PUBLIC CONTRACTS REVIEW BOARD

Case 1796 – CfT 021-0486/22 – CPSU5832/2022 – Supplies – Wound Dressing Emulsion

7th October 2022

The Board,

Having noted the letter of objection filed by Ms Jane Mifsud and Mr Kenneth Mifsud acting for and on behalf of Premiere Healthcare Limited, (hereinafter referred to as the appellant) filed on the 30th August 2022;

Having also noted the letter of reply filed by Dr Leon Camilleri acting for Central Procurement and Supplies Unit (hereinafter referred to as the Contracting Authority) filed on the 6th September 2022;

Having noted the letter of objection filed by Dr Matthew Paris on behalf of Dalli Paris Advocates acting for and on behalf of Cherubino Limited (hereinafter referred to as the Preferred Bidder) filed on the 1st September 2022;

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 4th October 2022 hereunder-reproduced.

Minutes

Case 1796 – CfT 021-0846/22 – Tender for the Supply of Wound Dressing Emulsion

The tender was issued on the 29th April 2022 and the closing date was the 29th May 2022. The estimated value of the tender, excluding VAT, was € 11,527.50.

On the 30th August 2022 Premiere Healthcare Ltd filed an appeal against the Central Procurement and Supplies Unit as the Contracting Authority objecting to their disqualification on the grounds that a cheaper compliant bid was recommended.

A deposit of € 400 was paid.

There were two (2) bids.

On the 4th October 2022 the Public Contracts Review Board composed of Mr Kenneth Swain Chairman, Mr Lawrence Ancilleri and Ms Stephanie Scicluna Laiviera as members convened a virtual public hearing to consider the appeal.

The attendance for this public hearing was as follows:

Appellant – Premiere Healthcare Ltd

Mr Kenneth Mifsud Representative

Mr Julian Mifsud — Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Leon Camilleri — Legal Representative
Dr Ian Ellul — Member Evaluation Committee

Preferred Bidder – Cherubino Ltd

Dr Matthew Paris — Legal Representative
Dr Francis Cherubino — Representative

Mr Kenneth Swain Chairman of the Public Contracts Review Board welcomed the parties and invited submissions.

Mr Kenneth Mifsud Representative of Premiere Healthcare Ltd said that their appeal would follow the lines of their appeal letter. The classification of the product offered by the winning bidder should be assessed by the Borderline Committee to establish whether it was a medicinal product or a medical device. If the product was the former its use is not authorised and it seems that it does not meet European standards. Moreover the CPSU was recommending for award a product that was different to the Formulary.

Dr Leon Camilleri Legal Representative for the Central Procurement and Supplies Unit said that in response to Appellant's first grievance the tender was clear that it was open to offers of medicinal products, medical devices and food supplements. Appellant was limiting what the tender actually requested. The Evaluation Committee (EC) had to follow the tender terms and bidders were not limited to having to offer only medicinal products. Section 3.1 of the Technical Specifications allows the choice of offer. As regard the second grievance Appellant had the possibility of using Regulation 262 of the PPR if it was not satisfied with the terms of the tender. There is no point in challenging it now. The argument that the Formulary was part of the tender was not valid.

Dr Matthew Paris Legal Representative for Cherubino Ltd stated that he was in agreement with the CPSU's submissions regarding public procurement, which argument is reinforced if one referred to a Court of Appeal case on then point of public procurement. The Appellant is not happy with the outcome of the evaluation as he does not agree with certain specifications. This point is *fuori termini* as there is a methodology to challenge the terms of a tender in Regulation 262 of the PPR. This was not utilised in this case and therefore by implication the Appellant accepted the full terms of the tender. The doctrine of self limitation makes the submissions of the Appellant inadmissible.

Mr Mifsud asked if the CPSU had vetted if the product offered is eligible to be placed on the Maltese market. They had merely relied on the certification that this was a medical device but it could actually be a medicinal product, which, if so would prohibit its registration in Malta. The tender title asks for wound dressing emulsion but does the offer meet this requirement?

Dr Paris pointed out that allegations had been made without any proof being provided. If Appellant wanted the matter referred to the Borderline Committee he could have taken this step himself.

Dr Leon Camilleri said that no proof had been submitted to substantiate the claim made. The EC followed the specifications laid down and there was no requirement that the product had to be medicinal. Any complaints on the terms of the tender could have been dealt with otherwise. The Appeal should not be upheld.

The Chairman thanked the parties for their submissions and said that the Board's decision would follow in the near future.

End of Minutes

Hereby resolves:

The Board refers to the minutes of the Board sitting of the 4th October 2022.

Having noted the objection filed by Premiere Healthcare Limited (hereinafter referred to as the Appellant) on 30th August 2022, refers to the claims made by the same Appellant with regard to the tender of reference CfT 021-0486/22 – CPSU5832/2022 listed as case No. 1796 in the records of the Public Contracts Review Board.

