LAWYER
DDR. RENATE HOLZEISEN
ALSO ADMITTED TO THE SUPREME COURTS
BAHNHOFALLEE, 7
I-39100 BOZEN (BZ)
TEL. 0471 - 97 73 28 ; FAX 0471 - 98 12 35
HOLZEISEN@HROP.COM

EUROPEAN COURT

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ACTION FOR ANULLMENT according to Art. 263 TFEU

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

Defendant:
European Commission

Concerning:
IMPLEMENTING DECISION OF THE EUROPEAN COMMISSION of 11 March 2021 granting a conditional marketing authorisation for the medicinal product for human use 'COVID-19 Vaccine Janssen-COVID-19 vaccine (Ad26.COV2-S [recombinant])' in accordance with Regulation (EC) No 726/2004 of the European Parliament and of the Council, together with its successive amendments and integrations.

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The above-mentioned plaintiffs, represented and defended by Renate Holzeisen, a lawyer admitted to the Italian Supreme Court, registered with the Bolzano Bar Association and with offices in I-39100 Bolzano, Bahnhofallee no. 7,

PROVIDED THAT

1. the European Medicines Agency (EMA) on 11.03.2021, based on the application submitted by Janssen-Cilag International NV on 16 February 2021, in accordance with Article 4(1) of Regulation (EC) No. 726/2004, issued its recommendation for conditional marketing authorisation of the medicinal product "**COVID-19 Vaccine Janssen-COVID-19 vaccine (Ad26.COV2-S [recombinant])" - EMA Assessment report "COVID-19 Vaccine Janssen" Procedure No. EMEA/H/C005737/0000** (Doc **A. 1**).
2. The European Commission ***'Having regard to the Treaty on the Functioning of the European Union, Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human*** *and veterinary use and establishing a European Medicines Agency, and in particular Article 10(2) and Article 14-a thereof, Having regard to* ***Commission Regulation (EC) No 507/2006 concerning the conditional marketing authorisation for medicinal products for human use falling within the*** *scope of Regulation (EC) No 726/2004', Having regard to the application submitted by the company on 16 February 2021 in accordance with Article 4(1) of that Regulation. 726/2004 of the European Parliament and of the Council, Having regard to the application submitted by the company on 16 February 2021 pursuant to Article 4(1) of Regulation (EC) No 726/2004,* ***Having regard to the opinion of the European Medicines Agency, which was adopted on March 11, 2021 by the Committee for Medicinal Products for Human Use, Whereas:*** *(1) The medicinal product "*COVID-19 Vaccine Janssen-COVID-19 vaccine (Ad26.COV2-S [recombinant]" *fulfils 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 Janssen-COVID-19 vaccine (Ad26.COV2-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 conditions laid down in Article 4 of that Regulation for the grant of a conditional marketing authorisation****, as set out in Annex IV.* *(3) The marketing authorisation for* ***'*COVID-19 Vaccine Janssen-COVID-19 vaccine (Ad26.COV2-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 "adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein (Ad 26.COV2-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 decided as follows:

"Article 1 - A ***conditional marketing authorisation as provided for in Article 3 and Article 14-a of Regulation (EC) No 726/2004 is granted for the medicinal product 'COVID-19 Vaccine Janssen-COVID-19 vaccine (Ad26.COV2-S [recombinant])', the characteristics of which are summarised in Annex I to this Decision. "****'COVID-19 Vaccine Janssen-COVID-19 vaccine (Ad26.COV2-S [recombinant])' is entered in the Union Register of Medicinal Products with the following number: EU/1/20/1525. Article 2 -The authorisation of the medicinal product referred to in Article 1 shall be subject to the requirements and conditions, including those relating to the manufacturing, set out in Annex II. These requirements shall be reviewed annually. Article 3 - The labelling and package leaflet of the medicinal product referred to in Article 1 shall comply with the conditions set out in Annex III. Article 4 - The authorisation shall be valid for one year from the date of notification of this Decision. Article 5 - This Decision is addressed to Janssen-Cilag International NV, Turnhoutseweg 30, 2340 Beerse, Belgie."*

- **European Commission Implementing Decision of 11.3.2021 granting a conditional marketing authorisation for the medicinal product for human use "COVID-19 Vaccine Janssen-COVID-19 vaccine (Ad26.COV2-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 European Union Implementing Decision - Annex I (Summary of Product Characteristics), Annex II (A. Manufacturer of the active substance/ biological origin and manufacturer responsible for batch release; B. Conditions or restrictions on supply and use, C. Other terms and conditions of the marketing authorisation; D. Conditions or restrictions on the safe and effective use of the medicinal product; E. Specific obligations under the "specific terms and conditions" of the marketing authorisation), Annex III (Labelling and package leaflet), Annex IV (Conclusions of the European Union Implementing Decision). Conditions or restrictions for the safe and effective use of the medicinal product; E. Specific obligations to complete measures under the marketing authorisation granted under "special conditions", Annex III (labelling and package leaflet), Annex IV (Conclusions of the European Medicines Agency on the granting of marketing authorisation under "special conditions" (Doc. **A. 2.2**).
4. Although international experts assume that the "Covid-19 vaccine Janssen" (like all genetically based experimental Covid-19 "vaccines" currently conditionally approved by the EU) 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** was **included in the package leaflet and directions for use**, which **de facto** means at least a partial

admission of the serious risk affecting a broad population[1]. With the EU Commission's implementing decision of 22 April 2021, the decision for the conditional approval of the "Covid-19 Vaccine Janssen" was therefore amended and the annexes were added accordingly (Doc. **A.2.3**).

5. With the EU Commission's implementing decision of 07.05.2021, the decision for the conditional approval of "Covid-19 Vaccines Jannsen" was amended once again and the annexes were added accordingly (doc. **A. 2.4**).

6. Having said all of the above, the above-mentioned applicants hereby file an action for a declaration of invalidity pursuant to Article 263 TFEU of the above-mentioned Implementing Decision of the EU Commission of 11 March 2021, including all subsequent amendments and integrations, on the following grounds.

Legal standing according to Art. 263 TFEU

7. The plaintiffs all work in the field of health care or care for the elderly and nursing as doctors, nurses, caregivers for the elderly, etc. and have thus been affected by a Covid 19 vaccination obligation introduced by the Italian government since 1 April 2021. **The Italian government introduced a "COVID-19 vaccination obligation" with immediate effect for all staff working in the field of health and care with Legislative Decree No. 44 of 1 April 2021 (Art. 4) (D.L. 1 Aprile 2021 n. 44;** Doc. **A.3).**
All those who do not immediately get "vaccinated" with the experimental substances currently on the market by BionTech-Pfizer (Comirnaty), Moderna, AstraZeneca (now Vaxzevria) and Johnson & Johnson (Janssen) will lose their professional licence by law and will be suspended from employment without salary (if working as employees) until 31 December 2021, or will have to close their practice, pharmacy, etc. (if working in private practice).
This means that there is a clear legal obligation for the plaintiffs to be vaccinated in Italy since 1 April 2021, and therefore, on the grounds set out in the action for annulment, there is an absolute risk of imminent danger.
The plaintiffs are faced with the alternative either to be "vaccinated" with these experimental substances, the medium- and long-term effects of which have not been researched and which have already been proven to lead to severe side effects in the short term, and thus to expose themselves to the concrete risk of the most severe immediate side effects and, in addition, to medium- and long-term effects, the enormous dimensions of which cannot yet be assessed, or lose their jobs or work permits.

8. Italy, like other EU Member States, is also applying the vaccine "COVID-19 Vaccine Janssen" to the general population.

9. "**COVID-19 Vaccine Janssen**" is the fourth substance that has been **conditionally approved** by the European Commission in the EU as a so-called Covid "vaccine", centrally based on genetic engineering. The three other substances (manufacturers:

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[1] From p. 29 of the Annexes to the Implementing Decision, the following is stated verbatim: "*Blood disorders. The combination of blood clots and low levels of "platelets" (cells that help blood clot) in the blood has been observed very rarely after vaccination with COVID-19 Vaccine Janssen. This includes severe cases with blood clots, including in unusual places (e.g. brain, liver, intestine, spleen) in some cases together with bleeding. These cases occurred within the first three weeks after vaccination and mostly in women under 60 years of age. One fatal outcome has been reported. Seek medical attention immediately if you notice severe or persistent headache or blurred vision, unexplained bruising on the skin outside the vaccination site that occurs a few days after vaccination, develop shortness of breath, chest pain, leg swelling or persistent abdominal pain. Inform your healthcare professional that you have recently received COVID-19 Vaccine Janssen".*

BioNTech, Moderna and AstraZeneca) that have meanwhile been approved as so-called Covid "vaccines" are also experimental in nature and have nothing in common with a conventional vaccine.

10. On 16 February 2021, 5 March 2021 and 29 March 2021, respectively, the majority of the applicants have already filed an action for annulment against the respective implementing decision of the EU Commission concerning the conditional approval of the experimental Covid "vaccine". The proceedings in question have the numbers T-96/21, T-136/21 and T-165/21.

11. **Due to the centralised authorisation of "COVID-19 Vaccine Janssen" on 11.03.2021, the European Commission 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.**

12. **In October 2020, the EU Commission had concluded a contract with Janssen Pharmaceutica NV for the supply of "vaccine" doses for 200 million people with an option to purchase the "vaccine" for another 200 million people. I.e. the contract was concluded five months before market approval**. The EU Commission President's press release exposes in plain terms that contracts were concluded without the efficacy and safety of all Covid vaccines that had been (illegally) licensed to date having been established. The EU Commission's press release of 8 October 2020 (Doc. **A.4**.) states the following verbatim: ""The President of the European Commission, Ursula von der Leyen, said: "*It is worrying how the coronavirus continues to spread in Europe, so it is **imperative** that we **find** a vaccine, and **quickly.** I am very pleased that we have been able to conclude an **agreement with Johnson & Johnson to purchase vaccine for 200 million people.** This is now our third agreement with a pharmaceutical company. **With this, we aim to provide EU citizens with safe and effective vaccines as soon as they are found**.""* ... sic! There is no need to comment on such kind of statements in view of the obvious inconsistency and the ex-ante revelation that the conditional approval of these experimental substances, sold to us as Covid-19 vaccines, are the **prelude to an illegal experimental clinical field study on the entire population of the European Union**. In this context, it should be noted that the current version of the EU Commission's decision contested here provides on page 20 of Annex II that **the marketing authorisation holder does not have to submit the study report for the purpose of "confirming" the efficacy and safety of the vaccine until 31 December 2023.**

13. Therefore, the above-mentioned plaintiffs clearly have standing to bring an action pursuant to Article 263 TFEU, as 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.

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

15. Even before the implementation decision challenged here, individual plaintiffs sent a warning letter electronically on 19.12.2020 to the EU Commission and the EMA in particular, requesting them to refrain from authorising experimental active substances based on genetic engineering due to the enormous risks, which are currently impossible to assess in their entirety (see warning letter of 19.12.2020 in Doc. **A. 5**). Incidentally, there was no reaction or response to this warning.

16. According to **Art. 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 have the **fundamental right** to **physical integrity** enshrined in **Art. 3 of the**

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

17. 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. 6.1**), under which on 07.10.2020 the EU Commission concluded an initial agreement with the pharmaceutical company Janssen Pharmaceutica NV on the purchase of a potential vaccine for 200 million people with an option for a further delivery for 200 million people. As the European Commission's own press release indicates, the EU Commission is funding the development of these experimental substances in the form of **purchase guarantees**. The funds provided are considered a down payment for the vaccines, which will be purchased by the Member States.

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

19. **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 already approved experimental "vaccines" (currently there are four: COVID-19 Vaccine Comirnaty, Moderna, AstraZeneca- now Vaxzevria-, and Janssen)**. **By summer 2021, at least 70% of adults in the EU should be vaccinated**. **The EU Commission is** thus **exerting unmistakable and clear pressure towards vaccinating the population with experimental substances based on genetic engineering** (see below). Since the Member States (especially Italy) have become highly financially dependent on the European Community due to the disastrous economic effects of repeated lockdowns, lends the pressure exerted by the European Commission on the individual Member States in the direction of covid vaccination a particular "quality" (Doc. **A. 6.2**).

