

29 May 2020

UNICEF CLARIFICATION NOTICE (No. 7)

REFERENCE: RFP-DAN-2020-503174 PERSONAL PROTECTIVE EQUIPMENT (PPE) FOR COVID-19 PANDEMIC RESPONSE

The following comments are offered in order to clarify articles within the above tender document. Clarification and Correction comments will be issued on an as needed basis in order to respond to inquiries received from potential Proposers.

INFORMATION UPDATE:

There have been a large number of proposals submitted through Window 2 from Traders providing incomplete information requiring multiple rounds of clarifications with the impact of delaying the evaluation process.

As per clause 3.12.2.3 of the RFP document there is a preference to engage with high impact suppliers and manufacturers on a direct basis for this range of commodities.

ANNOUNCEMENT:

We are extending the closing date for Window 3 by one calendar week to close on the 7th June 2020 at 23h59 CET.

CLARIFICATIONS:

1. Question raised

We are undergoing certification of our product, protective coveralls, by EN13034:2014, this standard acquires us Type 6 of protection and can acquire us only Category 2, category 3 is impossible. Also, we are doing tests by EN14126:2003, for barrier for infective agents, if we'll pass it with class 2, can we qualify for your PPE tender? As we found in your specification that it is necessarily our coverall be Category 3?

UNICEF response:
Coverall must be category III.

2. Question raised

In the file: Technical Questionnaire PPE Tender 2020 - RFP 503174, how do we add several products e.g. 2-3 different suppliers/gowns for 1 gown (S0305140). All these suppliers meet the specifications. Should we just add more columns for the other products or add several files?

UNICEF response:

In Annex D Technical Proposal Template, please submit under alternative offer under U282700. You need to include all requested documents separately for each product offered maintaining the folder structure for each product.

In Annex E Commercial Proposal Template Section 4 Proposal Sheets there is one template Tab for Alternative Proposal. In case you intend to submit more than one alternative product (or if you want to make two or more different offers for a specific item), please copy and paste the Alternative Proposal into an additional tab and maintain respectively for the required number of alternative products. Please refer additionally to Question 7 below.

3. Question raised

Section 7&8: For the account mng / Org Structure, do you also want BIOs about the people involved?

UNICEF response:

Biographies are not requested. Proposers are to include an overview of the planned account management should the proposer be awarded under this RFP in response to clause 3.12.10

- Section 9 PPE Experience: Is there a format that you prefer to receive the references in?
- Section 9 PPE Experience: do you need proof of the references to be attached to the tender proposal? (e.g. Signed letter from client)

UNICEF response:

There is no predetermined format. Please submit information that clearly demonstrates experience in PPE delivery (e.g. list of fulfilled contracts with indication of types and volumes of products delivered). If reference from clients are available, such are welcomed.

- Advance payments are indicated as acceptable to place the order, however, the proof is required that by paying in advance better prices and quality can be obtained. Do we have an indication of how this proof is to be demonstrated? Is a letter from manufacturers stating so needed?

UNICEF response:

Please take note that the preferred payment conditions are payment after delivery. If advance payment is necessary required, the bidders are invited to provide explanation that such terms will result in increased production availability and favourable pricing.

- Do you need letters from the suppliers confirming and guaranteeing their production capabilities?

UNICEF response:

Please provide such information in Section 11 Proposer Manufacturer Relations to confirm your ability to deliver the products included in your Proposal. These can be in the form of guarantee letters, copies of distribution agreements or authorization letters from manufacturers.

4. Question raised

Please clarify whether UNICEFF will accept Coverall Protection without taped seams.

UNICEF response:

Please refer to the specifications in Annex B Technical Specifications.

5. Question raised

Please clarify whether UNICEFF will accept Gown ,surgic, non sterile, non woven disp. (S03051380 without taped seams

UNICEF response:

Please refer to the specifications in Annex B Technical Specifications.

6. Question raised

Our Company has not provided audited financial statements to UNICEF in the past 12 months. If we complete the Level 2 registration on the United Nations Global Marketplace site will that be sufficient?

UNICEF response:

To be eligible for an award, the proposer must submit the requested documentation to the UNICEF Supplier Evaluation Unit (or relevant UN Agency or NGO equivalent requested documentation to the relevant procurement entity). If a supplier has not undergone this review, the financial statements can be also submitted along with the Proposal. UNICEF may also accept non-audited financial statements.

