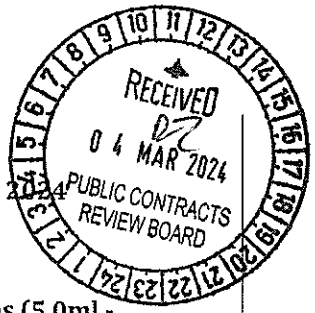
IN THE PUBLIC CONTRACTS REVIEW BOARD



2nd March 2024

Re: 418 - Objection Cft 020-3432/23 - Supply of Hypodermic Syringes (5.0ml - 6.0ml)

Reply of the **Central Procurement and Supplies Unit** (CPSU) on behalf of the Department of Health to the reasoned application lodged by ProCare Ltd (the objector).

On the 4th of April 2023 a call for tenders for the supply of Supply of Hypodermic Syringes (5.0ml-6.0ml) was issued.

A number of bids were submitted and a recommendation was made in favour of the offer made by Krypton Chemists Ltd (Recommended bidder) being the cheapest priced offer satisfying the administrative and technical criteria;

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

Not accepted. Samples submitted have no labelling printing on packaging. Samples submitted are not compliant with the minimum labelling requirements which are the batch no/Lot Number, Expiry date, serial number and Global trade item number. These requirements have been requested in the tender dossier Sections 29.5 and 29.6.

The objector felt aggrieved with the decision of the evaluation committee and filed its objection based on 7 grievances.

CPSU humbly disagrees with the grievances raised and is hereby replying in the same order of the grievances raised.

Submissions

On the First Grievance – About the Factual incorrectness of the reason given

1. In its first grievance the objector states essentially that it is not true that the product offered does not have labelling on the packaging, and goes on to say that the samples submitted are very clearly labelled;

2. The samples handed to the evaluation committee were individually packed in a blank packaging without a single word printed on the packaging as will be demonstrated to this Honourable Board;

3. Moreover, the secondary packaging also does not include the labelling as requested for medical devices;

4. The objector attempts to disregard the primary packaging of each and every syringe and consider the secondary packaging as the bulk packaging. This is not permissible and is factually incorrect;

5. The bulk packaging as described by the objector is a pack of 2400 syringes. From a practical point of view, a ward, let alone a nurse, will not be given a pack of 2400 syringes, and thus it is essential that the information requested by the tender document is on each and every packaging of individual syringes;

6. Moreover and without prejudice to the above, the tender document clause 29.6 of the Special conditions requires that labelling is on each and every product, and not on the secondary packaging:

Each product requires the following details:

Global Trade Item Number (GTIN) (Issued in full compliance with GS1 standards)
Batch/lot number
Expiry date
Serial Number

7. The contracting authority is by no means considering the product as a medicinal product, however it is undauntedly a medical device and the offered product also fails to meet the regulations applicable for medical devices[1], particularly those relating to packaging;

8. Without prejudice to the above, the main point of this objection and of the evaluation remains that the labelling above mentioned in paragraph 6 is requested for **each product** and the objector failed to provide this;

9. For the above reasons and submissions, this first grievance ought to be rejected.

On the Second Grievance – About the lack of clarity of the decision

10. In its second grievance the objector claims that the decision of the contracting authority was not clear in its reason for refusal provided.

11. The objector goes on to state that *"samples submitted have no labelling printing on packaging"* and *"samples submitted are not compliant are not compliant with the minimum labelling requirements"* are contradictory and left the objector at a loss;

12. If there is a party that should know the product well, this is the objector and the contracting authority is to say the least, very surprised by these claims. If the product does not have any labels printed, how can it ever meet the minimum label requirements? This is natural and logic and the contracting authority does not see any ambiguity and lack of clarity in all of this;

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[1] REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

13. For the above reasons and submissions, this second grievance ought to be rejected

On the Third Grievance – About the fact that the Contracting Authority acted Ultra Vires

14. In its third grievance the objector states that the tender document did not confer upon the contracting authority the right to reject technically compliant offers. This is factually incorrect as the contracting authority can reject technically compliant offers if there are cheaper technically compliant offers;

15. Subordinately, if what the objector meant was that the contracting authority cannot reject compliant offers on the basis of non-compliance, CPSU naturally agrees, however in this case, as already explained, the objector's product was not compliant and thus CPSU acted correctly and definitely did not act ultra vires;

16. For the above reasons and submissions, this third grievance ought to be rejected.

On the Fourth Grievance – About the fact that the contracting Authority changed the evaluation criteria and technical specifications while deciding on the Objector's offer

17. In its fourth grievance objector states that contracting Authority changed the evaluation criteria and technical specifications. CPSU rebuts this unfounded claim which was not substantiated in any way;

18. In part of this grievance objector says that the syringes offered are not medical devices, which leaves CPSU wondering as to what these syringes are;

19. Syringes are from their very nature medical devices classified in class I or Class IIa under the Medical Devices Regulations[2] and what the evaluation committee did was, apply the tender conditions applicable to medical devices, and to conditions applied for all products supplied, in full respect to all the general procurement;

20. For the above reasons and submissions, this fourth grievance ought to be rejected.

On the Fifth Grievance – About the obligation to give reasons for decisions

21. In its fifth grievance the objector submits that the contracting authority failed to give reasons for its decision;

22. CPSU respectfully submits that if the contracting authority failed to give reasons for its decision, a 9-page letter of appeal on substantive grievances would surely not be possible;

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[2] Regulation (n1)

23. As this Honourable Board will surely note, the evaluation committee did give sufficient reasons for the rejection of the objector's offer as required by law and in line with all the principles of administrative and natural justice;

24. For the above reasons and submissions, this fifth grievance ought to be rejected;

On the sixth Grievance - About the obligation to exercise discretion in a just and proper manner

25. Had the rejection been on the basis of sample testing, debating the extent of the evaluation committee's discretion would have been much more understandable;

26. Whilst definitely acknowledging the fact that evaluation committees have an element of discretion in their evaluation process, this is limited especially in this case and similar cases, where the product is deemed not to be compliant not due some failure during the use but do to criteria which can be objectively ascertained;

27. If the tender document is requesting that the medical devices are labelled in accordance with legislation in force and that the elements of clause 29.6 should have been fulfilled, and the product supplies does not even have a label, then discretion plays a little role, if it plays any role at all, as the decision was taken on objective grounds.

28. For the above reasons and submissions, this sixth grievance ought to be rejected;

On the seventh Grievance – About the fact that the Contracting Authority did not act according to procedure

29. As the objector fails to substantiate or at least explain this grievance, CPSU rebuts as unfounded in fact and at law and for this reasons, this seventh grievance ought to be rejected.

CPSU hereby reserves its right to present further evidence and submissions both written and orally to further substantiate their reply in relation to the said application throughout the hearings.

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

Avv. Alexia J Farrugia Zrinzo
alexia@360legalmalta.com
204/3 Old Bakery Street
Valletta

Avv. Leon Camilleri
leon@360legalmalta.com
204/3 Old Bakery Street
Valletta