

TERMS OF REFERENCE FOR IAC

DRAFT 2 August 2007

1. Functions

The Independent Assessment Committee (IAC) is the principal decision-making group regarding the eligibility of a vaccine for the Advanced Market Commitment (AMC). The AMC Secretariat is housed at the GAVI Secretariat and comprises two staff members. An AMC is a transparent and credible commitment for a future market. The total amount available, the price per dose or regimen (as the case may be), and the target product profile (TPP) are established in advance to encourage industry investment and to provide clear assurances of the value of the potential market. Establishing a credible and independent process to set the vaccine TPPs and to determine whether or not a vaccine meets those specifications is critical to the success of the AMC. The IAC is the cornerstone of this process and is responsible for ensuring that the TPP setting process and the decision of whether a product meets the TPP and is eligible for AMC funding, is fair, transparent and credible to all signatories of the Framework Agreement and other stakeholders. A background of these functions is provided in annex 2.

1.1. Oversee the establishment of TPPs

The IAC has the final authority to accept, amend or reject a TPP. The development of the TPP would be delegated to the World Health Organization (WHO). The TPP would determine the required public health performance standards – for example, the level of effectiveness in target populations against a certain endpoint.

1.2. Monitor and report scientific progress throughout the process

The IAC will review information periodically gathered by the AMC Secretariat over the life of the Pneumo AMC about the AMC's influence on the development and production of pneumococcal vaccines, including progress towards a vaccine that would meet the TPP. The IAC will also review and approve the annual progress report to donors prepared by the AMC Secretariat to ensure accuracy and be aware of progress towards a target vaccine.

1.3. Modify TPPs if appropriate.

Modification of the TPPs would occur only in exceptional circumstances (e.g. a recognition that the goals set in the TPP are unachievable with current technologies) and re-setting a TPP will follow the same process as its initial establishment. The IAC is responsible for deciding if a TPP should be modified.

1.4. Oversee the determination of whether a product meets the TPP

The IAC will have the final authority to decide whether a product meets the TPP, and thus is eligible for AMC funding. The IAC, with the advice of WHO would assess whether the Target Product Profile as defined by the TPP expert group has been met, which would ensure international quality and safety standards are met and allow for public procurement

1.5. Resolve disputes

The IAC will have the capacity to monitor and resolve disputes and complaints associated with the carrying out of the above activities. A lack of consensus for decision-making purposes within the IAC will be dealt with through the voting rules as described in the IAC Procedural Bylaws (Annex 3).

Note from the WB: *Disputes or claims brought by external parties in connection with an LAC decision or the LAC itself will need to be addressed in the framework agreement and will be a topic of discussion for the legal subgroup. The same issues may also need to be further addressed in the LAC Procedural Bylaws.*

2. Membership

The IAC will comprise nine members with no financial or institutional conflict of interest or potential conflict of interest, or who have duly disclosed any such conflict of interest to the AMC Secretariat, in the specific products under consideration. IAC members are acknowledged experts from around the world and their expertise will reflect knowledge of developing countries and the IAC's functions, and is expected to include:

- public health expertise,
- health economics,
- vaccine business development,
- contract law, and
- clinical performance and delivery systems.

Members and the chair of the IAC will serve in their personal capacities, and not as representatives of any organization or group (e.g., of their employer or its interests).

IAC members, including the Chairperson, shall be nominated by a selection panel in consultation with the AMC donors through a written call for nominations. Members of the IAC, including the Chairperson, shall be appointed to serve for an initial term of up to six years. Such terms may be renewed once. In the initial appointment of nominees to the IAC, three members will serve 2-year terms; three will serve 4-year terms and three will serve 6-year terms so that all terms do not end simultaneously. Following the initial terms, all future nominees will serve a six year term.