7. Question raised

- When there are two suppliers for a single item, how should we complete sections 4-6?
- Section 4 We will create a tab for each supplier. Is there a way you want to see those tabs distinguished for convenient reference in other sections?

UNICEF response:

Please submit your proposal using applicable Item Tab for the offered product. In order to submit proposal for the same item from another manufacturer please use the Alternative Proposal. In Section 4 there is one template Tab for Alternative Proposal. In case you intend to submit more than one alternative product (or if you want to make two different offers for a specific item), please copy and paste the Alternative Proposal into an additional tab and maintain respectively for the required number of alternative products. You may use Cells A42-H42 ("Specify any further conditionality of the offer(s)") to indicate the Manufacturer to differentiate between multiple alternative offers to one same item.

- Section 5 Should we list a column for every tab or combine the quantities offered in a single tab for the item number?

UNICEF response:

Please list a separate column for each product offered. If you are offering 3 different products, please maintain 3 separate columns.

- Section 6 We will need to create individual tabs to represent details from each supplier. How do you want us to distinguish them?

UNICEF response:

In Sections 5 and 6 where only Item number must be used, in case of a number of Alternative products (Item number 220) you may include the additional reference to Item number and manufacturer to differentiate (e.g. in case you are offering Alternative to Item 10, please maintain in "220 - it. 10 - XXXX manufacturer"); In Section 5 please use Cells A45-H43 to include any additional information.

- When we have multiple items which do not correspond to any item number, how do we distinguish them? For example, we have great prices on tubs of disinfectant wipes and noninvasive ventilators. We can use item number 220 for both, but they will be indistinguishable on Section 5.

UNICEF response:

Such items are not subject to this RFP. Please refer to Annex A Tender Products and Quantities for detailed list of products required.

8. Question raised

In order to provide the maximum capacity we can, for some UN material codes, offer different products of different manufacturers. All of them meet the required specifications of each UN code. How can we provide the technical specifications in section 9. Technical Questionnaire. The file provides only one input column per UN material code.

UNICEF response:

Please use U282700 for alternative offer. UNGM UN classification codes are not used in the RFP submission templates.

9. Question raised

How will individual purchase orders (PO) be placed? Central by UNGM, or decentral by the 13 UN agencies or individual country organizations?

UNICEF response:

RFP clause 4.1: Resultant Purchase orders and supply arrangements, including LTAs, may be established by any of the participating Agencies and NGOs with the proposers in alignment with the decisions taken by the PRG.

10. Question raised

Will a PO contain multiple UN material codes?

UNICEF response:

UNGM UN classification codes are not used in the RFP submission templates. Please refer to RFP 3.10 AWARD/ADJUDICATION OF PROPOSALS for details of evaluation and award process.

11. Question raised

Who will pay invoices for individual Purchase orders? UNGM or the individual UN agencies or country organizations?

How will we receive PO's? (email, web entry on out order portal, EDI/API?)

UNICEF response:

The payment will be done by the Party to the Contract.

RFP Clause: 3.10.4 AWARDS BY UN AGENCIES AND NGOs PARTICIPATING IN THIS RFP

This RFP issued by UNICEF includes demand from other UN organizations and NGOs. The United Nations Agencies, Funds and Programmes and named NGOs as listed in Section 1.1 of this RFP will be entitled to place orders and establish LTAs under the prices and terms received in response to this RFP, in accordance with the agreed demand coordination and PRG advise. Orders placed by other United Nations entities and NGOs constitute a contractual agreement between the supplier and the ordering United Nations entity or NGO. UNICEF will not be a contractual party to these orders and has therefore no obligations or liabilities for orders not issued by UNICEF.

Please refer to RFP 3.10 AWARD/ADJUDICATION OF PROPOSALS for details of evaluation and award process.

12. Question raised

Next to a web portal with status updates and other inquiries, we will also offer a customer service helpdesk to support order entry and to support inquiries on order status, etc. What opening hours do you require for this (incl. time zones). Which languages need to be supported?

UNICEF response:

In case of award the Purchase Order will be issued and shared via e-mail. The Suppliers are expected to ensure effective communication via e-mail and telephone communication as may be required.

