PUBLIC CONTRACTS REVIEW BOARD

Case 1579 – CT2326/2020 – Tender for the Supply of Safety Blood Collection Set & Holder 21G x ¾"

14th June 2021

The Board,

Having noted the letter of objection filed by Dr Alessandro Lia on behalf of Lia & Aquilina Advocates acting for and on behalf of Prohealth Ltd, (hereinafter referred to as the appellant) filed on the 15th March 2021;

Having also noted the letter of reply filed by Dr Marco Woods on behalf of Central Procurement and Supplies Unit (hereinafter referred to as the Contracting Authority) filed on the 24th March 2021;

Having taken cognisance and evaluated all the acts and documentation filed, as well as the submissions made by the legal representatives of the parties;

Having heard and evaluated the testimony of the witness Mr Paul Calleja who is a Nurse as summoned by Dr Alessandro Lia acting for and on behalf of Prohealth Ltd;

Having heard and evaluated the testimony of the witness Dr Christopher Barbara who is the Chairman of the Pathology Department at Mater Dei Hospital as summoned by Dr Marco Woods acting for and on behalf of Central Procurement and Supplies Unit;

Having heard and evaluated the testimony of the witness Mr Stephen Decelis who is a Senior Allied Health Practitioner and is an Evaluator on this tender;

Having heard and evaluated the testimony of the witness Mr Mark Bondin who is a representative of the Appellant company on this tender;

Having noted and evaluated the minutes of the Board sitting of the 10th June 2021 hereunder reproduced.

Minutes

Case 1579– CT 2326/2020. Tender for the Supply of Safety Blood Collection Set & Holder 21G x ¾"

The tender was published on the 30th October 2020 and the closing date was the 1st December 2020. The value of the tender was € 1,374,450.

On the 15th March 2021 Prohealth Ltd filed an appeal against the Central Procurement and Supplies Unit as the Contracting Authority objecting to their disqualification on the grounds that their offer was not technically compliant

A deposit of € 6,872 was paid.

There were ten (10) bidders and thirteen (13) bids.

On 10th June 2021 the Public Contracts Review Board (PCRB) composed of Mr Kenneth Swain as Chairman, Dr Charles Cassar and Mr Carmel Esposito as members convened a public virtual hearing to discuss the objections.

The attendance for this public hearing was as follows:

Appellant – Prohealth Ltd

Dr Alessandro Lia	Legal Representative
Mr Mark Bondin	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Marco Woods	Legal Representative
Ms Rita Zammit	Chairperson Evaluation Committee
Mr Stephen Decelis	Representative
Ms Jacqueline Borg	Representative
Mr George Grech	Representative
Mr Edmond Balzan	Representative

Preferred Bidder – Europharma

Mr Alex Fenech	Representative

Interested party – Krypton Chemists

Mr Matthew Arrigo	Representative

Mr Kenneth Swain Chairman of the Public Contracts Review Board welcomed the parties. He noted that since this was a virtual meeting all the parties agreed to treat it as a normal hearing of the Board in line with Article 89 of the Public Procurement Regulations. He then asked Appellant's representative to make his submissions.

Dr Alessandro Lia Legal Representative for Prohealth Ltd stated that the Contracting Authority had disqualified Appellant's offer on two parameters - an unsteady needle and difficulty in withdrawing the needle from the vein. Appellant is appealing as in his view these parameters are purely subjective and the terminology 'makes it difficult' used to describe these so called shortcomings is farfetched as extreme methods were used in coming to this conclusion. The present incumbent supplying this product provides exactly the same product as that turned down and there is no medical or technical reason for failing the product offered.

Dr Marco Woods Legal Representative for the Central Procurement and Supplies Unit (CPSU) said that Appellant's claim that the technical specifications are particular to one supplier is not correct. A witness will give the reasons for the exclusion of this bid. The work of the evaluators is to assess all offers transparently which is precisely what happened in this case. The end-users and the evaluators choose the equipment that best benefits patients but Appellants bid failed on two points as detailed.

Mr Paul Calleja (230779M) called as a witness by the Appellant testified on oath that he has spent twenty years as a nurse in the Emergency Department. His qualifications include a Masters degree and for the last five years he has been working in the private elderly sector. He detailed how blood is collected and the equipment extracted after collection. He stated that the 'wings' make no difference as there is no right or wrong way as to how it is done. He had personally tested Appellant's product and encountered no problems with withdrawing the needle which was stable throughout. The needle might feel slightly unstable if the equipment was used single-handedly with the safety mechanism behaving normally without any problems.

