PUBLIC CONTRACTS REVIEW BOARD

Case 1019 – CFT 019-10029/2015 – Tender for the Supply of Custom Packs for Cataract Surgery

The Publication Date of the Call for Tenders was 22 January 2016 whilst the Closing Date for Call of Tenders was 22 February 2016. The Estimated Value of the Tender, (Exclusive of VAT) was € 118,800.

Seven (7) Bidders have submitted offers for this Tender.

On 10 October 2016, Medina Healthcare Ltd filed an Objection against the decision of the Central Procurement and Supplies Unit to award the Tender to Charles de Giorgio Ltd for the price of € 97,878 (Exclusive of VAT) against a deposit of € 490.

On 7 February 2017, the Public Contracts Review Board composed by Dr Anthony Cassar as Chairman, Mr Lawrence Ancilleri and Mr Carmel Esposito as members convened a Public Hearing to discuss the Objection.

The Attendance for this Public Hearing was as follows:

Appellant – Medina Healthcare Ltd

Mr Andrew Cutugno	Representative
Mr John Soler	Representative
Dr Frank Testa	Legal Representative

Recommended Bidder – Charles de Giorgio Ltd

Mr Neville Schembri	Representative
Dr Maxine Montanaro	Legal Representative

Contracting Authority – Central Procurement and Supplies Unit

Ms Ruth Saliba	Chairperson, Evaluation Board
Ms Renee Mifsud	Secretary, Evaluation Board
Mr Mario Vella	Member, Evaluation Board
Dr Stefan Zrinzo Azzopardi	Legal Representative

Following an introduction by The Public Contracts' Review Board Chairman, Dr Anthony Cassar, the Appellants were invited to make their submissions.

Dr Frank Testa, the Legal Representative for Medina Healthcare Ltd opened by saying that the Letter of Objection written by his clients and dated 10 October 2016 said that contrary to what the Letter of Rejection dated 3 October 2016 said his clients submitted all the items which were requested in the Tender.

If one had to see the Technical Specifications which there were in the Tender, one would see that it was not true that the Appellants' bid was non-compliant. If one had to analyse the Letter of Rejection, there were two reasons which did not appear to be shown in the Technical Specifications.

Dr Testa continued by saying that the third paragraph of the Letter of Rejection *inter alia* stated that,

"*It is only the contents of the bottle which are sterile and the bottle itself canot be opened in a sterile way by the scrub nurses to be used during the surgery itself therefore not according to specs*"

The Appellants felt that the message which they were getting from the Contracting Authority was that it was only the contents which were sterile whilst the packaging was not, which meant that it was an aseptic packaging.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board asked about the meaning of aseptic packaging for which Mr Andrew Cutugno on behalf of Medina Healthcare Ltd replied that it meant that the product was sterile but it also had a package on the outside which would protect its sterility. That meant that even the outside of the bottle would have to be sterile in order for the product to be used in a sterile environment.

Dr Frank Testa, the Legal Representative for Medina Healthcare Ltd continued by saying that his argument was that here there was an added element, the whole package had to be sterile. The same paragraph of the Letter of Rejection continued by saying *inter alia* that,

"*BSS offered is labelled as "not for injection".*

If one had to see Section 4 of the Tender Document, continued Dr Testa, the latter required,

"*Sterile Custom Packs for Cataract Surgery plus BSS 15mls"*

The Appellants' Legal Representative continued by saying that the Letter of Objection mentions that he was offered this product as a separate product. This was not contested but there was a Request for Clarification wherein the answer was that the product could have been given in a separate way.

What Medina Healthcare Ltd were contesting was the non-sterility of the package. In order to understand the Tender Document, the Appellants had to make an assumption which shouldn't be the case especially in medical products as there should have been clear indications of what was requested by the Central Procurement and Supplies Unit.

Dr Frank Testa continued by saying that the issue discussed here regarding sterility. What the Appellants were strongly contesting was the addition of the fact that even the packaging had to be sterile and this did not result in the Tender Document and the specifications submitted by his clients clearly result in the sterility of the products offered.

The Appellants were saying that the specifications in the Tender Document indicated clearly which products were requested and these were submitted as they are also found in the market. If the Contracting Authority requested aseptic packaging the Appellants would have given them aseptic packaging.

Dr Frank Testa continued by mentioning the other contested issue, that the BSS offered was deemed by the Central Procurement and Supplies Unit was "*not for injection*" and argued that there was nowhere in his client's product which indicated such condition. There were procedures which need this product to be done.