13. Question raised

In case of larger quantities per PO, we will allocate the production to several production plants. Do you require that all parts of a single PO are consolidated and delivered at one air- or seaport, or can we deliver these sub deliveries of a single PO to multiple (max 3) air or ocean ports?

UNICEF response:

Please include the applicable FCA conditions into your Proposal for each product in Annex E Section 4 Proposal Sheets. In case of award a separate PO is issued for each shipping mode.

14. Question raised

We understand that the provided demand overview (scenario 1) is the best estimate at the moment. Do you have a process in place that updates this estimate on a ongoing base and can support a rolling forecast that we can use to optimize the S&OP plans for our factories?

UNICEF response:

At the moment the updated information was not published by UN Agencies, please refer to the information currently included in the RFP and offer your available production capacities in your Proposal.

15. Question raised

There is no mutual NDA submitted as part of the tender documents. We have no issue with sharing the contracts with our manufacturers. At this stage, however, we would like to share signed LOI's for this Tender with all manufacturers that show the products, available capacities and export approval.

UNICEF response:

Please provide such information in Section 11 Proposer Manufacturer Relations to confirm your ability to deliver the products included in your Proposal. These can be in the form of guarantee letters, copies of distribution agreements or authorization letters from manufacturers.

16. Question raised

We are designing an optimized cashflow process that benefits all parties involved (UNICEF and the, other Agencies, Supplier and Manufacturer), guarantees the required production capacity and limits risk at the same time. Is UNICEF, in general, willing to consider a payment process based on a transferable Letter of Credit (LC), submitted by UNICEF, that will be used for payments at the moment of delivery of the goods?

UNICEF response:

Such payment methods are not acceptable to UNICEF.

According to RFP Clause 3.12.1.2: Payment Terms. Invoices may be issued to UNICEF only after the delivery terms of the Purchase Order (as issued in accordance with the provisions of the LTA-G) have been fulfilled. The standard terms of payment are net 30 days, after receipt of invoice. Payment will be effected by bank transfer in the currency of the Purchase Order.

Please refer to UNICEF General Terms and Conditions for additional details on the payment process.

17. Question raised

I have a question for you. Our products which are our face shields & anti fogging goggles are in process of being FDA approved, we should have our FDA operator as soon as next week. We are excited to have our products FDA approved as they are already being used in hospitals for medical applications. Our FDA classification will be ""LYU,"" which are ""surgical and infection control devices."" Due to Covid-19 we have not had time to get a CE mark on our product or testing which certifies that the products are ANSI compliant. We do believe that the products are compliant, especially since they are about to be FDA approved, however we do not have any testing that certifies that they are ANSI compliant or CE approved. Being that our product is about to be FDA approved for medical use, but not yet approved by ANSI or CE, would you kindly let me know how this may affect our likelihood in being considered for RFP-DAN-2020-503174?"

UNICEF response:

Please submit your offer and we will assess in accordance with RFP evaluation criteria.

18. Question raised

Does a manufacturer/supplier require to submit a marketing approval from one of the IMDRF Management Committee for Face shield

Or a manufacture/supplier can submit a compliance certificate (Declaration of Conformity) for the products with affix CE marking on them?

UNICEF response:

It is required to confirm compliance of offered products with regulatory requirements for marketing clearance, i.e. GMPALS (Australia), Device License (Canada, Japan), CE Class IIa (EU),

510k Device Letter Class II medical device (USA). For further information please refer to para 4./ in the Annex C Technical Requirements.

19. Question raised

We do not see any information re. a requirement for bidders to submit a bond (surety-bond) to guarantee their performance of potential agreements. Is there no such requirement for the above mentioned tender?

UNICEF response:

The bid security is not required to participate in this RFP.

20. Question raised

The delivery term required in this tender is FCA named airport/Seaport. Could you please explain under this term?

- The seller loads the goods in the truck and transport it to the nearest Airport/Seaport and from there onward, the buyer is responsible. The seller's responsibility is done
- 1) Or the buyer picks up the goods from seller's factory and manages the transportation itself to the nearest terminals.

