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EUROPEAN COURT

ACTION FOR ANNULMENT pursuant to Art. 263 TFEU

Plaintiff:
Mr .... resident in Italy ....., Italian citizen, father of two minors.

Defendant:
European Commission

Subject:

(1) **Commission Implementing Decision of 10.10.2022 granting a marketing authorisation for the medicinal product for human use "Comirnaty—Tozinameran, COVID-19 mRNA vaccine (nucleleioside modified)" in accordance with Regulation (EC) No 726/2004 of the European Parliament and of the Council and repealing Decision C(2020) 9598(final), together with its successive amendments and integrations, and the previous Implementing Decisions required by that Decision.**

(2) **IMPLEMENTING DECISION OF THE EUROPEAN COMMISSION of 31.5.2021 amending the conditional marketing authorisation granted for Comirnaty—Tozinameran, COVID-19 mRNA vaccine (nucleleioside modified) for human use by Decision C(2020) 9598 (final) together with its successive amendments and integrations, and the previous implementing Decisions required by this Decision—initial decision for paediatric use from 12 years of age.**

(3) **COMMISSION IMPLEMENTING DECISION of 21.12.2020 granting a conditional marketing authorisation for the medicinal product for human use "Comirnaty - COVID-19 mRNA vaccine (nucleoside-modified)" (nucleoside-modified)" in accordance with Regulation (EC) No 726/2004 of the European Parliament and of the Council**

(4) **Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to advanced therapy medicinal products—Annex I, Part IV, point 2.1, last sentence.**

(5) **COMMISSION DIRECTIVE 2009/120/EC of 14 September 2009 amending, as regards advanced therapy medicinal products, Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use—Annex, Part IV, point 2.1., last sentence.**

Mr ... in his capacity as father of two minor children, represented and defended by DDr. Renate Holzeisen, a lawyer admitted to the Italian Supreme Court, registered with the Bolzano Bar Association and with offices at I-39100 Bolzano, Bahnhofallee 7,

PROVIDED THAT

1. **By Commission Implementing Decision of 10.10.2022** (published in the Official Journal of the European Union on 30.11.2022) **granting a marketing authorisation for the medicinal product for human use "Comirnaty—Tozinameran" in accordance with Regulation (EC) No 726/2004 of the European Parliament and of the Council** and repealing Decision C(2020) 9598 (final) (doc. **A1**), **the European Commission**
"Having regard to the Treaty on the Functioning of the European Union,
Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency, and in particular Articles 10(2) and 14-a(8) thereof,
Having regard to the data submitted by BioNTech Manufacturing GmbH, on 17 June 2022,
Having regard to the opinion of the European Medicines Agency, formulated on 15 September 2022 by the Committee for Medicinal Products for Human Use,
Whereas

(1) On 21 December 2020, authorisation for the placing on the market of "Comirnaty - tozinameran, COVID-19 mRNA vaccine (nucleoside-modified)" was granted by Decision C(2020) 9598(final) subject to certain requirements, in accordance with Article 14-a of Regulation (EC) No 726/2004 and Regulation (EC) No 507/2006.
(2) **The specific obligations of the conditional marketing authorisation are fulfilled, in view of the data submitted on 17 June 2022.**
(3) …
(4) **The medicinal product "Comirnaty - tozinameran, COVID-19 mRNA vaccine (nucleoside-modified)" complies with the requirements set out in 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.**
(5) **It is therefore appropriate to replace the conditional marketing authorisation with a marketing authorisation not subject to specific obligations.**
(6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

has adopted this decision:

Article 1
A marketing authorisation pursuant to Article 3 of Regulation (EC) No 726/2004 is granted for the medicinal product "Comirnaty—Tozinameran, COVID-19 mRNA vaccine (nucleoside modified)", the characteristics of which are summarised in Annex I to this Decision. "Comirnaty—Tozinameran, COVID-19 mRNA vaccine (nucleoside-modified)" shall be entered in the Union Register of Medicinal Products under the following number: EU/1/20/1528.
Article 2
The marketing authorisation concerning the medicinal product referred to in Article 1 shall be subject to compliance with the conditions set out in Annex II and, in particular, with those relating to manufacture and importation, control and issue.
Article 3

The labelling and package leaflet concerning the medicinal product referred to in Article 1 shall comply with the conditions set out in Annex III.

Article 4

The placing on the market of "Comirnaty—Tozinameran, COVID-19 mRNA vaccine (nucleoside-modified)" shall be subject to this Decision from the date of its notification.

The period of validity of the marketing authorisation shall be five years from the date ofnotification of this Decision.

Article 5

This Decision repeals and replaces Decision C(2020) 9598(final) of 21 December 2020.

Article 6

This Decision is addressed to BioNTech Manufacturing GmbH, An der Goldgrube 12, 55131 Mainz, Deutschland.

2. Three (III) annexes are attached to the above Commission Implementing Decision—Annex I (Summary of Product Characteristics), Annex II (A. Manufacturers of the biological active substances and manufacturers responsible for batch release, B. Conditions or restrictions regarding supply and use, C. Other conditions and requirements of the marketing authorisation, D. Conditions or restrictions with regard to the safe and effective use of the medicinal product) Annex III (Labelling and package leaflet) (doc. **A.2.**).
3. **By Implementing Decision of 31.5.2021 concerning the variation to the conditional marketing authorisation granted by Decision C(2020) 9598 (final) for the medicinal product for human use "Comirnaty – COVID 19 mRNA vaccine (nucleoside-modified)"**, the European Commission, having obtained the opinion of the European Medicines Agency, adopted on 20 May 2021 and on 28 May 2021 the following decisions May 2021 and delivered by the Committee for Medicinal Products for Human Use on 28 May 2021, the European Commission, amending the original decision, conditionally authorised the substance "Comirnaty—COVID-19 mRNA vaccine" **also for children aged 12 years and above.** (doc. **A.3**).
4. Three (III) Annexes are attached to this above-mentioned Implementing Decision by the European Union—Annex I (Summary of Product Characteristics), Annex II (A. Manufacturers of the biological active substances and manufacturers responsible for batch release, B. Conditions or restrictions regarding supply and use, C. Other conditions and requirements of the marketing authorisation, D. Conditions or restrictions with regard to the safe and effective use of the medicinal product, **E. Specific obligation to complete post-authorisation measures for the conditional marketing authorisation)**, Annex III (labelling and package leaflet) (doc. **A.4.**).
5. On **21.12.2020**, the **European Commission** had adopted **an implementing decision granting a conditional marketing authorisation for the medicinal product for human use "Comirnaty-COVID-19-mRNA vaccine (nucleoside-modified)" in accordance with Regulation (EC) No 726/2004 of the European Parliament and of the Council** (doc. **A.5**)

   Having regard to the Treaty on the Functioning of the European Union,

   Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and in particular Articles 10(2) and 14-a thereof,

   Having regard to Commission Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council,

   Having regard to the application submitted by BioNTech Manufacturing GmbH, on 1 December 2020, under Article 4(1) of Regulation (EC) No 726/2004,

   Having regard to the opinion of the European Medicines Agency, formulated on 21 December 2020 by the Committee for Medicinal Products for Human Use,

Whereas:

(1) The medicinal product "Comirnaty - COVID-19 mRNA Vaccine (nucleoside modified)" complies with the requirements set out in 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. (2) "**Comirnaty—COVID-19 mRNA Vaccine (nucleoside modified)" falls within the scope of Regulation (EC) No 507/2006, in particular Article 2(1). In addition, as set out in Annex IV, the medicinal product meets the requirements of Article 4 of this Regulation for the granting of a conditional marketing authorisation.** (3) Authorisation for the placing on the market of "**Comirnaty—COVID-19 mRNA Vaccine (nucleoside modified)**" should therefore be granted **subject to certain requirements, in accordance with Article 14-a of Regulation (EC) No 726/2004 and Regulation (EC) No 507/2006.** (4) The Committee for Medicinal Products for Human Use considered that "Single-stranded, 5'-capped **messenger RNA** produced using a cell-free in vitro transcription from the **corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2" is a new active substance.** (5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use",

decided to authorise "Comirnaty" for persons aged 18 years and above.

6. **Annex II** to this above-mentioned Implementing Decision on conditional marketing authorisation (doc. **A.6**) explicitly provides for the following **point E** (**Specific obligation to complete post-authorisation measures for the conditional marketing authorisation):**

This being a conditional marketing authorisation and pursuant to Article 14-a of Regulation (EC) No 726/2004, the MAH shall complete, within the stated timeframe, the following measures:

Description	**Due on**
In order to complete the characterisation of the active substance and finished product, the MAH should provide additional data.	July 2021 Interim reports: 31 March 2021
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.	July 2021 Interim Reports: 31 March 2021
In order to confirm the consistency of the finished product manufacturing process, the MAH should provide additional validation data.	31 March 2021
To confirm the purity profile and ensure comprehensive quality control and batch-to-batch consistency throughout the life cycle of the final product, the marketing authorisation holder should provide additional information on the synthesis process and control strategy for the excipient ALC-0315.	July 2021 Interim Reports: January 2021 April 2021
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.	July 2021. Interim reports: January 2021, April 2021
In order to confirm the efficacy and safety of Comirnaty, the MAH should submit the final Clinical Study Report for the randomized, placebo-controlled, observer-blind study C4591001.	**December 2023**

7. **Annex IV** to the Commission's Implementing Decision of 20.12.2020 **(Conclusions on the granting of the conditional marketing authorisation presented by the European Medicines Agency)** literally states: "The CHMP having considered the application is of the opinion that the risk-benefit balance is favourable to recommend the granting of the conditional marketing authorisation as further explained in the European Public Assessment Report."

8. **In particular, according to these "specific conditions", which should have been fulfilled for the conditional marketing authorisation under EU Regulation No 507/2006 and Article 14-a of Regulation (EC) No 726/2004, it was foreseen that within December 2023 "In order to confirm the efficacy and safety of Comirnaty, the MAH should submit the final Clinical Study Report for the randomized, placebo-controlled,**
9. **observer-blind study C4591001"**
10. The same condition[1] is also provided in the Annexes to the Implementing Decision of 31.05.2021, which "conditionally" authorised the use on minors aged 12 years and above (doc **A.4**).
11. Annex II (doc. **A.8**) to the Commission Implementing Decision of 26.11.2021 amending the conditional marketing authorisation granted by Decision C(2020) 9598(final) for the Comirnaty Covid 19 mRNA vaccine (nucleoside modified) for human use and extending its use to **children aged 5 years and above** (doc. **A.7**) also provides for the above-mentioned conditions.
    In addition, a further condition was provided as follows:
    "In order to confirm the efficacy and safety of Comirnaty, the MAH should *submit the final Clinical Study Report for the randomized, placebo-controlled, observer-blind study C4591007.—due date: July 2024."*
12. Annex II, point D (doc. **A.10**) **to the Commission's Implementing Decision of 16.9.2022 amending the conditional marketing authorisation granted by Decision C(2022) 9598(final) for the medicinal product for human use "Comirnaty—Tozinameran" (**doc. **A.9**) **was the last time the two conditions set out above concerning the clinical study reports for randomised placebo-controlled, observer-blind studies were mentioned.**
13. The conditional marketing authorisation was subsequently converted into a marketing authorisation without specific conditions by the Commission Implementing Decision of 10.10.2022 granting a marketing authorisation for the medicinal product for human use "Comirnaty-Tozinameran—COVID-19 mRNA vaccine (nucleoside-modified)" in accordance with Regulation (EC) No 726/2004 of the European Parliament and of the Council and repealing Decision C(2020) 9598 (final) (doc. **A.1, A.2**) **without fulfilling the specific conditions of the conditional approval referred to above.** See below.

<u>Legitimacy of the plaintiff to sue</u>

14. The plaintiff is the father of two minors.
15. The mother of the two joint children had filed an appeal with the competent regional court of ... (Italy) requesting that the court authorise the Covid 19 "vaccination" of the two joint children even against the father's will. The plaintiff was strongly opposed to this and filed an objection.
16. The Regional Court of ... (Italy), despite the objection of the unlawfulness of the authorisation of the two mRNA substances "Comirnaty" by Pfizer-BioNTech and Spikevax by Moderna, decided the question of the unlawfulness of the marketing authorisation of COMIRNATY and Spikevax (the only two so-called "Covid-19" vaccines), which was still conditional at that time. Covid-19 "vaccines" that are also authorised for minors in the EU), the question of EU illegality was not referred to the European Court of Justice for a preliminary ruling pursuant to Art. 267 TFEU. The mother was authorised by the Regional Court .... (Italy) to carry out the Covid 19 "vaccination" of the two children, despite the objection of the father, who is the plaintiff here.
17. Mr. .... filed an appeal against this first-instance decision to the Higher Regional Court of ..... and again requested a preliminary ruling from the European Court of Justice under Article

1 In the meantime, only the one concerning the submission of additional validation data for the purpose of the consistency of the manufacturing process of the final product with a due date of 2021 had been dropped.

267 TFEU on the legality of the marketing authorisation of the two mRNA substances ("Covid 19 vaccines") Comirnaty and Spikevax (doc. **A.11**).

