WHO *Evidence Considerations* for *Vaccine Policy* Development (ECVP): generic framework for vaccines/monoclonal antibodies in development

1. The concept and strategic intent of the WHO Evidence Considerations for Vaccine Policy (ECVP) framework.

1.1 Purpose and intended audience of the WHO ECVP guidance

There are frequently significant delays between vaccine licensure and introduction in lower income countries [1], sometimes requiring the generation of data post-licensure to support definitive policy and/or introduction decisions [2]. The WHO Evidence Considerations for Vaccine Policy (ECVP) framework is a new approach to facilitate the early engagement and consequent alignment between the stakeholders involved in vaccine development and those that are responsible for regulatory, policy and introduction decisions, on the intended use cases and aspirations for policy recommendations. It aims to mutually outline the clinical trial and observational data or evidence anticipated to be needed for policy decisions for new vaccine classes, and thereby to minimise delays between vaccine licensure and policy formulation, adoption and introduction, particularly in lower income countries.

The promotion and accelerated development of vaccines with optimal suitability and effectiveness for use in LMICs is a major objective of the World Health Organisation (WHO), as elucidated in the Immunisation Agenda 2030 (IA2030) [3]. Under the auspices of its Product Development for Vaccines Advisory Committee (PDVAC) [4]), WHO develops Preferred Product Characteristics (PPCs) for new vaccines in WHO priority disease areas, early in clinical development. PPCs articulate preferential product characteristics for programmatic use and impact, and whilst some policy, implementation, and practice components are alluded to, the data and evidence needs for policy consideration are not directly addressed. Enhanced clarity on what is required for establishing global policy recommendations may limit bottlenecks and shorten time to introduction and use if the data needs can be anticipated and generated during development programmes. However, no formal mechanisms or systematic approaches currently exist to align stakeholders on the essential evidence anticipated to facilitate global policy recommendations and country introduction decision-making for pipeline vaccines, and to communicate this to vaccine developers.

The ECVP is intended to engage and align the multiple stakeholders who have an interest in the vaccine policy and introduction pathway. For example, while regulators review the safety, quality and efficacy data to approve a vaccine, licensure alone is insufficient for policy and deployment; national and global policymakers need to consider additional aspects such as cost-effectiveness, programmatic fit and performance against other outcomes that may not have been definitely quantified during clinical trials for regulatory approval, such as those that might impact vaccine transmission on a population level; vaccine developers/manufacturers/funders need clarity on what data is needed to position a vaccine for policy consideration to ensure vaccine use and return on investment; immunization partners seek to ensure the vaccine is acceptable to and effective in end-users who both deliver and receive the vaccine. The ECVP also seeks to catalyse early discussion with the various WHO advisory committees beyond PDVAC,

including the Immunization and vaccines related implementation research advisory committee (IVIRAC) and the Global Advisory Committee on Vaccine Safety (GACVS) and ultimately WHO Strategic Advisory Group of Experts on Immunization (SAGE) [5].

1.2 The development of the ECVP concept and generic framework

The ECVP concept was developed through consultation beginning in May 2021, with preventive TB vaccines intended for adults and adolescents proposed as the first exemplar. Both the concept of a generic vaccine ECVP framework, and the specific need for such a tool in the context of TB vaccines for adults and adolescents was discussed. Stakeholders involved in the ECVP consultation included vaccine developers, regulators, financing and procurement agencies, national and regional immunization technical advisory groups (NITAGs and RITAGs respectively), country level decision makers, researchers, technical experts and representatives of civil society [6]. In addition to published WHO PPCs for priority vaccines [7], there was broad and robust consensus on the need for earlier policy guidance for priority vaccines in general.

As such, this generic ECVP template has been developed by an expert working group of stakeholders described above. The framework can be adapted to describe the appropriate considerations for other vaccines against priority pathogens. The exemplar ECVP for TB vaccines intended for adults and adolescents has been drafted by that same expert working group, including TB subject matter experts, and consultation of the draft is underway.. Once finalised, the ECVP framework will be published on the WHO PDVAC website. The depth and specificity of the guidance within ECVPs will likely differ depending on the stage of vaccine development and the level of certainty of each parameter for the particular vaccine; early ECVPs may be more general. For this reason, the ECVP guidance will be updated throughout the development and lifecycle of the vaccine.

