EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Addressed to: We For Humanity, trust-in-humanity@pm.me

15 September 2021
EMA/520052/2021
Stakeholders and Communication Division

Dear Sirs and Madams,

Thank you for your letter addressed to Emer Cooke.

As an introductory remark EMA finds the comparisons you make both inaccurate and inappropriate. Indeed, it might be perceived as demeaning the suffering and dignity of those who experienced the terrible events of the holocaust.

The reference to medical experimentation is incorrect as all four COVID-19 vaccines authorised in the EU have a marketing authorisation. Once a medicinal product is granted a marketing authorisation by a regulatory authority, it can no longer be considered as an experimental product and any reference to a medical experiment does not apply.

For a medicine to be authorised in the EU through EMA, the Agency's human medicines committee (CHMP), composed of scientific experts from all EU Member States, must conclude that the medicine's quality, safety and efficacy are properly and sufficiently demonstrated.

COVID-19 vaccines have been evaluated following the same stringent scientific requirements for quality, safety and efficacy as for any medicine currently on the EU market. Authorisation is granted after a positive benefit-risk balance has been established based on all available data.

All EU-authorised COVID-19 vaccines have a conditional marketing authorisation. In Europe, conditional marketing authorisations are foreseen by EU legislation for the authorisation of medicines in emergency situations, in response to public health threats duly recognised by the WHO or the European Commission. Please note that conditional marketing authorisations are not exclusively reserved for public health emergencies. They are also granted to medicines for orphan diseases or for seriously debilitating or life-threatening diseases on the basis of less comprehensive clinical data than normally required (though nonetheless with a positive benefit-risk balance), and with obligations on the marketing authorisation holders for the data to be completed afterwards.

The authorisation guarantees that the vaccines meet rigorous EU standards for safety, efficacy and quality and that comprehensive data is still generated post-approval. It also offers a robust post-authorisation regulatory framework based on legally binding obligations.

In addition, enhanced and stringent safety monitoring is in place for all COVID-19 vaccines, to ensure that the benefits always outweigh the risks.

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When millions of people are vaccinated, it is inevitable that rare but serious incidents or illnesses will be detected after vaccination. Clinical trials cannot be powered to detect all rare events as it would render them unfeasible. The EU regulatory system's role is to rapidly detect such incidents, investigate whether there may be a link to the vaccine and to take any necessary action to protect the health of EU citizens and ensure that the vaccine continues to be used safely.

Unfortunately, there is a lot of misinformation circulating on the internet, especially in relation to side effects and deaths related to COVID-19 vaccines. This is mostly triggered by a misunderstanding of the safety monitoring process and the data that comes from safety monitoring databases such as EudraVigilance, the official source of information on suspected side effects in the EU. EMA and the national competent authorities continuously monitor this database to detect any new safety issues. Public access to these figures from this database is available through the following website: http://www.adrreports.eu. However, by its very nature such data is complex, ever changing, highly technical and difficult to interpret. While EMA provides public access to this information for transparency reasons, it cannot supply everyone with the necessary technical skills and understanding to interpret it.

It is essential to understand that EudraVigilance accepts side effect reports submitted by patients and healthcare professionals describing medical events observed following the use of a vaccine, without requiring any proof that the vaccine was the cause. It only confirms that the reported event occurred sometime after the vaccine was given.

The fact that someone has had a medical issue or died after vaccination does not mean that this was caused by the vaccine. This may have been caused, for example, by health problems not related to the vaccination. For most medicines, the vast majority of reported suspected side effects are not eventually confirmed to be due to the vaccine.

Please note that a high number of suspected side effect reports is expected due to the large number of people being vaccinated in a short period of time as well as people's heightened awareness of the importance of reporting any suspected side effects. Furthermore, thousands of people in the EU get sick or die every day, for all sorts of reasons. Considering the number of people who are vaccinated (nearly 400 million people in the EU have received the vaccines to date) a very high number of side effects after vaccination is therefore expected to be reported after vaccination.

As you may know, EMA has identified a few rare but serious side effects with COVID-19 vaccines, and in some, but by no means all cases, these have proved fatal. EMA has communicated on these side effects and this information is included in the safety updates (see https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-authorised#safety-updates-for-authorised-covid-19-vaccines-section).

