



Programmatic Suitability for Prequalification (PSPQ) Standing Committee

INAUGURAL CALL FOR NOMINATIONS

CLOSING DATE: 30 June 2011

Submission/Questions: Ms Christine Jolly - jollyc@who.int

The World Health Organization is soliciting calls for the nomination of members for its new Programmatic Suitability for Prequalification (PSPQ) Standing Committee.

While the assessment of the suitability of vaccines for the immunization services where they are intended to be used has always been part of prequalification (PQ), historically the assessment of the product summary files (PSFs) to determine programmatic suitability had not been formally structured, with the outcome based on individual expert inputs and WHO PQ Secretariat consensus. As part of the PQ review, a formal process and criteria for assessing the programmatic suitability of vaccines intended for low and middle income countries was developed.

The standing committee will be charged with reviewing and providing guidance in all instances where vaccines are not in compliance with the critical characteristics, or where a vaccine presentation is deemed to be unique or innovative.

Two standing committee members are being sought—one, with experience in regulatory considerations for developing country vaccine use. The second must be a recognized as an expert in developing country immunization programmes and delivery. One of these members will also serve as the committee chair. The remaining three positions on the committee will be filled by members of WHO's Immunization Practices Advisory Committee.

The standing committee will begin its work in September 2011 with the formal launch of the PSPQ process scheduled for January 2012.

Prequalification Overview

The full responsibility for recommending World Health Organization (WHO) prequalification (PQ) of a vaccine lies with the WHO PQ Secretariat, with a final decision being taken by the Director of the WHO Department of Immunization, Vaccines, and Biologicals (IVB).

As part of the WHO vaccine 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). 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).

Recently, the emergence of unique vaccine presentations such as relatively large packed volumes, pre-filled syringes that do not include an auto-disable feature, injection device materials that require non-standard disposal methods, and fully liquid low multidose 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.

Programmatic suitability characteristics and the role of the standing committee

On receipt of the PSF, the PQ secretariat will screen all vaccines. 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 was also identified.

1. **'Mandatory'** characteristics are those where compliance is compulsory at the time of application for WHO prequalification and must be unconditionally met prior to evaluation of the PSF.
2. 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 relevant section of the PSF to the Programmatic Suitability of Vaccine Candidates for WHO Prequalification (PSPQ) Standing Committee and inform the manufacturer of the screening results. The PSPQ Standing Committee can then make a recommendation, with or without consultation with the manufacturer and additional technical experts, and with consideration of public health need, to accept or reject the application for prequalification and the evaluation of the PSF.
3. 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.
4. **'Preferred'** characteristics are intended to reflect what WHO, procuring agencies and national immunization programmes would want in a best case scenario and expect in the future; these characteristics are intended as guidance to 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.

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 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 for prequalification evaluation.	
Preferred	Prequalification evaluation proceeds.	

The decision to grant approval to continue with the evaluation for prequalification can only be taken by the PQ Secretariat and Director IVB and will include consideration of recommendations from the PSPQ Standing Committee and issues such as the safety risk posed, in addition to the public health importance of the vaccine, i.e. public health impact, globally and regionally, of not having access to the vaccine.

Criteria for PSPQ standing committee membership

To assure the highest integrity, and hence public confidence, ensuring no conflict of interests exist will be a primary consideration in selecting committee members. As part of the application process, all candidates will be required to complete a detailed declaration of interests form, in which all potential conflicts must be disclosed. This includes any work members be involved in that is funded by vaccine manufacturers, device manufacturers or product development partnerships.

Standing committee members will be selected to ensure an appropriate range of expertise. As a minimum, all members must demonstrate the proof of having the qualities, skills and experience listed below:

- An understanding of the vaccination and immunization issues facing developing countries;
- An outstanding record of achievement and personal credibility within own field, appropriate to the remit of the Committee;
- Technical expertise in one or more of the following:
 - Developing and managing immunization programs at the country level, including campaigns and/or routine immunization, either from a logistics or service delivery perspective;
 - In-depth knowledge of regulatory processes used in developing countries for vaccines;
 - Formulation and development of vaccines, including packaging and presentation for developing country markets;
- Experience of operating at a strategic level in the public or other sectors;
- Experience of working effectively in high level advisory committees;
- Ability to evaluate complex issues and weigh up conflicting opinions;
- Ability to influence at a senior level;
- Good command of English;
- A broad range of expertise and interest.

