WHO Product Development for Vaccines Advisory Committee (PDVAC)

Context for and goals of this meeting

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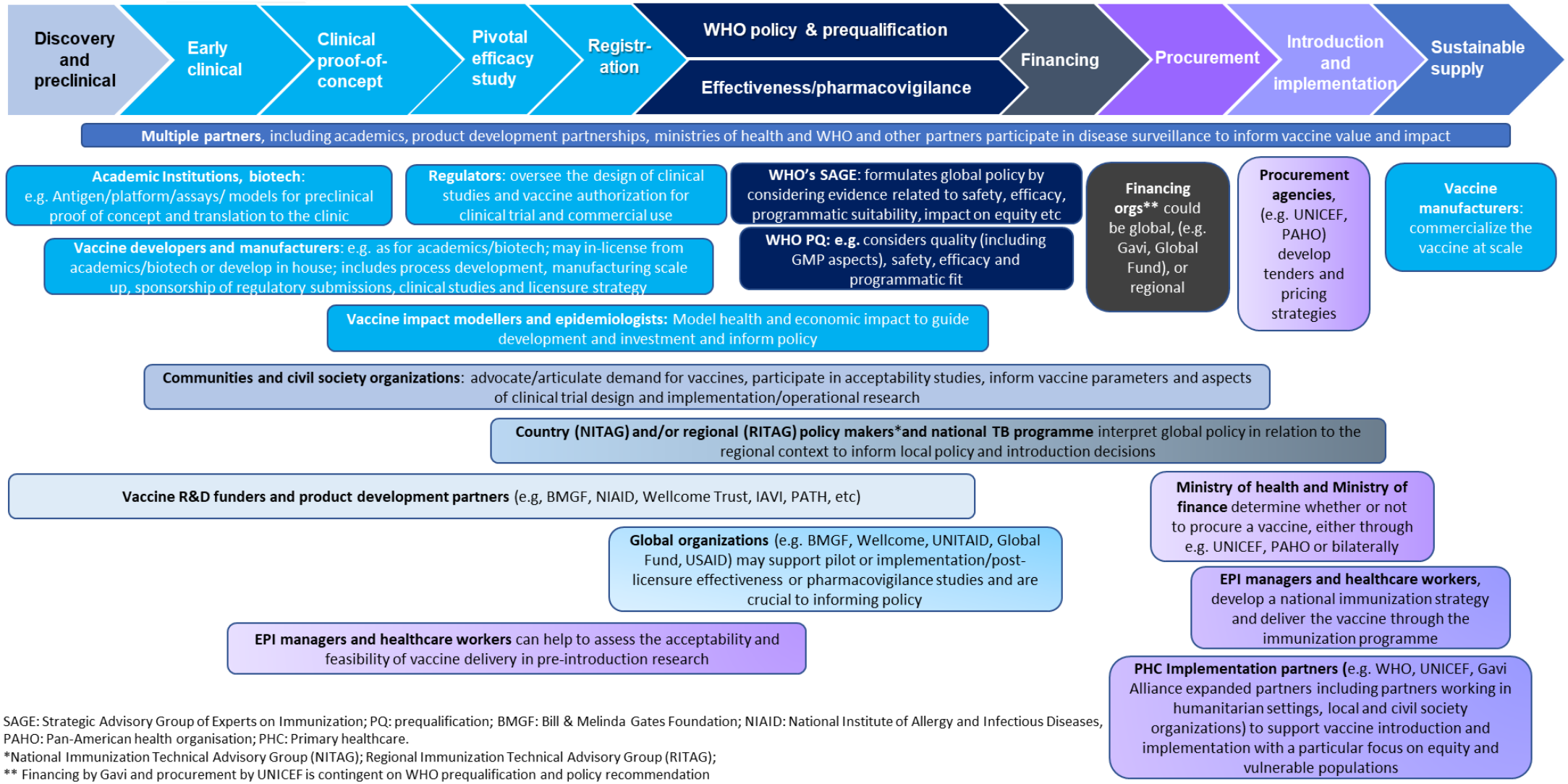
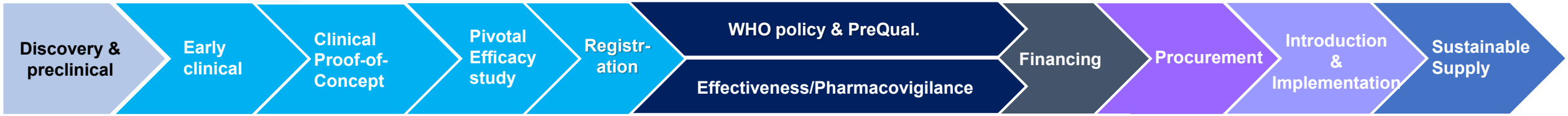
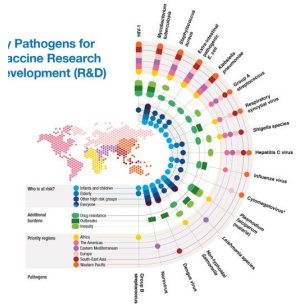
PDVAC takes a strategic view of the end-to-end process



