EXECUTION VERSION

Dated 7 March 2011

ADVANCE MARKET COMMITMENT

PROCEDURES MEMORANDUM

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Part 1 Introduction

1.1 "**Advance Market Commitment**" or "**AMC**" is an initiative to encourage private sector investment to accelerate the availability of priority new vaccines for poorer countries in relation to which the GAVI Alliance is a stakeholder. This Procedures Memorandum describes the procedures that would be applicable to any AMC, including the following:

(i) how vaccine manufacturers may apply to become an AMC-Registered Manufacturer which may participate in a particular AMC;

(ii) the procedures and requirements for an Application for AMC Eligibility;

(iii) the procedures for AMC Registered Manufacturers to enter into Supply Agreements with UNICEF;

(iv) Eligible Country Application Procedures; and

(v) ongoing monitoring and reporting obligations.

1.2 Unless defined in this Procedures Memorandum, terms which are capitalised in this Procedures Memorandum have the meanings given to them in the master definitions schedule dated 12 June 2009 signed by, among others, the GAVI Alliance and IBRD (the "**Master Definitions Schedule**").

Part 2 AMC Registered Manufacturer Registration Procedures

2.1 AMC Registered Manufacturer Application Package

Manufacturers interested in participating in an AMC must submit to the AMC Secretariat an information package (the "**AMC Registered Manufacturer Application Package**") which shall include the following:

(i) details of an applicant's legal status and registration/corporate incorporation information;

(ii) particulars of an applicant's licence and/or registration from the relevant National Regulatory Authority, if any;

(iii) relevant data regarding vaccine production, supply and delivery activity undertaken by an applicant (if any), including, an overview of any existing vaccine portfolio, number of years of production and supply of such vaccine, quantities supplied annually for the past three years and the number of countries in which such vaccine has obtained the requisite licensing and in which they are currently marketed;

(iv) estimated timeline for making an Application for AMC Eligibility, if any; and

(v) estimated timeline for submitting a Product Summary File to WHO.

A copy of all AMC Registered Manufacturer Application Packages shall be forwarded by the AMC Secretariat to UNICEF, the GAVI Alliance and IBRD.

2.2 Application Receipt Acknowledgment and AMC Registered Manufacturer Agreement

As soon as reasonably possible following receipt of the AMC Registered Manufacturer Application Package, the GAVI Alliance and IBRD shall enter into an AMC Registered Manufacturer Agreement with the applicant substantially in the form attached at Schedule 1. The AMC Secretariat shall promptly deliver to UNICEF a copy of each signed AMC Registered Manufacturer Agreement.

Part 3 Application for AMC Eligibility

3.1 Introduction

An AMC Registered Manufacturer may submit an Application for AMC Eligibility in accordance with the procedures described in this Part 3.

3.2 Administrative Procedures

3.2.1 An Application for AMC Eligibility may only be submitted to the AMC Secretariat once WHO has accepted such candidate vaccine for assessment in accordance with WHO's procedures applicable at the time for assessing the acceptability, in principle, of vaccines for purchase by United Nations agencies ("**WHO Prequalification**").

3.2.2 An Application for AMC Eligibility may be submitted at any time during the Offer Period.

3.2.3 Each Application for AMC Eligibility must be accompanied by an AMC-Eligible Vaccine Information Package which shall include the following:

(i) the Product Summary File submitted to WHO and a copy of the written confirmation from WHO that the Product Summary File has been accepted for review; and

(ii) a "**TPP Eligibility Justification Document**" which is a written explanation from the applicant confirming how the candidate vaccine meets the TPP. For each TPP criteria as set out in Schedule 2, the explanation must either refer to relevant information in the Product Summary File; or provide a clear explanation describing how the candidate Vaccine meets the TPP.

3.2.4 The AMC-Eligible Vaccine Information Package shall be delivered to the AMC Secretariat in two hard copies and electronically in a format designated by the AMC Secretariat. Applicants are advised to contact the AMC Secretariat with any questions about the procedures, criteria requirements regarding an Application for AMC Eligibility in accordance with paragraph 3.2.6 below.

