

## **PUBLIC CONTRACTS REVIEW BOARD**

### **Case 1701 – CT2179/2021 – Tender for the Supply of Levodopa 10mg with Carbidopa 10mg tablets**

**5<sup>th</sup> April 2022**

The Board,

Having noted the letter of objection filed by Dr Clement Mifsud Bonnici and Dr Calvin Calleja on behalf of Ganado Advocates acting for and on behalf of Vivian Corporation Ltd, (hereinafter referred to as the appellant) filed on the 7<sup>th</sup> February 2022;

Having also noted the letter of reply filed by Dr Alexia J Farrugia Zrinzo and Dr Leon Camilleri acting for Central Procurement and Supplies Unit (hereinafter referred to as the Contracting Authority) filed on the 17<sup>th</sup> February 2022;

Having heard and evaluated the testimony of the witness Ms Daniela Galea (Representative of Vivian Corporation Ltd) as summoned by Dr Clement Mifsud Bonnici acting for Vivian Corporation Ltd;

Having heard and evaluated the testimony of the witness Dr Ian Ellul (Chairperson of the Evaluation Committee) as summoned by Dr Alexia J Farrugia Zrinzo acting for the Contracting Authority Ltd;

Having heard and evaluated the testimony of the witness Ms Denise Dingli (Member of the Evaluation Committee) as summoned by Dr Alexia J Farrugia Zrinzo acting for the Contracting Authority Ltd;

Having taken cognisance and evaluated all the acts and documentation filed, as well as the submissions made by representatives of the parties;

Having noted and evaluated the minutes of the Board sitting of the 24<sup>th</sup> March 2022 hereunder-reproduced.

#### **Minutes**

#### **Case 1701 – CT 2179/2021 – Tender for the Supply of Levodopa 100mg with Carbidopa 10mg Tablets**

The tender was issued on the 14<sup>th</sup> July 2021 and the closing date was the 24<sup>th</sup> August 2021. The value of the tender excluding VAT, was € 120,120.

On the 7<sup>th</sup> February 2022 Vivian Corporation Ltd filed an appeal against the Central Procurement and Supplies Unit as the Contracting Authority objecting to their disqualification on the grounds that their offer was deemed not to be technically compliant.

A deposit of € 600 was paid.

There were two (2) bidders.

On the 24th March 2022 the Public Contracts Review Board composed of Mr Kenneth Swain as Chairman Mr Lawrence Ancilleri and Ms Stephanie Scicluna Laiviera as members convened a public virtual hearing to consider the appeal.

The attendance for this public hearing was as follows:

**Appellant – Vivian Corporation Ltd**

Dr Clement Mifsud Bonnici	Legal Representative
Ms Jasmin Ellul	Representative
Ms Daniela Galea	Representative

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

Dr Alexia Farrugia Zrinzo	Legal Representative
Ms Denise Dingli	Chairperson Evaluation Board
Dr Ian Ellul	Member Evaluation Board
Ms Christianne Farrugia	Representative

**Recommended Bidder – Europharma Ltd**

Mr Michael Peresso	Representative
Mr Alex Fenech	Representative

Mr Kenneth Swain Chairman of the Public Contracts Review Board welcomed the parties. He noted that since this was a virtual meeting all the parties agreed to treat it as a normal hearing of the Board in line with Article 89 of the Public Procurement Regulations. He then invited submissions.

Dr Clement Mifsud Bonnici Legal Representative for Vivian Corporation Ltd said that there are two aspects to this appeal – one was the aspect of facts and one of rights. He requested that witnesses be heard to ascertain facts.

Ms Daniela Galea (326880M) called as a witness by Appellant testified on oath that she was responsible for compiling and submitting the tender. She recalled uploading the technical offer , the Summary of Product Characteristics (SPC), the licence, financial bid and other requested documents. The SPC submitted was the one prepared by the Marketing Holder. The information contained in the SPC was repeated in the Technical Offer. The particular medicines mentioned in the tender were registered with the Malta Medicines Authority.

