PUBLIC CONTRACTS REVIEW BOARD

Case 1757 – CfT021-0847/21 (CPSU 106085D21JB) – Supplies - Tender for the Supply of Alphacalcidol 1MCG Capsules

18th July 2022

The Board,

Having noted the letter of objection filed by Dr Francis Basile acting for and on behalf of Cherubino Ltd, (hereinafter referred to as the appellant) filed on the 5th May 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 16th May 2022;

Having heard and evaluated the testimony of the witness Ms Corinne Bowman (Pharmacist & Member of the Evaluation Committee) as summoned by Dr Matthew Paris acting for Cherubino Ltd;

Having heard and evaluated the testimony of the witness Ms Corinne Bowman (Pharmacist & Member of the Evaluation Committee) as summoned by Dr Alexia Farrugia Zrinzo acting for Central Procurement and Supplies Unit;

Having heard and evaluated the testimony of the witness Dr Edward Basile Cherubino (Medical Doctor and representative of Cherubino Ltd) as summoned by Dr Matthew Paris acting for Cherubino 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 5th July 2022 hereunder-reproduced.

Minutes

Case 1757 – CfT 021-0847/21 – Tender for the Supply of Alphacalcidol 1mcg Capsules

The tender was issued on the 17th September 2021 and the closing date was the 11th Ocotber 2021. The value of the tender, excluding VAT, was € 114,000.

On the 5th May 2022 Cherubino 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 to be technically not compliant.

A deposit of € 570 was paid.

There were four (4) bids.

On the 5th July 2022 the Public Contracts Review Board composed of Mr Kenneth Swain as Chairman, Dr Charles Cassar and Mr Lawrence Ancilleri as members convened a virtual public hearing to consider the appeal.

The attendance for this public hearing was as follows:

Appellant – Cherubino Ltd

Dr Matthew Paris	Legal Representative
Dr Francis Cherubino	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Alexia Farrugia Zrinzo	Legal Representative
Ms Joannah Bugeja	Chairperson Evaluation Committee
Dr Alison Anastasi	Representative
Ms Denise Dingli	Representative

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

Dr Matthew Paris Legal Representative for Cherubino Ltd stated that the offer of the Appellant had been excluded on incorrect grounds. Supplier claims in a clarification that the product is indicated for Hypocalcaemia in all conditions where there is a disturbance of calcium metabolism. However these claims were not indicated in the documents originally submitted. The letter dated 24th November 2021 from the manufacturer of the product La Nova Farmacia does not tally with the submissions in terms of items 1.3 (section 4.4) and 1.4 (section 5.1 and 5.2) of the specifications. However what is alleged is not correct.

The product Alphacalcidol treats low calcium conditions continued Dr Paris. The specification in Section 3 indicates what conditions it is used for i.e. vitamin D analogue – the Appellant's offer is for Alphacalcidol which meets what was requested. The Contracting Authority claims that the product offered is not suitable for certain conditions. Appellant is the incumbent supplier of this product and the Authority is buying exactly the same actual product with identical properties which treat Hypocalcaemia. There is therefore a discrepancy between the reason for exclusion and the reasons stated since medical knowledge establishes that the product meets all functional specifications listed including items 5.1 and 5.2 referred to earlier.
Dr Alexia Farrugia Zrinzo Legal Representative for the Central Procurement and Supplies Unit said that the required functional specifications had not been met by the product offered according to the Summary of Product Characteristics (SPC). There was no reply to the clarification note but instead additional documents were submitted in which requirements were listed. This document came under Note 3 restrictions and therefore the Authority followed the correct course of action.

Ms Corinne Bowman (104674M) called as a witness by the Appellant testified on oath that she was a Pharmacist by profession and the sole evaluator in this tender. She stated that she was not involved in the writing of the tender. A question was put referring to the tender offer form schedule.

Dr Farrugia Zrinzo interposed to point out that questions could only be put on the evaluation decision not on the tender specifications which could have been dealt with by an appeal under PPR 262.

Dr Paris replied that he was only trying to establish if the product called for makes sense.

The Chairman said that the Board met the objection of the Authority as it is the evaluation that is being challenged.

Dr Paris therefore asked that it be recorded verbatim that:

'Dr Matthew Paris on behalf of Cherubino Ltd at this point asked a question to the only technical evaluator in relation to the matrix found in page 3 of the Technical Offer Form and in particular whether medically the specifications indicated made sense or otherwise.'

