PUBLIC CONTRACTS REVIEW BOARD

Case 999 – 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, Cherubino 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 – Cherubino Ltd

Dr Francis B Cherubino	Representative
Dr Danica Caruana	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 requesting to both parties to focus their arguments on the Product Code following which he invited the Appellants' to make their submissions.

Dr Danica Caruana, the Legal Representative for Cherubino Ltd, opened by stating that on 4 July 2016, her clients have received a letter from the Contracting Authority which stated that they were rejected on financial grounds. This decision was revoked on 5 August 2016 where first through an e-mail and then through an official letter, the Central Procurement and Supplies Unit informed the Appellants that their offers were being rejected because, "*The Declaration of Conformity was invalid due to missing items code*". The same letter informed also that Pharma-Cos Ltd was being recommended for award.

Dr Caruana continued to explain that subsequently Cherubino Ltd filed their Objection which stated that the Declaration of Conformity was in line with the relevant EU directives. In their Reasoned Reply dated 24 October 2016, the Contracting Authority also speaks about these directives wherein "*the standards to be followed for such equipment are defined as per Subsidiary Legislation 427.24 Medical Devices Regulations*".

The Reasoned Reply also refers to Schedule 5 of this directive which was eventually transposed in Maltese Legislation and which says 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*".

The Declaration of Conformity, continued to explain Dr Caruana, is a certificate issued by the manufacturer or its agent if the latter is not based at an EU state which confirms that the product which is issued in the market is conformed to the above mentioned directive.

Dr Caruana argued that the Declaration of Conformity presented by her clients, Cherubino Ltd, gives a clear indication of the products in question. If one had to look at the Tender Literature, one can see the "*IV Cannulas for Advanced Needle Technology which are available in the following specifications*". These are divided into two because these can come in two different filters and then one can find the Product description.

The products submitted by Cherubino Ltd reflect exactly the Declaration of Conformity submitted with the same according to Dr Caruana. The mentioned products were the same products shown in the submitted Technical Specifications.

Besides, Cherubino Ltd sought a clarification from Ing Sarah Caruana from the Malta Competition and Consumer Affairs Authority who defined the Declaration of Conformity as a single Declaration drawn by the manufacturer to demonstrate the fulfilment of the EU requirements related to a product. Dr Danica Caruana concluded by wondering why the Evaluation Board was insisting on the Product Code when the Legislation does not provide for this.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit opened his submissions by saying that effectively this Appeal stands on whether the Declaration of Conformity needs the Product Code or not and how to interpret the ruling issued through the EU Directive. The Evaluation Board felt that without any product code, the Declaration of Conformity was incomplete.

At this point, Ing Michael Cassar, ID 142564, a Director of the Market Surveillance Department within the Malta Competition and Consumer Affairs Authority was summoned to testify under oath.

Dr Stefan Zrinzo Azzopardi for the Contracting Authority, started by asking the witness whether the Authority which he forms part of has any remit with regards to medical devices for which the answer was in the affirmative.

Dr Zrinzo Azzopardi then queried whether there is any verification procedure in order to eventually confirm the adequacy of the product for which Ing Cassar replied that they follow the EU Directive for Medical Devices. The latter says that products must have the CE mark and the Authority has to verify whether this makes sense or not through a procedure.

Dr Zrinzo Azzopardi asked the witness whether the manufacturer had to make a declaration. Ing Cassar replied that it was part of the procedure for the manufacturer to make a Declaration of Conformity which shows that the product is conform to the Legislations.

Dr Stefan Zrinzo Azzopardi for the Central Procurement and Supplies Unit then asked what elements this Declaration must have for which the witness replied that the directive obliges for certain information such as the manufacturer's name, signature, date, product information and full reference of the product to be clearly illustrated in this one pager.

Dr Zrinzo Azzopardi proceeded to show the witness the certificate submitted by the Appellants and asked the witness whether in his opinion this was a complete one or not. Ing Cassar replied that the Declaration submitted had two missing items. First and foremost it does not make any reference to the standard EN ISO 13485, which is a standard qualification for quality management system. The latter obliges the manufacturer to be conforming and certified according to this standard.