18. Although it was the **court of last instance** in this type of proceedings, the Higher Regional Court of ... also did not refer the question of the validity and interpretation of the Commission's implementing decisions concerning the marketing authorisation of Pfizer/BioNTech's COMIRNATY (and Moderna's Spikevax), which is essential for the decision, to the European Court of Justice for a preliminary ruling.
19. **The plaintiff, in his capacity as a father entrusted with parental responsibility and thus responsible for the protection of the health and life of his children, as well as his two children themselves, were thus denied legal protection!**
20. **The integrated legal protection system for the guarantee of EU law and the legality of the decisions of the EU institutions has unfortunately not granted the plaintiff, and thus his children, the legal protection to which they are entitled as EU citizens!**
21. Within the framework of the complete procedural path foreseen by the Italian EU Member State for this type of procedure, the plaintiff has unsuccessfully requested the referral pursuant to Article 267 TFEU of the fundamental issue of the legality of the Commission's implementing decisions of 21.12.2020 and 31.05.2021 concerning the (conditional) marketing authorisation of COMIRNATY (as well as those Commission decisions concerning the marketing authorisation of Spikevax).
    Throughout the course of the proceedings at first instance, the Italian courts failed to refer the question of the legality of the EU Commission's implementing decisions on the conditional marketing authorisation of the two so-called Covid-19 "vaccines" to the European Court of Justice for a preliminary ruling within the meaning of Article 267 TFEU on the legality of the implementing decisions on the marketing authorisation of the two mRNA Covid-19 vaccines.
22. Therefore, due to the urgency of the case—the health, indeed the lives of his two children are at stake, as will be explained below—the plaintiff has no other option than to bring a direct action for annulment before this court against the decisions of the EU Commission, which, as will be explained below, are grossly contrary to EU law.
23. His active legitimacy to litigate according to Art. 263 TFEU is also given, among other reasons, because these decisions have a manifest **regulatory character**.
24. "Comirnaty—Tozinameran, COVID-19 mRNA vaccine" (hereinafter referred to as "COMIRNATY") is the first genetic engineering-based substance centrally authorised by the European Commission, which was initially conditionally authorised as a so-called "Covid vaccine" for persons aged 18 years and older, and then on 31 May 2021 also for children aged 12 years and older. Subsequently, the marketing authorisation was extended to children aged 5 years and older (Commission implementing decision of 26 November 2021) and subsequently also granted for use in babies aged 6 months and older (Commission implementing decision of 20 October 2022).
25. Due to the centralised authorisation by European Commission decision of COMIRNATY on 31.05.2021 for children 12 years and older, this active substance was automatically authorised in each member state for children 12 years and older, i.e. no further decision by the Italian member state was needed to authorise this active substance also on Italian territory.
26. On 10 October 2022, by Commission decision, the conditional marketing authorisation was simply converted into a nonconditional marketing authorisation without the necessary conditions being met in accordance with Article 14-a of Regulation (EC) No 726/2004.
27. The Italian Medicines Agency (*Agenzia Italiana del Farmaco*, AIFA) has published all the decisions of the European Commission referred to in the subject-matter of this action in Italian, *sic et simpliciter*, with effect for the entire Italian population.

CAUSES OF ACTION

CAUSE OF ACTION I

28. **Gross violation of Articles 168 and 169 TFEU, Articles 3, 35 and 38 EU Charter of Directive 2001/83/EC Art. 8, 11, 26, 54, 58, 59, 86 et seq., 101 et seq., Annex I, Part I, Part III, Part IV, as well as of Regulation (EC) No. 726/2004 Art. 3 to 7, 10a, 12, 14-a, as well as of the UN Declaration on the Human Genome and Human Rights**
by circumventing the high testing standards provided for gene-based medicinal products
(1) **on the basis of an unfounded and factually illogical exclusion of the application of the authorisation provisions provided for advanced therapy medicinal products to substances which are formally declared as vaccines against infectious diseases but which in fact match gene therapy medicinal products**
(2) **in any case, for failure to involve the specific EMA Committee for Advanced Therapies, which is necessary, irrespective of the classification as gene therapy medicinal product, solely on the basis of the genetic make-up and the mode of action of the substance**
(3) **in any case, due to violation of the authorisation requirements provided for vaccines based on genetic engineering**

(1)

29. **Commission Directive 2009/120/EU of 14 September 2009 amended EU Directive 2001/83/EU of the Parliament and of the Council to the effect that substances declared as vaccines against infectious diseases are not considered gene therapy products.**

The literal wording of the COMMISSION DIRECTIVE 2009/120/EC of 14 September 2009 amending, as regards advanced therapy medicinal products, Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, ANNEX "PART IV **ADVANCED THERAPY MEDICINAL PRODUCTS**" is as follows:
2.1 Gene therapy medicinal product
Gene therapy medicinal product means a biological medicinal product which has the following characteristics:

a) **it contains an active substance which contains or consists of a recombinant nucleic acid used in or administered to human beings for the purpose** of regulating, repairing, replacing, **adding** to or removing a nucleic acid sequence.
b) **its** therapeutic, **prophylactic** or diagnostic **effect is directly related to the recombinant nucleic acid sequence it contains or to the product resulting from the expression of that sequence.**
Gene therapy medicinal products shall not include vaccines against infectious diseases.

30. **This single absolute phrase "*Gene therapy medicinal products shall not include vaccines against infectious diseases*" leads to the simple exclusion of substances, irrespective of their composition and mode of action, from the much stricter, more demanding regulation of marketing authorisation requirements that is necessarily imposed by the legislator on gene therapy medicinal products and advanced therapy medicinal products as a whole, simply because they are defined as "vaccines against infectious diseases".**
31. This leads to the absurd situation that substances, although constructed and acting like gene therapy medicinal products, are excluded from this strict EU authorisation regime for advanced therapy medicinal products, which is necessary to protect the health of the entire EU population, only because they are defined as "vaccines against infectious diseases", and are treated like conventional vaccines, with which they have nothing in common!
32. **A conventional "vaccine" contains an antigen.**

33. **COMIRNATY does not contain antigens, but the blueprint for parts of the virus (the spike protein of the SARS-CoV-2 virus, which is a dangerous toxin), and thus of a foreign substance, which the body is supposed to produce itself. COMIRNATY is therefore a so-called pro-drug.**
34. **Therefore, the injection directly causes the body to produce a harmful substance itself and not a specific defensive or protective substance as is the case with conventional vaccinations. The formation of antibodies and thus protective substances only takes place in the second step.**
35. It is absolutely incomprehensible why substances containing or consisting of a recombinant nucleic acid, which is injected into humans to add a nucleic acid sequence (in the specific case the mRNA, which is then supposed to lead to the production of the SARS-CoV-2 spike protein) are excluded from the definition of "gene therapy medicinal product" and thus from the obligatory and very strict licensing regulations for "advanced therapy medicinal products".
36. Unless in 2009, quite deliberately and in violation of the most fundamental principles of pharmaceutical law—and thus of the **precautionary principle** and the **fundamental right to life and health**, which is also anchored in EU law—the precondition was created that substances which de facto act like gene therapy medicinal products can be authorised without complying with the necessarily strict authorisation requirements for gene therapy medicinal products. This seems to be precisely the case.
37. "The approval of gene therapeutics as conventional vaccines was based on a scientifically and medico-legally invalid foundation. This leads to incalculable consequences for the health of the population, down to the smallest children who are repeatedly injected with these substances in mass "vaccination" campaigns.
38. Gene-based medicines intended for a few patients with very specific disease patterns are subject to high testing standards—but absurdly not those gene-based medicines that are "formally" declared as "vaccines for infectious diseases" (such as COMIRNATY) and are injected into healthy (!) people. Since the end of December 2020 until 2 December 2022, almost one billion doses of these "vaccines" have been administered to people in the EU—until October 2022 on the basis of only conditional marketing authorisations, which were then converted into non-conditional marketing authorisations in absolute contravention of EU law, *sic et simpliciter*, without the manufacturers having fulfilled the conditions (see below).
39. This came about through the influence of powerful lobbies: With Directive No. 2009/120/EC, as explained above, the EU Commission excluded "*vaccines against infectious diseases*" from the group of specially regulated gene therapy medicinal products as early as 2009 through a legal redefinition without the involvement of the European Parliament: "*Gene therapy medicinal products shall not include vaccines against infectious diseases*". This definition was only amended following comments from the pharmaceutical industry (doc. **A.12**). **The original draft directive (**doc. **A.13) had provided for a broad definition of gene therapy medicinal product in favour of the protection of public health which would have included gene-based Covid 19 injections.**
40. The pharmaceutical companies argued, among other things, that the strict safety requirements provided for in the draft directive would make the production of mRNA gene therapy products considerably more expensive. The EU Commission subsequently amended the text of the directive (doc. **A.12**).
41. **The exclusion of gene-based vaccines against infectious diseases from the group of gene therapy medicines saves the manufacturers numerous time-consuming and financially expensive preclinical studies. These are essential for assessing the safety of the medicinal product and of the persons participating in clinical trials.**
42. As a matter of principle, clinical trials must not be started without the results of preclinical studies. They normally shed light on, among other things, the distribution of the medicinal products in the body, the biochemical conversion and degradation as well as their excretion within the framework of so-called pharmacokinetics—including, in the case of gene therapy

medicinal products, the risk of gene transfer into the germline—, possible changes in the genetic material of cells (genotoxicity), cancer risks, the influence of the medicinal products on important parameters for basic functions of the human body (safety pharmacology) and interactions with other medicinal products.

43. The consequence of the redefinition: To date, it has not been scientifically proven whether the mRNA-based Covid-19 "vaccines" (including COMIRNATY by BioNTech) that are administered en masse are not genotoxic or carcinogenic after all, as fundamental studies were omitted.[2] And to date, their mutagenic effect (i.e. permanent DNA damage) has not been ruled out. On the contrary, see below.

44. COMIRNATY is an **experimental mRNA-based substance** that has **absolutely nothing to do with conventional vaccines in terms of its mode of action and production**.
The European Commission's implementing decision of 21 December 2020 (doc. **A.5**), which initially conditionally authorised Comirnaty ("Covid-19 mRNA nucleoside-modified vaccine)" for general, including mass, use, states verbatim
"*(4) The Committee for Medicinal Products for Human Use considered that 'Single-stranded, 5'-capped* ***messenger RNA (mRNA)*** *produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2' is a* ***new active substance.***"

45. In Annex I, point 5 (Pharmacological properties) to the 10.10.2022 implementing decision challenged here (doc. **A.2**), the mechanism of action is stated as follows:

"**The nucleoside-modified messenger RNA in Comirnaty is formulated in lipid nanoparticles, which enable delivery of the non-replicating RNA into host cells to direct transient expression of the SARS-CoV-2 S antigen. The mRNA codes for membrane-anchored, full-length S ...**".

46. Nucleosides are the building blocks of RNA. RNA is a nucleic acid and is essential for protein synthesis. The blueprint for proteins in the human body are stored in the human genome, in the DNA in the cell nucleus, where they are transcribed into mRNA. Once the mRNA with the construction plan for the protein is formed, the mRNA leaves the cell nucleus. Outside the cell nucleus, ribosomes read this construction plan and form the corresponding protein. There are more than a hundred thousand mRNA molecules in a human cell at the same time. The ribosomes only manage to read the information within a short time, because the mRNA usually decays quickly.

47. In the case of the "mRNA vaccine", however, the mRNA is synthetically produced in the laboratory. According to the observation made two years ago—which is in stark contradiction to the official claim made to the public that this synthetic mRNA remains in the upper arm muscle (where the injection takes place) (false claim, which is also in the official approval documents, see above)—this substance enters the entire body and can even cross the brain-blood barrier (*Nature Neuroscience, The S1 protein of SARS-CoV-2 crosses the blood-brain barrier in mice, Elizabeth M. Rhea et al*) and has been found in the bodies of people treated with this substance even months after injection. **After a few particles are absorbed and spike protein is produced by them, this spike protein can facilitate the passage of further "vaccine" particles into the brain** (*A Case Report: Multifocal Necrotizing Encephalitis and Myocardities after BNT162b2 mRNA Vaccination against Covid-19*).

48. **There is not only great concern but clear evidence that synthetic mRNA injected into the body can retrotranscribe into DNA and that these DNA copies can insert into the DNA of human cells, i.e. into the human genome. Therefore, the genetic information of the RNA**

2 Zulassungsdesaster, RA Renè M. Kieselmann, Prof. Dr. Gerd Morgenthaler, Dr. Amrei Müller, Prof.Dr. Günter Reiner, RA Dr. Patrick Riebe, Rain Dr. Brigitte Röhrig, Prof.Dr. Martin Schwab. Online: https://www.berliner-zeitung.de/politik-gesellschaft/das-zulassungsdesaster-lobbyarbeit-und-rechtsbruch-im-fall-der-mrna-praeparate-li.314750

can contaminate and change the human genome (*Intercellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b in vitro in human liver cell line, Markus Alden et al; Potential mechanisms for human genome integration of Genetic Code from SARS-CoV-2 mRNA vaccination: implication for disease—Kyriakopoulos et. al*).

