**Case 1296 – CT 2377/2018 – Tender for the Supply of Uncemented Total Hip Replacement System 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 23rd January 2019 whilst the closing date of the call for tenders was 16th April 2019. The estimated value of the tender (exclusive of VAT) was € 1,080,400.

On the 16th January 2019, Technoline Ltd filed a Call for Remedy against the Central Procurement and Supplies Unit as Contracting Authority claiming that the tender was inherently a Services rather than a Supplies contract.

On 11th April 2019 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Mr Carmel Esposito and Mr Lawrence Ancilleri as members convened a public hearing to discuss the objections.

The attendance for this public hearing was as follows:

**Appellants – Technoline Ltd**

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| Dr Maria Grech | Legal Representative |
| Mr Ivan Vassallo | Representative |
| Mr Bjorn Bartolo | Representative |

**Contracting Authority – Central Procurement and Supplies Unit**

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| Dr Marco Woods | Legal Representative |
| Mr Herbert Doublet | Representative |
| Ms Miriam Haydon | Representative |
| Mr Stanley Iles | Representative |
| Ms Rita Zammit | Representative |

**Department of Contracts**

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| Dr Franco Agius | Legal Representative |

**Others**

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| Mr Emanuel Spiteri | Representative A M Mangion Ltd |
| Mr Ray Vella | Representative A M Mangion Ltd |
| Mr Keith Vassallo | Representative Associated Equipment Ltd |
| Mr Paul Calleja | Representative Cherubino Ltd |
| Dr Francis Cherubino | Representative Cherubino Ltd |

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

Dr Maria Grech Legal Representative for Technoline Ltd said that the main issue she is raising is that the procurement indicated in this tender was a service rather than a supply. This was indicated clearly in the terms of the tender in that individuals had to perform a task, they were required to scrub and assist during medical operations, had to be at Mater Dei Hospital full time but be used as required. Since the surgical team consisted of persons who had to scrub and others who were not required to, it was impossible for this task to be undertaken by the same person. Individuals who had to work in the sterile part of the theatre had to be registered under the Health Care Professions Act, although the Contracting Authority maintains that registration is not essential as the individuals concerned may be certified or accredited. Technoline Ltd would still offer the service required but not under such unreasonable conditions. In an operating theatre there were qualified nurses available to handle sterile equipment, obviating the need for a further person from the contractor.

Mr Ivan Vassallo (254865M) called as a witness by the Board confirmed on oath that staff assisting in operations had either to scrub or to assist without the need to scrub. The ones who did not scrub opened the boxes which were then handed as a the sterile pack to a scrubbed person. A bigger problem is compliance if something goes wrong under the proposed requirements. Warranted individuals would be protected but others were not bound by privacy and ethical restrictions. The tender specifications needed to be changed to ensure compliance and a degree of ethics and to deal with the question of liability of non-medical staff which is a very worrying aspect.

Dr Franco Agius Legal Representative of the Department of Contracts said that Public Procurement Regulations 26 and 27 allow mixed procurement in a contract and therefore the classification was correct. The specifications were so worded since the Contracting Authority did not wish to limit the Government's liability. The responsibility of which type of implant replacement is used lies with the supplier not with the Government. The matter of liability and ethics is the responsibility of the tenderer.

Mr Stanley Iles (463763M) called as a witness by the Contracting Authority testified on oath that he is the Senior Manager of the Operations Theatre in the Health Department. He stated that all operations are carried out only by Government employees but if technical assistance is needed they then involve manufacturers' agents. This happens because there are different types of prosthetics and implant designs on which guidance is needed in putting them together correctly. This is also the practice in hospitals abroad. Scrubbing by the agents, who do not participate in operations, is essential not to put patients at risk and to limit the sterile field to the shortest possible time – hence the need for assistance by trained personnel of the representatives of the implant manufacturers.

Mr Vassallo said that it is not correct to allow people not bound by professional oath to participate in operations. The tender terms do not cover all possible circumstances as they are unclear and need clarification to avoid future problems.

Dr Agius stated that liability and damages are regulated by the Civil law and the legal relationship is between the employer and employee.

