

# Assessing the Programmatic Suitability of Vaccine Candidates for WHO Prequalification

Immunization, Vaccines and Biologicals



World Health  
Organization

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# Abbreviations & acronyms

AD	auto-disable
DCVMN	Developing Country Vaccine Manufacturers' Network
EPI	Expanded Programme on Immunization
gPPP	Generic Preferred Product Profile
HBV	hepatitis B virus
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IPAC	Immunization Practices Advisory Committee (WHO)
IVB	Department of Immunization, Vaccines and Biologicals (WHO)
MD	multi-dose (vial)
MDVP	Multi-dose Vial Policy (WHO)
PAHO	Pan American Health Organization
PQ	prequalification
PSF	product summary file
PSPQ	Programmatic Suitability of Vaccine Candidates for WHO Prequalification
QSS	Quality, Safety and Standards Team (WHO)
SAGE	Strategic Advisory Group of Experts (WHO)
SD	single-dose (vial)
TechNet	Technical Network for Strengthening Immunization Services
TLAC	Technologies and Logistics Advisory Committee (WHO)
UNICEF	United Nations Children's Fund
VPPAG	Vaccine Presentation and Packaging Advisory Group
VVM	vaccine vial monitor
WHO	World Health Organization

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# 1. Foreword

Industry may never be able to create such a vaccine, but the aspiration to work towards the development of products that incorporate the essence of that dream — products that are low-cost, high-efficacy, heat-stable, multi-antigen, user-friendly and environmentally-friendly — is critical to uphold as the driving force underlying new and innovative vaccine development.

In recent years, the drive towards accelerated new vaccine development has tended to emphasize the important social benefits of reduced morbidity and mortality, in some cases at the expense of attention to many of the highly desirable product characteristics mentioned above.

As a result, new vaccines have emerged that, although generally safe and effective in the prevention of major diseases, often incorporate characteristics that are undesirable in a developing country setting — complex handling, high cold-chain capacity requirements, complex waste-disposal requirements and very high cost.

Experience has shown that, once a new vaccine product reaches the clinical trial stage, it is extremely costly and time-consuming to reformulate the product in order to incorporate additional characteristics that were not contemplated in the original experimental design. It is therefore crucial to consider packaging and presentation characteristics from the earliest stages of pre-clinical development. This is often done through reference to target product profiles.

It is important to disseminate guidance for industry, to assist product development teams and pre-clinical scientists, to identify characteristics and innovations that are highly valued in terms of future vaccine products intended for use in developing countries, and to vigorously encourage them to include those characteristics from the earliest stages of pre-clinical study. Previous work to develop such guidance includes that of the Malaria Vaccine Initiative<sup>1</sup>, the Target Product Profile (TPP) for the Advance Market Commitment (AMC) for pneumococcal conjugate vaccines<sup>2</sup> and the Vaccine Presentation and Packaging Advisory Group, which more recently developed a Generic Preferred Product Profile (gPPP)<sup>3</sup> for new vaccines. The World Health Organization (WHO) prequalification (PQ) process is the mechanism available to the international community to assess whether new vaccine products adequately feature mandatory, critical and preferred characteristics, and are suitable for use in developing countries.



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To achieve standardization and uniformity of the programmatic suitability requirement for prequalification, vaccines that are already prequalified, or were in the process of prequalification at the time of the implementation of this process and which are not compliant with its requirements will follow a transition process, described later in the document.

A Programmatic Suitability of Vaccine Candidates for WHO Prequalification (PSPQ) Working Group was formed and charged with drafting an initial version of this document early in 2010. The PSPQ Working Group was made up of representatives from national ministries of health, international organizations (WHO, UNICEF, PAHO) and others with experience in the procurement of vaccines and the management of national immunization programmes.

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## 2. Background

As part of WHO's vaccine prequalification (PQ) process, product summary files (PSFs) are assessed by the WHO PQ Secretariat to determine '*the suitability of the vaccine for the immunization services where it is intended to be used*' (p.6, WHO/IVB/05.19<sup>4</sup>). Assessed characteristics include '*... presentations offered ... labelling, information provided on package inserts ... , and packaging ...*'. This is part of the broader process intended 'to ensure that vaccines used in national immunization services in different countries ... meet particular operational specifications for packaging and presentation' (p.1, WHO/IVB/05.19<sup>4</sup>).

Although the assessment of the suitability of vaccines for the immunization services where they are intended to be used has always been part of PQ, historically, the assessment of the PSFs to determine programmatic suitability had not been formally structured, with the outcome based on individual expert inputs and WHO PQ Secretariat consensus.

In recent years, the emergence of unique vaccine presentations, such as relatively large packed volume pre-filled syringes that do not include an auto-disable feature, injection device materials that require non-standard disposal methods and fully liquid low multi-dose vials without preservative, has driven the need to explicitly define the characteristics that determine programmatic suitability and the process for assessing compliance with these characteristics.

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## 3. Purpose of this document

In this document we wish to describe clearly the screening process and set of rules by which all prospective vaccine prequalifications will be judged in terms of their programmatic suitability for developing country public-sector immunization programmes. We also describe the consequences of not complying with these characteristics on the screening and PQ processes. Furthermore, we wish to indicate very clear preferences for future vaccines that will result in greater compliance with developing country needs, and that will facilitate universal immunization without requiring massive and unrealistic investment in additional cold-chain capacity, human resources, waste-disposal facilities, etc.

Hence, the purposes of this document are as follows:

- to define the characteristics that determine programmatic suitability;
- to define the process for assessing compliance with these characteristics;
- to indicate vaccine characteristic preferences to industry and other vaccine-development groups.

The characteristics described here are to be used in a screening process that is intended to avoid the resource- and time-consuming process of formal PSF evaluation for vaccine candidates that are not in compliance with programmatic suitability characteristics.

WHO recognizes that programmatic suitability characteristics can vary by WHO region and expects that this variation will be expressed in the procurement and tendering process.

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# 4. Vaccine characteristics that determine programmatic suitability

## 4.1 Sources of information

Vaccine characteristics that determine programmatic suitability were identified by reviewing existing WHO Department of Immunization, Vaccines and Biologicals (IVB) policy and technical guidance, by reviewing current discussions in WHO IVB advisory groups, such as the WHO Technologies and Logistics Advisory Committee (TLAC) in 2008/2009 and the subsequent WHO Immunization Practices Advisory Committee (IPAC), by reviewing the work of groups such as the Vaccine Presentation and Packaging Advisory Group (VPPAG), through discussion with immunization programme personnel and by reviewing other relevant documents.

During this process it was recognized that, over the past few years, several groups have developed advice and recommendations on issues related to the programmatic suitability of vaccines destined for use in the public sector immunization programmes of developing countries. These include target product profiles for pneumococcal, rotavirus and human papillomavirus vaccines, the gPPP developed by the VPPAG, and topic-specific recommendations from the TLAC, such as those for thermostability and handling visual cues. It is expected that additional advice will be generated by IPAC.

## 4.2 Types of vaccine characteristics

Vaccine characteristics that were identified as determinants of programmatic suitability for prequalification were organized into three groups: mandatory; critical, and unique and innovative characteristics. A category of preferred characteristics is also identified (see Table 1 on page 8).