20. **The "European Vaccination Strategy" places health workers at the top of the list of priority groups to be "vaccinated".**

21. **On 17.03.2021, the EU Commission presented a draft regulation for the introduction of a digital green certificate** (doc. **A. 6.3**). **The digital green certificate serves as proof that a person has been vaccinated against COVID-19, has received a negative test result, or has recovered from COVID-19.**
The declared aim is to find a safe way to lift restrictions and travel in Europe. On 25/03/2021, the European Parliament decided to fast-track the introduction of the EU-wide vaccination certificate. On 28/04/2021, the EU Parliament adopted its position on the Covid passport. Health Commissioner Stella Kyriakides urged EU countries to speed up their Corona vaccination campaigns. It is "crucial that there is no gap between doses delivered and doses administered and that no vaccines go unused" Kyriakides told an online conference of EU health ministers. The massive pressure that the EU Commission is exerting on EU member states towards general compulsory vaccination is obvious.
There is therefore no question that the digital vaccination card will be introduced, and with it discrimination against all those EU citizens who do not wish to be "vaccinated" with the **experimental genetically based substances (such as COVID-19 Vaccine Janssen).**

22. The plaintiffs are not only subject to an enormous **de facto compulsory vaccination, which has been centrally established by the EU Commission and already formalised by the Italian government**, but also, as EU citizens particularly affected by this (because they belong to a prioritised group of persons in the vaccination programme specified by the EU Commission and are therefore subject to compulsory

Covid vaccination in Italy) for the following reasons, exposed to a **concrete, enormous, and (according to EU law) unlawful health risk** brought about by the EU Commission with the contested implementing decision (including subsequent amendments and integrations).

CLAIM REASONS

23. **Premise**

24. "COVID-19 Vaccine Janssen" 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 with the information for the formation of a viral protein of SARS-CoV-2. I.e., just as with the mRNA-based experimental "Covid vaccines" (such as Comirnaty from Pfizer/BioNTech and Moderna), the **generation of the viral protein in the** "Covid-19 Vaccine Janssen" only takes place **in the human body after the virions of the vector virus have entered the cell**.
After the vector virus, to 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 vaccinated person 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 gene expression (see below) in our body, **viral mRNA finally ends up on the ribosomes and is fed to 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 effective in our organism. In other words, 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 operating in full swing and producing protein in various shapes, sizes and structures according to specific procedural blueprints. The ribosomes have a slit on the outside where these blueprints are read like through a scanner so that the protein required at a partiular time can be produced correctly. The blueprint instructions are transported to this gap by messengers. This task is performed by the [messenger RNA messenger RNA (mRNA)]. “ [2]
The mRNA is a recombinant nucleic acid and is used to add a nucleic acid sequence to human cells to form the spike protein of SARS-CoV-2 that would otherwise not be present in the cells. By definition, RNA is also a nucleic acid (RiboNucleidAcid).
An **mRNA**, also known as **messenger RNA, is** a single-stranded ribonucleic acid (RNA) that carries genetic information for building a protein. In a cell, it is formed as the transcript of a section of deoxyribonucleic acid (DNA) belonging to a gene. With an mRNA, the building instructions for a specific protein are available in the cell; it transports the message necessary for protein building from the genetic information 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

[2]Clemens G. Arvay, Corona vaccines, salvation or risk? Mode of action, protection and side effects of the hope carriers, Quadriga, 2021

(whatever body cells) produce due to the foreign mRNA, and which should lead to antibody formation.

25. **The active substance "COVID-19 Vaccine Janssen" therefore factually corresponds to a prophylactic 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 gene therapy medicinal products, but which are declared as vaccines against infectious diseases (such as "COVID-19 Vaccine Janssen"), in absolute disregard of the mode of action, is incomprehensible in view of the precautionary principle applicable in the EU, particularly in the field of health, and of the fundamental rights of EU citizens to a high level of health protection (Art. 35 EU Charter) and to physical integrity (Art. 3 EU Charter), is incomprehensible and violates fundamental principles of EU law (see plea no. 3 below).

26. Having said that, the pleas in law put forward here are primarily those which, irrespective of the legal assessment as to whether the active substance 'COVID-19 Vaccine Janssen' should have been 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 advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004.2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 should have been applied to the active substance "COVID-19 Vaccine Janssen", because the implementing decision contested here must also be recognised and declared null and void as being contrary to EU law irrespective of the assessment of this issue.

27. **1. annulment for infringement of Article 2 (scope) of Commission Regulation (EC) No 507/2006 of 29 March 2006**

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

29. Before a medicinal product for human use can be authorised for marketing in one or more Member States, it usually has to undergo extensive studies to ensure that it is safe, of high quality and effective when used in the target population. The rules and procedures to be followed to obtain a marketing authorisation are laid down in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use and in Regulation (EC) No 726/2004 (recital 1 Regulation EC No 507/2006).

30. In order to address health care gaps and in the interest of public health, it may be necessary to grant marketing authorisations for **certain categories of medicinal products** 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).

31. 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 diseases;**
2. Medicinal products to be **used in emergency situations against a public health threat 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) clearly does not exist for the medicinal product "COVID-19 Vaccine Janssen".

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

33. **1.1 Violation of Article 2 point 1. EU Regulation No. 507/2006**

34. **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 probably the most cited scientist in the world), has already classified the mortality rate of the disease COVID-19 caused by SARS-CoV-2 in the range of that of an influenza disease in March 2020 (**Doc. **A. 7).** With 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. 8**), Ioannidis has **demonstrated 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**.

35. The fact that the COVID-19 disease caused by the SARS-CoV virus is not a "life-threatening disease in the actual sense" for the population is also confirmed by the fact that in **Italy,** for example, even if only now, **after more than 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. 9).** It has been proven that serious complications of Covid 19 disease (which occur in a very small percentage of sufferers) are primarily caused by 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 successfully used drugs contrary to the official instructions and recommendations of the Italian Ministry of Health and the Medicines Agency, whose official use they even had to dispute in court afterwards (see judgement of the Council of State of Rome 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. 10**) were able to demonstrably treat almost all of their covid 19 patients at home without hospitalisation, leading to a complete cure of the disease. The same group of GPs went to the competent administrative court in Lazio to obtain a judicial stay of an order issued by the Italian Ministry of Health to GPs on 9 December 2020 (namely to treat essentially with paracetamol, to wait and not to use the drugs otherwise commonly used against covid-19), which 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 incorrect instruction of the Italian Ministry of Health of 9.12.2020, which would not have allowed GPs to

prescribe curative medicines to their patients to the best of their knowledge and belief - Doc. **A.11**).

36. 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 has occured in the past, and which has led to a de facto artificially inflated pandemic **due to the failure of sanitary systems of certain Member States (such as primarily Italy** - investigations by the Italian public prosecutors are underway) as **well as a worldwide misuse of RT-PCR tests,** as will be demonstrated below.

37. **1.2. Invalidity due to violation of Regulation (EC) No. 507/2006 Art. 2 point 2.**

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

39. On 30 January 2020, the WHO declared the pandemic status caused by SARS-Cov-2, which allegedly endangers the world population (Doc. **A. 12.1**).

40. The question of the proper determination of a "public health threat" is to be determined according to the provisions of the *International Health Regulations* 2005 (IHR) of the World Health Organisation. The regulations, which are to be interpreted according to 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 according to Art. 12 IHR.

41. **The proper determination of a threat to public health must therefore be examined against the provisions of the IHR.** According to Art. 12 (4) IHR, the Director General is obliged to include the following **five criteria in** his decision:

    1. **the information provided by the contractual 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 the 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 interference with international traffic.**

42. In accordance with this decision catalogue, the Director General convened an emergency committee on 23.1.2020 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.12.2**).

43. On 13.01.2020, WHO published a first PCR test guideline (A. **13.1**) based on the Corman-Drosten protocol of 13.01.2020 (Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR (A. **13.2**) - see also *Summary table of available protocols*

in this documents (A. **13.3**), which shows that the Corman-Drosten PCR test protocol (also called "Charitè 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.13.4**).
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.

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

45. The claimed crisis situation of the global public health threat due to the SARS-CoV-2 virus was ultimately mapped by a global **misuse of 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 in reality, as well as an enormous number of people worldwide who have allegedly died from the disease caused by SARS-Cov-2 infection (Covid-19).

46. 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). **PCR is a system with which specific DNA sequences can be multiplied or copied outside the living organism, *in vitro***. To achieve this, enzymes and building blocks are used that are also responsible for duplicating DNA in the body's cells. The amount of DNA grows exponentially because each time a larger number of templates is available. Hence the term **"chain reaction". Thus, 2 first become 4, then 8, then 16. etc. copies. After 20 cycles, the initial DNA has already produced more than 1 million copies, and after 30 cycles, more than 1 billion copies. Hence the term "chain reaction". From a certain threshold value (cycle threashold; 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 this CT is reached. Since in infectious events several thousand initial pathogens must be present to form an infectious dose, the ct will already be reached at a maximum of 25 cycles, whereby a tolerance range up to 30 is possible and coincides with publications in the case of SARS-CoV-2 that from ct 30, any correlation of the PCR result with an infectiousness no longer exists.** However, the corona virus does not have DNA, but RNA. The genetic material is therefore present in a different form. The **Corona test** is therefore not a simple PCR, but an **RT-PCR**. **RT stands for reverse transcriptase. This is an enzyme that can transcribe RNA into DNA.** This happens in a step before the actual PCR, but in the same reaction vessel.

47. **Scientists worldwide who are familiar with microbiology and with the PCR test have pointed out from the beginning that it is not possible to <u>detect a virus with the PCR test,</u> but only nucleic acids that remain as fragments of viruses. The <u>tests can therefore say nothing about the infectiousness of a person who has tested positive, unless there is also a clinical diagnosis</u>. And if <u>a person was tested without symptoms, logically no statement about the presence of an infection is possible.</u> Therefore, the term "new infection", which is used worldwide in this context, is simply wrong. Only small amounts of viruses or their fragments are contained in the samples taken from the mouth and throat of humans. They have to be multiplied to make them visible. These fragments can also come from an "old infection" that has already been overcome,**

namely when the immune system has successfully fought the viruses and the person concerned is healthy again and no longer infectious.

The more viruses still in the body, the fewer cycles of replication are needed for detection. This number - the so-called Ct value - therefore obviously provides important diagnostic information. However, it is not usually transmitted by the laboratories.

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

48. **All this was and still is not taken into account by the authorities. Laboratories do not report this number of cycles needed for detection. But this is now finally being demanded by the WHO.**

On 14.12.2020 **(**Doc. **A. 14.1), WHO issued recommendations for users of RT-PCR tests for the first time (and admittedly 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.** This names 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 in patients with high levels of circulating virus (viral load), relatively few cycles are required for virus detection and the Ct value will therefore 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:

"Include 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, the positive predictive value also decreases. 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 the test results along with clinical signs and symptoms, confirmed status of all contacts, etc."***

So it is **recommended not to rely only on the result of the PCR test, but also to consider clinical symptoms. With this, the WHO also says that there can be no such thing as "asymptomatically ill"**.

This is part of the WHO recommendation is self-evident:

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

49. **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 amplification cycles are used and that with a low prevalence (percentage of real infections in the population) there are many false positive results anyway. The WHO is now also warning against this. Admittedly, much too late and only at a time when, lo and behold, elsewhere (USA, UK) the first active substances based on genetic engineering and propagated as Covid "vaccines" had already been approved.**

50. In another clear recommendation published in its bulletin on 20.01.2021 (Doc. **A. 14.2), WHO again warns against false-positive results of the PCR test, as follows:**

The WHO guideline Diagnostic testing for SARS-CoV-2 states that careful interpretation of weak positive results is required. ***The cycle threshold (Ct) required for virus detection is inversely proportional to the patient's viral load. If the 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 ***tools for diagnosis****,* ***so health care providers need to consider each result in combination with the time of sample collection, sample type, assay specifics, clinical observations, patient history, confirmed status of all contacts and epidemiological information.***

Actions to be taken by IVD users:

1. ***Please read the instructions for use carefully and completely.***
2. *Contact your local representative if any aspect of the instructions for use is unclear to you.*
3. *Check the IFU on each incoming consignment to detect any changes to the IFU.*
4. ***Give the Ct value in the report to the requesting health care provider.***

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

What this also says is that **tests on people without symptoms are simply pointless**. A **positive test result cannot correspond to the clinical picture, because the absence of symptoms means that there is no disease. The type of mass testing widely organised by various governments therefore contradict the WHO guideline, because almost only people without symptoms are tested**.

