REPUBLIC OF CYPRUS
MINISTRY OF HEALTH

Start of rolling review for adapted Spikevax COVID-19 vaccine

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

The review concerns a bivalent vaccine. This means it will target two strains of SARS-CoV-2, in this case the original strain and the Omicron variant of concern.

The review will initially focus on data from laboratory studies (non-clinical data) and data on chemistry, manufacturing and controls (CMC), which relate to the manufacturing of the vaccine. As the company makes progress in the development of its bivalent vaccine, EMA will receive more data, including data on the immune response against the original strain and the Omicron variant of concern.

By starting a rolling review, EMA will be able to assess these data as they become available. The review will continue until there is enough data for a formal application. EMA will communicate further on the outcome of the rolling review or an eventual application.

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.

This rolling review process 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.

More about the vaccine

Spikevax 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 SARS-CoV-2 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, 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.

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 Spikevax, EMA's human medicines committee (CHMP) will be able to 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.

Ministry of Health

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