PUBLIC CONTRACTS REVIEW BOARD

Case 1339 - CFT 020-1269/18 – Tender for the Supply of Controlled Plaque Rupture Balloons

The publication date of the call for tenders was the 11th December 2018 whilst the closing date of the call for tenders was 7th January 2019. The estimated value of the tender (exclusive of VAT) was € 25,200.

On the 27th June 2019 A.T.G. Co Ltd filed an appeal against the Central Procurement and Supplies Unit as the Contracting Authority contesting the decision to disqualify them as their bid was considered technically non-compliant. A deposit of € 400 was paid.

There were four (4) bidders.

On 8th August 2019 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Mr Lawrence Ancilleri and Mr Carmel Esposito as members convened a public hearing to discuss the objections.

The attendance for this public hearing was as follows:

Appellants – A.T.G. Co. Ltd

Dr Franco Galea	Legal Representative
Mr Oliver Attard	Representative

Recommended Bidder – V.J. Salomone Pharma Ltd

Mr Christopher Treeby Ward	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Marco Woods	Legal Representative
Ms Rita Zammit	Chairperson Evaluation Committee
Ms Claudine Aitken	Member Evaluation Committee
Ms Pauline Sultana	Representative

Dr Anthony Cassar, Chairman of the Public Contracts Review Board, welcomed the parties and invited submissions.

Dr Franco Galea Legal Representative of A.T.G. Co Ltd said that according to the refusal letter sent to Appellants their bid was not acceptable as there was no reference to harmonisation

standards in their submission as requested in Section 2.3.ii of the Technical specifications. Harmonisation standards are the basis on which a manufacturer obtains the Declaration of Conformity (DoC), copy of which was tabled as Doc 1. According to European Directive 93/42 once a product is certified by the accreditation board it is definite that that product meets the required standards. If in any doubt the Contracting Authority, in line with Note 7, could have sought clarification regarding the technical literature. If the product certification was not acceptable the Authority should have sought either clarification on the submissions or rectification on any missing information. There was also the additional possibility of the Authority consulting the Institute of Standards and Metrology to verify that the DoC meets the required standards.

Dr Marco Woods Legal Representative of the Central Procurement and Supplies Unit referred to page 25 of the tender documents where it is specifically laid out that beside the DoC bidder was to submit, as a separate document, reference to the relevant harmonized standards used. Only the DoC was submitted without any reference to the harmonized standards. The literature lists do not include harmonized standards as part of the specifications. Clause 2 (b) does not apply in this case as it refers to missing information without referring to the required standards – hence the reason why no rectification was sought, apart from been prejudicial to other bidders.

Dr Galea said that the DoC was based on standards – seeking rectification would not have prejudiced anyone as the product was the same and clarification or rectification would not change the product or the terms of the tender.

Dr Woods mentioned that it was very clear that the literature lists were additional information, whilst the DoC and the references to harmonization standards were an essential part of the submissions.

Ms Claudine Aitken (344097M) called as a witness by the PCRB testified on oath that she was a deputy charge hand nurse and part of the evaluation committee. She confirmed that the Appellants' DoC made no reference to harmonization standards which are the International Standardization Organisation (ISO) yardstick incorporated in the European Union (EU) directives. Witness had no technical expertise in medical devices but was aware that standard 13485 was a quality management system that was general to all medical devices. In reply to a question witness stated that she was not familiar with the accreditation process of the EU but reiterated that standard 13485 covers the medical equipment requested in the tender.

Dr Galea said that if the Contracting Authority had any doubts as to whether the DoC meets the required standards they should have referred the matter to the Institute of Standards and Metrology, which is a state body, for confirmation of EU competence and accreditation.

Dr Woods emphasised that the tender requisites wanted both a DoC and a reference to standards. If Appellants felt that the DoC met both requirements the easiest thing would have been to seek clarification. Bidders accepted in full the terms of the tender when they submitted the bid and were aware that there are missing documents.

Dr Galea again said that there was no need for reference to standards as the DoC confirms that those standards exist. If Appellants' shortcomings fell under Note 3 then Contracting Authority should have asked for clarification – if they fell under Note 2 (b) they could have asked for rectification.

In his concluding remarks Dr Woods said that a clarification would not have provided the harmonization standards whilst the literature lists only provide additional information over and above the technical specifications requested in Note 4.

Mr Christopher Treeby Ward Representative of the Recommended Bidder said that the issue of a DoC means that the relevant product must have reached the required standards; however the terms of the tender have to be adhered to and bidder must provide what is requested immaterial of other considerations.

The Chairman thanked the parties for the submissions and declared the hearing closed.

