

PUBLIC CONTRACTS REVIEW BOARD

Case 1024 – 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 2 February 2017, Drugsales Ltd filed a Pre-Contractual Objection against the Central Procurement and Supplies Unit.

On 21 February 2017, the Public Contracts Review Board composed by Dr Anthony Cassar as Chairman, Mr Lawrence Ancilleri and Mr Carmel Esposito 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 Philip Moran	Representative
Ms Dagmar Slivkova	Representative
Dr Douglas Aquilina	Legal Representative
Dr Andrea Gera de Petri	Legal Representative

Contracting Authority – Central Procurement and Supplies Unit

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

Department of Contracts

Ms Susan Camilleri	Procurement Manager
Ms Alicia Vella Lethridge	Procurement Manager
Dr Christopher Mizzi	Legal Representative

Other Interested Parties

Ms Damaris Lofaro	Representative, Technoline Ltd
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Dr Anthony Cassar, the Chairman of the Public Contracts Review Board, remarked that the Reasoned Letter of Reply issued by the Department of Contracts and the Central Procurement and Supplies Unit was wrongly dated on 20 January 2017 which could not be the case since Drugsales Ltd have filed the Pre-Contractual Objection on 2 February 2017.

Dr Cassar continued by saying that since this was the second time that the Appellants have filed a Pre-Contractual Concern, the Public Contracts Review Board was not going to tolerate certain repetitions from the first Public Hearing.

Dr Christopher Mizzi, the Legal Representative for the Department of Contracts added that this Pre-Contractual Concern was regarding the implementation of the decision which the Public Contracts Review Board has issued on 14 December 2016. The technical issues were already settled.

Following this short introduction, Dr Anthony Cassar, the Chairman of the Public Contracts Review Board, invited the Appellants to make their submissions.

Dr Douglas Aquilina, the Legal Representative of Drugsales Ltd submitted that since this was their second Pre-Contractual Objection on this Tender, he requested that the Acts from their first Pre-Contractual Objection were to come in also in this case in order for the Public Contracts Review Board to take recognition of them.

Dr Aquilina then summarized the reasons why this time his clients were appealing. He said that the Objection regarded the Transcatheter Aortic Valve Implantation (TAVI) Device precisely the ones manufactured by Edwards Life Sciences whom Drugsales Ltd were the local representatives. These devices do not use the technology of recapturability but use balloon self-expandable technologies which reach the same targets as the former technology mentioned and as was confirmed by the Public Contracts Review Board in the previous decision.

There were other valves which were self-expandable and which developed thanks to recapturability in order to have more accuracy and to reach the desirable results compared to the ones used by Edwards Life Sciences. The Appellants continued by saying that they objected with regards to recapturability and when the parties appeared before the Public Contracts Review Board, the latter decided to accept the Objections which they have raised and confirmed the recognizance of other products like the ones used by Edwards Life Sciences which give the same results but due to their configuration do not possess the ability to remove and reposition the valves.

Dr Douglas Aquilina continued by explaining that it was also clear that there were limitations in this sense since Edwards' products, despite reaching the same targets and results, was being prejudiced since the Award Criteria does not apply for their technology.

For Dr Aquilina, the decision of the Public Contracts' Review Board was a clear one wherein other alternative products such as balloon expandable procedures which perform the same function and render the same designed results should be accepted and treated as such in allocation of points. This means that if the product supplies by Drugsales Ltd reach the same targets, it has to be treated in the same way according to the Appellants and not given a mere one, two or five points.

Following the decision issued by the Public Contracts Review Board, what happened was that the points allocated were as follows:

- a) 25 points for Full Recapturability
- b) 20 points for Partial Recapturability
- c) 10 points for No Recapturability instead of the 1 point previously allocated.

Besides, Dr Aquilina noted that the Central Procurement and Supplies Unit added “*or Balloon Expandable Technology*” where the No Recapturability points were allocated which effectively did not change anything since points were still going to be lost since both technologies were going to reach the same results anyway.

