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

Brussels, 29 January 2021

Today, the European Commission has granted a conditional marketing authorisation (CMA) for the COVID-19 vaccine developed by AstraZeneca, the third 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: *"Securing safe vaccines for Europeans is our utmost priority. With the AstraZeneca vaccine now authorized, 400 million additional doses will be available in Europe. I expect the company to deliver these doses as agreed, so that Europeans can be vaccinated as soon as possible. We will continue doing all we can to secure more vaccines for Europeans, our neighbours and our partners worldwide."*

Stella **Kyriakides**, Commissioner for Health and Food Safety, said: *"With this newly authorised vaccine, our portfolio continues to take shape. Our EU Vaccines Strategy has always aimed to have a vaccine portfolio that is broad and diverse, with different technologies used, to maximise our chances of providing safe and effective vaccines to citizens as soon as possible. The European Medicines Agency's authorisation today is another step towards delivering on this promise. The Commission continues to work around the clock to secure more vaccines for Europe and our international partners. We are leaving no stone unturned in our fight against this pandemic."*

The AstraZeneca vaccine will be given to adults aged 18 years and older for preventing COVID-19. The vaccine causes the immune system (the body's natural defences) to produce antibodies and specialised white blood cells that work against the virus, so giving protection against COVID-19. People vaccinated will receive two injections of the AstraZeneca vaccine.

According to EMA, most of the participants in the studies were between 18 and 55 years old. There are not yet enough results in older participants (over 55 years old) to provide a figure for how well the vaccine will work in this group. However, protection is expected, given that an immune response is seen in this age group and based on experience with other vaccines; as there is reliable information on safety in this population, EMA's scientific experts considered that the vaccine can be used in older adults. More information is expected from ongoing studies, which include a higher proportion of elderly participants.

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 marketing authorisation.

The AstraZeneca vaccine is based on an adenovirus, a harmless virus which delivers the 'instructions' from the virus that causes COVID-19.This allows the body's own cells to make the protein unique to the COVID-19 virus. The person's immune system recognises that this unique protein should not be in the body and responds by producing natural defences against infection by COVID-19.

Next steps

According to the contract signed with the European Commission on 27 August 2020, AstraZeneca will deliver the total amount of 400 million doses throughout 2021. These will add to the 600 million doses of the vaccine by BioNTech-Pfizer and the 160 million doses of the vaccine by Moderna.

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 it also ensures that this COVID-19 vaccine meets the EU standards, as for all other vaccines and medicines.

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. CMAs are foreseen in the EU legislation specifically for public health emergencies and is considered the most appropriate regulatory mechanism in this pandemic for granting access to all EU citizens and for underpinning mass vaccination campaigns.

AstraZeneca submitted an application for a CMA for their vaccine to EMA on 11 January 2021. However, assessment already started beforehand. EMA had started assessing non-clinical data from laboratory studies in October 2020 and updated its rolling review end of December 2020 on the vaccine's safety, effectiveness and quality. 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 marketing authorisation.

For More Information

Safe COVID-19 vaccines for Europeans

EU Vaccines Strategy

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

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EMA and COVID-19 vaccines

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Factsheet: Health benefits of vaccines

Factsheet: Authorisation process

Factsheet: Long-term safety

EU's current portfolio

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