PUBLIC CONTRACTS REVIEW BOARD

Case 1238 – CFT 020-1155/18 –Tender for the Supply of Consumables for Negative Pressure Wound Therapy with Equipment on Loan on a Pay Per Use Basis

Call for Remedies before the Closing Date for Competition

The publication date of the call for tenders was the 2nd November 2018 whilst the closing date of the call for tenders was 19th November 2018 (extended till 10th December 2018). The estimated value of the tender (exclusive of VAT) was € 140,000

On the 16th November 2018, Cherubino Ltd filed a Call for Remedy against the Central Procurement and Supplies Unit as Contracting Authority on the grounds that the tender does not provide terms for a fair and competitive bid.

On 4th December 2018 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Dr Charles Cassar and Mr. Richard A Matrenza as members convened a public hearing to discuss the objections.

The attendance for this public hearing was as follows:

Appellants – Cherubino Ltd

Dr Alan Zerafa	Legal Representative
Dr Francis Cherubino	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Stefan Zrinzo Azzopardi	Legal Representative
Dr Alison Anastasi	Representative
Ms Rachel Camilleri	Representative
Ms Mirian Wubbels	Representative

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

Dr Alan Zerafa Legal Representative for Cherubino Ltd said that his clients' first concern was that the tender asks for supplies on a long term basis of two types of equipment (Lots 1 and 2). It is stipulated in the technical specifications that the equipment in Lot 1 must have a portable weight that does not exceed 1.12kgs. There is no degree of tolerance allowed and his clients are requesting that a margin of tolerance in the weight is allowed. Minimum variances do not affect the performance of the equipment or the patients.

Dr Stefan Zrinzo Azzopardi Legal Representative of the Central Procurement and Supplies Unit, sought permission to introduce a witness to explain what this equipment was and how it worked.

Ms Miriam Wubbels Cassar (311966M) stated under oath that she was a Tissue Viability Nurse at Mater Dei Hospital. The apparatus mentioned was used in the treatment of deep wounds and was used to extract exudates from wounds through a vacuum system. Type 1 is large and static and Type 2 is portable so that the patient has mobility while using it. Patients are advised that the longer the equipment is in use the better the result, as interrupting treatment delays its effectiveness, and therefore the weight of the equipment (which is carried over the shoulder like a handbag) is critical – the weight of the apparatus plus the container totals 1.5 kgs. An apparatus lighter in weight than this will only treat superficial wounds.

Dr Cherubino, in questioning the witness made reference to PCRB Case 1168 where it was established that tolerances in specifications of a tender were allowed. Witness then stated that if the patient felt that the equipment was heavy to carry around, then they will switch if off once it starts filling up. The decision on what was the optimum weight for this equipment was based on the most common products on the market, of which there were a number of suppliers.

Dr Stefan Zrinzo Azzopardi said that the weight of the equipment mattered as it was used by different ages. Since the tender specified only the maximum weight it followed that there was a degree of tolerance in the specifications. There were three elements considered by the CPSU – the efficacy of the apparatus, its weight and the weight overall in use after exudates.

Dr Cherubino said that +/- 100 grams would make no difference in weight; all they were asking was a degree of tolerance. Only two suppliers meet the parameters set and only one manufacturer can participate under these terms.

Dr Zrinzo Azzopardi pointed out that Cherubino Ltd's letter of objection was asking for a 250 grams tolerance, not simply 100 grams – step by step this could go on escalating. PCRB Case 1168 earlier referred to did not deal with capping but with a +/- situation in the concentration of a product.

Mrs Wubbels was recalled by the Chairman to give further testimony. In her view the whole system – the static and the portable equipment should come from the same firm – there were two or three suppliers of complete systems.

Dr Zerafa said that the second point where a remedy was sought was with the requirement to provide a minimum of thirty reference sites where models of their equipment have been installed in hospitals in Europe. This is restrictive, excessive and limits fair competition. There are other developed countries where the product is used and it is not a reasonable condition to impose. Such excessive number is designed to limit competition and possibly favour one brand. The limitation to Europe is not reasonable and would favour certain suppliers and limit competition. In fact demanding 30 referees with more than ten years use points to only one possible supplier.

Dr Zrinzo Azzopardi mentioned that it was necessary to stipulate European standards as standards outside Europe varied. The CPSU had instances where the equipment delivered was not up to standard even though a Declaration of Conformity was submitted. There where cases of poor performance of equipment even with DOC or CE markings. The CPSU needs peace of mind that the product delivered will fulfil the requirements, and hence only through Euro standards could they be assured of this. CPSU must have comfort that the product works effectively and asking for Euro references does not limit competition but ensures quality.

Dr Cherubino stated that if the Contracting Authority found fault with a bidders' product they had remedies under the contract. Certain countries had the same high standard as Europe and a product cannot be excluded because of origin or production process (Article 42 § 4 of the Euro Directive). References of usage of product do not have to be from Europe if the product meets all requirements and has proper certification. Only one firm in Europe can provide 30 references – this therefore limits competition.