For your convenience, we have presented an overview of these figures up to 5 August 2021:

Signal	Vaccine	No. reported cases	No. reported deaths among cases reported	No. doses administered or people vaccinated	Reported in safety update of:
Capillary leak syndrome	Vaxzevria	6	1	78 million doses EEA & UK	18-Jun[1]
Capillary leak syndrome	COVID-19 Vaccine Janssen	3	2	18 million doses worldwide	14-Jul[2]
Guillain Barré syndrome	COVID-19 Vaccine Janssen	108	1	21 million people worldwide	11-Aug[3]
Immune thrombocytopenia	COVID-19 Vaccine Janssen	120	4	21 million people worldwide	11-Aug[2]
Myocarditis/ pericarditis	Comirnaty	145/138	5	177 million doses EEA	14-Jul[4]
Myocarditis/ pericarditis	Spikevax	19/19	5	20 million doses EEA	14-Jul[5]
Thrombosis with thrombocytopenia syndrome	Vaxzevria	479	100	51.4 million EU/EEA	14-Jul[6]
Thrombosis with thrombocytopenia syndrome	COVID-19 Vaccine Janssen	8	1	7 million in US + 27,000 in clinical trials worldwide	22-Apr[7]

Even in these cases, which represent analyses of events that we consider plausibly linked to vaccination, we cannot definitively say that the vaccine caused any of the deaths reported. However, you will note that the numbers involved are very small in comparison to the huge numbers of persons given the vaccines, as well as in comparison to the numbers of deaths associated with COVID-19 infection (currently estimated by the European Centre for Disease Control at around 750,000 in the EU alone, see https://www.ecdc.europa.eu/en/cases-2019-ncov-eueea#:~:text=COVID-19%20situation%20update%20for%20the%20EU%2FEEA%2C%20as%20of,%20%207.40%20%2027%20more%20rows%20).

The full information on the known side effects with the currently approved COVID-19 vaccines can be found in section 4 of their package leaflet linked here:

[1] https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccine-safety-update-vaxzevria-previously-covid-19-vaccine-astrazeneca-18-june-2021_en.pdf
[2] https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccine-safety-update-covid-19-vaccine-janssen-14-july-2021_en.pdf
[3] https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccine-safety-update-covid-19-vaccine-janssen-11-august-2021_en.pdf
[4] https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccine-safety-update-comirnaty-14-july-2021_en.pdf
[5] https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccine-safety-update-spikevax-previously-covid-19-vaccine-moderna-14-july-2021_en.pdf
[6] https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccine-safety-update-vaxzevria-previously-covid-19-vaccine-astrazeneca-14-july-2021_en.pdf
[7] https://www.ema.europa.eu/en/documents/covid-19-vaccine-safety-update/covid-19-vaccine-safety-update-covid-19-vaccine-janssen-22-april-2021_en.pdf

Comirnaty – https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf

COVID-19 Vaccine Moderna (now known as Spikevax) – https://www.ema.europa.eu/en/documents/product-information/spikevax-previously-covid-19-vaccine-moderna-epar-product-information_en.pdf

Vaxzevria - https://www.ema.europa.eu/en/documents/product-information/vaxzevria-previously-covid-19-vaccine-astrazeneca-epar-product-information_en.pdf

COVID-19 vaccine Janssen - https://www.ema.europa.eu/en/documents/product-information/covid-19-vaccine-janssen-epar-product-information_en.pdf

Please note that as already explained to your representative Mr Engel in his previous communication with the Agency, it is simply untrue that the FDA identified a list of serious side effects of the vaccines prior to their authorisation. This piece of misinformation, widely circulated on social media, apparently relates to an FDA presentation describing Adverse Events of Special Interest (AESIs). These are serious medical events that are either plausible as side effects, due to the known mechanism of the vaccine or in the context of SARS-CoV-2 infection, or have occurred after use of other vaccines, and for which the pharmacovigilance system therefore needs to be particularly alert and monitor, both during clinical studies and once distribution and use of the vaccine has started. This does not mean the events were due to the vaccine. We would urge you not to circulate misinformation about this issue, as it can mislead the public with negative consequences for their health.

It is also untrue to assert that children are at 'zero risk' from COVID-19. Though the risk of death may be lower than in older age groups, UNICEF reports nearly 9,000 COVID-related deaths among persons under 20 years of age as of May 2021 (see https://data.unicef.org/topic/child-survival/covid-19/). In addition, substantial numbers of children are hospitalised and the medical literature indicates that some have long-lasting symptoms that have impacted their ability to study and have a normal life. In addition, since vaccination helps reduce the spread of the virus and the development of more harmful variants, vaccination of children may also help to protect their families and the wider community.

Finally, please note that EMA's legal mandate does not extend to issues of consent, the choice of vaccinations or the design of vaccination programmes, which are the responsibility of national medicines agencies.

We hope you find this information helpful.

Your sincerely,

Juan García Burgos

Dr Juan García Burgos
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