A fundamental **requirement for "official" and "court-proof" 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.**

52. **Although even the WHO now warns against the worldwide misuse of the PCR test, it is blithely continued by governments and authorities.** The persons 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. Reducing this threshold to 30 cycles reduces the number of "confirmed cases" by 40 to 90 per cent, as studies in the USA have shown, according to a report in the New York Times (Doc. **A. 15.1). The "case numbers" in Italy, Austria, Germany, Europe and generally worldwide would again be significantly reduced with this scientifically based correction to a Ct value of 25. Epidemiologically, it would only make sense to record infectious people. But this is not being done.**

53. With the PCR test, therefore, an enormous number of false results are to be expected if, as happens throughout 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 (Charitè protocol), which contains a large number of gross scientific errors (**A.15.2.).**

54. On the subject of infectivity of people without symptoms, there are the results of the largest study to date from Wuhan (Doc. **A.16**). It was conducted after the lockdown, which lasted in the Chinese city of 11 million from 23 January 2020 to 8 April 2020. SARS Cov-2 nucleic acid screening was conducted throughout the city from 14 May 2020 to 1 June 2020. This is what the study calls it because the **PCR test does not test and detect a virus, but only parts of it, i.e. the nucleic acids.**
10.6 million residents 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 for 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 viruses.

55. **The PCR test is therefore not suitable for detecting active infection or even infectivity. However, the WHO's upholding of the declaration of the alleged public health threat posed by SARS-Cov-2 is based on the numbers detected by this test.**

56. **Any "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 any executive and legislative action based on them is set or unconstitutional.**

57. This has already been stated in a judgment of 11.11.2020 of a court of appeal in Portugal (Doc. **A.17.1**).

The main points of the court's decision are as follows:
A medical diagnosis is a medical act that only a doctor is legally authorised to perform and for which that doctor 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 unhealthy by decree or law, 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, without the involvement of a registered medical practitioner 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) is contrary to [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 medical practitioner.*
The Portuguese Court of Appeal further stated the following:
"Based on the scientific evidence currently available, this test [the RT-PCR test] is not, in and of itself, capable of determining beyond reasonable doubt whether positivity actually corresponds to SARS-CoV-2 virus infection 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."
With reference to Jaafar et al. (2020; https://doi.org/10.1093/cid/ciaa1491 - Doc**. A. 17.2**), the Court concludes that "**when a person tests positive by PCR, if 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 the PCR tests currently carried out in Portugal is unknown.
With reference to Surkova et al. (2020; https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(20)30453-7/fulltext **-** Doc**. A. 17.3),** the court further states that any diagnostic test must be interpreted in the context of the actual likelihood of disease as assessed prior to the performance of the test itself, and expresses the opinion that *"in the current epidemiological landscape, there is an increasing likelihood of Covid 19 tests producing false positives, with significant implications for individuals, the healthcare system and society".*
The court's summary of its decision against the appeal of the regional health authority reads as follows: *"Given the scientific doubts expressed by experts, i.e. those who play a role, about the reliability of the PCR tests, given the lack of information about the analytical parameters of the tests, and in the absence of a medical diagnosis proving the presence of infection or risk, this court can never determine whether C was in fact a carrier of the SARS-CoV-2 virus or whether A, B and D were exposed to a high risk."*
By decision of the District Court of Weimar No. 9F 148/21 of 08.04.2021 (Doc. **A.17.4**), it was confirmed on the basis of the expert opinion of Prof.Dr. rer.hum.biol. Ulrike Kämmerer that the RT-PCR test cannot detect an infection (Doc. **17.5**).

58. *As can be seen in the development of the pandemic in Italy, it was the* RT-PCR tests 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 summer 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 enrolled in a lung cancer screening study between September 2019 and March 2020. The aim was to track the date of the Corona outbreak, its frequency and temporal and geographical variations in Italian regions. The study, published on 11 November in the Tumori Journal (Doc. **A. 17.6**) 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 unexpected 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 the illness caused by the virus, but to the measures proposed by China and implemented by the Italian government, such as the lockdown. They led to Romanian nurses fleeing the country, leaving nursing homes without staff. Hospitals quickly became overburdened and became the main source of infection.

59. But that is not all. The Italian statistics agency ISTAT had already presented data in May 2020 (Doc. **A. 17.7**) 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.

60. 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, since it is at least a case of gross negligence that caused Italy to slide so unprepared into a "virus-heavy" period. A lot of staff, especially in the elderly care sector, came from Eastern Europe. They fled the country at the beginning of the border closures. Homes for the elderly were suddenly without staff and, after several days without care, the residents were transferred to hospitals. This led to the collapse of the medical care system 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. Other factors in northern Italy that have a negative impact include severe air pollution (there are EU Treaty infringement proceedings pending), excessively frequent antibiotic resistance, a known high level of asbestos exposure due to the former fibre cement production and textile industry as well as on-site asbestos mining, and a particular genetic susceptibility to inflammatory diseases (favism, Lombardy subtype) and treatment errors (currently being investigated by the Italian public prosecutors).

61. **Due to serious scientific errors in the Corman-Drosten PCR test protocol (also called the Charitè protocol -** doc. **A. 13.2) - and massive conflicts of interest among the authors of the protocol, twenty-two scientists from around the world demanded an urgent retraction of the scientific publication on the Corman-Drosten PCR test protocol from the scientific journal Eurosurveillance on 27 November 2020** (doc. **A. 18.1.**).

The basis for the RT-PCR test, which has determined and limited our lives since March 2020, is a study entitled "*Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR*". It was submitted on 21 January by a number of authors, including Christian Drosten, Victor Corman, Olfert Land and Marco Kaiser (doc. **A. 13.4**).

The Corman-Drosten study was submitted to Eurosurveillance on 21 January. Already on 22 January, the review was supposedly completed - which, however, is usually not 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 there was in terms of conflicts of interest, which were only partially disclosed on 30 July, when criticism of them grew louder. Olfert Landt is the managing director of TIB Molbiol, Marco Kaiser is a senior researcher at GenExpress and scientific advisor to TIB Molbiol, the company that claims to have been the "first" to produce the PCR kits based on the protocol published in the Drosten manuscript. According to its own account, the company had already distributed the test kits before the study had been submitted. The involvement of C.Drosten and V.Corman as heads of viral diagnostics and thus also of PCR diagnostics for SARS-CoV-2 in the commercial "Labor Berlin" of the Vivantes group (with Charitè), in view of the

considerable interest in high numbers of diagnostics applicants that this entailed, is still unclear.

The scientific errors, according to the international group of scientists, 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 is not verified and is also not recommended by the WHO for testing.
2. The binding temperature is set too high, so that non-specific binding is promoted, whereby gene sequences other than those of SARS-CoV-2 can also be detected.
3. **The number of evaluation cycles is specified in the paper as 45; a threshold up to which the reaction is evaluated as true positive is not defined for the CT value. It is generally known that RTPCR-tests with a number of cycles above 30 do not allow conclusions to be drawn about contamination of the sample with the sought-after virus**.
4. No biomolecular validation has been carried out, so there is no confirmation that the amplificates are genuine, actually arise and indeed detect the sequence sought.
5. Neither positive nor negative controls were carried out with regard to virus detection. Above all, 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. **Due to the imprecise experimental set-up, there is a risk of false-positive results.**
8. **Given 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 cumulative expertise in the field in question. Among them are, for example, the ex-Chief Science Officer of Pfizer Dr. Michael Yeadon, the geneticist Kevin McKernan, the driving force behind the Human Genome Project, who holds several patents in the field of PCR diagnostics, the molecular geneticist Dr. Pieter Borger, PhD, the specialist in infectious diseases and preventive medicine Dr. Fabio Frankchi, the microbiologist and immunologist Prof. emerit. Dr Makoto Ohashi and the cell biologist Prof. Dr Ulrike Kämmerer.

On 11.01.2021, the Scientific Group submitted a scientific integration of its request to withdraw the publication (Doc. **A. 18.2**).

Eurosurveillance refuses to withdraw the publication of the protocol that has been responsible for a huge number of false positive cases worldwide for a year now, and this with an ictu oculi, anything but scientific justification (Doc. **A. 18.3**). Scientists worldwide are stunned and appalled by this development.

62. **This highly flawed Charitè protocol continues to be used on** a **massive scale around the world, but especially in Europe, including 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. 18.4) to** a request for disclosure submitted by a group of doctors for the purpose of creating transparency about the RT-PCR test products used (Doc. **A. 18.5**)

63. **The WHO incomprehensibly only officially pointed out in December 2020 for the first time that PCR test results alone are no proof of a virus infection, after people who had been subjected to a positive PCR test alone were and are**

automatically declared to be infected with SARS-CoV-2 for more than 11 months, and still ongoing (!).

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

64. **At the time of approval of the active substance "COVID-19 Vaccine Janssen" on 11.3.2021, the short-term recommendations of the Emergency Committee of 29.10.2020** (Doc. **A. 19) were in force on the basis of the same invalid WHO database, which depicted an incorrect infection rate.**

In view of the effective mortality rate of Covid-19 (Doc. **A. 7** and **A. 8**), as presented and documented by top experts such as John P.A. Ioannidis, who have been recognised worldwide for decades, it is incomprehensible how the WHO, in its *"Statement on the fifth meeting of the International Health Regulations (2005) Emergency Committee regarding the coronavirus disease (COVID-19) pandemic" of* 30 October 2020 (Doc. A. 19), could continue to assume a very high global risk associated with Covid-19 and maintain the declaration of a public health emergency of international concern (PHEIC). October 2020 (Doc. **A. 19**), the global risk associated with COVID-19 remained very high and the declaration of a Public Health Emergency of International Concern (PHEIC) was maintained. [3]

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

Therefore, it has not yet been proven that Covid 19 disease, which can be severe in very rare cases, is a causal disease caused 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-" or untreatable disease in the strict sense.**
Therefore, the **mandatory conditions for a conditional marketing authorisation of a medicinal product laid down in Article 2 of Commission Regulation (EC) No 507/2006 of 29 March 2006 have not been met for the substance "COVID-19 Vaccine Janssen" and the implementing decision of the European Commission contested here is unlawful for this reason alone and must therefore be declared null and void.**

*

66. **2. annulment for infringement of Article 4 Regulation (EC) No 507/2006**

67. Although a conditional marketing authorisation may be based on less extensive data, the **risk-benefit balance** 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).

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[3] *"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."*

68. **The granting of conditional marketing authorisations should be limited to those cases where only the clinical part of the application dossier is less comprehensive than usual. Incomplete preclinical or pharmaceutical data should only be allowed when a medicinal product is to be used in emergency situations against a threat to public health** (Recital 4 EC Regulation No 507/2006). As stated above, a crisis situation consisting in a threat to public health has not been properly established.

69. In addition, the **experimental active substance "COVID-19 Vaccine Janssen", which is based on genetic engineering, is intended for use on "healthy people". To disregard not only clinical but also preclinical or pharmaceutical data prior to application is a gross violation of the precautionary principle**.

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

71. 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 the same as the normal procedure laid down in Regulation (EC) No 726/2004 (recital 8 Regulation No 507/2006).
Conditional authorisations are valid for one year and may be renewed in accordance with Regulation (EC) No 726/2004.

72. **Patients and healthcare professionals should be clearly informed that the marketing authorisation is conditional. It is therefore necessary that this information is clearly stated in the summary of product characteristics of the medicinal product concerned as well as in its package leaflet.** (Recital 10 Regulation No 507/2006).

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

1. **A conditional marketing authorisation may be granted if the Committee considers that all of the following conditions are met, although comprehensive clinical data on the safety and efficacy of the medicinal product have not been submitted:**
   - 73.1.a. **The risk-benefit balance of the medicinal product as defined in Article 1(28a) of Directive 2001/83/EC is positive;**
   - 73.1.b. **The applicant is expected to be able to provide the comprehensive clinical data;**
   - 73.1.c. **a medical care gap can be closed;**
   - 73.1.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.**

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

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

2. For the purposes of point (c) of paragraph 1, a **health care gap** shall be understood as the absence of a **satisfactory means of diagnosis, prevention or treatment of a condition authorised in the Community** or, even if this is the

case, **the absence of a significant therapeutic benefit of the medicinal product concerned for the patients affected by that condition**.

80. **2.1. <u>invalidity due to the absence of a positive risk-benefit balance according to Article 1(28a) of Directive 2001/83/EC</u>**

81. To determine the risk-benefit ratio, both components, i.e. the benefit and the risk, must be able to be assessed and evaluated on the basis of facts.

