

**From:** [REDACTED] (SANTE) on behalf of SEYCHELL Martin (SANTE)  
**To:** [REDACTED] (PPRE)  
**Cc:** [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (JICUS); [REDACTED] (ORDRE); [REDACTED] (SANTE); SEYCHELL Martin (SANTE); [REDACTED] (SANTE); [REDACTED]  
**Subject:** RE: Summary: J&J TC on COVID 19 Vaccine  
**Date:** mardi 7 avril 2020 15:56:02  
**Attachments:** [image001.png](#)

---

Dear [REDACTED],

thank you for information on Johnson-Johnson's development program for COVID-19, provided in your correspondence as well as in the teleconference on 27 March 2020. Please find below our views.

As regards the EU regulatory system provides mechanisms to speed up development and approval of medicinal products, including vaccines: a scientific advice; European Medicines Agency's (EMA) PRIME scheme for enhanced scientific support to medicines for unmet needs; the accelerated assessment and conditional and 'under exceptional circumstances' marketing authorisation procedures.

In addition, the Member States can make investigational or repurposed treatments available to COVID 19 affected patients through Early Access Programmes which are though coordinated and implemented by the MS independently and under national rules. For example compassionate use scheme allows the use of an unauthorised medicine for patients who have a disease with no satisfactory authorised therapies or who cannot enter a clinical trial. For investigational medicinal products for which an application under the centralised procedure is pending, Member States have to notify to EMA compassionate use programmes. That notification may then trigger a scientific opinion of the EMA. The recommendations are however optional, and are only implemented by the Member States that wish to use them for their patients.

EMA encourages developers of potential vaccines to contact the Agency to discuss their strategy for evidence-generation. EMA will review the received proposals and will contact developers with the most relevant proposals for an initial discussion. For potential novel coronavirus treatments or vaccines scientific advice is free of charge and can be fast-tracked.

EMA has activated its plan for managing emerging health threats. An EMA Task Force (ETF) is convened as part of this plan. It includes the chairs of its main committees) plus other relevant experts. The ETF mandate includes an advice to manufacturers on developing medicinal products, contribution to product-related assessment, related European and International cooperation and interaction with stakeholders.

We have understood that you are already in contact with the EMA as regards the scientific advice for your COVID-19 vaccine.

The application of the GMO framework is a competence of Members States. COM is aware of certain difficulties in application of GMO framework and conduct of clinical trials and is trying to find pragmatic solutions, particularly in the context of the COVID-19 outbreak.

The Commission is aware of the manufacturing and supply issues related to the expected use of

the new COVID vaccines. Joint procurement may be one of the avenues to be explored and liability issues may be addressed in this context.

I would like to assure you, that the Commission , together with the European Medicines Agency and with Members States are working actively to make COVID-19 therapies, including vaccines, available as soon as possible to patients.

Best regards,

---

**Martin Seychell**

Deputy Director General (DDG1) – DG SANTE

European Commission

Rue Breydel 4, 1040 Brussels, Belgium

B232 07, [REDACTED]

Tel: +32 2-2 [REDACTED]

e-mail: [REDACTED]

---

The views expressed in this e-mail are my own and may not, under any circumstances, be interpreted as stating an official position of the European Commission.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

○ [REDACTED]

