1 - For the products for which commercial & technical submissions have already been made by us within 1st submission window period (June 15th), please let us know the process to be followed if we wish to make any changes (addition of information etc) in already submitted commercial or technical offers for forth coming submission windows (July, Sep & Nov’2020).

If the changes are related to your commercial offer, please inform in a separate email to our secured bid section email address, that you would like to withdraw your offer from 15 June 2020. Then, please submit a new offer in any of the following window submission close dates.

However, if you are required to submit additional technical documentation, please ensure to follow the instructions from the tender documents regarding “How to submit technical documentation.”

2- By when we can expect to hear on evaluation results on commercial & technical offers against each submission window.

 As the tender will close end November, the evaluation/award process will be ongoing into 2021.

3- Since the deadline is too close, in case we do not manage to submit all the information within Window 1, can be submit the information in Window 2?

From a first reading this seems possible, as under the Submission Schedule it is mentioned:

Q

*“Proposals will be accepted for products as described in each window throughout the period the tender is open; however, preference for submission is as per below:”*

UQ

Can you please clarify this?

If you cannot submit your commercial offer by 15 June, yes please submit during next submission deadline or any submission deadline thereafter. However, the evaluation process will not begin until the technical documentation is received corresponding to your commercial offer.

4 - Regarding submission timelines windows 1, with regulatory approval and marketing authorisation, however, we have a product still not registered globally. Thus, kindly confirm we still can bid in window 1.

Regarding submitting offers during the first window deadline, the first deadline should be for offers with regulatory approval and marketing authorisation. Therefore, for offers that do not have everything in place, please submit during Window 2 or any window thereafter.

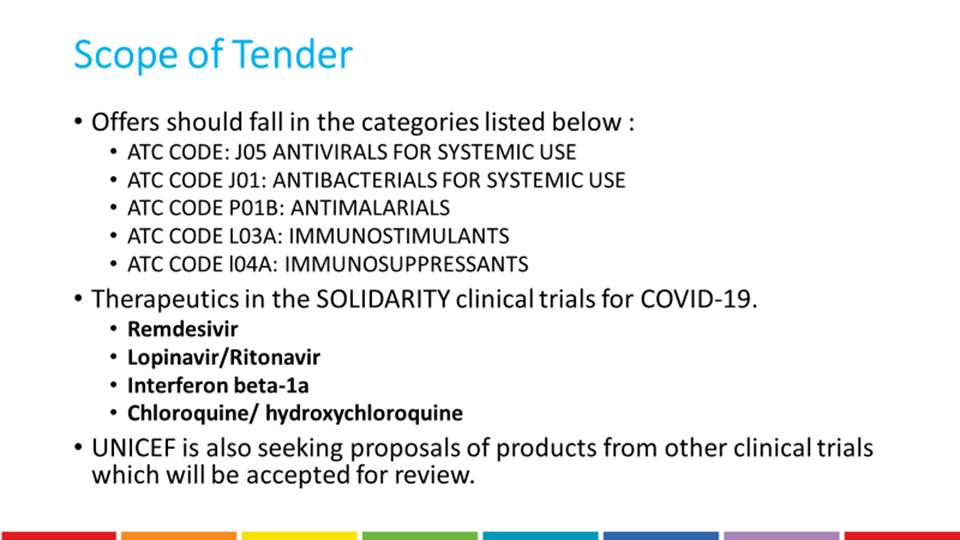
5 - We have both Marketing and Regulatory Approvals, can we submit its offer on 07th September 2020 or by 30th November 2020? Can we submit its Commercial offer by 15th June 2020 even if the technical documents (dossiers) will not be ready and thereafter submit the dossiers once ready provided the tender is still open?

You may submit your commercial offer by any submission deadline; however, the evaluation process will not begin until both the commercial and technical documents are received. As the last submission window is 30 November 2020, please ensure to have your last commercial offer(s) sent to our secured bid email. If technical documentation is not ready at that date, please ensure to send no later than one week after.