- ‘Mandatory’ characteristics: those for which compliance is compulsory at the time of application for WHO prequalification and which must be unconditionally met prior to evaluation of the PSF.
- ‘Critical’ characteristics: compliance with critical characteristics is also compulsory. However if, upon screening of the PSF, the PQ Secretariat identifies a deviation from the characteristic value, then it will refer the relevant section of the PSF to the PSPQ Standing Committee and inform the manufacturer of the screening results. The PSPQ Standing Committee can then make a recommendation, consulting with the manufacturer and additional technical experts when needed, and taking into account the public-health need, to accept or reject the application for prequalification and the evaluation of the PSF.

- By definition, there is no guidance regarding vaccine candidates with characteristics or characteristic values not otherwise specified as ‘mandatory’ or ‘critical’. Because of this, vaccine candidates with unique and innovative programmatic suitability characteristics will be referred to the PSPQ Standing Committee for review, discussion and recommendation.
- ‘Preferred’ characteristics are intended to reflect what WHO, procuring agencies and national immunization programmes would want in a best-case scenario and would expect in the future; these characteristics are intended as a guidance for manufacturers. It is expected that national immunization programmes and procuring agencies will select vaccines with preferred characteristics over those that do not have these characteristics. Compliance with preferred characteristics is not compulsory although, with time, these characteristics may become ‘critical’ characteristics.

The decision to grant approval to continue with the evaluation for prequalification can be taken only by the PQ Secretariat and Director IVB and will include consideration of recommendations from the PSPQ Standing Committee, issues such as the safety risk posed and the public-health importance of the vaccine, i.e. the impact on global and regional public health of a lack of access to the vaccine.

**Table 1: PQ Secretariat decisions regarding compliance and deviations with vaccine programmatic suitability characteristics**

Type of characteristic	Compliance	Deviation
Mandatory	Prequalification evaluation proceeds	Rejection of application for prequalification evaluation.
Critical	Prequalification evaluation proceeds	Referral to the PSPQ Standing Committee for review, discussion and recommendation. After consideration of the PSPQ Standing Committee advice, the vaccine may be accepted or rejected by the PQ Secretariat / Director IVB for prequalification evaluation.
Unique and innovative	Referral to the PSPQ Standing Committee for review, discussion and recommendation. After consideration of the PSPQ Standing Committee advice, the vaccine may be accepted or rejected by the PQ Secretariat / Director IVB for prequalification evaluation.	
Preferred	Prequalification evaluation proceeds.	

### 4.3 Vaccine characteristics that will affect the acceptance for prequalification

#### 4.3.1 Mandatory requirements

Mandatory requirements are those for which compliance is compulsory at the time of application for WHO prequalification and which must be unconditionally met prior to evaluation of the PSF (see Table 2 below and **Figure 2** on page 13). Table 2 presents mandatory characteristics and their values.

**Table 2: Mandatory vaccine characteristics and characteristic values**

Characteristic	Applies to...	Value
Anti-microbial preservative	Only vaccines that: <ul style="list-style-type: none"><li>are in ready to use (no reconstitution) presentation;</li></ul> and <ul style="list-style-type: none"><li>are in multi-dose containers of more than two doses per vial.</li></ul>	The vaccine presented for prequalification should be adequately preserved (WHO/EPI). This is defined by having either the standard thiomersal concentration (i.e. thiomersal concentration is >50 µg per ml for monovalent HBV vaccine and >100 µg per ml for other vaccines) or the preservative having demonstrated its anti-microbial efficacy to control contamination for 28 days using a multi-challenge test. [A generic protocol is available from WHO/QSS. Alternative testing approaches chosen by the manufacturer may be acceptable and will be reviewed on a case-by-case basis].
Thermostability / storage	All vaccines	The vaccine or any component presented for prequalification should not require storage at less than -20°C (WHO EPI).
Dose volume	Only vaccines that are: <ul style="list-style-type: none"><li>injectable;</li></ul> and <ul style="list-style-type: none"><li>indicated for infants and/or young children (&lt;5 years old).</li></ul>	The vaccine presented for prequalification should not be more than ml per dose for indicated use in children aged 5 years or younger (WHO EPI).

#### 4.3.2 Critical characteristics

Compliance with ‘critical’ characteristics is also compulsory. However, if upon screening of the PSF the PQ Secretariat identifies a deviation from the characteristic value, then the PQ Secretariat will refer the application to the PSPQ Standing Committee and inform the manufacturer of the screening results (see Table 3 below and **Figure 2** on page 17). The PSPQ Standing Committee can then make a recommendation, consulting with the manufacturer and additional technical experts when considered necessary, to accept or reject the application and the evaluation of the PSF. Table 3 shows critical characteristics and their values.

**Table 3: Critical vaccine characteristics and characteristic values**

Characteristic	Applies to...	Value
Schedule	All vaccines	<p>The following are deemed to meet this characteristic and do not require further review by the PSPQ Standing Committee.</p> <ul style="list-style-type: none"> <li>• If the proposed vaccine is meant for use in children under five, it should be recommended to be given at one or more of the following regular immunization visits: <ul style="list-style-type: none"> <li>- within 24 hours after birth; <ul style="list-style-type: none"> <li>or</li> </ul> </li> <li>- at not more than three visits, 4 to 8 weeks apart, with the first visit at or after 6 weeks of age and the third visit at or before 6 months of age; <ul style="list-style-type: none"> <li>or</li> </ul> </li> <li>- at not more than one visit between 9 and 24 months of age; <ul style="list-style-type: none"> <li>or</li> </ul> </li> <li>- at not more than one visit between 8 and 24 months of age; <ul style="list-style-type: none"> <li>or</li> </ul> </li> <li>- at not more than one visit in the fifth year of life.</li> </ul> </li> <li>• If the proposed vaccine is designed to be given to adolescents aged 9 to 15 years, it should require no more than four contacts through health service or school-based immunization programmes.</li> <li>• If the proposed vaccine is given as a single dose and designed exclusively for use in reactive campaigns (pandemics, disasters, humanitarian action).</li> <li>• If the proposed vaccine is given post-exposure.</li> <li>• If the proposed vaccine is targeted at individuals over 5 years of age, and dose intervals are two weeks or more apart.</li> </ul> <p>If the vaccine does not fit into one of the above criteria, it must be reviewed by the PSPQ Standing Committee (WHO EPI)</p>
Process of preparation for administration	Oral vaccines	<p>The vaccine presented for prequalification should be packaged in a single component/ready-to-use format (WHO EPI).</p>
Thermo-stability / storage	All vaccines	<p>The vaccine presented for prequalification should not require storage below +2°C for longer than 6 months (WHO/IVB/06.106).</p>
Vaccine vial monitor (VVM)	All vaccines	<p>Proof of feasibility and intent to apply a VVM to the proposed vaccine, as defined below.</p> <p>The vaccine presented for prequalification presents data confirming that it has a thermostability profile that will enable it to be matched to a current WHO-approved VVM type (VVM2, VVM7, VVM14 or VVM30) or a future VVM type approved by WHO (WHO/V&amp;B/99.187, WHO/IVB/07.048).</p> <p>Signed declaration, as part of the cover letter submitted along with the file for prequalification confirming that the manufacturer will apply a VVM to the vaccine, and has the technical capacity to do so if requested by the purchasing specifications.</p>

