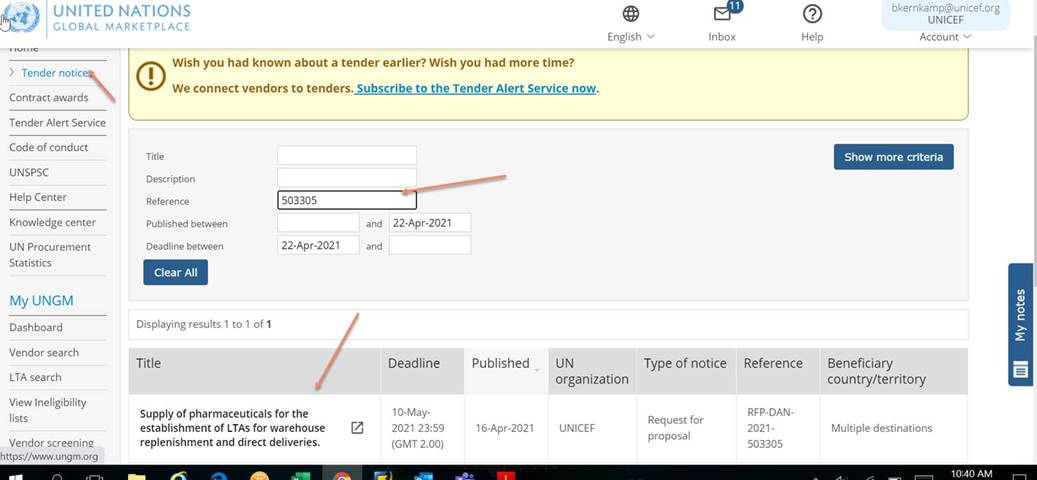
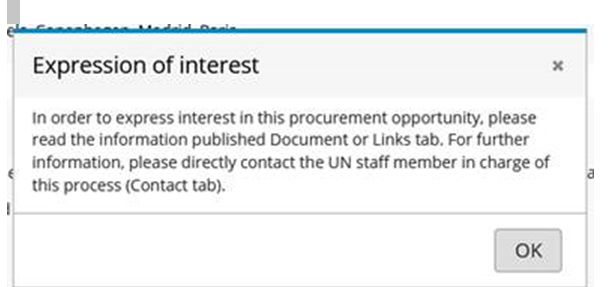
**Webinar 1 - Friday, 23 April 2021 - Questions and Answers**

1) Open links that I have provided using Google Chrome

2) You can also access tender through UNGM "Tender Notices" then in Reference Field enter "503305"

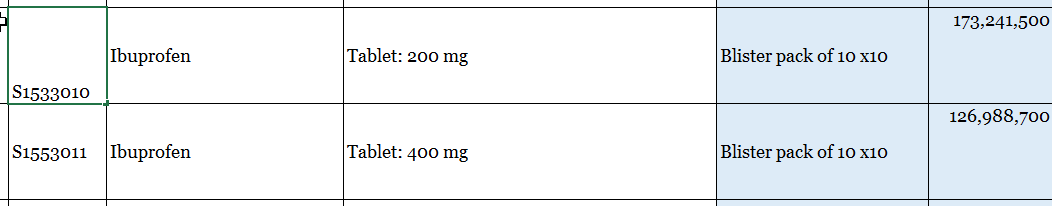


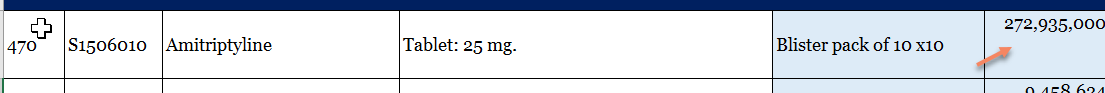
3) Expression of Interest



Some of you have received this pop-up, the most important is that you have access to the documents in order to prepare your proposal.

4) Forecast is based upon pack size except tablets, where forecasted number is total tablets over 3 year period. (revised forecast uploaded in Annex B, 03 May 2021.)





5) Tender samples submission

Response:

Quality assessment is done principally via technical assessment of pharmaceutical product dossiers, samples and manufacturer Good Manufacturing Practices (GMP).

Proposers will be contacted if and when such samples are required.

The deadline for the submission of samples will be indicated at the time of request.