Dr Ian Ellul (296980M) called as a witness by the Contracting Authority testified on oath that he is a Chemist by profession and was a member of the Tender Evaluation Committee (TEC). He stated that on opening of the tender it was realised that the Technical offer was uploaded

twice but the SPC was missing. Since this came under Note 3 the TEC could not request it. It was later confirmed by the IT section that the SPC was missing.

Questioned by Dr Mifsud Bonnici witness confirmed that the SPC came under Note 3 restrictions.

Ms Denise Dingli (126682M) called as a witness by the Authority confirmed on oath that she was the Chairperson of the TEC. She was made aware of the missing document and personally checked to make sure that it was missing.

This concluded the testimonies.

Dr Mifsud Bonnici said that there is here a situation where the Appellant claims that it uploaded the SPC whilst the Authority says that it did not. This is an instance where one has to deal with the point of proportionality and look at what is the aim of the tender and apply the principle of non-discrimination. Appellant accepts that this is a Note 3 matter and is not subject to rectification, but the Court of Appeal decisions have changed the outlook on this point and it is up to the Board to uphold that. The Appellant would not gain any advantage by filing the missing document.

The Court of Appeal ruling is to ensure that the tender terms are not changed and reference was made to Case 362/2014 (para 13 to 16) where the bidder was required to submit copy of the licence and the Court decreed that the principles of transparency will not be affected even though the matter came under Note 3. In Case 7/2020 (V J Salomone vs CPSU) there was doubts whether the SPC had been submitted but in this case the call was cancelled through the passage of time. The Multigas case was different as it was argued that there was no need to submit a SPC whilst in the AIB insurance Brokers Case (237/2021) the Appeal Court stated that the principle of proportionality would not be observed if a favourable offer was discarded because of a missing document which could easily be made available. In today's Case the technical offer was submitted and all that was needed was to confirm the details with the SPC – even if the technical offers could be rectified it would avoid many holdups of tenders in future.

Dr Alexia Farrugia Zrinzo Legal Representative for the Contracting Authority said that in the process of evaluating a tender all documents need to be examined. It has been proved in evidence that the SPC was not submitted - this came under Note 3 and the TEC needed it to put their mind at rest that things were in order. In Case 317/2020 the Appeal Court clarified that certain documents were essential to meet the tender requirements; since this document was not presented there was no alternative except to refuse the offer.

Dr Mifsud Bonnici stated that the arguments just put forward have changed since the Court of Appeal decision – in the Salomone case the Court held that the lack of an SPC did not alter the tender terms.

Mr Alex Fenech Representative for Europharma Ltd claimed that his company has never appealed on similar cases. If Appellant felt that the submission of certain documents should not come under Note 3 he should have sought pre-contract remedies.

Dr Farrugia Zrinzo said that the Authority must insist on the importance of the SPC and it was clear that it was a Note 3 item and the lack of it prevented the TEC from evaluating the tender completely – all parties must respect the tender terms.

The Chairman noted that there are no further submissions, thanked the parties and declared the hearing closed.

End of Minutes

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**Hereby resolves:**

The Board refers to the minutes of the Board sitting of the 24<sup>th</sup> March 2022.

Having noted the objection filed by Vivian Corporation Ltd (hereinafter referred to as the Appellant) on 7<sup>th</sup> February 2022, refers to the claims made by the same Appellant with regard to the tender of reference CT2179/2021 listed as case No. 1701 in the records of the Public Contracts Review Board.

Appearing for the Appellant: Dr Clement Mifsud Bonnici

Appearing for the Contracting Authority: Dr Alexia J Farrugia Zrinzo

Whereby, the Appellant contends that:

- a) On 28 January 2022, the Appellant received a letter of rejection stating that its bid was technically non-compliant as follows: “*SmPC not submitted at tendering stage in breach of Section 3 Clause 2.1 of the Tender Dossier. This is not rectifiable and thus offer cannot be evaluated.*” The Appellant is aggrieved by the Contracting Authority's decision and this is for the following reasons.
- b) First the Appellant did upload the SmPC on ePPS.
- c) Second, and even if, for argument's sake, the Appellant did not submit the relevant SPC, then the Contracting Authority should have allowed the Appellant to submit it afresh by way of a rectification or clarification in application of the principle of proportionality.