Dr Zrinzo Azzopardi commented that seeking 30 references was perhaps a bit hard and this can be revised but it was essential for standards to be maintained.

Dr Zerafa then moved on to the third matter that was causing concern to Appellants. There is a distinction between service and supply contracts. In this case there is leasing of equipment which is a service but also a supply of consumables. The tender states that this is on a pay per use basis whilst the financial bid form requests bidders to quote on a pay per treatment basis. There are twelve possible types of consumables and treatments vary with the patients in the types of consumables used – there must therefore be a variance in price. Appellants' concern is the ambiguity of the cost of the service. It is impossible to make a fair and just offer as there is no such thing as a typical case – it therefore cannot be a contract for service.

Dr Alison Anastasi Representative of the CPSU said that before the letter of appeal was submitted a clarification had been issued that the service was based on a number of treatments worked on a typical basis of a change of dressing every three days – this gives a balanced outlook as the contract was on a long term basis, and what was being requested by the Contracting Authority was not a product but a service. The CPSU pays for a number of treatments which were calculated on the basis of consumables used in previous years. The model used in this case was a novel one with the risk shared between both sides – this avoids the risk of a gamble of high stocks being kept 'just in case' and the Government paying for the stock at the end of the contract.

Dr Cherubino said that a pay on consumption basis is the only logical system and eliminates the risk of running out of supplies. The price per treatment can vary whilst a fixed price eliminates guess work and is predictable. (He tabled minutes of PCRB Case 1168 and tender terms on CT 2231/2014 with particular reference to page 16).

Concluding Dr Zrinzo Azzopardi said that the proposed model applies to all and was not restricting competition. There is an element of risk on both sides but it was a more efficient system as it provided security of supplies and no risk of a supplier ending up with uncalled for stocks.

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

This Board,

having noted this Call for Remedies filed by Cherubino Limited, (hereinafter also referred to as the Appellants), before the closing date for competition on 16 November 2018, refers to the contentions made by the same Appellant with regard to the Tender of Reference CFT 020-1155/18 issued by the Central Procurement and Supplies Unit and listed as Case No 1238 in the records of the Public Contracts Review Board.

Appearing for the Appellants: **Dr Alan Zerafa**

Appearing for the Contracting Authority: **Dr Stefan Zrinzo Azzopardi**

Whereby, the Appellants contend that:

a) **with regard to the specifications of two types of equipment in Lot 1 and Lot 2, the Contracting Authority should stipulate an allowance of tolerance in respect of the weight of these machines, as minimum variances will not affect the patient;**

b) the stipulated minimum condition relating to reference sites is excessive and such a condition will restrict fair competition. In this respect, the Appellants also refer to the fact that such reference sites are restricted to Europe and such a condition would favour particular suppliers;

c) it is somewhat difficult to quote a price, as the Tender consists of a service and supply, in that, there is the leasing of the equipment and the supply of consumables. In this regard, the Appellants contend that the only logical system is to quote a fee on a consumption basis.

This Board has also noted the Contracting Authority's "*Letter of Reply*" dated 22 November 2018 and its verbal submissions during the Public Hearing held on 4 December 2018, in that:

a) the Central Procurement and Supplies Unit contend that the maximum weight of the equipment was established whilst taking into consideration that such equipment will be used by frail elderly patients and people suffering from serious wounds, so that the lighter the equipment to carry, the better;

b) the Contracting Authority maintains that it is of the utmost importance to ensure that the equipment being procured is of the highest standards and has been proved to be efficient through reference sites of hospitals within Europe. At the same instance, the Contracting Authority contends that the standards and list of approved products may vary between Europe and countries outside Europe and the Central Procurement and Supplies Unit applies the European standards;

c) the Contracting Authority insist that what is being requested is a service and not a product, in that the annual expenditure of previous years has been based on consumables used. Realistic statistics should form a sound basis for the bidders to quote a realistic price.

This same Board has also noted the testimony of the witness, namely Ms Miriam Cassar Wubbels who was duly summoned by the Central Procurement and Supplies Unit.

This Board, after having examined the relevant documentation to this concern and heard submissions made by the parties concerned, including the testimony of the witness duly summoned, opines that the issues to be considered are:

1. **The allowance of tolerance in weight of the equipment;**
2. **The reference sites within Europe**
3. **Supply or service**

1. **<u>The allowance of tolerance in weight of the equipment</u>**

With regard to Cherubino Limited's first concern, this Board would respectfully refer to the fact that although the Tender does not mention a tolerance allowance of weight of the equipment, it does mention a maximum so that there is allowed a range of weight up to a maximum of 1,200g (1.2kg). The most important factors to be taken into consideration in establishing a maximum weight of the equipment, which has to be worn by the patient, is the type of user of such equipment and the daily duration of the use. One must also take into account the fact that the stipulated maximum weight will be increased at any one time through extracted exudates from the wound. At the same instance, through credible explanations given by the technical witness, this Board was informed that this equipment is portable so that the patient has to wear it and patients are advised that the longer the equipment is used the better the result, so that the weight of the

equipment and the container reaches a level of weight of 1.5kgs. This Board also notes that the equipment is used by frail elderly patients or others suffering from serious wounds and it would be more strenuous for a patient to carry the equipment if it is heavier than 1.2kgs. This Board, would emphasize the issue that, when one realises and assesses the role of the equipment and the medical state of the users, the weight of the equipment is of great importance and every effort should be made to ease as much as possible the well-being of the patient. In this regard, this Board notes that there are various suppliers on the market who can deliver such equipment with the dictated weight of 1.2kgs and in this regard, this Board does not find any limitation to open competition through the imposition of a maximum weight of the equipment so dictated in the Tender Dossier.