Prior to being appointed as IAC members, at the commencement of each IAC meeting and prior to renewal of term and upon any change in member affiliation, nominees shall be required to complete an IAC declaration of interest (see Annex 1). In addition, IAC nominees shall be required to sign confidentiality agreements prior to confirmation by the AMC Secretariat of their appointment as IAC members. The confidentiality agreements will require IAC members to hold and treat as confidential certain information received by them in connection with vaccine firms. A register of members' interests and signed confidentiality agreements shall be maintained by the AMC Secretariat. All papers presented to the IAC, which may include pre-publication copies of research reports, or documents of commercial significance, shall be treated as confidential. IAC deliberations are generally expected to be done publicly, but it may, as needed, hold confidential sessions that may not be publicly disclosed by IAC members.

Note from the WB: *The legal subgroup can discuss further whether other material might be put into the confidentiality agreements (for example, provisions that would help to bind LAC members into the LAC structure).*

Membership to the IAC may be terminated through a majority vote [of IAC members] for any of the following reasons:

1. failure to attend two consecutive IAC meetings
2. change in affiliation resulting in a conflict of interest); and
3. a lack of professionalism involving, for example, a breach of confidentiality.

Note from the WB: *The legal subgroup and donors will need to discuss further whether any other grounds should require members to step down. It is important to note they are not considered directors as noted in some comments. Elaboration of such other grounds will also make reference above consistent with these termination of appointment provisions, since we note above that there will be some scope for LAC Selection Panel to be responsible for discontinuation and appointments/renewals of terms of LAC members. Need to consideration whether it is worth allowing for the possibility that, as the AMC Pneumo initiative evolves and progresses, the skill-set needs of*

the IAC may need to change to cope with the needs of a particular time. From this perspective, it would be worth considering how and who, apart from IAC members themselves, can terminate appointment of an IAC member.

3. Meetings and Operational Procedures

Please see Annex 3 (IAC Procedural Bylaws).

ANNEX 1: DECLARATION OF INTERESTS

DECLARATION OF INTERESTS FOR IAC MEMBERS

The assistance of distinguished authorities knowledgeable in a variety of medical and scientific professions is essential to the solution of international health issues. **It is expected that persons qualified to serve as members of the Independent Assessment committee (IAC) may have private interests related to the subject of their expertise. At the same time, it is imperative that situations be avoided in which such interests may unduly affect, or may be perceived to affect, an expert's impartiality or the outcome of work in which he/she was involved.**

To assure the highest integrity, and hence public confidence, in the activities of the IAC, regulations and policies require that all experts serving in an advisory role disclose any circumstances which could give rise to a conflict of interest (i.e., any interest which may affect, or may reasonably be perceived to affect, the expert's objectivity and independence). Accordingly, in this Declaration of Interest form, you are requested to disclose any financial, professional or other interest relevant to the IAC discussions and 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 the AMC Secretariat. You are also required to inform the AMC Secretariat of any change in this information that occurs before or during the course of the IAC's work. If the AMC Secretariat considers that a potential conflict of interest exists, one of several outcomes can occur, depending on the circumstances involved: (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. Non-completion of the DOI form would preclude further consideration of an expert's participation as an IAC member.

Experts are requested to agree that any relevant conflicts may be **publicly disclosed** to other meeting participants and in the resulting report or other work product.

Name:

Institution:

Email:

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, your employer and your immediate family members (i.e., spouse (or partner with whom you have a similar close personal relationship) and your minor children).

- Do you or your organization have any financial interest in a vaccine supplier? If so, please list them and the specifics of your interest?
- Do you or your organization have any other interest in the subject that would compromise your independence?

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 .

Independent Assessment Committee TORs DRAFT

DECLARATION. I hereby declare on my honour that the disclosed information is true and complete to the best of my knowledge. I will undertake carriage of my duties as an IAC member individually and that I will make all reasonable efforts to ensure that the IAC as a committee is run in accordance with the IAC procedural bylaws and any other documents from time to time governing IAC operations or nature.

Should there be any change to the above information due to the fact that I acquire additional interests, I will notify the responsible staff of the AMC Secretariat and complete a new declaration of interests detailing the changes.

