COVID-19: EU coordination for safe and effective vaccination

Pharmaceutical companies apply for authorisation to the European Medicines Agency (EMA), the first condition they have to meet in order to deploy their vaccines on the EU's market. Vaccines can be administered to the population only following a positive opinion by EMA and approval from the European Commission.

How are COVID-19 vaccines being fast-tracked for approval?

Normally, pharmaceutical companies submit all the necessary data about a vaccine to EMA at the end of the development process.

With COVID-19, they do it as soon as available. This process is called 'rolling review'.
When applying for marketing authorisation, most of the data have already been assessed, allowing EMA to issue an opinion much sooner.

COVID-19 vaccines need to comply with the same quality, safety and efficacy requirements as any other vaccine in the EU.

Roadmap for vaccine approval and deployment

1 authorisation application by vaccine developers to the European Medicines Agency (EMA)

2 independent scientific evaluation by EMA, in compliance with EU pharmaceutical legislation

3 positive opinion by EMA if benefits are far greater than potential risks

4 marketing authorisation by the European Commission

5 equal access by all EU countries to a number of doses proportionate to their population size

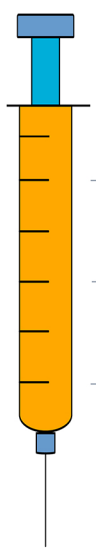
6 deployment to the population across the EU

7 monitoring of safety, effectiveness and any side-effects by EMA, paired with information exchange between EU countries

conditional marketing

Almost 2.6 billion doses already secured

In million doses:



AstraZeneca
Up to 400

Janssen P. NV
Up to 400

CureVac
Up to 405

Sanofi-GSK
Up to 300

BioNTech-Pfizer
Up to 600

Moderna
Up to 460

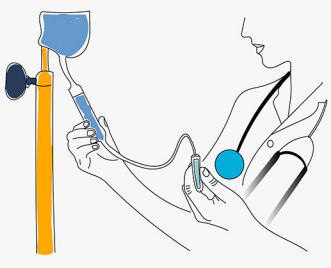
Novavax and Valneva
In addition, the Commission has concluded exploratory talks with Novavax (up to 200 million doses) and Valneva (up to 60 million doses).

Doses have been secured through advance purchase agreements (APAs) with vaccines developers. By means of the APAs, the European Commission and EU countries cover part of the upfront costs of developing a vaccine.

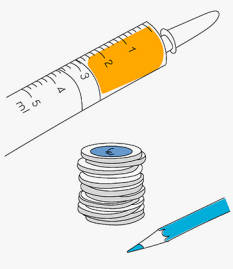
In return, EU countries secure the right to purchase a sufficient number of doses, within a given time frame and at an affordable price.

Funding comes from the EU's Emergency Support Instrument and is a down payment on the doses that EU countries eventually acquire.

Key elements for effective vaccination campaigns across the EU

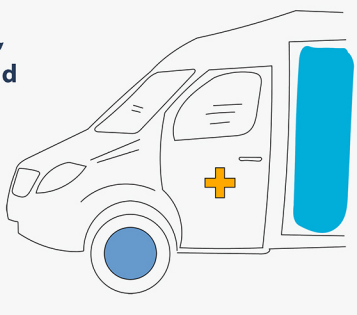


capacity to deliver skilled workforce and equipment

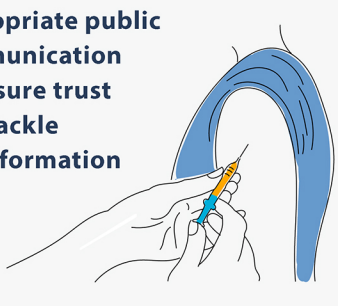


easy and affordable access

safe storage, transport and deployment



appropriate public communication to ensure trust and tackle misinformation



Council of the European Union
General Secretariat

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