UNICEF response:

According to RFP clause 3.12.3.2: Incoterms. Proposers are requested to quote prices in accordance with the following delivery terms (INCOTERMS 2020):

FCA named airport/seaport (PROPOSER TO SPECIFY NAME OF AIR/SEAPORT)

Please refer to FCA definition as per International Commercial Terms (INCOTERM) published by the International Chamber of Commerce (ICC).

- 2) If the proposer bids the items under the payment term such as 100% advance given that the item he had proposed fulfills all the requirements. Will UNICEF be able to accept the proposal with 100% Advance payment required?

UNICEF response:

Understanding the current market constraints, UNICEF and other participating UN Agencies and NGOs are willing to consider offers of firm contracts and advance payment terms in order to achieve access to committed, significant and immediate production capacity increases and meaningful quantities of quality assured, affordably priced products. Proposers should note that the ability of the participating organizations to engage in agreements with firm/advance terms is finite and offers including such terms therefore need to demonstrate credibly how they will have a catalytic impact to achieve access to the needed supplies. For further details refer to Clause 3.1 of the RFP document.

3) Under the labeling requirement, should there be UNICEF logo printed on the products as well or the manufacturers information is fine?

UNICEF response:

RFP clause 4.9 Packing, Packaging, Packing List, Labelling and Dangerous Goods Instructions.

The Proposer will comply with the requirements for packing, packaging, packing list and labelling of goods set out on the UNICEF Supply Website (http://www.unicef.org/supply/index_41950.html) and the additional requirements (if any) for packing, packaging, packing list, labelling set out below in this Solicitation Document. This includes those requirements that apply to dangerous goods. The classification of goods (including packaging) as "dangerous goods" is a supplier responsibility and must be communicated to UNICEF when submitting the Proposal. For any goods (including packaging) classified as dangerous goods, Proposers must submit all relevant Material Safety Data Sheets indicating accurate classification for transport purposes, storage, labelling and shipping requirements when submitting the Proposal.

4) While going through the Tender documents, we did not see anything regarding Bid Security/Performance Security. It is not required?

UNICEF response:

The bid security is not required to participate in this RFP.

5) There are some products listed with no requirement mentioned for the standard. There is no standard/certificate requirement in the Annex B. That means the General Standard required?

UNICEF response:

Please refer to Annex B Technical Specifications and Annex C Technical Requirements for required information.

6) And please mention if there is any experience required or should the audit report meet some requirement?

7) And if the Financial documents and audit report are not sent to UNICEF evaluation unit and submitted with the proposal. Will that work?

UNICEF response:

Please refer to RFP clause 3.10.5 SUPPLIER REGISTRATION AND EVALUATION.

The financial documents can be submitted with the Proposal, please use Annex E Section 14 Additional Information.

21. Question raised

We would like to offer You a huge number of FFP2 respirators or gowns.

We registered to Your system but we do not know how to proceed.

We have already sold large quantities to German authorities and would like to offer to You now. How should we do that?

UNICEF response:

Please read the RFP document and submit your Proposal according to the RFP requirements and conditions.

22. Question Raised

Annex D - Section 9 - Tech Questionnaire for Item 10 - Row 42 : Air permeability :

The measurement unit you indicate is a distance followed by the symbol of water : H₂O.

Should it not be a distance traveled by an airflow (volume applied to a specific surface area) over a certain amount of time (per second for instance) ?

OR a volume of airflow over a certain amount of time (per second for instance) ?

Just a distance followed by H₂O is slightly puzzling."

UNICEF response:

The specifications included in Annex D are correct.

23. Question Raised

Please guide me to understand the below 2 points in technical requirement sheet:

Conformity with production standards

a. The manufacturer should hold the product technical documentation as per the IMDFR/GHTF requirements (goods that do not meet these standards shall not be acceptable to UNICEF):

c. The labelling of the product shall meet the requirements as described in the below standards and guidance documents:

1. ISO 13688:2013 Protective clothing -General requirements
2. ASTM F 1301 Labelling of chemical protective clothing
3. ANSI Z535.4-1991 American National Standard for Product Safety Signs and Labels "

UNICEF response:

This is well explained in Annex C. For more info, please refer to the mentioned standards.

24. Question Raised

One of the Type IIR Mask suppliers has an expired QMS from TUV Sud from 20th April 2020 for the masks, and now the earliest appointment to renew is only on the 29th of May, with the new certificate released in Mid-June. Therefore, at the time of the May, 31st submission, the supplier "technically" won't have a valid QMS.

