

Queries received for UNICEF Request for Proposal (RFP) 503305 for Anesthetics, Analgesics (Opioid & Non-Opioid), Antidotes, and Mental Health received after 23 April 2021 to present:

1) RFP 503305 will now close on Monday, 7 June 2021 23.59 Copenhagen time. Once you have clicked on "Express Interest" you will receive notification regarding this tender.

2) Please ensure to only send your Commercial offer/proposal to UNICEF secured email, supplybid@unicef.org, as informed on page 1 of tender document only, else your offer will be invalidated. Please do not upload your offer to the UNGM.

3) Please ensure to send your **Technical documentation** to sharepoint as informed by our technical team and informed in Annex 2h..

4) LTA will be for 24 + 24 months, + possible 12 extension (page 6 tender document)

5) Samples only required, when requested upon by technical team (page 7 tender document)

6) Question: *I would like to ask if the Section 5: "Commitment and authorization" has to be filled and signed one for each product or one cumulative with all products listed?*

Answer: Section 5 – must be completed for each product.

7) For the products that you are offering and currently have an LTA (LTA for that particular product) with UNICEF, please only upload the following Technical Documents:

- Annex 2a- Manufacturer Technical Questionnaire, annex 2f-Technical offer form and annex 2g - Technical declaration.

We have just shared the link to your SharePoint folder for uploading **Technical documents only**. Take note that you are not able to share the link. The link is specific to your email only.

Please follow instructions in Annex 2h (see attached).

Please ensure that all documents uploaded to the SharePoint are **tagged** appropriately. Furthermore, ensure that you complete the excel file-Product Mfg site locator, which is found in the site documents folder.

Invitees can offer alternative pack sizes, strengths, and dosage forms **ONLY** if they are not able to offer the preferred ones. Alternative pack sizes, strengths and dosage forms will only be considered and evaluated if we do not receive adequate offers for our preferred pack size, strength, and dosage form.

8) *we have a short question: we took the common texts as a basis for the english mock ups but the product we will offer in the tender is based on the portugese product. Should we keep the portugese product name or should we also translate the product name to English?*

Answer: We refer you to section 1 of Annex 1 (UNICEF Technical requirements for Pharmaceuticals)- here you will see our requirements.

In addition to the question you raised: Prominence should be given to the INN name and not the brand name.

9) Are there any delivery schedules available? We are moving production site and it should fully operate in Q3 2022 – would it be acceptable?

Answer: At this point of time, we can only provide an estimated forecast as informed in the product list.

Answer: Regarding production site, we would suggest you provide data for the current site unless you have sufficient Technical documents for the new site. Please take note: if you change the manufacturing site later on we will need the Technical documents for the new site (process validation & stability data).

10) Are other offered pack sizes accepted?

Answer: We prefer the pack size indicated in the tender; however, will review alternative pack sizes.

11) ENG packaging is mandatory, are there any additional requests in this case?

Answer: We prefer English & French labelling. And the rest of our Technical requirements can be found in Annex 1.

12) If samples are needed will you be able to prepare import licensing for them – these products are strictly controlled substances and it is illegal to send them without authorizations.

Answer: We will inform you of the procedure once we get to the sample evaluation stage.

13) When first deliveries expected? Is there any expectation for lead time?

Answer: Expected lead time is the best realistic lead time your company can offer for a product.

14) In relation to the API declaration, could you please let us know the information that our API supplier has to include in the following fields:

UNICEF Item description:
UNICEF ITB/RFP/RFQ number and/OR:
UNICEF Purchase Order Number:

Answer:

Annex 2e- must be completed by the FPP manufacturer.

Use annex B to complete the section you are asking about.

UNICEF Item description: the INN name of product offered (general description)

UNICEF ITB/RFP/RFQ number and/OR: The solicitation number (RFP etc.

UNICEF Purchase Order Number: n/a.

15) In Annex 2c section 3.4 ('Manufacturing Process Validation'), we are required to either submit validated batch size or any batch size planned for validation (with PV protocol reference number provided).

Answer: Please go ahead and submit the information that you have.

If a document is missing give a reason why it is missing and when you expect to share it.

16) If a forecast is not indicated in the Product list this means that the product is new to UNICEF. Therefore, no procurement history is available.

17) Is there any way of knowing the previously awarded prices:

Answer: Unfortunately, it is not possible to provide pricing from previous awards. However, you can review the UNICEF supply catalogue regarding indicative pricing for some products.

<https://supply.unicef.org/>

18) Penalty in case of failure to deliver. While I see the penalty for delivery of non-confirming items, there is no mention of failure to deliver or delay in delivery. Please advise the penalty for that.

Answer: Please see page 17 of the Contractual provisions where this information is provided. Below for your convenience.

Information on goods (including packaging) to 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, labeling and shipping requirements when submitting the Proposal.

