From:
 (SANTE)

 Sent:
 mardi 18 mai 2021 13:15

 To:
 SANTE CONSULT-C1

Subject: FW: EU Strategy on Therapeutics - Clarification

Pls, for ares and to

From: (SANTE) < @ec.europa.eu> Sent: Tuesday, May 18, 2021 10:49 AM To: (SANTE) < @ec.europa.eu> Cc: (SANTE) < @ec.europa.eu>; (SANTE) @ec.europa.eu>; (SANTE) < @ec.europa.eu>; (SANTE) < @ec.europa.eu>

Subject: Re: EU Strategy on Therapeutics - Clarification

We replied to him once (I shared the link to ARES with you some time ago) and so far he stopped contacting us. But this was still before the adoption.

Best,

Wysłane z iPhone'a

(SANTE) < <u>@ec.europa.eu</u>> w dniu 18/05/2021, o godz. 10:25:

This consultant called me again last week; I told him that I am not involved in this area of work and that I do not have information on the strategy. He keeps bombarding me.

Can your team reply to him or if you do not can you give me a standard reply, please?

From: < @acumen-publicaffairs.com>

Sent: Tuesday, May 18, 2021 10:23 AM

To: (SANTE) < @ec.europa.eu>

Subject: EU Strategy on Therapeutics - Clarification

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,

| Co | nsu  | ltani |   |
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| ~~ | IIJU | Luli  | ١ |

<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

<u>Linkedin</u> | <u>Twitter</u>

From: < @ec.europa.eu>

**Sent:** 04 May 2021 11:35

To: < @acumen-publicaffairs.com>

Subject: RE: EU Strategy on Therapeutics request

Dear

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 who has already provided you with the same information earlier.

Kind regards,

| From:  | <          | acumen-public    | affairs.com>      |  |  |
|--|------------|------------------|-------------------|--|--|
| <b>Sent:</b> Friday, April 23, 2021 1:09 PM  |            |                  |                   |  |  |
| To: (5                                       | SANTE) <   |                  | @ec.europa.eu>    |  |  |
| Subject: EU Strategy on Therapeutics request |            |                  |                   |  |  |
| Dear,  |            |                  |                   |  |  |
| Thank you for the pho                        | one call j | ust now, as agre | ed I am following |  |  |

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 5<sup>th</sup> 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,

M: + 32

<u>Linkedin</u> | <u>Twitter</u>

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