Product Development for Vaccines Advisory Committee (PDVAC)

AGENDA

Hybrid F2F/Virtual meeting

9-11 December 2024 (open session); 12 December 2024 (closed session)

PDVAC chair: Prof. Ruth Karron; PDVAC Vice-chair: Dr Raman Rao

Context for the meeting:

The COVID-19 pandemic demonstrated the unprecedented impact that vaccines can have on global health, by setting new paradigms for development and regulatory timelines, with many vaccines based on novel manufacturing platforms. The result has been to challenge the status quo for vaccines that have spent decades in the pipeline, with a renewed focus on vaccine prioritization and the need for innovative approaches to accelerate regulatory approval and to optimise efficiency of delivery. However, with routine immunization programmes still struggling to 'catch-up' post-pandemic comes the realization that immunization programmes will not be able to afford to procure, or to practically deliver, the multitude of vaccines that are in the pipeline today, casting doubt over their demand and potential uptake.

Novel combinations or presentations that are easier to administer may be able to alleviate some of the over-crowding at certain points in the immunization schedule so that new vaccines can be delivered. Emerging vaccine manufacturing platforms such as mRNA technology may facilitate combinations of antigens that collectively tackle a single syndrome, such as respiratory illness, whilst leveraging and further sustaining investments in regional capacity building. Innovative delivery technologies such as microarray patches are at last coming of age, and could have applicability to several vaccines, enabling vaccination by community health-workers and the potential to rapidly respond to outbreaks. Passive immunization approaches are also expanding to protect young infants, using monoclonal antibodies or maternal immunization. These methods offer an alternative for pathogens where active vaccine development has proven challenging, providing immediate immunity without requiring the recipient to generate an immune response. However, passive immunization faces significant hurdles, including the high production costs of monoclonal antibodies and the logistical complexities of delivering vaccines during pregnancy through antenatal care. As such, the theme of this PDVAC meeting is to discuss innovative approaches to accelerate regulatory approval and optimise programmatic efficiency, within the context of priority vaccines that will be reviewed.

Additionally, the meeting will reflect on lessons learned from RSV immunization product development, a pathogen that was prioritized by PDVAC at its inception in 2014 and for which SAGE policy recommendations have been recently made. This will highlight the importance of early prioritization and strategic guidance in shaping the research pipeline and identify areas where PDVAC could have provided additional input to facilitate product development and policy decisions. At the end of 2023, PDVAC endorsed the global list of 17 endemic priority pathogens, and 34 associated use cases, for new vaccine development, that were developed for monitoring progress under the Immunization Agenda 2030's (IA2030) strategic priority 7 on research and innovation. During its closed meeting PDVAC will consider the 34 use cases as part of its agenda to identify those that should be IVB priorities, and where PDVAC and the secretariat should actively engage, resources permitting.

What is PDVAC?

The Product Development for Vaccines Advisory Committee (PDVAC) provides external advice to WHO related to priority infectious pathogens for endemic diseases, the 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). Its annual meetings feature open sessions with focused updates from global immunization stakeholders, as well as on pipeline vaccines and cross-cutting immunization topics, where specific feedback from PDVAC is sought. These sessions will also include horizon-scanning updates on the status of vaccine development, intended to inform and potentially guide future PDVAC engagements. *Please note that PDVAC does not consider epidemic pathogens; that is under the purview of the WHO R&D Blueprint.*

Information on previous PDVAC meetings can be found here.

Objectives:

- Discussion of some of the innovative approaches to accelerate vaccine regulatory approval and to enable programmatic efficiency, in the context of vaccines in the current pipeline for endemic pathogens.
- Review the progress of pipeline and emerging vaccine and monoclonal antibody candidates against specific endemic pathogens, including those on the endorsed 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:

- Specific input/strategic advice for new vaccines as outlined in the agenda.
- PDVAC endorsement of the approach to develop a strategic framework for development of combination vaccines.
- PDVAC endorsement of: the revised PPC for next generation influenza vaccines; the R&D roadmap and PPC for *S.* Typhi/Paratyphi A bivalent vaccines.
- Proposed areas/actions/priorities where IVB and PDVAC should engage to guide product development for vaccines and monoclonals for global endemic pathogen priorities.

