PUBLIC CONTRACTS REVIEW BOARD

Case 1771 – CfQ 021-2211/22 – CPSU 6097/22 – Quotation for the Supply of Fluorodeoxyglucose F-18 Injections

2nd August 2022

The Board,

Having noted the letter of objection filed by Dr Matthew Paris on behalf of DalliParis Advocates acting for and on behalf of Cherubino Ltd, (hereinafter referred to as the appellant) filed on the 24th June 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 4th July 2022;

Having heard and evaluated the testimony of the witness Ms Corinne Bowman (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 Helen Vella (Representative of the Medicines Authority) as summoned by Dr Matthew Paris acting for Cherubino Ltd;

Having heard and evaluated the testimony of the witness Dr Caroline Muscat (Director of Operations at the Medicines Authority) as summoned by Dr Leon Camilleri acting for the Central Procurement and Supplies Unit;

Having heard and evaluated the testimony of the witness Ms Corinne Bowman (Member of the Evaluation Committee) as summoned by Dr Leon Camilleri acting for the Central Procurement and Supplies Unit;

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 26th July 2022 hereunder-reproduced.

Minutes

Case 1771– CfQ021-2211/22 – Call for Quotations for the Supply of Flourodeoxyglucose F-18 Injections.

The Call for Quotations was issued on the 26th May 2022 and the closing date was the 2nd June 2022. The estimated value of the call, excluding VAT, was € 4,380

On the 24th June 2022 Cherubino Ltd filed an appeal against Central Procurement and Supplies Unit as the Contracting Authority objecting to their disqualification on the grounds that their offer as not the cheapest bid.

A deposit of € 400 was paid.

There were two (2) bids.

On the 26th July 2022 the Public Contracts Review Board composed of Mr Kenneth Swain as Chairman, Dr Charles Cassar 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 – Cherubino Ltd

Dr Matthew Paris	Legal Representative
Dr Francis Cherubino	Representative
Mr David Cherubino	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Leon Camilleri	Legal Representative
Dr Alexia Farrugia Zrinzo	Legal Representative
Ms Monica Sammut	Chairperson Evaluation Committee
Ms Corinne Bowman	Member Evaluation Committee
Ms Federica Bonnici	Member Evaluation Committee
Mr Adrian Spiteri	Member Evaluation Committee
Dr Alison Anastasi	Representative

Preferred Bidder – JV Healthcare Ltd

Mr Damien Stellini	Representative

Department of Contracts

Dr Mark Anthony Debono	Legal Representative

Mr Kenneth Swain Chairman of the Public Contracts Review Board welcomed the parties and before inviting submissions said that the Board was proposing that due to the similarity of the legal arguments in this Case and in Case 1772 both Cases should be heard simultaneously. This was agreed.

Dr Paris Legal Representative for Cherubino Ltd as a preliminary point deprecated the fact that the information he requested, on behalf of the Appellant, from the Department of Contracts (DoC) had not been provided. The only information provided was the name of the product with the DoC replying to the rest of the request by a 'without prejudice' basis letter. This is intended to prevent the Appellant making reference to the letter and goes totally against the guidelines issued by the Chamber of Advocates.

The crux of the objection, said Dr Paris, is that certain *de minimis* information is required to enable an informed decision to be reached. Appellant requested pertinent information regarding market registration but all that was received was the brand name. This violates Article 40 of the PPR. The South Lease case upheld the right to request relevant information. Appellant was requesting details on points 2.1 to 2.4 regarding the market registration and on 3.8 submissions by the preferred bidder in the Technical offer.

Dr Leon Camilleri Legal Representative for the Central Procurement and Supplies Unit said that the South Lease decision does not create jurisprudence and does not bind later decisions. He referred to the Varec ruling that one party may refuse to provide information.

Dr Alexia Farrugia Zrinzo Legal Representative for the CPSU noted that the principle in the South Lease Case was part of the Court's considerations but not part that binds the decision.

The Chairman proposed a short recess for the Board to consider the points made regarding the request for information.

On resumption the Chairman stated that the Board is disappointed that the Department of Contracts representative did not attend this hearing and attempts are still being made to contact him. The Board considered the request by Appellant regarding the technical information and is of the view that this information in this Case is of relevance to the appeal. To continue to hear this Case expeditiously, an objective that is of major import to this Board, it feels that the best way of finding out this information here and now is by having a member of the Evaluation Committee to testify on points 2.1 to 2.4 and 3.8 so that the hearing of this Case can be completed today.

