

EXECUTION VERSION

Dated

2009

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

2009 between:

- (1) **THE GAVI ALLIANCE**, a non-profit foundation registered in the canton of Geneva (registry number CH-660-1699006-1) with offices at 2, Chemin des Mines, Geneva, Switzerland (the “GAVI Alliance”); and
 - (2) **INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT**, an international organisation which maintains its headquarters at 1818 H Street, N.W., Washington, D.C., 20433, United States of America (“IBRD”);
- each a “Party” and together the “Parties”.

Whereas:

- (A) 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.
- (B) 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.
- (C) 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.
- (D) 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:

1 Definitions, Interpretation and Construction

1.1 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.

1.2 Interpretation

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

2 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.

3 The Offer

3.1 IBRD Offer

- 3.1.1** 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.
- 3.1.2** 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.
- 3.1.3** 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.

3.2 The GAVI Alliance Offer

- 3.2.1** 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.
- 3.2.2** 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.
- 3.2.3** 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.

3.2.4 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.

3.3 Offer Period

3.3.1 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”).

3.3.2 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.

3.3.3 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:

- (a) 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;
- (b) any amounts payable to IBRD under this Agreement have been paid; and
- (c) 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.

3.3.4 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.

4 Obligations Several

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

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

5 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.

6 Representations, Warranties and Undertakings

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

- 6.1.1** 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;
- 6.1.2** 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;
- 6.1.3** 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
- 6.1.4** 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.

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

- 6.2.1** it is duly established and existing under its constitutive articles of agreement;
- 6.2.2** 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;
- 6.2.3** 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
- 6.2.4** 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.

6.3 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.

7 Miscellaneous Provisions

7.1 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.

7.2 Variation

7.2.1 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.

7.2.2 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:

- (a) no amendment shall be permitted that would have a consequential greater liability for any Grantor;
- (b) the Grantors have been notified at least 20 Business Days prior to any such amendment, variation or waiver; and
- (c) 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.

7.2.3 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.

7.3 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:

7.3.1 if to the GAVI Alliance:

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

Attention: Tim Nielander
Email: tnielander@gavialliance.org
Telephone: +41 (22) 909 2988
Fax: + 41 (22) 909 6550

7.3.2 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

7.4 Deemed Receipt

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

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

7.4.2 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 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).

7.5 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.

7.6 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.

7.7 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.

7.8 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.

7.9 Governing Law

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

7.10 Dispute Resolution

7.10.1 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.

7.10.2 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:

- (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 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.

7.11 Effective Date

This Agreement shall be effective and binding upon the parties hereot 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

1 Definitions, Interpretation and Construction

1.1 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.

1.2 Interpretation

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

2 AMC Offer Amount and the Remaining AMC Offer Amount

2.1 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).

2.2 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.

2.3 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.

3 Registration by Vaccine Manufacturers

3.1 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.

3.2 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.

4 Application for AMC Eligibility

- 4.1** 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.
- 4.2** 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.
- 4.3** Once a determination has been made by the IAC on an Application for AMC Eligibility, the AMC Secretariat shall: (i) inform all AMC Registered Manufacturers who have submitted an Application for AMC Eligibility of the results of the IAC's determination; and (ii) publish the IAC's determination on the AMC Website.
- 4.4** Promptly following the determination in Condition 4.3, the AMC Secretariat shall notify GAVI Eligible Countries of the AMC Eligible Vaccines.

5 GAVI Strategic Demand Forecast and Calls for Supply Offers

- 5.1** The GAVI Alliance shall publish the GAVI Strategic Demand Forecast on the AMC Website at the latest one month after each semi-annual meeting of the GAVI Alliance Board. 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.
- 5.2** A Call for Supply Offers shall be made in accordance with the AMC Procedures Memorandum when the GAVI Strategic Demand Forecast indicates that, at any point during the immediately following five-year period, there will be an increase of at least 10 million doses in the annual quantity of AMC-Eligible Vaccines required to meet demand from GAVI Eligible Countries, or when there are unallocated quantities of supply commitments which exceed 10 million doses.
- 5.3** 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.

6 Entry into Supply Agreements

- 6.1** 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.
- 6.2** 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.
- 6.3** 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.
- 6.4** 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.
- 6.5** 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.
- 6.6** 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.
- 6.7** No 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.

7 AMC Period and Vaccine Purchase Price

7.1 The “**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.

7.2 The 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.

7.3 For 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.

7.4 No 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.

7.5 Based 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.

7.6 IBRD 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.

7.7 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.

7.8 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.

8 Tail Period, Tail Price, Tail Price Cap and IAC Inflation Review

8.1 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

8.2 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.

8.3 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).

- 8.4** 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

- 8.5** 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.

- 8.6** 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.

- 8.7** 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.

- 8.8** 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.

- 8.9** 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.

- 8.10** 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.
- 8.11** 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.
- 8.12** 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.
- 8.13** 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.
- 8.14** 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).
- 8.15** 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).

8.16 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.

9 Independent Assessment Committee

9.1 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.

9.2 Review and Modification of the Target Product Profile

9.2.1 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.

9.2.2 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:

- (a) 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
- (b) 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.

9.3 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 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.

9.4 Review and Modification of AMC Prices

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

- (a) 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
- (b) as permitted in accordance with Condition 8.

9.5 IAC Actions, Decisions and Determinations

- 9.5.1 All decisions and determinations of the IAC in connection with any aspect of the AMC Pneumo Initiative shall:
- (a) be final and shall not be subject to appeal or further adjudication by any other person, body or tribunal; and
 - (b) be binding on AMC Registered Manufacturers and AMC-Eligible Manufacturers.
- 9.5.2 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.
- 9.5.3 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.
- 9.5.4 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.

10 AMC Funds Suspension Events

- 10.1 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.
- 10.2 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).

- 10.3** 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.
- 10.4** 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.

11 AMC Cancellation Events

- 11.1** 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**").
- 11.2** 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.
- 11.3** 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.

12 Ongoing Industry Consultation

12.1 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.

13 Confidentiality

13.1 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.

13.2 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;

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

¹ Use for Supply Agreements.

² Use for Provisional Supply Agreements.

³ Use for Provisional Supply Agreements

⁴ Delete as applicable

⁵ Delete as applicable

⁶ Delete as applicable

⁷ Delete as applicable

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 Transaction Documents" means the Stakeholders Agreement, the Offer Agreement (including the AMC Terms and Conditions and pro-forma Supply Agreement scheduled thereto), each Grant Agreement, each AMC Registered Manufacturer Agreement, the AMC Procedures Memorandum and the IAC Charter and Bylaws by and between the [list all stakeholders: GAVI, IBRD and [list donors] as Grantors] and effective as of [June ,] 2009.

(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.

(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

(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.

⁸ To be included in a Provisional Supply Agreement.

(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 8 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 at the beginning of [January] and the beginning of [July] during each calendar year during the Vaccine Purchase Period. 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 6 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 UNICEF][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 [UNICEF][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 UNICEF 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 VI, 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 later of the following events: (a) signing by both Parties; and (b) UNICEF's receipt of notice from GAVI that it has received written confirmation from outside counsel for GAVI that this Agreement is not inconsistent with the AMC Documents. 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.

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.

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 WHO <i>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.
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.

Attribute	Minimally Acceptable Profile
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

