PUBLIC CONTRACTS REVIEW BOARD

Case 1009 – CT 2181/2015 – Tender for the Supply of Transcatheter Aortic Valve Implantation (TAVI) Device on a Pay Per Use Basis

The Publication Date of the Call for Tenders was 7 October 2016. The Estimated Value of the Tender, (Exclusive of VAT) was € 1,080,000.

On 15 November 2016, Drugsales Ltd filed a Pre-Contractual Objection against the Central Procurement and Supplies Unit.

On 5 December 2016, the Public Contracts Review Board composed by Dr Anthony Cassar as Chairman, Dr Charles Cassar and Mr Lawrence Ancilleri as members convened a Public Hearing to discuss the Objection.

The Attendance for this Public Hearing was as follows:

Appellant – Drugsales Ltd

Ms Giulia Attard Montalto	Representative
Mr Filip Hejkal	Representative
Ms Dagmar Slivkova	Representative
Dr Douglas Aquilina	Legal Representative
Dr Andrea Gera de Petri	Legal Representative

Contracting Authority – Central Procurement and Supplies Unit

Mr Paul Cassar	Representative
Ms Doreen Gouder	Representative
Mr Joseph Xuereb	Representative
Dr Stefan Zrinzo Azzopardi	Legal Representative

Department of Contracts

Ms Susan Camilleri	Procurement Manager
Dr Christopher Mizzi	Legal Representative

Others

Ms Damaris Lofaro	Sales Executive, Technoline Ltd

Following an introduction by The Public Contracts' Review Board Chairman, Dr Anthony Cassar, the Appellants were invited to make their submissions.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit suggested that first the witnesses were to be called to testify and then each party would have the chance to state their case.

Dr Douglas Aquilina, the Legal Representative for Drugsales Ltd wanted to explain the Appellant's concerns first since the discussion was to be around something technical. The product contended was a specific, medical and very technical product; the Transcatheter Aortic Valve Implantation, known as TAVI, devices.

When a heart surgery is done, the usual way to this is by making an open heart surgery. These TAVI devices allow the surgeon to use a catheter, a small tube, to enter through the blood vessels and open the valve from the inside. This technology was developed during the last ten years from Edwards, who were the manufacturers which supplied products to Drugsales Ltd.

Dr Aquilina continued by saying that there were two ways how the valves open. The technology used by Edwards, wherein the balloon opens from the inside remotely. There is also another way how to do this which is used by their competitors wherein the valve is opened with the body heat but this procedure takes longer.

In order to counter any movements which might happen if the second option is used, the competitor have launched a new technology called recapturability wherein if one notices that the valve was not opening correctly, the surgeon could re-close and re-direct the valve to where it was supposed to be opened. This shows that this technology is not as accurate as the one used by Edwards continued Dr Aquilina.

The Appellants contended that the outcome was that the balloon valve used by Edwards had a position accuracy of 99% whilst the competitors' procedure accuracy was of 98.7%. With the recapturability procedure, one might have some setbacks since one would have to intervene more on the patient and there are some risks which could be avoided. There are studies which also show this.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit said that what was being proposed by the Contracting Authority was a MEAT Tender and was prepared under the supervision of medical professionals with a number of criteria which had their relative points.

Here the Appellants were contesting the recapturability element and the Contracting Authority understood that the latter's concerns regarded whether this element had to be included in the Tender or not. Effectively this was not the only element which was contested and the Contracting Authority was going to discuss what led them to include the recapturability at a later stage.

At this moment, Professor Robert Xuereb, ID Card Number 170962 M was summoned by Drugsales Ltd to testify under oath.

Following Professor Xuereb's testimony, Dr Nicolas Treffort, Passport Number 07CH67947 was also summoned by Drugsales Ltd to testify under oath.

Following Dr Treffort's testimony, a third witness was summoned to testify under oath by Drugsales Ltd, Mr Martin Blazek carrying ID Card Number 201524647.

At the end of Mr Blazek's testimony, Dr Douglas Aquilina, the Legal Representative for Drugsales Ltd contended that everyone understood what the Technology is all about. What one has to check about is the award criteria regarding recapturability. Profs Xuereb, a leading cardiologist in Malta was summoned and he spoke about the importance of getting the result in fact on all the other criteria the Appellants agreed such as the pacemaker rate and the paravulvar leaks.