Questioned by Dr Woods witness stated that he was approached by Appellant to test the product which however was not tested on a human being. The butterfly clicking is automatic as is the needle withdrawal.

Dr Christopher Barbara (615562M) called as a witness by the Authority testified on oath that he is the Chairman of the Pathology Department at Mater Dei Hospital. He explained in detail the process in the use of the product. A problem was encountered when gauze used on withdrawing the needle covers the 'wings' which makes the product awkward to handle. Witness could not confirm whether the equipment was tested artificially or on a patient.

In reply to questions from Dr Lia witness said that he was asked for his opinion on certain products he was given but was not aware of the manufacturer of the product evaluated by him. The product shown to him at this hearing is the same as the one currently in use at Mater Dei Hospital. He had not been given or seen the Instructions for Use (IFU) of the product and his advice had only been sought on doubtful products without him knowing the source of products he was checking.

Questioned by Dr Woods witness stated that he has forty years experience of using similar products to the one in this case. It is important that the operator has total control over the product in use. He agreed that pulling the tube if the 'butterfly' is not accessible because of the gauze, causes harm to patient.

Mr Stephen Decelis (8776M) called as a witness by the Authority testified on oath that he is a practitioner at Mater Dei Hospital. Witness confirmed that he requested samples and on receipt he chose the usable ones and sent them to the phlebotomist for testing. He repeated the reasons he was given for rejecting certain samples, namely the gauze covering the 'butterfly' mechanism which leads to pulling on the tube and the risks involved thus.

In reply to questions by Dr Lia witness stated that he was an evaluator with two others answerable to Ms Rita Zammit, and confirmed that not all but only certain samples were sent for testing and the IFUs were not sent to the end-users. Witness was aware that the end-users had to be given training by the winning bidder and that the winning bid is the present incumbent and therefore there was no need to send IFU since it was not a new product. He confirmed that he relied on the judgement of the end-users who were persons of many years experience.

Mr Mark Bondin (352380M) called as a witness by Appellant testified on oath that the offered product was tested before the bid was submitted. The needle is perfectly stable and the IFU makes it perfectly clear how the product should be used. Methods vary between the different products.

Dr Lia said that it was obvious that all the reasons given for refusal of the bid were based on the views of one doctor and not on those of the evaluation committee. The IFU was part of the offer and should have been followed and no proof has been provided that the needle is unstable. It is inexplicable how out of many offers rejected only the most expensive one was accepted. The Board has heard that the

safety mechanism is not interfered with by the use of the gauze. Reference was made to PCRB Case 1512 where it was held that there should be no subjectivity in decision involving medical matters.

Dr Woods stated that it was incorrect to say that only one doctor tested the product as advice was sought also from end-users. Witnesses had testified as to the awkwardness of the safety mechanism which experienced end-users well trained in the use of similar products had come across. In PCRB Case 1247 it was held that even if a product is complaint it might not necessarily be the most practical to use. The General Rules covering Tenders in Rule 16.3 it is stated that when the samples do not corroborate the offer the tender should be disqualified.

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

End of Minutes

Hereby resolves:

The Board refers to the minutes of the Board sitting of the 10th June 2021.

Having noted the objection filed by Prohealth Ltd (hereinafter referred to as the Appellant) on 15th March 2021, refers to the claims made by the same Appellant with regards to the tender of reference CT 2326/2020 listed as case No. 1579 in the records of the Public Contracts Review Board.

Appearing for the Appellant:	Dr Alessandro Lia
Appearing for the Contracting Authority:	Dr Marco Woods

Whereby, the Appellant contends that:

a) ***<u>The reasons given by the Contracting Auhority are unfounded –</u>***

   i. Technical condition number 4 – *"[n]eedle must be stable and does not move in its holder"*. Prohealth cannot fathom how the Contracting Authority could have reached such a conclusion. The appellant contends that the product offered is stable, steady and does not move in its holder. This is evidenced by a demonstrative video pertaining to the supplier's product.

   ii. Technical condition number 10 – the appellant contends the second reason given by the Contracting Authority. The product offered by Proheatlh incorporates a safe mechanism

and the device is easily activated and covers the needle into a protective cover without the need to pull the tubing. This is evidenced by a demonstrative video pertaining to the supplier's product. Prohealth's product has a system whereby the safety device is triggered as the needle is being withdrawn from the skin, has an audible click and once the safety mechanism is activated, it cannot be reversed. Moreover, the safety mechanism is not above the butterfly, but in reality, below it.

b) ***The Contracting Authority is exercising an element of subjectivity which goes beyond what is permitted in the relative procurement procedure and in accordance with the applicable award criterion***

i. The sole award criterion is the price on those offers satisfying the administrative and technical criteria.

ii. To assess Prohealth's offer, the Contracting Authority is basing itself on a discretionary interpretation and a subjective opinion of the 'steadiness' of the product and of the 'ease of use' thereof. The Contracting Authority should have a certain degree of leeway but such leeway should always be construed within the basic principle of transparency and non-discrimination. This leeway cannot give an evaluating committee allowance to create an uneven subjectivity or a flexible discretionary tool.

