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European Commission - Questions and answers

Questions and Answers: Conditional Marketing Authorisation of COVID-19 Vaccines in the EU*

Brussels, 11 December 2020

With which companies have you concluded COVID-19 vaccine agreements?

The EU has secured 2.3 billion doses, based on the agreements with six different companies:

- BioNTech-Pfizer for up to 600 million doses;
- AstraZeneca for up to 400 million doses;
- Sanofi-GSK for up to 300 million doses;
- Johnson and Johnson for up to 400 million doses;
- CureVac for up to 405 million doses;
- Moderna for up to 160 million doses.

In addition, the Commission concluded talks with Novavax, for up to 200 million doses, and with Valneva, for up to 60 million doses. The vaccines produced by two of these companies have been approved by the Commission to be placed on the market: BioNTech/Pfizer (21 December 2020) and Moderna (6 January 2021).

Which vaccine candidates are currently being reviewed by the European Medicines Agency?

The Commission has given the conditional marketing authorisation for the vaccines developed by BioNTech and Pfizer on 21 December, and Moderna on 6 January following EMA positive assessment of its safety and efficacy.

The EMA received an application for a marketing authorisation by AstraZeneca and Oxford University on 12 January. An opinion by EMA could be given by 29 January. No other vaccine producer has formally applied for a marketing authorisation to EMA. In order to accelerate the process, EMA has started a rolling review on the vaccine produced by Johnson and Johnson.

What is the process for authorising a COVID-19 vaccine in the EU?

Independent scientific safety, efficacy and quality assessment by the European Medicines Agency

Any vaccine developer that wishes to put a vaccine on the market in the EU, should **first request a marketing authorisation for the vaccine**. The request is submitted to the European Medicines Agency (EMA), which assesses the safety, efficacy and quality of the vaccine. If the EMA gives a positive recommendation, the Commission can proceed with the authorisation of the vaccine on the EU market

In response to public health threats such as the current pandemic, the EU has a specific regulatory tool in place to allow early availability of medicines for use in emergency situations. In such emergency situations, the Conditional Marketing Authorisation (CMA) procedure is **specifically designed to enable marketing authorisations as quickly as possible**, as soon as sufficient data becomes available. It provides the EU with a robust framework for accelerated approval and post-authorisation safety and safeguards and controls.

For its assessment, the **EMA** will undertake an **independent, thorough and robust review of all the evidence submitted by the vaccine developer**. The process contains several checks and balances and is based on a system of peer reviews with many experts involved: two rapporteurs responsible for the assessment, a peer reviewer, specialised Committees and working parties (e.g. the Pharmacovigilance Risk Assessment Committee (PRAC) for safety, the Biologics Working Party for quality) and finally EMA's Committee on Human Medicines (with members from all Member States) which issues the **recommendation**.

The Committee on Human Medicines will only issue a positive recommendation when the evidence shows convincingly that the benefits of vaccination are greater than any risks from the vaccine.