With regards to recapturability, this does not affect the outcome of the patients. It is a technology which was developed in the context of the product which was not precise and since it was not precise, the recapturability was developed. The way how the result is reached is not relevant and there are EU cases such as the Dundalk and the Unex one which shows this.

Dr Aquilina continued to argue that the main criterion in this case had to be the precision of deployment. At the end of the day, the discussion centred on a matter of 99% and 98.7%. One cannot go and tell the Appellants that recapturability is a criterion which was objectively justifiable.

If a criterion is made, a justification why it was made has to be done. In this case there was no justification whether it is medical or legal for recapturability because it's true that the product currently used is self-expanding and that recapturability give those better results in their self-expandable technology wherein the latter is necessary otherwise they'll have a higher pacemaker rate, a higher stroke rate and hence they cannot compete. That is why the recapturability technology was developed.

The Appellants continued by explaining that there were other products which are balloon-expandable. Their results are the same. One cannot talk about recapturability and say that there is a free competition. Dr Aquilina disagreed with the Contracting Authority on their argument that Drugsales Ltd can compete, hence there is no distortion of the competition and there are other EU cases such as the Dupont-Menuz which strengthen this argument.

Dr Douglas Aquilina, the Legal Representative for Drugsales Ltd argued that in this case there is a technology which is being favoured against another technology where the results are still the same. There are no objective clinical reports which show that the recapturability self-expandable product is better than the balloon-expandable product.

The Appellants referred to all the studies which they were going to present to the Board regarding balloon-expandable and self-expanding technologies where one can compare the accuracy positioning of both technologies. These show 99% accuracy for the balloon-expandable technology and 98.7% accuracy on the self-expanding one, following repositioning.

When one sees the positioning results, both technologies are at the same level but as seen, repositioning can lead to further complications since the procedure takes longer, you have

more expenses and more risks of strokes since the longer the operation takes the more you are exposed to risks.

Dr Aquilina explained that although the debate was about award criteria, effectively this became a discussion on the technical specifications because according to the Tender Document you either have the recapturability or else you don't since you either get 25 or 20 points or else you get nothing.

This Tender has 70% of the award going on these technical criteria, since the prices are well known and are similar and these valves are specialised and expensive and research is ongoing to develop them. One cannot compete if there is a difference of 25 points and Edwards cannot bid as things stand as they will never win the Tender.

The Appellants contended that the Department of Contracts know well enough that despite the fact that there are seven competitors, these are already a few in number and one cannot eliminate any Bidder.

At this point, Drugsales Ltd has presented to the Public Contracts Review Board a number of documents regarding different studies and related data on the devices and their technologies.

Dr Douglas Aquilina, the Legal Representative for Drugsales Ltd continued by saying that everybody knows what are the principles and the directives of the European Union namely free competition, proportionality, no discrimination and so on. These were modified by Article 18 wherein the basic principle which deny the drafting of a Tender to favour anyone of the competitors.

With this criterion, Drugsales Ltd were eliminated from the Tender race where in reality they have a product better than the others and this is shown by different studies. Even Prof Xuereb said in his testimony that the position and how the stroke and mortality rates can affect him. Dr Aquilina questioned why the Tender did not choose to emphasise on the mortality rates instead.

Dr Christopher Mizzi, the Legal Representative for the Department of Contracts opened his arguments by saying that here there was a Pre-Contractual Concern wherein a particular clause regarding the recapturability was being attacked. It was important to note that recapturability was not mandatory in this Tender. There were other specifications which were described as minimum requirements for this Tender.

When one was talking about the sub-criteria, these were requirements which go beyond the minimum eligible to Tender. At the sub criteria point no one was being excluded. The Public Contracts Review Board had already other occasions wherein a Bidder raised unsuccessfully complaints that because he will get eliminated because he got less marks. This was not defendable from the Appellants.

