

## **Manufacturers Frequently Asked Questions**

### **How to enter into an AMC Registered Manufacturer Agreement**

#### **What is registration and why does a supplier need to register?**

Registration is a pre-requisite to participate in the AMC Pneumo Initiative, specifically; it's a pre-requisite to make Supply Offers in response to a Call for Supply Offers by UNICEF.

Through the AMC Registered Manufacturer Agreement, manufacturers acknowledge and agree to the Terms and Conditions of the AMC Pneumo Initiative which are scheduled to the AMC Offer Agreement. AMC registered manufacturers are not obliged in any way to participate in the AMC deal.

#### **Where do I find instructions on how to enter into an AMC Registered Manufacturer Agreement?**

The process to be followed by manufacturers interested in entering into an AMC Registered Manufacturer Agreement can be found in Part 2 of the AMC Procedures Memorandum 'AMC Registered Manufacturer Registration Procedures'.

In summary, manufacturers interested in participating in the AMC Pneumo Initiative must submit to the AMC Secretariat an information package as set out in Part 2.1 of the AMC Procedures Memorandum (the "**AMC Registered Manufacturer Application Package**"). After receiving a complete package from a manufacturer, the GAVI Alliance and IBRD shall enter into an AMC Registered Manufacturer Agreement with such applicant substantially in the form attached as Schedule 1 of the AMC Procedures Memorandum.

#### **Is there a deadline for submitting an AMC Registered Manufacturer Application Package or for entering into an AMC Registered Manufacturer Agreement?**

No. Manufacturers can submit an AMC Registered Manufacturer Application Package at any time during the Offer Period (i.e. up to 2020 or when the AMC \$1.5 billion is allocated in its entirety).

As becoming an AMC Registered Manufacturer is a pre-requisite to participate in UNICEF Calls for Supply Offers, manufacturers wishing to participate in UNICEF's next Call for Supply Offers should submit their application as soon as possible.

#### **Is there a specific template/form for the AMC Registered Manufacturer Application Package?**

No, there is no specific template. Manufacturers simply need to submit all the information listed in part 2.1 of the AMC Procedures Memorandum.

## How to participate in Calls for Supply Offers and enter into Supply Agreements

### Where do I find information on how to participate in Calls for Supply Offers?

All information on this topic can be found on the AMC Procedures Memorandum at Part 4: 'Supply Offers and Supply Agreements'.

### What are the requirements to participate in UNICEF's Calls for Supply Offers and to submit a Supply Offer?

The only pre-requisite to submit a supply offer is that such manufacturer needs to have entered into an AMC Registered Manufacturer Agreement.

In order for UNICEF to award quantities to an AMC Registered Manufacturer who has submitted a Supply Offer, such manufacturer's vaccine should either be deemed AMC eligible by the AMC Independent Assessment Committee or pre-qualified by WHO or its Product Summary File ("PSF") should have been accepted by WHO for review. However, Supply Offers by AMC Registered Manufacturers which do not meet these technical requirements are strongly encouraged as this information on vaccines in development will guide UNICEF's decision on the quantities to award at any given point in time.

### Is there a template for submitting a Supply Offer?

Yes, a specific template is included as part of the AMC Call for Offers to be issued by UNICEF. Supply Offers shall include all information listed in Part 4.3 of the AMC Procedures Memorandum: 'Contents and Requirements of a Supply Offer'. UNICEF may request further information and schedule discussions with manufacturers if they deem necessary.

### What is the pre-requisite to enter into a Supply Agreement or a Provisional Supply Agreement?

Upon a complete assessment of each Supply Offer, UNICEF can enter into Supply Agreements only with AMC Eligible Manufacturers, in other words, only with manufacturers whose vaccines are pre-qualified by WHO and are deemed eligible for AMC funding by the Independent Assessment Committee.

UNICEF can also decide to enter into Provisional Supply Agreements with those AMC Registered Manufacturers whose vaccine is currently going through the pre-qualification process with WHO and in respect of which, UNICEF has received written confirmation that the Product Summary File has been accepted by WHO for pre-qualification. Provisional Supply Agreements will automatically convert into 'Supply Agreements' once vaccines are pre-qualified by WHO and are deemed eligible for AMC funding by the Independent Assessment Committee.

### Can UNICEF award less than the total demand forecasted?

Yes, UNICEF may decide to award less than the total demand forecasted for the vaccine if this would support the creation of a healthy vaccine market including multiple manufacturers, meeting developing country preferences and matching supply with demand.

### **How would the Supply Agreement operate with regards to UNICEF's rights upon supplier default<sup>1</sup>?**

According to the Pro-Forma Supply Agreement, UNICEF's intent is to sanction Suppliers who are unable to meet their Annual Supply Commitment Quantities obligations for reasons unrelated to the complexity of manufacturing biological products.

Therefore, the Supplier's failure to accept a Purchase Order issued to it under the agreement, or its failure to complete delivery of the full amount of vaccines ordered under an accepted Purchase Order issued to it under the agreement, will not constitute a 'material' or 'fundamental' breach of that agreement (i) as long as (a) such failure is caused by an unanticipated incident in the production of Vaccines (as defined in the agreement) that results from the complex nature of biologicals manufacture, and (b) the Supplier notifies UNICEF about such incident immediately and provides UNICEF with a plan for ensuring that a similar incident does not occur again and provides continuing on-going assurances about compliance with this plan or (ii) if such failure does not prevent the Supplier from meeting its Annual Supply Commitment Quantities.

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<sup>1</sup> AMC Offer Agreement, Annex 1 Form of Supply Agreement, Article VIII paragraph 3

## Applications for AMC Eligibility

### What is AMC Eligibility and why is it important for a manufacturer intending to participate in the AMC Pneumo Initiative?

If a vaccine is deemed to be 'AMC Eligible' by the Independent Assessment Committee, such vaccine has satisfied the minimum pre-determined technical criteria to be eligible for AMC funding (the "**Technical Product Profile**" or "**TPP**").

AMC Eligibility is a pre-requisite to enter into an AMC Supply Agreement with UNICEF and to receive AMC funding.

### Is there a specific time-frame to apply for AMC Eligibility?

No, an Application for AMC Eligibility can be submitted at any time during the Offer Period (i.e. up to 2020 or when the AMC \$1.5 billion is allocated in its entirety), but may only be submitted to the AMC Secretariat once WHO has accepted such candidate vaccine for WHO pre-qualification assessment (Product Summary File ("**PSF**") accepted by WHO).

### Is there a specific template or form for an Application for AMC Eligibility?

No, there is no specific template or form, but the Application for AMC Eligibility must be accompanied by an AMC-Eligible Vaccine Information Package which must include all items listed in the Procedure Memorandum. While there is no pre-specified format for the package, the AMC Secretariat suggests the following to ensure speedy processing:

- 1- Submission of the Product Summary File ("**PSF**") submitted to WHO along with written confirmation that the Product Summary File has been accepted by WHO for vaccine prequalification; and
- 2- A "TPP Eligibility Justification Document" which is a short and clear written explanation from the applicant confirming how the candidate vaccine meets the TPP making all the necessary cross-referencing to the PSF. There is no suggested template for this document.