Date: _____ Signature _____

Note from the WB: *Further consideration could be given by the legal subgroup as to whether in addition to a declaration of interests, a declaration could be given by each member stating something like: (i) that each member will undertake the carriage of their duties as LAC members in their individual capacities; (ii) that they will act, or forbear, in accordance with the LAC Procedural Bylaws and any other documents from time to time governing; (iii) declaration of understanding and acknowledging the terms of the Framework Agreement and agreeing to work to preserve its intent and provisions.*

ANNEX 2: BACKGROUND ON IAC ROLES AND RESPONSIBILITIES

3.1. Oversee the establishment of the Target Product Profile (TPP)

The IAC will exercise an independent oversight role in setting the vaccine TPPs for the AMC, delegating the task of defining the TPP for pneumococcal vaccines to an appropriately constituted scientific and technical group (the TPP expert group) with in-depth knowledge about pneumococcal disease and vaccines. The TPP will determine the required public health performance standards – for example, the level of effectiveness in target populations against a certain endpoint. Other measures relevant to public health impact may also be defined such as the maximum number of doses per treatment, compatibility with available delivery systems (e.g. dosing schedule, temperature sensitivity, method of application), minimum duration of immunity, and non-interference with other public health interventions. The TPP will also be based on the product quality and safety standards established by functional regulatory authorities

TPPs will be set by the IAC first requesting the World Health Organization (WHO) to convene an expert advisory group to recommend TPP terms¹. This activity is within WHO's global mandate, and is already being done for licensed vaccines by WHO, through its Department on Immunization, Vaccines, and Biologicals (IVB). As denoted in the TPP TORs, this expert group will present its recommendations to SAGE (an advisory group on immunizations to the WHO Director General) for approval. Upon approval, they will be provided to the IAC. If the recommendations are then also confirmed by SAGE, they will become official WHO policy on performance. WHO Member States have a high level of confidence in WHO policy recommendations, so this approach will ensure a wide acceptance of the TPPs. The final decision to accept a TPP rests with the IAC.

A TOR for the TPP process (to be attached) prepared by WHO outlines the steps WHO will follow to provide the requested support and details how WHO will interact with the IAC. The IAC will first be responsible for vetting nominees who would participate in the TPP expert group, and second, have a member, or members sit with SAGE during the final approval process. The preparation of background papers for the expert committee will also be delegated to WHO, with participation from the AMC Secretariat. This process is anticipated to be completed by November 9th at the SAGE meeting.

Note from the WB regarding the TPP process: *[to be attached to this IAC TOR? Do we need to attach it?]*

The IAC has the final authority to accept, amend or reject a TPP. Given the scientifically rigorous method and consultation surrounding the TPP it is unlikely that a TPP recommended to the IAC by the SAGE would be rejected. In the unlikely event where the TPP is rejected, the AMC Secretariat will facilitate a mechanism to resolve points of difference including a joint meeting of the IAC and the SAGE.

Note from the WB: *(the process for revising or adjusting the TPP will require further detail to be provided in the framework agreement and may require additional provisions to go into the IAC Procedural Bylaws, depending on how we choose to bind IAC members into the structure).*

3.2. Monitor and report scientific progress throughout the process

The IAC will review information periodically gathered by the AMC Secretariat about the AMC's influence on the development and production of pneumococcal vaccines, including progress

¹ In the case of the pneumococcal vaccine pilot, given timing considerations, the donor committee made an exception and requested WHO directly to carry out this process, with the WHO SAGE approving the TPP members rather than the IAC.

towards a vaccine that would meet the TPP. To minimize the transaction cost of reporting while also ensuring transparency, an annual review process convened by the IAC will be held. Manufacturers, AMC participants and interested parties would consider the science as well as complementary issues such as demand creation. The IAC will also review and approve the annual progress report to donors prepared by the AMC Secretariat .

3.3. Modify TPPs if appropriate

A general principle of the AMC structure is that in exceptional circumstances, TPPs may be revised to relax the TPP requirements in the event a TPP cannot be met by industry.