In addition, one member will be selected to Chair the committee. This member should, in addition, hold the following capabilities:

- Proven expertise managing a high-level senior team of experts;
- Ability to manage complex workflows amongst various partners to deadline;
- Excellent interpersonal and communication skills to support effective discussion with a range of stakeholders;
- Proven experience reaching consensus amongst various groups
- Ability to remain neutral and non-biased

Time commitment and workload

The time commitment required of members will be highly variable, depending on the quantity of applications received for pre-qualification that require further consultation. Each time a vaccine PSF is referred to the PSPQ standing committee, the Chair will assign one member to take on the role of primary reviewer, and two other members to act as secondary reviewers. The amount of time required by each reviewer will vary based on the complexity of the issue being discussed, however it is anticipated that the primary reviewer will need to spend double the time of the secondary reviewers on each file. .

Workload for the PSPQ standing committee is likely to be heaviest 2-3 weeks following the deadline for PSF submission, which are tentatively scheduled in 2012 for: 3 January, 31 May and 30 September.

It is anticipated that the standing committee will meet virtually, conducting its meetings via email and by teleconference. Should an in-person meeting be necessary, costs will be covered by WHO.

Appointments and tenure

During this inaugural nomination process, members will be appointed for a minimum period of three years, at which point, in order to stagger the length of service thereby assuring that not all Committee members rotate out simultaneously, members' terms will either end, or continue for an additional one to two years.

Conflict of Interests

Ensuring there are no conflict of interests for PSPQ standing committee members is of the highest priority. As part of the application process, all candidates will be required to complete a detailed declaration of interests form, in which all potential conflicts must be disclosed. This includes any work members be involved in that is funded by vaccine manufacturers, device manufacturers or product development partnerships. In addition, a conflict of interests declaration will need to be completed by members prior to each product review. If there is a product that comes to the committee for review for which a member may have a specific conflict of interest, that member will be required to recuse him/herself from the discussion.

All members serve in their personal capacity and should refrain from promoting the policies and views and products of the organization/institution for which they work. Likewise, it should be clear that PSPQ recommendations do not commit the organization/institution with which members may be affiliated.

Prior to being appointed to the PSPQ standing committee, nominees and members will be required to complete a WHO declaration of interest form and a confidentiality agreement. Nominees will be asked declare any potential conflict of interests now and report regularly on any potential conflicts of interests that arise in the course of their tenure. In addition, any relevant business interests, positions of authority or other connections with organisations relevant to the work of the PSPQ standing committee must be disclosed. Any actual or perceived conflict of interests will be fully explored by the Secretariat. Members with declared interests will be asked to excuse themselves from participating in the discussion and decision-making of the issues relating to that interest. A member who is in any doubt as to whether they have an interest which should be declared, or whether they should take part in the proceedings, should ask the Secretariat for guidance.

How to apply

The following documents must be submitted in order to be considered for membership on PSPQ standing committee. For nominations submitted by a third party, the nominees will be contacted by the Secretariat and expected to confirm their interest through submission of a complete application package.

1. **Curriculum vitae (CV)** should include your career history and list your main areas of employment or other relevant activity and other public appointments. You should also include details of any relevant academic, professional or vocational qualifications. Your CV will be used in the assessment of your expertise. The CV should be written in English. Ensure you include all contact details including, if available, a cell phone number.
2. **A letter of motivation** highlighting what your contribution to the PSPQ standing committee would be. It is important that you provide evidence that you have the "Qualities required for membership".
3. **A completed declaration of interests form** (see Appendix 1).
4. Complete contact information for **two referees**, at least one of whom must be related to your recent professional and/or voluntary activity. They may or may not be approached prior or after review of nominations by the selection panel.

Key deadlines

Applications must be submitted by 30 June 2011, marked to the attention of the PSPQ secretariat committee. Please submit all applications by email to: **Ms Christine Jolly - jollyc@who.int**

Successful applicants will be contacted by **1 August 2011**. The first Standing Committee teleconference is scheduled for the first week of September 2011. If you will not be available that week, please indicate that along with your application.

Once we receive your application

We will process nominations as quickly as possible and will keep nominees informed at key stages. Self applications are expected to be submitted with all necessary information. For nominations submitted by a third party, the nominees will be contacted by the Secretariat and expected to confirm their interest through submission of a complete application package.

