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EUROPEAN COURT

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ACTION FOR ANNULMENT according to Art. 263 TFEU

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Applicants:
The present action for annulment is brought on behalf of the following applicants*:

Defendant:

European Commission

Concerning:

EUROPEAN COMMISSION IMPLEMENTING DECISION of 21/12/2020 on the granting of conditional approval of the medicinal product for human use "Comirnaty" – COVID-19-mRNA-based vaccine (nucleoside-modified)" in accordance with Regulation (EC) No. 726/2004 of the European Parliament and of the Council, including subsequent amendments and integrations.

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The undersigned lawyer RA DDr. Renate Holzeisen, admitted in Italy also to the Supreme Courts, registered with the Bar Association of Bolzano and with office in 7 Bahnhofallee, I-39100 Bolzano,

PROVIDED THAT

1. the European Medicines Agency (EMA) issued its recommendation with comment for the conditional marketing authorisation of the medicinal product "Comirnaty" - COVID-19 mRNA vaccine (nucleoside-modified) on 21 December 2020, based on the application submitted by BioNTech Manufacturing GmbH on 1 December 2020, in accordance with Article 4(1) of Regulation (EC) No. 726/2004, - **EMA Assessment report "Comirnaty" Procedure No. EMEA/H/C005735/0000** (doc **A.1**)
2. 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 Community procedures for the authorisation and supervision of medicinal products for human** and veterinary **use** and establishing a European Medicines Agency, and in particular Article 10 (2) and Article 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, Having regard to the application submitted by BioNTech Manufacturing GmbH on 1 December 2020 pursuant to Article 4(1) of Regulation (EC) No 726/2004, **Having regard to the opinion of the European Medicines Agency delivered 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)" fulfils the requirements of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001, for establishing 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, and in particular Article 2(1) thereof. Furthermore, the medicinal product fulfils the conditions laid down in Article 4 of that Regulation for the granting of a conditional marketing authorisation, as set out in Annex IV. establishing the Community code relating to medicinal products*** *(4) The Committee for Medicinal Products for Human Use considered that 'Single-stranded, 5'-capped messenger RNA (mRNA) produced using cell-free in vitro transcription from the appropriate DNA templates and 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"*

has decided as follows:

"*Article 1* ***- A conditional marketing authorisation as provided for in Article 3 and Article 14-a of Regulation (EC) No 726/2004 is granted for the medicinal product 'Comirnaty' - COVID 19 mRNA vaccine (nucleoside modified), the characteristics of which are summarised in Annex I to this Decision.*** *"Comirnaty - COVID 19 mRNA vaccine (nucleoside-modified)' is entered in the Union Register of Medicinal Products with the following number: EU/1/20/1528. Article 2 - The authorisation of the medicinal product referred to in Article 1 shall be subject to the requirements and conditions, including those relating to the manufacturing, set out in Annex II. These requirements shall be reviewed annually. Article 3 - The labelling and package leaflet of the medicinal product referred to in Article 1 shall comply with the conditions set out in Annex III. Article 4 - The authorisation shall be valid for one year from the date of notification of this Decision. Article 5 - This Decision is addressed to BioNTech Manufacturing GmbH, An der Goldgrube 12, 55131 Mainz, Germany."* **- European 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 (**Doc. **A.2.1.).**

3. Four (IV) annexes are attached to the above-mentioned Implementing Decision of the European Union - Annex I (Summary of Product Characteristics), Annex II (A. Manufacturer of the active substance(s) of biological origin and manufacturer(s) responsible for batch release), Annex III (Labeling and Package Leaflet), Annex IV (Conclusions of the European Medicines Agency on the granting of marketing authorization under "special conditions" (Doc. **A.2.2.**).

4. By implementing decision of January 8, 2021, on the variation of the conditional marketing authorization granted by Decision C(2020) 9598 (final) for the medicinal product for human use ""Comirnaty" - COVID-19 mRNA vaccine (nucleoside-modified)", the European Commission, following the opinion of the European Medicines Agency delivered by the Committee for Medicinal Products for Human Use on January 8, 2021, decided to amend the original decision (Doc. **A.2.3.).**

5. By implementing decision of 2 February 2021 on the variation of 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, following the opinion of the EMA

delivered by the Committee for Medicinal Products for Human Use on 2 February, decided to amend the original decision (doc**. A.2.4.).**

6. Having said all of the above, an action for declaratory judgment and declaration of invalidity pursuant to Article 263 TFEU of the above-mentioned Implementing Decision of the EU Commission dated December 21, 2020, together with all subsequent amendments and integrations, is hereby brought on the following grounds.

Legal standing according to Art. 263 TFEU

7. All of the plaintiffs are working in the field of health care or care for the elderly as doctors, nurses, caregivers for the elderly, etc., and have been exposed to an ever-increasing pressure towards compulsory Covid vaccination for almost two months now. Italy, like other EU Member States, has started to predominantly administer vaccination of "Comirnaty" in the last week of December 2020.

8. “Comirnaty" is the first mRNA-based substance in the EU to be conditionally approved centrally by the European Commission as a so-called Covid "vaccine". The two other substances now approved as so-called Covid "vaccines" (manufacturers: Moderna and AstraZeneca) are also experimental in nature.

9. Especially persons working in the field of health care and nursing, such as the plaintiffs, have been experiencing an immense pressure, starting from a social-moralizing pressure up to the threat of consequences under labor law, should they not undergo the so-called Covid-"vaccination".

10. Virologists who have, over the course of the last year, become the exclusive house and court advisors of the governments of the EU member states, are publicly called upon to "legally prosecute" in particular those EU citizens who work in the field of health care and nursing and who, in view of the risks associated with the experimental Covid "vaccines" and their unproven benefits (see below), refuse to expose themselves to these genetic-engineering based substances (see a corresponding article in the Italian-language South Tyrolean daily newspaper Alto Adige of 13/01/2021 - Doc. **A.3.1.).**
From internal communications of the South Tyrolean Sanitary Authority as well as from communications of the South Tyrolean Medical Association to the physicians, it is evident how the Sanitary Authority, Superiors and the Medical Association, respectively, request and exert pressure for employees (physicians, paramedics) as well as freely practicing physicians registered with the Medical Association, to undergo the Covid "vaccination":
Email correspondence from the South Tyrolean Sanitary Authority indicates that the Italian Ministry of Health requested that they report which employees were participating in Covid vaccination and which were not (Doc. **A.3.2).**

11. Italy, like other EU Member States, has started the administration of the Covid "vaccine" "Comirnaty" (Doc. **A.3.3**), as foreseen in the Covid national "vaccination plan" of 7/12/2020 (Doc. **A.3.4.**). The plaintiffs in the health and care sector are accused of lacking a sense of responsibility, as well as a lack of solidarity towards the employees and the patients/ caregivers entrusted to them (Docs. **A.3.5, A.3.6,** and **A.3.7**).

12. Massive reports of compulsory vaccination (currently with Corminaty) are also coming in from the rest of the country, to the detriment of health and care workers (**A.3.8.** and **A.3.9.)**. The "Comirnaty"-refusers among the staff working in the health care and nursing sector are concretely threatened with dismissal.

13. **The centralized approval of "Comirnaty" on 21/12/2020 means that the European Commission has automatically approved this active ingredient in every Member State, i.e. no further decision of the individual Member State was required to approve this active ingredient also on Italian territory.**

14. Therefore, the above-mentioned plaintiffs clearly have the right to bring an action pursuant to Article 263 TFEU, since the contested implementing decision of the EU Commission and the preceding opinion of the EMA have a direct effect on the personal position of the plaintiffs and their fundamental right to physical integrity, which is protected by the EU Treaty.

15. The Plaintiffs are **directly and personally affected** by the unlawful marketing authorization of "Comirnaty", as their fundamental rights to bodily integrity (Art. 3 EU Charter), to a high level of health protection (Art. 168 TFEU, Art. 35 EU Charter) and to consumer protection (Art. 169 TFEU, Art. 38 EU Charter) are grossly violated by this Implementing Decision, as set forth below.

16. Individual plaintiffs have already requested the EU Commission and the EMA, in particular, to refrain from an approval of the mRNA-based experimental active substances, such as "Comirnaty", due to the enormous risks involved, which are currently impossible to assess in their entirety, by means of a warning letter sent electronically on December 19, 2020, prior to the implementation decision challenged here (see warning letter of December 19, 2020 in Doc. **A.4**). Incidentally, no reaction or response to this warning has been received.

17. According to **Article 168 TFEU**, **a high level of human health protection** must be ensured in the definition and implementation of all Union policies and activities. EU citizens are entitled to the **fundamental right to physical integrity** enshrined in **Art. 3 EU Charter,** and the **fundamental right to a high level of health protection** enshrined in **Art. 35 EU Charter**.

18. On June 17, 2020, the EU Commission presented a **"European Vaccine Strategy"** for the **rapid development**, production and dissemination of a Corona vaccine (Doc. **A.5)** under which a contract for the initial purchase of 200 million doses of vaccine **on behalf of all EU member states**, and an option to order a further 100 million doses was agreed with the pharmaceutical company BioNTech/Pfizer on Nov. 11, 2020. According to the undisclosed contract, **delivery** was to take place **as soon as a proven safe and effective vaccine against Covid-19 became available**, according to the EU Commission's "communication releases."The "European vaccination strategy" specified by the EU Commission should aim to "**ensure the quality, safety and efficacy** of vaccines." The fact that the European vaccination strategy has not fulfilled this requirement provided by law al *condicio sine qua non*, specifically in the approval of the active substance "Comirnaty", is explained and documented below.

On January 19, 2021, the EU Commission presented a communication advising member states to accelerate EU-wide vaccination of the already approved experimental "vaccines" (most notably "Comirnaty"). By March 2021, at least 80% of people over 80 and 80% of health and social care workers in all

member states should be vaccinated. By summer 2021, at least 70% of adults in the EU are to be vaccinated. **The EU Commission is thus exerting unmistakable and clear pressure in the direction of vaccinating the population with experimental substances based on genetic engineering** (see below). Since the Member States (including Italy in particular) have become highly financially dependent on the European Community due to the disastrous economic effects of repeated lockdowns, lends the pressure exerted by the European Commission on individual Member States towards covid vaccination an exceptional "quality". **The "European vaccination strategy" places healthcare workers at the top of the list of priority groups to be "vaccinated"**

19. The plaintiffs see themselves as exposed to an enormous pressure, which has been demonstrably built up by the EU Commission towards mandatory vaccination on the one hand, and on the other hand, as particularly affected EU citizens (by virtue of belonging to a prioritized group of persons in the vaccination program specified by the EU Commission), for the reasons stated below, and therefore as exposed to a concrete, unreasonable and unlawful enormous health risk, which was brought about by the EU Commission with the implementation decision contested here (including subsequent amendments and integrations) and which is contrary to EU law.

PLEAS FOR ACTION:

Premises

20. "Comirnaty" is an experimental mRNA-based substance which, in terms of mode of action and production, has absolutely nothing in common with conventional vaccines.
The mRNA is a recombinant nucleic acid and is used to add a nucleic acid sequence to human cells to form the spike protein of SARS-CoV-2 that would not otherwise be present in the cells. RNA, by definition, is also a nucleic acid (RiboNucleidAcid).
An **mRNA,** also known as **messenger RNA**, is a single-stranded ribonucleic acid (RNA) that carries genetic information for building a protein. In a cell, it is formed as the transcript of a section of deoxyribonucleic acid (DNA) belonging to a gene. With an mRNA, the building instructions for a specific protein are available in the cell; it transports the message from the genetic information to the protein-building ribosomes, which is necessary for protein building.

The prophylactic-therapeutic effect is directly related to the product resulting from the expression of this sequence: the spike protein, which the cells (whichever body cells) produce on the basis of the injected foreign mRNA, and which is intended to lead to antibody formation.
Therefore, the active substance "Comirnaty" effectively constitutes a gene therapy drug.

21. **The exclusion from the definition of "gene therapy medicinal product" in Commission Directive 2009/120/EC of 14 September 2009, of active substances that in fact act like a gene therapy medicinal product, but which are declared as vaccines against infectious diseases (such as "Comirnaty"), in absolute disregard of the mode of action, is, in view of the precautionary principle that applies in the EU, particularly in the health sector, and the fundamental rights**

of EU citizens to a high level of health protection (Art. 35 EU Charter) as well as to physical integrity (Art. 3 EU Charter), not comprehensible and violates fundamental principles of EU law (see following plea no. 3)**.**

22. Having said that, the pleas in law put forward here are primarily those which, irrespective of the legal assessment of whether the active substance "Comirnaty" is subject to the *lex specialis* consisting in Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007, on novel therapies (advanced therapy medicinal products) and amending Directive 2001/83/EC and Regulation (EC) No. 726/2004 should have been applied, because the implementing decision contested here must also be considered as being contrary to EU law and thus void and declared null and void, irrespective of the assessment of this issue.

(1) Invalidity due to violation of Article 2 (Scope) of Commission Regulation (EC) No. 507/2006 of March 29, 2006.

23. The EU Commission **conditionally approved** the active ingredient "Comirnaty" **for one year** on the basis of Commission Regulation (EC) No. 507/2006 of March 29, 2006.

24. Before a medicinal product for human use can be authorized for marketing in one or more member states, it must usually undergo extensive studies to ensure that it is safe, of high quality and effective when used in the target population. The rules and procedures to be followed to obtain a marketing authorization are 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 and in Regulation (EC) No 726/2004 (recital 1 Regulation EC No 507/2006).

25. In order to fill healthcare gaps and in the interest of public health, it may be necessary, **for certain categories of medicinal products**, to grant marketing authorisations on the basis of less extensive data than is normally the case and to make them subject to certain conditions (hereinafter referred to as 'conditional marketing authorisations'). These should include those medicinal products ... to be used **in emergency situations against a public health threat which have been duly established either by the World Health Organization or by the Community under Decision No. 2119/98/EC of the European Parliament and of the Council of 24 September 1998 (for the setting up of a network for the epidemiological surveillance and control of communicable diseases in the Community (**Recital 2 Regulation EC No 507/2006).

26. Article 2 of Regulation (EC) No 507/2006 defines the scope of the provisions for the conditional marketing authorization of medicinal products for human use as follows:

"This Regulation shall apply to medicinal products for human use covered by Article 3(1) and (2) of Regulation (EC) No 726/2004 and belonging to one of the following categories:

1. Medicinal products 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 World Health Organization or by the Community under Decision No. 2119/98/EC;**

3. medicinal products designated as orphan medicinal products under Article 3 of Regulation (EC) No 141/2000.

The circumstance mentioned under point 3., is clearly not present for the medicinal product ""Comirnaty"".

27. **In its implementing decision, the EU Commission generally refers to the scope of Regulation (EC) No. 507/2006, and "in particular", but not only, to Art. 2. point 1).**

28. **1.1 Violation of Art. 2. point 1. EU Regulation No. 507/2006**

29. **John P A Ioannidis (Meta-Research Innovation Center at Standford - METRICS - Stanford University), one of the ten most cited scientists in the world (in the field of medicine arguably the most cited scientist in the world), has ranked the mortality rate of COVID-19 caused by SARS-CoV-2 in the range of that of influenza as early as March 2020 (**Doc. **A. 6**). In a peer-reviewed study published in the Bulletin of the World Health Organization on October 14, 2020; Type: Resarch Article ID: BLT.20.265892 (Doc. **A.7**), Ioannidis **demonstrated that the worldwide panic at the end of January 2020 regarding an alleged high mortality rate associated with SARS-Cov-2 infection was and is simply unfounded.**

30. The fact that COVID-19, a disease caused by the SARS-CoV virus, is not a life-threatening disease in the true sense of the word is also confirmed by the fact that **in Italy**, for example, even if only now, i.e. after **almost a year (!), the instructions of the Ministry of Health for a therapy of the patients at home by the family doctors in private practice shall finally come out** (see interview with the new president of the Italian Medicines Agency AIFA published in the Italian daily newspaper "La Verità" of 03/02/2021 in Doc. **A.8**). It has been proven that serious complications of Covid 19 disease (which occur in a very small percentage of sufferers) are primarily due to inadequate treatment of the symptoms of the disease in the first days of illness. Those general practitioners or primary care physicians in private practice who researched the available information themselves and, contrary to the official instructions and recommendations of the Ministry of Health and the Medicines Agency, successfully used medicines whose official use they subsequently even had to dispute in court (see judgment of the Council of State of Rome no. 09070/2020 of 11/12/2020 regarding the suspension, at the request of a group of general practitioners, by the administrative jurisdiction of last instance of the ban imposed by the Italian Medicines Agency on the use of Hydroxychloroquine for the treatment of Covid 19 patients - Doc**. A.9)** have been shown to be able to treat almost all of their covid-19 patients at home without hospitalization, leading to a complete cure of the disease.

