

From: [REDACTED] [JPPBE]
To: SEYCHELL Martin (SANTE)
Cc: [REDACTED] (SANTE) [REDACTED] (SANTE) [REDACTED] [JJCUS] [REDACTED] [JRDBE]; [REDACTED] [JANBE]
Subject: Summary: J&J TC on COVID 19 Vaccine
Date: dimanche 29 mars 2020 17:30:05
Attachments: [image001.png](#)
[liability.pdf](#)

Message sent on behalf of [REDACTED] **and** [REDACTED]

Dear Mr. Seychell,

Thank you very much for the time on Friday.

As explained during our call, we believe that, based on the key attributes of our technology platforms and our established developmental and manufacturing capabilities, Janssen is well positioned to respond to the COVID outbreak, through making a SARS—CoV-2 vaccine available in large volumes in the 2021 timeframe.

As explained, to allow speedy development and early approval of the vaccine, it will be important to ensure regulatory requirements which are globally aligned and are adapted to the emergency situation. Several areas of attention are worth mentioning:

1. Regulatory environment

- We, as a Company, are very pleased with the outcome of the recent workshop of ICMRA (International coalition of Regulatory Authorities) related to COVID-19 vaccine development. We hope that this initiative is the start of an intensified partnership between the regulatory agencies, especially FDA, EMEA, WHO and that this will result in harmonized, pragmatic, requirements. We also appreciate the fast response from [REDACTED] (EMA) and from [REDACTED] with whom we already had a national scientific advice procedure on Friday March 27.
- We are looking forward to engage in further dialogue with EMA (telecom is being planned).
 - o During these discussions we would initially focus on our need to identify early onwards the single point of contact European Agency (ie rapporteur ?) for scientific/regulatory discussions during this development process. We would hope that the [REDACTED] can be appointed as such a contact, in view of its long standing in depth vaccine/biologicals experience. The [REDACTED] agency would certainly have the expertise needed as co-rapporteur countries.
 - o Another area of discussion with EMEA is to explore which regulatory framework could be used in Europe to mimic the 'Emergency Use Authorization' process in the US which allows to roll out large scale vaccination based on a limited data package. Based on current discussions with FDA's Center for Biologics Evaluation and Research (CBER), such an authorization could be granted, if phase I and IIa are successful, as early as [REDACTED]. Potentially even earlier under certain scenarios.
 - o As to clinical trials in Europe, there are several national regulations that might impact overall fill/finish capacity (biocontainment requirement for the filling at BSL2). In addition, country specific GMO regulations create potential extra delays in study start. Clarity on the acceptability of multidose presentations would also significantly address the filling capacity gap.

2. Liability :

- The COVID vaccine is being developed under accelerated timelines. While there is a substantial amount of human safety data with the vaccine platform used, it cannot be excluded that some very rare events (linked to the COVID specific inserts) would occur during an accelerated, early large scale roll out of a COVID vaccination program. Therefore, the company is seeking [REDACTED].
- To address this need, the US government has already triggered the Prep Act (declaration under the Public Readiness and Emergency preparedness act for medical countermeasures against COVID-19 march 17, 2020 – see copy attached)

The company is seeking a similar [REDACTED] in Europe

3. Vaccine Supplies :

The worldwide need for vaccines will be enormous. It is J&J's intent to make vaccines available globally. To that end J&J is and will be making at risk capital investments to expand its manufacturing capacity globally.

Plans are well underway to establish manufacturing in the US. We have progressed well in our negotiations with [REDACTED] on vaccine [REDACTED] with [REDACTED].

To further expand the capacity of the existing plant in [REDACTED] we are mapping out which factories in Europe are at the appropriate high-tech level to partner with us in a tech transfer to their facilities.

Over the past few weeks, [REDACTED] has expressed potential interest in [REDACTED] the building up of vaccine stock. In this context, it has not been fully clarified to what extent this would also cover needs for Europe.

Therefore it is important to clarify Europe's plan with respect to access to and allocation of supply of the vaccine once it is available. We learned with interest, and welcome your plan to come to a , EU Joint Procurement Process.

Similar to the agreements in the US, it will be important to come to a financing mechanism, driven by Europe, which addresses procurement of the vaccine supplies [REDACTED]

[REDACTED]
[REDACTED]
[REDACTED]
and thus share the risk with the Company.

4. Free flow of goods/critical employees

Manufacturing vaccines is a complex process, which involves a large series of raw material, sourced throughout the world. In addition, as a global company we are seeking the fastest path to reach the population in need for the vaccine across the globe. Therefore, it is critical that borders remain open within EU and with rest of the world for the free flow of materials related to the development of the vaccine.

In conclusion, we propose to set up 4 workstreams (we added the liability) with a clear point of contact from the European Commission, to work out in more details these topics. We will make the necessary teams available from our side to provide you with additional insights on the different aspects (including the estimate of financing support required)

1) Science and regulatory pathway to speed up the vaccine approval and other regulatory matters.

We trust that the interaction with EMEA will cover the 'subject matter expertise' of the

vaccine. This particular workstream should focus on identifying potential gaps in current process and address these.

- We need to have additional discussions on further acceleration of clinical trials
- Regulations around GMO, BSL2 vs BSL1 filling, ...

2) What is the future vaccination strategy, and how does it drive the supply and capacity needs for Europe (including support for Logistics and production of the vaccine – scaling up of manufacturing)

3) At risk financing for building vaccine inventory, advanced purchasing agreements and/or procurement contracts.

- Procurement at European level vs country level

4) Liability: starting the discussion on a European/ global level on liability in emergency use as well as during large scale vaccination.

Kind regards,

Johnson & Johnson Executive Committee

&

Vaccines, Janssen Pharmaceuticals R&D

Janssen Vaccines & Prevention B.V.

From: [REDACTED] [JPPBE]

Sent: vrijdag 27 maart 2020 11:59

To: martin.seychell@ec.europa.eu

Cc: [REDACTED]@ec.europa.eu; [REDACTED]@its.jnj.com; [REDACTED] [JRDBE]

Subject: TC on COVID 19 Vaccine

Dear Mr. Seychell,

Please find attached a highly confidential deck on our COVID-19 vaccine platform and project.

We kindly ask you to treat it as such and to not disclose it to third party or otherwise publicly.

Kind regards,

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