1.3 The process of developing WHO ECVP guidance for vaccines against priority diseases, and selection of priority vaccines for the ECVP framework

In accordance with Strategic Priority 7 of IA2030 (on Research and Innovation), priority disease areas are identified by WHO's expert Product Development for Vaccines Advisory Committee (PDVAC), in partnership with regional and country level stakeholders [8]. Development of ECVP guidance may be considered warranted when a number of vaccine candidates are poised to enter, or are already in phase 3 clinical development. WHO initiates the process by establishing a subject matter expert working group to develop the vaccine-specific ECVP. The initial vaccine ECVP draft will undergo broad and public consultation. It will also undergo informal review by WHO's SAGE to assess its potential utility and role in the product development process, prior to finalization. While vaccine manufacturers are critical stakeholders, WHO policy precludes their involvement in the ECVP development process because of perceived conflict of interest. However, their input will be invited through bilateral discussions with WHO on product development/licensure plans, as well as broader WHO stakeholder convenings on the potential approval pathways that also included regulators. Vaccine manufacturers will be invited to comment on the draft during public consultation of the ECVP document.

This generic ECVP framework, and the vaccine-specific ECVP documents represent the current understanding of what will likely be important for global policy recommendation but it is not a formal WHO guideline; it uncovers gaps in knowledge, such as the specific pre-implementation research studies that are needed to inform policy and it aims to serve as a foundation for future discussion. Depending on

the stage of product development, the ECVP is expected to be reviewed and potentially revised within 24-36 months of publication to remain current, and revisited every 24-36 months, to ensure continued stakeholder alignment. Triggers for ECVP revision may be catalysed by scientific advice from national regulatory authorities on the efficacy study designs, new information on anticipated delivery or program integration strategies or clarity on what specific pre-implementation research is needed, for example.

1.4 The relationship of the WHO ECVP and the WHO Strategic Advisory Group of Experts on Immunization (SAGE)

Although the ECVP template is based on SAGE's evidence to recommendation decision making framework, it should be noted that the ECVP discussions and the considerations document itself are not associated with the independent SAGE evidence to recommendation process that is required for all vaccines seeking WHO policy recommendation, and does not preclude or supersede the SAGE process. However, vaccine-specific ECVPs will be reviewed by SAGE before finalization, and the ECVP existence will likely catalyse earlier formal discussions with SAGE on the anticipated evidence needs for future policy deliberations on priority vaccines, as they approach pivotal studies.

To maintain the independence of SAGE, there will be no overlap in SAGE members who participate in development of a vaccine ECVP and the SAGE working group members for that vaccine, the latter which is usually established a vaccine approaches licensure, approximately 3 years after the ECVP development (assuming the ECVP is developed prior to phase 3 clinical study design).

1.5 The structure of the ECVP, and guidance on its interpretation

The ECVP document includes six tables to describe the following parameters:

- Table 1: Vaccine Product Related Parameters
- Table 2: Regulatory Strategy Considerations for Initial Licensure
- Table 3: Vaccine Delivery related Parameters for the Priority Populations
- Table 4: Vaccination of Specific Populations
- Table 5: Implementation Considerations
- Table 6: Engagement and potential timelines or triggers

Each section identifies:

- High Priority parameters in red: expected to be critical for SAGE and other policy bodies at the regional and country level;
- Medium Priority parameters in blue: for which data and evidence are likely to be beneficial for policy recommendation.

Tables 1, 3, and 4 stratify the attributes and data that are expected to inform **initial policy recommendations** in the priority target population/s, likely based on licensure and pre-implementation studies vs. **expanded policy recommendations** in additional key populations that are likely based on phase IV/effectiveness studies.

Please note that while the ECVP identifies the data and evidence anticipated to inform policy and introduction decision-making for vaccines of particular importance to lower income countries, and proposes the various stakeholders that are essential to engage across different parameters (see section

6), *it does not identify the entity responsible for resourcing and generating the data*. The funding for the proposed evidence-generation studies, vaccine introduction activities, and purchase of vaccines is likely to come from several sources/entities and will require collaboration and co-ordination across organisations in both the public and private sector.

General notes:

HIGH PRIORITY parameters are listed in red, i.e**.** attributes and/or policy considerations that are expected to be **critical** for key stakeholders (including national regulatory agencies, SAGE, country level decision makers and NITAG/RITAG members)

MEDIUM PRIORITY parameters are listed in blue, i.e., attributes and/or policy considerations for which data and evidence are likely to be **beneficial** for licensure or policy considerations

Definitions of parameters are shown in *italics* in the parameter column. In some cases, the parameter may not be applicable to the vaccine or the indication for which the ECVP is being developed. In this case, please insert 'not applicable'.

