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# Withdrawal of application to change the marketing authorisation for Bimervax (COVID-19 vaccine (recombinant, adjuvanted))

HIPRA Human Health S.L.U. withdrew its application for the use of Bimervax JN.1 in the prevention of coronavirus disease 2019 (COVID-19).

The company withdrew the application on 5 February 2025.

## What is Bimervax and what is it used for?

Bimervax is a vaccine for preventing COVID-19 in people aged 16 years and older.

The originally authorised Bimervax contains the active substance selvacovatein, a protein produced in the laboratory that consists of part of the SARS-CoV-2 (the virus that causes COVID-19) spike protein from the Alpha and Beta strains.

As SARS-CoV-2 keeps evolving, Bimervax has been adapted to target more recent strains of the virus. This helps maintain protection against COVID-19.

The adapted Bimervax targeting the XBB.1.16 strain contains the active substance damlecovatein, a protein produced in the laboratory that consists of part of the SARS-CoV-2 spike protein from the XBB.1.16 strain.

Bimervax is given as a single injection, usually in the muscle of the upper arm.

Bimervax does not contain the virus itself and cannot cause COVID-19.

The vaccine has been authorised in the EU since March 2023. Further information on Bimervax's current uses can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/bimervax.

## What change had the company applied for?

The company applied to include an adapted version of Bimervax targeting the JN.1 strain of SARS-CoV-2.

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## How does Bimervax work?

Bimervax works by preparing the body to defend itself against COVID-19. The vaccine contains a protein produced in the laboratory that consists of part of the SARS-CoV-2 spike protein. It also contains an 'adjuvant', a substance to help strengthen the immune response to the vaccine.

When a person is given the vaccine, their immune system will identify the protein as foreign and produce natural defences — antibodies and T cells — against it. If, later on, the vaccinated person comes into contact with SARS-CoV-2, the immune system will recognise the spike protein on the virus and be prepared to attack it. The antibodies and immune cells can protect against COVID-19 by working together to kill the virus, prevent its entry into the body's cells and destroy infected cells.

Adapted vaccines are expected to help maintain protection against the virus as it evolves, since they contain a spike protein more closely matching circulating variants of the virus.

## What did the company present to support its application?

The company provided data on the quality of the adapted vaccine and laboratory data to demonstrate that Bimervax JN.1 is able to trigger an adequate immune response against the JN.1 strain of SARS-CoV-2.

## How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and had prepared questions for the company. After the Agency had assessed the company's latest responses to the questions, there were still some unresolved issues.

## What did the Agency recommend at that time?

The Agency had concerns regarding the presence of a new impurity in batches of Bimervax JN.1, which had not been previously observed in Bimervax. Based on the review of the information and the company's responses to the Agency's questions, at the time of the withdrawal, it was unclear whether the impurity in the vaccine might affect the vaccine's safety or its ability to produce an appropriate immune response.

Therefore, at the time of the withdrawal, the Agency's opinion was that the company had not provided enough information to support the application for the use of Bimervax JN.1 in the prevention of COVID-19.

## What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of application, the company stated that the technical information needed to address EMA's questions would require several months of work. Since the JN.1 variant was recommended for the vaccination campaign of autumn 2024, there was no longer a commercial interest to pursue this application, and the company decided to focus efforts on future recommended variants instead.

## Does this withdrawal affect participants in clinical trials?

The company informed the Agency that there are no clinical trials with Bimervax JN.1.

## What is happening with the originally authorised Bimervax vaccine and Bimervax XBB.1.16 for the prevention of COVID-19?

The originally authorised Bimervax vaccine and Bimervax XBB.1.16 continue to be authorised for the prevention of COVID-19.