# Independent Assessment Committee Charter and Bylaws

# Charter

# ARTICLE I

There is hereby established an independent committee to be known as the Independent Assessment Committee ("**IAC**") which shall undertake review, assessment, approval and monitoring responsibilities in connection with any and all Advance Market Commitments in accordance with the provisions of this IAC Charter and Bylaws and the AMC Procedures Memorandum.

## ARTICLE II

Unless otherwise defined in this IAC Charter and Bylaws, the following terms shall have the respective meanings set out below:

"Advance Market Commitment" or "AMC" means an initiative to encourage private sector investment to accelerate the availability of priority new vaccines for developing countries in relation to which the GAVI Alliance is a stakeholder;

"**AMC Eligibility**" means the eligibility of an AMC-Eligible Manufacturer to receive funds subject to and in accordance with specific terms and conditions of the relevant Advance Market Commitment;

"**AMC Eligibility Determination Meeting**" means an IAC Meeting convened to review, consider, and approve or reject Applications for AMC Eligibility;

"**AMC-Eligible Manufacturer**" means an AMC Registered Manufacturer whose Application for AMC Eligibility has been approved by the IAC;

"**AMC-Eligible Vaccine**" means a candidate vaccine in respect of which an Application for AMC Eligibility has been considered and approved by the IAC;

"**AMC-Funded Price**" means that portion of the Vaccine Purchase Price for each dose of AMC-Eligible Vaccine which is payable under a Supply Agreement that is not a Co-Payment;

"AMC Objectives" means:

- (i) to accelerate the development of vaccines that meet developing country needs as specified in the Target Product Profile;
- to bring forward the availability of effective vaccines for developing countries by guaranteeing the initial purchase price for a limited quantity of new vaccines that represents value for money and incentivises manufacturers to invest in scaling-up production capacity to meet developing country vaccine demand;
- to accelerate vaccine uptake by ensuring predictable vaccine pricing for countries and manufacturers, including binding commitments by participating companies to supply the vaccines at low, long-term and sustainable prices; and
- (iv) to pilot the effectiveness of the AMC mechanism as an incentive for needed vaccines and to learn lessons for possible future Advance Market Commitments;

"**AMC Period**" means in respect of each Supply Agreement, the period beginning on the date on which any instalment of the AMC-Funded Price is first payable to an AMC-Eligible Manufacturer and

ending on the date when the AMC-Funded Price is last payable to the relevant AMC-Eligible Manufacturer;

"**AMC Procedures Memorandum**" means the memorandum outlining the application, assessment, review and monitoring procedures and processes that apply to vaccine manufacturers, AMC Registered Manufacturers, AMC-Eligible Manufacturers, the AMC Secretariat, the GAVI Alliance, the IAC, IBRD and GAVI Eligible Countries as disclosed on the AMC Website;

"**AMC Registered Manufacturer**" means a vaccine manufacturer who has entered into an AMC Registered Manufacturer Agreement with the GAVI Alliance and IBRD and who shall be eligible to submit an Application for AMC Eligibility;

"AMC Registered Manufacturer Agreement" means the agreement, substantially in the form attached at Schedule 1 of the AMC Procedures Memorandum and entered into between a vaccine manufacturer, the GAVI Alliance and IBRD upon delivery by such vaccine manufacturer of an AMC Registered Manufacturer Application Package indicating such manufacturer's interest in participating in an Advance Market Commitment;

"**AMC Registered Manufacturer Application Package**" shall have the meaning given to it in paragraph 2.1 of the AMC Procedures Memorandum;

"**AMC Secretariat**" means the individuals designated by the GAVI Alliance to provide administrative support to the Independent Assessment Committee in respect of any and all Advance Market Commitments;

"**AMC Website**" means the website maintained by the AMC Secretariat with respect to the relevant Advance Market Commitments;

"**Application for AMC Eligibility**" means an application submitted by an AMC Registered Manufacturer in accordance with the AMC Procedures Memorandum;

"**Business Day**" means a day (other than a Saturday or Sunday) on which the IBRD is open for general business in Washington DC;