This was followed by Dr Farrugia Zrinzo requesting that the following is recorded verbatim:

'Dr Alexia Farrugia Zrinzo on behalf of the CPSU refers the Applicant to Regulation 262 of the PPR which specifically provides for a request for remedies prior to the closing date of tender submissions. Thus, Appellant had every opportunity to file a request under Regulation 262 had it had any objection to the way the tender was written and published. In the present proceedings the Appellant is to abide by the grievances as presented in its objection since the Evaluation Board was bound to act and evaluate upon the tender documents as published.'

The evidence of Ms Corinne Bowman was resumed.

Witness stated that the functional specifications requires the product to be licenced for use on the local market. She agreed that the words 'Vitamin D and analogue' do not makes sense but said that she could not comment on the wording of the tender as this was not her role. She concentrated on hypocalceama and cholestatic liver disease which the offered product satisifies. Vitamin D analogue is there to replace vitamin D.

Referred to item 4.4 in the SPC witness said that the wording was merely a warning as to what could happen. The product offered was not licenced for hypocalceama but only for rickets and osteomalacia. Appellant's product was not licenced for hypocalceama *per se* but for particular indications as listed. Asked to state how the product affected the patient under item 5.1 (calcium in serum) witness stated that she is not a doctor and could not comment. Renal impairment is a condition not an impairment.

Questioned by Dr Farrugia Zrinzo witness said that licences for use of a product are issued by the Medical Authorities. The use of this product is authorised by the manufacturing country health authority and the SPC is a final certification of authorised indication. The product in question is indicated for use in items 1.1 and 1.2 only in the SPC, is not suitable for items 1.3 and 1.4 whilst item 1.5 was not part of the basis of the evaluation.

Dr Edward Basile Cherubino (167284M) called to testify by the Appellant stated on oath that he has been practising as a Medical Doctor for 12 years. He explained the use of alphacalcidol product and that it is a vitamin D analogue for treatment of Hypocalcaema. By means of a screen share he explained the various conditions of low calcium and the treatment of these conditions. Witness explained that alphacalcidol gives better absorption of calcium in the intestines. Referred to item 5.1 witness stated that the wording of that item indicates that the increased calcium in the serum treats Hypocalceama. The alphacalcidol treats the consequences of the condition of the diseases mentioned earlier. Vitamin D analogue boosts calcium level absorption to treat Hypocalceama.

Dr Farrugia Zrinzo referred witness to the therapeutic indications in item 4.1.He replied that ostomalacia is the result of cholestatic liver disease and that the product cannot treat liver disease but the consequence of the disease on the bones. What the text states is that the product treats ostomalacia which covers all the conditions mentioned. Alphacalcidol can treat any condition where low calcium levels prevail.

Ms Corinne Bowman (104674M) recalled as a witness by the Contracting Authority said on oath that at the evaluation stage she had to match the product offered by Appellant to the four functional steps specified, but this offer did not meet all indications unlike the other offers submitted. The evaluation had to abide by what was offered. The response to the clarification did not match the product licence and hence the query was not clarified.

In reply to questions from Dr Paris witness stated that the registration of medicines in Malta was not part of the evaluation process and at tendering stage Appellant's product was not registered in Malta but offered instead the Italian product number.

This concluded the testimonies.

Dr Paris said that Appellant product satisfies all requisites as one cannot ignore the fact that the Appellant is the incumbent supplier of the same product and hence there are no doubts about the effectiveness of the product. It is incorrect to claim that the product is not registered by virtue of the fact that it is the incumbent. Through testimony heard it resulted that the schedule is incorrect whether one made use of Regulation 262 or not. Also witness agreed that specification 1.5 of the table does not make sense – in an evaluation one cannot pick and choose which items to exclude. Rules apply on all points and the same yardstick has to be used. On that point alone *de minimis* the tender should be re-evaluated or cancelled. Both witnesses expressed scepticism about the specifications in the table, sometimes referred to as indications in others as conditions. In Court of Appeal Case 173/22 the principle of substance over form was confirmed, and the Evaluation Committee has to ensure that all terms are fully met. Appellant never had any doubts about its product and the fault was in the specification not in the offer. A re-evaluation with a medical expert as part of the panel is necessary as there were serious mistakes in the way the tender was formulated.

