BAHNER ■

fachanceltscancelheidelberg doctor | medicine | health law

beatebahner

fachanwardingformedizinrecommendiatoringformedicautoringsprings

representa t ion | advisories |

contracts www.beatebahner.

de

| BAHNER ■ law firm | voßstr. 3 | 69115 heidelberg

December 27, 2021

Legal opinion on criminal liability

of the manufacturer Biontech, the representatives of the authorities involved, the vaccinating physicians, the employers involved,
Judges (especially family court judges), guardians ad litem, parents and other involved parties

according to the German Medicines Act

(punishable by imprisonment for up to 10 years)

through the production, distribution and use (vaccination) of Pfizer/Biontech's Comirnaty vaccine.

The legal opinion was prepared by **Beate Bahner, specialist lawyer for medical law** and **author of** the book "Corona vaccination: What doctors and

patients should absolutely know".

law firm
bahner voßstr.
3
69115 heidelberg

0 62 21 / 33 93 68 0 tel
0 62 21 / 33 93 68 9 fax
info@beatebahner.de

sales tax
identification
32011/30304

commerzbank
IBAN DE26 6708 0050 0521 9486 00
BIC DRESDEFF670|

Table of contents

List of abbreviations

AMGArzneimittelgesetz
AMWHVArdinance on the manufacture ofmedicinal products and active substances ECEuropean Community
EC European Community
EMAEuropean Medicines Agency
EUEuropean Union
ff.cont
GMPGood Manufacturing Practice
in connection with
LNPLipid nanoparticles
mRNAmessengerribonucleic acid (also known as messenger RNA or messenger RNA)
m.w.Nwith further evidence
PEIPaul Ehrlich Institute
Ph. EurPharmacopoeia Europea, European Pharmacopoeia or European Pharmacopoeia RKIRobert Koch Institute
RLDirective
SOSpecial Obligations
VOdecree
WMAWorld Medical Association

Corona vaccination with the substance Comirnaty must not be performed under any circumstances:

There is a concrete danger to life!

1. Vaccination with Comirnaty is a criminal offense according to § 95 AMG

The Comirnaty vaccine must not be vaccinated under any circumstances. Every physician and every person who carries out a vaccination or has it carried out or contributes to it commits an offense according to § 95 para. 1 no. 1 in connection with. No. 3a German Medicines Act (AMG):

§ Section 95 AMG: Penal provisions

(1) Punishable by imprisonment for up to three years or a fine,

*1. whoever, contrary to **section 5**, paragraph 1, places a medicinal product **on** the market or **uses it on others** ...*

....

*3a. in contravention of **Section 8** (1) No. 1 or (2), also in conjunction with Section 73 (4) or Section 73a, manufactures, places on the market or otherwise trades in medicinal products or active substances.*

*The **attempt is punishable**.*

*(3) In **particularly serious cases,** the penalty is imprisonment from one year to **ten years**. As a rule, a particularly serious case exists if the offender*

1. by one of the acts referred to in paragraph 1

a) endangers the health of a large number of people,

*b) another to **the risk of death** or **serious injury**. **to** body or health.*

1.1 Violation of § 8 AMG due to serious deviation from the recognized pharmaceutical rules

1.2 Purpose and definitions of the AMG

The vaccine Comirnaty from Biontech must not be vaccinated because its production by Biontech violates the German Medicines Act (AMG) in an **unprecedented** and **deliberate manner.**

The purpose of the German Medicines Act (AMG) is to ensure, in the interest of a proper supply of medicines to humans and animals, the **safety of the** trade in medicines, in particular the **quality**, efficacy and **safety of** medicines in accordance with the following regulations, Section 1 AMG.

All Corona vaccines, and thus also the Comirnaty vaccine, are so-called medicinal products within the meaning of Section 2 (1) of the German Medicines Act (AMG) according to Section 4 (4) AMG and are therefore also subject to the regulations of the German Medicines Act.

§ 2 AMG Definition of medicinal product

(1) Medicinal products are substances or preparations of substances,

1. intended for use in or on the human ... body and intended as agents having properties for the cure or mitigation or prevention of human ... diseases or pathological conditions.

§ 4 Other definitions

(4) ***Vaccines are medicinal products within the*** *meaning of Section 2 (1) which contain antigens or recombinant nucleic acids and which are intended to be used in humans or animals for the production of specific defense and protective substances and, insofar as they contain recombinant nucleic acids, are intended exclusively for the prevention or treatment of infectious diseases.*

1.3 Prohibitions to protect against deception

To ensure people's safety, the Medicines Act contains various prohibitions, violations of which are considered criminal offenses and are therefore sanctioned by fines and even imprisonment.

The production of the Comirnaty vaccine violates the so-called "prohibition of deception" of Section 8 (1) No. 1 AMG in several respects. According to this, it is prohibited to manufacture or market medicinal products or active ingredients **whose quality is** not insignificantly **reduced by** deviation from the recognized pharmaceutical rules.

> ***§ Section 8 AMG: Prohibitions to protect against deception***
>
> *1) It is prohibited to manufacture or place on the market medicinal products or active substances that are*
>
> *1. are not insignificantly reduced in quality due to deviation from the recognized pharmaceutical rules.*

1.4 Legal basis of the recognized pharmaceutical rules

The production and marketing of the vaccine Comirnaty, which has also been vaccinated in children and adolescents since July 2021, seriously deviates from the recognized pharmaceutical rules within the meaning of Section 8 (1) No. 1 of the German Medicines Act (AMG) for various reasons and thus also from the rules of so-called "good manu- facturing practice" applicable **throughout Europe** (and internationally).

These "**recognized pharmaceutical rules"** are mandatory for all manufacturers in the following legislation:

- in the European Directive **RL 2001/83/EC,**
- in the European **Directive 2003/94/EC** and
- in the **Ordinance on the Manufacture of Pharmaceuticals and Active Pharmaceutical Ingredients (AMWHV)**

1.5 Massive violations of "good manufacturing practice

Good Manufacturing Practice (GMP) refers to **guidelines for quality assurance of the production processes** and environment in the production of pharmaceuticals and active ingredients, but also cosmetics, food and feed.

Quality assurance plays **a central role** in **pharmaceutical manufacturing**, as **quality deviations** here can have a **direct impact on** consumer **health.** A GMP-compliant quality management system serves to ensure product quality and compliance with the mandatory requirements of the health authorities for marketing.

Corresponding guidelines for the pharmaceutical sector have been issued, for example, by the **European Commission**, cf. for example

https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/Statistics/GKV/Notices/GMP-Guideline/Introduction-EG-GMP-Guideline.pdf.pdf.

The Pharmaceutical Inspection Co-Operation Scheme (PIC/S), the U.S. Food and Drug Administration (FDA), and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) (formerly for Active Substances and Quality Risk Management).

