RECHTSANWALT
DDR. RENATE HOLZEISEN
ZUGELASSEN AUCH BEI DEN OBERSTEN GERICHTSHÖFEN
BAHNHOFALLEE, 7
I-39100 BOZEN (BZ)
TEL. 0471 – 97 73 28 ; FAX 0471 – 98 12 35
HOLZEISEN@HROP.COM

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 06/01/2021 on the granting of conditional approval of the medicinal product for human use "COVID-19 Vaccine Moderna-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 above-mentioned plaintiffs, represented and defended by 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. on 6 January 2021, the European Medicines Agency (EMA), based on the application submitted by MODERNA BIOTECH SPAIN S.L. on 1 December 2020, in accordance with Article 4(1) of Regulation (EC) No. 726/2004, submitted its recommendation with opinion for conditional marketing authorisation of the medicinal product "COVID-19 Vaccine Moderna-COVID-19 mRNA vaccine (nucleoside-modified)" - EMA Assessment report "COVID-19 Vaccine Moderna" Procedure No. EMEA/H/C005791/0000 (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 MODERNA BIOTECH SPAIN S.L. 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 6 January 2021 by the Committee for Medicinal Products for Human Use, Whereas:***

*(1) The medicinal product "*COVID-19 Vaccine Moderna-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) **'COVID-19 Vaccine Moderna-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.*** *(3) The marketing authorisation for* ***'COVID-19 Vaccine Moderna-COVID-19 mRNA vaccine (nucleoside-modified)'*** *should therefore be granted subject to certain conditions laid down in Article 14-a of Regulation (EC) No 726/2004 and in Regulation (EC) No 507/2006. (4) The Committee for Medicinal Products for Human Use considered that 'CX-024414 (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*** **'COVID-19 Vaccine Moderna-COVID-19 mRNA vaccine (nucleoside-modified)',** ***the characteristics of which are summarised in Annex I to this Decision.*** "COVID-19 Vaccine Moderna-COVID-19 mRNA vaccine (nucleoside-modified)" *shall be entered in the Union Register of Medicinal Products with the following number: EU/1/20/1507. 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 MODERNA BIOTECH SPAIN, S.L., Calle Monte Esquinza 30, 28010 Madrid, Espana." -* **European Commission Implementing Decision of 6/1/2021 granting a conditional marketing authorisation for the medicinal product for human use "COVID-19 Vaccine Moderna-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 European Union Implementing Decision - Annex I (Summary of Product Characteristics), Annex II (A. Manufacturer of the active substance(s) of biological origin and manufacturer responsible for batch release), Annex III (Labelling and Package Leaflet), Annex IV (Conclusions of the European Medicines Agency on the granting of marketing authorisation under "special conditions" (doc. **A.2.2.**).

4. On 25 January 2021, a linguistic correction of the Annexes to the Implementing Decision was deposited (Doc. **A.2.3**).

5. Having said all of the above, the above-mentioned applicants hereby bring an action for a declaration of invalidity pursuant to Article 263 TFEU of the above-mentioned Implementing Decision of the EU Commission of 6 January 2021, including all subsequent amendments and integrations, on the following grounds.

6. Legal standing according to Art. 263 TFEU

The plaintiffs all work in the field of health care or care for the elderly as doctors, nurses, caregivers for the elderly, etc. and have therefore been exposed to constantly mounting pressure for Covid vaccination, for one and a half months now. Italy, like other EU member states, vaccinates with the "COVID-19 Vaccine Moderna".

7. **“COVID-19 Vaccine Moderna"** is the second mRNA-based substance to be **conditionally approved** by the European Commission in the EU as a so-called Covid “vaccine“. The two other substances (manufacturers: BioNTech and AstraZeneca) that have meanwhile been approved as so-called Covid "vaccines" are also of an experimental nature and have nothing in common with a conventional vaccine.

8. The applicants have already filed an action for annulment on 16 February 2021 against the EU Commission's implementing decision of 21 December 2020 concerning the conditional approval of the experimental Covid "vaccine" "Comirnaty" (BioNTech). The procedure in question bears the procedure number T-96/21.

9. In particular, people such as the plaintiffs, who work in the health and care sector, are subjected to immense pressure, ranging from social moralising pressure to the threat of consequences under labour law, if they do not undergo the so-called Covid "vaccination".

10. A number of virologists, who for a year now have been the exclusive advisors to the governments of the EU member states, are publicly calling for the "legal prosecution" of those EU citizens who work in the health and care sector and who, in view of the risks associated with the experimental Covid "vaccines" and the unproven benefits (see below), refuse to expose themselves to these substances based on genetic engineering (see article in the Italian-language South Tyrolean daily newspaper Alto Adige of 13/01/2021 - Doc. **A.3.1.**). Internal communications from the South Tyrolean Sanitary Authority as well as communications from the South Tyrolean Medical Association to doctors show how the Sanitary Authority or superiors and the Medical Association, respectively, call on, and exert pressure on staff (doctors, paramedics), as well as freely practising doctors registered with the Medical Association, to undergo Covid "vaccination".

11. For example, email correspondence from the South Tyrolean Health Service shows that, at the request of the Italian Ministry of Health, they had to report which staff members were participating in the Covid vaccination and which were not (Doc. **A.3.2**).

12. Italy, like other EU Member States, has started administering the Covid "vaccine" "COVID-19 Vaccine Moderna" as foreseen in the Covid national "vaccination plan" of 7/12/2020 (Doc. **A.3.3.**). The plaintiffs in the health and care sector are accused of a lack of responsibility and solidarity towards the staff and the patients/caregivers entrusted to them (Docs. **A.3.4, A.3.5** and **A.3.6**).

13. Reports of Covid vaccination coercion are also received en masse from the rest of the country, to the detriment of health and care workers (Docs. **A.3.7.** and **A.3.8.**).

14. **The "refusers of the experimental Covid vaccines" among health and care workers are directly threatened with dismissal.** See the letter served on one of the plaintiffs by the employer. (Doc. **A.3.9.**)

15. The centralised authorisation of "COVID-19 Vaccine Moderna" on 6/1/2021 means that the European Commission has automatically authorised this active substance in every Member State, i.e. no further decision by the

Italian Member State was required to authorise this active substance on Italian territory as well.

16. Therefore, the above-mentioned plaintiffs clearly have standing 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 protected by the EU Treaty and their fundamental right to physical integrity.

17. The applicants are **directly and personally affected** by the unlawful marketing authorisation of COVID-19 Vaccine Moderna, as their fundamental rights to physical integrity (Article 3 of the EU Charter), to a high level of human health protection (Article 168 TFEU, Article 35 of the EU Charter) and to consumer protection (Article 169 TFEU, Article 38 of the EU Charter) are infringed by this implementing decision, as set out below.

18. Even before the implementing decision challenged here, individual plaintiffs sent a warning notice electronically on 19/12/2020 to the EU Commission and the EMA in particular, requesting them to refrain from authorising the mRNA-based experimental active substances due to the enormous risks, which currently cannot be assessed in their entirety (see warning letter of 19/12/2020 in **doc. A.4**). Incidentally, there was no reaction or response to this warning notice.

19. 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 Article 3 of the EU Charter** and the **fundamental right to a high level of human health protection enshrined in Article 35 of the EU Charter.**

20. It is the EU Commission that on 17 June 2020 presented a **"European vaccine strategy"** for the **rapid development**, production and dissemination of a Corona vaccine (Doc. **A.5.1**), under which a contract was concluded with the pharmaceutical company Moderna, on 25 November 2020, for the purchase of a potential COVID-19 vaccine. It allows for the purchase of an initial 80 million doses of vaccine on behalf of all EU Member States - with an option for a further 80 million doses. According to the undisclosed contract, delivery should take place as soon as a proven safe and effective Corona vaccine is available. On 15 December 2020, the Commission took the decision to purchase another 80 million doses. On 17 February, the Commission approved a second contract with Moderna for the additional purchase of 300 million doses **on behalf of all EU Member States** (150 million in 2021, with an option for a further 150 million in 2022).

21. The "European vaccination strategy" specified by the EU Commission should aim at "**ensuring the quality, safety and effectiveness** of vaccines". The fact that the European vaccination strategy did not meet this legal requirement *al condicio sine qua non*, especially with regard to the approval of the active ingredient "COVID-19 Vaccine Moderna", is explained and documented below.

22. **On 19/01/2021, the EU Commission presented a communication in which it calls on the member states to accelerate the EU-wide vaccination of the experimental "vaccines" already approved (there are now three: COVID-19 Vaccine Moderna, Comirnaty and AstraZeneca). 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 towards vaccinating the population with experimental substances based on genetic engineering** (see below). Since the Member States (especially

Italy) 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 the individual Member States towards covid vaccination a particular "quality" (Doc. **A.5.2**).

23. **The "European vaccination strategy" places health workers at the top of the list of priority groups to be "vaccinated".**

24. **A few days ago, the EU Commission announced a concrete plan to present a draft law before the end of March, for the introduction of a digital vaccination passport in which Corona vaccinations, Covid diseases and negative tests would be recorded. The declared aim is to find a safe way to lift restrictions and travel in Europe. Health Commissioner Stella Kyriakides urged EU countries to speed up their Corona vaccination campaigns. Kyriakides told an online conference of EU health ministers that it was "crucial that there is no gap between doses delivered and doses administered and that no vaccines go unused". The massive pressure that the EU Commission is exerting on the EU Member States towards compulsory vaccination is obvious (**Doc. **A. 5.3 + A.24). The new Italian Prime Minister and former head of the ECB, Mario Draghi, who was not elected by the Italian people, has declared himself to the Italian media as an absolute supporter of this vaccination pass (**Doc. **A.5.4.). There is therefore no question that the Italian government will support the introduction of the digital vaccination card at EU level, and with it the discrimination of all those EU citizens who do not want to be "vaccinated" with the experimental genetically based substances (such as COVID-19 Vaccine Moderna).**

25. The plaintiffs are not only exposed to an enormous pressure - which in concrete terms is condensed into a **direct, de facto general compulsory vaccination, demonstrably centralised and built up by the EU Commission** - but also, as EU citizens particularly affected by this (because they belong to a prioritised group of people in the vaccination programme specified by the EU Commission), for the following reasons, are exposed to a concrete, unreasonable and unlawful health risk, which has been brought about by the EU Commission through the contested implementing decision (including subsequent amendments and integrations).

GROUNDS FOR COMPLAINT

26. **Premise**

27. "COVID-19 Vaccine Moderna" is an experimental mRNA-based substance that has absolutely no similarity to traditional vaccines, regarding its mode of action and production.

28. 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 otherwise not be present in the cells. By definition, RNA 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 certain 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 supposed to lead to antibody formation.

29. **The active substance "COVID-19 Vaccine Moderna" therefore factually corresponds to a gene therapy drug.**
The exclusion from the definition of "gene therapy medicinal product" in Commission Directive 2009/120/EC of 14 September 2009 of active substances, which in fact act like a gene therapy medicinal product, but which are declared as vaccines against infectious diseases (such as "COVID-19 Vaccine Moderna"), in absolute disregard of the mode of action, is not justified in view of the precautionary principle which applies in the EU, particularly in the health sector, and the fundamental rights of EU citizens to a high level of health protection (Article 35 of the EU Charter), as well as to physical health. 35 EU Charter) and to physical integrity (Art. 3 EU Charter), it is incomprehensible and violates fundamental principles of EU law (see plea no. 3 below).

30. Having said that, the pleas in law put forward here are primarily those which, irrespective of the legal assessment of whether the active substance "COVID-19 Vaccine Moderna" 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.

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

32. The EU Commission has **conditionally** authorised the active substance "COVID-19 Vaccine Moderna" **for one year** on the basis of Regulation (EC) No 507/2006 of 29 March 2006.

33. Before a medicinal product for human use can be authorised for marketing in one or more Member States, it usually has to 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 authorisation are laid down 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).