Dr Farrugia Zrinzo said that the tender cannot be related to other past tenders and any reference to such must not be considered. Witness confirmed that the evaluation was carried out on the documents submitted and the Evaluation Committee observed the principles of equal treatment, proportionality and self-limitation. The putting aside of specification point 1.5 proves precisely that all parties were treated equally and proportionality followed as each point of each offer was considered. The Evaluation Committee was limited by what was presented at tendering stage. The SPC as presented did not address the specifications as claimed by Appellant who had the facility of using Regulation 262 if it disagreed with the specifications – none of the other bidders seem to have had any problems. The evaluation decision is correct and should be upheld as all principles were correctly applied.

There being no further submissions the Chairman thanked the parties and declared the hearing closed.

End of Minutes

Hereby resolves:

The Board refers to the minutes of the Board sitting of the 5th July 2022.

Having noted the objection filed by Cherubino Ltd (hereinafter referred to as the Appellant) on 5th May 2022, refers to the claims made by the same Appellant with regard to the tender of reference CFT021-0847/21 (CPSU106085D21JB) listed as case No. 1757 in the records of the Public Contracts Review Board.

Appearing for the Appellant:	Dr Matthew Paris
Appearing for the Contracting Authority:	Dr Alexia Farrugia Zrinzo

Whereby, the Appellant contends that:

a) ***Offer is cheapest technically complaint*** (sic)- The rejection letter, inter alia states that, *"Clarification response did not satisfy that these specifications were in the original document namely SPC submitted at tendering stage"*. Whereas the appellants maintain that the Literature submitted clearly caters for the medical requirements and use of the product requested, wherein it also submitted a further clarification as requested on the same, the referred documents fall within the Literature criteria of the Tender, wherein in any such case, the same Tender provides that, Tenderers will be requested to either clarify/rectify any incorrect and/or incomplete documentation, and/or submit any missing documents within five (5) working days from notification. Cherubino maintains that its offer is valid, being the cheapest technically compliant offer in this procedure.

b) ***Principle of proportionality*** - The contracting authority should have applied the principle of proportionality in evaluating this tender, a principle which was not upheld in the current context. The principle is well recognised both by local legislation (Article 39 of S.L. 601.02) as well as in local jurisprudence, such as Krypton Chemists Limited vs Direttur tal-kuntratti (Court of Appeal judgment 336/2018). Adopting the principle to the case under examination, would have maintained that should the literature not have been clear enough to the evaluation committee it should resort to the mechanisms catered for in the tender as stated above, whilst the offer by the Cherubino should have retained its status within the evaluation, without further action.

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 16th May 2022 and its verbal submission during the virtual hearing held on 5th July 2022, in that:

a) The reason provided for the rejection was the below: *"Supplier is claiming that the product 'is indicated for hypocalcaemia in all conditions where there is a disturbance of calcium metabolism' 'including cholestatic liver disease' as per letter attached in clarification response. However these claims were not found in the documents originally submitted especially not in the sections indicated in the TOF: 1.3 Hypocalcaemia could not be confirmed in section 4.4. of SPC as indicated and 1.4 cholestatic liver disease could not be confirmed in section 5.1 and 5.2 as indicated in TOF. Clarification response did not satisfy that these specifications were in the original document namely SPC*

submitted at tendering stage". The Objector was aggrieved with this decision and filed the present appeal based on 2 grievances.

b) The main reason for the disqualification of the objector from this tendering process due to lack of technical compliance was because the functional specifications 1.4 (hypocalcaemia) and 1.5 (Cholestatic liver disease) in item reference of section 3 of the technical offer form, which were mandatory criteria, were confirmed by the tenderer, however did not result from the Summary of Product Characteristics (SPC) despite the fact that the tenderer indicated that these functional specifications can be shown from sections 5.1 and 5.2 and 4.4 of the SPC. Since the technical offer form is note 3 and therefore only a clarification can be requested, the evaluation committee requested a clarification with the below wording. *"In the technical offer form, it has been indicated that the product has the functional specifications of 'hypocalcaemia' (with reference to SPC section 4,4) and 'Cholestatic liver disease' (with reference to SPC section 5.1 and 5.2). However these indications were not found at the sections referred to. Kindly clarify since you have indicated 'yes' to these functional specifications."*

