care units is between 5-10% of the total number of units. In large hospitals, with an important flow of urgencies, this leads the intensive care unit to function for most of the time in a continuous flow. Ce constat montre que l'unité de soins intensifs constitue un véritable carrefour dans l'hôpital, susceptible d'être facilement saturé et parfois même de ne plus être capable d'assurer sa mission."[456]

655 This just-in-time operation and its consequences affect university hospitals in particular: for example, the CHUV (Lausanne) stated in its 2017 annual report that occupancy "in intensive care is close to 90% and the optimum for acute beds is 85%". In previous years, the occupancy rate of the intensive care units ("soins intensifs adultes") was even slightly higher (2015: 92.4%; 2016: 91.6%).[457] In contrast, the occupancy rate of the intensive care units ("soins intensifs adultes") at the CHUV (Lausanne) was 87.8% in 2019 and just 81.1% in 2020, although the annual report states that the intensive care units were strengthened ("renforcés") in 2020 in view of Sars-Cov-2.[458] **A utilisation rate of around 90% in intensive care units at university hospitals was thus considered quite normal in the past.**

656 As recently as 2015, it was even criticised that a bed occupancy rate of "only" 80% was a problem: the hospitals were "too big" and thus unprofitable.[459] A free quota of approx. 20% therefore indicates actual normal operation.[460] And according to a comprehensive evaluation by PWC of 20 October 2021 on the profitability of Swiss hospitals, Swiss hospitals

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456 Revmed, "L'unité de soins intensifs, carrefour dans l'hôpital: développer l'interdisciplinarité et une vision de système", 12.12.2007, *https://www.revmed.ch/revue-medicale-suisse/2007/revue-medicale-suisse-137/l-unite-de-soins-intensifs-carrefour-dans-l-hopital-developper-l-interdisciplinarite-et-une-vision-de-systeme.*

457 CHUV, "Rapport d'activité 2017", https://rapportsannuels.chuv.ch/2017/, 28.06.2022, p. 7 and p. 12.

458 CHUV, "Rapport d'activité 2020", https://rapportsannuels.chuv.ch/2020/, 28.06.2022, p. 7 and p. 14.

459 NZZ, "Schweizer Spitäler nur zu 80 Prozent ausgelastet", 05.04.2015, https://www.nzz.ch/nzzas/nzz-am-sonntag/eiskalte-betten-schweizer-spitaeler-nur-zu-80-prozent-ausgelastet-1.18516688.

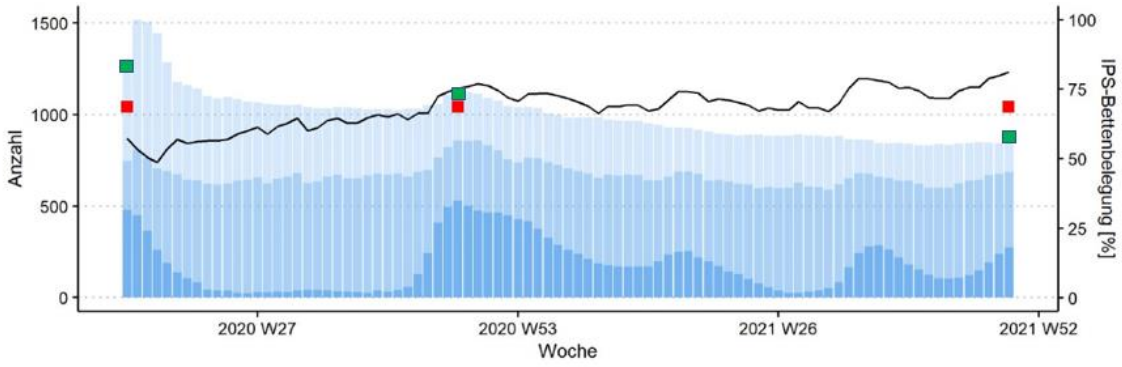
460 Nau, "'No crisis': Hospital CEO criticises 'fear reporting'", 16.09.2021, https://www.nau.ch/news/schweiz/keine-krise-spital-ceo-kritisiert-angst-berichterstattung-66003628.

suffered significant losses in turnover and earnings even in the pandemic year 2020,[461] which does not point to an overload of hospitals and a particular threat from Sars-CoV-2.

3.2. Politically intended reduction of beds

657 In addition, from 1982 to 2019, hospital capacities in Switzerland were continuously reduced - by as much as 63% in terms of beds.[462] Since COVID-19 first appeared in Switzerland (with the exception of a brief maximisation phase in March/April 2020), capacities for intensive care have been continuously reduced by around 15 to 20% (see chart below).[463]

Abbildung 12. Zeitlicher Verlauf der Auslastung der IPS-Betten, COVID-19- und nicht-COVID-19-Patientinnen und -Patienten für die Schweiz und Liechtenstein[13].



01.04.2020

	Gemeldet
Covid-19	501
Non-Covid-19	248
Freie Betten	557
Total	1306

18.11.2020

	15-Tagesschnitt	Gemeldet
Covid-19	516,33	524
Non-Covid-19	332,53	320
Freie Betten	278,53	283
Total	1127,4	1127

16.12.2021

	Gemeldet
Covid-19	294
Non-Covid-19	416
Freie Betten	149
Total	859

461 PWC, "Schweizer Spitäler: So gesund waren die Finanzen 2020", 20.10.2021, summary p. 38 ("Leistungserbringer ertragsseitig unter Druck"), https://www.pwc.ch/de/publications/2021/spitalstudie-2021.pdf.

462 H+, "Hospitals, beds and population - number of hospitals and beds in relation to population, as of 1947", as of 2019, *https://www.hplus.ch/de/zahlen-statistiken/h-spital-und-klinik-monitor/gesamtbranche/strukturen/spitaeler/spitaeler-betten-und-bevoelkerung*.

463 FOPH, "Situation report on the epidemiological situation in Switzerland and the Principality of Liechtenstein - Week 49", 15.12.2021, p. 14 , archived at: *https:*//www.bag.admin.ch/bag/de/home/krankheiten/ausbrueche-epidemien-pandemien/aktuelle-ausbrueche-epidemien/novel-cov/situation-schweiz-und-international.html#2030838475, "Previous daily and weekly reports", "2021_Q4", "211215_KW49_EN"; FOPH, "Information on the current situation, intensive care units (IS)", 29.06.2022, *https://www.covid19.admin.ch/de/hosp-capacity/icu?time=total*.

658 This development cannot be reconciled in any way with the alleged epidemiological threat of an unprecedented epidemic. This reduction in the number of beds is in stark contradiction to the constitutional duty of the Confederation and the cantons to jointly ensure, within the scope of their competences, "sufficient, high-quality basic medical care accessible to all" (Art. 117a of the Federal Constitution). Yet it is precisely the Federal Council that opposes a solution proposed by parliament to expand capacities with completely incomprehensible justification (allegedly "lack of data")[464] - only to conjure up the panic scenario of hospital overload again at the same time.

3.3. Manipulated case numbers in the hospitals

659 In addition, there is a massive manipulation of the alleged Sars-CoV-2 cases in the hospitals. This circumstance was already criticised at the beginning of 2021, but was officially kept under wraps and was only taken up by the mass media in January 2022. Corresponding comments are therefore made at the end (N 679).

3.4. Interim conclusion

660 Also with regard to the utilisation of the hospitals, no particular threat from SARS-CoV-2 could be determined as early as spring 2021.

4. Irrelevant criterion of "high case numbers" (PCR test)

661 The drivers of the "pandemic" were always the "case numbers" generated by means of PCR tests. However, the PCR test result is completely worthless on its own, even according to the WHO, as it only serves as an *aid to* diagnosis in connection with clinical observations (= symptoms), which was already stated at the beginning of 2021:

> "Most PCR assays are indicated as an aid for diagnosis, therefore, health care providers **must** consider any result in combination with timing of sampling, specimen type, assay specifics, clinical observations, patient history, confirmed status of any contacts, and epidemiological information." [465]

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464 20minuten, "Federal Council does not want to help hospitals - 'because of missing data'" , 13.12.2021, https://www.20min.ch/story/bundesrat-will-spitaelern-nicht-helfen-wegen-fehlender-daten-473960531628.

465 Internet Archive, WHO, Information Notice for IVD Users, 14.12.2020, https://web.archive.org/web/20201214195523/https://www.who.int/news/item/14-12-2020-who-information-notice-for-ivd-users; WHO, "WHO Information Notice for Users 2020/05 Nucleic acid testing (NAT) technologies that use polymerase chain reaction (PCR) for detection of *SARS-CoV-2", 20.01.2021, https://www.who.int/news/item/20-01-2021-who-information-notice-for-ivd-users-2020-05.*

662 Nevertheless, positive PCR test results in persons without symptoms have been and are still being recorded in Switzerland (and worldwide) as "COVID cases", which is definitely not in line with the WHO recommendation.[466] The Federal Council has long been aware of this problem. In its statement of 26 August 2020 in response to the motion of National Councillor Verena Herzog of 19 June 2020 on the question of why large-scale testing of the population was not carried out, the Federal Council at that time - correctly - still positioned itself as follows:[467]

> "[...] In the view of the Federal Council, systematic large-scale testing as well as testing of representative samples from the mainly healthy and symptom-free population is not a suitable means of obtaining precise information on the epidemiological situation. **Virus detection in an asymptomatic person is difficult to interpret, as it could be a remnant of a cured infection. In addition, with a sample consisting almost exclusively of healthy persons, the probability of false test results is very high**. Moreover, taking the sample is an invasive procedure that cannot be easily prescribed by the state [...]".

663 The suitability of the PCR test for diagnosing an illness due to infection with SARS-CoV-2 was also disputed as early as 2020 by the Robert Koch Institute[468] and in studies[469] . PCR test results alone do not allow any reliable conclusions to be drawn about an actual threat to public health: results can be positive even if there is no symptomatic disease at all.[470]

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466 FOPH, "New Coronavirus (Covid-19) Suspicion, Sampling and Reporting Criteria", 02.05.2022, https://www.bag.admin.ch/dam/bag/de/dokumente/mt/msys/covid-19-verdachts-meldekriterien.pdf.download.pdf/Verdachts_Beprobungs_und_Meldekriterien.pdf.

467 Parliament, "Reply Federal Council to Motion Herzog (20.3859)", 19.06.2020, *https://www.parlament.ch/de/ratsbetrieb/suche-curia-vista/geschaeft?AffairId=20203859.*

468 "However, the detection of the SARS-CoV-2 genome does not constitute direct evidence of a patient's infectiousness. ", RKI, "Epidemiological Bulletin 39/2020", 24.09.2020, p. 8, https://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2020/Ausgaben/39_20.html.

469 JEFFERSON et al , "Viral Cultures for Coronavirus Disease 2019 Infectivity Assessment: A Systematic Review", 03 Dec 2020, https://doi.org/10.1093/cid/ciaa1764.

470 BORGER et al, "Review report Corman-Drosten et al. Eurosurveillance 2020 - External peer review of the RTPCR test to detect SARS-CoV-2 reveals 10 major scientific flaws at the molecular and methodological level: consequences for false positive results", 27.11.2020, https://cormandrostenreview.com/report/; BORGER et al., "Addendum: Peer reviewed literature and preprints covering wet-lab experiments, in silico analysis of the Corman Drosten protocol-design, meta-data analysis on EuroSurveillance.org and further discussion", 11.01.2021, https://cormandrostenreview.com/addendum/; BULLARD et al., "Predicting infectious SARS-CoV-2 from diagnostic samples", 22.05.2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7314198/; BYINGTON, "A positive PCR test may not mean positively ill", 05.08.2015, https://healthcare.utah.edu/thescope/shows.php?shows=0_8pwxdv0o; JAAFAR et al, "Predicting infectious SARS-CoV-2 from diagnostic samples (Correlation between 3790 qPCR positive samples and positive cell cultures including 1941 SARS-CoV-2 isolates)", 28.09.2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7543373/; MIN-CHUL et al., "Duration of Cul-

The alleged relevance of asymptomatic transmission has long been refuted.[471] Accordingly, even the Federal Supreme Court stated in a decision of November 2021:[472]

> **"Meanwhile, it is not at all controversial and, incidentally, generally accepted that a positive PCR test is not a diagnosis of disease and is of little significance on its own [...]."**

664 Laboratory values should therefore only be used as a supplement to a clinical diagnosis based on symptoms and should never be considered in isolation. The high number of cases by no means originates exclusively from sick persons or persons suspected of being infected. Rather, they were and are purposefully fabricated by excessive testing of symptomless, healthy persons.

665 Even with regard to the "number of cases", no particular threat from SARS-CoV-2 could be identified by spring 2021 at the latest.

5. Conclusion

666 Neither at the time of the first temporary approval in December 2020, let alone at the time of the indication extension to adolescents aged 12 years and older, was there any life-threatening or disabling disease that would seriously threaten the entire target population of COVID "vaccinations" according to the data available at the time.

667 On the contrary, the alpha/beta variant of SARS-CoV-2, with an infection fatality rate (IFR) of around 0.15%, was just as dangerous as a normal (moderate) flu, which neither led to a significant excess mortality nor to an overload of hospitals. This is all the more true for adolescents, whose IFR was in the range of 0.002% and thus close to zero.

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turable SARS-CoV-2 in Hospitalized Patients with Covid-19", 18.02.2021, https://pubmed.ncbi.nlm.nih.gov/33503337/; VERNAZZA, "Infectivity and PCR Positivity - Not the Same", 28.01.2021, https://infekt.ch/2021/01/infektiositaet-und-pcr-positivitaet-nicht-das-gleiche/.

471 CAO et al, "Post-lockdown SARS-CoV-2 nucleic acid screening in nearly ten million residents of Wuhan, China", 20.11.2020, https://www.nature.com/articles/s41467-020-19802-w; Ärzteblatt, "New Wuhan study: asymptomatic do not transmit Corona" , 01.12.2020, https://www.aerzteblatt.de/studieren/forum/138997; WHO, "Transmission of SARS-CoV-2: implications for infection prevention precautions", 09.07.2020, https://www.who.int/news-room/commentaries/detail/transmission-of-sars-cov-2-implications-for-infection-prevention-precautions.

472 Judgement 2C_228/2021 of the Federal Supreme Court of 23 November 2021, E. 5.2.

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

1. In general

668 On the lack of danger of SARS-CoV-2 for the general population, see in detail above N 633 ff. In the following, only additional findings are highlighted, which further support the non-existing danger from the outset:

1.1. No over-mortality but even under-mortality

669 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.[473] If SARS-CoV-2 had actually been life-threatening or if we had actually been in the midst of a deadly pandemic, there would certainly not have been any under-mortality, but a *massive* over-mortality (see also Supplement **20**, p. 11).

