

### 3<sup>rd</sup> Webinar for RFP-503183 for COVID-19 Related Medicines

Minutes of meeting / Questions and response

**Question:** will you share the presentation after the meeting?

**UNICEF MNC reply:** Yes, the presentation will be shared with all registered participants.

**Question:** will you announce the windows for 2021?

**UNICEF MNC reply:** It depends on the outcome of this RFP and the global COVID-19 situation and the development of a COVID vaccine.

**Question:** how the procurement against this tender will be. I mean who will be the procurement against this tender. I mean what will be the minimum order quantity or it will be against our MOQ / batch size. And what will be the lead time? or will it be our lead time.

**UNICEF MNC reply:** Currently we cannot provide any forecasts as there is no past procurement of products for COVID 19 treatment. The order quantity will be informed by the suppliers offered MoQ or batch size requirements. The lead time indicated in the offers is the suppliers lead time.

**Question:** All the evaluation reports will come together after all windows will get closed? Or there will be window wise result followed by LTA?

**UNICEF MNC reply:** Evaluations are done continuously, and LTAs established upon successful outcome of completed commercial and technical. Window periods provide timelines at which new offers can be included for evaluation.

**Question:** Is UNICEF procuring this from own budget? Or are you just facilitating on behalf of countries?

**UNICEF MNC reply:** UNICEF procures medicines using its own budget or on behalf of governments and partners who choose to use UNICEF as a procurement agency.

**Question:** In sharefolder, there is a folder named as "other documents" - Is this mandatory requirement? Or is the product technical documents sufficient?

**UNICEF MNC reply:** Technically yes, but it depends on the nature of molecule offered for submission, documents required may differ, for molecules which do not yet have approval from NRA/SRA/WHO for COVID-19 treatment and different for repurposed or new molecules approved by WHO or SRA for COVID-19 treatment. When you will submit the commercial offer and make a request to create a SharePoint link, you will receive detailed information about the same.

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**Question:** Will Supplier know which destination country the product goes to?

**UNICEF MNC reply:** Yes, in the cases of a direct shipment, but not necessarily if products are first delivered to UNICEF warehouse for onward distribution to countries.

**Question:** From when we submit the tender, approximately how many weeks will pass until we are given the information?

**UNICEF MNC reply:** It is difficult to say, as evaluation is continuous and subject to the dossiers and documents made available from supplier for UNICEF technical team to review and evaluate, along with the commercial team who will be evaluating the commercial terms and conditions and all of which has to be clubbed for a final evaluation. Furthermore, some technical evaluation is also subject to SRA and/or WHO PQ approval, if products are not yet approved, then this will have to be concluded before an evaluation can be finalized.

**Question:** How will UNICEF handle pharmacovigilance/drug safety reporting requirements?

**UNICEF MNC reply:**

UNICEF is not the marketing authorization holder for any products (i.e. have not registered any products anywhere) and therefore does not have a legally appropriate position to handle concerns related to patient safety.

MAHs are the 'owner' of a medicinal product and as such primarily responsible for ensuring that the objectives for PV are being met and that appropriate action can be taken when needed.

UNICEF only plays a facilitating role in cases of pharmacovigilance, i.e. UNICEF will pass information between the supplier (and ultimately the marketing authorization holder) and the source such as the patient/country office/government, etc.

Adverse events (pharmacovigilance) of pharmaceuticals received within UNICEF are recorded as complaints for which there is a complaint handling management system.

**Question:** Will UNICEF support the facilitation of regulatory approval in countries?

**UNICEF MNC reply:** No,

UNICEF encourages companies to register their products in the countries where they are distributed, however this is not mandatory for UNICEF when it procures products from suppliers and establishes

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long term agreements through a tender. But if it is required, the company/supplier is responsible for registering the product in the recipient country.

**Question:** is there a risk of "grey market"

**UNICEF MNC reply:** UNICEF does not foresee any risk within the UNICEF supply chain.

**Question:** Can we supply/ship only the UNICEF Copenhagen warehouse and specify the countries where supplies can be distributed?

**UNICEF MNC reply:** Yes, suppliers have the option to specify the countries where the supplies should be distributed in the commercial offer, however UNICEF prefers to have products on LTA accessible to all the low- and middle-income countries where it has programs. The individual countries where supplier wants their product to be distributed can be included in the commercial offer accordingly if this suits supplier best.

**Question:** Window 4: has the deadline of 30<sup>th</sup> Oct, Window 5: has the deadline of 30<sup>th</sup> Nov

So please correct if my understanding is correct or not? For Financial offer the deadline is 30<sup>th</sup> Oct 2020.

And for Technical document to be submitted ... the deadline is 30<sup>th</sup> Nov 2020.

The deadlines signal the end of a window period and this is when the UNICEF Assurance Centre downloads all new offers submitted for evaluation. Suppliers can submit both commercial and technical offers in the same window or decide to submit them in different windows, however the commercial offer submission must precede the technical offer submission