EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
The Director

Brussels
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Dear Dr Plicka,

I have been asked to reply to your letter dated 29 December 2020 addressed to President von der Leyen concerning the authorisation of COVID-19 vaccines which was registered as received by the Commission on 10 March 2021. We have also received your confirmatory request of 26 April 2021. I apologise for the delay in replying to your correspondence.

The European Commission is coordinating a common European response to the coronavirus outbreak. Safe and effective vaccines are important in the fight against the SARS-CoV-2 virus and the return to our normal lives.

Due to the urgency of the pandemic, vaccines against the SARS-CoV-2 virus (COVID-19 vaccines) are being developed and authorised in an accelerated manner. But they still meet the same high standards as all other vaccines.

Massive investments have been made to develop rapidly COVID-19 vaccines. It was possible for the development to be done more quickly by combining different phases of the clinical trials.

The European Commission does not organise directly clinical trials but through its research and innovation funding programmes support has been made available for the development of the vaccines. In addition, the European Medicines Agency (EMA) is providing guidance for medicine developers and pharmaceutical companies to help speed up development and approval of COVID-19 related medicines.

To obtain a marketing approval for a vaccine in the EU, a vaccine developer needs to submit the results of all testing/investigations to the medicines regulatory authorities in Europe as part of a 'marketing authorisation' application. In the case of COVID-19 vaccines applications are being submitted to the EMA through the centralised procedure which allows the marketing of a medicine on the basis of a single EU-wide assessment

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and marketing authorisation valid throughout the EU. The European Commission takes a decision on whether or not to issue the marketing authorisation on the basis of the recommendation from the EMA. In line with its COVID-19 Vaccine Strategy[1], the Commission reduced the time taken to complete the authorisation procedure for COVID-19 vaccines.

The applications for authorisation of COVID-19 vaccines undergo a comprehensive scientific assessment carried out by EMA's expert scientific committees for human medicines and safety - the Committee for Medicinal Products for Human Use (CHMP) and the Pharmacovigilance Risk Assessment Committee (PRAC).

For COVID-19 medicines, EMA has put in place rapid review procedures to deliver assessments of applications in the shortest possible timeframes while ensuring robust scientific opinions. Key to this shortening of timescales are 'rolling reviews'. In a public health emergency, EMA assesses data for promising vaccines as they become available. EMA can therefore start evaluating data while the development is still ongoing. When the medicine's development is progressed enough for a marketing authorisation application, the formal assessment procedure can take place in a very short timeframe because the data have already been scrutinised during the rolling review.

The EMA's CHMP, once it has concluded its scientific evaluation of the data and after assessing the quality, safety and efficacy of the medicinal product in question, makes a recommendation to the Commission on whether the medicine should be granted a marketing authorisation in the EU.

The European Commission authorises COVID-19 vaccines in accordance with the applicable legislation, namely, Regulation (EC) No 726/2004 of the European Parliament and for the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p.1).

An essential phase in the decision-making for the authorisation of the COVID-19 vaccines is the consultation of the Member States through the Comitology process. Member States are responsible for the marketing and use of the product in their countries so they give their opinion on the authorisation before a decision is granted by the Commission.

The final stage is the adoption by the Commission through a decision taken by the College of Commissioners.

The names and dates of authorisation of the COVID-19 vaccines are given below. In addition, there is the link to their specific webpages in the Union Register of medicinal products[2] where copies of the initial authorisation decision, accompanying annexes and subsequent amendments can be found:

- Comirnaty - 21 December 2020 - https://ec.europa.eu/health/documents/community-register/html/h1528.htm
- COVID-19 Vaccine Moderna – 6 January 2021 - https://ec.europa.eu/health/documents/community-register/html/h1507.htm

[1] COM(2020) 680 final

[2] https://ec.europa.eu/health/documents/community-register/html/index_en.htm

- Vaxzevria (formerly COVID-19 Vaccine AstraZeneca) - 29 January 2021 - https://ec.europa.eu/health/documents/community-register/html/h1529.htm
- COVID-19 Vaccine Janssen - 11 March 2021 - https://ec.europa.eu/health/documents/community-register/html/h1525.htm

The vaccines have been granted conditional marketing authorisations which can be used, for example during public health emergencies, to speed up approval.