34. In order to fill healthcare gaps and in the interest of public health, it may be necessary **for certain categories of medicinal products** to be granted marketing authorisations on the basis of less comprehensive data than would normally be the case and subject to certain conditions (hereinafter referred to as 'conditional marketing authorisations'). This should include those medicinal products ... intended to be used **in emergency situations against a public health threat duly identified either by the World Health Organisation or by the Community in the framework of Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community ...** (Recital 2 Regulation EC No 507/2006).

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

"This Regulation shall apply to medicinal products for human use falling within the scope of 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 conditions**;
2. medicinal products intended to be **used in emergency situations against a threat to public health duly identified either by the World Health Organisation or by the Community under Decision No 2119/98/EC;**
3. medicinal products designated as orphan medicinal products in accordance with Article 3 of Regulation (EC) No 141/2000.

The circumstance mentioned under point 3) is clearly not present for the medicinal product "COVID-19 Vaccine Moderna".

36. **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).**

37. **1.1 Violation of Art. 2. point 1. EU Regulation No. 507/2006**

38. **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 the disease 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 on 14 October 2020 in the Bulletin of the World Health Organization; Type: Resarch Article ID: BLT.20.265892 (Doc. **A.7**), **Ioannidis proved that the panic spread worldwide at the end of January 2020 regarding an alleged high mortality rate associated with SARS-Cov-2 infection was and is simply unfounded.**

39. 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, although only now, i.e. **after almost a year** (!), **the instructions of the Ministry of Health for the treatment of patients at home by general practitioners are finally to be issued** (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**). Evidence shows 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 who took care of the 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 Rome Council of State ruling no. 09070/2020 of 11/12/2020 concerning the suspension, at the request of a group of general practitioners, by the administrative court 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**) were demonstrably able to treat almost all of their Covid-19 patients at home without hospitalisation and lead to a complete cure of the disease.

40. We are therefore demonstrably not dealing with a life-threatening and untreatable disease for the world population in the true sense, but with a corona virus-related infectious disease, as we have had in the past, and which, **due to the failure of sanitary systems in certain Member States (such as primarily Italy -**

investigations by the public prosecutor's office in Bergamo are ongoing) **as well as a worldwide misuse of RT-PCR tests**, has led to a de facto artificially inflated pandemic, as will be demonstrated below.

41. Invalidity due to violation of Regulation (EC) No. 507/2006 Art. 2 point 2.

42. According to Article 2(2) of Regulation (EC) No 507/2006, medicinal products may be conditionally authorised if they are intended to be used in **emergency situations against a threat to public health duly identified either by the WHO or by the Community in the framework of Decision No 2119/98/EC.**

43. The WHO declared the pandemic status of SARS-Cov-2 on 30 January 2020, which allegedly endangers the world population (Doc. **A.10.1**).

44. The question of whether a "threat to public health" has been properly established is to be determined in accordance with the provisions of the *International Health Regulations* 2005 (IHR) of the World Health Organisation. The provisions, which are to be interpreted in accordance with the Vienna Convention on the Law of Treaties, contain obligations binding under international law for both the WHO and the 196 contracting states to determine a **"public health emergency of international concern"** (PHEIC) by the WHO Director-General in accordance with Art. 12 IHR.

45. **The 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 decision:

1. **the information provided by the State Party;**
2. **the use of the decision scheme contained in Annex 2 of the IHR;**
3. **the advice of the Emergency Committee;**
4. **the scientific principles including available scientific evidence and other relevant information;**
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.**

46. In accordance with this list of decisions, the Director General convened an Emergency Committee on 23/01/2020 due to the Sars-Cov-2 outbreak in China in accordance with Art. 49 IHR. This expert committee disagreed on whether a recommendation for the existence of a PHEIC could be made and adjourned the meeting for reassessment until 30/1/2020. At the 2nd meeting of the Emergency Committee, a significant increase in case numbers and further affected countries with confirmed cases was noted and it was explicitly pointed out that due to the notification of the virus sequence by China, other countries had the possibility of virus identification through **rapid development of diagnostic tools**. 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**).

47. On 13 January 2020, the WHO published a first PCR test guideline (A.**11.1**) based on the Corman-Drosten protocol of 13 January 2020 (Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR (A.**11.2**) - *see also Summary table of available protocols in this documents* (A.**11.3**), which shows that the Corman-Drosten-PCR-test-protocol (also referred to as "Charité protocol") was the first one published.

On 23 January 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**).

Since 17 January 2020, laboratories worldwide have been working on the basis of

this protocol established by Corman, Drosten and others, for the 'detection' of the SARS COV-2 virus and commercial PCR kits based on it.

48. **Due to the fact that this very 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.**

49. The alleged crisis situation of the worldwide threat to public health due to the SARS-CoV-2 virus was ultimately represented by a **worldwide misuse of the PCR tests**. This misuse and misrepresentation 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, as well as an enormous number of people worldwide who have allegedly died from the disease caused by SARS-Cov-2 infection (Covid-19).

50. It is necessary for further understanding to briefly explain what a PCR test is, and specifically how a Corona PCR test works.

PCR stands for **Polymerase Chain Reaction**. It was developed in 1983 by Kary Mullis, who died in 2019 (and was awarded the Nobel Prize in Chemistry for PCR in 1993).

The PCR is a system with which specific DNA sequences can be multiplied or copied 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 multiplied is often referred to as the initial DNA. At the beginning of the process, it is put into a reaction vessel together with the multiplication 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. Then 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 put into a reaction vessel, for example, a small tube, together with the DNA letters, the polymerase and the primers.This tube is then placed into a so-called **thermocycler:** 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 only take place 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 certain genes of the SARS-CoV-2 virus. Namely, genes that occur in this form **only in SARS-CoV-2**. The fact that this unfortunately looks different in reality is explained later.

The reaction is initiated by raising the temperature of the DNA to 94°C, which causes the two strands of the double strand to separate from each other (denaturation). When cooling down, 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 depend individually on the primers, the extension of the DNA follows, at about 72 °C. Starting from the primers, the polymerases attach a new strand to the exposed

strands of the initial DNA, and 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 of the thermal cycler is simply raised again to 94°C and the process begins again. The amount of DNA grows increasingly exponentially, because each time a larger number of templates are available for amplification. Hence the term "**chain reaction". Thus, 2 first become 4, then 8, then 16 copies etc., 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 threshold; ct), the number of copies is recorded as positive in the measuring device, i.e. the more initial DNA was in the reaction, the faster the CT is reached. Since infectious events require the presence of several thousand source pathogens to form an infectious dose, the ct is reached at a maximum of 25 cycles. A tolerance range of up to 30 is possible, and is consistent with publications in the case of SARS-CoV-2, that from ct30 onwards, no correlation of the PCR result with infectiousness exists.**

However, the corona virus does not have DNA, but RNA.Hence, the genetic material exists in a different form, and 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, the so-called copy DNA (cDNA), thus contains the same genetic information as the virus genome.**

After the 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 any 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 you can already see during the runtime whether there are SARS-CoV-2 genes in the sample. This works via fluorescence.

51. **Scientists worldwide who are familiar with microbiology and with the PCR test have pointed out from the beginning that <u>you cannot detect a virus with the PCR test</u>, but only nucleic acids that remain as fragments of viruses. <u>The tests can therefore say nothing about the infectiousness of a person who has tested positive, unless there is also a clinical diagnosis. And if a person without symptoms is tested, logically no statement about the presence of an infection is possible.</u> The term "new infection", which is used worldwide in this context, is simply incorrect. 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 multiplied to make them visible. These fragments can also result from a previous infection that has already been overcome, namely when the immune system has successfully fought the viruses and the person concerned has recovered and is no longer infectious.**

<u>The more viruses that are still in the body, the fewer cycles of replication are needed for recognition. Hence this number - the so-called Ct value - obviously provides important diagnostic information. However, it is not usually reported by the laboratories.</u>

The number of cycles needed is inversely proportional to the viral load.

52. **All these facts were and still are not taken into account by the authorities; laboratories do not report the number of cycles needed for detection. WHO is finally demanding that they be reported.**

On 14/12/2020 (Doc. **A.12.1**), **the WHO issued recommendations for users of RT-PCR tests for the first time (and obviously much too late), 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 in the process 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 samples 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 is difficult to establish."*
And further:
"Report the Ct value in the report to the requesting health care provider."
And on the large proportions 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, health care providers are advised to consider test results along with clinical signs and symptoms, confirmed status of all contacts, etc."***
Hence 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 can be no such thing as "asymptomatically ill".**
Self-evidently, this part of the WHO's recommendation:
"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."

53. **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 for detecting an infection, that far too high multiplication (amplification) cycles are run and that with a low prevalence (percentage of real infections in the population) there are very many false positive results anyway. The WHO is now also warning against this, although 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.**

54. 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 for 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 sample should be collected and retested using the same or a different NAT-technology.
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. This means that the probability that a person with a positive result (SARS-CoV-2 detected) is actually infected with SARS-CoV-2 decreases with decreasing prevalence, regardless of the claimed specificity.
Most PCR assays are indicated as an ***aid to diagnosis, so healthcare providers must consider each result in combination with the time of sample collection, sample type, assay specifics, clinical observations, patient history, confirmed status of all contacts and epidemiological 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. **Pass on the Ct value in the report to the requesting healthcare provider.**

55. In other words, t**he PCR test is only useful in the context of a clinical diagnosis as evidence of coronavirus infection.**
What this also says is that **tests on people without symptoms are simply pointless as a positive test result cannot correspond to the clinical picture, because the absence of symptoms means that there is no disease. Hence the mass tests often organised by various governments contradict the WHO guideline, since almost only people without symptoms are tested.**
A fundamental **requirement for "official" and "legally binding" measurement technology, whether in industry, administration or health care, 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.**

56. **Although even the WHO has warned against the worldwide misuse of the PCR test, it blithely continues to be used by governments and authorities.**
The people tested are not told which RT-PCR test product is applied to them, nor how high the CT value is:
Most machines that evaluate the samples are set to a threshold of 37 to 40 cycles. Reduce this threshold to 30 cycles and the number of "confirmed cases" drops by 40 to 90 per cent, research in the US has 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 the Times of India reports (Doc. **A.13.2**), there, in contrast to Europe, more and more doctors are only sending the samples 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 hospitalisation is carried out, as a more serious course of the disease is to be expected. Above 25, no measures are considered necessary for symptomless persons.
If the Ct value is limited to 25, the "case numbers" are significantly reduced again. Epidemiologically, it would only make sense to record infectious people. However, this is not done.

57. With the PCR test, 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. This may also be due to the fact that one of the few experts advising the EU Commission is precisely Christian Drosten, who is responsible for the Corman-Drosten PCR-test-protocol (Charité protocol), which is riddled with gross scientific errors- (**A.13.3**.).

58. On the subject of infectivity of 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 23 January 2020 to 8 April 2020, in the Chinese city of 11 million. SARS Cov-2 nucleic acid screening (this is how the study refers to it because, as we know, **the PCR test does not test and detect a virus, but only parts of it, namely the nucleic acids)** was conducted throughout the city from 14 May 2020 to 1 June 2020.
10.6 million people over the age of 6 were invited to take the test, of whom 93%, or 9.9 million, showed up. The tests yielded a positive result in 300 people. 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 showed no evidence of replicable virus.

59. The PCR test is therefore not suitable for detecting an active infection, let alone infectiousness. However, the WHO's maintenance of the declaration of the alleged public health threat posed by SARS-Cov-2 is based on the numbers determined by this test.

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

61. This has also already been established in a ruling by a court of appeal in Portugal (Doc. **A.15.1**).
In its decision of 11 November 2020, a Portuguese Court of Appeal ruled against the Azores Regional Health Authority, declaring the quarantine of four people 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 decided 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 Court of Appeal upheld this 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 tests.

The main points of the court's decision are as follows:
A medical diagnosis is a medical act that only a physician is legally authorised 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 authority to declare someone sick or unhealthy; only a doctor can do this. No one can be declared sick or dangerous to health by decree or law, not even as an automatic, administrative consequence of the result of a laboratory test of any kind.

