PUBLIC CONTRACTS REVIEW BOARD

Case No. 719

DH 2056/14

Supply of Deep Brain Neurostimulators for Mater Dei Hospital

The tender was published on the 23rd May 2014. The closing date was the 30th May 2014.

The estimated value of the Tender was €120,000

Three (3) offers have been received for this tender.

On 4th July 2014 Messrs Europharma Limited filed an objection against the disqualification of their offer for being technically non-compliant.

The Public Contracts Review Board composed of Dr Anthony Cassar (Chairman), Dr Charles Cassar and Mr Lawrence Ancilleri as members convened a hearing on Monday the 14th July 2014 to discuss the objection.

Present for the hearing were:

Europharma Limited - Appellant

Mr Michael Peresso	Managing Director
Mr Alex Fenech	Representative
Mr Marco Grazzi	Representative
Dr Antoine Cremona	Legal Representative
Dr Julienne Portelli Demajo	Legal Representative

Technoline Limited - Preferred Bidder

Ms Damaris Lofaro	Representative
Mr Hilary Agius	Representative
Dr S Vancell	Legal Representative
Dr Paul Gonzi	Legal Representative

Central Procurement & Supplies Unit - Contracting Authority

Mr Stephen Mercieca	Chairman Evaluation Board
Mr Ian Attard	Member Evaluation Board
Mr Marnol Sultana	Representative
Mr Chris Attard Montalto	Representative
Dr Josanne Aquilina	Representative
Dr Adrian Mallia	Legal representative

The Chairman made a brief introduction and invited the appellant's representative to make his submissions.

Dr Antoine Cremona on behalf of the appellant explained that the product was used in the treatment of neurological disease. The hospital is already using the product and his client had information that the preferred bidder was the present supplier, the incumbent, of the product to the hospital. The contracting authority has now become familiar with the product being used and the number of suppliers of the product globally was very limited. There are about three suppliers of the product in Malta, the appellant, the preferred bidder and another. He said the issue the appellant had with this tender was a precise legal issue dealing with the tender specifications. He said that there is extensive European court of justice and this Board jurisprudence relating to how tender specifications should be drafted. He cited two European court of justice cases relating to the matter of specifications, case 359/93 the Unix case and case 45/87, the Dundalk case. In these cases the European court of justice basically said that in interpreting the directives, the contracting authority is prohibited from including in the specifications that clearly identify one product from another from the market. When publishing tender specifications the contracting authority should only refer to objective bench marks. Thus specifications should be limited to recognized standards like ISO. However in this tender, what happened it seems, although in good faith, is that the contracting authority, being familiar with the product being currently used, set the specifications of the present tender according to the specifications of that product. The cardinal principles of the European Legislation are: i) that technical specifications have to have also a functional requirement; ii) that the procurement process has to be open to the solutions that serve the same functions of what is being procured. The contracting authority has to open the market not restrict it.

Dr Cremona continued that the grounds for exclusion of his client's tender were given in the letter of rejection as being two. The first one related to the current; the letter said *"amplitude offered is 0 – 12.75mA against the 0-25mA plus or minus 1.0mA requested in the Tender Specifications"* This was precisely where the tender document breached the procurement regulations. The efficacy of the product has to arise from empirical data and from studies reported in medical journals it resulted that there is absolutely no functional need for the device to be beyond the threshold of 6.5-7mA. The range provided by appellant's device goes up to 12.75mA, the range as requested goes up to 25mA but that happens to be the technical specification of the existing device, the range which the contracting authority was familiar. This was the reason why the contracting authority should have chosen a standard benchmark that was objective, like ISO and not the specific specifications of existing products. Otherwise the market would never open up. He reiterated that there is no functional benefit to be gained by going beyond 7 mA. The specifications requested in the tender fail the tests of functionality and of non-exclusion of equally fit for purpose devices. Thus this specification was illegal and appellant's bid could not be rejected. In Malta we have only one specialist, Mr Zrinzo, who is able to use the product and appellant has literature published by Mr Zrinzo that shows that he is familiar with both solutions. So there is no barrier for other solutions to be used other than those being currently used. Dr Cremona insisted that technical specifications had to have a functional requirement as otherwise contracting authorities could tailor specifications to suit a particular bidder.