In recent cases, the Court of Appeal also directed the contracting authority to seek the rectification of a Note 3 document which was not uploaded by the bidder on the basis that no

advantage would be given to the bidder if this rectification was allowed. See specifically AIB Insurance Brokers Limited vs Transport Malta delivered on 27 October 2021 (Ref. 237/2021/1) which held:

*“30. Dak li ma jridux il-principji li jirregolaw l-offerti ghal kuntratti pubblici hu li offerent ma jithalliex, wara li nfethu l-offerti, jaghti taghrif gdid li effettivament ibiddel l-offerta meta jaf x'inbuma l-offerti l-obra, u ghalhekk jikseb vantagg mhux xieraq. Lanqas - kif senwa ngħad fil-każ ta' Intermarkets Stationery citat minn Osprey - ma għandu l-offerent jithalla jipprezenta dokument li bih jibdel il-kondizzjonijiet tal-offerta wara li jkun tefagħha.*

*31. Fil-każ tallum id-dokument niegħes ma huviex dwar kondizzjonijiet tal-offerta nfisba, iżda huwa obbligazzjoni li għandu jintrabat biha l-offerent li jhars il-kondizzjonijiet tas-sejha, u ma jibdel xejn mill-offerta nfisba.*

*Il-qorti għalhekk hija tal-fehma li xejn ma kien iżomm lill-awtorità kontraenti, hekk kif tintebab bin-nuqqas ta' dan id-dokument u qabel ma tiftab l-offerti, illi tagħti żmien lill-offerent biex jipprezenta ddokument.*

*Kif ingħad fil-każ ta' Cassar Petroleum Services, “ma humiex sejr in jinkisru l-principju tat-trattament ugħwali, il-principju ta' bla diskriminazzjoni, il-principju ta' għarfien reciproku u l-principju tattrasparenza jekk, bla ma jimbdlu l-kondizzjonijiet tal-offerta nfisba, jingħata żmien biex jingħieb dokument illi, bi żvista, ma tqegħid maddokumenti tal-offerta, waqt li certament ma jkunx qiegħed jithares il-principju tal-proporzjonalità jekk offerta vantagjuża tigi mwarrba għax ma ngiebx dokument li għad jista' jingħieb”.*

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 17<sup>th</sup> February 2022 and its verbal submission during the virtual hearing held on 24<sup>th</sup> March 2022, in that:

- a) CPSU and DOC submit that following the filing of the present objection, further verifications were made in relation to the documentation submitted by the objector in its online submission and it was ascertained that the objector did not submit its SmPC. CPSU and DOC therefore hold firm to the evaluation committee's decision to disqualify the objector as being technically non-compliant since the submission of the SmPC is not rectifiable.

Section 2.1 of Section 3 of the tender document requires that: *“The following technical documentation is to be submitted online through the prescribed Tender Response Format and by using the Tender Preparation Tool provided: i. Summary of Product Characteristics (SPC) of product being offered in one of the official languages of Malta (Applicable for medicinal products excluding Special Medicines’).*” Section 3 of the tender document is, as the objector is well aware, note 3 and therefore cannot be rectified; Such a request for rectification would breach the basic principals in procurement legislation of equal treatment, self-limitation and proportionality.

- b) The Objectors also quote a judgment of the Honourable Court of Appeal in the names of AIB Insurance Brokers Limited vs Transport Malta and stating that on the basis of the same judgment, the evaluation committee should have requested the submission of the SmPC since allegedly this does not change anything from the initial offer. CPSU and DOC respectfully disagree with the objector and submit that the judgment quoted, which does not relate to any medicinal product, does not apply to present case. CPSU and DOC in fact submit that in a relatively recent judgment in the names of Multigas Limited vs Central Procurement and Supplies Unit u d-Direttur tal-Kuntratti delivered on the 21st of January 2021 (case no 317/2020), the Court of Appeal amplified on the importance and relevance of the SmPC. The above cited Court of Appeal judgment is very relevant to the present case and it is therefore being quoted at length:

*“it-tieni ilment huwa aktar serju. Is-soġjeta' rikorrenti tgħid li hu minnu li hi ressqet certifikat antik koncernanti l-istandards tal-medical oxygen, pero', il-karatteristiki tal-prodott a nbidlux sad-data li fiha giet sottomessa l-offerta. Hija kienet diga' tforni prodott simili lis-CPSU a bażi ta' sejba precedenti, u darba li kollox baqa' l-istess ma debrilbiex li kellha tressaq certifikat aggornat. Hawnbekke ta' min jispijega x'inhuwa l-SPC (Summary of Product Characteristics). Fil-qosor, kull sena jiġi ppubblikat uffijjalment manual li jissejjab "Pharmacopeia" u li jinkludi d-dettalji (specifications) uffijjali tal-prodotti medici kollha li jinsabu fis-suq. L-ossigenu medicinali wkoll huwa inkluz f'dan id-dokument. Mal-offerta tagħha, is-soġjeta' rikorrenti ressqet kopja tal-ispecifications tal-prodott bekk kif jinsabu fl-edizzjoni tal-2005.*

*L-Autorita kontraenti debrilha għalhekk li kellha twarrab l-offerta – mhux tant minhabba xi nuqqas fil-prodott offert, iżda pjuttost għaliex l-SPC li suppost jirreferi għall-prodott mbunniex wiehed aggornat.*

*Dan ic-certifikat huwa importanti għall-evalwazzjoni tal-offerta, għamlet bażin is-soġjeta' rikorrenti li ressqet verżjoni antika - u di piu', bi- abbar pagna nieqsa!*

*Dik is-soġjeta' ma kellhiex tassumi li l-kumitat ta' evalwazzjoni jaf li ma nbidel xejn mic-certifikat prezentat li kien jirrisali għas-sena 2005. Mhux kompitu ta' dak il-kumitat iqabbel ic-certifikat tal-2005 ma' dak allura ricenti tal-2019, iżda kien dmir -offerent li jara li ressaq id-dokumenti kollha mitluba u rilevanti. Il-fatt li l-prodott meritu tas-sejba in kwistjoni ilu jiġi supplit lis- CPSU taht specifications identici huwa irrilevanti, għax il-kumitat ta' evalwazzjoni rid jipprocedi a bażi tad-dokumenti sottomessi għal dik is-sejba partikolari. Kull offerta trid issewvi dak mitlub fis-sejba, u jekk intalbet, kif inhu li jkun mistenni, li tigi pprezentata l-abbar edizzjoni tal-SPC, ma kellux isir mod iebor.*

*Dan id-dokument ma kienx semplicement dokument supplementari li jagħti prova tal-konformita' tal-offerta mal-ispecificazzjonijiet teknici. Is-sejba għall-offerta riedet li d-dikjarazzjoni li tinkludi l-SPC jikkostitwixxi fibhom infushom kundizzjonijiet teknici necessarji biex l-offerta tkun wahda konformi. Fi kliem iebor, sabiex il-prodott offrut jitqies li jissodisfa l-ispecificazzjonijiet teknici kien jehrieg li jkun hemm certu tip ta'*

*dokumentazzjoni fir-rigward tiegħu. Għalhekk, dan huwa każ ta' nuqqas ta' sottomissioni ta' dokument essenzjali biex l-offerta tigi kkunsidrata.”*

- c) In the above quoted judgment, the court of appeal did not state that the SmPC is a document which changes nothing from the offer. Contrary to that, the Court of Appeal stated that the SmPC is an integral part of the offer and therefore and necessary for the evaluation committee to determine if the technical specifications are respected. In the judgment of Multigas vs CPSU, the Court of Appeal did not state that CPSU should have requested Multigas to present a more recent version of the SmPC but stated that it was the bidder's duty to present all the requested and relevant documents. The objector clearly did not submit the SmPC which was so necessary for the evaluation of its offer and therefore the evaluation committee had no other option to proceed in the way that it actually proceeded.

This Board, after having examined the relevant documentation to this appeal and heard submissions made by all the interested parties including the testimony of the witnesses duly summoned, will consider Appellant's grievances.

