Meeting Minutes: Accelerated vaccine development and experiences with regulatory pathways for vaccines in emergency situations

26 of October 2020

Actions:

Action	Responsible	Date
Complete workshop feedback survey: https://www.surveymonkey.com/r/5NPZKKS?name=%5bname_value	All	October 30th
Email Julia.Kuhn@gatesfoundation.org if you would like a link to the meeting recording	All	Ongoing
Send out newsletter from manufacturer of VVM	Julia	(attached to email)

Decisions:

- N/A

ITEM 1iii: [Notes]

Overview of EUL/PQ and regulatory alignment to facilitate approvals at global level

Carmen Rodriguez-Hernandez (WHO) presented an overview of WHO's COVAX regulatory work to date as well as provided an overview of the EUL/PQ Roadmap. The EUL/PQ Roadmap template (which will be used for all COVID-19 vaccines) is expected to be published on the 30th of October.

- Estimating best case timelines to EUL/PQ
    - January 2021 – first full EUL/PQ **application** submission
    - Within days of approval by NRA/SRA in charge of oversight – timeline EUL/PQ **recommendation** (contingent on parallel review)
    - 1-month post EUL/PQ – translation to in-country **decisions or approval**

Specific questions/comments that were addressed:

- Remote/virtual inspections - WHO will discuss with relevant regulatory authorities in charge of the oversight of the vaccines how they can ensure all the data is provided to provide a recommendation. This will also include lot release data requirements.
- WHO is discussing a parallel review process with SRA's to address facilitating reliance at global level, via Regional champions
- There was a question on multi-dose vials and the MDV policy which has to aspects 1) Remaining doses vaccine once the vial is opened is to be discarded at the end of the immunization session (applies to lyophilized and preservative-free formulations) and 2) Vaccine can remain open for 28 days (if vaccine contains a preservative)
    - For COVID, most vaccines will be preservative free which means they will need to be discarded at the end of the session. Countries will need to be trained on this and there needs to be a balance between both public health needs for efficient implementation of MDV and wastage considerations.
- Post Approval Changes - intention is that WHO and regulatory authorities should review post approval changes in parallel and there are several working groups that are working on strategies for safety and monitoring, quality etc. and these points are considered in the roadmap

- Based on the extend of the data and the approval granted by regulatory authorities in charge of the oversight of the vaccines, WHO will determine whether the EUL or PQ process will be used.
- In the case where manufacturers have multiple manufacturing sites (involving multiple tech transfers) the SRA will receive a core dossier for specific sites and then later when the data is generated in other sites/ countries, it will be submitted to the relevant authorities.

Lessons Learned in the Development of an Ebola Vaccine

Jayanthi Wolf (Merck/MSD) presentation on the lessons learned from developing Merck/MSD's Ebola vaccine (ERVEBO). The ERVEBO vaccine is considered a GMO and in some countries is BSL-2

Specific questions/comments that were addressed:

- GMO: The OMCL was able to work with the GMO and it took time to allow for the necessary permits. As relates to import, each country has different regulatory requirements, and these should be taken into consideration as it relates to supply chain.
- Storage: Global Good developed Arktek portable freezers which met the ultra-cold chain storage needs for deployment in the field.
- Manufacturing cycle: currently manufacturing year-round to build up the global stockpile now that the vaccine is licensed.
- Dating: Industry thinking is in line with a flexible approach by providing the manufacturing date on the label while pursuing the EUL and then the expiry information can be updated based on stability information
- Shedding studies: there was very limited shedding, so no additional transmission studies were needed. A comprehensive environmental risk assessment was included in the Marketing Authorization Application.
- Approvals: Cathy Hoath (Merck/MSD) stated the importance of providing the dossier to African countries, reference authority and WHO all at the same time so the different stakeholders could pursue the review process of their choice. Collaborative reviews take a lot of coordination and Cathy emphasized the importance of industry in facilitating this relationship.

Bio Farma and Development of a novel oral polio vaccine (nOPV2)

Erman Tritama presented Bio Farma's experience with nOPV2 to date.

- Filing for WHO Interim EUL Interim and eventually PQ to supply nOPV2 to UNIVEF for use in outbreak response
- Accelerated scale-up in 10 months, used 50-dose vial and converted existing measles facility to multi-use

Accelerated development and WHO EUL submission for nOPV2

David Robinson spoke to CMC considerations for EUL

- Manufacturers will need to adhere to widely accepted commercial manufacturing standards, even for pilot- or clinical-manufacturing facilities if material from these facilities is intended to be made available under the EUL (or via PQ).
- Inspections: important for manufacturers to discuss with local NRA and WHO, given the potential for various travel restrictions.
- Labelling: alignment will be needed on release specifications and content of primary label

Ajoy Chakrabarti spoke to post-deployment monitoring and noted that unlike other disease areas there is less relevant infrastructure so this should be a consideration for manufacturers.

Final comments from Carmen

- Ebola clarification– there was no WHO EUL recommendation given to the vaccine due to complexities of the outbreak. The vaccine was used in country at risk, under a compassionate protocol. Data was generated and submitted to relevant authorities and PQ.
- nOPV2 – will be the first EUL that WHO is assessing however this vaccine is produced following a well-known platform for many years. Once the vaccine is recommended by WHO will be rolled out to countries following criteria endorsed by the Strategic Advisory Group of experts. Safety and efficacy will be monitoring following a Risk management plan.