PUBLIC CONTRACTS REVIEW BOARD

Case 1001 – CFT 019-10153/16 – Tender for the Supply of Blood Administration Sets

The Publication Date of the Call for Tenders was 1 July 2016 whilst the Closing Date for Call of Tenders was 1 August 2016. The Estimated Value of the Tender, (Exclusive of VAT) was € 22,796.80.

Eight (8) Bidders have submitted Eleven (11) offers for this Tender.

On 5 October 2016, Procare Ltd filed an Objection against the decision of the Central Procurement and Supplies Unit to award the Tender to Drugsales Ltd for the price of € 24,079.12 (Exclusive of VAT) against a deposit of € 400.

On 1 November 2016, the Public Contracts Review Board composed by Dr Anthony Cassar as Chairman, Dr Charles Cassar and Mr Richard A Matrenza as members convened a Public Hearing to discuss the Objection.

The Attendance for this Public Hearing was as follows:

Appellant – Procare Ltd

Mr Pierre Calleja	Representative

Recommended Bidder – Drugsales Ltd

Ms Claudia Dimech	Representative
Mr Stephen Farrugia	Representative
Mr Philip Moran	Representative

Contracting Authority – Central Procurement and Supplies Unit

Ms Marika Cutajar	Chairperson, Evaluation Board
Ms Josette Camilleri	Secretary, Evaluation Board
Mr Donald Attard	Member, Evaluation Board
Dr Stefan Zrinzo Azzopardi	Legal Representative

The Public Contracts' Review Board Chairman, Dr Anthony Cassar, opened the Public Hearing by explaining what happened in a previous Public Hearing for Case 999 wherein a Technical Witness was summoned under oath and explained that in the latter's opinion the Product Code was as important as the Technical Literature and the Product Description when identifying the quality of the Products submitted.

Following this opening statement, Dr Cassar invited the Appellants to state their case in front of the Public Contracts Review Board.

Mr Pierre Calleja, on behalf of Procare Limited, argued that the Letter of Rejection dated 28 September 2016 said that their offer has been rejected because the "*Declaration of Conformity is invalid since there is no item code*".

Following their Objection, the Appellants have also received a Reasoned Letter of Reply from the Central Procurement and Supplies Unit which stated that, "*The said regulation provides that "This declaration must cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference, and must be kept by the manufacturer*".

Mr Calleja continued by saying that in their Declaration of Conformity, their providers have quoted clearly the Product Name. This shows that Procare Limited was conform to the Tender requisites.

Dr Stefan Zrinzo Azzopardi, Legal Representative for the Central Procurement and Supplies Unit said that the Evaluation Board has followed the advice given by Ing Michael Cassar, Head of Marketing and Survaillance Unit, Malta Competition and Consumer Affairs Authority.

The way Mr Calleja quoted and the way with which the Evaluation Board referred to the matter was a question of interpretation on whether the Product Code which had to be done compulsory. In order for the Evaluation Board to have the absolute comfort that the product submitted was the product which would have been eventually submitted must have a product code.

The Central Procurement and Supplies Unit will leave it to the Public Contracts Review Board to determine whether the Evaluation Board interpreted correctly the advice on the basis of the documentation submitted and whether the latter was enough for the correct decision to be made concluded Dr Zrinzo Azzopardi.

At this stage, the Public Hearing was closed.

This Board,

Having noted the Appellant's Objection, in terms of the "*Reasoned Letter of Objection*" dated 5 October 2016 and also through their verbal submissions during the Public Hearing held on 1 November 2016 had objected to the decision taken by the Pertinent Authority, in that:

a) **Procare Ltd contends that the reason given by the Contracting Authority for the rejection of his offer was incorrect. In this regard, the appellant maintains that his offer did quote the product name which was illustrated in the Technical Literature submitted by the Latter and in view of this, the Contracting Authority was in a position to identify the product being offered.**

Having considered the Contracting Authority's "*Letter of Reply*" dated 24 October 2016 and also their verbal submissions during the Public Hearing held on 1 November 2016, in that:

a) **Central Procurement and Supplies Unit maintains that during the Evaluation Process, the Evaluation Board took into consideration the EU directive regarding medical devices, in that, the product had to**

include its name and product code. In this respect, the Appellants failed to submit the product code.

Reached the following conclusions:

1. **This Board, after having examined the relative documentation and heard submissions from the parties concerned opines that, the issue at stake, is the interpretation of Clause 2 of Annex V of the EU Directive 93/42/EEC which states that the "*Declaration of Conformity*" must "*cover one or more medical devices manufactured, clearly identified by means of product name, product code or other unambiguous reference, and must be kept by the manufacturer*".**

   This Board opines that this particular case entails the assessment of the identification procedure of a medical product to ensure conformity with the specific requirements in accordance with the EU Directive relating to the medical devices. The certificate of conformity had to be submitted by the prospective bidders to assure the Contacting Authority that the product offered can be identified from the submissions made and conforms to the specific dictated Tender Requirements.

In this regard, this Board contends that the EU Directive 93/42/EEC states that to be able to identify the product, there has to be stated a name, product code or other clear identification letters.

In this particular case, Procare Ltd did submit the name of the product accompanied with, the Technical Specifications as contained in the Technical Literature. Thus, the product being offered could be definitely identified.

At the same instance, this Board credibly contends that through the possible identification of the product, conformity could be validly evaluated without the listing of the product code.

This Board also notes that the full description of the product was submitted together with the name and Technical Specifications of the same. In this regard, the Evaluation Board, although acting on the advice of Technical Advisors, could have still validated the Appellant's Offer for further evaluation.

2. **This Board would like to treat the interpretation of the Clause of the EU Directive 93/42/EEC as follows:**

- **The main objective of this clause is to ensure that the "*Declaration of Conformity*" shall include enough information to enable the identification of the product being conformed. The Directive states that:**

  "*The identification of the object of the Declaration of Conformity, (eg. Name Type, Date of Manufacture <u>or</u> Model Number of a Product....)*"

  In this regard, this Board opines that what the Clause is requiring is a clear identification, either by name type or date of manufacture or product code. It does not state that these three identification factors should be cumulative or collective but any one of the requirements mentioned will suffice.

  In this particular case, this Board opines that Procare Ltd did submit sufficient information to enable the Evaluation Board to identify the product offered and assess its conformity and in this respect, this Board upholds the Appellant's Grievance.

In view of the above, this Board finds in favour of Procare Ltd and recommends that:

i) The Appellant's offer is to be re-integrated in the Evaluation Process;

ii) The deposit made by the Appellant is to be fully refunded.

Dr Anthony Cassar Chairman	Dr Charles Cassar Member	Mr Richard A Matrenza Member

4 November 2016