BO: Supplement **20:** Strong Facts: Switzerland, as of 13.04.2022

1.2. Even deeper IFR of SARS-CoV-2 ("Delta" variant)

670 From the beginning of June 2021 to December 2021, the "delta variant" of SARS-CoV-2 circulated primarily in Switzerland and worldwide.[474] The WHO classified the delta variant as a "variant *of concern*" due to an increased risk of infection.[475] The Public Health Agency also warned on 18 June 2021 that this variant was associated with higher transmissibility, a higher risk of hospitalisation and reduced effectiveness of the COVID "vaccination".[476]

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473 Juristen Komitee, "Declaration by Swiss lawyers: 2G certificate obligation is unconstitutional", 24.12.2021, *https://juristen-komitee.ch/wp-content/uploads/2021/12/2021-12-24_Deklaration-2G-DE.pdf.*

474 FOPH, "Information on the current situation, epidemiological course", 29.06.2022, https://www.covid19.admin.ch/de/epidemiologic/virus-variants?variants=VariantB11529,VariantB16172,VariantP1,VariantB1351,VariantB117,VariantC37,VariantB16171,VariantP2,VariantB1525,VariantB1526,VariantB11318; Statista, "Delta variant most common mutation in Europe", 26.08.2021, *https://de.statista.com/infografik/25185/infektionen-mit-der-delta-variante-des-coronavirus-in-europa/.*

475 WHO*, "Episode #45 - Delta variant", 05.07.2021, https://www.who.int/emergencies/diseases/novel-coronavirus-2019/media-resources/science-in-5/episode-45---delta-variant.*

476 Public Health England, "Risk assessment for SARS-CoV-2 variant: Delta (VOC-21APR-02, B.1.617.2)", 18.06.2021, *https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/994761/18_June_2021_Risk_assessment_for_SARS-CoV-2_variant_DELTA.pdf.*

671 But already on 9 July 2021, the "delta" variant proved to be obviously less dangerous: According to *Public Health England, the case fatality* rate (*CFR*) for the "delta variant" was just 0.2%, which was lower by a factor of 10 than the case fatality rate of the alpha variant. [477]

672 The *CFR is* known to be a factor of 10 to 20 higher than the *IFR* (N 634). Applying this finding to the *CFR of* 0.2% that was in the British government documents, we arrive at an **IFR of just 0.01-0.02%, which corresponds to a mild flu** and is significantly lower than the *IFR of* SARS- CoV-2 at the beginning of the pandemic. Or to put it another way: The **total population survives an infection with SARS-CoV-2 by 99.99%.**

673 However, the "vaccination" was not responsible for this lower *IFR of* the delta variant. *Public Health England* data from 23 September 2021 showed, on the contrary, that "vaccination" was associated with negative efficacy: for the period 23 August 2021 to 19 September 2021, 55% of recorded COVID cases occurred in vaccinated individuals, and 60.5% of COVID hospitalisations were caused by vaccinated individuals. Of a total of 3125 persons who died of COVID, 2284 were fully vaccinated, 111 were partially vaccinated and only 730 were unvaccinated.[478]

1.3. No overloading of hospitals

1.3.1. No overcrowding despite further reduction in beds

674 The previously (N 657 ff.) was also continued in 2021 - during the ongoing "pandemic" (see graph ibid. at the front). Despite this obviously politically intended shortage, the **intensive care units** were not even close to capacity at any time in 2021:[479]

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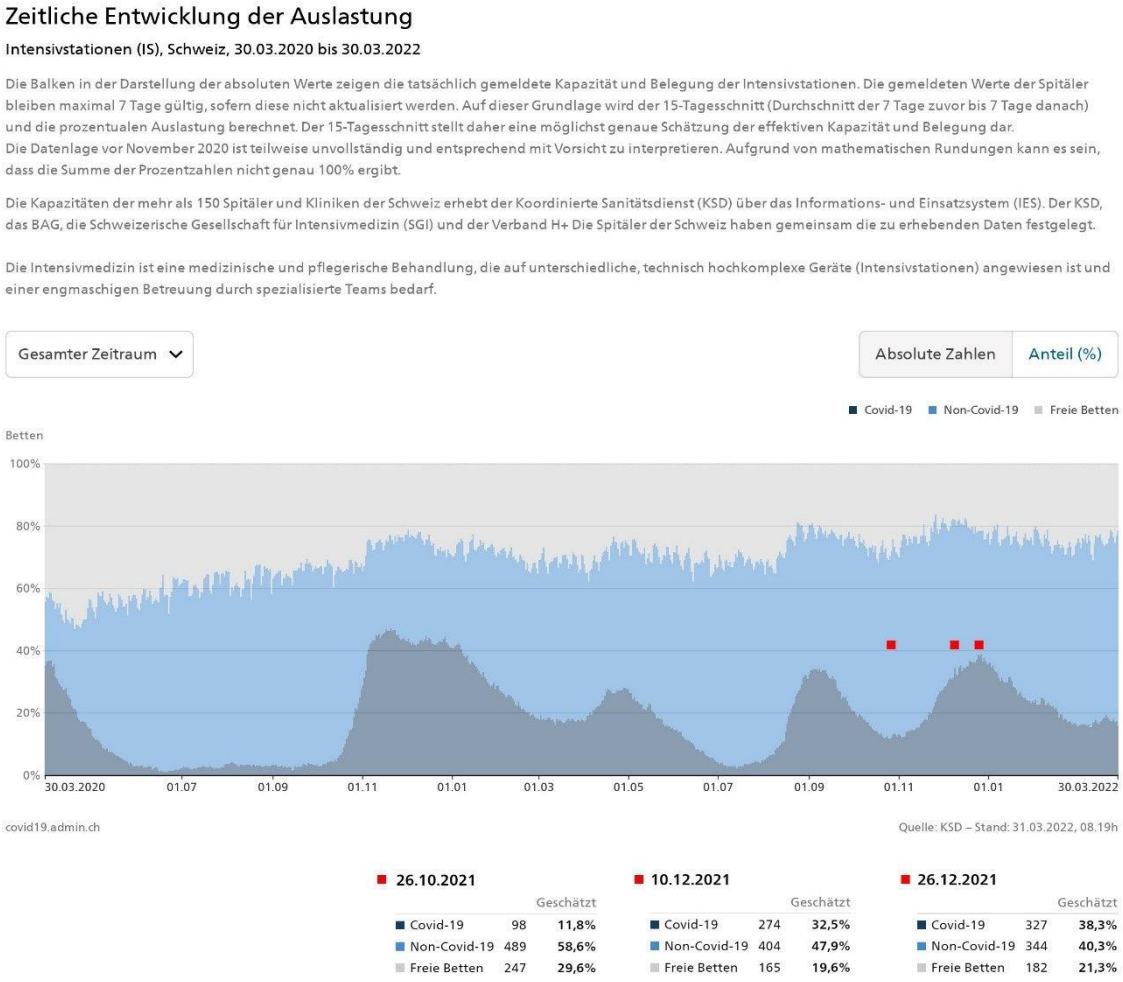
477 Public Health England, "SARS-CoV-2 variants of concern and variants under investigation in England", 09.07.2021, *https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1001358/Variants_of_Concern_VOC_Technical_Briefing_18.pdf.*

478 Public Health England, "COVID-19 vaccine surveillance report Week 38", 23.09.2021, *https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1019992/Vaccine_surveillance_report_-_week_38.pdf.*

479 FOPH, "Information on the current situation, intensive care units (IS)", Development of occupancy over time, Absolute figures / Proportion (%), 29.06.2022, https://www.covid19.admin.ch/de/hosp-capacity/icu?time=total.

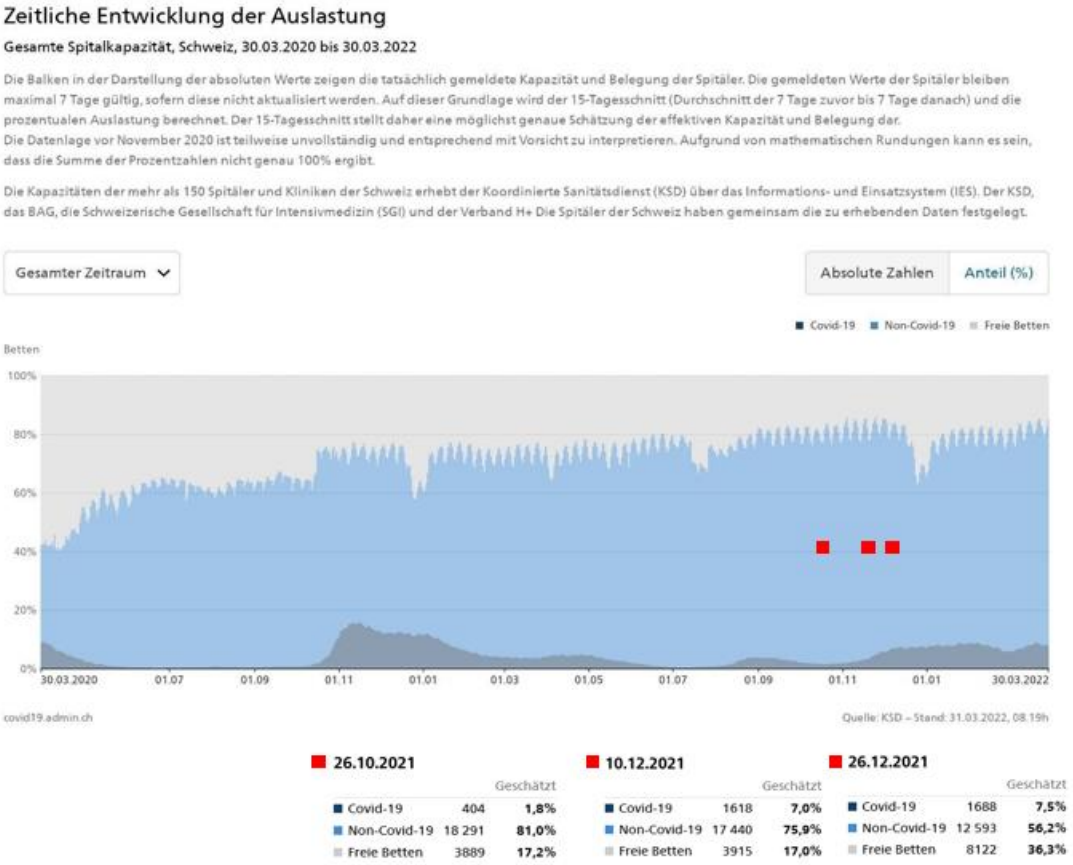


675 Neither at the time of the "booster" approval (26.10.2021), nor at the time of the approval of the children's "vaccinations" (10.12.2021), nor at the peak of the "wave" on 26 December 2021 were the intensive care units at the limit of their capacity: at all times there were still beds available to the extent of at least approx. 20%.[480]

676 Also with regard to the utilisation of **hospital beds as a whole, there was** no evidence of overcrowding - there were always around 20% free beds. As previously explained (N 654 ff.), an occupancy rate of "only" 80% is not at all profitable. In addition, COVID patients accounted for only a tiny proportion of the total hospital beds, usually well below 10%:[481]

480 Which tends to indicate under-occupancy, see in detail N 654 ff.

481 FOPH, "Information on the current situation, total hospital capacity", 29.06.2022, https://www.covid19.admin.ch/de/hosp-capacity/icu?time=total.



677 In view of the capacity utilisation of the hospitals, no particular threat from Sars-CoV-2 could be identified at the time of approval of the "booster" and children's "vaccinations" at the end of 2021.

1.3.2. Manipulated case numbers

678 To make matters worse, there is massive manipulation of the alleged SARS-CoV-2 cases in the hospitals. This circumstance was already criticised at the beginning of 2021, but was officially kept under wraps and only picked up by the mass media in January 2022. Corresponding explanations are therefore given below (N 714 ff.).

1.3.1. Smear campaign against the unvaccinated

679 In autumn 2021, "unvaccinated" people were accused of overburdening the health system. They should therefore be vaccinated - or forego intensive treatment, as Zurich's Health Director Natalie RICKLI publicly demanded at the beginning of September 2021.[482]

482 Blick, "Impfgegner müsste eigentlich auf eine Intensivbehandlung verzichten", 01.09.2021, https://www.blick.ch/schweiz/zuerich/zuercher-gesundheitsdirektorin-rickli-ueber-ungeimpfte-impfgegner-muessten-eigentlich-auf-eine-intensivbehandlung-verzichten-id16795363.html;

The unvaccinated were described as people who would make "common cause" with the virus and "ensure its continued existence".[483] They were "pests of the people".[484] They were denigrated as "covidiots",[485] "vaccination refusers", Corona "deniers",[486] "right-wing extremists",[487] "conspiracy theorists",[488] "aluhats"[489] and the like. They were stigmatised as "freaks", "drifters", "völkisch denkenend" or as "pathological cases", and under the title "These are the five types of vaccination refusers" they did not even shy away from inflammatory caricatures, which were in no way inferior to caricatures about Jews from the time of National Socialism.[490]

1.3.2. Disinformation campaign: "Epidemic of the unvaccinated".

680 The COVID-19 Task Force of the Confederation also contributed significantly to this campaign against the unvaccinated. At the media conference of 24 August 2021, the task force had already made the claim that an "epidemic of the unvaccinated" could be observed in hospitals because "90% of hospitalised COVID patients are "unvaccinated".[491] There was and is no evidence whatsoever for this claim:

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cf. also Tagesanzeiger, "Impfgegner müsste eigentlich auf eine Intensivbehandlung verzichten", 31.08.2021, https://www.tagesanzeiger.ch/impfgegner-muessten-eigentlich-auf-eine-intensivbehandlung-verzichten-564389128316.

483 Blick, "Vaccination opponents make common cause with the virus", 29.08.2021, https://www.blick.ch/meinung/kolumnen/editorial-von-sonntagsblick-chefredaktor-gieri-cavelty-die-impfgegner-machen-mit-dem-virus-gemeinsame-sache-id16787958.html.

484 NZZ, "In der Pandemie Geduld üben und Toleranz walten lassen", 15.09.2021, https://www.nzz.ch/meinung/geduld-ueben-und-toleranz-walten-lassen-ld.1643563?reduced=true.

485 NZZ, "Collapsed Communication: What if in the end "the covidiots" are right? ", 01.09.2020, https://www.nzz.ch/meinung/kollabierte-kommunikation-was-wenn-am-ende-die-covidioten-recht-haben-ld.1574096?reduced=true.

486 Bote, "Corona deniers wanted to break into emergency ward of Zurich Unispital", 13.12.2020, *https://www.bote.ch/nachrichten/schweiz/corona-leugner-wollten-in-notfallstation-von-zuercher-unispital-eindringen;art177490,1283608*.

487 SRF, "Corona measures critics: Increasingly aggressive - in word and deed", 01.04. 2021, https://www.srf.ch/news/schweiz/gewaltpotenzial-corona-massnahmen-kritiker-zunehmend-aggressiv-in-wort-und-tat.

488 Die Zeit, "The Corona vaccination is a dream for conspiracy theorists", 23.01.2021, https://www.zeit.de/digital/internet/2021-01/michael-butter-verschwoerungstheorien-corona-impfung-soziale-medien-querdenken.

489 NZZ, "Der mögliche Laborunfall in Wuhan und die Medien: Wenn Reflexe wichtig sind als Recherchen", 14.06.2021, https://www.nzz.ch/feuilleton/der-laborunfall-in-wuhan-und-die-medien-wenn-reflexe-wichtiger-sind-als-recherchen-ld.1629729?reduced=true.

490 Blick, "These are the five types of vaccination refusers", 05.09.2021, https://www.blick.ch/schweiz/nur-albaner-von-wegen-das-sind-die-fuenf-typen-der-imfpverweigerer-id16805316.html.

491 Swiss National Covid-19 Science Task Force, "Scientific Update 24.08.2021", 24.08.2021, https://sciencetaskforce.ch/wissenschaftliches-update-24-august-2021.

