From (SANTE)
Sent: Thursday, March 12, 2020 5:02 PM
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Cc: SEYCHELL Martin (SANTE) < @ec.europa.eu>; (SANTE) @ec.europa.eu>; (SANTE) @ec.europa.eu>; (SANTE) < @ec.europa.eu>; (SANTE) @ec.europa.eu>; (SANTE) < @ec.europa.eu>; (SANTE) @ec.europa.eu>; (SANTE) < @ec.europa.eu>; (SANTE) < @ec.europa.eu>
Subject: J&J meeting with M.Seychell, covid-19, pharma, med devices

BTO: Johnson &Johnson meeting with Martin Seychell, 11 March 2020

Participants: J&J , SANTE: Martin Seychell (DDG), B6) (B5) (C4), 01

Follow up:

1) J&J to provide more precise data on medical devices , including quantification and device types affected by the MRA running out on 26/05.
2) J&J to send further information on the resilience of their global supply chains and SANTE to organise meeting on global supply chains
3) J&J to send info on compounding law (pharmacies making compounds) and affects on pharmaceuticals

COVID-19 – Vaccine

Johnson& Johnson prioritising COVID-19 vaccine development (Janssen Vaccine) and have partnered with They have the capacity to rapidly upscale once vaccine authorised. Their vaccine plant is in
Possible Time scale: - animal model by end March, Phase I clinical trials 8-12 months, production
They asked for EU help on authorisation of vaccine.
J&J will respond to IMI call for vaccines on COVIS-19

Concerned about their pharmaceutical supplier in [redacted] –need to ensure that trucks will still be allowed.
I&J are not investing in diagnostics for COVID-19.

Shortages

I & I indicated that they do not face shortages as they source in Europe for Europe. They also have enough flexibility in their global supply chain to avoid shortages (in last 3 years no shortage) . They expressed the need for a discussion among the entire global supply chain, which SANTE confirmed as we need to look at this issue from the 2 end-points.

Pharma Strategy

I & I proposed to revisit G-10 (multi-stakeholder pharma forum run by GROW and stopped 7 years ago?) especially recommendation 6 on access(?)) to address the access and availability issue. Also, innovative payment models should be looked at, e.g in the area of gene-therapies. The importance to link to the Data strategy was underlined.

Coumpounding (pharmacy magistral preparations)

I&J expressed their concerns about the [redacted] legislation on coumpounding, stressing that it undermines the attractiveness of the EU market and the rules of law. I &I stated that they will provide more detailed information in a position paper that they will share with SANTE when ready.

Medical Devices - [redacted]

I&J asked for state of play as regards the [redacted] and clarity/guidance on consequences for medical device sector in case the [redacted] is not being upgraded to the new medical device regulation (MDR) before 26 May. SANTE explained that discussions are ongoing at highest level and that it is possible that the [redacted] will not be updated. SANTE informed that in the case the [redacted] is not updated, manufacturers will need to have certificates issued by EU notified bodies and that [redacted] products placed on the EU market need to have authorised representatives in [redacted] EU. I&I expressed concerns in relation to availability to adapt to this and indicated that one important device type affected is trauma devices. SANTE asked to provide more precise data, including quantification and device types affected.

Cancer

I&J invited to respond to the public consultation.

Conclusion: M. Seychell invited J&I to contact him about any issues which they were concerned about regarding COVID-19, shortages, pharma strategy and medical devices.