Dr Testa was understanding that the fact that this product was given separately was not contested by the Contracting Authority because apart from the fact that it was clearly indicated in the Technical Specifications that it was given separately, there was also a Request for Clarification about this which had as an answer,

"*Item can be supplied out of the sterile pack or as a separate item*".

The Appellants' Legal Representative continued arguing that they were clear on the fact that according to the Technical Specifications given, his clients had submitted a Technically compliant product and they were not agreeing with the reasons given in the Technical Specifications.

Dr Frank Testa then referred to a decision issued by the European Courts of Justice on case C19/2000 issued on 18 October 2001 which involved S I A C Construction Ltd and the County Council of the County of Mayo wherein a directive was given on the procedure of contracts in public works. Although this case was about different facts, a similar concept was being debated. The directive *inter alia* stated that,

"*the award criteria must be formulated in the contract documents or contract notice, in such a way as to allow all reasonably well-informed and normally diligent tenderers to interpret them in the same way.*"

This meant that if the Contracting Authority gave a particular type of specifications to three people and all three interpret the specifications differently, one would have failed with the specifications since there cannot be room for interpretation otherwise the Evaluation Board was being given discretion to disqualify bidders on specifications which weren't requested as it happened to the Appellants.

Dr Frank Testa for Medina Healthcare Ltd felt that the Technical Specifications should have been made in a way which was clear to all interested bidders. In this case, one couldn't disqualify the Appellants. The latter were reasonable when interpreting the contest of what was requested and if the Contracting Authority was not clear about the specifications, the Appellants shouldn't have been disqualified.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit opened his statements by submitting that he had listened to Dr Testa's submissions where he was justifying why his client's bid should not have been disqualified. The specifications were clear because what the Central Procurement and Supplies Unit was requesting was Sterile Custom Packs for cataract surgery.

What was being discussed should be taken in the context of cataract surgery. The Appellants were right in saying that the product offered, the BSS 15mls, was available and ready for use but its aim was not for cataract surgery. When putting everything in this context, one had to understand that one had to take everything within the ambit of this surgery.

Dr Zrinzo Azzopardi continued by arguing that if his clients were requesting things for cataract surgery in the same instance one had to submit the product offered and the BSS 15mls. One had to be sure that if BSS 15mls and the packaging used in an operating theatre was available, if there were any doubts a clarification should have been sought.

The Technical Specifications were linked to a cataract surgery therefore all the submitted products had to be submitted in the ambit of the latter, in the ambit of an operating theatre where everything had to be sterile. If there was a request for BSS 15mls in an ambit of cataract surgery, it was standard that the item had to be injectable.

At this point, Dr Stefan Zrinzo Azzopardi summoned Mr Mario Vella, the Chairman of the Ophtalmolgy Department holding ID Card 409066 M as a witness to testify before the Public Contracts Review Board under oath.

Following Mr Vella's testimony, Dr Frank Testa, the Legal Representative for Medina Healthcare Ltd stated that he had no doubts of the witness' technical capacities but his difficulty was in the way the Tender was drafted as what was requested and what was actually wanted weren't the same things.

Dr Testa insisted that the word assumption cannot be used in this case. One cannot come in the position that there was the need to assume something. The Technical Specifications had to be clear in such a way that the Bidder had to submit what the Contracting Authority actually requested.

What the Appellants were saying was that they gave what the Contracting Authority requested. If the latter was not clear enough then the Medina Healthcare Ltd shouldn't be sanctioned continued Dr Frank Testa who was eventually wondering whether whoever replied to this clarification had consulted with the doctor or not prior to sending the reply.

The clarification's answer was that the BSS, "*can be supplied out of the sterile pack or as a separate item.*" The Appellants were insisting that in the industry, this is called as an aseptical package. All this had threw them in the opposite way of where they had wanted to because if they received an answer that the item "*can be supplied out of the sterile pack*", the Contracting Authority wasn't consistent if then they sanctioned the Appellants on submitting a product as requested by the Clarification.

Dr Frank Testa, the Legal Representative of Medina Healthcare Ltd was not contesting the medical use of the product. His clients have read the Tender, studied the contents of the product submitted and ticked all the boxes. If there was another box which should have been

ticked, this should have been done by the Contracting Authority but the Appellants ticked all the necessary boxes. Dr Testa invited the Public Contracts Review Board to read both the decision C 19/2000 issued by the European Courts of Justice and also the reply to the Clarifications concerned.