"**Confidential Information**" means: (i) any information relating to an Application for AMC Eligibility; (ii) or any other information received in connection with an Application for AMC Eligibility or any other matters contemplated in the AMC Procedures Memorandum that is clearly marked or otherwise identified as confidential; or (iii) any other information received by any of the GAVI Alliance, IBRD, a procurement agency, the IAC or other stakeholder at any time during the relevant offer period and in relation to the AMC which is of a commercially sensitive or price-sensitive nature, provided that such term does not include information that: (a) is publicly available at the time of disclosure; (b) becomes publicly available following disclosure in accordance with the terms of the relevant AMC; (c) was lawfully known by the recipient prior to being disclosed; or (d) subsequently becomes publicly known through no act or omission by the recipient or any person acting on behalf of the recipient;

"**Confirmation of Member's Duties**" means the confirmation appended to these IAC Charter and Bylaws as Attachment A which each IAC Member is required to complete and submit to the AMC Secretariat on his or her appointment to the IAC;

"**Chairperson**" means the person appointed to chair meetings of IAC Members in accordance with these IAC Charter and Bylaws;

"**Conflict of Interest**" means any financial, professional or other interest of an IAC Member that may, or may be reasonably likely to, affect such IAC Member's objectivity and independence in carrying out his/her duties and responsibilities in accordance with these IAC Charter and Bylaws, the AMC

#### AMENDMENT NO.1 MARCH 2011

Objectives and the AMC Procedures Memorandum including, but not limited to, the interests of immediate family members, employers, close professional associates or any others with whom the IAC Member has or has had in the past a substantial common personal, financial or professional interest;

"**Co-payment**" means that portion of the Vaccine Purchase Price payable by the GAVI Alliance and the Recipient Countries per dose of AMC–Eligible Vaccine and shall be of an equivalent value to that of the Tail Price;

"**Cost Information**" means any information relating to the cost of production of the relevant AMC-Eligible Vaccine, including detailed information on the complete breakdown of cost of production, raw material costs, allocation of direct and indirect labour costs, per vial and per dose to demonstrate cost increases not absorbed by production efficiencies, such as increases in yield and decreases in other material costs;

"GAVI Alliance" means the GAVI Alliance, a non-profit foundation registered in the canton of Geneva, Switzerland (registry number CH-660-1699006-1), with offices at 2, Chemin des Mines, Geneva, Switzerland;

"GAVI Co-financing Policies" means the co-financing policies applicable to the GAVI Alliance, as such policies are available on the GAVI Alliance website;

"GAVI Eligible Country" means any country listed on the AMC Website http://www.gavialliance.org/support/who/index.php as such list may from time to time be amended, and "GAVI Eligible Countries" means more than one of them;

"**Grant Agreement**" means any grant agreement entered into by a Grantor with IBRD documenting long-term, binding grants from Grantors to IBRD for the benefit of the GAVI Alliance in connection with an Advance Market Commitment;

"**Grantor**" means any sovereign or other donors which has entered into a Grant Agreement with the IBRD, pledging long-term, binding grants to the IBRD for the benefit of the GAVI Alliance in connection with an Advance Market Commitment, and "**Grantors**" means all of them together;

"IAC Meeting" means a meeting of IAC Members duly convened in accordance with the IAC Charter and Bylaws;

"**IAC Member**" means a member of the Independent Assessment Committee who is appointed and serves in accordance with these IAC Charter and Bylaws;

"IAC Selection and Oversight Panel" means the panel constituted from time to time by members from each of the GAVI Alliance, IBRD, WHO, the International Federation of Pharmaceutical Manufacturers and Associations and the Developing Country Vaccine Manufacturers Network, which shall be responsible for, amongst other things, appointment of IAC Members, oversight and management of any conflict of interest issues that arise during the operation of the IAC, dismissal of IAC Members and selection of any new or replacement IAC Members as may be requested;

"**IBRD**" means the International Bank for Reconstruction and Development, an international organisation which maintains its headquarters at 1818 H Street, N.W., Washington, D.C. 20433, United States of America;

"Offer Period" shall have the meaning given to it in the terms and conditions relating to the relevant AMC;

"**Recipient Countries**" means GAVI Eligible Countries who have applied for and are receiving AMC-Eligible vaccines in accordance with the terms of the AMC Procedures Memorandum and "**Recipient Country**" means any one of them;

"**Supply Agreement**" means a supply agreement substantially in the form contained in the terms and conditions relating to the relevant AMC entered into between the GAVI Alliance, UNICEF or a procurement agency appointed by the GAVI Alliance to act on its behalf, and an AMC-Eligible Manufacturer;

