Urgent Open Letter from Doctors and Scientists to the European Medicines Agency regarding COVID-19 Vaccine Safety Concerns

Emer Cooke, Executive Director, European Medicines Agency, Amsterdam, The Netherlands

28 February 2021

Dear Sirs/Mesdames,

FOR THE URGENT PERSONAL ATTENTION OF: EMER COOKE, EXECUTIVE DIRECTOR OF THE EUROPEAN MEDICINES AGENCY

As physicians and scientists, we are supportive in principle of the use of new medical interventions which are appropriately developed and deployed, having obtained informed consent from the patient. This stance encompasses vaccines in the same way as therapeutics.

We note that a wide range of side effects is being reported following vaccination of previously healthy younger individuals with the gene-based COVID-19 vaccines. Moreover, there have been numerous media reports from around the world of care homes being struck by COVID-19 within days of vaccination of residents. While we recognise that these occurrences might, every one of them, have been unfortunate coincidences, we are concerned that there has been and there continues to be inadequate scrutiny of the possible causes of illness or death under these circumstances, and especially so in the absence of post-mortems examinations.

In particular, we question whether cardinal issues regarding the safety of the vaccines were adequately addressed prior to their approval by the European Medicines Agency (EMA).

As a matter of great urgency, we herewith request that the EMA provide us with responses to the following issues:

- 1. Following intramuscular injection, it must be expected that the gene-based vaccines will reach the bloodstream and disseminate throughout the body [1]. We request evidence that this possibility was excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.
- 2. If such evidence is not available, it must be expected that the vaccines will remain entrapped in the circulation and be taken up by endothelial cells. There is reason to assume that this will happen particularly at sites of slow blood flow, i.e. in small vessels and capillaries [2]. We request evidence that this probability was excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.
- 3. If such evidence is not available, it must be expected that during expression of the vaccines' nucleic acids, peptides derived from the spike protein will be presented via the MHC I pathway at the luminal surface of the cells. Many healthy individuals have CD8-lymphocytes that recognize such peptides, which may be due to prior COVID infection, but also to cross-reactions with other types of Coronavirus [3; 4] [5]. We must assume that these lymphocytes will mount an attack on the respective cells. We request evidence that this probability was excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.
- 4. If such evidence is not available, it must be expected that endothelial damage with subsequent triggering of blood coagulation via platelet activation will ensue at countless sites throughout the body. We request evidence that this probability was excluded in pre-clinical animal models with

- all three vaccines prior to their approval for use in humans by the EMA.
- 5. If such evidence is not available, it must be expected that this will lead to a drop in platelet counts, appearance of D-dimers in the blood, and to myriad ischaemic lesions throughout the body including in the brain, spinal cord and heart. Bleeding disorders might occur in the wake of this novel type of DIC-syndrome including, amongst other possibilities, profuse bleedings and haemorrhagic stroke. We request evidence that all these possibilities were excluded in pre-clinical animal models with all three vaccines prior to their approval for use in humans by the EMA.
- 6. The SARS-CoV-2 spike protein binds to the ACE2 receptor on platelets, which results in their activation [6]. Thrombocytopenia has been reported in severe cases of SARS-CoV-2 infection [7]. Thrombocytopenia has also been reported in vaccinated individuals [8]. We request evidence that the potential danger of platelet activation that would also lead to disseminated intravascular coagulation (DIC) was excluded with all three vaccines prior to their approval for use in humans by the EMA.
- 7. The sweeping across the globe of SARS-CoV-2 created a pandemic of illness associated with many deaths. However, by the time of consideration for approval of the vaccines, the health systems of most countries were no longer under imminent threat of being overwhelmed because a growing proportion of the world had already been infected and the worst of the pandemic had already abated. Consequently, we demand conclusive evidence that an actual emergency existed at the time of the EMA granting Conditional Marketing Authorisation to the manufacturers of all three vaccines, to justify their approval for use in humans by the EMA, purportedly because of such an emergency.

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

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

In view of the urgency of the situation, we request that you reply to this email within seven days and address all our concerns substantively. Should you choose not to comply with this reasonable request, we will make this letter public.

This email is copied to:

Charles Michel, President of the Council of Europe

Ursula von der Leyen, President of the European Commission.