From this, the court concludes that *"when carried out without prior medical observation of the patient, and without the involvement of a medical practitioner registered with the Medical Council, 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 combine the above terms) violates [a number of laws and regulations] and may constitute a criminal offence of unlawful professional conduct if those acts are performed or dictated by someone who lacks the capacity to do so, that is, someone who is not a licensed physician.*

The Portuguese Court of Appeal further stated the following:
"On the basis of the scientific evidence currently available, that test [the RT-PCR test] is not capable, in and of itself, of establishing beyond reasonable 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 Tribunal 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 US), 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 tests 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 Tribunal 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 regional health authority's appeal reads as follows:
Given the scientific doubts expressed by experts, i.e. those who matter, 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 existence 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."

62. As can be seen just from the development 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 it was.
The researchers investigated the presence of SARS-CoV-2-specific antibodies in blood samples from 959 asymptomatic individuals who participated 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 geographical variations in Italian regions.
The study, published on 11 November in the Tumori Journal (doc. **A.15.4**) and led by the director of the National Cancer Institute in Milan, Giovanni Apolone, 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 people. Positive cases were clustered in the second week of February 2020, mainly in Lombardy.
This study shows an unexpectedly very early circulation of SARS-CoV-2 in asymptomatic individuals in Italy several months before the identification of the first patient, confirming the outbreak and spread of the coronavirus pandemic already in 2019.
The study also shows that the massive problems and deaths in Italy are not due to illness from 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 infections.

63. But that is not all. The Italian statistics agency 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.

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

65. **Due to serious scientific errors in the Corman-Drosten PCR-test-protocol (also called the Charité protocol** - doc. **A.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**.)

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.** 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 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 at the commercial "Labor Berlin" of the Vivantes group (with Charité) and the considerable interest in high numbers of diagnostics that this entailed, is still unexplained.

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. **the 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.

The twenty-two scientists have considerable cumulative expertise in the field in question. Among them is, 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-, molecular geneticist Dr Pieter Borger, PhD, specialist in infectious diseases and preventive medicine Dr Fabio Frankchi, microbiologist and immunologist Prof. emerit. Dr Makoto Ohashi, and the cell biologist Prof. Dr Ulrike Kämmerer. On 11/01/2021, the scientists submitted a scientific integration of their request to withdraw the publication (doc. **A.16.2**).

66. **This highly flawed Charité-protocol continues to be used on a massive scale worldwide, but especially in Europe, and so also in Italy.**

See, as evidence of this, 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**).

67. **The WHO incomprehensibly only officially pointed out in December 2020 for the first time that PCR test results alone were no proof of a virus infection, after people who had been exclusively subjected to a positive PCR test had, for 11 months, been and are still being automatically declared as infected with SARS-CoV-2.**

Despite repeated WHO instructions in December 2020 and January 2021, most countries (with a few exceptions, such as India) continue with the unscientific and grossly unconstitutional practice of declaring people "SARS-CoV-2 infected" based on a PCR test result alone.[1]

68. **At the time of approval of "COVID-19 Vaccine Moderna" on 06/1/2021, 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 data base, which depicted an incorrect infection rate.**

In view of the effective mortality rate of Covid-19, as presented and documented by top experts such as John P.A. Ioannidis, who have been indisputably recognised worldwide for decades, it is also 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**), concludes that the global risk associated with COVID-19 remains very high and the declaration of a Public Health Emergency of International Concern (PHEIC) could be maintained.

69. **Based on the above statements and the documents deposited in relation to them, 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.**

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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 conditions for a conditional marketing authorisation of a medicinal product laid down in Article 2 of Commission Regulation (EC) No 507/2006 of 29 March 2006 are not met for the substance "COVID-19 Vaccine Moderna" and the implementing decision of the European Commission contested here is unlawful for this reason alone and must therefore be declared null and void.**

*

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

71. 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).

72. **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 used in emergency situations against a threat to public health.** (Recital 4 EC Regulation No 507/2006).

As stated above, the crisis situation consisting in the threat to public health has not been properly established.

73. Furthermore, the experimental active substance "COVID-19 Vaccine Moderna", 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.

74. 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, harmlessness, and efficacy of the medicinal product** (recital 5 Regulation No 507/2006)

75. 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 renewable in accordance with Regulation (EC) No 726/2004.

76. **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).

77. **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.

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

79. **In the present case, as stated above, this crisis situation was never identified "in a proper manner".**

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 concerned** does not confer **a significant therapeutic benefit on the patients affected by that condition.**

80. **2.1 Invalidity for failure to demonstrate a positive risk-benefit balance according to Article 1(28a) of Directive 2001/83/EC**

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

82. **2.1.1 Non-existence of a demonstrable benefit**

83. Contrary to Moderna's statements that "COVID-19 Vaccine Moderna" had an efficacy level of 94 percent (see, for example, Apotheken Umschau of 28/01/2021- 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, in an article published on 4 January 2021, scientifically substantiated these doubts again in detail 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"…

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…*

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?

We need the raw data. Addressing the many open questions about these trials requires access to the raw trial data. But no company seems to have shared data with any third party at this point … Moderna's data sharing statement states data "ma be available upon request once the trial is complete". This translates to sometime in mid-to-late 2022, as follow-up is planned for 2 years."

84. **Based on the officially available data, scientists therefore conclude that the efficacy of "COVID-19 Vaccine Moderna" is far lower than the reported 94 per cent.**

85. **Furthermore, there is no proof that people "vaccinated" with "COVID-19 Vaccine Moderna" cannot become infected and cannot be carriers of the SARS-COV-2 virus.** In the first place, **the studies are likely designed in such a way that this proof cannot be provided at all.** In his article published in the BMJ on 21/10/2020, Peter Doshi literally stated "...*But what does it mean exactly when a vaccine is declared "effective"? ...Peter Hotez, dean of the National School of Tropical Medicine at Baylor College of Medicine in Houston, said, "Ideally, you want an antiviral vaccine to do two things ... first, reduce the likelihood you will get severely ill and go to the hospital, and second, prevent infection and therefore interrupt disease transmission." Yet the current phase III trials are not actually set up to prove either. None of the trials currently under way are designed to detect a reduction in any serious outcome such as hospital admissions, use of intensive care,*

or deaths. Nor are the vaccines being studied to determine whether they can interrupt transmissions of the virus". (Doc. **A.18.4**).

The Moderna Chief Medical Officer himself warned in an interview on 24/11/2020 (https://twitter.com/axios/status/1331090810666844161) **against over-interpreting the results of the "modest" clinical trials.** Literally, he stated "*So far, it is not clear whether the vaccine will prevent you from potentially carrying the virus temporarily and infecting others".*

The "vaccine" manufacturer itself thus confirms that there is no data that the "vaccine" also prevents the transmission of the virus (Doc. **A.18.5**)

86. The Robert Koch Institute explicitly states the following on its homepage: "*It is not yet known how long the vaccine protection lasts. 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.25**).

87. **The proof of benefit, in the sense of a positive therapeutic effect of the active substance "COVID-19 Vaccine Moderna", has therefore not been provided and for this reason alone the conditional authorisation is contrary to EU law.**

88. **2.1.2 <u>Significant risks not identified and thus undetermined and currently indeterminable risk</u>**

89. 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."*

90. **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 conducted to detect interactions."</u>***

Considering the fact that the so-called. Given the fact that the so-called Covid "vaccines", such as "COVID-19 Vaccine Moderna", are primarily intended for the protection of the elderly and the population with health problems, and that this population group usually takes one or more medicines on a regular basis**, the fact that the interactions of "COVID-19 Vaccine Moderna" with other medicines are not known must be taken into account, that the interactions of "COVID-19 Vaccine Moderna" with other medicinal products have not been tested, must lead to the conclusion that the risks emanating from "COVID-19 Vaccine Moderna", for this reason alone, are currently in no way ascertainable, let alone assessable and evaluable.**

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

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

92. Substantial risks associated with the administration of the active substance "COVID-19 Vaccine Moderna" have already been 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 the first mRNA-based active substance "Comirnaty" by BioNTech (Doc. **A.19**).

93. Unfortunately, this petition was ignored, as was the warning sent electronically, also by plaintiffs, primarily to the EU Commission and the EMA on 19/12/2020 (Doc. **A.4)**.

94. From the scientific assessment prepared by Prof.Dr.rer.nat. Stefan W. Hockertz, toxicologist, immunologist, and pharmacologist, European reg. toxicologist (doc. **A.20.1**), the following is stated with regard to the risks of administration of the active substance "COVID-19 Vaccine Moderna" that have not been taken into account (page numbers quoted refer to EMA open assessment report - doc. **A.1**):**"**Basically, the use of the word "vaccine" for mRNA1273 by Moderna is misleading and promotes a positive mindset in the reader about the product in terms of protective effect. According to the scientific definition, the new technique of introducing mRNA into human cells counts as gene therapy, and the vaccine therefore constitutes a **gene therapy product**. As defined by the FDA, human gene therapy is the modification or manipulation of the expression of a gene or **the alteration of the biological properties of living cells for therapeutic purposes**. Since the adverse events and especially the long-term side effects of gene therapy products have not even begun to be studied, **it is inappropriate** to speak of mRNA1273 as a protective vaccine in the classical style. For the sake of simplicity and for a better comparison of the expert opinion with the original report of EMA, the term "vaccine" will continue to be used in the following. **Nevertheless, it should be kept in mind that this is a gene therapy product that alters human cells.** https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy...

The applicant assures that all specimens of clinic phase 3 trail will be followed up 24 months after the second vaccination

Long-term damage from the vaccination cannot be determined due to the massively shortened observation time of the clinical phase study. It is known that **side effects of a vaccination can also occur far in the future**.p.15; „The applicant intends to continue the ongoing pivotal phase 3 study P301 with all participants to be followed until 24 months after the second dose to obtain long-term data and to ensure sufficient follow-up to support a standard marketing authorisation." …

Product impurities:

Impurities of the mRNA:

The first batches of the vaccine, which included the early clinical trial batches, had higher purity than the proposed limits and from some batches of the current vaccine administered to clinical trial III participants. The lower RNA purity values measured in some batches are not acceptable to the EMA.

Currently, too little batch analysis data is available from the commercial manufacturing process to provide more accurate information on the effect of the lower RNA purity vaccine. Once this information is available, the specifications and limits will still be adjusted after approval by Moderna.

In the Phase II study, comparable neutralizing antibody responses were observed in subjects receiving effective doses of 40 g and 79 g. In addition, the non-clinical setting showed that lower purity batches were as effective as higher purity batches. Considering the totality of the data, the EMA justifies the proposed lower purity limit.

If doses of 40g and 79g are effective, why inject 100g of RNA twice. More RNA needs more lipids and solvents leading to higher toxicity and harm of the body (see below)?

Multiple protein bands:
There were multiple protein bands produced from the mRNA. These additional protein bands should be compared with respective positive and negative controls. EMA is not sure if other proteins/peptides are formed in addition to the spike protein. If this occurs, a protein sequence analysis must be performed to exclude possible homologies with other peptides that could lead to molecular mimicry (**protein mimicry leads to autoimmune diseases**). Moderna has to analyse the additional bands and data have to be submitted to EMA.
p.19:“ Additional bands are observed by an in-vitro translation assay. To further elucidate the nature of these additional bands, data should be provided. Furthermore, additional details should be provided for the *in vitro* translation method and the negative and positive controls used, since the number and intensity of unspecific bands observed still leaves some uncertainty regarding the possible translation of additional proteins/peptides. In this context additional characterisation data or a scientific justification are requested (**REC**).”
Impurities through dsRNA: It must be ensured that the contamination with double-stranded dsRNA always remains at a low level, since **dsRNA has an immunostimulatory effect. What is the control strategy and what is the level of dsRNA contamination in the final product?**p. 20: “… it is emphasised that the control strategy should ensure that dsRNA levels will always be at a sufficiently low level when the manufacturing process is run within the registered process parameter ranges, considering its potentially immune-stimulatory properties.
“**Impurities in lipid SM-102:**
Impurities of lipid SM-102 were detected. It is likely that these impurities are also found in the final product. The nature of the impurities has not clearly been described, so that one cannot make any statement about what damage to the body might occur. Moderna describes the impurities as product-related substances and process-related impurities (elemental impurities, solvent residues, peroxides, water content, and inorganic impurities). Although vaccination is already underway**, there is a lack of data to assess the risk of hazardousness for the body. All impurities should be evaluated with different toxicological risk assessments.** In addition the applicant will perform an assessment of mutagenic impurities based on ICH M7.
Moderna should test intermediates and the final product for impurity of benzene, which may be present e.g. in toluene or acetone. The applicant undertook to submit a risk assessment for the presence of benzene in SM-102. **Benzene is one of the substances proven to cause cancer in humans**. Epidemiological studies have shown clear links between occupational exposure to benzene and the occurrence of leukemias and lymphomas. In animal studies, benzene also leads to the development of tumors in other tissues and organs.
p. 23: „The information provided on potential impurities in SM-102 comprise product related substances and process related impurities (elemental impurities, residuals solvents, peroxides, water content and inorganic impurities). The applicant will provide an evaluation of mutagenic impurities based on ICH M7 **(REC)**.”
p.23: „A test on benzene, which might be present in e.g. toluene or acetone should be performed on the final excipient or on a suitable intermediate if not otherwise justified. The applicant committed to present a risk assessment for the presence of benzene in SM-102 **(REC)**.”
Impurities in lipid PEG2000-DMG:

During the synthesis of PEG2000-DMG, **polydispersity as a form of impurity was detected**. To measure polydispersity by gel-permeation-chromatography as a measure of the width of molecular weight distributions is very important for the correct interpretation and comparison of different, during synthesis obtained, molecular weight distributions of polymers. The provided information of the results of the gel-permeation-chromatography was not sufficient since the reporting of impurities in the batch analysis data does not match the current characterization data.

