

EXECUTION VERSION

DEED OF AMENDMENT AND RESTATEMENT

dated

7 March 2011

THE GAVI ALLIANCE

and

INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT

RELATING TO THE ADVANCE MARKET COMMITMENT FOR PNEUMOCOCCAL VACCINES

OFFER AGREEMENT, IAC CHARTER & BYLAWS AND PROCEDURES MEMORANDUM

ORIGINALLY DATED 12 JUNE 2009

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THIS DEED is dated 7 March 2011 and made between:

- (1) **THE GAVI ALLIANCE**, a non profit foundation (registry number CH-660-1699006-1) with offices at 2 Chemin des Mines, Geneva CH-1202, Switzerland (the "**GAVI Alliance**"); and
- (2) **INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT**, an international organization which maintains its headquarters at 1818 H Street, NW, Washington, DC 20433, United States of America (the "**IBRD**").

Whereas:

- (A) On 12 June 2009 the GAVI Alliance and the IBRD entered into the Original AMC Offer Agreement.
- (B) the parties now wish to amend and restate the Original AMC Offer Agreement and certain other Transaction Documents.

IT IS AGREED as follows:

1. DEFINITIONS AND INTERPRETATION

1.1 Definitions

In this Deed:

"Amended AMC Offer Agreement" means the Original AMC Offer Agreement as amended and restated in the form set out in Schedule 1 (*Amended AMC Offer Agreement*).

"Amended AMC Procedures Memorandum" means the Original Procedures Memorandum as amended and restated in the form set out in Schedule 3 (*Amended AMC Procedures Memorandum*).

"Amended IAC Charter and Bylaws" means the Original IAC Charter and Bylaws as amended and restated in the form set out in Schedule 2 (*Amended IAC Charter and Bylaws*).

"Master Definitions Schedule" means the master definitions schedule dated 12 June 2009 and signed by, amongst others, the parties hereto.

"Original AMC Offer Agreement" means the offer agreement dated 12 June 2009 and initially entered into between GAVI Alliance and IBRD.

"Original AMC Procedures Memorandum" means the memorandum dated 12 June 2009 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.

"Original IAC Charter and Bylaws" means the constitutive documents of the IAC dated June 2009 as disclosed on the AMC Website.

1.2 **Incorporation of defined terms**

- (a) Unless a contrary indication appears, a term defined in the Master Definitions Schedule has the same meaning in this Deed (including the recitals).
- (b) The principles of construction set out in Clause 1 (*Interpretation*) of the Master Definitions Schedule shall have effect as if set out in this Deed.

2. **AMENDMENT**

2.1 **Amendment**

On and with effect from the date hereof,

- (i) without prejudice to the terms of the Original AMC Offer Agreement governing the rights and obligations of the relevant parties up to the date of this Deed, the parties to this Deed agree that pursuant to the execution by them of this Deed, the Original AMC Offer Agreement (including the AMC Terms and Conditions and pro-forma Supply Agreement scheduled thereto) shall be amended and restated in the form set out in Schedule 1 (*Amended AMC Offer Agreement*) hereto, so that the rights and obligations of the parties to this Deed shall on and from the date of this Deed be governed by and construed in accordance with the provisions of the Amended AMC Offer Agreement;
- (ii) without prejudice to the terms of the Original IAC Charter and Bylaws, the parties to this Deed agree that pursuant to the execution by them of this Deed, and acting upon the advice of the IAC, the original IAC Charter and Bylaws shall be amended and restated in the form set out in Schedule 2 (*Amended IAC Charter and Bylaws*); and
- (iii) without prejudice to the terms of the Original Procedures Memorandum, the parties to this Deed agree that pursuant to the execution by them of this Deed, the Procedures Memorandum shall be amended and restated in the form set out in Schedule 3 (*Amended AMC Procedures Memorandum*).

2.2 **Continuing obligations**

The provisions of the other Transaction Documents shall, save as amended by this Deed, continue in full force and effect and shall be construed in accordance with the amendments and restatements pursuant to Clause 2.1 (*Amendment*) above.

2.3 **Waiver of Claims**

The parties by their execution of this Deed agree unconditionally and irrevocably to waive any breach of a Transaction Document which has occurred on or following 6 July 2010 as a consequence of either of them performing any of their obligations, or exercising any of their rights, thereunder in accordance with the relevant provisions of the Transaction Documents as if the same had at such time already been amended in the manner provided for under this Deed, and agree that they shall not hereafter claim to the contrary.

3. **REPRESENTATIONS**

Each of the parties to this Deed, each in relation to itself, makes and gives its respective representations and warranties as set out in Clause 6 (*Representations, Warranties and Undertakings*) of the Amended AMC Offer Agreement in each case by reference to the amendments effected pursuant to this Deed.

4. **MISCELLANEOUS**

4.1 **Incorporation of terms**

The provisions of Clause 7.3 (*Communications*) of the Amended AMC Offer Agreement shall be incorporated into this Deed as if set out in full in this Deed and as if references in those clauses to “this Agreement” are references to this Deed.

4.2 **Counterparts**

This Deed may be executed in any number of counterparts, and this has the same effect as if the signatures on the counterparts were on a single copy of this Deed.

5. **EFFECTIVENESS OF THIS DEED**

This Deed shall be effective and binding upon the parties hereto upon the date hereof.

6. **GOVERNING LAW AND DISPUTE RESOLUTION**

6.1 **Governing Law**

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

6.2 **Dispute Resolution**

(a) **Negotiation**

Any dispute arising out of or in connection with this Deed shall be referred first to each party who shall meet and endeavour to resolve the dispute between them within 20 IBRD Business Days of receiving notice of such dispute. For the avoidance of doubt, any notification of such dispute shall be made in accordance with Clause 7.3 of the Amended AMC Offer Agreement. Any joint written decision of the parties from such meeting shall be binding upon the parties.

(b) **Arbitration**

Any dispute, controversy or claim arising out of or relating to this Deed including a dispute as to the validity or existence of this Deed and/or this Clause 6.2, which has not been settled by agreement of the parties pursuant to Clause 6.2(a), shall be submitted to arbitration by three arbitrators in accordance with the UNCITRAL Arbitration Rules in effect on the date of this Deed 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 third arbitrator, who shall act as chairman of the tribunal, shall be chosen by the two arbitrators appointed by or on behalf of the parties. If he is not chosen by the two arbitrators within 30 days of the date of appointment of the later of the two party-appointed arbitrators to be appointed, he shall be appointed by the International Chamber of Commerce;
- (c) no arbitrator shall be of the same nationality as any party to this Deed;
- (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 Deed 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 to each dispute which is a subject of this order shall be treated as having consented to that dispute being finally decided in accordance with the procedure at the seat and in the language specified in the arbitration agreement in the contract under which the arbitrator who ordered the consolidation was appointed, save as otherwise agreed by all parties to the consolidated proceedings or ordered the arbitrator in the consolidated proceedings. 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 Deed has been executed and delivered as a Deed on the date first stated above.

SCHEDULE 1
AMENDED AMC OFFER AGREEMENT

EXECUTION VERSION

Dated 7 March 2011

THE GAVI ALLIANCE
and
*INTERNATIONAL BANK FOR RECONSTRUCTION AND
DEVELOPMENT*

OFFER AGREEMENT

relating to the Advance Market Commitment for Pneumococcal Vaccines

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This Offer Agreement (the “**Agreement**”) is made on 7 March 2011 **between:**

- (3) **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**”); and
- (4) **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**”);

each a “**Party**” and together the “**Parties**”.

Whereas:

- (5) IBRD has entered into grant agreements with certain grantors to receive funds from such grantors in a total amount equivalent to USD 1.5 billion over a specified period in order to establish a pilot advance market commitment for pneumococcal vaccines.
- (6) In support of this initiative, IBRD wishes to make an offer, subject to the AMC Terms and Conditions, to vaccine manufacturers to pay a certain portion of the Vaccine Purchase Price in respect of an AMC-Eligible Vaccine to be supplied by such vaccine manufacturer pursuant to a Supply Agreement. The IBRD offer is limited in amount and is valid for a limited period only.
- (7) In support of this initiative, the GAVI Alliance wishes to make an offer and solicitation, subject to the AMC Terms and Conditions, for written requests by AMC-Eligible Manufacturers to negotiate in good faith and to enter into one or more Supply Agreements for AMC-Eligible Vaccines.
- (8) IBRD and the GAVI Alliance wish to record the terms of their respective offers as set out herein.

NOW THEREFORE in consideration of the mutual benefits to be derived and the conditions and promises contained herein, the parties to this Agreement agree as follows:

7. DEFINITIONS, INTERPRETATION AND CONSTRUCTION

7.1 Definitions

Unless otherwise expressly defined in this Agreement (including the recitals and the AMC Terms and Conditions scheduled hereto) all capitalised terms shall have the meaning (if any) given to them in the master definitions schedule dated the date hereof and signed by, amongst others, the parties hereto (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.

7.2 Interpretation

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

8. **INCORPORATION OF AMC TERMS AND CONDITIONS**

This Agreement expressly and specifically incorporates by reference the AMC Terms and Conditions set out in Schedule 1, as though the same were set out in full in this Agreement. In the event of any conflict between the provisions of this Agreement (including the AMC Terms and Conditions), and the provisions of Supply Agreements, the provisions of this Agreement (including the AMC Terms and Conditions) shall prevail. All references to “**this Agreement**” herein shall be construed to mean this Agreement including the AMC Terms and Conditions.

9. **THE OFFER**

9.1 **IBRD Offer**

- (a) During an AMC Period and subject at all times to the AMC Terms and Conditions, IBRD hereby agrees to pay to the GAVI Alliance, or to such party as the GAVI Alliance may from time to time direct, from Grant Payment Amounts due and payable under the respective Grant Agreements (after giving effect to any applicable Hedging Transactions) such amounts as may be requested by the GAVI Alliance from IBRD in order to meet the AMC-Funded Price portion of the Vaccine Purchase Price where such amount is due and payable in connection with the Supply Agreements. For the avoidance of doubt, IBRD’s payment obligations under this Clause 3.1.1 are not reduced or eliminated by a counterparty’s failure to pay IBRD under an applicable Hedging Transaction.
- (b) As and when requested by the GAVI Alliance in accordance with Clause 3.1.1 above, IBRD shall pay in accordance with the provisions of Condition 7, to the GAVI Alliance, or such other party as the GAVI Alliance may direct, the AMC Offer Amount of USD 1.5 billion. For the avoidance of doubt and notwithstanding any other provision contained in this Agreement or under the AMC Terms and Conditions, the maximum cumulative amount that IBRD shall be obliged to pay under Section 3.1.1 shall not exceed the AMC Offer Amount of USD 1.5 billion.
- (c) IBRD hereby agrees to perform its obligations in connection with the AMC Pneumo Initiative in accordance with the terms of this Agreement, including the AMC Terms and Conditions set out in Schedule 1.

9.2 **The GAVI Alliance Offer**

- (a) Subject to prior approval of the applicable budget for each Supply Agreement by the GAVI Alliance Board, the GAVI Alliance shall request that UNICEF, or another procurement agency acting on its behalf, negotiates each Supply Offer, in good faith with each AMC-Eligible Manufacturer for a reasonable period of time not exceeding 60 IBRD Business Days, provided that the aggregate Supply Commitment in Supply Agreements and Provisional Supply Agreements does not at any time exceed 200,000,000 doses of AMC-Eligible Vaccine annually prior to the end of such negotiation period. Where Supply Commitments equal 200,000,000 doses of AMC-Eligible Vaccine annually prior to the end of such negotiation period, any ongoing negotiations shall be terminated.

- (b) Subject to the AMC Terms and Conditions and the execution of a Supply Agreement, the GAVI Alliance shall pay, or procure the payment to, each AMC-Eligible Manufacturer the portion of the Co-Payment attributable to it during the AMC Period under each Supply Agreement.
- (c) The GAVI Alliance shall promptly advise IBRD, in accordance with Condition 7.4 of the AMC Terms and Conditions, of the relevant amounts from time to time payable by IBRD under Clause 3.1.1.
- (d) The GAVI Alliance hereby agrees to perform its obligations in connection with the AMC Pneumo Initiative in accordance with the terms of this Agreement, including the AMC Terms and Conditions set out in Schedule 1.

9.3 Offer Period

- (a) Subject to the provisions in this Clause 3.3, the offers in Clauses 3.1 and 3.2 shall be valid from the date of this Agreement up to and including the earlier to occur of: (i) the date upon which aggregate Supply Commitments equal 200,000,000 doses of AMC-Eligible Vaccine annually; (ii) the AMC Total Cancellation Date; and (iii) 31 December 2020 (the “Offer Period”).
- (b) If at 31 December 2020 the cumulative Supply Commitment of all Supply Agreements entered into is less than 200,000,000 doses of AMC-Eligible Vaccine annually and an AMC Total Cancellation Notice has not been delivered, then IBRD and the GAVI Alliance may in their sole discretion agree to extend the duration of the offers in Clauses 3.1 and 3.2 for a period to be determined by IBRD and the GAVI Alliance, in consultation with the IAC.
- (c) If as at the earlier of: (i) the date on which the Remaining AMC Offer Amount is reduced to zero; (ii) the 31 December 2020; and (iii) the AMC Total Cancellation Date:
 - (j) all amounts payable by IBRD under the Offer Agreement and the AMC Terms and Conditions up to but not exceeding the AMC Offer Amount have been paid and discharged;
 - (k) any amounts payable to IBRD under this Agreement have been paid; and
 - (l) IBRD has Surplus Funds,
 then IBRD shall: (i) calculate, on a pro rata basis taking into account any Grantor Default, the amount of funds attributable to each Grantor; and (ii) convene a meeting of all Grantors to consult and discuss in good faith how such remaining funds shall be applied.
- (d) In the event that a Supply Agreement is terminated for any reason, the Offer Period may be recalculated to enable the Supply Commitment in respect of such Supply Agreement to be reallocated to another AMC Eligible Manufacturer.

10. OBLIGATIONS SEVERAL

- 10.1 Neither Party to this Agreement is responsible for the obligations of the other Party to this Agreement.