Is there anything I can do to provide as proof so that it won't be disqualified for this reason? Or will it be disqualified for the Type IIR mask since they are medical devices even if it will arrive 2 weeks later?"

UNICEF response:

Please submit your Proposal once you have all documents corresponding to RFP requirements for specific item offered. You may use submission Window 4 to submit your Proposal.

25. Question Raised

Can you please help me find the document to put all the technical specification etc?

UNICEF response:

All documents are made available via UNGM (<https://www.ungm.org/Public/Notice/106842>). The technical response template is Annex D.

26. Question Raised

Item 10 and 40 – is it planned to place an order for the complete second tranche and how long will decision process in general take?

UNICEF response:

The tentative expected lead-time for evaluation completion and recommendation for award will vary dependent on the number of offers received. It is in UNICEFs best interest to make awards as soon as possible to secure available supply. The target is 15 working days after each Window closing date, however this will be dependent upon the number of offers to be evaluated and the completeness of the offers received.

As per clause 2.8.1 Awards with an estimated value over USD 500,000 made by UNICEF as an outcome of the RFP be published on the following site: http://www.unicef.org/supply/index_27009.html , advising the product group, awarded supplier and total value of award.

Please refer to 3.10.2 BASIS FOR AWARDS for details of award process.

27. Question Raised

We are to create a new copy of the 'UNICEF Material Number' folder found in Annex D for each item we are responding on.

Does this include Section 9 'Technical Questionnaire' which obviously allows you to respond on every item (or do you include a copy of this for each with on the sheet for that specific item filled out)?

Where there are different material numbers for variations of the same item (e.g. S0305117, S0305126 & S0305127 all refer to Coveralls in different sizes) should we submit a complete set of documents for each variation?

UNICEF response:

1) No, it does not include section 9. Section 9 should be only one and include all your offers: please fill in one Technical questionnaire with all your offers and when you offer more than one

offer for the same item, those offers should be submitted as alternative offers (U number tab in the questionnaire).

2) In case there are different material numbers of the same item (e.g. different size), please submit a complete set of documents for each variation.

XXX is a newly appointed XXXXX delivery partner of XXXX. As such, we have only one previous client, but XXXXX of course has hundreds. Since it is ultimately their experience that is relevant can we still submit an application without having passed all of Level 1, 2 or 3 supplier registration? Obviously we can provide references from past clients in non-PPE related business dealings?

UNICEF response:

RFP clause is mandatory as follows: 2.7.1 UNICEF is part of the United Nations Global Marketplace (UNGM). Accordingly, all proposers are requested to become a UNICEF vendor by creating a vendor profile and submitting their national incorporation license/certificate at the Level 1 stage of vendor registration process in the UNGM website: www.ungm.org. Please submit the details of your organizational structure in Annex E Sections 7,8 and 14 and we will evaluate.

28. Question Raised

If we do send in a bid on window 3, can we also provide a more competitive bid for the same products/deliveries in window 4 and not risk being rejected for submitting 2 bids.

UNICEF response:

Considering the scale and urgency of demand there are multiple submission windows during this RFP. Proposers may submit proposals through one or more of the submission windows. For the detailed submission schedule refer to clause 3.4.1. and 3.4.2 of the RFP document.

29. Question Raised

We are going to submit multiple alternative products with minor deviation with the requirements, for at least two "UNICEF Material No", for example, S0305138 and S0305116, but the alternative offer sheet under Annex D Folder 9, is with the same number U282700. How should we mark to distinguish which offer is an alternative to which product?

UNICEF response:

In the Technical Questionnaire, Tab U282700, in the top row in the *Product Technical Specifications* section, please indicate the main offer (Material Number + Short Description) you are submitting that specific alternative offer for.

30. Question Raised

Subsequently, when we have multiple alternative offers for one product, and when we need to fill in the Commercial Proposals under Annex E Section 5, for instance, 3 alternative offers from 3 manufacturers who have different monthly capacities and delivery schedule, how should we fill in the form in Section 5? Should we put each alternative offer into one column, corresponding the 'product name and number' as in the technical Folder 9, with their respective delivery schedule, quantity, and the total year of production etc.?