Ms Corinne Bowman (104674M) called as a witness by the Appellant stated on oath that she was one of the Evaluators on this tender and said that according to Clause 2.8 in the Technical Offer Form the preferred bidder's company is licenced by a competent authority in Europe. The SPC in Section 7 states that the product offered is called ' Moltek' with a registration number 2014/346 and the country of licencing is indicated as Turkey.

[At this stage Dr Mark Anthony Debono Legal Representative for the Department of Contracts joined the hearing.]

Mr Adrian Spiteri(139581M) called as a witness by the Appellant testified on oath that in reply to specification 3.8 the preferred bidder had confirmed that the product was 'Moltek' with Turkey as the country of registration and with a registration number 2014/346.

Ms Helen Vella (77367M) called as a witness by the Appellant testified on oath on the three procedures to be followed to register a medical product with the Medicines Authority. If a product is not registered in Europe it can be registered in Malta – the process usually takes about one year. The product can also be registered by the EU in which case the registration is valid throughout Europe. The Medicines Authority is the only registration authority in Malta . It is not possible to have an *'ad hoc'* process and registration must follow the EU Directives. Referred to the details on the product 'Moltek' witness confirmed that it was not registered or licenced locally and the product was not known. There does not appear to be an application to register the product.

Questioned by Dr Camilleri witness said that the product could be registered in Malta but derogation of procedure cannot be obtained from any other source.

Dr Caroline Muscat (376794M) called to testify by the Contracting Authority stated on oath that she is the Director of Operations at the Medicines Authority and had received a request for approval of Article 20 for this product.

Ms Corinne Bowman recalled to testify by the Contracting Authority gave a brief description of the properties of the product in question and its use in the diagnostic procedures. After production the product has a shelf life of 12 hours.

This concluded the testimonies.

Dr Paris referred to the lack of response to his request for information from the DoC and the CPSU. Since Appellant has been deprived of this information it should be refunded the deposit whatever the outcome of this case. He referred to the Firetech Case in the Court of Appeal which was similar to this

case and the refund of deposit was ordered on appeal. It is outrageous that the DoC should act like this.

According to Dr Paris, the product has a shelf life of 12 hours but only 110 minutes from arrival at Mater Dei Hospital. According to the Technical Offer the product is not registered in Europe but comes from Turkey – on this alone there is disparity between what is stated and what is offered and is enough to fail the bid. The CPSU in their reply point out the Clause that the preferred bidder has 90 days to register the product – the Medicines Authority explained how long in reality the process to register is (365 days not 90 days), and that the exemption to this is only in extraordinary circumstances according to the EU Directive. The alternative bidder is offering a product already registered and there are no circumstances to use the Section 20 exemption. There are no pending applications therefore there is only one product registered and available.

The CPSU, said Dr Paris, is trying to contract with someone that *a priori* cannot fulfil the contract and on which they cannot seek damages as the circumstances were known beforehand. Article 585 of the Civil Code makes it clear that an impossibility cannot be subject of a contract and the DoC is trying to twist the law to award the tender to a non-compliant bidder. There is definite proof that the contract will fail to the detriment of the patients and the principle of proportionality will be rendered ineffective if this contract is awarded. The facts in articles 2.8 and 3.8 do not match with what is declared in the offer.

Dr Camilleri stated that the Board understands that the product can be registered and there is exemption so it is not impossible that the product is used in Malta if the procedure is followed. The Board is here to decide the procurement procedure not the contractual obligations. The Evaluation Committee followed the correct steps in choosing the bid that followed the correct steps. The contract is not part of the evaluation process and since the tender allows later registration it is not in the realm of the Board to decide but that the process was carried out correctly. In a similar case, Cherubino vs Director of Contracts, it was held that the way a contract is dealt with was not a matter for the PCRB – this is backed by other cases. In line with equal treatment and self-limitation there is no reason to exclude the preferred bidder as prior registration is not one of the criteria.

Dr Paris concluded by saying that here has been no rebuttal of the claim that the offer on points 2.8 and 3.8 do not tally with the tender requirements.

There being no further submissions the Chairman declared the hearing closed.

End of Minutes

Hereby resolves:

The Board refers to the minutes of the Board sitting of the 26th July 2022.

