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WHO Product Development for Vaccines Advisory Committee Meeting on Measles-Rubella Microarray patches (virtual meeting)

21 June 2023, 1-3pm CET (open session)

Draft Agenda and Concept Note

Context

Measles and rubella microarray patches (MR-MAPs) are critical to achieving measles and rubella eradication, and the need for their expedited product development was recommended by WHO's SAGE in 2016. Since then, two MR-MAP candidates have entered clinical development (Vaxxas; Micron Biomedical), and very recently Micron Biomedical announced the first proof-of-concept data in infants from a Phase 1/2 study in the Gambia. Vaccination by MR-MAP was safe and well tolerated. At day 42, MR-MAP demonstrated equivalent measles and rubella seroprotection rates as MR administered to infants via the sub-cutaneous route, who were MR-vaccine naïve at the start of the trial. In the wake of this highly anticipated and exciting clinical data, MR programme and MAP stakeholders are eager to understand how to expedite the MR-MAP pathway to licensure and use.

As we and others have discussed previously (here), investment in and establishment of a pilot manufacturing facility for MR-MAPs will be needed to scale-up and manufacture clinical trial material for the phase III pivotal licensure study. Since the decision to invest in vaccine manufacture has been deferred until after clinical proof-of-concept, there could now be approx. 2.5 years before the start of the pivotal licensure study of MR-MAP. While partners are actively working on acceleration and de-risking strategies (including engaging an additional antigen supplier) there is – in the meantime - **an opportunity to address pertinent clinical, pre-implementation and operational research questions in the next 2 years to better design the phase III licensure study and prepare for timely introduction.** As such, this PDVAC meeting will focus primarily on these questions, and not on the late-stage product development aspects, which are rapidly evolving.

Objectives of the meeting:

This PDVAC meeting will:

- briefly review the status of the clinical and human factor studies for MR-MAPs and the phase 1/2 data from Micron Biomedical;
- consider the timeline and regulatory/WHO prequalification (PQ) implications for a MR-MAP with an additional MR antigen;
- review the anticipated priority use cases for introduction of MR-MAP, including findings from the WHO CAPACITI Innovation Framework, and discuss the implications on and remaining questions related to the critical product attributes;
- discuss the priority clinical and pre-implementation research questions that need to be conducted for MR-MAP in the next 2 years.

AGENDA

21 June 2023, 1-3pm CET

Chairs: Ruth Karron & Raman Rao

Time	Topic	Proposed speaker
1.00 – 1.10pm	Welcome and opening remarks, Context for and objectives of the meeting	Ruth Karron & Raman Rao Birgitte Giersing
1.10 – 1.35 15 + 10	Presentation of MR-MAP Phase 1/2 clinical study data, including acceptability findings of Micron MR-MAP	Ed Clarke (LSHTM)
1.35 – 1.50 10 + 5	Overview of MR-MAP candidates in product development o Plan for additional phase 2s and PATH human factors studies	Courtney Jarrahian (PATH) (pre-recorded)
1.50 – 2.05 5 + 10	Potential timeline and regulatory implications for development with a different MR antigen	Birgitte Giersing (WHO)
2.05 – 2.30 15 + 10	MR-MAP priority use case analysis and critical product attributes o Consideration of VVM30 and controlled temperature chain (CTC)	Mateusz Hasso-Agopsowicz (WHO) Anna-Lea Kahn (WHO) (pre-recorded)
2.30 – 3.00 (2' framing)	Discussion on critical attributes and key clinical/product development research questions for MR-MAP	Ruth Karron & Raman Rao to chair Birgitte Giersing (framing)
3.00 – 4.00	**PDVAC closed session**	