EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA recommends COVID-19 Vaccine AstraZeneca for authorisation in the EU

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EMA has recommended granting a conditional marketing authorisation for COVID-19 Vaccine AstraZeneca to prevent coronavirus disease 2019 (COVID-19) in people from 18 years of age. This is the third COVID-19 vaccine that EMA has recommended for authorisation.

EMA's human medicines committee (CHMP) has thoroughly assessed the data on the quality, safety and efficacy of the vaccine and recommended by consensus a formal conditional marketing authorisation be granted by the European Commission. This will assure EU citizens that the vaccine meets EU standards and puts in place the safeguards, controls and obligations to underpin EU-wide vaccination campaigns.

"With this third positive opinion, we have further expanded the arsenal of vaccines available to EU and EEA member states to combat the pandemic and protect their citizens," said Emer Cooke, Executive Director of EMA. "As in previous cases, the CHMP has rigorously evaluated this vaccine, and the scientific basis of our work underpins our firm commitment to safeguard the health of EU citizens."

Combined results from 4 clinical trials in the United Kingdom, Brazil and South Africa showed that COVID-19 Vaccine AstraZeneca was safe and effective at preventing COVID-19 in people from 18 years of age. These studies involved around 24,000 people altogether. Half received the vaccine and half were given a control injection, either a dummy injection or another non-COVID vaccine. People did not know if they had been given the test vaccine or the control injection.

The safety of the vaccine has been demonstrated across the four studies. However, the Agency based its calculation of how well the vaccine worked on the results from study COV002 (conducted in the UK) and study COV003 (conducted in Brazil). The other two studies had fewer than 6 COVID-19 cases in each, which was not enough to measure the preventive effect of the vaccine. In addition, as the vaccine is to be given as two standard doses, and the second dose should be given between 4 and 12 weeks after the first, the Agency concentrated on results involving people who received this standard regimen.

These showed a 59.5% reduction in the number of symptomatic COVID-19 cases in people given the vaccine (64 of 5,258 got COVID-19 with symptoms) compared with people given control injections (154 of 5,210 got COVID-19 with symptoms). This means that the vaccine demonstrated around a 60% efficacy in the clinical trials.

Most of the participants in these 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.

COVID-19 Vaccine AstraZeneca is given as two injections into the arm, the second between 4 to 12 weeks after the first. The most common side effects with COVID-19 Vaccine AstraZeneca were usually mild or moderate and got better within a few days after vaccination. The most common side effects are pain and tenderness at the injection site, headache, tiredness, muscle pain, general feeling of being unwell, chills, fever, joint pain and nausea. The safety and effectiveness of the vaccine will continue to be monitored as it is used across the EU, through the EU pharmacovigilance system and additional studies by the company and by European authorities.

Where to find more information

The product information approved by the CHMP for COVID-19 Vaccine AstraZeneca contains prescribing information for healthcare professionals, a package leaflet for members of the public and details of conditions of the vaccine's authorisation.

An assessment report with details of EMA's evaluation of COVID-19 Vaccine AstraZeneca and the full risk management plan will be published within days. Clinical trial data submitted by the company in the application for marketing authorisation will be published on the Agency's clinical data website in due course.

More information is available in an overview of the vaccine in lay language, including a description of the vaccine's benefits and risks and why EMA recommended its authorisation in the EU.

How COVID-19 Vaccine AstraZeneca works

COVID-19 Vaccine AstraZeneca is expected to work by preparing the body to defend itself against infection with the coronavirus SARS-CoV-2. This virus uses proteins on its outer surface, called spike proteins, to enter the body's cells and cause disease.

COVID-19 Vaccine AstraZeneca is made up of another virus (of the adenovirus family) that has been modified to contain the gene for making the SARS-CoV-2 spike protein. The adenovirus itself cannot reproduce and does not cause disease. Once it has been given, the vaccine delivers

the SARS-CoV-2 gene into cells in the body. The cells will use the gene to produce the spike protein. The person's immune system will treat this spike protein as foreign and produce natural defences – antibodies and T cells – against this protein.

If, later on, the vaccinated person comes into contact with SARS-CoV-2, the immune system will recognise the virus and be prepared to attack it: antibodies and T cells can work together to kill the virus, prevent its entry into the body's cells and destroy infected cells, thus helping to protect against COVID-19.

Conditional marketing authorisation

The European Commission will now fast-track the decision-making process to grant a decision on the conditional marketing authorisation for COVID-19 Vaccine AstraZeneca, allowing vaccination programmes to be rolled out across the EU.

EU legislation foresees that conditional marketing authorisation (CMA) is used as the fast-track authorisation procedure to speed up approval of treatments and vaccines during public health emergencies.

A CMA guarantees that the vaccine meets rigorous EU standards for safety, efficacy and quality and is manufactured and controlled in approved, certified facilities in line with high pharmaceutical standards that are compatible with large-scale commercialisation. CMAs allow for the authorisation of medicines that fulfil an unmet medical need on the basis of less complete data than normally required. This happens if the benefit of a medicine or vaccine's immediate availability to patients outweighs the risk inherent in the fact that not all the data are yet available. However, the data must show that the benefits of the medicine or vaccine outweigh any risks.

Once a CMA has been granted, AstraZeneca must provide further data from ongoing studies within pre-defined deadlines to confirm that the benefits continue to outweigh the risks. The company will also carry out studies to provide additional assurance on the pharmaceutical quality of the vaccine following the scaling-up of the manufacturing.

Monitoring the safety of COVID-19 Vaccine AstraZeneca

In line with the EU's safety monitoring plan for COVID-19 vaccines, COVID-19 Vaccine AstraZeneca will be closely monitored and subject to several activities that apply specifically to COVID-19 vaccines. Although large numbers of people have received COVID-19 vaccines in clinical trials, certain side effects may only emerge when millions of people are vaccinated.

Companies are required to provide monthly safety reports in addition to the regular updates required by legislation and conduct studies to monitor the safety and effectiveness of the vaccines as they are used by the public. In addition, independent studies of COVID-19 vaccines coordinated by EU authorities will give more information on the vaccine's long-term safety and benefit in the general population.

These measures will allow regulators to swiftly assess data emerging from a range of different sources and take appropriate regulatory action to protect public health if needed.

Assessment of COVID-19 Vaccine AstraZeneca

During the assessment COVID-19 Vaccine AstraZeneca, the CHMP had the support of EMA's safety committee, PRAC, who assessed the risk management plan of COVID-19 Vaccine AstraZeneca, and the COVID-19 EMA pandemic task force (COVID-ETF), a group that brings together experts from across the European medicines regulatory network to facilitate rapid and coordinated regulatory action on medicines and vaccines for COVID-19.

Related content

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- Press briefing on EU recommendation for COVID-19 Vaccine AstraZeneca (29/01/2021)
- Coronavirus disease (COVID-19)
- Treatments and vaccines for COVID-19
- COVID-19 vaccines: key facts
- Committee for Medicinal Products for Human Use (CHMP)
- Pharmacovigilance Risk Assessment Committee (PRAC)
- EMA publishes safety monitoring plan and guidance on risk management planning for COVID-19 vaccines (13/11/2020)

External links

- Clinical data website

Contact point

EMA press office
Tel. +31 (0)88 781 8427
E-mail: press@ema.europa.eu
Follow us on Twitter @EMA_News

CONTACT

European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

Tel: +31 (0)88 781 6000

For delivery address, see:
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