PUBLIC CONTRACTS REVIEW BOARD

Case 1288 – CFQ 020-20200/2018 – Supply of Low Profile Gastronomy Kits Sz 16Fr

The publication date of the call for tenders was the 27th April 2018 whilst the closing date of the call for tenders was 7th May 2018. The estimated value of the tender (exclusive of VAT) was € 6,161.

On the 25th January 2019 Cherubino Ltd filed an appeal against the Central Procurement and Supplies Unit as the Contracting Authority objecting that their bid had been excluded as it was not technically compliant. The Contracting Authority subsequently decided to cancel the tender. A deposit of € 400 was paid.

There were three (3) bidders.

On 21st March 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 – Cherubino Ltd

Dr Francis Cherubino	Representative

Contracting Authority – Central Procurement and Supplies Unit (CPSU)

Dr Marco Woods	Legal Representative
Ms Marika Cutajar	Chairperson Evaluation Committee
Mr Donald Attard	Member Evaluation Committee
Mr Eman Gravino	Representative

Dr Anthony Cassar Chairman of the Public Contracts Review Board welcomed the parties and invited them to make their submissions.

Dr Francis Cherubino Representative of Cherubino Ltd stated that the tender was for the supply of Gastronomy Kits in Sizes 14Fr, 16Fr and 18 Fr. Since the Company had tendered for all three sizes and appealed against the CPSU decision to reject offers on all three sizes he would be dealing with all three appeals in parallel. Cherubino Ltd was notified that the reason for the rejection was the non-mention of ISO 13485 in the Declaration of Conformity (DoC) submitted in the tender. This was a misunderstanding of the purpose of a DoC which was a declaration by the manufacturer of a product that it meets all the requirements as requested by the European

Directives. The award of the CE mark is preceded by prior quality assurance regarding manufacturing, design, safety and all matters relating to the product. ISO 13485 is therefore included in the CE mark and there is no need to mention it in the DoC. Section 4 of the Technical Specifications in the tender (tabled as Doc 1) or the literature list makes no reference to the need to submit an ISO – when it is specifically required the Contracting Authority asks for it. The content of a DoC is dictated by EU directives and ISO 13485 is not included in these directives. This is confirmed in an exchange of emails with the Malta Competition and Consumer Affairs Authority (MCCAA) (tabled as Doc 2). It is beyond the scope of the CPSU to ask for it and it follows from that, that there was no justification to cancel the tenders.

Dr Marco Woods Legal Representative of the Central Procurement and Supplies Unit referred to para 22, section 2.3.2 of the technical specifications which goes further than the DoC, namely references to harmonisation standards which had to be submitted.

The Chairman pointed out that the Authority's letter quoted the lack of ISO as the reason for rejection.

Mr Mark Zammit (425874M) called as a witness by the Contracting Authority testified on oath that he is the Advanced Pharmacy Practitioner at the CPSU. He stated that it was not necessary for the ISO to be shown in the DoC but should have been referred to in the harmonised standards. When questioned by the Chairman witness said that a decision to change the specifications was the reason for the cancellation of all three calls for quotations.

Mr Donald Attard (304763M) called as a witness by the Contracting Authority testified on oath that he was one of the evaluators of the tenders. He confirmed that nowhere in the tenders' submissions was there any reference to ISO 13485. The committee was advised during the evaluation process that there was need to change the tender specifications.

Dr Cherubino said that it was very clear that the need to provide an ISO number was not a requisite in the tender. Subsequently the tender had been cancelled as the CPSU had decided to change the specifications. It was very unfair to cancel tenders after evaluation – there was work involved for the tenderers and besides bid prices became public knowledge.

Dr Woods stated that the Appellant had not objected to the cancellation of the tenders. He re-iterated that the harmonised standards, which include ISO 13485, made no reference to it in the submissions by Appellants and the Authority was correct in rejecting and subsequently cancelling the tender. He referred to PCRB Case 1211 which he claimed also dealt with the lack of ISO submissions in a DoC.

Dr Cherubino referred to the submitted DoC (tabled as Doc 3) which clearly states that the products 'are in conformity with all the requirements foreseen by the 93/42 Directive on Medical Devices...', and this had been confirmed by the MCCAA. The reason for refusal was incorrect and once repealed leads directly to the uplifting of the cancellation of the tenders.

The Chairman thanked the parties for their submission and declared the hearing closed.

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This Board,

having noted this Objection filed by Cherubino Limited (herein after referred to as the Appellants) on 25 January 2019, refers to the claims made by the same Appellants with regard to the Tender of Reference CFQ 020-20200/2018 listed as Case No 1288 in the records of the Public Contracts Review Board, awarded by the Central Procurement and Supplies Unit (herein after referred to as the Contracting Authority).