After receipt of the applications:

- We will acknowledge receipt of your application and its completeness (by e-mail) and we will check it for eligibility. We will rely on only the information you provide on your application form and CV to assess whether you have the experience required at the appropriate level. We will contact you should any details need to be clarified, or any further information requested;
- Telephone interviews may be scheduled between nominees and the Secretariat or members of the selection panel to clarify areas of uncertainties about your experience and expertise and ask specific questions to explore whether you meet the specified qualities;
- Nominations will first be screened for eligibility by the Secretariat. When a large number of nominations are received, it is possible that your application will be “pre-assessed” and compared with other applications before it is passed to the selection panel for consideration. Therefore, an application might not be considered in full by all the panel;
- Candidates who best fit the criteria and match the needed expertise with due consideration to ensuring a proper balance will be proposed for appointment to the Director: IVB who will make the final decision;
- To facilitate a smooth rotation process, candidates may also be preselected for seats expected to become vacant;
- Successful candidates will receive a letter inviting them to serve on Standing Committee and that will specify the beginning and duration of term; some nominations may not be successful but will be kept on an open roster of qualified nominees for later consideration depending on new vacancies and subject to adjustment of balance on the Committee. Nominees will be notified accordingly.
- Unsuccessful nominations will also be notified by the Secretariat.

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APPENDIX 1

DECLARATION OF INTERESTS FOR WHO EXPERTS

The assistance of distinguished authorities knowledgeable in a variety of medical and scientific fields is essential to WHO's work on global health issues. **It is expected that individuals who are qualified to serve as an expert for WHO may have private interests related to their expertise. But, at the same time, it is imperative that situations are avoided in which such interests may unduly affect, or may be perceived to affect, an expert's impartiality.**

To assure the highest integrity, and hence public confidence, in its activities, WHO policies require that all experts serving in an advisory role agree to disclose any circumstances which could give rise to a **potential conflict of interest** (i.e., any interest which may affect, or may reasonably be perceived to affect, the expert's objectivity and independence). Since you have been selected as a WHO expert in the activity described below, you are requested to disclose in this Declaration of Interest (DoI) form any financial, professional or other interest relevant to the subject of the work or meeting in which you will be involved and any interest that could be significantly affected by the outcome of the meeting or work. You are also asked to declare relevant interests of others who may, or may be perceived to, unduly influence your judgment (such as immediate family members, employers, close professional associates or any others with whom you have a substantial common personal, financial or professional interest).

Kindly complete this form and submit it to WHO Secretariat, well in advance of the meeting or work. You are also asked to inform the Secretariat if any change in this information occurs before or during the course of the meeting or work. Non-completion of a DoI form at any stage precludes participating as an expert.

It should be clarified that the giving of affirmative answers to questions in a DoI form would not automatically disqualify or limit your participation as an expert. Rather, your answers will be screened by the Secretariat to determine if a potential conflict of interest may exist or may be perceived to exist. One of several outcomes can occur, depending on the circumstances (i.e., the nature and magnitude of the interest, its timeframe, the availability of sufficient measures to safeguard the integrity of the decision-making process if the expert is permitted to participate).

After reviewing the disclosures in the DoI form, the Secretariat may conclude that no potential conflict exists or that the interest is irrelevant or insignificant. If it appears that a conflict of interest exists and is potentially or clearly significant (or may be reasonably perceived to be so), one of the following three options, or a combination of these options, may be applied by the Secretariat: (i) you may be invited to continue to participate in the meeting or work, provided that your interest would be publicly disclosed; (ii) you may be asked not to take part in the portion of the meeting, discussion or work related to your interest, or not participate in related decisions; or (iii) you may be asked not to take part in the meeting or work altogether.

Any relevant conflicts will be **publicly disclosed** to other participants at the start of the activity and in the resulting report or other work product. The Secretariat will assume that you consent to such a disclosure, unless you check "no" in the space provided on the last page of this form. In **a later audit or investigation**, the contents of your DOI form may be made available to persons outside of WHO if the objectivity of the work or meeting in which you are involved is questioned and the Director-General considers disclosure to be in the best interests of the Organization, although only after discussion with you. By completing this DoI form, it is assumed that you agree to these conditions.

Name: Institution: Email:

Date and title of meeting or work, including description of subject-matter to be considered (if a number of substances or processes are to be evaluated, a list should be attached by the organizer of the activity):

Please answer each of the questions below. If the answer to any of the questions is "yes", briefly describe the circumstances on the last page of the form.

The term "you" refers to yourself and your immediate family members (i.e., spouse (or partner with whom you have a similar close personal relationship) and your minor children). "Commercial entity" includes any commercial business, an industry association, research institution or other enterprise whose funding is significantly derived from commercial sources with an interest related to the subject of the meeting or work. "Organization" includes a governmental, international or non-profit organization. "Meeting" includes a series or cycle of meetings.

