PUBLIC CONTRACTS REVIEW BOARD

Case 1823 – CfT 021-0335/22 – CPSU 5555/22 – Supplies – Tender for the Supply of Blinatumomab 38.5 Micrograms Powder for Concentrate and Solution for Solution for Infusion

7th December 2022

The Board,

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 appellant) filed on the 3rd November 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 14th November 2022;

Having also noted the letter of reply filed by Mr Damien Stellini acting for JV Healthcare Ltd (hereinafter referred to as the Preferred Bidder) filed on the 15th November 2022;

Having also noted the letter of reply filed by Dr Mark Anthony Debono acting for the Department of Contracts (hereinafter referred to as DoC) filed on the 11th November 2022;

Having heard and evaluated the testimony of the witness Dr Ian Ellul (Member of the Evaluation Committee) as summoned by Dr Matthew Paris acting for Cherubino Limited;

Having heard and evaluated the testimony of the witness Dr Francis Cherubino (Representative of Cherubino Limited) as summoned by Dr Matthew Paris acting for Cherubino Limited;

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

Having heard and evaluated the testimony of the witness Ms Julia Pirotta (Secretary of the Evaluation Committee) as summoned Dr Leon Camilleri 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 representatives of the parties;

Having noted and evaluated the minutes of the Board sitting of the 1st December 2022 hereunder-reproduced.

Minutes

Case 1823 – CPSU 5555/22 – CfT 021-0335/22 – Tender for the Supply of Blinatumomab 38.5 Micrograms Powder for Concentrate and Solution for Solution for Infusion

The tender was issued on the 18th March 2022 and the closing date was the 11th April 2022. The estimated value of the tender excluding VAT, was € 127,455.44.

On the 3rd November 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 bid was deemed not to be the cheapest offer.

A deposit of € 637.28 was paid.

There were four (4) bids.

On the 1st December 2022 the Public Contracts Review Board composed of Mr Kenneth Swain as Chairman, Ms Stephanie Scicluna Laiviera and Dr Vincent Micallef as members convened a public virtual 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 Leon Camilleri	Legal Representative
Dr Alexia Farrugia Zrinzo	Legal Representative
Mr Daniel De Gaetano	Chairperson Evaluation Committee
Dr Ian Ellul	Member Evaluation Committee

Preferred Bidder – JV Healthcare Ltd

Dr Norval Desira	Legal Representative
Mr Damian Stellini	Representative

Director of Contracts

Dr Mark Anthony Debono	Legal 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 said that the preliminary request for information had been partly met but Appellant still requests details on one particular point in the technical form and suggested that perhaps one of the evaluation members can provide this information, namely the replies to points 3.7 and 3.8.

Dr Ian Ellul (296980M) called to testify by Appellant stated on oath that the replies provided by the preferred bidder in the Technical Offer form were as follows: on point 3.7 it answered 'Not Applicable' and on point 3.8 the answer was 'YES'.

Ms Amanda Camilleri (0007777M) called to testify by the Appellant stated on oath that she is the Regulatory Project Leader in the Licensing Department of the Medicines Authority. Her role is the issuing of licences for Market Authorisation holders. She confirmed that the product 'Blincyto' is registered with the European Medicines Agency (EMA) and is authorised for use in every member

state with local distribution registration in Malta. Economic operators can apply for parallel trading permits but without such permits the product cannot be marketed in Malta.

Dr Francis Cherubino (167384M) called as a witness by Appellant testified on oath that he is a Director of Cherubino Ltd and formed part of the team submitting the bid and that his Company is authorised to market the product in Malta as it is registered and has a letter of access from the manufacturer. Witness explained that one needs the permit of the Company through a letter of access to distribute the product and thereafter there is no need for further registration. If one is not the official distributor then one needs to apply to EMEA to furnish parallel distribution notice. Cherubino has such letter of access confirming that it is licensed in Europe to distribute this product int terms of Article 38 of the tender. There are no records displayed in the public register of EMEA that any one has a permit for parallel distribution. Cherubino's bid meets the requirement of Article 38 but no one else does.

Dr Leon Camilleri Legal Representative for the CPSU questioned the witness who replied that although the tender states so, it is not possible for the product to be registered in Malta in 90 days as the required licence is not issued in Malta and the tender gives no other option except registration in Malta.

