

## WHO Product Development for Vaccines Advisory Committee (PDVAC)

Context for and goals of this meeting

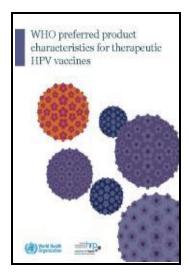


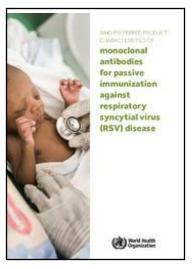
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### What does PDVAC do?



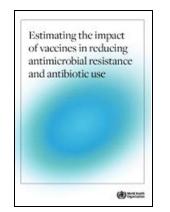


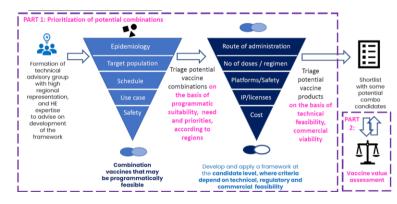




Prioritization of new vaccines in the pipeline

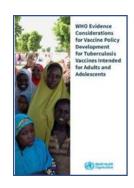






Develop strategic value frameworks for research decision making across country, regional and global level stakeholders

# Advises on development of vaccine platforms





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

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

WHO policy & prequalification **Pivotal** Discovery Clinical Introduction Registr-**Early** Sustainable efficacy **Procurement** and proof-of-Financing and ation clinical supply preclinical study concept Effectiveness/pharmacovigilance Multiple partners, including academics, product development partnerships, ministries of health and WHO and other partners participate in disease surveillance to inform vaccine value and impact Academic Institutions, biotech: Regulators: oversee the design of clinical WHO's SAGE: formulates global policy by Procurement Financing Vaccine e.g. Antigen/platform/assays/ models for preclinical studies and vaccine authorization for considering evidence related to safety, efficacy, agencies, orgs\*\* could manufacturers: proof of concept and translation to the clinic clinical trial and commercial use programmatic suitability, impact on equity etc (e.g. UNICEF, be global, (e.g. commercialize the PAHO) WHO PQ: e.g. considers quality (including Gavi, Global Vaccine developers and manufacturers: e.g. as for academics/biotech; may in-license from vaccine at scale develop GMP aspects), safety, efficacy and academics/biotech or develop in house; includes process development, manufacturing scale Fund), or tenders and programmatic fit up, sponsorship of regulatory submissions, clinical studies and licensure strategy regional pricing strategies Vaccine impact modellers and epidemiologists: Model health and economic impact to guide development and investment and inform policy Communities and civil society organizations: advocate/articulate demand for vaccines, participate in acceptability studies, inform vaccine parameters and aspects of clinical trial design and implementation/operational research

Country (NITAG) and/or regional (RITAG) policy makers\*and national TB programme interpret global policy in relation to the

regional context to inform local policy and introduction decisions

Vaccine R&D funders and product development partners (e.g., BMGF, NIAID, Wellcome Trust, IAVI, PATH, etc)

Global organizations (e.g. BMGF, Wellcome, UNITAID, Global Fund, USAID) may support pilot or implementation/postlicensure effectiveness or pharmacovigilance studies and are crucial to informing policy

EPI managers and healthcare workers can help to assess the acceptability and feasibility of vaccine delivery in pre-introduction research

SAGE: Strategic Advisory Group of Experts on Immunization: PQ: pregualification: 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);

Ministry of health and Ministry of

finance determine whether or not to procure a vaccine, either through e.g. UNICEF, PAHO or bilaterally

> develop a national immunization strategy and deliver the vaccine through the immunization programme

Alliance expanded partners including partners working in humanitarian settings, local and civil society organizations) to support vaccine introduction and implementation with a particular focus on equity and

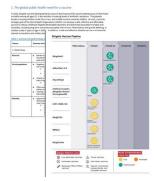
EPI managers and healthcare workers,

PHC Implementation partners (e.g. WHO, UNICEF, Gavi vulnerable populations

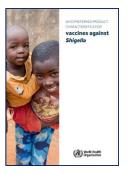
<sup>\*\*</sup> Financing by Gavi and procurement by UNICEF is contingent on WHO prequalification and policy recommendation

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





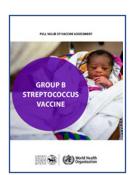




What's known?

What's needed?

What attributes?



What impact?

WHO Evidence
Considerations
for Vascine Policy
Development
for Tuberculosis
Vascines Intended
for Adults and
Adolescents

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
- Influenza (value assessment)
- Salmonella (PPCs and Roadmaps)
- TB (clinical and policy)
- Combination vaccines
- Klebsiella

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

# Overview of existing technical guidance documents

Vaccine	Preferred Product Characteristics (PPC)	Vaccine Value Profile (VVP)*	Full Vaccine Value Assessment (FVVA)	R&D Roadmap	Evidence Considerations for Vx policy (ECVP)	Other
ТВ	Vaccines for infants, adults and adolescents, therapeutic	In progress		<u> </u>	<u> </u>	Global framework for country introduction
HIV	Monoclonals					
Shigella	Vaccines for infants	<u> </u>	*			
Gonococcus	Vaccines for young people	<u> </u>				
RSV	Monoclonals for infants Vaccines for infants	<u> </u>		<u> </u>		
ETEC	Vaccines for infants	<u> </u>		*		
HSV	Vaccines for young people	<u> </u>				
GAS	Vaccines infants and young children  To be revised		*	<u> </u>		
Next- generation Influenza	Improved influenza vaccines Universal-type influenza A vaccines Revised – version 2 to be discussed		In progress			
GBS	Vaccines for pregnant women				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, Salmonella enterica serovar Paratyphi A, Leishmaniasis, Chikungunya, Hookworm, Schistosomiasis, Klebseilla, Non-thypoidal salmonella; \* developed by partners,

