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Call with Commissioners Kyriakides and Breton and medicine and medical device supply chain stakeholders

Commissioners Kyriakides and Breton 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).

██████████ (EMA) noted that the EU Exec Steering Group work is progressing on demand forecasting of medicines, particularly those used in the ICU setting for Covid 19 patients. He highlighted one potential shortage of Pneumovax 23 that is being monitored.

██████████ (ECDC) presented a revised approach of classifying epidemiology of Covid-19 across member states, into three distinct groups. She recommended improved communication and protection of the most medically and socially vulnerable.

Summary: all attendees welcomed the opportunity to meet and acknowledged the benefit of ongoing and future collaboration to strengthen preparedness for the second wave of Covid-19. No specific shortages reported. A number of medicinal products/ medical devices potentially at risk of shortage are being monitored e.g. medical gloves, in vitro diagnostics tests, influenza vaccines, remdesivir and favipiravir. Participants called for member states to share demand data, avoid unilateral stockpile arrangements and continue to minimise export restrictions. With regard to Brexit, the main concerns raised were the difficulty to comply with the requirements in due time by the end of the transition, even though preparedness efforts are made. This could be solved by a time limited derogation of 1 year, for FMD and IE/NI Protocol, a mutual recognition agreement (MRA) for Good Manufacturing Practice (GMP) inspections, import testing and also clarification of the details surrounding the implementation of the Northern Ireland protocol.

Medical Devices - European Federations + members' views

██████████ - Medtech Europe (Medical devices)

- Shortages: No immediate concerns for PPE – possible risk of shortages for gloves, IVD tests. Ventilator demand is above average but can maintain supply.
- Called for EC and ECDC testing guidelines to be adopted and implemented in member states to inform supply requirements.
- Would like to see clearing house maintained as it has been a useful tool for discussion and solution identification.
- Need to put in place policies and procedures, including procurement processes, to allow systems and services operate through the second wave. Industrial capacity and resilience needs to be better coordinated and supported.
- Ensure export restrictions are kept to a minimum.

- Green lanes at the borders for the beginning of January would ensure smooth transit of products from UK and not be disrupted due to BREXIT (e.g. ventilators from UK where there are several manufacturing sites).

- COCIR (Medical devices)

- Patient care: need to identify ways to ensure routine screening/ procedures are not delayed due to Covid-19.
- Recommended harmonised approaches to contract tracing are agreed.
- On the EU Budget, COCIR raised their disappointment on the MFF and Horizon Europe cluster, as the numbers are lower than the ones proposed.
- Vaccines: call for ECDC to share information on role of antibodies and testing guidance.
- Digital Health infrastructure must remain a priority.
- Brexit: concerns raised relating to export restrictions and movement of people for training/ technical reason, identifying solutions and welcome extension to 2023, impact of tariffs unknown.

Medicines - European Federations + members' views

AESGP (European Self-Care Industry)

- Asked for regulatory flexibilities to go beyond ICU medicines.
- Call for materials and ingredients to be considered as essential goods and prioritised at European borders.
- Brexit concerns relate primarily to issues with implementation of the Northern Ireland protocol. If this is maintained 68-90% of products may not be available in Northern Ireland from January 2021. Call for a derogation of 12 months in the IE/NI Protocol.

Medicines for Europe (Generics producers)

- As member states struggle to share demand data with industry locally, need to improve demand planning. While complete information may not be available at national level, it is preferable to use what information is available, rather than using industry data to monitor stock levels in member states.
- Need clarification on ICU medicine joint procurement agreement – window for manufacturing is closing, deadlines have not been respected.
- With regard to Brexit, most issues resolved, with special attention to most vulnerable member states, IE, MT, CY. Concerns relating to mutual recognition agreement for Good Manufacturing Practice inspection. Consider option of a technical agreement between UK and EU, akin to those that exist with other highly regulated markets. With regard to Northern Ireland, MfE will continue to work with EC to continue finding a solution for the FMD, keeping services informed of issues. Asked for more information on replacement of inspectorate resources in absence of MHRA experts.

EFPIA

- Called for information sharing between member states and manufacturers to identify demand and patient needs.
- Concerns on ongoing national legislative developments introducing unilateral stockpile arrangements. European solutions are welcomed, such as a standard protocol for member states.
- Brexit: concerns regarding absence of MRA GMP inspection and import testing- risk of UK imposing 4-6week time delay (UK waiving testing for 2 years). Propose a one year phasing period for the Northern Ireland protocol provisions, including the Falsified Medicines Directive. Details need to be clarified to ensure no impact on supply of medicines to European patients.

Vaccines Europe (Vaccines)

- MS should be encouraged to ensure no/ minimum disruption to national immunisation programmes.
- With regard to Covid-19 vaccine deployment (due to multi dose presentation, complex formulations), manufacturing and distribution (including labelling, cold storage) requirements specific to these vaccines will need to be carefully considered. There is not complete evidence that there will be sufficient stock of associated medical devices e.g. glass vials, syringes, needles.
- On Brexit, concerns around absence of an MRA was reiterated.

EUCOPE (Pharmaceutical Entrepreneurs)

- Expect greater cooperation between EC and member states to ensure no disruptions to internal market.
- Highlighted need to ensure adherence to Cross Border Healthcare Directive, including reimbursement component, and also ensure provisions are observed by member states for the benefit of all European patients.

CEFIC (APIs)

- Highlighted need for clarity on demand data from member states, not just for ICU medicines, but for all essential medicines to inform supply needs.
- Concerns noted: disruption of supply/ structural shortages due to unexpected closures in China, in light of pollution laws.
- Noted a fivefold increase in orders and pre-orders for raw materials and continue to liaise with Vaccines Europe to ensure continued supply.
- Will provide comprehensive report, mapping information on EU production of APIs and intermediates, to EC in October.
- Need a consolidated list of medicines at risk of shortage, requested ongoing regulatory flexibility and co-ordinated industrial policy to mitigate and preventative measures to address shortages in the longer term.

Distribution

GIRP

- Asked for distribution/ wholesale sector to be recognised as critical component of medicines supply chain infrastructure, to have access to restricted areas, to continue engagement with the Commission and optimisation of the overall supply chain.
- Requested guidance for distributors with regard to logistic requirements of Covid-19 vaccines associated consumables, similar to US Centres for Disease Control and Prevention (CDC) guidance.
- Brexit: reiterated concern re: supply to Northern Ireland. Distribution centres in NI hold only a limited range of high volume medicines, low volume products are shipped overnight from mainland UK.

Healthcare professionals

European Association of Hospital Pharmacists (Hospital pharmacists)

- Expect difficulties with regard to shortages of particular medicines during the 2nd wave e.g. vaccines (Covid-19 and influenza), remdesivir, favipiravir.
- Encourage member states to take measures to avoid adoption of counterproductive measures e.g. stockpiling and co-ordinated procurement strategies. Welcome ESI and joint procurement services.
- Reiterated need to ensure non Covid-19 patients have access to healthcare services

(Pharmaceutical Group of the European Union (Community pharmacists)

- Call for increased MS acknowledgement of role of the pharmacist, including permission to substitute in instances of shortage, point of care testing once available and vaccine administration.
- Reiterated need to consider more vulnerable MS with regard to Brexit – IE, MT, CY.

Commissioner Kyriakides concluded the meeting thanking all participants and proposed the next meeting be scheduled next month.