European Commission

COVID-19 vaccine

The most important breakthrough to stop the COVID-19 pandemic will undoubtedly be treatment and vaccination. A safe and effective vaccine will grant protection against the coronavirus, avoid resurgence of the disease, allow normal life to resume and provide a lasting solution to this global health crisis. It is an unprecedented global challenge requiring vaccine to be produced under a substantial time pressure and to meet a demand of billions of doses. It is essential that the EU has access to it.

To accelerate the development and deployment of universally available and affordable vaccinations, treatments and diagnostics, on 4 May, the EU joined forces with global partners to launch the Coronavirus Global Response pledging effort.

More than 90 vaccines are under development but only a handful have so far entered clinical trials. The European Medicines Agency (EMA) and the Commission have mechanisms in place to significantly accelerate the evaluation and approval of a vaccine. The main factor for the success of these ongoing efforts would be the generation of data from clinical trials to prove safety and efficacy. If one or more successful vaccines are identified, scaling up production for a global supply will be an important challenge. In view of a foreseeable scarcity of vaccine supply, it is critical to assess already now whether Member States would support a concerted action and cooperation at EU level to ensure that access is equitable and that therapies and vaccines are affordable across the EU. Another important element to consider is how to manage the risks associated with the rapid development and introduction of a new vaccine to the market.

Activities at the EU level

As of April 30, the WHO blueprint list of COVID-19 vaccines in development includes 8 candidates in clinical evaluation and 94 candidates in preclinical evaluation. Three candidates are receiving support from the Commission through Horizon 2020 and Member States are investing into several candidates. The European Medicines Agency (EMA) is playing a central role providing scientific advice.

The EU legislation provides mechanisms to significantly speed up development and approval of medicines and vaccines to ensure the quickest availability as possible. There are different models for ongoing COVID-19 vaccine development (e.g. inactivated virus, protein based). In some cases (e.g. recombinant technologies, RNA and DNA vaccine platforms), the marketing authorisation will automatically be granted through the centralised system with an assessment by EMA, followed by a Commission decision. In other cases, vaccine authorisations can be granted at national level.

To ensure that research on vaccines is outcome oriented, Ministers of Health would need to engage in close cooperation with Research and Technological Development Ministries. At EU level, the Research & Innovation Ministries have agreed to an ERAvsCORONA action plan[1] for short term coordinated research and innovation actions. The first action was the creation of an ad-hoc working group with Member States' research and innovation representatives and the Commission to address COVID-19 related research in a holistic manner, including vaccines, their manufacturing, and financing. The second action relates to supporting large EU wide clinical trials for clinical management of COVD-19 patients.

1 https://ec.europa.eu/info/sites/info/files/research_and_innovation/research_by_area/documents/ec_rtd_era-vs-corona.pdf

Key challenges:

- Rapid transfers of research results: There is a necessity for a swift transfer of research results in products needed for public health actions. This would entail quick decisions on the portfolio of the most promising COVID-19 vaccine candidates based on agreed selection criteria and enter them in clinical trials using an EU wide trials network.
- Infrastructure: Ensuring sufficient infrastructure for clinical trials (human resources, protocols, critical mass environments to conduct the studies) is a central part of a robust assessment of the quality, safety and efficacy of a vaccine.
- Liability: Given the time pressure to develop a vaccine against COVID-19, manufacturers will most likely refuse to take the full responsibility for possible adverse effects. Public authorities need to consider the possibility of sharing liability.
- Licensing: Given that significant financial resources will be involved, fair licensing and IPR conditions should be ensured.
- Production capacity: It is likely that more than one vaccine will be needed to cover the global demand for COVID-19 vaccine and existing production capacity will not be sufficient. Public support to upscale production therefore needs to be considered. To do so, public-private partnership or the use of instruments such a pre-commercial public procurement will likely be required. Purchase commitments could be secured through the EU joint procurement procedure as an immediate response.
- Equitable access: Once a vaccine is developed, access must be secured. Several pre-contracts for the production of COVID-19 vaccines are already in place. Biomedical Advanced Research and Development Authority (BARDA) in the United States is one example. Some Member States are also establishing bilateral contracts with pharmaceutical vaccine producers. This may affect availability of vaccines for other Member States as well as world-wide. Efforts to ensure equitable access at world and European level must be combined.
- Definition of needs: To undertake negotiations with industry to secure vaccine supply for Europe, the EU needs to define: the number of doses needed, the target population, timelines of administration and the qualified staff required. Member States could agree to do this in a coordinated way and give a mandate and support to the Health Security Committee for this action.

Conclusion

Achieving the objective of access to a safe and effective vaccine would require the following actions:

- Ensure allocation of resources for research and vaccine manufacturing.
- Establish a critical mass of clinical and research networks, including an EU wide clinical trials network.
- Secure access to the portfolio of the most promising vaccine candidates for the European population.
- Enable the EU to negotiate with industry as a powerful counterpart and ensure upscale of production and EU-wide access to the required vaccine.
- Decide on a common approach to the liability issues.
- Address the licencing and IPR issues by entering into early discussions with industry.
- Carry out an assessment of the number of vaccine doses needed, at EU level.
- Ensure that vaccine distribution in Europe is efficient and targeted to the needs.
- Ensure effective management of limited available vaccine capacities, for instance through a European vaccination/ immunisation plan, and exchange of information on manufacturing capacity.