



# *EU STRATEGY ON COVID-19 THERAPEUTICS*

**Directorate-General for Health and Food Safety**  
**Health promotion, disease prevention, financial instruments**

***HTA NETWORK***  
***7 July 2021***

# EU strategy on COVID-19 therapeutics

- ✓ A building block for the European Health Union
- ✓ Complementing the successful EU strategy for COVID-19 vaccines
- ✓ Building an EU portfolio of therapeutics to enhance the response to COVID-19
- ✓ Increasing Member States' capacity to meet the demand for therapeutics during the pandemic



## How?

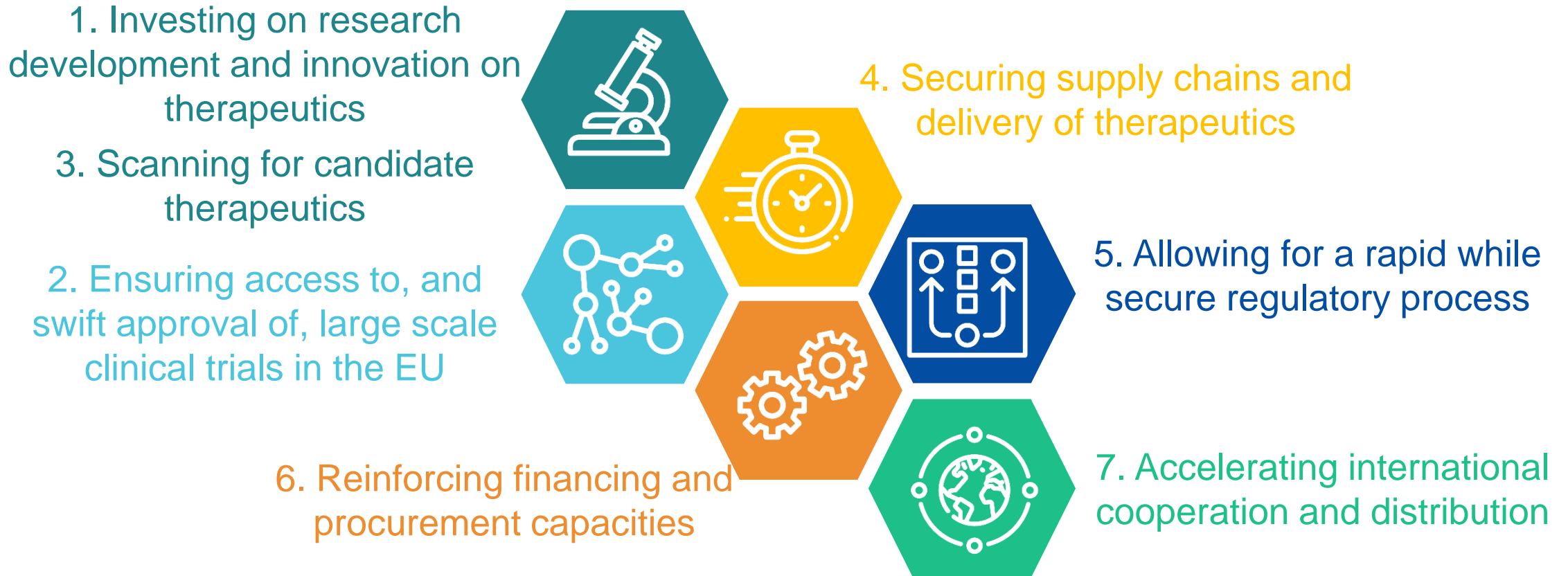
Using a coordinated EU approach that covers the whole lifecycle of therapeutics + EU funding to deliver greater impact



## Targets on therapeutics

- Portfolio of ten promising therapeutics (by October); five identified on June 29
- Three new therapeutics authorised by October 2021, and possibly two more by the end of the year

# New strategy with lessons learned from the pandemic



# Key actions

## 1. RESEARCH, DEVELOPMENT AND INNOVATION

- Establish a ‘therapeutics innovation booster’ platform – [by July 2021](#).
- Monitor and further support research and development, including on long COVID based on the results of ongoing and upcoming initiatives under Horizon Europe.