Characteristic	Applies to...	Value
Materials, primary and secondary packaging, and injection material	All vaccines	The vaccine presented for prequalification should be packaged in materials that can be disposed of appropriately in the field using standard procedures (e.g. pit burning and burying, low temperature incinerations, etc.) (WHO EPI).
Pre-filled injection devices	Only vaccines that are delivered in pre-filled injection devices	The vaccine presented for prequalification in a pre-filled injection device should include an auto-disable (AD) feature (WHO/V&B/99.25)9.
Dose volume	Only injectable vaccines	The vaccine presented for prequalification should be dosed in standardized volumes (e.g. 0.5, 0.1, 0.05 ml) that can be easily measured using available AD syringes (WHO EPI).
Anti-microbial preservative	Only vaccines that: <ul style="list-style-type: none"> <li>are in ready to use (no reconstitution) 2-dose vial presentations;</li> </ul> or <ul style="list-style-type: none"> <li>are not live attenuated, in multi-dose presentations and require reconstitution.</li> </ul>	The vaccine presented for prequalification should be adequately preserved* (WHO/EPI).
Antigenic stability after reconstitution	Only vaccines that: <ul style="list-style-type: none"> <li>are in multidose presentations;</li> </ul> and <ul style="list-style-type: none"> <li>require reconstitution of one or more components;</li> </ul> and <ul style="list-style-type: none"> <li>are adequately preserved.</li> </ul>	The components of the vaccine must show antigenic stability for 28 days after reconstitution. (Appropriate testing protocol may be chosen by the manufacturer and will be reviewed by the PQ Secretariat on a case-by-case basis).
<p>* This is defined by having either the standard thiomersal concentration (i.e. thiomersal concentration is &gt;50 µg per ml for monovalent HBV vaccine and &gt;100 µg per ml for other vaccines) or the preservative having demonstrated its anti-microbial efficacy to control contamination for 28 days using a multi-challenge test. [A generic protocol is available from WHO/QSS. Alternative testing approaches chosen by the manufacturer may be acceptable, and will be reviewed on a case-by-case basis.]</p>		

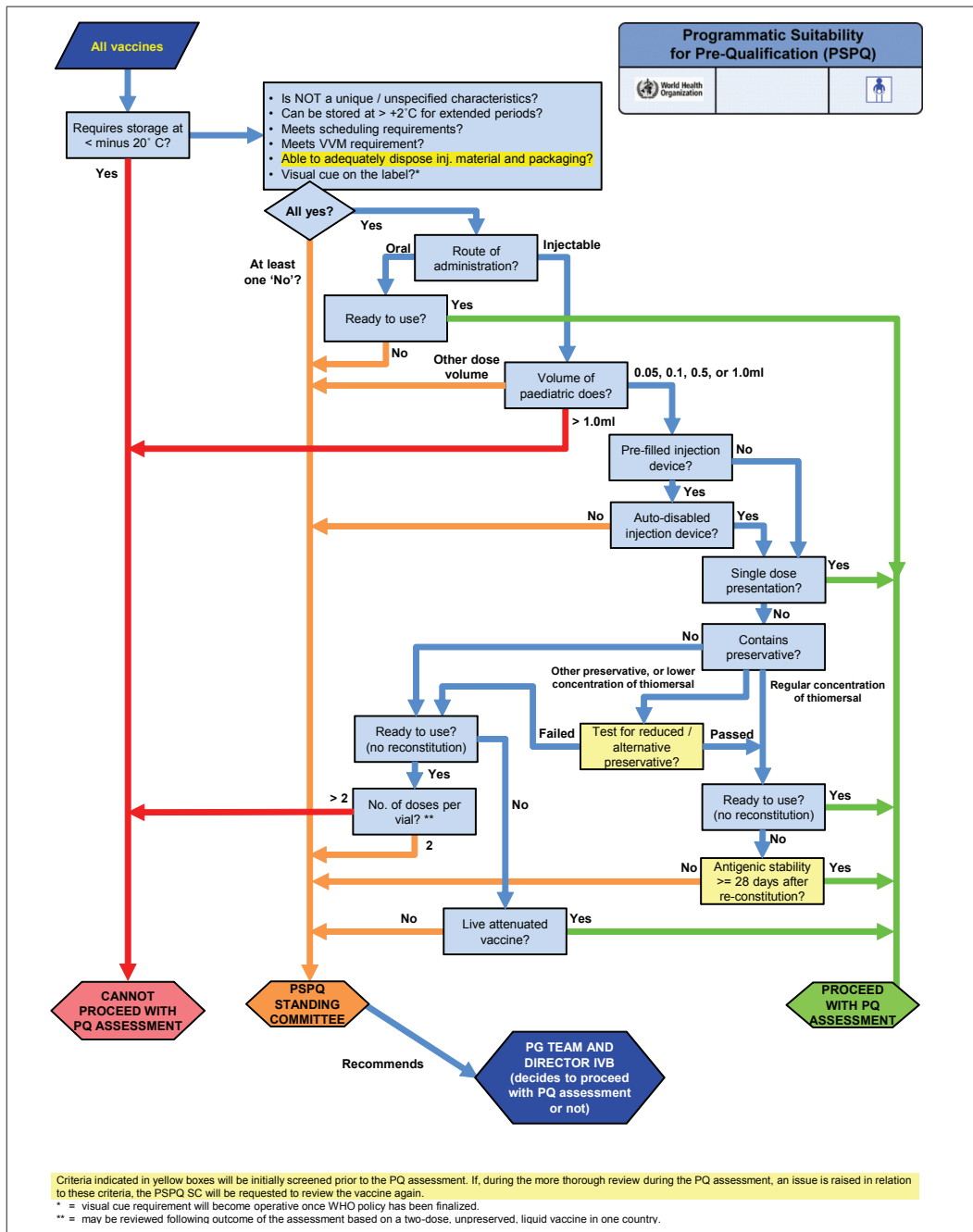
The following critical characteristic will become operative when WHO policy on visual cues has been finalized.

Visual cue regarding handling and discard	All vaccines in multi-dose vials	All proposed vaccines presented for prequalification that are, or can be used as multi-dose vials, should be marked on the label of the primary container with the appropriate WHO visual cue for handling and discard (VPPAG gPPP3: visual cue regarding discard; TLAC).
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**Please note:** For the application of the Multi-Dose Vial Policy<sup>10</sup> (MDVP), a decision will be made if a multi-dose vial can be safely kept open for subsequent vaccination sessions, or if the vial should be discarded at the end of the session. This decision will be made by the PQ Secretariat, based on the review of the data available to the PQ team. Should the vaccine have been referred to the PSPQ Standing Committee, the Standing Committee may make a recommendation on this decision, and the antigenic stability will then be taken into consideration.



Figure 1: Vaccine characteristics that affect acceptance for prequalification



Thus, for PQ, the decision on whether an opened vaccine vial should be discarded at the end of the session is an outcome of this process, not a criteria in deciding whether to start the prequalification assessment of a vaccine.

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### 4.3.3 *Unique or innovative characteristics*

By definition, there is no guidance regarding vaccine candidates with characteristics or characteristic values not otherwise specified as ‘mandatory’ or ‘critical’. As the use of fractional doses<sup>1</sup> is still experimental, any fractional dose use would fall into this category of ‘unique’ or ‘innovative’ characteristic, and would be referred to the PSPQ Standing Committee, irrespective of anti-microbial preservatives or antigenic stability.