**"Tail Period**" means in respect of each Supply Agreement, the period beginning on the date immediately following the last day on which the AMC-Funded Price is payable to an AMC-Eligible Manufacturer and ending on the date such Supply Agreement is terminated;

**"Tail Price**" means the price specified in a Supply Agreement as the price payable by Recipient Countries and/or the GAVI Alliance per dose for an AMC–Eligible Vaccine during the Tail Period as such price may be amended or modified from time to time;

**"TPP**" or "**Target Product Profile**" means the vaccine requirements which specify the product criteria and other requirements that a candidate vaccine must meet in order to be eligible for funding under any AMC, as such target product profile may be amended or supplemented from time to time;

"**Vaccine Purchase Price**" means the aggregate price payable by the GAVI Alliance, or a procurement agency acting on behalf of the GAVI Alliance, for each dose of AMC-Eligible Vaccine during the AMC Period and consists of the AMC-Funded Price and the Co-Payment;

"**Vice Chairperson**" means the person appointed to assist the Chairperson in meetings of IAC Members in accordance with these IAC Charter and Bylaws; and

"**WHO**" means the World Health Organization, an international health institution having its headquarters at Avenue Appia 20, 1211 Geneva 27, Switzerland.

# ARTICLE III TPP Review and Approval Process

## (a) **Authority**

The IAC shall be authorised to:

- (i) review the process adopted by WHO for the purposes of developing a TPP in respect of a particular AMC; and
- (ii) provide its approval of a TPP presented to it by the AMC Secretariat in respect of a particular AMC.

## (b) IAC Process

- (i) In an IAC Meeting, the IAC shall:
  - (A) review the process and related materials provided to it by the AMC Secretariat relating to the development of a TPP by WHO;
  - (B) be permitted to request any further information from the AMC Secretariat that the IAC may require in order to give its final approval of a particular TPP; and
  - (C) provide its final approval of a TPP if, in its sole discretion: (I) the WHO's most current applicable process for developing a particular TPP has been met in

all respects; and (II) the AMC Objectives will not be materially prejudiced by applying the TPP in question to the relevant AMC.

- (ii) If the IAC does not approve the TPP or if it requests any revisions to a TPP, the IAC shall provide a written explanation of its rationale to the AMC Secretariat to be delivered to WHO.
- (iii) A TPP that has received final approval by the IAC shall be promptly presented to the AMC Secretariat for application to a particular AMC.

# ARTICLE IV TPP Modification

## (a) Authority

Upon providing its final approval to a TPP in accordance with Article III, the IAC shall only be authorised to modify such TPP if, in its sole discretion, the IAC determines that it is not possible for any manufacturer to develop a vaccine that meets the TPP within the Offer Period, provided that such modifications shall not be more stringent than those initially developed for the applicable AMC.

#### (b) Process

- (i) In an IAC Meeting, the IAC may:
  - (A) decide to commence an inquiry regarding a particular TPP's ability to meet the AMC Objectives;
  - (B) request the WHO to review a TPP and consider and/or recommend less stringent requirements;
  - request that clearance of any proposed modification of the TPP is obtained by the WHO;
  - (D) communicate with the WHO if necessary during any review process of the TPP; and
  - (E) following a specific recommendation by WHO to the IAC to revise the TPP, the IAC shall consider and approve the WHO's proposed modification to the TPP in accordance with Article III hereof.
- (ii) Any TPP modified by the WHO upon the recommendation of the IAC shall be subject to the same review and approval processes listed in Article III.

# ARTICLE V AMC Eligibility Determination

#### (a) **Authority**

The IAC shall determine in its sole discretion whether any vaccine submitted by an AMC Registered Manufacturer in an Application for AMC Eligibility meets or exceeds the relevant TPP requirements.

#### (b) **Process**

### (i) Submission

In an AMC Eligibility Determination Meeting, the IAC shall review all Applications for AMC Eligibility presented to it by the AMC Secretariat. Any decision taken by the IAC in respect of all Applications for AMC Eligibility at such meeting shall be final.

### (ii) Applications for AMC Eligibility

- (A) The AMC Secretariat shall be responsible for collating all Applications for AMC Eligibility received from AMC Registered Manufacturers.
- (B) At least 30 Business Days prior to the AMC Eligibility Determination Meeting, the AMC Secretariat shall provide IAC Members with copies of all Applications for AMC Eligibility, including any other related information provided by AMC Registered Manufacturers in relation to such Application for AMC Eligibility.

