PUBLIC CONTRACTS REVIEW BOARD

Case 1426 – CT 2088/2019 – Tender for the Supply of Paracetamol Injections

The tender was published on the 8th August 2019 and the closing date of the call for tenders was the 17th September 2019. The estimated value of the tender (exclusive of VAT) was € 286,960.

On the 17th January 2020 A.M.Mangion Ltd filed an appeal against Central Procurement and Supplies Unit as the Contracting Authority objecting to their disqualification on the grounds of their bid being deemed to be non-compliant. A deposit of € 1,435 was paid.

There were five (5) bidders.

On 20th February 2020 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Mr Lawrence Ancilleri and Mr Carmel Esposito as members convened a public hearing to discuss the objections.

The attendance for this public hearing was as follows:

Appellants – A.M. Mangion Ltd

Dr Steve Decesare	Legal Representative
Dr Lisa Abela	Legal Representative
Mr Ray Vella	Representative

Recommended Bidder – Ecosse Ltd

Mr Ben Fenech	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Marco Woods	Legal Representative
Ms Tracy West	Secretary Evaluation Committee
Mr Adrian Spiteri	Member Evaluation Committee

Department of Contracts

Dr Franco Agius	Legal Representative

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

Dr Steve Decesare Legal Representative of A.M.Mangion Ltd said that by way of a preliminary plea the Board will note that a new clause had been added in the Authority's letter of reply; namely Ethics clause 21.2 (potential conflict of interest) in the general rules governing tenders. This is not part of the technical non-compliance reasons but added after the administrative compliance test was completed. One cannot go back to stages of the tender that had already been evaluated and now there are two reasons for disqualification whereas before there was only one. It was also inexplicable why in originally disqualifying one bidder the Authority had now disqualified a second one.

The Chairman said that the Board will take the point on the ethics clause into consideration when reaching their decision on the main objection.

Dr Franco Agius Legal Representative of the Department of Contracts stated that additional points can be raised in line with jurisprudence and he referred to two Appeal cases Krypton Chemists vs Director of Contracts and BAC vs Director of Contracts where it was held that the Authority could go to the first step of the evaluation at any stage.

Dr Decesare said that re-opening the administrative compliance stage meant that a full evaluation would be carried out. He sought the production of a witness regarding the conflict of interest claim.

Dr Franco Agius (496577M) called as a witness by the Public Contracts Review Board testified on oath that he is an Assistant Director at the Department of Contracts. He confirmed that he is familiar with Public Procurement Regulation (PPR) 21.2 which article lays down the scope and intentions of providing transparency in bids and that the definition of the term conflict of interest is not exhaustive in the PPR. The scope of the law is to determine what a conflict of interest is and refers to situations where an economic operator has economic, financial or a personal interest which he is obliged to declare (MTR(?) vs Director of Contracts).

In reply to question from Dr Decesare witness said that the phrase 'a particular link' in the general regulations is vague and covers any relationship or link with another economic operator which must be disclosed if it is likely to prejudice the transparency of the tender. Vagueness is in the extensiveness of any situation that might lead to a conflict of interest.

Dr Decesare requested from witness a clear reply as to what constitutes a conflict of interest and where it exists.

Witness replied that there were separate offers from two companies with one common shareholder with no declaration of conflict – failing to declare links between two bidders is misrepresentation and could lead to disqualification. Any links must be declared immaterial of the situation.

Dr Decesare pointed out that the declaration required on the ESPD is to ensure that there is no distortion of competition. Witness is now claiming that if there is the possibility of a conflict of interest a bidder cannot compete as the EPPS allows only an 'Agree' answer.

Witness replied that the clause mentioned in the EPPS refers holistically to the agreement with the ethics clause to which reply, Dr Decesare commented that on this point witness was contradicting his earlier statement.

Dr Decesare said that at this point he wished to deal with the main objection and sought to call a witness.

Mr Adrian Spiteri (139581M) called as a witness by the Public Contracts Review Board testified on oath that he is a Chemist by profession and was an evaluator in this tender. He agreed that according to the World Health Organisation (WHO) the definition of vial is a small container for parenteral medicinal product with a stopper and overseal the contents of which are removed after piercing the stopper and that under this definition both vial and bottle are defined as containers.

Three different type of bottles were then exhibited to witness who was asked to describe their characteristics by Dr Decesare.

Witness said that the largest bottle was a large glass bottle with a screw on cap whilst he agreed with the description that the smallest of the bottles was a small container for parenteral medical products with stopper and overseal, contents of which could be removed by piercing the stopper with single or multi-use and that it meets the WHO definition of a vial.

The Chairman at this stage pointed out that in their conclusion in the evaluation report the evaluation committee had referred to bottles rather than vials in their recommendation of award.