- 10.2 **The rights and obligations of each Party under or in connection with this Agreement are separate and independent.**

11. OBLIGATIONS OF THE RELEVANT PARTY ONLY

The obligations of each of the Parties under this Agreement shall not be obligations or responsibilities of, nor guaranteed by, the other Party, nor of or by any other person, entity, sovereign, state, organisation or alliance.

12. REPRESENTATIONS, WARRANTIES AND UNDERTAKINGS

12.1 The GAVI Alliance represents and warrants to IBRD upon the date of this Agreement that:

- (a) it is duly established and validly existing under the laws of its place of incorporation and that it has full power and authority to enter into, perform and deliver, and has taken all necessary action to authorise its entry into, performance and delivery of this Agreement and the transaction contemplated herein;
- (b) this Agreement has been duly authorised, executed and delivered by it and constitutes valid and legally binding obligations of it and enforceable against it in accordance with its terms;
- (c) all actions or things required to be taken, fulfilled or done (including, without limitation, the obtaining of any consent or licence or the making of any filing or registration) for the entry by it into this Agreement, the carrying out of the other transactions contemplated herein (save for specific matters required at the time of specific transactions or other events in the future), or for the compliance by it with the terms thereof, as the case may be, have been obtained and are in full force and effect; and
- (d) the execution and delivery of this Agreement and the carrying out of the other transactions contemplated herein and compliance with its terms do not and will not: (a) conflict with or result in a breach of any of the terms or provisions of, or constitute a default under, the documents constituting it, or any indenture, trust deed, mortgage or other agreement or instrument to which it is a party or by which it or any of its properties is bound; or (b) infringe any existing applicable law, rule, regulation, judgment, order or decree of any government, governmental body or court, domestic or foreign, having jurisdiction over it or any of its properties.

12.2 IBRD represents and warrants to the GAVI Alliance upon the date of this Agreement that:

- (a) it is duly established and existing under its constitutive articles of agreement;
- (b) this Agreement has been duly authorised, executed and delivered by it and constitutes valid and legally binding obligations of it, and will not result in a breach by IBRD of any terms of, or constitute a default under, any agreement or undertaking of IBRD;
- (c) all actions or things required to be taken, fulfilled or done (including without limitation the obtaining of any consent or licence or the making of any filing or

registration) for the entry by it into this Agreement, the carrying out of the other transactions contemplated herein (save for specific matters required at the time of specific transactions or other events in the future), or for the compliance by it with the terms thereof, as the case may be, have been obtained and are in full force and effect; and

- (d) the execution and delivery of this Agreement and the carrying out of the other transactions contemplated herein and compliance with its terms do not and will not: (a) conflict with or result in a breach of any of the terms or provisions of, or constitute a default under, the documents constituting it, or any indenture, trust deed, mortgage or other agreement or instrument to which it is a party or by which it or any of its properties is bound; or (b) infringe any existing applicable law, rule, regulation, judgment, order or decree of any government, governmental body or court, domestic or foreign, having jurisdiction over it or any of its properties.

12.3 At all times during the Offer Period, each of the GAVI Alliance and IBRD undertake not to enter into, or procure the entry into of, any supply and purchase arrangements of pneumococcal vaccines for GAVI Eligible Countries which have more favourable terms for vaccine manufacturers and suppliers than those set out in the Transaction Documents. The GAVI Alliance undertakes to obtain this same commitment from any procurement agent acting on its behalf. For the avoidance of doubt, the provisions of this Clause 6.3 shall only apply during the Offer Period.

13. MISCELLANEOUS PROVISIONS

13.1 Further Assurances

Each of the Parties agrees to use its reasonable endeavours to perform (or procure the performance of) all further acts and things, and execute and deliver (or procure the execution and delivery of) such further documents, as may be required by law or as may be reasonably required to implement and/or give effect to this Agreement and the transactions contemplated hereby.

13.2 Variation

- (a) Any amendment to or variation of this agreement (including the AMC Terms and Conditions and the pro-forma Supply Agreement scheduled thereto) shall notwithstanding any provision thereof be subject to prior consultation with the Grantors. 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.
- (b) Any amendment, modification or waiver of the Transaction Documents (other than this Agreement (as to which see Clause 7.2.1 above), or the Registered Manufacturer Agreement and the Transactions Documents to which the Grantors are party (as to which see Clause 7.2.3 below), may notwithstanding any provision of such Transaction Documents be agreed to in writing by the GAVI Alliance and IBRD provided that:
 - (m) no amendment shall be permitted that would have a consequential greater liability for any Grantor;

- (n) the Grantors have been notified at least 20 Business Days prior to any such amendment, variation or waiver; and
- (o) any such amendment, variation or waiver corrects or is intended to correct clerical errors, including typographical mistakes, errors of grammar, words or numbers which, in the opinion of IBRD and the GAVI Alliance is proven.
- (c) For the avoidance of doubt, no Transaction Document to which any Grantor is a party, or the AMC Registered Manufacturer Agreement shall notwithstanding any provision thereof, be amended or varied without the prior written consent of such Grantor, or in the case of the Registered Manufacturer Agreement, all of the Grantors.

13.3 Communications

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:

(a) **if to the GAVI Alliance:**

The GAVI Alliance
2, Chemin des Mines,
Geneva, 1202
Switzerland

Attention: Managing Director Law & Governance

Telephone: +41 (22) 909 6504

Fax: + 41 (22) 909 6550

(b) **if to IBRD:**

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

Attention: Director, Multilateral Trusteeship and Innovative
Financing Department

Telephone: + 1 202 458 0019

Fax: + 1 202 614 0249

13.4 Deemed Receipt

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

- (a) if delivered in person or by courier, on the date it is delivered; and
- (b) 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 receipt 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).

13.5 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 or the GAVI Alliance, acting in any capacity under any articles of agreement, statutes or by laws or other constitutive documents as may be applicable, or any applicable law, all of which are expressly reserved.

13.6 Partial Invalidity

If any provision of this Agreement is prohibited by or is unlawful, invalid or unenforceable under any applicable law of any jurisdiction, such provision shall, as to such jurisdiction (only), be ineffective to the extent of such prohibition without invalidating the remaining provisions hereof, unless the elimination of such provision substantially impairs either Party's rights or benefits arising under this Agreement. Any such prohibition in any jurisdiction shall not invalidate the affected provision in any other jurisdiction.

13.7 Disclosure

Subject to the confidentiality provisions of Condition 13 of the Conditions, each of the Parties may disclose this Agreement, any amendments to this Agreement, as well as information relating to the transactions contemplated in connection with this Agreement.

13.8 Counterparts

This Agreement may be executed in any number of counterparts and by the relevant parties on separate counterparts, each of which is an original but all of which together constitute one and the same instrument.

13.9 Governing Law

This Agreement shall be governed by, and interpreted in accordance with, the laws of England and Wales.

13.10 Dispute Resolution

- (a) Negotiation

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 them within 20 IBRD Business Days of receiving notice of such dispute. For the avoidance of doubt, any notification of such dispute shall be made in accordance with Clause 7.3. Any joint written decision of the parties from such meeting shall be binding upon the parties.

(b) Arbitration

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 7.10, which has not been settled by agreement of the parties pursuant to Clause 7.10.1, 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:

- (p) the arbitration shall be administered by the International Bureau of the Permanent Court of Arbitration;
- (q) the third arbitrator, who shall act as chairman of the tribunal, shall be chosen by the two arbitrators appointed by or on behalf of the parties. If he is not chosen by the two arbitrators within 30 days of the date of appointment of the later of the two party-appointed arbitrators to be appointed, he shall be appointed by the International Chamber of Commerce;
- (r) no arbitrator shall be of the same nationality as any party to this Agreement;
- (s) 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;
- (t) 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;
- (u) 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;
- (v) the parties agree to waive any right of appeal against the arbitration award;
- (w) the place of arbitration shall be the Hague, the Netherlands; and
- (x) the language of the arbitral proceedings shall be English.

13.11 Effective Date

This Agreement shall be effective and binding upon the parties hereto on June 12, 2009, provided that at such date, the Stakeholders Agreement has been signed by all the parties thereto.

Schedule 1

AMC Terms and Conditions

SCHEDULE 2 Definitions, Interpretation and Construction

PART I Definitions

Unless otherwise expressly defined in this Agreement (including the recitals) all capitalised terms shall have the meaning (if any) given to them in the master definitions schedule dated the date hereof and signed by, amongst others, the parties to the Offer Agreement (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.

PART II Interpretation

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

SCHEDULE 3 AMC Offer Amount and the Remaining AMC Offer Amount

PART I The AMC Offer Amount shall be utilised to finance the AMC-Funded Price of 200,000,000 doses annually of AMC-Eligible Vaccines from one or more AMC-Eligible Manufacturers during the Offer Period. In consideration for its agreed pro rata share of the AMC Offer Amount, each AMC-Eligible Manufacturer shall enter into a Supply Agreement under which it agrees to supply AMC Eligible Vaccine in respect of its pro rata share of 200,000,000 doses annually of such AMC- Eligible Vaccines. Each AMC-Eligible Manufacturer may enter into more than one Supply Agreement provided that each AMC-Eligible Manufacturer shall be only entitled to payment from that portion of the AMC Offer Amount which is proportionate to such AMC-Eligible Manufacturer’s Supply Commitment(s).

PART II During the Offer Period, IBRD shall deliver a formal notice of the Remaining AMC Offer Amount to the AMC Secretariat and the GAVI Alliance on each anniversary of the entry into of the Offer Agreement, such notice to be promptly published on the AMC Website.

PART III IBRD shall deliver a formal notice to the AMC Secretariat and the GAVI Alliance as soon as the Remaining AMC Offer Amount is reduced to USD 35 million, such notice to be promptly published on the AMC Website.

SCHEDULE 4 Registration by Vaccine Manufacturers

PART I In order to be able to make an Application for AMC Eligibility, a vaccine manufacturer must submit an AMC Registered Manufacturer Application Package to the AMC Secretariat in accordance with the AMC Procedures Memorandum. A vaccine manufacturer may submit an AMC Registered Manufacturer Application Package at any time during the Offer Period.

PART II As soon as reasonably possible following receipt of such AMC Registered Manufacturer Application Package, the GAVI Alliance and IBRD shall use their

reasonable endeavours to enter into an AMC Registered Manufacturer Agreement with the relevant vaccine manufacturer substantially in the form set out in Schedule 1 of the AMC Procedures Memorandum.

SCHEDULE 5 Application for AMC Eligibility

PART I Each AMC Registered Manufacturer may submit an Application for AMC Eligibility at any time within the Offer Period. Each Application for AMC Eligibility shall be made in accordance with the application procedures from time to time in effect as set out in the AMC Procedures Memorandum and disclosed on the AMC Website.

PART II The IAC shall in its sole discretion determine whether a vaccine submitted by an AMC Registered Manufacturer in an Application for AMC Eligibility is an AMC-Eligible Vaccine. All determinations by the IAC shall be final and shall be made in accordance with the procedures and requirements set out in the AMC Procedures Memorandum and the IAC Charter and Bylaws.

PART III Once a determination has been made by the IAC on an Application for AMC Eligibility, the AMC Secretariat shall publish the IAC's determination on the AMC Website.

PART IV Promptly following the determination in Condition 4.3, the AMC Secretariat shall notify GAVI Eligible Countries of the AMC Eligible Vaccines.

SCHEDULE 6 GAVI Strategic Demand Forecast and Calls for Supply Offers

PART I The GAVI Alliance shall publish the GAVI Strategic Demand Forecast on the AMC Website annually and as soon as the necessary information is available from the last procurement cycle and relevant GAVI Alliance Board meeting. The GAVI Strategic Demand Forecast outlines the estimated demand for AMC-Eligible Vaccines, the estimated supply of AMC-Eligible Vaccines and the estimated supply shortfall for which Calls for Supply Offers are made.

PART II In support of achieving the AMC Objectives, a Call for Supply Offers may be issued once per calendar year or more or less frequently if so decided by the GAVI Alliance in consultation with UNICEF. A written explanation of the decision to issue or not to issue a Call for Supply Offers based on such consultation will be provided to all parties of the AMC Stakeholders Agreement.

PART III The GAVI Alliance, or a procurement agency acting on its behalf, shall at all times have regard to the provisions of paragraphs 4.2, 4.3 and 4.4 of the AMC Procedures Memorandum in any assessment of a Supply Offer.

SCHEDULE 7 Entry into Supply Agreements

PART I Subject to the Offer Agreement (in particular Clause 3) and the provisions of Condition 6.6, the GAVI Alliance, or a procurement agency acting on its behalf, may enter into Supply Agreements with AMC-Eligible Manufacturers in good faith and in a commercially reasonable manner only upon:

- (a) approval by the IAC of an Application for AMC Eligibility;
- (b) the then applicable GAVI Strategic Demand Forecast indicates a cumulative increase of at least 10 million doses in the immediately following five years when

compared against the immediately preceding GAVI Strategic Demand Forecast or unallocated quantities of Supply Commitment exceed 10 million doses;

- (c) approval of the applicable GAVI Co-Payment budget by the GAVI Alliance Board for such Supply Agreement including any required Firm Order Timing payments for the relevant Supply Agreement; and
- (d) any requisite internal procedures and processes of the relevant procurement agency acting on behalf of the GAVI Alliance have been complied with, provided that such procedures and processes are not in any way inconsistent with nor modify the Transaction Documents.

PART II Notwithstanding any other provision herein, an AMC-Eligible Manufacturer shall only be entitled to receive payments from the AMC Offer Amount under Clause 3.2 of the Offer Agreement if such AMC-Eligible Manufacturer enters into a Supply Agreement substantially in the form attached in Schedule 1 within a reasonable period of time and in any case no later than five months from the time of a Call for Supply Offers.

PART III Subject to the provisions of Condition 6.5, each Supply Agreement shall have: (a) an AMC Capacity Development Period of up to 5 years; (b) a Supply Commitment Period of at least ten years; and (c) a Supply Commitment of at least 10 million doses per year.

