REF ARES: sante.ddg1.b.4(2020)6029247

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).

[redacted]
out of scope
[redacted]

[redacted]
out of scope
[redacted]

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.

[redacted]

[redacted]

- [redacted] – [redacted]
- [redacted]
  out of scope
- [redacted]
- [redacted]
- [redacted]

[redacted] out of scope [redacted]

[redacted]

[redacted] out of scope [redacted]

[redacted]

[redacted]

- [redacted]
- [redacted] out of scope [redacted]
- [redacted]

[redacted]

- [redacted] out of scope [redacted]
- [redacted] – [redacted]
- [redacted]

[redacted] 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.

[redacted] 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.

[redacted]

- [redacted]
  out of scope
- [redacted]

[redacted]

- [redacted]
- [redacted]
- out of scope
- [redacted]
- [redacted]

[redacted]

- [redacted]
  out of scope
- [redacted]
- [redacted]

[redacted]

- [redacted]
- [redacted]
  out of scope
- [redacted]

[redacted]

- [redacted]
  out of scope
- [redacted] –

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