# The PDVAC ecosystem

WHO policy & PreQual. **Pivotal** Clinical Introduction Registr-**Discovery & Early** Sustainable Efficacy **Procurement** Proof-of-**Financing** clinical ation Supply preclinical study Concept **Implementation** Effectiveness/Pharmacovigilance



IA2030 envisions a world where everyone, everywhere, at every age, fully benefits from vaccines to improve health and well-being.

PDVAC: product development





Full vaccine Value assessments; PPC and R&D Roadmap are critical

IVIRAC: Immunization and Vx Related Implementation Research AC

Need and timing for norms and standards; timing of regulatory approval is critical

ECBS: Expert Committee on Biological Standardization

Need, timing and scope for market study; timing of regulatory approval is critical

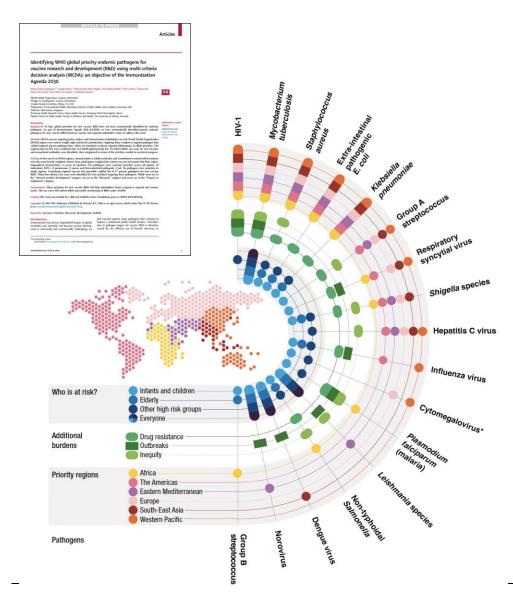
TAG on Market Access for Vaccines

Early engagement on vaccines for global policy; PPC; ECVP and FVVA are helpful

SAGE: Strategic Advisory Group of Experts on Immunization

Early engagement vaccine priorities, vaccine attributes and evidence needs RITAGs: Regional immunization technical advisory groups

# PDVAC's link to IA2030 Strategic Priority 7



# Objective 7.2: To identify R&D priorities: list of global endemic pathogen targets for new vaccines

Action categories:	Research	Advance Product Development	Prepare to Implement	
Pathogens:	Group A streptococcus Hepatitis C virus HIV-1 Klebsiella pneumoniae	Cytomegalovirus     Influenza virus     (broadly protective vaccine)     Leishmania     species     Non-typhoidal     Salmonella      Norovirus     Plasmodium     falciparum     (malaria)     Shigella species     Staphylococcus     aureus	Dengue virus     Group B streptococcus     Extra-intestinal pathogenic E. coli     Mycobacterium tuberculosis     Respiratory syncytial virus	

#### 17 Pathogens; 34 total use cases

Indicator	Definition
SP 7.2 a	% of use cases that have vaccines or monoclonal antibodies (mAbs) in Phase 3 trials
SP 7.2 b	% of use cases with licensed vaccines or mAbs that have supportive or permissive policy recommendations  • Licensed: by WHO-listed authority (WLA) or transitional WLA  • Policy recommendations: by SAGE if within SAGE scope, by a NITAG if not in SAGE scope

Webinar posted at: https://youtu.be/b0AbwShNuV0?si=e0SA6AUOHD4kwtTf

# Contributors to the IA2030 Endemic Pathogen Prioritization

## Strategic discussions and guidance

PDVAC Members and meeting participants SAGE Members and

meeting participants

SP7 Working Group members and meeting participants

WHO IVB and AFRO VPD Gavi policy team

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## Methodology advice

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#### **Translation review**

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regional and

country levels

#### **Consultation partners**

African CDC
Global NITAG Network
PAVMN, Africa
HITAP, Thailand
WHO regional offices,
CEPI, WHO R&D Blueprint
team members

#### **Project team**

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#### <u>Bridges to Development</u> Angela Hwang

Ísis Umbelino Alan Brooks Anastasia Pantelias Maria Dreher

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# Objectives of this meeting

- > PDVAC endorsement of:
- the approach to develop a strategic framework for development of combination vaccines.
- the revised PPC for next generation influenza vaccines;
- the R&D roadmap and PPC for S.
   Typhi/Paratyphi A bivalent vaccines.
- Building on the endemic pathogen prioritization list, identification of priority vaccines and vaccine use cases for IVB and PDVAC focus
- Proposed areas/actions/priorities where IVB and PDVAC should engage to guide product development for vaccines and monoclonals for global endemic pathogen priorities.

### Three types of session:



For endorsement – related to approval of guidance documents, such as PPCs, that have been developed by technical advisory groups and been through public consultation



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



For information: relevent information that is helpful to know.

# Orientation to the PDVAC website: All slides and reports