Having noted the objection filed by Cherubino Ltd (hereinafter referred to as the Appellant) on 24th June 2022, refers to the claims made by the same Appellant with regard to the tender of reference CfQ 021-2211/22 (CPSU6097/22) listed as case No. 1771 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 &Dr Leon Camilleri

Whereby, the Appellant contends that:

a) ***Product by Cherubino is the only compliant tender -*** The call for quotations, produced four [4] different offers by two [2] different tenderers, three [3] of which are offered by the appellant company [Cherubino] and another offer by Messrs. JV Healthcare limited. Appellant company contends that in accordance with article 6 [Criteria for award], its products on offer are the only ones that satisfy the satisfy the administrative and technical criteria and thus the only compliant tenderer.

b) ***Product by Messrs. IV Healthcare Limited is not registered and is non registrable -*** Through confirmation by CPSU, the product on offer is manufactured outside the European Union and is not registered with the Medicine's (sic) Authority. The product on offer does not have the necessary market authorisation and thus cannot be placed on the Maltese market, in breach of article 4[1] of S.L, 387 of 2004. In addition, no market authorisation may be granted to 'Molotek',(sic) since any such authorisation would be in breach of article 5[1][b] of S.L. 387 of 2004. Finally, there are no exceptional circumstances as warranted or described *inter alia* through article 17 of S.L. 387 of 2004 and/or article 20[1] of Chapter 458 of the Laws of Malta to grant a market authorisation to Molotek(sic). As a matter of fact that product which has been recommended for award cannot be used in Malta for the purposes it has been acquired for.

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 24th June 2022 and its verbal submission during the virtual hearing held on 26th July 2022, in that:

a) CPSU submits that the tender document is clear in stating that it is the contractor's duty to register the product and it is not a sine qua non condition that the product is registered at the time of tender submission.

b) So much so, section 9.11 of the special conditions provide that *"For medicinal products registered by the contractor following the signing of the contract, a copy of the registration certificate issued by the Licensing Authority of Malta must be submitted to CPSU within 90 days from signing of the contract. If the product is not registered within the stipulated timeframe, the Contracting Authority will reserve the right to purchase the product on the account of the defaulting contractor until such time that the product is registered."*

c) The above is also reflected in Section 3 Article 1.2.1 (ii) of the Tender Dossier which provide that: *"If the medicinal product being offered is not registered locally, it is hereby confirmed that product/s shall be registered*

within 90 days from award of Contract. Failure of this, the Contracting Authority reserves the right, at its own discretion, to purchase registered product on the account of the defaulting contractor until the product is locally registered."

d) CPSU therefore submits that the evaluation committee was in its right and within the prescribed terms and specifications to recommend for award an offer which is not registered in Malta being the cheapest compliant offer. The onus would then shift on the contractor to obtain some form of registration in Malta from the Licensing Authority.

e) Should the contractor fail to obtain some form of authorisation/license in Malta, then the Contracting Authority will have the right to purchase on the account of the contractor as provided in Section 3 Article 1.2.1 (ii) of the Tender Dossier, quoted above.

f) CPSU therefore submits that the evaluation committee was within its right and in observance of the tender document and the general principles of public procurement in recommending JV Healthcare Limited's offer for award.

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) This Board takes note of the various testimonies under oath that took place during the hearing. Most relevant are:
   i. Ms Corinne Bowman - who confirmed that the country of licensing of 'Moltek' (preferred bidder's product) is indicated as 'Turkey'.
   ii. Ms Helen Vella - who stated that the process of registration usually takes about one year, that the Medicines Authority is the only registration authority in Malta, that the product 'Moltek' is not registered or licensed locally and there does not appear to be an application for its registration.

b) Reference is also made to the Technical Offer form, which falls under the remit of 'Note 3'. In Part 2 question 2.8 which states 'I confirm that the company I am representing is licensed by the competent authority in Europe to trade this medicinal product', the Preferred Bidder stated 'Yes'. The country of registration, Turkey, was established as a fact during the course of the hearing. What was stated in the Technical Offer form by the Preferred Bidder does not match with the facts presented. Being a 'Note 3' document, no rectifications are allowed.

c) Even though this Board agrees with the arguments brought forward by the Appellant, that it is 'irresponsible' to award the contract to an economic operator who does not have his product as yet registered in Malta, this due to the fact that it will take approximately one year to register such product, when the tender dossier provides only for a 90 day period, and there are allegedly no

'clearcut' extra-ordinary circumstances as mentioned in the Medicines Act to register such a product, this Board will rest on its paragraph (b) above to uphold Appellant's grievances.

The 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 'Notice of Award' letter dated 14th June 2022;
c) To cancel the Letters of Rejection dated 14th June 2022 sent to Cherubino Ltd;
d) To order the contracting authority to re-evaluate all the bids received in their entirety in the tender, through a newly constituted Evaluation Committee composed of members which were not involved in the original Evaluation Committee, whilst also taking into consideration this Board's findings;
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**	**Ms Stephanie Scicluna Laiviera**
Chairman	**Member**	**Member**