3.2.5 Upon receipt of a completed Application for AMC Eligibility, the AMC Secretariat shall notify such AMC Registered Manufacturer of the timing of each of the IAC's review and determination stages in relation to its relevant application.

3.2.6 Any and all communications, correspondence and queries relating to any current or prospective Applications for AMC Eligibility shall be made in writing to the AMC Secretariat at the following address:

Address:	AMC IAC AMC Secretariat GAVI Alliance Secretariat Chemin des Mines 2 1202 Geneva Switzerland
Attn:	AMC Manager
Phone:	+41 (22) 909 7167
Fax:	+41 (22) 909 6550

Email: amc@gavialliance.org

3.3 IAC Review and Determination Procedures

3.3.1 No later than five IBRD Business Days after receipt of a completed Application for AMC Eligibility, the AMC Secretariat shall submit copies of such application to the IAC for their review and consideration.

3.3.2 As soon as possible after the receipt of the completed Application for AMC Eligibility, the IAC may:

(i) submit questions, if any, to the WHO to clarify any aspects of the Application for AMC Eligibility; and/or

(ii) request technical assistance from WHO in the review and assessment of the candidate vaccine in relation to any criteria in paragraph B of Schedule 2.

The IAC shall, in its sole discretion and in accordance with the IAC Charter and Bylaws, determine whether a candidate Vaccine submitted by an AMC Registered Manufacturer in an Application for AMC Eligibility meets or exceeds the relevant TPP in accordance with the process set out below:

3.3.3 AMC Eligibility Determination

(i) If the candidate vaccine does not meet WHO Prequalification, the IAC shall not give any further consideration to the Application for AMC Eligibility relating to such vaccine and such vaccine shall be deemed to be ineligible to participate in the relevant Advance Market Commitment.

(ii) If the candidate vaccine meets WHO Prequalification, the IAC shall request from WHO a written report outlining how each TPP criteria listed in paragraph A of Schedule 2 has been met by such vaccine.

(iii) Subject to the requirements of the IAC Charter and Bylaws, the AMC Secretariat shall schedule an AMC Eligibility Determination Meeting as soon as reasonably possible after receipt by the AMC Secretariat of an Application for AMC Eligibility in respect of which the relevant candidate vaccine has met WHO Prequalification.

(iv) At an AMC Eligibility Determination Meeting, the IAC shall review and consider whether the candidate vaccine meets the TPP criteria listed in paragraph B of Schedule 2 and make its final determination regarding whether such candidate vaccine meets the TPP. The IAC may request representatives from WHO to attend any such meeting.

(v) The AMC Secretariat shall prepare official minutes of each IAC Meeting which shall be published on the AMC Website. The official minutes of each IAC Meeting shall be subject to the confidentiality provisions of Condition 13 of the Conditions.

(vi) All determinations and decisions of the IAC are final and not subject to appeal or further adjudication by any other person, body or tribunal pursuant to the terms of the AMC Registered Manufacturer Agreement.

3.3.4 Communication of AMC Eligibility Determination

Within 15 IBRD Business Days after the AMC Eligibility Determination Meeting, the GAVI Alliance (acting through the AMC Secretariat) shall: (a) inform an applicant whose candidate vaccine is eligible for participation in the applicable Advance Market Commitment; or (b) notify an applicant whose candidate vaccine is ineligible for participation in the applicable Advance Market Commitment. The GAVI Alliance shall copy UNICEF on any such response.

Part 4 Supply Offers and Supply Agreements

4.1 Calls for Supply Offers

4.1.1 UNICEF, acting on behalf of the GAVI Alliance shall issue a Call for Supply Offers 20 IBRD Business Days following the publication of the GAVI Strategic Demand Forecast. Such Call for Supply Offers shall be based on the GAVI Strategic Demand Forecast for the immediately following 15 years and shall be in respect of the period beginning no later than the immediately following five years.