The Appellants insisted on the fact that nowhere in the Tender Document there was requested that the BSS was to be submitted together in the pack. It was the contents which should have been sterile. If a particular specification was requested, and aseptic packaging is a common practice in the medical camp, the Appellants were wondering why aseptic packaging was not requested immediately.

Dr Frank Testa insisted that this gave his clients no option but to assume that the packaging had to be aseptic and with reference to the sentence issued by the European Courts of Justice, the Appellants could not risk to make any assumptions. Secondly, with regards to the injection issue, if there were any doubts in that regard, there was no doubt in the Letter of Rejection that,

"*BSS offered is labelled as "not for injection"*.

There was nowhere in Section 4 of the Technical Specifications which show that the item requested had to be good for injections. If one had to assume that the product needed had to be for that usage that would be another story, concluded Dr Frank Testa.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit replied that with regards to the latter point issued by the Appellants, the following sentence, namely, "*Therefore this cannot be used as intraocular irrigating solution*", had also to be considered.

As explained clearly by Mr Vella, the question regarding the internal usage was because if this solution is used in a closed eye situation the product would be good but if it was to be used during a surgery, one had to use a different product.

Dr Zrinzo Azzopardi concluded by saying that the request was made within the ambit of cataract surgery. Therefore if the request was for cataract surgery, the fact that one had a situation requiring an operating theatre show that the Contracting Authority was insisting that all specifications requested from the Bidders were clear both from the packaging side and from the contents.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board then asked whether the Central Procurement and Supplies Unit was insisting that the Tender Specifications were clear enough for the suppliers to know exactly what was requested for which Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit replied in the affirmative, adding also that his clients need this because it was within the ambit of a cataract surgery. This was also confirmed by Mr Mario Vella, who previously testified under oath.

Dr Frank Testa, the Legal Representative for Medina Healthcare Ltd insisted that they did not agree with this because the Tenders could have been done in an easy way by asking the Bidders to give them all which was required for a cataract surgery to be done. The Contracting Authority should know well enough what specifications were needed.

The Tenders were made in this way because the Contracting Authority knew what was needed and it cannot disqualify the Appellants. If what the latter submitted was not enough, the next time the Tender should have been issued in a better way concluded Dr Testa.

At this stage, the Public Hearing was adjourned to Tuesday 21 February 2017 at 09:00 wherein the Public Contracts Review Board will transmit the decision taken for this Objection verbally and then distribute a hard copy of the same to all parties concerned.

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This Board,

Having noted this Objection filed by Medina Healthcare Ltd (hereinafter referred to as the Appellant) on 10 October 2016, refers to the Contentions made by the latter with regards to the award of Tender of Reference CFT 019-10029/2015 listed as Case No 1019 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 Appellant: Dr Frank Testa

Appearing for the Contracting Authority: Dr Stefan Zrinzo Azzopardi

Whereby, the Appellant contends that:

a) The product submitted was Technically Compliant and in accordance with what was requested in the Tender Document. In

this regard, Medina Healthcare Ltd maintains that the Tender Specifications did not specify clearly what the Central Procurement and Supplies Unit is now requesting.

At the same instance, the Appellant insists that it is not proper for its offer to be rejected, primarily due to the lack of clarity in the Technical Specifications as dictated by the Contracting Authority and in this context, the Appellant had to make assumptions in formulating the offer.

b) There was nowhere in the Technical Specifications which indicate that the product requested was to be used for injections. Again, in this regard, due to the non-clarity of the Technical Specifications, Medina Healthcare Ltd JV had to assume the Application of the Product to be offered.

This Board also noted the Contracting Authority's "*Letter of Reply*" dated 2 February 2017 and its verbal submissions during the Public Hearing held on 7 February 2017, in that:

a) The Contracting Authority contends that the utilisation of the Tendered product was clearly denoted for cataract surgery, in that it

was common knowledge to all importers of such activity that the product must be fully sterile to be applied in operating theatres. In this regard, Medina Healthcare Ltd's product was not suitable for the intended yet knowledgeable application.

b) **With regards to the Appellant's Second Contention, the Central Procurement and Supplies Unit insist that since the product had to be applied during surgery, Medina Healthcare Ltd's product could not be used as an "*intraocular irrigating solution*", i.e. with the eyes open during surgery.**

This same Board also noted the Testimony of the witness namely, Mr Mario Vella duly summoned by the Central Procurement and Supplies Unit.

This Board, after having considered the merits of this case, arrived at the following conclusions:

1. **After having heard the Technical Testimony and examined the relative documentation relating to this Appeal, this Board would like to respectfully state that since this is a product of a medical nature,**

one had to analyse the Testimony of the Medical Expert in depth when treating the Appellant's Grievances.

