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EMA evaluating data on booster dose of COVID-19 vaccine Comirnaty

EMA has started evaluating an application for the use of a booster dose of Comirnaty to be given 6 months after the second dose in people aged 16 years and older. Booster doses are given to vaccinated people (i.e. people who have completed their primary vaccination) to restore protection after it has waned.

EMA's human medicines committee (CHMP) will carry out an accelerated assessment of data submitted by the company that markets Comirnaty, including results from an ongoing clinical trial in which around 300 adults with healthy immune systems received a booster dose approximately 6 months after the second dose.

The CHMP will recommend whether updates to the product information are appropriate. The outcome of this evaluation is expected within the next few weeks, unless supplementary information is needed, and will be communicated by EMA.

Separately, EMA is also assessing data from the literature on the use of an additional, third dose of an mRNA vaccine (Comirnaty or SpikeVax) in severely immunocompromised people (i.e., with weakened immune systems). People with severely weakened immune systems who do not achieve an adequate level of protection from their standard primary vaccination may need an 'additional' dose as part of their primary vaccination.

EMA will also communicate on the outcome of these evaluations in due course.

While these evaluations are ongoing, EMA and the European Centre for Disease Prevention and Control (ECDC) have highlighted their current position regarding the need for additional and booster doses of COVID-19 vaccines in a separate communication. Although EMA and ECDC do not consider the need for COVID-19 vaccine booster doses to be urgent in the general population, EMA is evaluating the present application to ensure evidence is available to support further doses as necessary.

Advice on how vaccinations should be given remains the prerogative of the national immunisation technical advisory groups (NITAGs) guiding the vaccination campaigns in each EU Member State. While EMA assesses relevant data, Member States may already consider preparatory plans for administering boosters and additional doses.

Comirnaty is a vaccine for preventing COVID-19. It is currently authorised for use in people aged 12 and older. It contains a molecule called messenger RNA (mRNA) with instructions for producing a protein, known as the spike protein, naturally present in SARS-CoV-2, the virus that causes COVID-19.

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The vaccine works by preparing the body to defend itself against SARS-CoV-2. More information about the vaccine is available.