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

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- **EFPIA (Originators) –** [redacted]
  Reiterated no major concerns. Borders are open, essential workers and good 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.

With regard to distribution of Covid vaccines, smooth deployment will be essential. Will liaise with Commission about how member states will plan for vaccination campaigns. Bottlenecks must be avoided.

Sanofi provided an update on the influenza vaccine supply challenges. Manufacturers have made efforts to increase production, an increased demand of 30% compared to 2019 was met by industry.
Long term policy changes are required to ensure improved control and response for future years. Early information and careful planning from member states is essential.
With regard to production, the flu vaccine time to market is one year- two step process:

- Drug substance with strains
- Downstream filling, packaging

WHO provides information on strains for Northern hemisphere at the end of February and for the southern hemisphere in September. Production switches from northern strain to southern strain, therefore once a certain date has passed, further production of the northern strain is not posible. The vaccines are delivered from August to October for the northern hemisphere.

This year filling and packaging was extended to end of November to increase supply.

EMA highlighted that the issue of capacity and supply is multifaceted and all stakeholders must work towards future solution driven approaches. For example earlier identification of strains by WHO, would facilitate earlier forecasts, although ECDC said this may not be a possibility.

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Close:
EC flagged that health package, to be announced on 11 November, will reinforce the mechanisms established during the pandemic and will include extended roles for the European Centre for Disease Prevention and Control and the European Medicines Agency. This package will serve to formalise the monitoring of shortages of medical products and enhance cooperation on cross border health threats.

It was also noted that on 15 October the Commission presented a document on Preparedness for COVID-19 vaccination strategies and vaccine deployment. The document outlines the key elements to be taken into consideration by Member States for their COVID-19 vaccination strategies in order to prepare the European Union and its citizens for when a safe and effective vaccine is available, as well as priority groups to consider for vaccination first.