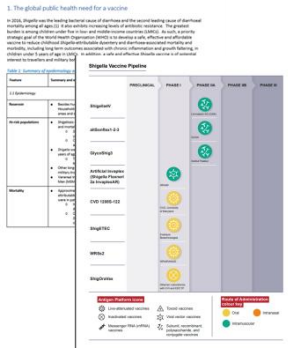
SAGE: Strategic Advisory Group of Experts on Immunization; PQ: prequalification; BMGF: Bill & Melinda Gates Foundation; NIAID: National Institute of Allergy and Infectious Diseases, PAHO: Pan-American health organisation; PHC: Primary healthcare.
*National Immunization Technical Advisory Group (NITAG); Regional Immunization Technical Advisory Group (RITAG);
** Financing by Gavi and procurement by UNICEF is contingent on WHO prequalification and policy recommendation

PDVAC Technical Advisory Groups develop WHO guidance to inform vaccine development and investment decisions

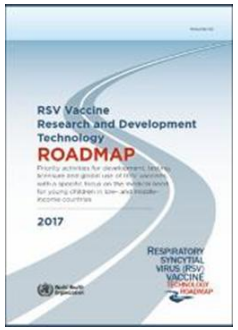




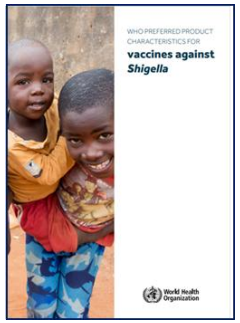
Which pathogens?



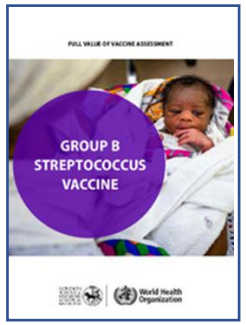
What's known?



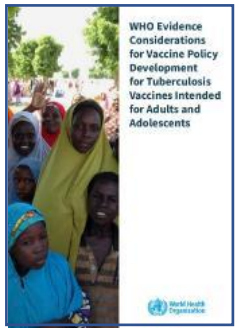
What's needed?



What attributes?



What impact?



What evidence for policy-makers?

Technical guidance documents are developed by groups of subject matter experts, as PDVAC Technical Advisory Groups (TAGs)

Current / imminent PDVAC TAGs:

- GBS (clinical and policy)
- Vaccines and AMR
- Salmonella (PPCs and Roadmaps)
- TB (clinical and policy)
- Combination vaccines
- Klebsiella
- Shigella

Please note: PDVAC's scope is **endemic vaccines** where there is a disproportionate LMIC burden

Objectives of this meeting

- 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 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.

Three types of session:

For discussion: request to provide technical and strategic advice; some specific questions may be posed.

For information: relevent information that is helpful to know.

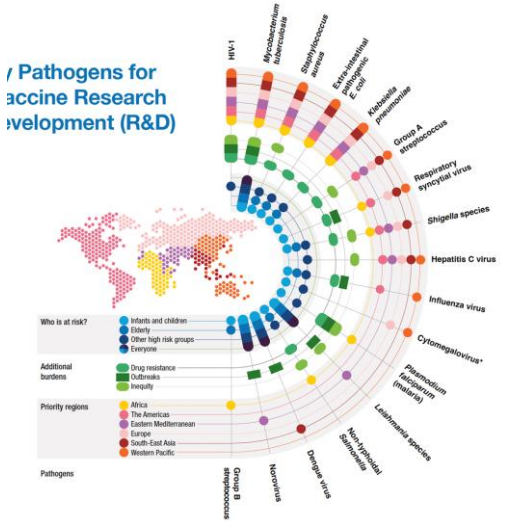
For endorsement – related to approval of guidance documents that have been developed by technical advisory groups and been through public consultation (closed session)

Desired outcomes of this meeting

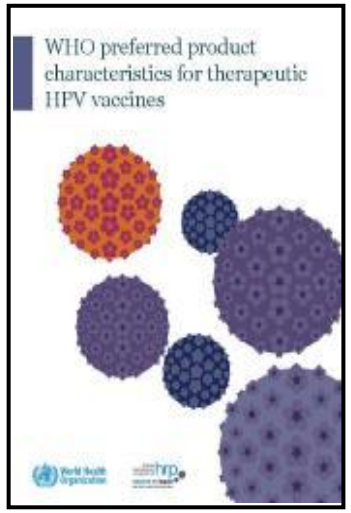
- Specific input/strategic advice for new vaccines as outlined in the agenda.
- PDVAC review and advice on the progress towards the framework and shortlist for new combination vaccines.
- PDVAC endorsement of:
  - Refinements needed for the PPC for shigella vaccines
  - ECVP for GBS vaccines (closed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

