COVID-19 vaccines: key facts

ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-vaccines-key-facts

September 14, 2020

There are currently no authorised vaccines for COVID-19 in the European Union (EU). The European Medicines Agency (EMA) is liaising closely with developers of potential COVID-19 vaccines, mobilising its own resources and cooperating with regulatory partners, to ensure safe and effective vaccines reach patients as soon as possible.

Why are vaccines to prevent COVID-19 urgently needed?

COVID-19 vaccines are medicines that aim to prevent disease caused by the novel coronavirus SARS-CoV-2 by triggering an immune response.

The current Coronavirus disease (COVID-19) pandemic is a **global crisis**, with devastating health, social and economic impact.

COVID-19 can cause severe disease and death with yet unknown long-term consequences in people of all ages, including in otherwise healthy people.

Safe and effective vaccines for COVID-19 are needed to **protect individuals** from becoming ill, especially healthcare professionals and **vulnerable populations**, such as older people or those with chronic diseases.

Is there a vaccine to protect against COVID-19?

There are **no vaccines approved** yet in the EU to prevent or treat any of the human coronavirus infections, including those causing the common colds or more serious conditions.

Due to the urgency posed by the pandemic, efforts are ongoing to develop and study COVID-19 vaccines in order to approve and make them available **as soon as possible**.

For the latest information, see Treatments and vaccines for COVID-19.

It is not currently known what **level of protection** can be reached with the vaccines in development. Reasonably effective vaccines, together with other public health measures and therapeutic treatments, will be a key component in overcoming COVID-19.

Did you know..?

Vaccines work by preparing a person's **immune system** (the body's natural defences) to recognise and defend itself against a specific disease.

Most research on COVID-19 vaccines involves generating responses to all or part of a protein (**spike protein**, or protein S) that is unique to the virus that causes COVID-19. When a person receives the vaccine, it will trigger an immune response.

If the person is infected by the virus later on, the immune system recognises the virus and, because it is already **prepared to attack the virus**, protects the person from COVID-19.

You can find more information on theEuropean Vaccination Information Portal.

What process and methods are being used to develop and approve COVID-19 vaccines?

COVID-19 vaccines are being developed following the same legal requirements for pharmaceutical **quality, safety and efficacy** as other medicines.

Like all medicines, COVID-19 vaccines' effects are first tested in laboratory, including in animals, then vaccines are tested in human volunteers.

For more information, see COVID-19 vaccines: development, evaluation, approval and monitoring.

Did you know..?
Before approval, all vaccines in the EU are evaluated against the **same high standards** as any other medicine.

What is different for COVID-19 vaccines is that speed of development and potential approval is much faster due to the **public health emergency**.

EMA has put in place a dedicated expert task force and rapid review procedures to evaluate high-quality applications from companies in the shortest possible timeframes, while ensuring **robust scientific opinions.**

The European Commission will make use of all existing flexibilities to accelerate the approval of any potential vaccines for use across the EU, but this will only be possible if EMA receives sound scientific evidence that allows establishing that vaccines' benefits are greater than any risks.

You can find more information on how vaccines and other medicines are **evaluated and authorised** in the EU on:

- COVID-19 vaccines: development, evaluation, approval and monitoring
- European Vaccination Information Portal
- Authorisation of medicines
- How EMA evaluates medicines for human use
- From laboratory to patient: the journey of a centrally authorised medicine
- European Commission: Coronavirus vaccines strategy

Why did development only start after the pandemic was declared?

Vaccines can only be developed when the infectious agent is known.

Since SARS-CoV-2 is a **new virus** that had not been seen before, development of a vaccine to protect against COVID-19 could only be started once the virus emerged and its **genetic make-up** had been analysed.

However, vaccine development builds on experience and technologies used for other vaccines.

When will the vaccines be approved?

At present it is **not known** whether COVID-19 vaccines will be approved or how long this will take, as timelines are difficult to predict.

