

UNICEF Webinar - Request for Proposal (RFP) 503183 Medicines for Covid-19 Case Management

Questions/Answers July 03 2020.

1 Can we exclude some markets from our bid (e.g., US, EU?)

We are procuring medicines for low- and middle-income countries; therefore, we do not anticipate medicines will be required in the US and EU markets.

2 What strength of Interferon Injection?

We would like strength used in the Covid clinical trial.

3 Does UNICEF have an established process on collection of drug safety information from countries without the marketing authorization holder's legal presence

There is a process within Unicef and therefore requires in-house consultation, we will revert once feedback is received.

4 Is hydroxychloroquine still requested?

Yes, still requested.

5 Can we deliver only to Copenhagen?

We require both DAP Copenhagen Warehouse and FCA delivery terms according to Incoterms 2020; however, if you submit for only one delivery term, please ensure to clearly indicate in your commercial offer.

6 Chloroquine 150mg or 250mg?

Please offer the strength is used in the clinical trial.

7 What strength LPV/r is required?

Please offer the strength used in the clinical trial.

8 how will failure to supply penalties be applied when there are no demand forecasts? What will we be measured against?

This tender process is to establish a Long Term Arrangement (LTA), not a contract to supply, once we have a demand to supply, the LTA holder will be issued purchase order(s) which is the binding contract.

9 Will UNICEF buy products only for children and women, or does it cover all COVID-19 patients?

Products will be for women, children and their families and any other covid patient if the demand is there.

10 Following the outcome of the Solidarity Trail and the subsequent results of LPV/r, would there be a potential long-term requirement of LPV/r for the RFP; and how would this translate to volumes in the future?

The potential long term requirement and subsequent volumes will depend on whether the product will be recommended for treatment by WHO for treatment

11 Which other UN agencies could potentially buy products under this agreement? Is there ongoing coordination?

UNICEF provides a service to partners therefore cannot say which other UN agency could potentially procure but we do offer Procurement Service to partners which could procure on the behalf of other UN agencies, governments or other partners.

12 Is the supplier required to accept all POs?

The supplier is not required to accept all purchase orders. If the supplier does not accept the purchase order, the supplier must inform UNICEF within 5 days of Purchase order receipt; in order that we can plan accordingly.

13 lead time

Your offer must tell us what the lead time (the length of time the shipment will be ready for handover to freight forwarder) and please indicate the nearest port.

14 is it mandatory to supply from unicef audited manufacturing line only?

The manufacturing line must be inspected and approved by UNICEF Quality Insurance team prior to any orders to take place.

15 All the medicines are authorized for other indications on the product information (labeling) would we need to re-label in order to quote and supply?

For quoting not needed but for supply yes is required and labelling will be needed to be updated according to any new indications as approved by WHO or NRA for Covid treatment.

16 Would Unicef be providing advice on the new indications, posology to include on the new labeling?

It will be the manufacturer's responsibility.

17 What languages are required for artwork and labelling?

English and French are required for the artwork and labelling.

18 Will you require a specific juvenile indication?

If the clinical indication has been approved using the juvenile population then, yes.

19 Would Unicef be placing orders before the conclusion of the clinical trials? What happens in Unicef purchases and then the results of the clinical trials indicate that the product is not suitable for the proposed indications, dosages etc

No orders will have to wait until clinical trials have been concluded and what the recommendations will be. We will not be placing PO's for covid treatment because it will not have been indicated in the WHO guidelines for covid treatment.

20 So in the technical questionnaires we would only have to include the currently information, right?

Yes, the technical questionnaire, must include only the current information.

21 UNICEF will not be providing support to get local authorization for the COVID-19 indication.

Our intention with the bid is for UNICEF to supply countries where we do not currently have regulatory and/or marketing approval. **How will UNICEF manage pharmacovigilance and regulatory requirements in countries where we do not have a local legal representation?**

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.

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.

Currently pharmacovigilance is handled through our complaints procedure, DP047 as you have highlighted below it states the following: "Adverse events (pharmacovigilance) of pharmaceuticals received within UNICEF are recorded as complaints for which there is a complaints handling management system".

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**For further technical details, please see the technical requirement documents in the tender.