Dr Christopher Mizzi continued that there was a competition with points awarded and nobody knows where these points will go. It is then up to the Evaluation Board where these marks will eventually go and besides; these were not conclusive since there was also the Financial Bid.

This happens when a Tender is awarded with the MEAT criteria. There are different weightings between the price and the technique. One cannot say that he will get eliminated because the price can change a lot of things.

Dr Christopher Mizzi argued that on the other hand the Public Contracts Review Board had to see the effects that this decision can take because if the latter accepts the Appellant's complaint since it would show that the Review Board was siding with the Appellant, hence the entrance of the principle of discrimination.

At this stage there was no breach of the Public Procurement Regulations since everything was published as confirmed by Profs Xuereb. The Contracting Authority had the right to make the Technical Specifications which it required most. The Technical Specifications are there in order for the products to be evaluated.

The Evaluation Board without the Technical Specifications and the points awarded correctly can have issues when evaluating. This is something which the Evaluation Board has to see when the time comes. At this stage it was not the Public Contracts Review Board's job to enter into comparisons of different criteria when it comes to published criteria which have already marks allocated.

Dr Christopher Mizzi concluded that the fundamental test which the Public Contracts Review Board has was whether it was satisfied that the recapturability criterion as explained from their witness is up to standard with the other criteria where there is agreement. At the end of the day, there are health issues involved where the technical points raised by the witness are very important.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit said that there was an issue regarding one of the tables presented by the Appellants since it was not a head to head trial; hence there is an objection on how the statistics were conducted.

He also continued with what Dr Mizzi was saying by contending that there was a technology where there are a number of companies which can offer it and there are others which can't. The fact that the Contracting Authority was requesting a particular technology is not something which the latter can't do since at the end of the day if one had to go with the idea which is planned in the Pre-Contractual Concern, new ideas can never be introduced.

Dr Zrinzo Azzopardi continued by saying that at the end of the day, the scope of this procedure is for one to see that these criteria were objective and is not specifically directed to award the Tender to a particular Bidder. After all there is always an element of competition because there are a number of Bidders who can compete.

Dr Douglas Aquilina, the Legal Representative for Drugsales Ltd replied that it was obvious that this was the stage where his clients had to place their Pre-Contractual Concern. They were saying that the award criteria had to be justified like all the other conditions in the Tender and that they didn't heard one reason why recapturability was included.

Dr Aquilina continued that this was not a question that there were other bidders who were offering self-expandable technologies unlike Drugsales Ltd. The latter have the balloon-expandable technology which for many years has been offering excellent results. There was

a good reason why Edwards have 47% of the market. The fact that there are conditions which exclude certain competitors goes against the spirit of free competition.

At this stage, the Public Hearing was closed.

This Board,

Having noted this Pre-Contractual Objection filed by Drugsales Ltd (herein after referred to as the Appellant) on 15 November 2016, refers to the Contentions made by the latter with regards to Tender of Reference CT 2181/2015 listed as Case No 1009 in the records of the Public Contracts Review Board, awarded by the Central Procurement and Supplies Unit (herein after referred to as the Contracting Authority).

Appearing for the Appellant: Dr Douglas Aquilina

Appearing for the Contracting Authority: Dr Christopher Mizzi

Dr Stefan Zrinzo Azzopardi

Whereby, the Appellant contends that:

a) **The High Points allocated to the Technical item "*Recapturability*" will limit the competitiveness of his offer from contesting with other**

Bidders, whilst at the same instance, Drugsales Ltd maintain that his product will yield the same desired result;

b) The relevance given by the Central Procurement and Supplies Unit to the Technical Criteria "*Recapturability*" is not so important to the Tendered Medical procedure and this condition goes against the principles of Public Procurement as it is impeding a prospective Bidder from participating on a Level Playing Field.

Board also noted the Contracting Authority's "*Letter of Reply*" dated 5 December 2016 and its verbal submissions during the Public Hearing held on 5 December 2016, in that:

a) The Central Procurement and Supplies Unit contend that the Technical Specifications and the relevant issues on which points will be awarded were based on the expert advice of the professional technical people who have wide experience of the procedure being tendered for and through where the most relevant issue were identified. In this regard, great consideration was taken for the patient's well being. One of these important issues was "*Recapturability*";

b) The Contracting Authority maintains that "*Recaptuarability*" is an important requirement and in no way, does this issue impel the Appellants from competing. In this regard, the Central Procurement and Supplies Unit, through the issue of these parameters, had observed all the principles of transparency and equal treatment.

