EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 October 2020
EMA/565800/2020
European Medicines Agency

Dear Signatories,

Subject: Reply to open letter concerning the transparency and evaluation of vaccines for COVID-19

Thank you for your open letter of 15 October 2020 about EU policies for COVID-19 vaccines.

In your letter you highlight, amongst other things, the importance of transparency with regard to scientific data and of maintaining the highest regulatory standards in the evaluation of potential vaccines. I would like to address these points in particular, as they touch on EMA's values and our core work in protecting public health.

I completely agree that any authorised COVID-19 vaccines must have the highest possible degree of efficacy and safety. In response to the pandemic, EMA and regulatory agencies in Europe have focussed their resources on speeding up processes for evaluation and authorisation of treatments and vaccines. However, this does not signify a change in the standards of quality, safety and efficacy. As for other vaccines in the EU, the highest regulatory standards will continue to apply, and the integrity and independence of the scientific assessment will not be compromised.

One tool EMA is using to speed up the evaluation of vaccines is the 'rolling review.'
Typically, developers submit applications for marketing authorisation only after they have all the necessary data, and the submission is followed by an evaluation that can last up to 210 days. With the rolling review, developers can submit data from finalised studies as and when they become available, allowing EMA to start evaluating data at an earlier stage and before the developer submits a formal application. The result is a swifter review of data with no change to the robustness of the evaluation.

When an evaluation is complete, EMA has the option of recommending a conditional marketing authorisation. This type of approval can be granted if, despite the available data not being as extensive as normally required for an approval, the benefits from faster access to a potentially life-saving medicine outweigh the risks of having less comprehensive data. Approval can then be granted on the condition that the company will supply the additional complementary information within defined timelines, including the results of further studies, once the vaccine is on the market.
The use of conditional marketing authorisations would not be unique to this pandemic situation. Over the years, several medicinal products granted conditional marketing authorisation have gone on to receive full authorisation after more data were collected to confirm the benefit-risk balance, as requested as a condition to the marketing authorisation.

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In the context of this pandemic, I can guarantee that EMA will only recommend a conditional authorisation if the benefits of faster access to a potentially life-saving product outweigh the risks of not having comprehensive data at the time of authorisation. You can find out more about the approval process of vaccines on the COVID-19 pages on our website.

I also fully share your view about the importance of transparency, which is more relevant than ever in the present circumstances. In addition to meeting the public demand for information, making clinical data publicly available will support and make global research more efficient and allow public scrutiny and independent review. Transparency is also key to reinforcing trust in regulatory decisions and in any vaccines eventually authorised.

You may be aware that for many years EMA has been a pioneer in ushering in an unprecedented level of transparency with respect to the evaluation of medicines. In relation to COVID-19, we are increasing our transparency measures still further. We will now publish the product information with details of the conditions of use before the formal marketing authorisation is granted and we will publish the risk management plan in full. In addition, we will expedite the publication of the full EPAR (European Public Assessment Report) and commit to making it available within 3 days of authorisation by the European Commission. The EPAR is a critical piece of information which provides the public with comprehensive information about EMA's assessment and the rationale for its opinion.

Furthermore, we will publish all clinical data submitted to EMA in applications for COVID-19 medicines, once personal data have been anonymised and any commercially confidential information redacted in accordance with EU legislation.

In response to the pandemic, we are also increasing our direct engagement with stakeholders. Representatives of patients and healthcare professionals now participate in the meetings of EMA's COVID-19 Pandemic Task Force, where they can enrich the discussions with their unique perspectives and experiences as users of medicines. EMA also regularly updates the Agency's network of EU organisations representing patients, consumers and healthcare professionals (Patients' and Consumers' working party and Healthcare Professionals' working party) on the progress of EMA's COVID-19 activities.

I hope this letter provides some reassurance about EMA's commitment to be as transparent and open as possible and to maintain the highest regulatory standards of quality, safety and effectiveness when evaluating COVID-19 vaccines. It is only by keeping to these commitments that we can effectively combat the devastating effects of this pandemic.

Yours sincerely,

Professor Guido Rasi
Executive Director