### (iii) Communication with AMC Registered Manufacturers

- (A) The AMC Secretariat shall at all times be responsible for all correspondence and communication with AMC Registered Manufacturers in connection with Applications for AMC Eligibility.
- (B) IAC Members may at any time communicate directly or indirectly with any AMC Registered Manufacturer about any Application for AMC Eligibility that has been, or is likely to be, submitted to the IAC in order to assist the IAC with the process of AMC Eligibility Determination.
- (C) IAC Members may require manufacturers to provide additional information for the purpose of assessing AMC Eligibility. In such cases, IAC Members shall contact the IAC Chairperson or Vice Chairperson and inform him or her of the additional information required. The IAC Member with the requests for additional information shall copy all IAC Members as well as the AMC Secretariat in any such correspondence. The IAC Chairperson or Vice Chairperson will review the request for information and if approved will request that the AMC Secretariat liaise with the applicable manufacturer. She or he shall make herself or himself available for any necessary meeting or conference call with such manufacturer. The AMC Secretariat will also attend any meeting or conference call between the IAC and an AMC Registered Manufacturer in order to record minutes of the discussion. The AMC Secretariat will prepare minutes of any such meetings for review within five business days. IAC Members shall review and approve such minutes within ten business days after receipt. The minutes may be published on the applicable AMC Website to the extent that the information contained in such minutes does not any any time include any Confidential Information.

## (iv) AMC Eligibility Determination Meetings

The IAC shall review and consider each Application for AMC Eligibility and any information submitted with it pursuant to any communications permitted under Article V(b)(iii)(B) above and including, in respect of any pre-qualified vaccines, any recommendations from WHO on the areas that have been reviewed by WHO during

the pre-qualification process. The IAC shall not be required to consider any incomplete or inaccurate applications.

## (v) IAC Actions

Having reviewed and considered each Application for AMC Eligibility:

- (A) the IAC may approve an Application for AMC Eligibility during the AMC Eligibility Determination Meeting and request that the AMC Secretariat provide a written confirmation of such approval to such manufacturer; or
- (B) the IAC may reject an Application for AMC Eligibility, in which case the relevant AMC Registered Manufacturer may re-submit an Application for AMC Eligibility at the next or any subsequent AMC Eligibility Determination Meeting.

### (vi) AMC Eligibility Determination Meeting Minutes

- (A) The AMC Secretariat shall prepare minutes from each AMC Eligibility Determination Meeting and shall distribute drafts of such minutes to the IAC for review within five Business Days of the relevant AMC Eligibility Determination Meeting.
- (B) IAC Members shall review such minutes for accuracy and consistency. Any requests for revision of such minutes or an approval of such minutes shall be made by the IAC within ten Business Days after receipt.
- (C) The minutes of an AMC Eligibility Determination Meeting shall be published on the applicable AMC Website to the extent that the information contained in such minutes does not at any time include any Confidential Information.

# ARTICLE VI Monitoring and Reporting Roles

## (a) **Authority**

The IAC shall review information provided to it by the AMC Secretariat from time to time in relation to a particular AMC. Such information shall include information regarding the AMC's influence on the development and production of specific vaccines, including progress made in incentivising development of vaccines that would meet the TPP. The IAC shall be authorised to review and approve each annual progress report coordinated and prepared by the AMC Secretariat.

#### (b) IAC Process

The IAC may permit IBRD or the GAVI Alliance to join its meetings as an observer. In such meetings, the IAC may review and report on developments of an AMC as well as discuss and deliberate other matters that may be significant to achieving the AMC Objectives.

# ARTICLE VII Review and Modification of AMC Prices

(a) Authority

The IAC shall be authorised to review and modify the Tail Price and/or the Tail Price Cap where: (i) requested by an AMC Registered Manufacturer where there has been a legal or regulatory change that creates requirements for higher levels of capital investment, quality control activities and other expenses that materially affects the cost of production of an AMC Eligible Vaccine provided that such request is accompanied by relevant Cost Information; and/or (ii) otherwise permitted under the terms and conditions of the relevant Advance Market Commitment.

