A CALL TO OUR HEALTH AGENCIES, GOVERNING BODIES OF THE EUROPEAN UNION AND ITALY:

THERE IS AN URGENT NEED FOR COMPLETE TRANSPARENCY REGARDING THE SERIOUS DANGERS OF THE MRNA PRODUCTS IN USE

Governing Bodies, Health Authorities and Agencies by definition and by law exist to serve and protect public health. One key responsibility of these agencies is to ensure the proper evaluation and scrutiny of any new medicines before their authorization and approval for general use. This is particularly necessary with entirely new substances and technologies, such as the recently introduced gene-based COVID-19 "vaccines."

The proper conduct of these approval procedures requires full transparency and that the precautionary principle be applied. Absolute transparency is in everyone's best interest, and in an open, democratic society should be by both the authorities and the people. However, it has been established that the well-defined procedures for the approval of new medicines, and the standards of transparency and of due diligence which are necessary to safeguard them, have been violated in connection with the authorizations of the COVID-19 "vaccines." These violations need to be mended with urgency.

The lack of transparency, on the part of the national and EU authorities in their authorizations of the mRNA products, is putting the entire population, now also including the children, at serious risk. In order to restore the missing transparency, CHD Europe is submitting a comprehensive FOIA request.

Dr. Renate Holzeisen, Children's Health Defense Europe has filed this FOIA request on 22nd July 2022 to the EU, EMA and European Commission, as well the the two Italian authorities responsible for fundamental public health (the national Ministry of Health, Istituto Superiore della Sanità and Aifa). These authorities are requested, with urgency, to disclose information on the so-called mRNA "vaccines" against COVID-19, namely, Comirnaty from Pfizer-BioNTech and Spikevax from Moderna.

There is plausible and experimental evidence that the mRNA contained in Pfizer/ BioNTech's Comirnaty and Moderna's Spikevax "vaccines" can be back-transcribed into DNA and then be inserted into the human genome. Such insertion events will cause gene mutations, which may lead to cancer and leukemia. The scientific opinion attached to our F.O.I.A. shows that reverse transcription from RNA into DNA, followed by insertion into the cells' chromosomes, is a mechanism that has been

known for many decades. It must also be assumed that the risk of reverse transcription, insertion, and mutagenesis increases with each further inoculation. (LINK TO THE SCENTIFIC REPORT OF EVIDENCE)

Furthermore, since it has been proven experimentally that the actual nature and function of the two substances Comirnaty and Spikevax can lead to an alteration of the human genome, it is clear that the "labelling" of the substances has been erroneous.

The two mRNA substances have been formally categorized as "vaccines", even though overwhelming data and facts show that they do not fulfil the function of a vaccine. The mislabeling of these two substances as "vaccines against infectious diseases" excluded them from the regulators' formal definition of gene therapy, which was then used to justify the omission of testing for genotoxicity, carcinogenicity and mutagenicity.

It is clear that these mRNA COVID-19 "vaccines" have exactly the mechanism of a gene therapy drug, since the inoculated mRNA is intended to change the protein expression of the human body cells so as to produce the spike protein. Moreover, since they do not actually have the function of traditional vaccines for the prevention of infectious diseases, the safety studies to be carried out by the manufacturers should have been subject in their entirety to the more restrictive provisions for advanced therapy products (as provided for in recital 10 of Reg. EC No. 1394/2007). Finally, this more extensive documentation should have been submitted for evaluation to the EMA's Committee for Advanced Therapies, since only that Committee guarantees, or at least should guarantee, the specific expertise that is necessary to evaluate substances that affect cell physiology through a genetic mode of action.

By permitting and encouraging or even mandating the repeated inoculation of these experimental substances, which have the potential to mutate the human genome, the national and EU authorities are placing the entire population, including children, at serious risk. To remedy this situation, there is an urgent need for absolute transparency.

To that end, CHD has requested the urgent release of the following:

1. The documentation proving the involvement of the Committee for Advanced Therapies in the respective procedure of the conditional marketing authorization of the two mRNA substances, Pfizer/BioNTech's Comirnaty and Moderna's Spikevax, as well as the opinion issued by the Committee for Advanced Therapies on the aspect of genotoxicity and/or related carcinogenicity risks, as well as on the mutagenicity of these two substances.

2. The documentation proving the evaluation (including the respective outcome) of the genotoxicity, carcinogenicity and mutagenicity of the two substances Comirnaty by Pfizer/BioNTech and Spikevax by Moderna.

To the addressees of the Italian institutions Ministry of Health, Istituto Superiore della Sanità and AIFA), in addition to the above, we also requested

3. The opinion of the Government's Technical Scientific Commission on the genotoxicity, carcinogenicity and mutagenicity of the two mRNA substances, Pfizer/BioNTech's Comirnaty and Moderna's Spikevax.

For information, please contact:
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Documentation in English, click here.
Documentation in Italiano, click here.