Appearing for the Appellant:	Mr Kenneth Mifsud
Appearing for the Contracting Authority:	Dr Leon Camilleri & Dr Alexia Farrugia Zrinzo
Appearing for the Preferred Bidder:	Dr Matthew Paris

Whereby, the Appellant contends that:

a) First grievance -

The recommended product, is classified as a Medical Device in the Country of Source. Classification of a product in Malta may not necessarily reflect the overseas Classification, and for this reason there is in place 'The Borderline Classification Committee', which is responsible for classifying products, considered as Borderline, and whose decision supersedes the overseas manufacturer's classification when placing such products on the market in Malta. There are hundreds of products which are classified as food supplements or Medical Devices in the country of source but are classified as Medicinal products in Malta:

Familiarisation with this list would show, for example, that a product, based on herbal remedies and indicated for « relief for minor burns and scalds. Can help relieve pain, prevent blistering and promote rapid healing » was classified as a Medicinal product by the Borderline Classification Committee. Prior to award recommendation, offered products are screened or should be screened by the Procurement Section - CPSU, for Regulatory compliance with Maltese legislation. Whilst a

Declaration of Conformity may have been provided, in this case, Regulatory clearance should have been further sought from the Borderline Classification Committee, especially since a Medicinal and a non-Medicinal were being offered.

The Tender is headed Wound Dressing Emulsion and the technical specifications detail a product for cutaneous application for first degree burns and superficial second degree burns, secondary erythema due to radiotherapy treatments, and uninfected skin wounds. These are acute Medical conditions which require curative treatment, especially in the hospital environment, and can only be treated utilising Medicinal Products, "administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action or to making a medical diagnosis;'.

b) Second grievance -

There is a discrepancy between what is presently shown on the Formulary Lists, and what is being recommended for purchase, for this particular product. Both Formularies show that the Wound Dressing Emulsion approved by the Hospital Management has the active ingredient Trolamine, (presently Biafine®). The product which is being recommended is not a Wound Dressing Emulsion as originally approved for inclusion in the Hospital List by the Drugs Therapeutics committee, shown on the Hospital Formulary and the tender heading but a *"Soothing cream to give relief to the skin following sunburn, burns and superficial ulcers) / protects and moisturizes the skin / "Due to its protective and moisturising action Neoviderm skin emulsion soothes the skin, favouring the physiological normalisation process"*

An approved wound dressing emulsion, should at least be proven / authorised to: a) provide a temporary protective physical barrier, b) absorb wound drainage, and c) provide the moisture necessary to optimize re-epithelialization.

Prior to Trolamine being accepted by the Drugs & Therapeutics Committee (DTC) in 2005, for inclusion into the Hospital formulary, extensive information was requested from the manufacturer to ensure the Quality, Safety and Efficacy of this medicinal product, a review which took a disproportionately long time, so much so that the intervention of the Ombudsman was requested to investigate such delay, (Case no. F 0142).

It is both misleading and professionally incorrect for a Medical Device to be recommended to replace or be considered compliant with the specifications of a Medicinal product backed up with Safety, Quality and Efficacy reports. Medicinal products and Medical devices are independently regulated through different EU Directives, and the annual fees to maintain their individual files are considerably different. The discrepancy in the specifications approved for the medicinal product (Trolamine) by the DTC, and what has been recommended by the Evaluation Committee is risking

the reputation of the prescribing physicians as well as the well being of patients at the receiving end, who get an inert product rather than a curative one.

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 6th September 2022 and its verbal submission during the virtual hearing held on 4th October 2022, in that:

a) First grievance -

The main argument of the objector with regards to this first grievance is that the recommended product is a medicinal device and not a medicinal product. The tender document does not contain any clause which expressly or implicitly, requires that the product offered should be a medicinal product. To the contrary, the tender document in section 3.1 of the Technical Specifications caters for the Standards required in Medicinal Products, Medicinal Devices and Food Supplements. Moreover the Technical offer form contains alternative sections to be filled depending on the classification of the product on offer, being a Medicinal Product, a Medical Device or Food Supplements. The arguments that the cases which will be treated with the product on offer require a Medicinal Product and not a Medical Device is therefore irrelevant at this stage since the tender did not impose such a requirement. If the objector was not in agreement with the requirements and wording of the tender document, it had the opportunity to seek a remedy before offer closing time in terms of regulation 262 of the Public Procurement Regulations, a procedure which the objector did not opt for. The technical specifications as published are therefore the only criterion which the evaluation committee could use in order to determine compliance and eventually make a recommendation, in line with the established principle of self limitation. Since the recommended product and bidder was fully compliant with the requirements of the tender document, irrespective of the arguments of the objector in its first grievance, the evaluation committee could never make a different recommendation for award to that which was made.

b) Second grievance -

In its second grievance the objector argues that there is a discrepancy between what is presently shown in the formulary and what was being recommended for purchase. With regards to this matter CPSU first and foremost submits that the Formulary is not mentioned in any part in the tender document, thus the evaluation committee was not in any way bound by the provisions of the Formulary list or had in any way to consult such list. Without prejudice to the above submission to which it holds firm, CPSU submits also that the objector is misquoting from the formulary as the formulary simply states - *"Wound Dressing Emulsion (Currently Tralomine [Biafine®])*. The product on the formulary is Wound Dressing Emulsion, and the fact that it is currently *Tralomine [Biafine]"*, does not mean that tomorrow it could not be any other brand, depending on who is successful in an open competitive call.