## (b) IAC Process

In an IAC Meeting:

- (i) The IAC may commence an inquiry into the Tail Price and the Tail Price Cap base on an application received by an AMC Registered Manufacturer and/or and AMC-Eligible Manufacturer on the basis of the terms and conditions of the relevant AMC.
- (ii) The IAC may request that an independent expert group be convened by the AMC Secretariat, the GAVI Alliance and IBRD and other independent experts to advise the IAC whether a price adjustment is appropriate and necessary to achieve the AMC Objectives.
- (iii) The IAC shall consider any advice or recommendation of such independent expert group in good faith and may adjust the applicable pricing or formula to give effect to such advice or recommendation.
- (iv) The IAC shall provide a report on its activities under this Article VII and the AMC Secretariat shall make such report available on the AMC Website, provided that such report shall not at any time include any Confidential Information and shall be made available subject to the terms and conditions of the relevant AMC.

# ARTICLE VIII Dispute Resolution

# (a) **Authority**

The IAC shall be authorised to monitor and resolve any issues relating to its responsibilities set forth in this Charter. IAC Members who violate their Confirmation of Member Duties may be subject to removal from the IAC by the IAC Selection and Oversight Panel.

## (b) IAC Process

IAC Members shall vote and otherwise make decisions with respect to any matter which comes before the IAC, in accordance with the IAC Charter and Bylaws and the Confirmation of Members Duties signed by each IAC Member.

# ARTICLE IX Amendments and Modifications

The Charter and Bylaws may be amended with the consent of IBRD and the GAVI Alliance, acting upon advice of the IAC. All proposed amendments shall be published on the applicable AMC Website.

# **Bylaws**

# ARTICLE I Members & Appointment

#### (a) IAC Members

At any time, the IAC shall be composed of not less than nine members and not more than eleven members (inclusive of a Chairperson and Vice Chairperson) (each, an "IAC **Member**", or together, the "IAC **Members**"). Each IAC Member shall complete a Confirmation of Member Duties as set out in Attachment A. Each IAC Member serves in its personal capacity, and not as a representative of any organisation or group, including its employer. Each IAC Member shall perform its duties and responsibilities solely for the purpose of meeting the AMC Objectives in accordance with the IAC Charter and Bylaws and the Confirmation of Member's Duties.

#### (b) Appointment and Term

IAC Members, including the Chairperson, are appointed by the IAC Selection and Oversight Panel. Subject to the other provisions of the IAC Charter and Bylaws, IAC Members, including the Chairperson, shall serve for an initial term of up to six years, subject to reappointment. Each IAC Member's term of appointment may only be renewed once. IAC Members whose terms have expired shall remain in office until they resign or a successor is appointed by the IAC Selection and Oversight Panel. IAC Members' terms of office shall expire on resignation or death and the IAC Selection and Oversight Panel shall appoint a successor as and when it may be required. Of the ten IAC Members initially appointed, the initial terms of three members shall expire at the end of three years, the initial terms of four members shall expire at the end of four years, and the initial terms of three members shall expire at the end of six years.

#### (c) Chairperson

The Chairperson shall have such powers and duties as those usually appertaining to the office of a chairperson to determine the rules of order necessary to complete meeting agendas and accomplish the tasks required by meeting agendas, subject to the specific requirements prescribed in these Bylaws.

#### (d) Vice Chairperson

The IAC may appoint a Vice Chairperson who shall assist the Chairperson in carrying out his or her duties. If for whatever reason, the Chairperson is unable to perform his or her duties, the Vice Chairperson shall perform the duties of the Chairperson until a successor is chosen by the IAC Selection and Oversight Panel. The Vice Chairperson shall have the same powers as the Chairperson when serving in the Chairperson's capacity. The Vice Chairperson shall perform such other duties as from time to time may be assigned to him or her by the Chairperson and/or the IAC as a whole.

#### (e) Resignation & Removal

 Any IAC Member may resign from the IAC at any time by delivering written notice to the IAC Chairperson or by giving an oral or written notice at any IAC Meeting. Unless otherwise agreed by the IAC Members, any such resignation shall take effect 30 Business Days after delivery of such notice of resignation.