Because of this, vaccine candidates with unique and innovative programmatic suitability characteristics will be referred to the PSPQ Standing Committee for review, discussion and recommendation. In such cases, manufacturers are advised to contact WHO at the early stages of vaccine development in order to discuss such characteristics, rather than presenting them at the time of PQ evaluation.

Figure 1 on page 10 presents a flow chart that describes the vaccines’ characteristics and their effects on acceptance for prequalification.

### 4.4 **Preferred characteristics: vaccine characteristics that reflect programmatic preference but will not affect the acceptance for prequalification evaluation**

Preferred characteristics will not be reviewed or assessed by the PSPQ Standing Committee because these characteristics will not directly influence the prequalification process. However, it is expected that national immunization programmes and procuring agencies will select vaccines with these preferred characteristics over those vaccines that do not meet these characteristics.

Preferred characteristics are intended to reflect what WHO, procuring agencies and national immunization programmes would want in a best-case scenario and would expect in the future; these characteristics are intended as guidance to manufacturers. Compliance with preferred characteristics is not compulsory, although with time these characteristics may become ‘critical’ characteristics. Table 4 shows preferred characteristics and their values.

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<sup>1</sup> For instance, using smaller vaccine quantities to immunize a person, frequently through the use of intradermal administration; this method allows a single-dose vial to be used for multiple vaccinations.

**Table 4: Preferred vaccine characteristics and characteristic values**

Characteristic	Applies to...	Value
Maximum packed volume	All vaccines	A smaller packed volume is preferred. Where appropriate, components should be packed/shipped together, e.g. for ready-to-use presentations: pre-filled AD syringe with needle, etc. Packaging devices should be considered, to assure components are shipped together, e.g. vial clip. (WHO EPI, VPPAG gPPP: maximum packed volume; see Guidelines on the international packaging and shipping of vaccines <sup>11</sup> .
Dose volume	Oral vaccines	Smaller volumes and standardized volumes are preferred (WHO EPI).
Doses per primary container, non-campaign setting	All vaccines	Vials with ≤10 doses per vial are preferred (WHO EPI, VPPAG gPPP: optimal number of doses per primary container, work programme).
Doses per primary container, campaign setting	All vaccines	Vials with ≥ 0 doses per vial are preferred (WHO EPI).
Doses per secondary container	All vaccines	Should reflect logistics schedule and needs in order to minimize stock accumulation at the peripheral level (WHO EPI).
Process of preparation for administration	All vaccines	Single component/ready to use (e.g. liquid) formats are preferred (WHO EPI). For multi-component vaccines, vaccines with a short and simple preparation process are preferred (WHO EPI).
Thermo stability / storage	All vaccines	Vaccines and diluents that can be stored for extended periods at temperatures above +8°C are preferred (TLAC).
Freeze sensitivity	All vaccines	Vaccines that are not damaged by freezing temperatures (<0°C) are preferred (TLAC).
Materials, primary and secondary packaging and injection material	All vaccines	Materials that minimize environmental impact are preferred (VPPAG gPPP: materials).
Secondary packaging, diluents and vaccines	Vaccines requiring reconstitution	Diluents and vaccines should have the same number of doses per secondary container.

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## 5. The process of screening vaccine candidates before evaluation of the Product Summary File (PSF)

In order to avoid the resource- and time-consuming process of PSF evaluation for vaccine candidates that are not in compliance with programmatic suitability characteristics, the characteristics identified here will be screened by the PQ Secretariat, with the support of the PSPQ Standing Committee, before evaluation of the PSF. The screening process has two objectives:

- to assess compliance with mandatory and critical characteristics;
- to identify other unique and innovative characteristics and assess their acceptability.

The PQ Secretariat screening process is shown in Figure 2.

After it is determined that a vaccine is a PQ priority<sup>2</sup>, vaccine candidates will be screened for compliance with the mandatory characteristic values. If screening reveals that mandatory characteristics are not met, then the submission will be rejected.

If there is compliance with mandatory characteristics, then the PQ Secretariat will assess critical characteristics and identify unique and innovative characteristics. Critical characteristics are important but, in the case of deviation, allowance is given for recommendations from the PSPQ Standing Committee. If identified, unique and innovative characteristics should be assessed by the PSPQ Standing Committee.

While all PSPQ criteria will be screened and evaluated initially, there are three critical criteria outlined in section 4.3.2 *Critical characteristics* which will be reviewed again in more depth at the beginning of the PQ assessment (i.e. the formal PSF evaluation). They are as follows:

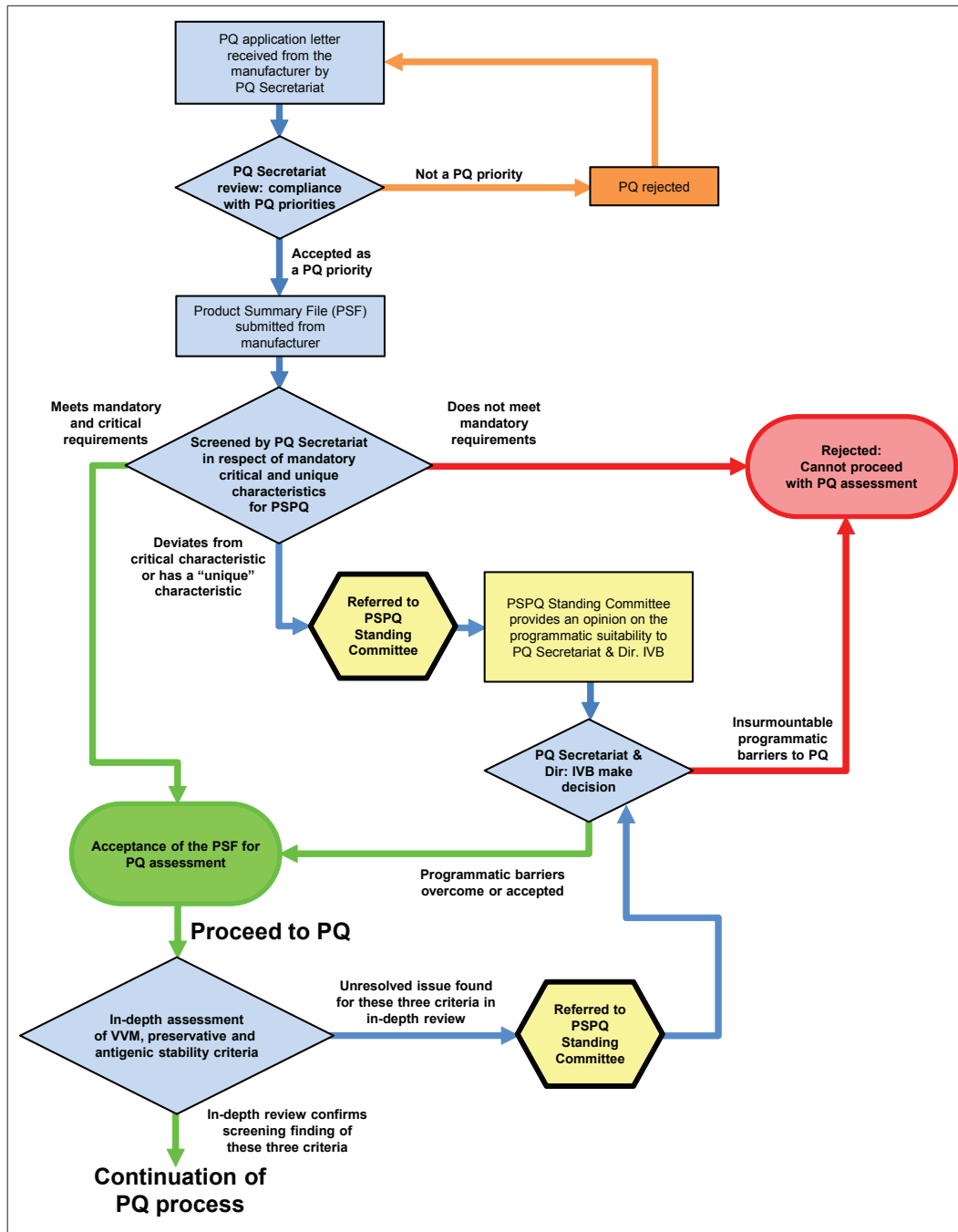
- vaccine vial monitor (VVM);
- anti-microbial preservative (absence, reduced concentration thiomersal or alternative preservative);
- antigenic stability after reconstitution.