PART IV Each Supply Agreement shall specify: (a) the amount of annual Supply Commitment; (b) the agreed AMC Capacity Development Period; and (c) arrangements for the sale of AMC-Eligible Vaccines from spare capacity during the AMC Capacity Development Period, if applicable.

PART V During an AMC Capacity Development Period, an AMC-Eligible Manufacturer may make a commitment to supply under a Supply Agreement from any doses of AMC-Eligible Vaccine that it may have available for supply and distribution. The terms of any such supply from spare capacity shall be as set out in the relevant Supply Agreement.

PART VI Notwithstanding any other provision in this Agreement, the GAVI Alliance, or a procurement agency appointed by the GAVI Alliance to act on its behalf, may in its sole discretion enter into a Provisional Supply Agreement with an AMC Registered Manufacturer where:

- (a) the aggregate number of doses of AMC-Eligible Vaccine available under all existing Supply Agreements (excluding any pending Supply Offers) is insufficient to meet projected demand from GAVI Eligible Countries at any point in the immediately following five years by at least 10 million doses annually; and
- (b) WHO has accepted such manufacturer's Product Summary File for review.

For the avoidance of doubt: (i) an AMC Registered Manufacturer may not supply any vaccine under a Provisional Supply Agreement until its relevant vaccine becomes an AMC-Eligible Vaccine; and (ii) the GAVI Alliance, or a procurement agency acting on its behalf, shall have regard to the provisions of paragraphs 4.2, 4.3 and 4.4 of the AMC Procedures Memorandum in assessing any Supply Offers in connection with a Provisional Supply Agreement.

PART VIINo later than five IBRD Business Days following the date of execution of a Supply Agreement or a Provisional Supply Agreement, the AMC Secretariat, acting on behalf of the GAVI Alliance shall:

- (a) post a notification on the AMC Website disclosing the date of entry into and the parties of such Supply Agreement and/or Provisional Supply Agreement; and
- (b) notify IBRD of the entry into of each Supply Agreement and/or Provisional Supply Agreement.

SCHEDULE 8AMC Period and Vaccine Purchase Price

PART IThe “**Vaccine Purchase Price**” is the price payable under a Supply Agreement for each dose of AMC-Eligible Vaccine during the AMC Period and is equal to USD 7. The Vaccine Purchase Price consists of the AMC-Funded Price and the Co-Payment, where:

- (a) “**AMC-Funded Price**” means that portion of the Vaccine Purchase Price that is not a Co-Payment; and
- (b) “**Co-Payment**” means that portion of the Vaccine Purchase Price payable by the GAVI Alliance and the Recipient Countries pursuant to a Supply Agreement.

PART IIThe GAVI Alliance, or a procurement agency appointed by the GAVI Alliance to act on its behalf, may agree with an AMC Eligible Manufacturer in each Supply Agreement the amount of each of the AMC-Funded Price and the Co-Payment that shall be due and payable during the AMC Period, provided that the Vaccine Purchase Price for each dose shall not exceed USD 7 at any time during the AMC Period. Where an AMC Eligible Manufacturer has agreed to an AMC-Funded Price and Co-Payment in accordance with this Condition 7.2, such Co-Payment during the AMC Period shall be equivalent to the Tail Price of such AMC-Eligible Vaccine in the Tail Period.

PART IIIFor the avoidance of doubt, the Vaccine Purchase Price does not include any amounts payable under a Supply Agreement in respect of fulfilment, injection safety, vaccination services support, freight costs and delivery charges.

PART IVNo later than 30 IBRD Business Days prior to the date on which a Purchase Order is placed under a Supply Agreement, the GAVI Alliance shall provide a GAVI Payment Demand Notice to IBRD specifying, *inter alia*, the amount of the AMC-Funded Price due and payable and directing payment of such amount by IBRD to the GAVI Alliance, or to such other party as the GAVI Alliance may direct.

PART VBased upon the Semi-Annual GAVI Alliance Estimate and the GAVI Payment Demand Notice, IBRD shall continue to pay to the GAVI Alliance, or to such other party as the GAVI Alliance may direct (as the case may be), from Grant Payment Amounts due and payable under the respective Grant Agreements (after giving effect to any applicable Hedging Transactions) the AMC-Funded Price portion of a Vaccine Purchase Price during the AMC Period, as requested by the GAVI Alliance from time to time pursuant to Condition 7.4; provided that the maximum cumulative amount so payable by IBRD shall not exceed the AMC Offer Amount.

PART VIIBRD shall have no responsibility or liability whatsoever in respect of the payment of a Co-Payment amount, nor any other fees, costs, expenses, indemnities,

reimbursement, charges or similar amount(s), from time to time payable in connection with a Supply Agreement.

PART VII Upon receiving any funds from IBRD pursuant to Condition 7.5, the GAVI Alliance shall add to such amount all additional amounts due from the GAVI Alliance, including the portion of the Co-Payment for which it is responsible, and shall pay or procure the payment of the cumulative amount due to an AMC-Eligible Manufacturer under a particular Supply Agreement.

PART VIII For the avoidance of doubt, any portion of the Co-payment due and payable by a Recipient Country under a Supply Agreement shall, in accordance with existing practice, be paid directly by such Recipient Country to UNICEF, or such other procurement agency appointed by the GAVI Alliance to act on its behalf. Any non-payment or default by a Recipient Country in respect of its portion of the Co-Payment shall be dealt with by the GAVI Alliance pursuant to the GAVI Co-financing Policies.

SCHEDULE 9 Tail Period, Tail Price, Tail Price Cap and IAC Inflation Review

PART I During the Tail Period, each AMC-Eligible Manufacturer who has entered into a Supply Agreement shall supply an AMC-Eligible Vaccine at the Tail Price. Such Tail Price shall be equivalent to the Co-Payment agreed in Condition 7.2 which is payable in respect of such AMC-Eligible Vaccine during the AMC Period. Subject to Condition 9.4.1, such price shall not at any time exceed the Tail Price Cap. An AMC-Eligible Manufacturer may decrease the amount of the Tail Price at any time and shall give notice of such decrease as specified under the relevant Supply Agreement. All provisions of this Condition 8 that apply to the Tail Price shall apply to the Co-Payment during the AMC Period.

Tail Price

PART II Subject to Condition 8.3, where any Supply Agreement specifies a Tail Price less than the Tail Price Cap, then:

- (a) if and when notified by an AMC-Eligible Manufacturer, the IAC shall increase such Tail Price annually at the rate of increase in the Index up to the then applicable Tail Price Cap; and
- (b) the IAC may increase such Tail Price where requested to make an increase in an amount greater than the increase in the Index up to the Tail Price Cap, provided that such request shall be accompanied by relevant Cost Information.

For the avoidance of doubt, an AMC-Eligible Manufacturer may request an increase in the Tail Price under its Supply Agreement in accordance with and at the same time as any request for an increase in the Tail Price Cap in accordance with this Condition 8. The IAC shall be required to make any determination in relation to this Condition 8 as soon as possible and in any case within a reasonable timeframe.

PART III Notwithstanding any increase in the Tail Price Cap, the Tail Price and the Tail Price Cap in respect of a specific Provisional Supply Agreement and/or Supply Agreement shall not be amended, modified, varied or supplemented at any point during the Firm Order Timing Period of such a Supply Agreement. Within 30 IBRD Business Days from the expiry of a Firm Order Timing Period under a Supply Agreement, if and when notified by an AMC-Eligible Manufacturer, the IAC may make a single increase to the

Tail Price under such Supply Agreement up to the then-current Tail Price Cap; **provided that** the provisions in Condition 8.2 shall apply to any such increase. Thereafter, any increase in the Tail Price and Tail Price Cap applicable to such Supply Agreement shall be dealt with in accordance with the provisions of this Condition 8. For the avoidance of doubt, where an AMC-Eligible Manufacturer exercises its right in accordance with Condition 6.5 to supply AMC-Eligible Vaccines during the AMC Capacity Development Period, then the remaining provisions of this Condition 8 shall not apply in respect of such period provided that if and when notified by an AMC-Eligible Manufacturer, the IAC shall increase such Tail Price annually at the rate of increase in the Index up to the Tail Price Cap of such Supply Agreement (without taking into account any other modification to the Tail Price Cap).

PART IV Subject to Article II, paragraph 11 of each Supply Agreement, the Tail Price does not include amounts in respect of fulfilment, injection safety, vaccination services support, freight costs and delivery charges.

Tail Price Cap

PART V At any time on or after the earlier to occur of:

- (a) each third anniversary of the date of the Offer Agreement; or
- (b) a cumulative 7 percent increase in the Index since the date of the Offer Agreement or since the date of the last IAC Inflation Review, whichever is later,

an AMC Registered Manufacturer and/or an AMC-Eligible Manufacturer who has entered into a Provisional Supply Agreement or Supply Agreement may submit a written request to the AMC Secretariat that the IAC review and consider an increase to the Tail Price Cap in accordance with the provisions of this Condition 8 (an “**Inflation Review Application**”). The IAC shall conduct no more than one IAC Inflation Review in any calendar year.

PART VI Any such request may be accompanied by relevant Cost Information, for such manufacturer in respect of the relevant AMC-Eligible Vaccine. Where a request is made specifically to increase the Tail Price Cap in an amount greater than the increase in the Index, then such request shall be accompanied by relevant Cost Information for such manufacturer in respect of the relevant AMC-Eligible Vaccine.

PART VII The IAC may appoint independent third parties with the appropriate expertise to advise it or to verify any Cost Information received from a manufacturer to support its request. Any independent third party expert appointed by the IAC in accordance with this Condition 8.7 shall be required to enter into confidentiality arrangements on the same terms as the IAC 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.

PART VIII Upon receipt of an Inflation Review Application under Condition 8.5, the AMC Secretariat shall notify all other manufacturers on the AMC Website that such

application has been received and request that all AMC Registered Manufacturers provide to the AMC Secretariat within 20 IBRD Business Days either: (a) an independent Inflation Review Application on an AMC Registered Manufacturer's behalf; or (b) a confirmation that each AMC Registered Manufacturer is not intending to submit an Inflation Review Application in that calendar year.

PART IX Subject to the following, the IAC may, upon review of all information provided by a manufacturer (if any) and in its sole discretion, increase the Tail Price Cap in an amount no greater than the increase in the Index. Where a request is made specifically to increase the Tail Price Cap in an amount greater than the increase in the Index, then the IAC may increase the Tail Price Cap in an amount greater than the increase in the Index, such amount to be determined in its sole discretion, taking into consideration the AMC Objectives and the criteria set out in Condition 8.10 below.

PART X The IAC shall in its assessment of any matters relating to this Condition 8, other than Condition 8.2(a):

- (a) take into account current and projected rates of inflation and other Cost Information, where provided or otherwise publicly available;
- (b) consider how to allocate cost increases between: (i) GAVI-Eligible Countries (in line with the then current GAVI Co-financing Policies); (ii) the GAVI Alliance; and (iii) manufacturers as a whole in a reasonable manner; and
- (c) ensure that pricing of AMC-Eligible Vaccines remains consistent with the AMC Objectives, taking into account cost per DALY implications.

PART XI The AMC Secretariat shall disclose on the AMC Website the basis for any IAC determination to increase the Tail Price Cap as well as any relevant minutes arising during an IAC Inflation Review, including the process and assessment criteria that the IAC used in reaching its final decision. For the avoidance of doubt, any disclosure on the AMC Website relating to an Inflation Review Application or an IAC Inflation Review pursuant to Condition 8.2(a) shall not include any information relating to the identity of the manufacturer who has submitted an Inflation Review Application, any manufacturing or operating costs information submitted in conjunction with an Inflation Review Application that is not publicly available and/or any Confidential Information received by the AMC Secretariat, the GAVI Alliance or the IAC in connection with such Inflation Review Application.

PART XII Once the IAC has made a determination under this Condition 8, any increase to the Tail Price Cap shall take effect immediately for the next applicable Purchase Order in respect of all existing Supply Agreements and Provisional Supply Agreements; provided that where there has been any increase to the Tail Price above the then applicable Tail Price Cap, such increase shall be subject to budgetary approval by the GAVI Alliance Board. An increase in the Tail Price Cap under this Condition 8 may result in an increase of the Tail Price under each Supply Agreement in accordance with Condition 8.2.

PART XIII Each AMC-Eligible Manufacturer may, at the time of making a Supply Offer or entering into a Supply Agreement, elect to: (i) waive its right to the inflation adjustment provisions of this Condition and in particular Conditions 8.2 and 8.5 above; or (ii) be bound by modified inflation adjustment provisions as set out in Conditions 8.14 and 8.15 below. Any waiver or modification of the inflation adjustment provisions in accordance with Conditions 8.14 and 8.15 below shall be considered in the assessment of a Supply Offer, where applicable.

PART XIV Condition 8.2 may only be modified to: (i) permit an AMC-Eligible Manufacturer to increase the Tail Price at the rate of increase in the Index up to the then applicable Tail Price Cap at a less frequent interval than once a year; (ii) not permit, at any time, any increases in the Tail Price at a rate greater than the rate of increase in the Index up to the then applicable Tail Price Cap; and/or (iii) not permit increases of the Tail Price at a rate greater than the increase in the Index up to the Tail Price Cap as currently permitted under Condition 8.2(b).

PART XV Condition 8.5 may only be modified to permit: (i) an Inflation Review Application to be submitted on a less frequent interval than on each third anniversary of the date of the Offer Agreement; and/or (ii) the setting of a minimum required rate of cumulative

increase in the Index since the date of the Offer Agreement or since the date of the last IAC Inflation Review, whichever is later, before which an Inflation Review Application may be submitted, such minimum rate to be greater than the 7 percent currently permitted under Condition 8.5(b).

PART XVI Any waiver or modification made pursuant to Condition 8.13 above shall only operate as a waiver or modification to the relevant Supply Agreement in relation to the AMC-Eligible Manufacturer making such waiver or modification. No waiver or modification made pursuant to Condition 8.13 above shall be deemed to be an amendment to the Conditions as set out in this Schedule 1 to the Offer Agreement and as applies to all other AMC Registered Manufacturers and AMC-Eligible Manufacturers.