Dr. Holzeisen, human rights lawyer, is based in Italy. She is a member of the board of Children's Health Defense Europe and is also President of the Italian Legal Confederation for Human Rights (Confederazione legale per i Diritti dell'Uomo).

EXECUTIVE SUMMARY OF THE SUBMITTED F.O.I.A. REQUEST

Executive Summary of the Submitted F.O.I.A. Request

Children's Health Defense Europe have submitted an urgent F.O.I.A. request by our board member, Dr. Renate Holzeisen, to the EU (EMA and European Commission) and national (Italian Ministry of Health and Istituto Superiore della Sanità and Aifa) authorities responsible for public health to obtain fundamental information on the so-called Covid-19 mRNA "vaccines" (Comirnaty from Pfizer-BioNTech and Spikevax from Moderna).

Since the injection of these two substances into the body causes the nucleic acid contained in the two substances to cause the production of a specific spike protein (that of the SARS-CoV-2 virus) within the framework of so-called cellular protein expression, and this mechanism corresponds exactly to what EU regulations require for so-called gene therapy medicinal products.

There is plausible and experimental evidence that the mRNA contained in Pfizer/ BioNTech's substance Comirnaty can be retro-transcribed into DNA and can insert itself into the human genome. We have attached to our request a scientific report setting out this evidence, recalling the decisive facts in this regard established in science some time ago.

Contrary to what was officially declared to the population by the institutions responsible for the "vaccination" campaign, this synthetic mRNA does not remain in the muscle of the arm where inoculation takes place, but can be dispersed throughout the body, even crossing the blood-brain barrier (Nature Neuroscience: The S1 protein of SARS-CoV-2 crosses the blood-brain barrier in mice, Elizabeth M. Rhea et al) and has been found in the bodies of people treated with these substances even months after inoculation. After some particles have been absorbed and spike protein has been produced by them, this spike protein may facilitate the passage of other "vaccine" particles into the brain (**A Case Report: Multifocal Necrotizing Encephalitis and Myocarditis after BNT162b2 mRNA Vaccination against Covid-19**).

There is now not only great concern, but also evidence that inoculated synthetic mRNA can be back-transcribed into DNA, and that these DNA copies can insert themselves into the chromosomal DNA of human cells. Therefore, genetic information from RNA can contaminate and alter the human genome (Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b" in vitro in human liver cell line, Markus Alden et al).

The scientific opinion attached to our F.O.I.A. shows that reverse transcriptase from RNA into DNA is a mechanism that has been known for many decades. So, nothing new and, above all, nothing that can be ruled out. On the contrary! The risk of reverse transcription and chromosomal insertion, of course, increases with each further inoculation.

The two mRNA substances Comirnaty and Spikevax have been formally "categorized" as "vaccines" - even though, as the facts show, they do not fulfill the function of a vaccine. And evidently, they are substances which, on the basis of a labelling of mere convenience, have been formally categorized as "vaccines", irrespective of their real nature, without having such a function. Apart from the obvious mislabelling, these two substances should, in any case, have been tested for genotoxicity, carcinogenicity and mutagenicity, for the following reasons.

Although "vaccines against infectious diseases" have been excluded from the definition of "gene therapy medicinal products", in consideration of the real nature and function of the two substances Comirnaty and Spikevax (which, as set out above and documented here, can lead to an alteration of the human genome, with retro-transcription of mRNA modified at the level of nucleosides), and having noted, therefore, the erroneous "labelling" of the substances Comirnaty and Spikevax, it is absolutely necessary to take into consideration what the European legislator has provided for gene therapy medicinal products.

According to point 2 of Annex I Part IV of Directive 2001/1983 (definitions 2.1)

"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 with a view to regulating, repairing, replacing, adding or deleting a genetic sequence ;

b) its therapeutic, prophylactic or diagnostic effect relates to the recombinant nucleic acid sequence it contains or to the product of the genetic expression of this sequence'.

Considering that the two substances Comirnaty by Pfizer/BioNTech and Spikevax by Moderna contain recombinant nucleic acid (RNA) and this can be reversely transcribed into DNA with modification of the human genome (see above), it is clear that these two substances can develop a genetic function that in fact falls within the definition of gene therapy drugs.

As regards the specific requirements for gene therapy products, the EU legislator also provides in Annex I Part IV Directive 2001/83 that

- Clinical studies must indicate the duration of function of the nucleic acid sequence and the proposed dosage regimen.
- Biodistribution studies must include research on persistence, clearance and mobilisation. Biodistribution studies must additionally assess the risk of germline transmission.
- Investigation of shedding and risk of transmission to third parties shall be provided with the environmental risk assessment…
- Repeated dose toxicity studies shall be provided when multiple dosing of human subjects is intended. The mode and scheme of administration shall closely reflect the planned clinical dosing. For those cases where single dosing may result in prolonged functionality of the nucleic acid sequence in humans, repeated dosing toxicity studies shall be considered. The duration of the studies may be longer than in standard toxicity studies, depending on the persistence of the gene therapy medicinal product and the anticipated potential risks. A justification for the duration shall be provided.
- Genotoxicity studies shall be performed
- Carcinogenicity studies shall be performed.
- Studies on the effects on fertility and general reproductive function must be performed.
- Embryo-foetal and perinatal toxicity studies and germ line transmission studies shall be provided.
- Integration studies must be performed for any gene therapy medicinal product
- Studies on potential immunogenic and immunotoxic effects shall be performed.
- Shedding studies to address the excretion of the gene therapy medicinal products must be included.

