EU strategy on COVID-19 therapeutics

Pharmaceutical Committee, 17 September 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

(i) Portfolio of ten promising therapeutics (by October); five identified on June 29

(ii) Three new therapeutics authorised by October 2021, and possibly two more by the end of the year

Communication: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021DC0355

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New strategy with lessons learned from the pandemic

1. Investing on research development and innovation on therapeutics

3. Scanning for candidate therapeutics

2. Ensuring access to, and swift approval of, large scale clinical trials in the EU

4. Securing supply chains and delivery of therapeutics

5. Allowing for a rapid while secure regulatory process

6. Reinforcing financing and procurement capacities

7. Accelerating international cooperation and distribution

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Key actions

1. RESEARCH, DEVELOPMENT AND INNOVATION

- Establish a ‘therapeutics innovation booster’ platform – by July 2021.
- Monitor and further support research and development under **Horizon Europe**.

2. LARGE-SCALE CLINICAL TRIALS IN THE EU

- The **EU-wide network for COVID-19 therapeutic trials** is currently based on three large-scale, multi-centre adaptive platform trials (REMAP-CAP, EU-SolidAct, DisCoVeRy)
- Combined, it will eventually encompass around 200 trial sites in at least 16 different Member States.
- Further support for cooperation and directly to national competent authorities

Key actions

3. SCANNING FOR CANDIDATE THERAPEUTICS

- Establish a broader portfolio of **ten** potential COVID-19 therapeutics – by October ‘21
- and identify **five** of the most promising ones – on June 29 2021.
- Set up an interactive mapping platform for promising therapeutics, to analyse their development phases, production capacities and supply chains – by mid 2022

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.

Key actions

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. 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 with Member States **advance purchase agreements**, **innovation partnerships** for promising new therapeutics.
- **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 (**ACT-A**).

First deliverable: five promising candidate therapeutics

1 repurposed

A new COVID-19 indication for existing medicines:

- baricitinib immunosuppresant from Eli Lilly: an application for extension of marketing authorisation for COVID-19 indication is under assessment

4 new mAbs

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
Q&A: https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_3301

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Next deliverable: broader portfolio

- Therapeutics in development that have the potential to serve as the **EU's future therapeutic arsenal to fight the disease**
- The portfolio shall cover different types of products needed for different patient populations and different stages and severity of the disease.
- **There are currently no particular reward, nor financial instruments linked to the portfolio**
- However relevant candidates will be able to benefit from **regulatory flexibilities**, scientific support from EMA, **funding opportunities** under Innovation Booster, HERA, EU-FAB. Also match-making events, joint procurement, advance purchase agreements, innovation partnership and rescEU stockpiling could be deployed.
- **Portfolio of 10 by mid-October**

European Expert Group on SARS-CoV-2 variants

Advises the Commission on:

- the categorisation of SARS-CoV-2 variants;
- the need to develop new or adjusted vaccines specific for SARS-CoV-2 variants, and the time of deployment
- **the composition of the Union portfolio of COVID-19 therapeutics**;
- the need for new or additional public health measures (eg. border restrictions) due to circulating SARS-CoV-2 variants.

Sub-group on COVID-19 therapeutics

European Commission

Selection criteria

- **Diverse portfolio approach**
- **Soundness of scientific approach and technology used** (pharmacological rationale)
- **Stage of development**
- **Availability of relevant clinical outcome results from clinical trial(s)**
- **Absence of (new) major identified safety issues**
- **Unmet need** and/or **therapeutic added value**
- **Efficacy against new SARS-CoV-2 variants** (relevant only for some product categories)
- **Suitability of the product for the particular healthcare setting**
- **Intention to engage at an early stage with EMA to obtaining scientific advice**
- **Candidate therapeutics already within the regulatory process**

Product categories

Target Group \ Category	I. Antivirals	II. Immune-modulators	III. Other treatments (eg. symptomatic, anticoagulant)
Pre-exposure prophylaxis	X		
Post-exposure prophylaxis	X		
Asymptomatic virus carriers	X		
Outpatients: mild to moderate	X	[X]	[X]
Hospitalized: moderate to severe	X	X	X
Hospitalized: critical		X	X
long-COVID-19			X

Your feedback

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Thank you

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