PUBLIC CONTRACTS REVIEW BOARD

Case 1319 – CT 2048/2018 – Tender for the Supply of Recombinant Human Erythropoietin

The publication date of the call for tenders was the 10th May 2018 whilst the closing date of the call for tenders was 19th June 2018. The estimated value of the tender (exclusive of VAT) was € 608,606.48 for three lots.

On the 22nd March 2019 V J Salomone Pharma Ltd filed an appeal against the Central Procurement and Supplies Unit as the Contracting Authority requesting the cancellation of the tender as no presentation fully met the tender specifications. A deposit of € 3,041 was paid.

There were three (3) bidders.

On 30th May 2019 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Dr Charles Cassar and Mr Richard Matrenza as members convened a public hearing to discuss the objections.

The attendance for this public hearing was as follows:

Appellants – V J Salomone Pharma Ltd

Dr Veronica Galea Debono	Legal Representative
Mr Chris Treeby Ward	Representative
Mr John S Forte	Representative
Ms Vanessa Said Salomone	Representative

Recommended Bidder – Cherubino Ltd

Dr Francis Cherubino	Legal Representative
Mr Paul Calleja	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Marco Woods	Legal Representative
Ms Monica Sammut	Chairperson 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 before inviting submissions stated that letters of objection must show what motivated an appeal. In this Case the reason given for objecting to the award is not the motive and is late in terms of the action which could have been taken. To ensure fairness the Case will be heard nonetheless.

Dr Veronica Galea Debono Legal Representative of V J Salomone Pharma Ltd apologised on behalf of her clients for the lack of motivation in their appeal and said that their objection on the award of the tender was simple. Section 4 of the Technical Specifications requests a product that can be used intravenously (IV) or subcutaneously (SC) and to be valid for use in all circumstances. This description is not correct. None of the bids offered a product that met the description given and similar tenders issued before covered only specific, not all, circumstances. The two sentences in Section 4 create anomalies. In fact, an interim request (issued two days before this appeal was submitted) by the CPSU for this same product was worded differently and correctly but was at odds with the wording of this tender. It has to be borne in mind that there is a difference of some € 98,000 in the tendered prices. Since no product falls within the tender specifications it should be cancelled and re-issued with the correct wording to enable equal participation and a level playing field. It is crucial that the tender reflects the wording used in the interim request as in the existing situation neither the Appellants nor the preferred bidder met the specifications of the tender.

Mr Chris Treeby Ward (488073M) a Chemist by profession called as a witness by the Appellants testified on oath that the product Erythropoietin could be administered IV or SC. He tabled a document (Doc 1) indicating and comparing the use of the products submitted by the two competing bidders. Witness stated that the product offered by the preferred bidder cannot be used in all circumstances. The brand Binocrit offered by the Appellant met the requirements listed in both the first and second sentences listed in Section 4 of the technical specifications.

Mr Mark Zammit (425874M) called as a witness by the Contracting Authority testified on oath that he is an Advanced Pharmacy Practitioner representing the CPSU. In reply to questions he stated that in his view the recommended product meets the requirements laid out in the first two sentences of Section 4 in all cases. He explained that the product is a hormone supplement to increase the production of the number of red blood cells. The tender was requesting a product that produced an identical hormone in the laboratory and was administered through pre-filled syringes in the treatment of anaemia caused by chronic renal failure in both children and adults. It could be administered both IV and SC with the latter allowing it to be self-administered without the need of hospital visits. The product offered by Cherubino as listed in the document (Doc 1) tabled earlier is relevant as it meets the requirements of the tender. The product Binocrit, offered by the Appellants, does not qualify for the treatment of children as it cannot be administered SC. This

was clear from a detailed reference to the summary of product characteristics (SPC). The safety of Binocrit has not been established regarding its use SC and this was an important issue.

Further questioned by Dr Galea Debono witness stated that the formulary of this product must be considered in the context of the set protocol in the treatment of renal failure but does not exclude its use for other purposes if approved by the Exceptional Committee. However, the core use is in renal failure.

At this point witness was asked to withdraw while the Legal Representatives of both parties argued whether it was allowable to make references to past tenders in the course of this hearing, Dr Galea Debono insisted that she was only referring to an interim order issued by the CPSU and not to a previous tender, while Dr Agius was formally objecting to questions which made any reference to anything except the Case in process.

The Chairman said that he would allow questions provided there was no reference to previous tenders.

Mr Mark Zammit resuming his testimony, in reply to questions from the Chairman, said that it appeared to him that the main focus of the specifications approved by the Department of Pharmaceutical Affairs was on renal failure. In the context of the specifications the first sentence of Section 4 was the key one with the second sentence backing it – one must consider them holistically.

At this stage Dr Galea Debono tabled copy of an email sent by the CPSU (Doc 2) requesting an interim supply of the product under consideration two days before Appellants submitted their appeal and the specification of which did not include children.

Witness stated that the crucial point in the CPSU tender is that according to Protocol 65 the product can only be given free of charge in cases of chronic renal failure. He tabled a copy of Protocol 65 (Doc 3) which limits the use and the context of use of the product.