If Recapturability was really an important criterion for the Contracting Authority, the latter should have kept the 1 point allocation for non-recapturable products but then make a proviso wherein if the Bidder concerned has a balloon-expandable technology which would reach the same results, then points would have to be allocated.

Dr Douglas Aquilina continued to explain that his clients have requested a clarification, wrote a letter through their advocates but did not receive any answers. The Contracting Authority knows that they have not implemented the decision issued by the Public Contracts Review Board correctly since the difference between one and ten points is the same one.

If the Public Contracts Review Board has decided that there were products such as the one used by Edwards Life Sciences which do not offer recapturability and use an alternative technology which provides the same results, these should have been treated equally and given the same points.

The Appellants continued arguing that this same Board has accepted that the recapturability which was fair enough to them but only to products which were self-expandable and not on products which are not applicable to this case. If the Technology does not applied, the Appellants were wondering how this was going to apply against them.

The fact that the Public Contracts Review Board did not specify how the Contracting Authority should have implied the decision which the former took with regards to the first Objection, led to the latter giving the impression that they did not understand the previous decision taken by the Public Contracts Review Board and instead of one point, they gave ten which did not change anything.

Dr Douglas Aquilina, representing Drugsales Ltd, then proceeded to explain how one should have implemented the decision taken by the Public Contracts Review Board. The Central Procurement and Supplies Unit had either to say that the criteria did not apply to products which use other technologies but lead to the same results while keeping recapturability to distinguish from self-expandable balloons or else the Contracting Authority should have specified the aims which they wanted to reach through this Tender; namely the precision of deployment of the valve.

Dr Aquilina also suggested that if the Contracting Authority really wanted a Level Playing Field they should have scrapped altogether the recapturability requisition from the Tender. They had different alternatives on how to implement the decision taken by the Public Contracts’ Review Board but there was no change by increasing the marks for no recapturability from one to ten. The latter said that there were other products which give the same results despite not offer recapturability.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board said that one cannot just go and remove the recapturability requirement.

Dr Douglas Aquilina, the Legal Representative for Drugsales Ltd replied that there were three options which one of them was this and if the Contracting Authority wanted they could have taken that option and still would have been compliant with the decision taken by the Public Contracts Review Board.

Drugsales Ltd were not contesting the latter decision. They acknowledged that the recapturability requisition was there to stay; they were just saying that there were other products which were as good as recapturability since they reach the same targets and these cannot be penalised as they are doing by giving them one or ten points when other products are getting twenty-five.

The Appellants argued that if they have a product which does not offer recapturability and gets the same results and treatment, this should be treated like with like and not given only ten points.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board, then asked about the correspondence which the Appellants sent but for which they have received no reply.

Dr Douglas Aquilina, the Legal Representative for Drugsales Ltd replied that they have requested a clarification and the Contracting Authority have kept the same position. His clients then sent a legal letter in order to try and avoid appearing before the Public Contracts Review Board.

Dr Christopher Mizzi, the Legal Representative for the Department of Contracts, said that at submission stage the Public Procurement Regulations request that there shall be no communication between the Contracting Authority and any particular Bidder except by clarifications during submission period or by raising a Pre-Contractual Concern as otherwise might be tantamount to divulging information and hence giving an advantage to any particular Bidder. This was something which the Department of Contracts does not do at Tender Stage.

Dr Douglas Aquilina, the Legal Representative for Drugsales Ltd said that the Objection was a clear and was requesting the Public Contracts Review Board to clarify how the decision issued on 14 December 2016 has to be precisely implemented in order to avoid any further Appeals.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit submitted that effectively the decision which was currently being discussed was establishing that some of these medical devices had the recapturability technology and others which did not have.

The Evaluation made during Pre-Contractual Concerns was to see why and what modalities specified certain Technical Specifications. This point was discussed mainly in the previous Objection and the decision stated that Recapturability was something which shouldn't be excluded.

Dr Zrinzo Azzopardi feels that in reality the current situation was tantamount to an interpretation or direction being requested on a decision which was already taken. The binary

which one has to take in taking the decision was that all the headings were approved by the Public Contracts Review Board and that a decision was taken in that sense. Therefore the way with which the Contracting Authority has implemented the decision taken was in line since no heading was requested to be changed or removed.

