PUBLIC CONTRACTS REVIEW BOARD

Case No. 920

CFT 019/10381/2015

Tender for Supply of Implantable Cardiac Resynchronisation Therapy Defibrillator Without Leads (Lot 1).

The Tender was published on the 4th September 2015. The closing date was on the 5th October 2015. The estimated value of the Tender is €120,000.00 (Exclusive of Vat).

Seven (7) offers have been received for this Lot of the Tender.

On the 22nd February 2016 Technoline Limited filed an Objection against the decision of the Contracting Authority to award the Tender to VJ Salomone Pharma Limited.

The Public Contracts Review Board composed of Dr Anthony Cassar (Chairman), Dr Charles Cassar and Mr Lawrence Ancilleri as members convened a hearing on Thursday the 7th April 2016 to discuss the Objection.

Present for the hearing were:

Technoline Limited:

Mr Ivan Vassallo	Representative
Mr Craig Doermann	Representative
Ms Damaris Lofaro	Representative
Dr Paul Gonzi	Legal Representative

VJ Salomone Pharma Limited:

Mr Chris Treeby Ward	Representative

Central Procurement and Supplies Unit:

Ms Doreen Gouder	Secretary Evaluation Board
Dr Mark Adrian Sammut	Member Evaluation Board
Mr Frankie Caruana	Member Evaluation Board
Ms Marika Cutajar	Representative
Dr Stefan Zrinzo Azzopardi	Legal Representative

The Chairman pointed out that the Letter of Objection should contain all the reasons for the Objection. He then made a brief introduction and invited the Appellant's representative to make his submissions.

Dr Paul Gonzi on behalf of Technoline Ltd explained that he would make submissions on each of the specifications that the latter had identified where the Recommended Bidder was deemed to be non compliant, starting with specification 10. This required "*availability of atrial antitachycardia pacing algorithms*" and the Appellant is contending that the recommended devices do not have these and so do not meet with specifications. Central Procurement Supplies Unit in the Letter of Reply is stating that the Preferred Devices do in fact comply. He said that this would be explained by the Appellant's Technical person.

Specification 10

Damaris Lofaro on behalf of the Appellant said that the Contracting Authority in the Letter of Reply is claiming that the Preferred Device "*has in fact the required algorithm to reduce and prevent atrial tachycardias*" this meant that the requirements were for the device to have an algorithm to rectify any irregularity in the top chamber of the heart.

Ms Lofaro had researched definitions of "*atrial tachycardias pacing algorithms*" and from reliable sources "*PACE*" obtained the definition as pacing stimulating techniques for termination of *atrial arrhythmias*. Prevention and reduction is not enough to qualify for ATP because there is no interruption of the arrhythmias.

VJ Salomone Pharma Ltd also supplies newer devices that provide termination of arrhythmias but did not offer these. All researched items consider ATP to need to terminate the episode of arrhythmias. The recommended device is suitable for ventricular arrhythmias that is, of the lower chamber of the heart.

Mr Craig Doermann on behalf of the Appellant, under oath stated that he had been employed with Metronics for the last 20 years; he had a BA (Nursing). He has worked as a technical consultant. Mr Doermann explained that ATP or *Atrial tachychardias* pacing algorithms are used in therapy to terminate heart rhythm abnormalities in the atrium, or top chamber of the heart.

While the Appellant's device as offered was able to provide this, the Recommended Bidder's did not since the technology it uses are not ATP. This results from several studies of earlier devices. The Preferred Device is used to prevent the onset of the arrhythmia. Prevention algorithm is normally referred to as overdrive algorithm and not antitachycardia.

The correction by the Preferred Device may be done manually by the operator through the computer using a protocol but the decision is not taken by the device itself. This is not the same as requested and the procedure has to be performed in a clinic. He was not aware that the Tender Document used the word "automatic" for this specification.

The pacemakers are typically intended for patients to leave the hospital and to act outside of a clinic setting. Untreated atrial arrhythmia could degenerate to fibrillation. The Recommended Bidder's device cannot be useful in cases of atrial fibrillations.

Dr Mark Adrian Sammut, ID NO. 115673M, Consultant Cardiologist specializing in

electrophysiology and member on the Evaluation Board, under oath stated that the Tender Specifications required a device that had the capability to override fast heart rates in the atrial chamber – referred to as atrial tachycardia or fast heart rates in the upper chamber of the heart. One way of doing this is by speeding up the rate in the fast chambers of the heart through a pacemaker.

The Tender required availability of an antitachycardia mechanism and never specified that this should be done automatically. The Appellant is claiming that its offered device can do this automatically, but from his experience, automatic does not work. He believes that manual operation of the device is superior.

Dr Sammut does not agree that the preferred equipment would require clinic attendance because the said equipment has the ability to transmit the relative data to a home monitoring unit. This allows for any necessary adjustments to be made within 5 minutes. The witness continued by explaining that atrial tachycardia is not a life-threatening condition. Patients who are not on a home monitor are examined on a regular basis at the clinic and any irregularity would be shown during this examination.