If, during this in-depth assessment, a deviation from the criteria is found that was not recognized earlier during the screening, then the vaccine will be referred back to the PSPQ Standing Committee for a second time.

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<sup>2</sup> [http://www.who.int/immunization\\_standards/vaccine\\_quality/pq\\_priorities/en/](http://www.who.int/immunization_standards/vaccine_quality/pq_priorities/en/).

Figure 2: Process for screening WHO prequalification documents to determine programmatic suitability of the vaccine



As noted above, under special circumstances when there is limited access to a vaccine of public- health importance, applications for vaccine candidates that are non-compliant with critical characteristics may be granted approval for evaluation of the PSF by the WHO PQ Secretariat and the Director IVB.

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The decision to grant approval can only be taken by the PQ Secretariat and Director IVB and will include consideration of recommendations from the PSPQ Standing Committee, and any additional issues. The public-health impact, both globally and regionally, of not pre-qualifying a vaccine, will also be taken into consideration in the final decision. To reiterate: the referral for review of programmatic suitability by the Standing Committee of any given vaccine, implies neither rejection nor clear acceptance for prequalification. The review of the Standing Committee is thus put into place to allow human judgment on these vaccine features, after the company's representation, and to make a recommendation of this to the PQ Secretariat and the Director IVB.

## 5.1 The PSPQ Standing Committee

An important element of the screening process is the support provided by the PSPQ Standing Committee (see 10.1 Appendix 1: Terms of Reference: Programmatic Suitability of Vaccine Candidates for WHO Prequalification (PSPQ) Standing Committee).

The PSPQ Standing Committee serves as the main advisory body to the WHO PQ Secretariat and to the Director IVB on *'the suitability of the vaccine for the immunization services where it is intended to be used'* (p.6, WHO/IVB/05.19<sup>4</sup>) in order 'to ensure that vaccines used in national immunization services in different countries ... meet particular operational specifications for packaging and presentation' (p.1, WHO/IVB/05.19<sup>4</sup>).

The PSPQ Standing Committee mandate is to provide recommendations and technical advice, and to assist the WHO PQ Secretariat and Director IVB to make informed decisions based on information provided by manufacturers, the input of external technical experts and other resources.

The PSPQ Standing Committee advises the WHO PQ Secretariat and the Director IVB:

- on the programmatic suitability of vaccine candidates that are non-compliant with critical characteristics;
- on the programmatic suitability of vaccine candidates that present with unique and innovative characteristics.

The recommendations of the PSPQ Standing Committee will be based on information provided by manufacturers, the input of approved external technical experts and public-health needs.

The maximum allowed time for review by the PSPQ Standing Committee is three months. During a PSPQ Standing Committee review, the time clock for the PQ screening process will be stopped.

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## 6. Procedure for consultations requested by vaccine manufacturers before submission of an application for WHO prequalification

For discussion and interpretation of characteristics not described in the PSPQ paper, a vaccine manufacturer should contact the PQ Secretariat. The PQ Secretariat will identify a focal point who will arrange for a discussion between the manufacturer and the WHO PQ Secretariat. WHO may include the PSPQ Standing Committee in these discussions.

In this context, vaccine manufacturers may desire to request pre-application discussions with the WHO PQ Secretariat on prioritized vaccine candidates, or other vaccine candidates of public-health importance that:

- are non-compliant with mandatory characteristics;
- are non-compliant with critical characteristics;
- have unique and innovative characteristics.

As is the case with the application review process described above, the maintenance of confidentiality before, during, and after discussions is expected from all participants.

Although official minutes will be issued for the record of these discussions, the outcomes of the discussions are not binding on the WHO PQ Secretariat at the point of the prequalification assessment.

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# 7. Implementation of the PSPQ requirements

## 7.1 Timeline for implementation of the PSPQ

These new PSPQ guidelines came into effect at the end of 2011. As a result of this:

- 1) Any vaccine newly submitted for prequalification on or after January 2012 will be required to conform to the PSPQ guidelines as part of WHO's prequalification process.
- 2) Any vaccines that had been submitted to WHO for prequalification prior to, or on 31 December 2011, but where the prequalification process had not yet been completed by January 2012, were initially exempt from being required to adhere to the PSPQ guidelines.
- 3) Vaccines that had received WHO prequalification prior to January 2012 are not currently required to comply with the PSPQ guidelines.

## 7.2 Transition of PSPQ non-compliant products

To achieve standardization and uniformity of the programmatic suitability requirement for prequalification, vaccines that are already prequalified, or were in the process of prequalification at the time of the implementation of this process and which are not compliant with its requirements, will follow a transition process.

- All currently prequalified vaccines and vaccines that were in the process of being prequalified (items b and c above), will be screened against the PSPQ criteria by the PQ Secretariat before the end of 2012.
- Vaccines that do not meet the mandatory and critical characteristics will be referred to the Standing Committee for review, and the relevant manufacturer informed.
- If the Standing Committee report recommends that the non-compliance makes the product unsuitable for continued prequalification, the PQ Secretariat will contact manufacturers and discuss, on a one-on-one basis, the concerns identified and the changes required in order to bring the product into compliance, along with a negotiated time frame to do so.



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The process should ensure that manufacturers have a fair chance and sufficient time to make the vaccines comply with PSPQ requirements. However, if an agreement cannot be reached with a manufacturer regarding a timeline for bringing a product into compliance with PSPQ criteria, or if the manufacturer does not comply with PSPQ requirements within the timeline negotiated and agreed upon, the product may then be removed by the PQ Secretariat from the list of prequalified products. The decision will take into account the public-health impact, including the availability of sufficient alternative products meeting the programmatic needs of countries.

### **7.3 Procedure for changes to PSPQ process and criteria**

The PSPQ process and criteria will be reviewed at a minimum every three years by the PQ Secretariat, in consultation with the PSPQ Standing Committee, IVB team and the WHO regional offices. Expert input will be requested, as needed.

