



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 December 2020
EMA/637050/2020

EMA receives application for conditional marketing authorisation of Moderna COVID-19 vaccine

EMA has received an application for conditional marketing authorisation (CMA) for a COVID-19 mRNA vaccine by Moderna Biotech Spain, S.L. (a subsidiary of Moderna, Inc.). The assessment of the vaccine known as Moderna Covid-19 vaccine (also referred to as mRNA1273) will proceed under an accelerated timeline. An opinion on the marketing authorisation could be issued within weeks, depending on whether the data submitted are sufficiently robust and complete to show the quality, safety and effectiveness of the vaccine.

Such a short timeframe is only possible because EMA has already reviewed some data on the vaccine during a [rolling review](#). During this phase, EMA assessed data from laboratory studies and also started assessing data on immunogenicity (how well the vaccine triggers a response against the virus) and safety from an early study.

EMA will now assess the data submitted as part of the formal application for conditional marketing authorisation. The Agency and its scientific committees will continue working on the assessment over the Christmas period. If the data submitted are robust enough to conclude on the quality, safety and effectiveness of the vaccine, EMA's scientific committee for human medicines (CHMP) will conclude its assessment during an extraordinary meeting scheduled for 12 January. These timelines are based on the type of data assessed so far in the context of the rolling review and may be subject to change as evaluation proceeds. EMA will communicate on the outcome of its assessment accordingly.

During the review, and throughout the pandemic, EMA and its scientific committees are supported by the [COVID-19 EMA pandemic task force](#), 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.

What is a conditional marketing authorisation?

In the EU, 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. CMAs are being used in the context of the pandemic to promptly respond to the public health threat. However, the data must show that the benefits of the medicine or vaccine outweigh any risks. Once a CMA has been granted, companies must provide further data from ongoing or new studies within pre-defined deadlines to confirm the benefits continue to outweigh the risks.

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



What may happen next?

If EMA concludes that the benefits of the vaccine outweigh its risks in protecting against COVID-19, it will recommend granting a conditional marketing authorisation. The European Commission will then fast-track its decision-making process with a view to granting a conditional marketing authorisation valid in all EU and EEA Member States within days.

As for all medicines, EU authorities continuously collect and review new information on medicines once they are on the market and take action when needed. In line with the EU [safety monitoring plan for COVID-19 vaccines](#), monitoring will take place more frequently and will include activities that apply specifically to COVID-19 vaccines. Companies for example will provide monthly safety reports in addition to the regular updates required by the legislation and conduct studies to monitor the safety and effectiveness of COVID-19 vaccines after their authorisation.

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.

[Key facts](#) on COVID-19 vaccines and more information about how these [vaccines are developed, authorised and monitored](#) in the EU can be found on the EMA website.

How is the vaccine expected to work?

Moderna Covid-19 vaccine is expected to work by preparing the body to defend itself against infection with the coronavirus SARS-CoV-2. The virus uses a protein on its outer surface called a spike protein to enter the body's cells and cause disease. Moderna Covid-19 vaccine contains the genetic instructions (mRNA) to produce the spike protein. The mRNA is covered in small lipid (fat) particles that help deliver the mRNA into the cells and prevent it from being degraded. When a person is given the vaccine, their cells will read the genetic instructions and produce the spike protein. The person's immune system will then treat this protein as foreign and produce natural defences — antibodies and T cells — against it. 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.