31. Thus, we are demonstrably not dealing with a life-threatening and untreatable disease in the true sense for the world population, but with a corona virus-related infectious disease, as we have had in the past, and which, **due to the failure of sanitary systems of certain Member States (such as primarily Italy -** investigations by the public prosecutor's office of Bergamo on this are ongoing) and **a worldwide misuse of RT-PCR tests**, has led to a de facto artificially inflated pandemic, as will be demonstrated below.

32. **1.2. Invalidity due to violation of Regulation (EC) No. 507/2006 Art. 2 Point 2.**

33. Medicinal products can be conditionally authorized according to Art. 2 point 2 Regulation (EC) No. 507/2006 if they are to be used **in emergency situations against a threat to public health duly identified either by WHO or by the Community under Decision No. 2119/98/EC.**

34. On January 30, 2020, the WHO declared the pandemic status caused by SARS-Cov-2, which allegedly endangers the world population (Doc. **A.10.1).**

35. The question of whether a "threat to public health" has been properly assessed is to be determined under the provisions of the International Health Regulations 2005 (IHR) of the World Health Organization. The regulations, which are to be interpreted under the Vienna Convention on the Law of Treaties, contain obligations binding under international law on both WHO and the 196 States Parties to determine a **public health emergency of international concern (**PHEIC) by the WHO Director-General under Article 12 of the IHR.

T**he proper determination of a public health threat must therefore be assessed against the provisions of the IHR.** The Director-General is required by Art. 12(4) IHR to include the following **five criteria** in his or her decision:

1.<u>the information provided by the State Party;</u>

2. the use of the decision scheme contained in Annex 2 of the IHR;

3. the advice of the Emergency Committee;

4. <u>scientific principles, including available scientific evidence and other relevant information;</u>

5. an assessment of the risk to human health, the risk of cross-border spread of the disease, and the risk of disruption to international traffic.

36. In accordance with this set of decisions, the Director General convened an Emergency Committee on 23/1/2020 due to the Sars Cov-2 outbreak in China, in accordance with Article 49 of the IHR. This expert committee disagreed on whether to recommend the presence of a PHEIC and postponed the meeting to 30/01/2020 for reassessment. At the second meeting of the emergency committee, a significant increase in case numbers and more affected countries with confirmed cases was noted and it was specifically pointed out that due to the notification of the virus sequence by China, other countries had the possibility of virus identification through **<u>rapid development of diagnostic tools.</u>** As a result, the Emergency Committee decided to propose a PHEIC, which was announced by the Director General on the same day (Doc. **A.10.2**).

37. On 13/01/2020, the WHO published an initial PCR test guidance document **(A.11.1)** based on the Corman-Drosten protocol of 13.01.2020 (Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR (**A.11.2**) - *see also Summary table of available protocols in this document* (**A.11.3**), which indicates that the Corman-Drosten PCR test protocol (also called the "Charité protocol") was the first to be published.

On January 23, 2020, this Corman-Drosten protocol was published by the authors (including Christian Drosten) in the scientific journal Eurosurveillance (Europe's journal on infectious disease epidemiology, prevention and control since 1996) **(A.11.4).** As of January 17, 2020, laboratories worldwide have been working on the basis of this protocol established by Corman, Drosten, and others for "detection" of the SARS COV-2 virus and commercial PCR kits based on it.

38. Due to the fact that this PCR test protocol was designed with a number of so-called amplification cycles far exceeding the scientific gold standard (see below) and other gross scientific errors, the so-called "case numbers", i.e. the number of persons tested positive for "SARS-Cov-2", have already increased explosively towards the end of January 2020.

39. The claimed crisis situation of the global public health threat due to the SARS-CoV-2 virus was ultimately mapped **by a global misuse of PCR testing**. This misuse and misapplication has resulted in an enormous number of people worldwide claimed by the authorities to be infected with SARS-Cov-2 at the time of the test, but who were

not actually infected, as well as an enormous number of people worldwide who have allegedly died from the disease caused by SARS-Cov-2 infection (Covid-19).

40. For further understanding, it is necessary to briefly explain what a PCR test is and how a Corona PCR test specifically works.PCR stands for **Polymerase Chain Reaction**. It was developed in 1983 by Kary Mullis, who passed away in 2019 (and was awarded the 1993 Nobel Prize in Chemistry for PCR).
The PCR is a system that can be used to amplify or copy specific DNA sequences outside the living organism, *in vitro*. To do this, enzymes and building blocks are used that are also responsible for duplicating DNA in the body's cells. The DNA that is to be replicated is often referred to as the **starting DNA**.
At the beginning of the process, it is placed in a reaction vessel together with the amplification enzymes and building blocks. The reaction mixture includes the individual **"DNA letters"** adenine, guanine, thymine and cytosine, as well as chemicals that ensure the reaction environment. In addition, there is a so-called **DNA polymerase**, an enzyme that can assemble these building blocks. Then there are the **primers**. These are very short, single-stranded pieces of DNA. They form the starting point at which the polymerase begins to assemble the DNA building blocks.The DNA is therefore placed in a reaction vessel, for example, a small tube, together with the DNA letters, the polymerase and the **primers,**. This is then put into a so-called **thermal cycler.** This is a device that can automatically change the temperature and both heat and cool the tube during PCR.
The basic principle of PCR is relatively simple and is based on the fact that the various steps of the polymerase chain reaction each take place only at certain temperatures.If the primer does not find an exactly matching DNA segment, it cannot attach.
The primers are therefore gene-specific. In the case of the Corona tests, they should be matched to specific genes of the **SARS-CoV-2** virus. And specifically to genes that only occur in this form in SARS-CoV-2. The fact that this unfortunately looks different in reality will be explained later.
The reaction is initiated by strongly heating the DNA (94°C), which causes the two strands of the double strand to separate from each other (denaturation). Upon cooling, the primers can now bind to the matching regions of the single strands. After this attachment phase with temperatures in the range of 60°C, which are individually dependent on the primers, the DNA is elongated at about 72 degrees Celsius. Starting from the primers, the polymerases attach a new strand to the exposed strands of the parent DNA. New double strands are formed. **One initial double-stranded DNA becomes two.**

This completes the **first cycle of PCR**, consisting of denaturation, addition and extension. To further amplify the DNA, the temperature is simply raised again to 94 degrees Celsius by the thermal cycler and the process begins again. The amount of DNA grows increasingly exponentially in the process because a larger number of templates are available each time. Hence the term **"chain reaction"**.
Thus, 2 first become 4, then 8, then 16 copies and so on, until, after 20 cycles, the initial DNA has already produced over 1 million copies and, after 30 cycles, over 1 billion copies. Hence the term "chain reaction". From a certain threshold value (cycle threashold; ct), the number of copies is recorded in the measuring instrument as positive, i.e. the more initial DNA was in the reaction, the faster this CT is reached. Since in infectious events several 1000 exit pathogens must be present to form an infectious dose, the ct will already be reached at a

maximum of 25 cycles, a tolerance range up to 30 is possible and coincides with publications in the case of SARS-CoV-2, that from ct30 onwards there is no longer any correlation of the PCR result with an infectivity. However, the corona virus does not have DNA, but RNA. The genetic material is therefore present in a different form. The Corona test is therefore not a simple PCR, but an **RT-PCR. RT stands for reverse transcriptase. This is an enzyme that can transcribe RNA into DNA.** This happens in a step before the actual PCR, but in the same reaction vessel.
Just like polymerase, reverse transcriptase needs a primer to help it find a starting point. Starting from the primer, the reverse transcriptase then attaches the complementary DNA building blocks to the viral RNA. **The resulting DNA strand, known as copy DNA (cDNA), thus contains the same genetic information as the viral genome.**
After separation of the DNA-RNA double strand by heating, the DNA strand is used as a template for PCR. After that, the cycles run as in normal PCR. However, the corona test has another special feature. It is a so-called **real-time PCR** (abbreviated with a q or r. In the Corona test, for example, RT-qPCR, sometimes also qRT-PCR). This means that one can already see during runtime whether SARS-CoV-2 genes are present in the sample. This works via fluorescence.

41. **Scientists worldwide who are familiar with microbiology and with the PCR test have pointed out from the beginning that you cannot detect a virus with the PCR test, but only nucleic acids that remain as fragments of viruses. Therefore, the tests cannot tell anything about the infectivity of a person who has tested positive, unless there is also a clinical diagnosis. And if a person was tested without symptoms, logically no statement about the presence of an infection is possible. The term "new infection", which is used worldwide in this context, is simply wrong. Only small amounts of viruses or their fragments are contained in the samples taken from the mouth and throat of humans. They have to be amplified to make them visible. These fragments can also originate from an "old infection" that has already been overcome, namely when the immune system has successfully fought the viruses and the person concerned is healthy again and no longer infectious.**

42. **The more viruses still in the body, the fewer cycles of replication are needed for detection. So this number - the so-called Ct value - obviously provides important diagnostic information. However, it is not usually communicated by laboratories.**
The number of cycles needed is inversely proportional to the viral load. All this has not been and is still not taken into account by the authorities. Laboratories do not report this number of cycles needed for detection. However, this is now finally being demanded by the WHO.

43. **On 14/12/2020** (Doc. **A.12.1), the WHO issued for the first time (and obviously much too late) recommendations for users of RT-PCR tests, as it had received feedback from users about an increased risk of false SARS-CoV-2 results when testing samples with RT-PCR reagents on open systems.** Named are problems that have been pointed out by independent scientists and people with mathematical common sense for many months**.**
"The design principle of RT-PCR means that patients with high levels of circulating virus (viral load) will require relatively few cycles for virus detection and therefore the Ct value will be low. Conversely, a high Ct value in specimens means that many cycles were required for virus detection. *In certain*

circumstances, the distinction between background noise and the actual presence of the target virus can be difficult to determine."
And further:
"Communicate the Ct value in the report to the requesting healthcare provider."
And on the large percentages of false positives:
"As with any diagnostic procedure, the positive and negative predictive values for the product in a given test population are important to note. As the positivity rate for SARS-CoV-2 decreases, so does the positive predictive value. This means that the probability that a person with a positive result (SARS-CoV-2 detected) is actually infected with SARS-CoV-2 decreases as the positivity rate decreases, regardless of the specificity of the test product. ***Therefore, healthcare providers are advised to consider test results along with clinical signs and symptoms, confirmed status of all contacts, etc."***

44. ***So it is recommended not to rely only on the result of the PCR test, but also to consider clinical symptoms. With this, the WHO also says that there cannot be "asymptomatically ill" people.***
This part of the WHO's recommendation is self-evident:

"Users of RT-PCR reagents should read the instructions for use carefully to determine whether manual adjustment of the PCR positivity threshold is required to account for any background noise that may cause a sample with a high cycle threshold (Ct) to be interpreted as a positive result."

45. It is almost unbelievable: The RT-PCR test has now been used worldwide for twelve months to detect SARS-Cov-2 infections. Renowned scientists have pointed out from the beginning that the PCR test is not suitable to detect an infection, that much too high multiplication (amplification) cycles are run and that with low prevalence (percentage of real infections in the population) there are many false positive results anyway. The WHO now also warns of this. Evidently, much too late and only at a time when, lo and behold, elsewhere (USA, UK) the first mRNA-based agents propagated as covid "vaccines" had already been approved.

46. *In another clear recommendation published in its bulletin on 20/01/2021 (Doc.* ***A.12.2****),* **the WHO again warns against false-positive results of the PCR test, as follows:**
The WHO Guideline Diagnostic Testing for SARS-CoV-2 states that careful interpretation of weak positive results is required. ***The cycle threshold (Ct) required for virus detection is inversely proportional to the patient's viral load. If test results are not consistent with the clinical picture, a new specimen should be collected and retested using the same or a different NAT technology.*** *The WHO advises PCR test users that disease prevalence alters the predictive value of test results;* ***as disease prevalence decreases, the risk of a false positive result increases****. That is, the likelihood that a person with a positive result (SARS-CoV-2 detected) is actually infected with SARS-CoV-2 decreases with decreasing prevalence, regardless of claimed specificity.*

Most PCR assays are indicated ***as tools for diagnosis; therefore, healthcare providers must consider each result in combination with the time of specimen collection, specimen type, assay specifics, clinical observations, patient history, confirmed status of all contacts, and epidemiologic information.***

Actions to be taken by IVD users:

1. ***Please read the Instructions for Use carefully and completely.***
2. *Contact your local representative if any aspect of the Instructions for Use is unclear to you.*
3. *Check the IFU on each incoming shipment to identify any changes to the IFU.*
4. ***Share the Ct value in the report with the requesting healthcare provider.***

In other words, **the PCR test is only useful in the context of a clinical diagnosis as evidence of a coronavirus infection.**

What this also says is that **testing in individuals without symptoms is simply meaningless. A positive test result cannot be consistent with the clinical picture, because the absence of symptoms means that there is no disease. The various mass tests organized by a number of governments therefore contradict the WHO guideline, since almost only people without symptoms are tested.**

47. A fundamental **requirement for "official" and "court-proof" measurement technology, whether in industry, administration or healthcare, is that the measurement must be calibrated, reproducible and repeatable. It must be validated and the tolerances must be known and included in the evaluation of the measurement. None of this applies to the PCR test.**
Although even the WHO has meanwhile warned against the misuse of the PCR test, which is applied worldwide, it is widely continued by governments and authorities.

The persons tested are neither informed which RT-PCR test product is applied to them, nor what the CT value is.
Most machines that evaluate samples are set to a threshold of 37 to 40 cycles. Reduce that threshold to 30 cycles and the number of "confirmed cases" decreases by 40 to 90 percent, studies in the United States have shown, according to a New York Times report (Doc. **A.13.1). The rising "case numbers" in Italy, Austria, Germany and Europe in general would immediately look different with this scientifically based correction!**

As reported by the Times of India (Doc. **A.13.2**), in contrast to Europe, more and more physicians in that country send the samples only to laboratories that announce the Ct value with the result. If the Ct value is between 20 and 25, quarantine at home is sufficient. Below 20, on the other hand, immediate hospitalization is undertaken, as a more serious course of the disease is to be expected. Above 25, no measures are considered necessary in symptomless individuals.
If the Ct value is restricted to 25, the "case numbers" are again significantly reduced. Epidemiologically, it would only make sense to record infectious people. This is not how it is done though.
With the PCR test, therefore, an enormous number of false results are to be expected if, as happens in most of the EU, the basic rules for sensible testing are not observed.

48. .On the subject of infectivity in people without symptoms, the results of the largest study to date from Wuhan are now available (Doc. **A.14**).

It was conducted after the lockdown, which lasted from January 23, 2020 to April 8, 2020, in the Chinese city of 11 million. SARS Cov-2 nucleic acid screening (this is how it is referred to in the study, **since the PCR test is not suited to detect any viruses, but only parts of viruses, namely nucleic acids**) was conducted throughout the city from May 14, 2020 to June 1, 2020.
10.6 million people over the age of 6 were invited to take part in the test, of whom 93%, or 9.9 million showed up. In 300 people, the tests yielded a positive result. All contacts of these positives were accurately noted and followed up. However, all 1,174 close contacts tested negative and were followed for 14 days with no change.

The researchers point out that very few asymptomatic cases - 0.303/10,000 - were detected after the lockdown, and there was no evidence of infectivity in these individuals. Virus culture also did not reveal any evidence of replicable virus.

49. **Thus, the PCR test is not capable of detecting active infection or even infectivity. However, the WHO's upholding of the declaration of the alleged public health threat posed by SARS-Cov-2 is based on the numbers generated by this test.**

Any "case numbers" generated solely by RT-PCR test results are not a basis for a "proper" determination of a crisis situation in terms of a (global) public health threat, and any executive and legislative actions based on them are unlawful or unconstitutional.