The Chairman asked why the Contracting Authority was not prepared to clarify the conditions and avoid problems both at the tender stage but more importantly during the evaluation process.

Mr Vassallo re-iterated that the matter of liability and compliance should be regulated – the relationship is not only with the contractor but with the patient and his relatives for the general benefit of everyone. This calls for the need for product specialists who are true professionals – there are currently forty companies in this line who do not employ health professionals.

Dr Agius said that he is in agreement that the tender requires product specialists. The Contracting Authority is buying equipment, not a service. Without supply there will not be a service. The onus of responsibility must remain with the tenderer.

The Chairman said that there is a supply and a service; therefore the tender terms need clarification otherwise there will be problems for all bidders. And what happens at the evaluation stage, asked the Chairman?

*At this stage Dr Agius asked the Board for a short recess to enable him to consult with the Contracting Authority.*

After the recess Dr Agius said that he had consulted with the Contracting Authority, and their preference was that the responsibility remains with the contractor. What they suggested is that the role of product specialist is taken by a key person accredited by the manufacturer and endorsed by the supplier, in other words that the supplier has the liability to provide a competent person to fulfil this role.

The Chairman pointed out that as helpful as this proposal was, one still needed a guide mark when evaluating otherwise the risk of ending up with inexperienced people was still there. There must be a set benchmark of competency. The Board will decide what benchmarks to set down within the framework that the onus is still on the supplier.

Mr Stanley Iles, recalled as a witness, testified that in his view the current suppliers had personnel who were well trained and versed in providing the right service. If a manufacturer certified a person's competency it denotes the ability to provide a professional support service.

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

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**This Board,**

**having noted this Call for Remedies filed before the Closing Date of Competition by Technoline Limited (herein after also referred to as the Appellants) on 16 January 2019 refers to the claims made by the same Appellants with regard to the Tender of reference CT 2377/2018 listed as Case No 1296 in the records of the Public Contracts Review Board, and issued by the Central Procurement and Supplies Unit (herein after referred to as the Contracting Authority).**

**Appearing for the Appellants:** **Dr Maria Grech**

**Appearing for the Contracting Authority:** **Dr Marco Woods**

**Appearing for the Department of Contracts:** **Dr Franco Agius**

**Whereby, the Appellants contend that:**

a) **the Tender Document requests the suppliers' representative to be present, during medical operations, to hand over the medical supply. In this regard, the Appellants maintain that such a representative should be a person who is well versed in such procedures and should hold qualifications and experience and be licensed to attend such delicate operations;**

b) **since the Procurement, in this Tender, involves the presence of an individual during operations who might assist the operating staff in the**

**setting or adjustment of the product, the Tender refers to a service rather than to a supply only;**

c) **with regard to the issue of liability, if something goes wrong, during the operation procedure and in this respect, they point out that warranted individuals are protected against any liability, but others are not, so that the latter should be provided with the necessary protection against any possible claims.**

**This Board also noted the Contracting Authority's 'Letter of Reply' dated 22 March 2019 and its verbal submissions during the hearing held on 11 April 2019, in that:**

a) **the Central Procurement and Supplies Unit contends that it agrees with the fact that the supplier's representative should be a product specialist accredited by the manufacturer and endorsed by the supplier;**

b) **the Contracting Authority maintains that in accordance with the Public Procurement Regulations, it is empowered to allow mixed procurement in a contract, so that, the classification of the Tender, as a procurement supply, is correctly designated;**

c) **the Contracting Authority insists that it is the responsibility of the supplier to provide a competent person so that the responsibility for any possible claims lie with the supplier.**

**This same Board also noted the testimony of the witness namely Mr Stanley Iles, Senior Manager of the Operating Theatres who was duly summoned by the 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 technical witness duly summoned, opines that the issues that merit consideration are threefold namely:**

a) **The Supplier's Representative**
b) **The Designation of the Tender**
c) **The Provision for Possible Claims of Liability**

1. **<u>The Supplier's Representative</u>**

a) **First and foremost, this Board would emphasize that the tendered product consists of a medical implant applied during a "*hip replacement*" operation, so that, consideration is being emphasized**

**towards the well-being of the patient. At the same instance, one must also acknowledge the fact that, the supplier's representative must be present during this delicate operation. In this respect, this Board refers to item 1.1 (4) – Technical Specifications – Support, as follows:**

"*Product Specialist/Representative will be responsible to give the necessary support and information required during every procedure and to handle the implants to the Surgeon during Surgery. The Product Specialist/Representative will be required to scrub/assist during Surgery as well*."

