



EUROPEAN MEDICINES AGENCY  
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## EMA recommends Valneva's COVID-19 vaccine for authorisation in the EU

EMA has recommended granting a marketing authorisation for COVID-19 Vaccine (inactivated, adjuvanted) Valneva for use in the primary vaccination of people from 18 to 50 years of age.

COVID-19 Vaccine (inactivated, adjuvanted) Valneva contains inactivated (killed) whole particles of the original strain of SARS-CoV-2 that cannot cause disease. It is the sixth vaccine recommended in the EU for protecting against COVID-19 and, together with the vaccines already authorised, will support vaccination campaigns in EU Member States during the pandemic.

After a thorough evaluation, EMA's human medicines committee (CHMP) concluded by consensus that the data on the vaccine were robust and met the EU criteria for efficacy, safety and quality.

The main study conducted with Valneva's vaccine is an immunobridging trial. Immunobridging trials compare the immune response induced by a new vaccine with that induced by an authorised comparator vaccine proven to be effective against the disease.

Results from the study, which involved nearly 3,000 people aged 30 years and older, showed that the vaccine triggers the production of higher levels of antibodies against the original strain of SARS-CoV-2 than the comparator, Vaxzevria. In addition, the proportion of people who produced a high level of antibodies was similar for both vaccines.

Additional data from this study also showed that the vaccine is as effective at triggering the production of antibodies in people aged between 18 and 29 as it is in people aged 30 years and older.

The CHMP therefore concluded that COVID-19 Vaccine (inactivated, adjuvanted) Valneva is expected to be at least as effective as Vaxzevria at protecting against the disease. Based on the data provided, it was not possible to draw any conclusion on the immunogenicity of Valneva's vaccine (its ability to trigger the production of antibodies) in people above 50 years of age; therefore, the vaccine is currently recommended only for use in people between 18 and 50 years of age.

There are limited data on the immunogenicity of COVID-19 Vaccine (inactivated, adjuvanted) Valneva against variants of concern, including Omicron subvariants which are currently the dominant strains in many EU countries.

The side effects observed with COVID-19 Vaccine (inactivated, adjuvanted) Valneva in studies were usually mild and cleared within a couple of days after vaccination. The most common ones were



tenderness or pain at the injection site, tiredness, headache, muscle pain and nausea (feeling sick) or vomiting.

The safety and effectiveness of the vaccine will continue to be monitored as the vaccine is used across the EU, through the EU pharmacovigilance system and additional studies by the company and European authorities.

Based on the available evidence, the CHMP concluded that the benefits of COVID-19 Vaccine (inactivated, adjuvanted) Valneva outweigh its risks and recommended granting a standard marketing authorisation in the EU.

### **Standard marketing authorisation**

The dossier for the vaccine includes the results from an immunobridging trial. Although efficacy placebo-controlled trials have been the gold standard for authorising COVID-19 vaccines so far, EMA considers that a well-justified and appropriately designed immunobridging study is adequate for authorising future COVID-19 vaccines at this point in the pandemic. This is because there are now a number of COVID-19 vaccines authorised in the EU that are proven to be safe and effective and that can be used as comparators in studies. Additionally, at present, it would be difficult to recruit enough individuals who have not been vaccinated nor previously exposed to the virus to conduct large efficacy clinical trials.

The European Commission will now fast-track the decision-making process to grant a decision on the standard marketing authorisation for COVID-19 Vaccine (inactivated, adjuvanted) Valneva, allowing this vaccine to be included in vaccination programmes rolled out across the EU. A standard marketing authorisation is considered appropriate for this vaccine since the immunobridging study met its objectives and data provided are considered sufficient.

### **Where to find more information**

The [product information](#) for COVID-19 Vaccine (inactivated, adjuvanted) Valneva contains information for healthcare professionals, a package leaflet for members of the public and details of the vaccine's authorisation.

An assessment report with details of EMA's evaluation of COVID-19 Vaccine (inactivated, adjuvanted) Valneva and the full risk management plan will be published shortly. Clinical trial data submitted by the company in the application for marketing authorisation will be published on the Agency's [clinical data website](#) in due course.

More information is available in an [overview of the vaccine in lay language](#), including a description of the vaccine's benefits and risks and why EMA recommended its authorisation in the EU.

### **How COVID-19 Vaccine (inactivated, adjuvanted) Valneva works**

COVID-19 Vaccine (inactivated, adjuvanted) Valneva works by preparing the body to defend itself against COVID-19. The vaccine contains whole particles of the original strain of SARS-CoV-2 that has been inactivated (killed) and cannot cause the disease. It also contains two 'adjuvants', substances that help strengthen the immune responses to the vaccine.

When a person is given the vaccine, their immune system identifies the inactivated virus as foreign and makes antibodies against it. If, later on, the vaccinated person comes into contact with SARS-CoV-2, the immune system will recognise the virus and be ready to defend the body against it.

COVID-19 Vaccine (inactivated, adjuvanted) Valneva is given as two injections, usually into the muscle of the upper arm, 28 days apart.

### **Monitoring the safety of COVID-19 Vaccine (inactivated, adjuvanted) Valneva**

In line with the EU's [safety monitoring plan for COVID-19 vaccines](#), COVID-19 Vaccine (inactivated, adjuvanted) Valneva will be closely monitored and subject to several activities that apply specifically to COVID-19 vaccines. Although large numbers of people have received COVID-19 vaccines in clinical trials, certain side effects may only emerge when millions of people are vaccinated.

The company is required to provide monthly safety reports in addition to the regular updates required by legislation. In addition, [independent studies](#) of COVID-19 vaccines coordinated by EU authorities will give more information on the vaccine's long-term safety and benefits in the general population.

These measures will allow regulators to swiftly assess data emerging from a range of different sources and take any necessary regulatory action to protect public health.

### **Assessment of COVID-19 Vaccine (inactivated, adjuvanted) Valneva**

During the assessment of COVID-19 Vaccine (inactivated, adjuvanted) Valneva, the CHMP had the support of EMA's safety committee, the PRAC, who assessed the risk management plan of the vaccine, and the [COVID-19 EMA pandemic task force \(COVID-ETF\)](#), a group that brings together experts from across the European medicines regulatory network to facilitate rapid and coordinated regulatory action on medicines and vaccines for COVID-19.

COVID-19 Vaccine (inactivated, adjuvanted) Valneva [was evaluated as part of 'OPEN'](#), an initiative started in December 2020 with the aim of increasing international collaboration in the EU review of COVID-19 vaccines and therapeutics. More information can be found on the [EMA's governance during COVID-19 pandemic](#) webpage.