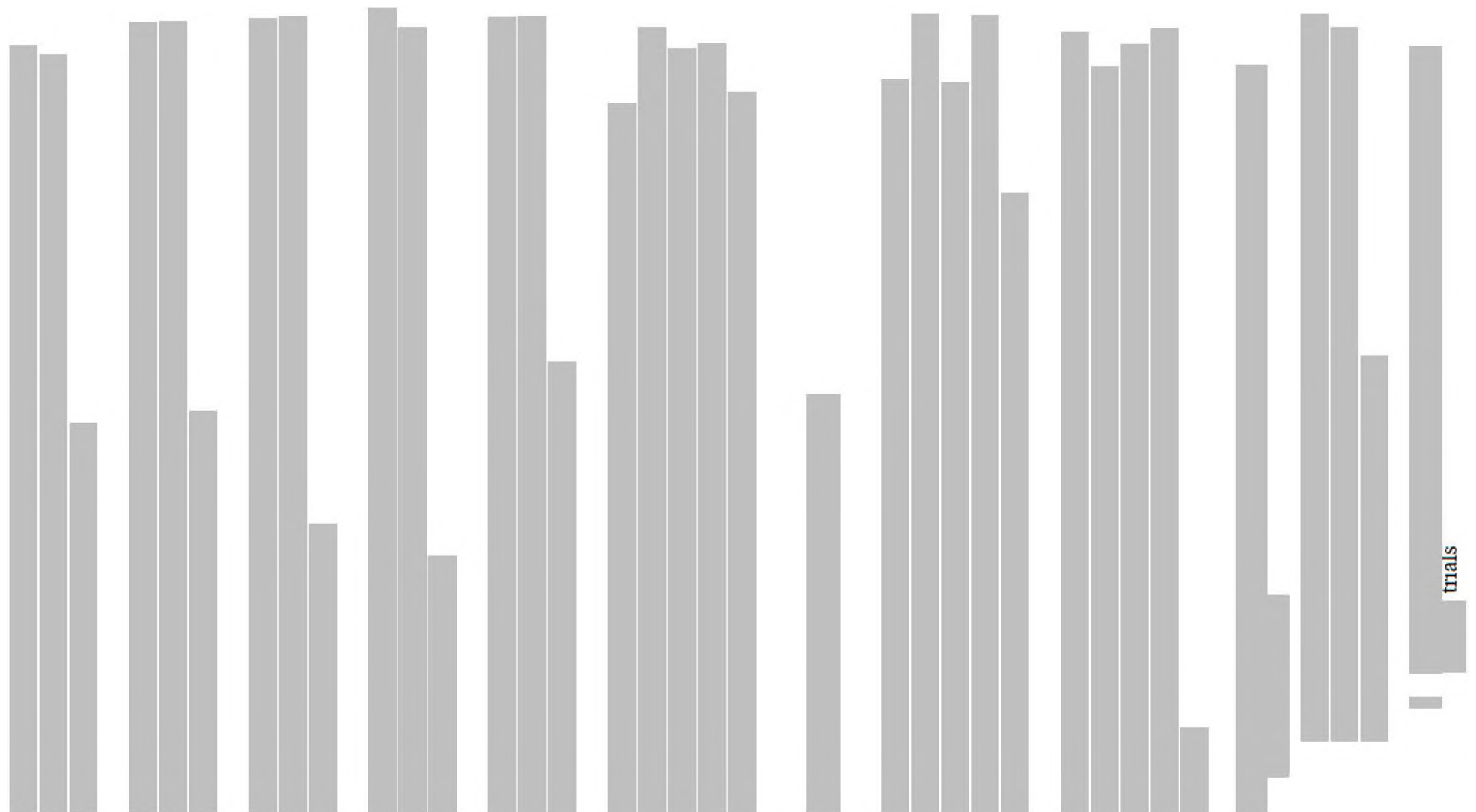
**Liability:**

• [REDACTED]

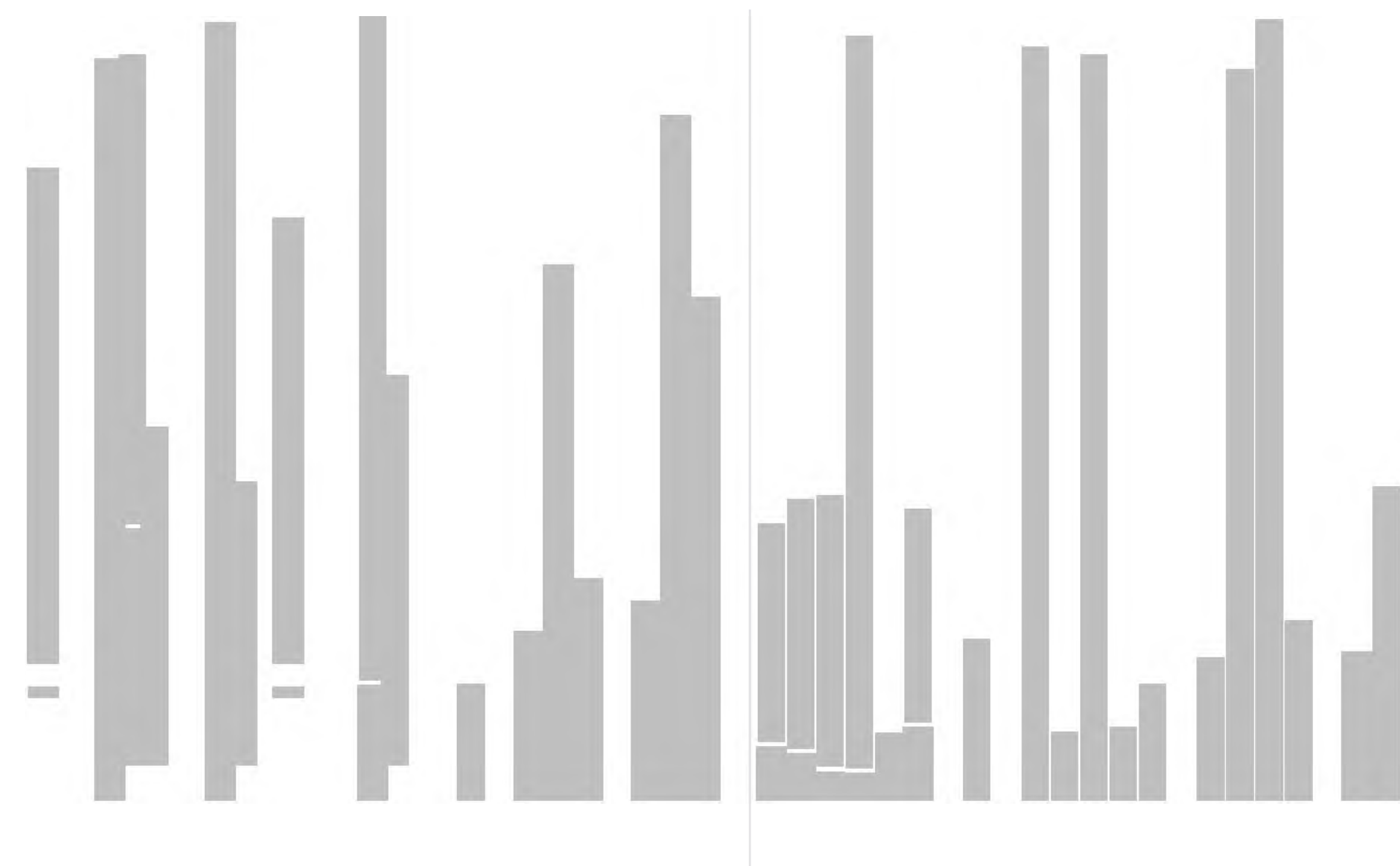
• To address this need, the US government has already triggered the Prep Act  
[REDACTED]  
[REDACTED]

-  
[REDACTED]

REDACTED AS ALREADY INCLUDED IN DIFFERENT DOCUMENTS



REDACTED AS ALREADY INCLUDED IN DIFFERENT DOCUMENTS



REDACTED AS ALREADY INCLUDED IN DIFFERENT DOCUMENTS