Doctors and scientists can sign the open letter by emailing their name, qualifications, areas of expertise, country and any affiliations they would like to cite, to Doctors4CovidEthics@protonmail.com

References

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Yours faithfully,

Professor Sucharit Bhakdi MD, Professor Emeritus of Medical Microbiology and Immunology, Former Chair, Institute of Medical Microbiology and Hygiene, Johannes Gutenberg University of Mainz (Medical Doctor and Scientist) (Germany and Thailand)

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Professor Stefan Hockertz, Professor of Toxicology and Pharmacologym, European registered Toxicologist, Specialist in Immunology and Immunotoxicology, CEO tpi consult GmbH. (Scientist) (Germany)

Dr Lissa Johnson, BSc BA(Media) MPsych(Clin) PhD, Clinical Psychologist and Behavioural Psychologist, Expertise in the social psychology of torture, atrocity, collective violence and fear propaganda, Former member Australian Psychological Society Public Interest Advisory Group (Clinical Psychologist and Behavioural Scientist) (Australia)

Professor Ulrike Kämmerer PhD, Associate Professor of Experimental Reproductive Immunology and Tumor Biology at the Department of Obstetrics and Gynaecology, University Hospital of Würzburg, Germany, Trained molecular virologist (Diploma, PhD-Thesis) and Immunologist (Habilitation), Remains engaged in active laboratory research (Molecular Biology, Cell Biology (Scientist) (Germany)

Associate Professor Michael Palmer MD, Department of Chemistry (studied Medicine and Medical Microbiology in Germany, has taught Biochemistry since 2001 in present university in Canada; focus on Pharmacology, metabolism, biological membranes, computer programming; experimental research focus on bacterial toxins and antibiotics (Daptomycin); has written a textbook on Biochemical Pharmacology,

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https://doctors4covidethics.medium.com/urgent-open-letter-from-doctors-and-scientists-to-the-european-medicines-agency-regarding-covid-19-f6e17c311595

The authors, led by <u>Dr. Sucharit Bhakdi</u>, professor emeritus of medical microbiology and immunology, and former chair, Institute of Medical Microbiology and Hygiene, Johannes Gutenberg University of Mainz, have not yet received a response from the EMA.

In a written statement Wednesday, the group said:

https://www.lifesitenews.com/news/12-prominent-scientists-and-doctors-to-eu-regulators-address-urgent-safety-concerns-or-halt-covid-vaccines

In a public statement the group said...

"No sooner did we deliver our letter than the Norwegian Medicines Agencywarned that COVID-19 vaccines may be too risky for use in the frail elderly, the very group these vaccines are designed to protect. We would add that, by virtue of the mechanisms of action of the vaccines, to stimulate the production of spike protein, which has adverse pathophysiological properties, there may also be vulnerable people who are not old and already ill. New data shows that vaccine side effects arethree times as common in those who have previously been infected with coronavirus, for example. None of the vaccines have undergone clinical testing for more than a few months, which is simply too short for establishing safety and efficacy.

"Therefore, as a starting point, we believe it is important to enumerate and evaluate all deaths which have occurred within 28 days of vaccination, and to compare the clinical pictures with those who have not been vaccinated.

"More broadly, with respect to the development of COVID-19 vaccines, the Parliamentary Assembly of the Council of Europe has stated in their Resolution 2361, on 27th January 2021, that member states must ensure all COVID-19 vaccines are supported by high quality trials that are sound and conducted in an ethical manner. EMA officials, and other regulatory bodies in EU countries, are bound by these criteria. They should be made aware that they may be violating Resolution 2361 by applying medical products still in phase 3 studies.

"Under Resolution 2361, member states must also inform citizens that vaccination is NOT mandatory and ensure that no one is politically, socially, or otherwise pressured to become

vaccinated. States are further required to ensure that no one is discriminated against for not receiving the vaccine."

The letter comes as apetition against UK Government plans for vaccine passports passed 270,000 signatures, more than double that required to compel consideration for debate by MPs. The petition will be debated in the UK Parliament on 15th March 2021.

Doctors and scientists can sign the open letter by sending their name, qualifications, areas of expertise and country of practice to:Doctors4CovidEthics@protonmail.com.

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https://pressat.co.uk/releases/breakig-news-doctors-scientists-write-to-ema-re-covid-19-vaccine-safety-be11df3b8f9d599b2560dea639700355/

Video prof. Sucharit Bhakdi MD je v tuto chvíli buď na uvedené strínce https://www.lifesitenews.com nebo na https://lbry.tv/@Doctors4CovidEthics:d/Prof.-Sucharit-Bhakdi-statement-on-EMA-open-letter.ENG:0