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EUROPEAN COURT

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ACTION FOR ANNULMENT according to Art. 263 TFEU

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

Defendant:
European Commission

Concerning:
EUROPEAN COMMISSION IMPLEMENTING DECISION of 29/01/2021 on the granting of conditional approval of the medicinal product for human use "COVID-19 Vaccine AstraZeneca-COVID-19-mRNA-bwased vaccine (ChAdOx1-S[rekombinant]" – 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 attorney-at-law, DDr. Renate Holzeisen, admitted in Italy also to the Supreme Courts, registered with the Bar Association of Bolzano and with office in 7 Bahnhofallee, I-39100 Bolzano,

PROVIDED THAT

1. the European Medicines Agency (EMA) on 29 January 2021, based on the application submitted by AstraZeneca AB on 12 January 2021, in accordance with Article 4(1) of Regulation (EC) No. 726/2004, issued its recommendation with opinion for the conditional marketing authorization of the medicinal product **"COVID-19 Vaccine AstraZeneca-COVID-19 vaccine (ChAdOx1-S [recombinant])" - EMA Assessment report "COVID-19 Vaccine AstraZeneca" Procedure No. EMEA/H/C005675/0000** (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 authorization 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 authorization for medicinal products for human use** falling within the scope of Regulation (EC) No. 726/2004 of the European Parliament and of the Council, Having regard to the application submitted by the company 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 29. January 2021 by the Committee for Medicinal Products for Human Use, Whereas :** (1) The medicinal product* "COVID-19 Vaccine AstraZeneca-COVID-19 vaccine (ChAdOx1-S [recombinant]" *complies with the requirements of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. (2) **"COVID-19 Vaccine AstraZeneca-COVID-19 Vaccine (ChAdOx1-S [recombinant])" falls within the scope of Regulation (EC) No 507/2006, and in***

particular Article 2(1) thereof. Furthermore, the medicinal product fulfils the requirements set out in Article 4 of Annex IV to that Regulation for the grant of a conditional marketing authorization. *(3) Marketing authorization for* ***'COVID-19 Vaccine AstraZeneca-COVID-19 vaccine (ChAdOx1-S [recombinant])'*** *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 'chimpanzee adenovirus encoding SARS-CoV-2 spike glycoprotein (ChAdOx1-S)' 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 adopted the following:*

"Article 1 - ***A conditional marketing authorization in accordance with Article 3 and Article 14-a of Regulation (EC) No 726/2004 is granted for the medicinal product 'COVID-19 Vaccine AstraZeneca-19 vaccine (ChAdOx1-S [recombinant])', the characteristics of which are summarized in Annex I to this Decision."*** *"COVID-19 Vaccine AstraZeneca-COVID-19 vaccine (ChAdOx1-S [recombinant])" is entered in the Union Register of Medicinal Products with the following number: EU/1/21/1529. Article 2 - The marketing authorization of the medicinal product referred to in Article 1 shall be subject to the obligations laid down in Annex II, which shall be reassessed annually. Article 3 - The labeling and package leaflet of the medicinal product referred to in Article 1 shall comply with the conditions listed in Annex III. Article 4 - The duration of the authorization shall be one year from the date of notification of this Decision. Article 5 - This Decision is addressed to AstraZeneca AB, 151 85 Södertälje, Sverige."*

- European Commission Implementing Decision of Jan. 29, 2021, granting a conditional marketing authorization for the medicinal product for human use "COVID-19 Vaccine AstraZeneca-COVID-19 vaccine (ChAdOx1-S [recombinant])" in accordance with Regulation (EC) No. 726/2004 of the European Parliament and of the Council (*Doc. **A.2.1.).***

3. Four (IV) annexes are attached to the above-mentioned implementing decision of the European Union - Annex I (Summary of product characteristics), Annex II (A. Manufacturer of the active substance(s) of biological origin and manufacturer responsible for batch release), Annex III (Labeling and package leaflet), Annex IV (Conclusions of the European Medicines Agency on the granting of marketing authorization under "special conditions" (Doc. **A.2.2.**).
4. Due to serious side effects (blood clots, cerebral venous thrombosis resulting in death, hemorrhage, and platelet deficiency), allocation of the "vaccine" was suspended in many parts of the EU (including Italy - see Doc. **A.2.3.**) by the national medicines authorities pending the decision of the European Medicines Agency (EMA). Although international experts assume that the "Covid-19 vaccine AstraZeneca" can causally lead to blood clots and subsequently also to death (see below under point 2.1.2.), the EMA, based on the safety assessment by the Pharmacovigilance Risk Assessment Committee (PRAC), continues to claim a positive benefit-risk ratio of the "vaccine". However, **a warning has been included in the SmPC,** which is **de facto** at least a partial **acknowledgement of the serious risk affecting a wide population** (Doc. **A.2.4**.).
5. By implementing decision of the EU Commission dated March 19, 2021, the decision for the conditional approval of "Covid-19 Vaccine AstraZeneca" was therefore amended and the annexes were added accordingly (Doc. **A.2.5**.).
6. Having said all this, the above-mentioned plaintiffs hereby file an action for declaratory judgment and declaration of nullity pursuant to Art. 263 TFEU of the above-mentioned

Implementing Decision of the EU Commission of 29 January 2021, including all subsequent amendments and integrations, on the following grounds of action.

Right to bring an action pursuant to Art. 263 TFEU

7. The plaintiffs are all working in the field of health care or care for the elderly and nursing as doctors, nurses, caregivers for the elderly, etc. and therefore have been exposed to a constantly growing pressure towards Covid vaccination for one and a half months now. Italy, like other EU member states, is also vaccinating the general population with the "COVID-19 Vaccine AstraZeneca".

8. **"COVID-19 Vaccine Zeneca"** is the third centrally GM-based substance **conditionally approved** by the European Commission in the EU as a so-called Covid "vaccine". The two other substances that have now been approved as so-called Covid "vaccines" (manufacturers: BioNTech and Moderna) are also experimental in nature and have nothing in common with a conventional vaccine.

9. The majority of the plaintiffs have already filed an action for annulment on February 16, 2021, and March 5, 2021, respectively, against the EU Commission's implementing decision of December 21, 2020, concerning the conditional approval of the experimental Covid "vaccine" "Comirnaty" (BioNTech) and against the EU Commission's implementing decision of January 6, 2021, concerning the conditional approval of the experimental Covid "vaccine" Moderna. The proceedings in question hang with the procedure numbers T-96/21 and T-136/21.

10. An immense pressure is exerted, especially on persons like the plaintiffs, who work in the field of health care and nursing, starting from a social moralizing pressure up to the threat of consequences under labor law, if they do not undergo the so-called Covid-"vaccination".

11. A number of virologists, who for a year now have been the exclusive advisors to the governments of the EU member states, have been publically calling to "legally prosecute" in particular those EU citizens who work in the field of health care and nursing and who, in view of the risks associated with the experimental Covid "vaccines" and the unproven benefits (see below), refuse to expose themselves to these substances based on genetic engineering (see in this respect 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".

12. 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**).

13. Italy, like other EU Member States, has started administering the Covid "vaccine" "COVID-19 Vaccine AstraZeneca" 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**).

14. 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.**).

15. **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.**)

16. **The centralised authorisation of "COVID-19 Vaccine AstraZeneca" on 29/01/2021 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.

17. 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.

18. The applicants are **directly and personally affected** by the unlawful marketing authorisation of COVID-19 Vaccine AstraZeneca, 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.

19. 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.

20. 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.**

21. 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 AstraZeneca, on 14 August 2020, for the purchase of a potential COVID-19 vaccine.

22. 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 AstraZeneca", is explained and documented below.

23. **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 four: COVID-19 Vaccine Comirnaty, Moderna, AstraZeneca and Janssen). By March 2021, at least 80% of people over 80 and 80% of health and social care workers in all Member States are to 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 (including Italy in particular) have become highly financially dependent on the European Community due to the disastrous economic effects of repeated lockdowns, lends the pressure exerted by the European Commission on the individual Member States towards covid vaccination a particular "quality" (Doc. **A.5.2**).

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

25. **On March 17, 2021, the EU Commission presented a draft regulation for the introduction of a digital green certificate** (Doc. **A.5.3**). **The digital green certificate**

will serve as proof that a person has been vaccinated against COVID-19, has received a negative test result, or has recovered from COVID-19.

The goal is said to provide a safe way to lift restrictions and travel in Europe. On March 25, 3021, the European Parliament decided to fast-track the introduction of the EU-wide vaccination certificate. Health Commissioner Stella Kyriakides urged EU countries to speed up their Corona vaccination campaigns. It was "<u>crucial that there is no gap between doses delivered and doses administered and that no vaccines go unused"</u> Kyriakides told an online conference of EU health ministers. The massive pressure that the EU Commission is exerting on EU member states towards compulsory vaccination is obvious.

<u>Therefore, there is no question that the digital vaccination passport will be introduced, 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 AstraZeneca).</u>

26. 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 unacceptable enormous health risk in violation of EU law,** brought about by the EU Commission with the implementation decision contested here (including subsequent amendments and integrations).

<u>GROUNDS FOR COMPLAINT</u>

27. **<u>Premise</u>**

28. "COVID-19 Vaccine AstraZeneca" is an experimental substance based on **genetically modified carrier viruses (specifically DNA chimpanzee adenoviruses**), which has absolutely nothing to do with conventional vaccines in terms of mode of action and production.

These carrier viruses (also called vectors) are inserted the information for the formation of a viral protein of SARS-CoV-2. That is, just as with the mRNA-based experimental "Covid vaccines" (such as Pfizer/BioNTech's Comirnaty and Moderna), **the generation of the viral protein in the "Covid-19 Vaccine AstraZeneca" occurs only in the human body after the virions of the vector virus have entered the cell.**

After the vector virus, into which the gene sequence for the construction of a viral antigen has been inserted, is injected into the human body (upper arm muscle), the virions of the vector virus penetrate into the cells of the vaccinee and start a kind of infection process there. This infection process leads to the release of the genetic blueprint for a viral antigen of SARS-CoV-2 into the human cells of the "vaccinated" person.

Through the gene expression (see below) of our body, **viral mRNA finally ends up at the ribosomes and is fed to the protein biosynthesis, so that the viral antigen is formed.** The biological mode of action of this vector vaccine is based on **complex integration mechanisms in the human cells of the vaccinated person**. Protein biosynthesis is the central process of gene expression, i.e. the process in which our genes are expressed or become active in our organism, i.e., protein biosynthesis is the implementation of the information from our genes and thus, by definition, a genetic process. The genetic information lying dormant in the cell nucleus as DNA, which contains the blueprint for our proteins, must be continuously fed to protein biosynthesis, which takes place outside the cell nucleus in the so-called ribosomes. The ribosomes are, so to speak, our "protein factories", which are constantly in full operation and produce protein in various shapes, sizes and structures according to specific recipes. The ribosomes have a cleft on the outside where the

recipes are read like in a scanner so that the protein that is needed at the moment can be produced correctly. The recipes are transported to this cleft by messengers. This task is performed by [messenger RNA (mRNA)]."[1]

The mRNA is a recombinant nucleic acid and is used to add a nucleic acid sequence to human cells to form the spike protein of SARS-CoV-2 that would not otherwise be present in the cells. 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 (which is necessary for protein building) to the protein-building ribosomes,

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 AstraZeneca" therefore factually constitutes 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 AstraZeneca"), 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 AstraZeneca" 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 AstraZeneca" **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

[1] Clemens G. Arvay, Corona Impfstoffe, Rettung oder Risiko? Wirkungsweisen, Schutz und Nebenwirkungen der Hoffnungsträger, Quadriga, 2021

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 AstraZeneca".

36. I**n 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.
The same group of GPs went to the competent administrative court in Lazio to obtain the judicial suspension of an instruction given by the Italian Ministry of Health to GPs on December 9, 2020 (namely to treat essentially with paracetamol, to wait and not to use the drugs otherwise usually used against Covid-19) that was extremely dangerous to the health (survival) of those suffering from Covid-19 (see Cautelar Order of the Administrative Court of 2. March 2021 and the corresponding, for the relevant part, suspended medically erroneous instruction of the Italian Ministry of Health of Dec. 9, 2020, which would not have allowed primary care physicians, to the best of their knowledge, to prescribe curative medicines to their patients - Doc. **A.10**).

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.11.1**).

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.11.2**).

47. On 13 January 2020, the WHO published a first PCR test guideline (**A.12.1**) based on the Corman-Drosten protocol of 13 January 2020 (Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR (**A.12.2**) - *see also Summary table of available protocols in this documents* (**A.12.3**), 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.12.4**). 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", had 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. 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 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 initial copies become 4, then 8, then 16 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.

51. **Scientists worldwide who are familiar with microbiology and with the PCR test have pointed out from the beginning that you cannot detect a virus with the PCR test, but only nucleic acids that remain as fragments of viruses. 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. 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.**
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.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.13.1), 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".**

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

53. **It is almost unbelievable: the RT-PCR test has now been used worldwide for fourteen 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.13.2**), **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, <u>clinical observations, patient history</u>, 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 a 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.14.1**). **With this scientifically based correction, the "case numbers" in Italy, Austria, Germany and Europe in general would be reduced to a fraction!**
As the Times of India reports (Doc. **A.14.2**), 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.14.3**.).

