EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

COVID-19 Vaccine Janssen: EMA recommendation on booster dose

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EMA's human medicines committee (CHMP) has concluded that a booster dose of COVID-19 Vaccine Janssen may be considered at least two months after the first dose in people aged 18 years and above.

The recommendation follows data showing that a booster dose of COVID-19 Vaccine Janssen given at least two months after the first dose in adults led to a rise in antibodies against SARS-CoV-2 (the virus that causes COVID-19). The risk of thrombosis in combination with thrombocytopenia (TTS) or other very rare side effects after a booster is not known and is being carefully monitored.

CHMP also concluded that a booster dose with COVID-19 Vaccine Janssen may be given after two doses of one of the mRNA vaccines authorised in the EU, Comirnaty (from Pfizer/BioNTech) or Spikevax (from Moderna).

As for all medicines, EMA will continue to look at all data on the safety and effectiveness of COVID-19 Vaccine Janssen.

At national level, public health bodies may issue official recommendations on the use of booster doses, either following one dose of COVID-19 Vaccine Janssen or two doses of the mRNA vaccines, taking into account the local epidemiological situation, availability of vaccines, and emerging effectiveness and the limited safety data for the booster dose.

Data supporting the booster recommendation for COVID-19 Vaccine Janssen will be available in the updated product information.

National immunisation campaigns

The implementation of vaccination campaigns in the EU remains the prerogative of the national immunisation technical advisory groups (NITAGs) guiding the vaccination campaigns in each EU Member State. These bodies are best placed to take into account the local conditions, including the spread of the virus (especially any variants of concern), the availability of vaccines and the capacities of national health systems.

EMA will continue working closely with national authorities and the European Centre for Disease Prevention and Control (ECDC) to evaluate available data and provide recommendations to protect the public during the ongoing pandemic.

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- Spikevax (previously COVID-19 Vaccine Moderna)
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- European Centre for Disease Prevention and Control (ECDC)

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