PUBLIC CONTRACTS REVIEW BOARD

Case 1307 – CT 2266/2017 - Tender for the Supply of Electro Surgery Suction/Irrigation Device

The publication date of the call for tenders was the 19th December 2017 whilst the closing date of the call for tenders was 23rd January 2018. The estimated value of the tender (exclusive of VAT) was € 152,177.04

On the 18th January 2019 ProHealth Ltd filed an appeal against the Central Procurement and Supplies Unit as the Contracting Authority objecting that their bid was rejected as being technically not compliant. A deposit of € 760 was paid.

There were four (4) bidders.

On 2nd May 2019 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Dr Charles Cassar and Mr Carmel Esposito as members convened a public hearing to discuss the objections.

The attendance for this public hearing was as follows:

Appellants – ProHealth Ltd

Dr Alessandro Lia	Legal Representative
Mr John Jaccarini	Representative
Mr Mark Bondin	Representative

Recommended Bidder – Associated Equipment Ltd

Mr Keith Vassallo	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Marco Woods	Legal Representative
Ms Marika Cutajar	Chairperson Evaluation Committee
Ms Solange Vella	Representative
Mr Patrick Ghigo	Member Evaluation Committee
Mr Edmond Balzan	Representative
Ms Josette Camilleri	Representative

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

Dr Marco Woods Legal Representative of the Central Procurement and Supplies Unit (CPSU) requested that a witness be heard before submissions were made.

Mr Jo-Etienne Abela (27575G) called as a witness by the Contracting Authority testified on oath that he was a Consultant Surgeon and Deputy Chairman of the Department of Surgery at Mater Dei Hospital, with many years experience as a surgeon. The device under consideration in this tender has three functions – suction, irrigation and a metal hook used for dissection during operations. Witness tested the equipment during a minor operation lasting one-half to three-quarters of an hour. Witness explained that to change the modality position of the hook the surgeon usually uses one hand – in using this device it was difficult to do so and the surgeon had to use both hands. In a lengthy operation (four to five hours) this creates difficulties as the surgeon has to feel comfortable with the equipment to ensure patient is safe. The ergonomics of the device requires it to be easy to handle – apart from that criticism the device is good.

Questioned by Dr Alessandro Lia, Legal Representative of ProHealth Ltd, witness said that he was not involved in the evaluation of the tender but was an end-user evaluator and had carried out the test on the basis of the use of the instrument and not on a ticking of boxes procedure. One other surgeon was present during the testing and they were of the view that during a lengthy operation the device would create problems as it was difficult to handle and thus would put the patient at risk.

Dr Lia, in his submissions, stated that the reason given for the device not being technically compliant was that the tip was difficult to go in and out. According to Section 1.1 of the tender specifications Appellants had satisfied all the parameters – the reason now given for the rejection was outside these parameters. The Contracting Authority had now created new parameters. The requisites in asking for a sample did not make any provision for the evaluation of that sample. Page 7, clause c (iii) of the tender made no reference to provision for additional technical requirements – if that is what the CPSU required they should have stated it.

Dr Woods said that in the evaluation process the first checks are made to ascertain that the specifications are met. The evaluation committee are entitled to ask for samples to ensure compliance. He compared this Case to a previous PCRB Case 1247, where the product offered met the specifications but then it was found that the samples were difficult to operate. Similarly in this Case the device submitted met the specifications but failed the test. If the surgeon was not comfortable using it then the patient was not safe.

Dr Lia re-iterated that the tender does not state that the sample is to be evaluated through testing. or that there will be further evaluation of sample. If the CPSU wanted to have further parameters then they should have stated it. The Appellant followed the tender instructions in their totality. He made reference to PCRB Case 1256 where the Board had stated that the tender documents must describe exactly what was required.

Dr Woods in his final submission said that the evaluation committee were entitled to ask for samples and to have them tested. The devise in this Case had been tested by two surgeons – the evaluation of samples was an integral part of the evaluation process and that is how a decision is reached.

Concluding Dr Lia said that if it was the intention to evaluate sample then the tender should have stated it. Slipshod wording on tender should not penalise bidders – it had been accepted after all that the Appellant was technically complaint and his offer had been rejected erroneously.