Specifications 5 and 9

Ms Damaris Lofaro on behalf of the Appellant contends that the Recommended Bidder's device is not able to optimize the output. This is confirmed by the product manual. Furthermore the Technical Specifications of the Tender all mention that all the requirements have to be done by the device itself and that there would be no need to be re-hospitalized to have the devices adjusted.

Had the Appellants knew that an older cheaper device would have been acceptable, they would have offered a device with those characteristics. The Recommended Bidder's device was not the latest available technology while the Appellant's was.

Dr Stefan Zrinzo Azzopardi for the Contracting Authority said that all bidders can request clarifications if anything in the Tender Document was not clear enough. But this point has now been surpassed and the Board has now to see whether the specifications had been followed.

Mr Ivan Vassallo on behalf of the Appellant pointed out that whoever issued the Tender was expected to know exactly that implanted pacemakers should work automatically or autonomously. This enabled patients to have as few hospitalizations as possible. He claims that the recommended device will not be able to provide treatment for patients automatically. There was no need for the Appellant to ask for clarifications because everyone knew what a pacemaker should do.

Dr Stefan Zrinzo Azzopardi for the Contracting Authority said that the contention here seems to be the word '*automatic*'. The Appellant thinks that automatic means that the device should adjust the settings itself. The Contracting Authority understood that the device would follow the settings set by the operator. The Evaluation Board evaluated '*automatic*' according to the needs of the said Authority and this was within the parameters. He stressed that there was a case of the Appellant asking for clarification in this point.

Dr Mark Adrian Sammut on behalf of the Contracting Authority explained that pacemakers

have functions that are automatic and other functions that are not. It is obvious that the pacemaker itself has to be automatic in order to help a heart from slowing down. The other functions may be or not automatic. The functions that he desired should be automatic were so in order to help the physician in the treatment of the patient. He prefers applying the antitachycardia mechanism manually because he believes that he could better that a device that does so automatically. Nowhere in the Tender there was mentioned that the device should act automatically. The word automatically was used for '*ventricular*' tachycardia and fibrillation and not for '*atrial*'.

He explained in lay terms that the upper chambers of the heart are the atrial while the lower chambers form the ventricular. In this case the specifications asked for automatic for ventricular, that is lower chambers, because ventricular tachycardia was potentially fatal. The atria does not need automatic. The issue is the atrial. Appellant has submitted a device that claims to have an automatic mechanism to stop atrial events. But frankly he did not believe in. This can be applied manually by the physician, and for this reason the specifications for the atrial did not mention automatic. The Recommended Bidder's device can raise the heart rate automatically and can regulated increased heart rates caused by the pacemaker itself. He reiterated that there was no need for an automatic atrial anti-tachycardia pacing and the Tender did not request this. Both the Appellant's and the Recommended Bidder's devices provide automatic heart rate response.

Specification 11:

Ms Damaris Lofaro said that this Specification required "availability of algorithms to minimize ventricular pacing in the presence of a satisfactory intrinsic rhythm". This means that when the heart is working normally algorithms that minimize the pacing in the lower chamber.

Technoline Ltd was contending that the Recommended Bidder's device does not meet this specification. Ms Lofaro explained the difference between an algorithm and a set of rules. The Appellant's device automatically adjusts the heart rate. This enables the reduction of re-admission to hospital and the battery life of the device.

This is completely different from the set of rules that the physician has to calculate and make assumptions with reference to the Recommended Bidder's device. Ms Lofaro finally pointed out Clause 21.4 that requested clinical studies that demonstrate the accuracy of the offered devices. The Appellant had submitted the necessary literature. The Recommended Bidder's device not only does not have this algorithm to minimize ventricular pacing but it has no clinical evidence to substantiate that it has.

Dr Mark Adrian Sammut for the Contracting Authority said that he considers IRS plus as an algorithm, so the chosen device does have an algorithm that minimizes ventricular pacing. He is convinced that the chosen device is according to specifications. The device requested in this Tender is not a normal pace maker whose function is to prevent a slowing of the heart.

The Tender is for a special pace maker, whose main function is to help the heart to work more efficiently. The function of this is to pace the heart so that each beat is more effective. It needs to reduce useless ventricular pacing.

Mr Craig Doermann for the Appellant said that the definition of a cardiac resynchronization

therapy device refers to the ability to synchronize the left side and the right side of the heart and make them beat together by pacing them. IRS plus does not allow the synchronization of the left side with the right side.

Dr Mark Adrian Sammut for the Contracting Authority, on being asked by PCRB Chairman confirmed that all the algorithms requested by the Tender specifications were supplied by the Recommended Bidder's device.

At this point the hearing was closed.