4.1.2 Following each update of the GAVI Strategic Demand Forecast, UNICEF shall either: (i) issue a Call for Supply Offers; or (ii) announce that a Call for Supply Offers will not be made. For the avoidance of doubt, a Call for Supply Offers shall only be made where the GAVI Strategic Demand Forecast has increased by at least 10 million doses in the immediately following five years or where there are unallocated quantities of Supply Commitment which exceed 10 million doses.

4.1.3 Calls for Supply Offers shall be made until the earlier of when the Remaining AMC Offer Amount equals zero and 2020.

4.2 Eligibility of Manufactures to make Supply Offers

4.2.1 Subject to paragraph 4.3 below, all AMC Registered Manufacturers will be eligible to make a Supply Offer in response to a Call for Supply Offers provided that such Supply Offer is submitted no later than 20 IBRD Business Days after a Call for Supply Offer.

4.2.2 Each Supply Offer shall be evaluated by UNICEF acting on behalf of the GAVI Alliance on the basis of the Mandatory Requirements, Quantitative Requirements and Qualitative Requirements listed in paragraphs 4.3 and 4.4 below. During this process, it is expected UNICEF may request further clarification and conduct discussions with the relevant manufacturer. Priority will at all times be given to products that are WHO pre-qualified and that are AMC–Eligible Vaccines.

4.3 Contents and Requirements of a Supply Offer

A "**Supply Offer**" from a manufacturer shall include, but may not be limited to, the following:

4.3.1 Technical and Financial Mandatory Requirements

(i) For vaccines that are not AMC-Eligible Vaccines, if available, a copy of written confirmation from WHO that the Product Summary File has been accepted for review by WHO;

(ii) the Supplier's Vaccine Production Plan, the requirements of which are set out in Schedule 3; and

(iii) financial information required for evaluation by UNICEF and application to the United Nations Global Marketplace, including a complete copy of the latest audited financial statements, auditor's report and related notes thereto.

4.3.2 Quantitative Requirements

(i) Commencement date of the Vaccine Purchase Period offered;

(ii) Supply Commitment Quantities on an annual basis for the Vaccine Purchase Period;

(iii) price quotation for the Tail Price in US$; and

(iv) production and availability forecasts.

4.3.3 Qualitative Requirements

(i) Description of the vaccine, including vaccination schedule, standard shelf-life, vial size and presentation, product mix offered, weight and volume;

(ii) number of years the manufacturer has produced and delivered the offered product(s);

(iii) correlation with production of other products;

(iv) experience in vaccine production and delivery of similar scale to that offered;

(v) quality aspects, including quality control and any past non-compliance or irregularities; and

(vi) account management information.

4.4 Assessment of a Supply Offer

4.4.1 In determining the annual Supply Commitment to be awarded to a supplier ("**Supply Commitment Quantity**"), UNICEF shall consider the qualities of the Supply Offer relating to:

(i) the ability to support the AMC Objectives with the Supply Commitment Quantity offered and timelines for availability;

(ii) the feasibility of the Supplier's Vaccine Production Plan for the production of the Supply Commitment Quantity;

(iii) the offered Tail Price including any waiver or modification of the inflation adjustment provisions pursuant to Condition 8 of the Conditions;

(iv) AMC-Eligible Manufacturer's experience in vaccine production and delivery of similar scale; and

(v) past performance record with UNICEF, if applicable.

4.4.2 Furthermore, demand and market specific elements shall be considered to assure that the Supply Commitment Quantities are in support of:

(i) ensuring supply for the actual demand as represented by the GAVI Alliance approved quantities for each GAVI Eligible Country;

(ii) GAVI Eligible Country preferences for a particular product as indicated in the respective Eligible Country Applications; and

(iii) the objectives of continued vaccine supply and contributing to the creation of a healthy vaccine market including multiple manufacturers.

4.4.3 UNICEF's decision on Supply Commitment Quantities shall be made based on the above-mentioned criteria, including any advice from WHO or any other multilateral or technical partner in respect of certain aspects of the Supply Offer, as well as

advice and recommendations from the Procurement Reference Group. UNICEF may decide to award less than the total quantity forecasted for the Vaccine if this would support achieving the AMC Objectives including contributing to the creation of a healthy vaccine market including multiple manufacturers, meeting developing country preferences and matching supply with demand.