SCHEDULE 10 Independent Assessment Committee

PART I Establishment and Operation

The Independent Assessment Committee has been established and constituted in accordance with the IAC Charter and Bylaws. The IAC shall operate in accordance with the provisions of the IAC Charter and Bylaws and the AMC Procedures Memorandum.

PART II Review and Modification of the Target Product Profile

1. The IAC shall be authorised to review the process adopted by WHO for the purposes of developing the TPP and to provide its approval of a TPP presented to it by the AMC Secretariat.
2. Upon providing its final approval of a TPP in accordance with Condition 9.2.1, the IAC shall be authorised to modify such TPP in its sole discretion, provided that:
 - (y) the IAC determines, in its sole discretion, that it is not possible for any manufacturer to develop a vaccine that meets the TPP within the relevant Offer Period; and
 - (z) the criteria and product requirements specified in the TPP may only be amended so as to make them equally or less stringent in its application to candidate vaccines.

PART III AMC Eligibility Determination

The IAC shall determine in its sole discretion whether any vaccine submitted by a Registered Manufacturer in an Application for AMC Eligibility meets or exceeds the respective TPP requirements. The IAC shall make any such determination in accordance with the procedures and provisions set out in the IAC Charter and Bylaws and the AMC Procedures Memorandum.

PART IV Review and Modification of AMC Prices

1. The IAC shall be authorised to review the Tail Price and/or Tail Price Cap:

- (aa) upon the request of an AMC Registered Manufacturer or an AMC-Eligible 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 affect the cost of production of the relevant AMC-Eligible Vaccine, provided that any such request is accompanied by relevant Cost Information, which shall upon request be treated confidentially; and/or
- (bb) as permitted in accordance with Condition 8.

PART VIAC Actions, Decisions and Determinations

1. All decisions and determinations of the IAC in connection with any aspect of the AMC Pneumo Initiative shall:
 - (cc) be final and shall not be subject to appeal or further adjudication by any other person, body or tribunal; and
 - (dd) be binding on AMC Registered Manufacturers and AMC-Eligible Manufacturers.
2. In order to assist the IAC in making any inquiry, review, modification or determination, the IAC may at any time engage or rely upon external expert advice from experts, 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.
3. The IAC shall at all times be entitled to receive administrative support from the AMC Secretariat when in the process of taking any actions, decisions, deliberations or determinations in accordance with the IAC Charter and Bylaws and the AMC Procedures Memorandum.
4. Subject to Condition 13, all IAC actions, decisions and deliberations (including minutes of AMC Eligibility Determination Meetings) shall be disclosed on the AMC Website by the AMC Secretariat.

SCHEDULE 11AMC Funds Suspension Events

PART I During the AMC Period, the GAVI Alliance may at any time temporarily suspend further payments in connection with the relevant Supply Agreement to the relevant AMC-Eligible Manufacturer in the event that both the GAVI Alliance and IBRD (acting together) determine that any of the following (each an “**AMC Funds Suspension Event**”) has occurred in respect of such AMC-Eligible Vaccine or AMC-Eligible Manufacturer as the case may be:

- (a) the licence for an AMC-Eligible Vaccine is revoked, withdrawn, cancelled or suspended by the relevant regulatory authority;
- (b) the WHO pre-qualification approval of an AMC-Eligible Vaccine is revoked, withdrawn, cancelled or suspended;
- (c) an AMC-Eligible Vaccine is subject to a material inquiry or investigation by the IAC, an international organisation or a relevant health regulatory authority;

- (d) an AMC-Eligible Manufacturer has failed to comply in a material way with the provisions applicable to it as set out in the AMC Procedures Memorandum, the AMC Registered Manufacturer Agreement or a Supply Agreement;
- (e) an AMC-Eligible Manufacturer becomes insolvent or subject to any Insolvency Proceedings or Creditor's Event; or
- (f) both the GAVI Alliance and IBRD (acting together) have made a determination that there has been an irremediable dilution in the extent to which the AMC Objectives are being met.

PART III If both the GAVI Alliance and IBRD (acting together) determine that an AMC Funds Suspension Event has occurred, the AMC Secretariat shall prepare an AMC Funds Suspension Notice in respect of each relevant AMC-Eligible Vaccine. Each relevant AMC-Eligible Manufacturer shall be provided with a copy of such notice and such notice shall be published on the AMC Website. Such notice shall be subject to the confidentiality provisions of Condition 13 of the Conditions. IBRD and the GAVI Alliance shall use all reasonable endeavours to work together for a period of up to 60 IBRD Business Days from the date the AMC Funds Suspension Notice, or such other period of time as may be agreed between IBRD, the GAVI Alliance and the relevant AMC-Eligible Manufacturer to identify a means of remedying the AMC Funds Suspension Event (and/or the cause thereof).

PART III During any AMC Funds Suspension Period and as of the date on which such AMC Funds Suspension Event occurs, the obligations of all parties under the Offer Agreement (including the Conditions) and the Supply Agreement shall be suspended and no further payments shall be made by:

- (a) IBRD to the GAVI Alliance in respect of any payments due to such AMC-Eligible Manufacturer or such other party as directed by the GAVI Alliance, which is due and payable on or after the date on which such AMC Funds Suspension Event occurs in connection with the terms of the Offer Agreement and these Conditions; and
- (b) the GAVI Alliance, or any procurement agency on its behalf, in connection with the terms of the relevant Supply Agreement in respect of any amounts which are due and payable on or after the date on which such AMC Funds Suspension Event occurs.

PART IV If an AMC Suspension Funds Event that has occurred is remedied to the GAVI Alliance's satisfaction or otherwise waived by the GAVI Alliance, then the AMC Secretariat shall notify all parties that the AMC Funds Suspension Period has ended and payments referred to in Conditions 10.3 (a) and (b) shall recommence.

SCHEDULE 12 AMC Cancellation Events

PART II If at the end of, or at any time during an AMC Funds Suspension Period (or any extension thereof), both the GAVI Alliance and IBRD (acting together) determine that the AMC Funds Suspension Event or Events (and/or the cause thereof) in question cannot be remedied to their satisfaction or that any steps that have been identified to remedy such event have not been taken to their satisfaction, then both the GAVI Alliance and IBRD (acting together) may determine that an AMC Cancellation Event

has occurred in respect of such AMC-Eligible Manufacturer or AMC-Eligible Vaccine, as the case may be (an “**AMC Cancellation Event**”).

PART III If both the GAVI Alliance and IBRD (acting together) determine that an AMC Cancellation Event has occurred, then the AMC Secretariat shall deliver an AMC Cancellation Notice to the affected AMC-Eligible Manufacturer and shall publicly disclose the fact of such cancellation by publishing a copy of the AMC Cancellation Notice on the AMC Website. The AMC Cancellation Notice shall specify the AMC Cancellation Date and the affected AMC-Eligible Manufacturer and AMC-Eligible Vaccine. All obligations of IBRD, the GAVI Alliance (and/or any procurement agency acting on behalf of the GAVI Alliance) and the relevant AMC-Eligible Manufacturer under the Offer Agreement (including the Conditions) and any Supply Agreements (including any payment obligations) in respect of such affected AMC-Eligible Manufacturer and the affected AMC-Eligible Vaccine shall cease on the AMC Cancellation Date in question.

PART IIII Where there has been an AMC Cancellation Event in respect of all existing AMC-Eligible Manufacturers and AMC-Eligible Vaccines, then the AMC Secretariat shall deliver an AMC Total Cancellation Notice to each AMC-Eligible Manufacturer and AMC Registered Manufacturer and shall publicly disclose such cancellation by publishing a copy of the AMC Total Cancellation Notice on the AMC Website. The AMC Total Cancellation Notice shall specify the AMC Total Cancellation Date. All obligations of IBRD, the GAVI Alliance (and/or any procurement agency appointed by the GAVI Alliance to act on behalf of the GAVI Alliance) and the relevant AMC-Eligible Manufacturer under the Offer Agreement (including the Conditions) and all outstanding Supply Agreements (including any payment obligations) in respect of all AMC-Eligible Manufacturers and all AMC-Eligible Vaccines shall cease on the AMC Total Cancellation Date.

SCHEDULE 13 Ongoing Industry Consultation

PART I In order to monitor the progress and developments of the AMC Pneumo Initiative, IBRD and the GAVI Alliance, may from time to time during the AMC Period:

- (a) engage in ongoing consultations with AMC Registered Manufacturers and other vaccine industry participants; and
- (b) subject to Condition 13, collate for review by the IAC any information obtained in the course of its consultations in paragraph (a) above as well as any publicly available information and data relating to AMC Registered Manufacturers and other vaccine industry participants.

SCHEDULE 14 Confidentiality

PART I In the event that any of the GAVI Alliance (including the AMC Secretariat) or IBRD obtains any Confidential Information during the Offer Period, each of them agrees:

- (a) not to disclose such Confidential Information to any person other than where such disclosure is: (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 or IBRD of their respective obligations under this Condition 13;

- (b) not to use any Confidential Information except as necessary to perform its responsibilities and duties, as set out in the Transaction Documents; and
- (c) to promptly return any Confidential Information obtained by it to the relevant party who has provided such information to it, or otherwise destroys it, as instructed by the provider of the information, as the case may be.

PART II Where disclosure is made pursuant to Condition 13.1(a)(ii) above, the AMC Secretariat 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.

ANNEX 1

Form of Supply Agreement

PRO-FORMA SUPPLY AGREEMENT

THIS SUPPLY AGREEMENT (hereinafter, this “Agreement”) is made this [] day of [] between UNICEF, the United Nations Children’s Fund, an international, inter-governmental organization established by the General Assembly of the United Nations by resolution No. 57(1) of 11 December 1946 as a subsidiary organ of the United Nations, having its headquarters at UNICEF House, Three United Nations Plaza, New York, New York, 10017 U.S.A. (hereinafter, “UNICEF”) and [*name of supplier plus jurisdiction of registration and address of headquarters*] (hereinafter, the “Supplier”, together with UNICEF the “Parties” and each a “Party”)

WHEREAS, UNICEF works with governments, civil society organizations, and other organizations around the world to advance children's rights to survival, protection, health, development and participation and is guided by the Convention on the Rights of the Child;

WHEREAS, the GAVI Alliance (hereinafter, “GAVI” or the “Foundation”), a Swiss private foundation established through cooperation between governments, UNICEF, the World Health Organisation and the World Bank, private foundations and corporations, research institutions and other actors is a mechanism for supporting developing country Governments in their implementation of immunisation programmes and is committed to supporting the development of affordable pneumococcal vaccines and the use of such vaccines in GAVI Eligible Countries;

WHEREAS, GAVI administers the AMC Pneumo Initiative, the details of which are described more fully in the Offer Agreement, which provides time-limited support to promote the purchase of pneumococcal vaccines as inputs to government immunisation programmes in Eligible Countries;

WHEREAS, the Board of Directors of the GAVI Alliance has designated UNICEF as the procurement agency to be used by governments receiving support for the purchase of pneumococcal vaccines using funding support from GAVI, including under the AMC Pneumo Initiative;

WHEREAS, the Supplier is an [AMC-Eligible Manufacturer with an AMC-Eligible Vaccine]¹ OR [AMC-Registered Manufacturer which has had its Product Summary File accepted for review by WHO]²;

WHEREAS, the requirements of Condition 6.1 [or 6.6]³ of the AMC Terms and Conditions as to the conditions precedent for UNICEF to negotiate and enter into a [Provisional]⁴ Supply Agreement with the Supplier have been met and the requirements of section 4.4 of the AMC Procedures Memorandum have been met;

¹ Use for Supply Agreements.

² Use for Provisional Supply Agreements.

³ Use for Provisional Supply Agreements

⁴ Delete as applicable

WHEREAS, the Supplier has communicated to UNICEF a Supply Offer in response to UNICEF's Call for Supply Offers and UNICEF has [following negotiation]⁵ accepted the Supplier's Supply Offer [as amended]⁶ (which [amended]⁷ Supply Offer is hereinafter referred to as the "Supplier's Supply Offer");

WHEREAS, the Supplier's Supply Offer includes [a representation, upon which UNICEF is relying in entering into this Agreement, that the Supplier has reached] OR [the Supplier's Vaccine Production Plan for reaching] OR [the Supplier's Vaccine Production Plan for obtaining WHO prequalification and AMC-Eligibility and reaching] the production capacity required for it to be able to comply with its obligations under this Agreement in a timely manner;

WHEREAS, at GAVI's request, UNICEF and the Supplier have negotiated the amount of pneumococcal vaccines that will be made available by the Supplier under this Agreement for possible purchase by UNICEF [once the Supplier has obtained WHO pre-qualification and AMC Eligibility]⁸ and UNICEF is entering into this Agreement with the Supplier.

NOW THEREFORE, UNICEF and the Supplier hereby agree as follows:

ARTICLE I DEFINITIONS

1. In this Agreement, in addition to the terms defined above, the following terms have the following meanings unless otherwise specified:

(a) "AMC Documents" means the Stakeholders Agreement, the Offer Agreement (including the AMC Terms and Conditions and pro-forma Supply Agreement scheduled thereto), , the AMC Registered Manufacturer Agreement, the AMC Procedures Memorandum and the IAC Charter and Bylaws.

(b) "Carrier" means any entity who, in contract of carriage with the freight forwarder, undertakes to perform or to procure the performance of transport by rail, road, air, sea, inland waterway or by a combination of such modes.

(c) "Freight Forwarder" means any entity who undertakes to perform or procure the performance of transport by rail, road, air, sea, inland waterway or by a combination of such modes.

(d) "GAVI Strategic Demand Forecast" or "GAVI SDF" means the strategic demand forecast for pneumococcal vaccine developed by GAVI and referred to in Article II, paragraph 12 of this Agreement.

⁵ Delete as applicable

⁶ Delete as applicable

⁷ Delete as applicable

⁸ To be included in a Provisional Supply Agreement.

(e) “GAVI Target Annual Demand” means 200 million doses, being GAVI’s projected and target demand for pneumococcal vaccine once it is introduced in the majority of GAVI Eligible Countries.