50. This has also already been established in a ruling by a court of appeal in Portugal (Doc. **A.15.1**).
In its November 11, 2020 decision, a Portuguese appeals court ruled against the Azores Regional Health Authority, declaring the quarantine of four individuals unlawful. Of these, one person had tested positive for covid with an RT-PCR test; the other three were considered to be at high risk of exposure. As a result, the regional health authority ruled that all four were infectious and a health risk, so they had to be isolated. A procedure that has been regular practice among health authorities across the EU for the past year.
The lower court had ruled against the health authority, and the appeals court upheld that decision with arguments that explicitly support the scientific view of many experts (such as the former Chief Science Officer of pharmaceutical giant Pfizer; Mike Yeadon) because of the lack of reliability of PCR testing.

The main points of the court's decision are as follows:
A medical diagnosis is a medical act that only a physician is legally authorized to perform and for which that physician is solely and completely responsible. No other person or institution, including government agencies or courts, has such authority. It is not the responsibility of the health department to declare someone ill or in danger of becoming ill. Only a physician can do this. No one can be declared sick or dangerous to health by decree or law, even as an automatic, administrative consequence of the result of a laboratory test of any kind.
The court concludes that *"when performed without prior medical observation of the patient, without the participation of a physician registered in the Medical Board, who has assessed the symptoms and requested the tests/examinations deemed*

necessary, any act of diagnosis, or any act of public health surveillance (such as determining whether there is a viral infection or a high risk of exposure, which summarize the above terms) violates [a number of laws and regulations] and may constitute a criminal offense for unlawful professional practice if these acts are performed or dictated by someone who lacks the ability to do so, that is, someone who is not a licensed physician.
The Portuguese Court of Appeals further stated the following:
"On the basis of the scientific evidence currently available, this test [the RT-PCR test] is not capable, in and of itself, of establishing beyond doubt whether the positivity actually corresponds to infection with the SARS-CoV-2 virus, for several reasons, two of which are of primary importance: The reliability of the test depends on the number of cycles used; the reliability of the test depends on the viral load present."

Citing Jaafar et al. (2020; https://doi.org/10.1093/cid/ciaa1491 - Doc. **A.15.2**), the court concludes that **"if a person tests positive by PCR when a threshold of 35 cycles or higher is used (as is the norm in most laboratories in Europe and the United States), the probability that that person is infected is <3% and the probability that the result is a false positive is 97%."** The court also notes that the threshold for cycles used for PCR testing currently performed in Portugal is unknown.
Citing Surkova et al. (2020; https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30453-7/fulltext - Doc. **A.15.3**), the court further states that any diagnostic test must be interpreted in the context of the actual probability of disease as assessed before the test itself is performed, and expresses the opinion that *"in the current epidemiological landscape, there is an increasing likelihood that covid-19 tests will yield false positive results, with significant implications for individuals, the healthcare system, and society."*

The court's summary of its decision against the appeal of the regional health authority reads as follows:
"Given the scientific doubts expressed by experts, i.e., those who play a role, about the reliability of the PCR tests, given the lack of information about the analytical parameters of the tests, and in the absence of a medical diagnosis proving the presence of infection or risk, this court can never determine whether C was in fact a carrier of the SARS-CoV-2 virus or whether A, B, and D were exposed to a high risk."

51. As can be seen just from the evolution of the pandemic in Italy, it was RT-PCR testing and subsequent regulatory action that led to a massive increase in deaths, both those with and without infection. Covid-19 disease and SARS infections have been detected in Italy as early as the summer of 2019, long before it was known what the problem was.
The researchers examined the presence of SARS-CoV-2-specific antibodies in blood samples from 959 asymptomatic individuals enrolled in a lung cancer screening study between September 2019 and March 2020. The aim was to track the date of the Corona outbreak, its frequency, and temporal and geographic variations in Italian regions.
The study, published Nov. 11 in Tumori Journal (Doc. **A.15.4**) and led by Giovanni Apolone, director of the National Cancer Institute in Milan, says something absolutely unexpected: Antibodies to the new coronavirus were found in 14% of the samples tested from September 2019.

SARS-CoV-2 specific antibodies were detected in a total of 111 out of 959 individuals. Clustered positive cases occurred in the second week of February 2020 and there predominantly in Lombardy.
This study shows an unexpected very early circulation of SARS-CoV-2 in asymptomatic individuals in Italy several months before the identification of the first patient and confirms the outbreak and spread of the coronavirus pandemic already in 2019.

52. The study also shows that the massive problems and deaths in Italy are not due to the virus but to the measures proposed by China and implemented by the Italian government, such as the lockdown. They led to Romanian nurses fleeing the country, leaving nursing homes without staff. The hospitals thus quickly became overburdened and the main source of infection.
But that is not all. The Italian statistical authority ISTAT had already presented data in May 2020 (Doc. **A.15.5**) showing that almost half of the excess mortality in the period 20/02 to 31/03 was not due to Covid-19 but to other causes. Incidentally, the data from Austria and Germany also show something similar.

53. Northern Italy was one of the hotspots of the Corona crisis in Europe. The reason for this, however, is not the virus but the fact that the social and medical systems in northern Italy collapsed rather quickly and completely. Italian prosecutors are conducting extensive investigations into this, after it is at least gross negligence that caused Italy to slide so unprepared into a "virus-heavy" period. A lot of staff, especially in the elderly care sector, came from Eastern Europe. They fled the country at the beginning of the border closures. Homes for the elderly were suddenly without staff and the inmates were shipped to hospitals after a few days without care. This led to the collapse of medical care in March, April 2020. Also incomprehensible is the immediate requirement of cremation of bodies in Covid-19 deaths. Not only did this result in extremely important autopsies not being carried out, which would have immediately provided important insights into the actual effects of this viral disease, but it also "produced" images of the removal of coffins by the military, which can be explained by the fact that in Italy the cremation of corpses is traditionally done much less frequently than in other countries, and therefore in the spring of 2020 the capacity simply did not exist for a sudden increase in "forced demand". And it was precisely this removal of coffins that had been piled up for many days that was then irresponsibly exploited by politicians and the media for scaremongering.

54. Further incriminating factors in northern Italy include severe air pollution (there are EU Treaty infringement proceedings pending), excessively frequent antibiotic resistance, a known high level of asbestos exposure due to the former fibre cement production and textile industry as well as local on-site asbestos mining, and a particular genetic susceptibility to inflammatory diseases (favism, subtype Lombardy) and treatment errors (Italian public prosecutors are also investigating this).

55. **Due to serious scientific errors in the Corman-Drosten PCR test protocol (also called Charitè protocol - doc. 11.4) - and massive conflicts of interest among the authors of the protocol, twenty-two scientists from all over the world demanded an urgent retraction of the scientific publication on the Corman-Drosten PCR test protocol from the scientific journal Eurosurveillance on 27.11.2020** (doc. **A.16.1**.).

56. **The basis for the RT-PCR test, which has been determining and limiting our lives since March 2020, is a study entitled *"Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR"*. It was submitted on 21 January**

by a number of authors, including Christian Drosten, Victor Corman, Olfert Land and Marco Kaiser (Doc. **A.11.4**).
The Corman-Drosten study was submitted to Eurosurveillance on 21 January. Already on 22 January, the review was supposedly done - which, however, usually cannot be done in less than 4 weeks - and on 23 January, the study was published. This "warp speed" procedure, which is currently also used to develop vaccines, was facilitated by the fact that **Christian Drosten and Chantal Reusken were and still are both authors of the study and editors of Eurosurveillance.**

57. But that is by no means all that existed in terms of conflicts of interest, which were only partially disclosed on 30 July when criticism of them grew louder. Olfert Landt is the managing director of TIB Molbiol, Marco Kaiser is a senior researcher at GenExpress and a scientific advisor to TIB Molbiol, the company that claims to have been the "first" to produce the PCR kits based on the protocol published in the Drosten manuscript. According to its own account, the company had already distributed the test kits before the study had been submitted. The involvement of C.Drosten and V.Corman as heads of viral diagnostics and thus also of PCR diagnostics for SARS-CoV-2 in the commercial "Labor Berlin" of the Vivantes group (with Charitè) and the considerable interest in high numbers of diagnostics that this entailed, remains unexplained.

58. According to the international group of scientists, the scientific errors are as follows:

1. the design of the primers is inadequate: inaccurate base composition, too low GC content, too high concentrations in the test. The only scientifically relevant PCR (N gene) is presented, but it is not verified and, moreover, is not recommended by the WHO for testing.
2. The binding temperature is chosen too high, so that a non-specific binding is promoted, whereby other gene sequences than those of SARS-CoV-2 can also be detected.
3. T**he number of evaluation cycles is given in the paper as 45, a threshold up to which the reaction is considered true positive is not defined for the CT value. It is generally known that RTPCR tests above a cycle number of 30 regularly no longer allow conclusions to be drawn about contamination of the sample with the virus being sought.**
4. No biomolecular validation was carried out, therefore there is no confirmation that the amplificates are genuine, really arise and also detect the sequence sought.
5. Neither positive nor negative controls have been carried out with regard to virus detection. In particular, there are no in-test controls.
6. There are no standardised operating procedures available to ensure that the test is repeated in user laboratories under the same conditions. **The test still does not have CE certification, which is mandatory for in-vitro diagnostics, so it is "*not for human use, only for research*".**
7. **There is a risk of false-positive results due to the imprecise experimental design.**
8. **In view of the very short period between submission and publication of the study, it is very unlikely that a peer review process took place at all. If a peer review did take place, it was inadequate because the errors pointed out, including formal errors, were not found.**

59. The twenty-two scientists have substantial cumulative expertise in the field in question. Among them are, for example, the ex-Chief Science Officer of Pfizer, Dr..

Michael Yeadon, the geneticist Kevin McKernan, the driving force behind the Human Genome Project, who holds several patents in the field of PCR diagnostics, the molecular geneticist Dr. Pieter Borger, PhD, the specialist in infectious diseases and preventive medicine Dr. Fabio Frankchi, the microbiologist and immunologist Prof. emerit.Dr.Makoto Ohashi and the cell biologist Prof. Dr.Ulrike Kämmerer.

60. On 11/01/2021, the Scientific Group submitted a scientific integration of its request to withdraw the publication (doc. **A.16.2**).
Eurosurveillance refuses to withdraw the publication of the protocol that has been responsible for a huge number of false positive cases worldwide for a year now, and this with an ictu oculi, anything but scientific justification (Doc. **A.16.3**). Scientists worldwide are stunned and appalled by this development.

61. **This highly flawed Charitè protocol continues to be used on a massive scale worldwide, but especially in Europe, and so also in Italy.**
As evidence of this, see the response of the sanitary authorities of the Autonomous Province of Bolzano and the Autonomous Province of Trento (doc. **A.16.4**) to a request for disclosure submitted by a doctors' group for the purpose of creating transparency about the RT-PCR test products used (doc. A.16.5).

62. **The WHO incomprehensibly officially pointed out, for the first time, as late as in December 2020 that PCR test results alone are no proof of a virus infection, after automatically declaring persons who had been subjected to a PCR test alone, and who tested positive, to be infected with SARS-CoV-2, for the last eleven months and ongoing (!).**

63. **Despite the WHO's repeated instructions in December 2020 and January 2021, most countries (with a few exceptions, such as India) continue to follow the unscientific and grossly unconstitutional approach of declaring people "infected with SARS-CoV-2", solely on the basis of a PCR test result.**

64. **At the time of approval of the agent "Comirnaty" on 21/12/2020, the short-term recommendations of the Emergency Committee of 29/10/2020 (**Doc. **A. 17) were in force on the basis of the same invalid WHO database, which depicted an incorrect infection rate.**

65. In view of the effective mortality rate of covid-19, as presented and documented by top experts such as John P.A. Ioannidis, who for decades have been indisputably recognised worldwide, it is incomprehensible how the WHO in its "*Statement on the fifth meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic*" of 30 October 2020 (doc. **A.6** and **A.7**), arrived at the conclusion that the global risk associated with COVID-19 remained very high and the declaration of a Public Health Emergency (PHEIC) could be maintained..[1]

66. **Based on the above explanations and the documents deposited in this regard, it must be assumed that a large number of the allegedly positive SARS-Cov-2 test results recorded worldwide are simply false and therefore the WHO and the EU could not or have not made a proper determination of the crisis situation in the sense of a threat to public health according to Art. 2 Para. 2 Regulation 507/2006.**

1*„WHO continues to assess the global risk level of the COVID-19 pandemic as very high … The Director General determined that the COVID-19 pandemic continues to constitute a PHEIC."*

Therefore, it has not yet been proven that Covid-19 disease, which can be severe in very rare cases, is a causal disease triggered by SARS-CoV-2, as only a correlation of disease and RT-PCR positivity has been used for assessment so far.

Furthermore, it is clear that **the disease Covid-19 caused by SARS-Cov-2 is not a "life-threatening disease" and not treatable disease in the strict sense.**

Therefore, the mandatory requirements for a conditional marketing authorisation of a medicinal product as laid down in Article 2 of Commission Regulation (EC) No 507/2006 of 29 March 2006 are not met for the substance "Comirnaty" and the implementing decision of the European Commission contested here is unlawful for this reason alone and must therefore be declared null and void. 67. 2.

67. **(2) Invalidity due to infringement of Article 4 of Regulation (EC) No 507/2006**

68. Although a conditional marketing authorisation may be based on less extensive data, the **risk-benefit balance** as defined in Article 1(28a) of Directive 2001/83/EC should still be positive. In addition, the public health benefit of the immediate availability of the medicinal product on the market should outweigh the risk due to the lack of additional data (Recital 3 EC Regulation No 507/2006).

69. **The granting of conditional marketing authorisations should be limited to those cases where only the clinical part of the application dossier is less comprehensive than usual. Incomplete preclinical or pharmaceutical data should only be allowed when a medicinal product is to be used in emergency situations against a threat to public health** (Recital 4 EC Regulation No 507/2006).

70. As stated above, the crisis situation consisting in the threat to public health has not been established in a procedurally correct manner.

71. Moreover, the experimental active substance "Comirnaty", which is based on genetic engineering, is intended for use on "healthy persons". To disregard not only clinical but also preclinical or pharmaceutical data prior to application is a gross violation of the precautionary principle.

72. In order to strike a balance between closing gaps in medical care through easier access to medicines for patients on the one hand, and preventing the authorisation of medicines with an unfavourable risk-benefit ratio on the other, **it is necessary to link such authorisations to certain conditions. The marketing authorisation holder should be required to initiate or complete certain studies to demonstrate that the risk-benefit balance is positive and to answer open questions on the quality, safety and efficacy of the medicinal product** (recital 5 Regulation No 507/2006).

73. As Regulation (EC) No 726/2004 applies to conditional marketing authorisations, unless otherwise provided for in this Regulation, the procedure for the assessment of a conditional marketing authorisation is also in line with the usual procedure laid down in Regulation (EC) No 726/2004 (recital 8 Regulation No 507/2006).
Conditional marketing authorisations are valid for one year and may be renewed in accordance with Regulation (EC) No 726/2004.

74. **Patients and healthcare professionals should be clearly informed that the authorisation is conditional. It is therefore necessary that this information is**

clearly stated in the summary of product characteristics of the medicinal product concerned and in its package leaflet. (Recital 10 Regulation No 507/2006).

75. **Article 4 (Conditions):**

1. A conditional marketing authorisation may be granted if the Committee considers that all 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 is positive;

b. The applicant is 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.

76. **In emergency situations, a conditional marketing authorisation may be granted under Article 2(2), provided that the conditions set out in points (a) to (d) of this paragraph are met, even if complete preclinical or pharmaceutical data have not yet been submitted.**

In the present case, as stated above, this emergency situation was never "properly" established.

2. For the purposes of paragraph 1(c), a **health care gap** means that there is **no satisfactory means of diagnosis, prevention or treatment of a condition authorised in the Community** or, even if there is, that **the medicinal product in question does not provide a significant therapeutic benefit to patients affected by that condition.**

77. **2.1 Invalidity due to the absence of a positive benefit-risk balance according to Article 1(28a) of Directive 2001/83/EC**

78. In order to determine the risk-benefit balance, both components, i.e. the benefit and the risk, must be able to be assessed and evaluated on the basis of the facts.

79. **2.1.1 Non-existence of a demonstrable benefit**

80. Contrary to the statements of Pfizer-BioNTech that "Comirnaty" would have a degree of effectiveness of 95% (see for example Apotheken Umschau of 18 November 2020 - Doc. **A.18.1), the scientist and co-editor of the British Medical Journal (BMJ), Peter Doshi, already expressed great doubts about this in November 2020 (**Doc. **A.18.2) and then scientifically substantiated these doubts in detail in an article published on 4 January 2021 as follows (**Doc. **A.18.3):**

"Five weeks ago, when I raised questions about the results of Pfizer's and Moderna's covid-19 vaccine trials, all that was in the public domain were the study protocols and a few press releases. Today, two journal publications and around 400 pages of summary data are available in the form of multiple reports presented by and to the FDA prior to the agency's emergency authorization of each company's mRNA vaccine. While some of the additional details are reassuring, some are not. Here I outline new concerns about the trustworthiness and meaningfulness of the reported efficacy results.

