EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Health systems, medical products and innovation
Medicines: policy, authorisation and monitoring

PHARM 827

PHARMACEUTICAL COMMITTEE
17 September 2021

Subject: **Therapeutics strategy**[1]

Agenda item 3

Background

While the COVID-19 vaccination campaign progresses well in Europe, the availability of therapeutics for affected patients is still limited, with so far only one product, remdesivir authorised at EU-level[2]. On 6 May 2021, the European Commission published the EU Strategy on COVID-19 Therapeutics[3], which takes a holistic approach to address therapeutics, covering research, development, authorisation, manufacturing and deployment.

The strategy sets out several actions to identify candidate therapeutics and support the most promising ones. Among other actions, the strategy lays down that the Commission shall first establish a list of five promising candidates (published[4] in June 2021) and then create a broader portfolio of ten potential candidates by October 2021.

Portfolio of candidate therapeutics

The portfolio will indicate therapeutics in the product development pipeline, which have the potential to serve as **the EU's future therapeutic arsenal to fight the disease**, and should remain live and dynamic given the uncertain nature of drug development as well as the evolution of the pandemic including the emergence of variants.

There are **currently no particular reward, nor financial instruments linked to the portfolio**, however the relevant candidates will be able to benefit from all the support identified under the EU strategy on therapeutics such as regulatory flexibilities,

[1] This document has not been adopted by the European Commission and, therefore, it does not reflect an official position of the European Commission. It is only meant to be a tool for discussion and the views expressed therein do not necessarily reflect those of the Commission and its services.
[2] Dexamethasone is also endorsed by EMA for authorisation by national medicines agencies.
[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52021DC0355R(01)
[4] https://ec.europa.eu/commission/presscorner/detail/en/ip_21_3299

scientific support by the European Medicines Agency (EMA), funding opportunities under e.g. Horizon Europe and/or from the match-making activities.

European expert group on SARS-CoV-2 variants and sub-group on therapeutics

The Commission has created a European expert group on SARS-CoV-2 variants that will advise the Commission on the needs for new or adapted vaccine development in the light of emerging scientific findings (e.g. duration of vaccine effectiveness) and the appearance and spread of virus variants.

A dedicated sub-group has also been tasked to make recommendations to the Commission for the inclusion of candidates in the EU's COVID-19 therapeutics portfolio. It is the experts' task to define the desired product categories and the selection criteria for inclusion of the different therapeutics in the portfolio. The sub-group will also identify the products for the portfolio and update it regularly thus keeping it live and dynamic.

Next steps

The expert sub-group on COVID-19 therapeutics is expected to communicate the first 10 candidate-therapeutics of the portfolio by October 2021.

The experts have prepared the draft **selection criteria** and the **identified product categories** of interest. These two documents will serve the basis for selecting the most promising candidates. The European Commission is consulting the Pharmaceutical Committee, seeking guidance whether the sub-group should consider any additional elements before finalising their tasks.

The documents will be sent separately as an annex, by 10 September.