Dr Ian Ellul called to testify by the Contracting Authority stated on oath the he is a Chemist by profession and formed part of the Tender Evaluation Committee (TEC). On evaluating the first offer the TEC came across the question if a product is centrally authorised and a local distributor with parallel distribution exists can it be allowed to other firms? Interpreting the tender and the law the TEC concluded that if an economic operator states that he can offer the product then it is given the benefit of the doubt that it will get authorisation. From the legal aspect, under EU directives parallel distribution is allowed. Witness went on to explain that this product is to be used on only one patient. According to the Superintendent of Public Health if ten or less patients are to have access to medication it still has to be provided under a current procedure.

In reply to questions from Dr Norval Desira, Legal Representative for JV Healthcare Ltd witness said that he has eight or nine years' experience of evaluating tenders. Referred to Clause 9.11 in the tender witness said that this clause, allowing 90 days to register a product, was very common in tenders and was made to enable more competitive tendering – this extra period for registration benefits competition and is intended to prevent a monopoly situation arising. Witness confirmed that Cherubino's bid was the highest priced out of four bids.

Ms Julia Pirotta (496595M) called as a witness by the Authority stated on oath that she is a Chemist at the CPSU Procurement Section and had prepared the tender document. She explained that there are two types of medication, referred to as formulary or main station products. The latter is bought specially for a specific number of approved patients. This tender is for main station medication required for one patient who required 56 vials as indicated in the tender.

This concluded the testimonies.

Dr Paris said that the points made about competition are irrelevant. In Article 3.8 the preferred bidder states that it is licenced by the European Medicines Authority to trade this product – in fact it replied 'yes' in the technical offer without any qualifications. This part comes under Note 3 and cannot be altered. Referring to PCRB Cases 1771 and 1772, Dr Paris said that they are identical to this situation where the declaration made did not conform with the facts presented and was not substantiated. An EMEA registered product cannot be traded unless parallel trading notification is obtained and the product cannot be registered locally. – even now the application has not been submitted. The bid of JV Healthcare is not valid. Under Article 39 of the PPR self-limitation has to be observed. The cost of

the bid is immaterial and irrelevant and what matters is that the terms of the tender cannot be met by the preferred bidder. Article 985 of the Civil Code lays down that the impossibility of fulfilment cannot be the subject of a contract. The tender obligation, under Clause 9.11 is inapplicable as we are here dealing with EMEA registration not the Medicines Authority in Malta and neither that nor access to parallel trading exists. The compassionate process referred to which is regulated by EU Commission Directive 726/24 only covers medicines for which there is no marketing authorisation in line. The tender recognises that there is no marketing authorisation. Self-limitation must be applied and the similarity to Cases 1771 and 1772 noted as they are very apt decisions.

Dr Desira said that this appeal was both frivolous and vexatious. The arguments put forward were about registration in Malta which was not an issue as parallel distribution exists and the product is registered in Holland with the preferred bidder having 90 days to register it. All Appellant is seeking is to maintain its monopoly. All that the tender is seeking is dealing in parallel trading and fair competition and to remove the monopolistic practices.

Dr Camilleri said that the reference to the Civil Code should be considered in the context that the Contracting Authority should not doubt the *bona fide* of any offer as no economic operator ever bids on a matter that is not achievable or cannot materialise. *Bona fide* should never be doubted.
Dr Ellul in his testimony stated that the tender allows registration in 90 days so how can the TEC disqualify a bidder if the tender allows it – self-limitation would not be observed faithfully if the terms are ignored. The TEC cannot ignore a bid because bidder is not registered and this is something that is similar to other tenders allowing 90 days registration. One has to emphasise the difference between execution and evaluation. If the bid and the offer match the requirements then it is compliant. In the Case Cherubino vs Department of Contracts (3/10/2017) the Appeal Court stated that it was not necessary for a bid to be fully able to meet all the terms so long as it was capable of performing as promised.

Continuing Dr Camilleri said that Dr Paris had quoted two PCRB Cases were the situations were totally different to the present. In this case there is Euro authorisation and it has been clarified that the product is being bought for one sole patient. S.L. 458.34 Regulation 2.2 states that authorisation shall not apply for individual *bona fide* patients. The recommended bidder had time to register with another option available, namely that the existing circumstances were exceptional. The Appellant's claim that this is not a case of registration but parallel importation is not valid as the product is registered in Europe. The award recommendation should be confirmed.