UNICEF response:

Please refer to Question 7 above.

31. Question Raised

According to requirements in Annex C, Item C – “Attachments that shall be submitted with the offer for each product”, the table with 7 items, where should we insert these documents/information? As in the Technical Proposal 9 folders and Commercial Proposal 15 sections, they include some of the documents required in Annex C Item C, some do not. The 7 items in Annex C item C are not exactly in consistency with the Annex D and Annex E. We are a bit puzzled.

UNICEF response:

Please refer to RFP section 3.8.11 Table 4. Commercial Submission Check List for details on submission of commercial proposal under Annex E Commercial Proposal Template. Please submit one Commercial Proposal maintaining the folders structure as per Annex E.

Please refer to RFP clause 4.10. Technical File Submission, Table. 5 Technical Submission Check List for details on submission of technical proposal. Please submit maintaining the folder structure for each offered product.

Please additionally refer to Clarification Notice (No. 5) dated April 28, 2020 Section ADDITIONAL INFORMATION 1. List of general recommendations to the Proposals submission format.

32. Question Raised

In addition, Under Item C of Annex C, No 7 “Sustainability goals”, should each factory provide these info separately, or should the supplier/proposer provide one write-up for all factories, or for each factory?

UNICEF response:

The Proposal shall provide the required information providing the required details as applicable to the list of offered manufacturers.

33. Question Raised

We are going to offer several products, which are not 100% the same (maybe 97% the same) as required specs or packing, etc. They are with minor deviations. If we fill in the forms in Annex D and Annex E with the original Reference Number and Material Code listed on Annex A, we are not able to “highlight the deviation in bold/red text” as required. In this case, should we ONLY fill in the form as Alternative Offer?

UNICEF response:

Please submit your Proposal under the Alternative Proposal.

34. Question Raised

If the above answer is yes, when we are required to fill in the RFP Reference Item Number in several sections under Annex E, what should we fill inside? Shall we put U282700 +Supplier's Product Reference No? Or shall we still fill in the Original Material Code + Supplier's Product Reference No? Please advise.

UNICEF response:

Please refer to Question 7 above.

35. Question Raised

We are a manufacturer of PPE from India. Our products match the highest safety and regulatory standards of the country and we hold a certificate for ISO 16603 as well as ASTM F 1670/F. However, no lab in India has the facility to test for ISO 16604:2004 or any equivalent international standard. Due to the lockdown imposed courier activities have been greatly reduced at it is not possible to send samples abroad for testing. We are interested in bidding for the above mentioned tender so is there any kind of exemption or assistance UNICEF can provide us with? Similarly, India does not have the facility for IMDRF examination which is required by the UNICEF. We can however get a US FDA registration of the type attached. Will this kind of a certificate be enough for the tender? Thank you

UNICEF response:

Please submit your Proposal in line with RFP requirements and we will evaluate. Please refer to Annex B and Annex C for detailed requirements.

36. Question Raised

We got registered on Unicef Website this month as we would like to supply PPE Coveralls due to the shortage of PPE Coveralls globally.

We are an export company based in India and manufacture apparels for some well known American and European brands. Since there has been a shortage of coveralls globally, we would like to supply PPE Coveralls to the Unicef.

Attached are the report's from XXXXX in India which is the Lab for approving PPE Coveralls.
As we have got our coveralls tested in India, Our PPE has passed the Synthetic Blood Penetration Test- XXXXXXXX
Attached are two approved ppe reports by XXXXX.

UNICEF response:

Please submit your Proposal in line with RFP requirements and we will evaluate. Please refer to Annex B and Annex C for detailed requirements.

37. Question Raised

As discussed we would like to apply for supply to UNICEF and the associated organisations and have registered online for this. Our product offering is for our own UK manufactured face visor, produced in our medical device manufacturing facilities and certified to CE Class II PPE. Our product and company has been approved by the UK government cabinet office and comes recommended by the NHS.

Whilst we are capable of meeting your demand and production volumes of 1,000,000 a week are feasible, we would need a commitment from UNICEF or its associates that we will win a significant volume of the tender – unless there is a different route outside of the tender that we would prefer to take.

