2019 WHO Product Development for Vaccines Advisory Committee (PDVAC) Consultation
CHAIR: David Kaslow
26-28 June 2019
Salle B, WHO Headquarters, Geneva, Switzerland

Concept note

Established in 2014, the Product Development for Vaccines Advisory Committee (PDVAC) is an independent standing WHO committee of experts that provides external advice to WHO's Department on Immunization, Vaccines and Biologicals (IVB), related to development of vaccine and monoclonal antibody products for infectious diseases. The committee's remit covers disease areas where there is substantial disease burden in low- and middle-income countries (LMICs), where none of these products currently exist, but where there is some ongoing research and development activity which may benefit from WHO guidance. This committee may also have a role where vaccines are already licensed, and development of improved products, including novel presentations or innovative immunization technologies is a priority for WHO.

In recent years, the strategic role of PDVAC has evolved to look beyond the most expeditious route to licensure for priority vaccine and technology candidates. The committee aims to anticipate the near- and long-term barriers and roadblocks to investment in product development, by developing approaches to ensure a clear understanding of country preferences and development of products that meet the needs of LMICs. Consideration of the full public health value (FPHVV) for vaccines and novel technologies is becoming an increasingly critical element of the PDVAC approach to identifying public health priorities. In addition, the PDVAC provides recommendations on the impact of cross-cutting activities that may benefit several candidates, such as novel manufacturing platform technologies or strategies, or strategies for informing the FPHVV of vaccines.

The Decade of Vaccines, and its accompanying Global Vaccine Action Plan (GVAP) are coming to an end in 2020, and work is already underway across global and regional stakeholders to define strategic goals for the next decade. Goals of the PDVAC 2019 meeting will include discussion of the strategic themes for determining R&D priorities and goals for 2021-30, as well as reviews of the status of, and product development needs for pathogen-specific candidates.

Objectives of the meeting

This will be the 6th annual meeting of PDVAC. The objectives for the 2019 meeting are to:

1. Review the progress of candidates against specific priority pathogens, as well as cross-cutting initiatives and delivery innovation development, over the last 12 months;
2. Consider strategic themes for determining R&D priorities and goals for 2021-30;
3. Identify areas where WHO's Initiative for Vaccine Research can lead and/or facilitate the R&D agenda for the next decade.

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Day 1: Wednesday 26th June 2019: What should be the post-2020 global strategic priorities for vaccine R&D?

Time	Topic	Duration	Detail	Moderators, speakers & panelists
8.00	Registration & coffee			
8.15 – 8.30	Welcome & Introductions			Martin Friede / David Kaslow
8.30 – 9.00	Planning for the next decade	20 +10	Overview of the Immunization agenda 2030 – the 6 strategic pillars	Ann Lindstrand (WHO EPI)
9.00 – 10.00	Post 2020 strategic planning for R&D and innovation	10' 20' + 30'	Look back at lessons learned from GVAP Global R&D agenda & Strategic priorities for the next decade	Carolyn Deal (NIAID) Martin Friede (WHO)/ David Sarley (BMGF)
10.00 – 10.30	Coffee			
10.30 – 12.45	How is the perceived value of vaccines and associated technologies evolving?	5' 25' 15' 10' ' 10' 10' 15' +45 min	Remarks: The Concept of the full public health value of vaccines (FPHVV) Value attribution framework for Antimicrobial resistance & Roadmap Value of vaccines that have high morbidity and low mortality Value of vaccine delivery innovations Manufacturer's perspective: Merck Manufacturer's perspective: Biological E Perspective of Gavi Plenary discussion	Alejandro Cravioto (SAGE Chair) Holly Prudden & Matt Hasso (WHO) Maria Elena Botazzi (Baylor) Birgitte Giersing (WHO) Jeff Blue (Merck) Ramesh Matur (Biological E) Sophie Mathewson (Gavi) Moderator: David Kaslow (PATH)
12.45	Lunch			

