From: SANTE CONSULT-B5
Sent: 26 February 2021 15:29
To: [redacted](SANTE); [redacted](SANTE); [redacted](SANTE); [redacted](SANTE); [redacted](SANTE); [redacted](SANTE)
Cc: [redacted]
Subject: Minutes of meeting with Vaccines Europe- regulatory issues regarding COVID-19 vaccines -18 September 2020

Dear colleagues,

Kindly find below the minutes of the meeting with VE on 18 September.

Kind regards,
B5 unit

Minutes of meeting with Vaccines Europe- regulatory issues regarding COVID-19 vaccines -18 September 2020

Vaccines Europe (VE) gave a presentation with the main issues outlined in the agenda i.e possibility for EU EUA, labelling flexibilities , GMP inspections.

The Commission explained that there is no legal provisions for an EU wide EUA but for labelling flexibilities a memorandum of understanding (MoU) has been drafted and expected to be agreed between MS by the end of the month. It is based on Article 63(3) of Directive 2001/82. The MoU will outline principles to allow the use of one language (e.g EN) for packaging and labelling, multi dose vials, separate distribution of package leaflet and others. The Commission also re-assured VE on the collaboration of EC, EMA and EDQM to ensure a smooth OCABR process ; it also explained the framework of operation on GMP inspections. Reference to a published document published by EMA on flexibilities for COVID-19 medicines was made: https://ec.europa.eu/health/sites/health/files/human-use/docs/guidance_regulatory_covid19_en.pdf

VE agreed to follow developments in the EC and EMA website but no other follow up meeting was required.

Agenda

- Could the Commission clarify on whether the Commission is considering early distribution of unlicensed vaccines?
- VE anticipates that the global (ie. worldwide) life-cycle management of Covid-19 vaccines will be particularly challenging and may put supply at risk.
    - Could the Commission update VE on potential collaborations between EU and non-EU authorities to streamline the review and approval of CMC variations?

        - Is the Commission accepting the implementation of ICH Q12 principles as recommended by VE?
    - Testing on importation: Could the Commission clarify whether the requirement will be waived for COVID-19 vaccines?
    - GMP inspections: Could the Commission clarify if reliance on inspections performed other authorities will be accepted?
    - Labelling/packaging:
        - Is English accepted by all MSs as the language for immediate and outer packaging?
        - Is the proposal of simplified leaflet accepted?
        - By when can we expect the approval of the information on immediate packaging, outer packaging and abridged leaflet?
        - Could the Commission confirm the need for serialization?
        - Could the Commission confirm the agreement from all MSs for GTIN
        -

Participants:

EC participants:

- [redacted] Unit B5: Medicines: policy, authorisation and monitoring
- [redacted] Unit B5: Medicines: policy, authorisation and monitoring
- [redacted] Unit B5: Medicines: policy, authorisation and monitoring
- [redacted]
- [redacted] Unit B4: Medical products: quality, safety, innovation

Vaccines Europe participants:

- [redacted]
- [redacted]
- [redacted]

- [redacted]