2. <u>Reference sites within Europe</u>

With regards to the Appellants' second contention, this Board would, first and foremost, emphasize the fact that it is the duty and obligation of the Contracting Authority to ensure that, the equipment it is procuring, is of the highest standard and in accordance with the

updated available equipment which renders the optimum objective. In this particular case, medical equipment which will facilitate the cure of serious wounds, so that the Central Procurement and Supplies Unit is rightly requesting references as to where and which hospitals in Europe such offered equipment is being used, and has been tested.

The technical specifications and conditions of a Tender must, in all respects, be attainable and must not preclude potential prospective Bidders to compete. In this particular case, the Contracting Authority is requesting 30 reference sites and although the objective of the latter is to ensure that the equipment has been successfully tried and tested through use in hospitals throughout Europe, this Board finds that such a mandatory condition is too rigid to attain by potential substantial Bidders. In this regard, this Board would advise the Contracting Authority to rectify such a condition to a level, which is reasonable and attainable by the general potential Bidders, as long as the number of reference sites dictated will ensure enough comfort to the same Authority that the equipment being offered is in use in hospitals in Europe with positive results. In this respect, this Board upholds Cherubino Limited's concern.

With regard to the Appellants' other concern as to the limitation of reference sites in Europe only, this Board notes that the Contracting Authority's concern is that Standards outside Europe varied and the latter, quite appropriately, requires peace of mind that the product, (equipment), fulfils the requirements. At the same instance, this Board also acknowledges the fact that such equipment conforms with the fact that standards and list of approved products may vary between Europe and other Countries. In this regard, this Board is comfortably convinced that such a condition does not restrict competition and the Authority's decision to limit reference sites to Europe is justified, so that this Board does not uphold Cherubino Limited's Second Contention with regards to reference site outside Europe.

3. <u>Supply or service</u>

With regard to the Appellants' third concern, this Board would respectfully refer to what is being requested by the Contracting Authority in that the Tender is for "*supply of consumables for negative pressure wound therapy with equipment on loan on a pay per use basis.*"

Although the heading of the Tender included a supply, it then says, "*on a pay per use basis*", so that the Tender is being costed on the number of usage on patients, which represent a service. Such a statement is clearly explained in a clarification reply sent by the Central Procurement and Supplies Unit as follows,

"***<u>The Appellants' Clarification request</u>:***

"Price for Treatments per Patient"

2.1 – Can the department please clarify whether this Tender is based on Pay per Use (supply) or Pay per Treatment per Patient (service)?

2.2 – If the latter applies, can the department please define the term treatments?

2.3 – There are a vast variety of wounds requiring different treatment approaches for different timelines. Can the department please give an indication of treated wound types and respective numbers over a specific period?

<u>CPSU's answer to this clarification request was the following</u>:

Dear Economic Operator,

Answers as per below:

Question 1: Article 3.1 does not state that instillation and drainage are required, so we confirm that the latter are not needed for Type 1.

Question 2.1: Pay per Treatment per Patient (service)

Question 2.2: Yes. Whenever a change in dressing is needed. And this had been estimated to be changed every 3 days.

Question 2.3: Agreed. The technique is being used with chronic wounds or wounds that are expected to present difficulties with healing. E.g. diabetes mellitus, peripheral vascular disease, and complications of post-surgery. Since the last system

that was being used is obsolete, this service is currently not being implemented.

***Thanks and Regards*"**

From the above clarifications, the Contracting Authority made it clear that it was requesting a rate for treatment per patient. At the same instance, this Board notes that enough reliable statistical information was made available to the Appellants' to be able to quote a reasonable fee, and since this was on a long term basis, such information gives a balanced and reasonable outlook of the Tender. In this regard, this Board is credibly convinced that this is a service Tender.

In view of the above, this Board,

i) **does not uphold Cherubino Limited's first concern;**

ii) **upholds the Appellants' concern in that the number of reference sites imposed is excessive. However, this Board upholds the Central Procurement and Supplies Unit's decision that reference sites should be restricted to Europe;**

iii) **confirms that this Tender is a service contract and therefore upholds the principle of "*Pay per Treatment for Patient*";**

iv) **instructs the Central Procurement and Supplies Unit to revise the mandatory condition of 30 Reference Sites to a more reasonable and attainable level which can be achieved by prospective Bidders, through a clarification note.**

Dr Anthony Cassar Chairman	Dr Charles Cassar Member	Mr Richard A Matrenza Member

18th December 2018