With regards to Medina Healthcare Ltd's First Grievance, this Board would like to first and foremost point out that the Tender Document indicated from the very start that it was for the "*Supply of Custom Packs for Cataract Surgery*".

In this regard, this Board would like to justifiably point out that even the Technical Data Sheet as submitted by the Appellant; the main heading for the item description denoted the purpose of the usage for this particular product.

It is common knowledge that suppliers of such medical activities would be aware of the strictly dictated specification due to the product's application during surgery.

In this regard, this Board credibly establish the fact that Bidders were aware of what they had to offer. If, on the other hand, Medina Healthcare Ltd had some doubts about the product, he had all the remedies at law to seek clarification.

From the Expert's Testimony, it was made vividly clear that the product had to be utilised during surgery so that all the contents and packaging of the product had to be sterile. The Appellant's product did not consist of a complete sterile component which could be applied during surgery.

At the same instance, this Board expresses the fact that the Technical Specification could have been drafted in a more direct way, although the Appellant's Contention that he had to make assumptions should not stand, as he had all the remedies available if in doubt and in this respect, the Appellant did not avail himself of such a remedy.

Another issue in this regard, which this Board noted was that the Appellant in his Letter of Objection did state that he can supply the product, as it was described and explained, so that, it is an established fact that the Appellant's submitted offer does not comply with what was requested.

In this regard, this Board feels that the Appellant was aware from the beginning that the Tender was issue for the "*Supply of Custom Packs*" to be utilised during cataract surgery, so that the sterilisation of the whole component was of the greatest importance.

At the same instance, this Board credibly feels that if Medina Healthcare Ltd was in doubt, it was their decision to make assumptions which product they were submitting instead of seeking clarifications prior to the submission of their offer.

In this respect, this Board is justifiably convinced, through the Expert's Testimony that the Appellant's product is not technically compliant for the intended application, the latter of which was clearly noted in the Tender Document and in this regard, there were remedies which the Appellant did not avail of, instead of making assumptions. In this regard, this Board does not uphold Medina Healthcare Ltd's First Grievance.

2. **With regards to the Appellant's Second Contention, this Board would like to justifiably emphasize the fact that the product requested was clearly denoted to be used for surgery. All Bidders were aware that this product will be utilised during cataract surgery and in this regard, this fact alone, according to the Expert's Testimony, indicated that the product will be applied inside the eye and this can only be through injecting the "*Balanced Salt Solution*".**

The Expert confirmed that the product submitted by the Appellant was not labelled that it can be used as an "*Intraocular irrigating solution*", in other words inside the eye. All Bidders were aware that the requested product was for cataract surgery and the latter procedure is carried out inside the eye. In the case of surgery, such a solution must be labelled in such a way that it can be used "*intravenously*".

In this regard, it was evidently and technically proved that the Appellant's product was not compliant and therefore, this Board credibly establishes the fact that such assumptions made by the Appellant in submitting his offer could have been avoided through clarifications.

In this instance, this Board opines that the incorrect offer made by the Appellant was not due to the non-clarity of the Technical Specifications since it is a known layman's knowledge that a cataract operation is carried out inside the eye and therefore the "*Balance Salt Solution*" to be applied must be labelled specifically for that purpose.

It was obvious that the fact that the application of such a solution had to be carried out "*intravenously*" shows that the solution would be

applied through an injection. Medina Healthcare Ltd's product was not suitable for such an application. In this regard, this Board rejects the Appellant's Second Contention.

3. **This Board respectfully refers to the decision of the European Courts of Justice wherein the directive was,**

"*The Award Criteria must be formulated in the Contract Documents or Contract Notice, in such a way as to allow all reasonably well informed and <u>normally diligent</u> Tenderers to interpret them in the same way*"

In this regard, this Board would like to point out that the issue in the quoted case was the award criteria and not the drafting of the Technical Specifications in a Tender. However, the same decision clearly denotes that, normally, prospective Bidders who are diligent in their activity, would understand the dictated Technical Conditions and in the case under this Appeal, this Board strongly feels that the Appellant was aware that the product was intended to be applied during cataract surgery so that the Technical Specifications were vivid enough for the Appellant which proper product was to be supplied.

In view of the above, this Board confirms the decision taken by the Central Procurement and Supplies Unit; finds against Medina Healthcare Ltd and recommends that the deposit paid by the latter should not be refunded.

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

21 February 2017