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By email: withdrawnproducts@ema.europa.eu emer.cooke@ema.europa.eu Emer Cooke

Executive Director

European Medicines Agency

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Brussels, 1 December 2023

Dear Mrs Cooke,

Thank you for your reply (EMA/451828/2023) to our letter of October 4th. We have taken good notice of your answers and they do clarify different issues, that we addressed in our letter. However, some points still remain unaccounted for.

Not authorized for transmission prevention

You full heartedly confirm that the Covid vaccines are not authorized for transmission control and you add: “The indications are for protecting vaccinated individuals only.” This confirmation shocks us in the light of the official vaccination campaigns in EU member states and declarations from responsible national authorities, which stated that citizens should actively seek vaccination not for themselves but for others. These official campaigns were very clearly pushing the notion of preventing transmission, for which there was no marketing authorization. Responsible ministers of Public Health stated in some kind of orchestrated effort that they could go “from door to door, from arm to arm” for vaccinations.

Based on this off-label encouragement, as not to say coercion when taking into account the severe restrictions imposed on the non-vaccinated, by high-level officials, who lacked any kind of official registration as medical doctors, citizens were lied to, emotionally blackmailed and manipulated into taking a vaccine, a booster and yet another vaccine.

While you were aware of this off-label use contrary to your own recommendations, you did not warn the public against these campaigns. Nevertheless, you are well aware of the safety risks when medicines are used off-label. This off-label use should have provoked a warning from your organization. We are not aware of any such warning. Can you clarify this?

No informed consent

This leads to the second point where your answer affirms our claims concerning a lack of informed consent. The information pushed by government officials and state media was in clear contradiction to the EMA's marketing authorization. There was, as you state in your response "[a] lack of data on transmissibility". Informing the public that vaccination would render the individual in a state of in-transmissibility, was therefore completely the opposite of the purpose of the marketing authorization.

Off-label use comes with unknown safety risks. In your own words: "All safety information should be considered carefully before administering or recommending vaccination." These considerations should have been done by medical professionals based on individual anamneses of a specific patient, because -as quoted above- "the indications are for protecting individuals only".

There were no medical doctors or other medical experts who could make an individual risk assessment regarding the vaccination because even the medical professionals were not adequately informed about the possible adverse events. There were only the online documentations of the vaccines of 224 and 574 pages respectively. We have not found legally required distinct documents for vaccinations and boosters.

This made it nearly impossible to adequately determine the presence of a medical indication to recommend or administer respectively a vaccine or a booster. Information about the restricted marketing authorization was also very poorly disseminated.

Even more, most people were vaccinated without any contact with doctors. The mass-vaccinations were mainly performed by non-health professionals recruited for vaccinating the masses without prior informed consent, which poses a serious problem in itself; a problem you should have addressed.

It is unbelievable that three years after the first off-label mass vaccinations with an experimental medicine, you are "currently considering ways to improve the way information is presented in

SmPC's and package leaflets". This acknowledges the fact that there is a serious problem with the information provided to both medical professionals and patients. Have you tried in any way to convince your counterparts in the Member States to get informed consent from the vaccinated?

Adverse event registration

In fact informed consent was hardly possible and therefore your responsibility regarding the proper use of the vaccines and the information spread by Member States regarding these vaccines, weights all the more heavy. As informed consent lacked and misinformation propagated by the governments of member states was unchallenged, your responsibility to monitor the safety of the products and your responsibility to end marketing authorization on signals of severe adverse events cannot be exaggerated. In this respect, you state: "We expect many reports of conditions occurring at or soon after vaccinations". This implies that data on adverse events within fourteen days of vaccination are of the utmost importance to assess the risks related to the vaccines. However, Member State officials adopted the policy that as it would take ten to fourteen days for the vaccine to produce spike proteins, adverse events within fourteen days after vaccination were often not to registered as related to the vaccination; on the contrary, adverse events were more often considered a symptom of a Covid-infection. This also excluded the recognition of Covid- breakthrough infections or confused vaccine-related infections for Covid-infections. Could you answer the question how you can assess the safety of the Covid-vaccines without reliable data on adverse events "at or soon after vaccination"? Could you provide us your assessments?

As the Infection Fatality Rate (IFR) dropped below 1%, the risk-benefit balance became seriously more sensitive for adverse events. Therefore, this underreporting of adverse events should be of grave concern to you. This is even more important for administering Covid-vaccines to the younger part of the population in the EU as younger people are almost without risks of severe illness caused by SarsCov2.

Given your own restricted marketing authorization, your own recommendation to assess individually whether vaccination is a valid treatment, and your responsibility in assessing the safety, you recommended vaccination for vulnerable people. The off-label use of the vaccines on young healthy people to prevent transmission should have triggered a warning from the EMA not to generally promote

vaccination on this group as the risks of adverse events outweigh the health risks of the SarsCov2 infection.

Given your own expectations, you should have protested against these registration policies. Could you please answer why you did not do so?