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 24th March 2021 and its verbal submission during the virtual hearing held on 10th June 2021, in that:

a) The reasons given by the Contracting Auhority are unfounded –

i. Technical condition number 4 – *"[n]eedle must be stable and does not move in its holder"*. The CPSU contend that an evaluation was carried out on the samples as submitted by the objectors. These samples are tested by end users, which in this case were phlebotomists, whose daily job entails that of drawing blood from patients. In evaluting the sample, the end user noticed the needle was not stable, therefore posing a risk to both the patient and the end user. The demonstrative video is produced by the manufacturer itself with the intent to market and sell its product.

ii. Technical condition number 10 – here again, the sample was tested by the end users. CPSU contend that in the case of the samples provided by the objectors, when the phlebotomist concluded the drawing of blood and placed a piece of gauze over the needle to absorb any excess blood leak, due to the awkward positioning of the in-vein activation system, the said trigger is covered by the gauze making it difficult to trigger the system. Therefore, the only method to trigger the in-vein activation system, when placing the gauze over the

activation system, is by pulling on the tubing, with a high possibility of causing an injusry to the patient. CPSU also contend that although instructions for use were given on how to activate the said safety mechanism, through usage and after the said evaluation carried out, the phlebotomists still encountered difficulties in activating the said safety mechanism whilst drawing blood from patients.

b) <u>The Contracting Authority is exercising an element of subjectivity which goes beyond what is permitted in the relative procurement procedure and in accordance with the applicable award criterion</u>

CPSU submit that the Board ought to take into consideration the risks which arise because of the difficulty to activate the said safety mechanism of the product as submitted by the objectors. Such risks include contamination of both the blood being collected, the patient as well as the phlebotomist/end user, thus futher emphasising the importance of patient safety as well as health worker safety.

This Board, after having examined the relevant documentation to this appeal and heard submissions made by all the interested parties including the testimony of the witnesses duly summoned, will consider Appellant's grievances, as follows:

When considering the Appellant's greivances, the Board makes reference to the following points and will discuss both grievances in their entirety:

i. Both the Appellant company and the Contracting Authority called up witnesses who have vast experience in the process of drawing blood from patients for medical purposes. Under oath Mr Calleja stated *"He had personally tested Appellant's product and encountered no problems with withdrawing the needle which was stable throughout. The needle might feel slightly unstable if the equipment was used single-handedly with the safety mechanism behaving normally without any problems"*. On the other hand, Dr Christopher Barbara stated, also under oath *"A problem was encountered when gauze used on withdrawing the needle covers the 'wings' which makes the product awkward to handle."*
ii. The Evaluation Committee is allowed to have a certain element of 'leeway' in evaluating the bids received with respect to Technical Specification. This has been noted in PCRB and Court of Appeal cases on numerous occasions. However the decision and recommendation of the Evaluation Committee needs to be as clear as possible. In this particular case, the Board opines that subjectivity played an important role. In fact the two witnesses mentioned above, stated

under oath, different opinions on the quality of the product proposed by the Appellant company.

iii. The product tendered for is intended to be used at Mater Dei Hospital and its utilisation may be needed to be applied under pressure and stress. An important element to keep in mind is that the least discomfort is to be given to the patient, hence the experts (i.e. end users) opinion should be given its due importance in the matter at hand. In this regard, the Board again makes reference to the fact that two experienced witnesses gave conflicting remarks about the Appellant's product.

Due to the above points and after due consideration, the Board upholds Appellant's grievances.

In conclustion this Board opines that;

Having evaluated all the above and based on the above considerations, concludes and decides:

a) To uphold the Appellant's concerns and grievances;
b) To cancel the Letter of Acceptance dated 5th March 2021 sent to "EuroPharma Ltd";
c) To cancel all the Letters of Rejection dated 5th March 2021;
d) To order the contracting authority to re-evaluate the bids received in the tender through a newly composed Evaluation Committee;
e) After taking all due consideration of the circumstances and outcome of this Letter of Objection, directs that the deposit be refunded to the Appellant.

Mr Kenneth Swain	**Dr Charles Cassar**	**Mr Carmel Esposito**
Chairman	**Member**	**Member**