Each assessment of a Supply Offer shall take no more than 40 IBRD Business Days after the receipt of any Supply Offer.

4.5 Entry into of Supply Agreements and Provisional Supply Agreements

4.5.1 Upon a complete assessment of each Supply Offer and upon the satisfaction of the terms and conditions of the relevant Advance Market Commitment, UNICEF may enter into a Supply Agreement with an AMC-Eligible Manufacturer or Provisional Supply Agreement with an AMC Registered Manufacturer in good faith and in a commercially reasonable manner. UNICEF shall use its reasonable efforts to reach agreement in principle to a Supply Agreement with a manufacturer within 20 IBRD Business Days from receipt by the manufacturer of notification of the Supply Commitment Quantities being awarded to such manufacturer. A manufacturer shall communicate its acceptance of the proposed award in a formal letter to UNICEF which constitutes an agreement in principle. Thereafter, UNICEF shall use its reasonable efforts to enter into a Supply Agreement within 30 IBRD Business Days from reaching an agreement in principle to a Supply Agreement.

4.5.2 In accordance with the terms of each individual Provisional Supply Agreement, once the manufacturer in question meets AMC Eligibility, then such manufacturer shall be entitled to supply its AMC Eligible Vaccine in accordance with the terms of the Provisional Supply Agreement as if such agreement were a Supply Agreement.

4.5.3 The procurement process shall be done in accordance with the rules and regulations then applicable for UNICEF acting on behalf of the GAVI Alliance. UNICEF will work with the Procurement Reference Group throughout the procurement process.

Part 5 Eligible Country Application Procedures

5.1 Any country eligible for support from the GAVI Alliance for vaccines may submit an Eligible Country Application to the GAVI Alliance in accordance with the then-current GAVI Alliance guidelines and application procedures set forth at www.gavialliance.org.

5.2 The GAVI Alliance shall process all such applications in a timely manner and present any application recommended for approval by the Independent Review Committee to the GAVI Alliance Board for funding approval. Information on result of applications, as well as annual progress reports and comprehensive multi-year plans and financial sustainability plans for GAVI Eligible countries are regularly updated on the GAVI Alliance website and can be found at: http://www.gavialliance.org/performance/country_results/index.php.

Part 6 GAVI Ongoing Programme Monitoring Procedures

6.1 The GAVI Alliance shall prepare an annual report in respect of each Advance Market Commitment no later than 30 IBRD Business Days prior to the first GAVI Alliance Board meeting of each calendar year, such report to be approved by the IAC press for publication on the AMC Website (the "**AMC Annual Report**").

6.2 Each AMC Annual Report prepared by the GAVI Alliance may include the following information collated by the AMC Secretariat including information gathered through the following types of evaluation as may be conducted by the GAVI Alliance from time to time:

6.2.1 key events in the implementation of the AMC, with particular reference to timelines, plans and projections;

6.2.2 data relating to new trials for the relevant vaccines and new investments in production capacity for the relevant vaccines targeted at GAVI Eligible Countries;

6.2.3 updates on mortality data, burden of disease, and related projections;

6.2.4 updates on the implementation of activities to support the introduction and use of the relevant vaccines including in respect of the GAVI Co-Financing Policies and activities to forecast demand; and

6.2.5 data relating to the procurement of the relevant vaccine.

6.3 Each AMC Annual Report shall be subject to the confidentiality provisions of Condition 13 of the Conditions.

Schedule 1
AMC Registered Manufacturer Agreement

Dated [●]

THE GAVI ALLIANCE

and

INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT

and

[*APPLICANT*]

AMC REGISTERED MANUFACTURER AGREEMENT

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This AMC Registered Manufacturer Agreement (this "**Agreement**") is made on [●] between:

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

(2) **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 ("**IBRD**"); and

(3) **[●]** a vaccine manufacturer incorporated in [●] (the "**Applicant**")

Whereas

(A) Pursuant to the Offer Agreement entered into between the GAVI Alliance and IBRD, the Applicant intends to participate in the AMC Pneumo Initiative.

