REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

Press release

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

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

"This vaccine provides us with another tool to overcome the current emergency," said Emer Cooke, Executive Director of EMA. "It is a testament to the efforts and commitment of all involved that we have this second positive vaccine recommendation just short of a year since the pandemic was declared by WHO.

"As for all medicines, we will closely monitor data on the safety and effectiveness of the vaccine to ensure ongoing protection of the EU public. Our work will always be guided by the scientific evidence and our commitment to safeguard the health of EU citizens."

A very large clinical trial showed that COVID-19 Vaccine Moderna was effective at preventing COVID-19 in people from 18 years of age.

The trial involved around 30,000 people in total. Half received the vaccine and half were given dummy injections. People did not know whether they received the vaccine or the dummy injections.

Efficacy was calculated in around 28,000 people from 18 to 94 years of age who had no sign of previous infection.

The trial showed a 94.1% reduction in the number of symptomatic COVID-19 cases in the people who received the vaccine (11 out of 14,134 vaccinated people got COVID-19 with symptoms) compared with people who received dummy injections (185 out of 14,073 people who received dummy injections got COVID-19 with symptoms). This means that the vaccine demonstrated a 94.1% efficacy in the trial.

The trial also showed 90.9% efficacy in participants at risk of severe COVID-19, including those with chronic lung disease, heart disease, obesity, liver disease, diabetes or HIV infection. The high efficacy was also maintained across genders, racial and ethnic groups.

COVID-19 Vaccine Moderna is given as two injections into the arm, 28 days apart. The most common side effects with COVID-19 Vaccine Moderna were usually mild or moderate and got better within a few days after vaccination. The most common side effects are pain and swelling at the injection site, tiredness, chills, fever, swollen or tender lymph nodes under the arm, headache, muscle and joint pain, nausea and vomiting. 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 Moderna 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 Moderna, 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 Moderna works

COVID-19 Vaccine Moderna 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

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

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 COVID-19 Vaccine Moderna is recommended for a conditional marketing authorisation, the company that markets COVID-19 Vaccine Moderna 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 COVID-19 Vaccine Moderna

In line with the EU's safety monitoring plan for COVID-19 vaccines, COVID-19 Vaccine Moderna 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. In addition, independent studies of COVID-19 vaccines coordinated by EU authorities will also 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 Moderna

During the assessment COVID-19 Vaccine Moderna, the CHMP had the support of EMA's safety committee, PRAC, who assessed the risk management plan of COVID-19 Vaccine Moderna, 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.

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Ministry of Health
6 January 2021