Proposers will be contacted individually to provide samples and instructions to submit the samples will be sent with the request for the provision of samples.

6) WHO-GMP certificate:

Q: Our manufacturer have WHO-GMP Certificate plant which is issued by Drug Authority, Govt of India.

 Kindly let us know if above WHO-GMP plant is eligible to participate for this Tender

A: We would like to refer you to the tender document and its annexes: <https://www.ungm.org/Public/Notice/126014>

* In particular to Annex 1, Annex 2, Annex 2a.

These will provide you with an understanding of our requirements with regard to the manufacturing site and also what is expected of you

7) What are required filled bottoms for below items (response in red)

|  |  |  |  |
| --- | --- | --- | --- |
| **Item No. / Material No.** | **Product Name** | **Product Strength** | **Filled Volume required** |
| Item No. 60 (Material No.: S1555206) | Lidocaine Injection: 1%(hydrochloride) in vial.(preservative free)  Preferred 20ml | Lidocaine Inj. 10mg/ml (1%) | 2 ml **Or** 5 ml **Or** 10 ml **Or** 20 ml |
| Item No. 70 (Material No.: S1555280) | Lidocaine Injection: 2% (hydrochloride) in vial. (preservative free)  Preferred 50ml | Lidocaine Inj. 20mg/ml (2%) | 2 ml **Or** 5 ml **Or** 10 ml **Or** 20 ml |

Invitees can offer alternative pack sizes, strengths and dosage forms **ONLY** if they cannot 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 size, strength and dosage form.

8) Q1: Always as regards of the methadone in the annex b there are the following strengths: Oral liquid: 5 mg/5  mL and 10 mg/5  mL (hydrochloride). (Procured NS long ago) – it is a typing error or you are requesting the Methadone 5mg/ in 5 ml?  Generally the used strength is 5mg/ml in 1000ml and 10mg/ml in 500ml

Q2 As regards of the others products, like Ketamine, pethidine etc, may we offer our formulations and dosages?

Q3 The quantity request are in single unit?

A1: the information was extracted from the WHO EML (-there is no typo error)

***Tablet:*** *5 mg; 10 mg (as hydrochloride)*

***Oral liquid:*** *5mg/ 5mL; 10mg/ 5mL (as hydrochloride)*

***Concentrate for oral liquid:*** *5 mg/ mL; 10mg/ mL (as hydrochloride).*

Please feel free to offer the products that you have under your portfolio for consideration.

A2. Please feel free to offer what you have.

A3. Preference is for single unit; however you can offer the pack sizes that you have under your portfolio for consideration.

9) Technical dossiers submission process for manufacturers:

For detailed information, please refer ANNEX 2 – INSTRUCTIONS FOR TECHNICAL PROPOSALS

This section is intended to ensure that technical dossiers are submitted in a manner that they can be easily identified, stored, retrieved and assessed in an efficient manner.

All technical documents MUST be UPLOADED to a UNICEF SharePoint  site as per instructions in Annex 2h.

For your SharePoint site to be established, send email to [rshonhiwa@unicef.org](mailto:rshonhiwa@unicef.org)  with full name and address of bidder and INN descriptions of products of interest and their respective manufacturing sites

**Please ensure that you have made the commercial offer before sending the request for establishing SharePoint for uploading technical documents.**

**Please do not uploading any commercial offer or commercial information in Technical dossiers Submission**

10) Q: Does UNICEF have its own dossier we could use or you are looking for manufacturer which have their own Drug Master Files?

A: UNICEF has its own dossiers for product and Manufacturing site evaluation.  Please refer the link for the dossiers formats Link directly to tender in UNGM:

<https://www.ungm.org/Public/Notice/126014>

Quality assessment is done principally via technical assessment of pharmaceutical product dossiers, samples and manufacturer Good Manufacturing Practices (GMP).

1. Technical information required for technical evaluation is collected through the Interagency Finished Pharmaceutical Product Questionnaire (IAFPPQ- **Annex 2c**) which is based on the World Health Organization (WHO) Model quality assurance system for procurement agencies (MQAS)
2. Manufacturer GMP related information is collected through the UNICEF Technical Questionnaire for Pharmaceutical Manufacturers (**Annex 2a).**

Please refer Annex 1: UNICEF Technical requirements for Pharmaceuticals