Tables 1,3 and 4 describe parameters and data expectations for both initial and expanded policy. **Initial Policy** denotes considerations for initial/interim policy recommendations based on data from licensure and pre-implementation studies. **Expanded Policy** denotes considerations for expanded policy recommendations; data supporting expanded policy could be generated to address gaps in and expand Initial Policy recommendations.

Please note that in instances where a vaccine parameter is proposed to inform initial policy, the assumption is that this is also relevant for expanded policy, however there may be additional considerations in the case of expanded policy. In these scenarios, the parameter should be stratified and described for both initial and expanded policy.

Table 1: Vaccine Product Related Parameters

	Critical parameters Beneficial parameters	Preferential vaccine product attributes	Initial Policy	Expanded Policy	Supportive data required	Rationale
1.1	Disease indication *(effect expected of the vaccine e.g. prevention of disease, severe disease, infection, transmission, recurrence)*					
1.2	Priority Target Population/s *(the populations who are most at risk of disease and will be the primary recipients of the vaccine following licensure)*					
1.3	Target countries *(countries where the vaccine is intended to be introduced soon after vaccine licensure)*					
1.4	Duration of protection for the disease indication					
1.5	Schedule *(dosing regimen for the primary series)*					

	Critical parameters Beneficial parameters	Preferential vaccine product attributes	Initial Policy	Expanded Policy	Supportive data required	Rationale
1.6	Schedule *(dosing regimen for booster)*					
1.7	Route of administration					
1.8	Co-administration with other vaccines *(administration of more than one vaccine on the same day, as part of the expected delivery schedule)*					
1.9	Measure of efficacy *(percentage reduction of outcomes of interest in the vaccinated compared to the unvaccinated group under optimal conditions e.g. randomized controlled trial)*					
1.10	Efficacy endpoints in the clinical trial *(utilizing standardized case definitions as feasible)* *- Primary endpoints (e.g. prevention of disease indication in*					

	Critical parameters Beneficial parameters	Preferential vaccine product attributes	Initial Policy	Expanded Policy	Supportive data required	Rationale
	the target population with/without laboratory confirmation)					
1.11	Secondary and exploratory endpoints *(endpoints not selected as the primary endpoint, such as infection, specific disease complication)*					
1.12	Safety/reactogenicity					
1.13	Measure of Effectiveness *(i.e. ability of vaccine to prevent outcomes of interest in the real-world setting)*					
1.14	Measure of efficacy/ effectiveness against variant/s of concern or bacterial antigenic variation					
1.15	Measure of Immunogenicity *(type of immune response/s that the vaccine generates and their magnitude over time, should reference a*					

	Critical parameters Beneficial parameters	Preferential vaccine product attributes	Initial Policy	Expanded Policy	Supportive data required	Rationale
	correlate/ surrogate of protection if known)					

Table 2: Regulatory Strategy Considerations for Initial Licensure

Regulatory strategies for initial licensure will be specific to individual countries and the maturity of their national regulatory authority (NRA). Countries with a NRA operating at WHO maturity level 3 or higher for vaccines [9] may facilitate WHO prequalification (PQ), whereas those with less established NRAs may rely on WHO PQ or a reliance model/collaborative procedure with other agencies for approval. WHO PQ will be essential for accelerating approvals in countries not having mature NRAs and to support vaccine financing. Joint or harmonized reviews between NRAs are an important consideration which might accelerate approvals in all high burden countries (HBCs) and should be planned for before or during licensure studies.

	Regulatory strategy for initial licensure	Regulatory considerations	Rationale
2.1	Anticipated National Regulatory Authority (NRA) for initial licensure and its maturity level [9]		
2.2	Anticipated WHO prequalification strategy *(i.e. may include EU-Medicines for all (EU-M4all) [10]*		
2.3	Potential for expedited regulatory approval *(e.g. conditional marketing (or use) authorization (CMA or CMA [11, 12] or emergency use mechanism other*		

	Regulatory strategy for initial licensure	Regulatory considerations	Rationale
	accelerated or parallel pathway)[13]		
2.4	Potential for WHO Emergency Use Listing [14]		
2.5	Potential/ need for a joint or harmonised review strategy *(e.g. African Vaccine Regulatory Forum (AVAREF) [15], International Coalition of Medicines Regulatory Authorities (ICMRA)) [16]*		

Table 3: Delivery related Parameters

Vaccine developers are advised to generate data in adherence with the mandatory, and where possible the preferred criteria described in WHO's PSPQ guidance [17] on vaccine thermostability, storage temperature and presentation.