Any proposed changes will be presented to IPAC for endorsement, along with a proposed timeline for compliance with the new characteristics for both new, and already prequalified, products. The timeline for implementation will vary on a case-by-case basis, depending on the magnitude of the change. IPAC will be asked to endorse both the new, or modified criteria, as well as the timeline for its implementation. Changes will not come into effect until after they have received IPAC endorsement.

However, should the criteria need to be changed to address issues of safety, the PQ Secretariat reserves the right to implement these changes with immediate effect, and without further consultation. Products that do not comply with changes to the PSPQ criteria, implemented in order to address safety concerns, will have their prequalification status withdrawn with immediate effect.

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## 8. Summary and conclusions

After a review of WHO policy, and technical guidance and other sources, four mandatory and ten critical vaccine characteristics were identified. Also identified was a process for the review of unique and innovative characteristics that are not already identified as mandatory or critical. Characteristics that are preferred, but not yet considered as mandatory or critical, were also identified.

These characteristics are to be used in a screening process, which is intended to avoid the resource- and time-consuming process of formal PSF evaluation, for vaccine candidates that are not in compliance with programmatic suitability characteristics.

It is expected that, in an effort to maintain an up-to-date document, characteristics will be updated by the PQ Secretariat when new or updated WHO policies and guidance becomes available. It may also be updated based on experience and lessons learned from evaluating characteristics, especially those that are unique and innovative.

Programmatic suitability characteristics can vary by WHO region, and it is expected that this variation will be expressed in the procurement and tendering process.

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## 9. References

- 1) Malaria Vaccine Initiative. Public-sector preferences for RTS,S/AS01 malaria vaccine formulation, presentation, and packaging. October 2008.
- 2) Advance Market Commitment (AMC) for pneumococcal conjugate vaccines. Part I: Target Product Profile (TPP) for the Advance Market Commitment (AMC) for pneumococcal conjugate vaccines: Master table ([http://www.vaccineamc.org/pneu\\_amc.html](http://www.vaccineamc.org/pneu_amc.html), accessed April 2010)
- 3) Vaccine Presentation and Packaging Advisory Group (VPPAG). Generic preferred product profile (gPPP), v2.1 AUG09 (<http://sites.google.com/site/vppagp/gppp>, accessed April 2010).
- 4) WHO/IVB/05.19. Procedure for assessing the acceptability, in principle, of vaccines for purchase by United Nations agencies. Geneva, World Health Organization, 2005 (<http://www.who.int/immunization/documents/en/>, accessed April 2010).
- 5) WHO recommendations for routine immunization - summary tables ([http://www.who.int/immunization/policy/immunization\\_tables/en/index.html](http://www.who.int/immunization/policy/immunization_tables/en/index.html)).
- 6) WHO/IVB/06.10. Temperature sensitivity of vaccines. Geneva, World Health Organization, 2006 (<http://www.who.int/immunization/documents/en/>, accessed April 2010).
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- 8) WHO/IVB/07.04. WHO-UNICEF policy statement on the implementation of vaccine vial monitors: the role of vaccine vial monitors in improving access to immunization. Geneva, World Health Organization, 2004 (<http://www.who.int/immunization/documents/en/>, accessed April 2010.).
- 9) WHO/V&B/99.25. Safety of injections – WHO-UNICEF-UNFPA joint statement on the use of auto-disable syringes in immunization services. Geneva, World Health Organization, 1999 (<http://www.who.int/immunization/documents/en/>, accessed April 2010).
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- 11) WHO/IVB/05.23. Guidelines on the international packaging and shipping of vaccines. Geneva, World Health Organization, 2005 (<http://www.who.int/immunization/documents/en/>, accessed April 2010).

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# 10. Appendices

## 10.1 Appendix 1: Terms of Reference: Programmatic Suitability of Vaccine Candidates for WHO Prequalification (PSPQ) Standing Committee



Draft August 2011

### Background

In the context of the World Health Organization (WHO) procedure for the prequalification (PQ) of vaccines for procurement by United Nations agencies, the WHO PQ Secretariat will assess *'the suitability of the vaccine for the immunization services where it is intended to be used'* (p.6, WHO/IVB/05.19<sup>4</sup>). This is part of the broader process intended *'to ensure that vaccines used in national immunization services in different countries ... meet particular operational specifications for packaging and presentation'* (p.1, WHO/IVB/05.19<sup>4</sup>).

Recently, the emergence of unique vaccine presentations and the expectation that innovation will continue into the future have driven the need to explicitly define the characteristics that determine programmatic suitability and the process for assessing compliance with these characteristics. WHO is committed to providing guidance to industry, and transparency and objectivity to the WHO decision-making process, of what is a programmatically suitable vaccine for PQ purposes (see *Assessing the programmatic suitability of vaccine candidates for WHO prequalification*). In addition, WHO would like to use this process to indicate vaccine characteristics that will not impact on the PQ process, but are identified as preferred characteristics.

As part of this procedure, it is expected that, for some PQ applications, the WHO PQ Secretariat will require support from an independent advisory group which will be referred to as the Programmatic Suitability of Vaccine Candidates for WHO Prequalification (PSPQ) Standing Committee.

### Roles and responsibilities

Within the context of the WHO procedure for the PQ of vaccines for procurement by UN agencies, the PSPQ Standing Committee acts as an advisory body to the WHO PQ Secretariat and the Director IVB.

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The PSPQ Standing Committee mandate is to provide, on request, recommendations and technical advice on the programmatic suitability of vaccine candidates:

- that are non-compliant with critical characteristics;
- that present with unique and innovative characteristics.

The recommendation being sought is either:

- acceptance of the application to be further reviewed for prequalification;
- rejection of the application. (In rejecting an application, the PSPQ Standing Committee may include a recommendation for resubmission after validation, by research, of the acceptability of specific characteristics).

The PSPQ paper listing mandatory, critical and preferred characteristics should be used for guidance (see *Assessing the programmatic suitability of vaccine candidates for WHO prequalification*).

The recommendations and technical advice of the PSPQ Standing Committee will be based on information provided by manufacturers, the input of external technical experts and public-health need.

Recommendations of the PSPQ Standing Committee are not binding on the PQ Secretariat or Director IVB.

The PSPQ Standing Committee has no executive, regulatory or decision-making function.

## **Membership**

The PSPQ Standing Committee consists of five members.

- One member should have expertise in the management of developing country immunization programmes;
- one member should have regulatory expertise relating to vaccines used in developing country immunization programmes;
- two or three members will be designated from the WHO Immunization Programme Advisory Committee (IPAC).

PSPQ Standing Committee members shall serve in their personal capacity.

A public call will be issued for nominations for the remaining two or three non-IPAC positions in the PSPQ Standing Committee. Nominations will be received and selection will be made by an independent selection panel assembled by the PQ Secretariat. The three IPAC positions will be selected from nominations from the IPAC membership (excluding observers). Selections for both non-IPAC and IPAC positions will be based on qualifications and ability to contribute to the accomplishment of PSPQ Standing Committee objectives. Final approval of selections will be made by the PQ Secretariat and Director IVB.

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Prior to taking up their responsibilities for WHO, PSPQ Standing Committee members will be required to complete a WHO Declaration of Interests form and a WHO Confidentiality Agreement. A register of members' Declaration of Interest forms and Confidentiality Agreements will be maintained by WHO.

