European Commission authorises second safe and effective vaccine against COVID-19

Brussels, 6 January 2021

Today, the European Commission has granted a conditional marketing authorisation (CMA) for the COVID-19 vaccine developed by Moderna, the second COVID-19 vaccine authorised in the EU. This authorisation follows a positive scientific recommendation based on a thorough assessment of the safety, effectiveness and quality of the vaccine by the European Medicines Agency (EMA) and is endorsed by the Member States.

The President of the European Commission, Ursula **von der Leyen**, said: *"We are providing more COVID-19 vaccines for Europeans. With the Moderna vaccine, the second one now authorised in the EU, we will have a further 160 million doses. And more vaccines will come. Europe has secured up to two billion doses of potential COVID-19 vaccines. We'll have more than enough safe and effective vaccines for protecting all Europeans."*

Stella **Kyriakides**, Commissioner for Health and Food Safety, said: *"We are all in this together and united. This is why we have negotiated the broadest vaccine portfolio in the world for all our Member States. Today we are authorising a second safe and effective vaccine from Moderna, which together with BioNTech-Pfizer, will ensure that 460 million doses will be rolled out with increasing speed in the EU, and more will come. Member States have to ensure that the pace of vaccinations follows suit. Our efforts will not stop until vaccines are available for everyone in the EU."*

Moderna submitted on 30 November 2020 an application for marketing authorisation to EMA, which had already started a rolling review of the data in November. Thanks to this rolling review, EMA has been assessing the quality, safety and efficacy of the vaccine as data has become available. EMA's human medicines committee (CHMP) has thoroughly assessed the data and recommended by consensus that a formal conditional marketing authorisation is granted. A conditional marketing authorisation is one of EU's regulatory mechanisms for facilitating early access to medicines that fulfil an unmet medical need, including in emergency situations such as the current pandemic.

On the basis of EMA's positive opinion, the Commission has verified all the elements supporting the marketing authorisation and consulted Member States before granting the conditional market authorisation.

The Moderna vaccine is based on messenger RNA (mRNA). mRNA plays a fundamental role in biology, transferring instructions from DNA to the cells' protein making machinery. In an mRNA vaccine, these instructions produce harmless fragments of the virus, which the human body uses to build an immune response to prevent or fight disease. When a person is given the vaccine, their cells will read the genetic instructions and produce a spike protein, a protein on the outer surface of the virus which it uses to enter the body's cells and cause disease. The person's immune system will then treat this protein as foreign and produce natural defences — antibodies and T cells — against it.

Next steps

Moderna, with whom the Commission signed a contract on 25 November, will deliver the total amount of 160 million doses between the first and the third quarters of 2021. It will add to the 300 million doses of the vaccine distributed by BioNTech/Pfizer, the first vaccine to have been authorised in the EU on 21 December 2020.

Background

A conditional marketing authorisation (CMA) is an authorisation of medicines on the basis of less complete data required for a normal marketing authorisation. Such a CMA may be considered if the benefit of a medicine's immediate availability to patients clearly outweighs the risk linked to the fact that not all the data are yet available. However, once a CMA has been granted, companies must provide within certain deadlines further data including from ongoing or new studies to confirm that the benefits continue to outweigh the risks.

Moderna submitted on 30 November 2020 an application for a CMA for their vaccine to EMA. EMA has

already been assessing data on the vaccine's safety, effectiveness and quality and results from laboratory studies and clinical trials in the context of a rolling review. This rolling review and the assessment of the CMA application allowed EMA to quickly conclude on the safety, effectiveness and quality of the vaccine. EMA recommended granting the conditional marketing authorisation as the benefits of the vaccine outweigh its risks.

The European Commission has verified whether all necessary elements – scientific justifications, product information, educational material to healthcare professionals, labelling, obligations to marketing authorisation holders, conditions for use, etc. - were clear and sound. The Commission also consulted the Member States, as they are responsible for the vaccines marketing and the use of the product in their countries. Following the Member States' endorsement and on the basis of its own analysis, the Commission decided to grant the conditional market authorisation.

For More Information

EU Vaccines Strategy

Questions and Answers: Conditional marketing authorisation of COVID-19 vaccines

Safe COVID-19 vaccines for Europeans

EU Coronavirus Response

EU's legislation on medicinal products

EMA and COVID-19 vaccines

Factsheet: How vaccines work

Factsheet: Health benefits of vaccines

Factsheet: Authorisation process

Factsheet: Long-term safety

EU's current portfolio

IP/21/3

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