(B) In accordance with the terms of the AMC Procedures Memorandum, the Applicant hereby applies to be registered as an AMC Registered Manufacturer in order to be able to make an Application for AMC Eligibility.

NOW THEREFORE, the parties to this Agreement agree as follows:

1 Definitions, Interpretation and Construction

5.3 Unless otherwise expressly defined in this Agreement (including the recitals) all capitalised terms shall have the meanings (if any) given to them in the Master Definitions Schedule dated [●] and entered into between, among others, the GAVI Alliance and IBRD (the "**Master Definitions Schedule**"), and the provisions of Clause 2 of the Master Definitions Schedule shall apply to this Agreement as if they were set out herein.

5.4 The provisions of Clause 1 of the Master Definitions Schedule shall apply to this Agreement as if they were set out herein.

6 Application, Acknowledgment and Agreement

6.3 In accordance with the provisions of the AMC Procedures Memorandum, the Applicant has submitted to the GAVI Alliance and IBRD an AMC Registered Manufacturer Application Package.

6.4 The Applicant hereby acknowledges and agrees:

6.4.1 to the terms and conditions of the Offer Agreement, (including the AMC Terms and Conditions and pro-forma Supply Agreement scheduled thereto) which are expressly and specifically incorporated by reference into this Agreement, as though the same were set out in full in this Agreement;

6.4.2 that in accordance with Condition 4 of the Terms and Conditions, determinations regarding AMC Eligibility are at the sole discretion of the IAC and there is no guarantee that an Applicant's vaccine may be granted AMC Eligibility even if it meets the Conditions;

6.4.3 until it enters into a Supply Agreement and/or Provisional Supply Agreement, to provide to IBRD, the GAVI Alliance, and such other procurement agency as may be specified by the GAVI Alliance to the Applicant, an annual update of the Applicant's WHO prequalification process and expected timing for an Application for AMC Eligibility; and

6.4.4 to promptly notify each of the GAVI Alliance and IBRD in the event of the occurrence of any of the circumstances giving rise to an AMC Suspension Event under Condition 10.

6.5 In consideration of the acknowledgement and agreement in Clause 2.2 and having received the completed AMC Registered Manufacturer Application Package, the GAVI Alliance and IBRD hereby confirm the Applicant's status as an AMC Registered Manufacturer as of the date hereof.

7 Confidentiality

7.3 Where any party has access to Confidential Information, such party agrees:

7.3.1 not to disclose such Confidential Information to any person other than where such disclosure is either: (i) approved in writing by all the parties hereto; or (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;

7.3.2 not to use any Confidential Information except as necessary to perform its obligations under the Transaction Documents;

7.3.3 promptly to 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 it, as instructed by the AMC Secretariat or the provider of the Confidential Information, as the case may be; and

7.3.4 that this provision shall survive indefinitely.

8 Unconditional and Express Waiver of all Claims

8.3 The Applicant hereby acknowledges and agrees that, the GAVI Alliance, the IAC, IBRD, each of the Grantors, and any other person, entity, sovereign state, organisation, alliance or stakeholder in any way involved in the AMC (the "**Excluded Parties**") are not responsible for any liabilities, claims, actions, damages, losses, fines, penalties, costs or expenses of any kind or nature (including, without limitation, those associated with entering into this Application and Agreement, or for infringement or misappropriation of intellectual property) arising directly or indirectly from or relating to the Applicant's participation in the AMC other than those arising out of negligence, wilful default or fraud of the Excluded Parties (the "**Liabilities**"). The Applicant hereby acknowledges that each of the Excluded Parties has entered into this Agreement (in the case of the GAVI Alliance and IBRD only), the other Transaction Documents to which such Excluded Party is a party, and the AMC Pneumo Initiative as a whole, in reliance on the agreement and acknowledgment of the Applicant contained in this Clause 4.1.

