Product Development for Vaccines Advisory Committee (PDVAC)

DRAFT AGENDA

Intercontinental Hotel, Geneva, Switzerland
Hybrid F2F/Virtual meeting
5-6 December 2022
Meeting chairs: Dr David Kaslow & Prof. Ruth Karron

Context for the meeting:

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.

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. Within IA2030 is the need to monitor progress of vaccine development towards a "short list" of global R&D targets. As such, a prioritization framework and process is needed to align on priorities, targets, and a mechanism for monitoring and evaluation." This call for mutually defined targets is in keeping with the IA2030 core principles of "people-centred, country-owned, partnership-based, and data-guided." **PDVAC has been charged with proposing the short list of pathogen targets for new vaccines (where vaccines do not yet currently exist), for endorsement by the WHO Strategic Advisory Group of Experts on Immunization (SAGE) in April 2023.**

This PDVAC meeting will present progress towards identifying the priority pathogen short-list, based on a new partnership model with regions, and a methodology based on multi-criteria decision analysis (MCDA). It aims to leverage vaccine value profiles that have been developed by independent expert writing groups for 18 pathogens. The meeting aims to accommodate both 'deep-dive' 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.

This will be the first in-person meeting for PDVAC since 2019. PDVAC has convened virtually for topic specific meetings since the beginning of the COVID-19 pandemic and a virtual meeting on Group A Streptococcus is scheduled for 30 September. Information on previous meetings can be found here.

Objectives:

- To review the progress towards partnering with regions to identify priority pathogens for new vaccines as indicators for IA2030 strategic priority 7 (SP7);

- Review the progress of pipeline and emerging vaccine and monoclonal antibody candidates against specific pathogens, and reaffirm/identify pathogen priorities and critical activities needed to advance new products;
- To discuss the 'full-value of vaccines assessment' (FVVA) concept and its use in prioritising vaccines for intended for low-and middle-income countries;
- 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:

- Input on the strategy, progress and contingency plans towards identifying a 'short-list' of priority pathogens for IA2030, by March 2023;
- Clarification of PDVAC's role in the SP7 scope, and ways of working with the SP7 working group;
- Specific input/strategic advice for Shigella, therapeutic HPV, GBS and TB vaccines and the monoclonal antibody platform (questions to be defined);
- Horizon-scanning of and strategic advice on vaccines that are approaching proof-of-concept, including on elements of the FVVA that are needed;
- Proposals for IVB partnership models/collaborations to drive PDVAC recommendations.

Day 1: Prioritisation of pathogens for vaccine development & vaccine specific sessions

Session	DRAFT topic	Proposed speaker
Scene-setting		
8.00 – 8.30	Welcome and introductions	Kate O'Brien (WHO) David Kaslow and Ruth Karron All
8.30 – 9.30 45' + 15'	Overview of the PDVAC and vaccine product delivery research (PDR) unit scope and activities - Highlights for vaccines that will not be covered in meeting (previous mtgs in 2022, incl iNTS and GAS) - TB vaccines – ECVP and roadmap - Focus on regional priority setting - Goals of this PDVAC meeting	WHO PDR secretariat
Building the Regional R&D partnership model		
9.30 – 09.45	IA2030 and the SP7 working group on Research & Innovations: remit and objectives	Kwaku Asante (Kintampo Health Research Centre &SP7 WG co-lead)
09.45 – 10.15	**Coffee break**	
10.15 – 11.00	Regional engagement strategy to identify IA2030 priority pathogens, includes vaccine value profiles Preferences survey – interim and preliminary	Birgitte Giersing, Mateusz Hasso-Agopsowicz, Erin Sparrow (WHO); Angela Hwang
11.00 – 11.30	Catalytic funding in platforms techs, WHO and other mRNA hubs	Nicaise Ndembi (Africa CDC) Martin Friede (WHO)
11.30 – 12.15	Panel discussion: Bridging the gap between global, regional and country priority setting	Moredreck Chibi (AFRO) Raman Rao (Hilleman) Debbie King (Wellcome)