The possible presence of **mutagenic impurities** in PEG2000-DMG should be evaluated and the results will be **submitted not after approval, because mutagenicity is a dangerous toxicological risk for people**. Polydispersity and numerical limits should be included in the post-approval specification for PEG2000-DMG. **The current reporting of impurities is not acceptable.** Also, characterization data for impurities that are currently under "**content unknown**" should be provided **only after** approval.p. 25:“ The polydispersity was analysed by GPC Information on the impurity profile has been provided. That information is not sufficient since reporting of impurities in the batch analysis data is not consistent with the current characterisation data. Potential presence of mutagenic impurities in PEG2000-DMG should be evaluated and the results will be provided post-approval **(REC)**…. The specification is currently not acceptable. Polydispersity should be included in the specification for PEG2000-DMG post-approval. Numerical limits for specified and unspecified impurities will be included in the PEG2000-DMG specification post-approval. The current reporting of impurities is not acceptable. Characterisation data for impurities which are reported under ‘content of unknown’ should be provided post-approval **(REC)**.”

Possible contamination of nitrosamines:

There is no quantitative risk assessment for nitrosamines in the nanoparticle or in the final product. Nitrosamines are considered to be **strong carcinogen** that may produce cancer in diverse organs and tissues including lung, brain, liver, kidney, bladder, stomach, esophagus, and nasal sinus.

p. 34: „The applicant provided a preliminary risk evaluation regarding potential nitrosamine contaminations in the finished product, which is considered acceptable, but should be complemented with a quantitative risk assessment, especially focusing on nanoparticle constituents. (**REC**).“

10. Contamination of DNA:

EMA allows a waiver of in-process control testing for plasmid DNA residues and plasmid DNA copy number. The percentage of covalently closed circular DNA is routinely monitored after chromatography. However, this method has not yet been validated and requires further monitoring. In articular, residues of linearized plasmid DNA have not been satisfactorily tested because analytical data from sufficient batches are lacking.

The risk of integration of linear DNA residues into the host cell genome and thus the development of cancer cells is not discussed.

p.18: „The linearised plasmid DNA is considered as the starting material.The manufacture is described in sufficient detail, covering: Origin of the DNA sequence, plasmid map, generation of the host cell line, transformation and purification of the host cell line, plasmid cell banking system and stability testing and the linearised plasmid DNA is in principle thoroughly tested. Specifications are in general appropriate for authorization, however, will be reviewed after a sufficient number of batches has been produced (**REC**).

The omission of an in-process control test for plasmid retention and plasmid copy number is sufficiently justified. Percent covalently closed circular DNA (%cccDNA) is routinely monitored post-polishing chromatography. However, evidence regarding qualification/validation of methods used for release testing should be provided (**REC**). Furthermore, sources for all appropriate reference materials/assay controls for plasmid and linearised DNA plasmid manufacturing are requested (**REC**). …

Comparison of process A vs process B:

1.Batch comparison:

Analytical comparison data from different batches from different processes were generated and compared. **No definitive conclusions can be made regarding the comparability of the processes for Scale A (clinic) and Scale B (commercial).** The final validation report including an assessment of comparability will be requested. Differences are based on description and justification of process changes including locations, scales, raw materials, process equipment, and evaluation of process performance in terms of critical process parameters and IPCs, as well as statistical evaluation of comparability of release test results.

The EMA did not verify that the characterization data of the commercial batches manufactured by Lonza are identical to the batches from the clinical trial. The comparability studies have yet to be performed.The final specifications for lipidnanoparticles and the final product have not yet been analysed and implemented. Moderna must first collect analysis data from the batches now being produced for folk vaccination.

People are being vaccinated with substances where it is not yet possible to say whether the vaccine from commercial production is identical to the vaccine from the clinical phase.

p. 28: „Analytical comparability data were generated with four Phase 1/Phase 2 and six Phase III pilot scale A batches from Moderna, TX; three pilot scale A PPQ batches from Catalent intended for clinical/emergency use authorisation/commercial use outside EU, and one scale B batch from Rovi, Spain (EU finished product manufacturer intended for commercial use). A similar approach to comparability was used across manufacturing processes. Comparability between the processes has been shown by a) comparison of the processes and description of the changes, b) extended characterisation (physico-chemical properties, particle size, and impurities) of Phase 1/2 and Phase 3 clinical lots and PPQ lots up to Scale A and c) batch release results. Further Scale A to Scale B comparability will be based on description and justification of process changes including sites, scales, raw materials, process equipment and evaluation of process performance with respect to CPPs and IPCs as well as statistical evaluation of comparability of release testing results. Extended analytical characterisation testing is not performed at the level of the finished product as part of comparability studies as finished product characteristics are the same as for mRNA-loaded LNP intermediate. Nonetheless, results are available for one commercial scale B lot manufactured at the finished product manufacturing site for the EU market (Rovi, Spain) therefore, although there is sufficient comparability information to justify approval in this pandemic, no final conclusion can be drawn with regard to Scale A to Scale B comparability. The final validation report including an assessment of comparability is requested (**Specific obligation 2**).“

p. 27: „The applicant committed to provide comparability results including extended characterisation data using the full panel of characterisation methods from all PPQ

batches manufactured by Lonza AG, CH demonstrating that the commercial product manufactured at the Lonza, Visp site is representative of the material used in the clinical trials. (**Specific Obligation 2**)."
p. 32: „As mentioned earlier, a commitment to tighten the specifications when more batch analysis data from routine manufacturing are available has been provided. The applicant should establish final specifications for LNP and the finished product no later than 30-06-2021 (**Specific Obligation 3**).

Non-clinical aspects

1. Secondary pharmacodynamics:

No studies on secondary pharmacodynamics have been performed.

Secondary pharmacodynamics measures the relationship between amount of drug and corresponding adverse response of the body to it. It is **excessively important to know how the drug affects the organism**, which is not related to the primary target effect.

2.Safety pharmacology:

No studies on safety pharmacology have been performed.

Safety pharmacology is important to identify and investigate potential adverse pharmacodynamic effects of new chemical entities on physiological functions in relation to exposure in the therapeutic range and beyond.

3. Pharmacodynamic drug interactions:

No studies on pharmacodynamic drug interactions have been performed.

That means, there are no studies concerning the behaviour of the vaccine on an organism that shows physiological changes due to diseases, genetic mutations, aging or influence of other drugs.

p. 43: „No studies on the secondary pharmacodynamics, safety pharmacology, and pharmacodynamics drug interactions have been performed, which is in accordance with applicable guidelines."

Pharmocokinetic (PK)

No ADME studies have been performed.

ADME (Absorption, Distribution, Metabolism, Excretion) describes the availability/utilization of the vaccine in the organism. One examines how the vaccine is absorbed, distributed in the body, metabolized by the metabolism and how it is excreted. All four points affect the strength and timing of the vaccine's effect on cells and tissues. It is not acceptable that EMA claimed that ADMA studies are not relevant to investigate the development and licensure of a new vaccine.

A vaccine with completely new technology needs to be closely monitored in every direction, including, in particular, how the components of the vaccine are absorbed, metabolized and broken down by the body and whether any residues are excreted which can contaminate the environment and pollute supplies such as drinking water.

p. 47: „No dedicated ADME studies with mRNA-1273 were conducted, which is acceptable as generally nonclinical PK studies are not relevant to support the development and licensure of vaccine for infectious diseases. However, distribution studies should be conducted in the case of new formulations or novel excipients used."

Distribution study:

a) the distribution study was **not performed with the original vaccine** but with another RNA, mRNA-1647, in a **non-GLP way** (GLP = good laboratory

practice) as 100 g **single-dose** IM injection in Sprague Dawley rats.

The mRNA-1647 contains six different mRNAs but the same composition of lipidnanoparticles (LNP). Although the composition of the LNP determines the tissues which they penetrate, the amount and length of the six mRNAs dictate the particle size and thereby also **the intake quantity and toxicity of the LNP/mRNA-complex** by the cells which will be different from the original vaccine mRNA-1273.
5 rats were sacrificed for each timepoint (2, 8, 24, 48, 72 and 120 hours after injection). Thereafter, they looked for the presence of mRNAs in the blood and in different organs:
In most organs (except kidney) the mRNAs were found already after the shortest timepoint of 2 hours (peak between 2-24 hrs); in particular mRNA was found at the injection site of the muscle, the plasma, lymph nodes, **heart, lung, male sex organ, liver, spleen, eye, and brain**.
Due to the toxic effect of the LNP/mRNA-complexes on cells (see below) there will be massive damage on multiple organs especially the heart and the brain which are quite sensitive tissues. **Importantly, here is the evidence that the vaccine can cross the blood-brain barrier.**
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The half-life of the mRNAs in muscle was 14.9hr, in proximal lymph nodes 34.8hr, in distal lymph nodes 31.1hr, in spleen 63hr. Uptake of the vaccine by the cells were fast because in plasma the half-life was only 2.7-3.8hr.
There is **no information available how long the vaccine is present in the body** since investigations were stopped at 120hr post-injection. Such substances normally decompose exponentially in the body and residues remain in the body for a relatively long time. There are publications available which measured the presence of luciferase mRNA in mice/rats which were still visible at 35 days. The exact time until degradation was not measured since a different mRNA was taken, which may lead to **a different stability time**. Likewise, the **RNA was injected only once**. To make a better comparison with the current folk vaccination, it would have been necessary to inject twice. The components of the vaccination then linger much longer in the body and, accordingly, greater damage could also be recorded.
b) No distribution, metabolism, and pharmakokinetics were performed on the novel toxic lipid component SM-102.
However, data were generated with a structural homolog lipid SM-86. Efficient metabolism via ester hydrolysis and rapid elimination of the remaining aliphatic acid head group via biliary (bile) and renal (kidney) clearance were reported within 168 hours. Due to structural similarity between SM-86 and SM-102, Moderna just hypothesised that SM-102 distributes similarly and is efficiently and rapidly metabolized and eliminated via the bile and kidneys. **A hypothesis is not evidence**.
There are no information about the presence of the toxic cationic lipid in several organs and how this lipid is metabolised in those organs. In terms of the vaccine from BioNTech it is hypothesised that the cationic lipid ALC-0315 has a **half-life of 20-30 days and needs 4-5 months for 95% elimination. This very long terminal half-life leads to a high risk for permanent organ damage and development of autoimmune diseases**.

