

COVID-19 vaccines:

How are they developed, authorised and put on the market?

DECEMBER 2020



Due to the urgency of the pandemic, COVID-19 vaccines are being developed and authorised faster than usual.

BUT THEY WILL MEET THE SAME HIGH STANDARDS AS ALL OTHER VACCINES.



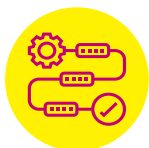
HOW WERE THE COVID-19 VACCINES DEVELOPED SO QUICKLY?



Massive investments have been made to develop rapidly COVID-19 vaccines.

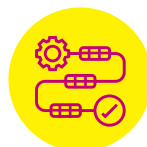


Scientists were able to speed up some parts of the process, by combining different phases of clinical trials or conducting some studies at the same time.



Some COVID-19 vaccines were developed using the **same methods as for other vaccines**.

This means that it will be easier to **use existing facilities** to make COVID-19 vaccines in massive quantities.

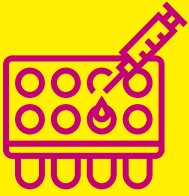


The European Medicines Agency began to look at the resulting data even before companies asked it to authorise a vaccine.

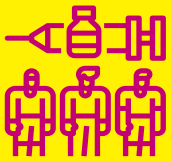
Some vaccines for COVID-19 have been developed using **new methods** that can increase the **volume** and **speed of production** compared to other types of vaccines.

COMPANIES ARE INCREASING THEIR CAPACITY TO QUICKLY PRODUCE MILLIONS OF DOSES OF APPROVED COVID-19 VACCINES.

APPROVING THE VACCINE



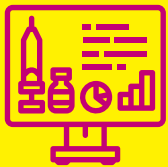
Like all medicines, vaccines are first **tested in the laboratory**.



They are then tested on human volunteers in several rounds of studies called **clinical trials**.



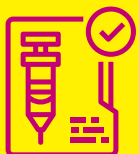
These trials help confirm how the vaccines work and ensure that their **benefits outweigh any potential side effects or risks**.



Once there is sufficient data from research and clinical trials, companies can apply to the European Medicines Agency for **authorisation** to put the vaccine on the market.



The European Medicines Agency evaluates all the data and conducts an independent and **thorough scientific assessment** of the vaccine.



Based on the Agency's scientific assessment, the European Commission grants **a marketing authorisation** in the EU. The vaccine can then be used.



CONDITIONAL MARKETING AUTHORISATION

During a public health emergency, a **conditional marketing authorisation** may be granted for a medicine or vaccine.

This may happen when **the benefit of providing it immediately outweighs the risk** of having less comprehensive data than normally required. In these cases, the producer commits to providing additional information according to a defined timetable.

IN ANY CASE, THE EUROPEAN COMMISSION WILL ONLY GRANT A MARKETING AUTHORISATION ONCE THE EMA'S ASSESSMENT SHOWS THAT THE VACCINE IS BOTH SAFE AND EFFECTIVE.



VACCINATION CAMPAIGNS

Companies then produce the approved vaccines on a large scale. The quantity of vaccines that each country will receive is usually calculated **based on its population**.

People can be vaccinated according to national vaccine programmes. These usually prioritise specific groups such as **healthcare professionals and vulnerable populations** (older people or people with underlying medical conditions).

The Commission supports EU countries in the preparation and implementation of their vaccine campaigns.

SAFETY AND EFFECTIVENESS

The safety and effectiveness of vaccines which have received conditional marketing authorisations are **rigorously monitored, as for all medicines**, through the **EU's established medicines monitoring system**.

In addition, special measures are in place to quickly collect and evaluate new information. For example, manufacturers must usually send a safety report to the European Medicines Agency every six months. For COVID-19 vaccines, **safety reports must be sent every month**.

The European Medicines Agency will set up **additional large-scale safety monitoring** given the exceptionally high numbers of people expected to receive the vaccines.



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