(f) “Master Definitions Schedule” means the agreement dated 12 June 20009 between GAVI Alliance and the International Bank for Reconstruction and Development, and the Republic of Italy, the United Kingdom, the Government of Canada, the Russian Federation, the Kingdom of Norway, and the Bill & Melinda Gates Foundation which defines the terminology of the AMC .

(g) “Purchase Order” means the Purchase Order issued by UNICEF to the Supplier under this Agreement from time to time.

(h) “Supplier’s Annual Vaccine Supply Commitment Quantity” means the number of doses of the Vaccine referred to in Article II, paragraph 1 of this Agreement (subject to any reductions as may be made in accordance with the provisions of Article IV, paragraphs 3 and 4 of this Agreement), being the number of doses that the Supplier will offer for sale to UNICEF during each twelve (12) month period during the Vaccine Purchase Period.

(i) “Supplier’s Total Vaccine Supply Commitment Quantity” means the cumulative total number of doses of the Vaccine in the Supplier’s Annual Vaccine Supply Commitment Quantities.

(j) “Vaccine” means a pneumococcal vaccine that has been prequalified by WHO and accepted by GAVI as an AMC-Eligible Vaccine.

(k) “Vaccine Purchase Period” means the period beginning on the date determined in accordance with Article II of this Agreement and ending at the conclusion of this Agreement.

(l) “Vaccine Purchase Period Trigger Notice” means the written notice referred to in Article II, paragraph 4 of this Agreement.

(m) “Vaccine Purchase Price” means the per dose purchase price to be paid by UNICEF to the Supplier pursuant to this Agreement as set out in Article II, paragraph 9.

(n) [others]

2. Capitalised terms used in this Agreement, including in the recitals to this Agreement, will, unless defined in this Agreement, have the same meaning as in the Master Definitions Schedule.

ARTICLE II
SUPPLY AND PURCHASE OF VACCINES;
CHANGES TO QUANTITY AND PRICE; STRATEGIC
DEMAND FORECASTS TO BE PROVIDED TO SUPPLIER

Supplier to Make Vaccines Available to UNICEF during the Vaccine Purchase Period

1. During each twelve (12) month period of the Vaccine Purchase Period and subject to this Agreement, the Supplier will have available for sale and delivery to UNICEF or at UNICEF's instructions during such twelve (12) month period not less than [amount in words] ([amount in figures]) doses of Vaccine, being the Supplier's Annual Vaccine Supply Commitment Quantity.
2. The availability of Vaccines during each twelve (12) month period of the Vaccine Purchase Period will be distributed reasonably throughout such period.

The Vaccine Purchase Period; the Vaccine Purchase Period Trigger Notice

3. The Vaccine Purchase Period will commence on [date] and continue for one hundred and twenty (120) months continuously and without interruption or suspension thereafter; provided however that UNICEF may agree to extend the date on which the Vaccine Purchase Period commences by up to but not more than a total of sixty (60) months from the date of this Agreement.
4. At least three (3) months prior to the start of the Vaccine Purchase Period, the Supplier will deliver to UNICEF a written notice (hereinafter, the "Vaccine Purchase Period Trigger Notice") confirming that its production capacity is such that it can make the Supplier's Annual Vaccine Supply Commitment of Vaccines available to UNICEF throughout the Vaccine Purchase Period and in accordance with the terms of this Agreement.
5. This Agreement will automatically terminate if the Supplier fails to deliver the Vaccine Purchase Period Trigger Notice to UNICEF on or before the day that is three (3) months prior to the date that the Vaccine Purchase Period is scheduled to commence in accordance with Article II, paragraph 3 above. In the event of such automatic termination the provisions of Article VIII, paragraph 9 of this Agreement will apply.

UNICEF to Purchase Vaccines from Supplier during the Vaccine Purchase Period

6. Subject to the provisions of Article VIII paragraph 2, during each of the first three (3) periods of twelve (12) months during the Vaccine Purchase Period, UNICEF will issue Purchase Orders to the Supplier for such amount of the Vaccines as UNICEF shall in its absolute discretion determine, following consultation with GAVI and taking into account anticipated Eligible Country demand, during the relevant period; provided however that such amounts shall not be less than the following in the respective twelve (12) month periods:
 - (a) Months 1-12: twenty percent (20%) of the Supplier's Annual Vaccine Supply Commitment;
 - (b) Months 13-24: fifteen percent (15%) of the Supplier's Annual Vaccine Supply Commitment;

(c) Months 25-36: ten percent (10%) of the Supplier's Annual Vaccine Supply Commitment.

7. During months 37 to 120 of the Vaccine Purchase Period, UNICEF will, subject to receiving the necessary funds from GAVI, issue Purchase Orders to the Supplier for such amount of the Vaccine as UNICEF shall in its absolute discretion determine, following consultation with GAVI and taking into account anticipated Eligible Country demand, during the relevant period.

8. UNICEF may, subject to receiving the necessary funds from GAVI, issue Purchase Orders to the Supplier for the purchase of Vaccines prior to the delivery of the Vaccine Purchase Period Trigger Notice should UNICEF conclude there is sufficient demand and available funding for such Vaccines and should such Vaccines be available for purchase, in which case the provisions of Article III, paragraph 4 will apply.

Price; Price Re-Setting; Possible Price Adjustments

9. (a) Subject to the provisions of Article II, paragraph 11 below, the Supplier will sell the Vaccines to UNICEF and, subject to receiving the necessary funds from GAVI, any purchases of Vaccines by UNICEF from the Supplier will take place at the following prices per dose during the following times:

(i) during the AMC Period, a price per dose of seven dollars US (USD 7.00) (hereinafter, the "Vaccine Purchase Price"); and

(ii) during the Tail Period, a price per dose of *[amount in words]* (*[amount in figures]*) or such other price as GAVI may instruct UNICEF in accordance with Article II, paragraph 10 below (hereinafter, the "Tail Price").

(b) It is understood that:

(i) the Vaccine Purchase Price paid to the Supplier will include the AMC-Funded Price as that term is defined in the Master Definitions Schedule and that the payment of this portion of the Vaccine Purchase Price will be subject to the provisions of the AMC Documents (including, but not limited to, the AMC Terms and Conditions and in particular Condition 10 and 11 thereof);

(ii) in accordance with the provisions of the AMC Documents, and subject to the provisions of Article II, paragraph 11 below, the aggregate amount paid as the AMC-Funded Price to the Supplier will be determined by GAVI and will be the product of (X) one and one half billion dollars US (USD 1.5 billion); multiplied by (Y) a fraction the numerator of which will be the Supplier's Annual AMC Supply Commitment Quantity and the denominator of which will be two hundred million (200,000,000) such fraction being expressed as a percentage; and

(iii) the aggregate amount paid as the AMC-Funded Price to the Supplier will be disbursed on a per dose basis.

10. At any time during the Tail Period, GAVI may give UNICEF written notice, with a copy to the Supplier, of a change to the Tail Price, and the price set out in all Purchase Orders issued after the date such notice is received by UNICEF shall be adjusted accordingly. It is understood that the Supplier may request GAVI to issue such notice to UNICEF.

11. The Vaccine Purchase Price and Tail Price specified in this Agreement include all costs of packaging, temperature monitoring devices as required by WHO Guidelines on the international packaging and shipping of vaccines (WHO/IVB/05.23) or any later revision, Vaccine Vial Monitors (VVM), and delivery in accordance with INCOTERM FCA to the designated airport.

GAVI's Strategic Demand Forecasts to be Provided by UNICEF

12. UNICEF will provide the Supplier with the GAVI SDF promptly upon receiving it from GAVI. The GAVI SDF is expected to be produced by GAVI as soon as the necessary information is available from the last procurement cycle and relevant GAVI Alliance Board meeting. The GAVI SDF will set out the annual quantity of Vaccines that GAVI anticipates UNICEF will be requested to purchase from all AMC-Eligible Manufacturers during the Vaccine Purchase Period, it being understood that the providing of the GAVI SDF creates no obligations between UNICEF and the Supplier.

ARTICLE III ACTIVITIES PRIOR TO VACCINE PURCHASE PERIOD

The Supplier's Supply Offer; the Supplier's Pneumo Vaccine Production Plan

1. (a) The Supplier's Supply Offer, together with the Supplier's agreement to accept and be bound by the provisions of the relevant AMC Documents, are the bases on which UNICEF, at the request of GAVI, is entering into this Agreement. The Supplier's Supply Offer is incorporated into this Agreement in full; provided however that in the event of any inconsistency between this document and the Supplier's Supply Offer, the terms of this Agreement will prevail.

(b) The Supplier will deliver a report to UNICEF on implementation of the Supplier's Pneumo Vaccine Production Plan every six (6) months from the date of this Agreement until the delivery of the Vaccine Purchase Period Trigger Notice. It is understood that UNICEF will consult with both WHO and GAVI about each such six-monthly report and may, in its discretion, provide a copy of such reports to both WHO and GAVI on the understanding that it will be made available within WHO and GAVI on a strictly "need to know" basis. UNICEF shall have no obligation to verify that the Supplier's Pneumo Production Plan has been made available within WHO and GAVI on a strictly "need to know" basis and shall have no liability if it is made available within either WHO or GAVI on anything other than a strictly "need to know" basis.

(c) The Supplier will notify UNICEF immediately upon becoming aware of factors which reasonably indicate that it may not be able to deliver the Vaccine Purchase Period Trigger Notice within the period specified in Article II, paragraph 5 above.
2. (a) Should UNICEF conclude, following consultations with WHO and, in its discretion, with GAVI, upon reviewing any of the six-monthly reports delivered by the Supplier under Article III, paragraph 1(b) above that the Supplier is not making acceptable progress

towards being able to issue the Vaccine Purchase Period Trigger Notice within the period specified in Article II, paragraph 5 above, or should the Supplier provide the notification referred to in Article III, paragraph 1(c) above, UNICEF and the Supplier will consult as to the appropriate course of action. Such consultations may result in an understanding as to actions to be taken by the Supplier and a timetable for such actions; provided however that any change to the commencement date of the Vaccine Purchase Period will require GAVI's prior agreement and will be subject to the provisions of Article II, paragraph 3 of this Agreement. Actions agreed upon pursuant to this Article III, paragraph 2 will not constitute a waiver of any rights available to UNICEF under this Agreement including those as to termination of this Agreement.

(b) Should UNICEF conclude, following consultations with WHO and, in its discretion, with GAVI, that notwithstanding such consultations and understanding, the Supplier is not likely to be able to deliver the Vaccine Purchase Period Trigger Notice within the period specified in Article II, paragraph 5 above, UNICEF will be entitled to terminate this Agreement on thirty (30) days' notice without liability. In exercising its right under this Article III, paragraph 2(b), UNICEF will consult with WHO and with GAVI.

Supplier's Production Capacity Forecasts

3. As soon as the Supplier has established capacity to make any amount of Vaccines available to UNICEF for purchase, and every six (6) months thereafter until the end of the Vaccine Purchase Period, the Supplier will deliver to UNICEF a forecast of its production of Vaccines showing: (i) during the twelve (12) months from the date of the first report, monthly availability; (ii) for the period thereafter, quarterly availability.

Sales of Vaccines Prior to the Delivery of the Vaccine Purchase Period Trigger Notice

4. Prior to the delivery of the Vaccine Purchase Period Trigger Notice, the Supplier may sell Vaccines to UNICEF and UNICEF may purchase Vaccines from the Supplier and such sales will be carried out in accordance with the following provisions:

(a) such sales will be on the same terms and conditions, including as to price, as sales during the Vaccine Purchase Period;

(b) unless otherwise agreed by the Parties, the Supplier's Total Vaccine Supply Commitment Quantity will be reduced by the total amount of Vaccines delivered to UNICEF by the Supplier prior to the Vaccine Purchase Period;

(c) unless otherwise agreed by the Parties, the Supplier's Annual Vaccine Supply Commitment Quantity will be reduced by the total amount of sales of Vaccines to UNICEF prior to the delivery of the Vaccine Purchase Period Trigger Notice, and such reduction will be applied as follows: the amount of such sales shall be applied in full against the Supplier's Annual Vaccine Supply Commitment for the final twelve (12) month period of the Vaccine Purchase Period; and any remaining balance of the amount of such sales shall then be applied against the Supplier's Annual Vaccine Supply Commitment for the preceding twelve (12) month period of the Vaccine Purchase Period until the amount of such sales is fully applied.

ARTICLE IV
OPERATIONAL DEMAND FORECASTING TO
BE PROVIDED; POSSIBLE ADJUSTMENT TO SUPPLIER'S
ANNUAL VACCINE SUPPLY COMMITMENT QUANTITY

Purchasing Obligations: Demand Forecasting

1. The Supplier acknowledges that UNICEF is under no obligation to purchase Vaccines other than those referred to in Article II, paragraph 6(a), (b), and (c) above, and that UNICEF will not be liable for any costs, expenses or other claims by the Supplier in the event that it purchases no other Vaccines under this Agreement.

2. UNICEF will provide to the Supplier the following non-binding procurement forecasts:

(a) UNICEF Annual Demand Forecasts. Three (3) months prior to the beginning of the Vaccine Purchase Period and each twelve (12) months thereafter during the Vaccine Purchase Period, UNICEF will provide to the Supplier a non-binding forecast (hereinafter, the “UNICEF Annual Demand Forecast”) of the quantities of Vaccines it is likely to procure during the following year.

(b) UNICEF Monthly Demand Forecasts. On or about the date UNICEF issues the first Purchase Order for Vaccines to the Supplier, whether during the Vaccine Purchase Period or prior thereto, and during the first full week of each month thereafter, UNICEF will provide the Supplier with a forecast of the quantities of Vaccines likely to be procured by UNICEF each month over the upcoming twelve-month period. The forecast will be provided more frequently than every month in the event of significant changes to the forecast. The Supplier will advise UNICEF in writing within one (1) week of receipt of the forecast (i) whether it is in agreement or disagreement with the forecast; and (ii) whether it is or is not able to meet the forecast demand. If it is not in agreement with the forecast or is not able to meet the forecast demand, the Supplier may propose amendments to the forecast demand which UNICEF may, in its absolute discretion, accept or decline to accept.