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.15**). 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 on 11 November 2020 (Doc. **A.16.1**).
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.16.2**), 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.16.3**), 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.16.4**) 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 hastily fleeing the country, leaving nursing homes abruptly 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.16.5**) 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 large number 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 residents 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 genetii 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.12.4) - 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.17.1**.)
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 Landt and Marco Kaiser (Doc. **A.17.1**):

The Corman-Drosten study was submitted to *Eurosurveillance* on 21 January. Already on 22 January, the review was supposedly done – which typically, however, 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 ever 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.17.2**).
Eurosurveillance has been refusing to retract the publication of the protocol responsible for a vast number of false positive case numbers worldwide for one year now, and this with an, *icutu oculi,* anything but scientific justification (Doc. **A.17.3**). Scientists worldwide are stunned and appalled by this development.

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.17.4**) 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.17.5**).

67. Incomprehensively, the WHO only officially pointed out for the first time in December 2020 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.[2]

68. **At the time of approval of "COVID-19 Vaccine AstraZeneca" on 29/01/2021, the short-term recommendations of the Emergency Committee of 29/10/2020 (**Doc. **A. 18) were in force on the basis of the same invalid WHO data base, which depicted an incorrect infection rate.**
It is also incomprehensible, in view of the effective mortality rate of Covid-19 (Doc. **A.6** und **A.7**), as presented and documented by top experts such as John P.A. Ioannidis, who have been indisputably recognised worldwide for decades, 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.18**), 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. <u>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.</u>
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, **<u>the mandatory conditions for a conditional marketing authorisation</u>**

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[2] *„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."*

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 AstraZeneca" and the implementing decision of the European Commission contested here is unlawful for this reason alone and must therefore be declared null and void.

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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 AstraZeneca", 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 on the basis of the facts.

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

83. The "COVID-19 Vaccine AstraZeneca" was tested for efficacy in rhesus monkeys in March and April, usually the first test of a vaccine whose positive result allows further human trials. The result is available in the form of a BioRxiv preprint dated May 13, 2020 (Doc. **A.19**). All vaccinated monkeys treated with the so-called Oxford vaccine were exposed to the virus, as was the control group. However, there was **no difference in the amount of viral RNA detected in the vaccinated monkeys compared to the non-vaccinated animals.** That is, **all vaccinated animals were infected**. As justification to move forward with the studies with this vaccine, the authors presented evidence that the vaccine did not protect the animals from infection but did mitigate the disease.

Thus, there is no evidence that those "vaccinated" with "COVID-19 Vaccine AstraZeneca" cannot become infected and be carriers of the SARS COV-2 virus.

84. **The studies appear to be designed in such a way in the first place that this proof cannot be provided at all.**

85. The expert group consisting of Prof.Dr.Stefan Hockertz, immunologist, toxicologist and pharmacologist, Prof.Dr.Sucharit Bhakdi, M.D., former head of the Institute for Microbiology and Hygiene of the Johannes-Gutenberg University Mainz, Prof.Dr.med. Michael Palmer, specialist for medical microbiology and infection epidemiology and Ltd.Med.Dir.i.R.Dr. Wolfgang Wodarg, specialist for internal medicine, lung and bronchial diseases, states the following in their expert opinion **(**Doc. **A.20): „Stability of virus infectivity:** The holding times for the process intermediates of the active substance **are currently being determined** by a combination of two different studies; small scale for biochemical holding stability and commercial scale for microbial control. The determination of the holding times is ongoing and must first be validated and compared to the expected maximum holding times that can be applied without loss of infectiousness. The shorter the accepted holding times are, the more unstable the virus is. **Verification of the holding times is important to ensure consistent infectiousness of the virus particles**. A decrease in infectiousness would reduce the cellular uptake of the vaccine, which in turn would cause diminished spike protein production, resulting in little or no immune response. **The vaccine dose would then have no effect. At the time of approval, no verified data on the holding times were available … Comparison of different processes/batches:** Four different

processes were used in the development of the vaccine. According to EMA, processes 1, 2, and 3, which were used to produce the material used in the clinical trials, are comparable. A comparison between these three processes and the commercial process 4 was also provided to EMA, but the acceptance ranges for several attributes were **considered to be too large** and should be tightened as more manufacturing experience becomes available to ensure batch comparability between the processes. However, **the data package needed to assess comparability is not yet complete. It is not acceptable that such essential data should only be required after the approval.** For a new vaccine to be launched, in addition to efficacy and safety, batch-to-batch consistency must also be demonstrated to confirm the reliability of the manufacturing process. This has become a mandatory step in vaccine development and should not be neglected. **Until the final results of such studies are available, the commercial batches should not be considered equivalent...**

Reference standard: There are two different reference standards, one from process 3 and another from process 4, which were prepared from different virus and cell banks. The two reference standards were characterized using different tests, so that the comparability of the two processes cannot be determined. The applicant must now **generate a new reference standard** from a good manufactory practice (GMP) vaccine batch prepared by the commercial process 4. In addition, the applicant should perform a full characterization of the new reference standard including tests to analyse virus identity, virus protein fingerprint, transgene expression stability, and level of aggregated particles in the reference standard qualification protocol. Due to the very high variability of the biological systems used for the production of vaccines, vaccine manufacturers must take special care **to ensure that the different batches of a vaccine are of appropriate consistency** and that the immunogenic activity of each batch is equivalent to that of the vaccine preparation whose efficacy in the target species was originally demonstrated. Consistency can be demonstrated by regularly comparing the different batches with a reference standard that serves as a fixed point of reference in the manufacture and quality control of a vaccine. **Since with AZD1222 there is no well-characterized reference standard, it is not possible to compare the different batches of the vaccine with the reference standard and to check their suitability. Inefficient vaccine batches might then be produced. …**

Shelf life specification and infectiousness of the virus: The final product has a 4-6 fold lower shelf life specification for the concentration of infectious virus particles than the test product used during clinical trials. Infectiousness is of high importance, because only infectious virus particles can induce the biosynthesis of SARS-CoV-2 spike protein and elicit an immune response to it. Until conditional approval was granted, there was **no data produced to demonstrate the efficacy of the current vaccine doses or the acceptable immunogenicity of the commercial batches at the end of their shelf life.** The applicant was asked to clinically justify the shelf-life limit for infectiousness or to increase the shelf-life limit in keeping with the lowest infectious virus dose that demonstrates adequate immunogenicity or efficacy. According to EMA, the results of the clinical trials show that vaccination with only the low dose is less efficient in terms of immune response than is vaccination with a standard dose. A combination of one low and one standard dose did not result in a clear reduction in immune response in subjects relative to two full doses (see below). **The clinical consequences of the use of different doses have not been conclusively determined and the applicant has been asked to investigate this further**. **How can it be that a vaccine has already been licensed, while the efficacy of the commercial batches in terms of adequate immune response has yet to be established with certainty?** It is irresponsible to accept uncertainties in shelf life, since EMA cannot know for how long each batch will be used. Extended

storage obviously might reduce the amount of infectious virus particles to an extent that vaccination would result in little or no immune response....

a) Rhesus macaques (van Doremalen et al, 2020): …The applicants claim that two doses induce a higher IgG titre than a single dose (fig. 2b,c). **Based on the experimental design, this conclusion cannot be drawn; there thus is no experimental basis for the assumption that a double vaccination is necessary. The antibody titre increases with time. It was not investigated whether eight weeks (day 56) after a single vaccination (day 0) the macaques produce as many antibodies as on day 56 after a double vaccination (day 0 and 28) …**

- In the vaccinated group after infection with SARS-CoV-2 there was an unexpected finding of viral RNA in tissues of the gastrointestinal tract 7 days after challenge with SARS-CoV-2. This observation was not present in the group of nonvaccinated animals. In addition, clinical scores were worse in the double-dose study than in the single-dose study. The cause of these observations was NOT determined…

b) Rhesus macaques (study 6284): All data are taken from EMA's report and cannot be verified. The raw data are not published.

- **All but two vaccinated animals were reportedly healthy throughout the challenge** follow-up (days 3, 7, 14) and one animal showed laboured breathing
- Neutralizing antibodies were only seen in vaccinated animals but not in controls and a very high variability was observed. **Therefore, it is currently unclear whether the humoral response is associated with protection.**
- **No difference between vaccinated and control animals was observed in the T cell response**, and the number of activated CD4+ and CD8+ T cells in peripheral blood was even significantly lower in vaccinated animals compared to controls …

According to EMA, the pathology caused by SARS-CoV-2 infection was determined by computerized tomography (CT) scans on Day 5 and Day 12 post-challenge and by histopathology analyses, **but the data provided were insufficient to confirm protection by the vaccine.** Lung histopathology revealed **no clear difference between vaccinated animals and controls,** and disagreement was found in the dossier between data related to scores from the CT scans. As a result of this discrepancy, and considering the limitations of the histopathology determinations, **the reader cannot decide if the pathology assessment in this study is sufficient to prove any protection by the vaccine against the pathology caused by the SARS-CoV-2 infection …In conclusion, many studies showed no or only a slight protective effect of vaccination against an experimental SARS-CoV-2 challenge based on pathological analyses (rhesus macaques, ferrets). Also, the immunological response in the form of antibody formation and cytokine release between the vaccinated groups and unvaccinated groups showed either no or only partial differences. Further, there is a shortage of data on the cellular immune response. Data on Th1/2-biased response and T cell subtyping after vaccination and challenge was rather limited and, in some studies, completely absent. For the T cell responses, only interim data derived from study 20-01125 has been provided, and there is still no final data set available. Since the clinical data, in particular, are the predominant source of uncertainty, it cannot be concluded from these studies that the vaccine AZD1222 has a protective effect against SARS-CoV-2 pathology in animals.**

It must be noted that the animals in these studies were young and healthy. Infection with SARS-CoV-2 is only possible by application of a high viral load directly into the respiratory tract (trachea). Translating this to humans, it is

important to remember that the most vulnerable groups are older and have underlying diseases that make them more susceptible to severe forms of COVID-19. If this vaccine is unable to protect even these young healthy animals from COVID-19 disease, then this raises grave doubts about its efficacy in humans with many comorbidities.It must be noted that the animals in these studies are young and healthy. Infection with SARS-CoV-2 is only possible by infection of a high viral load directly into the respiratory tract (trachea). Translating this to humans, it is important to remember that the vulnerable groups are older and have underlying diseases that make them more susceptible to severe courses of COVID-19. If this vaccine is unable to protect these young healthy animals from COVID-19 disease, then this raises extensive doubts about its efficacy even in humans with many comorbidities....

Risk of inefficacy due to dual use of the same adenovector: In 2004, a vaccine against HIV based on a mix of three adenovectors (Ad5) was developed and used in human trials. Early results indicated that the vaccine was well tolerated, even with repeated intramuscular injections, and was capable of inducing T-cell responses to HIV antigens. However, **after three years**, the study **was stopped** prematurely because subjects in the treatment group had higher rates of HIV infection than subjects in the placebo group. Although several theories have emerged to explain the increased tendency to acquire HIV, none of these theories has been directly investigated, and so this phenomenon remains not yet fully understood. Also in 2009, an Ad5-based vaccine against HIV with different HIV antigens was used in a two-dose human trial that also **ended 4 years later** when the vaccine failed to reduce the rate of HIV infections. The reason for the ineffectiveness was the **use of the same adenovector for both injections**. The new strategies in the field now use heterologous vector pairs and inserts to enhance the T-cell response. These prior observations are consistent with the results of the **clinical trial for AZD1222, which also showed no increased T-cell response after the second vaccination with the same vector. These are only two examples to highlight the importance of carrying out long-term clinical trials, since not only side effects but also the efficacy of a vaccine can only be clearly determined over time. The duration of the AZD1222 clinical trials was far too short to judge long-term efficacy; and furthermore, only very few COVID cases were detected in both the vaccinated and the control groups, so that the reported efficacy is very questionable and varies between studies (44% - 80%) …**

Clinical studies in human trials: This application was supported by four clinical studies: study COV001 (UK, Phase I/II); study COV002 (UK, Phase II/III); study COV003 (Brazil, Phase II/III) and study COV005 (South Africa, Phase I/II).A dose of 5×10^{10} viral particles has been selected based on the experience from studies on a MERS vaccine derived from the same adenovirus vector (ChAdOx1). **A detailed investigation of the optimal vaccine dose for AZD1222 in humans, the required number of vaccine doses, and the time interval for administration of these doses was not performed.** The vaccine dose levels and associated parameters such as the number of injections and the time interval between them that are now being applied in the population **have not been scientifically validated** according to good clinical practice (GCP) and are therefore based solely on **assumptions**. **During the course of the studies important parameters were changed.** There was a modification from a single-dose to a double-dose regimen in the trials COV001 and COV002 and the recommended time interval between injections was also prolonged. The extension of the time interval before the second vaccine dose was based on logistics problems in the production of the vaccine in all 4 studies. This resulted in an extraordinarily large

variation of the effective interval between doses 1 and 2. The interval ranged from 3 to 23 weeks (normally 4-12 weeks). The time interval between the two doses is important for the interpretation of the immune response. Further, the antibody titres were not measured before and after the second dose was administered, **so that no statement can be made concerning the efficacy of or the need for a second dose.** Due to a miscalculated potency of some batches, a number of subjects were inadvertently vaccinated with only half of the intended dose. Therefore, different pools of subjects were created when analyzing the data (affecting 3 out of four studies; COV001, COV002, COV005). One pool had received the standard dose twice (SD/SD), another pool had received a mix of low and standard dose (LD/SD or SD/LD), and the third pool was created as combined LS/SD, SD/LD and SD/SD. **Thus, a valid comparison of vaccine efficacy in terms of dose, timing of administration, and number of doses is not possible from these studies.** A proper clinical trial has **pre-specified, non-variable parameters** that must be strictly adhered to. Such a serious deviation from the protocol within the trial series and the resulting confusion of the individual parameters **must inevitably lead to the disqualification of the studies.** In the pooled study, the **LD/SD group showed better humoral response and vaccine efficacy than the higher dose study SD/SD**. An explanation for this cannot be obtained from the studies, as too many parameters were changed after the start of the study. Therefore, it is not possible to clarify the extent to which this effect can be attributed to the LD/SD dose administered, the time interval between the two doses, or the distribution of other factors between the SD/SD and LD/SD groups. On the basis of the available data, the committee **assumes** that greater protection can be expected with a longer interval between the first and second dose, because higher levels of neutralizing antibodies were induced when the second dose was administered after longer intervals. Nevertheless, it cannot be completely excluded that the variation in the response was caused by different dosage regimen (LD/SD vs. SD/SD) rather than different timing. For the analysis of the immunogenicity of the vaccine, only COV002 and COV003 were taken from the 4 studies conducted and pooled together. In those studies, an approved MenACWY vaccine was administered as control and **study personnel was not blinded to the vaccine** to be administered. Also, **efficacy could not be demonstrated in subjects older than 55 years of age** due to the low number of COVID-19 cases in this age group (8 cases in the AZD1222 group and 9 cases in the control group in subjects 56-65 years, and 2 and 6 cases in the vaccine and control group in subjects <65 years of age). Efficacy against asymptomatic infection could not be demonstrated.