The term "good manufacturing practice" was introduced in 1962 by the Food and Drug Administration through the current good manufacturing practice (cGMP) initiative, cf.

https://de.wikipedia.org/wiki/Gute_Herstellungspraxis

In Germany, the application of good manufacturing practice for the production of medicinal products and active pharmaceutical ingredients is regulated in the **Ordinance on the Production of Medicinal Products and Active Pharmaceutical Ingredients (AMWHV).**

2. Use of essential components of the vaccine on/in humans not intended

2.1 Novel nano-lipids used in vaccine for the first time

According to Pfizer/Biontech's own product information, the vaccine consists of the following two excipients, among others:

1. (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) **(ALC-0315)**
2. 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide **(ALC-0159),** in the following only **ALC-0315 and ALC-0159**

These substances **ALC-0315 and ALC-0159** are so-called "**par- ticle-forming nanolipids**", also called "**lipid nanoparticles**" (**LNP**), which are demonstrably used in the Biontech vaccine "BNT162b2".

Lipid nanoparticles were chosen as a carrier medium to protect the mRNA from degradation and to facilitate penetration into somatic cells. The LNPs consist of a mixture of phospholipids, cholesterol, PEGylated lipids, and **cationic or ionizable lipids**. The phospholipids and choleste- rin have structural and stabilizing functions, while the PEGylated lipids support prolonged distribution throughout the body.

The ingredients are listed as the **first two constituents in the** Pfizer/Biontech Comirnaty **product information** ("Annex I Summary of Product Characteristics") submitted to the Euro- pean Medicine Agency (EMA).

Proof: Product information on Comirnaty, page 16

https://www.ema.europa.eu/en/documents/product-information/comirnaty-e-par-product-information_en.pdf

Both **substances ALC-0315 and ALC-0159** are also mentioned in the **safety report of** the **Paul Ehrlich Institute** (PEI), which is responsible for vaccines, dated February 4, 2021.

Evidence: PEI **safety report** dated 4.2.2021, p. 14

https://www.pei.de/SharedDocs/Down- loads/EN/newsroom/dossiers/safety-reports/safety-report-27-12-to-31-01-21.pdf.

2.2 No use of ALC-0315 and ALC-0159 on/in humans.

According to the information provided by various manufacturers of these substances (e.g. **Echelon, Ca- yman, MedChem)**, these substances are **not to be used on or in humans,** but exclusively for research purposes, cf. for example the information provided by the US company Echelon Bioscienses:

"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."

https://www.echelon-inc.com/product/alc-0315/

https://www.echelon-inc.com/product/alc-0159/

The statement "not for human use" on the homepage of the company Echelon Bioscienses was removed by the company on the same day of the announcement of the non-approval of these substances for human use on Dec. 19, 2021. However, the original page is saved as a PDF.

The statements remaining on the homepage now read only as follows: "**for research only**". However, this means the same, namely the **lack of suitability of** the substance ALC-0315 as an ingredient of a medicinal product for use in or on humans.

3. Violation of § 55 AMG (Pharmacopoeia)

Normally, only those starting materials are used in the manufacture of medicinal products which are included in the **European** or **German Pharmacopoeia** (§ 55 AMG) and for which there are so-called "monographs". These monographs contain the manufacturing and testing steps for the corresponding substances.

§ 55 (1) AMG reads:

*"(1) The Pharmacopoeia is a **collection of recognized pharmaceutical rules on the quality, testing,** storage, administration and designation of medicinal products and the **substances used in their manufacture, published by** the Federal Institute for Drugs and Medical Devices in agreement with the Paul Ehrlich Institute and **the** Federal Office for Consumer Protection and Food Safety.*

§ 55 (8) AMG regulates:

*"(8) In the manufacture of medicinal products, **only substances** and the containers and wrappings, insofar as they come into contact with the medicinal products, **may be used,** and only dosage forms **may be** prepared, **which comply with the recognized pharmaceutical rules."***

3.1 The ingredients ALC-0315 and ALC-0159 are not included in the pharmacopoeia

The two ingredients included in BioNTtech's product information for the Comirnaty vaccine are as follows

(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)
(ALC-0315)

2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide
(ALC-0159)

are **not included in the Pharmacopoeia**, neither in the German Pharmacopoeia nor in the European Pharmacopoeia.

They were **developed** by Biontech as a **new formulation** and are produced by various manufacturers on behalf of Biontech - including in Germany - for the production of the Comirnaty vaccine.

These are therefore so-called "**novel excipients**".

3.2 Novelty of excipients confirmed by EMA report

The novelty of these two adjuvants of the Comirnaty vaccine is also explicitly confirmed in the original "Assessment Report" of the Euro- pean Medicine Agency (EMA) of Feb. 19, 2021. There it states:

> *"All excipients **except the functional lipids ALC-0315 and ALC-0159** and the structural lipid DSPC comply with Ph. Eur.*
>
> *The functional lipid excipients ALC-0315 and ALC-0159 are classified as **novel excipients**".*

Translated, this means that the two lipids **ALC-0315 and ALC-0159 do** not comply with European pharmaceutical regulations.

The same **EMA assessment report dated February 19, 2021** (Assessment Re- port) states further down on page 23:

> *Novel excipients:*
>
> ***Two novel excipients are included in** the finished product, the cationic lipid ALC- 0315 and the PEGylated lipid ALC-0159. **Limited information** regarding the novel excipients are provided.*

The EMA itself thus states that only limited in- formation was submitted for the two substances ALC-0315 and ALC-0159.

Evidence: Assessment Report EMA Comirnaty v. 19.2.2021 (Assessment Report EMA), Page 23

> https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf.

3.3 Special requirements for novel excipients

If a substance is not included in the European or German Pharmacopoeia, special requirements are placed on its documentation. The Annex to **Directive 2001/83/EC** regulates under Module 3, Number 3.2.2.4 d):

> ***d) Novel excipients:***
>
> *If an excipient(s) is (are) used for the first time in a medicinal product or if this is done by a new route of administration,* ***comprehensive information on the manufacture****,* ***characterization*** *and controls shall be provided, with cross-references to both the preclinical and clinical data on uncertainty in accordance with the active substance format described above.*
>
> ***A document containing detailed chemical, pharmaceutical and biological information shall be presented.*** *The presentation of these data shall be in the same order as in the chapter on active substances under Module 3.*
>
> *The information on a novel excipient (novel excipients) may be submitted as a stand-alone document in the form described above. If the applicant and the manufacturer of the novel excipient are not the same, this document shall be provided to the applicant for submission to the competent authority.*
>
> *Additional information on the* ***toxicity studies with the novel excipient*** *shall be provided under Module 4 of the application****.***
>
> ***Clinical studies*** *are to be submitted under Module 5.*

3.4 First-time and novel use of excipients

The ingredients ALC-0315 and ALC-0159 are being used in a drug for **the first time**. On the other hand, this is also done "**by a new method of administration**". The legal requirements of **Directive 2001/83/EC** Module 3, Para.
3.2.2.4 d) are thus fulfilled. Before using these two excipients, it is therefore mandatory to carry out special studies, special data and special documents on the

- Production
- Characterization
- Controls

regarding the chemical, pharmaceutical and biological information of the two novel and first-time ingredients ALC-0315 and ALC- 0159.