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

This Board,

having noted this objection filed by ProHealth Limited (herein after referred to as the Appellants) on 18 January 2019, refers to the claims made by the same Appellants with regard to the tender of reference CT 2266/2017 listed as case no 1307 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 Alessandro Lia

Appearing for the Contracting Authority: Dr Marco Woods

Whereby, the Appellants contend that:

a) **their main concern refers to the fact that their offer was fully compliant and yet it was rejected for the alleged reason that when the sample was tested, the tip of the device was found to be very difficult to 'Go in and out'. In this respect, Appellants maintain that the tender did not make any reference as to the evaluation of the sample, so that, the Authority has now changed the parameters of the tender requirements.**

This Board also noted the Contracting Authority's 'Letter of Reply' dated 29 January 2019, and its verbal submissions during the hearing held on 2 May 2019, in that:

a) **the Authority insists that, the reason why samples are requested is, so that these are tested and in this particular case, although Appellants' device was compliant when tested, it was found that, the mechanism of this medical device was not so comfortable to use by the surgeon, especially during lengthy operations.**

This same Board also noted the testimony of the witness namely, Mr Jo-Etienne Abela Consultant Surgeon duly summoned by Central Procurement and Supplies Unit.

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, opines that, the issue that merits consideration in this particular case, is the testing of the sample.

1. **This Board acknowledges the fact that this procurement consists of a medical device used in operations and from the testimony of the technical end user, it was also established that such an instrument had to be deployed by the surgeon performing the operation, for a substantial length of time (number of hours) so that, such a device had to perform its expected function in the smoothest possible manner whilst, at the same instance, be comfortable to handle, during such delicate medical operations.**

2. **This Board would also confirm that, as and when the Contracting Authority requests samples, the latter must conform with the dictated specifications and must achieve the main objective of the relative procurement. At the same instance, samples are also requested so as to be tested, especially where devices or equipment, form the core of the procurement. It is to be appreciated and acknowledged that various types of equipment achieving the same functions are available. However, one**

must also acknowledge that each equipment and device has its own operational system and, hence, differences in the operational mode of each device, exist.

3. In this particular case, Appellants' product when tested, had one of its components namely, the tip which has to go in and out, not very comfortable to be used by the Surgeon during lengthy operations and in this regard, this Board would refer to Mr Abela's testimony, as follows:

"Xhud: Dan il-prodott, fi prodott wiehed hemm essenzjalment tliet prodotti. Hemm prodott li jaspira l-fluwidi, suction. Hemm parti mill-prodott li tirriga, tispara l-ilma gol-area tal-kirurgija u imbghad hemm aspett iehor tal-prodott li tohrog hook, tohrog parti metal li tintuza biex taghmel dissection, biex taqta l-istrutturi waqt l-operation. Jigifieri dan essenzjalment huwa three in one. Huwa strument baziku imma important hafna ghalina. Jiena meta evalwajt il-prodotti in question, uzajtu ghal procedura li damet nofs siegha, tliet kwarti, jigifieri operation zghira. Fl-opinjoni tieghi, il-mekkanizmu biex johrog il-hook ghax dan l-istrument ma jistax jintuza bil-hook barra l-hin kollu ghax il-hook huwa sharp u jaqta' u jkun hemm partijiet tal-operation li allahares noqghodu

nuzaw il-hook kull darba ghax naghmlu hafna hsara. Jigifieri hemm hin tal-operation fejn il-hook irid ikun gewwa. Issa biex naqilbu minn modalita ghal ohra, jekk jista jkun is-Surgeon ikollu jaghmel it-tibdil b'id wahda, minghajr ma jaqla idu mill-istrumenti l-ohra. Issa jiena sibt li f'operazzjoni zghira, nofs siegha, tliet kwarti, kien qed ikolli diffikulta biex nohrog il-hook b'idi wahda, jigifieri kull darba kien qed ikolli naqla idejja mill-istrument l-iehor biex nohrog il-hook u dik hija xi haga li f'operation ta' nofs siegha, tliet kwarti forsi ma tantx taghmel differenza imma f-operations twal u meta nghid operations twal qed nghid anke ghaxar (10) sieghat, imbghad issir problema."