In conclusion, at the time of approval, no evidence was available to support the need for a booster dose or the induction of protective immunity in old people by the vaccine. Moreover, evidence was lacking regarding the activity against emerging SARS-CoV-2 variants. In a new study in February 2021, dual dosing of ChAdOx1-nCoV19 was shown to confer no protection against mild and moderate Covid-19 due to the B.1.351 variant. Whether the vaccine protects against severe disease caused by this variant could not be determined in this trial. Likewise, no firm conclusions can be drawn about vaccine efficacy in terms of dose amount and timing of administration."

86. 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 colonization with the pathogen SARS-CoV-2 or against transmission of the pathogen to other persons. Therefore, despite vaccination, it is necessary to protect oneself and one's surroundings by observing the AHA + A + L rules (spacing rules, MNS)." (Doc.* **A.21**).

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

88. **2.1.2 <u>Significant risks not identified and therefore 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 under appeal here (**Doc. **A.2.2),** point 4.5 **<u>(Interactions with other medicinal products and other interactions*), "no interaction studies have been conducted."</u>**
Considering the fact that the so-called. Covid "vaccines", such as "COVID-19 Vaccine AstraZeneca", are intended to be used on the general population, and a considerable proportion of the population regularly consumes one or more drugs, **the fact, that the interactions of "COVID-19 Vaccine AstraZeneca" with other drugs have not been tested, must lead to the conclusion that the risks emanating from "COVID-19 Vaccine AstraZeneca" 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 marketing authorization!

91. **2.1.3 <u>Failure to take into account essential risks that never allow a conditional approval of a drug intended for a basically healthy population.</u>**

92. Substantial risks associated with the administration of the active ingredient "COVID-19 Vaccine AstraZeneca" were already submitted to the EMA with a petition submitted on 01/12/2020 by Dr.med. Wolfgang Wodarg and Dr. Mike Yeadon concerning the then imminent approval of the first experimental genetic engineering based Covid "vaccine" produced active ingredient "Comirnaty" by BioNTech (Doc. **A.22.**). Unfortunately, this petition was ignored, as was the warning letter (Doc. **A.4**) also sent electronically by plaintiffs to the EU Commission and the EMA on December 19, 2020.

93. The scientific opinion written by the four experts (Doc. **A.20**) states the following with regard to omitted studies and not considered risks of administration of the active substance "COVID-19 Vaccine AstraZeneca":

94. **<u>“No tests for adventitious agents were performed:</u>**
With regard to the *in vivo* **test for unrelated (adventitious) biological agents, the applicant requested deletion of the necessary tests. EMA agreed to this, citing the need to bring the overall number of animal tests in line with the regulatory 3R considerations** (replacement, reduction and refinement in relation to animal use). However, prior experience shows that in the manufacture of biological products the possibility of adventitious agents must be taken seriously. In a number of cases, adventitious agents occurred in a marketed product. Examples are the monkey virus SV40 in polio vaccine, bacteriophages in measles and polio vaccines, and reverse transcriptase activity contamination by an unrecognized avian retrovirus in measles, mumps and rubella (MMR) vaccine as well as porcine circovirus and porcine circovirus DNA sequences in rotavirus vaccine. Since AZD1222 is produced with biological materials, **there is a need to protect against possible contamination with adventitious pathogens.** The World Health Organization (WHO) defines adventitious agents as microorganisms that may have been unintentionally introduced into the manufacturing process of a biological medicinal product. These agents can include bacteria, fungi, mycoplasma/spiroplasma, mycobacteria, rickettsia, protozoa,

parasites, transmissible spongiform encephalopathy (TSE) agents (prions), **and viruses**. Adventitious pathogens could be inadvertently introduced into a vaccine through the starting materials used for production. Therefore, **extensive testing during vaccine production is recommended to demonstrate their absence**. However, the purification procedures used for live viral vaccines must necessarily be rather gentle and may not permit the comprehensive, reliable elimination of other live microbes. **An adventitious agent can only be detected in a vaccine when thorough tests *in vitro* and in animals are performed** to determine its nature and origin. It will also be necessary to evaluate its potential for human infection and pathology, and to identify the vaccine lots affected in order to take risk mitigation measures. To accomplish this, archived samples of each batch of the vaccine are needed. **These tests are vital for human health, and it is not acceptable to skip them in order to reduce the number of animal tests…**

Control of impurities: Various intermediates are generated **without established acceptance criteria or limits regarding the removal of process-related impurities**. Several impurities are known in these intermediates, e.g. residual host cell DNA, host cell protein, and nucleases. **At the time of approval, the protocols did not specify any limits for process-related impurities. The applicant is unable to provide this information because the limits have not yet been validated.** However, since most impurities will be tested in the active substance, this approach was accepted by EMA. The applicant indicated that the parameters will also be monitored and reviewed during the validation studies once sufficient manufacturing experience has been gained …

Non-clinical aspects …**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 **extremely important to know how the drug affects the organism**, in ways unrelated to the **Safety pharmacology: Some** safety pharmacology investigations 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. **Pharmacodynamic drug interactions: No studies** on pharmacodynamic drug interactions have been performed. This means that there are no studies available concerning the **behaviour of the vaccine** on an organism that shows physiological **changes due to diseases, genetic mutations, aging or the influence of other drugs**. … **Primary pharmacodynamic studies**: … **Due to the experimental design, a comparison between studies with one dose vs. two doses cannot be performed. The antibody titre increases with time. It was not investigated whether seven weeks (day 49) after a single vaccination (day 0) the subjects produced as many antibodies as on day 49 after a double vaccination (day 0 and day 28). In the single-dose study, the challenge with SARS-CoV-2 occurred on day 21, whereas in the double-dose study it occurred on day 49. There was no formal negative control, i.e., there was no unvaccinated group used as comparison … Mice (study 1, van Doremalen *et al.*, 2020): …** high IFN-gamma immune response (Th1 response) in vaccinated and non-vaccinated group **with no differences between both groups …** low IL-4 and IL-10 immune response in vaccinated and non-vaccinated group **with no differences between both groups. Not all data points of investigated animals were plotted in the figure 1 for immune response.** For example, vaccine group 1 (fig.1a) with 5 animals was reduced to 3 animals (fig. 1b); vaccine group 2 (fig.1a) with 8 animals was reduced to 5 animals (fig. 1b). There is no explanation why some data points were excluded from the graphs. **If no antibody titre was observed in some animals within the vaccinated group, then this must be**

indicated … Pharmocokinetics (PK) Pharmacokinetics comprises the absorption, distribution, metabolism, and excretion of a drug (ADME for short). These parameters control the availability and utilization of the drug – or here, the vaccine – in the organism. In ADME studies, one examines how the vaccine is absorbed, distributed in the body, degraded by metabolism, and ultimately excreted. All four parameters affect the strength and timing of the vaccine's effect on cells and tissues. It is not acceptable for EMA to claim that ADME studies are not relevant to the development and licensing of a new vaccine. **With the exception of some experiments concerning distribution, which did not use the vaccine itself but some related recombinant virus constructs (see below), no ADME studies have been performed. A vaccine which uses 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….**Distribution study: … The viruses were found in all tissues examined. There were no investigations done on the central and peripheral nervous systems and bone marrow. Based on the presence of the virus in all analysed tissues, it must be assumed until proven otherwise that the vaccine also enters the nerve tissue and bone marrow with potential unforeseeable adverse effects.** … **It has not been investigated how long the viruses persist in the body. Also, a non-validated PCR test was used for the detection of the viruses …Study 514559:** This **is the most important study,** since the mice will get a single intramuscular (IM) dose of the **original AZD1222** vaccine and tissue analyses will be made also at early time points up to day 29 after injection. The study will detect virus DNA by a **validated** quantitative PCR method. More tissues including bone marrow from the left femur, brain, spinal cord and sciatic nerve will be examined. **It must be emphasized that this study is of high relevance and pivotal. At the time of approval, these data were not yet available, and there thus was no information on which tissues the vaccine enters or which organs the viruses affect, how long they remain in the body, and how they are degraded.** Indeed, DNA persistence was shown in various other published preclinical studies that demonstrated the presence of the vectors of DNA vaccines for **up to 2 years upon IM injection** with low but detectable expression and immunogenicity in a mouse model….**Toxicology: … The assessment report does not provide any detailed information about what exactly has been investigated. They refer to the positive results of other studies that have taken the same ChAdOx1 vector but a different insert (not SARS-CoV-2 spike protein) or to studies with another adenovirus (AdCh63). Transparency regarding the results of the altered blood parameters could help better understand whether the thrombosis that occurs in some of the vaccinated people is due to the vaccine. No such blood parameters were determined in the subjects during the clinical phases either. In this context, we must note that there is reason to believe that the SARS-CoV-2 spike protein itself causes adverse effects on blood coagulation; therefore, model studies that pertain to the vector only but not to this specific insert are inherently incomplete. … Death in gene therapy in a human clinical trial:** In the year 1999, researchers at the University of Pennsylvania investigated the first death in a gene therapy phase I experiment. They used a replication-defective adenovirus, Ad5-vector, deleted in viral genes E1 and E4 (injection: 6×10^{11} virus particles) to deliver potentially therapeutic DNA to the liver. Approximately 18 hours later, an 18 years old subject was noted to have altered mental status and jaundice. The subsequent clinical course was marked by **systemic inflammatory response syndrome, biochemically detectable disseminated intravascular coagulation, and multiple organ system failure,**

leading to death 98 hours following gene transfer. Post-mortem examination was consistent with the clinical course, and **vector DNA sequences were readily detectable in most tissues**. The subject had shown high serum levels of IL-6 and IL-10 but normal TNFα immediately after infusion of the vector. **This experience points to the limitations of animal studies in predicting human responses.** Further studies are absolutely necessary to gain a better understanding of the immune response and toxicity of replication-defective adenovirus vectors and also to understand the substantial differences between subjects in host response to systemically administered vectors. **Based on current knowledge, it is irresponsible to already administer adenovirus-based vaccines such as AZD1222 to healthy people – particularly on such a large scale as has been done since immediately after the approval. Risk of recombination with wild type viruses:**
Clinical use of adenovirus vectors could lead to recombination of DNA with wild-type viruses when the vector enters cells already infected with other viruses of the same family. This could make the replication-defective vaccine adenovirus replication-competent again. The result would be replication and spread of the vaccine virus in the body and the risk of disease, which might even be transmissible – including to people in whom the vaccination is contraindicated. **Adenovirus-mediated occurrence of thrombi and thrombocytopenia:** A former study examined the occurrence of thrombosis after adenovirus-mediated gene transfer into normal and atherosclerotic arteries. A replication-deficient adenovector expressing the β-galactosidase reporter gene was injected into normal and atherosclerotic arteries. Animals were examined for thrombi and for the presence of β-galactosidase activity 3 days after the injection. When injected with buffer only, thrombus formation did not occur. In contrast, **nonocclusive thrombus was present in atherosclerotic arteries exposed to replication-deficient adenovirus.** β-galactosidase activity was found predominantly in the endothelial layer of the transfected arteries. Thrombi were formed whether or not the adenovirus possessed a transgene. **This experiment clearly demonstrates that thrombus frequently occurs in atherosclerotic arteries after adenovirus-mediated gene transfer.** In a preclinical study in rhesus monkeys, administration of a replication-incompetent adenovirus vector was shown to reduce platelet counts and platelet half-lives in a dose-dependent manner. Injection of 6×10^{12} particles /kg resulted in a severe thrombocytopenia (reduction of the platelet count by up to 90%) and a decrease in platelet half-life from normally 111 hours to 22 hours. Another study in the same animal species with administration of $1x10^{13}$ particles of an E1-deleted recombinant adenovirus or a virus that had been rendered replication-incompetent by UV irradiation also showed severe thrombocytopenia and evidence of disseminated intravascular coagulation. The same was observed in rabbits after injection of 5×10^{11} infectious adenovirus particles/kg. A reduction of platelets by 80-90% was measured within 48 hours. Also, clinical studies using adenoviral vectors for gene therapy have demonstrated thrombocytopenia. For example, injection with 10^{10}-10^{13} adenoviral particles encoding a thymidine kinase gene in patients a metastatic liver tumors showed grade 1 thrombocytopenia in 6 of 16 patients (38%) and grade 3 in 1 subject (6%). In a phase I clinical trial on the intra-tumoral injection of 10^{12} adenovirus particles expressing heat shock protein 70, two patients developed thrombocytopenia (7%), with one classified as grade 4.How adenovirus particles trigger thrombi and thrombocytopenia is still poorly understood. Some studies have demonstrated that adenovirus can bind directly to platelets and trigger their activation and aggregation both *in vitro* and *in vivo*. Activated platelets contribute to blood clotting both through mutual aggregation and through facilitating, on their cell surfaces, membrane-dependent reactions of the plasmatic coagulation cascade, ultimately resulting in fibrin activation and aggregation. It was determined that **platelet**