49. The scientific expert opinion "*The immunological and biochemical principles of mRNA vaccine toxicity*" by two microbiologists and a pulmonary specialist (Dr. med. Michael Palmer, Prof. Dr. med. Sucharit Bhakdi, Dr. med. Wolfgang Wodarg—doc. **A.14**) shows **that reverse transcription of RNA into DNA is a mechanism that has been known for many decades** (since the 1970s)! Therefore, it is nothing new, and especially nothing that can simply be ruled out. Quite the opposite! The risk of reverse transcription increases, of course, with each additional injection.
50. The experts write: "***Apparently, EMA's experts were assuming that RNA in general will not affect the integrity of the host cell genome. The first exception to this rule has been known since 1970 ... it could hardly be considered a novelty in 2020***".
51. The mRNA-based substance COMIRNATY was "formally" categorised as a "vaccine", although, as the facts show, it in no way fulfils the function of a vaccine. Apparently, the mRNA substance COMIRNATY is a substance that has been categorised as a "vaccine" on the basis of a "convenience label", although it does not have the function of a conventional vaccination, but is a **pro-drug** that is **constructed and acts like a gene therapy drug** and therefore has to be classified under **advanced therapy medicinal products**.
52. Although COMIRNATY has been formally defined by the EMA as a vaccine against an infectious disease, and therefore would not qualify as a gene therapy medicinal product under Commission Directive 2009/120/EC of 14 September 2009 and Directive 2001/83/EC Annex IV, point 2.1. last sentence, the effective nature and mode of action of COMIRNATY is that of a gene therapy medicinal product. And therefore it is necessary to refer to the provisions foreseen by the European legislator for this particular category of products.
53. **The essential difference between the authorisation procedure for advanced therapy medicinal products (including gene therapy medicinal products) and that for conventional vaccines can be summarised as follows.**
54. For gene therapy medicinal products, Annex I, Part IV of Directive 2001/83 provides, inter alia, as follows:

    1. Introduction: **.... Risk factors that may be considered include: ... the level of integration of nucleic acids sequences or genes into the genome, the long time functionality, the risk of oncogenicity and the mode of administration or use …**
    3. Specific requirements regarding Module 3

    3.2.2 Specific requirements

    In addition to the requirements set out in sections 3.2.1 and 3.2.2 of Part I of this Annex, the following requirements shall apply:

    a) information shall be provided on all the starting materials used for the manufacture of the active substance, including the products necessary for the genetic modification of human ... cells ...

    4.2 Specific requirements for gene therapy medicinal products

    4.2.1 Pharmacology

    a) In vitro and in vivo studies of actions relating to the proposed therapeutic use (i.e. **pharmacodynamic 'proof of concept' studies) shall be provided using models and relevant animal species designed to show that the nucleic acid sequence reaches its intended target (target organ or cells) and provides its intended function (level of expression and functional activity). The duration of the nucleic acid sequence function and the proposed dosing regimen in the clinical studies shall be provided.**

    b) **Target selectivity: When the gene therapy medicinal product is intended to have a selective or target-restricted functionality, studies to**

confirm the specificity and duration of functionality and activity in target cells and tissues shall be provided.

Note: Contrary to claims made to the general public that the injected substance would remain in the affected upper arm muscle and that the formation of the spike protein would be concentrated there, both the nanolipids and the spike protein have been detected throughout the human body! Palmer et al. in their expert opinion on mRNA vaccines in general (doc. **A.14**) comment: "*2.1.* ***mRNA vaccines are distributed throughout the body and prominently affect the blood vessels". The assertion that the mRNA/lipid nanoparticles remain at the site of injection is now widely known to be a blatant untruth. The "vaccines" rapidly spread from the site of injection to regional lymph nodes and to the blood circulation*** *... Moreover, in contrast to most viruses,* ***mRNA vaccine nanoparticles can be taken up by any cell type, including the endothelia, which form of the innermost cell layer of the blood vessels.... 2.2 The expression of spike protein in the body is widespread and long-lasting. Studies on a model mRNA vaccine have shown that the lipid nanoparticles, after intramuscular injection, rapidly enter the bloodstream. They subsequently accumulate preferentially in certain organs including the liver, the spleen, and the ovaries. ... at least the blood vessels themselves are exposed to the vaccine in every organ and every tissue, from which we have to expect widespread expression of the foreign antigen... Another important consideration is how soon the antigen is expressed, and how long this expression lasts....a fairly long-lasting expression of spike after mRNA vaccination was also reported by Röltgen et al., who still detected the spike protein in lympfh nodes 60 days after the second injection, and at this same time point also showed the continued presence of mRNA encoding the spike.*** *Similarly, Magen et al. detected strong spike protein expression and continued presence of the RNA at one month after vaccination.…"*

4.2.2 **Pharmacokinetics**

a) Biodistribution studies shall include investigations on persistence, clearance and mobilisation. **Biodistribution studies shall additionally address the risk of germline transmission.**

Note: on this Palmer et al in their expert opinion on mRNA vaccines in general (doc. **A.14**): "*4.2 Pharmacokinetics of mRNA vaccines. The properties of the lipid nanoparticles ... exert a strong influence on their transport and their fate within the human body. 4.2.1 Organ distribution of model mRNA vaccines. ... the transport of vaccine lipid nanoparticles may resemble that of lipoproteins ... the amount of lipoprotein particles taken up and turned over varies greatly between the cells of different organs. The following organs take up particularly large amounts:*

(1) the liver has a central place in lipoprotein metabolism...
(2) endocrine glands which produce steroid hormones ... These includes the testes, the ovaries, and the adrenal glands,
(3) the placenta requires lipoprotein both for supplying the fetus and for its won production of progestin hormones, which are necessary to sustain pregnancy,
(4) the lacting breast glands acquire fat and cholesterol from lipoproteins and repackage them for release into the breast milk.

With this in mind, we can understand some of the observations on the distribution of mRNA vaccines within the body ...Moderna, according to EMA's report on this vaccine, ... submitted some animal data on a model vaccine ... In this study, the levels o mRNA rather than of the lipids were measured. The results of Moderna's study are incompletely described in the report, but on page 47 we read:
Increased mRNA concentrations (compared to plasma levels) were found in the spleen and eye. ... Low levels of mRNA could be detected in all examined tissues except the kidney. This included heart, lung, testis and also brain tissues ... liver distribution of mRNA-1647 is also

evident in this study, consistent with the literature reports that liver is a common target organ of LNPs." ...
regardless of the tissue in any specific organ, at least the blood vessels and their endothelia will be exposed to the vaccine particles in each and every organ. Accordingly, vasculitis and thromboembolic events are somewhat likely to occur in all organs. Additional tissue-specific pathology might be expected to focus on organs with high levels of accumulation. *However, as we will see presently, the findings of these animal studies likely do not give a complete picture of mRNA vaccine distribution in practice. 4.2.2. Correlation of model vaccine organ distribution with histopathological findings ...* ***we have seen evidence of inflammation and of vaccine-induced spike protein expression in heart muscle*** *... and the brain ..., even though these organs accumulated only comparatively low or moderate levels of the model vaccine in Pfizer's and Moderna's animal experiments.* ***The observed inflammation is particularly remarkable with respect to the brain, which is supposed to be protected by the blood-brain barrier. In this context, we must note two important caveats: 1. The blood-brain barrier breaks down when the brain tissue is afflicted by inflammation. Accordingly, vasculitis within the brain that was induced by the first injection of an mRNA vaccine might soften up the blood-brain barrier and facilitate the entry of vaccine particles delivered with a subsequent booster injection. It would therefore have been important to examine the organ distribution of the vaccine not only after the first injection, but also after one or more repeat injections. However, this was not done in Pfizer's and Moderna's animal studies.***

2. The SARS-CoV-2 spike protein has been shown in several studies to compromise the integrity of the blood-brain-barrier ... Spike protein which may be expressed elsewhere but reaches the brain through the bloodstream may facilitate penetration of vaccine particles into the brain.... These considerations, in combination with histopathological findings, strongly suggest that mRNA vaccines distribute more widely and effectively than Pfizer's and Moderna's very limited animal studies on model vaccine would indicate…

4.2.3. Time course of elimination and duration of activity. *We had seen in Section 4.1.4. that the* ***mRNA can become separated from the lipids after the cellular uptake of the vaccine nanoparticles. The elimination of both ingredients must therefore be considered separately.***
4.2.3.1. Time course of mRNA elimination. *... it must be stressed out that none of these studies used the mRNA deployed in the COVID-19 vaccines, and furthermore that all studies were carried out in rodents. These results can therefore not be directly applied to the current crop of mRNA vaccines and their use in human patients. ...* ***Covid-19 vaccine mRNA has been detected at 60 days after injection in lymph nodes ... and at 30 day within muscle tissue of a limb other than the one which had been injected ... Long-lasting persistence of the vaccine mRNA in blood plasma samples of injected patients was recently reported by Fertig et al. ... these studies on humans show that the vaccine mRNAs may persist much longer than Pfizer's and Moderna's animal studies would suggest.***
4.2.3.2. Time course of lipid elimination. *...According to EMA report ...* ***Moderna submitted no data on the elimination of the two synthetic lipids contained in their Covid-19 mRNA vaccine. ... While EMA reassures us that accumulation of the lipids within the body is unlikely, we must note that firstly the information provided is entirely insufficient by the usual standards of drug development and approval, and secondly that absence of lipid accumulation does not imply absence of cumulative toxicity.****"*

a) **Investigations of shedding and risk of transmission to third parties shall be provided** with the environmental risk assessment, unless otherwise duly justified in the application on the basis of the type of product concerned.

4.2.3.Toxicology

a) **Toxicity of the finished gene therapy medicinal product shall be assessed.** In addition, depending on the type of product, **individual testing of active substance and excipients shall be taken into consideration**, the in vivo effect of expressed nucleic acid sequence-related products which are not intended for the physiological function shall be evaluated

Note: On this Palmer et al. in their expert opinion on mRNA vaccines in general (doc. **A.14**): "*4.3. Lipid nanoparticle toxicity. ... two synthetic lipid species. The PEG-conjugated lipids are the less abundant of the two, and the only mechanism of harm on record consists in allergic reactions to these lipids. In contrast,* ***the cationic lipids account for almost half of the total lipid in the vaccine LNPs, and they can exert toxicity outright, without any "assistance" from the adaptive immune system. ...***
4.3.2. ***Inflammatory signalling by cationic lipids. Several experimental studies have shown that cationic lipids similar to those used in the Pfizer and Moderna COVID-19 vaccines induce strong inflammatory reactions. ... This agrees with the frequent observation of local and also systemic inflammatory reactions among COVID-19 vaccine recipients...."***
5. Genotoxicity of mRNA vaccines ... 5.2.1.4. Summary. Even though this had not yet been experimentally demonstrated when the COVID-19 mRNA vaccines were given emergency approval, ***there was ample precedent to suggest the strong possibility that DNA copies of the vaccine mRNA would arise and be inserted into the cellular genome. Rather than waving away this risk as they did, EMA and other regulators should have obligated Pifzer and Moderna to carry out the necessary studies for excluding this risk before green-lighting authorisation...The results reported by Aldén et al.****, even though preliminary in some respects, pose some very serious questions that* ***can no longer be ignored by the regulatory authorities....*** ***Gene inactivation. Insertion may occur within a gene and disrupt it. This can lead to the loss of important cellular gene products (i.e., proteins) and thus, potentially, to the development of disease including cancer.*** *...* ***Gene regulation. Transcriptional and epigenetic regulatory mechanisms may be affected, thus modulating protein expression levels upward and downward with unpredictable and undesirable results.*** *Indirect regulatory effects may effect even distant genes located on other chromosomes"...* ***Activation of oncogenes... the occurrence of malignancies through DNA integration and activation of cancer-promoting genes (oncogenes) has been demonstrated in clinical trials*** *... for the genetic treatment of children ....* ***These malignancies will typically become manifest only several years after the completion of treatment.*** *Therefore, thorough* ***long-term investigations concerning possible genotoxic effects of the chromosomal integration are absolutely necessary, in both the pre-clinical and the clinical trial stages, for a valid benefit-risk analysis.... The risk of insertion into the chromosomal DNA must be taken seriously.... Autoimmune-like disease. Integration of the spike protein gene into the host cell could lead to permanent expression of this antigen and thus induce chronic autoimmune-like disease... Germline integration****. ... Pfizer's own experiments indicate a high level of vaccine accumulation in the ovaries ... Furthermore, LINE-1 and other retrotransposons are active and cause genomic insertion events in human oocytes ... In combination, these* ***findings, indicate that the mRNA gene sequences may be integrated into the DNA of oocytes, and hence into the human germline. Insertion into male germline cells cannot be ruled out*** *either, even though in the cited animal study the tissue levels of the model mRNA vaccine in the testes was significantly lower than in the ovaries. Should this indeed come to pass—****should the germline cells of vaccinated individuals be rendered transgenic—then the risk of spawning or conceiving transgenic children will not be limited to these individuals only, but it will necessarily be shared by their current or future spouses. In effect, an entire generation of future parents will be exposed to this risk.*** *... Summary.* ***Integration of the mRNA sequences into somatic cells is likely and implies a risk of cancer and of autoimmune disease. Moreover, the risk of germline integration, resulting in transgenic offspring, cannot be denied. These risks must urgently be addressed through in depth-animal studies.***

Meanwhile, the authorisations of any and all mRNA vaccines in current use must urgently be revoked.*"*

b) Single-dose toxicity studies may be combined with safety pharmacology and pharmacokinetic studies, e.g. to investigate persistence.

c) **Repeated dose toxicity studies shall be provided when multiple dosing of human subjects is intended.** The mode and scheme of administration shall closely reflect the planned clinical dosing. **For those cases where single dosing may result in prolonged functionality of the nucleic acid sequence in humans, repeated toxicity studies shall be considered. The duration of the studies may be longer than in standard toxicity studies depending on the persistence of the gene therapy medicinal product and the anticipated potential risks.** A justification for the duration shall be provided.

d) **Genotoxicity shall be studied.** ...[3]

e) **Carcinogenicity shall be studied**[4]. ... depending on the type of product, the tumourigenic potential shall be evaluated in relevant in vivo/in vitro models.