Appearing for the Appellants: **Dr Francis Cherubino**

Appearing for the Contracting Authority: **Dr Marco Woods**

Whereby, the Appellants contend that:

a) **their main objection refers to the fact that their offer was rejected due to the alleged claim that their product's "*Document of Conformity*" (DOC), did not make reference to the relative ISO Standard. In this regard, Appellants maintain that, apart from the fact that the Tender Document did not request ISO Standards, the Appellants' products "*Document of Conformity*" was fully compliant according to the relative European Directives.**

This Board has also noted the Contracting Authority's 'Letter of Reply' dated 1 February 2019 and also its verbal submissions during the Public Hearing held on 21 March 2019, in that:

a) **The Central Procurement and Supplies Unit refers to Paragraph 22, Section 2.3.2 of the Technical Specification which clearly states that, the "*Document of Conformity*" must refer to the relative harmonisation standards and in this regard, Cherubino Limited's Product Document of Conformity did not make reference to such standards.**

This same Board also noted the testimony of the witnesses duly summoned by the Central Procurement and Supplies Unit, namely:

1. **Mr Mark Zammit**
2. **Mr Donald Attard**

This Board has also taken note of the documents submitted by Cherubino Limited which consisted of:

1. **Document 1 – Literature which makes no reference to ISO 13425;**
2. **Document 2 – Correspondence between Cherubino Limited and the Malta Competition and Consumers Affairs Authority (MCCAA);**
3. **Document 3 – A document submitted by Cherubino Limited**

This Board, after having examined the relevant documentation to this Appeal and heard submissions made by the parties concerned, including the testimony of the technical witnesses, opines that, the issue that merits consideration is the document submitted by Cherubino Limited.

1. **This Board would refer to the reason given by the Contracting Authority for the Appellants' product rejection, which states that:**

   "*Not accepted. No reference is made to ISO 13485 in the Declaration of Conformity or in any other document submitted*."

   In this regard, reference is being made to Paragraph 22 Section 2.3.2 of the Technical Specifications, which states the following:

   "*2.3 Medical Materials & Devices*

   The following technical documentation is to be submitted online through the prescribed Tender Response Format and by using the Tender Preparation Tool provided:

   i) Detailed product technical document/datasheet for product being offered;

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

   For products that do not fall under the medical device directive, a declaration is to be submitted confirming the classification of the product, together with certificate of compliance with the applicable legislation, (as applicable)"

   From the testimony of Mr Mark Zammit, this Board was credibly informed that there was no need for the particular ISO to be referred

to, in the "*Document of Conformity*"; however, reference should have been made to the harmonised standards. In this regard, this Board justifiably opines that the reason given by the Contracting Authority was not correct as, ISO 13485 was not mentioned, as a requirement in Clause 2.3.2 above. In this respect, this Board would respectfully remind the Contracting Authority that, as has been instructed previously by this same Board on numerous occasions, the Central Procurement and Supplies Unit should always give specific reasons for the rejection of an offer. At the same instance, this Board notes that although Clause 2.3.2 above states that the "*Document of Conformity*" should refer to the harmonised standards, it does not mention which particular standard the latter document should refer to in this regard. This Board directs that the technical specifications should be more explicit and detailed so that the exact requirements are easily transmitted to the prospective Bidder.

2. **This Board was also made aware that the Tender was recommended for cancellation due to a change in the specifications. In this respect, this Board opines that the technical specifications should not be changed or modified to include additional ones, at the delicate stage of the**

Evaluation Process but, should be well and truly established prior to the Publication of the Tender.

One has to acknowledge and appreciate the fact that, in the preparation of offers, economic operators undergo great work and expense, so that, it is not fair and transparent to cancel the Tender at Evaluation stage, when all the quoted prices are public. In this respect, this Board directs the Contracting Authority to avoid such similar circumstances.

In conclusion, this Board opines that:

a) **although Clause 2.3.2 indicated that the Document of Conformity had to refer to the harmonised standards, it did not specify the requirement of ISO 13485;**
b) **the Contracting Authority's reason for the rejection of the Appellants' offer was incorrect;**
c) **the Contracting Authority should have established the exact requirements prior to the publication of the Tender and not determine to change the specifications during the Evaluation process.**

In view of the above, this Board,

i) **upholds the contentions made by Cherubino Limited, in that, the "*Document of Conformity*" which they submitted did not request the reference to ISO 13485;**

ii) **directs that the Tender is to be cancelled due to the fact that it relates to health issues and that the technical specifications need to be changed**

iii) **directs that the deposit paid by the Appellants is to be fully refunded.**

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

28th March 2019

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