UNICEF response:

UNICEF cannot guarantee any minimum order volume. Please submit your Proposal which will be evaluated on a competitive basis in line with RFP requirements.

38. Question Raised

In the tender document, page 6, table 2 is stated material no. S0305146, Mask medical, type I:
In the attached Annex A there are no forecast under this material no. S0305146, Mask medical, type I.
Does this mean that UNICEF do not want to receive any offer of this product or can we submit an offer? If we can what are the required quantities?

UNICEF response:

Please submit your Proposal for item S0305146, Mask medical, type I.
Please note that there is no specific forecast for this item separately and the overall demand is included in forecast for item S0305109. Please include the best production capacity you can offer.

39. Question Raised

We understand that there should be only one (1) Commercial Proposal folder for all our products/items/PPE. However, since you wrote in Clarification #5 that we should have separate 1) Technical Proposal folders for each products/items/PPE offered, then how should we name these separate folders to avoid your confusion? This is especially confusing if we have 6 different Alternative Proposals -- thus, how do we name these 6 Technical Proposal folders (you said not to change anything about folder names or structure, but yet that's not possible if we have 6 alternative proposals, no?)

2) Also, in the U282700 it lists 6 'Bidder Alternative Offer' - how do we match them to different Technical Proposal folders?

3) Finally, regarding non-medical items -- how do we properly respond to your questions regarding Marketing license certificate? Do we leave it blank? Do we include a comment? Do we create a special new file in appropriate folders explaining that it's not a medical item?

UNICEF response:

1) Please create a folder for each offer (main and alternative) and include the folder structure as per Solicitation Document for each offer. Each offer should have its own folder structure with the relevant documents in it.

2) In order to match each alternative offer to each folder structure and univocally identify to which folder an offer refer to, please include in the name of the main folder the name of the commodity.

3) Please include a comment.

40. Question Raised

For the products, goggles and face shields, we can provide FDA certificates, but not CE certificates.

Would this be acceptable documentation to submit under the technical submission, folder 4 (Marketing license certificate)?

UNICEF response:

The FDA 510 (k) is acceptable.

41. Question Raised

Can I ask a quick follow-up question: In Annex D there are a number of submission requests that require an image file or a scanned document, QMS Certificates for example.

Do you want these to be placed in the appropriate folder (as Jpeg or any other preference) or do you want them pasted into the word document contained in the relevant folder?

UNICEF response:

Please include such as scanned document in applicable relevant folder.

Secondly, regarding FFP2 and FFP3 with valid CE certificates (EN149), we find that there are not so many companies in China that are suitably qualified. However, lately there are many companies receiving CE certificates for their KN95. So I wonder whether KN95 (with CE certificate or test report from Dekra or SGS) would be counted here in place of FFP2 or not? I realise that we can submit this as an alternative offer, but I wondered if it would translate directly for this particular item?

UNICEF response:

As per UNICEF Technical Provision for PPE, the product shall be assessed by at least one of the IMDRF regulatory authorities (or at minimum with SG1-N70:2011: Label and Instructions for Use for Medical Devices): The IMDRF Management Committee comprises regulatory authority representatives from the following jurisdictions:

- Australia, Therapeutic Goods Administration
- Brazil, National Health Surveillance Agency (ANVISA)
- Canada, Health Canada
- China, National Medical Products Administration
- European Union, European Commission Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
- Japan, Pharmaceuticals and Medical Devices Agency and the Ministry of Health, Labour and Welfare
- Russia, Russian Ministry of Health
- Singapore, Health Sciences Authority
- South Korea, Ministry of Food and Drug Safety
- United States of America, US Food and Drug Administration

A Lab Test Report from an CNAS accredited lab is required as well.

42. Question Raised

Can you specify what type of testing UNICEF requires for disposable face shields (UNICEF S0305116)?

UNICEF response:

The testing should conform to: CE EN 166 standard (or equivalent international standard).

43. Question Raised

Does the vendors bidding for this have to be able to supply full amount per week. Or can we submit with the production capacity we have currently?

UNICEF response:

Please submit your Proposal according to your production capacities indicating the available quantity on a weekly basis

44. Question Raised

When there are two suppliers for a single item, how should we complete sections 4-6?

Section 4 We will create a tab for each supplier. Is there a way you want to see those tabs distinguished for convenient reference in other sections?