"Suspected covid-19"

All attention has focused on the dramatic efficacy results: Pfizer reported 170 PCR confirmed covid-19 cases, split 8 to 162 between vaccine and placebo groups. But these numbers were dwarfed by a category of disease called "suspected covid-19"—

those with symptomatic covid-19 that were not PCR confirmed. According to FDA's report on Pfizer's vaccine, there were "3410 total cases of suspected, but unconfirmed covid-19 in the overall study population, 1594 occurred in the vaccine group vs. 1816 in the placebo group."

With 20 times more suspected than confirmed cases, this category of disease cannot be ignored simply because there was no positive PCR test result. Indeed this makes it all the more urgent to understand. ***A rough estimate of vaccine efficacy against developing covid-19 symptoms, with or without a positive PCR test result, would be a relative risk reduction of 19% (see footnote)—far below the 50% effectiveness threshold for authorization set by regulators. Even after removing cases occurring within 7 days of vaccination (409 on Pfizer's vaccine vs. 287 on placebo), which should include the majority of symptoms due to short-term vaccine reactogenicity, vaccine efficacy remains low: 29%*** *(see footnote).*

If many or most of these suspected cases were in people who had a false negative PCR test result, this would dramatically decrease vaccine efficacy. But considering that influenza-like illnesses have always had myriad causes—rhinoviruses, influenza viruses, other coronaviruses, adenoviruses, respiratory syncytial virus, etc.—some or many of the suspected covid-19 cases may be due to a different causative agent. But why should etiology matter? If those experiencing "suspected covid-19" had essentially the same clinical course as confirmed covid-19, then "suspected plus confirmed covid-19" may be a more clinically meaningful endpoint than just confirmed covid-19.

However, if confirmed covid-19 is on average more severe than suspected covid-19,we must still keep in mind that at the end of the day, it is not average clinical severity that matters, it's the incidence of severe disease that affects hospital admissions. With 20 times more suspected covid-19 than confirmed covid-19, and ***trials not designed to assess whether the vaccines can interrupt viral transmission,*** *an analysis of severe disease irrespective of etiologic agent—namely, rates of hospitalizations, ICU cases, and deaths amongst trial participants—seems warranted, and is the only way to assess the vaccines' real ability to take the edge off the pandemic.*

There is a clear need for data to answer these questions, but Pfizer's 92-page report didn't mention the 3410 "suspected covid-19" cases. Nor did its publication in the New England Journal of Medicine. Nor did any of the reports on Moderna's vaccine. The only source that appears to have reported it is FDA's review of Pfizer's vaccine.

The 371 individuals excluded from Pfizer vaccine efficacy analysis.

Another reason we need more data is to analyse an ***unexplained detail found in a table of FDA's review of Pfizer's vaccine: 371 individuals excluded from the efficacy analysis for "important protocol deviations on or prior to 7 days after Dose 2****." What is concerning is the imbalance between randomized groups in the number of these excluded individuals: 311 from the vaccine group vs 60 on placebo. What were these protocol deviations in Pfizer's study, and why were there five times more participants excluded in the vaccine group? The FDA report doesn't say, and these exclusions are difficult to even spot in Pfizer's report and journal publication.*

Fever and pain medications, unblinding, and primary event adjudication committees

Last month I expressed concern about the potential confounding role of pain and fever medications to treat symptoms. I posited that such drugs could mask symptoms, leading to underdetection of covid-19 cases, possibly in greater numbers in people who received the vaccine in an effort to prevent or treat adverse events. However, it

seems their potential to confound results was fairly limited: although the results indicate that these medicines were taken around 3–4 times more often in vaccine versus placebo recipients (at least for Pfizer's vaccine) their use was presumably concentrated in the first week after vaccine use, taken to relieve post-injection local and systemic adverse events. But the cumulative incidence curves suggest a fairly constant rate of confirmed covid-19 cases over time, with symptom onset dates extending well beyond a week after dosing.
That said, the higher rate of medication use in the vaccine arm provides further reason to worry about unofficial unblinding. Given the vaccines' reactogenicity, it's hard to imagine participants and investigators could not make educated guesses about which group they were in. The primary endpoint in the trials is relatively subjective making unblinding an important concern. Yet neither FDA nor the companies seem to have formally probed the reliability of the blinding procedure, and its effects on the reported outcomes.
Nor do we know enough about the processes of the primary event adjudication committees that counted covid-19 cases. Were they blinded to antibody data and information on patients' symptoms in the first week after vaccination? What criteria did they employ, and why, with a primary event consisting of a patient-reported outcome (covid-19 symptoms) and PCR test result, was such a committee even necessary? It's also important to understand who was on these committees. Pfizer's protocol says three Pfizer employees did the work. Yes, Pfizer staff members.
Vaccine efficacy in people who already had covid?
Individuals with a known history of SARS-CoV-2 infection or previous diagnosis of Covid-19 were excluded from Moderna's and Pfizer's trials. But still 1125 (3.0%) of participants in Pfizer's trials were deemed to be positive for SARS-CoV-2 at baseline.

Vaccine safety and efficacy in these recipients has not received much attention, but as increasingly large portions of many countries' populations may be "post-Covid," these data seem important.
By my count, Pfizer apparently reported 8 cases of confirmed, symptomatic Covid-19 in people positive for SARS-CoV-2 at baseline (1 in the vaccine group, 7 in the placebo group. But with only around four to 31 reinfections documented globally, how, in trials of tens of thousands, with median follow-up of two months, could there be nine confirmed covid-19 cases among those with SARS-CoV-2 infection at baseline? Is this representative of meaningful vaccine efficacy, as CDC seems to have endorsed? Or could it be something else, like prevention of covid-19 symptoms, possibly by the vaccine or by the use of medicines which suppress symptoms, and nothing to do with reinfection?"

81. **On the basis of the officially available data, renowned scientists, such as Peter Doshi, therefore conclude that the efficacy of 'Comirnaty' is less than 30 per cent, rather than the reported 95 per cent, and thus below the 50 per cent mark set by the FDA for the efficacy requirement of the Covid 19 'vaccines' (**Doc **A.18.4).**

82. **Furthermore, there is no evidence that those "vaccinated" with "Comirnaty" cannot become infected and be carriers of the SARS COV-2 virus.** Moreover, the studies are designed in such a way that this proof cannot be provided at all.

83. The Robert Koch Institute explicitly states the following on its homepage: "*It is not yet known how long the vaccination protection lasts. The protection also does not start immediately after vaccination, and some vaccinated persons remain unprotected.*

In addition, it is not yet known whether the vaccination also protects against colonisation with the pathogen SARS-CoV-2 or against transmission of the pathogen to other people. Therefore, despite vaccination, it is necessary to protect oneself and one's surroundings by observing the AHA + A + L rules (distance rules, MNS)." (Doc. **A.18.5).**

84. **The proof of benefit in the sense of a positive therapeutic effect of the active substance "Comirnaty" has therefore not been provided and for this reason alone the conditional authorisation is contrary to EU law.**

85. **2.1.2 <u>Material risks not identified and thus undetermined and currently indeterminable risk</u>**

86. According to Article 1 No. 28 Directive 2001/83/EC, a risk associated with the use of the medicinal product is defined as follows: *" - any risk relating to the quality, safety or efficacy of the medicinal product for the health of patients or for public health."*

87. **According to Annex I (Summary of Product Characteristics) to the European Commission's implementing decision contested here (**Doc **A.2.2),** point 4.5 **<u>(Interactions with other medicinal products and other interactions), *"no studies have been carried out to detect interactions".*</u>**

88. In view of the fact that the so-called Covid "vaccines", such as "Comirnaty", are primarily intended to be used to protect the elderly and the population with health problems, and that this population group usually takes one or more medications on a regular basis, **the fact that the interactions of "Comirnaty" with other medicines have not been tested must lead to the conclusion that the risks emanating from Cormirnaty are for this reason alone currently in no way ascertainable, let alone assessable and evaluable.**

89. This circumstance alone should therefore have led to a rejection of the application for authorisation!

90. **2.1.3 <u>Failure to take into account significant risks that would never allow a conditional marketing authorisation for a medicinal product intended for a fundamentally healthy population.</u>**

91. Substantial risks associated with the administration of the active ingredient "Comirnaty" were already submitted to the EMA in a petition submitted on 1/12/2020 by Dr. Wolfgang Wodarg and Dr. Mike Yeadon concerning the then imminent approval of "Comirnaty" (Doc. **A.19).**
Unfortunately, this petition was ignored, as was the warning sent electronically by plaintiffs on 19/12/2020 primarily to the EU Commission and the EMA (Doc. **A.4).**

92. From the report by Prof.Dr.rer.nat.Stefan W. Hockertz, toxicologist, immunologist and pharmacologist, European reg. toxicologist (Doc. **A.20)**, the following emerges concerning the disregarded risks of administering the active substance "Comirnaty":

93. **„II.It is my professional opinion that the design of the clinical trial and the clinical trial data originating from that trial is inadequate to accurately assess safety and efficacy of BNT162b2.**

94. **III.It is my professional opinion that the design of the BNT162b2-specific preclinical animal testing studies ad the data originating from those studies is inadequate to accurately assess quality, safety and efficacy of BNT162b2.**

95. **IV.It is my professional opinion that the risks associated with BNT162b2 far outweigh any potential benefits because: BNT162b2 far outweigh any potential benefits because:**

a.) BNT162b2 has not been properly tested in animals and humans;

b.) It has not been determined if BNT162b2 can stop transmission of the SARS-CoV-2 virus from BNT162b2 recipient to others and infection of BNT162b2 recipient;

c.) It cannot be ruled out that BNT162b2 may cause SARS-CoV-2 to evolve into deadlier forms;

d.) It cannot be ruled out that BNT162b2 causes disease enhancement (pathogenic priming, antibody dependent enhancement) and other adverse effects on the functioning of the immune system, threats to fertility/pregnancy and other serious injuries and threats to the health of BNT162b2 recipients; …

e.) BNT162b2 is not a vaccine as its ability to provide active acquired immunity to a particular infectious disease (COVID-19) has not been proven due to the flawed designs of the human trial and the preclinical animal models. If anything, BNT162 in essence performs like an experimental and unproven therapeutic drug with extremely questionable efficacy, except BNT162 would be taken strictly prophylactically, even by the perfectly healthy, and more than likely carries a significantly higher risk of serious and life-altering injury than a therapeutic drug. Consequently, therapeutic drugs are far superior to BNT162b2. For the avoidance of doubt, the use of the term "vaccine" in connection with a sentence or paragraph that also references BNT162b2 (e. g., ".. or other vaccines") does not change the fact that BNT162bs does not fall under the definition of a vaccine;

96. **V. It is my professional opinion that the public will suffer irreparable harm if the CMA of "Comirnaty" (BNT162b2) is being upheld, because both governments of EU member states and employers and other stakeholders in the EU have begun recommending BNT162b2 for widespread use. Because BNT162b2 has not been properly tested, important public policy decisions regarding its use are and will be based on misleading evidence. The medical and economic consequences to EU member states and their residents and citizens could hardly be higher.**

97. **VI. It is my professional opinion that if BNT162b2 remains approved without it being appropriately tested and its efficacy having been accurately being reviewed, then any potential acceptance or mandate of BNT162b2 is likely to be based on inaccurate evidence regarding BNT162b2, namely that it is safe and will reduce COVID-19 disease and deaths….**

98. **E. Threats to fertility, pregnancy and lactation**

99. **The design of the clinical trial is not adequate to assess threats to fertility, pregnancy, lactation and breast feeding of infants.**

I When comparing the information EMA is providing about BNT162b2 to the general public to the one BioNTech is providing for “recipients”, one notes interesting omissions relating to fertility, pregnancy and lactation.
This is the information provided on the EMA webpage regarding threats to pregnancy and breast-feeding:
“Animal studies do not show any harmful effects in pregnancy, however data on the use of “Comirnaty” during pregnancy are very limited. Although there are no studies on breast-feeding, no risk for breast-feeding is expected.”
And this is the information provided on page 114 (section “Conclusions on the clinical safety”) of the EMA’s assessment report for Corminaty:
“Long term safety data, interaction with other vaccines, data on use in pregnancy and other subgroups (e.g. frail subjects, or subjects with pre-existing autoimmune diseases) are missing at this stage.”
It is not clear on what grounds EMA made the determination that “… no risk for breast feeding is expected.”
The assessment report further states (page 56):
“The CHMP noted that no data are available on BNT162b2 placental transfer or excretion in milk.”
This means that it is unknown whether BNT162b2 (Corminaty) is excreted in human milk. A risk to newborns/infants cannot be ruled out.
The EMA also noted that it is not known if placental transfer/passage of BNT162b2 occurs (see page 50 and page 51 of the report):
“In the DART study, the test substances used were BNT162b1, BNT162b2 and BNT162b3, which were given to female rats twice before the start of mating and twice during gestation at the human clinical dose (30 µg RNA/dosing day). […] No effects on the estrous cycle or fertility index were observed. There was an increase (~2x) of pre-implantation loss (9.77%, compared to control 4.09%) although this was within historical control data range (5.1%-11.5%). Among fetuses (from a total of n=21 dams/litters), there was a very low incidence of gastroschisis, mouth/jaw malformations, right sided aortic arch, and cervical vertebrae abnormalities, although these findings were within historical control data. Regarding skeletal findings, the exposed group had comparable to control group levels of presacral vertebral arches supernumerary lumbar ribs, supernumerary lumbar short ribs, caudal vertebrae number < 5). There were no signs of adverse effects on the postnatal pups (terminated at PND21). It is noted that there is currently no available data on the placental transfer of BNT162b2. This information is reflected in section 5.3 of the SmPC.”
The placenta is the interface between mother and fetus. Functions of the placenta include gas exchange, metabolic transfer, hormone secretion, and fetal protection. Nutrient and drug transfer across the placenta are by passive diffusion, facilitated diffusion, active transport, and pinocytosis. Placental drug transfer is dependent on the physical properties of the placental membrane and on the pharmacological properties of the drug.
A transplacental passage of drugs may have detrimental effects on the fetus, including teratogenicity (abnormalities of physiological development) or impairment of fetal growth and development

100. II. **It is unknown whether BNT162b2 has an impact on fertility in human females. BNT162b2 is expected to induce the formation of humoral antibodies against spike proteins of SARS-CoV-2. Syncytin-1, which is derived from human endogenous retroviruses (HERV) and is responsible for the**

development of a placenta in mammals and humans, is therefore an essential prerequisite for a successful pregnancy. It is also found in homologous form in the spike proteins of SARS viruses. There is no indication whether antibodies against spike proteins of SARS viruses would also act like anti-Syncytin-1 antibodies. However, if this were to be the case this would then also prevent the formation of a placenta which would result in vaccinated women essentially becoming infertile. According to section 10.4.2 of trial protocol, a woman of childbearing potential (WOCBP) is eligible to participate if she is not pregnant or breastfeeding, and is using an acceptable contraceptive method as described in the trial protocol during the intervention period (for a minimum of 28 days after the last dose of study intervention). This means that it could take a relatively long time before a noticeable number of cases of postvaccination infertility could be observed.

101. **F. Antibody Dependent Enhancement (ADE)**

I.) For BNT162b2 to work, our immune system needs to be stimulated to produce a neutralizing antibody, as opposed to a non-neutralizing antibody. A neutralizing antibody is one that can recognize and bind to some region (epitope) of the virus, and that subsequently results in the virus either not entering or replicating in your cells. A non-neutralizing antibody is one that can bind to the virus, but for some reason, the antibody fails to neutralize the infectivity of the virus. In some viruses, if a person harbors a non-neutralizing antibody to the virus, a subsequent infection by the virus can cause that person to elicit a more severe reaction to the virus due to the presence of the non-neutralizing antibody.