It was then a question of how points should be allocated since the Tender was going to be awarded through the MEAT criteria. The procedure was a bit complicated and therefore it was already not easy to arrive to awarding the Tender. The point at this stage was that one had to be cautious and had to consider that the situation could not arrive to a point where the Pre-Contractual Concern would lead to more pressure being heaped on the procedure since it delays everything concerned with this Tender.

Dr Douglas Aquilina, the Legal Representative for Drugsales Ltd countered that if in the Tender Document originally it was stated that ten points were going to be given instead of one, the Appeal would have been filed anyway.

Secondly, if the decision taken by the Public Contracts Review Board was not going to be implemented, there was no other way other than filing a Pre-Contractual Concern. There was no interest from Drugsales' part to lengthen the procedures since they wanted to compete like every other Bidder for this Tender.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board remarked that what the Contracting Authority was saying was that a decision should be reached since the Pre-Contractual Concern puts them under pressure. The Public Contracts Review Board was ready to clear the matter and Dr Cassar was hoping that the decision which will now be reached was clear enough so that there would be no further Appeals with respect to this Tender.

Dr Christopher Mizzi, the Legal Representative for the Department of Contracts submitted that in point 2 of the decision reached by the Public Contracts Review Board on 14 December 2016 regarding the first Pre-Contractual Concern asserts *inter alia* that,

“this Board does not consider the inclusion as irrelevant, unsuitable or disproportionate”.

Dr Mizzi then continued to sustain Dr Zrinzo Azzopardi's previous statement by adding that once the recapturability heading was being accepted; different points were to be allocated for the different levels of recapturability available.

On the other hand, Dr Mizzi was disagreeing with the Appellants' arguments that maximum points were to be given if that heading was not submitted while on the other hand they were accepting anyway the recapturability factor. If the latter heading was to be kept and one is disassociating balloon expandable devices by giving maximum points, an anomaly was going to be created in the Tender which the Public Procurement Regulations does not permit.

If the Public Contracts Review Board rejected the recapturability heading, the Contracting Authority would have agreed with the Appellants but in this case where recapturability was being accepted, the maximum points, twenty-five had to be allocated.

Dr Christopher Mizzi then referred to the latter part of the decision where other alternative products, such as the balloon expandable technologies were involved, the Central Procurement and Supplies Unit decided to allocate ten points instead of a symbolic one point which in reality should have been zero since the Electronic Public Procurement System does

not allow this. If the recapturability heading had to be preserved, the discrepancy in points between products offered with the latter heading and products which did not offer recapturability should stay by allocating different points.

Dr Christopher Mizzi concluded his submissions by quoting an extract from the book called, “*Public Procurement and Competition Rules*” issued in 2011 by Albert Sanchez Graells which stated that technical specifications have two elements, whether they affect proportionality or competition rules. If either of these is respected, the Technical Specifications, in this case, the MEAT criteria, is acceptable as happens in this case.

If there are allegations which somehow can affect the competition since it excludes or treat in a different way other technologies, this does not affect the heading from staying since it is not disproportionate. These requirements, continued Dr Mizzi, are cumulative. For a Technical Specification to be removed by the Public Contracts Review Board has to either be disproportionate or else it goes against the Competition Law.

Dr Douglas Aquilina, the Legal Representative for Drugsales Ltd replied by saying that there were two different technologies, the self-expandable and the recapturable which lead to the same results. He argued that what the Contracting Authority was then saying was that if a Bidder offers a partially recapturable product, this was also going to be a prejudice against him.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board clearly stated that recapturability has got to be there and that the latter was not going to contradict its own decision.

At this stage, the Public Hearing was adjourned to Tuesday 7 March 2017 at 09:00 wherein the Public Contracts Review Board will transmit the decision taken for this Objection verbally and then distribute a hard copy of the same to all parties concerned.

