

Commissioners meeting with supply chain stakeholders 6 November 2020

Commissioner Kyriakides opened the meeting, thanked attendees for their work since the last meeting and highlighted current and future challenges. The meeting was moderated by Andrzej RYS (Director, DG SANTE).

Highlight issues:

- Influenza vaccine
 - Healthcare professionals noted that shortages reported in approximately half of member states. Demand for vaccines was impacted by Covid-19-, therefore there was an increase in what was considered to be 'at risk' groups. There was also an increased demand for the vaccine among those not considered to be part of the 'at risk' cohort.
 - Little corrective measures can be achieved for 2020. Consider approaches for future seasons. 2020 – 30% increased demand was met with no production days lost due to Covid-19
- Covid-19
 - Vaccine production – risk to availability of components and consumables e.g. syringes, glass vials, flexibags, stoppers. Increase demand on components may impact non Covid-19 biopharmaceuticals- may become problematic in 2021/22.
 - Vaccine distribution – call for approaches for smooth deployment with clear guidance.
 - Approach to diagnostics – reflect more on the use of antigen testing, both lab based and rapid tests, especially with a number of new tests now being made available.
 - Potential shortages of gloves and junior masks.
 - Concerns re increased airfreight cost and reduced ability (medical device), specifically China to Europe.
 - Demand forecasts would be welcome however EMA highlighted the pilot on demand forecasting is a mechanism to ensure the proposed approach is workable. The aggregated data from this will not be shared. Industry are recommended to continue to engage at member state level to determine demand.
- Requested of Commission:
 - Call for EU Strategy for Covid 19 therapeutics.
 - Call to increase capacity for raw materials and glass vials.
 - Call for clear guidance on distribution to support vaccine deployment schemes.
 - Consider approaches to Covid 19 testing in MS, particularly antigen testing.

Full note:

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Medicines

- [REDACTED] – [REDACTED]
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[REDACTED]
- **EFPIA (Originators)** – [REDACTED]
Reiterated no major concerns. Borders are open, essential workers and goods can move freely.

Called for increased visibility on level of stockpiles at member state level, in case of sudden surge in demand.

Would welcome EMA demand forecasting data when it becomes available.

NOTE: EMA clarified the pilot is a mechanism to test the approach outlined in the reflection paper. Once finalised the paper will be available to MS to report on the extended list of products. However, MS have not yet agreed to share this aggregated data beyond the network.

Raised issues with components used in manufacturing of non-Covid biopharmaceutical products e.g. syringes, vials, flexibags, single use materials. Components manufacturers suppliers are receiving requests from health authorities to prioritise Covid vaccine production. The lead time therefore for non-Covid related product manufacturers has extended from 12 weeks to 40 weeks. While this does not immediately impact the supply chain, there may be a risk to production/ fill finish in 2021/2022.

No export restrictions encountered, with the exception of Brexit related issues. The flexibilities, including acceptance of batch testing in UK for 1 year and soft launch of the FMD were welcomed. Remain hopeful for an MRA for GMP.

Called on the Commission for an EU Strategy for Covid-19 therapeutics as the vaccines strategy has proved hugely beneficial.

- **Vaccines Europe (Vaccines)** – [REDACTED]
Challenges with supply of components for Covid vaccines reported by two companies – this includes stopper backs, tubes, filters. Cannot exclude possibility of shortage of glass vials at this time.
Called on Commission to increase capacity for raw material and glass vials.