- (ii) The IAC Selection and Oversight Panel may, in its discretion, remove an IAC Member, without a vote by the IAC, if in the opinion of the IAC Selection and Oversight Panel:
  - an IAC Member has or is reasonably likely to have a conflict of interest based on an affiliation with any of an AMC Registered Manufacturer, the GAVI Alliance, IBRD, WHO, any procurement agency acting on behalf of the GAVI Alliance or any Grantor;
  - (2) credible evidence is presented to the IAC Selection and Oversight Panel that there is a material likelihood of an IAC Member violating the terms of their Confirmation of Members' Duties or materially prejudicing the AMC Objectives;
  - (3) an IAC Member has failed to attend three or more consecutive IAC Meetings without prior written notice to the rest of the IAC and/or the IAC Selection and Oversight Panel; or
  - (4) the IAC is unable to perform its functions due to the IAC Member's inability to vote at IAC Meetings due to a Conflict of Interest.

# ARTICLE II Sub-Committees and Advisors

- (i) The IAC may establish one or more standing or temporary sub-committees, each of which shall consist of two or more IAC Members. Such sub-committees shall be advisory in nature and shall not have nor exercise the authority of the IAC. Actions of sub-committees shall be reported to the IAC at its next meeting or as requested by the IAC.
- (ii) In order to assist the IAC in making any inquiry, review, modification or determination, the IAC may at any time engage or rely upon independent expert advice from consultants and/or other advisors as the IAC may deem necessary to make any inquiry, resolution or determination pursuant to the IAC Charter and Bylaws.

# ARTICLE III Meetings

## (a) Meeting Schedule

Subject to subparagraphs (b) and (c) below and to Article V(b)(iv) of the Charter, the IAC shall meet at least annually. The Chairperson, assisted by the AMC Secretariat, shall endeavour to ensure that all applicable documents and matters for consideration are provided with an agenda at least 30 IBRD Business Days before the applicable meeting.

## (b) AMC Eligibility Determination Meetings

Upon receipt by the AMC Secretariat of a complete and accurate Application for AMC Eligibility in accordance with the AMC Procedures Memorandum, the AMC Secretariat shall notify the IAC Members of the same and provide the IAC Members with such Application for AMC Eligibility. As soon as reasonably possible after receipt of such Application for AMC Eligibility, the Chairperson shall call an AMC Eligibility Meeting and shall review and consider such application in accordance with these IAC Charter and Bylaws.

## (c) Special Meetings

The IAC Chairperson may call a special meeting, in addition to its annual meeting and/or any AMC Eligibility Determination Meetings, upon at least 15 Business Days' written notice to IAC Members when the Chairperson deems it necessary or appropriate to further the AMC Objectives.

### (d) Meetings by Virtual Means of Communication

The IAC may convene an IAC Meeting by means of a telephone or video conference or other means whereby all persons participating in the meeting can hear each other. Participation by such means shall be deemed equivalent to an in-person participation. The IAC may not take decisions based on written consents (e.g., via fax or email).

### (e) Quorum

At least seven of the IAC Members for the time being holding office shall constitute a quorum for any IAC Meeting. If a quorum is not present at a meeting, the meeting shall be deemed adjourned and a new date and time shall be proposed by the Chairperson.

### (f) Voting

Each member shall be entitled to one (1) vote and all matters shall be determined by a two thirds (2/3) majority of the total number of IAC Members present at the relevant meeting. No member may act or vote by proxy. A member present at an IAC Meeting shall be presumed to have assented to the vote taken unless, upon request, his or her dissent or abstention is entered in the minutes of the meeting.

#### (g) Observers

The IAC Chairperson may allow observers to attend an IAC Meeting, in his or her discretion. Such observers shall not have any voting rights in respect of any determination to be taken by the IAC. The Chairperson may defer such decisions to the IAC for determination via a vote. Observers shall not be allowed to present to the IAC nor give any advice or recommendation to the IAC. Observers who attend an IAC Meeting shall be obliged to sign a confidentiality agreement, agreeing not to use any Confidential Information or disclose any Confidential Information to any person other than: (i) where such disclosure is approved in writing by the party to whom the Confidential Information relates; (ii) where such disclosure is made to any regulatory authority or any other person to which such delivery or disclosure may be necessary to comply with any rule, law, regulation or order; or (iii) where such information enters the public domain otherwise than as a result of a breach by other parties subject to similar confidentiality agreements.

# ARTICLE IV Conflicts of Interest

#### (a) **Disclosure**

IAC Members shall at all times disclose any Conflict of Interest as and when such conflict arises, by notice to the AMC Secretariat using the Conflict of Interest Declaration form set out in Exhibit A.

