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Start of rolling review for adapted Comirnaty COVID-19 vaccine

EMA has started a rolling review for a version of Comirnaty adapted to provide better protection against a specific variant or variants of SARS-CoV-2, the virus that causes COVID-19.

The review will initially focus on chemistry, manufacturing and controls (CMC), which relate to the manufacturing of the vaccine. As the company makes progress in the development of its adapted vaccine, EMA will receive more data, including data on the immune response to the vaccine as well as data on its efficacy against Omicron subvariants.

By starting a rolling review, EMA will be able to assess these data as they become available. The rolling review will continue until there is enough data for a formal application.

The details about the adapted vaccine, for example whether it will specifically target one or more SARS-CoV-2 variants or subvariants, are not yet defined. However, EMA's review will initially focus on CMC data for the component targeting Omicron subvariants.

The composition of adapted COVID-19 vaccines will ultimately depend on recommendations of public health authorities and the World Health Organization (WHO) as well as the considerations of regulatory bodies such as EMA and other members of the International Coalition of Medicines Regulatory Authorities (ICMRA). These bodies are working closely together to determine the appropriate strains for adapted COVID-19 vaccines.

Starting this rolling review is one of the ways authorities in the EU are working to ensure that EU Member States have timely access to adapted COVID-19 vaccines they may need to combat current and emerging SARS-CoV-2 variants.

EMA will communicate further on the outcome of the rolling review or an eventual application.

More about the vaccine

Comirnaty works by preparing the body to defend itself against COVID-19. It contains a molecule called 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.

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When a person is given the vaccine, some of their cells read the mRNA instructions and temporarily produce the spike protein. The person's immune system then recognises 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 as foreign 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.

More about the procedure

A rolling review is a regulatory tool that EMA uses to speed up the assessment of data for a medicine or vaccine during a public health emergency.

By starting this rolling review for Comirnaty, EMA's human medicines committee (CHMP) will be able review data from ongoing studies as they become available. The CHMP will therefore be in a position to come to an opinion soon after the company submits an application.