82. **2.1.1. <u>absence of demonstrable benefit</u>**
There is no evidence that those "vaccinated" with "COVID-19 Vaccine Janssen" cannot become infected and be carriers of the SARS-COV-2 virus.

83. In the first place, the **<u>studies are likely designed in such a way that this proof cannot be provided at all.</u>**

84. 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**):
"... **benefits of the vaccine in terms of upper respiratory tract protection are not clearly apparent**, as measured by viral load (infective and viral RNA material), histopathological scores and immunohistochemistry. A correlation of **upper respiratory tract protection with antibody titres is not clearly established. ... In the control animals in general, but especially in the age-matched control group, pneumonia induced after challenge was very mild and without clinical signs. A model without clear clinical findings is not suitable to study immunogenicity and viral clearance and is definitely not a disease model to study this vaccine.** If this model is not adequate, how can vaccine efficacy against the disease be demonstrated? Such challenge experiments have not been done in humans using a clinical trial, so we must rely on data from animal models. **If these data, such as in this case the efficacy of a vaccine in stopping the transmission of a disease, are not available, then no substantive benefit can be ascertained for that vaccine and the vaccine should not be licensed.** ...The cellular responses of IFN-γ production were rather low and variable. **It must also be noted that the animals in these studies were young and healthy. The animals could only be infected with SARS-CoV-2 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 individuals are older and have underlying diseases that make them more susceptible to severe COVID-19 disease. The inconsistent results of the animal studies leave in doubt the real extent of the protection from COVID-19 disease even in these young, healthy animals. In elderly humans with many comorbidities and generally less vigorous responses to vaccination, the protective effect of the vaccine seems even more doubtful.**
…. <u>Interference of adenovirus cross-immunity with vaccination:</u>
A broad pre-existing immunity against adenoviruses is common in the general population. Such immunity prevents the use of adenovirus serotypes which are common in humans for the construction of adenovector vaccines, because it would block the cellular uptake of such vaccine virus particles and reduce transgene product expression. ...**We currently know 90 distinct human adenovirus genotypes, and due to this large number of circulating viruses and their relative ease of transmission, the vast majority of people have been infected by multiple adenovirus types during childhood and throughout their lives. This means that a significant proportion of the human population has antibodies and T-cell**

immunity to these viruses. These natural exposures are likely responsible for long-lasting immunity that can interfere with human adenovector-based vaccines. ...**Adenovector immunity was not considered in the pre-clinical study for Ad26.COV2.S because the animals used in these studies are kept under clinically sterile conditions and are not naturally infected with adenoviruses. It is clear that our understanding of the global adenovirus serum epidemiology is incomplete, particularly with respect to African countries, which are often primary targets for vaccination campaigns.**
Once administered, adenoviruses induce potent inflammatory responses, in part due to the activity of structural viral proteins. ...Thus, many individuals who receive the vaccine will already have a distinct immune response to the virus. These individuals will have both neutralizing antibodies and specifically reactive T cells to the adenovirus-based vaccine**.** This cycle of natural infection poses an enduring problem for the use of adenoviruses as vectors for gene therapy or vaccines. **... According to EMA, the potential impact of natural or vaccine-induced pre-existing anti-Ad26 immunity on vaccine efficiency remains unclear. Based on experience with seroprevalence on adenovectors, we can assume that immunity to the vector severely limits the immunizing effect that can be expected of vaccine Ad26.COV2.S. .... The duration of protection beyond 8 weeks after vaccination is not known**. **Since the study is far from being completed, and the participants in the placebo group are now officially allowed to be vaccinated against SARS-CoV-2, it can be assumed that the study will not generate robust efficacy data.** This means that the trend of slightly better efficacy of protection against severe cases compared to mild symptomatic cases, which was seen in the preliminary data, **cannot be confirmed in the future**. **How long the neutralising and binding antibodies will be sustained after vaccination is also not clear**. **The efficacy of a vaccine can only be clearly determined over time. The duration of the Ad26.COV2.S 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.** Due to the limited number of cases, **data in individuals with one or more uncontrolled underlying diseases are lacking. There is no data on immunocompromised persons due to condition or immunosuppressive therapies and also no data on long term adverse events. "**

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

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

87. **2.1.2 <u>Material risks not recorded and therefore undetermined and currently indeterminable risk</u>**

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

89. **According to Annex I (Summary of Product Characteristics) to the European Commission's implementing decision contested here (**Doc**. A. 2.2),** point 4.5

(Interactions with other medicinal products and other interactions), *"no interaction studies have been carried out."*

In view of the fact that the so-called. Covid "vaccines", such as "COVID-19 Vaccine Janssen", are intended to be used on the general population, and a considerable proportion of the population regularly consumes one or more medicines, **the fact that the interactions of "COVID-19 Vaccine Janssen" with other medicines have not been tested** must **lead to the conclusion that the risks emanating from "COVID-19 Vaccine Janssen", 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 approval!

90. **2.1.3. failure to take into account significant risks that would never allow a conditional marketing authorisation of a medicinal product intended for a fundamentally healthy population.**

91. Significant risks associated with the administration of the active ingredient "COVID-19 Vaccine Janssen" were already submitted to the EMA in 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 sent electronically, also by plaintiffs, primarily to the EU Commission and the EMA on 19.12.2020 (Doc. **A. 5**).

92. The scientific opinion prepared by the four experts (Doc. **A. 20**) states the following with regard to omitted studies and unconsidered risks of administering the active substance "COVID-19 Vaccine Janssen":

"No tests for adventitious agents were performed in animal models:

Since Ad26.COV2.S 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.... Therefore, **to demonstrate their absence, extensive testing during vaccine production is recommended**. **An adventitious agent can only be detected in a vaccine when thorough tests *in vitro* and in animals are performed** ... **However, most important, the verification of possible adventitious agents in animal experiments was not described. Therefore, it is assumed that these important tests were not performed.** Prior experience shows that in the manufacture of biological products the possibility of adventitious agents must be taken seriously. ... **These tests are vital to human health, and it is therefore unacceptable to omit the important animal tests.... Control of impurities: ... data on elemental impurities are being collected and analysed only now, after approval. This is unacceptable. ... Non-clinical aspects 1. Secondary pharmacodynamics: No studies** on secondary pharmacodynamics have been performed. Secondary pharmacodynamics measures the quantitative relationship between the amount of drug and any adverse response of the body to it. It is **extremely important to know how the drug affects the organism**, in ways unrelated to the primary target effect. **1. safety pharmacology: No** safety pharmacology investigations have been performed with Ad26.COV.2 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.
Various considerations and concerns regarding points 1 and 2 are relevant. Only three are mentioned here:

1. **The vaccine induces the host cells to produce the spike proteins and present them to the immune system at the cell surface. It has been reported that cells can cleave off a fragment (the S1 peptide) of the spike protein. Conceivably, the released peptides can be transported in the bloodstream and give rise to adverse effects. The S1 peptide contains the entire receptor binding domain (RBD) and thus is able to bind to ACE2 receptors on other cells. The bound receptors will be taken up into the cells. The decreased amount of ACE2 remaining on the cell surface will disturb the balance of the renin-angiotensin hormone system, which may lead to cell damage, inflammation, and thrombosis.**
2. **Furthermore, newly synthesised spike protein molecules that remain uncleaved on the cell surface can also bind to ACE2 receptors on other cells, which may cause the two cells to fuse (this resembles the normal function of the protein, namely to induce fusion of the virus particle to the host cell membrane). The resulting syncytia (fused cells) are giant cells with multiple nuclei, and they can assume pathological activities. Small amounts of spike proteins suffice to set off this fusion cascade.**
3. **Platelets, too, are known to express ACE2 receptors on the cell surface and thus can bind the spike protein. *In vitro*, this results in direct platelet activation and aggregation, platelet spreading, leukocyte-platelet aggregate formation, and clot retraction. *In vivo*, such effects translate into an increased risk of thrombosis formation. Spike protein molecules also directly stimulate platelets to release granules, coagulation and inflammatory factor secretion.**

1. **In summary, the SARS-CoV-2 spike protein can cause significant damage to cells and to the human body in multiple ways. The vaccine under discussion, as well as all other currently used SARS-CoV-2 vaccines, induce the biosynthesis of this spike protein in our own body cells, in order to induce an immune response to it. This new and untested technique poses a grave risk of serious damage after vaccination in previously healthy humans. It is therefore medically and ethically unacceptable. 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: ... a) Syrian hamster (Mercado *et al.*, 2020; van der Lubbe *et al.* , 2021): ... 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 report does not describe which organs were studied and at what time points the DNA was found. The report also claims that in only one of the two studies all organs except the one specified were free of DNA. **What should we make of the second study, which apparently found DNA in other organs? There is no information on whether, for example, the central and peripheral nervous systems and bone marrow were studied.** Based on what is known about the biodistribution of adenoviruses in general, it must

be assumed, until proven otherwise, that the vaccine also penetrates the nervous tissue and bone marrow, with possible unpredictable adverse effects. **Also, these investigations did not employ the original vaccine. Even though these data are pivotal, they were not available at the time of approval.** 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. Transparency regarding the results of the possibly altered blood parameters could help better understand how the thrombosis that occurs in some of the vaccinated people is linked 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 and its elimination by the immune system cause adverse effects on blood coagulation; therefore, we need to know whether the relevant blood parameters in this model have been investigated or not. The reported increase of fibrinogen suggests inflammation; involvement of the blood vessels would trigger blood clotting.** An increased PTT would indicate consumption of coagulation factors by disseminated intravascular coagulation (in the absence of other causes such as vitamin K deficiency or liver damage). In that case, one would expect fibrinogen to be depleted also. An increased fibrinogen suggests inflammation but not DIC. **The EMA report does not discuss the question how the vaccine interacts with drugs that inhibit blood clotting. Interference of the vaccine with the coagulation system may cause both thrombosis and internal bleeding (see below); risk of the latter may well be increased in elderly people that are given such drugs to prevent acute cardiovascular events. ...C-reactive protein (CRP) in the blood is considered a general marker of inflammation. The observed increase in CRP therefore also indicates a pro-inflammatory effect of the vaccine. Elevated CRP levels have also been linked to an increased risk of heart attack.**

Death due to gene therapy in a human clinical trial: In the year 1999, researchers at the University of Pennsylvania caused 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 x ^{1011} 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 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 to replication-defective adenovirus vectors and of their toxicity, and also in order to understand the substantial differences in both between individual subjects. **Considering the limitations of our current knowledge, it is irresponsible to already administer adenovirus-based vaccines such as Ad26.COV2.S 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. **Spread of antibiotic resistance genes: ... If Ad26.COV2.S 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.** ... 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 tumour 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.... 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 tumours. Today, viral DNA integration is an important paradigm in tumour 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 Ad26.COV2.S. ... 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 tumour formation due to chromosomal integration of the virus DNA and the expression of cancer-promoting proteins.** ...Another recent study now proves in a

living animal model that adenovector integration also occurs *in vivo* in mouse liver cells. …
All of these questions have a direct bearing on the approval of the Ad26.COV2.S vaccine, but they cannot currently be answered. ... **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....** 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 Ad26.COV2.S.** ...**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. Carcinogenecity 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), there are very specific reasons to expect causation of cancers through the integration of viral DNA into the host cell genome. Therefore, the EMA's decision not to demand carcinogenicity studies is not acceptable and must be categorically rejected. … High risk of ADE and severe lung disease after vaccination: Antibody-dependent enhancement (ADE) of infection has been observed in human subjects with several natural virus species, but also with vaccines for respiratory syncytial virus (RSV), dengue virus and measles. Vaccine-elicited enhancement of disease was also observed with SARS and MERS viruses and with feline coronavirus, which are closely related to SARS-CoV-2. Moreover, SARS-CoV and SARS-CoV-2 are highly homologous, with 80% sequence identity at the genome level, and the viral receptor on host cells for both is ACE2. An antiviral vaccine that induces ADE will aggravate rather than mitigate the corresponding viral infection. The immune mechanisms of this enhancement invariably involve antibodies. ...Since the clinical trials were carried out on a greatly accelerated schedule, with overlapping rather than successive stages ("telescoping"), it has not been determined whether ADE will occur after SARS-CoV-2 immunization. **Based on review of numerous scientific data (see below), the likelihood that ADE will occur in recipients of this coronavirus vaccine is high enough to be significant to reject these vaccines...**It seems likely that infection with natural coronaviruses or injection with vaccines against them may not only cause the production of (partial) protective neutralizing antibodies to viral antigens, but also poses a unique problem related to the Th2 immune response. **Many animals immunised by coronavirus vaccines show eosinophilic pathology in the lungs after new infection with the wild type virus or after vaccination.** The same phenomenon has been reported after immunization of mice with recombinant coronavirus spike proteins.... **In summary, a Th2-type immunopathologic reaction with severe lung inflammation and eosinophil infiltration upon challenge of vaccinated animals has occurred in three animal models including two different inbred mouse strains with four different types of SARS-CoV vaccines, both with and without alum adjuvant. We must assume that the Johnson & Johnson vaccine may cause similar reactions and massive harm to humans when the vaccinated persons subsequently encounter the wild type virus.... The prior evidence that vaccine-elicited ADE of disease is likely to occur to some degree with COVID-19 vaccines is consistent with several SARS vaccine studies and**

with clinical observations in SARS and COVID-19. The severe disease cases in Hubei Province, China, and in other areas were noted to have been due to ADE. Thus, in all, the medical literature clearly indicates a potential risk that vaccine candidates which encode the SARS-CoV-2 viral spike and elicit anti-SARS-CoV-2 antibodies, be they neutralizing or not, will increase COVID-19 disease severity when the vaccinated individuals encounter the circulating wild type virus. It is therefore **irresponsible to vaccinate people with a vaccine that has not been properly tested, which would take several years, all the more since many of the individuals to be vaccinated already have pre-existing conditions that will prevent them from coping with additional lung disease. Such lung disease is highly likely to be triggered by infection with the wild type virus in the next flu season. Thromboembolic disease, thrombocytopenia, and disseminated intravascular coagulation:**