3.5 Further requirements for the excipients

The same is regulated by Section 13 (3) sentence 1 AMWHV: According to this provision, excipients may only be used in the manufacture of medicinal products if they have been produced in accordance with Good Manufacturing Practice.

Good Manufacturing Practice" is defined in the **EU GMP Guideline**, which is directly applicable in Germany due to the regulation in the AMWHV. The EU GMP Guide states in **Chapter 1 under Principles:**

> *The holder of a manufacturing authorization shall manufacture drugs in a manner **that ensures their suitability for their intended use**, complies with the requirements of the drug authorization or clinical trial authorization, as applicable, and does not expose patients to hazards due to inadequate safety, quality, or efficacy."*

RL 2001/83/EC Module 3, Number 3.2.2.4 a):

> *All materials required for the manufacture of the excipient(s) shall be listed, indicating at which stage of the process each material is used. Information on the quality and control of these materials shall be provided. In addition, relevant information shall be provided to **demonstrate that** the materials meet the **standards for their intended use.***

3.6 Impurities of the vaccine Comirnaty

It is clear from the statements on p. 23 of the EMA Assessment Report on the conditional approval of the vaccine dated February 19, 2021 (EMA Assessment Report) that the vaccines contain **impurities** due to the **lipid nanoparticles.**

> ***Lipid-related impurities have been identified in** the finished product and have been characterized. An investigation has been initiated and is ongoing to assess and review potential root causes. The outcome of the investigation shall be provided (SO2).*

Evidence: Assessment Report EMA Comirnaty v. 19.2.2021 (Assessment Report EMA), Page 23

https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf.

3.7 Additional conditions imposed by the EMA on Biontech

In this regard, in February 2021, Biontech was subject **to** three specific obligations ("SO") from the EMA to demonstrate the pharmaceutical quality of excipients ALC-0159 and ALC-0315, which **should have been fulfilled by July 2021** (SO2, SO4 and SO5):

In the context of the conditional marketing authorization, the applicant should fulfill the following specific obligations (SOs):

*• **SO2**: In order to ensure consistent product quality, the MAH should provide addi- tional information to enhance the control strategy, including the active substance and finished product specifications. Due date: July 2021. Interim reports: March 2021.*

*• **SO4:** In order to confirm the purity profile and ensure comprehensive quality control and batch-to-batch consistency throughout the lifecycle of the finished product, the MAH should provide additional information about the synthetic process and control strategy for the excipient ALC-0315. Due date: July 2021, Interim reports: January 2021, April 2021.*

*• **SO5:** In order to confirm the purity profile and ensure comprehensive quality control and batch-to-batch consistency throughout the lifecycle of the finished product, the MAH should provide additional information about the synthetic process and control strategy for the excipient ALC-0159.*

Evidence: Assessment Report EMA Comirnaty v. 19.2.2021 (Assessment Report EMA),p. 36 - 38

https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf.

3.8 Further contamination after whistleblower testimony

A whistleblower, employee of a company that produces the ingredient ALC-0315 for Biontech, also informed the undersigned that since a few weeks the substance ALC-0315 is no longer to be filtered 8 times by corresponding cartridges, but only 4 times. This means, of course, that considerably more pollutants and impurities remain in these nano-lipids and are introduced into people's bodies with the vaccination than with a double number of filtering.

This action also directly **contradicts the specific conditions imposed by the EMA** in the marketing authorization decision, the aim of which was to oblige the marketing authorization holder to ensure the perfect quality of the finished medicinal product (condition S02), the excipient ALC-0315 (S04) and the excipient ALC-0159 (S05).

This also gives rise to the fear of further massive contamination of the excipient, and in any case a **reduction in the quality of the vaccine**, which in a further point contradicts the recognized pharmaceutical rules within the meaning of § 8 AMG.

4. No evidence of quality and control of substances ALC-0315 and ALC-0159.

To date, the manufacturer Biontech has not provided any evidence, documents and data in accordance with the aforementioned legal requirements and the specific conditions of the EMA to prove the perfect quality and thus the suitability and safety of the excipients for use in the finished medicinal product Comir- naty. This results from the **latest assessment report of the EMA** for the extension of the conditional marketing authorization (Assessment Report EMA October 2021) from page 6, where it states:

> ***Specific Obligation SO2:***
>
> *In order to ensure consistent product quality, the MAH should provide additional information to enhance the control strategy, including the active substance and finished product specifications.*
>
> *Due date indicated in Annex II: July 2021*
>
> *Date of submission: 02/08/2021*

Current status: ***NOT FULFILLED***

Specific Obligation SO4:

In order to confirm the purity profile and ensure comprehensive qualitycontrol and batch-to-batch consistency throughout the lifecycle of the finished product, the MAH should provide additional information about the synthetic process and control strategy for the ***excipient ALC-0315.***

Due date indicated in Annex II: July 2021

Date of submission: *06/01/2021 / 26/07/2021*

Current status: ***NOT FULFILLED***

Specific Obligation SO5:

In order to confirm the purity profile and ensure comprehensive quality control and batch-to-batch consistency throughout the lifecycle of the finished product, the MAH should provide additional information about the synthetic process and control strategy for the ***excipient ALC-0159.***

Due date indicated in Annex II: July 2021

Date of submission: *06/01/2021 / 26/07/2021*

Current status: ***NOT FULFILLED***

Evidence: EMA Assessment report on the annual renewal of the conditional marketing authorization - Comirnaty - Oct. 2021, page 6 - 9

https://www.ema.europa.eu/en/documents/variation-report/comirnaty-h-c-5735-r-0046-epar-assessment-report-renewal_en.pdf.

4.1 Deadline for meeting the special requirements since July 2021

The **deadlines** for submission of documents demonstrating compliance with the specific requirements of the EMA with respect to lipid nanoparticles as novel and first-time adjuvants have thus **expired.**

The suitability of the two substances, the safety and efficacy of **ALC-0315 and ALC-0159** have been confirmed to date - **one year since the start of vaccinations** with

Comirnaty - still not proven. The specific requirements of the EMA to protect people from health and death hazards have **not been met** by Biontech.

Specific Obligation SO2: NOT FULFILLED!

Specific Obligation SO4: NOT FULFILLED!

Specific Obligation SO5: NOT FULFILLED!