This Board,

having noted this objection filed by A.T.G. Co Ltd (herein after referred to as the Appellants) on 27 June 2019, refers to the claims made by the same Appellants with regard to the tender of reference CFT 020-1269/18 listed as case no 1339 in the records of the Public Contracts Review Board, awarded by Central Procurement and Supplies Unit (herein after referred to as the Contracting Authority).

Appearing for the Appellants: Dr Franco Galea

Appearing for the Contracting Authority: Dr Marco Woods

Whereby, the Appellants contend that:

a) **Their offer was discarded by the Authority for the simple reason that the Declaration of Conformity (DoC) did not make reference to the harmonised standard. In this respect, Appellants maintain that since the DOC was submitted, the Authority could have asked for a clarification in this regard.**

This Board also noted the Contracting Authority's 'Letter of Reply' dated 12 July 2019 and its verbal submissions during the hearing held on 8 August 2019, in that:

a) **The Authority insists that the tender document clearly and explicitly requested the submission of reference to the harmonized standard used. In this regard, Appellants submitted only the DoC without any reference to standards applicable. At the same instance, the Authority could not request missing documentation, during evaluation stage.**

This same Board also noted the testimony of the witness namely,

Mr Claudine Aitken Deputy Charge Hand Nurse duly summoned by the Public Contracts Review Board.

This Board has also taken note of the documents submitted by A.T.G. Co Ltd which consisted of document 1 – EU Directive re: Medical Devices.

This Board, after having examined the relevant documentation to this appeal and heard submissions made by the parties concerned, including the testimony of the witness duly summoned, opines that, the issue that merits consideration is the non-submission of reference to a harmonised standard, by Appellants.

1. **First and foremost, this Board would emphasize the very fact that the Authority has the rights to stipulate any condition or specification in the tender document, provided these are reasonable and attainable and in this particular case, these basic conditions were strictly complied by the Authority.**

2. **The tender document clearly requested the following:**

   "A valid Declaration of Conformity for product being offered and refences to the relevant harmonized standards used (applicable if product falls under the medical device directive)."

   The product being requested does fall under the directive of medical devices, as was acknowledged by Appellants themselves, in fact

Appellants submitted the following declaration referring to the directive 2007/47/EC.

"We herewith declare that the above-mentioned products are in conformity with the provisions of the Council Directive: 93/42/EEC of June 1993 as amended by Directive 2007/47/EC and applicable standards for medical devices. The list of applicable standards for the products identified above is maintained in technical documentation of the device."

Through this declaration, Appellants are referring to the applicable standards as maintained in the technical documentation of the device; referring to the technical literature. This Board notes that there is no reference as to which harmonised standard the product is classified to fall under, so that mandatory information was missing from Appellants' technical offer.

3. **This Board, as had on numerous occasions, would again emphasize the importance which must be given by the tenderer, to ensure that, what is being requested in the tender dossier, must be submitted. In this respect, this Board opines that the mandatory requisite to refer to the appropriate harmony standard, was clearly denoted. At the same instance, it is the**

duty and obligation of the economic operator to ensure that submissions made by same should respect the conditions laid out in the tender dossier.

4. **With regards to Appellants' contention that, the Evaluation Committee should have asked for a clarification, this Board would strongly point out that, the Evaluation Committee cannot seek information which was not submitted in the original submission. At the same instance, clarifications on missing information cannot be made at the evaluation stage, as otherwise, there will be a rectification. In this contest, one has to stress the fact that, clarifications should never be made to rectify or include missing information which should have been submitted, in the first place. Clarifications should be made only, as a tool to clarify already submitted information.**

5. **With regards to Appellants' contention that the Evaluation Committee should have sought advice from the Institute of Standards and Metrology, this Board would point out that the Evaluation Committee, in this particular case, were not obliged to refer or try to justify missing information from Appellant's offer.**

In conclusion, this Board opines that:

a) **The tender dossier clearly and specifically requested that the DOC should refer and state the harmonised standard which the product refers to.**

b) **The Evaluation Committee could not ask for a clarification, as the reference to harmonised standards, was missing from Appellants' offer.**

c) **The Evaluation Committee quite appropriately adhered to the principles of self-limitation and equal treatment.**

d) **Appellants' were aware of what the Authority requested and in this regard, failed to submit a mandatory requirement stipulated in the tender dossier.**

In view of the above, this Board,

i. **upholds the decision of the Contracting Authority in the award of the tender,**

ii. does not uphold Appellants' contentions,

iii. directs that the deposit paid by appellants should not be refunded.

Dr Anthony Cassar	Mr Lawrence Ancilleri	Mr Carmel Esposito
Chairman	Member	Member

22 August 2019