

EN
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Answer given by Ms Kyriakides
on behalf of the European Commission
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To date the following progress has been made in implementing the COVID-19 therapeutics strategy:

Scanning for candidate therapeutics: in June 2020, the Commission published a list of five promising therapeutic candidates¹, those that are either under rolling review or evaluation by the European Medicines Agency (EMA). Moreover, in October 2021 the Commission published a broader portfolio of ten most promising therapeutics candidates, following an objective and science-based selection by experts².

Ensuring a rapid and flexible regulatory process is the priority. In November 2021, the Commission granted two marketing authorisations for Regkirona (regdanvimab) and Ronapreve (casirivimab / imdevimab).

There are currently five pending assessments³ of COVID-19 therapeutics by EMA:

- 2 products are under the rolling review⁴
- 3 applications for extension of indication for COVID-19 of already EU-wide authorised medicines⁵, and
- 1 application for the marketing authorisation of a new product⁶.

Joint procurement contracts: the Commission is helping to ensure that therapeutics are procured and delivered to Member States as soon as they are authorised. The Commission has already concluded four joint procurement⁷ contracts for the purchase of COVID-19 therapeutics and could launch more by the end of 2021.

The Commission will put forward a proposal to amend the general EU legislation on medicinal products for human use by the end of 2022 in accordance with the objectives of the pharmaceutical strategy for Europe⁸. Currently the work is ongoing on the evaluation of the current legislation's performance and the impact assessment of various policy options. An on-line public consultation on this initiative is open until 21 December 2021⁹.

¹ https://ec.europa.eu/commission/presscorner/detail/en/ip_21_3299

² https://ec.europa.eu/commission/presscorner/detail/en/IP_21_5366

³ <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/treatments-covid-19/covid-19-treatments-under-evaluation>

⁴ Evusheld and Molnupiravir

⁵ baricitinib, anakinra and tocilizumab

⁶ Sotrovimab.

⁷ https://ec.europa.eu/commission/presscorner/detail/en/ip_21_4827

⁸ https://ec.europa.eu/health/human-use/strategy_en

⁹ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12963-Revision-of-the-EU-general-pharmaceuticals-legislation_en