Possible Adjustment to Supplier's Total Vaccine Supply Commitment Quantity

3. Should the forecasted procurement quantity for any twelve (12) month period as disclosed in a UNICEF Annual Demand Forecast be lower than the Supplier's Annual Vaccine Supply Commitment Quantity,

(a) the Supplier may elect to make available to UNICEF the lesser amount of Vaccines without penalty, and shall do so by delivering a written notice to that effect to UNICEF no later than thirty (30) days of receiving the UNICEF Annual Demand Forecast; and

(b) the Supplier may propose and UNICEF may agree following consultation with GAVI, which agreement will not be unreasonably withheld, to reduce the Supplier's Annual Vaccine Supply Commitment Quantity for the next succeeding twelve (12) month period of the Vaccine Purchase Period by an amount to be agreed between the Parties.

4. The Supplier's Annual Vaccine Supply Commitment Quantity may be reduced by such amount, if any, as may be agreed between the Parties if both of the following events occur: (a) the GAVI SDF projects a reduction in the demand for Vaccines over a period of not less than three (3) consecutive twelve (12) month periods during the Vaccine Purchase Period; and (b) the cumulative amount of Vaccines to be made available during those three (3) consecutive twelve (12) month periods by all suppliers that have signed Supply Agreements with UNICEF, exceeds the demand projected for such period in that GAVI SDF.

5. Notwithstanding the provisions of Article IV, paragraph 4 above, at any time during the term of this Agreement UNICEF may, upon request by the Supplier, reduce the Supplier's Annual Vaccine Supply Commitment Quantity by such amount, if any, and for such period, if any, and on such terms as UNICEF may determine [in its sole discretion] (following consultation with GAVI) it is possible to reduce the Supplier's Annual Vaccine Supply Commitment Quantity without compromising the AMC Pneumo Initiative's prospects of achieving the AMC Pneumo Initiative's objectives.

ARTICLE V TECHNICAL SPECIFICATIONS

1. All Vaccines sold under this Agreement are to conform to the technical specifications set out in **Annex 1**.

ARTICLE VI GENERAL TERMS AND CONDITIONS OF SALE AND PURCHASE

General

1. UNICEF will purchase Vaccines under this Agreement by issuing to the Supplier the standard UNICEF Purchase Order in effect at the time such Purchase Order is issued. Such purchase will be subject to (a) the terms and conditions set out in the Purchase Order issued to the Supplier; (b) the standard UNICEF terms and conditions in effect at the time such Purchase Order is issued; and (c) the provisions of this Agreement.

2. The current standard UNICEF Purchase Order and the current standard UNICEF General Terms and Conditions are attached to this Agreement as **Annex 2A** and **Annex 2B** respectively.

3. UNICEF reserves the right to change or amend the standard UNICEF Purchase Order and the standard UNICEF General Terms and Conditions at any time and as frequently as it wishes. UNICEF will notify the Supplier of any changes or amendments to the standard UNICEF Purchase Order or the standard UNICEF General Terms and Conditions which UNICEF determines, in its absolute discretion, are material to this Agreement and the transactions contemplated by it. Upon receipt of such notice the Supplier will have thirty (30) days to give UNICEF ninety (90) days' written notice that it is withdrawing from this Agreement. Such withdrawal shall be without penalty to the Supplier, and the Supplier will have no claim against UNICEF or any other entity arising

out of or related to any change or amendment to the standard UNICEF Purchase Order or the standard UNICEF General Terms and Conditions. The provisions of Article VIII, paragraph 7 will apply to any withdrawal by the Supplier.

Account Management

4. The Supplier and UNICEF will each inform the other promptly, in writing, of the name and position of a responsible person who shall, on behalf of each party, be responsible for the administration of this Agreement, to ensure that cost, schedule and technical obligations are met.

5. The Supplier will provide responsive and comprehensive management of UNICEF as a key account. Without limiting the generality of the foregoing, the Supplier will: (a) allocate appropriate resources to effectively manage the communication and business operations between the Supplier and UNICEF; (b) provide monthly reporting as defined here within; (c) ensure efficient order processing, accurate and complete documentation and timely submissions for National Regulatory Release; (d) ensure that all aspects of this Agreement and subsequent Purchase Orders are carried out in full.

ARTICLE VII SPECIAL TERMS AND CONDITIONS OF SALE AND PURCHASE

1. The purchase of Vaccines in accordance with this Agreement will be subject to the special terms and conditions set out in this Article VII.

Timing of Purchase Orders

2. UNICEF will use best efforts to issue each Purchase Order at least six (6) weeks prior to the delivery date stated in such Purchase Order.

Delivery

3. The Supplier will deliver the Goods in accordance with FCA [NAMED AIRPORT] INCOTERMS 2000 to UNICEF in accordance with this Agreement and with the quantities and other instructions specified in the Purchase Orders. All risk of loss or damage to the Goods will remain with the Supplier until physical delivery takes place in accordance with the Agreement.

4. The Supplier will, at its own risk and expense, obtain any export license or other official authorisation and carry out all customs formalities necessary for the exporting of the Vaccines. All documents should clearly indicate the UNICEF Purchase Order number and country of destination.

5. “Delivery” will occur upon both the arrival of the Vaccines at the port of entry designated in the relevant Purchase Order and receipt by the consignee designated in the Purchase Order, and the verification by the designated consignee that the Vaccines are in a satisfactory condition. Inspection and verification of the Vaccines will be made as soon as reasonably practicable after arrival at the designated port of entry and the designated consignee will be entitled to reject and refuse acceptance of any Vaccines not conforming

to this Agreement. Payment for any non-conforming Vaccines will not be deemed an acceptance of the Vaccines.

6. The Supplier acknowledges that any inspection and/or verification of the Vaccines by the designated consignee is a visual inspection to verify, on a sample basis, the likely number of doses delivered and does not involve any determination as to quality or fitness for purpose.

Shipping Instructions (FCA INCOTERMS 2000)

7. The Supplier will, in good time to meet the delivery dates, contact the UNICEF-appointed freight forwarding agent designated in the Purchase Order (hereinafter, the “Freight Forwarder”) and provide the Freight Forwarder with cargo particulars and estimated/firm date of delivery, and obtain forwarding instructions from the Freight Forwarder.

8. The Supplier will notify UNICEF and the Freight Forwarder as soon as the Vaccines are ready to be shipped and will provide such notification using the UNICEF standard Notification of Goods Readiness form then in force.

9. (a) The Supplier will submit to the Freight Forwarder three (3) copies of the following documentation: (a) Invoice; (b) Packing List; the Packing List must clearly indicate the Purchase Order item number(s) contained in each package, a description of the goods, their value, quantity, gross weight, volume in cubic metres, dimensions and markings; (c) Release Certificate issued by the National Regulatory Authority of the country of manufacture for each lot of Vaccine supplied; (d) if applicable, hazardous goods documents, such as in the case of use of Dry Ice; (e) any other documents as specified in the relevant Purchase Order.

(b) The Supplier will provide these documents to the Freight Forwarder in good time to enable the Freight Forwarder to prepare the necessary forwarding arrangements and to distribute the required documentation to the consignee at least five (5) working days in advance of arrival of the Vaccines at the designated port of entry.

10. Instructions in Purchase Orders for some destinations, which specify that a longer period of advance notice shall apply, shall be followed.

11. One set of the following documents shall accompany the consignment when it is shipped and one set shall also be placed in shipping carton number one (the location of these documents shall be stated on the packing list): (a) Invoice; (b) Air Waybill (AWB); (c) Packing List; (d) Release Certificate issued by the National Regulatory Authority of the country of manufacture for each lot of vaccine supplied; (e) Vaccine Arrival Report; (f) Any other documents as specified in each Purchase Order.

Split Shipments

12. Splitting of shipments is not permitted unless unavoidable and communicated to and approved in writing by UNICEF in advance.

Vaccine Arrival Reports

13. It is recognised that completed Vaccine Arrival Reports will only be provided by UNICEF to the Supplier in the event of problems with specific shipments.

Temporary Storage

14. The Supplier agrees that if requested by UNICEF in writing, it will from time to time and at no cost to UNICEF store finished products of Vaccines for delivery at a later date. Storage of Vaccines will be under controlled environmental conditions to facilitate the conservation of the Vaccines. The storage facilities will comply with all national regulations for the storage of vaccines in force in the country where the storage facility is located.

Returns and Replacements

15. The Supplier will be responsible for all transportation costs related to the return and replacement of Vaccines not accepted by UNICEF. Vaccines returned to the Supplier will be recorded as credits to UNICEF and replacements shall be delivered promptly.

Payment

16. The Supplier shall submit invoices to:

UNICEF Supply Division
Finance/Invoice Certification Unit
UNICEF Plads
Freeport, DK 2100
Copenhagen, Denmark
Tel: +45 35 27 35 27
Fax: +45 35 26 94 21

for all Vaccines ordered and delivered to UNICEF, together with the following documents: (a) One original itemised Invoice and two copies, indicating the applicable Purchase Order number; (b) An original Packing List and one copy; (c) Copy of Release Certificate issued by the National Regulatory Authority for each lot of Vaccine supplied; (d) Proof of delivery to Freight forwarder, the Freight Forwarder's Certificate of Receipt or a true certified copy of the Air Waybill.

17. Unless otherwise authorised by UNICEF, a separate invoice must be submitted in respect of each Purchase Order issued pursuant to this Agreement and the Supplier will ensure that all invoices: (a) are submitted in English; (b) are payable in US Dollars; (c) refer to the Purchase Order pertinent to each particular delivery of Goods; (d) provide clear and specific details of the Goods that have been provided pursuant to a specified Purchase Order number; and (e) clearly state the deliveries that they cover.

18. Provided that the Supplier has performed its obligations under this Agreement to the satisfaction of UNICEF, and has submitted to UNICEF invoices and other supporting documentation required by this Agreement UNICEF will, unless otherwise specified in this Agreement or the Purchase Orders, make payment within thirty (30) days of receipt of documentation indicated in Article VII, paragraph 16.

19. No payment, acceptance or concurrence shall be construed as evidence that any matter or thing is complete, satisfactory or in accordance with the Supplier's obligation, and the Supplier shall thereby not be relieved or discharged from performing any obligation under the Agreement.

20. Payments for the Goods will be deposited into the Supplier's bank account as specified in the invoice(s).

21. UNICEF will not pay any charge for late payment unless expressly agreed to in writing.

ARTICLE VIII OTHER PROVISIONS

Term

1. This Agreement will become effective upon the signing by both Parties. It will remain effective until [].

Suspension

2. (a) In the event that UNICEF receives from GAVI an AMC Funds Suspension Notice in accordance with Condition 10.2 of the AMC Terms and Conditions, the obligations under this Agreement, including without limitation UNICEF's obligations under Article II, paragraph 6, will be suspended from the date such notice is received by UNICEF until the date, if any, that UNICEF receives from GAVI a written notice that the AMC Funds Suspension Event has been remedied. UNICEF will be entitled to treat any AMC Funds Suspension Notice received from GAVI as valid and effective and will be under no duty of enquiry to confirm that such notice has in fact been issued by GAVI or is validly issued, or that an AMC Funds Suspension Event has occurred.

(b) Should such written notice of an AMC Funds Suspension Event be received by UNICEF during one of the twelve (12) month periods referred to in Article II, paragraph 6 above, then upon receipt by UNICEF from GAVI of a written notice that the AMC Funds Suspension Event has been remedied, the Parties shall enter into good faith negotiations and the percentages referred to in Article II, paragraph 6 shall be reduced by such amount as the Parties may, in consultation with GAVI, agree; provided however that should the Parties fail to reach agreement within two (2) months of the receipt by UNICEF from GAVI of a written notice that the AMC Funds Suspension Event has been remedied the obligations referred to in Article II, paragraph 6 shall be deemed fulfilled in whole as if such AMC Funds Suspension Event had not occurred.

UNICEF Rights upon Supplier Default

3. Should the Supplier fail to meet the terms of this Agreement, the Supplier will be considered to be in default.

(a) Should UNICEF determine that the failure is a minor breach, UNICEF will be entitled to collect from the Supplier the amount of the damage caused and will be entitled to remedy the failure by adjusting relevant terms of this Agreement.

(b) Should UNICEF determine that the failure is a material breach, UNICEF will be entitled to collect from the Supplier the amount caused by the failure as well as any cost related to remedying the failure, including but not limited to the cost of replacement goods, and will be entitled to remedy the failure by adjusting relevant terms of this Agreement.

(c) Should UNICEF determine that the failure is a fundamental breach, UNICEF will be entitled to collect from the Supplier the amount caused by the failure as well as any cost related to remedying the failure, including but not limited to the cost of replacement goods, will be entitled to remedy the failure by adjusting relevant terms of this Agreement; and will be entitled to collect any funds provided to the Supplier that were paid in advance of the performance that was breached.

(i) Without limiting the generality of the foregoing or limiting UNICEF's discretion to declare the Supplier in fundamental breach of this Agreement, it is agreed and understood that a breach of the provisions of Article II, paragraphs 1 and 2 of this Agreement shall be a fundamental breach of this Agreement and that the Supplier shall be in fundamental breach of this Agreement if any of the following events occur in any calendar year during the AMC Purchase Period: (X) the Supplier declines to accept a Purchase Order for Vaccines, issued by UNICEF under this Agreement, in such amount as would make the cumulative amount of Vaccines to be purchased by UNICEF during that calendar year less than or equal to the Supplier's Annual Supply Commitment Quantity; and (Y) the Supplier fails to make delivery of the full amount of Vaccines set out in any Purchase Order within a reasonable, in UNICEF's opinion, time after receipt of such Purchase Order.

4. UNICEF shall give the Supplier written notice stating the failure.

5. UNICEF may terminate this Agreement for material and fundamental breaches, upon thirty (30) days written notice to the Supplier stating the reason for the termination.

6. Should the Supplier advise UNICEF in advance of the possibility of the Supplier not being able to meet a commitment, then the Supplier and UNICEF may review the situation and negotiate in good faith new applicable conditions and timing.

