

From: [REDACTED] (SANTE)
Sent: 27 March 2020 20:07
To: SEYCHELL Martin (SANTE)
Cc: RYS Andrzej Jan (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE)
Subject: Report from the TC with J&J on COVID 19 Vaccine
Attachments: FINAL DECK PRESENTATION EUROPEAN COMMISSION.pdf

Dear Martin,

Please find below a summary of the main points from the TC with JnJ- for your agreement. *I am not sure if they were more people participating in the TC*

Report from the TC with J&J on COVID 19 Vaccine 27 March 2020

Participants: M. Seychell (MS), [REDACTED] (DG SANTE); [REDACTED] (RTD)

[REDACTED] (J&J)

The presentation contains **confidential information**.

JnJ presented their plans for COVID-19 vaccine development. While they are progressing with studying vaccine candidates they are looking at the same time for possibilities to rapidly upscale production. While a lot of emphasis was put on the production [REDACTED], it is clear that actions with [REDACTED]

[REDACTED] are much more advanced. The company is in contact with EMA and [REDACTED] with regard to regulatory aspects and reaches out to the Commission as regards EU actions on regulatory flexibility, manufacturing and financial support.

First in human CTs are expected to be launched already in [REDACTED] in the [REDACTED] (**confidential information**); and potentially deployed in [REDACTED] by [REDACTED] under the Emergency Use Authorisation –They noted that the system in Europe is more complex for early access. There has been agreements for substantial [REDACTED] build manufacturing capacity [REDACTED]. JnJ are looking now also for possibilities to increase manufacturing capacity in EU [REDACTED]. The technology is quite difficult and they could identify only a small number of plans in the EU that could produce the vaccine. With about [REDACTED] doses prepared per plant a maximum production could reach [REDACTED] doses per year. Their vaccination plan and possible groups to be vaccinated will depend on the results and whether the vaccine will act against infection or reducing the gravity of the disease.

J&J asked support on the following issues

- Regulatory flexibility
 - Regulatory alignment international (FDA /EMA/WHO)
- GMO rules they asked for regulatory flexibility as the system is complex in many MS although they mentioned they see some flexibility in some MS
 - As regards filled/formulated final product they mentioned complicated rules for Biocontainment for Filling (BSL2 / 1) and containment requirements at trial site
 - They asked for more clarity as regards conditions for emergency approval in the EU.
- Manufacturing
 - Liability (during clinical development and emergency roll out)
 - Preserve cross continents/country flow of goods (equipment, reagents, raw material)-importance of Green lanes
 - Prioritization of supplies (supply allocation process)
- Finance support to de-risk
 - Financing of new facilities in EU to be considered
 - [REDACTED]

JnJ will send a summary of the discussion and more info on the three points after the meeting.

JnJ also noted that in addition to their vaccine development they are committed under IMI to screen existing molecules for possible repurposing against COVID-19.

From: [REDACTED] [JPPBE] <[REDACTED]@ITS.JNJ.com>
Sent: Friday, March 27, 2020 11:59 AM
To: SEYCHELL Martin (SANTE) <Martin.SEYCHELL@ec.europa.eu>
Cc: [REDACTED] (SANTE) <[REDACTED]@ec.europa.eu>; [REDACTED] (SANTE) <[REDACTED]@ec.europa.eu>; [REDACTED] [JJCUS] <[REDACTED]@its.inj.com>; [REDACTED] [JRDBE] <[REDACTED]@its.inj.com>
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,

[REDACTED]

Attention: The information contained in this email is intended only for the identified recipient and may be confidential. If you are not the intended recipient, please delete this email and notify me.

[REDACTED]



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