From: [redacted] (SANTE)
Sent: mardi 1 juin 2021 14:40
To: [redacted] (SANTE)
Subject: FW: EU Strategy on Therapeutics - Clarification

From: [redacted] (SANTE)
Sent: Monday, May 31, 2021 6:13 PM
To: '[redacted]@acumen-publicaffairs.com' <[redacted]@acumen-publicaffairs.com>
Cc: [redacted] (SANTE) <[redacted]@ec.europa.eu>; [redacted] (SANTE) <[redacted]@ec.europa.eu>
Subject: FW: EU Strategy on Therapeutics - 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. The Commission is preparing an action plan, which involves a number of different services and units inside DG SANTE.

Concerning the specific question on 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 give 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.

Regarding the COVID-19 'therapeutic innovation booster', it will ensure a clear overview of the COVID-19 therapeutics projects under development to better support the most promising ones, from preclinical research to market authorisation, where more investment is needed, so that medicines reach patients faster. The exact procedure still needs to be finalised and will be made available soon.

Hope this clarifies,

Kind regards

[redacted]

European Commission
Directorate-General for Health and Food Safety
Unit C1- Health promotion, disease prevention, financial instruments

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From: [redacted] <[redacted]@acumen-publicaffairs.com>
Sent: Tuesday, May 18, 2021 10:23 AM
To: [redacted] (SANTE) <[redacted]@ec.europa.eu>
Subject: EU Strategy on Therapeutics - Clarification

Dear [redacted],

Following the publication of the Therapeutics Strategy, I was wondering whether you could answer a couple of clarifying questions regarding the content of the Strategy.
As we are working with a number of pharmaceutical companies that would like to make COVID-19 therapeutics available to patients, we would very much welcome your input.

- One of the goals of the Strategy is to identify 10 promising therapeutic candidates and select 3 by October 2021 and 2 more by the end of the year. We understand that there will be a Therapeutics `Innovation Booster` in place by July 2021 which will be headed up by EMA, national authorities and the private sector. The platform will be responsible for the identification

and development of therapeutics, but what is the procedure behind it and how can industry with promising therapeutic products interact with the Commission on this? 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 Advanced Purchase Agreements happen at EU level and will participation by Member States be voluntary? Linked to this, would EU level negotiations on Advanced Purchase Agreements rule out Member States individually negotiating with the same commercial partners?
- Is there a negotiating team for COVID-19 therapeutics on behalf of the Commission? We understand that DG SANTE Unit C1 is leading on the Strategy, how can stakeholders with promising therapeutic candidates get in touch with the Commission to discuss next steps?

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

Kind regards,

<image003.png> M: + 32
Linkedin | Twitter

From:
Sent: 04 May 2021 11:41
To: <@ec.europa.eu>
Subject: RE: EU Strategy on Therapeutics request

Dear ,

Thanks for passing on this information – much appreciated.

Kind regards,


<image003.png> M: + 32

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From: [redacted] <[redacted]@ec.europa.eu>
Sent: 04 May 2021 11:35
To: [redacted] <[redacted]@acumen-publicaffairs.com>
Subject: RE: EU Strategy on Therapeutics request

Dear [redacted],

Thank you for your e-mail and the interest in the Commission work on Covid-19 therapeutics. As announced on 17 March, the Commission is working on the document on Covid therapeutics.

Please note that due to the current state of internal discussions within the Commission currently we are not in the position to discuss details of this initiative.

I have been informed that you have contacted also [redacted] who has already provided you with the same information earlier.

Kind regards,
[redacted]

From: [redacted] <[redacted]@acumen-publicaffairs.com>
Sent: Friday, April 23, 2021 1:09 PM
To: [redacted] (SANTE) <[redacted]@ec.europa.eu>
Subject: EU Strategy on Therapeutics request

Dear [redacted],

Thank you for the phone call just now, as agreed I am following up on the forthcoming EU Therapeutics Strategy by email.

I understand that the publication of the strategy has been postponed to 5th May, and I was wondering whether you'd be able to provide any additional information. For example, the overarching objectives of the strategy (such as developing, manufacturing, procuring), and the mechanisms used to achieve the objectives? It would be great if you were able to indicate whether there will be opportunities to provide opinions on this.

Any additional information you can provide on the strategy and next steps would be greatly received.

Thank you very much in advance. In the meantime you are, of course, more than welcome to contact me by email or phone.

Kind regards,

[redacted]

[redacted]

M: + 32 [redacted]
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<image002.png>
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