activation occurs rapidly after incubation with human adenovirus Type C5 (HAdv-C5) and that platelets express HAdv-C5 attachment receptor, CAR, suggesting that direct HAdv-C5 binding to CAR on platelets may be responsible for virus-mediated platelet activation. Secondly, the highly efficient binding of coagulation factor X to HAdv-C5 was also shown, which suggests a mechanism for the direct activation of the plasmatic coagulation cascade, with possibly devastating consequences. Also, different knockout (KO) mouse models helped to identify the function of specific host factors in the development of thrombocytopenia. Adenovirus injection in von Willebrand factor (VWF) KO mice did not show significant thrombocytopenia compared with wild-type mice. The formation of a thrombus involves numerous elements, including endothelial cells, platelets, plasma proteins, and shear stress changes. In the circulation, once a vessel wall is injured, collagen is exposed, which causes platelets to get activated and accumulate at the site of injury. VWF mediates platelet adherence to the injured vessel wall by binding to both the collagen and the platelet receptor. Activated platelets also recruit leukocytes. Fibrin and fibronectin are produced and cross-link together to form a protein plug to stop the blood loss. The VWF-KO study showed that adenovirus interferes with adhesion of platelets to a fibronectin-coated surface and thrombocytopenia occurs through platelet-leukocyte aggregate formation on endothelial cells. **Such uncontrolled activation and recruitment could lead to thrombosis, tissue damage, and loss of organ function.** The absence of thrombocytopenia in mice deficient in complement factors C3 and B also suggests a role of the complement system in this phenomenon. On March 18 2021, a letter concerning the gene therapy drug Zolgensma raised a red flag. This gene therapy drug is intended to cure spinal muscular atrophy. The letter is alarming because it reports several cases of thrombotic microangiopathy (TMA). The gene delivery method used for Zolgensma is essentially the same as that used with the AstraZeneca vaccine, with an only slightly different virus, namely the non-replicating recombinant adeno-associated virus serotype 9. Thrombotic microangiopathies (TMA) are a heterogeneous group of disorders that include hemolytic uremic syndrome (HUS) and thrombotic thrombocytopenic purpura (TTP). The incidence of thrombotic microangiopathy in children is estimated at a few cases per million per year. It is an acute and life-threatening condition characterized by **thrombocytopenia**, hemolytic anemia and acute kidney injury. Since gene therapy was approved for the treatment of children with spinal muscular atrophy, five confirmed cases of TMA have occurred in the approximately 800 children treated worldwide to date. **The novel method of introducing genetic material into human cells via adenoviruses or adeno-associated viruses appears to cause dangerous side effects, the causes of which are not at all clear. While such risks might be acceptable in otherwise incurable conditions such as spinal muscular atrophy, it is absolutely irresponsible to impose them on healthy people who have little or no risk to ever experience a severe course of COVID19. <u>Spread of antibiotic resistance genes:</u>**Due to the manufacturer's lack of transparency, it is not clear to the public whether the DNA vector of AZD1222 contains an expression cassette for an antibiotic selection marker. Typically, such vectors have not only the viral genome and the gene of interest with regulatory sequences, but also sequences required for propagation in bacteria, such as a bacterial origin of replication and selection markers. The selection marker is often a gene that confers antibiotic resistance. Regulatory agencies recommend removing it when producing vectors for therapeutic use. **If AZD1222 has an antibiotic resistance gene, this gene will be spread among the vaccinated population; it may then be transmitted to pathogenic bacteria and render them resistant to the antibiotic in question. …**

Genotoxicology: No studies on genotoxicology have been performed. EMA maintains that such studies are not relevant to viral vaccines, since no adjuvants or novel excipients are used in this product…. **The EMA's decision not to demand genotoxicity studies is irresponsible and incomprehensible.** Compared with other viral gene delivery systems, adenoviral viruses can infect most human dividing and nondividing cells for delivering genes *in vivo*, since almost all cells express the primary adenovirus receptor (CAR) and the secondary receptor integrin. If we accept AstraZeneca's premise that AZD1222 will follow a distribution pattern similar to that of the related HBV-encoding vectors (see Study 0841MV38.001, above), we must expect that the vaccine AZD1222 will be found in all tissues studied; accordingly, the genotoxic effects may also occur in many cell types and organs. It has been known for over 30 years that **foreign (viral) DNA can integrate into the genome of mammalian host cells.** These interactions are of interest not only in tumor virology and gene therapy, but also for the role of viral DNA as an evolutionary mechanism. Thus, it has been scientifically demonstrated in many ways that adenoviruses introduce their genetic material into the DNA of human cells via both non-homologous and homologous recombination. **The site of viral integration into host cell DNA cannot be controlled.** There are more than 70 different adenovirus-transformed cell lines that show non-identical patterns of viral DNA insertions into the host genome. In this context, hamster, mouse, rat, and human systems were studied *in vitro;* from the evidence, no highly specific sites of viral DNA insertion into the cellular genome could be deduced. However, in several cases, the cellular nucleotide sequences near the insertion sites were not altered, and many of these cross-over sites between adenovirus and cellular DNA are now known on the basis of the nucleotide sequences. **It should be emphasized that all integration sites in the host cell genome are shown to be transcriptionally active.** The resulting genotoxic effect can be manifested in many ways: a) **Gene inactivation:** Insertion may occur within a gene and disrupt it. This can lead to the loss of important cellular gene products (i.e., proteins) and thus, potentially, to the development of disease including cancer. b) **Gene activation:** Viral promoters and insertion of viral DNA in regulatory elements of genes may increase the transcription rate of genes. This, too, may lead to the formation of cancer cells, which may mature into clinically manifest tumors. Today, viral DNA integration is an important paradigm in tumor biology. c) **Gene regulation:** Transcriptional and epigenetic regulation mechanisms may be affected, thus up- and down-regulating protein expression levels with unpredictable and undesirable results. d) **Chromosomal damage:** Another very important observation of adenovector integration in cells is the occurrence of genome damage such as deletions of whole chromosome parts and rearrangement of genes. This tends to have particularly strong and disastrous consequences which exceed those of activation or inactivation of single genes in severity. e) **Autoimmune-like disease:** Integration of the spike protein gene into the host cell could lead to permanent expression of this antigen, and thus promote the risk of autoimmune-like disease. - The occurrence of malignancies through DNA integration and oncogene activation has been demonstrated, for example, in a clinical trial with a retroviral vector for the treatment of children with SCID-X1 (severe combined immune deficiency). **Therefore, thorough and long-term investigations concerning possible genotoxic effects by chromosomal integration in the pre-clinical and clinical trial stages are absolutely necessary for a proper and valid benefit-risk analysis of gene transfer vectors like the vaccine AZD1222.** Detailed information on genotoxicity after gene transfer is already available for vectors derived from viruses of the Retroviridae and Parvoviridae families. Between 60% and 75% of integrations of retrovirus-, lentivirus-, or adeno-associated virus (AAV)-based vectors **occur within or near genes**. There are only few studies on chromosomal integrations

of adenovector DNA after gene transfer in cell cultures, and even less is known about adenovector integration *in vivo*. **It is irresponsible to use an adenovirus vector as a vaccine on humans when so little scientific data is available**. Even though the regular adenovirus life cycle is extrachromosomal, **it is dangerous to assume that adenovectors will never integrate into the cellular genome; there are no studies to prove this point.** On the contrary, in previous ***in vivo*** studies it was shown that injection of hamsters with **wild-type adenovirus type 12 (Ad12) resulted in tumor formation due to chromosomal integration of the virus DNA and the expression of cancer-promoting proteins.** A previous study demonstrated vector integration into cells *in vitro* with a frequency between 10^3 and 10^6 for homologous and between 10^3 and 10^5 for heterologous recombination per cell. Since clinical gene transfer trials, including prophylactic vaccination of healthy volunteers against infectious diseases, generally involve the injection of as many as 10^{10} - 10^{13} virus particles, **we must necessarily expect that even at these low integration rates a substantial number of integration events of adenoviral vector DNA will occur *in vivo*.** The cited study claims that half of the integration events occurred within genes. **Preferential integration of viral DNA within active genes was observed in all vector systems tested so far.** Another recent study now proves in a **living animal model that adenovector integration also occurs *in vivo* in mouse liver cells.** The analysis of homologous and heterologous recombination events between adenovector DNA and chromosomal DNA in liver cells revealed numbers of 10, 3.2, and 0.45 vector genomes per cell when injected at $1x10^{10}$, $2x10^9$, and $5x10^8$ viral particles, respectively. Two-thirds of these integrations involved liver cells and one-third other cell types. The average integration rate of the adenovector into mouse chromosomal DNA was calculated to be $6.72x10^{-5}$/viral particle/hepatocyte for heterologous recombination and $3.89x\ 10^{-7}$/ viral particle/hepatocyte for homologous recombination. This means that out of 14880 adenovector particles, 1 will manage to integrate its genome into chromosomal DNA by heterologous recombination; the same will occur and out of 2.6×10^6 adenovector particles, 1 vector genome integrates into chromosomal DNA by homologous recombination. … The mechanism of insertion of foreign DNA into mammalian cells is not yet understood at the molecular level. There thus is a need for further research to understand these integration processes prior to approval of any vaccines based on DNA vectors. Currently, researchers mainly focus on the following topics: a) What are the characteristics of the chromosomal sites that are targeted by the insertion of foreign DNA, and at which sequence motifs does the foreign DNA recombine with cellular DNA? b) Is insertion random or not? c) What cellular or viral factors facilitate foreign DNA insertion? d) What are the effects of the inserted genes on the expression of host genes adjacent to the inserted DNA, or on the expression of genes located at more distant sites? **All of these questions have a direct bearing on the approval of the AZD1222 vaccine, but they cannot currently be answered.** In particular, the persistence of the vector DNA is unknown. P**reclinical studies after injection of plasmid pSO2C1 have shown the presence of episomal DNA for up to 2 years upon IM injection with low but detectable expression and immunogenicity in a mouse model.** According to the FDA, DNA persistence is not generally evident at ectopic sites in biodistribution and persistence studies, but remains detectable at the injection sites for periods exceeding 60 days. **Such long-lasting presence of foreign DNA in the nucleus of transfected cells increases the risk that it will ultimately integrate into the host chromosomes, and therefore the long-term risk of mutagenesis and oncogenesis.**To determine the toxicity of the DNA vector itself**, the long-term risk profile of such a gene therapy product should also take into account** the target cells, tissues and organs, as well as the patient population (age, immune status, mortality risk, etc.) and relevant disease

characteristics. Integrating gene therapy vectors can persist in the body over the life-span of the patient's transduced cells. According to a report entitled "Long term follow-up (LTFU) after administration of human gene therapy products; guidance for industry" (January 2020) by the Food and Drug Administration (FDA), leukemias have been reported in more than one trial where subjects received cells that had been genetically modified *in vitro* using gammaretroviral vectors. Advances in analytical approaches for integration site analysis in patient samples collected during LTFU have provided some insight into the possible mechanisms involved in the occurrence of **such delayed adverse events**. Such risks can be mitigated through improvements in vector design and the duration and design of LTFU observations. **In keeping with the generic FDA recommendation, a preclinical study in a relevant animal species should also have been performed with AZD1222 in order to assess the persistence of the vector DNA in cells of different tissues, since it is currently unknown how long this gene therapy product persists in the host after injection.** If there is evidence that the product is integrated, all clinical protocols should include LTFU observations for appropriate human subject protections. Only after completion of such a study could one reliably assess the risk of delayed side effects. In the absence of such specific information, some extent of adenovector insertion into the genome of host cells must be considered likely, for reasons that were discussed above. In this context, we note that the applicable FDA recommendation states that **for gene therapy products that can integrate into the genome, a long term observation study (LTFU) of up to 15 years is necessary, including the investigation of new clinical conditions such as new malignancies or hematological disorders, new incidence or exacerbation of a pre-existing neurologic disorder, rheumatologic or other autoimmune disorder, or potentially product-related infection. None of this has been done with AZD1222.** According to the FDA, gene therapy products derived from adenoviruses generally have a low risk of delayed adverse events. If only severely sick people are treated with such a gene therapy product, the risk-benefit ratio may well be acceptable, because the people so treated may subsequently recover from his/her´s disease. Typically, such treatment is contemplated and tried only on individuals with severe disease, for which no better conventional treatment is available. **But now millions of healthy people are to be vaccinated with the adenovector. Here, the risk of a previously healthy person getting a late adverse event is no longer proportionate and acceptable. <u>Carcinogenecity:</u> No studies** on carcinogenesis have been performed. EMA claims that such studies are not relevant for viral vaccines since no adjuvants or novel excipients are used in this product….**However, as discussed above (see section: genotoxicity), the EMA's decision not to demand carcinogenicity studies is not acceptable and must be categorically rejected. <u>Reproduction test (DART)</u> …**The main DART study in mice which should provide a definitive developmental and reproductive toxicology result is ongoing (study 490843). **There are no definitive data available yet. The results of this study are necessary for the final assessment of reproductive toxicology, and accordingly the final report will be provided by the applicant only post-authorisation. The lack of such data before approval represents another unacceptable risk.** …**<u>High risk of antibody-dependent enhancement:</u>** Antibody-dependent enhancement (ADE) of infection has been observed with several virus species. ADE can also be induced by antiviral vaccines, which will then cause these vaccines to aggravate rather than mitigate the corresponding viral infections. In 2005, the first SARS vaccine was developed using a modified poxvirus vector with the complete SARS-CoV viral spike protein and tested in Chinese rhesus monkeys. In 2019, another study was conducted on this vaccine. It was found to induce the production of large amounts of neutralizing antibodies shortly after injection. Although

