PUBLIC CONTRACTS REVIEW BOARD

Case 1000 – CFT 019-10153/16 - Tender for the Supply of Cannula IV Size 20g

The Publication Date of the Call for Tenders was 11 March 2016 whilst the Closing Date for Call of Tenders was 11 April 2016. The Estimated Value of the Tender, (Exclusive of VAT) was € 115,920.

Nine (9) Bidders have submitted Twelve (12) offers for this Tender.

On 30 September 2016, Medina Healthcare Ltd filed an Objection against the decision of the Central Procurement and Supplies Unit to award the Tender to Pharma-Cos Ltd for the price of € 95,220 (Exclusive of VAT) against a deposit of € 580.

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 – Medina Healthcare Ltd

Dr Michael Camilleri	Legal Representative
Dr Richard Camilleri	Legal Representative

Recommended Bidder – Pharma-Cos Ltd

Mr Stephen Attard	Representative
Mr Claudio U Martinelli	Representative
Mr Marcel K Mifsud	Representative

Contracting Authority – Central Procurement and Supplies Unit

Ms Marika Cutajar	Chairperson, Evaluation Board
Ms Rose Aquilina	Secretary, Evaluation Board
Mr Patrick Ghigo	Member, Evaluation Board
Dr Stefan Zrinzo Azzopardi	Legal Representative

The Public Contracts' Review Board Chairman, Dr Anthony Cassar opened the Public Hearing by explaining in the Public Hearing for Case 999 a Technical Witness was summoned and he testified under oath that the Product Code was important because in order for one to identify the product, this must have the Description, Technical Specifications and in fact the Product Code. These are a combination of verifications which confirm whether the Products submitted were those required by the Contracting Authority.

Following this Clarification, Dr Anthony Cassar, Chairman of the Public Contracts' Review Board asked the Appellants to state their case.

Dr Richard Camilleri, Legal Representative, Medina Healthcare Ltd, opened by saying that his offer was cheaper than the one submitted by the Recommended Bidder, Pharma-Cos Ltd, by € 25,000. His client's offer was refused due to a missing item code in their Declaration of Conformity submitted.

The Reasoned Letter of Reply submitted by the Central Procurement and Supplies Unit referred to the Medical Devices Directive issued by the European Union. One had to take Schedule 5 of this Directive and compare it with the reasons given by the Contracting Authority in this said letter and the Declaration of Conformity submitted by Medina Healthcare Ltd and whether these conform to the words in Schedule 5.

Dr Camilleri continued by saying that Medina Healthcare was conform to Schedule 5. First and foremost, the latter Schedule states, "*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*".

This declaration, continued Dr Camilleri, shows that the reasons for refusal of Medina Healthcare Ltd's offer submitted by the Contracting Authority do not stand with what Schedule 5 says because if one had to be careful to the words used in the regulations, the main words used were, "*product name, code or unambiguous reference*". Grammatically, a conjunctive word was used.

The second argument was whether the product submitted by Medina Healthcare Ltd had any item codes or unambiguous references. The product offered showed clearly a Serial Number which was 13 IV Cannula whilst the description cited "*A Safety IV Cannula with Catheter with or without injection valve and with or without wings.*" The numbers 14-26 indicate the needle range.

Dr Richard Camilleri continued his argument by stating that clauses 9a and 13.1 of the Medical Devices Directive use the phrase, "*Family of Products*". For a certificate to be issued, a Declaration of Conformity must be submitted.

Dr Camilleri then quoted two decisions by the Hon Court of Appeal, namely Cassar Petroleum Services vs Gozo Channel, (decided on 12 January 2014), and Ballut Blocks vs Hon Minister for Resources and Rural Affairs, (decided on 31 May 2013) which determined that the Evaluation Board had to keep in mind the Principle of Proportionality when issuing a recommendation for award. On this same basis, Clause 7.1.2 of the Tender Document allows for Clarifications to be sought should the need arise.

Dr Stefan Zrinzo Azzopardi, Legal Representative for the Central Procurement and Supplies Unit, countered that although he understood what was submitted with respect of the Principle of Proportionality, here we are discussing medical equipment and therefore the standards and guarantees requested were to be of a high level.

The Evaluation Board was correct in evaluating the Tender. It was not a question of discarding Tenders due to technicalities. Here there is also a question of interpretation. The Malta Consumer and Competition Affairs state that it is unacceptable to submit products without any product code. The Evaluation Board, continued Dr Stefan Zrinzo Azzopardi, must be assured that the Product Codes submitted correspond with the Declaration of Conformity.

Dr Richard Camilleri, Legal Representative for Medina Healthcare Ltd, appreciated the fact that the witness previously heard was an expert in the Regulation but one cannot discard the Legal Points of view. If the Central Procurement and Supplies Unit wanted to be sure of having high standards, they should have referred to Schedule 5 of the Medical Devices Directives. In a Tender one has to be clear in what is requesting. This was a question of legal interpretation.

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) Medina Healthcare 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, Medina Healthcare 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 Medina Healthcare 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 Medina Healthcare 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