6 - Product List

On pages 4 and 7 in the publication “WHO R&D Blueprint COVID 19 Experimental Treatments” (file downloaded from the link <https://www.who.int/who-documents-detail/covid-19-candidate-treatments>) are included products that we manufacture and market internationally. Can we submit an offer for those products?

Please find below the list of products of interest for RFP-DAN-2020-503183, which are products currently being investigated for COVID 19 treatment and were shared during the pre-bid webinar. It is important you work with your technical team to review the categories to determine which products your company can offer. Please submit your offer(s) accordingly to the categories.



7 - How to understand the requested supply volumes to offer the best price?

Unfortunately, we do not have a forecast at this time.

8 - Just a clarification, please confirm if for the products for which we already have LTA with UNICEF, can we offer a different price other than LTA for this RFP?

 Please submit your offer as this is a new tender which is separate from any current LTA’s held.

9- When is the next bid conference planned?

It will be planned prior to Window 2 submission deadline and will be posted to the UNGM.

10 - Par. 4.1 – Mandatory Technical Criteria

Shall a product cover all criteria from a. to e., or covering one or a few criteria only is enough to select a product? For example, all of our products cover criteria b. Is this sufficient?

* **Par. 4.1 – Mandatory Technical Criteria**
  1. All products must have or anticipate clinical approval for use in COVID-19 case Management
  2. And MUST at least qualify one of the following criteria
     1. Emergency Use Authorization by the World Health Organization (WHO) or a Stringent Regulatory Authority (SRA)
     2. Full approval by a Stringent Regulatory Authority
     3. Inclusion into relevant WHO clinical guidelines
     4. A positive opinion under Article 58 of the European Union Regulation EC9 No. 726/2004 or Canada S.C 2004, c.23(Bill C-9)
     5. Inclusion in SOLIDARITY or DISCOVERY Clinical trials. Submissions based on inclusion in other trials will be considered on a case by case basis as clinical trial data becomes more available

11 - Reference to the captioned RFQ, we would like to have clarity on the codes as there are different product codes for various markets.

Could you kindly let us know the way to identify those codes.

* **ATC codes**
  1. ATC codes are universal and for nomenclature they can be referred to <https://www.whocc.no/atc_ddd_index/?code=J05A&showdescription=yes>
  2. ATC codes mentioned in the RFQ is based on a very broad level and is for guidance for identifying the molecules used in COVID Clinical trials

12 - Will stability test for zone III and IV be mandatory required for the offered products, irrespectively to the different stability zone of the country of manufacturer?

The requirement is based on the conditions as a worst case scenario in recipient countries typically Sub-Saharan Africa (Zone IVb). Other offers will of course be considered.

13 - In the chapter **Safety, efficacy and/or therapeutic equivalence** of the Technical Requirements it is stated that “the product used in the therapeutic equivalence study should essentially be the same as the one that will be supplied i.e. same materials from the same suppliers, same formula and same manufacturing method(s)”.

What if API suppliers differs? What if the manufacturing process is a bit different? Will the results of such study be accepted?

Please note that UNICEF is not a regulatory body. In principle we will take advice from regulatory bodies. It is difficult to give clear guidance based on the comments. The API should as stated in the above be the same and when you state the API differs we will need to look into that, same apply for the manufacturing process.

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

Informed page 1 of tender document. For your convenience; Products are for specific use in the management of SARS-CoV-2 infected or exposed children, adolescents, women and their families in resource-limited settings

15 - Which countries are covered by this initiative?

UNICEF is procuring on behalf of governments and partners globally

16 - Which other UN agencies could potentially buy products under this agreement?