Witness replied that this was an error in the evaluation report.

In reply to question from Dr Decesare witness agreed that in the Council of Europe EDQH literature submitted by the Authority in their letter of reply the descriptions of vial and bottle were similar. Witness also agreed that the sample submitted by Appellants meets the definitions of both vials and bottles. Witness also confirmed that the evaluation committee did not seek to find out what an Ecoflac plus bottle (offered by Appellants) was, nor sought technical literature to be submitted or requested samples to properly evaluate it. The evaluation committee did not consult anyone before the decision to disqualify was taken.

At this stage Appellants requested the Board's permission to table literature showing the characteristics of the Ecoflac plus bottle but this was opposed by the Authority and the Board directed that the documents should not be tabled.

In reply to further questions witness stated that the offer from Appellants indicated a bottle and nowhere was there any reference to a vial. He again re-iterated that the reference to 'bottle' in the evaluation report's conclusion was an error, and that the evaluation committee had not checked what an Ecoflac plus bottle was, although the label on the bottle included words like 'intravenous use' 'paracetamol solution for infusion' etc. which is what the offer was specifying.

Witness was later recalled and asked by the Chairman if the product offered by Appellants meets the objectives of the tender. He confirmed that the product, namely, a painkiller delivered intravenously meets the requirements of the tender.

Dr Decesare said that through the documents submitted by the Contracting Authority it has been established that a vial has particular characteristics. In the definitions in several languages in the EDQH documents bottles and vials have the same characteristics, and are interchangeable in the WHO definitions. The Authority did not ask for technical literature or samples as they are allowed to do as they felt it not necessary since they decided that the Ecoflax bottle is a normal bottle with no further checks undertaken. They also claim that the definition of a bottle must be in a purely pharmaceutical context, yet all the Appellants definitions in their letter of appeal came from dedicated medical dictionaries. In a clarification the tender did not specify any particular characteristics required – it merely excluded bags. Significantly witness confirmed that the product offered met all the performance requirements of the tender. The product offered meets the requirements of the tender both regarding the product and the container which conforms to the WHO definition.

Turning to the question of the conflict of interest Dr Decesare mentioned that there were offers from Ecosse Ltd and A.M.Mangion Ltd – if a conflict of interest existed and these two companies acted in tandem to win the tender it would be paradoxical that he would be arguing the case for a product that is offered at a cheaper price. The procurement process is not an argument about conflict of interest but to ensure that there is no distortion of trade and there is no restriction on using the same qualified person. The Authority cannot decide for itself when to exclude but must follow the general tender regulations and cannot go beyond them. In Regulation 192 for instance the words used are 'may exclude'.

Reference was made to ECJ Case C538/07 (relationship of control to exclude bidder) and C 144/17 (tenders of both parties signed by same person) both of which cases dealt with aspects of conflict of interest.

Dr Agius stated that the point that the tender specified vial it not in contest. The Council of Europe definitions vary the terminology between vial and bottle and if the PCRB awarded the tender on the basis of this argument it would be tantamount to changing the terms of the tender. It would also prejudice other potential bidders who might have come forward if a different definition was

used. The use of a clarification or of a remedy was available to the Appellant but they chose not to use that avenue. The specifications demanded vial and it is not up to the evaluation committee to vary those requirements. A.M.Mangion Ltd offered a bottle; the preferred bidder offered a vial and it was up to the Appellant to prove equivalence.

The offer of the recommended bidder included a letter from A.M.Mangion Ltd – this link qualifies as grounds for exclusion under the General Rules covering Tenders. Appellants' offer left no doubt that they were offering a product in a bottle – the vial requisite is cast in stone and cannot be changed.

Dr Decesare said that the two companies involved are separate companies with different directors and different shareholders and there is therefore no link – hence the reason why it was not necessary to make any declarations and why there was no misrepresentation. Appellants offered exactly the same product. The WHO definition of vial meets all the terms quoted by the Contracting Authority in their letter of reply, paragraphs 16, 17 and 20. Other tenderers would not be prejudiced – it was up to any potential bidder to check if there is any difference between vial and bottle, as indeed there was no need to seek clarifications as the medical dictionaries all made it clear that the two words had synonymous definitions.

Dr Agius said that there is an obligation on the part of the bidder to disclose any links. Also, there must be a reason why there is a distinction between the word bottle and vial.

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

End of Minutes

Decision

This Board,

having noted this objection filed by A.M Mangion Ltd (hereinafter referred to as the Appellants) on 17 January 2020, refers to the claims made by the same Appellants with regard to the tender of reference CT 2088/2019 listed as case No. 1426 in the records of the Public Contracts Review Board awarded by

Central Procurement and Supplies Unit (hereinafter referred to as the Contracting Authority).