6. Liquidated Damages

6.1 Any LTA-G awarded in connection with this Solicitation Document will include the following clause on liquidated damages:

"In addition to, and without prejudice to any of the other rights and remedies of UNICEF, if the Supplier fails to deliver the Goods under any Purchase Order in accordance with the stated time for delivery, or if UNICEF exercises its right to reject Goods that do not conform to the requirements in this LTA-G and the relevant Purchase Order, UNICEF may claim liquidated damages from the Supplier and, at UNICEF's option, the Supplier will pay such liquidated damages to UNICEF or UNICEF will deduct such liquidated damages from the Supplier's invoice(s). Such liquidated damages will be calculated as follows: one half of one per cent (0.5%) of the Price of such Goods for each day of delay, until delivery of conforming Goods, up to a maximum of ten per cent (10%) of the value of the relevant Purchase Order. The payment or deduction of such liquidated damages will not relieve the Supplier from any of its other obligations or liabilities pursuant to this LTA-G and the relevant Purchase Order".

PART V - PROPOSER REPRESENTATIONS

19) Taxes

a. It is noted that UNICEF is exempt from duties. Are there clearance charges (or any other charges) the supplier will need to pay? Does this differ between FCA up to port and delivery up to the UNICEF Copenhagen warehouse?

Answer: Please ensure to read Incoterms 2020 for DAP and FCA delivery terms.

20) Importing without a product license in the EU

a. As we do not have a product license in the EU, how do we go about it? i.e. Does either party need to apply for an importation license?

Answer: Once orders are being placed with an LTA holder and if importation licenses are required, both country office and supplier, who liaise with the staff member who issued the purchase order, work together to obtain the documentation required to establish the import/export license.

21) UNICEF Supply Division Copenhagen Addresses:

UNICEF Office address: Oceanvej 10-12, 2150 Nordhavn, Copenhagen, Denmark

UNICEF Warehouse address: Skagerrakvej 6, 2150 Nordhavn, Copenhagen, Denmark

22) Is it correct to assume that the Port of Copenhagen and the Copenhagen Airport (Kastrup) is the nearest seaport/airport to the warehouse?

Answer: The port for FCA delivery terms is the nearest sea/airport at supplier premises

23) Do we need to fill in both DAP AND FCA? Or quote either one of? (Columns K to O)

Answer: It is preferred to offer both DAP and FCA delivery terms.

24) It is acceptable to provide multiple offers for one product. Kindly ensure to clearly indicate in commercial offer form as per below, as an example:

Item no.	Material code	Product	Product Description	Preferred pack type and/or size (Proposer may offer other pack types / sizes for consideration)
320	U351201	Paracetamol	Oral liquid: 120 mg/ 5mL	60 to 100 ml bottle
320	U351201	Paracetamol	Oral liquid: 120 mg/ 5mL	60 to 100 ml bottle

25) *Question: Current LTA holder for 2 products listed, do we have to win the tender to continue this cooperation?*

Answer: You must ensure to provide an offer for these products against this tender to be evaluated and considered for award. If awarded your cooperation will continue under a new LTA reference number and replace your current LTA.

26) It is to note that estimated forecast based is based upon procurement history for the past 3 years.

27) If you currently hold an LTA with us and will offer for the same products, please provide the following Technical Documents only:

- Annex 2a- Manufacturer Technical questionnaire
- Annex 2f- Technical offer form and Annex 2g- Technical commitment declaration.
- Reference is made to Annex 2

28) *Is an audit required of the manufacturing side (factory) before bidding or after winning a tender?*

Answer: The audit of the manufacturing site is performed during the Technical evaluation stage.

Meaning, that the audit of the manufacturing site occurs after the bids have been received and the audit will determine whether a bidder is offered a contract or not

29) *What if during the concluded contract, after winning the tender, we change the place of manufacture?*

Answer: There will be a need for a full Technical evaluation of:

- The new manufacturing site
- Product dossier
- Sample evaluation

The contract will be put on hold pending the outcome of the Technical evaluation mentioned above; however, products manufactured from the old manufacturing site will still be acceptable.

- Refer to Annex 1 – UNICEF Technical requirements for Pharmaceuticals for more details.

30) For liquid dosage forms, such as solutions, suspensions and emulsions, these must be packed with a dose dispensing device (calibrated according to corresponding dose mentioned in PIL and SmPC and must be able to supply the minimal and maximal dose per single dose). Liquid dosage forms without dose dispensing device will be not be considered/disqualified.

Our product has dropper cap. Will this be accepted?

Answer: At this stage we are not able to respond to the question of whether it is acceptable or not. We will only be able to do so once we have received all the offers and we will then evaluate what has been offered.

Therefore, please provide offer to what you have.

Invitees can offer alternative pack sizes, strengths, and dosage forms ONLY if they are not able to offer the preferred ones. Alternative pack sizes, strengths and dosage forms will only be considered and evaluated if we do not receive adequate offers for our preferred pack size, strength, and dosage form.