Note from the WB: *Further consideration will need to be given in connection with applicable processes for amending the TPP, including the level of input from the stakeholders, and the exact nature of the circumstances in which the TPP could be adjusted. For example, should the TPP only be capable of being modified in the event that a material requirement in the TPP cannot realistically be met by industry, and should such decisions be solely determined by the LAC (without consultation)?*

The TPP requirements will not be made more stringent than those initially established. Nonetheless, a recommendation that the TPP requirements should be relaxed could be disruptive and unfair for manufacturers investing in research and development to meet the original higher level. Re-setting a TPP will follow the same process as its initial establishment, with the IAC asking WHO to convene a group of experts.

Note from the WB: *to be discussed by legal subgroup as part of framework agreement; including clarity on the role between GAVI Board and LAC.*

The original size and price of the AMC along with the process for establishing the co-payment and tail price will be defined at the outset in the Framework Agreement. The “tail price” or “post-AMC price” (the long-term, developing country “market” price of the vaccine after the AMC is depleted), will be finalized by each manufacturer when it signs the AMC Supply Agreement. The setting of the tail price will ensure that developing country governments can make decisions on introduction of the vaccine based on predictable prices. However, an AMC price may be changed if there is a significant change in circumstances. In this case, the IAC would request the AMC Secretariat to convene a group of experts to evaluate the changed circumstances and decide whether a change in price is appropriate. Recommendations coming out of this process will then be communicated back to the IAC for decision and action.

Note from the WB: *The exact process to detail this needs to be discussed by legal counsel in the legal subgroup.*

3.4. Oversee the determination of whether a product meets the TPP

The IAC will have the final authority to decide whether a product meets the TPP, and thus is eligible for AMC funding. To meet the TPP, a product must meet the stated TPP standards as defined by the TPP expert group including quality and safety standards and the public health performance standards set out in the TPP.

At present, all vaccines procured by GAVI must be WHO-prequalified. The WHO prequalification process, in effect since 1987, is a process that assures United Nations procurement agencies of the suitability of a product for global use in national immunization programs. The process is widely respected and the list of prequalified vaccines is used by many countries as a guide for fast-track licensure. Given the important role of the WHO in the licensing decisions of countries and procurement processes of UN agencies, AMC-eligible products will also need to be pre-qualified by WHO. To minimize duplication and ensure the consistency of decisions, the following two processes would be adopted:

- (a) Assessing whether minimum quality and safety standards have been met:

Determining the quality (including purity and consistency), safety and efficacy of a vaccine is the mandate of national regulatory processes and authorities, through the licensing process. To avoid duplication and ensure consistent standards, the TPP should not have separate quality or safety standards. The IAC will accept that the vaccine meets the minimum required quality and safety standards if the vaccine has been licensed by a functional regulatory authority and is prequalified by WHO.

Note from the WB: *These requirements will form part of the TPP.*

(b) Assessing whether the public health performance standards in the TPP have been met and whether the products can be procured through normal channels:

These assessments would be made by using the WHO prequalification processes but using the established TPP standards.