these antibodies can effectively reduce viral load in the upper respiratory tract, they also enhance lung injury. **A positive correlation was found between the concentration of neutralizing antibodies in the serum and the degree of pathological damage in the lungs.** Further studies revealed that the virus enters macrophages with the help of Fc receptors (FcRs). FcRs are mainly distributed on immune cells and are receptors that target Fc moieties on antibodies. In this FcR-mediated ADE, the viral surface protein and the specific antibody induced by it form a virus-antibody complex. **The complex enhances viral adhesion through the interaction of the antibody´s Fc part with its receptor on the surface of specific cells.** There are two main types of macrophages. One is the classically activated macrophage (M1), whose main function is to secrete proinflammatory factors and mediate host defense against various bacteria, protozoa, and viruses. This type of macrophage has a strong ability to kill microorganisms. However, its activity also tends to cause tissue injury. Another type of macrophage is the alternatively activated macrophage (M2), which in most cases has anti-inflammatory functions and regulates wound healing. **It was shown that antibodies against SARS-CoV spike protein alter the function of M2 macrophages by binding to these cells' FcR.** Endocytosis of viral protein and immunodepression of these macrophages are thereby attenuated, while **cytokine expression increases**. **The macrophages, which were supposed to repair lung injury, are thereby transformed into cells that promote inflammation.** SARS-CoV and SARS-CoV-2 are highly homologous, with 80% sequence identity at the genome level, and the viral receptor for both is ACE2. Moreover, the severe cases in Hubei Province, China and in other areas were noted to have been due to ADE. **Thus, further studies are urgently needed to clarify the possible causation of ADE by antibodies against SARS-CoV-2 spike protein induced by vaccination**

… <u>Risk of coagulopathies due to an autoimmune attack.</u>

Coagulopathies are predictably the gravest immediate risk common to all gene-based "vaccines". Massive thromboembolic events must be expected to occur within the circulation and may be followed by disseminated intravascular coagulopathy (DIC) syndrome characterized by haemorrhagic diathesis and profuse bleedings. Several independent pathways may converge to cause these potentially fatal events. 1. **Autoattack of the immune system on spike-producing endothelial cells.** Once the "vaccine" enters the bloodstream, it will remain entrapped within the circulation and have a high propensity to enter endothelial cells that line the vessel walls. This uptake likely occurs most effectively at sites of sluggish blood flow, as has been shown with model studies on lipid nanoparticles. As will also be the case with mRNA COVID 19 vaccines, the spike proteins produced at the luminal cell surface are expected to be recognized by $CD8^+$ lymphocytes that are cross-reactive against other coronaviruses. In the most extensive published study, lymphocytes from 185 cryopreserved blood samples drawn before 2019 were examined, and cross-reactive $CD8^+$ cells were found in 70% of the donors. Less than 10% of the lymphocytes in the body are present in the circulation, the rest residing in lymphoid organs. **It can therefore be assumed with fair confidence that cross-reactive lymphocytes are prevalent in virtually all healthy adults.** This is borne out by another study wherein the presence of SARS-CoV-2 reactive lymphocytes was assessed in individuals with recent COVID 19 infections. Remarkably, reactive lymphocytes were detected in all patients, even in mild cases of the disease. The **first encounter of the naïve immune system with a truly novel virus would not produce such a rapid and vigorous CD8-response; thus, the observations can be taken as evidence of a secondary (boost) immune response.** The consequences are likely profound. Reactive $CD8^+$ lymphocytes residing in the lymphoid organs will be recruited to attack the spike-

producing endothelial cells. **Platelets will bind to and become activated at the resulting sites of vessel damage, triggering clot formation.** This will occur in an entirely unpredictable fashion, presumably in the smallest vessels and veins, and to unpredictable extent, depending on the immune status of an individual. Counter-intuitively, the severity of these events may be inversely proportional to the "fitness" and immune reactivity of the lymphocytes. In this context, priming and boosting of immune reactivity may intensify subsequent reactions in the context of both infection and "re-vaccination". Some of the worst reactions might be avoided by testing the immune status of patients before vaccination, but such recommendations have not been given with any of the recently approved recombinant vaccines. Moreover, to the extent that the second injection is effective, adverse reactions of this kind might also be more severe … 2. The spike protein appearing on the surface of the endothelial cell itself must be expected to bind to the ACE2 receptor expressed on platelets, which will lead to their activation and clot formation. 3. It has been shown that the spike protein molecules produced in excess are liberated from SARS-CoV-2 infected cells, entering the circulation of the patients to be deposited at distant sites. Their attachment to endothelial cells then triggers activation of the complement system with resulting damage to the vessel wall. 4. The AZ-"vaccine" has been found to induce formation of unique autoantibodies that bind to and activate platelets in the circulation. 5. It was already noted above that adenoviruses in general have a tendency to activate blood platelets; in the case of the AZ "vaccine", this will compound the effects of the SARS-CoV-2 spike protein. **In sum, the "vaccine" must be feared to vigorously promote vascular injury and clot formation in small vessels and veins throughout the body via multiple pathways. The severity of these events must be expected to vary substantially between individuals, depending on the level of their previous immunity to SARS-CoV-2, but also on happenstance – if the needle slices a blood vessel during intramuscular injection, a much larger than usual amount of the vaccine may enter the circulation directly, with proportionally more intense expression of the spike protein within the circulation. Not a single possible pathway leading to the potentially devastating event has been examined, let alone excluded, in any preclinical animal experiments. However, since the approval of the "vaccine", numerous cases of thromboembolic events and DIC have been observed in vaccinated individuals, which motivated the transient suspension of its use in as many as 15 countries, many of them EU members."**

95. **The risks pointed out by the experts are serious.**

96. **Up to 20/03/2021,** about **80,000 cases of side effects, about 54,000 serious side effect cases (420 registered deaths),** about **34,000 serious side effects on the nervous system were listed** in the official database of the EU regarding "COVID-19 Vaccine AstraZeneca"**.** As already noted under the premises, most EU countries had suspended the use of "COVID-19 Vaccine AstraZeneca" due to repeated serious adverse reactions resulting in death. However, **the European Medicines Agency (EMA) confirmed the positive recommendation for the continuation of the approval of "COVID-19 Vaccine AstraZeneca" at very short notice (an adequate review is hardly possible) and based on an objectively not comprehensible claim of a positive benefit-risk ratio.**

97. It is in no way comprehensible how the EMA can insist on its recommendation for the conditional approval of "COVID-19 Vaccine AstraZeneca", despite the fact that serious side effects with fatal consequences have already occurred, especially against the background that this substance is to be used on the entire population. **This grossly violates the precautionary principle enshrined in EU law, the fundamental right**

<u>of EU citizens to physical integrity (Art. 3 EU Charter), and the Union's obligation to guarantee the highest standard of safety in health care (Art. 168 TFEU).</u>

98. **On February 28, 2021, a group of twelve international experts wrote to the EMA asking it to comment within 7 days on serious substantiated risks posed by genetically engineered substances such as "COVID-19 Vaccine AstraZeneca" and, if the concerns cannot be allayed, to immediately withdraw the recommendation for conditional approval of these substances (**Doc. **A.22).** 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."

99. The scientific opinion attached to this application (Doc**. A.20)** deals in detail with the problem of **coagulation disorders, which could be caused by "COVID-19 Vaccine AstraZeneca".** There are several mechanisms involved. Some of these also involve the mRNA-based vaccines, but in the case of the AstraZeneca "Covid vaccine" (or "AZ vaccine" for short), there are additional risks associated with the nature of the adenovirus vector used here. Clinically, these coagulation disorders can take several forms: Acute occlusion of single large vessels, manifesting usually as myocardial infarction, stroke, or thrombosis; diffuse occlusion of many small vessels with subsequent organ failure; or consumption of platelets (thrombocytes) and plasmatic coagulation factors, with subsequent uncontrolled internal bleeding. This latter clinical picture is called consumption coagulopathy. Thus, it was in no way surprising to experts that after the introduction of the AZ "vaccine," reports of severe coagulopathy became more frequent, especially in younger people. Such reports prompted 15 countries, mostly EU members, to suspend their AZ "vaccination" program. An official investigation of such cases by the EMA followed, the results of which were announced by the EMA on March 18, 2021 (Doc. **A.2.4**. + Doc. **A.26**) The bottom line: at this time, the EMA believes that, despite the potential to cause blood clots, the benefits of AstraZeneca's vaccine would outweigh the risks and therefore recommends that vaccinations continue."

What was the basis for this decision? **The EMA had examined available data on two life-threatening conditions that occurred within 14 days of "vaccination." Consumptive Coagulopathy (5 cases) and Cerebral Sinus Vein Thrombosis (18 cases). Of these 23 total cases, 9 were fatal. Among the affected patients, 17 were younger than 50 years, including 12 patients with cerebral venous thrombosis and all 5 patients with consumptive coagulopathy. EMA also presented the numbers of cases of both conditions that would have been expected on average in the relevant sample and time period: 1.3 cases of cerebral venous thrombosis, and "less than 1 case" of consumption coagulopathy. <u>Thus, the EMA acknowledged that an association with vaccination could not be completely ruled out for these very rare conditions.</u> However, given that 20 million had been "vaccinated," the EMA postulated that the benefits far outweighed the risks.**

In reality, the EMA press release made it clear that the AZ "vaccine" has the potential to cause intravascular clotting, that the true risks far outweigh the theoretical benefits, and that any agency with the slightest sense of responsibility must suspend its continued use.

The following rationale is presented in this regard:

1. According to incidence figures published by the EMA for <50-year-old individuals in the "vaccinated" versus normal population, the risk of

cerebral venous thrombosis was increased by a factor of 9 (12 cases observed, 1.3 expected). Such clustering cannot be explained as chance (p<0.01).

2. For consumption coagulopathy, the EMA gives the expected value only as "less than 1". This is a grossly misleading representation. Consumptive coagulopathy never occurs for no reason in otherwise healthy individuals - it always underlies another serious illness, such as meningococcal sepsis. In otherwise healthy individuals, the only plausible expected value is 0, and therefore the ratio of observed to expected cases is infinitely high. Thus, there can be no doubt that these cases were indeed caused by the AZ vaccine.

3. Both consumption coagulopathy and cerebral venous thrombosis are normally rare events, and the absolute numbers of cases were not high even among those injected with the AZ "vaccine." **However, there is absolutely no reason to believe that these two diseases were the only manifestations of vaccine-induced coagulation disorders. Disease patterns such as myocardial infarction, stroke (thromboembolic or hemorrhagic), and deep vein thrombosis (often followed by pulmonary embolism) are disproportionately more common spontaneously, so their occurrence among vaccinated individuals will not necessarily arouse suspicion. However, until proven otherwise, it must be assumed that these diseases will also occur more frequently after vaccination. <u>It is therefore grossly misleading to include only the two already sufficiently documented but rare clinical pictures when weighing the benefits and risks of the vaccine, and to exclude these possibly much more frequent consequences.</u>**

4. <u>Even if we follow the EMA and consider only the two rare clinical pictures, a rough calculation still shows that the risk reaches the same order of magnitude as the benefit.</u> Let us assume that 10 million recipients of the "vaccine" were less than 60 years old, and that in this group there were 9 deaths due to consumption coagulopathy and cerebral venous thrombosis. This would be equivalent to 54 deaths after 60 million "vaccinations."

According to figures from the Robert Koch Institute, COVID-19 caused 52 deaths among the 60 million inhabitants of Germany belonging to this age group in the first 6 months of the pandemic.

The list of illnesses that could occur as a result of coagulation disorders after vaccination, begun under point 3, could be extended. For example, there are reports of patients dying of multi-organ failure shortly after vaccination. This could have been caused by diffuse microthrombosis in the affected organs. If the pulmonary vasculature is affected, this could lead to misdiagnosis of pneumonia. In combination with false-positive PCR, such cases would then be erroneously attributed to COVID 19 infection.

<u>Cerebral venous thrombosis, is always a life-threatening condition that requires immediate medical attention.</u> It could be that the EMA numbers represent just the tiny tip of a huge iceberg. The most common warning symptoms of CSVT are a stabbing headache, blurred vision, nausea and vomiting. In severe cases, stroke-like symptoms occur, such as speech disturbances, one-sided body sensation, weakness, and loss of consciousness. Many people reported such symptoms immediately after "vaccination." Clot formation in the deep veins of the legs, in some cases with subsequent pulmonary emboli, has also been repeatedly reported.

Overall, it should be noted that a thorough recording and honest assessment of all clotting disorders that occurred as a result of vaccination would alone turn the benefit/risk ratio stated by the EMA on its head.

