Product Development for Vaccines Advisory Committee (PDVAC)

AGENDA

Hybrid F2F/Virtual meeting
Auditorium z1 z2

6-8 October 2025
PDVAC chair: Prof. Ruth Karron; PDVAC Vice-chair: Dr Raman Rao

Context for the meeting:

Since January 2025, there has been a severe contraction in funding and support for vaccine R&D. Many donors and institutions have redirected attention and resources to other priorities, threatening not only the development of critical new vaccines for diseases that predominantly affect low- and middle-income countries (LMICs), but also undermining the long-term sustainability of global health innovation.

Concurrently, countries that depend on external support to introduce and scale new vaccines are facing increasing constraints. The Gavi replenishment in June 2025 saw a US$ 2.9 billion shortfall relative to its funding target, reducing its ability to support the timely adoption of new life-saving vaccines in LMICs. Few countries will 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. In this context, the work of the Product Development for Vaccines Advisory Committee (PDVAC) is more important than ever, to help prioritize investments, guide strategic decisions in vaccine product innovations, and ensure that the pipeline of vaccines remains aligned with the world's most pressing public health needs.

Given the constrained funding environment, innovative regulatory and clinical trial designs are needed to accelerate vaccine development and reduce the costs of clinical development. Adaptive and platform trials improve efficiency through flexible protocols and shared resources. Leveraging correlates of protection can reduce the need for large efficacy trials, while controlled human infection models (CHIM) offer rapid early insights into vaccine performance, helping to prioritize the most promising candidates quickly and cost-effectively. However, these novel approaches are not without risk, and both regulators and policy-makers need to be part of the early thinking as these strategies take shape.

Increasingly, routine immunization programmes in LMICs are struggling to deliver currently recommended vaccines. Novel combinations or presentations that are easier to administer may be able to alleviate some of the over-crowding at certain visits in the immunization schedule, increasing opportunities to vaccinate and enabling new vaccines to be introduced. 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, 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, and reprioritization and alignment in the current financial context. The agenda is framed within the context of the Immunization Agenda 2030 (IA2030) priority pathogens and use cases for new vaccines and monoclonal antibodies, undertaken by PDVAC in December 2024.

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 priority 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 products;
- 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 LMICs.

Desired outcomes:

- Specific input/strategic advice for new vaccines as outlined in the agenda.
- PDVAC review and advice on the progress towards the framework and shortlist for new combination vaccines.
- PDVAC endorsement of:
    - Refinements needed for the PPC for shigella vaccines
    - ECVP for GBS vaccines
- Review of PDR workplan for PDVAC priority vaccines for the next year, taking into consideration the current resource constraints (closed session).

Day 1, 6 October 2025: General Updates, cross-cutting vaccine development topics & vaccine specific sessions

Session	Topic	Speaker	Purpose
08:30-09:00	***Registration & welcome coffee***		
	Opening		
09:00-09:15	**Welcome**	Kate O'Brien (WHO), Ruth Karron (PDVAC), Raman Rao (PDVAC)	Information
09:15-09:45	**Introductions and housekeeping** - Introduction of PDVAC members - Declarations of interest & housekeeping	PDVAC Erin Sparrow (WHO)	Information
09:45-10:05	**Re-prioritization within WHO IVB and challenges facing immunization programmes and vaccine R&D**	Kate O'Brien (WHO)	Information
10:05-10:20	**Gavi recalibration 6.0 under funding constraints**	Marta Tufet (Gavi)	Information
10:45-10:55	**Context and goals of this PDVAC meeting**	Erin Sparrow (WHO)	Information
10:55-11:25	***Coffee break***		
11:25-11:45	**Immunization Agenda 20230 (IA2030) Strategic Priority 7 (SP7):** - Tracking progress in R&D for priority pathogens under SP7.2 - Progress under implementation research	KP Asante (co-chair SP7 working group) Olwen Wilson (MMGH) Meru Sheel, (co-chairs of the SP7 working group) Chinwe Iwu-Jaja (WHO-AFRO)	Information
11:45-12:45	**General updates** (on topics that will not have their own session) - GAS - Next generation influenza vaccine - MR-MAPS - AMR - Klebsiella - Next generation cholera - Next generation rotavirus - Norovirus - New salmonella vaccines - Malaria - HIV - RSV (paediatric)	WHO secretariat: Pierre Gsell Mateusz Hasso-Agopsowicz Rob Kaminski Ana Ibarz Lindsey Wu Erin Sparrow	Information
12:45-14:00	***Lunch break***		