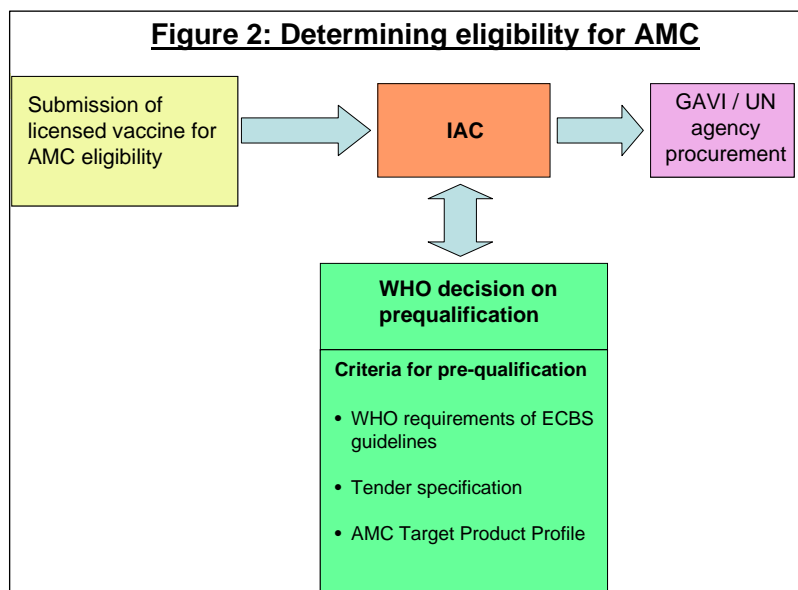
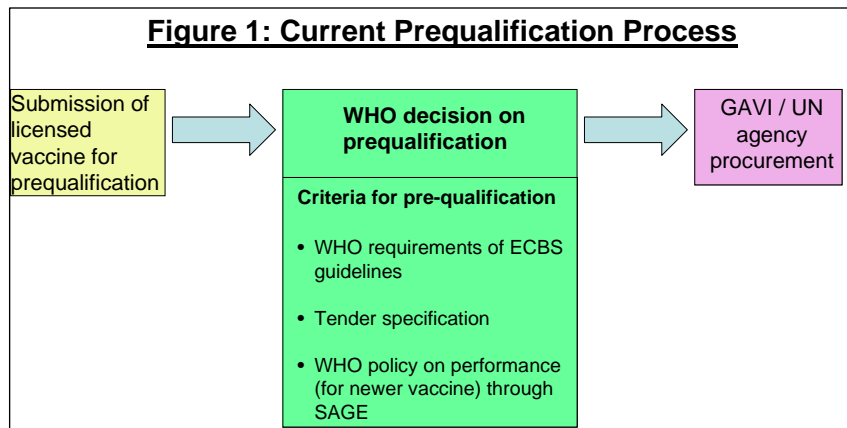
Note from the WB: *WHO routinely makes judgments on the safety and efficacy of vaccines and prequalifies them for procurement as part of its normative role; no disputes are anticipated as part of this. Details around disputes will be addressed in the framework agreement, and in IAC documents as necessary, and as noted previously.*

Figure 1 depicts the current WHO prequalification process for any product. A product is submitted for prequalification when there is an interested UN procurement agency buyer. The product is prequalified using an established process and based on three criteria:

meeting the specifications of the tender (packaging, thermostability, shipping criteria, presentation, etc); meeting the specifications of the relevant WHO “requirement” or ECBS guideline;² for newer vaccines, meeting the performance standards outlined in the WHO policy recommendation, developed generally through expert consultation and approved by the SAGE, relevant to field performance.

Figure 2 depicts how the current process will be modified to assess whether

AMC-eligible products meet the public health performance standards set out in the TPP and



² The ECBS guideline is a guideline outlining production requirements developed through WHO’s Expert Committee on Biological Standardization (ECBS).

whether the products can be procured through normal channels. For an AMC eligible product, the WHO prequalification team will assess the product against the performance standards in the TPP which would include all of the considerations in the prequalification process, in addition to the two other prequalification criteria. The WHO prequalification team will report its findings to the IAC, indicating the performance of the product against each of the prequalification criteria. The IAC will decide in the light of this recommendation whether the product is eligible for purchase under the AMC, and inform the AMC Secretariat . WHO may also be requested by a UN agency to pre-qualify vaccines that have public health value for more limited use (e.g. regional), but that do not meet the AMC TPP. It is believed that the proposed system would not constrain WHO from establishing regionally-appropriate performance standards and pre-qualifying non-AMC vaccines as required.

Thus, the IAC will make the final decision whether a product meets the TPP, and is eligible for AMC funding, based on the product being licensed and approved by a functional regulatory authority and being WHO pre-qualified. The precise details of this process are being developed with various experts and WHO.

3.5. Resolve disputes

The IAC needs the capacity to monitor and resolve disputes and complaints associated with the carrying out of the above activities, either by the IAC itself or by the organizations to which it delegated various tasks. It could act as an appeals group in case of challenges, for example, to TPPs, prices, and compliance determinations. The personal credibility of the IAC members and the independence and impartiality of the IAC itself will largely determine the confidence of stakeholders in the TPP and product-review processes and outcomes. The IAC's authority in connection with resolving complaints will be established in the AMC Framework Agreement and/or may need to be provided for in the IAC Procedural Bylaws or other IAC governance documentation.

