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EMA recommends first COVID-19 vaccine for authorisation in the EU

EMA has recommended granting a conditional marketing authorisation for the vaccine Comirnaty, developed by BioNTech and Pfizer, to prevent coronavirus disease 2019 (COVID-19) in people from 16 years of age. EMA's scientific opinion paves the way for the first marketing authorisation of a COVID-19 vaccine in the EU by the European Commission, with all the safeguards, controls and obligations this entails.

EMA's human medicines committee (CHMP) has completed its rigorous evaluation of Comirnaty, concluding by consensus that sufficiently robust data on the quality, safety and efficacy of the vaccine are now available to recommend a formal conditional marketing authorisation. This will provide a controlled and robust framework to underpin EU-wide vaccination campaigns and protect EU citizens.

"Today's positive news is an important step forward in our fight against this pandemic, which has caused suffering and hardship for so many," said Emer Cooke, Executive Director of EMA. "We have achieved this milestone thanks to the dedication of scientists, doctors, developers and trial volunteers as well as many experts from all EU Member States.

"Our thorough evaluation means that we can confidently assure EU citizens of the safety and efficacy of this vaccine and that it meets necessary quality standards. However, our work does not stop here. We will continue to collect and analyse data on the safety and effectiveness of this vaccine to protect people taking the vaccine in the EU."

A very large clinical trial showed that Comirnaty was effective at preventing COVID-19 in people from 16 years of age.

The trial involved around 44,000 people in total. Half received the vaccine and half were given a dummy injection. People did not know whether they received the vaccine or the dummy injection.

Efficacy was calculated in over 36,000 people from 16 years of age (including people over 75 years of age) who had no sign of previous infection. The study showed a 95% reduction in the number of symptomatic COVID-19 cases in the people who received the vaccine (8 cases out of 18,198 got COVID-19 symptoms) compared with people who received a dummy injection (162 cases out of 18,325 got COVID-19 symptoms). This means that the vaccine demonstrated a 95% efficacy in the clinical trial.

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The trial also showed around 95% efficacy in the participants at risk of severe COVID-19, including those with asthma, chronic lung disease, diabetes, high blood pressure or a body mass index ≥ 30 kg/m^2. The high efficacy was maintained across genders, racial and ethnic groups.

Comirnaty is given as two injections into the arm, at least 21 days apart. The most common side effects with Comirnaty were usually mild or moderate and got better within a few days after vaccination. They included pain and swelling at the injection site, tiredness, headache, muscle and joint pain, chills and fever. The safety and effectiveness of the vaccine will continue to be monitored as it is used across the Member States, 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 Comirnaty 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 Comirnaty, 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 Comirnaty works

Comirnaty works by preparing the body to defend itself against COVID-19. It contains a molecule called messenger RNA (mRNA) which has instructions for making the spike protein. This is a protein on the surface of the SARS-CoV-2 virus which the virus needs to enter the body's cells.

When a person is given the vaccine, some of their cells will read the mRNA instructions and temporarily produce the spike protein. The person's immune system will then recognise this protein as foreign and produce antibodies and activate T cells (white blood cells) to attack it.

If, later on, the person comes into contact with SARS-CoV-2 virus, their immune system will recognise it and be ready to defend the body against it.

The mRNA from the vaccine does not stay in the body but is broken down shortly after vaccination.

Conditional marketing authorisation

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.

A conditional marketing authorisation is a formal authorisation of the vaccine, covering all batches produced for the EU and providing a robust assessment to underpin vaccination campaigns.

As Comirnaty is recommended for a conditional marketing authorisation, the company that markets Comirnaty will continue to provide results from the main trial, which is ongoing for 2 years. This trial and additional studies will provide information on how long protection lasts, how well the vaccine prevents severe COVID-19, how well it protects immunocompromised people, children and pregnant women, and whether it prevents asymptomatic cases.

The company will also carry out studies to provide additional assurance on the pharmaceutical quality of the vaccine as the manufacturing continues to be scaled up.

Monitoring the safety of Comirnaty

In line with the EU's safety monitoring plan for COVID-19 vaccines, Comirnaty 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 the legislation and conduct studies to monitor the safety and effectiveness of the vaccines as they are used by the public. Authorities will also conduct additional studies to monitor the vaccines.

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 Comirnaty

During the assessment of Comirnaty, the CHMP had the support of EMA's safety committee, PRAC, who assessed the risk management plan of Comirnaty, 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.

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