



## Coronavirus: Commission proposes EU Strategy for the development and availability of therapeutics

Brussels, 6 May 2021

The European Commission is today complementing the successful [EU Vaccines Strategy](#) with a [strategy on COVID-19 therapeutics](#) to support the development and availability of much-needed COVID-19 therapeutics, including for the treatment of 'long COVID'. Today's Strategy covers the full lifecycle of medicines: from research, development and manufacturing to procurement and deployment.

It is part of the strong European Health Union, in which all EU countries prepare and respond together to health crises and ensure the availability of affordable and innovative medical supplies – including the therapeutics needed to treat COVID-19.

The Strategy includes clear actions and targets, including authorising three new therapeutics to treat COVID-19 by October 2021 and possibly two more by end of the year. Concretely:

- **Research, development and innovation**

- Invest €90 million in population studies and clinical trials to establish links between risk factors and health outcomes to further inform public health policy and clinical management, including for long-COVID patients.
- Set up a 'therapeutics innovation booster' by July 2021 to support the most promising therapeutics from preclinical research to market authorisation. It will build on current initiatives and investments in therapeutic development, working in a close cooperation with the European Health Emergency Preparedness and Response Authority (HERA) preparatory action on mapping therapeutics. It will therefore ensure the coordination of all research projects on COVID-19 therapeutics, stimulating innovation and boosting therapeutic development.

- **Access to and swift approval of clinical trials**

- Invest €5 million under the EU4Health programme to generate better, high-quality safety data in clinical trials, which will help produce robust results in a timely manner.
- Provide EU countries with financial support of €2 million under the EU4Health 2021 work programme for expedited and coordinated assessments to facilitate approval of clinical trials.
- Explore how to support developers of therapeutics to build capacity to produce high-grade material for clinical trials.

- **Scanning for candidate therapeutics**

- Invest €5 million to map therapeutics and diagnostics to analyse development phases, production capacities and supply chains, including possible bottlenecks.
- Establish a broader portfolio of 10 potential COVID-19 therapeutics and identify five of the most promising ones by June 2021.

- **Supply chains and delivery of medicines**

- Fund a €40 million preparatory action to support flexible manufacturing and access for COVID-19 therapeutics under the EU Fab project, which in turn will become over time an important asset for the future the European Health Emergency Preparedness and Response Authority (HERA).

- **Regulatory flexibility**

- Authorise at least three new therapeutics by October and possibly two more by the end of the year and develop flexible regulatory approaches to speed up the assessment of promising and safe COVID-19 therapeutics.
- Start seven rolling reviews of promising therapeutics by end-2021, subject to research and development outcomes.

- **Joint procurement and financing**

- Launch new contracts for the purchase of authorised therapeutics by the end of the year.
- Secure faster access to medicines with shorter administrative deadlines.

- **International cooperation** to make medicines available to all

- Reinforce engagement for the therapeutics pillar of the Access to COVID-19 Tools Accelerator.
- Boost 'OPEN' initiative for international collaboration.

## **Next Steps**

The Commission will draw up a portfolio of 10 potential COVID-19 therapeutics and by June 2021, identify the five most promising ones. It will organise matchmaking events for industrial actors involved in therapeutics to ensure enough production capacity and swift manufacturing. New authorisations, rolling reviews and joint procurement contracts will be up and running before the end of the year.

The therapeutics innovation booster, matchmaking events and preparatory action to support flexible manufacturing and access for COVID-19 therapeutics under the EU Fab project, will feed into the HERA, for which a proposal is due later in the year. The pilot project on access to health data will feed into the European Health Data Space proposal expected later this year.

Members of the College said:

Vice-President for Promoting our European Way of Life, Margaritis **Schinias**, said: *"The situation in many intensive care units across the continent remains critical. We need to focus both on vaccines and therapeutics, as two powerful and complementary ways to combat COVID-19. But currently we have only one authorised medicine to treat COVID-19. By acting on better availability of medicines today, we are making sure patients receive the treatments they need while also preparing our future biomedical preparedness. A coordinated strategy on quick access to therapeutics will boost our strategic autonomy and contribute to a strong Health Union."*

Commissioner for Health and Food Safety, Stella **Kyriakides**, said: *"Vaccinations save lives, but they cannot yet eradicate COVID-19. We need a strong push on treatments to limit the need for hospitalisation, speed up recovery times, and reduce mortality. Patients in Europe and across the world should have access to world-class COVID-19 medicines. This is why we have set a very clear goal: by October, we will develop and authorise three new effective COVID-19 therapeutics that can have the potential to change the course of the disease. We will do so by investing in research and innovation, the identification of new promising medicines, ramping up production capacity and supporting equitable access. Our Therapeutics Strategy is a strong European Health Union in action."*

Commissioner for Innovation, Research, Culture, Education and Youth, Mariya **Gabriel**, said: *"By increasing vaccine availability across Europe, more and more Europeans are now protected against COVID-19. In the meantime, the development of innovative medicines to treat coronavirus patients remains a priority when it comes to saving lives. Research and innovation is the first step to finding effective and safe therapeutics, which is why we are proposing to establish a new COVID-19 'therapeutics innovation booster' and will invest € 90 million in population studies and clinical trials."*

## **Background**

The Strategy on COVID-19 therapeutics complements the [EU strategy for COVID-19](#) vaccines from June 2020 and builds on ongoing work by the European Medicines Agency and the Commission to support research, development, manufacturing and deployment of therapeutics.

The Strategy forms part of a strong [European Health Union](#), using a coordinated EU approach to better protect the health of our citizens, equip the EU and its Member States to better prevent and address future pandemics, and improve the resilience of Europe's health systems.

## **More information**

[Therapeutics Strategy Communication](#)

[Therapeutics Strategy factsheet](#)

[European Commission's coronavirus response website](#)

[EU Vaccines Strategy](#)

[HERA Incubator](#)

[EU coronavirus research and innovation](#)

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