	Critical parameters Beneficial parameters	Preferential vaccine product attributes	Initial Policy	Expanded Policy	Supportive data required	Rationale
3.1	Vaccine delivery strategy/s for the primary target population *(e.g. routine, mass vaccination, school based) and potential for delivery integration into existing country programs*					

	Critical parameters Beneficial parameters	Preferential vaccine product attributes	Initial Policy	Expanded Policy	Supportive data required	Rationale
3.2	Vaccine thermostability and storage temperature requirements *(including during transportation to the point of administration, to determine suitability for use in LMICs)*					
3.3	Presentation *(including vial size, cold chain storage volume for secondary packaging, diluents, formulation (e.g. liquid, freeze dried), vaccine vial monitor, may include reference to application devices e.g. jet injector, if applicable)*					

Table 4 – Vaccination of Specific Populations

Vaccination of specific key populations (should be categorized as high or medium priority for a particular vaccine, or black when the population is not relevant/appropriate). For each key population, this table lists the important clinical considerations, and whether the population is a priority for initial or expanded policy and proposed delivery strategy. Please note that in instances where a population sub-group is proposed to inform initial policy, the assumption is that this is also relevant for expanded policy.

	Key populations	Clinical considerations	Initial policy	Expanded policy	Proposed Implementation strategy	Rationale
4.1	Persons living with HIV (PLHIV) *(diagnosed, anti-retroviral (ARV) controlled)*					
4.2	Persons living with HIV – undiagnosed or poorly controlled on ARVs					
4.3	Persons with diabetes					
4.4	Immunocompromised and immuno-suppressed persons, and those with autoimmune disease					
4.5	Malnutrition					
4.6	Persons who have previously had disease of interest *(i.e. people with a history of xx disease)*					
4.7	Persons with current disease of interest *(i.e. active disease with a positive diagnosis)*					
4.8	Persons with severe allergic reactions to vaccine components/ similar vaccine platforms					

	Key populations	Clinical considerations	Initial policy	Expanded policy	Proposed Implementation strategy	Rationale
4.9	Other key populations (e.g. migrants, refugees, homeless, living in high-risk congregate settings, drug users, alcoholics, miners, people living in high density areas)					
4.10	Pregnant persons					
4.11	Lactating persons					
4.12	Neonates (less than 1 month)					
4.13	Infants (less than 1 year)					
4.14	Children (1-9 years)					
4.15	Adolescents (defined by ICH as 12-18 years)					
4.16	Adults (18- 64 years)					
4.17	Persons older than 65 years					

Table 5. Implementation Considerations

Please note: this table provides information on the type of data that could inform policy, financing and introduction decisions by multiple actors, including policy-makers at the national, regional and global levels, as well as global financing agencies such as Gavi, civil society organisations and implementation partners such as Medicines sans Frontiers or the International Committee of the Red Cross and non-governmental organizations, who often fund studies to generate this data and evidence. It represents an initial view of the evidence that is believed will be important to support decision-making, and **is intended to serve as a starting point to catalyse dialogue with regard to refining the data needs and expectations from different stakeholders depending on their specific contexts and policy scenarios.** For this reason, the information in this table is not stratified by initial and expanded policy; data on many parameters will be necessary for initial policy making but needs further discussion within the specific vaccine introduction context, i.e., the precise evidence needs for a self-procuring middle-income country may be distinct from a lower-income, Gavi supported country, and this needs to be further elucidated. The parameters that are believed to be most important are shown in red (critical parameters).

It is anticipated that the studies and data described below will be generated by multiple stakeholders, potentially working in collaboration. Several parameters will form part of the Gavi vaccine investment strategy (VIS) and likely needed for Gavi financing and initial policy introduction in Gavi-supported countries. Some of this evidence generation will be commissioned directly by Gavi. If available, this information may also be helpful for countries who are not Gavi-supported or when making initial or expanded policy decisions.

The tables below may not be exhaustive; global, regional and national implementation partners may have unique data/evidence requirements to facilitate delivery in fragile and/or conflict settings. These partners should be consulted if they are intended to be engaged in the vaccine implementation strategy. This section may be particularly helpful for vaccine developers, as it offers improved granularity on the types of data that will likely inform policy decisions. To rationalise investment in late-stage vaccine development, and to facilitate initial policy and procurement decisions, it is intended that many of these activities will be initiated during clinical development and will likely be based on modelling estimates in early iterations. These estimates will be refined as data on the vaccine characteristics become available, for example related to efficacy and duration of protection, and modelling estimates are supplemented with (pre-)implementation and operational research data.