This same Board also noted the Testimonies of the witnesses namely, Profs Robert Xuereb summoned by Central Procurement and Supplies Unit and Dr Nicolas Treffort and Mr Martin Blazek all duly summoned by Drugsales Ltd.

This Board, after having treated the merits of this case, arrived at the following conclusions:

1. **This Board, would, first and foremost, emphasize the fact that this is a Pre-Contractual Concern which refers to a highly specialised medical matter so that it is not the competence of this Board to delve into the technicalities of the procedural substance but rather to establish whether the allocation of points to the Technical item, namely, "*Recapturability*", would, in actual fact limit the scope of competition.**

Through the experts' advice, the Central Procurement and Supplies Unit, quite appropriately, established four major criteria on which points will be awarded under the MEAT procedure. One of these criteria was "*Recapturability*" on which this concern is being raised and Drugsales Ltd are contending that the high allocation of points on this issue will limit their product's competitiveness.

In this regard, this Board followed closely the lucid explanations given by the Technical Witness, namely, Profs Robert Xuereb, on what the procedure involves. From this same testimony, it has been made credibly clear that the criteria dictated by the Contracting Authority were essential for the appropriate application of the whole procedure.

At the same instance, this Board would like to assert the fact that the Contracting Authority has all the rights to dictate the criteria issues and their relevance to the procurement of the most advantageous product available on the market.

This Board would like to justifiably point out that the Technical Specifications, especially in this particular case, are not capriciously drafted but rather to achieve with success the desired result for the

ultimate benefit of the patient and administrator of the procedure as such.

This Board also notes that the Technical Criteria carried a total of 70% weighting on the Total Evaluation Procedure whilst at the same time, the "*Recapturability*" issue represented 25% of the Technical Criteria.

The Technical Specification, as described in the Tender Document, with regards to "*Recapturability*" states that "*Fully recapturable is defined as having ability to remove and reposition valve after it has been fully deployed*", hence the product offered must be capable of being removed and repositioned.

From the testimonies given by the Technical Experts, this board is aware that there exist other products which give the same final result but due to the product's configuration, the latter does not possess the possibility of having the valve removed and repositioned, in other words, these products have a different technological procedure.

In this regard, this Board justifiably contend that there is a form of limitation by restricting the type of procedure to be adopted. One

has to leave room for other alternatives as long as the desired results can be achieved to the satisfaction of the Contracting Authority.

2. **With regards to the Appellant's Second Contention, this Board, acknowledges that the Central Procurement and Supplies Unit's main objective was to award and facilitate having the latest technology for the benefit of the patient, however, the Procurement is financed through public funds and as such, rules and regulations relating to the latter procedure must be observed.**

   On the other hand, this Board notes that the Technical issue of "*Recaptuarability*" was dictated in the Technical criteria on the advice of known successful technical experts and in this regard, this Board does not consider the inclusion as irrelevant, unsuitable or disproportionate and therefore declares that after hearing credible submissions from Profs Robert Xuereb, the inclusion of "*Recapturability*" is valid in the medical terms.

3. **This Board justifiably feels that certain medical submissions and opinions should not bear any relevance on the treatment of this concern and this same Board refers to the prime concern of**

Drugsales Ltd, in that the issue of "*Recapturability*" is limiting his chances of success.

In view of the above, this Board finds that, although it is not disputing the importance of the inclusion of "*Recaptuarability*" in the Technical criteria, at the same time it is credibly clear that those products which yield the desired results but do not have the possibility of "*Recapturability*" are definitely limited, if not at this particular stage, at a later one.

Having treated this concern, this Board recommends that a Clarification Note is to be issued by the Central Procurement and Supplies Unit whereby other alternative products such as "*Balloon Expandable*" procedures which perform the same function and render the same desired results are accepted and treated as such in the allocation of points.

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

14 December 2016