



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Comirnaty and Spikevax: EMA recommendations on extra doses and boosters

EMA's human medicines committee (CHMP) has concluded that an extra dose of the COVID-19 vaccines Comirnaty (BioNTech/Pfizer) and Spikevax (Moderna) may be given to people with severely weakened immune systems, at least 28 days after their second dose.

The recommendation comes after studies showed that an extra dose of these vaccines increased the ability to produce antibodies against the virus that causes COVID-19 in organ transplant patients with weakened immune systems.<sup>1, 2</sup>

Although there is no direct evidence that the ability to produce antibodies in these patients protected against COVID-19, it is expected that the extra dose would increase protection at least in some patients. EMA will continue monitoring any data that emerges on its effectiveness.

The product information of both vaccines will be updated to include this recommendation.

### Booster doses

It is important to distinguish between the extra dose for people with weakened immune systems and booster doses for people with normal immune systems.

For the latter, the CHMP has evaluated data for Comirnaty showing a rise in antibody levels when a booster dose is given approximately 6 months after the second dose in people from 18 to 55 years old. On the basis of this data, the Committee concluded that booster doses may be considered at least 6 months after the second dose for people aged 18 years and older.

The use of booster doses will follow official recommendations at national level as defined by public health bodies, taking into account emerging effectiveness data and any uncertainties about safety. The risk of inflammatory heart conditions or other very rare side effects after a booster is not known and is being carefully monitored. As for all medicines, EMA will continue to look at all data on the safety and effectiveness of the vaccine.

More information about the booster recommendations for Comirnaty will be available in the updated product information.

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<sup>1</sup> Kamar N, Abravanel F, Marion O, Couat C, Izopet J, Del Bello A. Three doses of an mRNA Covid-19 vaccine in solid-organ transplant recipients. *N Engl J Med* 2021;385:661-662.

<sup>2</sup> Hall VG, Ferreira VH, Ku T, et al. Randomized trial of a third dose of mRNA-1273 vaccine in transplant recipients. *N Engl J Med* 2021;385:1244-1246.



The Committee is currently evaluating data to support a booster dose for Spikevax. EMA will communicate the outcome when the evaluation is complete.

### **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.