8.4 Subject to any privileges and/or immunities which it may enjoy under the law of any applicable jurisdiction, the Applicant agrees promptly to indemnify, defend and hold

harmless each of: (i) the GAVI Alliance; (ii) IBRD; (iii) the IAC; (iv) each of the Governments receiving the vaccines; (v) each of the Grantors; and (vi) each of their respective directors, officers, agents, or employees (together, the "**Indemnified Parties**" and each an "**Indemnified Party**") from and against all liabilities, claims, damages, losses, costs or expenses (including legal fees, costs and expenses reasonably incurred) incurred by an Indemnified Party and arising out of or related to the purchase, distribution and use of any vaccines supplied by the Applicant under the AMC, including (without limitation) any such claim, damage, loss, cost or expense as may arise out of a breach of any representation, warranty or agreement of the Applicant contained herein or given by it in connection with these arrangements, and other than, in respect of each Indemnified Party, those attributable to any wilful default, fraud or negligence of that Indemnified Party. UNICEF, or any procurement agency acting on behalf of the GAVI Alliance, shall promptly give notice to the Applicant of any such liabilities, claims, damages, losses, costs, or expenses brought to its attention (including those brought to its attention by another Indemnified Party) and shall cooperate in a reasonable manner in their investigation and assessment provided that each indemnified Party shall be entitled at its sole discretion and acting reasonably at all times, to choose any legal or other representation which it may require in relation thereto and shall have full power to direct the conduct on its behalf of any legal or other proceeding which may arise as a result thereof. The Applicant hereby acknowledges that each of the Indemnified Parties has entered into this Agreement (in the case of the GAVI Alliance and IBRD only), the other Transaction Documents to which such Indemnified Party is a party, and the AMC Pneumo Initiative as a whole, in reliance on the agreements of the Applicant contained in this Clause 4.2.

8.5 For the avoidance of any doubt and notwithstanding the provisions of Clause 1.5 of the Master Definitions Schedule, each of the Excluded Parties and the Indemnified Parties which is not a signatory to this Agreement shall have the right to enforce the rights conferred upon it by this clause, as if it were a party to this Agreement, pursuant to section 1(1) of the Contracts (Rights of Third Parties) Act 1999.

8.6 The provisions of this Clause 4 shall survive the termination of this Agreement.

9 Variation

No amendment to or variation of this Agreement shall be effective unless in writing and signed by or on behalf of each of the parties.

10 Communications

10.3 Unless otherwise specifically provided in this Agreement, all notices, reports and communications hereunder shall be in writing, sent by facsimile or overnight courier to the receiving party at the respective address set forth below, or at such other address specified by notice similarly given:

10.3.1 if to the GAVI Alliance:

The GAVI Alliance
2, Chemin des Mines
Geneva
Switzerland

Attn: [●]

Telephone: [●]

Fax: [●]

10.3.2 if to IBRD:

International Bank for Reconstruction and Development
1818 H Street, NW
Washington DC 20433
United States of America

Attn: Director, Multilateral Trusteeship and Innovative Financing Department

Telephone: [●]

Fax: [●]

10.3.3 if to the Applicant:

[●]

Attn: [●]

Telephone: [●]

Fax: [●]

10.4 Deemed Receipt

The date on which any communication under this Agreement shall be deemed effective is as follows:

10.4.1 if delivered in person or by courier, on the date it is delivered; and

10.4.2 if sent by facsimile transmission, on the date that transmission is received by the recipient in legible form,

unless the date of that delivery or receipt, as applicable, is not a business day (in the place of the relevant notice) or any communication is delivered or received, as applicable, after the close of business on a business day (in the place of receipt of the relevant notice), in which case that communication shall be deemed given and effective on the next business day (in the place of receipt of the relevant notice).

11 Rights and Obligations

The obligations of each party to this Agreement are several and not joint. No party is responsible for the obligations of any other party under this Agreement. The rights and obligations of each party under or in connection with this Agreement are separate and independent.