Note: see note under Toxicity above and in addition to this Prof.S. Bhakdi et al in their expert statement specifically on Comirnaty and its use "*Expert statement regarding Comirnaty—COVID-19 mRNA vaccine for children*" (doc. **A.15**):

"**3.2.3 Genotoxicity**

No studies have been carried out regarding genotoxicity, that is, damage to the human genetic material, which could lead to heritable mutations and cancer. In the EMA report ..., this is justified as follows:

No genotoxicity studies have been provided. This is acceptable because the components of the vaccine formulation are lipids and RNA, which are not expected to have genotoxic potential. The risk assessment performed by the plaintiff shows that the risk of genotoxicity related to these excipients [i.e. the synthetic lipids] is very low based on literature data.

In reality, it is known that the LNPs contained in BNT162b2 can enter all kinds of cells-that is, after all, the purpose of their inclusion in this vaccine preparation. It is also known that, once inside the cell, cationic lipids disrupt mitochondrial function (cell respiration) and cause oxidative stress, which in turn leads to DNA damage.

It should be mentioned that two of the lipids used by Pfizer-namely, the cationic lipid ALC-0315 and the PEGylated lipid ALC-0159, which account for 30-50% and for 2-6%, respectively, of the total lipid content-had not previously been approved for use in humans. Pfizer's and EMA's cavalier attitude to the use of novel and so far unproven chemicals as components in drug or vaccine preparations without comprehensive studies on toxicity, including genotoxcicity, is completely unscientific and unacceptable."

f) **Reproductive and developmental toxicity: Studies on the effects on fertility and general reproductive function shall be provided. Embryo-foetal and perinatal toxicity studies and germline transmission studies shall be provided ...**

Note: on this, Prof.S. Bhakdi et al. in their expert report prepared specifically for COMIRNATY (doc. **A.15**):

*"**3.1.1.7 Potential risks to fertility and to the breastfed newborn***

3 See note under 4.2.3. toxicology a)

4 See note under 4.2.3. toxicology a)

A high level of expression of spike in the ovaries raises the prospect of significant damage to that organ, with possible consequences for female fertility. *Uptake of the vaccine by mammary gland cells opens two possible pathways of toxicity to the breastfed child: firstly, the expression of spike protein and its secretion into the breast milk, and secondly, the wholesale transfer of the vaccine into the milk. The mammary glands are apocrine, which means that they pinch off and release fragments of their own cytoplasm into the milk; thus, anything that has reached the cytoplasm might also reach the breast milk. In this connection, we note that both the VAERS database and the EU drug adverse events registry (EudraVigilance) report fatalities in breastfed newborns after vaccination of their mothers (see Section 3.1.3.6). ....*

3.2.4 Reproductive toxicity

Reproductive toxicity was assessed using only one species (rats) and on only small numbers of animals (21 litters). ***A greater than twofold increase in pre-implantation loss of embryos was noted, with a rate of 9.77% in the vaccine group, compared to 4.09% in the control group.*** *Instead of merely stating ...that the higher value was "within historical control data range," the study should have stated unambiguously whether or not this difference was statistically significant; and if it was not, the number of experiments should have been increased to ensure the required statistical power. The same applies to the observations of "very low incidence of gastroschisis, mouth/jaw malformations, right sided aortic arch, and cervical vertebrae abnormalities".* ***Overall, these studies are inadequately described and apparently were also inadequately carried out."***

g) Additional toxicity studies

– **integration studies: integration studies shall be provided for any gene therapy medicinal product**, unless the lack of these studies is scientifically justified, e.g. because nucleic acid sequences will not enter into the cell nucleus. **For gene therapy medicinal products not expected to be capable of integration, integration studies shall be performed, if biodistribution data indicate a risk for germline transmission.**

Note: see also Note to 4.2.2 Pharmacokinetic (a).

– Immunogenicity and immunotoxicity: potential immunogenic and immunotoxic effects shall be studied. …

5. special requirements regarding module 5

5.1 Specific requirements for all advanced therapy medicinal products

5.1.1 The specific requirements in this section of Part IV are additional requirements to those set in Module 5 in Part I of this Annex. ...

5.1.6 **The efficacy of the proposed indications shall be supported by relevant results from clinical studies using clinically meaningful endpoints for the intended use.** In certain clinical conditions, evidence of long-term efficacy may be required. The strategy to evaluate long-term efficacy shall be provided

5.1.7 A strategy for the long-term follow-up of safety and efficacy shall be included in the risk management plan. ...

5.2 Specific requirements for gene therapy medicinal products

5.2.1 **Human pharmacokinetic studies**

Human phamacokinetics studies shall include the following aspects:

(a) shedding studies to address the excretion of the gene therapy medicinal products;

(b) biodistribution studies;

(c) pharmacokinetic studies of the medicinal product and the gene expression moieties (e.g. expressed proteins or genomic signatures).

5.2.2 Human Pharmacodynamic studies
Human pharmacodynamic studies shall address the expression and function of the nucleic acid sequence following administration of the gene therapy medicinal product.
5.2.3 Safety studies
Safety studies shall address the following aspects: ...
c) reassortment of existing genomic sequences;
d) neoplastic proliferation due to insertional mutagenicity.

55. **Regarding "vaccines", the European Community Code relating to medicinal products for human use (Directive 2001/83/EC) provides only the following very meagre provisions, which, moreover, all refer exclusively to conventional vaccines based on antigens and have nothing in common with mRNA injections such as COMIRNATY.**
56. **Vaccines are included in biological medicinal products in Part III of Annex I to Directive 2011/83/EC.**
57. In point **1.2** of **Part III** of its **Annex**, the European Medicines Code defines the requirements for the authorisation of vaccines, but refers exclusively to antigen-based substances.
58. There is absolutely no mention of the additional (apart from the general) requirements for advanced therapy products in the case of vaccines!
59. **The legal statement that, irrespective of their effective composition and mode of action, "vaccines against infectious diseases" are not gene therapy products must be established as scientifically unfounded and the corresponding passages of Directive 2001/83/EC of the European Parliament and of the Council (i.e. Annex I, Part IV, point 2.1, last sentence) and of Commission Directive 2009/20/EC (i.e. Annex IV, point 2.1, last paragraph) must be recognised as grossly unlawful under EU law and established with the necessary consequences.**
60. In addition, on the basis of the above, **the gross unlawfulness of the authorisation procedure (both that for the conditional authorisation and that for the authorisation that is no longer subject to a condition) as well as the marketing authorisation (the former conditional authorisation and the authorisation that is no longer conditional) must be recognised and declared and, as a consequence, the contested implementing decisions of the Commission must be declared null and void. In addition, the directives contested herein shall be annulled in relevant part on the grounds of breach of overriding principles of pharmaceutical law.**

(2)

61. It must also be taken into account that **the EU legislator in any case provides that the Committee for Advanced Therapies must be involved in the authorisation procedure for medicinal products which, even if they would not be classified as advanced therapy medicinal products, function in essential aspects like these (which is the case with COMIRNATY in any case)!**
62. In **recitals (8), (10), (11) (12) (13) (20) of Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products,** the EU legislator provides as follows:
63. (8) **This Regulation respects fundamental rights and observes the principles reflected in the Charter of Fundamental Rights of the European Union and takes into account the Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine.**
64. (10) "***The evaluation of advanced therapy medicinal products often requires very specific expertise, which goes beyond the traditional pharmaceutical field and covers areas bordering on other sectors such as biotechnology and medical devices.*** *For this reason, it is appropriate*

to create, within the Agency, a Committee for Advanced Therapies, which should be responsible for preparing a draft opinion on the quality, safety and efficacy of each advanced therapy medicinal product for final approval by the Agency's Committee for Medicinal Products for Human Use. ***In addition, the Committee for Advanced Therapies should be consulted for the evaluation of any other medicinal product which requires specific expertise falling within its area of competence.****"*

65. *(11)* ***"The Committee for Advanced Therapies should gather the best available expertise on advanced therapy medicinal products in the Community. The composition of the Committee for Advanced Therapies should ensure appropriate coverage of the scientific areas relevant to advanced therapies, including gene therapy ..., pharmacovigilance and ethics. Patient associations and clinicians with scientific experience of advanced therapy medicinal products should also be represented."***

66. *(12)* ***"To ensure scientific consistency and the efficiency of the system, the Agency should ensure the coordination between the Committee for Advanced Therapies and its other Committees, advisory groups and working parties, notably the Committee for Medicinal Products for Human Use, …"***

67. (*13) "****Advanced therapy medicinal products should be subject to the same regulatory principles as other types of biotechnology medicinal products. However, technical requirements, in particular the type and amount of quality, pre-clinical and clinical data necessary to demonstrate the quality, safety and efficacy of the product, may be highly specific.*** *… [T]hose requirements are already laid down in Annex I to Directive 2001/83/EC for gene therapy medicinal products ...*

68. *(20) "****Follow-up of efficacy and adverse reactions is a crucial aspect of the regulation of advanced therapy medicinal products.*** *The applicant should therefore detail in its marketing authorisation application whether measures are envisaged to ensure such follow-up and, if so, what those measures are. Where justified on public health grounds, the holder of the marketing authorisation should also be required to put in place a suitable risk management system to address risks related to advanced therapy medicinal products."*

69. Due to the abusive definition as "vaccine" set out above under point (1) or the purely formal legal—not corresponding to the factual circumstances—exclusion of all substances formally defined as "*vaccines against infectious diseases*" even contrary to the factual properties and effects, COMIRNATY was not subjected by BioNTech to a number of essential studies, which are, however, indispensable for a substance de facto acting like a gene therapy agent for the purpose of establishing its efficacy and safety!

70. **Even if one were to assume that COMIRNATY could not be classified as a gene therapy agent, due to its composition** (nucleic acid substance wrapped in nano-lipid particles) and mode of action (induction by injection of the nucleic acid substance, in the context of gene expression, the production of the spike protein and thus of a toxin), **the Committee for Advanced Therapies must in any case be involved in the approval procedure, since, indisputably, COMIRNATY has properties and modes of action that can only be adequately assessed by this special committee!**

71. Prof. S. Bhakdi et al. have explained the following in their Expert Statement (doc. **A.15**):
"3.1.1. ...
Comirnaty, like all other gene-based COVID-19 vaccines, causes the expression in vivo of one structural protein of SARS-CoV-2—namely, the so-called spike protein, which naturally occurs on the surface of the virus particle. ....The key idea behind the Comirnaty vaccine is as follows:
    (1) a synthetic mRNA that encodes the spike protein is complexed with a mixture of neutral and cationic (positively charged) synthetic lipids, which cluster together in lipid nanoparticles (LNPs);
    (2) after injection, the LNPs facilitate the uptake of the mRNA into host cells, where the mRNA will cause the expression (synthesis) of the spike protein;

(3) *the spike protein will appear on the surface of the host cells and induce an immune reaction itself."*

72. **The Committee for Advanced Therapies should have been involved in the approval procedure of COMIRNATY in any case, due to the composition and mode of action of the substance, irrespective of the legal definition as a "vaccine" against an infectious disease, in accordance with the necessity laid down by the EU legislator in recital (10) of Regulation (EC) No. 1394/2007! But this did not happen!**
73. On 22 July 2022, the signatory attorney DDr. Renate Holzeisen, also in the name and on behalf of Children's Health Defense Europe, submitted a request to the EU Commission and to the EMA for disclosure of the studies carried out by the EMA for the substances Spikevax by Moderna and Comirnaty by Pfizer/BioNTech, on genotoxicity, carcinogenicity and mutagenicity as well as on involvement in the approval process of the Commission for the advanced therapies (doc. **A.16**).
74. On 21.9.2022, EMA provided the first part of the response (doc. **A.17**) to the above-mentioned disclosure request, explicitly stating: "***... please note that none of the authorised COVID-19 vaccines, including Comirnaty and Spikevax, have received input by EMA-S committee for advanced therapies (CAT) and therefore, no documentation proving the involvement of the CAT Committee in the respective procedure of the conditional marketing authorisation (CMA) exist.***

"*Please note that mRNA COVID-19 vaccines are not gene therapy. According to the definition of gene therapy medicinal products in Annex I to Directive 2001/83/EC, PART IV, point 2.1., only such products are gene therapy medicinal products that are used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence. None of this is the case for mRNA vaccines. Therefore, the involvement of the CAT was not foreseen for any COVID-19 vaccine*".
75. **The EMA simply claims that COMIRNATY (and Spikevax) are not gene therapy medicinal products, completely ignoring the fact that mRNA vaccines not only fall within the definition of gene therapy medicinal products due to their composition and mode of action** (as explained under point (1)), **but that, irrespective of their qualification as gene therapy medicinal products, the involvement of the specific committee for advanced therapies would have been mandatory in the authorisation procedure for COMIRNATY (and Spikevax) due to their properties! See above recital (10) Regulation (EC) No 1394/2007.**
76. **The intention of the legislator is clear in this respect! In any case, the Committee for Advanced Therapies should have been involved in the authorisation process!**
77. **But this is exactly what did not happen! And for this reason alone, the approval process is grossly unlawful and the decisions of the EU Commission contested here must be declared null and void.**

(3)

78. **Even the stricter requirements for vaccines based on genetic engineering than those for conventional vaccines were grossly violated by the EMA and the Commission!**
79. The unbelievable audacity in the brutal disregard of the most fundamental principles of pharmaceutical law even goes so far that **the mRNA substances such as COMIRNATY** and Spikevax were and are **deliberately treated like conventional vaccines by the EMA and the European Commission in the approval procedure**, and not even the stricter requirements for vaccines based on genetic engineering were applied!
80. Regarding the genotoxicity studies, the EMA replies (Doc. **A.17**) as follows: "**…** ***Please note that no genotoxicity nor carcinogenicity studies have been submitted by the plaintiff of Comirnaty, as the components of the vaccine formulation are lipids and RNA that are not expected to have genotoxic potential. ....Genotoxicity or carcinogenicity studies are usually***

not required for the final vaccine formulation and therefore are not normally requested from the plaintiff. This is in line with the two WHO guidelines on the nonclinical evaluation of vaccines (WHO 2005, WHO 2013)."