The objector in its objection states that:

"An approved dressing emulsion, should at least be proven/authorised to: a) provide temporary protective physical barrier, b) absorb wound drainage, and c) provide the moisture necessary to potimize (sic) re-ephithelialization."

With all due respect to the objector, irrespective of these self-made requirements, the tender documents did not include such requirements and if the objector believe that the tender documents should have included such requirements, the procedure which had to be used was that before closing time of offers in terms of regulation 262 of the Public Procurement Regulations. Arguments on technical criteria which according to the objector should have been included /considered are at this stage irrelevant and should not be considered by this Honourable Board.

Moreover and as a general but cardinal submission, it is imperative that the objector understands that the role of the evaluation committee is not to compare the offered products with each other but to compare the offered products with the specifications as published in the tender document.

This Board also noted the Preferred Bidder's Reasoned Letter of Reply filed on 1st September 2022 and its verbal submission during the virtual hearing held on 4th October 2022, in that:

a) Cherubino is fully compliant - In its four-page submission, the appellant company has failed to specify which [if any] tender specifications Cherubino qua the recommended bidder has failed to adhere to. It has also failed to indicate, specify or in any other form declare the basis of its appeal, other than mentioning and referring to characteristics which were neither discussed by the tender document, nor deemed relevant by the contracting authority when issuing the call for tenders. It is a public procurement principle, enshrined also in the local legislation, that contracting authorities may only use parameters to evaluate tenderers which had been indicated and declared within the procurement document. The principle of self-limitation dictates that the parameters being discussed by the appellant are outside the scope of this tender procurement procedure, and thereby are totally inadmissible.

b) Remedy sought is fuori termine - Without prejudice to the aforesaid, if the appellant's claim are (sic) correct [a claim which Cherubino refutes], such should have been addressed through either a clarification or a remedy before the closing of the tender [in accordance with article 262 of S.L. 601.03], in any case, prior to the submission of the tender. It is confirmed through the tender document itself, but also through numerous PCRB decisions, that once a tenderer has submitted an offer, it has also implicitly accepted 'without reservation' any and all tender conditions. Thereby Cherubino hereby submits that the remedy sought by the appellant company, besides being totally unfounded, is also fuori termine, in that a remedy before the closing of the tender period, may only be submitted by an interested party by not later than two-thirds of the period available for tenderers to submit their offer.

This Board, after having examined the relevant documentation to this appeal and heard submissions made by all the interested parties, will now consider Appellant's grievances.

a) First grievance – This Board completely agrees with the arguments as brought forward by the Contracting Authority. Paragraph 3.1 of Section 3 caters for the Standards required in Medicinal Products, Medicinal Devices and Food Supplements. The Technical Offer form was also duly 'sub-divided' into three sections whereby one section was to be completed depending on whether a 'medicinal product', 'medical material and devices' or 'Chemicals, Disinfectants, Food Supplements dietary foods for special medical purposes, and Cosmetics' was being offered.

   It is a well-established principle in public procurement, that evaluation committees are to observe the principle of self-limitation and their evaluation is to follow the specifications of what is listed in the tender document.

   If appellants are not in agreement with how the technical specification have been listed and / or formulated, different remedies are available as per the Public Procurement Regulations ("PPR") (reference to regulation 262).

   Therefore, this first grievance is deemed irrelevant and is not being upheld.

b) Second grievance – Similar to the first grievance, this Board completely agrees with the arguments as brought forward by the Contracting Authority. The Contracting Authority is completely correct when it states *"…..it is imperative that the objector understands that the role of the evaluation committee is not to compare the offered products with each other but to compare the offered products with the specifications as published in the tender document."* The formulary is nowhere listed in the tender dossier. The principle of self-limitation is cardinal, especially in tendering procedures where the sole criterion for award is the price. If this principle is duly followed and adhered to, in turn all economic operators will have been dealt with similarly by using the 'same ruler principle' and hence a level playing field will be achieved. In such matters and arguments as presented by the appellant, the correct mechanism to be adopted was regulation 262 of the PPR. It is now futile to bring forward arguments about the formulary or whether economic operators offered medicinal products or medical devices when the specifications of the tender dossier allowed for a spectrum of options that could be offered. Once economic operators submit their bids, and the threshold as allowed by regulation 262 has elapsed, tenderers have *de facto* accepted the terms and conditions of the tender dossier. Therefore, such arguments are deemed *fuori termine* and irrelevant in appeals based on regulation 270 of the PPR.

   Hence, this Board does not uphold the Appellant's second grievance.

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**