681 *Firstly,* the officially reported proportion of "covid patients" (as of 24.08.2021) in Swiss hospitals at that time was just 3.7%.[492] To use this low rate as evidence of an epidemic of any kind - let alone to declare an epidemic of the "unvaccinated" - is already not serious *per se.*

682 *Secondly, there* was no solid data basis for the claim that up to 90% of these 3.7% were "unvaccinated". The FOPH wrote in the weekly situation reports that the vaccination status had been collected for hospitalised cases since 27 January 2021 and that reliable data on the vaccination status of ICU patients had been available "since March 2020".[493] However, this was obviously not true: as previously explained (N 573 ff.), **various hospitals did not yet systematically record the "vaccination status" even at the end of 2021.**

683 *Thirdly,* the same picture emerged from the official recording of "COVID deaths" by vaccination status: an analysis of the figures communicated by the *FOPH* showed that **at the beginning of September 2021, contrary to the official claims, information on the vaccination status** was **only available from around 60% of the hospitalised "COVID patients".**[494] Further analysis of the corresponding figures revealed that in the period from 14 November 2021 to 15 December 2021, 41.96% had been reported as "not vaccinated", 39.57% as "fully vaccinated", 0.92% as "partially vaccinated" and still a full 17.56% as "unknown".[495] This is another strong indication that the vaccination status had still not been systematically recorded.

684 By the end of 2021, it was already obvious that the claim of an "epidemic" or "pandemic" of the unvaccinated was completely untenable. Not only did vaccinated and unvaccinated patients balance each other out according to *official* figures in the hospitals, there was also no solid data basis for any blame due to the aleatory or even non-existent recording of the vaccination status.

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492 Specifically: 802 Covid-19 occupancies out of a total of 21,777: FOPH, "Information on the Current Situation, Total Hospital Capacity", 29.06.2022, https://www.covid19.admin.ch/de/hosp-capacity/icu?time=total.

493 See for example: FOPH, "Situation report on the epidemiological situation in Switzerland and the Principality of Liechtenstein - Week 50 (3.12. - 19.12.2021)", 22.12.2021, p. 18. and p. 23, https://www.bag.admin.ch/dam/bag/de/dokumente/mt/k-und-i/aktuelle-ausbrueche-pandemien/2019-nCoV/covid-19-woechentlicher-lagebericht.pdf.download.pdf/BAG_COVID-19_Woechentliche_Lage.pdf.

494 Ostschweiz, "A split has never been in the interests of the people", 09.09.2021, https://www.dieostschweiz.ch/artikel/eine-spaltung-war-noch-nie-im-sinne-des-volkes-v1gXDMw.

495 FOPH, "Information on the current situation, cases by vaccination status", period 15.11.2021 to 15.12.2021 in absolute numbers: 227 "not vaccinated, 214 "fully vaccinated", 5 "partially vaccinated" and 95 "unknown" (as of 19.12.2021), https://www.covid19.admin.ch/de/vaccination/status; Juristen Komitee, "Declaration by Swiss Jurists: 2G certificate obligation is unconstitutional", 24.12.2021, N 15, *https://juristen-komitee.ch/wp-content/uploads/2021/12/2021-12-24_Deklaration-2G-DE.pdf.*

685 Incidentally, these figures did not improve in the new year: as of 31 January 2022, the vaccination status was still officially unknown for 20% of hospitalisations related to COVID disease.[496]

1.4. Interim conclusion

686 At the latest with the "delta" variant, whose *IFR of* 0.01-0.02% corresponded to a mild flu, there was no sign of a life-threatening or disabling disease from June/July 2021 onwards that would have seriously threatened the entire target population of the COVID "vaccinations" and thus legitimised a temporary approval.

2. Concerning children in particular

2.1. SARS-CoV-2 is not a life-threatening danger for children

687 As already stated above (N 649 ff.), the *CDC,* among others, had already determined a mortality rate (IFR) of just 0.002% among adolescents in March 2021. Studies from the same period confirmed this estimate[497] and were confirmed again in July 2021: For children and adolescents, a lethality rate of just 0.0027% was calculated. [498]

688 The mortality risk of children thus tended towards zero, which was also shown by the concrete figures: In Switzerland, only four deaths (out of a total of more than 12,700 deaths) were registered in connection with a positive PCR test in the age groups 0 - 9 and 10 - 19 in the period 24.02.2020 to 28.02.2022.[499] Whether these four children died of or with Corona is thus not clarified.

689 On the contrary, it has been proven that children are extremely rarely seriously or even fatally ill with COVID-19.[500] According to Prof. Berger, Children's Hospital Zurich, children were often hospitalised for other reasons and only had an additional positive test for SARS-CoV-2 on admission to hospital. During the entire Corona crisis, there were never

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496 BAG, "Information on the current situation, cases according to vaccination status", 29.06.2022, https://www.covid19.admin.ch/de/vaccination/status?vaccStatusDevRel=relative.

497 IOANNIDIS as well as OKE et al. 447.

498 AXFORS/IOANNIDIS, "Infection fatality rate of COVID-19 in community-dwelling populations with emphasis on the elderly: An overview", preprint dated 13.07.2021, https://www.medrxiv.org/content/10.1101/2021.07.08.21260210v1.full.pdf.

499 FOPH, "Laboratory-confirmed deaths", 23.06.2022, https://www.covid19.admin.ch/de/epidemiologic/death.

500 LAZZERINI et al, "Characteristics and risk factors for SARS-CoV-2 in children tested in the early phase of the pandemic: a cross-sectional study, Italy, 23 February to 24 May 2020", 08.04.2021, https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2021.26.14.2001248#abstract_content.

more than four to five children being treated for COVID at the same time in the Children's Hospital Zurich.[501] Of 8,200 children tested at the Children's Hospital Zurich, only 451 (5.5%) tested positive for SARS-CoV-2, of which 104 (1.2%) were hospitalised briefly. Information on the reasons for hospitalisation or previous illnesses was not communicated.[502]

2.2. Long COVID and PIMS as a danger?

690 Long COVID and the "Paediatric Multisystemic Inflammatory Syndrome" (PIMS) are repeatedly mentioned as arguments for the "vaccination" of children.

2.2.1. Long COVID

691 According to an early study by the University of Zurich in March 2021, Long COVID lacks a uniform definition, which is why terminology, definitions and classifications vary. There is a high degree of measurement heterogeneity and bias, and estimates should therefore only be considered preliminary. The most commonly reported symptom is fatigue, followed by headache, breathing difficulties, smell and taste disorders, cognitive impairment, sleep and anxiety disorders.[503]

692 In a study conducted by the Technical University of Dresden in May 2021, almost the same symptoms were found in the comparison group of children and adolescents who did not suffer from COVID as in those who did. According to the researchers, the **symptoms** are **more likely to be due to the consequences of the lockdown** and other restrictions for the children than to SARS-CoV-2.[504] In the Swiss CIAO-CORONA study, "Long COVID" symptoms are also observed comparably rarely in children with and without antibodies.[505]

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501 Blick, "Vaccination chief Berger gives all-clear: 'Do not observe more children needing treatment'", 06.01.2022, https://www.blick.ch/politik/impf-chef-berger-gibt-entwarnung-beobachten-nicht-dass-mehr-kinder-behandlung-brauchen-id17123268.html.

502 Kinderärzte Zürich, "VZK-Kurzinformation aus dem Kinderspital Zürich", 07.05.2021, https://www.kinderaerzte-zuerich.ch/images/pdf/Kurzinformation_KISPI_VZK_20210507.pdf.

503 On the whole: NITTAS / PUHAN, "Long COVID: Evolving Definitions, Burden of Disease and Socio-Economic Consequences", 07.06.2021, https://www.bag.admin.ch/dam/bag/de/dokumente/mt/k-und-i/aktuelle-ausbrueche-pandemien/2019-nCoV/Literaturrecherchen/literaturrecherchen_long_covid_20210607.pdf.download.pdf/20210607_Literaturrecherchen_Long_Covid_EN.pdf.

504 BLANKENBURG et al, "Mental health of Adolescents in the Pandemic: Long-COVID19 or Long-Pandemic Syndrome? ", preprint of 11.05.2021, *https://www.medrxiv.org/content/10.1101/2021.05.11.21257037v1.*

505 RADTKE et al, "Long-term symptoms after SARS-CoV-2 infection in school children: population-based cohort with 6-months follow-up", preprint dated 21.05.2021, *https://www.medrxiv.org/content/10.1101/2021.05.16.21257255v2.*

693 This assessment was confirmed in September 2021 by an analysis of the British *Office for National Statistics* (*ONS*). In the age group 2 - 11 years, the **children in the control group (not suffering from COVID) showed** more **long COVID symptoms than those who had corona**:[506]

Table 1: Percentage of study participants (with 95% confidence intervals) reporting any of 12 symptoms four to eight weeks or 12 to 16 weeks after COVID-19 infection
UK: 26 April 2020 to 1 August 2021

Group	4 to 8 weeks after infection		12 to 16 weeks after infection	
	Participants with COVID-19	Control participants	Participants with COVID-19	Control participants
All people	9.4 (9.0-9.9)	4.1 (3.8-4.4)	5.0 (4.6-5.4)	3.4 (3.1-3.8)
Males	8.1 (7.5-8.8)	3.7 (3.3-4.1)	4.5 (4.0-5.1)	3.3 (2.9-3.8)
Females	10.7 (10.0-11.4)	4.4 (4.0-4.9)	5.4 (4.9-5.9)	3.6 (3.1-4.0)
Age 2 to 11 years	3.3 (2.5-4.5)	3.6 (2.7-4.8)	3.2 (2.3-4.5)	4.1 (3.0-5.5)
Age 12 to 16 years	4.6 (3.5-6.0)	2.9 (2.1-4.0)	3.0 (2.1-4.3)	1.3 (0.8-2.3)
Age 17 to 24 years	5.6 (4.4-7.1)	3.6 (2.6-4.8)	3.6 (2.5-5.1)	3.6 (2.5-5.1)

694 This shows that **not only Long COVID symptoms were described, but also other malaise was included in the statistics.** In addition, just one of the following 12 symptoms was enough to be included in the statistics: Fever, headache, muscle ache, weakness or tiredness, nausea or vomiting, abdominal pain, diarrhoea, sore throat, cough, shortness of breath, loss of taste, and loss of smell.[507] Despite this smorgasbord of possible late effects, the values determined in the age groups from 2 to 24 years are just 3 to 5.6%; in comparison to the total population, therefore, remarkably inconspicuous. A serious danger for the health of children and adolescents would definitely look different.

2.2.2. PIMS

695 As early as September 2021, *Paediatrics Switzerland stated* that "the very rare PIMS-TS syndrome (roughly estimated at 1:5,000 to 1:10,000 infections) [...] has so far not led to any deaths in Switzerland" and "according to current findings, only very rarely leaves residues" after up to one year of follow-up.[508] In a statement in December 2021, *Paediatrics*

506 ONS, "Technical article: Updated estimates of the prevalence of post-acute symptoms among people with coronavirus (COVID-19) in the UK: 26 April 2020 to 1 August 2021", 16 September 2021, https://www.ons.gov.uk/peoplepopulationandcommunity/healthandsocialcare/conditionsanddiseases/articles/technicalarticleupdatedestimatesoftheprevalenceofpostacutesymptomsamongpeoplewithcoronaviruscovid19intheuk/26april2020to1august2021.

507 See ONS, FN 506.

508 Paediatrics Switzerland, "COVID-19: School measures in the 4th wave", 20.09.2021, https://www.paediatrieschweiz.ch/news/covid-19-schulmassnahmen-4-welle/.

Switzerland then drew attention to the fact that hospitalisations with acute SARS-CoV-2 infection and with "PIMS" among 5 to 11-year-old children also remained rare in the Delta wave and had not changed unfavourably since the beginning of the pandemic. Robust data on the incidence of long-COVID in children was still lacking. ***Paediatrics Switzerland*** stressed that scientific data and paediatric pros and cons should guide decision-making, rather than short-lived politically coloured claims in the "current heated atmosphere". The comparatively **low disease burden in this age segment and the still poor safety and long-term data on mRNA vaccines for 5-11 year olds would call for caution and thoughtful decision-making**. **The Society appealed to all to allow *EKIF*, *FOPH* and *Swissmedic the* necessary time to complete this evaluation process with the "usual care and consideration", because this was owed to the youngest generation.**[509]

696 As early as September 2021, the EMA had announced that it was investigating whether COVID "vaccinations could trigger a PIMS." [510]

2.3. Children are not "superspreaders

697 Lastly, let's address the claim that children would pose a "danger" to adults, which is then supposed to justify child "vaccination" in some way (which of course it could not, even if the claim were true). The "superspreader" argument, however, does not hold water:

698 A large-scale study by the University Hospitals of Freiburg, Heidelberg, Tübingen and Ulm, which examined 328 families, including 717 adults and 548 children aged 6-14 years, concluded that children were infected significantly less frequently (34%) than adults (58%) and were five times more likely not to show any signs of illness in the event of a positive PCR test. Children nevertheless showed stronger and longer-lasting specific antibody levels than adults 11 - 12 months after infection, regardless of whether symptoms were present or not. The children's antibodies were well effective against different virus variants, so that even children who were not visibly ill were protected after infection. None of the infected children had to be treated in hospital.[511]

509 Paediatrics Switzerland, "COVID-19: Vaccination for 5-11 year olds", 07.12.2021, https://www.paediatrieschweiz.ch/news/impfung-fur-5-11-jahrige/.

510 Pharmazeutische Zeitung, "EMA examines new potential vaccine side effect", 03.09.2021, https://www.pharmazeutische-zeitung.de/ema-prueft-neue-potenzielle-impfnebenwirkung-127819/.

511 RENK et al, "Robust and durable serological response following pediatric SARS-CoV-2 infection", 10.01.2022, *https://www.nature.com/articles/s41467-021-27595-9#citeas.*

699 The transmission from children to adults is undoubtedly minimal.[512] A large-scale cohort study in Scotland including 300,000 adults from households with or without children aged 0-11 years concluded that there was no increased risk of COVID or hospitalisation for adults with children from March to October 2020, nor specifically after school opened in August 2020.[513]

2.4. Interim conclusion

700 **The risk for children to seriously contract COVID 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 - is manifestly not fulfilled.

3. Overall conclusion "severity of COVID

701 If no disease threatening the entire target population could be identified at the time of the first time-limited authorisation in December 2020 (N 638 ff.), this was even more true for the times of the approval of the booster and child "vaccinations" in autumn 2021: The **"delta" variant** prevailing at this time was still **accompanied by an infection death rate (IFR) of 0.01-0.02%, which meant that SARS-CoV-2 was still as "dangerous" as a mild flu.** For children, the risk of severe illness tended towards zero from the beginning of the Corona crisis.

702 In the autumn of 2021, COVID therefore manifestly did not represent a disease that would have been equally life-threatening for the entire target population or could have resulted in disability. **Thus, the basic prerequisite for a temporary authorisation Art. 9a HMG was lacking.** The "vaccines" should therefore in no way have been authorised a second time and, in addition, for children - rather, the temporary authorisations should have been suspended immediately and referred to the ordinary procedure.

