

EXECUTION VERSION

Dated

2009

**REPRESENTING THE REPUBLIC OF ITALY
THE MINISTRY OF ECONOMY AND FINANCE**

and

**REPRESENTING THE UNITED KINGDOM
HER BRITANNIC MAJESTY'S SECRETARY OF STATE FOR INTERNATIONAL
DEVELOPMENT**

and

**(HER MAJESTY IN RIGHT OF CANADA) THE GOVERNMENT OF CANADA
AS REPRESENTED BY THE MINISTER
FOR INTERNATIONAL COOPERATION, ACTING THROUGH THE
CANADIAN INTERNATIONAL DEVELOPMENT AGENCY**

and

**REPRESENTING THE RUSSIAN FEDERATION
THE MINISTRY OF FINANCE**

and

THE NORWEGIAN MINISTRY OF FOREIGN AFFAIRS

and

THE BILL & MELINDA GATES FOUNDATION

and

THE GAVI ALLIANCE

and

INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT

MASTER DEFINITIONS SCHEDULE

relating to the Advance Market Commitment for Pneumococcal Vaccines

Table of Contents

Contents	Page
1 Interpretation and Construction	1
2 Definitions.....	1

The undersigned hereby agree as follows:

1 Interpretation and Construction

In the Transaction Documents (including the recitals)

1.1 Headings, etc.

Headings used in the Transaction Documents shall not affect their interpretation. References to Sections, Schedules, Paragraphs or Articles in any Transaction Document shall, unless the context otherwise requires, be construed as references to the Sections, Schedules, Paragraphs or Articles of the relevant Transaction Documents.

1.2 Singular, Plural, Gender, person

Unless the context otherwise requires, words denoting the singular number only shall include the plural number also and *vice versa*. Words denoting one gender only shall include the other genders; and words denoting persons only shall include firms, corporations, sovereign nations, foundations and other organised entities, whether separate legal entities or otherwise, and *vice versa*.

1.3 Legal Agreements, Memorandum and other documents

References to a legal agreement, memorandum, charter, bylaws or any other document are to such documents as amended (providing that where consent is required to amend such consent has been obtained), supplemented or replaced from time to time and include any document that amends, supplements or replaces it.

1.4 Successors

A successor of any party shall be construed so as to include any assignee or successor in title of such party and any person who under the laws of the jurisdiction of incorporation or domicile of such party has assumed the rights and obligations of such party under the relevant agreement or to which under such laws, such rights and obligations have been transferred or any permitted assignee in accordance with the terms of the relevant agreement.

1.5 Contract (Rights of Third Parties) Act 1999

A person who is not a party to a Transaction Document has no right under the Contracts (Rights of Third Parties) Act 1999 or otherwise to enforce any term of such Transaction Document, except as may otherwise be provided in such Transaction Document.

2 Definitions

In the Transaction Documents (unless otherwise defined in a Transaction Document, in which case in respect of that Transaction Document only the definition contained therein shall apply) the following terms shall have the respective meanings set out below:

“Accession Date” means the date on which the accession of an Additional Grantor is effective;

“Additional Grantor” means any person who has become vested with all the authority, rights, powers, duties and obligations arising after the Accession Date as if originally named as an Initial Grantor, pursuant to Clause 2.8 of the Stakeholders Agreement;

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

“AMC Capacity Development Period” means the period during which an AMC-Eligible Manufacturer is developing Dedicated Manufacturing Capacity as such period is agreed to by the GAVI Alliance, or a procurement agency acting on behalf of the GAVI Alliance, and defined in the relevant Supply Agreement;

“AMC Cancellation Date” means the date upon which all rights and obligations of IBRD and the GAVI Alliance, and any procurement agency acting on its behalf, arising in respect of the AMC Pneumo Initiative under the Offer Agreement, the Conditions and the affected Supply Agreement(s) (including any payment obligations) in respect of an AMC-Eligible Manufacturer shall be terminated as notified pursuant to an AMC Cancellation Notice, in accordance with the terms of Condition 11;

“AMC Cancellation Event” has the meaning given to it in Condition 11;

“AMC Cancellation Notice” means a notice issued in accordance with Condition 11;

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

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

“AMC-Eligible Manufacturer” means an AMC Registered Manufacturer who’s Application for AMC Eligibility has been approved by the IAC;

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

“AMC-Eligible Vaccine Information Package” means detailed information in relation to an AMC vaccine candidate including the Product Summary Profile, written confirmation that the file has been accepted for review by WHO and the TPP Eligibility Justification Document;

“AMC-Funded Price” has the meaning given to it in Condition 7.1(a);