Note from WB: *As per previous comments, legal subgroup is to address these issues following discussion amongst legal counsel.*

ANNEX 3: IAC PROCEDURAL BYLAWS

Draft as of August 2007

Note from WB regarding the Bylaws: *query whether there is too much cross-reference and deference to the terms of the Framework Agreement. Perhaps the Bylaws need to be self-standing so that they lay down the procedures for operation of the LAC in as many respects as possible.*

ARTICLE 1

Roles and Responsibilities

The IAC (“**Committee**”) will perform the roles and responsibilities and will have the authority delegated to it under the terms of the Framework Agreement.

Note from WB: *Consideration should be given by donors and the legal subgroup as to the interim period – i.e. the period while the Framework Agreement has not been signed and where and what authority the LAC has from the donor committee or others. To be reviewed and discussed by legal counsels.*

ARTICLE 2

Committee Members

2.1 Committee Number

The Committee will consist of a minimum of nine members (“**Members**”) appointed in accordance with the following provisions: [•].

Note from WB: *The provisions will mirror those referred to in the LAC Terms of Reference. What other policies and procedures should the LAC adopt? They would be adopted and amended as defined herein. The LAC Procedural Bylaws should not cross-refer to the LAC Terms of Reference, since the latter will not exist once the Framework Agreement is signed and since the LAC Procedural Bylaws need to be a self-standing document on its own terms.*

2.2 Term of Members

Subject to Article 2.6 below, Members will serve for an initial term of [two, four or six years] commencing on the date of appointment. Three members would serve a two year term; three members would serve a four year term and three members would serve a six year term. Each Member will hold office until his or her successor is appointed in accordance with the Framework Agreement. The term of any Member will not exceed his or her initial term and one (1) consecutive term thereafter. New members will be selected through a panel process and open call for nominations as was done for the first nominees. The GAVI Board, in consultation with the donor committee will approve members.

Note from WB: *This part on selection to be updated based on establishment of LAC Selection Panel and didn't donors recently decide that the LAC Selection Panel, rather than the GAVI Board, would play an ongoing role with respect to LAC member matters?*

2.3 Chairperson

The Committee will appoint one Member to act as chairperson for any term of years selected by the Committee and in accordance with any limitations on such term established in the Framework Agreement. The Chairperson will set the rules of procedure for meetings of the

Committee, consistent with the Framework Agreement and these Bylaws. The Chairperson will have such powers and duties as those usually appertaining to the office of a chairperson and whatever other powers or duties as are prescribed by the Framework Agreement.

2.4 Vice chairperson

The Committee may also appoint a vice chairperson who will assist the Chairperson in carrying out his or her duties. In the event the chairperson cannot perform his or her duties, the vice chairperson will perform the duties of the Chairperson until the next meeting of the Committee. The vice chairperson will have, to the extent authorized by the Chairperson, the same powers as the Chairperson. The vice chairperson will perform such other duties as from time to time may be assigned to him or her by the Chairperson.

2.5 Vacancies

Vacancies will be filled in accordance with the process described in the Framework Agreement for appointing new Committee Members.

2.6 Resignation & Removal

2.6.1 Any Member may resign at any time by delivering written notice of at least 30 days to the Committee Chair or by giving oral or written notice at any Committee meeting.

2.6.2 The Committee may remove any Committee member in accordance with the voting requirements established in Article 3.

2.7 Committee Expenses

2.7.1 The expenses attributed to organizing Committee meetings and supporting the Committee and its functions will be borne by the AMC Secretariat.

2.7.2 Individual Committee Members *will receive an honorarium for serving on the Committee*. Member will be reimbursed reasonable travel expenses incurred for the purpose of attending Committee meetings.

Note: *Italicized text to be discussed/confirmed.*

2.8 Sub-Committees

The Committee may designate and appoint one or more standing or temporary sub-committees, each of which shall consist of two or more Members. Such sub-committees shall have and exercise the authority of the Committee, subject to such limitations and requirements as are set by the Committee in the document establishing such committee. All actions of any sub-committee will be reported to the Committee at its meeting next succeeding such action. Decisions that approve a price or target product profile cannot be made by a sub-committee but must be made by the full group.

