

From: [REDACTED] (SANTE)
Sent: vendredi 28 mai 2021 16:23
To: [REDACTED]@acumen-publicaffairs.com
Cc: [REDACTED] (SANTE); SANTE CONSULT-C1
Subject: FW: EU Therapeutics Strategy clarification

Dear [REDACTED],

Thank you for your interest in the EU strategy for Covid-19 therapeutics.

The aim of this strategy is to put in place a mechanism to speed up the entire process of development of therapeutics (encompassing clinical research and clinical trials, the manufacturing, the purchase and the availability of the products in the EU).

The majority of the actions planned in the strategy are now at an early stage of implementation and they will be defined more in detail in the near future.

Concerning the specific question on how the three therapeutics that will grant authorisations in the next months, as well as the two additional ones by the end of the year, the exact process of identifying them still needs to be finalised.

However, for your information, concerning the portfolio of 10 potential COVID-19 therapeutics that will be drawn up, the European Medicines Agency (EMA) is currently following-up a number of COVID-19 therapeutics under development. The ones at the more advanced stage of development have been included in the process to accelerate the scientific assessment through rolling review.

In a rolling review, EMA's Committee for Medicinal Products for Human Use (CHMP) reviews data as they become available from ongoing studies, before a formal application for a marketing authorisation is submitted. Once the CHMP decides that sufficient data are available, the formal application can be submitted by the company. By reviewing the data as they become available, the CHMP can reach its opinion sooner on whether or not the medicine or vaccine can be authorised. If the benefit risk of the medicines is considered favourable the EMA will recommend to the European Commission to grant a marketing authorisation.

For more information you may check the EMA page on COVID-19 therapeutics: [Treatments and vaccines for COVID-19 | European Medicines Agency \(europa.eu\)](#) or the specific page for scientific advice: [Scientific advice and protocol assistance | European Medicines Agency \(europa.eu\)](#)

The Commission will implement this strategy together with the Member States, by tailoring it to the different disease phases and degrees of severity – caused both by the original strain of SARS-CoV2 and its new variants.

As with the EU Vaccines Strategy, the EC will ensure supply and equitable access between Member States and by the end of 2021, the EC will engage in new joint procurement procedures for authorised therapeutics on behalf of Member States.

Joint Procurement is a voluntary mechanism and countries can chose to participate depending on their national epidemiological situation and individual needs.

Hope this clarifies.

Kind regards



European Commission

Directorate-General for Health and Food Safety

Unit C1- Health promotion, disease prevention, financial instruments

From: [REDACTED] <[\[REDACTED\]@acumen-publicaffairs.com](mailto:[REDACTED]@acumen-publicaffairs.com)>
Sent: Monday, May 17, 2021 5:02 PM
To: [REDACTED] (SANTE) <[\[REDACTED\]@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)>
Subject: EU Therapeutics Strategy clarification

Dear [REDACTED]

Thank you very much for your time on the phone just now and for agreeing to send over some additional information by email on the Therapeutics Strategy. It would be great if you were able to assist with any information on the following questions and any other points you feel would be relevant:

- What the process will be for arriving at 3 therapeutics by October 2021? The Strategy says that the Commission's aim is to have '*three new therapeutics **available** (my emphasis) by October 2021 and possibly two more by the end of the year.*' The Strategy stated that by June there will be a broader portfolio of ten potential COVID-19 therapeutics and the identification of five of the most promising ones. Would the additional two by the end of the year be from these five selected in June?
- What is the foreseen role of Member States in relation to the Therapeutics Strategy and whether this will be the same as for COVID vaccines?
- Will Advance Purchase Agreements happen at EU level and will participation by Member States be voluntary? Linked to this, would EU level negotiations on APAs rule out MS individually negotiating with the same commercial partners?

Any additional light they could shed on some of these topics would be very helpful.

Kind regards,

[REDACTED]

[REDACTED]

M: + 32

[Linkedin](#) | [Twitter](#)

Acumen
public affairs

EU Transparency Register ID: 85679286747-21