31) a. If the products that you are offering us have **SRA market authorization**, then complete the following Technical Documents:

- Annex 2a- Manufacturers Technical Questionnaire
- Annex 2f- Technical offer form & Annex 2g- Technical Commitment declaration
- Samples (these will be requested later- to be advised)

b. However if the product being offered **does not have SRA market authorization**, then complete the following Technical Documents:

- Annex 2a – Manufacturers Technical questionnaire
- Annex 2c- Interagency questionnaire, Annex 2d, annex 2e
- Samples (these will be requested later- to be advised)

c. Definition of SRA:

A regulatory authority which is:

- a member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), being the European Commission, the US Food and Drug Administration and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency (as before 23 October 2015); or
- an ICH observer, being the European Free Trade Association, as represented by Swissmedic, and Health Canada (as before 23 October 2015); or
- a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement, including Australia, Iceland, Liechtenstein and Norway (as before 23 October 2015).

32) Do we have to implement the Falsified Medicine Directive (FMD 2011/62/EU).

Answer: We would prefer products with: Obligatory safety features – a unique identifier and an anti-tampering device - on the outer packaging of medicines.

We prefer products with SRA market authorization (Falsified Medicine Directive (FMD 2011/62/EU) applies to these products

33) Since the tender is basically for the whole world we would like to know if we would have to deliver to the headquarter or directly in the countries? Is serialisation necessary for the packs?

Answer: Deliveries will be both for DAP UNICEF Supply Division Warehouse as well as FCA nearest named sea/airport (to supplier premisses)

Regarding packing please see page 15 of Contractual provisions:

4.2 Packing, Packaging and Labeling. All goods must meet the requirements for packing, packaging, packing list and labelling of the goods set out on the UNICEF Supply Website (<https://www.unicef.org/supply/technical-specifications-packing-packaging-and-labelling>) and the additional requirements (if any) for packing, packaging, packing list and labelling set out in this Solicitation Document. This includes those requirements that apply to dangerous goods.

34) Regarding expiry of CPP, as an example on 4th of August 2021. Please confirm if this is acceptable.

Answer: Submit the documents that you have, as for those that you don't have please state the reason why and if you are going to provide them at a later date you need to state the same in your response

35) Regarding Annex 2a, point 5.1 "product Licenses":

5.1 Product licenses

Please enclose a list of all products manufactured by your company and authorised for sale on the domestic market (country of origin).

For each licensed product, please categorise as follows:

The product is marketed on the domestic market.

The product is licensed but not marketed on the domestic market.

The licence is for export only

Kindly also list licences for each product held in other countries:

Please indicate how much in percentage your export is of the total production:

Please also list the name of any contract manufacturer, when a product not is fully manufactured by your company

If possible, please attach an indicative price list.

36) We assume that it must be fulfilled only with the information of the drug product that we offer in this TENDER, could you please confirm?

Answer: Share the information for the product that you are offering in this solicitation.

37) For Annex 2a, part 5.1, we are required to enclose a list of all products manufactured, together with the licenses for each product held in other countries? We have 400+ products, not included those registered and marketed overseas. Is that compulsory to list all the products with its licenses in other countries? Or we can just list the products that we are intending to bid for UNICEF supply?

Answer: include the products that you have offered in this solicitation plus another 20 or so other

products.

a. Is it compulsory to indicate the percentage of our export of total production? From which to which year? In total amount of total quantity or total shipment?

Answer: at this point this information is not required.

b. For Annex 2a, part 5.2, for those documents that will be updated from time to time (eg: Finished product specification, starting materials specification), when requested, we need to submit the latest version or the document version applicable for submission?

Answer: The requested documentation should be available if requested for. The question you should answer is – are the documents available yes or no?

c. For Annex 2c, is the in-use stability data required for syrup?

Answer: Yes @ ambient temperatures.

If Not available explain the reasons why or when you will provide the data.

d. For Annex 2c, please provide word file called "Section 5 - Signature and Commitment" and "Copy of the power of attorney". It is not in the bid documents.

Answer: Section 5- is now annex 2d

e. For Annex 2e, it looks like is some kind of declaration to be filled after we get the tender from UNICEF, it includes UNICEF item description/ purchase order. Do we need to fill this out right now?

Answer: Yes. This is required to be completed by the FPP manufacturer.

f. For Annex 2f, it looks like a simplified checklist of Annex 2c, if deem not applicable, we will not fill up Annex 2f

Answer: Annex 2f – Technical offer form to be completed by bidders offering products that have SRA market authorisation or current LTA holders of that product (-reference to annex 2).

g. For Annex 2a, section 7, contact person for UNICEF, kindly advise on who should be the point of contact.

Answer: the person UNICEF talks to, on the day to day running of the contract if awarded.

39) Please see attached documents regarding pallets and packaging.

40) Vendors must submit a Certificate of Pharmaceutical Product (CoPP or CPP) for each FPP according to the WHO Certification Scheme, or an equivalent, issued by the National Regulatory Authority in the country of manufacture/origin. Recommended CoPP/ CPP format is specified in the relevant WHO

Technical Report Series (WHO TRS 863, earlier versions not acceptable). The CoPP required for tender technical evaluation can be for any country. Specific country CoPPs may be required and requested during the procurement process.

41) Can a supplier make an offer for only one product in this tender?

Answer: Yes

42) Regarding item 160: S1552421 Acetylsalicylic acid 75mg tabs/PAC-1x28, the pack size of 28 is preferred as this item is a part of the IEHK (Interagency Emergency Health Kit.)