ARTICLE 3 Meetings

3.1 Annual Meeting Schedule

The Committee will meet at least once a year unless a more frequent meeting schedule is established, for a given year, by the Committee. The Committee Chair will endeavor to ensure

that all applicable documents and matters for consideration are provided with an agenda at least 21 days before the applicable meeting.

3.2 Special Meetings

The Committee Chair may call a special meeting, not scheduled as part of the annual schedule, upon at least 15 days' notice to the other Members.

3.3 Meetings by Telephone or other Means of Communication

The Committee may meet by means of a telephone conference or similar communications equipment whereby all persons participating in the meeting can hear each other at the same time. Participation by such means will constitute presence in person at a meeting. Decisions by email will not be permitted.

3.4 Quorum

A majority of the Members will constitute a quorum for any Committee meeting. If a quorum is not present at a meeting, a majority of the Members present shall adjourn the meeting and set a date and time for the meeting to reconvene.

3.5 Voting

3.5.1 Each Member will be entitled to one (1) vote and all matters will be determined by simple majority vote of the Members present at a Committee meeting. No Member may act or vote by proxy. A Member present at a Committee meeting will be presumed to have assented to the action taken unless his or her dissent or abstention is entered in the minutes of the meeting.

3.5.2 If there is a tie in any vote, the Chairperson will have the right to cast one additional and deciding vote. Committee decisions will be final and without appeal. Each decision shall include a brief statement of the reasons on which it is based.

3.5.3 In any vote, where there is no substantial majority agreement (e.g., of at least 2/3 majority of the Members present at the applicable meeting in agreement the Chairperson may table the decision and confer such matter to the AMC Donor Committee for guidance on the matter prior to raising it again at a subsequent Committee meeting.

Note from the WB: *Consideration is being given as to the distinction between 2/3 vote and a simple majority as noted in 3.5.1 and 3.5.3 and under what circumstances it should be referred to a donor committee.*

3.6 Observers

Note: *Process for inviting observers TBD.*

ARTICLE 4

Conflict of Interest

4.1 Conflict Defined

A conflict of interest may exist when the interests or activities of any Member may derive a financial or other material gain directly or indirectly such as a family member as a result of decisions taken while serving on the Committee.

4.2 Disclosure Required

Any possible conflict of interest will be disclosed to the Committee [, the AMC Secretariat and the IAC Selection Panel] and when any conflict of interest is determined to exist, by majority vote of the disinterested Members **Note from WB:** *[any role for outsiders?]*, the Member with the conflict will not deliberate or vote on the matter. However, any Member disclosing a possible conflict of interest may be counted in determining the presence of a quorum at a Committee meeting.

ARTICLE 5

Committee Records

The Committee will keep correct and adequate minutes and records of Committee proceedings, including the disclosure of any conflict of interest and the resolution of such matters. Such records will be made available to the AMC Donor Committee and to such other individuals as the Committee may determine in its discretion. Materials prepared by and for the Committee, including meeting minutes, will be in the English language.

Note from WB: *Donor committee needs to discuss if minutes should be made public.*

ARTICLE 6

Amendments to these Bylaws

Consistent with the requirements established in the Charter, the Committee may amend these Bylaws in accordance with the voting process described in Article 3.

Note from WB: *Consideration should be given to the insertion of some sort of period (for example, an [36] month period, starting from the date of the Framework Agreement and ending [36] months thereafter, when the Donors or other interested stakeholders can, by some sort of majority decision, come together and decide to amend the LAC Procedural Bylaws. The idea here is not to fetter the independence of the LAC, but to be sure that over the initial “teething” period of the project, stakeholders can insert and delete language from the Bylaws to cover unanticipated or unintended side effects as well as inconsistencies or lack of clarity, of existing language.*

Note from WB: *Overall, the LAC Procedural Bylaws will need to be progressively updated and “beefed up” as the structure of the project takes form.*