Also, the method of application of the lipids is also important in how the lipids are distributed throughout the body. An injection into the vein spreads faster than an injection into the muscle. It was not clearly described in the text how the injection took place, but it is assumed that an IV injection was performed which is not comparable to the present vaccination.

p. 53: „ Distribution, metabolism, and PK of the novel lipid component SM-102 have not been extensively studied in dedicated studies. However, data with SM-86, a close structural analogue, have been generated. These data show consistent biodistribution compared to the mRNA administered with the LNP. Furthermore, efficient metabolisation via ester hydrolysis and rapid elimination of the remaining aliphatic acid head group via biliary and renal clearance were reported. Quantitative Whole-Body Autoradiography (QWBA) confirmed the biodistribution of SM-86 and revealed no persistence of the lipid component in any tissue beyond 168 hours. Because of the reported structural similarity between SM-86 and SM-102, it is assumed that SM-102 will distribute similarly and will be efficiently and rapidly metabolised and eliminated via biliary and renal routes. SM-102 pharmacokinetics after IV administration of similar PEG2000-DMG containing LNPs were determined to be very similar to those parameters observed for SM-86. Altogether, these data do not suggest accumulation of SM-102 upon repeated dosing.“

Toxicology

It is not clear which organs were analysed for adverse effects.

Moderna refers to **adverse effects in the spleen** in toxicological studies in rats. They claim that no adverse effects were observed in the brain/CNS and eye but they **do not describe the method of analysis and the timepoints of investigations. Also, long-term damage was not investigated at all.**

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They have performed 7 toxicology studies. Only one of them addressed the original vaccine (mRNA-1273). In the other 6 studies they used other mRNAs together with the LNPs and therefore these data are worthless for the preparation of authorization. For all studies the LNPs were identical in composition to the vaccine.

Importantly, according to EMA, the study with the original vaccine was not conducted in compliance with GLP (good laboratory practice) and has significant procedural/methodological limitations.

A study without a GLP standard is useless for an evaluation of the toxicity of the vaccine mRNA-1273.

This is stated in the guidelines for non-clinical development of vaccine products. EMA overrides these guidelines and accepts the results of this study, stating that there were no clear differences in toxicity from the other 6 studies with other mRNAs which were done in line with GLP-compliance.

EMA assumes that the antigens produced, which are different in each study, cause the same immunological reactions and also the same adverse effects. They categorically exclude that there could be, for example, also adverse effects with interactions between spike antigen and other cell molecules that would not exist with the other proteins produced**. In fact, EMA excludes the possibility of a spike antigen typical adverse effect in the body.**

p. 48/49: „The product-specific Study 2308-123 was not conducted in GLP-compliance, and exhibits major procedural/methodological limitations. In principle these aspects would render this study inadequate for evaluating the repeated dose toxicity of mRNA-1273 to the extent recommended in relevant guidance on non-

clinical development of vaccine products. However, as no clear differences in toxicity are observed between study 2308-123 and the repeated dose toxicity studies conducted with other LNP-mRNA products, the latter studies are considered sufficient to support clinical development and MAA.
The six submitted non-product-specific (but LNP-specific) repeated dose toxicity studies were conducted in GLP-compliance and meet the recommended criteria set out by relevant guidelines. Considering that the translated antigens of the evaluated mRNA-products are expected to elicit similar immunologic reactions, and considering that all these products are based on the same LNP technology, the extent of the submitted repeated dose toxicity programme is deemed acceptable. In the light of this statement, the GLP and procedural/methodological limitations of study 2308-123 are accepted."
In general, all nanoparticles are toxic to cells. The toxicity of nanomaterials is directly related to the size, surface area, surface activity, shape, and composition (Cassee et al. 2002; Yang et al. 2009). The small size of nanomaterials makes it possible to cross the cell membrane and organelles such as mitochondria and increase the chance of escape from the cellular clean-up system. The small size also causes more interactions with cells and biomolecules that are similar in size with the nanomaterials. Due to the ability to bind and interact with biological agents, the mechanism of interaction between nanoparticles and living systems has particular complexities, which, depending on the operating environment, are due to a change in their surface properties.
To generate a nanoparticle with a lipid envelope is a type of technique that can be used to introduce RNA or DNA into cells. It is a standard method in research on *in vitro* cell cultures to turn genes on or off. **It requires thoroughly testing beforehand in what ratio to mix RNA to lipids and how much of either component can be put on cells without cell death.** Too much amounts will lead to cell death, too little has no/little effect. It is always a balance between wanted effect (protein expression) and toxicity. Each cell type tolerates different amounts of RNA and lipids. This has to be tested beforehand **which is not possible in the body (e.g. vaccination)**.
After injections the nanoparticles go into all cell types. The cells that are robust tolerate the LNP, the cells that are sensitive will die. **Therefore, this technique is not applicable *in vivo* in this way – especially not for healthy people.** This kind of technique is used in cancer patients to destroy the cancer cells with help of oxidative cell stress through cationic lipids in the LNPs. **The benefit-risk-balance is completely different in cancer patients to what is done now on healthy people during vaccination**.
The positive charge of the cationic lipids interacts with negative molecules of other lipids, proteins and DNA in cells. **Interaction with lipid membranes is an attack on the outer cell structure.** The cationic lipids oxidize unsaturated free fatty acids in the membrane (lipid peroxidation). This leads to a loss of membrane integrity. The **membrane become permeable** and ions can freely cross the membrane. The ion balance e.g. calcium concentration is disturbed in the cell and **proteins lose their function**. Also, the interaction of cationic lipids to mitochondria membranes within cells leads to lipid damage and production of oxygen radicals (ROS) which are highly reactive oxygen compounds, e.g. superoxide, hydrogen peroxide, hydroxyl groups. ROS are normally produced during regular metabolism in the presence of oxygen in small amounts by the cells during energy production. The cells have different mechanism to balance and eliminate ROS by producing antioxidants or/and uptake

of antioxidants from nutrients. **Interaction of cationic lipids with cell membranes causes too much ROS production and massive cell damage and oxidative stress**. Oxidative stress triggers further cell damage especially **DNA breaks** which are often irreversible since repair mechanisms fail due to the overload of ROS and oxidative stress. Consequences are **diseases like cancer** and tissue death (apoptosis, necrosis).
Furthermore, cationic lipids also change protein function by oxidizing amino acids in proteins. These modifications lead to a change of protein folding with **loss of function of these proteins and enzymes**. The damaged cell reacts with massively **release of cytokines**.
The main cellular constituents of blood are the erythrocytes, leukocytes and platelets. It is published that nanoparticles can easily access these cells and influence both their structure and function that can result in potentially toxic effects. The nanoparticles reach the blood system and come in direct contact with blood cells, endothelial cells and plasma proteins, where they can change the structure and critical functions of these blood components.
It is published that such **LNPs cause death of erythrocytes** *in vivo* which are very sensitive to oxidative stress. **The consequences are hemolysis and oxygen deficiency of the subjects.**
Also, plasma proteins can surround the surface of nanoparticles to form a protein/LNP complex and may even lead to increase cellular activation and **thrombotic complications** through nanoparticle-induced coagulopathy. In healthy individuals, the clot formation and fibrinolytic systems are highly regulated to ensure hemostatic balance, and any dysregulation can lead to impaired or weak clot formation (**poor hemostasis and rebleeding**) or overly strong occlusive clot growth (**thrombosis**). There are an increasing number of studies reporting that engineered nanoparticles may shift the hemostatic balance by perturbation of the coagulation system, **causing serious life-threatening conditions** such as deep vein thrombosis and disseminated intravascular coagulopathy. For example, disseminated intravascular coagulation, which is a common complication in cancer, may lead to multiple organ failure and even to death when left untreated, has been reported with intravenous administration of certain nanoparticles such as cationic dendrimers.
Therefore, it is very important that Moderna should make every effort to conduct thorough hemocompatibility studies on newly engineered nanoparticles that evaluate the interactions between the LNPs and all three cellular constituents of blood. These studies were NOT done, especially not in humans. It is possible to analyse those parameters. …
In general, adverse reactions were observed at all concentrations tested and in all studies; dose dependence was frequently observed.
Adverse Events observed: „, heart palpitations, shortness of breath … degeneration of muscle fibers … **vacuolization of liver cells** …**degeneration of liver cells … cell death**…. **There was no critical considerations about people with liver diseases such as hepatitis, liver cirrhosis, etc**… **reduction of the stem cells of the red blood cells** … **blood oxygen can be altered/reduced and harm organs. Low blood oxygen is one cause of heart attack and stroke.´… oxygen deficiency**. An undersupply with oxygen causes organ damage and can lead to **heart attacks and strokes**. Also, the condition of already **damaged organs worsens** …
…all experiments were done **on healthy and young rats. What happens in the**

pre-damaged humans and elderly? There were no critical considerations of clinical relevance in humans, and such analyses performed in animals **are not envisioned** in participants (with or without risk factors) in phase 3 clinical trial. **The consequences of overcoming the blood-brain barrier were not discussed. LNPs which reach the brain is extremely dangerous.** Nerve cells are very sensitive and die immediately after exposure to LNPs. This cell type shows no tolerance towards oxidative stress. LNPs in the brain is a reasonable explanation for the occurrence of **facial nerve paresis** 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 lead to facial paralysis.The consequences of LNPs in the eye was not discussed. Damage of retina or eye nerve can lead to **severe eye diseases and blindness**.

Genotoxicology

CONCLUSION: Basically, genotoxicology has not been studied well enough, as evidence of DNA damage *in vivo* is available but has not been followed up. It is reasonable to assume that this preparation is genotoxic and mutagen.
Carcinogenecity
No studies on carcinogenesis have been performed.
p. 50: „No carcinogenicity studies were submitted. This is scientifically acceptable and in line with relevant guidelines on non-clinical development of vaccine candidates. The components of the vaccine formulation are lipids and natural nucleosides that are not expected to have carcinogenic potential.“
There are several studies showing that LNPs can enter all organs and the cationic lipids cause oxidative stress. There have been numerous studies for over 20 years explaining in detail that oxidative stress leads to DNA damage and this is causative in development of cancer.
There is an increased of autoantigen production due to massive cell damage by cationic lipids and the elimination of spike proteins from the cells by the immune system.
There are several studies showing that LNPs can enter all organs and the cationic lipids cause oxidative stress. There have been numerous studies for over 20 years explaining in detail that oxidative stress leads to DNA damage and this is causative in development of cancer.
…
Autoimmune diseases:
There was no discussion about the possibility to develop an autoimmune diseases after vaccination.

a) There are hints that the spike protein can cause molecular mimicry in the body.
b) There is an increased of autoantigen production due to massive cell damage by cationic lipids and the elimination of spike proteins from the cells by the immune system.

Autoantigens are formed by apoptosis which has to be cleared by the immune system. In case of overloading the clearing system (e.g. too much cell damage and apoptosis or in immune-supressed people or vulnerable people for autoimmune diseases) the degradation of the autoantigens is not sufficient. The accumulation

of these autoantigens in the body leads to chronically excessive type I interferon release which, in turn, further triggers the inflammatory processes. At one point the autoantigens are targets for the formation of autoantibodies and activation of autoreactive cytotoxic T cells. This leads to further damages of tissues. **If the levels of autoantibodies are not decreasing and the tissues cannot recover an autoimmune disease can develop.**

Hypersensitivity against PEGylated lipid PEG2000-DMG:

Moderna uses a new PEGylated lipid which is not approved yet.**PEG triggers hypersensitivity and allergic reaction up to anaphylactic shock.** Subjects with previous formed antibodies against PEG display a hypersensitive reaction after receiving the vaccine. The antibodies cause a rapid elimination of LNP in the blood and the vaccination has failed then.
It is published that if one has already been in contact with PEG, it is possible that antibodies against PEG have been formed. The amount of PEG at the first contact does not play a role in the reaction at the second contact. As long as antibodies against PEG are present, the amount of PEG at the second contact determines how strong the immune reaction will be. ….
No immunogenicity data from the clinical phase III study were available for assessment at the time this report was written. The data cut-off was day 119 post-vaccination for Phase 1, and day 57 for post-vaccination for Phase 2. **This means that immunokinetics over time and the correlation of protection/risk could not be characterised.**

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95. **The risks identified by the expert are serious.**

96. 3,266 cases of vaccine side effects, of which 1,621 severe vaccine side effect cases, 725 severe nervous system side effects were listed in the official database of the EU regarding "COVID-19 Vaccine Moderna" until 27/02/2021. It is known that only a fraction of the adverse reaction cases are recorded, after deaths and cases of severe adverse reactions in particular are all too quickly dismissed either with a previous illness, or advanced age, without effective clarification of the cause of death. In many member states, autopsies and other necessary investigations are systematically omitted, even in the case of concrete reports of obvious group deaths in old people's homes, after inoculation with these experimental genetically based substances. This in turn means that **pharmacovigilance, which must be particularly accurate for a drug with only limited marketing authorisation, is largely absent** (Doc. **A. 20.2**).