Conditional marketing authorisations are a well tested model used for medicines approval for a long time. They can be granted for a medicine that addresses unmet medical needs of patients on the basis of less comprehensive data, including pharmaceutical and non-clinical data, than normally required. The available data must indicate that the medicine's benefits outweigh its risks (i.e. it has a positive benefit-risk balance) and the applicant should be in a position to provide the comprehensive data in the future. The authorisations have a robust post-authorisation regulatory framework based on legally binding obligations, safeguards and controls.

Conditional marketing authorisations are valid for one year and can be renewed annually. Once a conditional marketing authorisation has been granted, the marketing authorisation holder must fulfil specific obligations within defined timelines. These obligations could include completing ongoing or new studies or collecting additional data to confirm the medicine's benefit-risk balance remains positive. They are included in Annex II of the Commission decision, copies of which are available on the previously mentioned webpages of the Union Register of medicinal products. The CHMP assesses whether the obligations have been fulfilled.

The safety and effectiveness of the COVID-19 vaccines are rigorously monitored, as for all medicines, through the EU's established medicines monitoring system. In addition, special measures are in place to quickly collect and evaluate new information. For example, for new authorisations manufacturers usually must send a safety report to the EMA every six months. For COVID-19 vaccines, safety reports must be sent every month[3]. In addition, the EMA set up additional large-scale safety monitoring given the exceptionally high number of people expected to receive the vaccines[4].

Information on the known side effects of the vaccines are included in the product information addressed to the healthcare professionals and patients. This information can be found in the Annexes to the authorisation decisions. The information to healthcare professionals is included in Annex I "summary of product characteristics": section 4.8 of Annex I includes details of undesirable effects and lists the adverse reactions detected in clinical trials and post-authorisation experience; section 4.3 indicates if there are any contraindications; and, section 4.4 provides information on special warning and precautions for use. Annex III includes the "package leaflet: information for the user" of the vaccine, in section 4 details of possible side effects are given.

The details of the EMA assessments are published on their website. Below are details of the basis of the vaccine and the direct link to the European public assessment reports

[3] 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

[4] https://www.ema.europa.eu/en/news/ema-ecdc-join-forces-enhanced-post-marketing-monitoring-covid-19-vaccines-europe

(EPAR) that were adopted by the CHMP at the time of initial authorisation of the vaccines.

- Comirnaty[5] – mRNA vaccine (nucleoside modified) - https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf
- COVID-19 Vaccine Moderna[6] – mRNA Vaccine (nucleoside modified) - https://www.ema.europa.eu/en/documents/assessment-report/covid-19-vaccine-moderna-epar-public-assessment-report_en.pdf
- Vaxzevria[7] (formerly COVID-19 Vaccine AstraZeneca) – adenovirus - https://www.ema.europa.eu/en/documents/assessment-report/vaxzevria-previously-covid-19-vaccine-astrazeneca-epar-public-assessment-report_en.pdf
- COVID-19 Vaccine Janssen[8] - adenovirus - https://www.ema.europa.eu/en/documents/assessment-report/covid-19-vaccine-janssen-epar-public-assessment-report_en.pdf

The EPARs provide information on the evidence of the period of protection of the vaccine available at the time of initial authorisation. This evidence continues to be collected through on-going studies the outcomes of which will be submitted to EMA for their scientific assessment.

In the case of the authorisations related to the COVID-19 vaccines, the EMA is also committed to publishing the details of the underlying clinical trials which are accessible through their clinical data website[9].

The scientific assessment by the EMA and the Commission's authorisation procedure are in accordance with the regulatory framework. The authorised COVID-19 vaccines are under close monitoring, if emerging evidence requires an update of the marketing authorisation this will also be completed within the regulatory framework.

Yours sincerely,

(e-signed)

Andrzej Jan RYS

5 https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty

6 https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-moderna

7 https://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria-previously-covid-19-vaccine-astrazeneca

8 https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-janssen

9 https://clinicaldata.ema.europa.eu/web/cdp/home