81. **The EMA and the European Commission have thus explicitly stated that they have even violated the specific guidelines for DNA vaccines, because they explicitly and exclusively refer to the WHO guidelines for conventional vaccines, which have absolutely nothing to do with mRNA vaccines.**
82. **It must also be emphasised that WHO guidelines are in principle not binding in any way, and therefore the mere reference to the WHO guidelines for conventional vaccines is all the more absolutely unacceptable!**
83. **Furthermore, the EMA plainly states that no genotoxicity and carcinogenicity studies were carried out because the components of the substance (lipids and RNA) are not expected to have any genotoxic potential! With this statement, the EMA confirms that "Russian roulette is being played" with the entire unsuspecting EU population (and their descendants).**
84. However, the legal regulation of non-conventional vaccines (based on genetic engineering) requires more far-reaching studies than those foreseen for conventional vaccines.
85. "Studies missing according to EMA assessment report:
    The following preclinical studies, which according to the state of scientific knowledge should have been performed before the clinical trial, were never performed for COMIRNATY:
    (1) **on secondary pharmacodynamics,**
    (2) on **safety pharmacology with the "core battery" of studies on the effects on the cardiovascular system.**
        - Cardiovascular
        - nervous and
        - respiratory system.

    (3) on **pharmacokinetics** with
        - absorption / bioavailability,
        - distribution ("time-dependent distribution of the test substance in different organs and corpuscular blood components as well as plasma protein binding") and
        - Metabolism including gastrointestinal tract and first liver passage.
          In 2 different animal models (1 rodent and 1 non-rodent)

    (4) on **toxicology** with
        - Genotoxicity to the extent that it must be possible to assess the genotoxicity of the test substance (for example, by gene mutation studies in bacteria);
        - carcinogenicity to the extent that it must be possible to assess the carcinogenicity of the tet substance;
        - Reproductive and developmental toxicity, in so far as the dossier must allow the assessment of the effects of the test substance on the male reproductive organs.
        - antigenicity and immunotoxicity, if applicable.

86. **Justification by the EMA of the omission of the studies on safety pharmacology and on genotoxicity and carcinogenicity.**
    The EMA assessment report p. 45 (ASSESSMENT REPORT—doc. **A.25**) states the following:
    "***Safety pharmacology studies***
    No safety pharmacology studies were conducted with BNT162b2. The plaintiff refers to that they are not considered necessary according to the WHO guideline (WHO, 2005). In addition, no findings on vital organ functions have been recorded in the repeat dose toxicology studies. Thus, the absence of safety pharmacology studies is endorsed by the CHMP."
    WHO Guideline on nonclinical evaluation of vaccines (2005) and its EU predecessor (CPMP/SWP/465/95)

The 2005 WHO guideline, WHO guideline on nonclinical evaluation of vaccines, WHO Technical Report Series, No. 927, 2005 (doc. **A.19**) **The EU guidelines, which partly incorporate ICH guidelines (guideline on good clinical practice for the EU, Japan and the USA), do not refer to the 2005 WHO guideline either.**

87. **However, in the EU there was a guideline "Note for guidance on preclinical pharmacological and toxicological testing of vaccines" of the EMA (CPMP) from 1997 (CPMP/SWP/465/95** (doc. **A.22**)**.**
This guideline contained the studies required from a scientific point of view for the authorisation of new vaccines. The scope was defined as the following vaccines:
"*Within the context of this Note for Guidance,* ***new vaccines are those containing antigens not yet described*** *in the European Pharmacopoeia monographs or in WHO requirements, or using a new conjugate for a known antigen, or any new combination of known and/or new antigens....* (p. 2) **DNA-vaccines, gene therapy or genetically altered somatic cell therapy are not addressed in this Note for Guidance."** (p. 3)

88. **The Note for Guidance specifically excluded RNA, DNA and similar vaccines from its scope. This was logical since, as will be explained below, the specificity of DNA or gene-based vaccines was covered by the Guideline "CPMP note for guidance on the quality, preclinical and clinical aspects of gene transfer medicinal products (CPMP/BWP/3088/99)—**doc. **A.20**".

89. **For new vaccines, this guideline also considered studies on, for example, secondary pharmacodynamics, safety pharmacology and pharmacokinetics to be necessary:**
    - Secondary pharmacodynamics / safety pharmacology:
      "*The potential for undesirable pharmacological activities e.g.* ***on the circulatory and respiratory systems should be considered for new vaccines*** *(as defined in the Scope)* ***and investigated in appropriate animal models***." (p. 5)
    - Pharmacokinetics:
      The need for pharmacokinetics studies should be based on a case-by-case assessment. The novelty of the substance in question plays a crucial role, so that studies on biodistribution, histopathological examinations of lymph nodes near the injection site and virus excretion may have to be carried out for new substances. (p. 4)

90. **<u>Q&A document on the withdrawal of the Guideline (CPMP/SWP/465)</u>**
On the EMA page (doc. **A.21**), this guideline is shown as "withdrawn". In a Q&A, document from the EMA entitled "*Questions and answers on the withdrawal of the CPMP Note for guidance on preclinical pharmacological and toxicological testing of vaccines (CPMP/SWP/465)*" it is explained that <u>the original guideline has been withdrawn and replaced by the 2005 WHO Guideline</u>:
"*The WHO guideline on nonclinical evaluation of vaccines (2) was published in 2005 and was the result of a collaboration between experts from different regulatory agencies, health agencies, academic institutions and vaccine manufacturers. EU regulators took active part in this work. Following discussion within the CHMP Safety Working Party and Vaccine Working Party, it has been agreed to remove the CPMP guideline on preclinical pharmacological and toxicological testing of vaccines, and to refer to the WHO guideline on nonclinical evaluation of vaccines*".

91. With regard to validity and character, the Q & A document states that the **<u>WHO guideline</u>**, like the CHMP guidelines, is **<u>only of a recommendatory nature</u>** and is not binding. They can be deviated from with appropriate justification:
"*A* ***CHMP guideline does not have legal force****. As written in the EMA document describing the status of scientific guidelines: "Scientific guidelines are to be considered as a harmonised Community position, which if they are followed by relevant parties such as the plaintiffs, marketing authorisation holders, sponsors, manufacturers and regulators will facilitate assessment, approval and control of medicinal products in the European Union. Nevertheless,*

alternative approaches may be taken, provided that these are appropriately justified.“ (3). Therefore, by referring to the WHO guideline, the same principles apply”.

92. **Scope of application of the WHO Guideline 2005**

The WHO guideline defines its scope of application in section 1.1 as follows:

“***Vaccines for human use include*** *one or more of the following:* ***microorganisms inactivated*** *by chemical and/or physical means that retain appropriate immunogenic properties;* ***living microorganisms*** *that have been selected for their attenuation whilst retaining immunogenic properties;* ***antigens extracted from microorganisms, secreted by them or produced by recombinant DNA technology; chimeric microorganisms; antigens produced in vivo in the vaccinated host following administration of a live vector or nucleic acid or antigens produced by chemical synthesis in vitro****. The* ***antigens*** *may be in their native state, truncated or modified following introduction of mutations, detoxified by chemical or physical means and/or aggregated, polymerized or conjugated to a carrier to increase immunogenicity. Antigens may be presented plain or in conjunction with an adjuvant, or in combination with other antigens, additives and other excipients.*”

93. **The guideline focuses on “antigens”.** The guideline refers to “***antigens produced in vivo in the vaccinated host following administration of a live vector or nucleic acid***”, i.e. antigens that are produced by organisms after injection of mRNA into them and then obtained by extraction. An example of this is the vaccine Nuvaxovid, where the spike proteins are produced by the moth larvae and then “harvested” or extracted for inclusion in the vaccine.

94. **COMIRNATY is NOT an antigen as defined in this WHO guideline. Therefore, this guideline does NOT apply to mRNA injections such as COMIRNATY!**

95. Even if the guideline were to be considered applicable, further investigations would have had to be carried out by the manufacturer BioNTech before the start of the clinical trial.

96. **Regulations for the pharmacological-toxicological tests to be carried out**

97. 4.1 of the guideline (p. 45) states that **the following parameters must be examined within the framework of the toxicological studies:**

“*Potential toxic effects of the product should be evaluated with regard to* ***target organs, dose, route(s) of exposure, duration and frequency of exposure****, and* ***potential reversibility.***”

Furthermore, on p. 47, it is stated with regard to the parameters to be observed:

“***Toxicity studies should address the potential of the product for causing local inflammatory reactions, and possible effects on the draining lymph nodes, systemic toxicity and on the immune system. A broad spectrum of information should be obtained from the toxicity studies....***”

98. On
    - developmental toxicity
    - genotoxicity,
    - carcinogenicity and
    - pharmacokinetics

the guideline states that these studies “*are* ***normally*** *not needed*”.

However, given the **scope** of the guideline as defined in section 1.1, **mRNA injections do NOT** fall within the “normal” scope of the guideline, so the **plaintiff cannot rely on the exceptions defined in the WHO guideline.** In addition, the guideline points out that the necessity of corresponding investigations has to be assessed in the individual case of the respective product (pp. 44, 49, 51).

99. Furthermore, it must be taken into account that despite the possible exemption from studies to be submitted for the test substance, in the case of novel excipients or adjuvants, corresponding studies must be submitted for these components (p. 51 f.).

100. **The statements in this guideline on special considerations for certain types of vaccines (p. 54 f.) are also essential. In these cases, further investigations may be required in addition to those described in the guideline. This section specifically addresses DNA vaccines, among others. Reference is made to other WHO guidelines. The WHO guideline on DNA**

vaccines is explicitly mentioned (doc. **A. 23**)**. According to this guideline, the following examinations are also necessary in addition to the fundamentally required examinations:**

- **Biodistribution**
- **persistence and**
- **integration.**

101. It states on p. 78:
"***The duration and sites of expression of the encoded proteins over time should be investigated. If the encoded protein product is expected to persist for a considerable length of time, the impact of this should be addressed.***"
102. And **on p. 79 it is stated about developmental toxicity:**
"***Integration into reproductive tissue may result in germline alteration. The possibility of distribution to, integration or expression in germline cells must be investigated unless otherwise justified.***"
103. The latter means that **the relevant investigations must be carried out and that this requirement can only be deviated from in justified exceptional cases. For the deviation, in turn, investigations must be submitted which show that there is no risk of germline penetration.**
104. Finally, **the WHO Guideline 2005 contains in its "Appendix" a highly impressive list of organs that must be examined within the framework of a toxicity study after multiple administration, which is reproduced below as an excerpt:**

Appendix

List of tissues to be collected in a repeated dose toxicity study

adrenal glands

aorta

bone (femur) and articulation

bone (sternum) with bone marrow

bone marrow smears[1]

brain

bronchi (main-stem)

caecum

colon

duodenum

epididymides

eyes

heart

ileum

injection site(s) (a sample should be taken from the area of injection)

jejunum

kidneys and ureters

larynx

liver

lungs

lymph node (mandibular)

lymph node (mesenteric)

mammary gland

oesophagus

optic nerves

ovaries and oviducts
pancreas
parathyroid glands
Peyer's patches
pituitary gland
prostate
rectum
salivary glands (mandibular, parotid, sublingual)
sciatic nerves
seminal vesicles
skeletal muscle
skin
spinal cord (cervical, thoracic, lumbar)
spleen
stomach
testes
thymus
thyroid glands
tongue
trachea
ureters
urinary bladder
uterus (horns + cervix)
vagina
all gross lesions

105. **Concept Paper on Guidance for DNA vaccines.**
The same high safety standard also results from the "***Concept Paper on guidance for DNA vaccines***" of 15.3.2012, EMEA/CHMP/308136/2007 (doc. **A.24**).