12 Privileges and Immunities

Nothing in or relating to this Agreement shall be deemed to be or shall constitute a waiver of any of the privileges and immunities of IBRD and the GAVI Alliance, acting in any capacity under its articles of agreement of any applicable law, all of which are expressly reserved.

13 Governing Law and Dispute Resolution

13.3 This Agreement and any non-contractual obligations arising out of or in connection with it shall be governed by, and interpreted in accordance with, the laws of England and Wales.

13.4 Any dispute arising out of or in connection with this Agreement shall be referred first to each party who shall meet and endeavour to resolve the dispute between themselves within 20 IBRD Business Days of receiving notice of such dispute. The joint written decision of the parties from such meeting shall be binding upon the parties. For the avoidance of doubt, any notification of such dispute shall be made in accordance with Clause 6 including a dispute as to the validity or existence of this Agreement and/or this Clause 8.

13.5 Any dispute, controversy or claim arising out of or relating to this Agreement, including a dispute as to the validity or existence of this Agreement and/or this Clause 8, which has not been settled by agreement of the parties pursuant to Clause 8.2, shall be submitted to arbitration by three arbitrators in accordance with the UNCITRAL Arbitration Rules in effect on the date of this Agreement, save that, unless the parties agree otherwise, the following provisions shall apply:

(a) the arbitration shall be administered by the International Bureau of the Permanent Court of Arbitration;

(b) the arbitrators shall be appointed by agreement by the parties save that, in the event of dispute, the appointing authority for the arbitrators shall be the International Chamber of Commerce;

(c) no arbitrator shall be of the same nationality as any party to this Agreement;

(d) the parties shall not be required to give general discovery of documents, but may be required only to produce specific, identified documents which are relevant to the dispute;

(e) no information or documents acquired in the course of the arbitration may be disclosed to a third party without the consent of the arbitral tribunal;

(f) where more than one dispute arises under this Agreement and under any associated contract which, in the reasonable opinion of the first arbitral tribunal to be appointed in any of the disputes, are so closely connected that it is expedient for them to be resolved in the same proceedings, the first arbitral tribunal shall have the power to consolidate the proceedings (whether or not proceedings to resolve those other disputes have yet been instituted), provided that no date for exchange of witness statements has been fixed. The Parties shall comply with any such order for consolidation and the arbitral tribunal shall have the power to make a single award in respect of any number of arbitral proceedings which have been so consolidated. The Parties shall not seek to challenge any award so rendered on

the grounds that they were not a party to the arbitration or arbitrations under which the award was made;

(g) the parties agree to waive any right of appeal against the arbitration award;

(h) the place of arbitration shall be the Hague, the Netherlands; and

(i) the language of the arbitral proceedings shall be English.

In witness whereof, this Agreement has been executed by the parties on the date stated at the beginning thereof.

SIGNED by:
THE GAVI ALLIANCE acting by its attorney

in the presence of:

Name
Address

Occupation

SIGNED by:
INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT acting by its attorney

in the presence of:

Name
Address

Occupation

SIGNED by:
[APPLICANT]

in the presence of:

Name
Address

Occupation

Schedule 2
TPP Criteria in respect of the AMC Pneumo Initiative

The product specifications tabled below are called the target product profile (TPP). The specifications relate to the public health impact and suitability of the product, covering measures of vaccine efficacy, safety, dose-scheduling, presentation and packaging, and represent the minimally acceptable standard a vaccine needs to meet in order to be eligible for AMC support. This table must be read in conjunction with the accompanying Part II TPP Supplementary Information available on the AMC Website that provides the rationale for the selected criteria, and proposes more advanced product characteristics, that are desirable but not essential. For other pneumococcal vaccine types, such as protein-based vaccines, several attributes will require adaptation.

