EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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European Medicines Agency

Dear Honourable Members of Parliament Marcel de Graaff, Gilbert Collard, Francesca Donato, Joachim Kuhs, Mislav Kolakušić, Virginie Joron, Ivan Vilibor Sinčić and Bernhard Zimniok

Thank you for your letter of 4 October 2023 in which you call for the suspension of the marketing authorisations of the mRNA COVID-19 vaccines Comirnaty and Spikevax.

The European Medicines Agency is committed to protecting public health by conducting thorough scientific assessments of medicinal products for the EU. We are equally dedicated to ensuring that the public and their representatives in the European Parliament are informed of the reasons why their medicines are authorised and of the measures we take to monitor them once they are available.

We should also emphasise that EMA focuses mainly on one aspect of EU health policy, namely the authorisation and monitoring of medicines and vaccines. When our scientific committees issue recommendations, other bodies, such as the European Commission, the European Centre for Disease Prevention and Control (ECDC) and national health and vaccination authorities can consider them as they develop immunisation policies to protect the public.

Please find below direct responses to the questions you raise in your letter.

1. The authorised indications

   You state that based on the authorised indications, the vaccines 'should only be administered to individuals who seek personal protection, and they are not authorised for the purpose of reducing transmission or infection rates (transmission control)'. You also state that the authorised indication does not align with uses promoted by 'pharmaceutical companies, politicians, and health professionals'.

   You are indeed correct to point out that COVID-19 vaccines have not been authorised for preventing transmission from one person to another. The indications are for protecting the vaccinated individuals only.

   The product information for COVID-19 vaccines clearly states that the vaccines are for active immunisation to prevent COVID-19. In addition, EMA's assessment reports on the authorisation of the vaccines note the lack of data on transmissibility.

EMA will continue to be transparent about the approved uses of COVID-19 vaccines and identify areas where we need to tackle misconceptions.

2. Authorisation of vaccines targeting the Omicron XBB.1.5 subvariant

You note that data from clinical trials are not available for adapted vaccines targeting Omicron XBB.1.5 subvariant. Given this and the fact that the international public health emergency is over, you question the need for authorising the adapted vaccines at this time.

We would like to stress that the authorisation of adapted COVID-19 vaccines is not contingent on the continuation of the public health emergency. The authorised indications do not restrict the use of the vaccines to an emergency.

Furthermore, data from clinical trials were not a scientific requirement for the Omicron XBB.1.5 adapted vaccines because of the information derived from the originally authorised and earlier adapted vaccines.

In its decisions to recommend authorisation of vaccines targeting the Omicron XBB.1.5 subvariant, EMA's human medicines committee (CHMP) considered all the available data on both the originally authorised vaccines and earlier adapted ones, including data on safety, efficacy and immunogenicity (how well they trigger immune responses). In addition, the Committee assessed laboratory data on the responses of the adapted vaccines against XBB.1.5 and related strains of SARS-CoV-2, the virus that causes COVID-19. Please also note that for Spikevax XBB.1.5, the Committee assessed some clinical data from an ongoing study.

Where the ending of the public health emergency may be relevant is in the vaccination strategies of EU Member States and the advice given to the general population. In this regard, the product information for COVID-19 vaccines state that the use of the vaccines 'should be in accordance with official recommendations'.

3. Environmental risk assessments for genetically modified organisms (GMOs)

I understand you have concerns about Regulation (EU) No 2020/1043/EU ("the Regulation") which, as stated in its Article 2 of the Regulation, allows for the conduct of some clinical trials with products containing GMOs without a prior environmental risk assessment.

You also note that, according to Article 4, the Regulation shall 'apply as long as WHO has declared COVID-19 to be a pandemic or as long as an implementing act by which the Commission recognises a situation of public health emergency due to COVID-19'.

It is important to first clarify that mRNA vaccines are not considered genetically modified organisms. It is our understanding that the Regulation was intended for other vaccines, such as vaccines that 'contain attenuated viruses or live vectors, which may fall within the definition of a GMO.'[1]

That said, we can provide you with information on the status of the environmental risk assessments for Comirnaty and Spikevax.

At the time of the initial authorisations of Comirnaty and Spikevax, the CHMP noted in its published assessment reports that, due to their nature, 'vaccines and lipids are unlikely to result in a significant risk to the environment'. The Committee further noted that it was acceptable for environmental risk assessment studies not to be provided in the applications for marketing authorisation. You can find more information in the published assessment reports on EMA's website

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32020R1043