4.2 Pfizer's "Safety Data Sheet" dated 7/12/2021 does not contain data

The missing evidence of the special obligations ("SO") on the two nano-lipid substances is described in the current **safety paper**
"Safety Data Sheet" from Pfizer as of 7/12/2021 confirmed:

Even one year after use of the vaccine Comirnaty from Biontech contains this
"This can only be explained by the fact that these two substances **ALC-0315 and ALC-0159 are** still **not intended for use in medicinal products for human use.**

Therefore, the two ingredients ALC 0315 and ALC-0159 are admittedly already not classifiable, because they are already not substances that are suitable and intended for use in and on humans.

But also otherwise, in the column "Classification according to Regulation (EC) No. 1272/2008" **for all (!)** ingredients - including the ingredients ALC 0315 and ALC-0159 - there is always the statement "**No data available**".
"no data available".

Evidence: Safety Data Sheet Pfizer dated 7.12.2021, pages 1 to 3

https://safetydatasheets.pfizer.com/DirectDocumentDownloader/Document

It is simply impossible that after presumably several **billion Comirnaty vaccines vaccinated** worldwide and almost **100 million** Comirnaty doses vaccinated **in Germany,** there is still no data at all from Biontech on the

classification and to the special requirements of the EMA according to the recognized pharmaceutical rules should give!

No data available! No data available? No data available!

4.3 Inflammatory effect of lipid nanoparticles.

However, there are also no data on the two ingredients ALC 0315 and ALC-0159 with regard to the **assessment of toxicity**, cf. page 3 of the Pfizer Safety Data Sheet of 7.12.2021. Incidentally, this also applies to all other ingredients mentioned there. According to **Directive 2001/83/EC** Module 3, Number 3.2.2.4 d), such additional information on the toxicity studies with the novel excipient must be submitted.

The general toxicity **was determined** according to the product information of Biontech tested **only on rats:**

> ***General toxicity***
>
> *Rats administered Comirnaty intramuscularly (administration of 3 full human doses once weekly, producing relatively higher levels in rats due to body weight differences) showed edema and erythema at the injection site and an* ***increase in white blood cells*** *(including basophils and eosinophils)* ***consistent*** *with an* ***inflammatory response****, as well as vacuolization of portal hepatocytes without evidence of liver injury.*

Proof: Product information Comirnaty, p. 15

> https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf

Thus, from the toxicological preclinical studies in rats, there is clearly an inflammatory response, as reflected, incidentally, in the large number of adverse reactions reported.

4.4 Current study proves the danger of the two lipid nanoparticles

For example, a recent study shows that the lipid nanoparticles ALC 0315 and ALC-0159 have **strong inflammatory** effects. Injection of these LNPs leads to rapid and strong inflammatory reactions with activation of various inflammatory pathways and pro- duction of various inflammatory cytokines and chemokines. They are thus responsible for the range of **most severe side effects.**

The same dose of LNP administered **intranasally to the** animals led to similar **inflammatory reactions** in the **lungs** and resulted in **high mortality in the** experimental animals.

Evidence: study by Ndeupen, Quin et al v. 12/17/2021 "The mRNA-LNP platform's lipid nanoparticle component used in preclinical vaccine studies is highly inflammatory."

https://www.sciencedirect.com/science/article/pii/S2589004221014504

This current study thus not only proves the unsuitability of the two novel excipients, which are being used for the first time ever and for the first time in this way in humans. In particular, the study also shows that the lipid nanoparticles ALC 0315 and ALC-0159 are especially **dangerous to** humans**.** According to the authors, this hazard increases seriously with each additional vaccination (booster).

The myocarditis and pericarditis documented in the safety reports of the Paul Ehrlich Institute are evidence of the dangerous inflammatory reactions.

Proof: **Safety report Paul-Ehrlich-Institut** from 23.12.2021, page 5

https://www.pei.de/SharedDocs/Down- loads/EN/newsroom/dossiers/safety-reports/safety-report-27-12-20- to-30-11-21.pdf.

4.5 No studies and data on genotoxicity/carcinogenicity.

Furthermore, according to Pfizer/Biontech's own statements, there are **no** other **safety studies** on possible genotoxicity and **carcinogenicity (cancer induction)** by the Comirnaty vaccine. This is stated in the Comirnaty product information:

> ***Genotoxicity/carcinogenicity***
>
> *No genotoxicity or carcinogenicity studies have been performed.*

Proof: Product information Comirnaty, p. 15

https://www.ema.europa.eu/en/documents/product-information/comirnaty-e-par-product-information_en.pdf

4.6 No studies on interactions and in immunocompromisedindividuals.

Moreover, **no interaction studies** were conducted with regard to the simultaneous use of other drugs, see the product information on Comirnaty, p. 45:

> ***Interactions with other medicinal products and other interactions***
>
> *No studies have been conducted to detect interactions. Co-administration of Comirnaty with other vaccines has not been studied.*

Moreover, the **efficacy and safety of** the vaccine in **immunocompromised individuals**, including those on immunosuppressive therapy, has **not** even been evaluated, although it is precisely this patient group of people with severe pre-existing conditions that has been prioritized for the administration of the Corona vaccine since the beginning of vaccinations (even in children!):

The efficacy and safety of the vaccine have not been evaluated in immunocompromised individuals, including those on immunosuppressive therapy.

Proof: Product information Comirnaty, p. 45

https://www.ema.europa.eu/en/documents/product-information/comirnaty-e-par-product-information_en.pdf

4.7 No submission of the necessary documents for approval to the EMA

The legal requirements of Section 13 (3) sentence 1 AMWHV as well as the special obligations required by the EMA have thus obviously and intentionally not been fulfilled for the new excipients ALC-0315 and ALC 0159:

- There is a **lack of** data and evidence that the new excipients ALC-0315 and ALC 0159 **meet** the **standards for** their **intended use.**

- **There is** also a **lack of** the necessary data and evidence that their **suitability** for the intended use is **ensured.**

- Finally, there is a **lack of** necessary data and evidence that these two new excipients meet **the requirements of drug approval** or clinical trial approval.

- This means a **considerable reduction in quality** due to serious deviations of the manufacturing process from the "recognized pharmaceutical rules" as defined in Section 8 (1) No. 1 AMG.

- At the same time, it must be concluded from this that the manufacturer Pfizer/Biontech intentionally exposes the vaccinated persons or those yet to be vaccinated to a very serious risk due to **insufficient safety, quality or efficacy** within the meaning of Section 13 (3) AMWHV by manufacturing and distributing the Comirnaty vaccine.

5. Obligation of the German authorities to cause the suspension of the approval

Based on all these facts and legal violations presented and proven here, the German representatives at the European Medicines Agency (EMA) would in principle be obliged to demand an **immediate suspension of** the **marketing authorization** until the corresponding requirements for compliance with "good manufacturing practice" and thus the recognized pharmaceutical rules are fulfilled.