**From the above article, it is being stipulated that the supplier's representative, apart from delivering and handing over the product, may be also asked to assist during the surgery, so that such a person must be highly proficient and well versed to assist where necessary. At the same instance, this Board was made aware of the clinical procedure of the handing over of the implant and in this regard, the supplier's representative plays an important part in the overall medical operation.**

**b) During the submissions made by the Contracting Authority, this Board was informed that the former finds no difficulty in stipulating that, the supplier's representative must be accredited by the manufacturer of the product and endorsed by the supplier, however, this Board will go further than such a proposal. It is a known fact that, under normal commercial conditions, the person who is nominated by the manufacturer is automatically accredited by same, so that this**

**Board opines that, such a person should hold the following credentials included in his accreditation documents, as follows:**

- **be proficient in the product and its application;**
- **have attended seminars or courses in the application of the product;**
- **have had previous experience of the application of the product during medical operations of hip replacement;**
- **is well versed in critical circumstances where any form of adjustment of the product is necessary.**

**The above basic requirements should be indicated in the accreditation certificate of the person who will be nominated by the manufacturer, so that the person so selected will be of the proper calibre in the execution of the stipulated duties during the delivery and any necessary assistance at the operating theatre during a "*hip replacement*" operation.**

**2. <u>The Designation of Tender</u>**

**a) With regard to the Appellants' Second Contention, this Board upholds the fact that, this particular procurement involves a supply and a service, (if and when necessary). In this regard, this Board would respectfully point out that the Public Procurement Regulations permit the Contracting Authority to issue mixed procurement Tenders so that, this Board confirms that the designation of the Tender is appropriate,**

**but apart from the supply of the Hip Replacement System, there are conditions which involve the presence of the supplier's representative who might be asked to assist during the actual implant operation, if the need arises. At the same instance, this Board does not find the mode of designation of this Tender to be an issue of substance.**

**3. <u>The Provision for Possible Claims of Liability</u>**

**a) With regards to the Appellants' Third Contention, this Board would point out that the Contracting Authority is requesting a supply and a service, the latter, if required, so that, it is the responsibility of the supplier to ensure that the nominated representative is properly indemnified against any mishappenings on the part of the representative, during the delivery, handing over of the product and assisting during the operation. This Board acknowledges the fact that the representative need not be a medical person who is registered and licensed to perform operations, and in this respect, the supplier must ensure that the nominated person who will attend during the operation, when requested, is properly indemnified against all the possible risks in such a procedure.**

**In conclusion, this Board opines that:**

a) **the person who will deliver, hand over the product and assist during the "*Hip Replacement*" operation, must be accredited by the manufacturer and endorsed by the supplier. Such accreditation should include reference to points mentioned in paragraph 1 b) so that the person nominated by the supplier should be highly proficient in this procedure.**

b) **the designation of the Tender is correctly denoted and should be regarded as a mixed Tender, as duly allowed by the Public Procurement Regulations.**

c) **it is the responsibility of the bidder to ensure that the nominated representative is to be properly indemnified against risks which might arise in the fulfilment of the obligations by the supplier, as duly stipulated in the Tender Document.**

**In view of the above, this Board,**

i) **directs that the Central Procurement and Supplies Unit, through a clarification note, defines the required credentials and experience of the supplier's representative, as duly recommended during this Board's considerations;**

**ii) confirms that the Tender is appropriately designated;**

**iii) confirms that it is the responsibility of the bidder to ensure that the nominated representative be indemnified against any risks that might arise during the delivery of the product and assisting, when necessary, during the operation of "*Hip Replacement*"**

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| Dr Anthony Cassar<br>Chairman | Mr Carmel Esposito<br>Member | Mr Lawrence Ancilleri<br>Member |

*23rd April 2019*