		Helen Rees (Wits University, South Africa) & AFRO RITAG chair Ghassan Ddaibo (American University of Beirut)
12.15 – 13.15	**Lunch**	
Global priority setting activities		
13.15 – 13.30	Update on the Gavi Investment Strategy	Marta Tufet (Gavi)
13.30 – 14.00 15'+ 15'	The role of correlates on accelerating vaccine licensure	Debbie King (Wellcome Trust)
14.00 – 14.15	Evidence Considerations for Vaccine Policy	Birgitte Giersing (WHO)
14.15 – 15.15	**Group B Streptococcus** - GBS value proposition - Status of pipeline and potential licensure pathways - Regulatory consultations	Annelies Wilder-Smith (WHO) David Goldblatt (UCL) Richard Isbrucker (WHO)
15.15 – 15.45	**Coffee break**	
Vaccine specific sessions - Enteric and Diahroeal diseases		
15.45 – 15.50	Overview	Birgitte Giersing (WHO)
15.50 – 17.05	**Shigella** - Value proposition - Status of pipeline - Potential licensure pathways - Status of Limmatech's Shigella candidate	Bill Hausdorff (PATH) Cal MacLennan (BMGF) Birgitte Giersing (WHO) Patricia Martin (Limmatech)
17.05 – 17.40	**ETEC** Status of candidates, and plans for paediatric indications	Lou Bourgeois (PATH)
17.40 – 18.00	**Next generation rotavirus vaccine**	Duncan Steele (BMGF)
	Close meeting day 1	
18.00	***Cocktail***	

Day 2: Vaccine and platform specific sessions

Session	DRAFT topic	Proposed speaker
Vaccine specific sessions (cont)		
08.30 – 09.15	**Paratyphi A** - Value proposition - Status of pipeline & potential combos - Role of the CHIM in licensure	Adwoa Bentsi-Enchill (WHO) Cal MacLennan (BMGF) Andrew Pollard (University of Oxford)
09.15 – 09.45	**Norovirus** - Status of Hillevax, and plans for pediatric indication	Astrid Borkowski (Hillevax)
10.00 – 10.30	**RSV** - Vaccines - Monoclonal antibodies	Erin Sparrow, (WHO) Danny Feikin, (WHO) Heather Zar (University of Cape Town)
10.30 – 11.00	**Coffee break**	
11.00 – 11.45	**Malaria** –	

	- Overview of RTS,S status - Second generation vaccines - Monoclonal antibodies	Mary Hamel (WHO) Lindsey Wu (WHO)
11.45 – 12.15	Overview of progress in **STI vaccines** - Gonococcal vaccines - HSV - Chlamydia Syphilis	Carolyn Deal (NIAID)
12.15 – 12.45	**tHPV** : - Public health need for a tHPV - PPC considerations	Sami Gottlieb (WHO)
12.45 – 13.45	**Lunch**	
Cross cutting & Technology platforms		
13.45 – 14.30 45’	**Improved Influenza vaccines:** current pipeline and considerations for a revised PPC	Chris Chadwick (WHO), 20 mins Discussion 25 mins
14.30 – 15.30 45’	**Novel delivery technologies** - Focus and activities of the Vaccine Innovation Strategy (VIPS) and status of vaccine-MAPs - Use case, demand forecast and country consultations onr MR-MAP - Initial full vaccine value assessment for MR-MAP - Pipeline of other vaccine product innovations	Marion Menozzi Arnaud (Gavi) Mateusz Hasso-Agopsowicz (WHO Jean-PIerre Amorij (Unicef) Courtney Jarrahian (PATH)
15.30 – 16.00	**Coffee break**	
16.00 – 16.55	**Monoclonal antibodies** - Overview of preventative infectious disease mAbs in clinical development and WHO activities - Overview of traditional production technologies and novel ways to bring down costs - HIV mAbs to prevent perinatal transmission – need for targeted development for a paediatric indication	Erin Sparrow (WHO), Veysel Kayser (consultant) Theodore Ruel (IMPAACT) Shelly Malhotra (IAVI)
16.55 – 17.40	**The role of vaccines in reducing AMR:** WHO priorities and workstreams Case study: Klebsiella	Mateusz Hasso-Agopsowicz (WHO) Padmini Srikantiah (BMGF)
17.40	**Meeting close**	

Day 3: PDVAC closed session, 9th December (hybrid meeting)