	EMPLOYMENT AND CONSULTING Within the past 3 years, have you received remuneration from a commercial entity or other organization with an interest related to the subject of the meeting or work? Please also report any application or negotiation for future work.	
1a	Employment	Yes No
1b	Consulting, including service as a technical or other advisor	Yes No
	RESEARCH SUPPORT Within the past 3 years, have you or your research unit received support from a commercial entity or other organization with an interest related to the subject of the meeting or work? Please also report any application for future research support.	
2a	Research support, including grants, collaborations, sponsorships, and other funding	Yes No
2b	Non-monetary support valued at more than US\$1000 overall (include equipment, facilities, research assistants, paid travel to meetings, etc.)	Yes No
	INVESTMENT INTERESTS	

	Do you have current investments (valued at more than US\$10 000 overall) in a commercial entity with an interest related to the subject of the meeting or work? Please also include indirect investments such as a trust or holding company. You may exclude mutual funds, pension funds or similar investments that are broadly diversified.	
3a	Stocks, bonds, stock options, other securities (e.g., short sales)	Yes <input type="checkbox"/> No <input type="checkbox"/>
3b	Commercial business interests (e.g., proprietorships, partnerships, joint ventures)	Yes <input type="checkbox"/> No <input type="checkbox"/>
	INTELLECTUAL PROPERTY Do you have any current intellectual property rights that might be enhanced or diminished by the outcome of the meeting or work?	
4a	Patents, trademarks, or copyrights (also include pending applications)	Yes <input type="checkbox"/> No <input type="checkbox"/>
4b	Proprietary know-how in a substance, technology or process	Yes <input type="checkbox"/> No <input type="checkbox"/>
	PUBLIC STATEMENTS AND POSITIONS (during the past 3 years)	
5a	As part of a regulatory, legislative or judicial process, have you provided an expert opinion or testimony, related to the subject of the meeting or work, for a commercial entity or other organization?	Yes <input type="checkbox"/> No <input type="checkbox"/>
5b	Have you held an office or other position, paid or unpaid, where you may be expected to represent interests or defend a position related to the subject of the meeting or work?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	ADDITIONAL INFORMATION	
6a	If not already disclosed above, have you worked for the competitor of a product which is the subject of the meeting or work, or will your participation in the meeting or work enable you to obtain access to a competitor's confidential proprietary information, or create for you a financial or commercial competitive advantage?	Yes <input type="checkbox"/> No <input type="checkbox"/>
6b	To your knowledge, would the outcome of the meeting or work benefit or adversely affect interests of others with whom you have substantial common personal, financial or professional interests (such as your adult children or siblings, close professional colleagues, administrative unit or department)?	Yes <input type="checkbox"/> No <input type="checkbox"/>

6c	Is there any other aspect of your background or present circumstances not addressed above that might be perceived as affecting your objectivity or independence?	Yes <input type="checkbox"/> No <input type="checkbox"/>
7.	<p><i>TOBACCO OR TOBACCO PRODUCTS (answer without regard to relevancy to the subject of the meeting or work)</i></p> <p>Within the past 3 years, have you had employment or received research support or other funding from the tobacco industry or had any other professional relationship with an entity, directly involved in the production, manufacture, distribution or sale of tobacco or tobacco products or representing the interests of any such entity?</p>	Yes <input type="checkbox"/> No <input type="checkbox"/>

EXPLANATION OF "YES" RESPONSES: If the answer to any of the above questions is "yes", check above and briefly describe the circumstances on this page. If you do not provide, the amount or value of the interest, where requested, it will be assumed to be significant.

Nos. 1 - 4: 7 Type of interest, question number and category (e.g., Intellectual Property 4.a copyrights) <u>and</u> basic descriptive details.	Name of company, organization, or institution	Belongs to you, a family member, employer, research unit or other?	Amount of income or value of interest (if not disclosed, is assumed to be significant)	Current interest (or year ceased)

Nos. 5-6: Describe the subject, specific circumstances, parties involved, time frame and other relevant details

CONSENT TO DISCLOSURE. The Secretariat will assume that you consent to the disclosure of any relevant conflicts to other meeting participants and in the resulting report or work product, unless you check "no" in the space provided here. If you check "no", the Secretariat will not disclose the information without your prior approval, although this may result in your not being able to participate in the meeting or conference. **No:**

DECLARATION. I hereby declare on my honour that the disclosed information is true and complete to the best of my knowledge.

Should there be any change to the above information, I will promptly notify the responsible staff of WHO and complete a new declaration of interests which describes the changes. This includes any change which occurs before or during the meeting or work itself and through the period up to the publication of the final results.

Date: _____

Signature _____