## (b) IAC Meeting Participation

An IAC Member with a Conflict of Interest shall not deliberate or vote on a matter related to the conflict. However, any IAC Member with a Conflict of Interest may be counted in determining the presence of a quorum at an IAC Meeting.

### (c) IAC Meeting Validity

If the number of IAC Members present and unable to deliberate or vote due to a Conflict of Interest exceeds three members then such IAC Meeting shall be deemed adjourned and a further IAC Meeting shall not be convened until such time as the IAC Selection and Oversight Panel has removed the relevant IAC Members with a Conflict of Interest and has appointed sufficient IAC Members to meet the quorum and Conflict of Interest requirements.

# ARTICLE V IAC Records

The IAC shall be responsible for keeping accurate minutes and records of IAC proceedings. Where IAC Meetings cover Confidential Information or matters, including the disclosure and resolution of any Conflict of Interest, the IAC may request that minutes be drafted for public disclosure excluding such Confidential Information. Draft minutes and more detailed or specific meeting reports as requested by the IAC shall be prepared by the AMC Secretariat for review and approval by the IAC at its next meeting. The AMC Secretariat and IAC shall consult and jointly determine what IAC reports and related documents can be made publicly available, subject to confidentiality and other legal considerations. Materials prepared by and for the IAC, including minutes of IAC Meetings, shall be at all times in the English language.

# Attachment A Independent Assessment Committee

## Form of

# **Confirmation of Duties of IAC Members**

This Confirmation of Duties of IAC Members (this "**Confirmation**") sets forth the duties and responsibilities with which each member of the Independent Assessment Committee ("**IAC**"), (each an "**IAC Member**", and together the "**IAC Members**") agrees to comply while serving on the IAC.

Capitalised terms used in this Confirmation but not defined herein shall have the meanings given to them in the IAC Charter and Bylaws.

### (1) General

Each IAC Member shall:

- serve on the IAC in his or her individual capacity and perform all duties and responsibilities pursuant to the terms of this Confirmation, the IAC Charter and Bylaws;
- (b) attend all IAC Meetings in person or if such attendance is not reasonably possible, by telephone, video conference or similar means. If an IAC Member is unable to attend any IAC Meeting due to exigent circumstances, he or she shall notify the IAC Chairperson of his/her absence as soon as possible in advance of the relevant meeting; and
- (c) exercise due care and diligence in performing all duties and responsibilities pursuant to the terms of this Confirmation, the IAC Charter and Bylaws, including reviewing all information provided to it in connection with each IAC Meeting and the decisions required to be taken by the IAC at each IAC Meeting.

## (2) Decision Making

Each IAC Member shall make decisions, by voting or otherwise, while serving on the IAC:

- (a) in the interest of furthering the intent and purposes of the AMC Objectives;
- (b) in accordance with and subject to the scope of authority delegated to the IAC under the IAC Charter and Bylaws; and
- (c) in accordance with the IAC Charter and Bylaws.

#### (3) Confidentiality and Communications

Each IAC Member agrees to obtain the written consent of the GAVI Alliance prior to making any public statements in the media relating to the relevant AMC. In the event that any IAC Member obtains any Confidential Information while serving on the IAC, the IAC Member agrees:

(a) not to disclose such Confidential Information to any person, other than where such disclosure is either: (i) approved in writing by the party to whom the Confidential Information relates; (ii) made to any regulatory authority or any other person to which such delivery or disclosure may be necessary or appropriate to effect compliance with any law, rule, regulation or order; or (iii) where such information enters the public domain otherwise than as a result of a breach by the GAVI Alliance as IBRD of their respective obligations under the relevant AMC;

- (b) not to use any Confidential Information except as necessary to perform its responsibilities and duties, as set out in this Confirmation of Member Duties;
- (c) to promptly return any Confidential Information obtained by it to the AMC Secretariat (or such other party who has provided such information to it) or otherwise destroy such Confidential Information, as instructed by the AMC Secretariat or the provider of the information, as the case may be; and
- (d) that this provision shall survive indefinitely, even after his or her service on the IAC expires or is otherwise terminated.