This Board,

Having noted this Pre-Contractual Objection filed by Drugsales Ltd (herein after referred to as the Appellant) on 2 February 2017, refers to the Contentions made by the latter with regards to the award of Tender of Reference CT 2181/2015 listed as Case No 1024 in the records of the Public Contracts Review Board, issued 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 clarifications issued by the Central Procurement and Supplies Unit following the decision taken by the Public Contracts Review Board on 14 December 2016, still prejudiced their offer since, although reaching the same results as requested, the award criteria did not cater for the Appellant's product technology.**

To this effect, the Appellant maintains that the Contracting Authority did not adhere to the decision taken by the Public Contracts Review Board, in that, the alternative products which render the same end results, are to be treated equally with regards to the allocation of points. In fact, Drugsales Ltd insist that they were still being limited when competing against other Bidders.

This Board also noted the Contracting Authority's "*Letter of Reply*" dated 20 February 2017 and its verbal submissions during the Public Hearing held on 21 February 2017, in that:

a) **The allocation of points with regards to the recapturability was strictly based on the various levels of the latter available from the application of the product. It has been established that recapturability is to stay and therefore each product offered had different levels of recapturability so that points were awarded for full, semi and no recapturability.**

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

1. In arriving at its decision, this Board has considered the fact that the importance and the valid reasons for the application of “*recapturability*” had been credibly established and in this regard, the latter issue is a necessary feature in the product tendered for.

The main issue of this concern is whether the Central Procurement and Supplies Unit had adhered to the decision taken by the Public Contracts Review Board on 14 December 2016 or not. This Board would like to justifiably point out that since recapturability is a prime concern for the methodology of the application of the product being tendered for, the Contracting Authority, has in its own rights,

graded the extent of recapturability in so far as the allocation of points under the MEAT system.

It is a known fact that, although there are products which give the same end result, the method of application of these products do vary from one to the other. It is also a justifiable fact that the Central Procurement and Supplies Unit has to declare, under the MEAT system, the method and basis for the allocation of points to the Technical Aspect of the product.

In this case, the Contracting Authority has classified the various extents of recapturability as those which are “Fully Recoverable”, “Semi Recoverable” and “Not Recoverable”. In this regard, this Board points out that the bracketed wording, (balloon expandable) was not necessary as, at this stage, the Contracting Authority should not dictate the type but rather the classification of “Recoverability” for the purpose of allocation of points.

In the decision taken by the Public Contracts Review Board on 14 December 2016, it was decided that the Central Procurement and Supplies Unit should treat equivalent products which render the same end results on equal footing with regards to the allocation of points. However this does not imply that technologies which do not

satisfy the methodology of application of the product will be allotted the same points as those which fully satisfy these criteria.

If this event occurs, it would then distort the principle of “*Level Playing Field*”. At the same instance, this is a MEAT Tender and grading according to classifications dictated in the Tender Document must be respected. This Board also notes that the classification of “*Recapturability*” has been supported by Experienced Medical Experts in this field and in this regard, this Board opines that quantities method utilised for the allocation of points should not be disputed.

This Board would like to respectfully also point out that the Contracting Authorities have a broad discretion in dictating their own needs so that the fact that the latter, in this particular case, emphasized the requirement of “*recapturability*” in the product, the same Authority is properly catering for the proper product to fulfil their requirement.

This Board would also point out that the Appellant’s product does fall within one of the levels of “*recapturability*” as it will gain 10 points and not 0 or 1 point. It is then, up to the Evaluation Board to

choose the Most Advantageous and Economical Render, taking both the Technical and Financial Aspect of the offers into consideration.

- 2. This Board, after taking all aspects into consideration, opines that since the Appellant's product was not discarded and will be accorded appropriate points as to "recaptuarability", the Contracting Authority has adhered to the decision taken by the Public Contracts Review Board on 14 December 2016. However, through a clarification note, this Board is recommending that the bracket wording (balloon expandable) should not be included.**

In view of the above, this Board finds recommends that the Tender process should continue.

Dr Anthony Cassar
Chairman

Mr Lawrence Ancilleri
Member

Mr Carmel Esposito
Member

27 February 2017k