This is not true for all viruses, only particular ones. **This is called Antibody Dependent Enhancement (ADE), and is a common problem with Dengue Virus, Ebola Virus, HIV, RSV, and the family of coronaviruses.**
And in the same way that viral infections can involve ADE, so can the antibody responses raised by BNT162b2s. In fact, this problem of ADE is a major reason why previous vaccine trials for other coronaviruses failed. Major safety concerns were observed in animal models. If ADE occurs in an individual, their response to the virus can be worse than their response if they had never developed an antibody in the first place. Some of the earlier attempts at a SARS vaccine showed ADE effects in mouse and primate models.

102. II. **ADE can cause a hyperinflammatory response, a cytokine storm, and a generally dysregulation of the immune system that allows the virus to cause more damage to our lungs, liver and other organs of our body. In addition, new cell types throughout our body are now susceptible to viral infection due to the additional viral entry pathway. There are many studies that demonstrate that ADE is a persistent problem with coronaviruses in general, and in particular, with SARS-related viruses. ADE has proven to be a serious challenge with, and this is the primary reason many of such vaccines have failed in early in-vitro or animal trials**.

103. III. In the briefing document for the Vaccines and Related Biological Products Advisory Committee Meeting date December 10, 2020, the FDA noted on page 44:

"Pfizer submitted a Pharmacovigilance Plan (PVP) to monitor safety concerns that could be associated with Pfizer-BioNTech COVID-19 Vaccine. The Sponsor identified vaccine-associated enhanced disease including vaccine-associated enhanced respiratory disease as an important potential risk." [29]
EMA has also acknowledged that the risk of ADE needs to be investigated further:
"Any important potential risks that may be specific to vaccination for COVID-19 (e.g. vaccine associated enhanced respiratory disease) should be taken into account. The Applicant has included VAED/VAERD as an important potential risk and will further investigate it in the ongoing pivotal study and a post-authorization safety study."

104. IV. The Vaccines and Related Biological Products Advisory Committee Briefing Document on the vaccine contains disturbing indications that might be a safety signal on pathogenic priming, especially in older adults. [29]
Before those are reviewed, there are fundamental issues with the classification of serious adverse events. The first issue is the categorization of "Serious vs. Non-Serious" adverse events in the study and in the report. To a person experiencing neurologic adverse events including Bell's Palsy, neuroinflammatory and thrombotic events, these events are not "non-serious" and can, over time, develop into life-threatening conditions that require continuous medical intervention and repeated billable office visits for care. The short-term study excludes any means of detecting whether the initial exposure may play a fundamental root cause role in setting up patients for life-long chronic illness. BNT162b2 adverse events themselves seen in the BioNTech clinical trial may be indicative of pathogenic priming, especially since more serious adverse events were seen with the second dose. The second issue is that the design and analysis set-up of the study are biased against finding adverse events.

The report states:
"Among non-serious unsolicited adverse events, there was a numerical imbalance of four cases of Bell's palsy in the vaccine group compared with no cases in the placebo group, though the four cases in the vaccine group do not represent a frequency above that expected in the general population."
The comparison to baseline rates is meaningless because other vaccines are in use in the population. Thus, any risk due to BNT162b2 adds to or multiplies existing risk present in the population from other vaccines.
Among the 18-55 year-old participants, there were 370 solicited serious adverse events (SSAEs) in the vaccinated group and 73 in the unvaccinated. Of the vaccinated, 18% experienced SSAEs; in the placebo group, only 3% did, implying that SSAEs can be expected at a rate five times greater in the vaccinated compared to the unvaccinated.
These included severe fatigue, headache, chills, vomiting, diarrhea, muscle and joint pain. Whether these conditions represent instances of pathogenic priming, identifying individuals who are now at higher risk of serious morbidity and mortality if they become infected with SARS-CoV-2 is unknown, but given past studies, seems likely.
In the over 55 group, which was a smaller group, there were 60 SSAEs in the vaccinated group and 24 in the unvaccinated. Of the vaccinated, 6.5% experienced SAEs, compared to 1.4% in the unvaccinated, implying a 4.46 times increased risk overall of SSAEs due to vaccination.
However, in the older group, the vaccinated group was 10 times more likely to have a SSAE upon receipt of the second BNT162b2 dose than the first dose compared to

the 1:1 ratio in the unvaccinated. In the younger group, the vaccinated were only 3.61 times more likely to have second-dose SSAEs than the age-matched placebo group, which had about as many SSAEs in the first and second dose.
The patients in the study reviewed were healthy — and thus the spectrum of adverse events is not representative of those that might occur after BNT162b2 has come to market. In the previous studies in animals that are susceptible to SARS-CoV infection, the first dose was a vaccine, but the second was natural infection, leading to severe injury and often death. In the human trial for BNT162b2, both doses were from BNT162b2, so it is also not reassuring that these adverse events did not include the more serious and deadly conditions that afflicted animals. This human trial did not rule out pathogenic priming in any way.

105. V. The study should be extended to long-term follow up, including any further vaccination or exposure to SARS-CoV-2 viral proteins by infection.

106. G. Inadequate preclinical BNT162b2 testing in animals

107. The preclinical testing of BNT162b2 in animals was inadequate.

I The EMA'S CPMP "Note for guidance on preclinical pharmacological and toxicological testing of vaccines" (CPMP/SWP/465) was withdrawn on July 21, 2016 because the EMA had decided to reference the "WHO guidelines on nonclinical evaluation of vaccines" (hereafter referred to as the "WHO guideline").

II BioNTech completed two BNT162b2-specific preclinical 17 day toxicology (repeat-dose toxicity and acute toxicity) studies (no. 38166 and no. 20GR142) in rats. Another toxicology (developmental and reproductive toxicity) study in rats (no. 20256434 DART) is ongoing (preliminary results were made available mid-December 2020). BioNTech also completed one BNT162b2-specific preclinical pharmacology (in vivo immunogenicity and SARS-CoV-2 challenge) study in rhesus macaques.

III The last sentence in section 3.5 of the EMA BNT162b2-specific assessment report ("3.5. Uncertainties and limitations about unfavourable effects") reads as follows:

"The scientific data available at this stage do not raise noticeable concerns regarding immunogenicity or immunotoxicity of the PEG, but current evidence is not definitive."
This lack of evidence alone should have made EMA mandate that BioNTech performs a full set of standard toxicity studies in animals. The standards for such studies are set out in ICH Topic S 8 ("Immunotoxicity Studies for Human Pharmaceuticals"):
"Data from STS should be evaluated for signs of immunotoxic potential. Signs that should be taken into consideration are the following:

1) Hematological changes such as leukocytopenia/leukocytosis, granulocytopenia/ granulocytosis, or lymphopenia/ lymphocytosis;
2) Alterations in immune system organ weights and/or histology (e.g. changes in thymus, spleen, lymph nodes, and/or bone marrow);
3) Changes in serum globulins that occur without a plausible explanation, such as effects on the liver or kidney, can be an indication that there are changes in serum immunoglobulins;
4) Increased incidence of infections;

5) Increased occurrence of tumors can be viewed as a sign of immunosuppression in the absence of other plausible causes such as genotoxicity, hormonal effects, or liver enzyme induction.

Changes in these parameters could reflect immunosuppression or enhanced activation of the immune system. Immunosuppression is usually reflected by reduced values of immune parameters, whereas immunoenhancement is usually reflected by increased values. However, these relationships are not absolute and can be inverted in some cases. Similar to the assessment of risk with toxicities in other organ systems, the assessment of immunotoxicity should include the following:

Statistical and biological significance of the changes,

Severity of the effects,

Dose/exposure relationship,Safety factor above the expected clinical dose,

Treatment duration,Number of species and endpoints affected,

Changes that may occur secondarily to other factors (e.g. stress, see the Appendix, section 1.4), possible cellular targets and/or mechanism of action,

doses which produce these changes in relation to doses which produce other toxicities, and reversibility of effect(s)."

108. IV. The animal studies in rats did not meet the standards set out in page 47 of the WHO guideline:

"A complete gross necropsy should be conducted and tissues collected and preserved, gross lesions should be examined and organ weights recorded […]. Histopathological examinations of tissues should be performed and special attention paid to the immune organs, i.e. lymph nodes (both local and distant from site of administration), thymus, spleen, bone marrow and Peyer's patches or bronchus associated lymphoid tissue, as well as organs that may be expected to be affected as a result of the particular route of administration chosen. Histopathological examinations should always include pivotal organs (e.g. brain, kidneys, liver and reproductive organs) and the site of vaccine administration. The choice of tissues to be examined (ranging from a short list limited to immune and pivotal organs to a full list as provided in the Appendix) will depend on the vaccine in question, and the knowledge and experience obtained from previous nonclinical and clinical testing of the vaccine components. For example, full tissue examination will be required in the case of novel vaccines for which no prior nonclinical and clinical data are available. Therefore, the list of tissues to be tested should be defined on a case-by-case basis, following consultation with the relevant regulatory authority."

Surprisingly, the EMA assessment report (see pages 54 and 55) does not confirm that any histopathological examination of rat brains, kidneys and reproductive organs as well as a necessary full tissue examination required in case of novel BNT162b2s took place.

What is more, while the animal studies in rats apparently studied potential markers of pathogenic priming, it failed to measure one: interleukin-5 (IL-5), which had been found in prior coronavirus studies to be elevated in conjunction with pathogenic priming-induced disease enhancement.

Recalling that animal studies conducted on prior COVID vaccines found pathogenic priming leading to disease enhancement in older animals more than younger animals, older adults may be at highest risk of serious chronic illness due to autoimmunity resulting from BNT162b2-induced pathogenic priming.

Maternal or fetal toxicity in animals has not been properly assessed. Developmental toxicity tests assess the potential of a drug/vaccine to cause harm to the developing

fetus. They are conducted in female animals, who are force-fed the substance during their pregnancy and then killed, along with their unborn babies.
For small molecules (most pharmaceutical drugs are small molecules, although some drugs can be proteins), the generally accepted standard for preclinical animal studies to assess developmental and reproductive toxicity (including but not limited t0 embryo-fetal development [EFD]) is perform the necessary tests in two species (one rodent and one non-rodent).
According to ICH S5 (R3) guideline on reproductive toxicology: Detection of Toxicity to Reproduction for Human Pharmaceuticals, it is usually sufficient to conduct developmental toxicity studies in a single animal species.
“The animal species selected for testing of vaccines (with or without adjuvants) should demonstrate an immune response to the vaccine. The type of developmental toxicity study conducted, and the choice of the animal model, should be justified based on the immune response observed and the ability to administer an appropriate dose. Typically, rabbits, rats, or mice are used in developmental toxicity studies for vaccines. Even though quantitative and qualitative differences can exist in the responses (e.g., in humoral and cellular endpoints) between species, it is usually sufficient to conduct developmental toxicity studies in a single species.”
The sometime practice of testing for developmental toxicity in two species arose in the 1960s in the wake of the Thalidomide tragedy. Toxicologists struggled to replicate the characteristic limb defects seen in human babies in several species – that in itself should have rung alarm bells about extrapolation from animal species to humans. They finally achieved replication in a single strain of rabbit (the New Zealand white). Regulatory toxicologists are well aware that animal models of developmental toxicity are poorly predictive of human effects.
Given that until now no mRNA vaccine has ever reached the same stage of development that BNT162b2 did, EMA should have required BioNTech to test for developmental toxicity in two species.

109. V. What is even more surprising is that the EMA did not deem genotoxicity nor carcinogenicity studies in animals to be necessary (see page 55 of the report):

“No genotoxicity nor carcinogenicity studies have been provided. The components of the vaccine formulation are lipids and RNA that are not expected to have genotoxic potential.”
To be safely and efficiently transported in vivo without being degraded in the circulation, and to reach the cytosol across the cellular plasma membrane, mRNA needs a carrier. For BNT162b2, the vehicle of choice are lipid nanoparticles. Complexed with positively-charged lipids, mRNA is more stable and resistant to degradation and forms self-assembled virus-sized particles that can be administered via different routes. This mechanism essentially makes BNT162b2 perform like a nanodrug. Recent attention has been drawn to the toxic potential of nanodrugs since they often exhibit in vitro and in vivo cytotoxicity, oxidative stress, inflammation, and genotoxicity. A better understanding of the pharmacokinetic and safety characteristics of nanodrugs and the limitations of each delivery option is necessary for the further development of efficacious nanodrugs with high therapeutic potential and a wide safety margin.
It is not clear on what science and data the EMA is basing this expectation on. Because the cytotoxicity and genotoxicity depend on the solid lipid nanoparticles composition, more specifically, of the solid lipid and surfactant used in the

preparation. Some solid lipid or surfactant can increase the cyto- or genotoxic effect of solid lipid nanoparticles indicating that solid lipid nanoparticle composition plays an important role in the cytotoxic and genotoxic effect of these particles.

110. **VI. Since the EMA is deferring to the WHO on the question of which guidelines should be adhered to regarding the preclinical assessment of vaccines, it should have also reviewed and evaluated the animal studies conducted by BioNTech against the WHO guideline specific to the preclinical assessment of DNA and vaccines that applies to RNA/mRNA vaccines in an analogous manner (see page 60 of said guideline)**:

"Similarly, many aspects of the guidelines may be applicable to vaccines based on RNA, although again, different requirements are likely to apply especially for nonclinical safety testing for these types of vaccine."

At the very least, the EMA should have required BioNTech to conduct an adequate genotoxicity assessment specific to the fatty lipid nanoparticle coating around the mRNA (containing polyethylene glycol) that serves as a novel complexing material (see page 79 of said guideline):

"The standard battery of genotoxicity and conventional carcinogenicity studies is not applicable to DNA vaccines. However, genotoxicity studies may be required to address a concern about a specific impurity or novel chemical component, e. g. a complexing material that has not been tested previously."

111. **VII. BioNTech failed to select an appropriately designed animal model for their only BNT162b2-specific preclinical pharmacology (in vivo immunogenicity and SARS-CoV-2 challenge) study that included a SARS-CoV-2 challenge (administration of SARS-CoV-2 in previously immunized non-human primates** [**NHPs**]).

"Six rhesus macaques that had received two immunizations with 100 μg BNT162b2 and three age-matched macaques that had received saline were challenged 55 days after Dose 2 with 1.05 × 1.06 plaque forming units of SARS-CoV-2 (strain USA-WA1/2020), split equally between intranasal and intratracheal routes, as previously described. Three additional non immunized, age-matched rhesus macaques (sentinels) were mock-challenged with cell culture medium. Nasal and oropharyngeal (OP) swabs were collected and bronchoalveolar lavage (BAL) was performed at the times indicated, and samples were tested for SARS-CoV-2 RNA (genomic RNA or subgenomic transcripts) by reverse-transcription quantitative polymerase chain reaction (RT-qPCR; Fig. 4). All personnel performing clinical, radiological, histopathological, or RT-qPCR evaluations were blinded to the group assignments of the macaques."

One of the critical lessons learned from animal models selected for evaluating efficacy of vaccine candidates specific to SARS-CoV-1 was that the challenge virus should be administered at two different time-points, once when postimmunization neutralizing antibody titers are high, and later when neutralizing antibody titers have waned or are low. It also was suggested that viral titers and pathology should be evaluated at two different time points.BioNTech chose to administer the challenge virus SARS-CoV-2 at a single time-point which means that not data is available which could have enabled researchers (and, consequently, the EMA) to compare the effects and outcome of the challenge occurring when postimmunization neutralizing antibody titers are high versus the effect and outcome of the challenge occurring when neutralizing antibody titers have waned or are low.

