

17 June 2020

The development and distribution of an effective and safe vaccine against the coronavirus represents a lasting solution to the pandemic and a cornerstone of the European Commission's coronavirus response.

The deployment of a vaccine will **protect lives and livelihoods**, and **save billions of euros across Europe and the world**. There is no guarantee that a vaccine will be found, but it is our best bet to overcome this pandemic and return to our normal way of life.

#### CHALLENGES OF VACCINE DEVELOPMENT

Vaccine development is highly complex and usually takes around **10 years**, but the Commission intends to achieve it within a timeframe of **12 - 18 months**, if not earlier, without compromising on safety, quality or efficacy. The EU faces two major challenges:

- Early large-scale investments in production capacities are needed to reduce the risks of vaccine producers before guarantees exist that these vaccines will pass the clinical trials.
- Large quantities of raw materials need to be secured so that production can start as soon as clinical trials are concluded, or even earlier.





# **OBJECTIVES OF THE EU VACCINE STRATEGY**

- Ensuring the quality, safety and efficacy of vaccines.
- · Securing timely access to vaccines for Member States and their population while leading the global solidarity effort.
- Ensuring equitable and affordable access for all in the EU as early as possible.

# **TWO PILLARS**

**Securing the production** of a sufficient quantity of vaccines in the EU through **Advance Purchase Agreements** with vaccine producers via the Emergency Support Instrument. Additional financing and other forms of support can be made available on top of such agreements.

**Adapt the EU rules** to the current urgency in order to accelerate the development, authorisation and availability of vaccines while maintaining the standards for vaccine quality, safety and efficacy.

#### WHAT THE EU PROPOSES

The Commission and a number of Member States have been in discussions with vaccine producers. Building on this work, the Commission has put forward a proposal for joint action at the EU level. The Commission plans a centralised EU approach to securing supplies and providing support for the development of a vaccine.

Companies with a promising vaccine candidate, already in or close to starting clinical trials, are invited to contact the



Commission.

### **HOW IT WILL WORK:**



The Commission enters into Advanced Purchase Agreements with individual vaccine producers on behalf of Member States. In return for the right to buy a specified number of vaccine

doses in a given timeframe and at a given price, the Commission will finance a part of the upfront costs faced by vaccines producers from the **Emergency Support Instrument**. This funding will be considered as a down-payment on the vaccines that will actually be purchased by Member States. Additional support is possible through loans from the **European Investment Bank**. This approach will decrease risks for companies while speeding up and increasing manufacturing.

funding

will come from a

significant part of the

Emergency Support

€2,7 billi

# PROCESS AND GOVERNANCE



The Commission will set up a **steering board**. The steering board will be composed of **representatives of all participating Member States** to assist the Commission with guidance and expertise throughout the entire process.

The steering board will propose a small team of Member States experts who will support the Commission in the negotiations and form together with the Commission representatives the **joint negotiation team.** 

#### FINANCING CRITERIA

Criteria to decide which vaccine producers to support, include:

- soundness of scientific approach and technology used
- speed and ability of delivery or sufficient quantities of vaccines in 2020 and 2021
- costs
- risk sharing and liability coverage required
- coverage of different technologies
- production capacity in the EU

- global solidarity: a commitment to offer future doses of vaccines to partner countries to end the global pandemic
- early engagement with EU
  regulators with the intention to apply
  for an EU marketing authorisation for the candidate
  vaccine(s)

#### CORONAVIRUS GLOBAL RESPONSE

The proposed common EU approach to secure vaccines for Europeans complements the Global Response efforts towards universal access for a vaccine.

Supporting companies with clinical trials and with expanding production capacities will benefit the global population. Securing timely access to a vaccine for all Member States will allow economic and social activity to restart across borders and protect citizens from a new surge of the pandemic.

The Commission is ready to explore with international partners whether a significant number of high income countries would agree to pool resources to reserve vaccines from producers. They would not only do this for themselves, but also for low- and middle income countries. High income countries would thus act as an inclusive, international buyers group, accelerating the development of safe and effective vaccines and maximising access for all who need it most in the world.

The European Commission will ensure that the EU continues to play its part in resolving the coronavirus pandemic. **The EU will only be safe if the rest of the world is safe.** 



