

To: **All Economic Operators**

Date: 16th May 2022

Updated templates for Calls for Quotations and Calls for Tenders for the procurement of Medicinal Products and Medical Devices

Kindly be informed that as from this week, updated templates for the procurement of **Medicines** and **Medical Materials and Devices** are being introduced. These templates include revised conditions following discussions with the Chamber of Commerce (COC) and the Department of Contracts (DOC), as well as changes in line with the Medical Devices Directive.

Following please find the main changes in the revised templates:

- **Updated Selection Criteria (Section 1 of Document)** - In case of tenders for medical devices, economic operators who are not based within an EU country need subcontract with an EU based importer which satisfies the requirements of aforementioned articles.

Clause for EU based Importers Status – applicable for Medical devices (including active implantable medical devices), in vitro diagnostic medical devices and/or personal protective equipment)

A clause has been included in Clause 5(B)(a) of Section 1, to inform bidders that they must meet the requirements of the applicable regulations either on his/her own capacity, or through subcontracting. This is also reflected in Article 9.12 of the Special Conditions.

“A bidder, either on his/her own capacity, or through subcontracting, must meet the requirements of the applicable regulations (Medical Devices Regulation (Regulation (EU) 2017/745 – MDR)/In-Vitro Medical Devices Regulation (Regulation (EU) 2017/746 - IVDR) and personal protective equipment (Personal Protective Equipment Regulation (Regulation (EU) 2016/425 - PPER) as amended and/or as consolidated.”

- **Updated delivery period (Article 13 - Special Conditions)** – The initial delivery period for first order has been increased to 16 weeks from date of Confirmation of Order.

Initial delivery period for subsequent orders has been increased to 10 weeks from date of Confirmation of Order. Staggered orders will remain as is (with delivery to be made every four weeks).

- In line with the Circular issued by the DOC in 2021, the Contracting Authority is bound to procure 80% of the Contract Value (as at date of first award of Contract). Thereby, a minimum of 80% from each procurement cycle published will be utilised, e.g. for a procurement cycle awarded at a value of 50K Euro, – at least 40K Euro are bound to be taken up from that specific procurement cycle.
- **The Technical Offer Form** has been updated to include the requirements stipulated in the MDR. It is also being divided in two Parts – Part 1 is mandatory for all items and will include the specific details for the particular item/s being procured (as per specifications grid in Section 3 of the published dossier). Part 2 will be divided in 3 sections and bidders have to fill-in only one section as applicable (this part includes the standard questionnaire found in the current form).

With regards to the updated **Confirmation of Order template** in relation to supplies:

- The delivery period is being updated to reflect the changes in Article 13 of the Special Conditions (see 2nd point above). This will be applicable to tenders published with the updated conditions.

- **Staggered Orders**

Delivery period for staggered orders will remain as is (that is, at intervals of 4 weeks from date of first delivery).

The maximum number of staggered deliveries per Confirmation of Order will be limited to first delivery (3 months' supply) + 3 monthly top-ups. Thus, each Confirmation of Order can have a maximum of 4 deliveries.

Staggered orders are to be delivered accordingly as per quantities and on the respective delivery date as stipulated on the Confirmation of Order, even if it is low volume. The remaining shelf-life

conditions are to be in line with the respective published conditions and calculated on the due date for each respective delivery. It is pertinent that all suppliers stick to the date of the staggered orders in liaison with scheduling office, and that they refrain from supplying all staggered orders at one go.

- **Changes in Confirmation of Orders**

Once a Confirmation of Order is placed, any rescheduling will be communicated up to one month before delivery due date. CPSU is committing that there will be no cancellation, however there can be delivery postponements. In such case, the expiry date must be as per published conditions for all the different deliveries as per issued Confirmation of Order.

- **Last Confirmation of Order prior to expiry of contract agreement**

To avoid placing new Confirmation of Orders at the end of the contract period, the last Confirmation of Order can be placed only up to two months before the contract expires. (For example, if contract expires on 1st July 2022, last order must be placed by 1st May 2022.)

This is applicable only unless mutually agreed in writing through CPSU management, before the end of the contract period, between the Contracting Authority and the Economic Operator.

Should you have any queries regarding these updates, you are kindly asked to contact us on **info.cpsu@gov.mt**

Thanks in advance for your kind co-operation.

CPSU