VI. State of knowledge as of 2022

703 On the lack of danger of SARS-CoV-2 for the population as a whole, see in detail above N 633 ff. and above N 668 ff. In the following, only additional findings are highlighted that further substantiate the non-existing danger from the outset:

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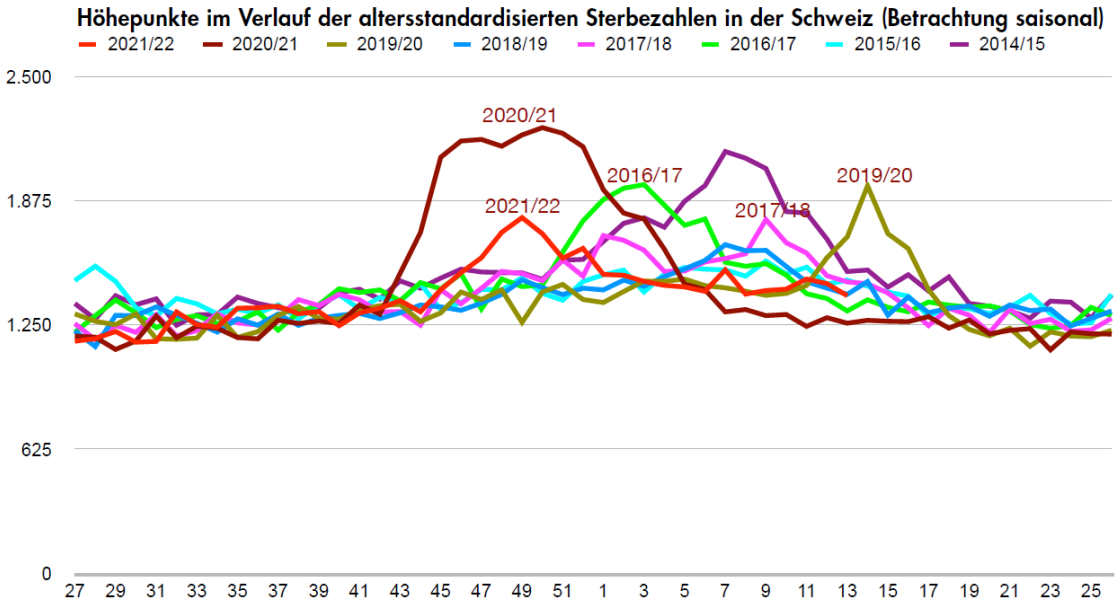
512 ZHU et al, "A meta-analysis on the role of children in severe acute respiratory syndrome coronavirus 2 in household transmission clusters", 06.12.2020, https://academic.oup.com/cid/article/72/12/e1146/6024998.

513 WOOD et al, 'Sharing a household with children and risk of COVID-19: a study of over 300 000 adults living in healthcare worker households in Scotland', 18 Mar 2021, *https://adc.bmj.com/content/106/12/1212.*

1. No excess mortality

704 As already stated above (N 669), there was an overall under-mortality in 2021 compared to previous years, despite short periods of significant over-mortality of persons over 65.

705 Even since the beginning of 2022 - and thus for the entire winter of 2021/2022 - no significant excess mortality has been discernible - on the contrary: the numbers have remained within normal limits in absolute terms (Supplement **20**, p. 2):



BO: Supplement **20:** Strong Facts: Switzerland, as of 13.04.2022

2. Further decreasing IFR of SARS-CoV-2 ("Omikron" variant)

706 On 24 November 2021, the South African Institute for Infectious Diseases *NICD* reported the detection of a new coronavirus variant: B.1.1.529. The *WHO* classified B.1.1.529 as a new "variant of concern" on 26 November 2021 and gave it the name "Omikron".[514] In Switzerland, "Omikron" replaced "Delta" as the predominant variant in January 2022.[515]

514 Berliner Morgenpost, "Omicron to Delta - The Spread of Corona Variants Worldwide", as of 25.04.2022, https://interaktiv.morgenpost.de/corona-virus-karte-infektionen-deutschland-weltweit/omikron-delta-ausbreitung-karte-corona-varianten.html; Internet archive, "The Omicron Variant: Separating Facts from Myths", 19.01.2022, https://web.archive.org/web/20220319122714/https://www.euro.who.int/de/health-topics/health-emergencies/pages/news/news/2022/01/the-omicron-variant-sorting-fact-from-myth.

515 BAG, "Information on the current situation, epidemiological course", 29.06.2022, https://www.covid19.admin.ch/de/epidemiologic/virus-variants?variants=VariantB11529,VariantB16172,VariantP1,VariantB1351,VariantB117,VariantC37,VariantB16171,VariantP2,VariantB1525,VariantB1526,VariantB11318.

707 On 22 December 2021, it was announced from South Africa, based on a large-scale study with over 68,000 people tested, that "Omikron" was associated with an 80% reduced risk of hospitalisation[516] and that the "Omikron wave" had already subsided by 31 December 2021 without any significant consequences for the health system. A large-scale Canadian study from Ontario, which compared the data of around 22,000 "Omikron" and "Delta" sufferers, also concluded on 2 January 2021 that "Omikron" was associated with a 65% lower risk of hospitalisation.[517] LIU et al., engineers from China, concluded based on the South African data in mid-January 2022 that the ***IFR*** (infectious death rate) of **"Omikron" was reduced by 88% compared to previous variants**.[518] Assuming an *IFR of* 0.01-0.02% for "Delta", which corresponded to the *IFR of* a mild flu (N 640), the **IFR for "Omikron"** based on the latest projections is just **0.001-0.002%**. Omikron is thus significantly less dangerous for the population as a whole than an influenza infection.

708 Although all these facts were already known in mid-January 2022, the *COVID task force was* already stirring up fear again at the same time with a "monster wave" and with a "worst-case scenario" that as a result of "Omikron" so many COVID patients could fill the intensive care units "as never before".[519]

709 From a medical and economic point of view, it is completely incomprehensible that a "vaccination" was maintained for a disease that was by now less dangerous than a mild flu. At this point at the latest, the approval of the COVID "vaccines" should have been suspended. Against this background and the well-founded data on the massive risks of the COVID "vaccines", which were known in the meantime, it seems downright contradictory that Swissmedic still concluded in mid-March 2022: "*The reports of adverse effects received and analysed so far do not change the positive benefit-risk profile of the Covid-19 vaccines used in Switzerland".* " [520]

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516 Bloomberg, "Omicron Has 80% Lower Risk of Hospitalization in South Africa", 22 Dec 2021, https://www.bloomberg.com/news/articles/2021-12-22/omicron-has-80-lower-risk-of-hospitalization-new-study-shows; WOLTER et al , "Early assessment of the clinical severity of the SARS-CoV-2 Omicron variant in South Africa", preprint dated 21 Dec 2021, https://www.medrxiv.org/content/10.1101/2021.12.21.21268116v1.

517 ULLOA et al , "Early estimates of SARS-CoV-2 Omicron variant severity based on a matched cohort study, Ontario, Canada", preprint dated 02.01.2022, https://www.medrxiv.org/content/10.1101/2021.12.24.21268382v2.

518 LIU et al. , "Reduction in the Infection Fatality Rate of Omicron (B.1.1.529) Variant Compared to Previous Variants in South Africa", 16.01.2022, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4010080.

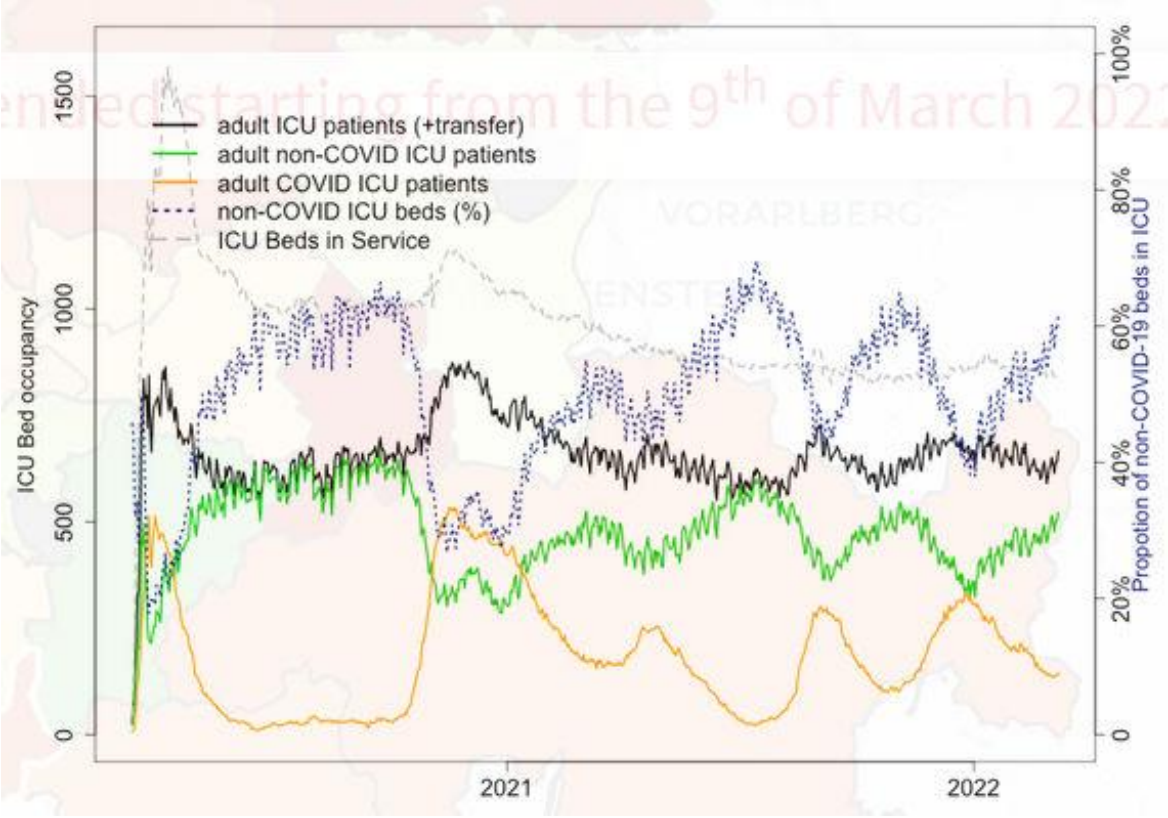
519 Blick, "But is it really dangerous? Taskforce warns of monster wave", 12.01.2022, https://www.blick.ch/politik/aber-ist-sie-wirklich-gefaehrlich-taskforce-warnt-vor-monsterwelle-id17137774.html.

520 Swissmedic, FN 1.

3. No overloading of the hospitals

3.1. General utilisation

710 The following graph of the "Near Real Time Monitoring of Intensive Care Occupancy" of the ETH Zurich[521] shows that the situation in the area of intensive care hospital beds continued to develop within the range of the completely normal in winter 2021/22:



711 The graph above also shows that the overall utilisation of intensive care beds has not been critical at any time during the last two years, but that the "COVID hospitalisations" (orange curve) in the intensive care units increased at the same time and in absolute synchrony as the "non-COVID hospitalisations" (green curve) decreased, while the overall utilisation remained unchanged. This indicates, once again, a false "labelling" of "COVID patients", in that every patient, regardless of the original reason for hospitalisation, was recorded as a "COVID hospitalised" after a positive PCR test on hospital admission.[522] If operations had been cancelled as a precaution because of overcrowded intensive care units due to COVID, it would naturally be expected that the green curve of "non-COVID

521 Health Geography and Policy Group ETH Zurich, "ICU monitoring", as of March 2022, https://icumonitoring.ch/.

522 Ostschweiz, "A picture is worth a thousand words", 19.08.2021, https://www.dieostschweiz.ch/artikel/ein-bild-sagt-mehr-als-tausend-worte-mmxEvLA.

hospitalisations" would fall and the orange curve of "COVID hospitalisations" would rise only after a slight time delay.

712 Nothing - really nothing - even hinted at a situation worthy of the name "pandemic".

3.2. Utilisation by COVID patients: Manipulated case numbers

713 Since the "bare" figures - to which Swissmedic is obliged to protect the health of the people in this country - were not even remotely sufficient to justify an emergency situation, the authorities and the media helped out with an unprecedented disinformation and smear campaign:

3.2.1. Additional number manipulation

714 The in no way justifiable over-reporting of "Corona patients" - an unprecedented manipulation of numbers - could no longer be concealed at the beginning of 2022: In January 2022, Federal Councillor CASSIS publicly admitted to[523] that every patient who had tested positive for SARS-CoV-2 in hospital was listed as a Corona patient - regardless of whether he or she had actually contracted Corona. According to numerous media reports - based on corresponding information from the hospitals - **about 50% (!) of the cases reported by the FOPH as "Covid-19 hospitalisations" were in fact not hospitalised at all because of a SARS-Cov-2 infection,** but for other reasons.[524]

715 The minutes of the COVID 19 task force meeting of 9 February 2022 also revealed that 1 out of 3 COVID patients at the Geneva University Hospital had infected themselves in hospital: "*Aux HUG, 1 patient sur 3 a été contaminé à l'hôpital.* "[525]

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523 "[...] Anyone who has an accident with a car and dies and is Corona-positive is a Corona-dead person. It depends on the [WHO] definition. [...]": SRF, "Arena - Die grosse Präsidenten-Runde zu Corona und zur EU", 07.01.2022, minute 37:52, *https://www.srf.ch/play/tv/arena/video/die-grosse-praesidenten-runde-zu-corona-und-zur-eu?urn=urn:srf:video:c2da2605-90ad-4b47-b2c6-fd88d0b64d4e* .

524 Blick, "Spitaleinweisungen wegen Corona sind tiefer als ausgewiesen", 07.01.2022, https://www.blick.ch/schweiz/in-genf-ist-fast-die-haelfte-der-statistisch-ausgewiesenen-corona-patienten-aus-anderen-gruenden-im-spital-gelandet-und-erst-dort-positiv-getestet-worden-spitaleinweisungen-wegen-corona-sind-tiefer-als-ausgewiesen-id17125098.html; NZZ, "Aus Angst, Fehler zu machen, begeht der Bund sein grössten Irrtum", 12.01.2022, https://www.nzz.ch/meinung/die-angst-davor-einen-fehler-zu-machen-verleitet-den-bund-zum-allergroessten-ld.1664035?reduced=true; Saldo, "Corona-Hospitalisierungen: Figures are too high", 18.01.2022, https://www.saldo.ch/artikel/artikeldetail/corona-hospitalisierungen-zahlen-sind-zu-hoch/.

525 FOPH, "Minutes of the 200th FOPH COVID-19 Taskforce Meeting", 02.02.2022, https://www.bag.admin.ch/dam/bag/de/dokumente/mt/k-und-i/aktuelle-ausbrueche-pandemien/2019-nCoV/tf-protokoll-februar-2022.pdf.download.pdf/Sammelmappe_Februar_Protokolle%20Taskforce%20Covid-19_geschw%C3%A4rzt.pdf.

716 If the already low occupancy figures for "corona patients" (N 676) are corrected downwards by half, the house of cards of the alleged threat of SARS-CoV-2 finally collapses.

3.2.2. Conclusion

717 By January 2022 at the latest, it was publicly and thus generally known that the threat posed by SARS-CoV-2 to the health system (and thus to people's health per se) had been *massively* overstated.

4. Irrelevant criterion of "high number of cases

718 Already before (N 661 ff.), it was explained in detail that the "case numbers" determined by the PCR test are in no way suitable for determining the actual threat posed by SARS-CoV-2 to human health.