106. **This concept paper deals with the necessity of establishing a guideline for "*DNA Vaccines against infectious diseases*". The background to this is the exclusion of "Vaccines against infectious diseases" from the definition of gene therapy medicinal products in 2009. Previously, these "DNA vaccines against infectious diseases" had also been covered by the guideline "CPMP note for guidance on the quality, preclinical and clinical aspects of gene transfer medicinal products (CPMP/BWP/3088/99)"** (doc. **A.20**)**. Due to the withdrawal, the CHMP considered it necessary to develop a new guideline for this type of medicinal product.** The concept paper literally states:

107. "*Guidance for DNA vaccines is provided in the CPMP note for guidance on the quality, preclinical and clinical aspects of gene transfer medicinal products (CPMP/BWP/3088/99), which came into effect in 2001 and is currently under revision. However, it is stated in Directive 2009/120/EC that 'gene therapy medicinal products shall not include vaccines against infectious diseases', and although some principles and requirements of gene therapy apply, the guidance provided in the current gene transfer guideline does not address specific aspects relevant for a DNA vaccine against infectious disease*".
108. **It is also clear from this Guideline that the special EMA Committee for Advanced Therapies must ALWAYS and EVERYWHERE be involved in the approval procedure for vaccines based on genetic engineering, but according to the explicit communication of the EMA this did not happen in the case of COMIRNATY!**
109. In the guideline "***CPMP note for guidance on the quality, preclinical and clinical aspects of gene transfer medicinal products (CPMP/BWP/3088/99)***" referred to in this concept paper, **high safety requirements are set for DNA *vaccines against infectious diseases*. Among other things, studies had to be carried out to prove at which sites / in which cells the proteins are produced, for how long they are produced, whether there is potential cross-reactivity, which immunomodulatory effects are triggered.**
110. **None of this was done for COMIRNATY because, as the EMA explicitly confirms in its assessment report, the guideline for conventional vaccines was simply used as a guide! This is sheer madness, to say the least!**
111. The clinical studies on the approved substance COMIRNATY, which were subsequently never completed (see the following Cause of Action II), were started without the above-mentioned mandatory preclinical studies having been carried out in accordance with the state of scientific knowledge before the start of the clinical study!
112. **Toxicity studies in rats and other studies prior to the FIH clinical trial—explanations in the book Project Lightspeed**

    Furthermore, the book "Project Lightspeed"[5] contains information on the completely insufficient studies carried out by BioNTech before the FIH clinical trials began. Interesting explanations can be found in particular on pages 217 and 218 on the toxicity study carried out on rats and on p. 174 f on in vitro studies with a pseudo-virus.

    In vitro study on the efficacy of antibodies with a pseudo-virus

    The information on the in vitro test on the efficacy of the antibodies formed, which was only carried out with a **pseudo-virus**—and not with the "SARS Cov-2 virus" in question—can already be found in the assessment report on p. 174 f. of the book. It also follows from these statements that even in the control dish with the cells of the previously unvaccinated vervet monkeys

    > "*only a small number of cells (had) become infected: 500 out of 40,000. When looking through the microscope, the resolution did not allow us to see the difference between 500 and 50 infected cells in order to determine to what extent a vaccine had an effect.*"

    These remarks in the book are particularly interesting in the context of what is said in the EMA's Assessment Report on p. 43:

    "*The relevance of the pseudovirus assay for authentic SARS-CoV-2 was not discussed. For technical reasons, it was not possible to determine a ratio of neutralising to non-neutralising antibodies*".

    Toxicity study in rats

    On pages 217 ff. the following comments can be found on the toxicity study carried out in rats. BioNTech employee Claudia Lindemann had found a passage in the WHO's "Guidelines on the quality, safety and efficacy of Ebola vaccines" that would allow,

5 Project Lightspeed – The Road to the BioNTech Vaccine – and to a Medicine of Tomorrow, Joe Miller, Uğur Şahin and Özlem Türeci, Rowohlt, October ²2021.

> "*.... to start phase I trials* (note: FIH clinical trial) *already after submission of an interim report. Such an interim report would have to include all the data that had been collected during observation of the rodents and that came from the blood samples taken after the injections..... But the most time-consuming part of the toxicological studies, the examination of the carefully removed organs and the microscopic control of these samples, would not necessarily have to be completed before the human studies began.....the federal agency's experts gave their green light*" (p. 218)

As a reminder, the guidelines cited so far, which reflect the state of scientific knowledge, require that the **distribution and effects of the test substance on all organs** be available **before the FIH clinical trial begins**. Furthermore, these studies must have been performed in 2 animal species, rodent and non-rodent. (see II.3.3, 4.2, III.2.2, 3).
BioNTech has thus started the FIH clinical trial on 20.4.2020,

> **without the results of the effects of the test substance on the organs of the test animals having been examined.**

Only blood parameters had been analysed.

113. **The requirements of the state of scientific knowledge are defined by the respective EU and ICH guidelines, which were presented here and which—as demonstrated above—were violated on a large scale.**
114. It should be noted **that the conduct of a clinical trial**, which in the present case has furthermore been conducted de facto (since 27 December 2020) on the entire unsuspecting EU population in gross violation of fundamental EU and international provisions (see below under Cause of Action III) **without the existence of the pharmacological-toxicological studies required by the state of scientific knowledge, constitutes a criminal offence.**"[6]
115. On the basis of the above, the current marketing authorisation of COMIRNATY must also be declared grossly unlawful under EU law and therefore null and void.

CAUSE OF ACTION II

116. **Gross violation of Artt. 168 and 169 TFEU, of Art. 3, 35 and 38 EU-Carta of Directive 2001/83/EC Art. 8, 11, 26, 54, 58, 59, 86 and ff, 101 and ff, Annex I, Part I, Part III, Part IV, of Regulation (EC) No 726/2004 Artt. 3 to 7, 10a, 12, 14, 14a, 20, 20a, 25a, 57, 81, 84a, of Commission Regulation (EC) No 507/2006 Artt. 5 and 7.**
Notwithstanding the omission of the most fundamental studies, on 10 October 2022 the initially only conditional marketing authorisation of COMIRNATY (BioNTech) was converted by the EU Commission, on the recommendation of the Committee for Medicinal Products for Human Use (CHMP) at the EMA, into a no longer conditional marketing authorisation, or authorisation without specific conditions!
117. **Special obligations** were imposed on BioNTech for the conditional marketing authorisation of COMIRNATY by the implementing decision of 21 December 2020 (doc. **A.5**) according to **Art. 14-a of Regulation (EC) No. 726/2004**, which are laid down in the conditions for the **conditional marketing authorisation** granted on the basis of **Commission Regulation (EC) No. 507/2006**, together with the deadlines for implementation.
118. **As part of the specific obligations under paragraph 4, the holder of a marketing authorisation granted under Article 14-a is required to complete ongoing studies or initiate new studies to confirm the positive risk-benefit balance.**
119. BioNTech should have completed the following studies with a positive outcome according to the last status of the conditional marketing authorisation before the absolutely illegal simple

6 Sections from para. 85–107, para. 109 and 111–113 by Dr Brigitte Röhrig, Attorney and expert for medicinal products law.

conversion into a marketing authorisation without specific conditions (see Annex II, point E to Commission Implementing Decision of 16.9.2022 on the variation of the conditional marketing authorisation for the medicinal product for human use "Comirnaty-Tozinameran" granted by Decision C(2020) 9598(final) (doc. **A.9** and **A.10**):

E. SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE CONDITIONAL MARKETING AUTHORISATION
This being a conditional marketing authorisation and pursuant to Article 14-a of Regulation (EC) No 726/2004, the MAH shall complete, within the stated timeframe, the following measures:

Description	**Due on**
In order to confirm the efficacy and safety of Comirnaty, the MAH should submit the final Clinical Study Report for the randomized, placebo-controlled, observer-blind study C4591001.	December 2023
In order to confirm the efficacy and safety of Comirnaty, the MAH should submit the final Clinical Study Report for the randomized, placebo-controlled, observer-blind study C4591007.	July 2024

120. **Even conditional marketing authorisations may be granted according to Art. 14-a point (3) "*only if the risk-benefit balance of the medicinal product is favourable and the applicant is likely to be able to provide comprehensive data*".**
121. **Only if the specific obligations set out in paragraph 4 of Article 14-a of Regulation (EC) No 726/2004 are fulfilled may the Commission, following an application by the marketing authorisation holder and after having received a positive opinion from the Agency, grant a marketing authorisation which, according to Article 14(2) and (3), is valid for five years and may be renewed.**
122. **If EMA concludes that the holder of an authorisation granted in accordance with Article 14-a of Regulation (EC) No 726/2004 has failed to comply with the obligations laid down in the authorisation, EMA shall inform the Commission thereof. The Commission must then adopt a decision amending, suspending or revoking the authorisation in accordance with the procedure laid down in Article 10 Regulation (EC) No 726/2004.**
123. **In 2021, it became known that BioNTech** (doc. **A.26**) **had disbanded the control groups of their studies, which had only been administered placebo, despite their condition from the conditional marketing authorisation. The reason given for disbanding the control group was that it was ethically problematic** (doc. **A.27**) **to withhold the vaccine from the unvaccinated.**
124. Again, the audacity of exposing the entire EU population to an illegal genetic experiment can hardly be topped. Because **releasing a preparation for general use that has not been systematically tested against the control group for effective efficacy and, above all, for safety, violates the most elementary principles of pharmaceutical law and human rights!** See also below in Cause of Action III.
125. The CHMP Committee at the EMA explicitly notes this process, which violates the marketing authorisation requirement, in its official assessment of the BioNTech application for conversion of the conditional marketing authorisation into a regular marketing authorisation (doc. **A.18**). It also recognises that, **due to the omission of the control group, the continuation of the study has become pointless because no further gain in knowledge about the efficacy and safety of the product can be expected.** Removal of traces on a large scale, the pharmaceutical industry and the authorities are not only effectively obstructing scientific clarification, but they are also finally continuing the genetic experiment carried out on the entire EU population since 2021, with suppression and the most fundamental violation of the entire legal framework!

126. **Instead of immediately sanctioning the manufacturer in the middle of 2021, in accordance with Art. 20a of Regulation No. 726/2004/EC, and amending, suspending or revoking the conditional authorisation, nothing happened.**
127. **On the contrary, by implementing decision of 10 October 2022** (doc. **A.1**)**, the Commission even granted the regular marketing authorisation and declared—despite the disbandment of the placebo group already at the beginning of 2021, and thus despite the definite impossibility of fulfilling the imposed conditions—that the specific conditions of the conditional marketing authorisation were fulfilled in view of the data submitted by BioNTech.**
128. **A regulatory authority cannot act any more brazenly and irresponsibly, or even criminally! This should actually lead to immediate criminal investigations throughout Europe and especially at the headquarters of the EMA, the EU Commission and the manufacturer, because the health and even the life of the entire EU population is in danger here!**
129. The Commission has violated legal provisions, specifically Article 14-a (8) of Regulation No 726/2004/EC and Article 7 of Commission Regulation No 507/2006/EC. These stipulate that a conditional marketing authorisation may only be converted into a regular marketing authorisation once the manufacturer has fulfilled all the conditions imposed by the conditional marketing authorisation. **The original condition was then to continue placebo-controlled clinical trials and to submit their results in 2023 or 2024.**
130. "**Multi-year, placebo-controlled studies** (doc. **A.28**) **are the "gold standard" for regulatory authorities worldwide to demonstrate efficacy and (long-term) safety of medicines. Without such valid studies, the regular marketing authorisation for medicinal products must be compulsorily refused according to Art. 12(1) of Regulation (EC) No 726/2004.**
131. **The disbandment of the control group clearly violated the authorisation requirement.** The manufacturers have no incentives for voluntary long-term studies. **Long-term data on the safety of mRNA vaccines can now no longer be collected in control groups. The EMA has not initiated its own comprehensive double-blind, placebo-controlled studies.**
132. **Observational data from the billion-fold administration of the mRNA preparations cannot replace a rigorous, placebo-controlled study. This is all the more true with such poor collection and evaluation of data on possible vaccine damage as we are currently experiencing.**
133. The lobbying influence in the approval process has led to the undermining of fundamental rules in medical law: If healthy people are vaccinated, higher safety standards are needed than if seriously ill people are subjected to a healing trial with gene therapy drugs."[7]
134. Also on the basis of the above, the marketing authorisation of COMIRNATY currently in force is grossly unlawful under EU law and therefore the Commission's implementing decision of 10.10.2022 granting a marketing authorisation for the medicinal product for human use COMIRNATY, which is challenged here, must be annulled.