It is in no way comprehensible how the European Medicines Agency (EMA) could give a recommendation for the conditional approval of "COVID-19 Vaccine Moderna" 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 Union's obligation to guarantee the highest standard of safety in public health (Art. 168 TFEU).**

On 28 February 2021, a group of twelve international experts wrote to the European Medicines Agency (EMA) asking it to comment within 7 days on serious substantiated risks posed by genetically engineered substances such

as "COVID-19 Vaccine Moderna" and, if the concerns cannot be allayed, to immediately withdraw the recommendation for conditional approval of these substances (Doc. **A.20.3).** The experts write the following:

"In particular, we question whether cardinal issues regarding the safety of the vaccines were adequately addressed prior to their approval by the European Medicines Agency (EMA).
As a matter of great urgency, we herewith request that the EMA provide us with responses to the following issues:
1. Following intramuscular injection, it must be expected that the gene-based vaccines will reach the bloodstream and disseminate throughout the body [1]. We request evidence that this possibility was excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.
2 . If such evidence is not available, it must be expected that the vaccines will remain entrapped in the circulation and be taken up by endothelial cells. There is reason to assume that this will happen particularly at sites of slow blood flow, i.e. in small vessels and capillaries [2]. We request evidence that this probability was excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.
3. If such evidence is not available, it must be expected that during expression of the vaccines' nucleic acids, peptides derived from the spike protein will be presented via the MHC I - pathway at the luminal surface of the cells. Many healthy individuals have CD8-lymphocytes that recognize such peptides, which may be due to prior COVID infection, but also to cross-reactions with other types of Coronavirus [3; 4] [5]. We must assume that these lymphocytes will mount an attack on the respective cells. We request evidence that this probability was excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.
4 . If such evidence is not available, it must be expected that endothelial damage with subsequent triggering of blood coagulation via platelet activation will ensue at countless sites throughout the body. We request evidence that this probability was excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.
5. If such evidence is not available, it must be expected that this will lead to a drop in platelet counts, appearance of D-dimers in the blood, and to myriad ischaemic lesions throughout the body including in the brain, spinal cord and heart. Bleeding disorders might occur in the wake of this novel type of DIC-syndrome including, amongst other possibilities, profuse bleedings and haemorrhagic stroke. We request evidence that all these possibilities were excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.
6. The SARS-CoV-2 spike protein binds to the ACE2 receptor on platelets, which results in their activation [6]. Thrombocytopenia has been reported in severe cases of SARS-CoV-2 infection [7]. Thrombocytopenia has also been reported in vaccinated individuals [8]. We request evidence that the potential danger of platelet activation that would also lead to disseminated intravascular coagulation (DIC) was excluded with all three vaccines prior to their approval for use in humans by the EMA.
7. The sweeping across the globe of SARS-CoV-2 created a pandemic of illness associated with many deaths. However, by the time of consideration for approval of the vaccines, the health systems of most countries were no longer under

imminent threat of being overwhelmed because a growing proportion of the world had already been infected and the worst of the pandemic had already abated. Consequently, we demand conclusive evidence that an actual emergency existed at the time of the EMA granting Conditional Marketing Authorisation to the manufacturers of all three vaccines, to justify their approval for use in humans by the EMA, purportedly because of such an emergency.

Should all such evidence not be available, we demand that approval for use of the gene-based vaccines be withdrawn until all the above issues have been properly addressed by the exercise of due diligence by the EMA.

There are serious concerns, including but not confined to those outlined above, that the approval of the COVID-19 vaccines by the EMA was premature and reckless, and that the administration of the vaccines constituted and still does constitute "human experimentation", which was and still is in violation of the Nuremberg Code."

97. **2.2. invalidity due to non-existence of the condition according to Article 4 (1) b) of Regulation (EC) No 507/2006 - applicant is not expected to be able to provide the comprehensive clinical data.**

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

The applicant of the marketing authorisation of "COVID-19 Vaccine Moderna" is not expected to be able to provide comprehensive clinical data for the following reasons:

99. 1.) As already stated above under point 2.1.1, **the studies on "COVID-19 Vaccine Moderna" are designed by the applicant in such a way that it cannot be understood whether this "vaccine" 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 **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!**

100. 2.) In view of the fact that "COVID-19 Vaccine Moderna" 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 is not entitled to a conditional authorisation. "(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".**

101. The implementing decision contested here is therefore unlawful for these reasons alone and therefore null and void.

102. **2.3 Nullity due to the non-existence of the prerequisite 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.**

103.

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 (provided the drugs are used correctly - e.g. not overdosed and not used in contraindications, e.g. favism, as was the case with Hydroxychloroquine, due to a fatal international indication that was allegedly issued in error).

104. As aready 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 incomprehensible prohibition of the use of this drug 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).

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.21.2)** and conducted toxic overdose studies in intensive care patients (the "SOLIDARITY" and "RECOVERY" studies - Doc **A.21.3**).

105. 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, even in ICU patients.

Dozens of studies and several metastudies have already established that the inexpensive Ivermectin is highly effective against covid (Doc. **A.21.4**). According to recent studies in several countries, the antiparasitic drug Ivermectin - a WHO essential drug - achieves up to 98% risk reduction (Doc. **A.21.5**) 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.21.6**), 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.21.7**) - 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 "COVID-19 Vaccine Moderna", is clear evidence that "COVID-19 Vaccine Moderna", unlike Ivermectin, is not suitable to close a medical care gap.

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.21.8**).

Apart from the fact that there are drugs that have been shown to treat Covid-19 patients very effectively 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; this also applies to Vitamin D.

106. In a Spanish randomized controlled trial (RCT - **Doc. A.21.9**), high-dose vitamin D (100,000 IU) reduced the risk of intensive care by 96%.

In a study (Doc. **A.21.10)** 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.21.11**) found a strong association between vitamin D deficiency and Covid 19 disease severity.

A 2017 meta-study (Doc. **A.21.12**.) found a positive effect of vitamin D on respiratory infections.

107. The use of zinc in combination with HCQ, for example, is equally successful. US physicians reported (Doc. **A.21.13.**) 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.21.14**) found that low plasma zinc levels (below 50mcg/dl) increased the risk of in-hospital death in Covid patients by 130%.

108. While European countries and the US 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".

FLCCC has developed a treatment protocol (Doc **A.21.8)** 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.

109. In contrast, India has adopted the treatment protocol specified by FLCCC and now manufactures this product under the brand name "Ziverdo Kit", at the cost of 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.21.15**). 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.21.16) t**hat 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."**

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.

Ivermectin has also been 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 "COVID-19 Vaccine Moderna", with a very modest positive effect, if any, and which in effect act like a "gene therapy drug" that 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.
The Ministry of Health approved the therapeutic use of this drug for six months. It is to be used together with other treatments, said its spokeswoman Zuzana Eliášová, as reported by the TASR news agency.

The drug can be legally imported into Slovakia and administered to patients. With this step, the ministry fulfilled the demand of the Association of Slovak Anaesthesiologists, the daily Denník N. reported (Doc. **A.21.17**).

Ivermectin is also demanded and partly already used in other countries. Prof. Paul R. Vogt, Clinic Director of Zurich University Hospital 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.21.18**), 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 welfare 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 to be "vaccines"), over medicines that have gone through proper approval procedures and whose modest side effects have long been known.

110. **2.4 Invalidity due to non-existence of the condition according to Regulation (EC) No 507/2006 -Article 4 (1) d) - non-existence of the benefit to public health, brought about by the immediate availability of the medicinal product on the market, outweighing the danger due to the lack of additional data.**

111. 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 "COVID-19 Vaccine Moderna" on the market. **This substance should never have been authorised in the procedure chosen for this purpose in view of the lack of preconditions and must be withdrawn from the market immediately.**

112. **3. Invalidity for breach 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.**

113. **3.1 Violation of the EU legal provisions for the authorisation of "advanced therapy medicinal products"**

114. 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.

The aim of active vaccination is to establish long-term effective protection. For this purpose, killed or only fragments of the pathogens, or attenuated 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. 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.

115. Annex I to the implementing decision under appeal (Doc. **A.2.2)** literally states on page 4**:** ***"The duration of the protective effect of the vaccine is not known and is currently being determined in ongoing clinical trials."***

116. **COVID-19 Vaccine Moderna" has been proven to lead neither directly nor successfully to active immunisation**.

The Robert Koch Institute explicitly states the following on its homepage: "How long the vaccination protection lasts is not yet known. 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).**

No active immunisation has been demonstrated for "COVID-19 Vaccine Moderna" and the objective of passive immunisation is also not present.

117. **"COVID-19 Vaccine Moderna" as mRNA cannot directly trigger an immune response. However, such a direct immune response is a mandatory function for vaccines. "COVID-19 Vaccine Moderna" 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 "COVID-19 Vaccine Moderna" 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 to alleviate severe consequences of infections caused by coronaviruses. The alleviation of**

disease symptoms are clearly functions attributed to medicines (including prophylactic), and not to vaccines.
Therefore, the active ingredient "COVID-19 Vaccine Moderna" 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.

118. **In fact, the active substance "COVID-19 Vaccine Moderna" corresponds to the definition of a "gene therapy medicinal product" according to 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 this sequence.

119. **"COVID-19 Vaccine Moderna" works exactly according to this principle. The active substance "COVID-19 Vaccine Moderna" should therefore have been subject to the specific requirements laid down in Part IV of Annex I for "advanced therapy medicinal products". This did not happen.**
For this reason, the European Commission's implementing decision challenged here (together with subsequent amendments and integrations) is grossly unlawful and void as a matter of law, because there has been a breach of the special provisions for advanced therapy medicinal products included 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 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 laying down Community procedures for the authorisation and supervision of medicinal products for human use, and in particular for gene therapy medicinal products.