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14.00 – 14.45	Country stakeholder engagement in shaping the R&D priorities and agenda – creating the pull	5' 10 min +30 min	Remarks: The challenges of, but necessity for regional and country engagement in vaccine R&D agenda setting The potential role of Total Systems Effectiveness Panel discussion:	Sinead Delaney-Moretlwe (Wits) Birgitte Giersing (WHO) Moderator: Sinead Delaney-Moretlwe (Wits) - James Heffelfinger (WHO WPRO) - Beno Yakubo (NAFDAC) - Yanfeng Lim (CHAI) - Ole Oleson (EDCTP) - William Ampofo (Uni of Ghana)
14.45 – 15.30	Creating sustainable R&D models to ensure a healthy vaccine and tech pipeline	45'	Remarks: How do we create the line of sight to a healthy market for novel vaccine candidates and technologies? Panel discussion	Martin Friede (WHO) Moderator: Martin Friede - Jerome Kim (IVI) - Barney Graham (NIAID) - Peter Dull (BMGF) - Patrick Tippoo (Biovac) - Darin Zehrung (PATH)
15.30 – 16.00	Coffee			

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16.00 – 17.30	Reducing the risk of the 'second valley of death' for vaccines	15' 10' 25' 40'	Presentation: Is there a "second valley of death" for vaccines? Regulatory support of vaccine development: Perspectives from the EU regulators Panel Discussion Open discussion	David Kaslow (PATH) Klaus Cichutek (PEI) Moderator: Cherry Kang (THSTI) Perspectives from: - Alejandro Cravioto (WHO SAGE) - Ann Ginsberg (IAVI) - Taryn Rogalski-Salter (Gates MRI) - Beno Yakubo (NAFDAC) - Marian Wentworth (MSH)
17.30 – 18.00	Discussion & close		○ What should be the R&D priorities for the next decade? ○ Which of the six immunization agenda 2030 pillars do they map to?	David Kaslow and Birgitte Giersing

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Day 2: 27th June:

Time	Topic	Duration	Detail	Speakers
8.30 – 10.30	A year in review	60' + 60'	- Overview of the major progress in vaccine product development and summary of IVR/PDVAC engagement for PDVAC priority pathogens - New data/major shifts - New initiatives - Looking ahead to next decade	Birgitte Giersing / Johan Vekemens / Sami Gottlieb (all WHO)
10.30 – 10.50	Coffee			
10.50 – 12.00	RSV Vaccines	15' 20' 10' + 25'	- Update on RSV vaccine pipeline and status - Resvax study results - Summary from WHO RSV TAG	Ruth Karron (JHU) Shabir Mahdi (RMPRU) Danny Feiken (WHO)
12.00 – 13.00	Lunch			
13.00 – 14.00	RSV monoclonal antibodies	5' 15' + 40'	- Brief update on MAb pipeline - Medi8897 study results	Ruth Karron (JHU) John DeVincenzo (UTHSC)
14.00 – 15.00	Tuberculosis	10' 20' +30'	- Pipeline overview and status of late stage candidates - WHO IVR activities on TB vaccines	Ann Ginsberg (IAVI) Johan Vekemans (WHO)
15.00 – 15.30	Coffee			
15.30 – 17.30	Enteric vaccines	15' + 15' 15' + 15' 15' + 15' 15' +15'	- Enteric burden of disease Working Group: report from 2018 workshop and overview of WG activities - Status update on non-replicating rotavirus vaccines (NRRV) - Paratyphoid vaccine development - Update on iNTS vaccine development and outcomes of BMGF/WT consultation	Mark Jit (LSHTM) & Holly Prudden (WHO) Fred Cassels (PATH) Andy Pollard (Oxford) Duncan Steele (BMGF)
18.00	Cocktail			

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Day 3: 28th June 2019 (morning - open session): Product development status and strategic issues for priority vaccines (cont)

8.30 – 09.30	Group B Strep	15' 20' + 25'	- Update on WHO IVR activities on GBS vaccine development - Introduction to a public health public proposition for GBS vaccine - Economic considerations to inform estimation of the value of GBS vaccine	Johan Vekemans (WHO) Mark Jit (LSHTM)
09.30 – 10.00	coffee			
10.00– 10.40	Development of vaccines for epidemic response	20' + 20'	Status of vaccine and manufacturing platform development	Melanie Saville (CEPI)
10.40 – 12.00	Vaccine Innovation Prioritization Strategy	10' 25' 15' + 30'	The need for novel vaccine delivery approaches Update to the Vaccine Innovation Prioritization Strategy The PATH microarray patch (MAP) Center of Excellence & the Delivery technologies working group Discussion	Mark Papania (CDC) Marion Menozzi-Arnaud (Gavi) & Birgitte Giersing (WHO) Darin Zehrung (PATH) All
12.00 – 13.00	Close/lunch			
13.00 – 17.00	Closed session: Committee only			