CAUSE OF ACTION III

135. **Violation of Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use.**

EU citizens, down to the very young (and the unborn) are de facto being used as guinea pigs for an illegally administered experimental substance. Since 2021, an illegal pharmacological-genetic and criminal experiment has been carried out on the entire EU population

7 RA René M. Kieselmann, Prof. Dr. Gerd Morgenthaler, Dr. Amrei Müller, Prof. Dr. Günter Reiner, RA Dr. Patrick Riebe, RAin Dr. Brigitte Röhrig, Prof. Dr. Martin Schwab. Online: https://www.berliner-zeitung.de/politik-gesellschaft/das-zulassungsdesaster-lobbyarbeit-und-rechtsbruch-im-fall-der-mrna-praeparate-li.314750

136. Recital (27) of Regulation (EU) No 536/2014 states that "Human dignity and the right to the integrity of the person are anchored in the Charter of Fundamental Rights of the European Union (the Charter)". In particular, the Charter states that interventions in the context of medicine or biology may only be carried out with the free informed consent of the person concerned. Directive 2001/20/EC contains detailed provisions on the protection of subjects. These provisions should be maintained.
137. Recital (30) of the Regulation states that "in accordance with international guidelines, the informed consent of a subject should be in writing. .... Prior to obtaining informed consent, the potential subject should receive information in a prior interview in a language which is easily understood by him or her. The subject should have the opportunity to ask questions at any moment. ..."
138. According to Art. 3 of the Regulation, "**A clinical trial may be conducted only if**

    a) **the rights, safety, dignity and well-being of subjects are protected and prevail over all other interests;** and

    ...

    According to Art. 4 of the Regulation, a clinical trial must undergo a scientific and ethical review and be authorised in accordance with the Regulation.

    Particularly strict rules apply to minors and other vulnerable groups (Art. 10 of the Regulation).

    Chapter V (Protection of Subjects and Informed Consent) of Article 28 (General Provisions) of the Regulation provides that a clinical trial may only be conducted under the following conditions: …

    b) the subjects ... have been informed in accordance with Article 29(2) to (6);
    c) the subjects ... have given informed consent in accordance with Article 29(1), (7) and (8);
    d) the rights of the subjects to physical and mental integrity ... are safeguarded;

    In Article 29 (informed consent), the EU legislator has provided the following:

    1. Informed consent shall be given ... in writing, dated and signed..…
    2. The information provided to the subject ... in order to obtain informed consent must
        a) enable the subject or his or her legally designated representative to understand:
            i. the nature, objectives, benefits, implications, risks and inconveniences of the clinical trial; …
        b) be kept comprehensive, concise, clear, relevant, and understandable to a layperson;
        c) be provided in a prior interview with a member of the investigating team who is appropriately qualified …;
        d) include information about the applicable damage compensation system referred to in Article 76(1); and
        e) include the EU trial number and information about the availability of the clinical trial results in accordance with paragraph 6.
    3. The information referred to in paragraph 2 shall be prepared in writing and be available to the subject ...
139. In addition, for clinical trials involving minors, the stricter rules provided for in Article 32 of the Regulation shall apply.
140. **The EU population, such as the two minor children of the plaintiff, were handed over by the EU Commission and the EMA to a mass experiment as guinea pigs for experimental substances based on genetic engineering.**
141. The EU population was and is kept in the dark about the fact that

    (i) the mRNA-based so-called Covid-19 "vaccines", such as COMIRNATY, are a substance which, due to their composition and mode of action, correspond to gene therapy medicinal products and thus to advanced therapy medicinal products,

(ii) not even the studies foreseen for "vaccines" based on genetic engineering have been done,

(iii) clinical trials initially envisaged were simply abandoned after a short time (because the results would show a disastrous picture both in terms of the lack of efficacy and the disastrous safety profile) and thus the efficacy and safety of this substance was never proven,

(iv) there is no pharmacovigilance commensurate with the property and mode of action of this substance, and therefore the data collected on side effects (especially the most severe—such as deaths) are dramatically underreported

(v) and yet, the 13,706 deaths and a total of 1,214,603 (mostly serious irreversible) side effects (doc. **A.29**) reported for COMIRNATY from the official database of reported side effects (EudraVigilance www.adrreports.eu) as of 18.2.2023 alone should never have led to a marketing authorisation, let alone a proper one.

142. **The mass use of this experimental substance, including on children, under false pretences, is a gross violation of the Nuremberg Code, because only those who are correctly and fully informed can make a "free" decision. The population deliberately misled has therefore not been able to make a "free" decision, and all "consent forms" signed by vaccinees are null and void.**

143. **Furthermore, in EU member states, such as Italy, there has been a far-reaching Covid 19 "vaccination obligation", which has de facto also affected the age group of the plaintiff's minor children, after children were also excluded from sporting and cultural activities, and thus from important social contacts, if they had not been Covid 19 "vaccinated".**

144. In the present case, the authorisation and thus the use in humans is not based on the legally required basis of comprehensive study results as detailed in Annex I 'Analytical, toxicological-pharmacological and medical or clinical standards and protocols in respect of the testing of medicinal products' of Directive 2001/83/EC.

145. **As stated in Causes for Action I and II, essential study data are missing, which would have had to be provided unconditionally in the case of a regular marketing authorisation for a medicinal product.** This is in contrast to serious scientific misconduct and undeclared safety concerns, so that, viewed as a whole, the **line was absolutely crossed in the case of mass vaccination without sufficient study results on human trials**.

146. At the same time, the Commission is pursuing a policy that establishes a de facto compulsory vaccination for the citizens of Europe, as can already be seen, among other things, from the European Vaccine Strategy of 17.6.2020, COM(2020) 245 final, as well as from the entire procurement volume of tens of billions of doses of vaccine (in the most radical violation of the obligation to transparency by the President of the Commission herself), also organised with concealed text messages. In addition, the EU Commission, together with the WHO, which is under the control of the pharmaceutical industry and the military complex, is forcing the introduction of the e-vaccination passport.

147. The lack of information and education, as shown above, combined with the fact that the Commission is also the licensing authority of Covid vaccines, and is establishing legislative measures that oblige individual citizens of the European Union to be vaccinated, violates mandatory legal principles of international law, known as *ius cogens*.

148. The principles on **consent requirements in medical studies** of the Helsinki Declaration go back to the **Nuremberg Code**, which has also found its way into the **offences of the Rome Statute of the International Criminal Court**.

149. **International law is not only an "integral part" of the Union legal order. Legal acts of the Commission that systematically and collectively violate *ius cogens* are *ipso iure* null and void in accordance with Article 53 of the Vienna Convention on the Law of Treaties, which is recognised under customary international law** (see further references in the literature: *Schmalenbach*, in: Calliess/Ruffert, EUV/AEUV (Fn. 1), Art. 216, Rapp. 1), Art. 216, marginal

no. 50; *Tomuschat*, in: von der Groeben/Schwarze, EUV/EGV (fn. 10), Art. 281, marginal no. 43; in detail *Schmalenbach*, in: Europarecht als Mehrebenensystem (fn. 4),67 (75 ff.)).

150. Apart from this, the agreement under international treaty law between the International Criminal Court and the European Union on cooperation and assistance of 10.4.2006, OJ 2006 L 115, p. 50) regulates in Art. 4 that the respective provisions of the statute are to be observed for the EU.

151. **The performance of medical or scientific experiments on human beings in peacetime, which violate the principles of medical ethics, constitute a violation of the Rome Statute of the International Criminal Court, since they are the result of the actions of the Commission or of Union policy. Under the alternative offence of Art. 7 para. 1 lit k of the Rome Statute of the International Criminal Court with reference to the prohibition in wartime concerning "inhumane treatment including biological experiments" as well as "intentional infliction of great suffering or serious impairment of physical integrity or health" according to Art. 8 para. 2 lit a of the Rome Statute of the International Criminal Court, the Commission and the Union policy are in violation of the Rome Statute of the International Criminal Court. 8 para. 2 lit. a of the Rome Statute for the deliberate commission of "other inhumane acts of a similar nature" can be sanctioned as "crimes against humanity" if great suffering or serious impairment of physical integrity is caused as a result of state action or the Union institutions.**
For this reason, too, the implementing decisions of the EU Commission challenged here must be declared null and void.

CAUSE OF ACTION IV

152. **Annulment of the contested implementing decisions on grounds of misuse and infringement of COMMISSION REGULATION (EC) No 507/2006 of 29 March 2006 concerning the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council**

153. It is obvious that the conditions for the applicability of Commission Regulation (EC) No 507/2006 have been artificially created in order to be able to place substances based on genetic engineering on the market without the necessary preconditions for this, within the framework of a conditional authorisation, and to apply them in a forced mass application (indirectly or even directly, with the threat of exclusion from professional and social life) to the entire unsuspecting population.

154. According to Art. 2 Regulation (EC) No. 507/2006, the conditional authorisation of a medicinal product can only be considered at all if
    1. the medicinal product is intended for the treatment, prevention or medical diagnosis of seriously debilitating or life-threatening diseases.
    2. medicinal products intended to be used in emergency situations against a threat to public health duly identified either by the WHO or by the EU under Decision No 2119/98/EC.[8]

155. **The alleged crisis situation, the declaration of which was necessary to even consider conditional approval of COMIRNATY & Co. was created by an incredibly brazen misuse of the RT-qPCR test and the enormous number of false positive SARS-CoV-2 infection cases it created worldwide (from the fourth week of January 2020). Without this artificially created enormous number (up to 97% percent) of false positive cases, Regulation (EC) No. 507/2006 could never have been applied.**

156. Prof. Dr. Ulrike Kämmerer concludes her expert opinion on the RT-qPCR test with the following conclusion (Doc. **A.30**): "Evaluation of the suitability of the RT-qPCR technique for the detection of possible infection and infectivity of individuals with respect to SARS-CoV-2.

8 Point 3 does not matter in this case.

1. In light of the problems and technical limitations outlined here, **RT-qPCR is not a suitable reliable (and approved) diagnostic tool for the detection of infectious (replication-capable) SARS-CoV-2 viruses.**
2. Furthermore, **the pure RT-qPCR test result is only a laboratory value which, in view of the aspects outlined, never permits a valid statement about the presence of infectious viruses and may only be used at all in conjunction with a clinical symptom diagnosis (ascertained by healthcare providers, in Germany medical doctors) to estimate a possible viral infection.**

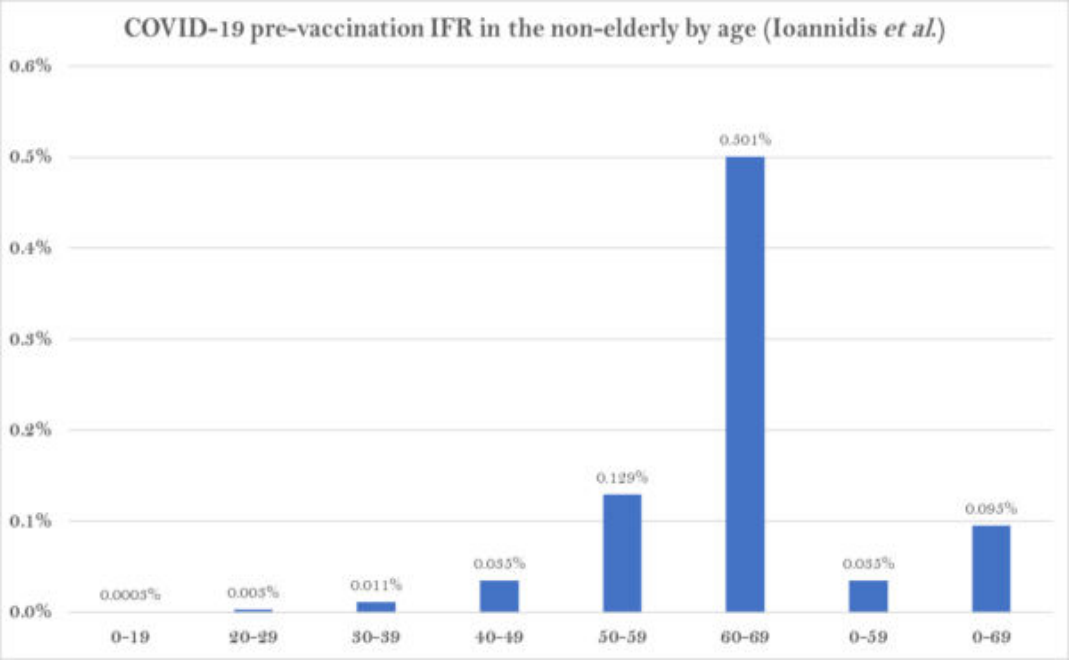
Summary:

For the testing of asymptomatic and even symptomatic persons on the basis of a nasopharyngeal swab, as it is done uncritically in large numbers and predominantly by non-medical personnel WITHOUT (here decisive: contrary to the WHO requirement!) anamnesis and symptom collection from the tested persons, the RT-qPCR used is not suitable in any form to detect an infection and above all an infectivity with SARS-CoV-2."