719 From the end of 2021, this became abundantly clear from the fact that the "laboratory-confirmed cases" had long since decoupled from the "laboratory-confirmed deaths" - despite the absolute peak in testing (see graph below).[526]

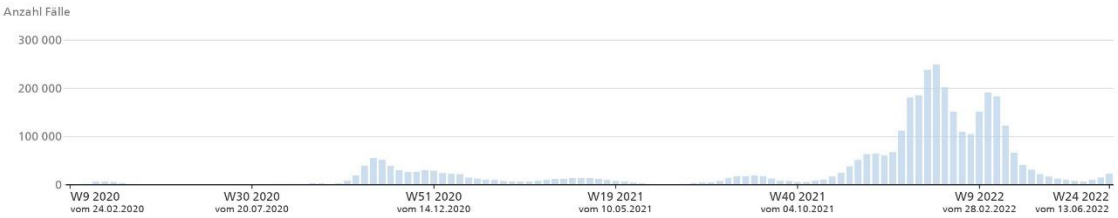
526 FOPH, "Information on the current situation, situation report week 24", as of 29.06.2022, https://www.covid19.admin.ch/de/weekly-report/situation; see also FOPH, "Situation report on the epidemiological situation in Switzerland and the Principality of Liechtenstein - week 50 (3.12.-19.12.2021)", 22.12.2021, p. 2, https://www.bag.admin.ch/dam/bag/de/dokumente/mt/k-und-i/aktuelle-ausbrueche-pandemien/2019-nCoV/covid-19-woechentlicher-lagebericht.pdf.download.pdf/BAG_COVID-19_Woechentliche_Lage.pdf.

Zeitliche Entwicklung

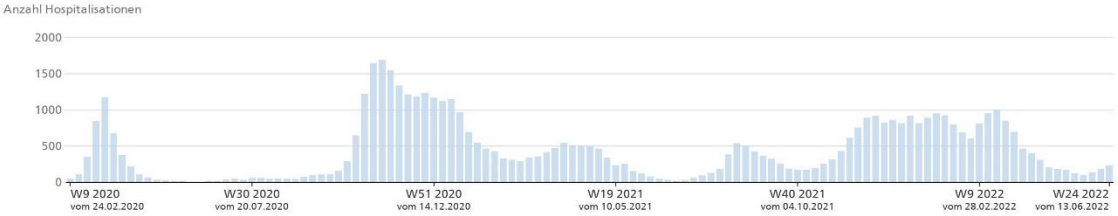
Bis Woche 24 vom 13.06.2022, Schweiz und Liechtenstein

Die Darstellung zeigt die Entwicklung der laborbestätigten Fälle, Hospitalisationen und Todesfälle sowie die Anzahl gemeldeter PCR- und Antigen-Schnelltests im Zusammenhang mit einer laborbestätigten SARS-CoV-2-Infektion seit Einführung der Meldepflicht für COVID-19 in der Schweiz und in Liechtenstein.

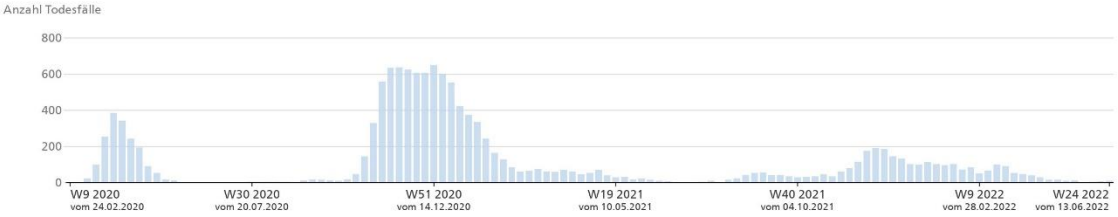
Laborbestätigte Fälle



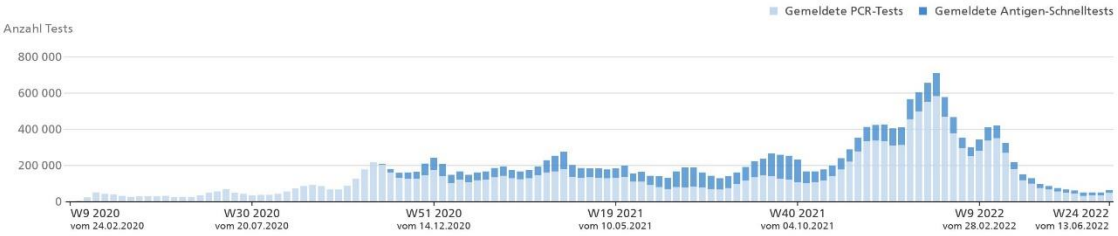
Laborbestätigte Hospitalisationen

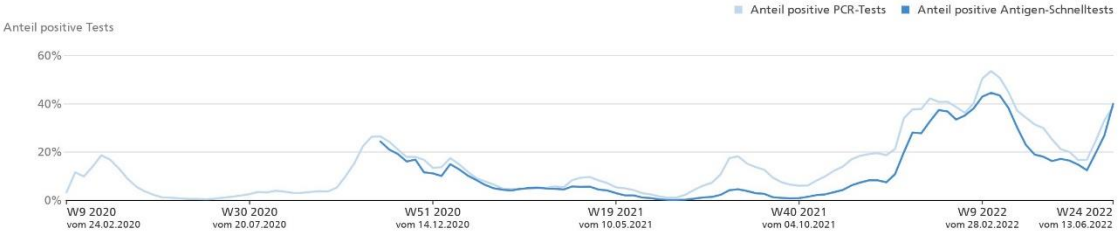


Laborbestätigte Todesfälle



Tests





covid19.admin.ch

Quelle: BAG – Stand: 28.06.2022, 06.07h

720 However, if deaths have decoupled from "case numbers", a temporary authorisation that can only be granted for life-threatening or disabling diseases is no longer justified in any way.

5. No evidence that SARS-CoV-2 endangers children

721 On 1 February 2022, the US organisation *ICAN* (*Informed Consent Action Network*), through its attorneys, submitted two Freedom of Information Act requests to the *CDC to* obtain all records of confirmed COVID-19 deaths in children aged 11 years or younger and in children aged 12 to 15 years. On 10 March 2022, *CDC* announced that the *NCHS* (National Center for Health Statistics) had not performed the requested analyses for this age group and could not provide any such analyses. **Although the *CDC*** had not performed the "analyses" of its own data for any of these age groups and was therefore unable, when asked by lawyers, to **provide even a single confirmed case of a healthy child aged 15 or younger who had died from COVID-19, it claimed on its website that COVID** *can* **cause death in children and teenagers**: "*In rare situations, the complications from COVID-19 can lead to death*".[527]

6. Long COVID and PIMS as a danger?

6.1. Danger of Long COVID in adults: Yes, but probably in advance for vaccinated persons

722 A causality between the COVID "vaccination" and the prevention of a COVID disease or severe courses of the disease is, as explained in detail in various places, not recognisable in the approval studies after a well-founded analysis.

723 To date, solid prospective studies have also failed to show that the vaccine reduces the incidence of long COVID.

724 On the other hand, there have been increasing reports in the public media of **long-COVID cases in vaccinated people, the so-called "post-vac syndrome".**[528]

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527 ICAN, "CDC Cannot Provide an Instance of a Single Confirmed COVID-19 Death in a Child Younger Than 16," 29 Mar. 2022, https://www.icandecide.org/ican_press/cdc-cannot-provide-an-instance-of-a-single-confirmed-covid-19-death-in-a-child-younger-than-16/; CDC, "Frequently Asked Questions about COVID-19 Vaccination for Children and Teens," 14 Apr. 2022, *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq-children.html.*

528 Fuldaer Zeitung, "Long Covid symptoms after Corona vaccination: a person affected reports", 13.04.2022, https://www.fuldaerzeitung.de/fulda/symptome-arzt-klinik-christian-mardin-corona-fulda-long-covid-impfung-experten-91446720.html; Hessenschau, "When doctors can't help and nobody believes you", 21.02.2022, https://www.hessenschau.de/gesellschaft/long-covid-nach-impfung-wenn-aerzte-nicht-

725 A study from India, which examined the data of around 700 people who had a positive PCR result from April to September 2021, concluded that a double "**vaccination" increased the risk of developing Long COVID to a comparable** (significant) **extent as an existing pre-disease or a severe course of COVID**. [529]

726 An article in *Science in* January 2022 reported on 34 post-vaccination cases that the US *National Institutes of Health* (*NIH*) had investigated and announced that researchers worldwide had begun to investigate whether the still "poorly understood biology of Long COVID, overlapped with mechanisms that caused certain side effects after the "vaccination".[530] *The NIH has* not yet been able to publish the findings on the patient cases. Two leading medical journals refused to publish the data because the data were "inconclusive" and it was only an "observational study". [531] Since prospective studies on the topic of "corona pandemic" and "COVID therapies" are rare and mainly less meaningful "observational studies" have been published in the last two years, this argumentation is hardly comprehensible.

727 A retrospective database analysis published in May 2022[532] , which analysed data from 113,474 unvaccinated COVID patients and nearly 34,000 fully vaccinated patients who had a breakthrough infection from 1 January to 31 October 2021 from the US Department of Veterans Affairs National Healthcare Database, concluded that the risk of developing Long COVID symptoms was reduced by a maximum of 15% in vaccinated compared to unvaccinated patients. The first author of the publication expressed disappointment: "We had hoped that vaccines would provide protection," said AL-ALY. "Unfortunately, the results showed us the opposite, providing imperfect protection."[533]

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helfen-koennen-und-niemand-einem-glaubt,corona-impfung-136.html; OÖ Nachrichten, "Does Corona vaccination trigger Long Covid?", 04.02.2022, *https://www.nachrichten.at/meine-welt/gesundheit/loest-die-corona-impfung-long-covid-aus;art114,3564678.*

529 ARJUN et al , "Prevalence, characteristics, and predictors of Long COVID among diagnosed cases of COVID-19", preprint dated 08.01.2022, https://www.medrxiv.org/content/10.1101/2022.01.04.21268536v1.full.

530 Science, "In rare cases, coronavirus vaccines may cause Long Covid-like symptoms ", 20.01.2022, https://www.science.org/content/article/rare-cases-coronavirus-vaccines-may-cause-long-covid-symptoms.

531 Ärzteblatt, "Rare cases of PIMS and Long COVID even after vaccination", 05.05.2022, https://www.aerzteblatt.de/nachrichten/133796/Seltene-Faelle-von-PIMS-und-Long-COVID-auch-nach-Impfung.

532 AL-ALY et al, "Long COVID after breakthrough SARS-CoV-2 infectionLong COVID after breakthrough SARS-CoV-2 infection", 25.05.2022, https://www.nature.com/articles/s41591-022-01840-0.

533 Healthline, "Vaccines Offer Modest Protection Against Long COVID, New Study Finds", 25.05.2022, https://www.healthline.com/health-news/vaccines-offer-modest-protection-against-long-covid-new-study-finds#Vaccines-are-an-imperfect-shield-.

728 By May 2022, 200 affected patients had been registered in a hospital outpatient clinic founded for "post-vac patients" at the Marburg-Giessen University Hospital, with a further 1800 patients on the waiting list.[534] Among other things, reactivation of an Epstein-Barr virus (EBV) infection was discussed as a possible cause of post-Vac syndrome. [535]

6.2. Long COVID and "PIMS" in children: No danger at all

729 It was already explained earlier that by the end of 2021 it was already clear that PIMS, just like Long COVID, did not pose a risk to children. This finding was also confirmed several times in 2022:

730 Philipp Jenny, President of *Paediatrics Switzerland*, rated the complication rate of Long-COVID or the PIMS as very low at the beginning of 2022. [536]

731 Up to 5.6.2022, 856 children and adolescents were reported in Germany who fulfilled the WHO case definition for PIMS. Cases were considered PIMS if, in addition to fever, elevated inflammatory markers (e.g. CRP), at least two organ involvement and a current or recent SARS-CoV2 infection could be detected and another infectious cause could be ruled out.[537]

732 Positive PCR test results were the exception in all patients, and antibodies were detected in a relevant proportion of patients. In most PIMS cases, the admission diagnosis was other than PIMS.[538] This evidence once again calls into question the validity of case ascertainment.

By 22 May 2022, 23 PIMS cases had been reported after COVID "vaccination". In an article in the German Medical Journal (Deutsches Ärzteblatt), attention was drawn to the fact that it is only possible to estimate how many PIMS cases there actually are in children due to a "vaccination" in Germany, as certainly not every single case is reported.[539] Even these figures are likely to represent only the tip of the iceberg, as experience shows, because only a fraction of vaccination side effects are reported.

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534 Stern, "Long Covid after Vaccination: The Paul Ehrlich Institute's Fatal Fear of the "Post-Vac Syndrome"", 02.06.2022, https://nebenwirkungen-covid-impfung.org/wp-content/uploads/wpforo/attachments/1516/51-LongCovidnachderImpfungPaulEhrlichInstitutundPostVac.pdf.

535 Medical Journal, FN 531.

536 Medinside, "Child vaccination: the SRF report has unsettled many members", 10.01.2022, https://www.medinside.ch/de/post/kinderimpfung-der-srf-beitrag-hat-viele-mitglieder-verunsichert.

537 DGPI, "PIMS Survey Update," Calendar Week 22, 2022, https://dgpi.de/pims-survey-update/#zentren-karte.

538 DGPI, FN 537.

539 Medical Journal, FN 535.

7. Overall conclusion "severity of COVID

733 Was already at the time of the first temporary admission in December 2020 (front N 638 ff.) and also at the time of approval of the booster and paediatric "vaccinations" in autumn 2021 (front N 670 ff.), this was all the more true since the appearance of the "Omikron" variant from the end of 2021: this was **accompanied by an infection death rate of only 0.001-0.002%, which meant that SARS-CoV-2 was now even less "dangerous" than a mild flu.** And again, it should be mentioned that the risk of a severe illness for children tended towards zero from the beginning of the Corona crisis (on this already in detail in N 687 ff.).

734 From the end of 2021 until now, COVID still did not manifestly represent a disease that would have been equally life-threatening for the entire target population or could have resulted in disability with considerable probability. **Thus, the basic prerequisite for a temporary authorisation Art. 9a HMG was still lacking.** The temporary authorisations for the COVID "vaccines" must therefore be suspended immediately and referred to the ordinary procedure.

E. MANDATORY DUTY TO MINIMISE RISK: VIGILANCE AND EDUCATION

I. Control of risks ("pharmacovigilance")

1. [No active monitoring]

735 [Remarks exclusively in criminal complaint.]

2. [Massive underreporting.]

736 [Remarks exclusively in criminal complaint.]

3. Swissmedic approves unblinding of registration studies

737 Swissmedic has been aware of the problem of unblinding the registration studies of COVID "vaccines" since the first temporary authorisation.

738 So she wrote to Moderna (Supplement **3**, p. 14).

> "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."

> "Because, the ability to answer the open question of duration of protection will heavily rely on an unvaccinated control group (blinded and/or unblinded). Alternatively, this question as well as that regarding protection of persons most at risk could also be answered by performing a household contact study [...]".

739 And to Pfizer (Supplement **2**, p. 6):

> "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".
>
> ("It is reasonable to assume that once a vaccine is widely available and encouraged, maintaining a double blind control group will be impossible. A Study with an alternative study design, e.g. a blinded crossover design or any study design, that will circumvent this problem, is strongly recommended").

740 **Based on these findings, Swissmedic should have rejected a temporary authorisation on formal grounds alone.** Due to the significantly lower level of evidence of the data currently generated without a comparator arm (placebo group), the starting position for the temporary authorisation granted has fundamentally changed, and the requirements for converting the temporary authorisations into a full authorisation are no longer met. The approval studies have been downgraded in terms of evidence level to qualitatively inferior "observational studies"[540] . The marketing authorisation holders will not be able to present data comparing efficacy and safety between vaccine and placebo over a period longer than a few months.

4. [Ignored messages from the manufacturers]

741 [Remarks exclusively in criminal complaint.]

5. Ignored third party studies

742 On the ignored analysis of the CCCA, see above N 317.

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540 PNC News, "Evidence classes: Why does not every study have the same strength of evidence?", 09.09.2019, https://www.pnc-aktuell.de/prophylaxe/story/evidenzklassen-warum-hat-nicht-jede-studie-die-gleiche-aussagekraft__8064.html.

