PUBLIC CONTRACTS REVIEW BOARD

Case 1598 – CT 2221/2020 – Tender for the Supply of Mesalazine 500mg Slow-Release Tablets

24th September 2021

The Board,

Having noted the letter of objection filed by Mr Neil Bugeja acting for and on behalf of E.J. Busuttil Ltd, (hereinafter referred to as the appellant) filed on the 15th April 2021;

Having also noted the letter of reply filed by Dr Marco Woods on behalf of Central Procurement and Supplies Unit (hereinafter referred to as the Contracting Authority) filed on the 26th April 2021;

Having heard and evaluated the testimony of the witness Mr Neil Bugeja (Pharmacist representative of the Appellant company) as summoned by Dr Massimo Vella acting for E.J. Busuttil Ltd;

Having heard and evaluated the testimony of the witness Mr Adrian Spiteri (Pharmacist at Mater Dei Hospital) as summoned by Dr Marco Woods acting for Central Procurement and Supplies Unit;

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

Having noted and evaluated the minutes of the Board sitting of the 13th July 2021 hereunder-reproduced.

Minutes

Case 1598 – CT 2221/2020. Tender for the Supply of Mesalazine 500mg Slow Release Tablets

The tender was published on the 18th November 2020 and the closing date was the 22nd December 2020. The value of the tender was € 355,506.35.

On the 15th April 2021 E.J.Busuttil Ltd filed an appeal against Central Procurement and Supplies Unit as the Contracting Authority objecting to their disqualification on the grounds that the preferred bidder's offer did not meet the tender requirements.

A deposit of € 1778 was paid.

There were two (2) bidders.

On 13th July 2021 the Public Contracts Review Board (PCRB) composed of Mr Kenneth Swain as Chairman, Dr Charles Cassar and Mr Lawrence Ancilleri as members convened a public virtual hearing to discuss the objections.

The attendance for this public hearing was as follows:

Appellant – E.J.Busuttil Ltd

Dr Massimo Vella	Legal Representative
Mr Neil Bugeja	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Marco Woods	Legal Representative
Mr Adrian Spiteri	Chairperson Evaluation Committee
Ms Denise Dingli	Member Evaluation Committee

Preferred Bidder – Europharma Ltd

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 asked Appellant's representative to make his submissions.

Dr Massimo Vella Legal Representative for E.J.Busuttil Ltd said that his clients submitted their offer in line with the tender details; however the preferred bidder's offer does not meet these requirements. The tender required that the tablets had to provide slow, continuous release – those offered by Europharma offered slow but not continuous release. The product must operate at all pH conditions – the CPSU state that the preferred bidder's offer is not pH independent but works only in certain conditions. Europharma's product misses a large part of the intestines before it starts being effective thus *ex-admissis* the offer does not meet the tender specifications. Three out of five conditions in the tender are not met although the Contracting Authority claims that the product still meets the requirements.

Dr Marco Woods Legal Representative for the CPSU said that the Authority's arguments are not as stated by Appellant but it maintains that the tender requirements are met since the Evaluation Committee carefully examined the submissions made.

Mr Neil Bugeja (275992M) called as a witness by the Appellant testified on oath that he is a Pharmacist with postgraduate qualifications. The specifications require four main points – dosage, slow release, continuous release from the duodenum to rectum and at all pH conditions. The SPC in Appellant's product indicates that the release is continuous in any pH conditions and is fully compliant with the tender. Documents submitted by the preferred bidder indicate that the tablet is coated which makes it sensitive to a patient's level of pH whilst release of drug is at a stage later than the duodenum and at a lower point in the intestines. There is no slow continuous release of the drug and the offer is therefore not compliant.

Mr Adrian Spiteri (139581M) called as a witness by the Authority testified on oath that he is a Senior Pharmacist at Mater Dei Hospital and stated that the preferred bidder's product used for remission of colitis condition is 100% compliant. The product must work throughout the intestinal system and works at a pH of 1.2 with some side effects. Both medications have the same characteristics to treat the same condition. Europharma is offering coated tablets which are different from those of Appellant

but studies offered by the latter indicate that there is no head-to-head comparison. The double coating referred to is equivalent to slow release and operates at all pH levels necessary.

Questioned by Dr Vella witness confirmed that the slow release requirement is for the entire intestinal system and for all pH conditions and agreed that the CPSU in their reply had indicated that a certain level of pH (which was not specified) was necessary before release. Witness agreed that Europharma's product will not work in the duodenum, jejunum and part of the ileum but the product was meant to work in the colon and the rectum and that makes it acceptable.

Mr Alex Fenech Representative for Europharma Ltd said that he is qualified as a Pharmacist. He said that their declaration indicated that their product works on the ileum and no doubt meets the requirements of the tender.