Overarching activities related to implementation should include development of **communication strategies** to facilitate vaccine acceptability, build awareness, and generate demand. This requires generation of a **robust communications and community engagement plan/program**, vaccine-related events (VRE) response plan, and supporting materials which are updated throughout the development process. Issues and myths on the disease and vaccination need to be identified and addressed, prior to and during vaccination campaigns.

	Parameter	Supportive data required	Rationale & notes
5.1	Feasibility *(i.e., practicality of vaccine implementation, including in HBCs (considering the logistics, delivery, and program relate considerations)* [18]		
5.2	Values and preferences of the target populations for vaccine *(i.e., the likely acceptability of the vaccine in the target populations and other key stakeholder groups)*		
5.3	Demand potential *(i.e., visibility into future uptake and market size, including for HBCs, that can inform market shaping discussions with stakeholders including donors, industry partners, and vaccine purchasers)*		
5.4	Health Impact *(i.e., the benefit of vaccination to the vaccinated individuals, and to the wider population [including indirect effects])*		
5.5	Economic impact		

	(i.e., contribution of vaccine introduction to micro- and macro-economic benefits per country)		
5.6	Value for money *(i.e., estimates on likely utility derived from budget spent in the target populations)*		
5.7	Economic evaluation/Alternative interventions *(i.e., Comparison of the cost and benefits, also relative to alternative treatment and prevention policy options [19]*		
5.8	Equity and social protection impact *(i.e., prioritizing the needs and rights of the most vulnerable, and ensuring equitable benefit from vaccines)*	•	
5.8	Access and affordability *(i.e., ensuring that the vaccine will be made broadly and equitably available at an affordable price)*		
5.9	Global health security impact *(i.e., the potential benefit of the vaccine in*		

	averting bio-security risks)		

Table 6: Engagement and potential timelines or triggers

This table provides guidance on the specific activities that would signal engagement with the multiple key stakeholders involved in vaccine product development, licensure, policy and implementation.

Two pathways are described:

A) The national policy development pathway, in which a country licenses a vaccine for introduction, with recommendations from the National Immunization Technical Advisory Group (NITAG), for a self-procuring country, and;

B) The global policy development pathway, which requires a recommendation from WHO's SAGE, as a prerequisite for WHO PQ. Financing by Gavi and procurement by UNICEF and the PAHO Revolving Fund are dependent on WHO policy and prequalification.

Although not explicitly shown in the pathways below, pilot demonstration studies may be needed to assess feasibility/acceptability and cost-effectiveness, to inform introduction decision-making. However, the intent of the ECVP is to avoid a scenario where vaccine introduction would be delayed until demonstration studies have been completed.

For each activity along the late-stage product development to uptake continuum, stakeholders are described according to the RACI matrix where:

R = Responsible: Who is responsible for undertaking the activity

A = Accountable: Who is accountable for the success of the activity and is the decision-maker

C = Consulted: Who needs to be consulted for technical or specialized input

I = Informed: Who needs to be informed and aware of this activity

A) The <u>national</u> policy development pathway

Stakeholder	Proof-of-efficacy	Registration	NITAG review	Country introduction (i.e. includes financing and procurement)	Phase IV/effectiveness studies
Vaccine developer/manufacturer					
Regulatory Authority(ies)					
Policymakers at the country level (National Immunization Technical Advisory Groups*)					
Political (government representatives/agencies, i.e. Ministry of health/finance)					
Funders/ Donors (if required)					
Civil society organizations					
Implementation partners (nationally and sub-nationally)					
National immunization programme					
Disease control programme					

B) The <u>global</u> policy development pathway

Stakeholder	Proof-of-efficacy	Registration	WHO policy & PQ	Vaccine financing	Vaccine procurement	NITAG review	Country introduction (i.e. includes financing and procurement)	Phase IV/ effectiveness studies
Vaccine developers/ manufacturers								
Regulatory Authority(ies)								
Global Policymakers (i.e. WHO and WHO SAGE)								
Political (government representatives/ agencies i.e. Ministry of health/finance))								
Funders/Donors (if required)								
Procurement agencies (i.e. UNICEF or PAHO Revolving Fund)								

Stakeholder	Proof-of-efficacy	Registration	WHO policy & PQ	Vaccine financing	Vaccine procurement	NITAG review	Country introduction (i.e. includes financing and procurement)	Phase IV/ effectiveness studies
Regional / national policy makers (RITAGs/NITAGs)								
Civil society organizations								
Implementation partners (nationally and sub- nationally)								
National immunization programme								
National disease programme								

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