A previous 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 thrombi were 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 thrombosis frequently occurs in atherosclerotic arteries after adenovirus-mediated gene transfer.** ...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, HAdv-C5 was also shown to bind avidly to coagulation factor X, which suggests a mechanism for the direct activation of the plasmatic coagulation cascade, with possibly devastating consequences.** ...**Such uncontrolled activation and recruitment could lead to thrombosis, tissue damage, and loss of organ function. If this occurs in multiple locations at once - a condition referred to as disseminated intravascular coagulation - it will also consume plasma coagulation factors and platelets. The upshot will be simultaneous diffuse, aberrant blood clotting and bleeding. The absence of thrombocytopenia in KO mice deficient in complement factors C3 and B also suggests a role of the serum complement system in this phenomenon.** ...**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.** ... **Risk of coagulopathies due to an autoimmune attack:**

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 characterised by haemorrhagic diathesis and profuse bleedings. Several independent pathways may converge to cause these potentially fatal events. **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 recognised 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, with 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. ...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 outcome has been examined, let alone excluded, in any preclinical animal experiments. However, in the main clinical study, a numerical imbalance was observed for the venous thromboembolic events with 11 subjects in the vaccine group (6 DVT, 4 pulmonary embolism, 1 transverse sinus thrombosis) versus 4 in the placebo group. Clotting disorder can also impact the health of the nervous system; 10 subjects in the COVID-19 group reported 12 serious adverse events compared to 8 subjects reporting 8 serious adverse events in the placebo group. Six serious adverse events are considered to be related to Ad26.COV2.S (2 facial palsies, 1 cerebral hemorrhage, 1 Guillain-Barre syndrome, 1 radiculitis brachial, and 1 transverse sinus thrombosis). No association was found in the placebo group. 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. ... <u>The risk-to-benefit ratio of the vaccine</u> It has already been discussed above that applying a vaccine with potentially grave risks to healthy persons is very problematic. Just how much of a benefit might we expect from this vaccine? Even assuming that it induces robust, long-lasting immunity, the benefit must be considered very small. The mortality due to COVID-19 in the general population is very low, as shown by Ioannidis. This is probably related to the documented fact that a very great majority of the adult population has some measure of cellular cross-immunity to SARS-CoV-2, presumably due to prior infection with conventional respiratory corona viruses. It must further be noted that, as the natural pandemic progresses, the proportion of individuals who have already been infected by the virus, and who will therefore now be immune, will continually increase. These individuals will derive no possible benefit from the vaccination, but they are likely at increased risk of adverse events, even though the clinical studies have failed to address this important question. Thus, the ratio of benefit to risk will decline with time, and the decline will likely be significant within even a few short months. The risk-benefit

relation must therefore be reassessed, and the conditional approval of the vaccines be reevaluated, at intervals shorter than the currently effective approval period of one year. **”**

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

96. **By 18.05.2021, the** official EU database on "COVID-19 Vaccine Janssen", which has not yet been used at all in a number of EU countries, **recorded around 4,200 cases of adverse reactions**, including around **140 registered deaths.**

97. It is in no way comprehensible how the EMA can insist on its recommendation for the conditional approval of "COVID-19 Vaccine Janssen", despite serious side effects with fatal consequences that 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 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).**

98. **On 28 February 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 Janssen" and, if the concerns could not be allayed, to immediately withdraw the recommendation for conditional approval of these substances** (Doc. **A.23**). 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 recognise 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, among 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.
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 Janssen"**. There are several mechanisms involved. Some of these also affect the mRNA-based vaccines, but in the case of the "Covid vaccine" Janssen, there are additional risks associated with the nature of the adenovirus vector used here. Clinically, these coagulation disorders can take various forms: Acute occlusion of single large vessels, manifesting mostly 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. It was therefore in no way surprising to experts that immediately after the introduction of the AstraZeneca "vaccine" and now repeatedly with the use of the "Janssen" substance, reports of severe coagulation disorders accumulated, especially in younger people. The EMA has reacted by merely integrating the product information on the substance "Janssen" and continues to claim a positive benefit-risk ratio (see press release of 20.04.2021**; doc. 24**.).
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 Janssen "vaccine". However, **there is absolutely no reason to assume that these two diseases were the only manifestations of coagulation disorders caused by the vaccination. Diseases such as heart attacks, strokes (thromboembolic or haemorrhagic), and deep vein thrombosis (often followed by pulmonary embolism) are disproportionately more frequent spontaneously, so that their occurrence among vaccinated persons will not necessarily arouse suspicion**. **However, until proven otherwise, one must assume that these diseases will also occur more frequently after vaccination. It is <u>therefore grossly misleading to include only the two already sufficiently documented but rare</u>**

clinical pictures when weighing up the benefits and risks of the vaccine, and to exclude these possibly much more frequent consequences.

The list of diseases 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 who died of multi-organ failure a short time after vaccination. This could have been caused by diffuse microthrombosis in the organs concerned. If the pulmonary vascular system is affected, this could lead to the misdiagnosis of pneumonia. In combination with false-positive PCR, such cases would then be erroneously attributed to COVID 19 infection.

Cerebral venous thrombosis, is always a life-threatening condition that requires immediate medical attention. It is likely that the EMA numbers represent only 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 impaired speech, one-sided body sensation, weakness, and loss of consciousness. Many people reported such symptoms directly after the "vaccination". Clot formation in the deep veins of the legs, in some cases with subsequent pulmonary embolisms, has also been repeatedly reported.

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

100. **2.2 Invalidity due to non-existence of the requirement according to Article 4 (1) b) of Regulation (EC) No 507/2006 - applicant is unlikely to be able to provide the comprehensive clinical data.**

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

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

102 1.) As already stated above under point 2.1.1, the **studies on "COVID-19 Vaccine Janssen"** 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 the **study designed by the applicant cannot provide comprehensive clinical data on the essential point of efficacy. For this reason alone, the condition for conditional approval set out in Art. 4 (1) b) is not fulfilled!**

103 2.) In view of the fact that "COVID-19 Vaccine Janssen" is in fact a substance that acts like a "gene therapy medicinal product", but the **authorisation procedure applied and the studies conducted do not comply with the special provisions for so-called "advanced therapies" (Commission Directive 2009/120/EC of 9 September 2009 and Regulation (EC) No 1394/2007 of 11 November 2007 on advanced therapy medicinal products). "(Commission Directive 2009/120/EC of 14.09.2009 and Regulation (EC) No 1394/2007 of 13.11.2007 on advanced therapy medicinal products), the applicant will by definition not provide the comprehensive clinical data required for a medicinal product that in fact acts like a "gene therapy medicinal product".**

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

105 **2.3 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 which can be filled by the authorised medicinal product.**

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 have it confirmed, on the basis of evidence of very good therapeutic successes, that they are allowed to use hydroxychloroquine on patients 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 judgement (Doc. **A. 10** - Consiglio di Stato - Council of State - Rome Judgment No. 0970/2020 of 11.12.2020).

In their fight against the low-cost hydroxychloroquine (Doc**. A. 25.1**) - which, thanks to its anti-inflammatory and antithrombotic properties, has also proved effective in the early treatment of high-risk patients - the opponents published a fabricated study in the Lancet (the Surgisphere scandal - Doc**. A. 25.2**) and conducted toxic overdose studies in intensive care patients (the "SOLIDARITY" and "RECOVERY" studies - Doc. **A. 25.3**).

108 But the drug "ivermectin", which has been used highly successfully in Covid-19, is very difficult to overdose, and unlike HCQ, it works as a prophylactic against infections and even in intensive care patients.

Dozens of studies and several metastudies have already established that low-cost ivermectin is highly effective against covid (Doc. **A. 25.4**).

According to recent studies in several countries, the antiparasitic drug ivermectin - a WHO essential drug - achieves risk reductions of up to 98% (Doc**. A. 25.5**) 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 illnesses (Doc. **A. 25.6**) even in high-risk patients in nursing homes with an average age of 90 years.

In addition, an analysis just published in the International Journal of Antimicrobial Agents found that African countries using ivermectin as prophylaxis against parasites have a much lower (Doc. **A. 25.7**) - even almost zero - incidence of covid compared to other African and non-African countries.

The very high reported efficacy of the low-cost ivermectin against SARS-like coronavirus infections, compared to the very modest and fundamentally questionable efficacy and the absolutely intangible and assessable risks of "COVID-19 Vaccine Janssen", is clear evidence that "COVID-19 Vaccine Janssen", unlike ivermectin, is not suitable for closing a medical care gap.

The specific question arises in this context: **why is ivermectin not widely used in the EU?**

Based on the above results, the US Front-Line Covid-19 Critical Care Alliance (FLCCC), for example, recommends ivermectin for covid-19 prophylaxis and early treatment (Doc**. A. 25.8**).

Apart from the fact that there are drugs with which Covid 19 patients can be treated very well and which, as in the case of ivermectin, can even be used prophylactically, it is obvious that the EU member state governments and the European Commission are not interested in recommending or promoting the use of other very inexpensive but efficient substances to the population. Vitamin D is one of them.

109 In a Spanish randomised controlled trial (RCT - Doc. **A. 25.9**), high-dose vitamin D (100,000 IU) reduced the risk of receiving intensive care by 96%.

In a study (Doc. **A. 25.10**) in a French nursing home, an 89% decrease in mortality was found in residents who had received high-dose vitamin D just before or during covid 19 disease.
A large Israeli study (Doc **A. 25.11**) found a strong link between vitamin D deficiency and the severity of Covid 19 disease.
A meta-study conducted in 2017 **(Doc. A. 25.12.**) found a positive effect of vitamin D on respiratory infections.

Equally successful is the use of zinc in combination with HCQ, for example.

US physicians reported (**Doc A. 25.13.**) an 84% decrease in hospital admissions, a 45% decrease in mortality in already hospitalised patients, and an improvement in patients' condition within 8 to 12 hours based on early treatment with zinc in addition to HCQ.
A Spanish study (Doc **A. 25.14**) found that low plasma zinc levels (below 50mcg/dl) increased the risk of death in hospitalised covid patients by 130%.