Dr Francis Cherubino Legal Representative of Cherubino Ltd said that other remedies were available to Appellants regarding the interpretation of the technical specifications prior to their submissions. He confirmed that their product was fully up to the specifications and this was backed by the product manufacturer. One cannot base tenders on some unknown future possible requirements of the Medical Department.

Dr Galea Debono said that the way the technical specifications in the tender were worded gave rise to doubts in interpretation. The phrase used ‘in all circumstances’ should cover all the specifications. None of the tenders were fully compliant and no one tenderer should have been awarded the contract.

Dr Franco Agius stated that the tender was a contract and one must have a holistic approach not extrapolate clauses in isolation. The allegations made in the letter of objection had not been proven.

Mr Zammit in his testimony had confirmed that the specifications had been met. Appellants had eliminated themselves through their claim that no offer had been compliant. This means that Appellants had no juridical interest in the appeal. They had remedies available prior to tendering which they did not make use of.

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

This Board,

having noted this objection filed by V.J. Salomone Pharma Limited (herein after referred to as the Appellants) on 22 March 2019, refers to the claims made by the same Appellants with regard to the tender of reference CT 2048/2018 listed as case no 1319 in the records of the Public Contracts Review Board, awarded by Central Procurement and Supplies Unit (herein after referred to as the Contracting Authority.

Appearing for the Appellants: Dr Veronica Galea Debono

Appearing for the Contracting Authority: Dr Marco Woods

Appearing for the Department of Contracts: Dr Franco Agius

Whereby, the Appellants contend that:

a) **their main contention refers to the fact that, the tender document, under section four (4), requested a product that can be used intravenously (IV) or subcutaneously (SC), to be applied in all circumstances. In this regard, Appellants maintain that none of the offers submitted met the technical specifications. Appellants also insist that similar tenders issued before,**

were more specific in denoting the application of the product, so that, the latest technical specifications where somewhat confusing and in this respect, Appellants maintain that the tender should be cancelled.

This Board also noted the Contracting Authority's 'Letter of Reply' dated 3 April 2019 and its verbal submissions during the hearing held on 30 May 2019, in that:

a) **the Authority maintains that Appellants in their 'Letter of Objection' admitted that their product was not compliant with the technical specifications. In this respect, the Authority contends that, the technical specifications were correct and clearly denoted what was being requested and since Appellants' product was technically non-compliant, their offer was appropriately rejected.**

This same Board also noted the testimony of the witness namely, Mr Mark Zammit duly summoned by Central Procurement and Supplies Unit.

This Board has also taken note of the documents submitted by V.J. Salomone Pharma Limited which consisted of:

Doc 1 – comparison of products submitted by the two competing Bidders,

Doc 2 – copy of email sent by Central Procurement and Supplies Unit on same product,

Doc 3 – submitted by Mr Mark Zammit – consisting of protocol 65, showing that the product can only be given free by the state, in cases of chronic renal failure.

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 issue meriting consideration, is the formulation of the technical specifications of the tender document.

1. **First and foremost, this Board would respectfully point out that, Appellants' 'Letter of Objection' was completely void of any motivation, apart from the fact that, no proof or evidence was provided for their alleged fact that, no compliant bids were submitted. However, for the sake of transparencies, this Board heard the appeal.**

2. **With regard to Appellants' claim that the technical specifications in section four (4), crate anomalies, this Board would refer to the description of the product being requested by the Authority, as follows:**

"RECOMBINANT HUMAN ERYTHROPOIETIN

CPV 33621000-9

Recombinant human erythropoietin solution for injection in pre-filled syringes for SC and IV use, licensed for both adults and children for the treatment of anaemia associated with chronic renal failure. The item must be licensed to be administered via the IV and SC route in all circumstances."

The above description clearly states that, the treatment refers to anaemia associated with chronic renal failure and the clause explicitly dictates that the product must be licenced to be administratively via the (IV) and (SC), in both applications, so that this Board opines that the product is to be applied in cases of renal failure. In this respect, this Board would also refer to the objective application of the product as vividly explained by the witness, Mr Mark Zammit, as follows:

Avukat : *Issa tista tispjegalna daqxejn is-CPSU xi xtaqet tixtri b'referenza specifika ghall-ewwel zewg sentenzi ta' section 4 please?*

Xhud : *L-ewwel haga xtaqt nghid very briefly x'inhu dan l-Erythropoietin. L- Erythropoietin huwa hormone li naghmluh gisimna stress li huwa mportanti hafna biex izid il-produzzjoni tac-celloli l- homor. Ir-red blood cells. Ikun hemm hafna kundizzjonijiet fejn ikun hemm anemiji, partikolarment f'pazjenti li jkollhom problemi bil-kliewi. Dawn in-nies ikollhom bzonn supplement regolari ta' dan il- hormone biex jistghu ikollhom ir-red blood cells u allura t-trasport ta' ossignu fid-demm f'livell li jkun adegwat. Issa fic-cirkostanza ta' din il-call, li kien qed jigi mitlub huwa prodott ta' l- Erythropoietin li huwa recombinant. Recombinant ifisser li mhux gej minn blood transfusions. Meta nghidu l-kelma recombinant, tfisser li jkun kopja identika pero maghmula fil-laboratorju. Tfisser ma jkunx gie l- Erythropoietin minn blood transfusions tan-nies. U hemm hafna brands differenti ta' human Erythropoietin differenti. Issa li gie mitlub li jkun pre-filled syringes, ifisser qed nitkellmu siringi li jkunu diga pre-filled, lesti biex jinghataw. Fis-sens mhux ampoule, pre-filled syringe, li trid tintuza f'kuntest ta' treatment ta' anaemia f'pazjenti li ghandhom chronic renal failure, problem fil-kliewi, kemm f'adulti u kemm fit-tfal, u fic-cirkostanzi t-tnejn*