157. **Furthermore, there has never been a real crisis situation**—unless it was caused, as in Italy, by absurd death-inducing and penal measures (systematic prevention of timely treatment of the sick at an early stage at home, prohibition of the use of drugs proven to be very efficient for the treatment of covid-19, such as ivermectin, hydroxychloroquine, etc.), or the use of a new drug for the treatment of the disease, placing Covid-19 sufferers in old people's homes, killing patients through an absurd massive use of ventilators etc.) caused—**because the Infection Fatality Rate (IFR) was low overall, and even more so for the population under 70 years of age.**

158. The most cited medical scientist in the world, **John Ioannidis, MD, together with other experts, shows the following in the study *Age-stratified infection fatality rate of Covid-19 in the non-ederly informed from pre-vaccinated national grunseroprevalence studies*** (doc. **A. 31**):

For persons up to 19 years of age, the IFR was 0.0003 per cent, for 20-29 years it was also 0.011%, for 30-39 years it was 0.011%, for 40-49 years it was 0.035%, for 50-59 years it was 0.129% and for 60-69 years it was 0.501%. This works out to 0.035% for those aged 0-59 and 0.095% for those aged 0-69.



The results “suggest that pre-vaccination IFR is extremely low in non-elderly populations. At the global level, ”the IFR is thus likely to have been 0.03% and 0.07% for 0-59 and 0-69 year olds, respectively".

In terms of the total population (including the oldest people), the IFR corresponds to that of a moderately severe flu.

159. **Thus, at no time did the basic conditions for a conditional marketing authorisation of COMIRNATY and the other so-called Covid-19 vaccines as provided for in Art. 2 of Commission Regulation (EC) No 507/2006 exist within the framework of a conditional marketing authorisation according to Commission Regulation (EC) No 507/2006.**

160. In addition, Article 4 of Regulation (EC) No 507/2006 provides for further conditions as follows:

(1) A conditional marketing authorisation may be granted if the Committee considers that all of the following conditions are met, although comprehensive clinical data on the safety and efficacy of the medicinal product have not been submitted:

a) The risk-benefit balance of the medicinal product as defined in point 28a of Article 1 of Directive 2001/83/EC must be positive;
b) The applicant must be expected to be able to provide the comprehensive clinical data;
c) A medical care gap can be closed;
d) The public health benefit of the immediate availability of the medicinal product on the market outweighs the risk due to the lack of additional data.

161. Re a): **The risk-benefit ratio could not be considered and explained as positive at any time, since essential information to exclude very serious risks (see under Causes of Action I and II) is still missing to this day.** Furthermore, due to the generally low *infection fatality rate* (comparable to that of a moderate flu for the total population and de facto zero for children and adolescents) and in view of the side effect cases recorded in the EudraVigilance database (including thousands of fatalities and hundreds of thousands of other most serious irreversible side effects) despite the lack of active pharmacovigilance, a positive risk-benefit ratio can never be established.

162. Re b): As stated in Cause of Action II, the placebo groups of the few clinical trials were deliberately and plannedly disbanded a few months after the start of the trials by offering the members of the control group to be injected with COMIRNATY as well. This deliberately made it impossible to fulfil this requirement as well, because the results would have provided an impressive picture of the disastrously negative benefit-risk ratio. This procedure violates fundamental principles of medicinal product law, including Regulation (EU) No. 536/2014 on clinical trials.

163. Re c): It has been proven by thousands of doctors worldwide that there has never been a de facto gap in medical care. The doctors treating their patients to the best of their knowledge and conscience have been able to successfully treat their patients at home, even very elderly ones, by using medicines such as ivermectin, hydroxychloroquine and others (very often in combination)—and this despite the fact that enormous obstacles had been put in their way by the governments and their vicarious agents!

164. Re d): Based on the above, there is no evidence of any benefit to public health, on the contrary. Apart from the already known enormous risks and side-effects (whereby an extreme under-reporting, especially of deaths, must be assumed), the risks listed under Causes of Action I and II are hardly comprehensible in their feared and currently in no way excludable dimensions. There may still be a great deal of individual physical (and economic) damage, and thus also economic and public health damage, to come to the entire EU population.

165. For these reasons, too, the Commission’s implementing decisions challenged here must be declared null and void.

CAUSE OF ACTION V

166. **Annulment of the contested implementing decision for gross violation of Articles 168 and 169 TFEU and Articles 3, 35 and 38 EU Charter**

167. On the basis of the facts and circumstances set out above and documented in this application, it is obvious that the implementing decisions of the EU Commission challenged here (first and foremost the Commission's implementing decision of 10.10.2022—Doc. **A.1**), grossly violate the principles anchored in Article 168 TFEU (Public Health) by the EU legislator. **The EU legislator has guaranteed EU citizens that a high level of health protection is to be ensured in the definition and implementation of all Union policies and activities.** Union action should be directed towards improving public health, preventing human illness and diseases, and **obviating sources of danger to physical and mental health**.

168. **The EU shall take measures to establish high standards of quality and safety for medicinal products and medical devices.**

169. All these obligations entered into with Art. 168 TFEU have been violated by both the European Commission with the implementing decisions contested here (first and foremost the Commission's implementing decision of 10.10.2022), as well as with Directive 2009/120/EC (Annex concerning Part IV point 2. 1, last sentence), as well as the European Parliament and the Council with Directive 2001/83/EC—Annex I, Part IV, point 2.1, last sentence, have been grossly violated, and they have thus concretely placed and continue to place the plaintiff's minor children (and the entire EU population) in a situation that endangers their health and their lives.

170. **Article 3 of the EU Charter (right to integrity)** guarantees to every person present in the EU: (1) Everyone has the right to respect for his or her physical and mental integrity **(2) In the fields of medicine and biology, the following must be respected in particular: the free informed consent of the person concerned, according to the procedures laid down by law, ..., the prohibition on making the human body and its parts as such a source of financial gain, ...**

171. In **Article 35 of the EU Charter (health protection)**, every person present in the EU **is guaranteed a high level of health protection in the definition and implementation of all Union policies and activities.**

172. In **Art. 169 TFEU (consumer protection)**, consumers are guaranteed that, in order to ensure a high level of consumer protection, the EU shall contribute to **protecting the health** and safety of consumers and to promoting their **right to information**.

173. And according to Art. 38 EU Charter (Consumer Protection), the policies of the Union shall constitute a high level of consumer protection.

174. On the basis of the foregoing, it is obvious that, with the implementing decisions contested here, the EU Commission has also grossly violated the fundamental right of the plaintiff and his minor children to consumer protection and the obligations applicable to the Commission in particular under Article 169 TFEU.

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175. The plaintiff therefore requests that this Court, on the basis of the cited multiple most severe violations of applicable EU law by legal acts in the nature of regulations, which furthermore directly and personally affect the plaintiff and his minor children, recognise and declare the Commission's implementing decisions contested here to be null and void on the grounds of gross unlawfulness of EU law. Similarly, the plaintiff requests that the parts of Directive 2001/83/EC of the European Parliament and of the Council and of Commission Directive 2009/120/EC (Annex I and Annex—Part IV, point 2.1. last sentence, respectively) which are contested here be declared null and void on the grounds of breach of overriding EU legal principles relating to medicinal products and of the obligation to protect human rights which is also anchored in EU law.

Bolzano/Italy 23.02.2023

Attorney DDr. Renate Holzeisen

The following documents are enclosed:

A.1. IMPLEMENTING COMMISSION DECISION of 10.10.2022 granting a marketing authorisation for the medicinal product for human use “Comirnaty—Tozinameran, COVID-19 mRNA vaccine (nucleoside modified)” in accordance with Regulation (EC) No 726/2004 of the European Parliament and of the Council and repealing Decision C(2020) 9598(final); p. 1 to p. 4 of the appendices; paragraphs 1, 13, 127, 167;

A.2. Annexes, I II and III to the EU Commission’s implementing decision of 10.10.2022; p. 5 to p. 199 of the appendices; paragraphs. 2, 13, 45;

A.3. COMMISSION IMPLEMENTING DECISION of 31.5.2021 amending the conditional marketing authorisation granted by Decision C(2020) 9598(final) for the medicinal product for human use “Comirnaty—COVID-19 mRNA vaccine (nucleoside modified)”; p. 200 to p. 203 of the appendices; paragraph 3;

A.4. Annexes, I II and III to the EU Commission’s implementing decision of 31.5.2021; p. 204 to p. 240 of the appendices; paragraphs 4, 10;

A.5. COMMISSION IMPLEMENTING DECISION of 21.12.2020 granting a conditional marketing authorisation for the medicinal product for human use “Comirnaty—COVID-19 mRNA vaccine (nucleoside modified)” in accordance with Regulation (EC) No 726/2004 of the European Parliament and of the Council; p. 241 to p. 244 of the appendices; paragraphs 5, 44, 117;

A.6. Annexes, I II and III to the EU Commission’s implementing decision of 21.12.2020; p. 245 to p. 278 of the appendices; paragraph 6;

A.7. COMMISSION IMPLEMENTING DECISION of 26.11.2021 amending the conditional marketing authorisation granted by Decision C(2020) 9598(final) for the medicinal product for human use “Comirnaty—Tozinameran, COVID-19 mRNA vaccine (nucleoside modified)”; p. 279 to p. 282 of the appendices; paragraph 11;

A.8. Annexes, I II and III to the EU Commission Implementing Decision of 26.11.2021; pp. 283 to 396 of the appendices; paragraph 11;

A.9. COMMISSION IMPLEMENTING DECISION of 16.9.2022 amending the conditional marketing authorisation granted by Decision C(2020) 9598(final) for the medicinal product for human use “Comirnaty—Tozinameran, COVID-19 mRNA vaccine (nucleoside modified)”; p. 397 to p. 400 of the appendices; paragraphs 12, 119;

A.10. Annexes, I II and III to the EU Commission’s Implementing Decision of 16.9.22; p. 401 to p. 596 of the appendices; para. 12, 119;

A.11. Higher Regional Court of .... , judgment of 11.05.2022
p. 597 to p. 629 of the appendices; paragraph 17;

A.12. European Commission, Enterprise and Industry Directorate-General, Implementation of the Advanced Therapies’ Regulation, Amendments to Annex I to Directive 2001/83/EC as regards advanced therapy medicinal products, 9 July 2008; p. 630 to p. 635 of the appendices; paragraphs 39, 40;

A.13. European Commission, Implementation of the Advanced Therapies’ Regulation—Public Consultation Paper—Proposals to amend Annex I to Directive 2001/83/EC as regards Advanced Therapy Medicinal Products, 8 Aril 2008; p. 636 to p. 651 of the appendices; paragraph 39

A.14. Michael Palmer MD, Sucharit Bhakdi MD, Wolfgang Wodarg MD, The immunological and biochemical principles of mRNA vaccine toxicity; p. 652 to p. 742 of the appendices; (colour print); paragraphs 49, 54;

A.15. Prof.Dr.med. Sucharit Bhakdi et al. expert statement regarding the use of Comirnaty COVID-19 mRNA vaccine in children; pp. 743 to p. 771 of the appendices; (colour print); paras 54, 71;
A.16. Attorney DDr. Renate Holzeisen for CHD, Request for Disclosure, F.O.I.A. according to art. 15 TFEU, art. 41 e 42 Charter of Fundamental Rights; p. 772 to p. 786 of the appendices; paragraph 73;
A.17. EMA, Comirnaty and Spikevax—ASK-117768 Batch 1- Letter to the requester, 21.09.2022; p. 787 to p. 790 of the appendices; paragraphs 74, 80;
A.18. EMA 853699/2022 Assessment Report, Comirnaty; p. 791 to p. 827 of the appendices; (colour print); para 125;
A.19. WHO guideline on nonclinical evaluation of vaccines; p. 828 to p. 864 of the appendices; paragraph 86;
A.20. EMA, Note for Guidance on the quality, preclinical and clinical aspects of gene transfer products; p. 865 to p. 898 of the appendices; paragraphs 88, 106;
A.21. EMA, Questions and answers on the withdrawal of the CPMP Note for guidance on preclinical pharmacological and toxicological testing of vaccines—21.07.2016; p. 899 to p. 904 of the appendices; paragraph 90;
A.22. EMA, CPMP, Note for guidance on preclinical pharmacological and toxicological testing of vaccines 17.12.1997; p. 905 to p. 912 of the annexes; paragraph 87;
A.23. WHO, Guidelines DNA vaccines 2007; p. 913 to p. 938 of the appendices; paragraph 100;
A.24. EMA, Concept paper on guidance for DNA vaccines 15.3.2012; p. 939 to p. 942 of the appendices; paragraph 105
A.25. EMA, Assessment Report Comirnaty 19.2.21; p. 943 to p. 1083 of the appendices; (colour print)
A.26. EMA, Assessment Report Comirnaty 596333/2021; p.1084 to p.1127 of the appendices;
A.27. WHO Covid-19 vaccine trial 29.11.21; p.1128 to p.1166 of the appendices;
A.28. NIH, Placebos in clinical trials; p. 1167 to p. 1171 of the appendices; (colour print)
A.29. EudraVigilance, Comirnaty reported adverse reactions; p. 1172 to p. 1174 of the appendices; (colour print)
A.30. Prof.Dr.rer.bio.hum. Ulrike Kämmerer PhD Evaluation of the suitability of the RT-qPCR technique for the detection of possible infection and infectivity of individuals with respect to SARS-CoV-2; p. 1175 to p. 1234 of the appendices; (colour print)
A.31. John Ioannidis et al. Age-stratified infection fatality rate of Covid-19 in the non-ederly informed from pre-vaccinated national seroprevalence studies; p. 1235 to p. 1285 of the appendices; (colour print)