Dr Vella said that the performance criteria were clearly stated. Their product Pentasa ticks all the boxes but preferred bidder's product only guarantees working from the ileum onwards. The witness did not deal with the pH requirements in the tender whilst the CPSU documents state that the product offered operates only in certain pH conditions. It is also not continuous but late release. The offer should be disqualified as it does not meet all the tender specifications.

Dr Woods said that this appeal indicates that Appellants had some doubts about their product. The evaluation committee is bound by the principle of self limitation which ties them down to evaluate what is presented. Appellant is trying to raise doubts about the preferred bidder's product when it is the technical specifications that are meant to deal with particular conditions and full information of compliance with specifications, which the evaluators confirmed. There was therefore transparency in the process. The role of the PCRB is to ensure that regulations are adhered to correctly and on this point there have been not one single submission that the technical requirements have not been met.

Dr Vella pointed out that the best proof is that presented by the CPSU documents and all witness did was to prove the points claimed by Appellant.

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

End of Minutes

Hereby resolves:

The Board refers to the minutes of the Board sitting of the 13th July 2021.

Having noted the objection filed by E.J. Busuttil Ltd (hereinafter referred to as the Appellant) on 15th April 2021, refers to the claims made by the same Appellant with regards to the tender of reference CT 2221/2020 listed as case No. 1598 in the records of the Public Contracts Review Board.

Appearing for the Appellant:	Dr Massimo Vella
Appearing for the Contracting Authority:	Dr Marco Woods

Whereby, the Appellant contends that:

a) The Appellant is in firm belief that the only product available that will meet the tender requirements is Pentasa 500mg Slow-Release Tablets by Ferring Pharmaceuticals.
b) This is corroborated by the manufacturer and therefore the Appellant is doubting the Evaluation Board's decision that the product of recommended bidder is compliant with the specifications detailed above.

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 26th April 2021 and its verbal submission during the virtual hearing held on 13h July 2021, in that:

a) In evaluating the offers, the evaluation committee is duty bound to analyse and review all information and documentation as submitted at Tendering Stage.
b) The successful bidder submitted a declaration issued by the mother company of the product in question, that being Mecolzine 500 MG Gastro-Resistant Tablets, satisfying all the technical specifications as listed in the tender document.
c) Mecolzine 500 MG Gastro-Resistant Tablets are locally authorised by the Malta Medicines Authority
d) Evaluation Committee reviewed all information and documentation submitted, which in this case also consisted in the official declaration as issued by FAES FARMA, the (PIL) Product Information Leaflet as well as the (SPC) Summary of Product Characteristics.
e) All specifications and requirements indicated in the tender document have been satisfied by the preferred bidder who also offered the cheapest price for the product.

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, as follows:

a) The Board notes that there are inconsistencies in the submissions presented by FAES FARMA which are the pharmaceutical company being represented by the Preferred Bidder.
    i. In their letter dated 18th December 2020 they state *"….. Mecolzine is an innovative formulation that used a special coating, Eudragit L and Eudragit S that allows to our products to avoid the release in the stomach and therefore increases the quantity of the active ingredient where the therapeutic effect is desired (from duodenum to rectum) by starting a delayed and prolonged release from pH 6."*
    ii. In their letter dated "07/2021" presented to this Board on 8th July 2021 they state *"….. Mecolzine is released in the specific area necessary to treat ulcerative colitis, from Ileum to Rectum."*

b) As per Mr Adrian Spiteri's testimony under oath whereby he stated *"Europharma's product will not work in the duodenum, jejunum and part of the ileum but the product was meant to work in the colon and the rectum and that makes it acceptable."* This Board notes that the Tender Dossier was not specific in any terms for ailments that this medicine is to be used for. The Tender Dossier requested the 'Supply of Mesalazine 500mg Slow Release Tablet (active ingredient released from duodenum to rectum' and further emphasising 'Mesalazine 500mg slow release tablets with a slow continuous release of drug from duodenum to rectum at all enteral pH conditions'. Hence, this Board opines that the 'prolonged release from pH6' as stated by FAES FARMA on 18th December 2020 should have been further investigated by way of clarification by the Evaluation Committee.

Hence this Board upholds Appellant's grievances.

In conclusion this Board;

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

a) To uphold the Appellant's concerns and grievances;
b) To cancel the Letter of Acceptance dated 6th April 2021 sent to "EuroPharma Ltd";
c) To cancel all the Letters of Rejection dated 6th April 2021;
d) To order the contracting authority to re-evaluate all the bids received in the tender through a newly composed Evaluation Committee composed of members which were not involved in the original Evaluation Committee;
e) after taking all due consideration of the circumstances and outcome of this Letter of Objection, directs that the deposit be refunded to the Appellant.

Mr Kenneth Swain	**Dr Charles Cassar**	**Mr Lawrence Ancilleri**
Chairman	**Member**	**Member**