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EMA receives application for conditional marketing authorisation of COVID-19 mRNA vaccine BNT162b2

EMA has received an application for conditional marketing authorisation (CMA) for BNT162b2, a COVID-19 mRNA vaccine developed by BioNTech and Pfizer. The assessment of BNT162b2 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 on the vaccine's quality (such as information about its ingredients and the way it is produced) as well as results from laboratory studies. EMA also looked at results on the vaccine's effectiveness and initial safety data emerging from a large-scale clinical trial as they became available.

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 29 December at the latest. 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.

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Once a CMA has been granted, companies must provide further data from ongoing or new studies within pre-defined deadlines to confirm that the benefits continue to outweigh the risks.

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 BNT162b2 expected to work?

BNT162b2 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. BNT162b2 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.