110 **While European countries and the US continue their aggressive military roll-out of experimental, expensive and dangerous agents declared as vaccines but de facto functioning like gene 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. 25.8**) 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 USA has been refusing emergency approval of ivermectin for the treatment of coronavirus for months on the grounds that "further testing is required". And the EMA, which is also obviously pursuing the interests of the pharmaceutical industry, but not of the EU population, and is grossly violating its control obligations, is doing the same, which in the case of ivermectin is tantamount to an outrageous scandal, after the drug has been in use for decades and serious side effects have been ruled out, in contrast to the experimental substances for the alleged prevention of disease from constantly mutating viruses, such as corona viruses, which admittedly guarantee the pharmaceutical industry an unprecedented and endlessly programmed profit (Doc. **A. 25.15)**

111 In contrast, India had adopted the treatment protocol specified by FLCCC and now manufactures this product under the brand name "Ziverdo Kit", and it costs only about $2.65 per person.
Although the U.S. National Institutes of Health (NIH) does not recommend treatment for SARS-COV-2 sufferers "unless the patient is hospitalised and requires oxygen", early treatment of coronavirus patients, including the use of hydroxychloroquine (HCQ), has begun in India.
Dr Makarand Paranjpe and his wife, both 77-year-old Indian doctors, fully recovered from the COVID-19 virus last November with early treatment, reports TrialSiteNews (TSN - Doc **A. 25.16**). 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 this replication as early as possible is the simple function of these low-cost and safe treatments. "*

Last March, as debates raged in the US over the merits of HCQ, India had already recommended it in its national guidelines, reiterating that it "*should be used as*

early in the disease course as possible...and avoided in patients with severe disease."

Following the discovery of ivermectin's effectiveness in treating the virus in June and subsequent extensive testing, the country's largest state, Uttar Pradesh (UP) (population 230 million), announced in August (Doc **A. 25.17**) 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 ivermectin is recommended there too," writes TSN's Mary Beth Pfeiffer.
Dr Anil K. Chaurasia, a doctor in UP, confirms that **from mid-September onwards, "there was a marked decline in COVID cases and deaths 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 also successful in other countries
FLCCC cited similar results in Peru, Argentina, Brazil and several other South American countries demonstrating the efficacy of ivermectin.
In his written testimony before the US Senate Committee, for example, an FLCCC representative told the committee that in Peru "the peak in 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 Janssen", which have a very modest positive effect, if any, and in effect act like a "gene therapy drug", should never have been approved in a fast-track procedure!

Ivermectin has recently also been available 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 spokesperson 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, reported the daily Denník N. (Doc**. A. 25.18**).

Ivermectin is also demanded in other countries and in some cases already used.
Prof. Paul R. Vogt, Clinic Director of the University Hospital Zurich and visiting professor at a university in Wuhan, had called for an emergency authorisation for ivermectin in an urgent appeal to the Swiss Federal Council at the end of December (Doc**. A. 25.19**). At least in such a way that people who want it can have regular access to the drug.
In Italy, a group of doctors who have 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. 10.**), have long since called on the Italian health authorities to approve ivermectin. To date, Italy, as in other EU countries, continues to rely on

experimental genetic engineering-based active substances that are extremely questionable in their use and highly dangerous (which, contrary to their mode of action, are declared as "vaccines"), for reasons that are not objectively comprehensible (if one wants to assume the well-being of the population as the goal), rather than on the use of medicines that have gone through proper approval procedures and whose modest side effects have long been known.

112 **2.4 Invalidity due to non-existence of the condition according to Regulation (EC) No 507/2006 - Article 4 (1) d) - non-existence of the public health benefit of the immediate availability of the medicinal product on the market and outweighing of the risk due to still missing additional data.**

113 Based on what has already been stated and documented above, the risk due to still missing additional data far outweighs the de facto non-existent public health benefit of the immediate availability of "COVID-19 Janssen" on the market.
This substance should never have been approved in the procedure chosen for this purpose in view of the missing prerequisites 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 Violation of the EU legal provisions for the authorisation of "advanced therapy medicinal products".**

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

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.
Passive vaccination involves injecting concentrates of antibodies that 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 contested here (Doc. **A.2.2**) states literally on page 4: ***"The duration of the protective effect of the vaccine is not known, as it is still being determined in the context of ongoing clinical trials".***

118 **"COVID-19 Vaccine Janssen" has not been shown to directly or successfully lead to active immunisation.**
The Robert Koch Institute explicitly states the following on its homepage: "*How long the vaccination protection lasts is not yet known. The protection also does not start*

immediately after vaccination, and some vaccinated persons remain unprotected. In addition, it is not yet ***known whether the vaccination also protects against colonisation with the pathogen SARS-CoV-2 or against transmission of the pathogen to other people. Therefore, despite vaccination, it is necessary to protect oneself and one's surroundings by*** *observing the AHA + A + L rules* (distance rules, MNS).*"* (Doc**. A. 21**).

No active immunisation has been demonstrated for "COVID-19 Vaccine Janssen", and the target of passive immunisation is also not available.

119 **"COVID-19 Vaccine Janssen" as a genetically modified carrier virus substance cannot directly trigger an immune response. However, such a direct immune response is an obligatory function for vaccines. "COVID-19 Vaccine Janssen" is a classical *prodrug*, i.e. the precursor of a drug, which must first be metabolised by the body's own functions - in this case RNA transcription and protein biosynthesis - into the hoped-for functioning drug. This process is known and described for therapeutic drugs (prodrug), but not for vaccines (the term "provaccine" is unknown). This fact that "COVID-19 Vaccine Janssen" requires endogenous activation also rules out the possibility that this gene therapy drug is a vaccine. It is a gene therapy drug that is supposed to have immunostimulatory effects to alleviate severe consequences of infections caused by coronaviruses. The alleviation of disease symptoms are clearly functions attributed to medicines (including prophylactic), not vaccines.**

Accordingly, the active substance "COVID-19 Vaccine Janssen" 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 substance "COVID-19 Vaccine Janssen" corresponds to the definition of a "gene therapy medicinal product" according to Annex I, Part IV (advanced therapy medicinal products), point 2.1. of Directive 2001/83/EC.** Gene therapy medicinal product means a biological medicinal product which has the following characteristics: (a) it contains an active substance which contains or consists of a recombinant nucleic acid used in or administered to human beings for the purpose of regulating, repairing, replacing, adding to or removing a nucleic acid sequence (b) its therapeutic, prophylactic or diagnostic effect is directly related to the recombinant nucleic acid sequence it contains or to the product resulting from the expression of that sequence.

121 **"COVID-19 Vaccine Janssen" works exactly according to this principle. The active substance "COVID-19 Vaccine Janssen" should therefore have been subject to the specific requirements laid down in Part IV of Annex I for "advanced therapy medicinal products"**. **This was not the case.**

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

122 **3.2. A<u>nnulment of the implementing decision on the basis of the manifest error of assessment and the inadequate statement of reasons contained in the authorisation dossier by the risk management plan, which cannot be approved</u>**

and which contains no or inappropriate risk mitigation measures, as well as infringement of the principle of proportionality under Article 5 TEU.

The applicant has not proposed any risk mitigation measures (RMMs) in the Risk Management Plan (RMP) with regard to important potential safety concerns and missing information, or has proposed inappropriate RMMs for identified safety concerns and missing information, so that the RMP is grossly flawed as safety was not sufficiently demonstrated by the applicant, so that the application for conditional marketing authorisation should have been rejected (see judgment of 19 December 2019, Vanda Pharmaceuticals Ltd, T-211/18, ECLI:EU:T:2019:892, paras 64, 131) (Doc. **A.26**).

123 In principle, RMM measures are generally aimed at preventing or reducing the occurrence of adverse reactions that are unavoidable and associated with exposure to a medicinal product or, in the event of the occurrence of adverse reactions, reducing their severity or impact on the patient. All safety concerns mentioned in the RMP must be managed by appropriate RMMs in accordance with Art. 30 (1) lit c Implementing Regulation 520/2012, which must also be given special consideration in the summary of the RMP in accordance with Art. 31 (1) Implementing Regulation 520/2012. The risk minimisation measures are intended to optimise the safe and effective use of a pharmaceutical product. Both the planning and implementation of risk minimisation measures and the evaluation of their effectiveness are central elements of risk management and crucial for the positive benefit-cost assessment. Whether proposed risk minimisation measures are sufficient or not can therefore be decisive for any decision on the authorisation of a medicinal product. (Vanda Pharmaceuticals Ltd, T-211/18, para 120)

124 The defectiveness of the final Public Assessment Report (PAR) EMEA/H/C/005737/0000 (doc. **A.1.**) refers to the fact that the RMMs, including the routine measures and pharmacovigilance activities according to the RMP submitted by the applicant under point 2.7 (p.180ff) were considered sufficient on the basis of the opinion of the Committee for Medicinal Products for Human Use and the Pharmacovigilance Risk Assessment Committee (PRAC) without adequate justification. In fact, however, according to Art. 30 (1) lit c Implementing Regulation 520/2012, an appropriate RMM, the effectiveness of which is to be assessed by pharmacovigilance, must be taken for each risk or safety concern. This means that the pharmacovigilance system can only be activated once RMMs have been taken. In accordance with the aforementioned provision *e contrario, this* results in a mandatory obligation to take RMMs for important identified as well as potential and missing information. If no RMMs are taken with regard to important risks, there is also **no RMP that can be approved.**

125 The significant safety risk of "Vaccine-associated enhanced disease (VAED) including vaccine-associated enhanced respiratory disease (VAERD)" was not sufficiently excluded by the applicant Johnson & Johnson to make valid statements and the observation period was too short to exclude the safety concerns of VAED/VAERD, in particular with regard to the novel viral mutations, with sufficient plausibility. Moreover, the risk is investigated in all clinical trials that are a condition of approval and the applicant itself has not been able to exclude this risk with certainty, as shown in the RMP, p. 46:

126 *„... If VAED, including VAERD was to be identified as a true risk, depending on its incidence and severity, it could negatively impact the overall risk-benefit balance of Ad26.COV2.S for certain individuals. ”*

127 With regard to the significant safety risk of VAED/VAERD, which is also referred to as "antibody-dependent enhancement" (ADE), reference should be made to the relevant

scientific explanations in the enclosed expert opinion (Doc. **A.20**). This consistently explains on pages 32-35 why the risk is to be classified as extremely high and comes to the following conclusion:

128 *"In summary, a Th2-type immunopathologic reaction with severe lung inflammation and eosinophil infiltration upon challenge of vaccinated animals has occurred in three animal models including two different inbred mouse strains with four different types of SARS-CoV vaccines, both with and without alum adjuvant. We must assume that the Johnson & Johnson vaccine may cause similar reactions and massive harm to humans when the vaccinated persons subsequently encounter the wild type virus."*

129 In addition, a variety of other scientific papers exist, 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 and 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."*

130 On the other hand, **due to the mass vaccination campaign, which provides for widespread exposure of the population, and the increased occurrence of virus mutations, there is a particularly high risk of a massive adverse health effect on the European population from VAED/VAERD. This blatantly contradicts the general principle of protection of public health established by the case-law and the precautionary principle of the Union** (Vanda Pharmaceuticals Ltd, T-211/18, para 46).

131 Consequently, there **is a serious error of reasoning in the implementing decision in that the applicant did not propose an RMM, which is contrary to the wording of the aforementioned provision**. It would not have been disproportionate to the risk if it had been included in the summary of product characteristics - Doc. **A.2.2** - as well as in the package leaflet. This would have made the real and serious health threat transparent for doctors as well as for health workers and those willing to be vaccinated. **Due to the omission, which consequently also includes pharmacovigilance, no one gains knowledge of this serious safety concern and there is also no risk control through pharmacovigilance measures**.

132 **Further errors of assessment and reasoning of the PAR lie in the fact that no RMMs were set with regard to the serious safety risk of venous thromboembolism, as a result of which serious damage to the health of vaccinated persons has occurred in the meantime, which led to a change instead of a suspension of the approval. This was despite the fact that 11 cases of venous thromboembolism occurred compared to 6 cases in the placebo group**. The causality was assigned by the applicant without further justification - like other identified side effects - to the comorbidities instead of the vaccination *and* a causal relationship was strikingly rejected: *"However, as the majority of the participants had underlying medical conditions (such as obesity, hypothyroidism, diabetes) that could have contributed to the thrombotic and thromboembolic events, the causal relationship between Ad26.COV2.S vaccination and venous thrombotic events was not shown".* (PAR P. 202). However, on 1 March 2021, the EMA was

informed by several renowned scientists[4] about the risks of activated blood clotting ("thromboembolism") from the conditionally licensed Covid vaccines. Shortly thereafter, these concerns materialised, particularly with regard to the Janssen vaccine. On 11 March 2021, the EMA issued a press release[5] precisely informing about this emerging safety risk regarding AstraZeneca's "vaccine", which essentially works in the same way as the "Janssen" substance, confirming that 30 cases of thromboembolism had been recorded as a safety signal on 10 March 2021 and that consultations on this matter were taking place in the PRAC. In light of this, the RMP should not have been approved by the PAR of 11 March 2021 as this safety risk was currently being investigated as a general risk of thromboembolic events within the EMA and about which the EMA should have been made aware and informed by independent scientists on 1 March 2021 and should have reached this assessment based on its own technical expertise. The non-inclusion in the summary of product characteristics as RMM cannot be a sufficient risk minimisation measure and the CHMP would have been obliged to adequately address this risk through RMM in terms of patient safety.

