Product Development for Vaccines Advisory Committee (PDVAC)

FINAL AGENDA

Hybrid F2F/Virtual meeting
12-13 December 2023 (open session); 14 December 2023 (closed session)
PDVAC chair: Prof. Ruth Karron; PDVAC Vice-chair: Dr Raman Rao

Context for the meeting:

In the aftermath of the COVID-19 pandemic, in which more than 30 vaccines were developed in record time but only a fraction were made available to low- and middle-income countries, the global vaccine R&D landscape is transforming.

There are now focused efforts, and committed resources, to establish vaccine manufacturing capability and capacity in all regions to ensure sufficient supply and more equitable access to vaccines. Beyond capacity building is the recognition that systematic investment in the entire vaccine R&D ecosystem is needed to effectively co-ordinate and strategize, to be positioned to respond – not only to the next pandemic – but to other priority diseases for which we currently do not have vaccines or where vaccine product innovation is needed.

Immunization Agenda 2030: A Global Strategy to Leave No One Behind (IA2030) is the global vision and strategy for immunization, aimed toward maximizing the impact of vaccines. One of its objectives is to collaborate across regions to identify pathogen priorities for new vaccine development, in keeping with the IA2030 core principles of "people-centred, country-owned, partnership-based, and data-guided". As such, a prioritization framework and process were needed to align on priorities, targets, and a mechanism for monitoring and evaluation.

Over the last 18 months, WHO has been collaborating with regional stakeholders to develop an approach and methodology to identify priority **pathogen targets for new vaccines (where vaccines do not yet currently exist), and based on the work to date, PDVAC is charged with proposing a short list of global priority pathogen targets for vaccine development.** This global list of priority pathogens will serve as indicators to monitor progress of vaccine R&D over the course of IA2030, but more importantly – for pathogens that afflict low resource settings - will help to inform the activities that WHO undertakes to advance development of these vaccines and prepare for their use.

The Product Development for Vaccines Advisory Committee (PDVAC) provides external advice to WHO related to priority infectious disease pathogens, associated vaccine and monoclonal antibody product development approaches and related manufacturing and delivery technologies. Its remit includes the prioritisation of target pathogens for vaccine and/or monoclonal antibody development and technology platforms, in addition to oversight of the development of preferred product characteristics (PPCs), technical/R&D roadmaps, full vaccine value assessments and consultations on product development pathways (see here). *Please note that PDVAC does not consider epidemic pathogens; that is under the purview of the WHO R&D Blueprint.*

This PDVAC meeting will present the progress towards identifying the priority pathogens at the regional level and propose vaccine development targets for the IA2030 global list. The meeting will also include

technical sessions on pipeline vaccines, where specific feedback is sought from PDVAC, as well as horizon-scanning sessions to provide an update on vaccine development status for information and potential future engagement.

Information on previous PDVAC meetings can be found here.

Objectives:

- To review the progress towards partnering with regions to identify priority pathogens for new vaccines for development and investment, and
- propose a short-list of global endemic pathogen priorities for monitoring and evaluation of IA2030;
- Review the progress of pipeline and emerging vaccine and monoclonal antibody candidates against specific pathogens, including those on the proposed global priority list and provide strategic advice on the critical activities that are already ongoing and/or needed to advance new vaccine and monoclonals for priority endemic pathogens;
- To discuss how WHO/IVB can effectively drive and/or partner with immunization stakeholders to support the development of multiple vaccines and vaccine-like monoclonals for low-and-middle-income countries.

Desired outcomes:

- Proposed list of global pathogen targets for new vaccine development, for alignment with WHO's Strategic Advisory Group of Experts on Immunization (SAGE);
- Input on the strategy for further engagement with regional stakeholders on regional pathogen priorities for vaccine development;
- Specific input/strategic advice for new vaccines including tuberculosis vaccines for adults and adolescents, combination vaccines, therapeutic vaccines for HPV and Salmonella vaccines including on elements of the Full Vaccine Value Assessments that are needed;
- Proposals for IVB partnership models/collaborations to drive PDVAC recommendations.

Day 1: Global and regional efforts on prioritisation of pathogens for vaccine development and manufacturing

Session	DRAFT topic	Proposed speaker
Scene-setting		
8.00 – 8.30	**Welcome and introductions**	Kate O'Brien (WHO) Ruth Karron and Raman Rao All
8.30 – 8.40	**Context for and goals of this PDVAC meeting**	Birgitte Giersing (WHO)
Regional R&D partnership and engagement		
08.40 – 08.50	**IA2030 and the SP7 working group** on Research & Innovation: update	Kwaku Poku Asante (Kintampo Health Research Centre & SP7 WG co-lead)
08.50 – 09.35 25' + 20'	**Regional engagement strategy to identify IA2030 global priority endemic pathogens (Objective SP7.2)… and beyond** - Proposal for the global endemic pathogen priority list	Mateusz Hasso-Agopsowicz (Birgitte Giersing, Erin Sparrow, Angela Hwang) (WHO)
09.35 – 10.20	**Vaccine development and manufacturing priorities in the Africa region** - WHO regional vaccine manufacturing strategy (including the mRNA hub) 15' - Partnerships for African Vaccine Manufacturing (15') - African Vaccine Manufacturing Accelerator (15')	Martin Friede (WHO) Abebe Genetu Bayih (Africa CDC) virtual Yalda Momeni (GAVI)
10.20 – 10.45	**Coffee**	
10.45 – 11.45	**Regional stakeholder Panel:** Are we on the right track towards improved collaboration in vaccine R&D and regional manufacturing across global, regional and country levels?	Moderator: KP Asante (SP7) - Cristiana Toscana (Universidade Federal de Goiás/WHO SAGE) - Helen Rees (WITS/AFR RITAG) - (Heeyoun) Gloria Cho, WHO WPRO - Ike James (Medicines patent pool) - Debbie King (Wellcome Trust) - Frauke Uekermann (CHAI)
Global priority setting activities		
11.45 – 12.15	**Combination Vaccines and the vaccine value proposition**	Bill Hausdorff (PATH/PDVAC)
12.15 – 13.00	Update on the **Gavi Vaccine Investment Strategy**	Marta Tufet (Gavi)
13.00 -14.00	**LUNCH**	