120. **3.2 <u>Annulment of the implementing decision on the grounds of manifest error of assessment and inadequate reasoning in relation to the risk minimisation measures proposed in the marketing authorisation dossier and breach of the principle of proportionality under Article 5 TEU.</u>**

121. **The risk minimisation measures proposed by Moderna** (Doc. **A.22) are not suitable to mitigate the potentially undesirable side effects. Accordingly, safety has not been sufficiently demonstrated (**see judgment of 19 December 2019, Vanda Pharmaceuticals Ltd, T-211/18, ECLI:EU:T:2019:892, paras 64, 131). See Risk Management Report (RMP) of 5.1.2021 (Doc. **A.23).**

122. In principle, risk minimisation measures are generally aimed at preventing or reducing the occurrence of adverse reactions that are unavoidable and associated

with exposure to a medicinal product or, in the event that adverse reactions do occur, reducing their severity or impact on the patient. Risk minimisation measures are intended to optimise the safe and effective use of a pharmaceutical product. **It is generally recognised by those involved in the field of pharmacovigilance that both the planning and implementation of risk minimisation measures and the evaluation of their effectiveness are key elements of risk management. Whether proposed risk minimisation measures are sufficient or not can therefore be crucial for any decision on the authorisation of a medicinal product.** (Vanda Pharmaceuticals Ltd, T-211/18, para. 120)

123. **The flaw in the assessment report of the Committee for Medicinal Products for Human Use (**doc. **A.1.) relates to the fact that the risk minimisation measures, including routine measures and pharmacovigilance activities according to the risk management plan version 1.0 submitted by the applicant under point 2.7 (p. 127) were considered sufficient on the basis of the opinion of the Committee for Medicinal Products for Human Use and the Pharmacovigilance Risk Assessment Committee without further justification, although they are inadequate to control the identified safety risks.**
The significant safety risk of "Vaccine-associated enhanced disease (VAED) including vaccine-associated enhanced respiratory disease (VAERD)" was not adequately excluded by the applicant Moderna and the observation in the clinical trial so far is based on too small a data set to draw valid conclusions and the observation period was too short to exclude the safety concerns on VAED/VAERD, in particular with regard to the novel viral mutations, with sufficient plausibility. Moreover, the risk is investigated in all clinical trials that are a condition of marketing authorisation and **the applicant itself has not been able to exclude this risk with certainty, as shown in the assessment report, p. 126:**
"In the pivotal trial, up to the data cut-off, 30 cases of severe COVID-19 were reported in the placebo group, while 0 case was reported in the vaccine group, providing no signal for a possible disease enhancement after vaccination with mRNA-1273."
"Generally, it cannot be foreseen whether potential future mutations of the SARS-CoV-2 virus may lead to a reduced susceptibility to the neutralising antibodies induced by vaccination with mRNA-1273. Therefore, even though the currently available data (non-clinical, clinical, neutralising capacity of antibodies) do not raise a concern at the time being, ***the possibility of enhanced disease cannot be excluded with certainty.*** *The current version of the RMP lists vaccine-associated enhanced respiratory disease as a safety concern and an important potential risk. The applicant will report any COVID 19 cases requiring hospitalisation and provide monthly safety updates including numbers of and information about relevant cases."*

124. The significant safety risk of VAED/VAERD with these mRNA-based substances was described by Prof. Dr.rer.nat. Stefan W. Hockertz in his scientific opinion of 15/02/2021 on the occasion of the first "experimental genetic engineering-based vaccine" Comirnaty (Pfizer/BioNTech), which was approved in the EU due to gross negligence and thus unlawfully (Doc. **A.23**). In addition, a large body of further

scientific work exists, notably by Cardozo et al, *Informed consent* disclosure to vaccine trial subjects of risk of COVID 19 vaccines worsening clinical disease, *The International Journal of Clincial Practice,* Oct 2020, https://doi.org/10.1111/ijcp.13795 .

The conclusions of the article call for comprehensive informed consent for trial subjects and post-approval, as it presents a significant safety risk, *"The specific and significant COVID-19 risk of ADE should have been and should be prominently and independently disclosed to research subjects currently in vaccine trials, as well as those being recruited for the trials and future patients after vaccine approval, in order to meet the medical ethics standard of patient comprehension for informed consent."*

125. On the other hand, **due to the mass vaccination campaign, which envisages nationwide exposure for the population, as well as the increased occurrence of virus mutations, there is a particularly high risk of a massive health impairment of the European population by VAED/VAERD. This is blatantly contrary to the general principle of protection of public health established by the case-law and the Union precautionary principle** (Vanda Pharmaceuticals Ltd, T-211/18, para 46).

126. **Consequently, there is a serious error of reasoning in the Implementing Decision in that the applicant did not propose routine or additional risk minimisation measures, even though the possibility of VAED/VAERD occurring constitutes a real health threat and requires inclusion in the summary of product characteristics -** Doc. **A.2.2 - as well as in the package leaflet, yet this measure was omitted, as can be seen on page 136.**

127. **No risk minimization measures were taken with regard to the missing long-term safety data and the applications to people suffering from autoimmune or inflammatory diseases, although this essential information is missing by definition due to the conditional approval and the missing studies. People with fragile health status and co-morbidities, such as chronic obstructive pulmonary disease, chronic neurological disease, diabetes, cardiovascular disease, were included in the summary of product characteristics as a routine risk minimization measure according to the assessment report, p. 140, but no warning about the safety risk due to the missing data appears under section 5.1 of the summary of product characteristics, so that even the marketing authorisation condition of the implementing decision was violated in this respect.**

128. The misleading risk minimisation information for persons with fragile health status and comorbidities in the summary of product characteristics led to the implementation of a wrong prioritisation strategy, which established a *de facto* compulsory vaccination obligation for the risk group of elderly and very elderly people ("nursing home residents") with unexpected safety risks without their being properly informed about these risks. As a result, there is a concrete risk of many deaths and seriously impaired health because the substance is used on people for whom it is generally contraindicated.

129. **According to established case law, the identified risk must be balanced against "simple" risk minimisation measures, such as warnings in the summary of product characteristics and in the package leaflet. In the case of a materiality of risk, the relevance of simple risk minimisation measures is often not sufficient** (Vanda Pharmaceuticals Ltd, T-211/18, para 132). **In the case at hand, however, the materiality of the identified unforeseeable risks is exceptionally high, so that the non-inclusion of simple risk minimisation measures, as well as of not a single additional risk minimisation measure, constitutes a particularly serious error of assessment as well as a defect in the statement of reasons, which results in the annulment of the act.**
This means that, in view of the incalculable potential for side effects, a safe and effective use of "COVID-19 Vaccine Moderna" must be excluded a priori, in particular for the identified risk groups for which no or insufficient risk minimisation measures have been taken.

130. **In the overall view of the mass vaccination of the population prescribed by the European Vaccination Strategy, which results in a high number of exposures in a short period of time, versus the medically absolutely incalculable health risks, in particular VAED/VAERD, as well as the lack of long-term safety data, for which no risk minimisation at all was provided, the Commission, respectively the EMA, exercised its discretion in the adoption of the legal act in a grossly erroneous and unjustified manner** (Assessment Report pp.136-141 - A.1), **since the regular health status of the entire population is massively and incalculably endangered by prophylactic gene immunisation without minimising the risks (**Vanda Pharmaceuticals Ltd, T-211/18, para. 53).

131. The plea of infringement of the principle of proportionality

132. **The implementing decision adopted is unlawful on the basis of the measures taken, since it is manifestly inappropriate to achieve the objective pursued by the competent institutions, namely the safe and effective use of the gene therapy medicinal product at issue against infectious diseases** (cf. in this sense, judgments of 4 May 2016, Pillbox 38, C-477/14, EU:C:2016:324, para. 49 and the case-law cited therein, and of 16 March 2016, Dextro Energy v Commission, T-100/15, EU:T:2016:150, para. 80).

133. The principle of proportionality in the area of public health means that, among the goods and interests protected by the TFEU, the health and life of humans rank highest (see, to that effect, judgment of 19 April 2012, Artegodan v Commission, C-221/10 P, EU:C:2012:216, para. 99 and the case-law cited there; see also, mutatis mutandis, on the respect of this principle by the Member States in the field of public health, judgment of 8 June 2017, Medisanus, C-296/15, EU:C:2017:431, para. 82 and the case-law cited there).

134. **For the control of safety risks by means of wholly absent or partially simple risk minimisation measures, considered both in isolation and in combination, less burdensome alternatives would have been available for the achievement of those objectives, in accordance with the enshrined principles**

of medicinal products law of 'safety, efficacy and quality', which correlate with the protection of human health and life, by refusing authorisation under Article 5 TEU as an inappropriate measure.

Therefore, the act at issue, which includes the approval of the risk management plan proposed by the applicant, constitutes an inappropriate measure with regard to the principles of medicinal product authorisation and public health mentioned above.

135. **3.3 Violation of the provisions of EU law concerning the correct indication of the characteristics of the medicinal product and a correct package leaflet.**

136. According to **Art. 9 para. 1 lit. c) Regulation (EC) No. 726/2004 as well as Art. 62 Directive 2001/83/EC, the characteristics of the medicinal product, in particular the associated risks or references to groups of persons for whom the medicinal product is not recommended**, must be correctly stated and the package leaflet must comply with this.

137. According to **Article 11(4.4) of Directive 2001/83/EC**, the summary of product characteristics must 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.**

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

139. According to **Art. 59 para. 1 lit. c) 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.**

140. **Due to the gross error of assessment set out above under point 3.2, which led to a failure to take account of significant safety risks, there is also an automatic breach of the provisions of EU law concerning the correct identification of the characteristics of the medicinal product and a correct package leaflet.**

141. **3.4.Invalidity due to violation of the EMA's own criteria for the surveillance of a "pandemic medicinal product" with enormous short-term exposure figures.**

142. According to Annex II, E - Specific obligation to complete post-authorisation measures under "special conditions" 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 "COVID-19 Vaccine Moderna" only in December 2022!**

This deadline is clearly outside a valid assessment period for review in terms of efficacy and safety etc. at the renewal date. Similarly, it is 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 authorisation.

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

144. ***"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.*** *Moreover, during a pandemic, the resources needed for a thorough assessment of PSURs in the format laid down 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 thus confirms the importance of the PSURs for the safety of the population to be vaccinated".* [2[1]]

145. The EMA itself thus 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 the latest" 6 months after placing on the market.

146. The actual "special conditions" (according to Art. 14a (4) of Regulation 726/2004) concern specific obligations to finalise the product and manufacturing quality of the active substance, which must be verified within the first 6 months, as well as, with regard to the **confirmation of efficacy and safety**, the submission of the final clinical study report for the randomised, placebo-controlled, observer-blind **study C4591001 by December 2022.**

147. **The health-threatening problem issue lies in the fact that the marketing authorisation holder is required to provide proof of efficacy and safety only 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.**

*

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

148. **4. Annulment 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.**

149. 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. 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 is concretely putting the applicants in a situation that endangers their health.

150. **Article 3 of the EU Charter (right to the integrity of the person**) guarantees every person present 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 consent after prior information 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 profit, ...**

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

152. **Article 169 TFEU (consumer protection)** guarantees consumers 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.**

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

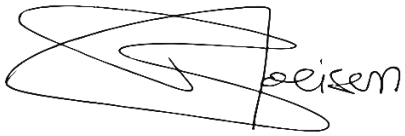
154. On the basis of the foregoing, it is obvious that the EU Commission has also grossly violated the applicants' fundamental right to consumer protection and the obligations laid down in Article 169 TFEU, which also apply to the Commission in particular, with the implementing decision challenged here.

*

155. The above-mentioned applicants therefore request that this honourable European Court, on the basis of the multiple gross violations of applicable EU law mentioned above, which affect the applicants directly and personally, declare the contested implementing decision null and void.

Bolzano, 5 March 2021

RA DDr. Renate Holzeisen



The following documents are deposited:

A1 EMA Assessment report "COVID-19 Vaccine Moderna" Procedure No. EMEA/H/C005791/0000 of 06/01/2021; p. 1 to 170 of the annexes; paragraph 1; (colour print).

A2 p. 171 of the annexes

A2.2 European Commission, Implementing Decision of 06/01/2021 granting a conditional marketing authorisation for the medicinal product for human use "COVID-19 Vaccine Moderna-Covid-19 mRNA vaccine (nucleoside modified)" in accordance with Regulation (EC) No 726/2004 of the European Parliament and of the Council; p. 172 to 175 of the Annexes; paragraph 2;

A2.3 Annexes I, II, III and IV to Implementing Decision C(2021) 94(final); pp. 176 to 208 of the Annexes; paragraph 3;

A2.4 Correction to the Annexes to the Implementing Decision of 25/01/2021, pp. 209 to 241 of the Annexes; paragraph 4;

A3 p. 242 of the Appendices (colour print)

A3.1 Alto Adige, online edition of the Italian language daily newspaper, article" L'infettivologo Galli: "Perseguire legalmente medici e infermieri no vax in Alto Adige" published on 13/01/2021; pp. 242 to 249 of the annexes; paragraph 10

A3.2. email message from the Coordinating Care Manager of the South Tyrolean Ambulance Service, dated January 2020; pp. 250 to 253 of the Annexes; paragraph 11;

A3.3. Covid "vaccination plan" Italy dated 7/12/2020; pp. 254 to 280 of the attachments; paragraph 12;

A3.4. email communication from those responsible for Merano Hospital (Autonomous Province of Bolzano - Italy) to hospital staff of 07/01/2021; pp. 281 to 282 of the annexes; paragraph 12;

A3.5. communication from those in charge of the Heinrich von Rottenburg - Kaltern retirement home to the staff, dated 25/01/2021; pp. 283 to 284 of the annexes; paragraph 12;

A3.6. email from the Medical and Dental Association of Bolzano to doctors with vaccination request, dated 15/01/2021; pp. 285 to 286 of the annexes; paragraph 12;

A3.7. AssoCareNews.it, article published on 04/01/2021 regarding a geriatric nurse who was forced to have the Covid vaccination against her will: "Cristina, OSS: "mi hanno costretta al vaccino ..., mi hanno minacciata"; pp. 287 to 288 of the annexes; paragraph 13

A3.8 Nurse Times, article published 08/01/2021 regarding threat of dismissal of 19 elderly care workers for refusing Covid "vaccination"; pp. 292 to 296 of attachments; paragraph 13;

A3.9 Studio Cardiologico Dr Maurizio Bina S.r.l., Cagliari 25/02/2021 - warning of staff not undergoing Covid vaccination; pp. 297 to 298, paragraph 14;

A4 RA DDr. Renate Holzeisen, warning letter of 19/12/2020 to EU Commission, EMA and others; "; pp. 299 to 373 of the annexes; paragraph 18; (colour print).

