PUBLIC CONTRACTS REVIEW BOARD

Case 1639 – CT 2044/2021 - Tender for the Supply of Colchicine Tablets

25th October 2021

The Board,

Having noted the letter of objection filed by Dr Steve Decesare and Dr Katya A. Gatt on behalf of Camilleri Preziosi Advocates acting for and on behalf of Pharma.MT Ltd, (hereinafter referred to as the appellant) filed on the 13th August 2021;

Having also noted the letter of reply filed by Dr Marco Woods acting for the Central Procurement and Supplies Unit (hereinafter referred to as the Contracting Authority) filed on the 19th August 2021;

Having heard and evaluated the testimony of the witness Ms Denise Dingli (Chairperson of the Evaluation Committee) as summoned by Dr Steve Decesare acting for the Appellant.

Having heard and evaluated the testimony of the witness Dr Ian Ellul (Member of the Evaluation Committee & Chemist) as summoned by Dr Steve Decesare acting for the Appellant.

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 19th October 2021 hereunder-reproduced;

Minutes

Case 1639–CT 2044/2021. Tender for the Supply of Colchicine Tablets

The tender was published on the 28th May 2021 and the closing date was the 1st July 2021. The value of the tender excluding VAT was € 250,686.

On the 13th August 2021 Pharma MT 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 to be not technically compliant.

A deposit of € 1,253 was paid.

There were seven (7) bidders.

On 19th October 2021 the Public Contracts Review Board 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 – Pharma MT Ltd

Dr Steve Decesare	Legal Representative
Mr Patrick Nicholl	Representative
Ms Elisa McKenna	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Alexia Farrugia Zrinzo	Legal Representative
Dr Leon Camilleri	Legal Representative
Ms Denise Dingli	Chairperson Evaluation Committee
Ms Tracy West	Member Evaluation Committee
Dr Ian Ellul	Member Evaluation Committee

Preferred Bidder – E J Busuttil Ltd

Ms Claire Busuttil	Representative

Department of Contracts

Dr Christine Busuttil	Legal Representative
Mr Mark Mizzi	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 invited submissions.

Dr Steve Decesare Legal Representative for Pharma MT Ltd sought permission to call a witness.

Ms Denise Dingli (126682M) called as a witness by the Appellant testified on oath that she was the Chairperson of the Evaluation Committee and stated that she is employed as a Senior Principal in the Government service. Her role was to oversee the evaluation and vet the final report. There were three members on the Committee. The evaluation was done by the technical expert on the Committee and she confirmed the decision of the evaluator. Witness confirmed that according to the tender the market authorisation could be applied for after the award of the tender but she had no personal knowledge of how to apply for such authorisation. According to the Contracting Authority Appellant was also disqualified because the SPC showed the wrong country of origin.

Witness stated that the disqualification letter was issued by the Department of Contracts based on the findings of the evaluation report, and agreed that the first reason for that disqualification was that in section 2.3 the registration number was missing but could be obtained at a later date; however she insisted that the tender had been rejected because of the difference in country of origin of the SPC.

Questioned by Dr Alexia Farrugia Zrinzo Legal Representative for the Central Procurement and Supplies Unit (CPSU) witness confirmed as correct the wording used in the rejection letter on point 2.3 and said that the Technical Specifications come within Note 3 of Clause 5 of the tender.

Dr Ian Ellul (296980M) called as a witness by Appellant testified on oath that he is a Chemist by profession employed by the CPSU and was one of the evaluators. He detailed the award criteria of the tender which were to ensure that the product offered met the tender requirements and was the cheapest technically compliant product. No clarifications had been sought in this tender.

Witness confirmed that Appellant's offer had been rejected on two counts – point 2.2 which states that the country of licensing is the Netherlands but the MA (Medical Authorisation) number starts

with the letters PA (which is Ireland) and point 2.3 which is assessed as missing. Witness confirmed that point 2.3 requested a licence number to be inserted and agreed that the tender allowed the product to be registered later – the technical offer however also asked for an EU product number which is general, with each country then issuing its own product number. If the country of licensing states Netherlands then its number should be stated.