# Where disclosure is made pursuant to paragraph (a)(ii) above, the IAC Member making such disclosure shall inform the IAC and the person to whom the Confidential Information relates of: (i) the details of such disclosure; and (ii) the law, rule, regulation or order under which the disclosure was made.

For the purpose of this Confirmation, "**Confidential Information**" means: (i) any information relating to an Application for AMC Eligibility; (ii) or any other information received in connection with an Application for AMC Eligibility or any other matters contemplated in the AMC Procedures Memorandum that is clearly marked or otherwise identified as confidential; or (iii) any other information received by any of the GAVI Alliance, IBRD, a procurement agency, the IAC or other stakeholder at any time during the relevant offer period and in relation to the AMC which is of a commercially sensitive or price-sensitive nature, provided that such term does not include information that: (a) is publicly available at the time of disclosure; (b) becomes publicly available following disclosure in accordance with the terms of the relevant AMC; (c) was lawfully known by the recipient prior to being disclosed; or (d) subsequently becomes publicly known through no act or omission by the recipient or any person acting on behalf of the recipient.

## (4) Conflicts of Interest

To help assure the highest integrity and public confidence in the IAC, each IAC Member agrees:

- to use good faith and reasonable efforts to avoid any Conflict of Interest situations; and
- (b) to immediately disclose any Conflict of Interest to the AMC Secretariat and to the IAC Chairperson in the form of the Conflict Interest Declaration attached hereto as Exhibit A.

For the purposes of this Confirmation, a "**Conflict of Interest**" means any financial, professional or other interest of an IAC Member that may, or may be reasonably likely to, affect such IAC Member's objectivity and independence in carrying out his/her duties and responsibilities in accordance with the IAC Charter and Bylaws, the AMC Objectives and the Procedures Memorandum including but not limited to, the interests of immediate family members, employers, close professional associates or any others with whom the IAC Member has or has had in the past a substantial common personal, financial or professional interest.

I CONFIRM THAT I HAVE READ AND UNDERSTOOD THIS CONFIRMATION OF DUTIES OF IAC MEMBERS AND AGREE TO PERFORM THE DUTIES AND COMPLY WITH THE REQUIREMENTS IDENTIFIED HEREIN. I AGREE THAT THIS CONFIRMATION IS MADE BY ME FOR THE BENEFIT OF, AND MAY BE RELIED UPON BY, THE IBRD AND THE GAVI ALLIANCE.

IAC Member Signature: \_\_\_\_\_

Date: \_\_\_\_\_

# Exhibit A Conflict of Interest Declaration

## (1) Timing for submission

Each IAC Member must complete and submit this Conflict of Interest Declaration Form to the AMC Secretariat immediately upon appointment to the IAC and thereafter annually until the earlier of the sixth anniversary of such IAC Members appointment to the IAC and such IAC Member's resignation from the IAC.

## (2) Updated on Change of Information

At any time during his/her appointment to the IAC, each IAC Member must update this Conflict of Interest Declaration Form if there is any change in information provided in this declaration.

## (3) Conflicts of Interest Disclosed Publicly

All Conflicts of Interest shall be publicly disclosed to other IAC Meeting participants and in any resulting report or other IAC work product.

## (4) Questions

Please answer each of the questions below on a separate page and attach it to this form. 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 you, your employer and your immediate family members (i.e., spouse (or partner with whom you have a similar close personal relationship) and any children under the age of 18).

- Do you or any organisation, institution or body with which you have a financial relationship, have any financial interest in any AMC Registered Manufacturer, IBRD, WHO, UNICEF, the GAVI Alliance or a Grantor? If so, please list them and the specifics of your interest.
- Do you or any organisation, institution or body with which you have a financial relationship, have any other interest in matters to be heard or reasonably likely to be heard and decided by the IAC that would compromise your independence?

I HEREBY DECLARE THAT THE DISCLOSED INFORMATION IS TRUE AND COMPLETE TO THE BEST OF MY KNOWLEDGE. IF AT ANY TIME DURING MY TERM OF APPOINTMENT TO THE IAC THERE IS ANY CHANGE TO THE INFORMATION PROVIDED IN THIS DECLARATION, I SHALL NOTIFY THE AMC SECRETARIAT AND THE CHAIRPERSON AND COMPLETE A NEW DECLARATION OF INTERESTS DETAILING THE CHANGES.

IAC Member Signature:\_\_\_\_\_

Date:\_\_\_\_\_