From the above testimony, it has been explained by the Consultant Surgeon that, for short duration operations, Appellants' product can be used but for lengthy operations, the said device is not so comfortable, especially when this Board was made aware that such a device has to be held by one hand during the operation. In this respect, this Board wanted to establish the normal time, such operations take and in this regard, reference should be made to an extract from the testimony of Mr Abela, as follows:

"Chairman: *Ikunu komuni dawn ta' ghaxar (10) sieghat?*

Xhud: *Mhux komuni. Ghalija hija iktar komuni operazzjoni ta 4 jew 5 sieghat. Still quite a long time. Hija operation twila. Jigifieri ultimately jiena bhala Surgeon irrid inkun cert li l-pazjent huwa safe. Issa l-pazjent huwa safe jekk is-Surgeon ikun komdu. Fl-evalwazzjoni tieghi dik kienet the main issue. Kien hemm issues ohra. L-issue l-iehor kien, ahna meta nuzaw strument, specjalment strument fil-laparoscopy, meta qed naghmlu minimally invasive surgery, l-istrumenti kemm jista jkun iridu jkunu ergonomic, jififieri huwa strument li joqghod easy ghal idejk u jghin l-andament tal-operazzjoni. Issa l-mekkanizmu li johrog il-hook hija parti mill-ergonomics tal-istrument. Jigifieri dik diga ma kinitx ghogbitni. L-istrument jikkwalifika, l-ispecs jikkwalifikahom imma x'hin tkun qed tuzah l-istrument, ghandu kif johorgu l-pajpijiet tas-suction u l-irrigation, fl-opinjoni tieghi qed jixhtu piz izzejjed fuq in-naha ta fuq tal-istrument li l-istess f'operation ta' nofs siegha probabbli ma nindunawx biha imma operation fit-tul, is-Surgeon jaf jghajja juzah. Il-funzjonijiet l-ohra tal-istrument, is-suction u l-irrigation huma tajbin. Il-hook innifsu x'hin johrog jahdem tajjeb. Jien il-kritka tieghi hija fl-ergonomics tal-istrument."*

From the above testimony, this Board establishes that the common length of time which the device is used for is four (4) to five (5) hours, so that the 'ergonomics' of the device, is most important and in this respect, this Board considers the all-important fact that, the Surgeon performing the operation must, at all times be comfortable whilst operating on the patient, for the benefit and well-being of the latter.

4. **This Board would refer to Appellants' contention in that, their product was fully compliant and not, as stated in the Authority's letter of rejection. In this regard, after having heard the testimony of Mr Abela, this Board confirms that Appellants' product is technically compliant but more adaptable for short duration operations. At the same instance, the Authority should have given the correct reason for rejecting Appellants' offer, in that, although their device was compliant, it was found that, when tested, was not suitable for lengthy operations.**

5. **With regard to Appellants' contention that the tender document should have stipulated that the sample was to be tested and the result thereof would affect the award criteria, this Board would confirm that, whenever the criteria for award is the price and samples are requested, the tender**

document, under 'Criteria for Award' should also include reference to the effect that the result of the testing of sample is also taken into account in the recommendation for award.

6. **With regard to Appellants' contention in that, the result of the test of sample was subjective, this Board, would, first and foremost, affirm the fact that the Authority had the duty and obligation to test such a sample, especially, in such an instance where the device is to be deployed in the medical field. This Board, as it has on so many occasions, would again emphasize the priority that should be given toward the wellbeing of the patient and such testing of samples would ensure safety and all necessary preventions which merit good and efficient medical practice and care.**

7. **With regard to Appellants' contention that the testing of the sample should have been carried out by more than one Surgeon, this Board is in agreement with such a proposal, however, one must also take into consideration the practicality of such an application of testing of samples in that, Surgeons are few in number and for a considerable time of their day are performing operations. At the same instance, this Board noted Mr Abela's credible testimony and opines that he has justifiably asserted**

the fact that for operations which might take four (4) to five (5) hours, Appellants' device cannot be comfortably handled with ease by the Surgeon.

In Conclusion, this Board opines that:

a) **Appellants' product is technically compliant but more suitable for short operations,**

b) **the Authority's reason for the rejection of Appellants' offer could have been better amplified,**

c) **when requesting samples and the procurement relates to medical devices, the award criteria should clearly denote that the result of the testing of such samples, will be taken into consideration in the award of the tender,**

d) **whenever possible, the testing of samples of medical devices, should be carried out by at least two independent end users.**

In view of the above, this Board,

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

ii. **confirms that although Appellants' offer is technically compliant, the offered device is more suitable for deployment in short operations,**

iii. **in view of ii. above, recommends that an amount of Euro six hundred (€600) form the deposit paid by Appellants, be refunded.**

Dr Anthony Cassar	Dr Charles Cassar	Mr Carmel Esposito
Chairman	Member	Member

16 May 2019