Day 1, 9 December 2024: Cross-cutting vaccine development topics

Session	Topic	Speaker	Purpose
08:30-09:00	***Registration & welcome coffee***		
	Opening		
09:00-09:20	**Welcome and introduction of PDVAC members**	Kate O'Brien (WHO), Ruth Karron (PDVAC), Raman Rao (PDVAC)	Information
09:20-10:05	**Keynote: From PDVAC prioritization to policy - 10 years of action on RSV** - Reflections from stakeholders	Erin Sparrow (WHO) Reflection panel: Moderator: Ruth Karron (PDVAC). Panellists: Tonya Villafana (Astra Zeneca), Julie Skinner (Pfizer), Jules Millogo (Merck/MSD), Sonali Kochar (SAGE)	Information
10:05-10:15	**Context for and goals of this PDVAC meeting**	Birgitte Giersing (WHO)	Information
	Strategic guideposts		
10:15-10:40	**Immunization Agenda 20230 (IA2030) Strategic Priority 7 (SP7):** - Overview of IA2030 SP7 - Updates on indicators & M&E	Meru Sheel, KP Asante (co-chairs of the SP7 working group)	Discussion
10:40-11:00	**Outcomes from the Gavi vaccine Investment Strategy (VIS)** - Outcomes of VIS 2024 & priority actions	Marta Tufet (Gavi)	Information
11:00-11:20	***Coffee break***		
	Strategic initiatives		
11:20-11:50	**Development of a Strategic Framework for novel Combination Vaccines** - Update on WHO/PATH/BMGF strategy/framework and plans	Bill Hausdorff (PATH)	Discussion
11:50-12:15	**Strategies to accelerate vaccine approval and de-risk investments** - Controlled human infection models & correlates of protection	Debbie King (Wellcome Trust)	Discussion
12:50-14:00	***Lunch break***		
	Updates from WHO committees and manufacturing associations		
14:00-14:15	**Updates from International Federation of Pharmaceutical Manufacturers and Associations (IFPMA)**	Paula Barbosa (IFPMA)	Information
14:15-14:30	**Updates from Developing Countries Vaccine Manufacturers Network (DCVMN)**	Rajinder Suri (DCVMN chair)	Information

14:30-14:45	**Updates from Strategic Advisory Group of Experts on Immunization (SAGE)** - Highlights from 2024 meetings	Joachim Hombach (WHO)	Information
14:45-15:00	**Updates from Technical Advisory Group on Market Access for Vaccines (TAG MVAC)** - TAG-MVAC overview & highlights for 2024	Tara Prasad (WHO)	Information
15:00-15:15	**Updates from Immunization and vaccines related implementation research advisory committee (IVIR-AC)** - IVIR-AC overview & highlights for 2024	Philipp Lambach (WHO)	Information
15:15-15:30	**Updates from Expert Committee on Biological Standardization (ECBS)** - New vaccine regulatory standards endorsed and planned	Ivana Knezevic (WHO)	Information
15:30-16:10	**VIPS and Vaccine-MAPs** - VIPS priorities - Update on global convening on the clinical and policy pathway for MR-MAP - Update on MR-MAPs and other vaccine MAPS	Marion Menozzi-Arnaud (Gavi), Mateusz Hasso-Agopsowicz (WHO), Darin Zehrung (WHO consultant, virtual), Courtney Jarrahian (PATH)	Discussion
16:10-16:30	***Coffee break***		
	Vaccine specific sessions - STI vaccines		
16:30-18:30	**Overview of progress in STI vaccines** - tHPV	Sami Gottlieb (WHO), Peter Dull (BMGF)	Discussion
18:30-18:40	***End of day 1*** - *Wrap up and housekeeping announcements*		
18:40-20:00	***Welcome Reception***		

