9 March 2011

Amendment AMC Legal Agreements
Detailed List of Modifications

AMC Offer Agreement

Provision: Condition 4.3, AMC Terms and Conditions
Amendment: "Once a Determination has been made by the IAC about an Application for AMC Eligibility, the AMC Secretariat shall publish the IAC's determination on the AMC website".

Provision: Condition 5.1, AMC Terms and Conditions
Amendment: "The GAVI Alliance shall publish the GAVI Strategic Demand Forecast on the AMC Website annually and as soon as the necessary information is available from the last procurement cycle and relevant GAVI Board meeting".

Provision: Condition 5.2, AMC Terms and Conditions
Amendment: "In support of achieving the AMC Objectives, a Call for Supply Offers may be issued once per calendar year or more or less frequently if so decided by the GAVI Secretariat in consultation with UNICEF. A written explanation of the decision to issue or not to issue a Call for Supply Offers based on such consultation will be provided to all parties of the AMC Stakeholders Agreement."

Provision: Pro Forma Supply Agreement
Amendment: "This Agreement will become effective upon signing by both Parties".

AMC Procedures Memorandum

Provision: Section 2.1
Amendment: "(iv) Estimated timeline for submitting a Product Summary File to WHO".

Provision: Section 3.2.3
Amendment: "The Product Summary File submitted to WHO *and* a copy of written confirmation from WHO to the manufacturer that the Product Summary File has been accepted for review".

Provision: Section 3.3.2
Amendment: "As soon as possible after the receipt of the completed Application for AMC Eligibility….."

Provision: Section 3.3.3.
Amendment: "Subject to the requirements of the IAC Charter and Bylaws, the AMC Secretariat shall schedule an AMC Eligibility Determination Meeting as soon as reasonably possible after receipt by the AMC Secretariat of an Application for AMC Eligibility in respect of which the relevant candidate vaccine has met WHO Prequalification".

Provision: Section 4.3.1(i)
Amendment: "For vaccines that are not AMC-Eligible Vaccines, if available, a copy of written confirmation from WHO that the Product Summary File has been accepted for review by WHO….."

Provision: Section 4.5.1
Amendment: "… UNICEF shall use its reasonable efforts to reach an agreement in principle to a Supply Agreement with a manufacturer within 20 IBRD Business Days from receipt by the manufacturer of notification of the Supply Commitment Quantities being awarded to such

manufacturer. A manufacturer shall communicate its acceptance of the proposed award in a formal letter to UNICEF which constitutes an agreement in principle.
….. Thereafter, UNICEF shall use its reasonable efforts to enter into a Supply Agreement within *30* IBRD Business Days from reaching an agreement in principle…".

IAC Charter and Bylaws

Provision: Article V(a), IAC Charter
Amendment: "The IAC shall determine in its sole discretion whether any vaccine submitted by an AMC Registered Manufacturer in an Application for AMC Eligibility meets or exceeds the relevant TPP requirements."

Provision: Article III(b) of the IAC Bylaws:
Amendment: "As soon as reasonably possible after receipt of such Application for AMC Eligibility, the Chairperson shall call and AMC Eligibility Meeting and shall review and consider such application in accordance with these IAC Charter and Bylaws."

Provision: New Provision, IAC Charter and Bylaws Article V (b) (iii)
Amendment: "IAC Members may require manufacturers to provide additional information for the purpose of assessing AMC eligibility. In such cases, IAC Members shall contact the IAC Chairperson or Vice Chairperson and inform them of the additional information required. He or she shall copy all IAC Members as well as the AMC Secretariat in any such correspondence. The IAC Chairperson or Vice Chairperson will review the request for information and if approved will request that the AMC Secretariat liaise with the applicable manufacturer. She or he shall make herself or himself available for any necessary meeting or conference call with such manufacturer. The AMC Secretariat will also attend any meeting or conference call between the IAC and an AMC Registered Manufacturer in order to record minutes of the discussion. The AMC Secretariat will prepare minutes of any such meetings for review within five business days. IAC Members shall review and approve such minutes within ten business days after receipt. The minutes may be published on the applicable AMC Website to the extent that the information contained in such minutes does not at any time include any Confidential Information".