14:00-14:15	**Relevance of the clinical trial action plan to vaccines**	Vasee Moorthy (WHO)	Information
14:15-14:50	**Inclusion of pregnant and lactating women** - Maternal immunization inclusion toolkit to advance inclusion of pregnant and lactating women in vaccine clinical trials - Discussion	Martina Penazzato (WHO)	Discussion
14:50-15:40	**Shigella vaccines** – Update on Shigella vaccine development and establishment of Shigella TAG – Shigella epidemiology: Considerations towards lower age for protection/immunization – Phase III Endpoint: Clinical Definition(s) – Phase III Endpoint: Progress towards use of qPCR as case detection method in Phase III studies – Phase III Endpoint: Potential impact of co-pathogens/infections in Phase III Shigella vaccine study design considerations – PDVAC Questions	Rob Kaminski (WHO) James Platts-Mills (UVA) Patricia Pavlinac (UW) Eric Houpt (UVA) Elizabeth Tacket Rogawski McQuade (Emory) Annelies Wilder Smith (WHO)	Discussion
15:40-16:10	***Coffee break***		
16:10-17:40	**Development of a Strategic Framework for novel Combination Vaccines** - Update and discussion on progress towards the WHO/PATH/BMGF strategy/framework - Highlights of emerging combinations	Bill Hausdorff (PATH) Mateusz Hasso-Agopsowicz (WHO) Peter Jay Hotez (Baylor College of Medicine) Maria Elena Bottazzi (Baylor College of Medicine)	Discussion
17:40-17:50	***End of day 1*** - *Wrap up and housekeeping announcements*		
17:50-19:30	***Welcome Reception***		

Day 2, 7 October 2025: 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) Raman Rao (PDVAC)	
09:15-10:15	**New TB vaccines for adults and adolescents** - Update on the TB Vaccine Accelerator - Update on the pipeline - Report back from the TAG and SAGE - Update from the Finance & Access WG	Birgitte Giersing (WHO) Willem Hanekom (PDVAC) Saskia den Boon (WHO) Tara Prasad (WHO)	Information
10:15-10:45	**Adjuvants** - Updates from the Vaccine Formulation institute	Nicolas Collin (VFI)	Information
10:45-11:15	***Coffee***		
11:15-11:45	**STI vaccine updates** - MenB vaccine for gonorrhoea prevention - Chlamydia	Sami Gottlieb	Information
11:45-12:00	**Updates on the WHO mRNA hub** - Prioritization of mRNA products	Pierre Gsell (WHO)	Information
12:00-12:40	**Leishmaniasis Vaccines** - Overview of burden of disease, product development & key challenges	Saurabh Jain (WHO) Paul Kaye (University of York)	Discussion
12:40-14:00	***Lunch break***		
14:00-14:40	**CMV vaccines** - Overview of burden of disease, product development & key challenges	Suresh Boppana (University Alabama at Birmingham)	Discussion
14:40-16:00	**Group B strep** - Update on Pfizer GBS vaccine phase III trial - Update on other products in the pipeline - Group B Streptococcus Surveillance Standards - Pathway to SAGE - Update on phase 3 trial and SToRR endpoint - PDVAC Questions	Iona Munjal (Pfizer) Kirsty Mehring Le Doare Kirsty Mehring Le Doare/ Musa Hindiyeh Kirsty Mehring Le Doare/Annelies Wilder Smith (WHO)	Discussion

16:00-16:30	***Coffee break***		
16:30-17:15	**R&D for new vaccines** - Views from industry on priorities and funding constraints	Vaccine Industry Panel (TBC)	Discussion
17:15-17:30	***End of open meeting*** - *Wrap up*	Ruth Karron; Raman Rao	

Day 3, 8 October: Closed session (PDVAC and ex-officio members, WHO staff only)

Room W, B-Building

09:00 Meeting start

09:00-09:15: Overview of the closed session, Ruth, Raman

09:15-09:30: Pathogen priorities – re-cap of further prioritization from Dec 2024, Erin

09:30-12:30: Recap from open sessions that were for discussion, WHO & PDVAC focal points

09:30-10:30

- Maternal immunization inclusion toolkit to advance inclusion of pregnant and lactating women in clinical trials
- GBS ECVP endorsement
- CMV

10:30-10:50 coffee break

- TB vaccines
- Adjuvants

10:50-12:35

- Leishmaniasis
- Combination vaccines
- Shigella vaccines

12:35-13:45: Lunch break

13:45-16:00: PDVAC workplan for next year (working coffee break at 15:00)

- Upcoming technical products and timelines for PDVAC review
    - Klebsiella R&D roadmap
    - Revised GAS roadmap and PPC
    - Revised shigella PPC
- Ongoing TAGs & prioritizing scope of work
- Potential dates for future PDVAC meetings (June)