Actions upon Termination

7. In the event that either Party exercises a right to terminate this Agreement, the Supplier shall take immediate steps to cease provision of Vaccines in a prompt and orderly manner and shall not undertake any forward commitments from the date of the termination notice; and the Supplier acknowledges that UNICEF shall only pay the Supplier for

Vaccines satisfactorily provided in accordance with the Agreement, to the date of the termination notice.

8. In the event that UNICEF exercises a right to terminate this Agreement for material or fundamental breach by a Supplier:-

- (a) the Supplier will repay to UNICEF all amounts, if any, paid by UNICEF to the Supplier in respect of Vaccine which have been ordered by UNICEF but not delivered by the Supplier prior to the date of the termination notice (which amount will include, without limitation, the Relevant Proportion of the total amount of the AMC Funded Price paid to the Supplier prior to the date of the termination notice); and
- (b) the Supplier will be liable to UNICEF for UNICEF's additional costs (including, without limitation, in respect of each dose of Vaccine acquired from alternative sources for a period of [3] years, the difference in amount (if any) by which the cost thereof exceeds the Vaccine Purchase Price during the AMC Period and the Tail Price during the Tail Period as applicable), if any, of procuring the Outstanding Vaccines from alternative sources; and
- (c) should GAVI, at any time and in its absolute discretion, determine that UNICEF is unable to procure all of the Outstanding Vaccines from alternative sources as contemplated in sub-paragraph 8(b) above, the Supplier shall pay to GAVI an amount (the "Repayment Amount") equal to the total amount of the AMC-Funded Price paid to the Supplier prior to the date of the termination notice less such amount of AMC-Funded Price, if any, repaid to UNICEF in accordance with sub-paragraph 8(a) above.

For the purposes of this Article VIII, paragraph 8:-

"Outstanding Vaccine" shall mean the Supplier's Total Supply Commitment Quantity less the number of doses of Vaccine delivered under this Agreement prior to the date of the termination notice.

"Relevant Proportion" shall mean such percentage as is equal to the percentage of the Supplier's Total Supply Commitment Quantity as is represented by the Outstanding Vaccine.

9. In the event this Agreement terminates in accordance with Article II, paragraph 5 of this Agreement, neither Party shall have a claim against the other for any amounts incurred in connection with this Agreement including, but not limited to, out-of-pocket expenses, losses, or the like; provided however that the Supplier shall, within thirty (30) days of the termination of this Agreement in accordance with Article II, paragraph 5, repay to UNICEF the total amount of the AMC-Funded Price paid to the Supplier prior to the automatic termination date.

Force Majeure

10. If either Party is prevented by force majeure from fulfilling its obligations under this Agreement, it shall not be deemed in breach of such obligations. The said Party shall use all reasonable efforts to mitigate consequences of force majeure. At the same time, the Parties shall consult with each other on modalities of further execution of the Agreement. “Force majeure” as used in this Agreement means natural catastrophes such as, but not limited to, earthquakes, floods, cyclonic or volcanic activity; war (whether declared or not); invasion, act of foreign enemies, rebellion, terrorism, revolution, insurrection, military or usurped power, civil war, riot, commotion, disorder; ionising radiation or contaminations by radioactivity; other acts of a similar nature or force.

Amendments and Modifications

11. This Agreement may only be amended or modified by written agreement signed by both Parties. No modification of or change in this Agreement or waiver of any of its provisions or additional contractual relationship with the Supplier shall be valid and enforceable against UNICEF unless affected by an amendment to this Agreement signed by the Supplier and UNICEF.

Alteration to Business or Operations

12. If during the term of this Agreement, the business or operations of UNICEF is reorganised, re-structured, amended or otherwise changed in such a way as to adversely affect its ability to perform this Agreement, or the governing entity of UNICEF determines that continued participation in this Agreement is no longer appropriate for it, UNICEF will give written notice to that effect to the Supplier, with a copy to GAVI, and the Parties will negotiate in good faith to determine the proper way to amend, assign, or otherwise conclude this Agreement, it being understood that there shall be no penalty to UNICEF and that UNICEF shall be entitled to withdraw from this Agreement without penalty upon ninety (90) days’ notice.

Settlement of Disputes

13. Any dispute relating to this Agreement and/or a Purchase Order shall be settled in accordance with the relevant provisions in the UNICEF General Terms and Conditions. The decisions of the arbitral tribunal shall be based on general principles of international commercial law. For all evidentiary questions, the arbitral tribunal shall be guided by the Supplementary Rules Governing the Presentation and Reception of Evidence in International Commercial Arbitration of the International Bar Association, 28 May 1983 edition.

Privileges and Immunities

14. Nothing in or related to this Agreement or any transaction arising out of this Agreement (including, but not limited to, any Purchase Order issued pursuant to this Agreement) shall be construed to be a waiver, express or implied, deliberate or inadvertent, of the privileges and immunities of UNICEF pursuant to the Convention on the Privileges and Immunities of the United Nations, 1946, or otherwise.

Notices

15. Any notice to be given between the parties shall be effectively given if sent by letter, fax or similar means of communication, postage prepaid or charged to the sender and addressed to the other party at the address shown below:

(a) If to UNICEF:

UNICEF Supply Division
Freeport
DK-2100 Copenhagen Ø
Denmark
Attention: Contracts Officer, Immunization Centre
Telephone: +45.3527 XXXX
Telefax: +45.35.250285
e-mail: []@unicef.org

(b) If to the Supplier:

Attention:
Telephone:
Telefax:
e-mail:

In witness whereof, the Parties by their duly authorised representatives, have executed this Agreement on the day and date first written above.

[signature blocks]

ANNEX 1

TECHNICAL REQUIREMENTS

The Vaccines supplied by the Supplier shall be pre-qualified by WHO and approved by the Independent Assessment Committee to be an AMC-Eligible Vaccine. Furthermore, the Vaccines shall meet the following technical specifications in addition to those set out elsewhere in this Agreement:

1. PRODUCTION AND TESTING

The vaccines shall be produced and tested in conformity with the at all times current requirements of national legislation of the country of manufacture and the following recommendations established by the World Health Organization (WHO), or any subsequent revisions.

- (a) Good Manufacturing Practices for Biological Products (WHO Technical Report Series No. 822, 1992) and Guideline for National Authorities on Quality Assurance for Biological Products (WHO Technical Report Series No. 822, 1992)
- (b) Good Manufacturing Practices for pharmaceutical manufacturers (WHO Technical Report Series No. 823, 1992)
- (c) Good Manufacturing Practices: Requirements for sampling of starting materials (WHO Technical Report Series No. 929, 2005. Annex 2)
- (d) Good Manufacturing Practices: Water for pharmaceutical use (WHO Technical Report Series No. 929, 2005. Annex 3)
- (e) Good Manufacturing Practices for pharmaceutical products: main principles (WHO Technical Report Series No. 908, 2003. Annex 4)
- (f) Basic elements of good manufacturing practices in pharmaceutical production (WHO Technical Report Series No. 902, 2002. Annex 5)
- (g) Good Manufacturing Practices for sterile products (WHO Technical Report Series No.902, 2002. Annex 6)
- (h) Guide for inspection of manufacturers of biological products (WHO/VSQ/97.03)
- (i) Regulation and licensing of biological products in countries with newly developing Regulatory Authorities (WHO Technical Report Series No. 858, 1995)
- (j) Guidelines for national authorities on quality assurance for biological products (WHO Technical Report Series No. 822, 1992)

- (k) General Requirements for the Sterility of Biological Substances (WHO Technical Report Series No. 530, 1973), Amendment 1995 (WHO Technical Report Series No. 872, 1998)
- (l) Requirements for the use of animal cells as in vitro substrates for the production of biologicals (WHO Technical Report Series No. 878, 1998)
- (m) Report of a WHO Consultation on Medicinal and other Products in relation to Human and Animal Transmissible Spongiform Encephalopathies (WHO/BLG/97.2)
- (n) Recommendations on risk of transmitting animal spongiform encephalopathy agents via medicinal products (WHO Technical Report Series No. 908, 2003)
- (o) Guidelines on regulatory expectations related to the elimination, reduction or replacement of thiomersal in vaccines (WHO Technical Report Series No. 926, 2004)
- (p) Guidelines on stability evaluation of vaccines (WHO/BS/06.2049 2006)
- (q) Guidelines on clinical evaluation of vaccines: regulatory expectations (WHO Technical Report Series No. TRS 924, 2004)
- (r) WHO guidelines on nonclinical evaluation of vaccines (WHO Technical Report Series No. 927, 2005)

2. VACCINES

- (a) Recommendations for the production and control of pneumococcal conjugate vaccines (WHO Technical Report Series No. 927, 2005, Annex 2)

3. CHANGES IN FORMULATION, METHODS OR PROCESSES

Changes introduced in formulation, in methods of manufacturing in facilities or in any other aspect of production which might result in a change of safety and/or efficacy of vaccine, or which change the licensing agreement between the manufacturer and the National Regulatory Authority should be notified to Department of Immunization, Vaccines and Biologicals, Quality, Safety and Standards (QSS), Team Coordinator, within one month of approval by the NRA of record. If manufacturing country regulations do not require approval of the changes by the NRA then WHO/QSS should be consulted in a timely manner before changes are introduced. Such changes may require additional activities by WHO to assure continued compliance with WHO requirements.

4. LABELS AND LEAFLETS

Vaccine primary container label will be that agreed to by WHO during prequalification or as revised and approved by WHO and shall be affixed with water-resistant adhesive so that the labels do not become loose or fall off. Labels shall state the

name of vaccine, name of manufacturer, place of manufacture, lot number, composition, concentration, dose and mode of administration, expiry date, storage temperature, and number of doses per primary container. Expiry date and lot number shall be printed on each primary container in indelible ink. Adsorbed vaccines shall have the warning "DO NOT FREEZE" and "shake well before use" printed on the label.

The package insert will be that agreed to by WHO during prequalification or as revised and approved by WHO and shall be printed at least in English, French, Portuguese and Russian. Spanish and Arabic are optional. Separate inserts in the language appropriate for the country of destination will be welcome. In all inserts, the following should be inserted under "Description of vaccines": "The vaccine fulfils WHO requirements for.....(name of vaccine)".

Inserts shall contain at least the information in the WHO Model Insert for that vaccine, where available. Any additional information provided by the manufacturer must not confuse or contradict WHO policy on the use of that vaccine.

Diluent primary containers labels shall be affixed with water-resistant adhesive so that the labels do not become loose or fall off. They must be labelled with the same information as the label of the vaccine primary container, except that "Diluent for....vaccine" should replace the name of the vaccine.

5. CLOSURES

Vaccine vials shall be fitted with closures that conform to ISO standards 8362-2 through 8362-7. The container/closure system must be the same as submitted for WHO prequalification.

6. RELEASE CERTIFICATION

Final acceptance of vaccines shall be subject to lot release by the National Regulatory Authority (NRA) of the country of manufacture or the NRA of Record agreed to with WHO during review for prequalification. Lot release certification must be based as a minimum on review of the lot summary protocols. Lot release certificates and Production and Control Summary Lot Protocols (according to WHO guidelines) will be provided upon request to consignees, UNICEF or WHO.

7. COMPLIANCE WITH TECHNICAL SPECIFICATIONS AND WHO REQUIREMENTS

Vaccines must meet all the WHO recommended requirements currently in force. It should be understood that if WHO requirements, which impact on the products being supplied, are changed during the period of validity of the Agreement, manufacturers will be required to implement such changes as soon as possible following notification by WHO via UNICEF.

UNICEF reserves the right to reject any material which does not conform to the required specifications and the awarded Supplier shall forthwith, at its own expense, make good any material which has been rejected.

8. RETENTION SAMPLES AND TESTING

Samples of each batch of vaccine supplied under this Agreement shall be retained by the supplier for one year beyond expiry date. At least 50 samples of each batch of vaccine supplied under this Agreement will be retained by the supplier to be provided, on request, to WHO/IVB/QSS for testing.

9. INTERRUPTION IN PRODUCTION AND RELEASE PROCESSES

Any issues arising which may result in problems with production, quality control and/or release of vaccine should be communicated in a timely manner to UNICEF and WHO/QSS.

10. ADVERSE EVENTS AND RECALLS

The Supplier shall comply with all applicable laws, regulations and requirements regarding vaccine safety. The terms used surrounding adverse experiences shall have the meanings set forth in the International Conference on Harmonization (ICH) of Technical Requirements of Pharmaceuticals for Human Use E2A.

The Supplier shall be solely responsible for global pharmacovigilance activities regarding the Vaccine including, but not limited to: Adverse Experience (AE) or Adverse Drug Reaction (ADR) reporting including literature review and associated reporting; AE/ADR follow-up reporting; preparation and submission of all safety reports to applicable regulatory agencies, as required; all interactions with health authorities; periodic submissions; labelling modifications; risk management; safety monitoring and detection and coordinating and implementing safety measures.

The Supplier shall promptly inform WHO/QSS and UNICEF of serious issues (actual or alleged) regarding Vaccine safety and shall provide them with information sufficient to consider such issues. WHO and UNICEF shall promptly notify Supplier of serious adverse events involving Supplier's Vaccine of which they become aware.

If any circumstance or event may require or make reasonably appropriate any recall or withdrawal of Vaccine or any field alert regarding the Vaccine, Supplier shall immediately notify WHO/QSS and UNICEF and other appropriate entities. When a recall, withdrawal or field alert is required or appropriate, the Supplier shall take all appropriate actions and shall bear all associated expenses.

11. INSPECTION OF FACILITIES

The Supplier shall permit UNICEF and WHO, or their representatives as may be designated under notice to the Supplier, to have access to their manufacturing and warehouse facilities at all reasonable times to assess (or periodically reassess) the production and capacity, testing, packaging and storage of the goods, and shall provide reasonable assistance for such assessment including the provision of copies of manufacturing protocols, lot production records, test results or quality control reports. UNICEF reserves the right to reject any Goods that do not conform to the required specifications.

12. VACCINE VIAL MONITORS (VVM)

Vaccine primary containers should be fitted with Vaccine Vial Monitors (VVMs). VVMs should comply with WHO Performance Specification E6/IN5 and in the Test Procedure for qualification E6/PROC5- March 2002 or any subsequent revisions.