Vaccine development is progressing, and in a best-case scenario, the Agency would receive **clinical data** on the most advanced vaccines in development **towards the end of 2020**.

Regulators would then carry out a scientific evaluation of the vaccine's safety, efficacy and quality, before concluding on whether there is sound scientific evidence supporting approval.

If the scientific evidence supports a positive benefit-risk assessment for any of the vaccines, the European Commission will grant a marketing authorisation valid across the EU in the shortest possible timelines.

For evaluation of other vaccines currently at earlier development stages, this would likely take place throughout 2021 and beyond.

For more information, seeTreatments and vaccines for COVID-19.

What type and amount of data is needed for approving a safe and effective vaccine?

COVID-19 vaccine developers need to submit specific data on their vaccine. EMA then carries out a **thorough assessment** of these data to reach a scientific opinion on whether the vaccine is safe, efficacious and of good quality and is therefore suitable to vaccinate people.

The data should show the vaccine's efficacy in protecting against COVID-19 (how well the vaccine works in clinical settings) and its safety.

Efficacy is measured by looking at how well the vaccine works in the study, for example how well the vaccine prevents symptomatic disease. These efficacy measures are called 'endpoints'. Efficacy endpoints are required because COVID-19 is a new disease and because there are no known indicators (such as the levels of antibodies in the blood) that can predict protection.

Did you know..?
The **safety requirements** for COVID-19 vaccines are the **same as for any other vaccine** in the EU and will not be lowered in the context of the pandemic.

The data submitted in a marketing authorisation application for a COVID-19 vaccine must include information on:

- the **group of people** to be given the vaccine;
- its **pharmaceutical quality**, including information on the identity and purity of the vaccine components and its content and biological activity (potency);
- data on each step of **manufacturing** and on the **controls** used to ensure that each batch of vaccine is consistently of good quality;
- **compliance** with international requirements for laboratory testing, vaccine manufacture and conduct of clinical trials ('good laboratory practice', 'good clinical practice' and 'good manufacturing practice');
- types of **immune responses** induced by the vaccine;
- the **effects** observed in the groups of people to be given the vaccine;
- the vaccine's **side effects** observed in vaccinees, including if there are any data in special populations such as older people or pregnant women;
- information intended to be gathered from **follow-up studies** after authorisation (e.g. long-term safety data or long-term immunity);
- **prescribing information** to be provided to patients and healthcare professionals (i.e. the summary or product characteristics or SmPC, labelling and package leaflet), which is drafted by the developer and reviewed and agreed by EMA's scientific committees;
- the **way risks will be managed** and monitored once the vaccine is authorised; the risk management plan (RMP), a document with information about any possible (known or potential) safety concerns with the vaccine, the way risks will be managed and monitored once the vaccine is authorised and what information is intended to be gathered from follow-up studies. The RMP is evaluated by EMA's safety committee, PRAC.

How long will immunity from a vaccine last?

Currently, because the virus is so novel, there is **not enough knowledge** on how long the immunity conferred by the vaccines will last after vaccination, or whether there will be a need for periodic booster doses.

Data from immunogenicity and efficacy studies in the long term will inform future vaccination strategies.

Vaccination policies are not decided by EMA but by public health agencies in EU member states. More information is available on the European Vaccination Information Portal.

Will vaccines protect vaccinated people if the virus mutates?

Typically, **viruses mutate** (the genetic material in the virus changes). This happens **at different rates** for different viruses and mutations do not necessarily affect how well the vaccine works against the virus.

Some vaccines against viral diseases remain **effective many years** after their development and provide long-lasting protection, such as vaccines for measles or rubella.

On the other hand, for diseases such as flu, virus strains change so often and to such an extent that the vaccine composition must be **updated on a yearly basis** for it to be effective.

The scientific community and regulators will monitor whether the coronavirus Sars-CoV-2 changes over time and, if so, whether vaccines can protect people from infection with new variants.