In accordance with Section 30 (2) No. 1 AMG, a German marketing authorization is to be revoked or a ban is to be ordered if incomplete information is provided or if ordered conditions are not complied with:

> ***§ Section 30 AMG: Withdrawal, revocation, suspension***
>
> *(2) The **competent higher federal authority may refuse the approval***
>
> *1. if incorrect or **incomplete information** has been provided in the documents pursuant to §§ 22, 23 or 24 or if one of the grounds for refusal pursuant to § 25 (2) No. 6a or 6b has been presented at the time of issue,*
>
> *2. **revoked if** one of the grounds for refusal under Section 25 (2) No. 2, 6a or 6b has subsequently occurred or if one of the **conditions imposed** under Section 28 has **not been complied with** and this deficiency has not been remedied within a reasonable period to be set by the competent higher federal authority; in this context, conditions under Section 28 (3) and (3a) shall be reviewed annually,*
>
> *3. revoked in consultation with the competent authority if the **quality tests** prescribed for the medicinal product have not been **carried out** or have **not** been **carried out** sufficiently,*
>
> *4. revoked in consultation with the competent authority if it turns out that the medicinal product has **not** been **manufactured in accordance with recognized pharmaceutical rules.***

The vaccine Comirnaty was not approved under German law, but under European law. Nevertheless, it is mandatory for the German representatives to apply to the EMA for the withdrawal, revocation or, in any case, the immediate provisional suspension of the conditional European marketing authorization of the vaccine Comirnaty.

Under these circumstances, it is simply **irresponsible** to continue to vaccinate millions of people in Germany with the vaccine Co- mirnaty and thus to "apply" it in the sense of § 5 AMG.

5.1 The failure of the Paul Ehrlich Institute

This applies all the more since, according to Section 32 (1) AMG, the batch of a vaccine **may** only be **marketed** in Germany - **despite the existence of a marketing authorization -** if the competent higher federal authority - in this case, the Paul Ehrlich Institute
- released the batch in question after carrying out a batch test.

Accordingly, a release may only take place if this governmental batch test has shown that the batch has been manufactured and tested according to **manufacturing and control methods that** correspond to **the** respective **state of scientific knowledge and** that it has the required quality, efficacy and safety:

> ***§ 32 AMG: State batch testing***
>
> *(1) The batch of a serum, a vaccine or an allergen may only be placed on the market if it has been released by the competent higher federal authority, without prejudice to the approval. The batch is to be released if a test (state batch test) has shown that the batch has been manufactured and tested according to manufacturing and control methods that correspond to the current state of scientific knowledge and that it* ***has the required quality, efficacy and safety****. The batch must also be released if the competent authority of another member state of the European Union has determined, following an ex- perimental examination, that the requirements specified in sentence 2 are met.*

5.2 Unprecedented violation of vaccine manufacturing good manufacturing practices

It is an unprecedented and egregious violation of all rules governing the manufacture of medicinal products, in particular the obligation under Section 8 of the German Medicines Act (AMG) to comply with the "recognized pharmaceutical rules"

1. that substances which are to be classified as essential components of the drug Co- mirnaty are used in a "vaccine" on humans, although these substances may only be used for research, but are expressly not intended for use on or in humans,

2. that for the two ingredients ALC-0315 and ALC-0159, which are both **novel** excipients and are used for the **first time** in humans through a new mode of application, no additional studies and data on classification and toxicity are provided - not even after one year.

3. that billions of people worldwide - and at the same time 83 million citizens in Germany - are kept in the dark about the fact that they are obviously participating in a "clinical trial", which violates the **Declaration of Helsinki, to which all physicians worldwide are legally bound,** and the Nuremberg Code.

5.3 People's unawareness of the ongoing clinical trial with Comirnaty

The fact that vaccination with Comirnaty is still an ongoing clinical trial process is most recently evident from the EMA's October 2021 assessment report, which states at the end of the report on page 43:

> *In order to confirm the efficacy and safety of Comirnaty, the MAH should submit the **final Clinical Study Report** for the randomized, placebo-controlled, observed blind study C4591001.*
>
> *Due Date: December 2023*

Evidence: EMA Assessment report on the annual renewal of the conditional marketing authorization - Comirnaty - Oct. 2021, page 43

https://www.ema.europa.eu/en/documents/variation-report/comirnaty-h-c-5735-r-0046-epar-assessment-report-renewal_en.pdf.

The final study report of the clinical trial is therefore not to be submitted for another two years, i.e. not until **December 2023**! Until then, the vaccination is an ongoing clinical study!

5.4 Special informed consent and consent to clinical trial

In view of the horrific vaccination trials carried out by the Nazis in the concentration camps - under the leadership of the Robert Koch Institute and many physicians and scientists as well as the pharmaceutical industry - it is mandatory for all physicians and manufacturers to provide information about the conduct of a clinical trial and to give explicit consent to a clinical trial with drugs and vaccines. This is mandatory for all physicians in the **Declaration of Helsinki** and regulated in § 15 of the **Model Medical Practitioners' Code of Conduct**. These regulations are based on the so-called **Nuremberg Code** (cf. Appendix), which was developed after the Nuremberg Medical Trials in 1947.

> ***Declaration of Helsinki, para. 21:***
>
> *Medical research involving human subjects must conform to generally accepted scientific principles and be based on a thorough knowledge of the scientific literature, other relevant sources of information, adequate laboratory testing, and, when appropriate, animal experimentation.*

> ***Declaration of Helsinki, para. 26:***
>
> *In medical research involving subjects capable of giving consent, each potential subject must be adequately informed (educated) about the objectives, methods, sources of funds, possible conflicts of interest, institutional affiliations of the researcher, anticipated benefits and potential risks of the study, any inconveniences that may be associated with it, intended actions after a study is completed, and any other relevant aspects of the study.*

Proof:

https://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Folder/International/Declaration_of_Helsinki_2013_20190905.pdf

Not a single person who has been vaccinated against Corona for a year has been informed and educated, in accordance with the Declaration of Helsinki and the specific medical disclosure obligations, that he or she is participating in an ongoing cli- nical trial of the Comirnaty vaccine, which will run until December 2023.

5.5 Criminal violations of pharmaceutical law

These are the **most serious and thus at the same time most criminal violations of the internationally applicable regulations** for the manufacture of medicinal products and of German pharmaceutical law that have ever been committed: Firstly, by Pfizer/Biontech itself as the manufacturer of the vaccine, then by the European regulatory authority and, of course, also by the competent German authorities, all officials, employees, physicians, scientists and politicians responsible for this.

All responsible persons are therefore to be prosecuted according to § 8 i.V.m. § Section 95 (1) No. 3a, (3) of the German Medicines Act (AMG), namely because of the realization of a **particularly serious case.**

6. Imprisonment for up to 10 years in a particularly serious case

In view of the aforementioned intentional violations, in the present case, the realization of the particularly serious case of the criminal offense pursuant to § Section 95 (3) of the German Medicines Act (AMG).