Membership in the PSPQ Standing Committee may be terminated for any of the following reasons:

- failure to respond to two consecutive requests for reviews;
- change in affiliation resulting in a conflict of interest;
- lack of professionalism including, for example, a breach of confidentiality.

### **Term**

All PSPQ Standing Committee members will be appointed to serve for a term of three (3) years. For the PSPQ Standing Committee members from IPAC, their term will end when their IPAC membership ends, or when the PSPQ Standing Committee term ends, whichever comes first. After leaving IPAC, former IPAC members are eligible to be nominated and serve in either of the non-IPAC positions. Standing Committee members can be reappointed once and can serve a maximum of two terms.

### **Chair**

A PSPQ Standing Committee Chair will be selected and appointed for one year by the PQ Secretariat and Director IVB from among the PSPQ Standing Committee members. The Chair is eligible to be reselected for appointment in the years following.

The Chair is responsible for:

- managing communications with the PQ Secretariat and Director IVB;
- managing the review process and approving all Standing Committee official records;
- approving any publications based on these records;
- updating the paper *Assessing the programmatic suitability of vaccine candidates for WHO prequalification*, as appropriate.

### **Modus operandi**

#### *Schedule of PSPQ Standing Committee activities*

PQ Secretariat requests to the PSPQ Standing Committee for recommendations and technical advice will be scheduled within two weeks of each submission deadline for PQ applications. Currently, the deadlines are as follows<sup>3</sup>:

- 31 January, 31 May and 30 September;
- specifically for seasonal influenza vaccines — July and November.

Communications between the PQ Secretariat and PSPQ Standing Committee may take place at other times during the year, as needed.

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<sup>3</sup> [http://www.who.int/immunization\\_standards/vaccine\\_quality/PQ\\_vaccine\\_manufacturers\\_guidance/en/index.html](http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_manufacturers_guidance/en/index.html).

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### *Management of communications between the PQ Secretariat and the PSPQ Standing Committee*

A focal point, designated by the PQ Secretariat, will manage all communications between the PQ Secretariat and PSPQ Standing Committee and will, in the case of a request for a recommendation or technical advice, monitor and support the review process.

Within two weeks of each PQ submission deadline, and as otherwise needed, the designated focal point will contact the PSPQ Standing Committee Chair and provide a summary of applications that are to be reviewed, the reason for review, and the expected timeline for their completion (a maximum of three months after the initiation date).

For each review the focal point will:

- provide the PSPQ Standing Committee Chair with the relevant section of the vaccine candidate product summary file (PSF);
- communicate to the vaccine manufacturer that the application will be reviewed by the PSPQ Standing Committee, the reason for the review, and the expected timeline for completion;
- monitor progress, with the PSPQ Standing Committee Chair, of each review and facilitate use of a standardized review coversheet template;
- facilitate confidential communications with the manufacturer;
- facilitate the process of approval by WHO and the manufacturer of external technical experts to be consulted confidentially;
- collect and register WHO Declaration of Interests forms and a WHO Confidentiality Agreement from approved external technical experts;
- facilitate confidential communications with approved external technical experts;
- collect a second draft review from the PSPQ Standing Committee Chair and facilitate any discussion of the draft between the PQ Secretariat and the PSPQ Standing Committee;
- collect the dated final review from the PSPQ Standing Committee Chair, deliver it to the PQ Secretariat, and formally close the review.

### *Procedure for review of a vaccine candidate for WHO prequalification by the PSPQ Standing Committee*

After being contacted by the focal point, the PSPQ Standing Committee Chair will convene the Standing Committee (see Figure 3 on page 29). The Chair will then:

- present the assigned reviews, the purpose for review and the timeline for completion;
- assign a lead and two secondary reviewers to each review and set a date for an initial presentation of the draft review to the Standing Committee;
- distribute relevant PSF documentation for each review to all PSPQ Standing Committee members;
- together with the focal point, monitor and facilitate progress with each review and use of a standardized review coversheet template.



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The maximum time allowed for review by the PSPQ Standing Committee is three months. During a PSPQ Standing Committee review, the time clock for the PQ screening process will be stopped.

The review should be conducted with specific reference to *'the suitability of the vaccine for the immunization services where it is intended to be used'* (p.6, WHO/IVB/05.19<sup>4</sup>) in order *'to ensure that vaccines used in national immunization services in different countries ... meet particular operational specifications for packaging and presentation'* (p.1, WHO/IVB/05.19<sup>4</sup>). The paper *Assessing the programmatic suitability of vaccine candidates for WHO prequalification* listing mandatory, critical and preferred characteristics should be used for guidance.

During a review, the PSPQ Standing Committee may engage in confidential discussions with manufacturers. The PSPQ Standing Committee may also engage in confidential discussions with external technical experts that have been approved by WHO and the manufacturer, and that have completed a WHO Declaration of Interests form and a WHO Confidentiality Agreement. Any requests for discussions with the manufacturer, or external technical experts, will be facilitated by the focal point and Chair, and should be made as soon after the review assignment as possible.

All material presented to the PSPQ Standing Committee, which may include unpublished material or documents from commercial entities, must be treated as confidential.

The recommendations of the PSPQ Standing Committee will be based on information provided by manufacturers, the input of approved external technical experts and public-health need.

At the first presentation of the draft review, the lead and secondary reviewers will make a presentation to the PSPQ Standing Committee concluding with a clear recommendation for acceptance or rejection of the vaccine candidate and a summary justification for the recommendation.

Discussion of the draft review will be led by the Chair with the objective of reaching consensus in the PSPQ Standing Committee. All PSPQ Standing Committee members need to participate and provide their opinion of the recommendation. When a simple majority, i.e. three of five members agrees on a recommendation, it will become the position of the PSPQ Standing Committee. Dissenting opinions can be included and, if this is done, they should be clearly identified in a separate section of the draft review. The lead reviewer is responsible for incorporating the final recommendation, a summary justification and discussion, into a second draft review.

When the second draft review is complete, the lead reviewer will present it to the Chair who will transfer it to the focal point for discussion by the PQ Secretariat.

When discussion, if any, between the PQ Secretariat and PSPQ Standing Committee is completed and incorporated into the draft review, a dated final review will be drafted by the lead reviewer and presented by the Chair to the focal point and PQ Secretariat, who will record the date of delivery and formally close the review.



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In addition to the final review, a standardized review coversheet template should be used to communicate the PSPQ Standing Committee recommendation (acceptance or rejection) and a summary justification. Additional administrative information should also be included in the template, such as: date of review assignment; the names of the Chair and primary and secondary reviewers; milestones such as the date of the first draft review by the PSPQ Standing Committee; the date of the second draft review by the PQ Secretariat, and the date of final review submission to the PQ Secretariat. The standardized review coversheet should be maintained by the lead reviewer, with support from the focal point and Chair.

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## 10.2 Appendix 2: Confidentiality and the public record of the PSPQ Standing Committee

The final review and the review coversheet serve as the record of requests to the PSPQ Standing Committee, and their recommendations, and constitute the official record of the PSPQ Standing Committee. PSPQ Standing Committee official records are confidential and can be shared only with the PQ Secretariat and the Director IVB. The PQ Secretariat is responsible for sharing official records with the manufacturer that submitted the PQ application letter and associated PSF.

