

From: SANTE CONSULT-C1
Sent: mercredi 16 juin 2021 10:22
To: [REDACTED]@merck.com
Cc: [REDACTED] (SANTE); [REDACTED] (SANTE); SANTE CONSULT-C1
Subject: FW: KIND FOLLOW UP: Strategy on COVID-19 Therapeutics - Implementation (list of candidates)

Dear [REDACTED],

As mentioned in our previous email, the details of the process to establish the list of 10 potential COVID-19 therapeutics by June 2021 are currently being finalised.

At this stage of the process we are not in the position to share more details.

Kind regards,
SANTE C1

European Commission

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

From: [REDACTED] <[REDACTED]@merck.com>
Sent: Friday, June 11, 2021 11:08 AM
To: [REDACTED] (SANTE) <[REDACTED]@ec.europa.eu>
Cc: [REDACTED] (SANTE) <[REDACTED]@ec.europa.eu>; SANTE CONSULT-C1 <SANTE-CONSULT-C1@ec.europa.eu>
Subject: RE: KIND FOLLOW UP: Strategy on COVID-19 Therapeutics - Implementation (list of candidates)

Dear [REDACTED],
Thank you for your response, I have some follow up questions: Will the details of the process for preparing the list be made publicly available, and if so, when; and is the end of June still the anticipated timeline for publishing the list of 5 medicines?
Many thanks and best regards,
[REDACTED]

From: [REDACTED] <[REDACTED]@ec.europa.eu>
Sent: Friday, June 11, 2021 9:42 AM
To: [REDACTED] <[REDACTED]@merck.com>
Cc: [REDACTED] <[REDACTED]@ec.europa.eu>; SANTE-CONSULT-C1@ec.europa.eu
Subject: RE: KIND FOLLOW UP: Strategy on COVID-19 Therapeutics - Implementation (list of candidates)

EXTERNAL EMAIL – Use caution with any links or file attachments.

Dear [REDACTED],

The details of the process to establish the list of 10 potential COVID-19 therapeutics by June 2021 are currently being finalised.

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.

Kind regards,

European Commission

Directorate-General for Health and Food Safety

Unit C1 Health promotion, disease prevention, financial instruments

From: [REDACTED] <[REDACTED]@merck.com>

Sent: Wednesday, June 9, 2021 4:04 PM

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

Cc: [REDACTED] (SANTE) <[REDACTED]@ec.europa.eu>

Subject: RE: KIND FOLLOW UP: Strategy on COVID-19 Therapeutics - Implementation (list of candidates)

Dear [REDACTED],

Thank you for your email.

We have already been engaged over the past months with the services of the European Commission (more particularly with [REDACTED]) as well as with the EMA on our therapeutic candidate currently in development. My question actually relates to the list of 5 promising candidates to be published by the end of June, which was announced in the Strategy for COVID-19 Therapeutics. As discussed with [REDACTED], I would like to know more about the process regarding the preparation of this list, such as the criteria, stakeholders involved, and timeline. [REDACTED] indicated that while the details were being worked out, a number of elements were ready and could be shared. Many thanks in advance for your response.

Best regards,

[REDACTED]
MSD (Europe) Inc.
6 Rond Point Schuman | B-1040 Brussels, Belgium
E-mail [REDACTED]@merck.com | www.merck.com
Transparency register n°: 09824113589-92



From: [redacted] <[redacted]@ec.europa.eu>
Sent: Wednesday, June 9, 2021 3:41 PM
To: [redacted] <[redacted]@merck.com>
Cc: [redacted] <[redacted]@ec.europa.eu>
Subject: FW: KIND FOLLOW UP: Strategy on COVID-19 Therapeutics - Implementation (list of candidates)

EXTERNAL EMAIL – Use caution with any links or file attachments.

Dear [redacted],

Thank you for your interest in, and support for, the EU COVID-19 therapeutics strategy as expressed in your emails of 7 and 9 June 2021.

The aim of the therapeutics strategy is to put in place a mechanism to speed up all the process, the development of products, the clinical research and clinical trials, the manufacturing, the purchase and the availability of the COVID-19 therapeutic medicines in the EU.

With respect to the authorisation of medicines in the EU, for centrally authorised medicines the European Medicines Agency (EMA) has engaged with developers of potential COVID-19 therapeutics. The aim is to provide advice on regulatory requirements so that any promising medicines can be made available as quickly as possible to patients, initially in the clinical trial setting and then, once authorised, through its placement on the market.

If developers of a potential COVID-19 therapy would be interested in seeking scientific advice from the EMA, details on how to do so are available on the EMA website: <https://www.ema.europa.eu/en/human-regulatory/research-development/scientific-advice-protocol-assistance>.

It is also possible for companies to submit applications whether or not they have received scientific advice. Once the development and the associated evidence is considered sufficient to support a marketing authorisation the dossier can be submitted for assessment by the EMA, details of how this can be done are also available on the EMA website: <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/guidance-developers-companies/covid-19-guidance-evaluation-marketing-authorisation>.

The Commission hopes that the support for the development of COVID-19 medicines will help bring safe and effective treatments earlier to patients, which will be important in the ongoing actions against the pandemic.

With best regards,

[Redacted]



European Commission

Directorate-General for Health and Food Safety

Unit C1 Health promotion, disease prevention, financial instruments

From: [Redacted] <[Redacted]@merck.com>

Sent: Wednesday, June 9, 2021 10:58 AM

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

Subject: KIND FOLLOW UP: Strategy on COVID-19 Therapeutics - Implementation (list of candidates)

Dear [Redacted],

I am kindly following up with you on the below email. Information you can share regarding the process for elaborating the list of therapeutics would be appreciated.

Many thanks and best regards,

[Redacted]

[Redacted]

MSD (Europe) Inc.

6 Rond Point Schuman | B-1040 Brussels, Belgium

E-mail: [Redacted] [merck.com](mailto:[Redacted]@merck.com) | www.merck.com

Transparency register n°: 09824113589-92



From: [Redacted]

Sent: Monday, June 7, 2021 4:36 PM

To: [Redacted] [@ec.europa.eu](mailto:[Redacted]@ec.europa.eu)

Subject: Strategy on COVID-19 Therapeutics - Implementation (list of candidates)

Dear [Redacted],

Thank you for your time earlier today. As discussed, I am interested in better understanding how the Commission's COVID-19 Therapeutics

Strategy will be implemented and more particularly regarding the list of candidate therapeutics the European Commission is planning to publish by the end of June. I would appreciate if you could share information regarding the process (notably criteria, stakeholders involved) and timeline regarding the elaboration of this list.

Many thanks and best regards,

MSD (Europe) Inc.
6 Rond Point Schuman | B-1040 Brussels, Belgium
E-mail: merck@merck.com | www.merck.com
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