As a rule, a particularly serious case exists if the perpetrator **endangers** the health of a **large number of people** or exposes another to **the risk of death or serious harm to body** or health by producing or using the vaccine:

§ Section 95 (3) AMG: criminal offense in particularly serious cases

(3) In particularly serious cases, the penalty is imprisonment from one year to ten years. As a rule, a particularly serious case exists if the offender

- *1.by one of the acts referred to in paragraph 1.*

  a) endangers the health of a large number of people,

  b) Exposes another to the risk of death or serious injury to body or health; or

  c) obtains large-scale pecuniary advantages for himself or for another person out of gross self-interest.

The **term of imprisonment** in these cases can be set up **to 10 years.**

In view of the clear wording of Section 95 (3) No. 1b of the German Medicines Act (AMG), a serious case can be assumed if, despite the serious violations of the German Medicines Act described above, a **single child** or a **single adult is** vaccinated, thereby **exposing** this (single) person to the **risk of** death or serious damage to body or health. Just how great this danger is is shown by the frightening reports of the Paul Ehrlich Institute in its meanwhile 16 safety reports.

6.1 1,427 reported deaths after vaccination with Comirnaty - including 6 children

The latest safety report from the Paul Ehrlich Institute, dated Dec. 23, 2021, documents for the **Comirnaty vaccine alone from the** start of vaccinations on Dec. 27, 2020, to Nov. 30, 2021, a period of only 11 months

- **113,792 total reported adverse events**
- **16,874 reported serious adverse events**
- **1,427 reported deaths after vaccination with Comirnaty,**
- **of which 6 reported deaths in children and adolescents**

These figures show - as, incidentally, have all previously published safety reports of the Paul Ehrlich Institute since the beginning of January 2021 - that the Comirnaty vaccine obviously carries the risk of death as well as the risk of serious harm to body or health.

Proof: Safety report Paul-Ehrlich-Institut from 23.12.2021

https://www.pei.de/SharedDocs/Down- loads/EN/newsroom/dossiers/safety-reports/safety-report-27-12-20- to-30-11-21.pdf.

6.2 16,674 reported serious adverse events after comirnaty

For the **Comirnaty vaccine** alone, the number of **serious adverse events** reported in **just 11 months was 16,874**, which may mean lifelong severe damage and disability.

According to the definition of Art. 1 No. 12 of Directive 2001/83/EC, a serious adverse reaction is an adverse reaction which

- is fatal or life-threatening,
- requires inpatient treatment or prolongation of inpatient treatment,
- results in permanent or serious disability or incapacity, or
- is a congenital anomaly or birth defect.

Evidence: Art. 1 No. 12 of Directive 2001/83/EC

https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32001L0083

6.3 Reporting rate for vaccine adverse events likely to be less than 1 percent

It is known that physicians report adverse drug reactions in only about 5% of all cases. If drugs and vaccines are considered "safe" and "effective", as has been claimed for months by the RKI, politicians and the media for the Corona vaccines, then the reporting rate is even less than 1 percent according to long-term studies.

Evidence: Bahner, Corona vaccination: What physicians and patients should absolutely know, p. 180 ff, with further references.

https://www.buchkomplizen.de/index.php?lang=0&cl=search&searchparam=Beate+bahner

It is therefore to be assumed - especially in view of the almost complete denial of a connection between health damage and preceding vaccination by the Paul Ehrlich Institute, by the vaccinating or post-treatment physicians and clinics as well as by the patients themselves - that these study results also and especially apply to the Corona vaccines. Side effects and deaths in connection with the Corona vaccine are probably reported in less than one percent of all cases.

Evidence: **Bahner**, Corona Vaccination, p. 179 ff., as above.

6.4 Projection of possible deaths from comirnaty

With a **reporting rate of only 5%,** this would mean (within 11 months!) already approx. **28,540 deaths** from Comirnaty vaccination alone, of which 120 were children.

With a **reporting rate of only 1%,** as many as **142,700 deaths** would have to be assumed in connection with the Biontech vaccination Comirnaty alone, of which about 600 would be children. With regard to children, these estimates only apply to a period of five months, as the Paul Ehrlich Institute's safety report only refers to the period of childhood vaccination between July and November 2021.

6.5 23 times more deaths from Corona vaccination

However, it is already definitely certain that, according to the figures of the Paul-Ehrlich-Institute itself, the Corona vaccinations have caused (at least!) **23 times more deaths** than all vaccinations in Germany in the last 21 years together.

Evidence: **Bahner**, Corona Vaccination, p. 154 ff, with further references, as above.

All persons responsible for this are therefore to be prosecuted under Section 8 in conjunction with Section 95 Para. § Section 95 (1) No. 3a, (3) of the German Medicines Act (AMG), namely because of the realization of a particularly serious case.

7. Offence of the vaccinating physicians and other involved persons according to §§ 5, 95 AMG

Irrespective of this, however, **all physicians who** administer such a vaccine, thus "using it on humans" within the meaning of Section 5 (1) AMG, also commit a criminal offense pursuant to Section 95 (1) no. 1 in conjunction with. §§ 5 and § 8 AMG, which can be punished with imprisonment of up to 3 years.

Already the **attempt** is punishable according to § 95 para. 2 AMG.
Furthermore, the act can also be committed **negligently**, Section 95 (4) AMG.

7.1 The prohibition of the use of medicinal products of concern according to § 5 AMG

Because the vaccination of humans with the Corona vaccine Comirnaty from Biontech, due to the obvious violation of § 8 AMG, at the same time violates the prohibition of § 5 AMG and is therefore a further **criminal offense according to § 95 para. 1 no. 1 AMG.**

According to § 5 AMG, it is expressly forbidden to place **questionable** medicinal products on the market or to use them on another person.

Medicinal products are considered to be of **concern if,** based on the current state of scientific knowledge, there are **reasonable grounds for suspecting** that they may **have harmful effects** when used in accordance with their intended purpose that **go beyond what** is **acceptable** according to the findings of medical science.

§ 5 AMG: Prohibition of medicinal products of concern

(1) It is prohibited to place on the market or to use in another person medicines of concern.

(2) Medicinal products are considered to be of concern if, according to the current state of scientific knowledge, there are reasonable grounds for suspecting that, when used as directed, they have harmful effects that go beyond what is acceptable according to the findings of medical science.

A vaccine that, according to the Paul Ehrlich Institute's own figures, causes (at least!) **23 times more deaths** within a period of only 6 months (January to July 2021) than all vaccinations in Germany in the last 21 years, clearly has such harmful effects in the sense of the
§ Section 5 (2) of the German Medicines Act (AMG), which **go beyond what is justifiable** according to the knowledge of medical science.

Thus, the criminal offense of § 5 AMG is also realized, so that through the vaccination, especially through the **continuation of the vaccination,** all vaccinating physicians realize the criminal offense and thereby make themselves liable to prosecution. Therefore, they are also liable to a fine or - depending on the extent of the vaccination and the harm to the vaccinated persons - also to imprisonment.

