

Ik denk dat Verordening 1234/2008 (de variatie verordening) moet worden aangepast, want daarvoor was een bijeenkomst bij elkaar geroepen waar het CBG aan deelnam. Ik zal er morgen verder naar kijken.

Vriendelijke groet,

5.1.2e

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Onderwerp: FW: EU regulator publishes guidance for coronavirus variant vaccines

Hi 5.1.2e

Vergt dit geen aanpassing van wetgeving, maar alleen van deze guidance door EMA?
Is hierover nog verdere besluitvorming voorzien, of is CHMP daarin het eindstation?

Groet 5.1.2e

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Ministry of Health Welfare and Sport

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Onderwerp: EU regulator publishes guidance for coronavirus variant vaccines

EU regulator publishes guidance for coronavirus variant vaccines

-- By 5.1.2e

February 25, 2021, 6:41 pm | [View in your browser](#)

The European Medicines Agency published guidance today for vaccine manufacturers looking to adapt their vaccines to provide protection against new coronavirus variants.

The [guidance](#) rests on the assumption that new variant vaccines would rely on the same technology and platform as the original approved vaccine, and that the main change would be in the antigen chosen to set off an immune response.

The EMA's human medicines committee has said there won't be the need to submit new large-scale safety and efficacy studies. Instead, immunogenicity studies can be used to indicate the efficacy of the variant vaccine, with the suggestion that researchers need at least one small clinical trial on the vaccine, with people receiving either the new variant vaccine or the original one.

The EMA said that manufacturers should also look at the efficacy of a single dose — a co-called booster — to people who have had the original vaccine. The immune response elicited by this shot should be compared with that shown in the original trial done for the first approval of the vaccine.

Manufacturers won't need to carry out more lab studies, and they would need to indicate that the vaccine will be produced in accordance with the same standards and processes as were used for the original vaccine.

The paper comes after a meeting earlier this month between internal regulators, [where similar conclusions were made](#).

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