

**From:** [REDACTED] (SANTE)  
**Sent:** mardi 15 juin 2021 15:58  
**To:** [REDACTED] (SANTE); [REDACTED] (SANTE)  
**Cc:** [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE)  
**Subject:** FW: Ares - Document "RE: EU Strategy on Therapeutics - Clarification" - Ares(2021)3608077

Dear [REDACTED] could you pls save this reply below in Ares and other places where needed.  
Thanks, best regards [REDACTED]

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**From:** [REDACTED] (SANTE)  
**Sent:** Tuesday, June 15, 2021 3:56 PM  
**To:** [REDACTED]  
**Subject:** FW: Ares - Document "RE: EU Strategy on Therapeutics - Clarification" - Ares(2021)3608077

Dear [REDACTED],

Thank you for your email. The details of the process to establish the list of 10 potential COVID-19 therapeutics are currently being finalised.

Please note that the participation in the matchmaking event on 12-13 July will be open to a range of organisations and we encourage you to participate at this event. Please find some more detailed information on the matchmaking event below.

Thanks again, best regards,

[REDACTED]

[REDACTED], [REDACTED]



**European Commission**

Directorate-General for Health and Food Safety

Unit C1 Health promotion, disease prevention, financial instruments

**EU matchmaking event on COVID19 therapeutics on the 12<sup>th</sup> and 13<sup>th</sup> of July 2021**

Following the adoption of the EU Strategy for COVID19 Therapeutics ([EU Therapeutics Strategy \(europea.eu\)](https://europea.eu)), the European Commission's Task Force for Industrial Scale-Up of COVID19 Vaccines and Therapeutics is organising an **EU matchmaking event on COVID19 therapeutics on the 12<sup>th</sup> and 13<sup>th</sup> of July 2021**. The objectives are to support the acceleration of the development and upscale of Covid-19 therapeutics production, enhance the participation of EU companies in the Covid-19 therapeutics value chains, speed up connection between organisations and help in retro-planning strategy for production.

A preparatory webinar took place on the 14<sup>th</sup> of June 2021. If you could not join us, please note that the webinar was recorded and uploaded, together with all information that you need to participate, in the matchmaking platform here: [European Matchmaking event - Development and production of COVID-19 therapeutics - Info \(b2match.io\)](#)

Please note that the registration began on 14 June 2021 at 2.30pm CEST.

We would also like to invite you to join the **technical webinar** that will take place on the 30<sup>th</sup> of June 2021. This webinar will provide more technical information on how to book meetings. The link to the webinar is here

<https://zoom.us/j/96622900660?pwd=TEdxdmIxd05tZENSaHM2WFFyczhxZz09>

We would also like to inform you that the Task Force has launched an **EU Survey** with the purpose of gaining understanding on the **needs of the EU organisations working in the development of new and repurposed medicines for COVID-19 therapeutics**, i.e. medicines specifically developed for an indication in treatment of COVID-19. We encourage you to participate in this EU Survey **by the 25<sup>th</sup> of June 2021**. Your answers will help us shape EU support in the best possible way. Please be aware that we intend to gather the maximum of answers as soon as possible in view of the urgency of the subject. The link to the EU Survey is here: <https://ec.europa.eu/eusurvey/runner/1ebcfe3c-498f-f080-e383-9a55fc44f00e>  
For any questions, please don't hesitate to contact us at: [GROW-TFIS@ec.europa.eu](mailto:GROW-TFIS@ec.europa.eu)

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**From** [REDACTED]  
**Sent:** Monday, June 7, 2021 2:50 PM  
**To:** [REDACTED] (SANTE) [REDACTED] [@ec.europa.eu](mailto:[REDACTED]@ec.europa.eu)>  
**Subject:** Re: Ares - Document "RE: EU Strategy on Therapeutics - Clarification" - Ares(2021)3608077

Dear [REDACTED],

I understand the process with EMA and already UNION are in the process of EMA approval (UNI911 - <https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/treatments-covid-19/covid-19-treatments-research-development#covid-19-treatments-that-have-received-ema-advice-section>). The product is in the clinical phase.

What we are trying to find out is on what basis, which criteria and which process the 10 potential COVID-19 therapeutics will be done? And how we can put UNION forward for that process. That was not clear from the webinar we attended and this is the process we are interested in knowing more about and seek guidance and help to understand.

I hope you can help us to understand this process better and thank you in advance for your quick reply and willingness to engage.

Kind regards

LYKKE

ADVICE

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**Fra:** [\[REDACTED\]@ec.europa.eu](mailto: [REDACTED]@ec.europa.eu)

**Dato:** fredag den 4. juni 2021 kl. 18.32

**Til:** [REDACTED]

**Cc:** [REDACTED]

**Emne:** FW: Ares - Document "RE: EU Strategy on Therapeutics - Clarification" - Ares(2021)3608077

Dear [REDACTED],

Thank you for your interest in, and support for, the EU COVID-19 therapeutics strategy as expressed in your email below of 1 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 signature]

[Redacted name], [Redacted name]



**European Commission**

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

**From:** [Redacted]  
**Sent:** Tuesday, June 1, 2021 7:23 AM  
**To:** [Redacted] (SANTE) <[Redacted]@ec.europa.eu>  
**Cc:** [Redacted]  
**Subject:** EU Treatment Strategy - meeting request UNION therapeutics

Dear [Redacted],

I am writing to you from Lykke Advice on behalf of our client **UNION therapeutics**, a clinical stage pharmaceutical company specialised in the research and development of medicinal products with microbiological and immunological effects. We attended the webinar on the 20<sup>th</sup> of May, where the treatment strategy was presented. We are taking the liberty to contact you as you suggested during the webinar to see if we could have a meeting in the coming weeks to discuss further the strategy and understand if UNION therapeutics can become one of the 10 therapies selected in June.

UNION has been working in Brussels to **drag the policymakers and other stakeholders' attention to the need of prophylaxis and treatment therapeutics to complement the COVID-19 response**. In fact, UNION strongly believes that therapeutics can play a crucial role in where vaccines risks being less effective e.g., in the [protection of vulnerable groups](#) (such as patients with immunosuppression) or against emerging variants of concern that may prove resistant to existing vaccines. In this perspective, UNION is developing two therapeutics based on niclosamide salt solutions, which recently demonstrated potential to eradicate Sars-CoV-2 in vivo murine models, with potency 30 times higher than remdesivir: a nasal spray aimed to COVID-19 prevention in vulnerable groups with risks of severe complications if infected by SARS-CoV-2 and for post-exposure, early-treatment prophylaxis i.e., in between infection and manifestation of symptoms; and a nebulisation for the treatment of inpatients to prevent severe complications of COVID-19 and reduce their hospitalisation time.

For the production of both products, **UNION has already identified key partners for a fully EU-based supply chain.**

In view of this, I attach a position paper outlining the general position of UNION, but we would like to meet and understand more in details about the criteria the EU will select the 10 therapies. Would you be available for a meeting with UNION therapeutics in the coming days to discuss the actions of the Strategy and the criteria more in details?

Kind regards,

[Redacted signature block]

Mobile: +32 [Redacted]

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