Publications based on the PSPQ Standing Committee official records can only be made with the explicit approval of the manufacturer, the PSPQ Standing Committee Chair, the PQ Secretariat and Director IVB.

Publications based on the PSPQ Standing Committee official records should be used to support and update the paper *Assessing the programmatic suitability of vaccine candidates for WHO prequalification* and inform policy and technical discussion in the vaccine community.

### *Procedure for consultations requested by vaccine manufacturers before submission of an application for WHO prequalification*

For discussion and interpretation of characteristics explicitly described in the PSPQ paper, a vaccine manufacturer should contact the PQ Secretariat.

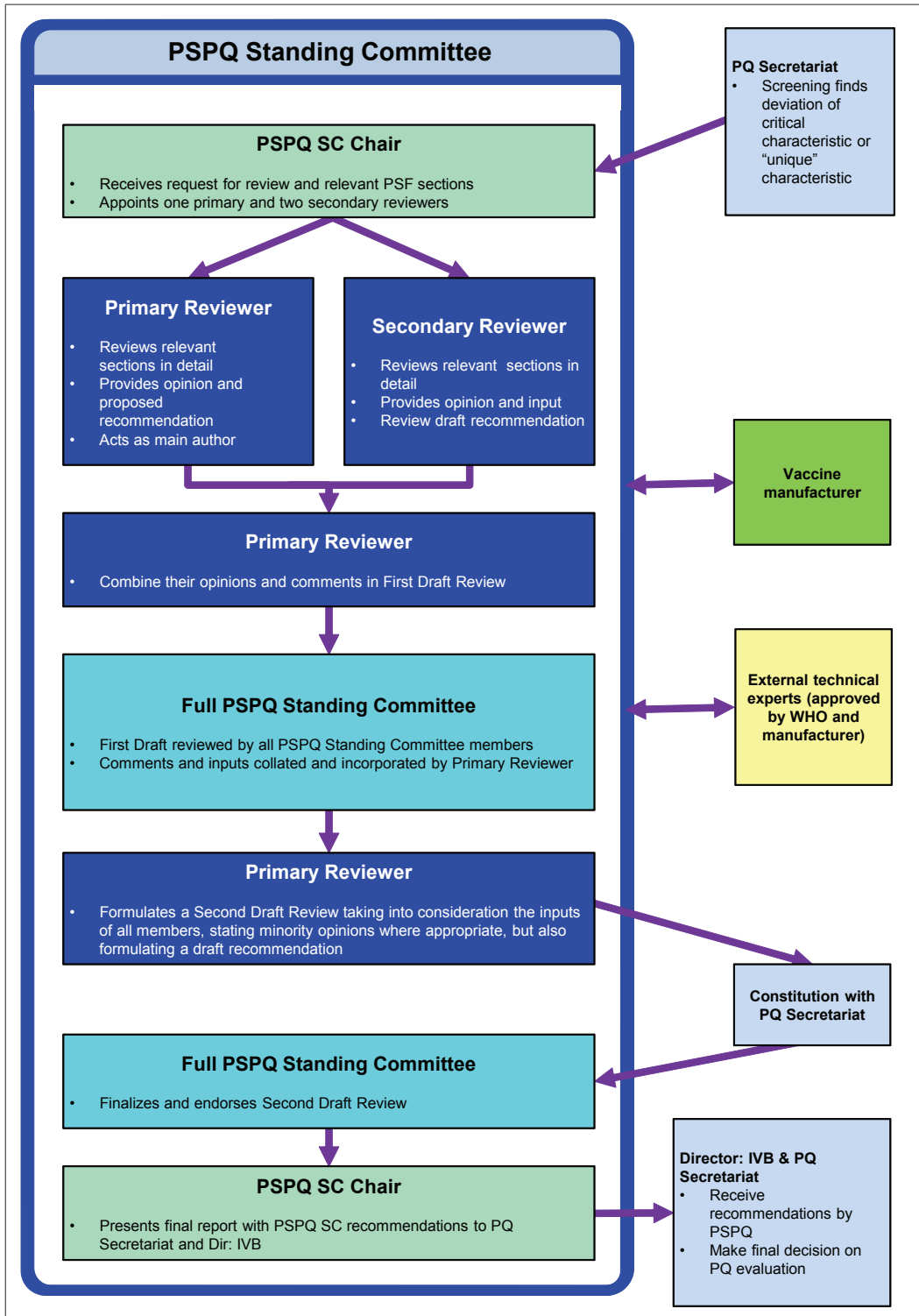
For discussion and interpretation of characteristics not described in the PSPQ paper, a vaccine manufacturer should contact the PQ Secretariat. The PQ Secretariat will identify a focal point who will arrange for a discussion between the manufacturer, WHO and the PSPQ Standing Committee.

In this context, vaccine manufacturers may wish to request pre-application discussions with the WHO PQ Secretariat on prioritized vaccine candidates, or other vaccine candidates of public-health importance that:

- 1) are non-compliant with mandatory characteristics;
- 2) are non-compliant with critical characteristics;
- 3) have unique and innovative characteristics.

As with the application review process described above, the maintenance of confidentiality before, during and after discussions is anticipated from WHO, the PSPQ Standing Committee and other participants.

Figure 3: The PSPQ Standing Committee review process



The World Health Organization has provided technical support to its Member States in the field of vaccine-preventable diseases since 1975. The office carrying out this function at WHO headquarters is the Department of Immunization, Vaccines and Biologicals (IVB).

IVB's mission is the achievement of a world in which all people at risk are protected against vaccine-preventable diseases. The Department covers a range of activities including research and development, standard-setting, vaccine regulation and quality, vaccine supply and immunization financing, and immunization system strengthening.

These activities are carried out by three technical units: the Initiative for Vaccine Research; the Quality, Safety and Standards team; and the Expanded Programme on Immunization.

The Initiative for Vaccine Research guides, facilitates and provides a vision for worldwide vaccine and immunization technology research and development efforts. It focuses on current and emerging diseases of global public health importance, including pandemic influenza. Its main activities cover: i) research and development of key candidate vaccines; ii) implementation research to promote evidence-based decision-making on the early introduction of new vaccines; and iii) promotion of the development, evaluation and future availability of HIV, tuberculosis and malaria vaccines.

The Quality, Safety and Standards team focuses on supporting the use of vaccines, other biological products and immunization-related equipment that meet current inter-national norms and standards of quality and safety. Activities cover: i) setting norms and standards and establishing reference preparation materials; ii) ensuring the use of quality vaccines and immunization equipment through prequalification activities and strengthening national regulatory authorities; and iii) monitoring, assessing and responding to immunization safety issues of global concern.

The Expanded Programme on Immunization focuses on maximizing access to high quality immunization services, accelerating disease control and linking to other health interventions that can be delivered during immunization contacts. Activities cover: i) immunization systems strengthening, including expansion of immunization services beyond the infant age group; ii) accelerated control of measles and maternal and neonatal tetanus; iii) introduction of new and underutilized vaccines; iv) vaccine supply and immunization financing; and v) disease surveillance and immunization coverage monitoring for tracking global progress.

The Director's Office directs the work of these units through oversight of immunization programme policy, planning, coordination and management. It also mobilizes resources and carries out communication, advocacy and media-related work.

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