II. Completely insufficient education of patients and the medical profession

1. Admission in an "ordinary procedure"?

743 As already shown in the introduction (N 6), Swissmedic announced at the end of 2020 that the first mRNA "vaccine" had been authorised in an "ordinary procedure" - which is simply not true.

2. Approval for pregnant and breastfeeding women

744 The demonstrably downplaying, misleading and incorrect wording in the Swiss drug information of Comirnaty® approved by Swissmedic paved the way for a vaccination recommendation for pregnant women by the FOPH, the Federal *Commission for Vaccination Questions* (*EKIF*) and the *Swiss Society of Gynaecology and Obstetrics* (SGGG) - from May 2021 only for pregnant women with chronic diseases, from September 2021 for all pregnant women from the 2nd trimester onwards. This significantly paved the way for the **approval of the drug for the second** trimester[541] - and thus made broad use for a vulnerable patient group possible in the first place, although neither at the time of the **approval nor to date were there any data from solid studies that proved its safety for pregnant women; on the contrary, existing data pointed to risks in the use of pregnant women.**

745 In the vaccination recommendation (Supplement **15**), the *ECIF* cited a study by SHIMABUKURO et al.[542] with a publication date of 17 June 2021 as the only alleged evidence for the safety of the COVID "vaccines" in pregnant women. This study is not a prospective study in which the safety of the COVID "vaccines" in pregnant women was investigated in two groups (vaccinated vs. unvaccinated), but an analysis of "surveillance data" from the USA, which were collected from 14 December 2020 to 28 February 2021. Database analyses are known to be significantly inferior to prospective controlled studies in terms of methodology and consequently in terms of significance.[543] Furthermore, the question arises as to why only a selected fraction of the available data from pregnant women was analysed in this study.

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541 SGGG, "SGGG Recommendation: Vaccination against COVID-19 in pregnancy and lactation", 14.09.2021, https://www.sggg.ch/fileadmin/user_upload/Dokumente/4_NEWS/Impfung_Covid-19_Schwangerschaft_Stillzeit_Begleitschreiben_14.09.2021_D.pdf.

542 SHIMABUKURO et al , "Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons", 21.04.2021, https://www.nejm.org/doi/full/10.1056/nejmoa2104983.

543 PNC News, FN 540.

746 In its "Epidemiological Bulletin" of 23.9.2021, the German Robert Koch Institute (*RKI*) denounced shortcomings of this study (*"... the risk of bias for the data from the V-safe Surveillance System presented in the study was assessed as "critical risk of bias" due to the lack of adjustment of incidences for confounding variables [...]"*) and rated it overall as "critical" in terms of biased presentation of data and bias:[544]

Tabelle 4: Risk of BIAS-Bewertung: Nicht-randomisierte Studien zur Wirksamkeit und Sicherheit der mRNA-Impfstoffe gegen COVID-19 bei Schwangeren

Study	Bias due to confounding	Bias in selection of participants into the study/analysis	Bias in classification of interventions	Bias due to deviations from intended interventions	Bias due to missing data	Bias in measurement of outcomes	Bias in selection of reported result	Summary
Blakeway	moderate [1]	low	low	low	low	low	low	moderate
Butt	moderate [2]	low	low	low	low	low	low	moderate
Dagan	moderate [1]	low	low	low	low	low	low	moderate
Goldshtein	moderate [1]	low	low	low	low	low	low	moderate
Shimabukuro	critical [3]	low	moderate [4]	low	low	moderate [5]	low	critical
Zauche	critical [3]	low	moderate [4]	low	low	moderate [5]	low	critical

[1] Residual confounding cannot be excluded; [2] test-negative design; [3] only unadjusted data reported; [4] vaccination status not verified in the registry; [5] outcome not verified

747 In the first version of the publication by SHIMABUKURO et al., a rate of "spontaneous abortions" of 12.8% (105/827) was given and classified as "normal" with an expected rate of 10-26%:[545]

544 RKI, "Epidemiologisches Bulletin", 23.09.2021, p. 25, https://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2021/Ausgaben/38_21.pdf?__blob=publicationFile; RKI, "Anhang zur wissenschaftlichen Begründung der STIKO-Empfehlung zur Impfung gegen COVID-19 Impf von Schwangeren und Stillenden", 27.09.2021, p. 9, https://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2021/Ausgaben/38_21_Anhang.html.

545 Table can still be found, among others, at Internet Archive, "Recommendation on vaccination in pregnancy by STIKO and RKI refers to flawed studies by CDC", 14.05.2022, https://web.archive.org/web/20220520165023/https://corona-blog.net/2022/05/14/empfehlung-zur-impfung-in-der-schwangerschaft-von-stiko-und-rki-bezieht-sich-auf-fehlerhafte-studien-von-der-cdc/.

Table 4. Pregnancy Loss and Neonatal Outcomes in Published Studies and V-safe Pregnancy Registry Participants.

Participant-Reported Outcome	Published Incidence*	V-safe Pregnancy Registry†
	%	*no./total no. (%)*
Pregnancy loss among participants with a completed pregnancy		
Spontaneous abortion: <20 wk[15-17]	10–26	104/827 (12.6)‡
Stillbirth: ≥ 20 wk[18-20]	<1	1/725 (0.1)§
Neonatal outcome among live-born infants		
Preterm birth: <37 wk[21,22]	8–15	60/636 (9.4)¶
Small size for gestational age[23,24]‖	3.5	23/724 (3.2)
Congenital anomalies[25]**	3	16/724 (2.2)
Neonatal death[26]††	<1	0/724

* The populations from which these rates are derived are not matched to the current study population for age, race and ethnic group, or other demographic and clinical factors.
† Data on pregnancy loss are based on 827 participants in the v-safe pregnancy registry who received an mRNA Covid-19 vaccine (BNT162b2 [Pfizer–BioNTech] or mRNA-1273 [Moderna]) from December 14, 2020, to February 28, 2021, and who reported a completed pregnancy. A total of 700 participants (84.6%) received their first eligible dose in the third trimester. Data on neonatal outcomes are based on 724 live-born infants, including 12 sets of multiples.
‡ A total of 96 of 104 spontaneous abortions (92.3%) occurred before 13 weeks of gestation.
§ The denominator includes live-born infants and stillbirths.

748 These figures were subsequently removed, as they were demonstrably incorrect. A corrigendum[546] showed that important data for a calculation and for a final benefit-risk assessment were missing at the time of publication: **For 905 of the 1224 participants** who were vaccinated within 30 days before the first day of the last menstruation or in the first trimester (the most sensitive phase of organ development), **no data on follow-up up to the 20th week were available.**

749 The table was subsequently corrected: [547]

546 SHIMABUKURO et al. , Correction to the study "Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons", 14.10.2021, *https://www.nejm.org/doi/full/10.1056/NEJMx210016?query=recirc_curatedRelated_article* .

547 SHIMABUKURO et al. , FN 542.

Table 4. Pregnancy Loss and Neonatal Outcomes in Published Studies and V-safe Pregnancy Registry Participants.

Participant-Reported Outcome	Published Incidence*	V-safe Pregnancy Registry†
	%	*no./total no. (%)*
Pregnancy loss among participants with a completed pregnancy		
Spontaneous abortion: <20 wk[15-17] ‡	Not applicable	104
Stillbirth: ≥ 20 wk[18-20]	<1	1/725 (0.1)§
Neonatal outcome among live-born infants		
Preterm birth: <37 wk[21,22]	8–15	60/636 (9.4)¶
Small size for gestational age[23,24]‖	3.5	23/724 (3.2)
Congenital anomalies[25]**	3	16/724 (2.2)
Neonatal death[26]††	<1	0/724

* The populations from which these rates are derived are not matched to the current study population for age, race and ethnic group, or other demographic and clinical factors.

† Data on pregnancy loss are based on 827 participants in the v-safe pregnancy registry who received an mRNA Covid-19 vaccine (BNT162b2 [Pfizer–BioNTech] or mRNA-1273 [Moderna]) from December 14, 2020, to February 28, 2021, and who reported a completed pregnancy. A total of 700 participants (84.6%) received their first eligible dose in the third trimester. Data on neonatal outcomes are based on 724 live-born infants, including 12 sets of multiples.

‡ A total of 96 of 104 spontaneous abortions (92.3%) occurred before 13 weeks of gestation. No denominator was available to calculate a risk estimate for spontaneous abortions, because at the time of this report, follow-up through 20 weeks was not yet available for 905 of the 1224 participants vaccinated within 30 days before the first day of the last menstrual period or in the first trimester. Furthermore, any risk estimate would need to account for gestational week–specific risk of spontaneous abortion.

750 As no further data on this analysis have been published to date, it is completely unclear on what basis the *ECIF* assumes in its vaccination recommendation of 21.01.2022 (Annex **15**) that the use of COVID "vaccines" is safe and, in particular, that "vaccination" in the first trimester is not critical: "*If accidental or unknowing vaccination occurs in the first trimester, this is no cause for alarm.* "

3. Admission for children and adolescents

751 For the claim "High clinical efficacy in younger children" see above N 20.

4. Admission for elderly and pre-diseased people

752 On the missing information and the classification as "target group 1" see already in detail above N 323 ff.

5. [Approval for immunocompromised persons].

753 [Remarks exclusively in criminal complaint.]

6. Misleading technical information for mRNA "vaccines

754 On the basis of three specific side effects of the mRNA "vaccines" (myocarditis; herpes zoster and thromboembolic events), it is examined below whether the drug texts corre-

sponded to the latest state of knowledge in this respect ("Adverse effects" section) and whether the medical profession and patients were adequately informed of hazards ("Contraindications" and "Warnings and precautions" sections) .

755 Since the patient information is an abridged version of the expert information for laypersons and since, in the case of COVID "vaccines", the person to be vaccinated is primarily informed by the attending physician or the attending medical specialist, the following argumentation is based exclusively on the text passages of the expert information for Comirnaty® and Spikevax®.

756 Normally, all side effects observed in clinical trials and after marketing authorisation ("post-marketing phase") are fully reported in the "Adverse effects" section of a medicinal product's summary of product characteristics. The information contained in this section is intended to adequately and completely inform physicians about risks associated with the medicinal product, so that they in turn can correctly inform their patients and carry out an individual "risk-benefit assessment".

757 In the case of the COVID "vaccines", the documentation under the heading "Adverse effects" is demonstrably incomplete, and known side effects are suppressed:

758 The Pfizer/BioNTech "*Post Marketing Pharmacovigilance Report*"[548] , which contained data on the first 2.5 months after marketing authorisation and which was presumably submitted to Swissmedic for review in April/May 2021, a high number of cases of adverse effects were reported, which unmistakably indicated an **increased incidence of cardiovascular and thromboembolic events, neurological diseases, immune-mediated and autoimmune diseases and, among others, herpes zoster diseases/reactivations in connection with Comirnaty®.**

759 Although these safety signals for the COVID "vaccines" were confirmed in the course of the nationally and internationally registered suspected cases of vaccine side effects, as explained in various places, they were not included in the drug texts.

6.1. Completely inadequate warning of myocarditis

760 As late as November 2021, Swissmedic had published case rates for the cases of myocarditis associated with the COVID "vaccines" (**0.3 cases/100,000 doses of Comirnaty®, 1.4 cases/100,000 doses of Spikevax®**), which corresponded to 1/6 to 1/3 of the official case rates from Canada (front N 389).

548 Pfizer, FN 278.

761 In the "Vigilance News" of May 2022[549] , Swissmedic published updated figures on the occurrence of myocarditis/pericarditis in connection with COVID "vaccination". For basic immunisation, the overall rate declared for COVID "vaccines" was 28.2 **cases**, for **Comirnaty® a** rate of **16.5 cases** and for **Spikevax® a** rate of **34.8 cases per million doses administered.** These case rates were now a factor of 2 to 5 higher than the case rates published in November 2021 and thus roughly corresponded to the Canadian figures which had already been published in 2021.

762 For booster vaccinations, the overall rate for the "vaccines" was 9.4, for Comirnaty® 10.8 and for Spikevax® 8.4 cases per million doses administered. One of the reasons Swissmedic gave for the lower myocarditis rates for the booster vaccinations was that the general willingness to report cases of myocarditis/pericarditis may have decreased in Switzerland during the booster vaccination campaign.

763 Table 1 of the "Vigilance News" of May 2022 also showed that the rate in **men** after a **basic immunisation** with **Spikevax® was** again significantly higher at **53.9 cases/million vaccine doses** and that the risk of myocarditis/pericarditis in connection with Comirnaty® after a booster was the same or even 2.6 times higher in women than with Spikevax®:

Tabelle 1: Geschätzte Melderaten nach mRNA-COVID-19-Impfung, nach Impfdosis und Geschlecht

Vaccine dose	Reporting rate estimates myocarditis/pericarditis per 1,000,000 doses	
	Female	*Male*
Cormirnaty 1st/2nd	9.8	21.4
Comirnaty booster	9.5	12.2
Spikevax 1st/2nd	14.7	53.9
Spikevax booster	3.7	13.1

764 Based on the EU adverse reaction figures, the adverse reactions reported by Swissmedic must be multiplied by at least a factor of 10 (N 501 f.), and based on international analyses (N 356) must be multiplied by a factor of at least 41 in order to reflect reality. If this is

549 Swissmedic, "Vigilance News - Edition 28", 05.2022, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/marktueberwachung/vigilance/vigilance-news-mai2022.pdf.download.pdf/DE_Vigilance-News-Edition_28_2022%2005%2023.pdf.

taken into account, the rate communicated by Swissmedic for myocarditis/pericarditis after basic immunisation is **1156.2 per million** (**1.16 per 1,000**) **doses of vaccine administered** instead of 28.**2, which** corresponds to an **"occasional"** and not "rare" **side effect** according to the official classification listed, among other things, in the technical information for Comirnaty®.

765 In the technical information for Comirnaty®[550] , the frequency of myocarditis/pericarditis was still stated as "not known" in May 2022 under the heading "Adverse effects", although concrete figures were available internationally and nationally, which Swissmedic itself had communicated.

766 In the section "Warnings and precautions" it was even misleadingly reported that only "very rare cases" of myocarditis and pericarditis had been observed after "vaccination" with Comirnaty®.

6.2. Complete lack of evidence of herpes zoster

767 Herpes zoster (shingles), which is caused by reactivation of the herpes zoster virus (responsible for chickenpox disease), is a **potentially serious disease** whose complications may include loss of employment, depression and social isolation.[551] According to the Swiss figures published by Swissmedic in the "Vigilance News" of June 2021[552] **, 60% of the reported cases of** herpes zoster were classified as **"severe".**

768 Pathophysiological mechanisms that could lead to a clustered occurrence of herpes zoster after COVID "vaccination" were revealed by experts in August 2021.[553]

769 As early as **May 2021, Swissmedic** reported **92 cases of herpes zoster** in connection with the COVID "vaccines"[554] and shortly afterwards addressed the occurrence of herpes zoster in connection with the COVID "vaccines" in the "Vigilance News" of June 2021[555] : **659 cases** (596 Comirnaty®, 63 Spikevax®) of **"herpes zoster" or "shingles" were reported there. "Shingles" that** were documented in the **WHO pharmacovigilance database** as at 12.4.2021. **Swissmedic concluded** that **herpes zoster** after COVID vaccina-

550 Swissmedicinfo, FN 48.
551 WAREHAM, "Herpes zoster", 07.06.2007, https://www.bmj.com/content/334/7605/1211.full.
552 Swissmedic, "Vigilance News - Edition 26", 06.2021, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/marktueberwachung/vigilance/vigilance-news-juni2021.pdf.download.pdf/DE_Vigilance-News-Edition_26_2021%2006.pdf.
553 Doctors for COVID Ethics, "Shots and Shingles: What Do They Tell Us?", 21.08.2021, https://doctors4covidethics.org/shots-and-shingles-what-do-they-tell-us/.
554 Swissmedic, "Side effects of Covid-19 vaccinations in Switzerland - Update", 7.5.2021, https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/nebenwirkungen-covid-19-impfungen-update-5.html.
555 Swissmedic, FN 552.

tion was **not an isolated case** and that **"healthcare professionals should develop an awareness of the possibility of herpes zoster as an adverse drug reaction under Covid-19 vaccines"**.