“AMC Funds Suspension Event” has the meaning given to it in Condition 10;

“AMC Funds Suspension Notice” means a notice issued in accordance with Condition 10;

“AMC Funds Suspension Period” means the period beginning on the date on which an AMC Funds Suspension Notice is given and ending on either: (i) the date on which an AMC Cancellation Event has occurred in respect of one or more AMC-Eligible Manufacturers and AMC-Eligible Vaccines, as applicable; (ii) the date on which the AMC Cancellation Event(s) that has occurred has been remedied to the satisfaction of the GAVI Alliance; or (iii) the AMC Total Cancellation Date;

“AMC Objectives” means:

- (i) to accelerate the development of pneumococcal vaccines that meet developing country needs as specified in the Target Product Profile;

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

“AMC Offer Amount” means USD 1.5 billion being the maximum cumulative amount payable by IBRD to the GAVI Alliance, or such other party as the GAVI Alliance may direct, during the AMC Period in accordance with the Conditions and the Offer Agreement;

“AMC Period” means in respect of each Supply Agreement, the period beginning on the date on which any instalment of the AMC-Funded Price is first payable to an AMC-Eligible Manufacturer and ending on the date when the AMC-Funded Price is last payable under all Supply Agreements entered into in the Offer Period;

“AMC Pneumo Initiative” means the Advance Market Commitment for pneumococcal vaccines as set out in the AMC Terms and Conditions;

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

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

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

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

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

“AMC Terms and Conditions” or **“Conditions”** means the conditions set out in Schedule 1 to the Offer Agreement;

“AMC Total Cancellation Date” means the date upon which all obligations of IBRD and the GAVI Alliance (and/or any procurement agency acting on behalf of the GAVI Alliance) under the Offer Agreement, 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 due to an AMC Cancellation Event in respect of all existing AMC-Eligible Manufacturers and AMC-Eligible Vaccines;

“AMC Total Cancellation Notice” means a notice delivered by the GAVI Alliance to all AMC Registered Manufacturers, AMC-Eligible Manufacturers and published on the AMC Website when there has been an AMC Cancellation Event in respect of all existing AMC-Eligible Vaccines and AMC-Eligible Manufacturers in accordance with Condition 11;

“AMC Website” means the website with respect to the Advance Market Commitments which can be found at <http://www.vaccineamc.org>;

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

“Call for Supply Offer” shall have the meaning given to it in the AMC Procedures Memorandum;

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

“Commitment Period” means the annual, semi-annual or quarterly period(s) in which the GAVI Alliance (or a procurement agency acting on its behalf) is committed to make payments to AMC-Eligible Manufacturers based on Supply Agreements entered into in accordance with the Stakeholders Agreement;

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

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

“Creditors’ Event” means any expropriation, attachment, sequestration, distress or execution which affects any material asset or assets of the relevant company and which is not discharged within 30 IBRD Business Days;

“Dedicated Manufacturing Capacity” means in relation to an AMC-Eligible Manufacturer, the capacity to supply an AMC-Eligible Vaccine from one or more vaccine production, manufacturing and distribution facilities in a quantity that is sufficient to meet Supply Commitments of such AMC-Eligible Vaccine under the AMC Pneumo Initiative;

“Eligible Country Applications” means applications submitted by a GAVI Eligible Country for an AMC-Eligible Vaccine in accordance with the AMC Procedures Memorandum;

“Firm Order Timing Period” shall mean in respect of each Supply Agreement, the period during which the provisions of Article II, paragraph 6 of such Supply Agreement apply;

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

“GAVI Alliance Board” means the board of directors of the Global Alliance for Vaccines and Immunization that is in place from time to time, or the executive committee of the GAVI Alliance Board, as appropriately authorised by the board of directors of the Global Alliance for Vaccines and Immunization from time to time;

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

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

“GAVI Payment Demand Notice” means a notice substantially in the form set out in Annex 3 of the AMC Terms and Conditions;

“GAVI Strategic Demand Forecast” means the forecast produced by the GAVI Alliance at the latest one month after each semi-annual meeting of the GAVI Alliance Board and which sets out the annual quantity of AMC-Eligible Vaccines that the GAVI Alliance anticipates will be required to meet demand from GAVI Eligible Countries in the immediately following 15 calendar years;

“Grant Agreement” means any grant agreement entered into by a Grantor with IBRD documenting long-term binding grants from Grantors to IBRD for the benefit of the GAVI Alliance in connection with the AMC Pneumo Initiative;

“Grant Payments” mean the payments which the Grantor undertakes to make to IBRD in the amounts set out or determined in the relevant Grantor’s Grant Agreement;