UNICEF response:

Please make sure to use Annex E Commercial Response Template currently posted on UNGM, which has separate tabs prepopulated for each product. In case you would like to offer more than one product for the same item (for example item 10, but differing only in Manufacturers), please maintain only one tab for item 10 and use the Alternative Proposal tab for each additional proposal for this item. Please use template excel line 42 "Specify any further conditionality of the offer(s)" to include details on the product manufacturer and manufacturer product reference to differentiate clearly.

Section 5 Should we list a column for every tab or combine the quantities offered in a single tab for the item number?

UNICEF response:

Please include separate column for each offered product. In case of multiple same products offered, please include for example: 220 (it. 10, Manufacturer XXXX) – meaning you offer Alternative to item 10 by xx manufacturer – which should precisely correlate with information maintained in Section 4.

Section 6 We will need to create individual tabs to represent details from each supplier. How do you want us to distinguish them?

UNICEF response:

Please use the same logic as for Section 5 outlined above.

When we have multiple items which do not correspond to any item number, how do we distinguish them? For example, we have great prices on tubs of disinfectant wipes and noninvasive ventilators. We can use item number 220 for both, but they will be indistinguishable on Section 5.

UNICEF response:

Please note that these items are not solicited under this tender. The Alternative Proposals tab is for items which correspond to the list of products according to Annex A Tender Products and Quantities, however slightly differ in terms of technical specifications or packaging requirements.

45. Question Raised

46.

There is obviously an opportunity to submit additional items, such as those that do not meet European standards but might be just as useful under Chinese standards. However, are we able to submit additional product lines? Our organisation has approval for a Covid Test and we wondered if this was of interest before we go about collating the info?

UNICEF response:

Please submit your Proposal under the Alternative Proposal.

47. Question Raised

To be eligible for an award, we must submit the requested documentation to the UNICEF Supplier Evaluation Unit (or relevant UN Agency or NGO equivalent requested documentation to the relevant procurement entity), but since we have not undergone this review, an application must be submitted through United Nations Global Marketplace (UNGM) website at <http://www.ungm.org>, under <http://www.ungm.org/NewSupplierRegistration.aspx>.

But <http://www.ungm.org/NewSupplierRegistration.aspx> is a dead end. Please advise how to proceed, since there is no registration website (Error 404, file not found).

UNICEF response:

Please note the correct link : <https://www.ungm.org/Account/Registration>

Furthermore, according to 3.12.8 we are required to send

(a) A copy of company's legal registration

(b) A complete copy of company's latest audited financial statements, with comparative figures for the previous year. This includes, but is not limited to, the following:

The report from the auditor (signed by the auditors)

The balance sheet,

The income statements, and notes thereto

to the UNICEF Supply Division, attention Supplier Evaluation Unit (SEU). How shall we provide these documents to the SEU and what is the address or Email-address of this entity?

UNICEF response:

Please see Clarification Letters 3 and 5

48. Question Raised

I would need a clarification on the minimum registration level required for RFP-DAN-2020-503174 ,because am confused our company is relatively young and is registering under level 1 and is yet to have a financial statement done this , we wouldn't want to expend time and resources only to be disqualified , so please can this be clarified.

UNICEF response:

Per section 2.7.1 UNICEF is part of the United Nations Global Marketplace (UNGM). Accordingly, all proposers are requested to become a UNICEF vendor by creating a vendor profile and submitting their national incorporation license/certificate at the Level 1 stage of vendor registration process in the UNGM website: www.ungm.org

49. Question Raised

The blank fields that we have to fill out in the Excel or Word editable sheets : Do these fields absolutely have to remain with a yellow background or is it acceptable to remove the yellow backgrounds of those fields when we fill them out ?

UNICEF response:

Per instructions do not change or modify any cells or sheets in the Excel file

For the documents we have to sign, scan and PDF: Is it ok to insert a signature in the editable versions and then PDF them automatically without having to necessarily print them out first? This is feasible and would save both paper and time.

UNICEF response:

Suppliers are welcome to submit a pdf copy of the excel file with the signature. What is important for us is we receive both the excel and signed pdf version.

Robert Matthews

29-05-2020

Robert Matthews
Contracts Manager, Health Technology Centre
UNICEF Supply Division