Appearing for the Appellants: Dr Steve Decesare

Appearing for the Contracting Authority: Dr Marco Woods

Whereby, the Appellants contend that:

a) **By way of a preliminary plea, they strongly contest the Authority's new alleged claim that, there existed a conflict of interest through the said Appellants participation in the tender. In this regard, Appellants insist that their offer was rejected solely on the alleged misinterpretation of the word vial, during the technical evaluation process of their offer.**

b) **Their main contention refers to the fact that their product is technically compliant, and the product is supplied in a small bottle, totally suitable to meet the objectives of this particular procurement. In this respect, the Authority is alleging that the container, i.e. small bottle is not a 'Vial', whilst Appellants are insisting otherwise.**

This Board also noted the Contracting Authority's 'Letter of reply' dated 29 January 2020 and its verbal submissions during the hearing held on 20 February 2020, in that:

a) **Through its 'Reasoned Letter of Reply' the Authority raised the issue that Appellants failed to declare that more than one offer is being submitted by Appellants, thus a conflict of interest existed.**

b) **Appellants' offer container consisted of a 'Bottle' whilst the tender document requested a 'Vial', so that Appellants' offer was technically non-compliant.**

This same Board also noted the testimony of the witnesses namely:

Dr Franco Agius duly summoned by the Public Contracts Review Board

Mr Adrian Spiteri duly summoned by the Public Contracts Review Board

Through its 'Letter of Reply' dated 29 January 2020, the Authority contends that Appellants failed to declare that they are not affected by any potential conflict of interest. The Authority insists that, there is a link between the preferred bidder namely Ecosse Ltd and the Appellants A. M. Mangion Ltd. In this regard, the Appellants maintain that such an alleged link involves two separate commercial entities, having different shareholders and directors and

such alleged link did not cause any distortion to trade or competition. Appellants also maintain that, such an alleged claim is being brought up by the Authority now, when Appellants' offer rejection was based purely on technical grounds.

This Board, after having examined the relationship between Appellants and the preferred bidder, opines that, although there is a common shareholder in both companies, the 'Conflict of Interest' element exists if both companies participated with the sole intention to suffocate and disrupt the competitive element, to the detriment of the other economic operators participating in the same tender. In this particular case, both companies competed with different brands of products, both quoting different and reasonable prices without hindering the spirit of competition.

This Board would respectively point out that, although the Authority has the right to raise the issue of conflict of interest now, same Board is somewhat at a loss as to why such an issue was not identified at the administrative compliance stage, so that a less intrusive measure would have been more appropriate.

After having considered the above-mentioned issues, this Board opines that there was no distortion of fair competition through the participation of both the

awarded bidder and Appellants and although, it would have been more appropriate for the Appellants to declare that there was no conflict of interest. Their actual participation in the tender does not merit any draconian measures. In this respect, this Board does not uphold the Contracting Authority's preliminary plea.

This Board, after having examined the relevant documentation to this appeal and heard submissions made by the parties concerned including the testimony of the witnesses duly summoned opines that, the issue that merits consideration is whether the container of Appellants' product meets the technical specifications of the tender document or not.

1. **this Board would respectfully refer to clause 1.1 of the technical specifications which states that:**

   *"**1.1. Product Specifications***

   Paracetamol 10mg/ml solution for infusion in 100ml vials, for intravenous administration"

   The issue, in this particular case, is the container referred to as a 'Vial'. In this respect, various interpretations were presented with regard to the interpreted meaning of a 'Vial', however, this Board is more concerned about the technical objectivity of the tendered procurement itself, which is the application of paracetamol intravenously.

2. **From submissions made by the witness Mr Adrian Spiteri, this Board was informed that , according to the World Health Organisation (WHO), the definition of a 'Vial' is a small container for parenteral medicinal product with a stopper and overseal; the contents of which are removed after piercing the stopper, so that, under this definition, both vial and bottle are defined as containers. An extract from the testimony of Mr Spiteri refers to this issue as follows:**

"Avukat : *Fil-fehma tal-WHO x'inhu vial?*

Xhud : *Naqra d-definition tal-WHO jigifieri?*

Avukat : *Jekk joghgbok*

Xhud : *A vial – a small container for . . . . medicinal products with a stopper and overseal. The contents are removed after piercing the stopper, both single dose and multi dose types exist."*

3. **This Board was vividly made aware that a 'Vial' has a very special function, in that, it is applied for intravenous injection of medicine through the fluid contained in this particular bottle (container) which has the characteristics as amplified by same witness Mr Spiteri during his testimony, as follows:**