The experts conclude their report (Doc. **A.20)** with the words:

„As pointed out in the Open Letter to EMA, ***all such cases could be rapidly diagnosed by the simple measurement of D-Dimers in blood, which betray that clot formation has taken place in the vasculature****. This fact must be heeded so that the causal link between thrombus formation is established without any more ado.* ***The grotesk mass human experiment must come to an end****."*

100. **2.2 <u>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.</u>**

101. According to Article 4 (1) b) of Regulation (EC) No 507/2006, a conditional marketing authorization can only be granted if the applicant is expected to be able to provide the comprehensive clinical data.The applicant of the marketing authorization of "COVID-19 Vaccine AstraZeneca" is not expected to be able to provide comprehensive clinical data subsequently for the following reasons:

102. 1.) As already stated above under point 2.1.1, **the studies on "COVID-19 Vaccine AstraZeneca" are designed by the applicant in such a way that it cannot be understood whether this "vaccine" prevents further infectivity or not.** This means that **<u>precisely on the essential point of efficacy, the study designed by the applicant cannot provide comprehensive clinical data. This already means that the condition for a conditional approval mentioned in Art. 4 (1) b) is not fulfilled!</u>**

103. 2.) In view of the fact that "COVID-19 Vaccine AstraZeneca" is in fact a substance that acts like a "gene therapy", but **the approval procedure applied and the studies conducted do not comply with the special provisions for the so-called "advanced therapies", (Commission Directive 2009/120/EC of September 14, 2009 and Regulation (EC) No. 1394/2007 of November 13, 2007 on advanced therapy medicinal products), the applicant will, by definition, not provide the clinical data comprehensive for a medicinal product acting factually like a "gene therapy medicinal product."**

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

105. **2.3 <u>Invalidity due to non-existence of the requirement according to Regulation (EC) No. 507/2006 - Article 4 (1) c) - non-existence of a medical supply gap that can be closed by the approved drug.</u>**

106. It is impossible to overlook 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 therapy of Covid 19 patients (provided they 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 allegedly issued in error).

107. As already explained above, Italian general practitioners, for example, had to go all the way to the last instance of administrative jurisdiction in order to obtain confirmation, on the basis of evidence of very good therapeutic successes, that they were allowed to use hydroxychloroquine on sick people in the early stages, contrary to the ban on the use of this drug, which was not comprehensible by the Italian Medicines Agency until the execution of the judgment (Doc. **A.9** - Consiglio di Stato - Council of State - Rome Judgment No. 0970/2020 of 11/12/2020).
In their fight against the <u>low-cost</u> hydroxychloroquine (Doc. **A.24.1)** - which, thanks to

its anti-inflammatory and antithrombotic properties, has also proven effective in the early treatment of high-risk patients - opponents published a fabricated study in the Lancet (the Surgisphere scandal - Doc. **A.24.2**) and conducted toxic overdose studies in ICU patients (the "SOLIDARITY" and "RECOVERY" studies - Doc **A.24.3).**

108. But the drug "ivermectin" used highly successfully in Covid-19 is very difficult to overdose, and unlike HCQ, it works as prophylaxis against infections and even in ICU patients.
Dozens of studies and several metastudies have already established that low-cost ivermectin is highly effective against covid (Doc. **A.24.4).**
According to recent studies in several countries, the antiparasitic drug ivermectin - a drug classified as essential by WHO - achieves up to 98% risk reduction (Doc. **A.24.5)** 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.24.6)** 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 had a much lower (Doc. **A.24.7)** - 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 non-assessable risks of "COVID-19 Vaccine AstraZeneca", is clear evidence that "COVID-19 Vaccine AstraZeneca", unlike ivermectin, is not suitable to fill 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.24.8).**

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 the 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 includes vitamin D.

109. In a Spanish randomized controlled trial (RCT - Doc. **A.24.9)**, high-dose vitamin D (100,000 IU) reduced the risk of receiving intensive care by 96%.
A study (Doc **A.24.10)** in a French nursing home found an 89% reduction in mortality in residents who received high-dose vitamin D just before or during covid 19 disease.
A large Israeli study (Doc **A.24.11**) found a strong association between vitamin D deficiency and Covid 19 disease severity
A 2017 meta-study (Doc **A.24.12)** found a positive effect of vitamin D on respiratory infections.
Equally successful is the use of zinc in combination with HCQ.

U.S. physicians reported (Doc. **A.24.13**.) an 84% decrease in hospitalizations, a 45% decrease in mortality in previously hospitalized patients, and improvement in patient condition within 8 to 12 hours based on early treatment with zinc in addition to HCQ.
A Spanish study (Doc **A.24.14**) found that low plasma zinc levels (below 50mcg/dl) increased the risk of in-hospital death in covid patients by 130%.

110. While European nations and the U.S. continue their aggressive military rollout of experimental, expensive, and dangerous agents declared as vaccines but de

facto functioning like gene therapeutics, 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.24.8**) 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 U.S. has for months denied emergency approval of ivermectin for the treatment of coronavirus, citing the "need for further testing." In Europe, the drug is largely ignored.

111. In contrast, India has adopted the treatment protocol specified by FLCCC and now manufactures this product under the brand name "Ziverdo Kit," and it costs only about $2.65 per person.

Although the U.S. National Institutes of Health (NIH) does not recommend treatment for SARS-COV-2 sufferers "unless the patient is hospitalized and requires oxygen," treatment of coronavirus patients has begun early in India, including the use of hydroxychloroquine (HCQ).

Dr. Makarand Paranjpe and his wife, both 77-year-old Indian physicians, fully recovered from COVID-19 virus last November with early treatment, reports TrialSiteNews (TSN - Doc **A.24.15**). 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 U.S. 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.24.16**) that it was replacing its HCQ protocol with ivermectin for the prevention and treatment of COVID-19."At 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 there, too, ivermectin is recommended," writes TSN's Mary Beth Pfeiffer.Dr. Anil K. Chaurasia, a physician in UP, confirms that **as of mid-September, "a marked decline in COVID cases and deaths was seen 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 AstraZeneca", 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.24.17**).

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.24.18**), 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.

112. **2.4. Invalidity due to nonexistence 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.**

113. 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 AstraZeneca" 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.**

114. **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.**

115. **3.1 <u>Violation of the EU legal provisions for the authorisation of "advanced therapy medicinal products"</u>**

116. 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.

117. 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."***

118. ***"COVID-19 Vaccine AstraZeneca" has been shown to lead neither directly nor successfully to active immunization.***

The Robert Koch Institute explicitly states the following on its hompage: *"How long the vaccination protection lasts is currently not known. Protection also does not begin immediately after vaccination, and some vaccinated persons remain unprotected. In addition,* ***it is not yet known whether the vaccination also protects against colonization with the pathogen SARS-CoV-2 or against transmission of the pathogen to other persons. Therefore, despite vaccination, it is necessary to protect oneself and one's surroundings by*** *observing the AHA + A + L rules (spacing rules, MNS)." (Doc.* ***A.21****).*

There is no evidence of active immunization for "COVID-19 Vaccine AstraZeneca", and the goal of passive immunization is also not present.

119. **"COVID-19 Vaccine AstraZeneca" as a genetically modified carrier virus substance cannot directly induce an immune response. However, such a direct immune response is a mandatory function for vaccines. "COVID-19 Vaccine AstraZeneca" is a classical prodrug, i.e. the precursor of a drug, which must first be metabolized by the body's own functions - in this case RNA transcription and protein biosynthesis - to become the hoped-for functioning drug. This process is known and described for therapeutic drugs (prodrug), but not for vaccines (the term "provaccine" is unknown). Also, this fact that "COVID-19 Vaccine AstraZeneca" requires endogenous activation precludes this gene therapy drug from being a vaccine. It is a gene therapy drug that is intended to have immunostimulatory effects to alleviate severe episodes of infection caused by coronaviruses. The alleviation of disease symptoms are clearly functions attributed to drugs (including prophylactic), and not to vaccines.**

Accordingly, the active ingredient "COVID-19 Vaccine AstraZeneca" 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.

120. **In fact, the active ingredient "COVID-19 Vaccine AstraZeneca" 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 in order to regulate, repair, replace, add to or remove a nucleic acid sequence (b) its therapeutic, prophylactic or diagnostic effect is directly related to the recombinant nucleic acid sequence it contains or to the product resulting from the expression of that sequence.

121. **"COVID-19 Vaccine AstraZeneca" works exactly according to this principle. Therefore, the specific requirements provided in Part IV of Annex I for "advanced therapy medicinal products" should have been applied to the active substance "COVID-19 Vaccine AstraZeneca". This was not done.**
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 violation of the requirements laid down by Regulation (EC) No. 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No. 726/2004 in Directive 2001/83/EC on the Community code relating to medicinal products for human use and in Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human use, and in particular for gene therapy medicinal products.

122. **3.2 <u>Annulment of the Implementing Decision on the grounds of manifest error of assessment and inadequate reasoning of the risk mitigation measures proposed in the marketing authorization dossier and breach of the principle of proportionality under Article 5 TEU.</u>**

123. The risk minimization measures proposed by AstraZeneca are not suitable to mitigate the potentially adverse 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) (Doc. **A.25**).

124. In principle, risk minimization measures are generally aimed at preventing or reducing the occurrence of adverse reactions that are unavoidable and associated with exposure to a pharmaceutical product or, if adverse reactions do occur, reducing their severity or impact on the patient. <u>Risk minimization measures are intended to optimize the safe and effective use of a pharmaceutical product.</u> It is generally recognized by those in the field of **pharmacovigilance** that **both the planning and implementation of risk minimization measures and the evaluation of their effectiveness are key elements of risk management. Whether or not proposed risk mitigation measures are adequate may therefore be critical to any decision on whether or not to approve a drug.** (Vanda Pharmaceuticals Ltd, T-211/18, para. 120)

125. The defectiveness of the final assessment report (Assessment Report) EMA/94907/2021 of the Committee for Medicinal Products for Human Use (Doc. **A.1**.) refers to the fact that **the risk minimization measures, including routine measures and pharmacovigilance activities** according to the risk management plan submitted by the applicant under point 2.7 (p.142 ff) based on the opinion of the Committee for Medicinal Products for Human Use and the Pharmacovigilance Risk Assessment Committee were considered sufficient **without adequate justification, although they are manifestly inadequate to control the identified safety risks.**

126. **The significant safety risk of "Vaccine-associated enhanced disease (VAED) including vaccine-associated enhanced respiratory disease (VAERD)" has not been adequately excluded by the applicant AstraZeneca and the clinical trial observation to date is based on too small a data set to draw valid conclusions and the observation period has been too short to exclude with sufficient plausibility the safety concerns about VAED/VAERD, particularly with respect to novel viral mutations. Moreover, the risk is investigated in all clinical trials that are a condition of approval, and the applicant itself has not been able to exclude this risk with certainty, as shown in the RMP, p. 25:**
"...the risk of VAED/VAERD cannot be ruled out. VAED/VAERD may be potentially serious or life-threatening, and require early detection, careful monitoring, and timely medical intervention."
"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 hospitalization and provide monthly safety updates including numbers of and information about relevant cases."

127. **The significant safety risk of VAED/VAERD is substantiated in the attached scientific opinion** (Doc. **A.20)**. In addition, a variety of other scientific papers exist, most notably Cardozo et al, Informed consent disclosure to vaccine trial subjects of risk of COVID 19 vaccines worsening clinical disease, The International Journal of Clinicial Practice, Oct 2020, https://doi.org/10.1111/ijcp.13795 The conclusions of the article call for comprehensive disclosure of VAED/VAERD risk to trial subjects as well as post-approval, as it is a significant safety risk:
"The specific and significant COVID19 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."

128. On the other hand, due to the **mass vaccination campaign, which foresees an area-wide 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 blatantly contradicts the general principle of public health protection established by case law as well as the precautionary principle of the Union** (Vanda Pharmaceuticals Ltd, T-211/18, para 46).

129. Consequently, there is a **serious error of reasoning** in the Implementing Decision, together with the subsequent integration/amendment in that **the applicant did not propose any routine or additional risk mitigation measures, although the possibility of VAED/VAERD occurrence is a real and serious health threat and an inclusion in the Summary of Product Characteristics** - Doc. **A.2.2** - **as well as in the package insert would have been readily available, but this action was omitted,** as can be seen in Table 38 on page 155 of the final assessment report.

130. Overall, **no risk mitigation measures** were applied to the missing safety information on *"Nervous system disorders, including immune-mediated neurological conditions, Vaccine-associated enhanced disease, including vaccine-associated enhanced*

respiratory disease (VAERD), Use in frail patients with co-morbidities, Long-term safety Use" described in the final assessment report on pp. 156-157.

131. *The risk minimization measure regarding the elderly appears, among others, in Appendix I in the Summary of Product Characteristics under item 5.1 regarding "elderly" with the following statement: "Among participants aged 56 to 65 years, 8 COVID-19 cases were reported in the COVID-19 vaccine AstraZeneca group (≥ 15 days post-dose2) compared to 9 cases in the control group; 2 and 6 cases of COVID-19 were reported for participants aged 65 years and older for the COVID-19 vaccine AstraZeneca group (≥ 15 days after dose2) and the control group, respectively."* **This risk minimization measure is inappropriate because it is not clear from the text that the vaccine is obviously ineffective for older individuals.**

132. **The misleading risk minimization statements for persons with fragile health status and comorbidities in the summary of drug characteristics led to the implementation of a false prioritization strategy that established a de facto vaccination requirement for the high-risk group of aged and very elderly persons ("nursing home residents") with unanticipated safety risks without being properly informed about them.** As a result, there is a concrete risk of many deaths and severely impaired health because the substance is applied to people for whom it is contraindicated in all cases.