li huma, adulti u tfal, irid jintuza kemm intra-venously, possibilment u kemm ukoll taht il-gilda, subcutaneously. Dawn il-pazjenti peress li jridu jehduha b'mod regolari, meta inti ghandek xi haga intra-venously, tehodha l-isptar bil-fors. Dawn il-pazjenti jehduha regolarment iridu, u jehduha regolarment impossibbli joqghodu jigu kuljum l-isptar. Allura ir-route subcutaneous hija l-istess route li tinghata biha l-insulina, taht il-gilda. Il-pazjent jista jitghallem facilment kif jehodha, jew il-genituri u jehodha regolarment minghajr il-bzonn li jigi l-isptar. Allura din l-ispecification qeghda li trid tintuza ghal pazjenti adulti u tfal li ghandhom renal impairment u ghandhom anemia minhabba fiha u kemm ghal adulti u kemm ghat-tfal tintuza kemm IV u kemm subcutaneous."

3. **From the submissions made, this Board was made aware that Appellants' product failed in the application of subcutaneous administration in paediatrics, as duly stated by the witness, as follows:**

"Chairman: Tal-appellant x'kellu nieqes?

Xhud : Tal-appellant li kien hemm issue kienet fis-subcutaneous administration fil-paediatrics. L-issue tal-prodott Binocrit kienet illi fuq ir- route subcutaneous, taht il-gilda fit-tfal. Ma kinitx tikkwalifika f'dik il-parti."

In this regard, this Board noted that Appellants are contesting the fact that, the interim request of procurement for the same product, contained different technical specifications, and in this respect, this Board is only concerned with the technical specifications of this particular tender and not about other interim measures which the Authority undertook to secure the supply of the same product.

4. The issue of this appeal is the interpretation of the technical specifications as stipulated in section four (4) of the tender document and from the testimony and credible explanations given by Mr Mark Zammit, this Board is credibly convinced that the technical specifications as duly dictated were clear enough to enable prospective Bidders to identify the product the Authority was requesting.

In this regard, this Board would also refer to an extract from Mr Zammit's testimony, as follows:

"Avukat : *Imma it is also subject to interpretation of the specs sa certu punt. Hemm daqxejn lok ghal interpretazzjoni fit-tieni sentenza*

Chairman : *Sur Zammit, fl-opinjoni tieghek, l-ispecifications tat-tender document, kienu cari bizzejjed?*

Xhud : *Iva*

Chairman : *Ma kienx hemm xi haga nieqsa li forsi wiehed jigi misunderstood jew inkella misinterpreted?*

Xhud : *Jien kif qed naraha, hemm paragrafu wiehed li qed jiddeskrivi xi jrid ikun henm. Jiena narah car."*

5. **This Board would respectfully point out that the issues raised by Appellants refer to instances, where such misunderstandings or misinterpretations of the technical specifications, could have been evened out through other remedies available to Appellants and in this regard, this Board regretfully notes that such remedies were not availed of by**

same. It is untimely and futile to challenge the specifications, at this particular tendering stage, when one takes into consideration that Appellants, in their own submission, admitted that their offer was not compliant.

6. **This Board also considered the fact that no evidence was presented by Appellants to prove that the decision to award the tender to the preferred Bidder was erroneous and, in this respect, this Board refers to Mr Zammit's testimony, in this regard, as follows:**

"Chairman : *U l-offerta tal-appellant kienet compliant in that respect, am I right?*

Xhud : *Tal-appellant?*

Chairman : *Sorry tal-preferred bidder*

Xhud : *Tal-preferred bidder iva."*

In conclusion, this Board opines that:

a) **Appellants' 'Letter of Objection' lacked the basic motivation to justify such an appeal;**

b) **The technical specifications as duly stipulated in the tender document were clear enough to enable prospective Bidders to identify the product being requested by the Contracting Authority;**

c) **Appellants' offer was technically non-compliant;**

d) **no evidence was provided by Appellants to prove the authority's award decision to be erroneous;**

e) **Appellants had the remedies to clarify any misinterpretation or misunderstandings of the technical specifications, prior to the submission of their offer and such remedies were not availed of by same.**

In view of the above, this Board,

i) does not uphold appellants' contentions;

ii) upholds the Contracting Authority's decision in the award of the tender;

iii) directs that the deposit paid by Appellants should not be refunded.

Dr Anthony Cassar	Dr Charles Cassar	Mr Richard A. Matrenza
Chairman	Member	Member

25 June 2019