Dr Adrian Mallia on behalf of the contracting authority said that the contracting authority has been obtaining the product for the last three years from the open market. The tender in question was a call for quotations below €120,000 thus falling under Part II of the Public

Procurement Regulations. He pointed out Regulation 7 of the Public Procurement Regulations that provided remedies for grievances encountered by tenderers at the pre-contractual stage. This regulation clearly outlines remedies for tenderers and specifies that any bidder had to follow the procedure when objecting to any grievance at that stage. The objectors had to follow that procedure. It was not in the public interest to have bidders raising the said grievances later on after submitting his tender and after the adjudication had been completed. The same regulation also allows recourse to the Court of Appeal to any bidder who still feels aggrieved after the pre-contractual remedies are given by the Director of Contracts. The submission of the concern in terms of regulation 7 even halts the tendering process until a decision is reached. Appellant in the present case had a path to follow, but for reasons known only to him opted not to follow this path. Appellant is basing his argument on the provision of Regulation 47. However as previously stated, the present tender was issued under Part II of the Public Procurement Regulations and in this part of the Regulations there is no reference to the said Regulation 47. The law does not refer direct contracting authority to comply with the provisions of regulation 47. The Rules and Regulations apply to tenders above the threshold and do not apply to tenders below the thresholds.

Dr Antoine Cremona for the appellant stated that it is not correct to state under European law tenders above the thresholds are regulated while those below are unregulated. The correct interpretation is that there are different rules that apply to different contract bands by value. There are rules in the secondary legislation that apply across the board. The concept remains the same, a least common multiple concept to have functional tender specifications. Contracting authorities are increasingly invoking the pre-award regulation 7 to avoid shouldering the responsibility for correct clear specifications. The Regulation gives a facultative right and the appellant can choose to decide when to object and raise concerns. That is a completely flawed logic. Sometimes it is not advisable to seek court proceedings against a contracting authority that would later judge your bid later on. It makes good commercial sense for bidders not to go against the contracting authority before the adjudication. That is why some bidders choose to file an objection at this stage of the proceedings after adjudication. It was worrying to see the contracting authorities consistently trying to invoke to this regulation 7.

The Chairman remarked that the concerns about the technical specifications could have been raised pre-contractually. Bidders could have informed the contracting authority that their product performed just as well as those asked for in the specifications.

Dr Antoine Cremona for the appellant said that the matter being so restrictive, the market was aware of what was needed by the contracting authority. He said that his client's bid was excluded on two issues, the frequencies and the current. However there were lots of other instances in the tender where the specifications are product specific. The whole tender was structured for one proprietary solution.

Mr Marco Grazzi for the appellant, under oath said that he was a specialist. He said that the product offered by the appellant provides the functions required to treat Parkinsons Disease patients as requested by the contracting authority.

Dr Josanne Aquilina, Consultant Neurologist, on behalf of the contracting authority under oath stated that she had no experience with the product offered. He job is to identify patients to undergo the treatment. It was a highly selective procedure.

The Chairman remarked that the Board needed to know whether the product offered by appellant serves its functional purposes.

Mr Chris Attard Montalto on behalf of the contracting authority, under oath said that he had prepared the tender specifications. He was not a member of the adjudication board. He had done research on the articles that were required by Dr Zrinzo who would be using the products for his patients. The products had been in use for three years and the tender specifications were based on the current product specifications as well as the requirements of the Specialist. He could not state whether the product offered by appellant had functional requirements but did not abide with the specifications. Replying to a question by Dr Cremona the witness said that he could not specify the functional requirements for having a 25 mA but he fixed the specifications in line with the neurologist requirements.

Dr Josianne Aquilina on behalf of the contracting authority said that the specialist chooses the patients and performs the surgery. The specialist's main concern is the clinical safety. He has vast experience of over ten years and has for the past four years used the same type of product. Dr Zrinzo feels that the hospital should continue using the same product being used at present. Dr Zrinzo has developed a system of his own where he implants electrodes using just image guided verification of the mounts. We do not use micro electro recording. All four electrodes are of equal size. The surgeon is not always available on site and is on call. It is not easy to program the patients and the local team has a learning curve, a slow learning curve. We have around 10 patients a year. The team prefers to use the system that is already in use although the specialist Dr Zrinzo is familiar with both systems.