In selecting animal models for vaccine evaluation, it is important to remember the principle underlying the so called “animal rule”, where data from more than one animal species is often required: each animal species should contribute something different to the understanding of disease and protection. At this time, no single animal model seems to offer a direct reproduction of what is seen in humans with SARS-CoV-2. Researchers have determined that the number of NHPs in a given preclinical study needs to be large enough to account for animal-to animal variability: a sample of 4 or 5 animals is not sufficient. [39] BioNTech chose to go with a sample size of immunized 6 NHPs which is clearly not appropriate.
The author (which include BioNTech’s CEO Uğur Şahin) of the scientific article describing this study in NHPs emphasized that the animal model they have chosen is infection-specific rather than disease-specific:
“In general, virus-challenged animals showed no clinical signs of significant disease. We conclude that the 2-4 year old male rhesus macaque challenge model is primarily a SARS-CoV-2 infection model and not a COVID-19 disease model.“
This critical limitation of the animal model selected for the challenge with SARS-CoV-2 should have caused BioNTech to select at least one more appropriate animal model (e. g., ferrets).
The Friedrich Loeffler Institute (FLI) – the national institute for animal diseases in Germany – has determined as early as April 2020 that animal models with ferrets are the preferred model for SARS-CoV-2 challenge studies in animals.
What is more, , the residues of the tested samples that were classified as positive or negative for SARS-CoV-2 by the RT-qPCR tests allowed as per the protocol for this animal study must be re-tested by nested RT-qPCR and Sanger sequencing method to confirm that the presumptive positive samples in fact contain a unique sequence of SARS-CoV-2 genome. (see rationale provided in sections D. I. 10. above)

112. **H. Bell’s Palsy**

Both the EMA and the FDA have acknowledged that the cases of Bell’s palsy that have occurred during the clinical trial

“Although the safety database revealed an imbalance of cases of Bell’s palsy (4 in the vaccine group and none in the placebo group), causal relationship is less certain because the number of cases was small and not more frequent than expected in the general population. Further signal detection efforts for these adverse events will be informative with more widespread use of the vaccine.”
“Four cases of peripheral facial paralysis were observed in vaccine arm (facial paralysis [n=4 BNT162b2; n=0 placebo] facial paresis [n=0 BNT162b2; n=1 placebo] in total 4/1 whole enrolled trial population, however the case of paresis was not considered for this calculation). Time to onset after injection with BNT162b2 was 3, 9 and 48 days after Dose 2 and 37 days after Dose 1, which suggest a possible association with the vaccination. The two subjects with a time to onset of 3 and 9 nine days had no previous history of Bell´s palsy, both subjects improved with prednisolone and the events were also deemed related to study intervention by the study physician. Taken together, this was considered to indicate there is a reasonable possibility of a causal relation to the vaccine, and to justify inclusion of peripheral facial paralysis (Bell´s palsy) in the SmPC 4.8 with a frequency as ‘rare’.”
Bell's palsy is a type of facial paralysis that results in a temporary inability to control the facial muscles on the affected side of the face. Symptoms can vary from mild to severe. They may include muscle twitching, weakness, or total loss of the ability to move one, and in rare cases, both sides of the face. Other symptoms include

drooping of the eyelid, a change in taste, and pain around the ear. Typically symptoms come on over 48 hours…

113. J. Allergic/anaphylactic reactions to PEG

In BNT162b2, polyethylene glycol (PEG) is found in the fatty lipid nanoparticle coating around the mRNA. At least 25 % percent of healthy people make antibodies to PEG and most do not know it, creating a concerning situation where many could have allergic/anaphylactic, potentially deadly, reactions to PEG-containing BNT162b2. [45] PEG antibodies may also reduce BNT162b2 effectiveness. Potential BNT162b2 recipients need to be pre-screened and monitored for anti-PEG.

In its recent vaccine safety monitoring report, the German Paul-Ehrlich-Institut suspects PEG to be the cause of multiple anaphylactic (serious allergic) reactions.

114. K. Deaths throughout the world after receipt of the BioNTech BNT162b2

Norway already weeks ago expressed increasing concern about the safety of BNT162b2 on elderly people with serious underlying health conditions after raising an estimate of the number who died after receiving inoculations to 29. [49]

The death of a Florida physician who developed an unusual blood disorder shortly after he received BNT162b2 is one of the first fatal cases being investigated. [50]

Until February 13, 2021 in the EU a total of 54.715 cases, of which a total of 879 death reports after receipt of BNT162b2 had been submitted to the Eudra Vigilance – European database of suspected adverse drug reaction reports (http://www.adrreports.eu/de/search subst.html**).**

115. In another scientific assessment (Doc. **A.21), Prof. Dr.rer.nat. Stefan Hockertz, stated the following about the danger posed by cationic lipids:**

Cationic lipids

a.) 30-50% in the LNP at Biontech

b.) Extremely toxic to cells due to positive charge; interacts with negative molecules in lipids, DNA, proteins.

c.) Ignoring numerous publications on toxicity of cationic lipids, shown both in cell cultures and in vivo in animal models.

The release of cationic lipids into the cytoplasm of the cell leads to interactions with other cell molecules e.g. the lipid membrane of the mitochondria (energy power plants) => leads to damage => leads to a production of oxygen radicals (=ROS = highly reactive oxygen compounds, e.g. superoxide=O2-, hydrogen peroxide H2O2; hydroxyl groups OH-).

ROS are always formed due to metabolism in the presence of oxygen in small amounts produced by the cells during energy production - cells have mechanism of balance/elimination through production of antioxidants and uptake by the cells of antioxidants from food.

If too much ROS is released => damage to the cell (oxidative stress)

d.) Changes/oxidises amino acids in proteins => changes folding => loss of function of proteins, enzymes

e.) Promotes cytokine release

f.) Attacks cell structures such as membranes; alters/oxidises unsaturated free fatty

acids (lipid peroxidation) => loss of membrane integrity => permeability => breakdown of ion balance e.g. calcium concentrations => functionality of proteins suspended
g.) Attacks DNA and RNA, e.g. DNA breaks; often irreversible as repair mechanisms fail/overload Massive oxidative stress => diseases, cancer and cell death (apoptosis, necrosis).

Technique: great technique if toxicity were gone; scientists are working on it, e.g. edaravone (scavenges oxygen radicals and reduces oxidative stress (clinical phase published 2019).

116. LNP in cancer therapy:

Chemotherapeutic and radiotherapeutic agents in cancer therapy are used to intentionally cause increased oxidative stress by generating ROS to kill the cancer cells.
The new LNP technique with cationic lipids is intentionally used in cancer therapy to generate exactly these ROS molecules to kill the cancer cells.
Targeting of cancer cells possible because they have different specific protein amounts on the cell surface than healthy cells; targeting via e.g. transferrin, folic acid
Publications known:
Prolonged LNP uptake via the lungs => increased DNA breaks =>lung diseases and lung cancer.
LNP uptake in the spleen: DNA breaks
LNP in blood: thrombosis and haemolysis (dissolution of red blood cells => oxygen deficiency)

With reference to open assessment report (BioNTech):

117. Distribution of LNP in the body:

A) Various publications where the LNP in the body was followed in vivo or the tissues were analysed post-mortem.
B) The results of these publications were similar to those of BioNtech in the public assessment report (even if all raw data are not published).
C) Depending on the way the LNP is introduced into the body (IM=intramuscular), IV=intravenous, epidermal, via inhalation etc) one sees similar dispersions
D) BioNtech: Study on rats and mice
- **LNP** with mRNA for luciferase via **IM (spreading of lipids in the body)**
- Lipids were radioactively labelled + luciferase mRNA
- Detection in many tissues already **after 15 min** => very fast spreading
  a.) Most LNP were detectable at the injection site.
  b.) Plasma
  c.) Liver 22% of LNP; (with IV injection 60% of cationic lipid dose; 20% of PEGylated lipid dose)
  d.) Spleen 1.1%
  e.) Adrenal gland 0.1%
  f.) Both reproductive organs (ovaries 0.1%)

-No information available on spread to other organs **LNP** with mRNA for luciferase **via IV (degradation of lipids based on LC-MS/MS)**
Plasma: detectable for cationic lipid approx. 12 days; PEGylated lipid 6 days
Because PEG degradation partly via excretion: PEGyl lipid 50% via excretion; cation lipid 1% via excretion (i.e. complete degradation in the cells)
Liver: half-life for cation lipid 3 weeks (total time to elimination to 5% = 4-6 weeks; half-life for PEGylated lipid peak 1 week).

No information on testing other organs *except liver, plasma, urine, stool/All under Pharmokinetics p.45 to 46 (middle); all in open assessment report for Biontech).*
LNP with mRNA for luciferase via IM (degradation of luciferase mRNA, only 2ug RNA injected, via in vivo bioluminescence = weak sensitivity).
Detection at injection site in muscle: peak 6h; still visible after 9 days (publication 2016: Luc 35 days still visible)
In the liver: peak 6h; gone after 2 days
Note: 2ug are less than in humans with 2x 30ug; stability of mRNA of luciferase and spike protein may be different(All under Pharmokinetics p.46 to 47 (middle), all in open assessment report for Biontech)

118. **Summary:**

1. Muscle
   (a.) Most LNP remain in the muscle at the injection site when injected IM.
   (b.) Gene expression can be detected within a few hrs and still after 9 days (luciferase RNA 2ug)
2. Plasma:
   (c.) lipid detectable virtually immediately and rapidly taken up by cells (only 1% left in plasma after 24hrs; cation lipid no longer detectable after 12 days
   3. Liver:
   d.) LNP Large proportion 20-60% goes into liver (depending on injection method).
   e.) LNP detectable there after 15min
   f.) Cation lipids detectable for at least 6 weeks; luciferase activity detectable for 2 days

➔ very rapid transport and uptake and long residence time of LNP in the body (note: point d) personal assessment)

119. <u>EMA: Question to the applicant how long the cationic lipid is in the body in humans?</u>

Applicant refers to publication by Mahmood et al, 2010 (*Note: did not find in database*): Based on the understanding of the process for half-lives and redistribution of LNPs from tissues, a similar half-life and time to 95% elimination in humans of the BioNtech vaccine is expected as in the publication, as lipids are similar.
For the cationic lipid, the half-life is about 20-30 days in humans and **4-5 months** for 95%elimination.
The EMA Committee itself says that it is a long terminal half-life (Note: p. 53 "If this is the case for ALC-0315 we may expect a half-life approximating 20-30 days in human for ALC-0315 and **4-5 months** for 95% elimination of the lipid (Mahmood et al, 2010)."

120. **No pharmacokinetics were done with the original vaccine.**
Note: The vaccine used was not the one now being given to the population, only the lipid envelope is like the vaccine but a different mRNA. The spike protein mRNA may have a different residence time in the body as the one tested (luciferase).

121. **Pre-clinic data: (no raw data available, descriptive only).**

- IM injection, 30ug, 3x, at 1 week intervals /day 1, day 8, day 15), autopsy on day 17 or day 36 (3 weeks recovery).
- Rats showed immune response

a.) enlargement of lymph nodes and spleen with increasing cell counts
b.) Increased production of lymphocytes (B, T) in bone marrow
c.) Production of neutralising AK
d.) Increased number of circulating white blood cells in the blood (neutrophils, monocytes,eosinophils, basophils)
e.) Cytokine release

- Body temperature +1°
- Body weight decreased although food intake remained the same

=> *Note: Rodents lose weight when exposed to severe stress. ….*

122. **Damage to the muscle:**

a.) *swelling, oedema, redness*
b.) *Myofibre degeneration, fibrosis, sclerosis and incrustations accompanied by subcutaneous inflammation and spread of this inflammation to adjacent tissues and epidermal hyperplasia.*

Subcutaneous inflammation = subcutaneous - lowest skin layer of 3 = fat layer with nerves and blood vessels; during inflammation fat cells die, releasing fatty acids => further inflammatory stimulus, leads to sclerosis (= hardening of the tissue due to an increase in connective tissue= fibrosis) and incrustations (storage of salts in a necrotic tissue); necrotic = tissue dies Myofibre degeneration = death of the cells of the muscle fibres
Consequence: Functional limitation
epidermal hyperplasia = increased cell division of the epidermis (top layer of skin)

Can also be recognised by blood parameters:

a.) 71x increase in alpha-2 macroglobulin - part of the immune response due to inflammation.
b.) 39x increase in alpha-1 acid glycoprotein (AGP) - increased due to injury to tissues from inflammation or infection
c.) 2.5x increase in fibrinogen - indication of inflammation of blood vessels, task of blood clotting

Note: What about elderly people in homes who take anticoagulants? Can the injured blood vessels be repaired at all or risk of haemorrhage? …

123. **Damage to the liver**

Hepatocellular periportal vacuolisation on autopsy day 17.
Hepatocellular = concerning the inside of the liver cells
Periportal = the liver cells located near the portal vein = entrance of blood into the liver.
Vacuolisation = BioNtech has not investigated what causes this; however, BioNtech guesses correctly = cation. Lipid is responsible; it is known in science that there are various reasons for vacuolisation such as ion imbalance
(*Note: cationic lipids cause ion imbalance*) => increase in osmotic pressure in the cell as water flows into the cell (to compensate) => formation of vacuoles; cell tries to get rid of the cationic lipids from the cytosol, which does not work; hence the encapsulation in vacuoles => cell malfunction and cell death; BioNtech says

vacuolisation was reversible; (*Note: the liver cells that died were replaced by healthy new cells). What happens in people with liver diseases such as hepatitis, cirrhosis, etc.? Can lead to organ failure*)....
Supported by blood parameters:
Increase in GGT enzyme: has various causes, e.g. liver cell damage due to drugs or poison; due to the death of liver cells, GGT is released into the blood in increased concentration.
Increase in AST (aspartate aminotransferase = for amino acid metabolism = transferring nitrogenous groups from one amino acid to another); occurs in liver inflammation and in heart damage
Increase in ALP (alkaline phosphatase; metabolic enzyme); produced in the bones, liver and 1-2 other organs; increase indicates liver inflammation and bone disease
Drop in albumin to globulin ratio (measurement of serum protein shifts); a drop indicates severe liver damage, as well as inflammation, digestive disorders due to reduced enzymes in the bile acid or exocrine part of the pancreas (fat and protein splitting) and/or protein losing nephropathy (= protein loss via stool and urine) ....

Note: Why is the liver damaged in particular - Why does the LNP go exactly there?

-Liver: function breakdown of cholesterol
-LNP has up to 50% cholesterol => bind lipoproteins like ApoE
-Liver possesses vast numbers of ApoE receptors (LDL-R, LRP1, VLDL-R etc.)
-Particularly strong uptake of LNP from the bloodstream via ApoE receptors in the liver; LNP accumulate there; concentration too high => then the liver cells die- depends on the degree of fitness of the liver; persons with already impaired liver function are likely to be particularly susceptible to liver damage after vaccination …

124. *Inflammation of the perineural tissue of the sciatic nerve and surrounding bones on day 17.*
-Strongest nerve in the body
-Note: What about paralysis?
-p.49: " Also, there was inflammation of the perineural tissue of the sciatic nerve and surrounding bone in most rats at d17."

125. *Inflammation in extra-capsular tissues of joints day 17.*
Note: What about arthritis patients?
p. 49: "A novel finding at 30ug was minimal extra-capsular inflammation in the joints at d17."
No raw data with animal numbers available.
Moderate to severe reduction of **red blood cells** and **reticulocytes** (precursors of red blood cells) = **severe haemolysis** observed.
And also decrease of red blood cell parameters like HGB (haemoglobin) and HCT (haematocrit = proportion of red blood cells in the volume of blood)
Note: Meaning => oxygen saturation in the blood must have gone down (no information about this described)
Increase in AGP (glycoprotein): marker for inflammation and marker for haemolysis;
P. 50: *"Haematology:* At 30ug BNT162b2 V9 and 100ug BNT162b2 V8, there was a moderate to strong reduction of reticulocytes (48-74%, not specified for V9) coupled to lowered red cell mass parameters (RBC, HGB, and HCT). " p. 50:

"Clinical pathology: A very strong but reversible increase (>100%) in pro-inflammatory acute phase proteins in the blood (A1AGP = AGP, A2M) was seen with both 30ug BNT162b2 V9 and 100ug BNT162b2 V8."
P. 54: "There was also a general increase in immune cells (LUC, neutrophils, eosinophils, basophils) and a decrease in red blood cell parameters (reticulocytes, RGB, HGB, HCT)."
- *Note: AGP reduces haemolysis-induced oxidative stress in red blood cells; red blood cells are particularly susceptible to oxidative stress as they carry oxygen-laden haemoglobin; the exchange of oxygen with the environment generates free radicals which the cell normally scavenges to avoid excessive oxidative stress; if oxidative stress is increased by the uptake of the cation lipids of LNP, it may not be able to be compensated for and LNP may be depleted. If the oxidative stress is increased by the uptake of the cation lipids of the LNP, it may no longer be compensated for and the red blood cells die as a result of the oxidative stress (haemolysis) => increase in AGP.*
During vaccination: measure oxygen content in the blood => dangerous for groups of people with e.g. heart diseases; risk of heart attacks due to oxygen deficiency; all organs are undersupplied with oxygen => aggravation of pre-existing diseases
Erythrocytes are preferably taken as a test model for research on oxidative stress, as they react very sensitively to it.
Widely known among experts, e.g.: Publication
2014 (Red blood cell oxidative stress impairs oxygen delivery and induces red blood cell aging);
1996 (oxidative stress in erythrocytes);
2020 (Toxicological profile of lipid-based nanostructures: are they considered as completely safe nanocarriers?) "Oxidative stress is one of the major mechanisms underlying cytotoxicity which results in nanomaterial-induced injury as an early event (Garbuzenko et al. 2009; Choi et al. 2010)."