We note that various publications, whether proven or not, are circulating regarding the insufficient monitoring of adverse events. In this regard, reference is made to the potential co-existence of

adverse events databases that are not available to the public. Could you clarify whether there is a difference between the information available to the public regarding adverse events and the information available to the EMA and/or producers of the Covid-vaccines?

Batch depended safety

We are disappointed that you did not address our question regarding the safety of different batches as reported in the study "Batch-dependent safety of the BNT16b2 mRNA Covid-19 vaccine" (Schmeling, Manniche, Hansen, EJCI (53) 8). This study could point to a violation of good manufacturing practices or more likely to covert experimental batch-dependent differences in dose. It seems as if you ignored this study. We would like to know why you did not inform the public about these safety issues? Why didn't you withdraw these batches with many side-effects and inform the vaccinated patients? Could you provide us with data of the all cause mortality related to the batches used in the EU for the last two years?

Did you take steps to further analysis the documented safety-issues in EU Member States?

Did you, your delegates or national counterparts investigate the content of different batches, which you received from the manufacturer and that you keep in store, to verify the quality of the batches? If so, how? If not, we request you to do this investigation immediately and to perform a full analysis of the content of the batches including investigation on the presence of DNA, DNA plasmid residues, the lipids (and the purity and chain length of these lipids) and SV40 parts. We request the results of these investigations, the OCABR reports, the used limits, together with your conclusions and recommendations.

Furthermore, we request clarification of the effect of these Covid-vaccines on the human intestinal bacteria, the microbiome, and the risk of changes in their DNA as a result of (parts of) the content of the vaccines.

Gene therapy

Furthermore, we want to stress over and over again that you have a primary responsibility for the safety of the citizens regarding medicines and therefore, we want to point out the following.

We cited Directive 2009/120/EC Annex IV art 2.1: "
Gene therapy medicinal products shall not include vaccines against infectious diseases
." This means to us
: it is prohibited to use gene therapy medical products to treat infectious diseases.

This makes very good sense, because it is good medical practice to have complete individual anamneses before exposing an individual to such an extremely invasive treatment as gene therapy. The safety of the patient has always priority. However, if you interpret this article as: "
when you apply gene therapy medical products to treat patients with an infectious disease, it shall not be considered to be gene therapy in a legal sense
", then this interpretation bypasses all safety precautions that surround gene therapy.

As the responsible authority for the safety of authorized medicines, it is your duty to use the first interpretation and to discard the second one. And even if you consider the second interpretation to be legally valid, you should have put in all your authority to counter this second interpretation, because legal definitions do not discard the enormous risks to the health of the populations in the Member States as a consequence of the massive use of experimental gene therapy. Could you elaborate your position?

Efficacy

Finally, you indicate that the spike protein generated by the mRNA therapy is the anti-gen which triggers the immune response (quote: "
for mRNA vaccines, the anti-gen (the particle that triggers the immune response) is not the mRNA substance itself but the spike protein formed after vaccination
").

Therefore, we have the following situation:

mRNA vaccine

Triggers replication of the spike protein

Triggers immune response to the spike protein

SarsCov2

Triggers replication of the SarsCov2 virus

Triggers immune response to the SarsCov2 virus

You suggest on the one hand that an immune response to the spike protein would have a positive effect on the immune response to the SarsCov2-virus.

On the other hand, you state that the mRNA vaccine efficacy "wanes over time" and "repeated exposure (to the virus) may increase the chance of infections even in vaccinated people". Here you clearly admit the poor, if not lacking, immunization following the vaccinations.

Can you clarify the time during which the vaccine is effective?

The effect of the vaccination is at best transient and the response to the vaccinations can be as bad as a response to SarsCov2 infection. How did you scientifically weigh the benefits of vaccinations over natural immunity?

In the light of the changing side-effects with newer batches (as shown in the above mentioned study) we would like to have your documentation on the efficacy (if any) of the batches used over the last twelve months.

Summary

From your letter it has become clear that:

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The vaccinations should have been administered based upon the individual health assessment of the patient by a medical professional; thus, the unspecific vaccinations put the health of individuals unnecessarily in danger;

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The campaigns based upon preventing transmission were promoting off-label use and therefore misleading;

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The documentation regarding informed consent was inadequate. Thus creating the opportunity for governments to manipulate the population;

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The registration of adverse events should have started at the moment of vaccination. Excluding conditions during the first fourteen days was in serious conflict with EMA's recommendations, thus compromising the risk assessment of the vaccines;

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Safety precautions regarding gene therapy were circumvented by means of a legal ‘loophole’, thus jeopardizing the health of the citizens in the EU;

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The Covid-vaccination does not induce lasting immunization at best, and does for sure not protect against SarsCov2 infections. Therefore, natural immunization should be promoted.

Given your responsibility to safeguard the health of the EU citizens, we request an answer to our questions as soon as possible, and given the governmental abuse of the current marketing authorizations, again request immediate suspension.

Yours sincerely,

Marcel de Graaff Member of the European Parliament

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