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

End of Minutes

Hereby resolves:

The Board refers to the minutes of the Board sitting of the 1st December 2022.

Having noted the objection filed by Cherubino Limited (hereinafter referred to as the Appellant) on 3rd November 2022, refers to the claims made by the same Appellant with regard to the tender of reference

CfT 021-0335/22 - CPSU 5555/22 listed as case No. 1823 in the records of the Public Contracts Review Board.

Appearing for the Appellant:	Dr Matthew Paris
Appearing for the Contracting Authority:	Dr Leon Camilleri & Dr Alexia J Farrugia Zrinzo
Appearing for the Preferred Bidder:	Dr Norval Desira
Appearing for the DoC:	Dr Mark Anthony Debono

Whereby, the Appellant contends that:

a) ***Preliminary -*** Reference is made to a request made to the Department of Contracts and the Central Procurement and Supplies Unit, wherein information about the brand, model and market authorization about the product submitted by JV Healthcare Limited was requested. In view of the fact that this information has not been supplied by the DOC/CPSU, and this in manifest breach of article 40 of the PPR, Cherubino is respectfully requesting the board to order DOC/CPSU to issue the requested information and to re-issue the rejection letter and this to ensure that the legal principle of equality of arms is upheld.

b) ***Messrs. JV Healthcare Limited does not meet the tender requirements -*** Although no confirmation was forthcoming from the DOC/CPSU, it is safe to say that the recommended bidder's offer is in breach of the tender specifications, most notably provision 3.8 of the tender offer form. The product being offered is not registered and/or has not been registered and licensed by Messrs. JV Healthcare Limited and/or does not have the necessary authorization by the competent authorities to trade the medicinal product on offer.

c) ***Doctrine of self-limitation -*** The doctrine of self-limitation is an important public procurement principle which has been referred to by this Honourable Board on various occasions, which seeks to ensure that tenderers are adjudged only on the basis of conditions stipulated within the tender document, this will ensure predictability and transparency. The Appellant company feels aggrieved by the decision of the evaluation committee, in particular since it failed to adhere to the mandatory requirement of the tender document, and in the process breaching this fundamental principle.

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 14th November 2022 and its verbal submission during the virtual hearing held on 1st December 2022, in that:

a) ***On the Preliminary Grievance -*** The grievance of the objector is that the information requested was not provided and is requesting for the cancellation and re issue of the letter of award. On this

preliminary plea CPSU submits that the same information on the product name was forwarded to the Objector on the basis of the Department of Contract policy that the brand and model of recommended products shall be disclosed if a request is made. In light of the above, the preliminary plea was unnecessary and should therefore be rejected unless withdrawn voluntarily by the objector. Moreover, CPSU submits that in such a situation, a request for information shall made immediately after a recommendation is made. In the present case the request was made on the 31st of October 17.57, after office hours whilst the objection was filed on the 3rd of November morning and received by CPSU at 11:41. In addition, the Department of Contract and/or CPSU never published the make/model/brand of the recommended bidder in the rejection letters but provide the same information upon request by any of the participating bidders. This case should not be an exception and there is no valid reason at law for the re publication of the rejection letter as the disclosure of the brand/make/model are not a requirement under the Public Procurement Regulations (PPR).

b) ***On the Second Grievance -*** 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. So much so, section 9.11 of the special conditions provides 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."*. The above is also reflected in Section 3 Article 1.2.1 (ii) of the Tender Dossier which provides 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."* 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.

Should the contractor fail to obtain some form of authorisation/license (sic) 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. Moreover and without prejudice to the above submitted, it is being submitted that the present call for tenders is for a named patient basis product for one patient only. In relation to named patient basis products, a procedure for a maximum number of 10 patients exists whereby the wholesaler, prescriber, patient, dispensing pharmacist, pharmaceutical unit of the licensing authority and the licensing authority can sign an application by means of which the product is exempted from registration. This procedure is an additional procedure to the other procedures available for economic operators to make their

product available on the market. 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.

c) ***On the Third Grievance - Principle of Self Limitation -*** On this count CPSU submits that its evaluation committee has throughout the evaluation process adhered to each and every fundamental principle of public procurement, including the principle of self limitation. In light of the above submission that the product at evaluation stage need not be already authorised or put on the market, the principle of self limitation has been strictly followed by the evaluation committee when making its recommendation.