Paragraph A

WHO Prequalification Criteria

Attribute	Minimally Acceptable Profile
(a) Immunogenicity	Immunogenicity should be demonstrated in accordance with WHO criteria, which are based on non-inferiority to a licensed pneumococcal vaccine as outlined in WHO *Recommendations for the production and control of pneumococcal conjugate vaccines*. (WHO Technical Report Series, No 927, 2005 and any subsequent published guidance).
(b) **Safety, reactogenicity and contra-indications**	The safety and reactogenicity profile should be comparable to, or better than that of the currently licensed pneumococcal conjugate vaccine. Contra-indications should be restricted to known hypersensitivity to any of the vaccine components.
(c) **Interference and co-administration with other vaccines**	There should be no clinically significant interaction or interference in relation to safety and immunogenicity with concurrently administered vaccines.
(d) **Product presentation**	The vaccine must be available in mono-dose or low multi-dose presentations. Mono-doses must be either a single dose vial or an auto-disable compact pre-filled device. Low multi-dose presentations must be formulated and labelled in compliance with WHO policy or guidance.
(e) **Storage and cold chain requirements**	The product must be stable at 2-8^{o}C with a shelf-life of at least 24 months and a vaccine vial monitor should be attached as outlined in *Making use of vaccine vial monitors. Flexible vaccine management for polio* (WHO/V&B/00.14).
(f) **Packaging and labelling**	Name and labelling must be in accordance with WHO *Recommendations for the production and control of pneumococcal conjugate vaccines*. (WHO Technical Report Series, No 927, 2005). Packaging must ensure minimal storage space requirements as set out in *Guidelines on the international packaging and shipping of vaccines* (WHO/IVB/05.23).
(g) **Product registration and**	The product must be WHO pre-qualified in accordance with

Attribute	Minimally Acceptable Profile
prequalification	*Procedures for assessing the acceptability, in principle, of vaccines for purchase by United Nations agencies* (WHO/IVB/05.19).
(h) **Post marketing surveillance**	Post-marketing surveillance should be conducted in accordance with national regulatory authorities and WHO prequalification requirements as set out in *Guideline for preparation of the product summary file for vaccine prequalification* (WHO/IVB/06.16), *Guidelines on clinical evaluation of vaccines: regulatory expectations* (WHO Technical Report Series, No 924, 2004) and any relevant published guidance.

Paragraph B

IAC Assessment Criteria

Attribute	Minimally Acceptable Profile
(a) **Vaccine serotypes**	The serotypes in the vaccine formulation must cover at least 60% of the invasive disease isolates in the target region, and must include serotypes 1, 5 and 14 which are the most frequent isolates in GAVI Eligible Countries.
(b) **Target population/ target age groups**	The vaccine must be designed to prevent disease among children <5 years of age and in particular be effective in those <2 years of age.
(c) **Dosage schedule**	Vaccine scheduling must be compatible with national infant immunisation programmes and consist of not more than 3 doses in the first year of life. The first dose must be shown to be administrable at 6 weeks of life or earlier.
(d) **Route of administration**	Intramuscular or subcutaneous.
(e) **Product formulation**	Liquid formulation with a standard volume of 0.5 ml/dose.

Schedule 3
Supplier Vaccine Production Plan

The Supplier Pneumo Vaccine Production Plan should include information regarding the vaccine, timeline of major milestones and plans for manufacturing and licensing, including the following:

i. Product and Production Capacity Development:

   a. product status and plans, including source of bulk antigens to be used, planned product presentations and packaging, and capacity for bulk and finished products;

   b. description of production site(s) and timeline(s) for development, if applicable;

   c. clinical trials conducted to date and planned, with relevant timelines to completion; and

   d. post-marketing surveillance strategy.

ii. National Regulatory Registration: status and plans for registration, including with the National Regulatory Authority that would be responsible for lot release of the relevant vaccine and planned product presentations thereafter.

iii. WHO pre-qualification timelines, if applicable.

iv The timeline for forwarding an Application for AMC Eligibility.

v. Status and timelines relating to such manufacturer's submission to the National Regulatory Authority and WHO for the approval of its manufacturing facility.

vi. Expected date for providing the Vaccine Purchase Period Trigger Notice.

vii. Expected date for commencement of the Vaccine Purchase Period.