14.00 – 15.00 45' + 15'	**Overview of the PDVAC and vaccine product delivery research (PDR) unit activities in 2023**: - Highlights for vaccines and cross-cutting activities that will not be covered in this meeting (HIV, monoclonals, Dengue, Influenza, AMR, Klebsiella, GAS, RSV) - WHO 3L meeting outcomes	WHO PDR secretariat
Vaccine specific sessions – next generation vaccines/new targets		
15.00 – 15.10	**Session intro** - Immune correlates for alternative regulatory pathways	Marco Cavaleri (EMA/PDVAC)
15.10 – 15.55	**Group B Strep** - Critical issues with immune correlates for licensure and policy - Update on TAG GBS Questions to PDVAC and discussion	Kirsty Le Doare (WHO) David Goldblatt (UCL, virtual)
15.55 – 16.30	**Coffee**	
16.30 – 17.15	**Chikungunya vaccines:** Introduction to session - Epidemiology and risk groups (5') - Impact modelling (5') - Landscape of Chik vaccines (7') - Determining immune correlates (12') Questions to PDVAC and discussion	Annelies Wilder-Smith, WHO Susan Hills, (CDC) Henrik Salje, (Uni of Camb) Tim Endy, (CEPI) Robin Levis, FDA (all virtual speakers)
17.15 – 17.20	**Meeting announcement from Martin Friede**	
17.20 – 18.00	**Shigella** - Opening comments - Status of pipeline and product development considerations - Plans for WHO regulatory consultation Questions to PDVAC and discussion	Bill Hausdorff (PATH/PDVAC) Cal MacLennan (BMGF) Rob Kaminski (WHO consultant)
	Close meeting day 1	
18.15	***Cocktail***	

Day 2: Vaccine and platform specific sessions (cont)

Session	DRAFT topic	Proposed speaker
Vaccine specific sessions		
08.30 – 09.45	**New tuberculosis vaccines** - Opening comments - Overview of the TB vaccine pipeline - WHO activities to accelerate vaccine development and prepare for uptake - Analysis of potential outcomes of clinical studies and implications on regulatory and policy strategies Questions to PDVAC and discussion	 Sonali Kochhar (University of Washington/SAGE) & Willem Hanekom (AHRI) Mark Hatherill (SATVI) Birgitte Giersing (WHO) Velislava Petrova (WHO Consultant)
09.45 – 10.45	**New malaria vaccines** Update on the implementation of RTS,S and R21 (5') Overview of next-generation malaria vaccine candidates and monoclonal antibodies (15') Multi-target vaccines - Pre-erythrocytic and blood stage vaccines (15') - Transmission blocking vaccines (15') Q&A (10')	 Mary Hamel (WHO) Lindsey Wu (WHO) Ashley Birkett (PATH) Patrick Duffy (NIAID)
10.45 – 11.15	**Coffee**	
Vaccine specific sessions – Salmonella vaccines		
11.15 – 12.45	**Salmonella vaccines** - Overview/opening comments (5') - Review of draft NTS vaccine PPC (20') - Emerging data: presentation of TyVAC TCV longevity data (10') Discussion and questions for PDVAC (20') - Clinical development considerations (10') - Combination Salmonella vaccine strategy; key take-aways from Kigali meeting and next steps (10') - Review of R&D roadmap (5') Discussion (10')	 Adwoa Bentsi-Enchill (WHO) Kate Emary (WHO) Andy Pollard (University of Oxford) Jean Louis Excler (IVI) (virtual) Adwoa Bentsi-Enchill (WHO) Kate Emary
12.45 – 13.45	**LUNCH**	
Vaccine specific sessions – STI vaccines		
13.45 – 14.30	**Overview of progress in STI vaccines** - Gonococcal vaccines - HSV - Chlamydia - Syphilis Discussion and questions for PDVAC (15')	 Carolyn Deal (NIAID)

14.30 – 15.30	**Therapeutic HPV vaccines (tHPV)** - Review and endorsement of draft tHPV PPC - Outcomes from the NCI/BMGF/DKFZ tHPV trial design/endpoints meeting Discussion and questions for PDVAC (30'): - Request for conditional endorsement of the PPC.	Sami Gottlieb (WHO) Peter Dull (BMGF)
15.30 – 16.00	**Coffee**	
16.00 – 16.45	**Update on MR-MAP (measles and rubella vaccines on microarray patches** - Update on the status of vaccine-MAP development - Outline of plans for a global convening on the clinical and policy pathway Discussion and questions for PDVAC (15')	Mateusz Hasso-Agopsowicz (WHO) Courtney Jarrahian (PATH) Darin Zehrung (WHO consultant)
16.45 – 17.25	**Industry Round table:** Perspectives from industry on effective R&D agenda setting and what is needed to strengthen collaboration.	Moderator: Raman Rao (Hilleman Laboratories/PDVAC) - Annaliesa Anderon- Pfizer - Mohammad Mainul Ahasan – Incepta Ltd - Ariane McCabe – GSK - Raches Ella – Bharat Biotech - Pedro Alonso - BioNTech
17.25-17.30	**Meeting close**	

Day 3: PDVAC closed session, 14th December (PDVAC and ex-officio members, WHO staff only)