770 In the Swissmedic report of **November 2021**[556] , **herpes zoster** was in **6th place of the 15 most frequent adverse reactions with 203** reported **cases in** connection with the administration of **Comirnaty® , and in** the Swissmedic report of May 2022, with 231 reported cases in the meantime, it was in 7th place[557] :

Übersicht der gemeldeten Impfreaktionen bei Impfstoff Comirnaty® von Pfizer/BioNTech (Grundimmunisierung, zwei Impfdosen)

Rangliste der 15 häufigsten Nebenwirkungen

Headache (10019211)	636
Pyrexia (10037660)	520
Fatigue (10016256)	499
Myalgia (10028411)	318
Chills (10008531)	272
Dizziness (10013573)	248
Herpes zoster (10019974)	231
Nausea (10028813)	218
Arthralgia (10003239)	214
COVID-19 (10084268)	197
Dyspnoea (10013968)	185
Pain in extremity (10033425)	181
Injection site pain (10022086)	157
Vaccination failure (10046862)	149
Rash (10037844)	131

771 No such events were reported for Spikevax®.

772 Cases of herpes zoster thus demonstrably occurred significantly more frequently than events such as nausea, arthralgia (joint pain), pain in the extremities or pain at the injection site, which were officially listed as known (frequent) adverse reactions in the expert information for Comirnaty®.[558] Even though adverse reactions not listed in the expert information may be reported more frequently than listed adverse reactions, since the medical profession is obliged to report all unknown and serious adverse drug reactions (ADRs)

556 Swissmedic, FN 259.
557 Swissmedic, FN 339.
558 Swissmedicinfo, FN 48.

according to Art. 59 HMG, this rating provides clear indications of the relevance of herpes zoster as an adverse reaction in connection with the administration of Comirnaty® in Switzerland.

773 By 4 May 2022, **7 publications** reported **the occurrence of herpes zoster associated with the COVID "**vaccines**".**[559]

774 Despite Swissmedic's own findings in June 2021, despite the high number of cases of herpes zoster nationally and internationally, despite various publications describing the connection in addition, and despite the fact that herpes zoster was still in 7th place on Swissmedic's "Ranking of the 15 most frequent adverse reactions" in May 2022, Swissmedic has not taken any steps to update the summary of product characteristics. To date, herpes zoster has not been listed as a potential side effect in the SmPC of Comirnaty® .[560]

6.3. Complete lack of evidence of thromboembolic side effects

775 As early as November 2021, **thromboembolic events were** unmistakably among the **most common serious** adverse events reported by the *EMA* (front N 344) .

776 In November 2021, Swissmedic itself reported **698 cases of** "**vascular disorders"** (which also include thromboembolic events such as thromboses and embolisms) in connection with the COVID "vaccines". 203 cases were related to Comirnaty® , 495 cases to Spikevax®[561] .

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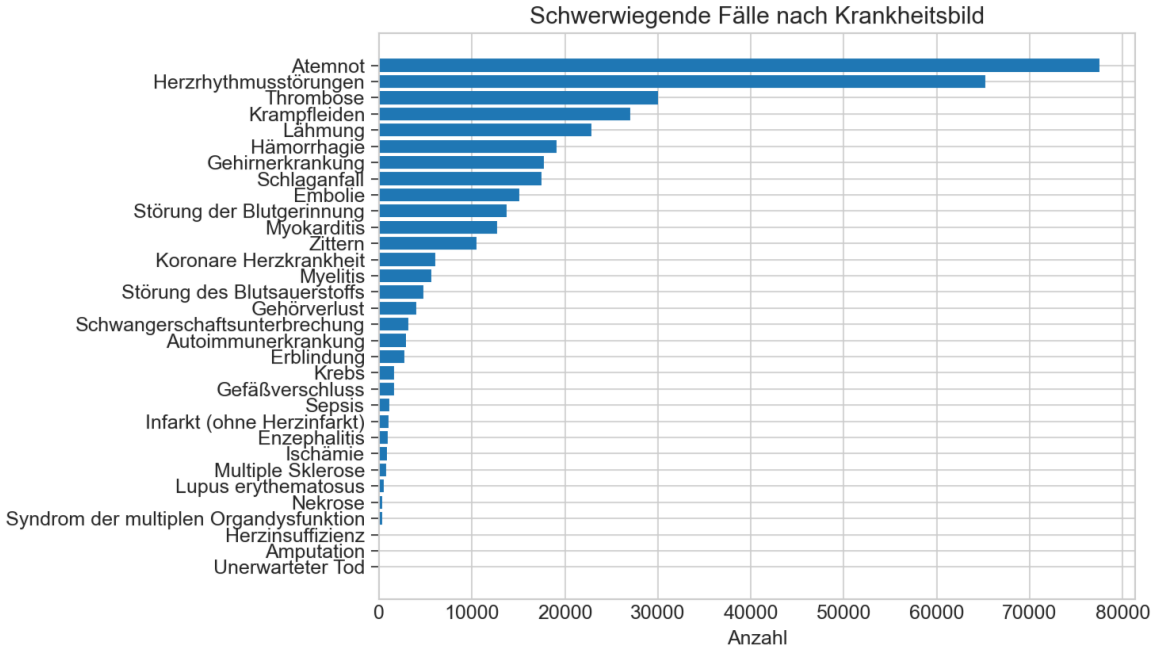
559 IWAI et al, "A Case of Acute Retinal Necrosis Associated with Reactivation of Varicella Zoster Virus after COVID-19 Vaccination", 22.11.2021, https://www.tandfonline.com/doi/abs/10.1080/09273948.2021.2001541; ZHENG et al, "Acute Retinal Necrosis from Reactivation of Varicella Zoster Virus following BNT162b2 mRNA COVID-19 Vaccination", 01.12.2021, https://pubmed.ncbi.nlm.nih.gov/34851795/; ABU-RUMEILEH et al., "Varicella zoster virus-induced neurological disease after COVID-19 vaccination: a retrospective monocentric study", 01.11.2021, https://link.springer.com/article/10.1007/s00415-021-10849-3; SARAIVA et al, "Varicella zoster virus reactivation following COVID-19 vaccination: a report of 3 cases", 04.03.2022, https://europepmc.org/article/pmc/pmc8903443; KATSIKAS et al., "Varicella Zoster Virus Reactivation Following COVID-19 Vaccination: A Systematic Review of Case Reports", 11.09.2021, https://www.mdpi.com/2076-393X/9/9/1013; MUNASINGHE et al, "Reactivation of varicella-zoster virus following mRNA COVID-19 vaccination in a patient with moderately differentiated adenocarcinoma of rectum: A case report", 26.02.2022, https://journals.sagepub.com/doi/full/10.1177/2050313X221077737; MOHTA et al., "Recurrent herpes zoster after COVID-19 vaccination in patients with chronic urticaria being treated with cyclosporine - A report of 3 cases, 20.11.2021", *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8661977/.*

560 Swissmedicinfo, FN 48.

561 Swissmedic, FN 259.

777 As of **6 May 2022,** Swissmedic reported **729 cases of** "**vascular disorders**": for Comirnaty®, the number of cases had increased to 261, for Spikevax® it had decreased to 468 - 27 "evaluated cases" had been deleted without explanation. [562]

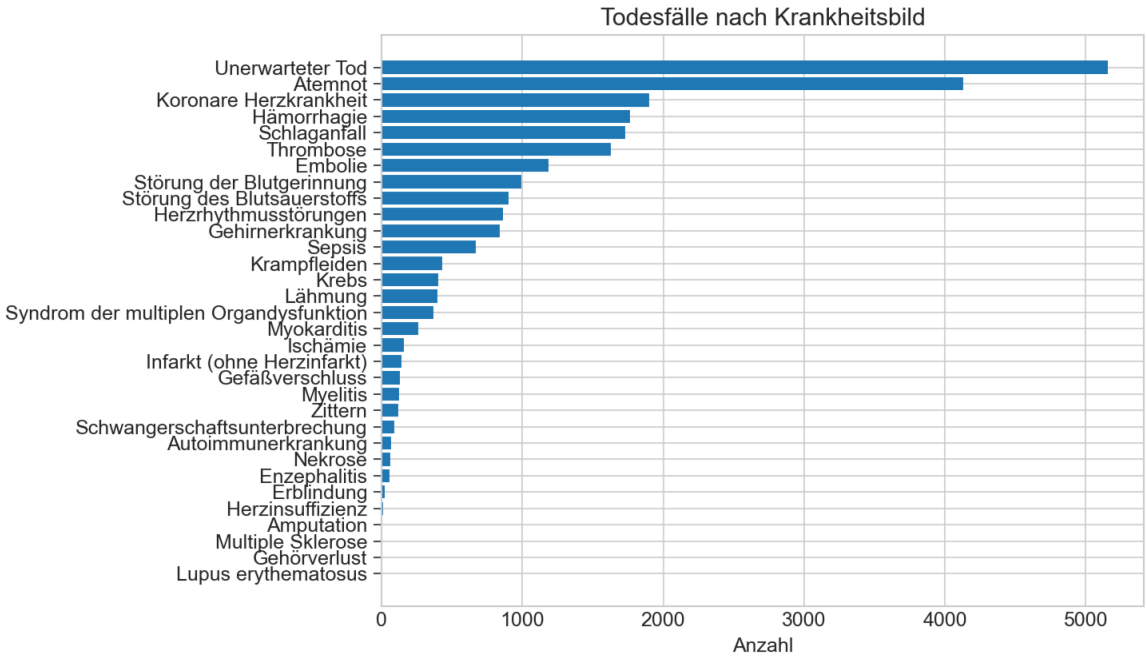
778 As of 6 May 2022, **clinical pictures associated with** a **thromboembolic event were** represented as the **main cause of serious** suspected **adverse events,** according to *EMA* figures: **Thrombosis** ranked **third**, **stroke ranked eighth** and **embolism ranked** ninth (Supplement **19**, p. 25):



779 All these thromboembolic events occurred even more frequently than myocarditis (11th place), for which a causal relationship with COVID "vaccination" has now been recognised.

780 In the case of deaths reported in a temporal connection with COVID "vaccinations", thromboembolic events were also in the top seven positions as the cause, well ahead of myocarditis (Supplement **19**, p. 26):

562 Swissmedic, FN 339.



BO: Supplement **19:** Daily report of serious side effects of COVID 19 vaccinations, Status 06.05.2022

781 By March 2022, more than 200 peer-reviewed publications had described the association between the occurrence of thromboembolic events and COVID "vaccinations" (front N 287 ff., N 435 ff. and N 553 ff.).

782 In view of this overwhelming data situation and the internationally available concrete figures on suspected cases of adverse reactions, it is incomprehensible why thromboembolic events were not listed in the expert information of Comirnaty® and Spikevax® until May 2022[563] and why Swissmedic did not draw the attention of either the medical profession or the public to this risk.

6.4. Patients with increased tendency to clot: "Contraindications" and "Warnings and precautions" completely inadequate

783 In the **"Contraindications"** section, the doctor is usually informed in **which cases** (e.g. for which diseases) he **must not administer or prescribe a medicine to** his patient **because he would otherwise expose him to a great risk**. The doctor is thus informed, for example, that he must not prescribe a "blood thinner" (anticoagulant for thrombosis treatment or stroke prophylaxis, e.g. Pradaxa®) to a patient with a high risk of bleeding, active bleeding or if the patient has had a cerebral haemorrhage within the last six months, because the patient could then "bleed to death". The increased risk of bleeding, active

563 Swissmedicinfo, FN 48 and FN 71.

bleeding or a cerebral haemorrhage within the last six months are listed in the "Contraindications" section for a "blood-thinning drug" such as Pradaxa®[564] in order to prevent the patient from being mistakenly treated with a drug that is unsuitable for him/her and thus suffering great harm.

784 In the section **"Warnings and precautions", the** doctor is informed of **possible dangers** or insufficient **data in connection with the medicinal product. For example, the** doctor's attention is drawn to the fact that he/she must not prescribe the sedative Valium® to alcohol-dependent patients (because of an increased addiction potential), to patients with an existing severe respiratory depression (because of additional suppression of breathing by Valium®) or to patients with impaired liver function (because of additional impairment of liver function by Valium®), or that he/she must do so only with great caution. Similarly, this section indicates to the doctor that no data are available for use in children under 6 months of age and that Valium® should therefore only be used in this age group with great caution and only if no alternative therapy is available.[565]

785 **It is clear from the above descriptions that missing or incomplete information on potential hazards under the headings "Contraindications" and "Warnings and precautions" can have serious consequences for doctors and patients.**

786 As shown above, **thromboembolic events were not listed as adverse events under the heading "Adverse events" until May 2022, despite clear data.** In the following, it is shown that the lack of information on such hazards is associated with far-reaching consequences:

787 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 hazard in this case in the section "Contraindications") or should only be administered with caution or under supervision (e.g. monitoring of certain coagulation parameters such as D-dimers) (listing of the hazard in this case in the section "Warnings and precautions").

788 Therefore, it would have to be pointed out in the expert information that the COVID "vaccines" must not be administered to patients with an increased risk of a thromboembolic event, e.g. patients who have already suffered a thrombosis/embolism, pregnant women, cancer patients or bedridden patients (reduced mobility), or only under close monitoring of the coagulation parameters.

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564 Swissmedicinfo, "Specialist information Pradaxa", as at 04.2022, https://www.swissmedicinfo.ch/ShowText.aspx?textType=FI&lang=DE&authNr=61385.

565 Swissmedicinfo, "Fachinformation Valium", as of 09.2018, https://www.swissmedicinfo.ch/ShowText.aspx?textType=FI&lang=DE&authNr=28840.

789 This was implemented accordingly for the oncological drug Revlimid®, which was also associated with an increased rate of thromboembolic events. Thus it states there under the heading "Warnings and precautions": "*Patients with known risk factors for the occurrence of a thromboembolism - including a previous occurrence of thrombosis - must therefore be closely monitored. Patients must therefore be instructed to seek medical attention if they experience symptoms such as shortness of breath, cough, chest pain or pain and/or swelling in the arms and legs.* "[566]

790 For the COVID "vaccines", the corresponding section concerning risks related to blood clotting only warns of haematoma (bruising), but not of thromboembolic events: "*Thrombocytopenia and coagulation disorders: As with other intramuscular injections, the vaccine should be administered with caution to persons receiving anticoagulant therapy or to persons with thrombocytopenia or a coagulation disorder (e.g. haemophilia), as bleeding or bruising may occur in this population following intramuscular administration.* "[567]

6.5. Interim conclusion

791 The preceding sections show that Swissmedic violated all requirements with regard to the COVID "vaccines": Safety signals from the studies and the post-marketing phase were demonstrably ignored, and drug texts were not updated with regard to identified risks. The population and the medical profession were not informed about hazards and were not given appropriate recommendations on how to behave. Swissmedic thus once again failed in its duty to protect the population from emerging risks.

