

RfP Publication Reference: RFP021-6125/20

File Referene: CPSU4126/20

Date: Tuesday, 05 January 2021

For the attention of all interested Economic Operators

**Request for Participation (Negotiated)**  
**for Over-labelling Services of Medicinal Products**

## Clarifications No. 1

Reference is made to the Request for participation in caption.

Hereunder please find a clarification which is construed to form an integral part of the RfP procurement document.

**Clarification 1:** A lot of service providers are on shut down over the Christmas period. Could we kindly request an extension on the closing date of this RFP?

**Answer 1:** Dear all, please note that this publication is extended with further 9 calendar days and hence the new closing date for submission of bids will be Wednesday, 20<sup>th</sup> January 2021, The clarification period is extended till 11 January 2021 at 12pm.

**Clarification 2:** The Financial bid form refers to a unit cost. Can you confirm this is a unit cost per pack?

**Answer 2 :** For the interpretation of this publication, unit cost will represent price per pack.

**Clarification 3:** The RFP requests that the cost for translations and artwork be incorporated in the overall unit cost. This is separate and cannot be combined into a unit pack cost. Translations and artworks are charged per word and at different rates depending on the language being translated. Could we kindly request that the cost for translations be quoted separately within the financial bid form so that Economic Operators can offer a price;

- For translation and artwork per word for EU languages
- For translation and artwork per word for non-EU languages and
- Per unit pack for over-labelling/over-stickering?

**Answer 3:** CPSU is only interested in EU languages (non-EU languages will be requested on exceptional case basis as per Sec 3: pg 9 of RFP). Whilst the cost for manufacture, artwork and translation may be worked out per unit pack, these should be quoted at the best flat rate available per each order volume, so that both comparability and competitiveness can be assured.

**Clarification 4:** The RFP has been split into 3 sub-types, each split into .0, .1a and .1b as per section 1.1.1 Table 1. For subtype 1 and 2, there is no scenario where the ATD or serialisation will be required since the types of relabelling described do not involve works on the immediate packaging and hence do not require opening of the pack. As a result, subsection a and b for subtypes 1 and 2 are not applicable. Kindly confirm.

**Answer 4:** The applicant may opt not to quote for any subsection however these may then be awarded to other contractors. Subtype 1 – The CPSU may import English language packs which may require ATD (particularly following Brexit but also dual language, pharmacy only items or products parallel imported and over-labelled in country of source). Subtype 2. CPSU may import foreign language packs which may require ATD (specifically from countries such as Italy who qualify for derogation period wrt FMD features). In each case the serialization may or may not be required according to timelines for enforcement / implementation by the Malta Medicines Authority

**Clarification 5:** The RFP requests a unit pack price for subtype 3 which requests over labelling of the immediate packaging. A pack may contain various quantities which require over labelling of the immediate packaging. Could we kindly request that the financial bid form be updated to allow Economic Operators to provide;

- a price per unit of the immediate packaging
- a price per outer pack for overlabelling

**Answer 5:** A pack may indeed contain various quantities which require over labelling of the immediate packaging (usually between 1-20 injection vials or 1-4 blisters) however the number of packs is the most practical unit for cost based comparison due to fixed costs for per batch production runs (where variable costs are expected to create significant differences the most competitive price per unit volume should be offered).

Medicine packs requiring only outer pack for overlabelling should be quoted under subtype 2.0

Medicine packs requiring outer pack and immediate packaging for overlabelling should be quoted under subtype 3.0, whereby there is no scope for quoting separately as both are required for marketing this type of pack.

*The closing date of this Request for Participation is being extended till **Wednesday, 20 January 2021**. Date by which Economic Operators may submit any clarifications or request additional information from the Contracting Authority is thus being extended till **11/01/2021**. The last date on which additional information can be issued by the Contracting Authority is being extended till **12/01/2021**.*

*All other tender documents, conditions and requirements, which are not superseded by this Clarification, remain in place.*