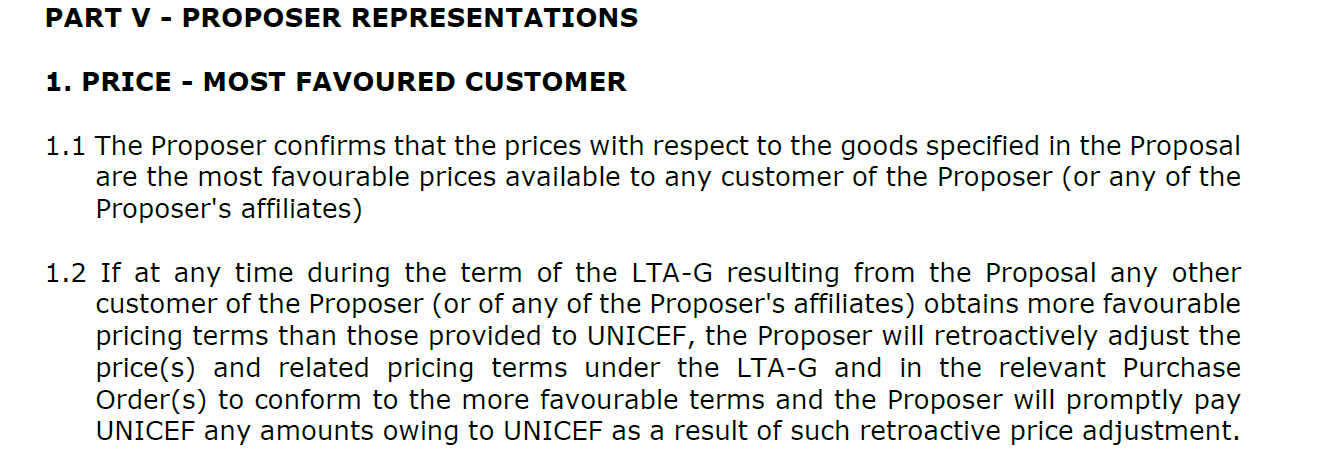
Currently only UNICEF.

17 - Our interferon beta is currently not approved for the treatment of COVID-19. Under which bid window should we issue a proposal?

You may submit at any window submission deadlines.

18 - How is the “most favorable price” defined?

As indicated in pg. 23 of tender document and below for your convenience.



19 - We are interested to bid for Remdesivir tender. However we do not have any Solicitation/Long term agreement (LTA-G) with UNICEF. Thus, kindly confirm how to proceed.

Kindly note that it is not necessary to have any previous experience with UNICEF or have an UNICEF LTA established with us to provide an offer. Therefore, please ensure to read tender document completely and follow instructions upon what information and documentation you are required to submit for both your commercial and technical offer.

20 - Technical Documents for new Molecules or new COVID indication

e.g. Remdesivir- where no Pharmacopeial monograph exists we will ONLY accept the technical documents from Originator only

21**-** Fixed dose combination (FDC) or single dose regimens e.g. Sofosbuvir+Ledipasvir

If a product with FDC is requested or is used in the COVID Clinical trials, we will only accept the FDC for the same product and not a single dose regimen.

22 - The list of the countries that are targeted with this bid is diversified and from different continents: so the bidder is requested to deliver to ALL of this countries (with his own logistics), or can a bidder be able to select a specific area (in our case as Moroccan branch : Africa)?

The intention is that deliveries can be made around the world on the 2020 Incoterms for FCA nearest named sea/airport delivery terms. Regarding FCA deliveries, the freight forwarder is appointed by UNICEF. However, if you would like to make an offer for deliveries in Africa only, please ensure to clearly indicate this in the Commercial Offer Form.

23 - All communication will be with you in Copenhagen I believe, would the delivery be in Copenhagen as well, and then you dispatch around the world, or you will be communicating the quantities and agenda of the delivery and it is up to us to secure the liaison and delivery?

Yes, the communication is with Copenhagen. Once the award is made, it will be myself and my colleagues who will place the eventual purchase orders which will indicate the quantities and which country the delivery is for.

It may also be possible that we will procure products into our Warehouse in Copenhagen. If this occurs, the Incoterms will be DAP UNICEF Copenhagen Warehouse. For this type of delivery, the bidder is responsible for the shipment from supplier premises to our Warehouse in Copenhagen. Therefore, as per the Commercial Offer Form, we ask for two prices per each product offered.