A5 p. 374 of the annexes

A5.1 EU vaccine strategy - extract from the EU Commission's website of 11/02/2021; pp. 375 to 393 of the annexes; paragraph 20;

A5.2. European Commission, communication-united-front-beat-covid-19_en (1).pdf, pp. 394 to 406, paragraph 22;

A5.3. EU wants Corona vaccination passport_ Law for _green passport_ in March - ZDFheute.pdf, pp. 407 to 414, paragraph 24;

A5.4. Draghi_ sì al passaporto vaccinale. Servono tre mesi, si lavora per l'estate - La Stampa.pdf, pp. 415 to 419, paragraph 24;

A6. MedRixiv - The infection fatality rate of COVID-19 inferred from sero-prevalence data, John P.A. Ioannidis, May 2020; pp. 420 to 430 of attachments; paragraph 38;

A7. Bulletin of the World Health Organization: Type: Research Article ID: BLT.20.265892 - Infection fatality rate of COVID-19 inferred from seroprevalence data, John P.A. Ioannidis, 14 October 2020; pp. 431 to 468 of the appendices; paragraph 38; (colour print).

A8. LaVerità, article on interview with new president of the Italian Medicines Agency announcing guidelines for GPs on home therapy for Covid 19 patients, "Via libera agli anticorpi monoclonali e alle linee guida per curarsi a casa", 03/02/2021; pp. 469 to 470 of attachments; paragraph 39;

A9. Consiglio di Stato, Judgment of the Council of State of Rome No. 09070/2020, dated 11/12/2020; pp. 471 to 507 of the Annexes; paragraph 39;

A10. P. 508 of the annexes

A10.1 WHO, Bulletin, 30/01/2020 - WHO Director-General's statement on IHR Emergency Committee on Novel Coronavirus (2019-nCoV); pp. 509 to 513 of the Annexes; paragraph 43;

A10.2 WHO, Bulletin, 30/01/2020 - Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV); pp. 514 to 522 of the Annexes; paragraph 46;

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A11.1 WHO, 17/01/2020, Interim guidance - Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases; pp. 524 to 530 of the Annexes; paragraph 47;

A11.2 Christian Drosten, Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR; pp. 531 to 543 of the Annexes; paragraph 47

A11.3 WHO, Summary table of available protocols; pp. 544 to 624 of the appendices; paragraph 47;

A11.4 Eurosurveillance, Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR; pp. 625 to 633 of the Annexes; paragraph 47;

A12. P. 619 of the appendices

A12.1 WHO, Bulletin, 14/12/2020 - WHO Information Notice for IVD Users; Pp 635 to 638 of the Appendices; paragraph 52;
A12.2 WHO, Bulletin, 30.01.2020 - WHO Information Notice for IVD Users 2020/05; pp. 640 to 643 of the Annexes; paragraph 54;
A13. P. 644 of the appendices
A13.1 The New York Times - Your Coronosvirus Test is Positive. Maybe It Shouldn't Be, 29/08/2020; pp. 645 to 649 of the Annexes; paragraph 56;
A13.2 Times of India - Covid-19 test reports must also state cycle threshold value: Doctors, 06/09/2020; pp. 650 to 653 of the Annexes; para 56;
A13.3. EU Commission, experts Christian Drosten and Lothar Wieler advise EU Commission, 18/03/2020, pp. 653 to 655, paragraph 57;
A14. Nature communications - Post-lockdown SARS-CoV-2 nucleic acid screening in nearly ten million residents of Wuhan, China; pp. 656 to 663 of the attachments; paragraph 58; (colour print)
A15. p. 664 of the annexes (colour print)
A15.1 Tribunal da Relacao de Lisboa, Conclusao, 11/11/2020; pp. 665 to 699 of the annexes; paragraph 61;
A15.2 Infectious Disease Society of America, Rita Jaafar and others, Correlation Between 3790 Quantitative Polymerase Chain Reaction-Positives Samples, pp. 700 to 702 of the Appendices; paragraph 61;
A15.3. The Lancet, Elena Surkova and others, False positive COVID-19 results: hidden problems and costs, 29/09/2020; pp. 703 to 705 of attachments; paragraph 61;
A15.4 Tumori Journal, Giovanni Apalone and others, Unexpected detection of SARS-CoV-2 antibodies in the prepandemic period in Italy, 11/11/2020; pp. 706 to 712 of the Annexes; paragraph 62;
A15.5 Istat - Istituto Nazionale di Statistica - Impact of the Covid-19 Epidemic on the total mortality of the resident population in the first quarter of 2020; pp. 713 to 716 of the annexes; paragraph 63;
A16. P. 717 of the appendices (colour print)
A16.1 Retraction request letter to Eurosurveillance + Review report Corman-Drosten et al. Eurosurveillance 2020, Dr Peter Borger and others 27/11/2020; pp. 718 to 747 of attachments; paragraph 65;
A16.2 Corman-Drosten Review Report, Addendum, last update 11/01/2021; pp. 748 to 807 of the Annexes; paragraph 65;
A16.3 Eurosurveillance, Response to retraction request and allegations of misconduct and scientific laws, 04/02/2021; pp. 808 to 820 of the annexes; paragraph 65;
A16.4. Südtiroler Sanitätsbetrieb and Azienda Provinciale per i Servizi Sanitari Provincia Autonoma di Bolzano, letters dated 26/11/2020 and 25/11/2020; pp. 821 to 828 of the Annexes; paragraph 66;
A16.5 Doctors' Group, requests for disclosure PCR test data Province of Alto Adige and Province of Trento dated 27/10/2020 and 26/10/2020; pp. 829 to 840 of the annexes; paragraph 66;
A17. WHO, Bulletin, Statement on the fifth meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic, 30/10/2020; pp. 841 to 848 of the Annexes; paragraph 68;
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A18.1. Apotheken Umschau, 28.01.2021; pp. 850 to 857 of the Annexes; paragraph 83;
A18.2. BMJ, Peter Doshi: Pfizer and Moderna's "95%effective" vaccines - let's be cautious and first see the full data, 26/11/2020; pp. 858 to 866 of attachments; paragraph 83;
A18.3 BMJ, Peter Doshi: Pfizer and Moderna's "95%effective" vaccines - we need more details and the raw data; pp. 867 to 872 of the Annexes; paragraph 83;
A18.4 BMJ, Peter Doshi, will covid-19 vaccines save lives? Current trials aren't designed to tell us, pp. 873 to 877, paragraph 85;
A18.5 Axios on Twitter" Moderna Chief Medical Officer Tal Zaks warns not to over-interpret vaccine results, 24/11/2020; pp. 878 to 880, paragraph 85;
A19. Dr.med Wolfgang Wodarg, Dr Michael Yeadon, Petiton/Motion ..., 01/12/2020; pp. 881 to 924, paragraph 92;
A20. P. 925 of the annexes
A20.1. Scientific opinion Prof. Dr. Stefan Hockertz pp. 926 to 968 of the Annexes; paragraph 94;
A20.2. 2020news, Stuttgart Attorney General's Office wants to prevent autopsy after vaccinations, pp. 969 to 1022 of attachments, paragraph 96;
A20.3. EMA's request by experts to withdraw recommendation for approval of GM-based Covid "vaccines", 28/02/2021, p.1023 to p.1029 of the Appendices, paragraph 98;
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A21.1. 1 hcqmeta.com: HCQ is effective for COVID-19 when used early: real-time meta analysis of 200 studies; pp. 1031 to 1098 of the appendices; paragraph 104; (colour print)
A21.2 The Guardian, Sugisphere: governments and WHO changed Covid-19 policy based on suspect data from tiny US company, 03/06/2020; pp.1099 to 1109 of attachments; paragraph 104;
A21.3 France Soir, Oxford, Recovery et Solidarity: Overdosage in two clinical trials with acts considered criminal? 25/06/2020 S. 1110 to 1117 of the annexes; paragraph 104;
A21.4. Swiss Policy Research - Covid-19: WHO-sponsored preliminary review indicates ivermectin effetctiveness, 31/12/2020; pp. 1118 to 1123 of the Annexes; paragraph 105;
A21.5. ivmmeta.com - Ivermectin is effective for COVID-19: real-time meta analysis of 37 studies; pp. 1124 to 1149 of the appendices; paragraph 105; (colour print)
A21.6 Science Direct - Bénéfice de l'invermectine: de la gale à la COVID-19, un exemple de sérendipité; pp. 1150 to 1155 of the appendices; paragraph 105; (colour print)
A21.7 Science Direct - A COVID-19 prohylaxis? Lower incidence with prophylactic administration of ivermectin; pp. 1156 to 1160 of appendices; paragraph 105; (colour print).
A21.8 FLCCC - Protocol for prophylaxis and early outpatient treatment of Covid-19; pp. 1161 to 1163 of the appendices; paragraph 105; (colour print)
A21.9 Science Direct - "Effect of calcifediol treatment and best available therapy versus best available therapy on ICU admission and mortality in patients hospitalised for COVID-19...". October 2020; pp. 1164 to 1168 of the appendices; paragraph 106;
A21.10. Sciece Direct - Vitamin D and survival in COVID-19 patients: A quasi-

experimental study; pp. 1169 to 1172 of the Appendices; paragraph 106;

A21.11. medRxiv - The link between vitamin D deficiency and Covid-19 in a large population; pp. 1173 to 1198 of the appendices; para. 106; (colour print)

A21.12. the bmj - Vitamin D supplementation for the prevention of acute respiratory infections: Systematic review and meta-analysis of individual participant data; pp. 1199 to 1221 of attachments; paragraph 106;

A21.13. ScienceDirect - COVID-19 outpatients: early risk-stratified treatment with zinc plus low-dose hydroxychloroquine and azithromycin: a retrospective case series study; pp. 1222 to 1255 of the appendices; paragraph 107;

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A21.15. TrialSiteNews - An unlikely nation fights this pandemic ... , 9 Jan 2021; pp. 1259 to 1264 of attachments; paragraph 107;

A21.16. The Indianexpress - Up: New protocol ivermectin to replace HCQ in treatment of covid patients; pp. 1265 to 1277 of attachments; para 109;

A21.17. Slovak Spectator - Use of parasitic drugs approved for treatment of coronavirus patients in Slovakia; pp. 1278 to 1282 of attachments; para 109;

A21.18. Daily Gazette, Coronavirus - Covid- 19: Instead of eradicating the virus we give it a cocktail of drugs; pp. 1283 to 1291 of attachments; paragraph 109;

A22. COVID-19 mRNA VACCINE Moderna RISK MANAGEMENT PLAN (RMP) pp. 1292 to 1387 of the appendices; paragraph 121;

A23. Prof. Dr. Stefan Hockertz, Expert Report, 15/02/2021; pp. 1388 to 1433 of the Appendices; paragraph 124;

A24. EU prepares digital vaccination card, Süddeutsche Zeitung, 2 March 2021, pp. 1434 to 1437 of the Annexes; paragraph 24;

A25. Robert Koch Institute COVID-19 and vaccination: answers to frequently asked questions, p. 20/21 pp. 1438 to 1440 of the Annexes; paragraph 86.