133 **Overall, the following missing information was identified (pp. 190-193): use during pregnancy and lactation, use by immunosuppressed patients, use by people with fragile health status with comorbidities, interaction with other medicines and vaccinations, and long-term safety data. Since these are not concrete safety risks, but rather a general clause-like (unmanageable) area without a robust side effect profile of comparable gene therapy medicines, this RMP is in any case an obstacle to approval.**

134 Due to the lack of RMM for persons with fragile health status and co-morbidities, a wrong prioritisation strategy or medically contraindicated *de facto* vaccination obligation could be implemented, especially for the covid risk groups of elderly, very old ("old people's home residents") as well as sick people exists without the safety risks being properly declared and thus not accessible to consent.

135 According to established case law, the identified risk must be set against "simple" RMMs, such as warnings in the summary of product characteristics and in the package leaflet. In the case of a materiality of risk, the relevance of simple RMMs is often not sufficient (Vanda Pharmaceuticals Ltd, T-211/18, para 132). **In the case at hand, however, the materiality of the identified unforeseeable risks is exceptionally high, which has a negative impact on the benefit-cost profile, so that the non-inclusion of simple RMMs and not a single "additional" RMM constitutes a particularly serious error of assessment and lack of reasoning and results in the nullity of the act**.

136 This means that, in view of the potential for side effects that cannot be assessed, safe and effective use of "COVID-19 Vaccine Janssen" can be ruled out *a priori,* especially for the identified safety risks for which no RMMs have been set.

137 **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 the shortest possible time, compared to the medically absolutely incalculable health risks, in particular VAED/VAERD, as well as the lack of long-term safety data, for which no risk minimisation was provided, the Commission, respectively the EMA, exercised its discretion in the adoption of the legal act in a grossly erroneous and groundless manner** (PAR p.180 ff - Doc.ff - Doc. **A.1**),

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[4]https://doctors4covidethics.medium.com/

[5]https://www.ema.europa.eu/en/news/covid-19-vaccine-astrazeneca-prac-investigating-cases-thromboembolic-events-vaccines-benefits

since the regular health status of the entire population is massively and incalculably endangered by prophylactic gene immunisation, without the risks having been declared, explained or correlatively minimised (Vanda Pharmaceuticals Ltd, T-211/18, para. 53).

138 **The plea of violation of the principle of proportionality**

139 The implementing decision adopted is unlawful on the basis of the measures taken, since it is manifestly inappropriate to achieve the objective pursued by the competent institutions, namely the safe and effective use of the gene therapy medicinal product at issue against infectious diseases (see, to that effect, judgments of Pillbox 38, EU:C:2016:49 and the case-law cited). 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).

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

141 **For the control of safety risks due to the complete absence or partial simplicity of RMMs, both in isolation and in combination, less burdensome alternatives would have been available to achieve these objectives, in accordance with the enshrined principles of medicines law of "safety, efficacy and quality", which correlate with the protection of human health and life, by refusing authorisation under Article 5 TEU as an inappropriate measure**. Therefore, the present legal act, which includes the authorisation of the RMP proposed by the applicant, constitutes an inappropriate measure with regard to the aforementioned principles of medicinal product authorisation and public health.

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

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

144 According to Art. 11 point 4.4. 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, where appropriate.

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

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

147 Due to the gross error of assessment set out above under point 3.2, which led to a non-observance of significant safety risks, there is automatically also a 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 Invalidity due to violation of the EMA's own criteria for the surveillance of a "pandemic medicinal product" with enormous short-term exposure figures.**

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, inter alia, Annex II, point C *"Other terms and conditions of the marketing authorisation",* the submission of Periodic Safety Update Reports (PSURs).

150 It is absolutely inadmissible that safety reports on a medicinal product with short-term enormous exposure figures do not have to be submitted until 6 months after authorisation, further exacerbating the threat to public health.

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

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

153 Although these "orientations" or "guidelines" are not legally binding, they can be taken into account to a certain extent as supplementary considerations in the risk-benefit assessment of a medicinal product (see, accordingly, judgment of 16 October 2003, AstraZeneca, C-223/01, EU:C:2003:546, para. 28).

154 Against this background, the EMA itself understandably confirms the view that the submission of PSURs of pandemic vaccines as gene therapy products after 6 months is too late,

155 The actual "special conditions" (according to Art. 14a para. 4 of the Regulation 726/2004) concern, among other things, specific obligations to complete product and manufacturing quality of the active substance (Annex II), which have to be verified within the first 6 months, as well as, with regard to confirmation of efficacy and safety, the submission of the final clinical study report under point E "Specific obligation to complete post-authorisation measures under "special conditions"", which obliges the marketing authorisation holder to submit the final clinical study report for the study VAC31518COV3001, for the purpose of confirming the efficacy and safety of "COVID-19 Vaccine Janssen" only on 31.12.2023! This deadline is clearly outside a valid assessment period for the review regarding efficacy and safety etc. at the extension date.

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156 The health-threatening problem lies in the proof of efficacy and safety to be provided by the authorisation holder, which is not to be provided until the end of December 2023, although an annual review is to take place according to the implementation decision. This results in an irresolvable contradiction that calls into question the legality of this condition and thus the authorisation itself.

157 **3.5 Annulment of the implementing decision on the grounds of misuse of powers by the Commission concerning clinical trials or the Declaration of Helsinki, while at the same time adopting legislative measures to establish de facto compulsory vaccination.**

158 **The implementing decision is void because Annex I (summary of product characteristics) and Annex III (labelling 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) lit. d Directive 2001/20 and Art. 107m para. 2 Directive 2001/83, which allow information in the sense of the prerequisite of consent, i.e. *informed consent,* about direct or indirect study participation or the studies running in parallel and largely missing study results as well as, in principle, missing studies. As a result, there is no valid consent of persons who are administered the substrate due to the de facto compulsory vaccination**.

159 The implementing decision in question is based, inter alia, on the authorisation basis of Art. 4 last sentence of Regulation 507/2006 "*In emergency situations as referred to in Article 2(2), a conditional marketing authorisation may be granted provided that the conditions set out in points (a) to (d) of this paragraph are met, even if complete preclinical or pharmaceutical data have not yet been submitted".* In addition, the recitals should be consulted, which stipulate: "The granting of conditional marketing authorisations should be limited to those cases where only the clinical part of the application dossier is less comprehensive than usual. Incomplete preclinical or pharmaceutical data should only be allowed when a medicinal product is to be used in emergency situations against a threat to public health."

160 In this tension, in the sense of the precautionary principle and the safety of medicinal products, the other legal requirements concerning clinical studies remain unaffected (cf. Directive 2001/20 as well as Art. 107m para. 2 Directive 2001/83).

161 **The enclosed scientific 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 must be clearly communicated and every person must be informed about and consent to the factual study participation. The priority application of the precautionary principle or patient safety, in fact, obliges the missing studies not to be subject to a lower standard of protection with regard to indirect study participation due to the conditional approval**.

162 In addition, the following studies were approved in the RMP, which obtained secondary data from electronic health database portals: Study VAC31518COV4003, Studíe VAC31518COV4001 and Study VAC31518COV4002.

163 **With reference to Art. 107m para. 2 of Directive 2001/83, this procedure contradicts the requirements of Union law with regard to the welfare and rights of the participants, since there is no consent and the study design is not suitable for measuring all identified missing safety information due to the secondary and thus highly error-dependent data analysis. Moreover, it is a prophylactic**

vaccination of healthy individuals whose health status must not be jeopardised under any circumstances by identifying significant safety risks only after realisation through a non-interventional PASS. Secondary aggregation of side-effect data is reactive and, from the point of view of patient safety and the precautionary principle, inflicts enormous damage to health and leaves the health-damaged persons "unprotected".

164 These serious scientific misjudgements, in particular the neglect of the fact that the vaccination is administered as a prophylaxis, as already sufficiently explained under the above 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 systematically considered as a whole**. Point 25 states: "*The participation of persons capable of giving consent in medical research must be voluntary. Although it may be appropriate to involve family members or community leaders, no person capable of giving consent may be included in a research project unless he or she consents voluntarily.*"

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

166 In the case at hand, the marketing authorisation and thus the use in humans is not based on the legally required basis of comprehensive study results as laid down in detail in Annex I "Analytical, toxicological-pharmacological and medical or clinical standards and protocols in respect of the testing of medicinal products" of Directive 2001/83/EC. **As can be seen from the scientific opinion (**Doc. **A.20), essential study data are missing, which would have had to be provided unconditionally in the case of a regular medicinal product authorisation**. For example, no ADME studies (Scientific Opinion, p. 18), both genotoxicity and carcinogenicity studies, pp. 24-30), ecotoxicity and insufficient studies on fertility (p. 31) were carried out, to name but a few aspects. In contrast, according to the expert report, there were serious scientific errors and undeclared safety concerns, so that, taken as a whole, the limit was absolutely exceeded in the case of mass vaccination without sufficient study results on human trials.

167 At the same time, the Commission is pursuing a policy of establishing 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 total procurement volume of 2.6 billion doses of vaccine 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 another push to establish de facto Europe-wide vaccination obligation in order to be able to claim fundamental rights, in particular freedom of movement.

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

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

170 International law is not only an "integral part" of the Union legal order. Legal acts of the Commission that systematically and collectively violate *ius cogens* are *ipso iure* null and void in accordance with Article 53 of the Vienna Convention on the Law of Treaties, which is recognised under customary international law (see further references in the literature: *Schmalenbach*, in: Calliess/Ruffert, EUV/AEUV (Fn. 1), Art. 216, marginal no. 50; *Tomuschat*, in: von der Groeben/Schwarze, EUV/EGV (fn. 10), Art. 281, marginal no. 43; in detail *Schmalenbach*, in: Europarecht als Mehrebenensystem (fn. 4),67 (75 ff.))

171 Apart from this, the Agreement 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.

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

173. International law is not only an "integral part" of the Union legal order. **Legal acts of the Commission that systematically and collectively violate *ius cogens* are ipso iure null and void in** accordance with Article 53 of the Vienna Convention on the Law of Treaties, which is recognised under customary international law (see further references in the literature: *Schmalenbach*, in: Calliess/Ruffert, EUV/AEUV (Fn. 1), Art. 216, marginal no. 50; *Tomuschat*, in: von der Groeben/Schwarze, EUV/EGV (fn. 10), Art. 281, marginal no. 43; in detail *Schmalenbach*, in: Europarecht als Mehrebenensystem (fn. 4),67 (75 ff.))

Apart from this, the Agreement 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.

174. **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 offence of Art. 7 para. 1 lit k of the Rome Statute of the International Criminal Court, with reference to the wartime prohibition of *"inhumane treatment, including biological experiments"* and *"intentionally causing great suffering or serious injury to body or health"* under Art. 8 para. 2 lit 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 deliberate 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 caused as a consequence of state or community action.

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175. **4. Annulment of the contested implementing decision on the ground of gross violation of Articles 168 and 169 TFEU and Articles 3, 35 and 38 EU Charter**

176. On the basis of the facts and circumstances set out above and documented in this application, it is obvious that the implementing decision of the EU Commission contested here 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 measures.**
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 medicines and medical devices.
The European Commission has grossly violated all of these obligations entered into under Article 168 TFEU with the implementing decision contested here and is concretely putting the applicants in a situation that endangers their health.

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

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

179. **Article 169 TFEU (consumer protection**) guarantees consumers that, in order to ensure a high level of consumer protection, the EU shall contribute to **protecting the health** and safety of consumers and to promoting their **right to information**.

180. And according to Art. 38 of the EU Charter (consumer protection), the Union's policies should represent a high level of consumer protection.

