

IN THE PUBLIC CONTRACTS REVIEW BOARD

3rd July 2023

Re: 058 - Objection - CT2319/2022 - Tender for the Supply of Rituximab Injections

Reply of the Central Procurement and Supplies Unit (CPSU) on behalf of the Department of Health to the reasoned application lodged by Vivian Corporation Ltd (the objector) for Lot 2 of the above captioned tender (CT2319/2022).

On the 19th of November 2022 a call for tenders for the supply of Rituximab Injections was issued.

A number of bids were submitted and a recommendation was made in favour of Mint Health Ltd (Recommended bidder) being the cheapest compliant bidder;

The Objector's offer was rejected on the basis of technical compliance for the reason below:

*"No data providing evidence of interchangability and switching with the currently procured biosimilar Truxima, as required in Section 3 - Specifications, Clause 1.1 Product Specifications, point 2.1 of the published tender dossier, was submitted by the bidder at tendering stage.*

*This is not rectifiable in line with Note 3 to Clause 5 of the published tender dossier."*

The objector felt aggrieved with the decision of the evaluation committee and filed its objection stating that the reasons for rejection were rectifiable.

CPSU respectfully disagrees with the Objection and is filing the below reply and submissions.

**Submissions**

1. CPSU respectfully submits that the evaluation committee's decision was legally correct for the below reasons:
2. The Technical Offer Form is a Note 3 document, meaning that this cannot be changed/rectified;
3. If the technical evaluation committee gives the objector the chance to clarify/rectify, this would effectively lead to a change in the Technical Offer Form in breach of established rules;
4. The Technical Specification, clause 2.1, reflected in the Technical Offer Form, requested:

*Rituximab (Truxima® or equivalent\*) 10mg/mL concentrate for intravenous infusion in 50mL vials. \*Equivalent in this case refers to other rituximab preparations with*



*evidence of interchangeability and switching with the currently procured biosimilar Truxima®, which data is to be submitted by the bidder.*

5. The instructions under the heading of Part 1 of the Technical Offer Form clearly state that:

*The information/technical specifications provided in the below table shall not be subject to rectifications.*

6. Moreover, the asterix (\*) in the specification quoted in paragraph 4 of this reply, leads to an important note highlighting the importance of this particular specification, which note states:

*Mandatory – Economic operators who do not adhere to the mandatory requirements established herein will be disqualified.*

7. The above all shows in CPSU's humble opinion that the Technical Offer Form is in its entirety a Note 3 document, particularly the clause in question and is thus not rectifiable as decided by the evaluation committee.

8. The objector implicitly admits that the reference to the literature which it provided does not prove interchangeability with the currently procured biosimilar Truxima®, when it bases its objection not on the argument that the indicated clause in the SPC (Section 2) does prove that the offered product is interchangeable with the biosimilar Truxima®, but on the argument that since reference is made to technical literature, this should be rectifiable in line with Note 2 rules.

9. Without prejudice to the submissions made above, that the Technical Offer Form is subject to Note 3, therefore not rectifiable, should this Honourable Board consider this part of the Technical Offer Form as subject to Note 2 rules, the decision of the technical evaluation committee would still hold as the information submitted would still be non rectifiable under Note 2 rules.

10. The General Rules Governing Tenders provide in clause 16.3, page 16 that:

*Rectifications are classified under Note 2 as follows:*

*2) Tenderers will be requested to either clarify/rectify any incorrect and/or incomplete documentation, and/or submit any missing documents within five (5) working days from notification.*

11. The above cited clause outlines the instances when rectifications are permissible under Note 2, which are 3:

- Incorrect Documentation
- Incomplete Documentation
- Missing Documentation

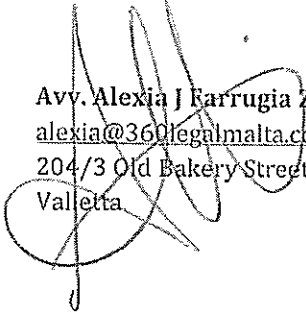
12. In its Technical Offer Form, the objector, when asked to refer to the technical literature to corroborate interchangeability, stated: Refer to point 2 of the submitted SmPC.
13. This SmPC is a document which due to its nature, cannot be incorrect, neither incomplete, thus the first 2 instances where Note 2 allows for rectification, are not applicable.
14. The third instance is missing documentation. This would have possibly been applicable if the document which the objector referred to, was not submitted with the original submission, which is not the case in this situation, as the SmPC was indeed submitted by the objector thus there was no missing documentation.
15. The same clause of the General Rules Governing Tenders, clause 16.3, page 16, also states that:

*Without prejudice to the possibility of requesting rectifications vis-a-vis Literature, if the Literature submitted with the Technical Offer does not corroborate the offer submitted, the tenderer shall be disqualified.*


This is what the evaluation committee did, and thus the objector cannot argue that the evaluation committee did not follow the law, the tender document and the General Rules Governing Tenders.

CPSU is hereby reserving its right to present further evidence both written and orally to further their submissions in relation to this objection.

In view of the above, the objection lodged by the objector ought to be rejected in full, whilst the decision of the Contracting Authority and the Evaluation Board confirmed, and the relevant deposit forfeited.



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