This Board,

Having noted the Appellant's Objection, in terms of the "*Reasoned Letter of Objection*" dated 22 February 2016 and also through their verbal submissions during the Public Hearing held on 7 April 2016 had objected to the decision taken by the Pertinent Authority, in that:

a) The Appellant Company contends that the Recommended Bidder's offer should have been deemed to be non-compliant on specifications Five (5), Nine (9), Ten (10) and Eleven (11). In this Regard the Appellant maintains that his offer did satisfy the Technical Specifications as follows:

(i) <u>Specification No 10</u>

The Appellant contends that the Recommended Device does not have the "*Availability of Atrial Antitachycardio pacing algorithms*",

so that their offer is not Technically Compliant, in this regard. In fact, the device offered by the Recommended Bidder was only suitable for "*Ventricular Arrhythmias*", ie for the lower chamber of the heart.

In this respect, the Appellant Company contends that the Preferred Device could only be corrected or adjusted to the patient's requirement in a clinic or hospital and not performed automatically whilst the Appellant's device can be set and adjusted automatically outside a clinic or hospital.

(ii) <u>Specifications Nos 5 and 9</u>

Technoline Ltd are contending that the Preferred Device is not able to optimize output as confirmed by the product manual. At the same instance, the Tender Specifications requested that for the device to be adjusted there will be no need for the patient to be re-hospitalized. After all, the purpose of this type of pacemaker was to enable the patient to live a normal life without having to attend hospital for any adjustment/setting. In this respect, the Preferred Device cannot satisfy this requirement.

(iii) <u>Specification No 11</u>

This specification requested the "*Availability of Algorithms to minimise ventricular pacing in the event of a satisfactory intrinsic rythm.*" In this regard, the device offered by VJ Salomone Pharma Ltd does not meet these specifications. On the other hand, the device offered by Technoline Ltd adjusts the heart rate automatically, thus reducing the needs to attend a clinic/hospital.

At the same instance, the Appellant Company refers to Clause 21.4 of the Tender Document wherein "*Clinical Evidence*" was requested by the Contracting Authority to demonstrate and prove the accuracy of the device being offered.

In this regard, the Appellant did submit this required documentation whilst the device submitted by VJ Salomone Pharma Ltd did not have "*Clinical Evidence*", to substantiate its accuracy.

Having considered the Contracting Authority's "*Letter of Reply*" and also their verbal submissions during the Public Hearing held on 7 April 2016, in that:

a) <u>Specification 10</u>

The Contracting Authority maintains that the above mentioned Specification requested the availability of an "*Antitachycardia Mechanism*". Nowhere, in the Tender Specifications was mentioned that this should be performed automatically.

The Contracting Authority rebuts the fact that the Preferred Device would require clinic attendance. Any necessary adjustments can be performed within five minutes and present no hazard to the patient's health.

b) <u>Specifications 5 and 9</u>

The Contracting Authority through experience preferred applying the "*Antitachycardia Mechanism*" manually as the procedure has proved to be better carried out this way, rather than carry the procedure automatically.

c) <u>Specification 11</u>

The Contracting Authority is convinced that the chosen device is according to the Technical Specifications as requested in the Tender Document.

Reached the following conclusions:

First and foremost, this Board would justifiably state that it's following decisions which are mostly based on the submissions made during the Public Hearing by medical experts. This Board also acknowledges the fact that the Technical Expert is an experienced consultant cardiologist specialising in "*Electro Physiology*" apart from being the end user of this Specialised device, (the pace maker).

Secondly, it is not this Board's competence to delve into the Technical Merits of the submissions made by both the Appellant Company and the Contracting Authority but rather to adjudicate the Evaluation Process of this Particular Tender and in this regard, this Same Board would like to consider the following points:

1. **<u>Tender Specifications</u>**

From the submissions made by the Appellant Company, it has been clearly

established that the word "*Automatically*" had been wrongly referred to by the Appellant. During the Technical Submissions it was vividly pointed out that the Tender Document nowhere implied or mentioned that the device should in all respects act automatically.

The word automatically was only used for "*Ventricular Tachycardia*" and "*Fibrillation*" and not for "*Atrial*". The latter does not need an automatic function.

This Board justifiably notes that the Technical Specifications of this Tender did not, in any way, request an "*Automatic Atrial Antitachycardia Pacing*". In this regard, this Board opines that the Appellant Company had all the remedial opportunity to ask for clarifications within the stipulated period, to clear any misunderstandings of any Technical Specification with the Contracting Authority.

In this respect, this Board justifiably points out that all the Technical Medical Jargon difficulties, if any, could have been clarified and Technoline Ltd did not avail itself of this remedial action.

2. **<u>Evaluation Process</u>**

This Board is credibly convinced that the Preferred Device is within the dictated Technical Specifications of the Tender. From the submissions made by the Consultant Cardiologist, this Board is comforted by the fact that the latter, who will be the end user, has credibly established as to why there was no need for a "*Fully Automatic*" device.

This Board also noted that the Preferred Device, which would carry out the necessary functions as stipulated in the Tender Document, was cheaper than that offered by the Appellant Company. In this regard, the Evaluation Process was carried out in a transparent and just manner.

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

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

14 April 2016