- a) ***First grievance – uploading of SmPC*** – From the outset, this Board will refer to the testimonies under oath of Dr Ian Ellul and Ms Denise Dingli, whereby they confirmed that the SPC document was not uploaded onto the e-tendering system. Dr Ellul went also into further detail by stating that the 'IT section' had also confirmed to him that the SPC was missing.
- b) ***Second grievance – allowance for rectification?*** –
- i. The Board will now delve into the matter of whether the Contracting Authority should have allowed the prospective bidder, now Appellant, the opportunity to submit a document which falls under Note 3, after it was ascertained that the document was missing in its submission of the original bid.
  - ii. Both the Appellant and Contracting Authority make references to recent Court of Appeal cases, namely AIB Insurance Brokers Limited vs Transport Malta (237/2021/1) as cited by the Appellant and Multigas Limited vs Central Procurement and Supplies Unit u Direttur tal-Kuntratti (317/2020) as cited by the Contracting Authority.
  - iii. The Board opines that the AIB Insurance Brokers Limited vs Transport Malta case is very clear when it states: “30. *Dak li ma jridux il-principji li jirregolaw l-offerti għal kuntratti pubblici hu li offerent ma jūthallix, wara li nfethu l-offerti, jagħti tagħrif għid li effettivament ibiddel l-offerta meta jaf x'inhuma l-offerti l-obra, u għalhekk jikseb vantagg mbux xieraq. Lanqas - kif senwa ngħad jil-każ ta' Intermarkets Stationery citat minn Osprey - ma għandu l-offerent jūthalla jipprezenta dokument li bih jibdel il-kondizzjonijiet tal-offerta wara li jkun tafgħha.”. Hence, one has to ascertain whether the SPC document is in fact a document which “was just requested” or whether it is a truly necessary document for the Contracting Authority to ascertain that the bid by the*

prospective bidder is essentially compliant and in line with the other declarations as submitted in its technical offer.

- iv. The Board notes however, that the case of AIB Insurance Brokers Limited vs Transport Malta did not deal with ‘medicinal’ and / or ‘pharmaceutical’ documentation. Therefore, the case of Multigas Limited vs Central Procurement and Supplies Unit u Direttur tal-Kuntratti which refers to the submission of the SmPC document is much more relevant to this case in order to determine whether the SmPC document is a document which is truly necessary for the Contracting Authority to ascertain that the bid by the prospective bidder is essentially compliant and in line with the other declarations as submitted in its technical offer.
- v. The Board opines, that the sentence as issued by the Court of Appeal (317/2020) whereby *“Dan id-dokument ma kienx semplicement dokument supplementari li jaghti prova tal-konformita’ tal-offerta mal-ispezifikazzjonijiet teknici. Is-sejba għall-offerta riedet li d-dikjarazzjoni li tinkludi l-SPC jikkostitwixxi fibom infushom kundizzjonijiet teknici necessari biex l-offerta tkun wahda konformi. Fi kliem iehor, sabiex il-prodott offrut jitqies li jissodisfa l-ispezifikazzjonijiet teknici kien jehtieg li jkun hemm certu tip ta’ dokumentazzjoni fir-rigward tiegħu. Għalhekk, dan huwa każ ta’ nuqqas ta’ sottomissioni ta’ dokument essenzjali biex l-offerta tigi kkeunsidrata.”* is very clear on the importance of the SPC document. This document was needed by the Contracting Authority, i.e. Evaluation Committee, in order to properly evaluate the bid it had in front of it. Since this document is listed under Note 3, should it have requested a rectification to its submission, the Board opines, that the Evaluation Committee would have gone against the principle of Self-Limitation.

Hence, this Board does not uphold the Appellant’s grievances.

### **The Board,**

Having evaluated all the above and based on the above considerations, concludes and decides:

- a) Does not uphold Appellant’s Letter of Objection and contentions;
- b) Upholds the Contracting Authority’s decision in the recommendation for the award of the tender,
- c) Directs that the deposit paid by Appellant not to be reimbursed.

**Mr Kenneth Swain**  
Chairman

**Mr Lawrence Ancilleri**  
Member

**Ms Stephanie Scicluna Laiviera**  
Member