"Avukat : *Issa bhala container, ghandu certu karatteristici li semmejt inti. Ghalfejn ghandu dawk il-karatteristici? Jigifieri x'inhi l-funzjoni ta' dawk il-karatteristici? Ghalfejn ghandu s-seal? Ghalfejn ghandu stopper u dawn l-affarijiet?*

Xhud : *Ghax ghandu dawk il-karatteristici ghax ovjament l-uzu tieghu huwa differenti minn dik ta' bottles. U according to WHO, bottles huma definiti differenti wkoll"*

At the same time, witness was shown a sample of Appellants' product, herein being referred to as a 'Small Bottle' and the function of same was confirmed by the witness, as follows:

"Avukat : *Mela ghandek tliet bottles quddiemek. Tajjeb. Ejja nduru d-definition li ghadek kif tajtni inti. Dak iz-zghir li ghandek hemm huwa small container?*

Xhud : *Small hija kelma relattiva*

Avukat : *Iva jew le?*

Xhud : *Small container*

Avukat : *Huwa for parenteral medicinal products?*

Xhud : *Iva*

Avukat : *Ghandu stopper fuqu? Iva jew le*

Xhud : *Iva ghandu stopper*

Avukat : *Ghandu overseal?*

Xhud : *Iva*

Avukat : *Jista' l-kontenut tieghu jigi removed after piercing the stopper? Jekk hemm bzonn nehhi l-overseal u ccekkjah*

Xhud : *Iva*

Avukat : *Jista jintuza ghal both single dose jew multi dose?*

Xhud : *Iva*

Avukat : *Tista tghidli fid-definition tal-WHO li tajtni inti liema wiehed minn dawk il-karatteristici m'ghandux dak il-vial? Ghax vial huwa dak kollu li ghadek kif ghidtli inti*

Xhud : *Il-problema hija li dan ma giex sottomess"*

4. **At this stage of consideration, this Board confirms that according to WHO, the definition of a vial is a small container having the characteristics of being used for parenteral medicine products, has an**

overseal stopper and after peircing the stopper the contents therein can be removed. In this regard, Appellants' product does have these characteristics.

5. **In this regard, this Board observes that the Evaluation Committe rested on the SPC of the product and since this document denoted the word 'Bottle' and not 'Vial', Appellants' offer was outrightly discarded and deemed technically non-compliant. However, from submissions and testimony of the witness namely Mr Adrian Spiteri, this Board notes that Appellants' product does in actual fact, have all the characteristics which meet the technical specifications of the tender document and satisfies the objective of the utilisation of the product, whether the container can be classified as a 'Bottle or 'Vial'.**

6. **It is apparent that, due to the fact that no samples were requested, the Evaluation Committee, in a subjective manner, ruled out Appellants' product due to the simple fact that Appellants' products' SPC did not indicate the word 'Vial' but from submissons made this Board establishes that Appellants' product can achieve the Authority's objective. This Board also opines, that, in cases such as these, the Authority should**

request samples with the offers, so that, the Evaluation Committee would be in a better situation to assess the offers objectively.

7. **This Board would respectfully refer to the conclusion of the evaluation report, which erronously denoted the incorrect bid for the award. In this respect, same Board is somewhat, at a loss, due to the fact that the General Contracts Committee (GCC) did not identify such an obvious misinterpretation of the award. In this regard, this Board would point out such a mistake is not to be taken lightly, as the conclusion of the evaluation report should represent the overall assessment of the offers and in this case, such a conclusion recommends the opposite to what was intended.**

In conclusion, this Board opines that:

a) **With regard to the Contracting Authority's claim that through the participation of Appellants and the preferred bidder, a conflict of interest was created and in this regard, Appellants failed to declare such conflict, this Board does not find any indication of distortion of fair competition in the evaluation process.**

b) From lenghty submissions and testimony of the witness, this Board opines that Appellants' product meets the stipulated technical specifications.

c) In cases such as these, the Authority should have requested the submission of samples so that the Evaluation Committee would be in a more objective situation to carry out their adjudication of offers.

d) Much emphasis has been made on the differnece between a 'Small Bottle' and a 'Vial', however, this Board opines that more importance should have be given on whether the application of Appellents' product attains the Authority's objectives or not.

e) The conclusion of the evaluation report was incorrect and it went unnoticed also by the GCC who approved the incorrect recommendation.

In view of the above, this Board,

i. cancels the Contracting Authority's decision in the award of the tender,

ii. directs the Authority to commence a re-evaluation process,

iii. directs that the Evaluation Committee requests samples of all the offers,

iv. directs that the Appellants' offer be re-integrated in the evaluation process,

v. directs that the deposit paid by Appellants be fully refunded.

Dr Anthony Cassar	Mr Lawrence Ancilleri	Mr Carmel Esposito
Chairman	Member	Member

12 March 2020