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

EMA has started evaluating an application for the use of a booster dose of Spikevax (Moderna's COVID-19 vaccine) to be given at least 6 months after the second dose in people aged 12 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 Spikevax (Moderna), including results from an ongoing clinical trial.

Based on this review, the CHMP will recommend whether updates to the product information are appropriate. EMA will communicate the outcome of the assessment in due course.

While this evaluation is ongoing, EMA and the European Centre for Disease Prevention and Control (ECDC) have highlighted their 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 guiding the vaccination campaigns in each EU Member State. While EMA assesses relevant data, Member States may already consider preparatory plans for giving boosters and additional doses.

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

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