133. According to established case law, the identified risk must be set against "simple" risk minimization measures, such as warnings in the summary of product characteristics and in the package insert. **For the case of materiality of risk, the relevance of simple risk minimization measures is often not sufficient** (Vanda Pharmaceuticals Ltd, T-211/18, para 132). **In the given case, however, the materiality of the identified unforeseeable risks is exceptionally high, so that the non-inclusion of simple risk minimization measures, as well as of not a single "additional" risk minimization measure, constitutes a particularly serious error of assessment as well as a defect in the statement of reasons, which results in the nullity of the act.**

134. This means that, in view of the incalculable potential for side effects, a safe and effective use of "COVID-19 Vaccine AstraZeneca" must be excluded a priori, in particular for the identified risk groups for which no or insufficient risk minimization measures have been taken.

135. 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 minimization** at all was provided, the Commission, respectively the **EMA**, exercised **its discretion** in the adoption of the legal act in a **grossly erroneous manner** and without justification (Assessment Report pp.142-157 - Doc. **A.1**), **since the regular health status of the entire population is massively and incalculably endangered by prophylactic gene immunization without correlatively minimizing the risks** (Vanda Pharmaceuticals Ltd, T-211/18, para. 53).

136. As already explained under point 2.1.3, **the risk of blood clotting disorders is highly alarming. Instead of withdrawing the product from the market until further absolutely necessary clarification, after the explanation provided by the EMA itself on 18/03/2021 (**Doc. **A. 26) is self-evident proof that the risk associated with "COVID-19 Vaccine AstraZeneca" is statistically at least as high as the benefit (which, moreover, is fundamentally unproven), the EMA has issued a recommendation for the maintenance of the conditional marketing authorization that is grossly contrary to EU law.**

This clearly contradicts the precautionary principle, which is fundamental in EU pharmaceutical law! **The statement of the EMA, according to which the benefit-risk ratio is positive, obviously lacks any factual justification and is, on the contrary, refuted by the EMA itself!**

137. **The complaint of violation of the principle of proportionality**

138. The issued implementing decision including the integration is unlawful due to the measures taken, since it is obviously unsuitable for achieving the objective that the competent bodies should pursue, i.e. the safe and effective use of the gene therapy medicinal product 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).

139. **The principle of proportionality in the field of public health means that, among the goods and interests protected by the TFEU, the health and life of persons 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 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).

140. For the control of safety risks through the complete absence or partial simplicity of risk minimization measures, considered both in isolation and in combination, less burdensome alternatives would have been available to achieve these objectives in accordance with the enshrined principles of pharmaceutical law of "safety, efficacy and quality", which correlate with the protection of human health and life (see under point 2.3. above). Therefore, **the authorization (even in conditional form) should not have been granted under Article 5 TEU because it was an inappropriate measure.**

141. **The approval of a highly risky gene therapy drug for application to the entire population radically contradicts the principle of proportionality!**Consequently, the present legal act, which includes the approval of the risk management plan proposed by the applicant, is an inappropriate measure with regard to the already mentioned principles of drug approval and public health.

142. **3.3 Violation of the EU legal provisions regarding the correct indication of the characteristics of the medicinal product and a correct package leaflet**

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

144. According to Art. 11 point 4.4 of Directive 2001/83/EC, the summary of product characteristics must contain the special warnings and precautions for use and, in the case of immunological medicinal products, any special precautions to be taken by persons dealing with immunological medicinal products and by persons administering these medicinal products to patients, as well as any precautions to be taken by the patient.

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

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

medicinal products and other interactions which may affect the action of the medicinal product, iv) special warnings.

147. **Due to the gross error of assessment set out above under point 3.2, which led to a failure to observe significant safety risks, there is also an automatic violation of the EU legal provisions regarding the correct statement of the characteristics of the medicinal product and a correct package leaflet.**

148. **3.4 <u>Invalidity due to violation of the EMA's own criteria for the monitoring of a "pandemic medicinal product" with enormous short-term exposure figures</u>.**

149. According to Art. 2 of the implementing decision contested here, the placing on the market is subject to obligations listed in Annex II, which are reassessed annually. These include, but are not limited to, Annex II, Item C "Other conditions and obligations of the marketing authorization" the submission of periodic safety update reports {Periodic Safety Update Reports (PSURs)} .

150. **It is absolutely unacceptable that safety reports on a drug with short-term enormous exposure numbers do not have to be submitted until up to 6 months after approval, further exacerbating the threat to public health**.

151. In this context, the approval of the pre-pandemic influenza vaccine *Aflunov* should be noted. In this regard, the EMA has called for a tighter submission of safety reports:
"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 rapid display of drug safety information, which is of paramount importance to the risk-benefit balance in a pandemic. *Immediate assessment of cumulative safety information, taking into account the magnitude 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 evaluation of PSURs in the format specified 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."*

152. While these "orientations" or "guidelines" are not legally binding, they may be taken into account to some extent as complementary considerations in the risk-benefit assessment of a medicinal product (see, mutatis mutandis, judgment of 16 October 2003, AstraZeneca, C-223/01, EU:C:2003:546, para. 28).

153. **To make matters worse, even after the implementing decision was amended in connection with the safety concerns about thrombocytopenia and coagulation disorders, the PSURs were not required to be submitted more closely. This made it clear that the population would not be adequately protected despite mass vaccination within a few weeks and months.**
The actual "special conditions" (according to Art. 14a para. 4 of the Regulation 726/2004) **concern, among other things, specific obligations to conclude product and manufacturing quality of the active substance,** which have to be verified within the first 6 months. Furthermore, also with regard to the **confirmation of efficacy and safety, the submission of the final clinical study report** under point E "Specific obligation to complete post-authorization measures under "special conditions"", which obliges the marketing authorization holder **to submit the final clinical study report for study D8110C00001, for the purpose of confirming the efficacy and safety of "COVID-19 Vaccine AstraZeneca" only on March 31, 2024!** This deadline is clearly outside a valid assessment period for review in terms of efficacy and safety etc. at the renewal date.

154. The health-threatening problem lies in the proof of efficacy and safety to be provided by the marketing authorization holder, which is not to be provided until the **end of**

March 2024 although an annual review is to take place in accordance with the implementation notice. This results in an **irresolvable contradiction**, which calls into question the legality of this condition and thus the approval itself.

155. **3.5 <u>Invalidity of the implementing decision due to the Commission's misuse of discretion regarding the clinical trials and the Declaration of Helsinki, respectively, while at the same time adopting legislative measures to establish a de facto compulsory vaccination.</u>**

156. The implementing decision including the integration/amendment is void because Annex I (summary of product characteristics) and Annex III (labeling and package leaflet) **do not contain sufficient information within the meaning of Article 8 of Regulation 507/2006 on patient safety, information and education in conjunction with Article 3(2)(d) of the Directive. 3 para. 2 lit. d RL 2001/20 and Art. 107m para. 2 RL 2001/83, which enable information as a prerequisite for consent, i.e. *informed consent*, about the direct or indirect participation in the study or the studies running in parallel and largely missing study results.** As a result, **<u>there is no valid consent for participation in the most far-reaching clinical studies</u>,** especially not from those who are administered the substance due to the de facto compulsory vaccination.

157. The present implementing decision is based, inter alia, on the basis for authorization of Article 4, last sentence, of Regulation 507/2006, according to which *"In emergency situations as referred to in Article 2(2), a conditional authorization may be granted provided that the conditions set out in points (a) to (d) of this paragraph are fulfilled, even if complete preclinical or pharmaceutical data have not yet been submitted."* In addition, the recitals should be consulted, which stipulate that *"the granting of conditional marketing authorizations 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 be allowed only when a drug is to be used in crisis situations against a threat to public health.*"

Apart from the fact that the crisis situation has never been properly established (see above under point 1.2.), it is basically to be noted that in the legal tension regarding **the safety of the medicinal product, the further legal requirements concerning the clinical studies remain unaffected in any case, even in the case of a real crisis situation** (cf. RL 2001/20 as well as Art. 107m para. 2 RL 2001/83).

158. **<u>The enclosed expert opinion demonstrably shows which essential preclinical and clinical studies have not been completed or have only been completed in a grossly deficient manner or are still in progress, so that in a serious overall scientific assessment in the sense of patient information, this fact would have to be clearly communicated, and each person would have to give their consent with regard to the actual study participation and be informed about it beforehand. The priority application of the precautionary principle and the fundamental right to health requires that persons who are administered the same substance with the same effects as study participants outside of a study program must be afforded the same protection</u>**.

159. In addition, the special condition of approval is linked to the performance of the safety study after approval in the USA (without code in the assessment report, p. 151) as well as in EU/UK with the study number D8111R00 006, which obtains secondary data from electronic health database portals. With reference to Art. 107m para. 2 RL 2001/83, this study contradicts the requirements of Union law with regard to the welfare and rights of the participants, since no consent is available and the study design is not suitable to measure all identified missing safety information due to the secondary and thus highly error-dependent data analysis, thus leaving the health-impaired persons "unprotected".

160. These serious scientific misjudgements, which have already been sufficiently explained under the other points of complaint, **must be qualified as a violation of the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects of the World Medical Association when considered systematically as a whole**. Point 25 states that ***"Participation in medical research by persons capable of giving consent must be voluntary.*** *Although it may be appropriate to involve family members or leaders of the relevant community, no person capable of giving consent may be included in a research project unless he or she consents voluntarily."*

161. This declaration was also recognized as a valid part of Union law in the second recital of Directive 2001/20: ***"The recognized principles for the conduct of clinical trials on human subjects are based on the protection of human rights and the dignity of the human being with regard to the application of biology and medicine, as stated, for example, in the 1996 version of the Helsinki Declaration. The protection of trial subjects is ensured by risk assessment based on the results of toxicological studies prior to the start of each clinical trial, reviews by the ethics committees and the competent authorities of the Member States, and by the provisions on the protection of personal data."***

162. In the present case, moreover, the authorization and thus the use in humans is not based on the legally required comprehensive **toxicological results.** These are **neither comprehensive in the sense of genotoxicity or carcinogenicity studies, which are completely missing, nor with regard to toxicity study 513351, characterized by serious scientific misconduct.**

163. **At the same time, the Commission is pursuing a policy that establishes a de facto compulsory vaccination** for European citizens, as is undoubtedly evident, inter alia, from the European Vaccine Strategy of 17/06/2020, COM(2020) 245 final, as well as from the current total procurement volume of 2.6 billion vaccine doses and the Commission Communication on "Arrangements for COVID-19 vaccination strategies and vaccine supply" of 15/10/2020, COM(2020) 680 final. The recent effort to introduce "digital green certificates" with the legislative proposal COM/2021/130 final, is a further push to establish the de facto Europe-wide vaccination obligation in order to make the enjoyment of fundamental rights, in particular freedom of movement, dependent on it.

164. **The lack of information and education, as shown above, in combination with the fact that the Commission is the licensing authority of Covid vaccines, including AstraZeneca, and at the same time establishes legislative measures that oblige the individual citizen of the European Union to be vaccinated, violates imperative legal principles of international law, which are referred to as *ius cogens***.

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

166. International law is not only an "integral part" of the Union legal order. **Legal acts of the Commission that systematically and collectively violate *ius cogens*** are **ipso iure void** in accordance with Article 53 of the Vienna Convention on the Law of Treaties, which is recognized under customary international law (see further references in the literature: Schmalenbach, in: Calliess/Ruffert, EUV/AEUV (fn. 1), Art. 216, marginal no. 50; Tomuschat, in: von der Groeben/Schwarze, EUV/EGV (fn. 10), Art. 281, marginal no. 43; in detail Schmalenbach, in: Europarecht als Mehrebenensystem (fn.4),67 (75 et seq.)).
Apart from this, the agreement under international treaty law between the International Criminal Court and the European Union on cooperation and assistance of 10/04/2006,

OJ 2006 L 115, p. 50) regulates in Art. 4 that the respective provisions of the statute are to be observed for the EU.

167. **The performance of medical or scientific experiments on human beings in peacetime, which violate the principles of medical ethics, could constitute a violation of the Rome Statute of the International Criminal Court, if they are the result of state policy or action. Under the alternative of Article 7(1)(k) of the Rome Statute of the International Criminal Court, with reference to the wartime prohibition on *"inhumane treatment, including biological experiments"* and "*intentionally causing great suffering or serious harm to physical integrity or health"* under Article 8(2)(a) of the Rome Statute of the International Criminal Court, a violation of the Rome Statute of the International Criminal Court could occur. 8 para. 2 lit. a of the Rome Statute on the willful commission of "*other inhumane acts of a similar nature*" could be sanctioned as *"crimes against humanity*" if great suffering or serious impairment of physical integrity is thereby caused as a consequence of state or community of states action.**

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168. **4. Annulment of the contested implementing decision due to gross violation of Art. 168 and 169 TFEU as well as Art. 3, 35 and 38 EU-Carta**

169. On the basis of the facts and circumstances set out above and documented in this application, it is obvious that the contested implementing decision of the EU Commission grossly 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 has to set measures to establish high quality and safety standards for medicinal products and medical devices.
The European Commission has grossly violated all of these obligations entered into with Article 168 TFEU with the implementing decision challenged here and is concretely putting the plaintiffs in a situation that endangers their health

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

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

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

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

174. Based on the foregoing, it is obvious that the EU Commission has also grossly violated the Plaintiffs' fundamental right to consumer protection and the obligations applicable in Article 169 TFEU, in particular also to the Commission, with the implementing decision challenged here.