The function of the so-called “Covid-19 vaccines” is exactly as described by the EU legislator for the definition of gene therapy medicinal products.

According to recital (10) of Regulation (EC) No 1394/2007, 'The evaluation of advanced therapy medicinal products often requires very specific expertise, which goes beyond the traditional pharmaceutical field'.

In recital (10) of Regulation (EC) No 1394/2007, the Community legislator provided also that 'In addition, the Committee for Advanced Therapies should be consulted for the evaluation of any other medicinal product, which requires expertise falling within its area of competence'.

Given that the so-called mRNA “Covid-19vaccines” (Pfizer/BioNTech's Comirnaty and Moderna's Spikevax) have exactly the function of a gene therapy drug (the inoculated mRNA is intended to cause the body-cells to produce the spike protein and thus trigger cellular protein expression), and apart from the fact that they should have been subject in their entirety to the more restrictive provisions for advanced therapy products (since they do not actually have the function of traditional vaccines for the prevention of infectious diseases), they should (as provided for in recital 10 of Reg. EC No 1394/2007) in any case have been submitted for evaluation to the Committee for Advanced Therapies, since only that Committee, within the EMA, guarantees, or at least should guarantee, that specific competence which is necessary to evaluate substances that affect cell physiology because they have a genetic function.

Irrespective of the necessity of submitting Pfizer/BioNTech's Comirnaty and Moderna's Spikevax, although inappropriately referred to as “Covid-19-vaccines”, to the Committee for Advanced Therapy Products for evaluation, it must be considered that under Directive 2001/83/EC Annex I (Analytical, Toxico-pharmacological and Clinical Standards and Protocols in respect of the testing of medicinal products) Part 3 (toxicological and pharmacological tests) the Community legislator has provided that the study of mutagenic potency serves to reveal the changes produced by a substance on the genetic material of individuals or cells with the effect of making their successors permanently or hereditarily different from their predecessors. This study is required for any new substance.

The two substances Comirnaty by Pfizer/BioNTech and Spikevax by Moderna are explicitly defined as 'new substances' by the European Commission in their respective conditional marketing authorisation decisions of 21.12.2020 and 06.01.2021.

From the scientific report signed by Michael Palmer, Sucharit Bhakdi and Wolfgang Wodarg (Expertise on the genotoxic risks of the Pfizer Covid-19 vaccine), it appears that there was very clear scientific data, already dating back decades, that should have led to the risk of the genotoxicity of the so-called mRNA Covid-19-“vaccines” (such as Pfizer/BioNTech's Comirnaty and Moderna's Spikevax) being taken seriously.

Based on all above it is clearly assessed that the principle of precaution has been violated. Due to the seriousness of the risk to which the national and EU authorities are exposing the entire population, including children, we have asked for the urgent disclosure of the following information:

1. the documentation proving the involvement of the Committee for Advanced Therapies in the respective procedure of the conditional marketing authorization of

the two mRNA substances Comirnaty by Pfizer/BioNTech and Spikevax by Moderna, as well as the opinion issued by the Committee for Advanced Therapies on the aspect of genotoxicity, the associated risk of carcinogenicity and mutagenicity of the two substances, and

2. the documentation proving the evaluation and respective outcome of the genotoxicity, carcinogenicity and mutagenicity of the two substances Comirnaty by Pfizer/BioNTech and Spikevax by Moderna.

Recipients of the Italian institutions (Ministry of Health, Istituto Superiore della Sanità and AIFA), in addition to the above, are also asked to disclosure:

3. the opinion of the Italian Government's Technical and Scientific Commission on the genotoxicity, carcinogenicity and mutagenicity of the two mRNA substances Comirnaty by Pfizer/BioNTech and Spikevax by Moderna.

Considering the enormous risk that the entire population, and primarily minors, run with the repeated inoculation of experimental substances that can potentially mutate the human genome, it is of the utmost urgency to establish absolute transparency regarding the evaluation which was carried out (or not carried out) by the EMA and the European Commission in general, by the Scientific Technical Committee established by Decree of the Head of the Civil Protection Department 371 of 5.2.2020, as well as by the Italian Ministry of Health, the AIFA and the Istituto Superiore della Sanità). This pertains in particular to the risk of genotoxicity, carcinogenicity and mutagenicity related to the (repeated) inoculation of the two mRNA-substances (Comirnaty by Pfizer/BioNTech and Spikevax by Moderna) for public health, i.e. Italian/European citizens.