7.2 Complicity, instigation and aiding and abetting by judges, parents and others

According to the general provisions of criminal law, not only vaccinating physicians themselves are liable to prosecution under Section 95 (1) no. 1 AMG. All persons who participate in a vaccination are also liable to prosecution according to the general regulations of complicity, instigation or aiding and abetting. This means:

- **Parents, foster parents, and caregivers who** seek to enforce vaccination of a minor child are committing criminal offenses,
- **Advocates** who enforce the vaccination request for a parent or child are subject to prosecution,
- **Judges who** allow the parent who is willing to vaccinate to decide whether to vaccinate the child, or even substitute their own consent for that decision, are guilty of criminal offenses,
- Legal **advisors who** recommend vaccination in family law proceedings are liable to prosecution,

- **Employers who** require their employees to be vaccinated with notice of termination or leave of absence without pay are subject to criminal penalties,
- **Physicians, clinics and health care personnel** who refuse to treat patients or visit, care for or accompany these patients by third parties due to the lack of vaccination of the patient or the third parties are liable to prosecution,
- **Operators and staff of old people's and nursing homes, homes for the disabled, children's homes and similar institutions** who refuse treatment of residents or visits, care or accompaniment of these residents by third parties due to lack of vaccination of the residents or the third parties are liable to prosecution.

➢ **Vaccination with Comirnaty is a criminal offense!**

➢ **The same applies to vaccination with Spikevax from Moderna!**

8. Vaccination is prohibited in case of allergy to ingredients

Incidentally, vaccination is also prohibited for the following additional reason: According to the product information and the package insert of the vaccine Comirnaty, it must not be used in case of allergies to one of the ingredients. This is explicitly stated in the instructions for use for users (i.e. for the vaccinating physicians) of Comirnaty:

> ***What should you consider before you receive Comirnaty?***
>
> *Comirnaty must not be used if you are allergic to the active substance or any of the other ingredients of this medicine listed in section 6.*

Proof: Comirnaty product information, p. 94

https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf

8.1 Each person must be examined and tested before vaccination

Therefore, allergies to the vaccine - and thus any contraindications - must first be ruled out. Before a vaccination with Comirnaty, the following steps must be carried out:

1. The person to be vaccinated must undergo a **specialist allergological examination** for all components of the vaccine Comirnaty before vaccination against Corona.
2. The examining specialist is **obliged to issue** a so-called **vaccination certificate of** the examined person regarding all components of the Comirnaty vaccine.
3. The same applies to the vaccine Spikevax with **Moderna**.

8.2 Preliminary immunization eligibility

Until then, a preliminary inoculation **capability of** all persons to be vaccinated is **to be assumed.** This is because it cannot be **ruled out that the** persons will be **allergic to** one of the two components ALC 0315 and ALC 0159 - which have not been approved and have not been tested for toxicity and allergenic effects.

Both the safety reports of the Paul Ehrlich Institute and the so-called "Red-hand letters" from manufacturers document a **large number of anaphylactic** reactio- **ns.**

Evidence: Safety report of the Paul Ehrlich Institute of 23.12.2021, p. 21

> https://www.pei.de/SharedDocs/Down- loads/EN/newsroom/dossiers/safety-reports/safety-report-27-12-20- to-30-11-21.pdf.

An anaphylactic reaction may well be **fatal.**

8.3 Medical confirmation of vaccination eligibility required

Therefore, the person's **ability to be vaccinated** must be determined by an **allergist, who** must specifically test these two components ALC 0315 and ALC 0159, as well as all other components of the vaccine, for possible allergic reactions in the person to be vaccinated.

After this individual and personal examination, the allergist must then **certify** the exclusion of allergic reactions to each individual component of the Comirnaty vaccine in the **form of a health certificate pursuant to Section 278 of** the **Criminal Code.**

In the absence of such a medical certificate of inoculability, in view of the absence of any evidence by Biontech of the suitability, quality and safety of the two ingredients ALC 0315 and ALC 0159 and of the vaccine as a whole, it is mandatory to assume that the person is **inoculable** due to the risk of allergic reaction to the ingredients of Comirnaty.

Whoever exposes a person, and even more so a minor child, to these dangers, acts **intentionally** with regard to a possible damage to health or even the death of this person.

9. Summary

1. A substance may only be used for the manufacture of a drug if the intended use is either described in a monograph according to the German or European Pharmacopoeia, or extensive additional studies, including toxicity studies and clinical studies, are submitted for the new excipients.
2. The purpose of all German and European pharmaceutical regulations is to protect people by ensuring the quality, safety and efficacy of medicines.
3. The EMA has therefore imposed special conditions on Biontech - particularly with regard to the two lipid nanoparticles ALC 0315 and ALC 0159 - as these are novel adjuvants to the Comirnaty vaccine that are being used in humans for the first time and in a novel way.
4. The corresponding special requirements of the EMA (specific obligations SO2, SO4, SO5) for these novel auxiliaries had to be fulfilled by Biontech until July 2021.
5. However, both the EMA report on the extension of the conditional approval of October 2021 and Pfizer's safety data sheet for Comir- naty of Dec. 7, 2021, indicate that these conditions have not been met and that the required documentation is **not available.** It says there "**No data available**" - "no data available".
6. This is a **violation of** the principles of good manufacturing practice and thus at the same time a violation of the **recognized pharmaceutical rules** within the meaning of Section 8 (1) No. 1 AMG. According to this, it is prohibited to market medicinal products that are "not insignificantly reduced in quality due to deviation from the recognized pharmaceutical rules".

7. The **quality** is already **reduced by** the fact that two essential components of the ingredients contained in Comirnaty are **not intended for use on or in humans** and are therefore considered "**novel excipients**" for which special documents and evidence must be provided.

8. In addition, **lipid-related impurities of** the vaccine are already documented in the **EMA** registration dossier. These impurities are likely to have even increased in view of further information on the reduction of the filtering processes of the excipient nanolipid ALC-0315. With the reduction of the filtering processes, the marketing authorization holder would thus also violate the conditions S02, SO4 and SO5 of the EMA in the marketing authorization notice.

9. Finally, according to the safety reports of the Paul Ehrlich Institute, the **vaccine** shows a frightening **number of** harmful **side effects** that go far beyond what is "acceptable" according to the findings of medical science.

10. Due to this fact, there is also a violation of § 5 para. 1 AMG, namely a violation of the prohibition of marketing and use of questionable drugs. Thus, not only the manufacturers, but also the **vaccinating physicians,** as well as all persons responsible for a vaccination with Comirnaty, are subject to the regulations of the AMG.