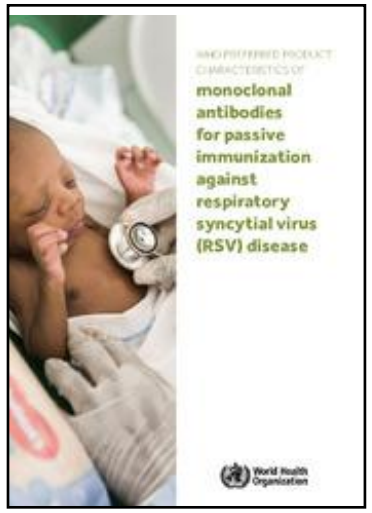
Backup

What does PDVAC do?



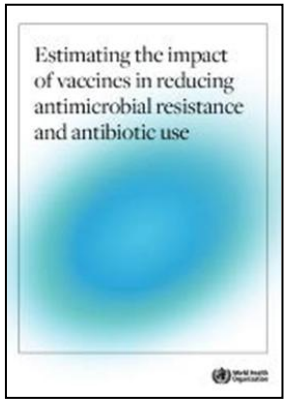
Prioritization of new vaccines in the pipeline

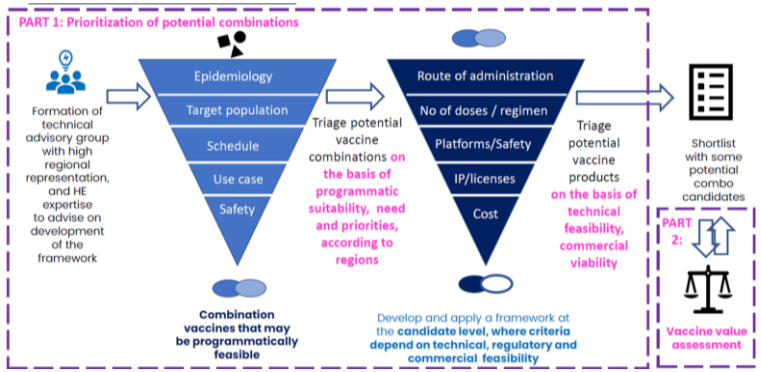




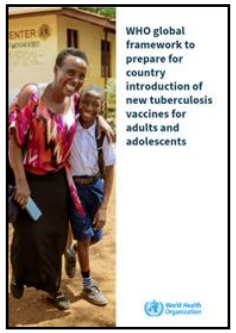
Advises on vaccine and monoclonal antibody *product development for LMIC use*

Advises on development of *vaccine platforms*





Develop strategic value frameworks for research decision making across country, regional and global level stakeholders



Develop new tools / guidance to facilitate and *de-risk product development for investment*

Vaccine	Preferred Product Characteristics (PPC)	Vaccine Value Profile (VVP)*	Full Vaccine Value Assessment (FVVA)	R&D Roadmap	Evidence Considerations for Vx policy (ECVP)	Other
TB	Vaccines for infants, adults & adolescents, therapeutic	**Publication in progress**	✓	✓	✓	Global framework for country introduction
HIV	Monoclonals					
Shigella	Vaccines for infants. **Revision to be discussed**	✓	✓ *			
Gonococcus	Vaccines for young people	✓				
RSV	Monoclonals for infants; Maternal immunization, paediatric vaccines	✓		✓		
ETEC	Vaccines for infants	✓				
HSV	Vaccines for young people	✓				
GAS	Vaccines infants and young children. **To be revised**		✓ *	**To be revised**		
Next-generation Influenza	Improved influenza vaccines Universal-type influenza A vaccines **Revised publication in progress**		**Publication in progress**	✓ *		
GBS	Maternal immunization	✓	✓	✓	**For PDVAC endorsement**	
S. Typhi/ Paratyphi A	✓	✓				
iNTS	✓	✓		✓		
Klebsiella		✓		**In progress**		
Malaria	Monoclonals for children; Vaccines (falciparum & vivax)	**In progress**				
MR-MAPs*	Vaccines		✓ *	✓	In progress	VIPS Action plan
tHPV	Vaccines to clear infection Vaccines to treat cervical precancers					

VVPs also for Norovirus, cytomegalovirus, Leishmaniasis, Chikungunya, Hookworm, Schistosomiasis, Non- thypoidal salmonella; * developed by partners.