This Board also noted the Preferred Bidder's Reasoned Letter of Reply filed on 15th November 2022 and its verbal submission during the virtual hearing held on 1st December 2022, in that:

a) JV Healthcare Ltd agrees completely with the reply issued by the Central Procurement and Supplies Unit (CPSU) to the objection lodged by Cherubino Limited dated 11th November 2022. JV Healthcare re-iterates that it has abided by all tender requirements and that the product supplied to CPSU will be a licenced product designated for use in Malta.

This Board also noted the DoC's Reasoned Letter of Reply filed on 11th November 2022 and its verbal submission during the virtual hearing held on 1st December 2022, in that:

a) Preliminary Plea - The DoC submits that the current procurement process is administered and determined by the Contracting Authority since the estimated procurement value is €127,455.44 in accordance with regulation 9(1)(a) of the Public Procurement Regulations, 2016. Therefore, the DoC hereby submits that the Public Contracts Review Board should forthwith dismiss the objection with regard to the DoC since it is not the legitimate and proper defendant to reply to the grievances of the objector.

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 now consider Appellant's grievances.

a) ***Preliminary –*** The Board notes that this plea has been extinguished in the course of the hearing. The 'missing' information has at that stage been provided through the initial testimony of Dr Ian Ellul. Moreover, this Board agrees with the written representations of the Contracting Authority whereby the make/model/brand of the recommended bidder are never and need not be published

in the rejection letters but such information is provided upon request by any of the participating bidders.

b) ***Merits –***

Initially this Board will list down what it considers to be most relevant to these proceedings. These are:

i. Paragraph 9.11 - Section 2 of the tender dossier where it is stated *"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 the signing of the contract. If the product……."* (bold & underline emphasis added)

ii. Testimony under oath of Ms Amanda Camilleri when she stated *"No"* when being asked by the Appellant's legal representative if a product which is registered through the European Medicines Agency ("EMA") requires further registration with the Malta Medicines Authority.

iii. Testimony under oath of Ms Amanda Camilleri whereby in respect of 'Parallel Trading' she stated that a new economic operator, in order to distribute an EMA registered medicinal product, needs to register with EMA in order to be issued with a 'Parallel Distribution Authorisation'. She also stated that the Malta Medicines Authority is not involved at all in this process. She continued by testifying that without this EMA authorisation, this product cannot be distributed within Maltese territory.

iv. Spec 3.8 of the Technical Offer Form which read as follow: "I confirm that the company I am representing is licensed by the competent authority in Europe to trade this medicinal product". The answer to this spec by the preferred bidder was "Yes".

Conclusions

i. It is evidently clear from the wording of paragraph 9.11 - Section 2 of the tender dossier that the "90 days" allowance, following signing of the contract, is only to be granted in cases where the products are to be eventually registered with the Licensing Authority of Malta, i.e. the Malta Medicines Authority.

ii. It is also very much clear, from the testimony of Ms Amanda Camilleri, that there are different ways and means on how a medicinal product is allowed to be distributed in Malta.

iii. Such product offered by the preferred bidder is already registered with EMA. Hence it has been ascertained, during the course of the hearing, that what was needed was a 'Parallel Distribution Authorisation'. These authorisations are issued by EMA and not by the Malta Medicines Authority.

iv. Therefore, this Board opines that:

A. paragraph 9.11 - Section 2 and its 90 days allowance are irrelevant to these proceedings since it is only referring to the Licensing Authority of Malta.

B. the response provided by the preferred bidder in Spec 3.8 of its Technical Offer Form is erroneous since at the time of closing date of the call for tenders, the preferred bidder was not in possession of such a document.

v. The Technical Offer Form, being a note 3 document, no rectifications are allowable.

Hence, this Board cannot but uphold the Appellant's grievance on the merits of this appeal.

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 24th October 2022;
c) To cancel the Letter of Rejection dated 24th October 2022 sent to Cherubino Ltd;
d) To order the contracting authority to re-evaluate all the bids received 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 Vincent Micallef**	**Ms Stephanie Scicluna Laiviera**
Chairman	**Member**	**Member**