“Grant Payment Amount” means, in respect of any Grant Payment Date, the amount of the Grant Payment due in accordance with, and as set out or determined in, that Grantor’s Grant Agreement;

“Grant Payment Date” means, in relation to each Grantor and its relevant Grant Agreement, the date on which a Grant Payment becomes due and payable in accordance with its Grant Agreement;

“Grant Payment Shortfall” means a shortfall in the aggregate Grant Payment Amounts received from the Grantors which are required to meet payment commitments under Supply Agreements to AMC-Eligible Manufacturers based on the Semi-Annual GAVI Alliance Estimate;

“Grantor Default” means a failure by a Grantor to pay Grant Payment Amounts when due under a Grant Agreement;

“Grantors” means the Initial Grantors and any Additional Grantors and **“Grantor”** means any one of them;

“Hedging Transaction” means any transaction entered into by IBRD for the purposes of hedging any currency, interest rate, basis risk or other exposure in relation to its present and future assets and/or liabilities associated with the AMC Pneumo Initiative in accordance with such IBRD policies and practices as may from time to time be applicable;

“IAC” or **“Independent Assessment Committee”** means the committee established on the date upon which the Transaction Documents enter into effect, and constituted in accordance with the IAC Charter and Bylaws;

“IAC Charter and Bylaws” means the constitutive documents outlining the roles and responsibilities of the IAC and the rules governing the activities of the IAC adopted on the date upon which the Transaction Documents enter into effect, and as disclosed on the AMC Website as needed from time to time;

“IAC Inflation Review” means a review of the Tail Price Cap by the IAC in accordance with Condition 8;

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

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

“IBRD Business Day” means a day (other than a Saturday or Sunday) on which the IBRD is open for general business in Washington D.C.;

“IBRD Demand Notice” means a notice substantially in the form set out in Schedule 1 of the relevant Grant Agreement and delivered by IBRD to a Grantor in accordance with clause 4.1 of such Grant Agreement;

“IBRD Shortfall Notice” means a notice substantially in the form set out in Schedule 2 of the relevant Grant Agreement and delivered by IBRD to a Grantor in accordance with clause 4.1 of a Grant Agreement;

“Independent Review Committee” means the GAVI Alliance advisory committee that provides objective, expert advice to the GAVI Alliance Board on country proposals and process;

“Index” means the OECD GDP Deflator published by the OECD on its website at www.oecd.org and used to adjust gross domestic product for changes in prices of goods and services included in the GDP of all OECD member states;

“Initial Grantors” means the Grantors whose names appear on page 3 of the Stakeholders Agreement;

“Insolvency Proceedings” means where any corporate action, legal proceedings or other procedure or step is taken in relation to: (a) the suspension of payments, a moratorium of any indebtedness, winding-up, dissolution, administration or reorganisation (by way of voluntary arrangement, scheme of arrangement or otherwise) of the relevant company (b) a composition, compromise, assignment or arrangement with any creditor of the relevant company; (c) the appointment of a liquidator, receiver, administrative receiver, administrator, compulsory manager or other similar officer in respect of the relevant company or any of its assets; or (d) enforcement of any security over any assets of the relevant company;

“Investment Income” means any income derived by IBRD from investing amounts received from Grantors under each Grant Agreement, as it may decide in its sole discretion based on and in accordance with the policies and procedures currently applied by IBRD;

“Maximum Shortfall Amount” shall have the meaning given to it in the relevant Grant Agreement;

“National Regulatory Authority” means the authority in each jurisdiction which is responsible for regulatory matters relating to vaccine evaluation, approval and licensing;

“Offer Agreement” means the offer agreement dated on or about the date hereof and entered into between IBRD and the GAVI Alliance;

“Offer Period” has the meaning given to it in clause 3.3 of the Offer Agreement;

“Procurement Reference Group” means the group which builds on non-industry expertise whose objective is to advise UNICEF on the implementation of the AMC procurement strategy which is managed by UNICEF and to report on the implementation of the AMC procurement strategy to the GAVI Alliance;

“Product Summary File” means the file containing all relevant information relating to a particular vaccine which is required to assist WHO in its prequalification process of such vaccine;

“Provisional Supply Agreement” means an agreement entered into between the GAVI Alliance or a procurement agency acting on its behalf and an AMC Registered Manufacturer in accordance with Condition 6.6;

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

“Remaining AMC Offer Amount” means on any date the AMC Offer Amount, less the aggregate of all amounts paid or due and payable by IBRD to or on behalf of the GAVI Alliance of the AMC Funded Price pursuant to the Conditions;