126. **No discussion of possible further consequences of the damage, no discussion of the consequences of the altered blood parameters, especially in relation to the use of the vaccine in humans with certain pre-existing conditions.**
All these parameters were not analysed in the human clinical trials!
Much of this could have been done (e.g. complete blood tests; muscle biopsies, oxygen saturation etc.).
There were no pharmacokinetic studies (residence time of lipids in plasma, excretion etc.).
Only study done e.g. clinic 1 in humans - lymphocyte count: observation of lymphopenia: reduction of lymphocytes (B and T cells) by half within 1-3 days; normalisation after one week => no explanation provided. *Quote "had no associated clinical effect".*

Note: Was observed in 1-2 other publications after vaccination, but no explanation here either. However, there is also at least one publication that observed an increase in lymphocytes after vaccination. Obviously it is not clear whether the loss of lymphocytes is only due to a redistribution of cells from the blood into the tissue or whether the cation lipids destroy them. Should be investigated.

127. ***Reproductive toxicity:*** (DART study with the vaccine).'

- Female rats twice before the onset of mating and twice during pregnancy with the clinical human dose (30 µg RNA/dose day)
- intramuscularly (IM) 21 and 14 days before the onset of mating and then on gestation day 9 and 20 (4 doses in total).
- SARS-CoV-2 neutralising antibody titres were found in the majority of females just before mating, in most females and foetuses at the end of gestation and in most offspring at the end of lactation.
- No effects on the female cycle or fertility index were observed. There was a 2-fold increase in preimplantation loss = within the range of historical control data.
- Among the fetuses (n=21), there was a very low incidence of gastroschisis (developmental disorder of the anterior abdominal wall), oral/jaw malformations, right aortic arch and cervical vertebral anomalies = all findings within the range of historical control data
- There was no evidence of adverse effects on the skeleton

Quote: "It should be noted that there are currently no data on placental transmission of BNT162b2.*"*
Note: Insufficiently studied

128. **Eco-toxicity and Environmental Risk Analysis (ERA)**
Quote: "As the active substance is a vaccine product (which is also based on naturally degradable mRNA and lipids), no ERA is considered necessary."
Note: I do not see it that way
a **We briefly become a GMO***; in the lab, anything that has had contact with genetically modified cells must be properly destroyed/autoclaved;*
b Vaccine manufacturers have not studied whether gene-modified cells, the artificial lipids or the vaccine are directly excreted from the body and thus enter the environment;
c They have shown that both lipids studied are excreted from the body of rats (PEGylated up to 50%) => enter the sewer system
No discussion of this
p. 51: "As the active substance is a vaccine product (which additionally is based on naturally degradable mRNA and lipids), no ERA is considered necessary."

129. **<u>The possibility of overcoming the blood-brain barrier was not mentioned.</u>**
Note: Extremely dangerous! Nerve cells are very sensitive and die immediately, even at very low stress (show no tolerance).
Possible explanation for the occurrence of facial nerve palsy in vaccinated individuals. Either the facial nerve is directly inflamed or the surrounding area is inflamed, causing swelling in the brain and pressure on the nerve. The nerve is then pressed against the bones, where it squeezes through. This can cause facial paralysis until the nerve is exposed again.
E.g. publication from 2017 (ApoE-modified solid lipid nanoparticles: A feasible strategy to cross the blood-brain barrier).
Has also been proven with Moderna (Moderna has the same technique with similar lipids of the same properties).

130. **No study has been done on genotoxicity (damage to genetic material**

that could lead to mutations and cancer). Justification Quote (p. 50) "This is acceptable as the components of the vaccine formulation are lipids and RNA which are not expected to have genotoxic potential.The risk assessment carried out by the applicant shows that the risk of genotoxicity related to these adjuvants (lipids) is very low based on literature data".

Note: ad reality: **there are several studies showing that LNPs can enter all organs and cation lipids cause oxidative stress. There have been numerous studies for over 20 years explaining in detail that oxidative stress leads to DNA damage and is causative in the development of cancer.**

131. **PEGylated lipid:**

- **PEG triggers hypersensitivity /allergic reaction to anaphylactic shock.**
- Leads to rapid elimination of LNP by means of previously formed antibodies against PEG from the blood => vaccination failed, as no spike protein is formed
- Publication 2006: if one has already been in contact with PEG, antibodies against PEG may have been formed; the amount of PEG at first contact does not matter; one forms AK or not; once AK (IgG) are in the blood, the amount of PEG at second contact determines how bad the immune reaction becomes
- Publication 2006: Hypersensitivity and Loss of Disease Site Targeting Caused by Antibody Responses to PEGylated Liposomes

132. **Point 5: no discussion of possible long-term consequences e.g. autoimmune diseases**

1. molecular mimicry (Dr. Wodarg, Syncytium)
2. increased production of autoantigens through massive cell damage by catio lipids and elimination of cells with spike proteins by the immune system.

133. Autoantigens formed by apoptosis => immune system must break down cell remnants => in case of overload (e.g. too much cell damage and apoptosis or immunosuppressed people or people vulnerable to autoimmune diseases) the cleansing command does not run smoothly => accumulation of autoantigens in the body => leads to chronically excessive type I interferon release (further heats up immune response) => suddenly the autoantigens are no longer cleared away, but the formation of autoantibodies against these autoantigens is initiated; and activation of autoreactive cytotoxic T cells => T cells and autoantibodies lead to further damage of tissues => if autoantibody levels decrease, tissues may recover, if not, **autoimmune disease may be established.**

Publications:

2019, DNA damage response and oxidative stress in systemic autoimmunity.
2018, extracellular DNA and autoimmune disease
2018, apoptotic cell-derived extracellular vesicles
2021 oxidative stress and lipid mediators modulate immune cell functions in autoimmune diseases".

134. The **risks pointed out by the expert are serious**, and it is in no way comprehensible how the European Medicines Agency (EMA) could give a recommendation for the conditional approval of "Comirnaty" against the background that this substance is to be used on the entire population and is currently already being used! **This grossly violates the precautionary principle enshrined in EU law, the fundamental right of EU citizens to physical integrity (Art. 3 EU Charter) as well as the obligation of the Union to guarantee the highest standard of safety in health care (Art. 168 TFEU).**

135. **2.2 <u>Invalidity due to non-existence of the requirement under Article 4 (1) b) of Regulation (EC) No 507/2006 - applicant unlikely to be able to provide the comprehensive clinical data.</u>**

136. According to Article 4(1)(b) of Regulation (EC) No 507/2006, a conditional marketing authorisation can only be granted if the applicant is expected to be able to provide the comprehensive clinical data.

137. The applicant for authorisation of "Comirnaty" is not expected to be able to submit comprehensive clinical data for the following reasons:

138. 1.) As already stated above under point 2.1.1, **the studies on "Comirnaty" are designed by the applicant in such a way that it cannot be understood whether "Comirnaty" prevents further infectivity or not.** Peter Doshi writes in the article published by him in the British Mediclal Journal (BMJ) on 4 January 2021: "... ***trials not designed to assess whether the vaccines can interrupt viral transmission ...".*** (Doc. **A.18.3**).
This means that **<u>the study designed by the applicant cannot provide comprehensive clinical data on the essential point of efficacy. For this reason alone, the condition for conditional authorisation set out in Article 4 (1) b) is not met!</u>**

139. 2.) In view of the fact that "Comirnaty" is in fact a substance that acts like a "gene therapy medicinal product", but **the authorisation procedure applied and the studies conducted do not comply with the special provisions for so-called "advanced therapies" (Art. 4(1)(b)), the applicant has not submitted comprehensive clinical data. "(Commission Directive 2009/120/EC of 14/09/2009 and Regulation (EC) No 1394/2007 of 13/11/2007 on advanced therapy medicinal products), the applicant will by definition not provide the comprehensive clinical data for a medicinal product that in fact acts like a "gene therapy medicinal product".**

140. The implementing decision contested here is therefore also unlawful on these grounds alone and therefore null and void. 141.

141. 2.3 **<u>Nullity due to the non-existence of the requirement according to Regulation (EC) No. 507/2006 - Article 4 (1) c) - non-existence of a medical supply gap that can be closed by the authorised medicinal product</u>**

142. It is obvious how for almost a year now it has been made difficult for treating physicians to use drugs that have long been on the market and have achieved very good results in the treatment of Covid 19 patients (if used correctly - e.g. not overdosed and not used in contraindications, e.g. favism, as was the case with Hydroxychloroquine due to a fatal internationally allegedly erroneously issued indication).

143. As already explained above, Italian family doctors, for example, had to go all the way to the last instance of administrative jurisdiction in order to obtain confirmation, based on evidence of very good therapeutic successes, that they were allowed to use Hydroxychloroquine on sick people in the early stages, contrary to the prohibition of the use of this drug, which was not comprehensible by the Italian Medicines Agency until the execution of the judgement (Doc. **A.9 -** Consiglio di Stato - Council of State - Rome Judgment No. 0970/2020 of 11.12.2020).

144. In their fight against the low-cost Hydroxychloroquine (doc. **A.22.1**) - which has also proven effective in the early treatment of high-risk patients thanks to its anti-inflammatory and antithrombotic properties - opponents published a fabricated study in the Lancet (the Surgisphere scandal - doc. **A.22 .2)** and conducted toxic

overdose studies in intensive care patients (the "SOLIDARITY" and "RECOVERY" studies - Doc **A.22.3**).

145. But the drug "Ivermectin", which was highly successful in Covid-19, is very difficult to overdose and, unlike HCQ, it works as prophylaxis against infections and even in ICU patients.
Dozens of studies and several metastudies have already established that the inexpensive Ivermectin is highly effective against covid (Doc. **A.22.4**).
According to recent studies in several countries, the antiparasitic drug Ivermectin - a WHO essential drug - achieves up to 98% risk reduction (Doc. **A.22.5**) in covid-19 in pre-exposure prophylaxis and up to 91% in early treatment. A recent study in France found a 100% reduction in severe and fatal covid disease (Doc **A.22.6**) even in high-risk nursing home patients with an average age of 90 years.
In addition, an analysis just published in the International Journal of Antimicrobial Agents found that African countries using Ivermectin as prophylaxis against parasites have a much lower (Doc **A.22.7**) - even near zero - incidence of covid compared to other African and non-African countries.
The very high reported efficacy of the low-cost Ivermectin against SARS-like coronavirus infections, compared to the very modest and fundamentally questionable efficacy and the absolutely intangible and assessable risks of "Comirnaty", is clear evidence that "Comirnaty", unlike Ivermectin, is not suitable to close a medical care gap.

146. In this context, the specific question arises: **why is Ivermectin not widely used in the EU?**
Based on the above findings, the US Front-Line Covid-19 Critical Care Alliance (FLCCC), for example, recommends Ivermectin for Covid-19 prophylaxis and early treatment (Doc. **A.22.8**).

147. Apart from the fact that there are drugs that have been shown to treat covid-19 patients very well and that, as in the case of Ivermectin, can even be used prophylactically, it is also evident that EU Member State governments, including the European Commission, show no interest in recommending or promoting the use of other very inexpensive but effective substances to the population. Vitamin D is one of them.
In a Spanish randomised controlled trial (RCT - **Doc. A.22.9**), high-dose vitamin D (100,000 IU) reduced the risk of intensive care by 96%.
In a study (Doc. **A.22.10)** in a French nursing home, an 89% reduction in mortality was found in residents who received high-dose vitamin D just before or during covid 19 disease.
A large Israeli study (Doc **A.22.11**) found a strong association between vitamin D deficiency and Covid 19 disease severity.
A 2017 meta-study (Doc. **A.22.12**.) found a positive effect of vitamin D on respiratory infections.

148. The use of zinc in combination with HCQ, for example, is equally successful.
US physicians reported (Doc. **A.22.13.**) an 84% decrease in hospital admissions, a 45% decrease in mortality in already hospitalised patients and an improvement in patients' condition within 8 to 12 hours based on early treatment with zinc in addition to HCQ.
A Spanish study (Doc **A.22.14**) found that low plasma zinc levels (below 50mcg/dl) increased the risk of in-hospital death in covid patients by 130%.

149. While European countries and the USA continue their aggressive military roll-out of experimental, expensive and dangerous agents declared

as vaccines but de facto functioning like gene therapy, India has developed an "amazingly" effective and safe COVID-19 treatment KIT that costs as little as $2.65 per person and has helped put the nation's case and death rates into "steep decline".

150. FLCCC has developed a treatment protocol (Doc **A.22.8**) that includes Ivermectin, which the group claims has resulted in up to 83% lower COVID-19 death rates than average in hospitals that have used it.
However, the Food and Drug Administration (FDA) in the US has for months denied emergency approval of Ivermectin for the treatment of coronavirus on the grounds that "further testing is needed". In Europe, the drug is largely ignored.

151. In contrast, India has adopted the treatment protocol specified by FLCCC and now manufactures this product under the brand name "Ziverdo Kit", and it costs only about $2.65 per person.
Although the U.S. National Institutes of Health (NIH) does not recommend treatment for SARS-COV-2 sufferers "unless the patient is hospitalised and requires oxygen", India has started treating coronavirus patients early, including the use of hydroxychloroquine (HCQ).
Dr Makarand Paranjpe and his wife, both 77-year-old Indian doctors, fully recovered from the COVID-19 virus last November with early treatment, reports TrialSiteNews (TSN - Doc **A.22.15**). She took Hydroxychloroquine and he took Ivermectin.
"We know that without any treatment, the virus enters the cells and multiplies," Paranjpe said. "This can cause diseases that become much more severe. Stopping that replication as early as possible is the simple function of these low-cost, safe treatments."
Last March, as debates raged in the US over the merits of HCQ, India had already recommended it in its national guidelines, reiterating that it "should be used as early in the disease course as possible...and avoided in patients with severe disease."
Following the discovery of ivermectin's effectiveness in treating the virus in June and subsequent extensive testing, the country's largest state, Uttar Pradesh (UP) (population 230 million), announced in August (Doc **A.22.16**) that it was replacing its HCQ protocol with Ivermectin for the prevention and treatment of COVID-19.
"By the end of 2020, Uttar Pradesh - which distributed free Ivermectin for home care - had the second lowest mortality rate in India, at 0.26 per 100,000 population in December. Only the state of Bihar, with a population of 128 million, was lower, and Ivermectin is recommended there too," writes TSN's Mary Beth Pfeiffer.

Dr Anil K. Chaurasia, a physician in UP, confirms that **from mid-September onwards, "a marked decline in COVID cases and deaths was observed in India ... [and the] steep decline in cases and deaths is still continuing."**

152. <u>The same results apply to neighbouring Bangladesh, one of the most densely populated nations in the world, where doctors also use home ivermectin therapy, and they have an even lower mortality rate, ranking 128th in the world.</u>

153. Ivermectin also successful in other countries
FLCCC cited similar results in Peru, Argentina, Brazil and several other South American countries demonstrating the effectiveness of Ivermectin.
In its written testimony before the US Senate committee, for example, an FLCCC

representative told the committee that in Peru "the peak of deaths occurred at the time distribution began" of ivermectin, which the country had approved for COVID-19 treatment in late spring. **Every Peruvian state experienced a "rapid and sustained decline in both case numbers and patient death rates" when ivermectin was circulated,** the FLCCC representative said.

Despite this new and comprehensive evidence, however, the US and EU steadfastly reject ivermectin as a means of combating coronavirus and instead continue to rely on high-risk experimental "vaccines", such as "Comirnaty", which have a very modest positive effect, if any, and in effect act like a "gene therapy drug", should never have been approved in a fast-track procedure!

Ivermectin has recently also been approved in Slovakia for the treatment of coronavirus patients in hospitals and can be obtained with a prescription from the pharmacy.

With this step, the Ministry fulfilled the demand of the Association of Slovak Anaesthetists, reported the daily Denník N. (Doc. **A.22.17**).