13. SHELF LIFE

Vaccine shall be supplied with the maximum shelf life possible consistent with current vaccine production technology and stability data. Unless separately authorized by UNICEF, the remaining shelf life at the time of dispatch shall not be less than the figures stated below:

Pneumococcal vaccine: 20 months

14. OVER LABELING

Over labeling will only be accepted if the following criteria are met:

- (a) The over labeling of the vaccine has been approved by the National Regulatory Authority of the producing country (released by NRA);
- (b) UNICEF is consulted prior to delivery; and
- (c) The receiving country agrees to receive the vaccine, and communicates this fact to UNICEF.

15. SHIPPING, PACKAGING AND PACKING

Packing/Shipping requirements must conform to the "Guidelines on the International Packaging and Shipping of Vaccines", WHO/IVB/05.23 of the World Health Organization or any subsequent revisions.

All containers, invoices and shipping documents are to bear the expiry dates of the vaccine and appropriate storage temperatures.

16. TIME TEMPERATURE MONITORING DEVICE

In order to monitor the cold-chain during international transit to Government central stores of vaccines, manufacturers are requested to include one time-electronic temperature data loggers that meet WHO requirements. These devices meeting WHO requirements for international shipments can be found at the following site: <http://www.who.int/vaccines-access/pqs.htm>. Detailed explanation of the temperature monitoring during international shipments can also be found in Chapter 2 (Temperature Monitoring Devices to be included in International Shipments) of the Guidelines on the International Packaging and Shipping of Vaccines, WHO/IVB/05.23 or any subsequent revisions.

ANNEX 2A
Standard UNICEF Purchase Order as of [date]

ANNEX 2B
Standard UNICEF General Terms and Conditions as of [date]

FULL RIGHT TO SELL/USE

The Supplier warrants that he has not and shall not enter into any other agreement or arrangement that restrains or restricts the rights of UNICEF, the recipient Governments and any other organizations on whose behalf UNICEF procures the Goods to use, sell, dispose of or otherwise deal with any goods acquired under the Agreement.

SUPPLIER'S REPRESENTATION

The Supplier represents and warrants that it has the personnel, experience, qualifications, facilities and all other skills and resources necessary to perform its obligations under the Agreement.

WARRANTIES

Unless specifically otherwise agreed by the Parties in writing, in addition to and without limitation of any other warranties stated in or arising under the Procurement Arrangement, the Supplier warrants and represents that the goods, including all packaging and packing thereof, conform to the specifications of the Procurement Arrangement, are fit for the purposes for which such goods are ordinarily used and for the purposes expressly made known in writing by UNICEF to the Supplier, and shall be of even quality, free from faults and defects in design, material, manufacturer and workmanship. If the Supplier is not the original manufacturer of the goods, the Bidder shall provide all manufacturers' warranties in addition to any other warranties hereunder.

INSURANCE

The Supplier shall maintain for an adequate period following any termination of this Agreement: Insurance against all risks in respect of its property and any equipment used for the performance of the Agreement; Workers' compensation insurance, or its equivalent, with respect to its employees, sufficient to cover all claims for personal injury or death in connection with the performance of the Agreement; Comprehensive general liability insurance in an adequate amount to cover all third party claims for death, bodily injury, including, but not limited to, products liability, or loss of or damage to property arising from or in connection with the Suppliers performance under this Agreement, including, but not limited to, liability arising out of or in connection with the use in the performance of the Agreement of any vehicles, boats, airplanes or other equipment, whether or not owned by the Supplier; and, such other insurance as may be agreed upon in writing between UNICEF and the Supplier.

The Supplier acknowledges and agrees that neither the requirement for taking out and maintaining insurance as set forth in the Agreement nor the amount of any such insurance, including, but not limited to, any deductible relating thereto, shall in any way be construed to limit the Supplier's liability arising under or relating to this Agreement.

ASSIGNMENT AND INSOLVENCY

The Supplier shall not, except after obtaining the written consent of UNICEF, assign, transfer, pledge or make other disposition of the Agreement, or any part thereof, or any of the Supplier's rights or obligations under this Agreement.

Should the Supplier become insolvent or should control of the Supplier change by virtue of insolvency, UNICEF may, without prejudice to any other rights or remedies, immediately terminate this Agreement by giving the Supplier written notice of termination.

INDEMNIFICATION

Within the framework of all applicable privileges and immunities, the Supplier agrees to indemnify, defend and hold harmless UNICEF, each of the Governments receiving the vaccines, and all parties making a financial contribution to the purchase of the vaccines (together, the “**Indemnified Parties**” and each an “**Indemnified Party**”) from and against all claims, damages, losses, costs and expenses (including reasonable legal fees) arising out of or related to the purchase, distribution and use of the vaccines supplied under these arrangements other than, in respect of each Indemnified Party, those attributable to any fault or negligence of that Indemnified Party. UNICEF shall promptly give notice to the Supplier of any such claims, damages, losses, costs and 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. The obligations under this clause do not lapse upon termination of this Supply Agreement.

UNETHICAL BEHAVIOUR

UNICEF strictly enforces a policy of zero tolerance concerning unethical, unprofessional or fraudulent acts of UNICEF suppliers/contractors. Accordingly, any registered company that is found to have undertaken unethical, unprofessional or fraudulent activities will be suspended or forbidden from continuing business relations with UNICEF.

CORRUPT AND FRAUDULENT PRACTICES

UNICEF requires that all suppliers/contractors associated with this purchase order/contract observe the highest standard of ethics during procurement and execution of the work. In pursuance of this policy UNICEF:

- (a) defines for the purpose of this provision the terms set forth as follows:
 - (i) ‘corrupt practice’ means the offering, giving, receiving or soliciting of any thing of value to influence the action of a public official in the procurement process or in the execution of a contract, and
 - (ii) ‘fraudulent practice’ means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of the client, and includes collusive practice among bidders (prior to or after bid submission) designed to establish bid prices at artificial non-

competitive levels and to deprive the client of the benefits of free and open competition;

(b) will reject a proposal for award if it determines that the selected supplier/contractor has engaged in any corrupt or fraudulent practices in competing for the contract in question;

(c) will declare a supplier/contractor ineligible, either indefinitely or for a stated period of time, to be awarded a UNICEF-financed contract if at any time it determines that it has engaged in any corrupt or fraudulent practices in competing for, or in executing a UNICEF-financed contract.

DISCLOSURE OF SANCTIONS OR TEMPORARY SUSPENSION

The Supplier represents and warrants to UNICEF that neither it, nor any of its subsidiaries, officers, or directors is subject to any sanction or temporary suspension imposed by the World Bank Group or any other inter-governmental or United Nations System Organisation at the time of execution of this Agreement. The Supplier will immediately inform UNICEF in writing if during the term of this Agreement the Supplier, or any of its subsidiaries, officers, or directors becomes subject to any sanction or temporary suspension imposed by the World Bank Group or any other inter-governmental or United National System Organisation, in which event UNICEF shall be entitled, in its absolute discretion and with no penalty, to terminate or suspend this Agreement.

OFFICIALS NOT TO BENEFIT

The supplier/contractor warrants that no official of UNICEF or the United Nations has received or will be offered by the supplier/contractor any direct or indirect benefit arising from this contract or the award thereof. The supplier/contractor agrees that breach of this provision is a breach of an essential term of the contract.

GUIDELINES ON GIFTS AND HOSPITALITY

Suppliers/contractors shall not offer gifts or hospitality to UNICEF staff members. Recreational trips to sporting or cultural events, theme parks or offers of holidays, transportation, or invitations to extravagant lunches or dinners are also prohibited.

CONFIDENTIALITY

The Parties shall keep confidential any documents, data or other information furnished to each other. The Parties may, however, disclose such information to their subcontractors or partners, as may reasonably be required to execute this Agreement, and provided that the subcontractors or partners shall be bound by similar confidentiality requirements.

ANNEX 2

Target Product Profile

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.

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. Immunogenicity	Immunogenicity should be demonstrated in accordance with WHO criteria, which are based on non-inferiority to a licensed pneumococcal vaccine as outlined in <i>WHO Recommendations for the production and control of pneumococcal conjugate vaccines</i> . (WHO Technical Report Series, No 927, 2005 and any subsequent published guidance).
C. 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.
D. 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.
E. 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.
F. 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.
G. Route of administration	Intramuscular or subcutaneous.

Attribute	Minimally Acceptable Profile
H. 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.
I. Product formulation	Liquid formulation with a standard volume of 0.5 ml/dose.
J. Storage and cold chain requirements	The product must be stable at 2-8°C with a shelf-life of at least 24 months and a vaccine vial monitor should be attached as outlined in <i>Making use of vaccine vial monitors. Flexible vaccine management for polio</i> (WHO/V&B/00.14).
K. Packaging and labelling	Name and labelling must be in accordance with WHO <i>Recommendations for the production and control of pneumococcal conjugate vaccines</i> (WHO Technical Report Series, No 927, 2005). Packaging must ensure minimal storage space requirements as set out in <i>Guidelines on the international packaging and shipping of vaccines</i> (WHO/IVB/05.23).
L. Product registration and prequalification	The product must be WHO pre-qualified in accordance with <i>Procedures for assessing the acceptability, in principle, of vaccines for purchase by United Nations agencies</i> (WHO/IVB/05.19).
M. Post-marketing surveillance	Post-marketing surveillance should be conducted in accordance with national regulatory authorities and WHO prequalification requirements as set out in <i>Guideline for preparation of the product summary file for vaccine prequalification</i> (WHO/IVB/06.16), <i>Guidelines on clinical evaluation of vaccines: regulatory expectations</i> (WHO Technical Report Series, No 924, 2004), and any relevant published guidance.

ANNEX 3

Form of GAVI Payment Demand Notice

[insert date]

To: International Bank for Reconstruction and Development
1818 H Street, N.W.
Washington, DC 20433
United States of America

Attention: Director, Multilateral Trusteeship and Innovative Financing Department

Dear [●],

Re: Grantor Grant Payment due in respect of the AMC Pneumo Initiative

We refer to the Stakeholders Agreement (the “***Stakeholders Agreement***”) dated [insert date] between, inter alia, [Grantor] and IBRD. Unless otherwise defined in this notice, all capitalized terms appearing herein shall have the meanings ascribed to them under the Stakeholders Agreement.

Pursuant to the Semi-Annual GAVI Alliance Estimate dated [insert date] and in accordance with the provisions of the Offer Agreement (including the Terms and Conditions) and the Stakeholders Agreement, [we hereby request Grant Payment Amounts in the amount of [insert amount and currency].

Please arrange for funds in the total amount of [insert amount and currency] to be sent to the following account on or before [●]

Account Name:	[●]
Account Number:	[●]
Bank Name and Address:	[●]
Swift/BIC Code:	[●]

Sincerely,

THE GAVI ALLIANCE

[●]

Authorized Representative

IN WITNESS whereof, this Agreement has been executed by the parties on the date stated at the beginning hereof.

SIGNED by
THE GAVI ALLIANCE
in the presence of:

}

Name
Address

Occupation

SIGNED by
**INTERNATIONAL BANK FOR
RECONSTRUCTION AND
DEVELOPMENT**

}

in the presence of:

Name

Address

Occupation

SCHEDULE 2

AMENDED IAC CHARTER AND BYLAWS

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:

1. to accelerate the development of vaccines that meet developing country needs as specified in the Target Product Profile;
2. 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;
3. 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

4. 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 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;

- (c) 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 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

- (i) 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:
 - (1) 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

- 1. 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.
- 2. 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:

- (a) 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:

- (a) 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: _____

SCHEDULE 3
AMENDED AMC PROCEDURES MEMORANDUM

EXECUTION VERSION

Dated 7 March 2011

**ADVANCE MARKET COMMITMENT
PROCEDURES MEMORANDUM**

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Part 1 Introduction

- (b) “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:**

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

the procedures and requirements for an Application for AMC Eligibility;

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

Eligible Country Application Procedures; and

ongoing monitoring and reporting obligations.

- (c) 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:

details of an applicant’s legal status and registration/corporate incorporation information;

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

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;

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

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:

- **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**”);
- **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
- [●] a vaccine manufacturer incorporated in [●] (the “**Applicant**”)

Whereas

- D. Pursuant to the Offer Agreement entered into between the GAVI Alliance and IBRD, the Applicant intends to participate in the AMC Pneumo Initiative.
- E. 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 <i>WHO Recommendations for the production and control of pneumococcal conjugate vaccines</i> . (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°C with a shelf-life of at least 24 months and a vaccine vial monitor should be attached as outlined in <i>Making use of vaccine vial monitors. Flexible vaccine management for polio</i> (WHO/V&B/00.14).
(f) Packaging and labelling	Name and labelling must be in accordance with WHO <i>Recommendations for the production and control of</i>

Attribute	Minimally Acceptable Profile
	<i>pneumococcal conjugate vaccines</i> . (WHO Technical Report Series, No 927, 2005). Packaging must ensure minimal storage space requirements as set out in <i>Guidelines on the international packaging and shipping of vaccines</i> (WHO/IVB/05.23).
(g) Product registration and prequalification	The product must be WHO pre-qualified in accordance with <i>Procedures for assessing the acceptability, in principle, of vaccines for purchase by United Nations agencies</i> (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 <i>Guideline for preparation of the product summary file for vaccine prequalification</i> (WHO/IVB/06.16), <i>Guidelines on clinical evaluation of vaccines: regulatory expectations</i> (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.

SIGNED, SEALED AND DELIVERED as
a DEED by **THE GAVI ALLIANCE** acting
by its duly authorised signatory, Helen
Evans

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HELEN EVANS

L.S.

in the presence of

ANTHONY R. BROWN

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SIGNED, SEALED AND DELIVERED as
a DEED by the **INTERNATIONAL BANK
FOR RECONSTRUCTION AND
DEVELOPMENT** acting by its duly
authorised signatory, Axel van
Trotsenburg

}

AXEL VAN TROTSENBURG

L.S.

in the presence of:

MINERVA PATENA

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