

Participants: J&J: [REDACTED] pharmaceuticals, [REDACTED]
[REDACTED] medical devices
SANTE: Martin Seychell (DDG), [REDACTED] B6) [REDACTED]
[REDACTED] B5), [REDACTED] (C4), [REDACTED] 01

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

Shortages

J & J 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

J & J 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)

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

Medical Devices - MRA with Switzerland

J&J asked for state of play as regards the MRA with Switzerland and clarity/guidance on consequences for medical device sector in case the MRA 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 MRA will not be updated. SANTE informed that in the case the MRA is not updated, manufacturers will need to have certificates issued by EU notified bodies and that Swiss products placed on the EU market need to have authorised representatives in the EU. J&J 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

J&J invited to respond to the public consultation.

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