11. Violations of Section 8 AMG and Section 5 AMG are classified as **criminal** offenses under Section 95 (1) No. 1 and No. 3a AMG and are punishable by up to 3 years imprisonment. **Negligent** commission is also punishable, Section 95(4) AMG.

12. A **particularly serious case of** this criminal offense with a **prison sentence of up to 10 years** exists if another person is exposed to the risk of death or serious harm to body or health, Section 95 (3) No. 2 AMG. In the present case, the particularly serious case is **intentionally realized** by the production, distribution and use of the vaccine Comirnaty contrary to the prohibitions of §§ 5 and 8 AMG.

13. **In** addition, vaccination must not be carried out in the case of **allergies** to a component of the vaccine. Therefore, all persons to be vaccinated must be tested in advance for a possible allergy to one of the components in order to exclude a possible **contraindication** to the vaccination.

14. Therefore, a person must not be vaccinated until he or she has been allergy tested for tolerance to each component of the vaccine, and

tolerability to all components of the vaccine Comirnaty confirmed by a doctor.

15. Until then, vaccination with the Comirnaty vaccine is prohibited because of the possibility of serious health hazards.
16. An infringement violates not only the above-mentioned provisions of the Medicines Act, but also other principles of common criminal law.
17. **All explanations also apply to the vaccine Spikevax from MODERNA!**

Heidelberg, December 27, 2021

Beate Bahner
specialist in medical law mediator in the health care sector

People much more easily believe a lie they have heard a hundred times, as a truth that is completely new to them.

Alfred Polgar, Viennese modernist writer, Jewish exile

10. Legal bases, approval documents and further literature

10.1 Legal basis

AMG: Arzneimittelgesetz (German **Medicines** Act)

https://www.gesetze-im-internet.de/amg_1976/AMG.pdf

AMWHV: Ordinance on the Manufacture of Pharmaceuticals and Active Pharmaceutical Ingredients

https://www.gesetze-im-internet.de/amwhv/AMWHV.pdf

RL 2001/83/EC: 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 https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32001L0083

Directive 2003/94/EC: Commission Directive 2003/94/EC of October 8, 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use.

https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32003L0094

EC Regulation No. 1272/2008: Regulation (EC) No. 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No. 1907/2006

https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32008R1272&from=DE

EU GMP Guide: Guide to Good Manufacturing Practice Part I - Medicinal Products

https://www.gmp-navigator.com/files/guidemgr/01_0_GMP-Guide_Part%201%20Drug_Jan2015.pdf.

Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects WMA

https://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/International/Declaration_of_Helsinki_2013_20190905.pdf

Model professional code of conduct for physicians

https://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/pdf-Ordner/Law/_Bek_BAEK_MBO-AE_Online_final.pdf

10.2 Registration documents for Biontech's Comirnaty vaccine

Product information about Comirnaty: Annex I Summary of Product Characteristics (German, 114 pages) - no date stated

https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf

EMA Assessment Report of the European Medicine Agency (EMA) EMA/707383/2020 Corr.1* dated 19.2.2021 (English 140 pages)

https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf

EMA Assessment report on the annual renewal of the conditional marketing authorisation - Comirnaty - EMEA/H/C/005735/R/0046 (Assessment report on the annual renewal of the conditional **marketing** authorisation) Status Oct. 2021 (English 43 pages)

https://www.ema.europa.eu/en/documents/variation-report/comirnaty-h-c-5735-r-0046-epar-assessment-report-renewal_en.pdf.

Safety Data Sheet (MSDS) from Pfizer dated 7/12/2021

https://safetydatasheets.pfizer.com/DirectDocumentDownloader/Document

10.3 Further literature

Safety report Paul-Ehrlich-Institut from 4.2.2021 on "Suspected cases of adverse reactions and vaccination complications after vaccination to protect against COVID-19 (reporting period 27.12. to 31.01.2021)".

https://www.pei.de/SharedDocs/Down- loads/EN/newsroom/dossiers/safety-reports/safety-report-27-12-to-31-01-21.pdf.

Safety report Paul-Ehrlich-Institut of 12/23/2021 on "Suspected cases of adverse reactions and vaccine complications after vaccination to protect against COVID-19 since the start of the vaccination campaign on 12/27/2020 until 11/30/2021".

https://www.pei.de/SharedDocs/Down- loads/EN/newsroom/dossiers/safety-reports/safety-report-27-12-20-to-30-11-21.pdf.

Study by Ndeupen, Quin et al dated 12/17/2021 "The mRNA-LNP platform's lipid nanoparticle component used in preclinical vaccine studies is highly inflammatory."

https://www.sciencedirect.com/science/article/pii/S2589004221014504

Book by Beate Bahner: Corona vaccination - What doctors and patients should absolutely know, publication date 21.9.2021 (available as paperback, audiobook and **free eBook**).

https://www.buchkomplizen.de/index.php?lang=0&cl=search&searchparam=Beate+railway

10.4 The Nuremberg Code of 1947

1. The voluntary consent of the subject is absolutely necessary. This means that the subject must be legally capable of giving consent; must be able to exercise judgment uninfluenced by force, fraud, trickery, pressure, subterfuge, or any other form of persuasion or coercion; must have sufficient knowledge and understanding of the subject in question to be able to make an informed decision. This last condition makes it necessary that, before consent is obtained, the subject be made aware of the nature, length and purpose of the experiment, the method and means to be employed, any inconvenience or danger which may reasonably be expected, and the consequences to his health or person which may result from participation. The duty and responsibility to determine the value of consent rests with anyone who orders, directs, or conducts the experiment. This is a personal duty and responsibility that cannot be passed on to others without penalty.

2. The experiment must be designed in such a way that fruitful results for the good of society can be expected, which cannot be obtained by other research means or methods. It must not be arbitrary or superfluous by its nature.

3. The experiment shall be designed and based on results of animal experiments and natural history knowledge of the disease or research problem such that the expected results will justify the conduct of the experiment.

4. The test must be carried out in such a way that all unnecessary physical and mental suffering and damage is avoided.

5. No experiment may be carried out if it can be reasonably assumed from the outset that it will lead to death or permanent harm, excluding at most those experiments in which the experimenter also serves as the test subject.

6. The threat must never exceed those limits imposed by the humanitarian significance of the problem to be solved.

7. Adequate preparation and appropriate devices shall be provided to protect the person being tested from even the slightest possibility of injury, permanent damage, or death.

8. The experiment may only be carried out by scientifically qualified persons. Greatest skill and caution are to be required at all stages of the experiment by those who conduct or perform the experiment.

9. During the experiment, the subject must remain free to terminate the experiment if he or she has reached a point, physically or psychologically, at which it appears impossible for him or her to continue.

10. At any time during the course of the experiment, the experimenter must be prepared to terminate the experiment if, on the basis of the good faith required of him or her, his or her special experience, and his or her careful judgment, he or she must suspect that continuation of the experiment might result in injury, permanent harm, or death to the subject.