Ms Damaris Lofaro on behalf of the preferred bidder said that the appellant is claiming that there is no clinical evidence of the benefits of using the specified range. She said that she had literature that shows that the range is needed for the benefit of the patients and that evidence exists.

Dr Paul Gonzi for the preferred bidder claimed that apart from the fact that appellant should have raised the matter at the pre-contractual stage; the appellant had submitted a tender knowing that it was in breach of the tender specifications.

Dr Antoine Cremona for the appellant filed some literature and a pen drive containing a video of an operation using the product in question.

At this point the hearing was closed.

This Board,

Having noted the Appellant's objection, in terms of the 'Reasoned Letter of Objection' dated 4th July 2014 and also through Appellant's verbal submissions during the hearing held on 14th July 2014,had objected to the decision taken by the pertinent Authority, in that:

a) **The Appellant claims that the technical specifications as dictated in the tender document were drafted entirely on the specifications of the present equipment/ product, being used by the Contracting Authority. As there are only three**

possible suppliers, the Preferred Bidder, who is the present supplier of such equipment, was (without ulterior motives) given an advantageous headway.

b) Appellant contends that the tender document was defective as the technical specifications should reflect the recognised standards. Same must also dictate a 'functional requirement' to make a broad spectrum of what is required from the tender requirements. In this particular case, the technical specifications were based and drafted on the already known knowledge of specifications of the product being used at present. Appellant's product provides the same 'functional requirements' and is cheaper.

Having considered the Contracting Authority's verbal submissions during the hearing held on 14th July 2014, in that:

a) The Contracting Authority maintains that the Appellant's complaints about the technical specifications as laid out in the tender document, could have easily been clarified, had the Appellant asked for clarifications at the stage where he is allowed through remedies in accordance with Regulation 7, of the Public Procurement Regulations.

b) In drafting, the technical specifications, the Contracting Authority confirms that the specifications were based on the current product being used, but in addition the Evaluation Board took into account the aspect of clinical safety of the patients being treated. This latter consideration was of the prime importance considered by the 'Consultant Neurological Surgeon'.

c) The Local specialised team has a slow 'learning curve' and in this regard, at present, no disruption in procedure would be advisable.

Reached the following conclusions:

1. **This is a specialised health issue and this Board opines that the 'Health' factor should be given great prominence. In this regard, the submissions made by Health Experts were considered of prime importance.**

2. **The Fact that most of the technical specifications were construed from the present knowledge of the product being utilised at present, may perhaps, give a slight advantage to the Preferred Bidder's offer. On the other hand, Appellant Company is, now, contesting the drafting of the technical specifications in the tender document at the stage of the award of the contract. The Appellant Company had all the necessary remedies under regulation 7 of the Public Procurement Regulations. This Board opines that the Appellant Company had the opportunities to submit all the complaints brought before to this Board prior to the submission of his signed tender document. Appellant did not abide by these remedies.**

3. **During the submissions made during the hearing of this appeal, this Board established the fact that, the Clinical procedure in using the product, being tendered for, has been adopted four years ago. The surgical procedure is carried out by an established and well experienced 'Consultant Neurological Surgeon' and although, the latter Specialist is fully aware of the products available, same is in favour, professionally, for the Preferred Bidder's Product for the following reasons:**

   i) Since the Specialised Team has a low Learning Curve, obviously due to the low incident of such medical conditions the 'Evaluation Committee' diligently, opted not to disturb the experience progress, by way of changing the Equipment being used in this medical clinical procedure.

   ii) The emphasis placed by the 'Consultant Neurological Surgeon', on the safety of the 'Patients', is not to be ignored by this Board.

4. **The Appellant's product did not meet the technical specifications as dictated in the tender document. Appellant was aware of such deficiency at the time of submitting his Bid.**

5. **This Board opines that the Evaluation Board acted in a just and transparent manner, especially when, in the evaluation process, importance and relevance was attributed to the Patient's safety.**

In view of the above, this Board finds against the Appellant Company and recommends that the deposit paid by Appellant should not be reimbursed.

Dr. Anthony Cassar Chairman	Dr. Charles Cassar Member	Mr. Lawrence Ancilleri Member

17 July 2014