154. Ivermectin is also demanded in other countries and in some cases already used.Prof. Paul R. Vogt, Clinic Director of the University Hospital Zurich and visiting professor at a university in Wuhan, had called for an emergency approval of Ivermectin in an urgent appeal to the Swiss Federal Council at the end of December (Doc. **A.22.18**). At least in such a way that people who want it can have regular access to the drug:

In Italy, a doctors' group that has already had to fight for the right to use hydroxychloroquine for the treatment of Covid 19 patients in court up to the last instance (Doc. **A.9**) has long since called on the Italian health authorities to approve ivermectin. To date, Italy, like other EU countries, continues, for reasons that are objectively (if one wants to assume the well-being of the population as the goal) incomprehensible, to prefer experimental genetic engineering-based active substances that are extremely questionable in their use and highly dangerous (which, contrary to their mode of action, are declared as "vaccines"), rather than the use of medicines that have gone through proper approval procedures and whose modest side effects have long been known.

155. India has been using the highly effective ivermectin very successfully and refuses to approve the experimental genetic engineering based "vaccine" "Comirnaty".

BioNTech/Pfizer had applied to the Indian authorities for approval of their COVID-19 mRNA vaccine. Due to safety concerns and question marks regarding the efficacy of the vaccine, approval has been denied. Therefore, BioNTech/Pfizer have withdrawn their application for approval, as reported by Deutsche Welle citing AP/reuters (Doc, **A. 23.1**).

The Indian authority reports on BioNTEch/Pfizer's presentation to obtain emergency approval for the COVID-19 mRNA vaccine BNT162b for the Indian market. The authority notes that - after market approval (so-called post-marketing phase) in other countries - paralysis, anaphylaxis and other adverse reactions have occurred, for which the causality with the vaccine is currently being investigated. The Indian committee criticised BioNTech for not submitting a plan to generate safety and immunogenicity data in the Indian population. After extensive consultations, according to the minutes, the committee did not recommend granting approval for the emergency use in India at that time (Doc. **A.23.2**).

According to the Deutsche Welle report, the Indian regulatory authority had

criticised the lack of immunogenicity studies for the vaccine. Immunogenicity is the property of a substance to trigger an immune system response, known as an immune response, in the animal or human body.

156. 2.4 **Invalidity for failure to meet the condition laid down in Regulation (EC) No 507/2006 - Article 4 (1) d) - failure to demonstrate the benefit to public health of making the medicinal product immediately available on the market, outweighing the risk due to the lack of additional data.**

157. Based on what has already been stated and documented above, the risk due to the lack of additional data far outweighs the de facto non-existent public health benefit of the immediate availability of "Comirnaty" on the market.
This substance should never have been authorised in the procedure chosen for this purpose in view of the missing preconditions and must be withdrawn from the market immediately.

158. **3 Invalidity for infringement of Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007, 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, and 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 use**

159. **3.1 Violation of the EU legal provisions for the authorisation of "advanced therapy medicinal products**

160. According to Directive 2001/83/EC Art. 1 point 4, vaccines are
active substances used to induce active immunity, or active substances used to induce passive immunity.

161. The aim of active vaccination is to build up long-term effective protection. For this purpose, killed or even only fragments of the pathogens or weakened pathogens that can no longer cause a serious illness themselves are administered. The body is thus fooled into thinking it has an infection and reacts by producing antibodies and so-called memory cells. If one is infected with the real pathogen in the future, these can quickly become active and fight off the disease. 162.

162. For some diseases, it is possible to build up rapid protection through passive immunisation. This can be necessary if a person is currently in contact with a pathogen and there is no sufficient vaccination protection against this disease. For this, however, one must realise that one has been infected.
In passive vaccination, concentrates of antibodies are injected, which usually come from people who are immune to the disease, e.g. through vaccination. In contrast to active vaccination, passive vaccination offers immediate protection, which, however, only lasts for a short time - about three months.

163. Annex I to the implementing decision challenged here (Doc. **A.2.2**) states literally on page 4: *"The duration of the protective effect of the vaccine is not known, as it is still being determined in ongoing clinical trials".*

164. **"Comirnaty" has been proven to lead neither directly nor successfully to active immunisation.**
The Robert Koch Institute explicitly states the following on its hompage: *"How long the vaccination protection lasts is currently not known. Protection also does not start immediately after vaccination, and some vaccinated persons remain unprotected. In addition, it is* ***not yet known whether the vaccination also protects against colonisation with the pathogen SARS-CoV-2 or against***

transmission of the pathogen to other people. Therefore, despite vaccination, it is necessary to protect oneself and one's surroundings *by observing the AHA + A + L rules (distance rules, MNS).*" (Doc. **A.18.5**).

There is no evidence of active immunisation for "Comirnaty", and the objective of passive immunisation is also not present.
"Comirnaty" as an mRNA cannot directly trigger an immune response. However, such a direct immune response is an obligatory function for vaccines. "Comirnaty" is a classical prodrug, i.e. the precursor of a drug, which must first be metabolised by the body's own functions - in this case protein biosynthesis - into the hoped-for functioning drug. This process is known and described for therapeutic drugs (prodrug), but not for vaccines (the term "provaccine" is unknown). This fact that "Comirnaty" requires endogenous activation also rules out the possibility that this gene therapy drug is a vaccine. It is a gene therapy drug that is supposed to have immunostimulatory effects in order to alleviate severe consequences of infections caused by coronaviruses. The alleviation of disease symptoms are clearly functions attributed to medicines (including prophylactic), not vaccines.

165. **Accordingly, the active ingredient "Comirnaty" clearly does not fall under the term "vaccine" as defined 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.**

166. **In fact, the active substance "Comirnaty" corresponds to the definition of a "gene therapy medicinal product" as set out in Annex I, Part IV (Advanced therapy medicinal products), point 2.1. of Directive 2001/83/EC**. 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.
"Comirnaty" works exactly according to this principle. The active substance "Comirnaty" should therefore have been subject to the specific requirements laid down in Part IV of Annex I for "advanced therapy medicinal products". This has not been done.

167. For this reason, the European Commission's implementing decision contested here (together with subsequent amendments and integrations) is grossly unlawful and void as a matter of law, because there is a breach of the rights conferred by Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 establishing a Community code relating to medicinal products for human use and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 establishing a Community code relating to medicinal products for human use. 726/2004 in Directive 2001/83/EC on the Community code relating to medicinal products for human use and in 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 use.

168. **3.2 <u>Invalidity due to the identified "potential important risks" and "missing information" according to the risk management plan without appropriate risk minimisation measures and incorrect risk presentation concerning the summary of product characteristics and package leaflet.</u>**

169. **Annex I concerning the summary of product characteristics and Article 3 in conjunction with Annex III concerning the package leaflet of the contested implementing decision contradict the content of the risk management plan of 21/12/2020** (Doc. **A. 24) which contains the relevant changes of the PRAC *rolling review* report of 18/12/2020 compared to the marketing authorisation application and which, according to Annex II lit. D of the contested implementing decision, constitutes the "conditions or restrictions for the effective use of the medicinal product".**

170. According to Article 9(4)(c) of Regulation (EC) 726/2004, details of any recommended measures to be included in the risk management system in order to ensure the safe use of the medicinal product are an integral part of the positive opinion of the Agency and thus of the marketing authorisation. These recommended changes as a consequence of the PRAC rolling review report of 18.12.2020 constitute an indispensable condition of the marketing authorisation concerning the effective use of the medicinal product.

171. The risk management plan of 21/12/2020, which contains the relevant amendments of the PRAC *rolling review* report of 18/12/2020 compared to the original risk management plan submitted by the applicant and which, according to Annex II lit. d) of the contested implementing decision, constitutes the "conditions or restrictions for the effective use of the medicinal product", contains ineffective risk minimisation measures, inter alia, within the meaning of Article 11(1)(c) of Regulation EC 520/2012.

172. In particular, with regard to "Vaccine-associated enhanced disease (VAED) including Vaccine-associated enhanced respiratory disease (VAERD)", no further risk minimisation measure was identified according to Table 30, and it was not requested to include this risk as an important potential risk in the summary of product characteristics and thus also in the package leaflet according to Table 31/33.

173. **With regard to the missing information concerning persons with fragile health status, in particular comorbidities (e.g. chronic obstructive pulmonary disease (COPD), diabetes, chronic neurological disease, cardiovascular disorders), information was provided in the summary of product characteristics according to Table 30 as a standardised risk minimisation measure. However, this is not found as a corresponding warning of "missing" information in Annex I. Rather, a positive reference is found. Rather, a positive reference is found in the context of individuals with co-morbidities:** *'There were no significant clinical differences in the overall efficacy of the vaccine in participants at risk for severe COVID-19, including those with one or more co-morbidities that increase the risk for severe COVID-19 (e.g., asthma, body mass-30 kg/m2, chronic lung disease, diabetes mellitus, hypertension)*", Appendix I, p 8. **Table 2 below shows that the group of people 75+years, was only 774 subjects. Explicit information on the lack of data on persons with fragile health status is completely missing and thus contradicts the RMP.**

174. The lack of long-term safety data according to Table 30 was also not included in the summary of product characteristics as a risk minimisation

measure according to the risk management plan.

175. According to **Art. 9(1)(c) of Regulation (EC) No 726/2004** and **Art. 62 of Directive 2001/83/EC**, the **characteristics of the medicinal product, in particular the associated risks or information on groups of persons for which the medicinal product is not recommended**, must be correctly included and the package leaflet must comply with this.

176. **According to Article 11(4.4) of Directive 2001/83/EC,** the summary of product characteristics shall include the special warnings and precautions for use **and, in the case of immunological medicinal products, any special precautions to be taken by persons handling immunological medicinal products and by persons administering these medicinal products to patients, as well as any precautions to be taken by the patient.**

177. According to **Art. 11 point 4.5. of Directive 2001/83 EC**, the summary of product characteristics must contain **the drug and other interactions.**

178. According to **Art. 59(1)(c) of Directive 2001/83/EC, the package leaflet shall be drawn up in accordance with the summary of product characteristics** and shall contain the following list **of information which must be known before the medicinal product is taken: (i) contra-indications, (ii) appropriate precautions for use, (iii) interactions with other medicinal products and other interactions which may affect the action of the medicinal product, (iv) special warnings.**

179. **The so-called *"missing information"* identified in the updated Risk Management Report (RMP) of 21/12/2020 following the PRAC rolling review report of 18/12/2020 would necessarily have had to be included in the marketing authorisation dossier (see annexes to the implementing decision contested here) in accordance with the aforementioned legal basis.**

180. **This applies in particular to Table 31, p. 98 RMP iVm PAR p. 115 (summary of RMP safety concerns, missing information)** (Doc. **A. 24**).

181. **In particular, the "important potential risk" VAERD should have been included in the package leaflet, as well as all other missing information (persons with fragile health status, etc.)**

"II.A List of Important Risks and Missing Information

Important risks of Comirnaty are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered.

Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Comirnaty. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine).

Table 31. List of Important Risks and Missing Information

Important identified risks Anaphylaxis
Important potential risks Vaccine-associated enhanced disease (VAED) including Vaccine associated enhanced respiratory disease (VAERD)
Missing information Use in pregnancy and while breast feeding
Use in immunocompromised patients
Use in frail patients with co-morbidities (e.g. chronic obstructive pulmonary disease (COPD), diabetes, chronic neurological disease,

cardiovascular disorders)
Use in patients with autoimmune or inflammatory disorders
Interaction with other vaccines
Long term safety data.

182. A look at the package leaflet shows that the EU regulation has clearly been violated.

183. As already mentioned, Annex I to the contested implementing decision explicitly states: *"4.5 No studies have been conducted to assess interactions. The concomitant administration of Comirnaty with other vaccines has not been studied."* For this reason, too, the implementing decision contested here is contrary to Eu law.

184. **3.3 Invalidity due to violation of the EMA's own criteria for monitoring a "pandemic medicinal product" with enormous exposure figures in the short term.**

185. According to Annex II, E - Specific obligation to complete post-authorisation measures under "special conditions" (p. 17 and 18) to the implementing decision contested here, **the marketing authorisation holder is obliged to file the clinical study report for the randomised, placebo-controlled, observer-blind study for the purpose of confirming the efficacy and safety of Comirnaty only in December 2023!This deadline is clearly outside a valid assessment period for review in terms of efficacy and safety etc. at the time of extension.** It is also absolutely inadmissible that safety reports on a medicinal product with short-term enormous exposure figures do not have to be submitted until 6 months after approval.

186. With regard to manufacturing conditions concerning the active substance and batch release, and essential safety aspects, Annex II to the contested implementing decision provides for the submission of periodic safety update reports (PSURs) in accordance with Directive 2001/83/EC, for the first time 6 months after authorisation.

187. In this context, the authorisation of the pre-pandemic influenza vaccine Aflunov should be mentioned. In this regard, the EMA has requested a tighter submission of safety reports:

188. ***"During a pandemic situation, the frequency of submission of periodic safety update reports (PSURs), as specified in Article 24 of Regulation 726/2004/EC, is not sufficient for monitoring the safety of a pandemic vaccine where high numbers of exposures are expected within a short period of time. Such a situation requires a rapid display of drug safety information, which is of utmost importance for the risk-benefit balance in a pandemic. The immediate assessment of cumulative safety information, taking into account the extent of exposure, will be crucial for regulatory decisions and for the protection of the population to be vaccinated.*** *Furthermore, during a pandemic, the resources needed for a thorough assessment of PSURs in the format set out in Book Volume 9a of the Rules Governing Medicinal Products in the European Union may not be sufficient for rapid identification of new safety issues. "1[1] The EMA itself confirms that the PSURs are not sufficient for the rapid identification of new safety issues."*[2[1]]

2[1] *Aflunov, Produktinformation,Implementing Decision Annex I, Product Information, https://ec.europa.eu/health/documents/communityregister/2020/20200625148560/anx_148560_de.pdf*

189. **Thus, the EMA itself confirms the view that the submission of the PSUR of pandemic vaccines as gene therapy medicinal products after 6 months is too late, which also follows from the wording of Article 107c(2)(b), which stipulates an obligation to submit the PSUR "at least" 6 months after the placing on the market.**

190. For the safe and effective use of Comirnaty, there is an obligation for the marketing authorisation holder to carry out the necessary pharmacovigilance activities and measures described in the agreed risk management plan and set out in Module 1.8.2 of the marketing authorisation, as well as any future agreed updates to the RMP.

191. The actual "special conditions" (according to Art. 14a(4) of Regulation 726/2004) concern specific obligations to complete product and manufacturing quality of the active substance to be verified within the first 6 months and, with regard to **confirmation of efficacy and safety**, the submission of the final clinical study report for the randomised, placebo-controlled, observer-blind **study C4591001 by December 2023.**

192. **The health-threatening problem lies in the proof of efficacy and safety to be provided by the marketing authorisation holder, which is only to be provided 2 years after marketing authorisation, although an annual review is to take place according to the implementation decision. This results in an irresolvable contradiction, which calls into question the legality of this condition and thus the authorisation itself.**

193. **(4) <u>Invalidity of the contested implementing decision on the grounds of gross violation of Articles 168 and 169 TFEU and Articles 3, 35 and 38 EU Charter.</u>**

194. On the basis of the facts and circumstances set out above and documented in this application, it is obvious that the implementing decision of the EU Commission challenged here violates the principles enshrined in Article 168 TFEU (Public Health) of 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.**

195. Union action should be directed towards improving public health, **preventing human illness and diseases, and obviating sources of danger to physical and mental health.**
The EU must take measures to set high standards of quality and safety for medicinal products and medical devices.
The European Commission has grossly violated all of these obligations entered into in Article 168 TFEU with the implementing decision contested here and concretely puts the applicants in a situation that endangers their health.

196. **<u>Article 3 of the EU Charter (right to the integrity of the person)</u>** guarantees every person in the EU the following: **(1) Everyone has the right to physical and mental integrity. (2) In the context of medicine and biology, the following must be respected in particular: the free informed consent of the person concerned, in accordance with the modalities established by law, ..., the prohibition of using the human body and parts thereof as such for the purpose of profit,**

197. **Article 35 of the EU Charter (health protection)** guarantees every person present in the EU that **a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.**

198. 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.**

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

200. On the basis of the foregoing, it is obvious that the EU Commission has also grossly violated the applicants' fundamental right to consumer protection and the obligations laid down in Article 169 TFEU, which also apply to the Commission in particular, with the implementing decision challenged here.

201. The above-mentioned applicants therefore request that this honourable European Court, on the basis of the multiple gross violations of applicable EU law cited above, which affect the applicants directly and personally, declare the implementing decision contested here, together with subsequent integrations and amendments, to be null and void.

Bolzano, 16 February, 2021
Attorney Renate Holzeisen