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

Avv./RA DDr. Renate Holzeisen

Bolzano, 29 March 2021

The following documents are filed:

A1 EMA Assessment report "COVID-19 Vaccine AstraZeneca" Procedure No. EMEA/H/C005676/0000 dated 29/01/2021; p. 1 to 182 of the appendices; paragraph 1; (color print)

A2 p. 183 of the annexes

A2.1 European Commission, Implementing Decision of 29/01/2021 granting conditional marketing authorization for the medicinal product for human use "COVID-19 Vaccine AstraZeneca-Covid-19 mRNA vaccine (ChAdOx1-S[recombinant])" in accordance with Regulation (EC) No 726/2004 of the European Parliament and of the Council; pp. 184 to 187 of the Annexes; paragraph 2;

A2.2 Annexes I, II, III and IV to Implementing Decision C(2021) 698 (final); pp. 188 to 224 of the Annexes; paragraph 3;

A2.3 AIFA, Italian Medicines Agency, PM of 15/03/2021; pp. 225 to 226 of the Annexes; paragraph 4; (color print).

A2.4 Paul Ehrlich Institute, COVID-19 vaccine AstraZeneca - Safety assessment result: the vaccine is safe and effective in the fight against COVID-19; pp.227 to 229 of the Annexes; paragraph 4 (color print);

A2.5 Commission Implementing Decision of 19/03/2021 C(2021) 1998 (final) together with the corrected Annexes, p.230 to 268 of the Annexes; paragraph 5;

A3 p.269 of the Annexes (color 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 on13/01/2021; pp.270 to 273 of the Annexes; paragraph 11;

A3.2. Email message from the Coordinating Care Manager of the South Tyrolean Ambulance Service, published onJanuary 2020; pp. 274 to 277 of the attachments; paragraph 12;

A3.3. Covid "Vaccination Plan" Italy published on Dec. 7, 2020; pp. 278 to 304 of the attachments; paragraph 13;

A3.4. email communication from the responsible persons of Merano Hospital (Autonomous Province of Bolzano - Italy) to the hospital staff dated 07/01/2021; pp. 305 to 306 of the annexes; paragraph 13;

A3.5. communication from the persons in charge of the Home for the Elderly Heinrich von Rottenburg - Kaltern to the staff, dated 25/1/2021; pp. 307 to 308 of the annexes; paragraph 13;

A3.6. email from the Bolzano Chamber of Physicians and Dentists to physicians requesting vaccination, dated 15.01.2021; pp. 309 to 310 of the annexes;

paragraph 13;

A3.7. AssoCareNews.it, article, 04.01.2021, about a geriatric nurse who was forced to receive the Covid vaccination against her will: "Cristina, OSS: "mi hanno costretta al vaccino ..., mi hanno minacciata"; pp. 311 to 315 of the attachments; paragraph 14;

A3.8 Nurse Times, article dated 08/01/2021 about the threat of dismissal of 19 geriatric nurses for refusing Covid "vaccination"; pp. 316 to 320 of the Appendices; paragraph 14;

A3.9 Studio Cardiologico Dr. Maurizio Bina S.r.l., Cagliari 25/02/2021 - warning of employees not undergoing Covid vaccination; pp. 321 to 322, paragraph 15;

A4 RA DDr. Renate Holzeisen, warning letter of 12/19/2020 to EU Commission, EMA, et al; "; pp. 323 to 397 of attachments; paragraph 19; (color print).

A5 p. 398 of attachments (color print).

A5.1 EU Vaccine Strategy - excerpt from EU Commission website, Feb. 11, 2021; pp. 399 to 415 of attachments; paragraph 21;

A5.2 European Commission, Communication "united front to beat covid-19", pp. 416 to 428, paragraph 23;

A5.3 European Commission - Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on a framework for the issuance, verification and acceptance of interoperable certificates of vaccination, screening and recovery to facilitate the free movement of goods during the COVID-19 pandemic (Digital Green Certificate), 17/03/2021, pp. 429 to 432, paragraph 25;

A6. MedRixiv - The infection fatality rate of COVID-19 inferred from seroprevalence data, John P.A. Ioannidis, May 2020; pp. 433 to 443 of the Appendices; 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, October 14, 2020; pp. 444 to 481 of the Appendices; paragraph 38; (color print).

A8. LaVerità, article on an interview with the new president of the Italian Medicines Agency announcing guidelines for family physicians for home therapy of Covid-19 patients, "Via libera agli anticorpi monoclonali e alle linee guida per curarsi a casa," February 03, 2021; pp. 482 to 483 of the appendices; paragraph 39;

A9. Consiglio di Stato, Judgment of the Council of State of Rome No. 09070/2020, dated 11 December 2020; pp. 484 to 520 of the Annexes; paragraph 39;

A10. Tribunale Lazio, Ordinanza pubblicata il 04/03/2020 + AIFA, nota del 09/12/2020; pp. 521 to 527 of the Annexes; para. 39;

A11. P. 528 of the Appendices

A11.1 WHO, Bulletin, 30/01/2020 - WHO Director-General statement on the IHR Emergency Committee on Novel Coronaviruses (2019-nCoV); pp. 529 to 533 of the Annexes; para. 43;

A11.2 WHO, Bulletin, 30/01/2020 - Statement on the second meeting of the International Health Regulations (2005) Emergency Commit

A12.1 WHO, Jan. 17, 2020, Interim guidance - Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases; pp. 544 to 550 of the attachments; paragraph 47;

A12.2 Christian Drosten, Diagnostic detection of 2019 Wuhan coronavirus by real-

time RT-PCR; pp. 551 to 563 of the appendices; paragraph 47;

A12.3 WHO, Summary table of available protocols; pp. 564 to 644 of the appendices; paragraph 47;

A12.4 Eurosurveillance, Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR; pp. 645 to 653 of the appendices; paragraph 47;

A13. P. 654 of the appendices

A13.1 WHO, Bulletin, Dec. 14, 2020 - WHO Information Notice for IVD Users; pp. 655 to 659 of the appendices; paragraph 52;

A13.2 WHO, Bulletin, Jan. 30, 2020 - WHO Information Notice for IVD Users 2020/05; pp. 660 to 663 of the Appendices; paragraph 54;

A14. P. 664 of the appendices

A14.1 The New Your Times - Your Coronosvirus Test Is Positive. Maybe It Shouldn't Be, Aug. 29, 2020; pp. 665 to 669 of attachments; paragraph 56;

A14.2 Times of India - Covid-19 test reports must also indicate cycle threshold: Doctors, 06/09/2020; pp. 670 to 672 of attachments; paragraph 56;

A14.3. EU Commission, experts Christian Drosten and Lothar Wieler advise EU Commission, 18/03/2020, pp. 673 to 675, paragraph 57;

A15. Nature communications - Post-lockdown SARS-CoV-2 nucleic acid screening in nearly ten million residents of Wuhan, China; pp. 676 to 683 of attachments; paragraph 58; (color print).

A16. P. 684 of attachments (color print).

A16.1 Tribunal da Relacao de Lisboa, Conclusao, 11/11/2020; pp. 685 to 719 of the Annexes; paragraph 61;

A16.2 Infectious Disease Society of America, Rita Jaafar and others, Correlation Between 3790 Quantitative Polymerase Chain Reaction-Positives Samples, pp. 720 to 722 of the attachments; paragraph 61;

A16.3. The Lancet, Elena Surkova and others, False positive COVID-19 results: hidden problems and costs, 09/29/2020; pp. 723 to 725 of attachments; paragraph 61;

A16.4 Tumori Journal, Giovanni Apalone and others, Unexpected detection of SARS-CoV-2 antibodies in the pre-pandemic period in Italy, 11/11/2020; pp. 726 to 732 of attachments; paragraph 62;

A16.5. Istat - Istituto Nazionale di Statistica - Impact of the Covid-19 epidemic on total mortality in the resident population in the first quarter of 2020; pp. 733 to 736 of the attachments; paragraph 63;

A17. P. 737 of attachments (color print).

A17.1 Retraction request letter to Eurosurveillance + Review report Corman-Drosten et al. Eurosurveillance 2020, Dr. Peter Borger and others Nov. 27, 2020; pp. 738 to 767 of attachments; paragraph 65;

A17.2 Corman-Drosten Review Report, Addendum, last update 11/01/2021; pp. 768 to 827 of attachments; paragraph 65;

A17.3 Eurosurveillance, Response to Retraction Request and Allegations of Misconduct and Scientific Laws, 04/02/2021; pp. 828 to 840 of the attachments; paragraph 65;

A17.4. South Tyrol Sanitary Company and Azienda Provinciale per i Servizi Sanitari Provincia Autonoma di Bolzano, letters dated 11/26/2020 and 11/25/2020; pp. 841 to 848 of the attachments; paragraph 66;

A17.5 Physicians Group, Requests for Disclosure PCR Test Data Province of Alto Adige and Province of Trento dated 27/10/2020 and 26/10/2020; pp. 849 to 860 of the attachments; paragraph 66;

A18. 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. 861 to 868 of the Annexes; paragraph 68;

A.19. BioRxiv Preprint: ChAdOx1 nCoV-19 vaccination prevents SARS-CoV-2 pneumonia in rhesus macaques; pp. 869 to 892 of the appendices; paragraph 83;

A.20 Prof.Dr.Stefan Hockertz, Prof. Dr. Sucharit Bhakdi, Prof.Dr. Michael Palmer, Dr.med. Wolfgang Wodarg, expert opinion of 26/03/2020, pp. 893 to 943 of the appendices; paragraph 85;

A.21 Robert Koch Institute COVID-19 and Vaccination: answers to frequently asked questions, p. 20/21 pp. 944 to 946 of the appendices; paragraph 86;

A.22 Call letter from a group of experts to the EMA, Feb. 28, 2021, pp. 947 to 953 of the appendices; paragraph 92;

A.23 Dr.med Wolfgang Wodarg, Dr. Michael Yeadon, Petiton/Motion ..., 17/12/2020; pp. 954 to 997, paragraph 92; (color print).

A.24 p. 998 of attachments

A.24.1 1 hcqmeta.com: HCQ is effective in COVID-19 when used early: Real-time meta-analysis of 200 trials; pp. 999 to 1066 of attachments; paragraph 107; (color print).

A.24.2 The Guardian, Sugisphere: Governments and WHO changed Covid-19 policy based on questionable data from small U.S. firm, 03.06.2020; pp. 1067 to 1077 of attachments; paragraph 107;

A.24.3 France Soir, Oxford, Recovery and solidarity: overdose in two clinical trials involving criminal acts? 25.06.2020 S. 1078 to 1085 of the attachments; paragraph 107;

A.24.4. Swiss Policy Research - Covid-19: WHO-sponsored preliminary review indicates ivermectin efficacy, 12/31/2020; pp. 1086 to 1091 of attachments; paragraph 108;

A.24.5. ivmmeta.com - Ivermectin is efficacious in COVID-19: real-time meta-analysis of 37 studies; pp. 1092 to 1117 of attachments; paragraph 108; (color print).

A.24.6 Science Direct – Bénéfice de l'invermectine: de la gale à la COVID19,unexemple de sérendipité; pp. 1118 to 1123 of attachments; paragraph 108;(color print).

A.24.7. Science Direct – A COVID-19 prohylaxis? Lower incidence associated withprophylactic administration of ivermectin; pp. 1124 to 1136 of attachments; paragraph 108; (color print).

A.24.8. FLCCC – Protokoll zur Prophylaxe und frühzeitigen ambulantenBehandlungvon Covid-19; pp. 1137 to 1139 of attachments; paragraph 108; (color print).

A.24.9. Science Direct – Effect of calcifediol treatment and best available therapy versus best available therapy on intensive care unit admission and mortality among patients hospitalized for COVID-19…". October 2020; pp.1140 to 1144 of attachments; paragraph 109;

A.24.10. Science Direct – Vitamin D and survival in COVID-19 patients: A quasi-experimental study; pp. 1145 to 1148 of attachments; paragraph 109;

A.24.11. medRxiv – The link between vitamin D deficiency and Covid-19 in a large population; pp.1149 to 1174 of attachments; paragraph 109;(color print).

A.24.12. the bmj – Vitamin D supplementation to prevent acute respiratory tract infections: systematic review and meta-analysis of individual participant data; pp. 1175 to 1197 of attachments; paragraph 109

A.24.13. Science Direct – COVID-19 outpatients: early risk-stratified treatment with zinc plus low-dose hydroxychloroquine and azithromycin: a retrospective case series study; pp. 1198 to 1231 of attachments; paragraph 109;

A.24.14. MedicalXpress – Lower zinc levels in the blood are associated with an increased risk of death in patients with COVID-19; pp. 1232 to 1234 of attachments; paragraph 109; (color print).

A.24.15. TrialSiteNews – An Unlikely Nation is Kicking This Pandemic … , 9. January 2021; pp. 1235 to 1240 of attachments; paragraph 111;

A.24.16. The Indianexpress – Up: New Protocol Ivermectin to replace HCQ in treatment of Covid patients; pp. 1241 to 1253 of attachments; paragraph 111;

A.24.17. Slovak Spectator – Use of parasite medication to treat coronavirus patients approved in Slovakia; pp. 1254 to 1258 of attachments; paragraph 111;

A.24.18. Tagblatt, Coronavirus – Covid- 19: Antstatt das Virus auszurotten geben wir ihm einen Medikamentencocktail; pp. 1259 to 1267 of attachments; paragraph 111;

A.25. COVID-19 mRNA VACCINE AstraZeneca RISK MANAGEMENT PLAN (RMP) pp. 1268 to 1374 of attachments; paragraph 123;

A.26 EMA, COVID-19-Vaccine AstraZeneca: benefits still outweigh the risks despite possible link to rare blood clots with low blood platelets. pp.1375 to 1381 of attachments; paragraph 99.