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

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

Bolzano, 19 May 2021
RA DDr. Renate Holzeisen

The following documents are deposited:

A1 EMA Assessment report "COVID-19 Vaccine Janssen" Procedure No. EMEA/H/C005737/0000 of 11.03.2021; p. 1 to 221 of the annexes; paragraph 1; (colour print)

A2 P. 220 of the appendices

A2.1. European Commission, Implementing Decision of 11.03.2021 granting a conditional marketing authorisation for the medicinal product for human use "COVID-19 Vaccine Janssen-Covid-19 mRNA vaccine (Ad26.COV2-S[recombinant])" in accordance with Regulation (EC) No 726/2004 of the European Parliament and of the Council; pp. 221 to 224 of the Annexes; paragraph 2;

A2.2. Annexes I, II, III and IV to Implementing Decision C(2021) 1763 (final); pp. 225 to 262 of the Annexes; paragraph 3;

A2.3. Implementing Decision of the EU Commission of 22.04.2021 on the amendment of the marketing authorisation for medicinal product for human use "COVID-19 Vaccine Janssen - COVID-19 vaccine (Ad26.COV2-S [recombinant])" + Annexes; p. 263 to 302 of the Annexes; paragraph 4;

A2.4. Implementing Decision of the EU Commission of 07.05.2021 amending the conditional marketing authorisation granted by Decision C(2021) 1763 (final) for the medicinal product for human use "COVID-19 Vaccine Janssen - COVID-19 vaccine (Ad26.COV2-S [recombinant])" + Annexes; p. 303 to 342 of the Annexes; paragraph 5;

A.3. D.L 1 Aprile 2021, art. 4; pp. 343 to 356 of the Annexes; para. 7;

A.4. European Commission, Press release, Coronavirus: Commission approves third contract to secure access to potential vaccine, 8.10.2020; pp. 357 to 359 of the annexes; paragraph 12;

A.5. RA DDr. Renate Holzeisen, warning letter of 19.12.2020 to EU Commission, EMA et al.; pp. 360 to 434 of the annexes; paragraph 15; (colour print)

A.6. p. 435 of the annexes (colour print)

A.6.1 EU Vaccine Strategy - extract from the EU Commission's website, 11.02.2021; pp. 436 to 452 of the Annexes; paragraph 17;

A.6.2 European Commission, Communication united front to beat covid-19, pp. 453 to 465, paragraph 19;

A.6.3 EU 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 on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic (Digital Green Certificate), 17.03.2021, pp. 466 to 469, paragraph 21;

A.7. MedRixiv - The infection fatality rate of COVID-19 inferred from seroprevalence data, John P.A. Ioannidis, May 2020; pp. 470 to 480 of the appendices; paragraph 34;

A.8. Bulletin of the World Health Organization: Type: Research Article ID: BLT.20.265892 - Infection fatality rate of COVID-19 inferred from

seroprevalence data, John P.A. Ioannidis, 14.10.2020; pp. 481 to 502 of the appendices; paragraph 34; (colour print);

A.9. LaVerità, article on interview with new president of the Italian Medicines Agency announcing guidelines for GPs for home treatment of Covid 19 patients, *"Via libera agli anticorpi monoclonali e alle linee guida per curarsi a casa",* of 03.02.2021; pp. 503 to 504 of attachments; paragraph 35;

A.10. Consiglio di Stato, Rome Council of State Judgment No. 09070/2020 of 11.12.2020; pp. 505 to 541 of the Annexes; paragraph 35;

A.11. Tribunale Lazio, Ordinanza pubblicata il 04.03.2020 + AIFA, nota del 09.12.2020; pp. 542 to 548 of the Annexes; paragraph 35;

A.12. S. 549 of the Annexes

A.12.1. WHO, Bulletin, 30.01.2020 - WHO Director-General's statement on IHR Emergency Committee on Novel Coronavirus (2019-nCoV); pp. 550 to 554 of the Annexes; paragraph 39;

A.12.2. WHO, Bulletin, 30.01.2020 - Statement on the second meeting of the International Health Regulations (2005) Emergency Committee regarding the outbreak of novel coronavirus (2019-nCoV); pp. 555 to 563 of the Annexes; paragraph 42;

A.13. p. 564 of the appendices (colour print)

A.13.1. WHO, 17.01.2020, Interim guidance - Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases; pp. 565 to 571 of the Annexes; paragraph 43;

A.13.2. Christian Drosten, Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR; pp. 572 to 584 of the appendices; paragraph 43;

A.13.3. WHO, Summary table of available protocols; pp. 585 to 665 of the annexes; paragraph 43;

A.13.4. Eurosurveillance, Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR; pp. 666 to 674 of the Annexes; paragraph 43;

A.14. S. 675 of the Annexes

A.14.1. WHO, Bulletin, 14.12.2020 - WHO Information Notice for IVD Users; pp. 676 to 680 of the Annexes; paragraph 48;

A.14.2. WHO, Bulletin, 30.01.2020 - WHO Information Notice for IVD Users 2020/05; pp. 681 to 684 of the Annexes; paragraph 50;

A.15. S. 685 of the Annexes

A.15.1. The New Your Times - Your Coronosvirus Test is Positive. Maybe It Shouldn't Be, 29.08.2020; pp. 686 to 690 of the Annexes; paragraph 52;

A.15.2. EU Commission, Experts Christian Drosten and Lothar Wieler advise EU Commission, 18.03.2020, pp. 691 to 693, paragraph 53;

A.16. nature communications - Post-lockdown SARS-CoV-2 nucleic acid screening in nearly ten million residents of Wuhan, China; pp. 694 to 701 of the appendices; paragraph 54; (colour print);

A.17. p. 702 of the appendices (colour print)

A.17.1 Tribunal da Relacao de Lisboa, Conclusao, 11.11.2020; pp. 703 to 737 of the Annexes; paragraph 57;

A.17.2. Infectious Disease Society of America, Rita Jaafar and others, Correlation Between 3790 Quantitative Polymerase Chain Reaction-Positives Samples, pp. 738 to 740 of the appendices; paragraph 57;

A.17.3. The Lancet, Elena Surkova and others, False positive COVID-19 results: hidden problems and costs, 29.09.2020; pp. 741 to 743 of the appendices; paragraph 57;

A.17.4. Weimar Local Court, Judgment No. 9F 148/21 of 08.04.2021; pp. 744 to 929 of the Annexes; paragraph 57;

A. **17.5**. Prof.Dr.rer.bio.hum. Ulrike Kämmerer, expert opinion; pp. 930 to 956 of the annexes; paragraph 57;

A.17.6. Tumori Journal, Giovanni Apalone and others, Unexpected detection of SARS-CoV-2 antibodies in the prepandemic period in Italy, 11.11.2020; pp. 957 to 963 of the Annexes; paragraph 58;

A.17.7. Istat - Istituto Nazionale di Statistica - Impact of the Covid-19 Epidemic on the total mortality of the resident population in the first quarter of 2020; pp. 964 to 967 of the annexes; paragraph 59;

A.18. p. 968 of the appendices (colour print)

A.18.1. Retraction request letter to Eurosurveillance + Review report Corman-Drosten et al. Eurosurveillance 2020, Dr Peter Borger and others 27.11.2020; pp. 969 to 995 of the Annexes; paragraph 61;

A.18.2. Corman-Drosten Review Report, Addendum, last update 11.01.2021; pp. 996 to 1055 of the Annexes; paragraph 61;

A.18.3. Eurosurveillance, Response to retraction request and allegations of misconduct and scientific laws, 04.02.2021; pp. 1056 to 1068 of the annexes; paragraph 61;

A.18.4. Südtiroler Sanitätsbetrieb and Azienda Provinciale per i Servizi Sanitari Provincia Autonoma di Bolzano, letters dated 26.11.2020 and 25.11.2020; pp. 1069 to 1076 of the annexes; paragraph 62;

A.18.5. Physicians' Group, Requests for Disclosure of PCR Test Data Province of South Tyrol and Province of Trento of 27.10.2020 and 26.10.2020; pp. 1077 to 1088 of the Annexes; paragraph 62;

A.19. 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. 1089 to 1096 of the Annexes; paragraph 64;

A.20. Prof.Dr.Stefan Hockertz, Prof. Dr. Sucharit Bhakdi, Prof.Dr. Michael Palmer, Dr.med. Wolfgang Wodarg, expert opinion of 03.05.2021, pp. 1097 to 1148 of the annexes; paragraph 84;

A.21 Robert Koch Institute COVID-19 and Vaccination: answers to frequently asked questions, p. 20/21 pp. 1049 to 1151 of the appendices; paragraph 85;

A.22 Dr.med Wolfgang Wodarg, Dr Michael Yeadon, Petiton/Motion ..., 01.12.2020; pp. 1152 to 1195, paragraph 91; (colour print);

A.23 Call letter of an expert group to the EMA of 28.02.2021, p. 1196 to 1202 of the annexes; paragraph 98.

A. 24 European Medicines Agency, Covid-19 Vaccine Janssen: EMA finds possible link to very rare cases of unusual blood clots with low blood platelets; pp. 1203 to 1209 of the attachments; paragraph 99.

A.25S . 1210 of the appendices

A.25.1 1 hcqmeta.com: HCQ is effective for COVID-19 when used early: real-time meta analysis of 200 studies; pp. 1211 to 1278 of the appendices; paragraph 107; (colour print)

A.25.2. The Guardian, Sugisphere: governments and WHO changed Covid-19 policy based on suspect data from tiny US company, 03.06.2020; pp. 1279 to 1289 of attachments; paragraph 107;

A.25.3. France Soir, Oxford, Recovery et Solidarity: Overdosage in two clinical trials with acts considered criminal? 25.06.2020 S. 1290 to 1297 of the annexes; paragraph 107;

A.25.4. Swiss Policy Research - Covid-19: WHO-sponsored preliminary review indicates ivermectin effetctiveness, 31.12.2020; pp. 1298 to 1303 of the Annexes; paragraph 108;

A.25.5. ivmmeta.com - Ivermectin is effective for COVID-19: real-time meta analysis of 37 studies; pp. 1304 to 1329 of the appendices; paragraph 108; (colour print).

A.25.6. Science Direct - Bénéfice de l'invermectine: de la gale à la COVID-19, un exemple de sérendipité; pp. 1330 to 1335 of the appendices; paragraph 108; (colour print).

A.25.7. Science Direct - A COVID-19 prohylaxis? Lower incidence associated with prophylactic administration of ivermectin; pp. 1336 to 1348 of the appendices; paragraph 108; (colour print)

A.25.8. FLCCC - Protocol for the Prophylaxis and Early Outpatient Treatment of Covid-19; pp. 1349 to 1351 of the Appendices; paragraph 108; (colour print).

A.25.9. 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. 1352 to 1356 of the appendices; paragraph 109;

A.25.10. Sciece Direct - Vitamin D and survival in COVID-19 patients: A quasi-experimental study; pp. 1357 to 1360 of the appendices; paragraph 109;

A.25.11. medRxiv - The link between vitamin D deficiency and Covid-19 in a large population; pp. 1361 to 1386 of the appendices; paragraph 109; (colour print)

A.25.12. the bmj - Vitamin D supplementation to prevent acute respiratory tract infections: systematic review and meta-analysis of individual participant data; pp. 1387 to 1409 of the appendices; paragraph 109;

A.25.13. ScienceDirect - COVID-19 outpatients: early risk-stratified treatment with zinc plus low-dose hydroxychloroquine and azithromycin: a retrospective case series study; pp. 1410 to 1443 of the appendices; paragraph 109;

A.25.14. MedicalXpress - Lower zinc levels in the blood are associated with an increased risk of death in patients with COVID-19; pp. 1444 to 1446 of the appendices; paragraph 109;(colour print);

A.25.15. European Medicines Agency, EMA advises against use of ivermection for the prevention or treatment of COVID-19 outside randomized clinical trials - 22.03.2021; pp. 1447 to 1450 of the Appendices; paragraph 110;

A.25.16. TrialSiteNews - An Unlikely Nation is Kicking This Pandemic ... , 9 January 2021; pp. 1451 to 1456 of attachments; paragraph 111;

A.25.17. The Indianexpress - Up: New Protocol Ivermectin to replace HCQ in treatment of covid patients; pp. 1457 to 1469 of the appendices; paragraph 111;

A.25.18. Slovak Spectator - Use of parasite medication to treat coronavirus patients approved in Slovakia; pp. 1470 to 1474 of the Annexes; paragraph 111;

A.25.19. Tagblatt, Coronavirus - Covid- 19: Instead of eradicating the virus we give it a drug cocktail; pp. 1475 to 1483 of the appendices; paragraph 111;

A.26. COVID-19 Vaccine (Ad26.COV2-S [recombinant]) RISK MANAGEMENT PLAN (RMP); pp. 1484 to 1587 of the Annexes; paragraph 122