Day 2, 10 December 2024: Immunization approaches and vaccine specific sessions

Session	Topic	Speaker	Purpose
08:30-09:00	Welcome coffee		
09:00-09:15	**Overview of day 2** **Reflections from day 1**	Ruth Karron (PDVAC)	
09:15-09:35	**Where are we with mRNA and regional vaccine production?**	Martin Friede (WHO)	Discussion
09:35-10:25	**Next generation influenza vaccines** - Overview of pipeline - Review & endorsement of updated PPC - Update on FVVA	Pierre Gsell (WHO) Philipp Lambach (WHO)	Recommendation
	Passive immunization - monoclonal antibodies		
10:25-10:55	**Monoclonal antibodies** - Advancements in the pipeline - WHO roadmap to increase access to mAbs - UNITAID initiative to expand access through novel business models - MPP technology transfer initiative	Erin Sparrow (WHO), Annie Cameron (UNITAID), Ike James (MPP)	Information
10:55-11:25	***Coffee***		
	Vaccine specific sessions – GAS vaccines		
11:25-12:55	**Group A Strep** - Outcomes of SAVAC meeting Oct 2024 - Latent RHD as an intermediate clinical endpoint for RHD	Pierre Gsell (WHO) Andrew Steer (MCRI); Andrea Beaton (CCHMC) Annelies Wilder-Smith (WHO)	Discussion
12:55-14:00	***Lunch break***		
	Vaccine specific sessions – GBS		
14:00-14:30	**Group B step vaccines** - Update on Vaccine Pipeline - Update on ECVP	Annelies Wilder-Smith (WHO) Kirsty Le Doare (WHO)	Discussion
	Vaccine specific sessions – TB vaccines		
14:30-16:10	**New Tuberculosis vaccines for adults and adolescents** – Status of vaccine candidates in the pipeline – Results from recent PoR trials (H56), and implications for trial designs/endpoints/licensure – Considerations for including asymptomatic tuberculosis in vaccine efficacy trial design – Sample size implications – Update on the TB Vaccine Accelerator – Discussion	Willem Hanekom (AHRI) Ann Ginsberg (BMGF) Mark Hatherill (SATVI)* Gavin Churchyard (Aurum Institute)* Richard White (LSHTM) Birgitte Giersing (WHO)	Discussion
16:10-16:30	***Coffee break***		

16:30-18:00	**Overview of progress in STI vaccines continued** - WHO STI research priorities - Gonococcal vaccines (incl. MenB) - HSV - Chlamydia - Syphilis	Carolyn Deal (NIAID), Sami Gottlieb (WHO)	Discussion
18:00-18:10	***End of day 2*** - *Wrap up and housekeeping announcements*		

Day 3, 11 December 2024: Vaccine specific sessions

Session	Topic	Speaker	Purpose
09:30-10:00	***Welcome coffee***		
10:00-10:05	**Overview of day 3**	Raman Rao (PDVAC)	
10:05-10:40	**Update on the impact of vaccines on AMR:** - Highlights from UNGA - AMR report - Klebsiella vaccines	Mateusz Hasso-Agopsowicz (WHO)	Discussion
10:40-11:35	**Funders roundtable:** - Perspectives from funders on funded areas and gaps in funding	Moderator: Raman Rao (PDVAC) Peter Dull (BMGF), Charlie Weller (Wellcome Trust), Justin Im (RIGHT foundation), Carolyn Deal (NIAID)	Information
	Vaccine specific sessions – Enteric vaccines		
11:35-12:15	**ETEC vaccines update** - Phase 2b results	Björn Sjöstrand (Scandinavian Biopharma), Tom Wierzba (Wake Forest School of Medicine)	Discussion
12:15-12:55	**Shigella** - Vaccine update - Potential Shigella Combination Vaccines - Outcome from Regulatory Science Meeting - Update GDB	Annelies Wilder-Smith (WHO), Cal MacLennan (independent expert), Rob Kaminski (WHO consultant), James Platts-Mills (UVA)	Discussion
12:55-14:00	***Lunch break***		
14:00-14:30	**Norovirus vaccines update**	Duncan Steele (BMGF)	Discussion
14:30-15:00	**Next generation rotavirus vaccines update**	Duncan Steele (BMGF)	Discussion
15:00-15:20	***Coffee break***		
15:20-16:00	**iNTS vaccines**	Annelies Wilder-Smith (WHO)	Discussion

	- Introduction/ Update on PPC & Roadmap - Global Non-typhoidal Salmonella Disease Burden - iNTS vaccine overview - iNTS Combo Meeting Objectives; iNTS CDP; iNTS Regulatory Science Objectives; Questions for Regulatory Science Meeting	John Crump (Univ Otago) Cal Maclennan (Independent expert), Jean-Louis Excler (IVI) Rob Kaminski (WHO)	
16:00-17:15	**Bivalent Salmonella Typhi/Paratyphi A** - Objective setting/Update on Regulatory Meeting - Update on paratyphoid CHIM - PPC and Roadmap Update	Annelies Wilder-Smith (WHO), Andrew Pollard (University of Oxford, recorded), Ana Belen Ibarz-Pavon (WHO consultant)	Recommendation
17:15-17:55	**Developers panel on priorities and combination vaccines**	Moderator: Raman Rao (PDVAC) Julie Skinner (Pfizer), Tonya Villafana (Astra Zeneca), Raches Ella (Bharat), Melanie Saville (PATH)	Information
17:55-18:05	**Meeting wrap-up**	Ruth Karron (PDVAC), Raman Rao (PDVAC), Birgitte Giersing (WHO), Martin Friede (WHO)	
	Meeting end		

Day 4: PDVAC closed session, 12th December 2024 (PDVAC and ex-officio members, WHO staff only)