“Semi-Annual GAVI Alliance Estimate” means a semi-annual calculation undertaken by the GAVI Alliance to determine total Grant Payment Amounts required to make payments to AMC-Eligible Manufacturers in respect of Commitment Periods in the immediately succeeding 36 calendar months;

“Stakeholders Agreement” means the stakeholders agreement relating to the AMC Pneumo Initiative dated on or about the date hereof and entered into between the Initial Grantors, the GAVI Alliance and IBRD;

“Supply Agreement” means a supply agreement substantially in the form contained in Annex 1 to the Conditions, entered into between the GAVI Alliance, or a procurement agency acting on behalf of the GAVI Alliance, and an AMC-Eligible Manufacturer;

“Supply Commitment” means the aggregate amount of doses of an AMC-Eligible Vaccine that an AMC-Eligible Manufacturer has agreed to supply under a relevant Supply Agreement;

“Supply Commitment Period” means the duration of supply under a relevant Supply Agreement as agreed to by an AMC-Eligible Manufacturer and the GAVI Alliance, or a procurement agency acting on behalf of the GAVI Alliance;

“Supplier’s Vaccine Production Plan” shall mean the plan submitted by a manufacturer in accordance with Schedule 3 of the AMC Procedures Memorandum;

“Surplus Funds” means any funds remaining after application by IBRD of: (i) all funds received under Grant Agreements; and (ii) all Investment Income, to meet IBRD payment obligations to the GAVI Alliance under the Offer Agreement and to meet any fees, costs, indemnities and expenses due to IBRD, each in accordance with the terms of the Stakeholders Agreement and the Offer Agreement;

“Supply Offer” shall have the meaning given to it in the AMC Procedures Memorandum;

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

“Tail Price” means the price no greater than USD 3.50 per dose of AMC-Eligible Vaccine as specified in a Supply Agreement to be the price payable by the GAVI Alliance and/or Recipient Countries for an AMC-Eligible Vaccine during the Tail Period (as such price may be amended or modified from time to time under the Transaction Documents);

“Tail Price Cap” means USD 3.50 as such cap may be amended or modified from time to time under the Transaction Documents;

“Target Product Profile” or **“TPP”** means the vaccine requirements contained in Annex 2 of the Conditions, approved by the IAC, and which specifies the product criteria and other requirements that a candidate vaccine must meet in order to be eligible for funding under the AMC Pneumo Initiative, as such target product profile may be amended or supplemented from time to time;

“TPP Eligibility Justification Document” means a written explanation from an AMC Registered Manufacturer confirming how the candidate vaccine meets the TPP. For each TPP criteria as set out in Schedule 2 of the AMC Procedures Memorandum, the explanation must either refer to relevant information in the Product Summary File; or provide a clear explanation describing how the candidate Vaccine meets the TPP;

“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;

“US Dollars” or **“USD”** means the lawful currency of the United States of America from time to time;

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

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

In witness whereof, this Master Definitions Schedule has been executed by the parties on the date stated at the beginning hereof.

SIGNED for and on behalf of
**THE MINISTRY OF ECONOMY
AND FINANCE OF THE
REPUBLIC OF ITALY**

}

in the presence of:

Name

Address

Occupation

SIGNED by The Right
Honourable Douglas Alexander
MP,
**HER BRITANNIC MAJESTY'S
SECRETARY OF STATE FOR
INTERNATIONAL
DEVELOPMENT**

}

in the presence of:

Name

Address

Occupation

SIGNED for and on behalf of
**(HER MAJESTY IN RIGHT OF
CANADA) THE GOVERNMENT
OF CANADA, AS
REPRESENTED BY THE
MINISTER FOR
INTERNATIONAL
COOPERATION, ACTING
THROUGH THE CANADIAN
INTERNATIONAL
DEVELOPMENT AGENCY**
Authenticated by
**Diane Jacovella,
Vice-President Multilateral
and Global Programs Branch,
CANADIAN INTERNATIONAL
DEVELOPMENT AGENCY**

}

in the presence of:

Name

Address

Occupation

Signed for and on behalf of

**REPRESENTING THE
RUSSIAN FEDERATION
THE MINISTRY OF FINANCE**

}

in the presence of:

Name

Address

Occupation

SIGNED for and on behalf of
**THE NORWEGIAN MINISTRY
OF FOREIGN AFFAIRS**

}

in the presence of:

Name

Address

Occupation

SIGNED by
**BILL & MELINDA GATES
FOUNDATION**

}

in the presence of:

Name

Address

Occupation

SIGNED by
THE GAVI ALLIANCE acting by
its attorney

}

in the presence of:

Name

Address

Occupation

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

}

in the presence of:

Name
Address

Occupation