Dr Stefan Zrinzo Azzopardi then asked the witness to comment on the product identification, with special reference to this case. The witness replied that the product submitted by Cherubino Ltd does not give him assurances that it is conforming with the Medical Devices Directorate because it does not refer to the EN ISO 13485.

The witness continued to explain that the Directive was amended in 2007 wherein it explained how the products had to be conforming to the Directive and there were new requirements on the same.

Dr Stefan Zrinzo Azzopardi commented that for a product to be identified, the Directive mentions a number of requirements. He then asked the witness whether in his opinion, the certificate submitted by Cherubino Ltd was complete or not for which Ing Cassar replied that it was not.

Dr Zrinzo Azzopardi then asked the witness to name any elements which can assure the latter of any product identification for which the witness replied that he needed to know the model and the things which are specifically made for this product.

Dr Anthony Cassar, Chairman Public Contracts Review Board, asked Ing Cassar whether the product submitted by Cherubino Ltd can be identified as being conform to the Directive for which the witness replied that the latter product was not specific enough to be identified.

Dr Danica Caruana, the Legal Representative for Cherubino Ltd, asked the witness to confirm that the product could not be identified unless it has a number or a code for which Ing Cassar replied that the code must be correlated with the information submitted.

Dr Caruana asked confirmation that the description which was given was not the same as the literature submitted by the Appellant for which Ing Cassar replied that he couldn't commit himself to saying that the description corresponds with the literature submitted.

Dr Danica Caruana then said that the description clearly indicates to which product it was referring for which Ing Cassar replied that it refers to a family of products given by the same manufacturer. Therefore, Dr Caruana continued, the Declaration of Conformity submitted by her clients, clearly indicated to which products it was referring.

Dr Caruana quoted Schedule 5 Clause 2 B of the EU Regulation 427.44 regarding the Medical Devices which *inter alia* states, "*product name, product code or other unambiguous reference*". The description illustrates what the Company was offering through the reviews submitted.

Dr Caruana then referred to the e-mail sent by Eng Sarah Caruana to Cherubino Ltd dated 27 September 2016 wherein the latter confirms that, "*if the medical device can be clearly identified by its product name and product description, under the Medical Devices Directives an article code is not a requirement*".

Dr Anthony Cassar, Chairman of the Public Contracts Review Board remarked that if Cherubino Ltd has submitted the Product Description and the Product Literature, one wonders what value the Product Number has. Ing Michael Cassar replied that the Directive asks for either the Product Name, or the Product Code or other unambiguous reference.

Dr Anthony Cassar, Chairman of the Public Contracts Review Board commented that therefore this is a question of how one interprets the English Language in that clause. He then proceeded to ask the witness whether he would recognise the model would he have been given a picture of it and its Technical Specification for which the reply was that the two might correspond but not exclusively.

Dr Anthony Cassar, Chairman of the Public Contracts Review Board then stated that the Declaration of Conformity submitted by the Appellants does not refer to another Company.

Dr Francis Cherubino who was representing Cherubino Ltd said that all these Objections to the decision taken by the Contracting Authority shows that everybody has understood the matter in another way.

Dr Stefan Zrinzo Azzopardi, Legal Representative of the Central Procurement and Supplies Unit concluded that the Evaluation Board had sought consultations and followed the advice given in a correct way. Now it was up the Public Contracts Review Board to determine whether the Central Procurement and Supplies Unit had followed the procedure in awarding this Tender

At this stage, the Public Hearing was closed.

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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) **Cherubino 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, Cherubino 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.

  At the same instance, this Board cannot but note the E-Mail dated 27 September 2016 by Ing Sarah Farrugia from the Malta Competition and Consumer Affairs Authority, confirming that the medical devices can be clearly identified by its product name and product description and that under the Medical Devices Directives, an <u>article code</u> is not a requirement.

In this particular case, this Board opines that Cherubino 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 Cherubino 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