III. Further omissions and appeasements by Swissmedic

1. Swissmedic: "Vaccines" are "safe

792 For the individual publicity announcements on the approval of mRNA "vaccines", see introductory N 5 ff.

2. Swissmedic: Probably no hereditary genetic damage/carcinogenic effect

793 In the technical information for Comirnaty® and Spikevax®, under the heading "*Preclinical data*", it has been stated since the temporary marketing authorisations were granted:

566 Swissmedicinfo, "Fachinformation Revlimid", as of 01.2020, https://www.swissmedicinfo.ch/ShowText.aspx?textType=FI&lang=DE&authNr=57712.

567 Swissmedicinfo, FN 48 and FN 71.

> "**Neither genotoxicity nor carcinogenicity studies have been conducted** (for Comirnaty®). **The components of the vaccine (lipids and mRNA) are not expected to have genotoxic potential.** "[568]
>
> "**Spikevax® has not been studied in animals for carcinogenicity or male infertility.** Given the **short-term administration of** Spikevax, long-term animal studies are not required to evaluate its carcinogenic potential.... The genotoxic risk to humans is considered to be low due to **minimal systemic exposure** after intramuscular administration, limited duration of exposure and negative in vitro results. "[569]

794 Without conducting appropriate studies, it is thus freely claimed that the "vaccines" would probably not have any mutagenic and carcinogenic effects. The formulations of "short-term administration" and "minimal systemic exposure after intramuscular application" are also false and misleading, since it had already been proven in studies before the temporary approval was granted that the lipid nanoparticles (LNP) and thus the mRNA contained therein accumulated after administration in various organs such as the liver and spleen - and did not remain in the muscle at the injection site (N 146 f.).

795 There was no question of "short-term administration" from the outset: Even **before the temporary authorisation was granted, it was known** (also to Swissmedic) that **regular booster vaccinations** were **planned due to the expected lack of effectiveness of** the "basic immunisation" (N 451).

796 "Swissmedic" only requested preclinical toxicity studies with regard to reproduction and development (Annex **2**, p. 7), although the *HMEC* (*Human Medicines Expert Committee)* commissioned by Swissmedic in connection with the assessment of the authorisation documentation of the COVID "vaccines" **had** explicitly **complained "that reproduction, genotoxicity and neurotoxicity studies were missing and should be provided subsequently"** (Annex **2**, p. 15). It has already been shown that the reproduction studies carried out were insufficient overall and also indicated an increased risk in pregnant women (N 109 ff.).

797 Swissmedic violated its duty to protect the Swiss population from risks associated with medicinal products by not requiring Pfizer and Moderna to soundly clarify key questions about the potential harmfulness of the COVID "vaccines" and their components in animal studies before using them in humans.

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568 Swissmedicinfo, FN 48.
569 Swissmedicinfo, FN 71.

798 Since the COVID "vaccines" do not formally correspond to a vaccine at all, as they demonstrably do not immunise (front N 564 ff.) and since these medicinal products are completely novel gene therapies that had never been authorised for use in humans in this form, Swissmedic's requirements with regard to preclinical studies should also have been all the more stringent. It would have been Swissmedic's duty to authorise the COVID "vaccines" only after solid preclinical data had become available proving that these novel medicinal products are not associated with an increased risk to reproduction, to genetic material or to the development of cancer. The fact that Swissmedic has not fulfilled this task to date is in no way comprehensible .

3. [Swissmedic: "No evidence of accumulation of the LNP"].

799 [Remarks exclusively in criminal complaint.]

4. Swissmedic: "No proven fatalities".

800 Swissmedic denied a causal relationship between the "vaccination" and the reported deaths: "*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. "*The reports of deaths have been analysed particularly carefully and in a few cases final results of autopsies are still pending, Swissmedic said.[570]

5. Swissmedic plays down side effects

801 As of **7 May 2021, Swissmedic reported 1953 suspected adverse reactions in** connection with the COVID vaccines, of which **35.9%** were classified as **serious.**[571] Among other things, **92 cases of herpes zoster** and **76 deaths were** reported in **a temporal connection** with the COVID "vaccination". Although the proportion of serious side effects was around 40% and this clearly deviated from the officially communicated side effect pattern of the 2-month data of the approval studies, where officially mainly "mild to moderate side effects" were reported (front N 163), Swissmedic came to the conclusion that the reports "***confirmed the side effect profile known from the licensing studies***", "the ***reports provide a clearer picture of the safety of the vaccines in daily use****" and*

570 Swissmedic, FN 571.

571 Swissmedic, "Side effects of Covid-19 vaccinations in Switzerland", 07.05.2021, https://www.admin.ch/gov/de/start/dokumentation/medienmitteilungen.msg-id-83437.html.

*"do **not change the known positive benefit-risk ratio of the two mRNA vaccines used***".

6. Swissmedic disseminates false information in "Vigilance-News

802 Swissmedic's journal "Vigilance News" is aimed at healthcare professionals and regularly informs them about news relating to 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".[572]

803 Swissmedic even reported further, stating: "There **are only a few examples of other signals in the literature...**". It remains unclear which literature Swissmedic is referring to here.

IV. "FAQ" on Swissmedic website

804 Swissmedic publishes *questions and answers about COVID-19 vaccines on* its website for the general public (*"FAQ on COVID-19 vaccines*") and still makes the following statements there, among others.[573]

1. Question: Are the COVID vaccines safe?

805 Answer: *"The vaccines against Covid-19 were thoroughly tested during their development and then carefully reviewed by Swissmedic experts. Only vaccines that are 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."*

806 Front (N 22 ff., N 189 ff., N 219 ff., N 290 ff., N 299 ff., N 437 ff., N 504 ff., N 555 ff.) provides detailed evidence that the COVID "vaccines" are largely ineffective and unsafe and that the quality has been insufficiently proven. In this response, Swissmedic omits the extremely relevant information for the public that the COVID "vaccines" were only approved for a limited period of time based on incomplete documentation and that reports of side effects and deaths in connection with COVID "vaccinations" are being reported worldwide on an unprecedented scale.

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572 Swissmedic, "Vigilance-News", May 2022 edition, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/marktueberwachung/vigilance/vigilance-news-mai2022.pdf.download.pdf/DE_Vigilance-News-Edition_28_2022%2005%2023.pdf.

573 Swissmedic, FN 201.

2. Question: Do the vaccines work?

807 Answer: *"Only vaccines with proven efficacy are licensed in Switzerland. The vaccine manufacturers have conducted 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 courses of the disease."*

808 Front (N 189 ff., N 290 ff., N 437 ff., N 555 ff.), it is shown that the COVID "vaccines" have not yet shown any relevant efficacy, neither in registration studies nor in "*real world evidence data".* To date, no prospective randomised study has shown that the COVID "vaccines" reduce severe courses. Current data from various countries show that hospitalisations and deaths due to COVID disease are driven by multiple vaccinees (see N 582 ff.) In the technical information for Comirnaty® as of December 2021, Pfizer, in consultation with Swissmedic (based on 3 versus 1 case in 36,621 study participants), declares an efficacy of 66.4% for "severe courses of COVID" (see above N 209).

809 Since Swissmedic is also aware of an analysis showing that the figures in the Comirnaty® registration trial are incorrect, that 1594 "symptomatic COVID *cases*" occurred in the vaccine group and 1816 in the placebo group in which no PCR test was subsequently carried out for undisclosed reasons ("*suspected but unconfirmed cases*"), and that the overall effectiveness of the vaccine, taking these figures into account, is only 19% (see N 200 f.), it is deliberately spreading misinformation with the incorrectly high efficacy figures in this answer.

3. Question: Isn't it healthier if I go through the disease to gain immunity?

810 Answer: *"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."*

811 This answer is false and misleading, as figures from various countries show that "vaccination" makes people more susceptible to COVID-related illnesses, hospitalisations and deaths (see N 582 ff.) and numerous studies published in the renowned journals *Nature* and *British Medical Journal, among others,* prove that the immunity generated by COVID

is broader and longer-lasting than after "vaccination" (front N 298 ff., N 478, N 505 ff, N 568 ff.). [574]

4. Question: Do mRNA vaccines change my DNA?

812 Answer: *"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 case 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."*

813 This answer is incorrect and contradicts Swissmedic's own assessment of this issue. It is clear from the letter of authorisation to Moderna that, with reference to a study published in December 2020 showing that viral RNA from SARS-CoV-2 could be integrated into the human genome in a roundabout way via "reverse transcription", Swissmedic itself assesses the risk as "very small", i.e. potentially present (front N 48 f.).

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574 FERRETTI et al, "Unbiased screens show CD8+T cells of COVID-19 patients recognize shared epitopes in SARS-CoV-2 that largely reside outside the spike protein", 20 Oct 2020, *https://www.cell.com/immunity/fulltext/S1074-7613(20)30447-7*; ISRAEL et al., "Large-scale study of antibody titer decay following BNT162b2 mRNA vaccine or SARS-CoV-2 infection", preprint dated 22/08/2021, *https://www.medrxiv.org/content/10.1101/2021.08.19.21262111v1*, final publication dated 31/12/2021, https://www.mdpi.com/2076-393X/10/1/64; GAZIT et al., "Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections", preprint of 25.08.2021, https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1; Science, "Having SARS-CoV-2 once confers much greater immunity than a vaccine - but vaccination remains vital", 26.08.2021, *https://www.science.org/content/article/having-sars-cov-2-once-confers-much-greater-immunity-vaccination-remains-vital; BMJ, "Vaccinating people who have had covid-19: why doesn't natural immunity count in the US?", 13.09.2021, https://www.bmj.com/content/374/bmj.n2101, https://www.nature.com/articles/s41586-021-03647-4; BMJ, "Correction - Vaccinating people who have had covid-19: why doesn't natural immunity count in the US?" 15.09.2021, https://www.bmj.com/content/374/bmj.n2272; SHRESTHA et al., "Necessity of COVID-19 vaccination in previously infected individuals", preprint dated 19/06/2021, https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v3*, definitive publication dated 31/12/2021, *https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciac022/6507165?login=false; COHEN et al., "Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells", 14.07.2021, https://www.cell.com/cell-reports-medicine/fulltext/S2666-3791(21)00203-2#%20;* MURCHU et al, "Quantifying the risk of SARS-CoV-2 reinfection over time", 18.05.2021, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8209951/pdf/RMV-9999-e2260.pdf;* Pharmazeutische Zeitung, *FN* 391.

5. Question: What vaccination reactions should I expect?

814 Answer: "*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 feverish or fever.* "

815 In this response, Swissmedic plays down the side effects by listing mainly mild events and thus pretending that the side effect profile is comparable to a flu vaccination. This is demonstrably not the case (see above N 262 ff.). In its reply, Swissmedic omits all the serious side effects which, according to the technical information of the COVID vaccines, can occur "very frequently" (such as enlarged lymph nodes [lymphadenopathy]), "rarely" (such as paralysis of the face [facial paresis]) or with an (allegedly) "unknown frequency" (such as myocarditis/pericarditis).[575]

6. Question: I am pregnant or would like to become pregnant soon. Can the vaccination affect my fertility?

816 Answer: *"The vaccine does not affect 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."*

817 Swissmedic's response is false, misleading, trivialising and contradicts the assessment of the *HMEC* commissioned by Swissmedic to assess the marketing authorisation dossier, which concluded that preclinical studies had identified a possible risk in pregnancies. Pregnant women were excluded from participation in the registration studies. To date, there are no solid data to support Swissmedic's statements, only indications pointing to a significantly increased risk for pregnant women (see above N 109 ff., N 396 ff., N 518, N 744 ff.). A corrigendum in the renowned *New England Journal of Medicine to* a study used by the *ECIF in* its vaccination recommendation (Supplement **15**) to substantiate the alleged safety of the vaccines in pregnant women reveals that at the time the study report was written, no follow-up examination had yet taken place up to the 20th week of pregnancy for 905 of the 1224 participants who were vaccinated within 30 days before the first day of the last menstruation or in the first trimester.[576] The data base for the claim that "vaccination" of pregnant women, especially during the first trimester, is thus absolutely insufficient. Current postmarketing data show risks for pregnant and breastfeeding women

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575 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.

576 SHIMABUKURO et al. , FN 542 and 546.

(see N 480, N 518). Pfizer/BioNTech themselves disclose safety concerns about the use of Comirnaty® in pregnant women in an "Informed Consent" form dated 15.12.2021 (N 396).

7. Conclusion: Swissmedic violates HMG Art.1 and the Ordinance on the Advertising of Medicinal Products (AWV).

818 In summary, it must be stated that the information disseminated by Swissmedic is demonstrably false, unbalanced and misleading. Critical information is deliberately withheld by Swissmedic, known risks are concealed and readers are persuaded to "vaccinate" based on a false positive benefit-risk ratio, at least indirectly and probably directly.

List of supplements Evidence Report (ER)

Supplement **1:**	Sources (list) ER
Supplement **2:**	Marketing authorisation decision Comirnaty from Pfizer incl. minutes of the HMEC meeting of 18.12.2020, Swissmedic, 19.12.2020
Supplement **3:**	Authorisation decision COVID-19 Vaccine from Moderna, Swissmedic, 12.01.2021
Supplement **4:**	Specialised information Comirnaty, Swissmedicinfo, 12.2020
Supplement **5:**	E-mail response regarding pharmacopoeia, Swissmedic, 06.01.2022
Supplement **6:**	Safety data sheet, Cayman chemical, 11.04.2021
Supplement **7:**	E-mail response regarding comirnaty fertility trials, Pfizer, 07.01.2021
Supplement **8:**	Periodic Safety Update Report #1 for COVID-19-mRNA-vaccine BNT162b2, 19.08.2021
Supplement **9:**	Daily report of serious adverse reactions to COVID-19 vaccinations, as of 01.04.2022
Supplement **10:**	E-mail response regarding serious deficiencies in the conduct of phase 3 studies of Pfizer mRNA vaccines: Consequences?, Swissmedic, 04.11.2021
Supplement **11:**	E-mail regarding analysis of the Pfizer study by the Canadian Covid Care Alliance, EpiLunar Partners AG, 04.01.2022
Supplement **12:**	E-mail response regarding analysis of the Pfizer study by the Canadian Covid Care Alliance, Swissmedic, 01.02.2022
Supplement **13:**	Daily report of serious adverse reactions to COVID 19 vaccinations, as of 17.09.2021
Supplement **14:**	Daily report of serious side effects of COVID-19 vaccinations, as of 11.02.2022
Supplement **15:**	Vaccination recommendation for mRNA vaccines against Covid-19, BAG/EKIF, Status 21.01.2022
Supplement **16:**	Daily report of serious side effects of COVID-19 vaccinations, as of 22.04.2022
Supplement **17:**	Cincinnati Children's Hospital medical centre, Informed Consent Form (Sub Study C), 14.12.2021
Supplement **18:**	Daily report of serious adverse reactions to COVID 19 vaccinations, as of 25.03.2022
Supplement **19:**	Daily report of serious adverse reactions to COVID 19 vaccinations, as of 06.05.2022
Supplement **20:**	Strong facts: Switzerland, as of 13.04.2022
Supplement **21:**	E-mail response regarding vaccination status, Cantonal Hospital St. Gallen, 23.08.2021
Supplement **22:**	University Hospital Zurich (USZ), "Internal information, recording vaccination status in KISIM", 30.11.2021
Supplement **23:**	Lucerne Cantonal Hospital, LUKiS News, recording certificate 'if clinically relevant', 27.11.2021