## 2. ENSURING ACCESS TO AND SWIFT APPROVAL OF LARGE-SCALE CLINICAL TRIALS IN THE EU

- Support cooperation in safety assessment and improve the generation of high-quality safety data in clinical trials.
- Provide national competent authorities with financial support for expedited and coordinated assessments to authorise clinical trials for COVID-19 treatments.
- Explore how to support developers of therapeutics in building capacity for material in line with ‘good manufacturing practice’ (GMP) for clinical trials and start providing GMP-grade materials.

# Key actions

## 3. SCANNING FOR CANDIDATE THERAPEUTICS

- Establish a broader portfolio of ten potential COVID-19 therapeutics – **by October** - and identify five of the most promising ones – **on June 29**.
- Set up an interactive mapping platform for promising therapeutics, to analyse their development phases, production capacities and supply chains.

# First deliverable: five promising candidate therapeutics

A new COVID-19 indication for existing medicines:

- baricitinib immunosuppressant (a medicine that reduces the activity of the immune system) from Eli Lilly: an application for extension of marketing authorisation for COVID-19 indication is under assessment

Newly developed monoclonal antibodies under rolling review - a regulatory tool to speed up the assessment of a promising medicine during a public health emergency:

- combination of bamlanivimab and etesevimab from Eli Lilly
- combination of casirivimab and imdevimab from Regeneron Pharmaceuticals, Inc. and F. Hoffman-La Roche, Ltd
- regdanivimab from Celltrion
- sotrovimab from GlaxoSmithKline and Vir Biotechnology, Inc.

**Press release:** [https://ec.europa.eu/commission/presscorner/detail/en/ip\\_21\\_3299](https://ec.europa.eu/commission/presscorner/detail/en/ip_21_3299)

**Q&A:** [https://ec.europa.eu/commission/presscorner/detail/en/qanda\\_21\\_3301](https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_3301)

# Key actions

## 4. SECURING SUPPLY CHAINS AND THE DELIVERY OF MEDICINES

- EU matchmaking event on COVID-19 therapeutics for industrial production – [12-13 July 2021](#).
- Support flexible EU manufacturing and access to COVID-19 therapeutics under the EU Fab project.

## 5. ENSURING A RAPID AND FLEXIBLE REGULATORY PROCESS

- Work towards granting an authorisation for three new COVID-19 therapeutics – [by October 2021](#).
- Subject to research and development outcomes, start seven rolling reviews for promising COVID-19 therapeutics (EMA) – [by end 2021](#).
- Launch pilot project ahead of upcoming European Health Data Space proposal to facilitate the EMA's and national medicine agencies' access to real-world data to check the safety and efficacy of therapeutics – [third quarter 2021](#).

# Key actions

## **6. FLEXIBLE, FIT-FOR-PURPOSE AND WELL-RESOURCED FINANCING AND PROCUREMENT CAPACITIES**

- Launch new joint procurements of COVID-19 authorised therapeutics in the EU on behalf of Member States – **by end 2021**.
- Explore the possibility of engaging with Member States in advance purchase agreements or innovation partnerships with producers of promising new therapeutics.
- Review options for a fast-track pathway for joint procurement of medical countermeasures.
- Stockpiling of therapeutics under rescEU/Union Civil Protection Mechanism.

## **7. INTERNATIONAL COOPERATION**

- Engage with international partners to develop COVID-19 therapeutics and ensure their fair distribution.
- Reinforce, together with Member States, engagement in the therapeutics pillar of the Access to COVID-19 Tools Accelerator.
- Step up EU support for affected countries through the Union Civil Protection Mechanism.



# Thank you