c) The objector by means of a letter signed by a representative of Lanova Farmaceutici Srl on behalf of the same, replied that: *"Further to your kind query, we confirm that Deril, containing the active ingredient Alphacalcidol 1mcg, is indicated for hypocalcaemia in all conditions where there is disturbance of calcium metabolism due to impaired 1 a-hydroxylation of vitamin D3, including cholestatic liver disease, hypoparathyroidism, D-resistant or D-dependant (pseudo-deficient) rickets and osteomalacia, rickets and osteomalacia due to renal alterations due to metabolism of vitamin D, renal osteodystrophy (this is caused by cholestatic liver disease) as well ostosteoporosis and postmenopausal osteoporosis. In section 4.4 of the same SPC, it also states that an overdose of Deril can in fact cause hypercalcaemia (too much calcium), that is the opposite of hypocalcaemia (low levels of calcium)."*

d) The reply to the requested clarification does not in any way indicate how sections 4.4 and 5.1 and 5.2, and not even the SPC in general, prove that the product offered conforms with the required specifications. The clarification in question concerned the Technical Offer form which is note 3 which referred to a SPC to prove that the offered product is suitable for 2 particular indications. The evaluation committee could only accept an explanation how the clauses referred to from the SPC catered for hypocalcaemia and Cholestatic liver disease and changes to (sic)could be allowed to the technical offer form. Clearly the clarification request was not addresses (sic) within the parameters of what is permissible under note 3. Moreover, and in reply also to the grievance that the evaluation committee did not respect the principle of proportionality, when excluding the objector's bid, it must be first emphasized that the clauses of the SPC indicated did not deal with the indications they should have been proving. Moreover, in their reply following the clarification request, the objectors did not refer to other literature or other clauses within the SPC but have merely presented a letter in reply.

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) During the hearing, multiple observations and arguments were brought forward in relation to the Technical Offer Form – Section 3 Other Product Details – sub section 3.10 Detailed Technical Specifications – part 1 'Functional specifications', whereby 5 specifications are listed. Argumentation ensued on whether these are 'functional specifications' as such and whether 'it makes sense' that these (1.1 Renal impairment, 1.2 Rickets, 1.3 Hypocalcaemia, 1.4 Cholestatic liver disease and 1.5 Vitamin D and analogue) should all be listed in such part of the Technical Offer form together. This Board opines that such arguments, if any, were to be brought forward under Regulation 262 of the Public Procurement Regulations ("PPR").
b) In this Board's opinion, the relevant aspects to be analysed are the following:
    i. Does the product offered by the appellant meet the technical specifications as set out in the tender dossier? and;
    ii. Could such technical specifications be met?
c) Appellant's product –
    i. Appellant answered "Yes" to all the five (5) 'Functional specifications' as listed in the Technical Offer Form (see point a above).
    ii. However not all of these 'Functional specifications' were present in the 'Therapeutic indications' as found in the SPC of the Appellant. 'Functional specifications' 1.3 Hypocalcaemia and 1.4 Cholestatic liver disease are not mentioned as 'Therapeutic indications' in the SPC of the Appellant.
    iii. Appellant brought argumentation that *"In section 4.4 of the same SPC, it also states that an overdose of Deril can in fact cause hypercalcaemia (too much calcium), that is the opposite of hypocalcaemia (low levels of calcium)."* Hence, appellant argues, that their product is viable for specification 1.3 Hypocalcaemia. This Board opines, however, that section 4.4 is "Special warnings and precautions for use" and not 'Therapeutic indications' which is the relevant section which lists down what the medicine / product is licensed for. Hence, even though the product on offer could in effect be used for Hypocalcaemia, it is still a fact that this is not indicated as one of its 'Therapeutic indications'.
    iv. Similar argumentation was brought forward for 1.4 Cholestatic liver disease, with this Board holding same opinion as above.
    v. This Board's opinion is also corroborated by the technical evaluator, Ms Corinne Bowman that when referred to item 4.4 in the SPC witness said that the wording was merely a warning as to what could happen. The product offered was not licenced for hypocalcaemia

but only for rickets and osteomalacia. Appellant's product was not licenced for hypocalcaemia *per se* but for particular indications as listed.

d) Could such technical specifications be met? –

i. Reference is made to the testimony under oath of Dr Edward Basile Cherubino, whereby he explained in detail the use of alphacalcidol product. Doubts emerged, henceforth, whether all such functional specifications could in effect be achieved and therefore if all of them can in fact be listed as 'Therapeutic indications'.

ii. This Board makes reference to technical literature and offer as presented by the preferred bidder. In its SPC, all of the 'Functional specifications' as per the Technical Offer Form are duly listed and described in detail. Therefore, this Board can conclude that evaluation process was correctly performed.

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