On point 2.3 of the Technical Offer witness confirmed that there were two possibilities – either to state the licence number or to indicate that the product was still to be registered. He confirmed that the SPC is issued by the Medicines Authority as indicated in page 22 of the tender (Section 4 Point 4.2) which point, he said, he had interpreted differently to what was stated in the tender. He agreed that Appellant could not insert an MA number as the number was not available.

On the question of the country of licensing of the SPC witness confirmed that the licence had to be in one of the official languages of Malta. This, the Evaluation Committee had interpreted such that it could be a translation according to the witness who also agreed that there is no difference between SPCs from different countries except for the authorisation number.

In reply to question from Dr Farrugia Zrinzo witness said that he had worked in the Medicines Department for 12 years and had obtained a Doctorate. He went on to say that the SPC relates to each particular country and had a particular number. European regulations insist on harmonisation of products and the product and authorisation should be from the same country.

Questioned further by Dr Decesare witness stated that there might be some small differences between SPCs from different countries but following harmonisation they basically follow the same template and once a product is authorised in Malta it has to bear that registration number.

That concluded the testimonies.

Dr Decesare said that the position was that either the product was authorised or it had to be subsequently registered. The tender clearly states that the authorisation is that granted by the Medicines Authority under Maltese law. There was only one reason given for the disqualification, the lack of a registration number, plus one comment. He stated that each country has an authorised registration number and SPC and if a product is not registered in Malta a copy of the registration must be submitted within 90 days and if not compliant then the Authority can call on another supplier to provide. The missing information was not a 'blank' as the Authority claims, but completed by stating that it will be registered.

The country of licensing was the Netherlands but the SPC according to he tender had to be in one of the languages of Malta. The point here is that SPCs are the same in both countries as the characteristics of the product are the same. That the tender asked for registration in Malta is clear and unambiguous but since Appellant was unable to give a Malta number he had to submit the SPC of another country - when different countries were stated why did the Authority not seek to clarify?

Reference was made to CJEU Case 131/16 and R (Hoole & Co) which both treat with the duty to seek clarifications if such clarifications do not change the bid. The CPSU in their reply claim that any authorising number suffices to go against the tender glossary.

Dr Farrugia Zrinzo said that if Appellant felt that the tender was ambiguous they should have resorted to seeking a remedy. The tender is very clear on what was requested. The SPC related to a particular country so why was Ireland related with the Netherlands registration? The Technical information requested a registration number which was not given and the SPC provided was incorrect therefore the technical requirement were not met.

Dr Decesare concluded by saying that it was now being claimed that the tender was ambiguous - the clarifications he had suggested were on the actual offer. The letter of disqualification gave one main reason and a side note regarding the different countries. It was never stated that the rejection was on this latter point.

End of Minutes

Hereby resolves:

The Board refers to the minutes of the Board sitting of the 19th October 2021.

Having noted the objection filed by Pharma.MT Ltd (hereinafter referred to as the Appellant) on 13th August 2021, refers to the claims made by the same Appellant with regards to the tender of reference CT 2044/2021 as case No. 1639 in the records of the Public Contracts Review Board.

Appearing for the Appellant:	Dr Steve Decesare
Appearing for the Contracting Authority:	Dr Alexia Farrugia Zrinzo

Whereby, the Appellant contends that:

a) ***Disqualification due to missing information -*** The Department of Contracts ("DOC") letter states that Pharma's offer was disqualified since the *"Technical Offer form (not rectifiable as per tender conditions) has section 2.3 missing. Thus offer could not be validated"*. Therefore, the reason for disqualification is that the DOC considered that section 2.3 of Pharma's technical offer form is missing. This is entirely incorrect as a submission was made for section 2.3. It is evident therefore that Section 2.3 was not missing in Pharma's Technical Offer. Presumably, what is meant by this statement is that the MA/QL/PI/EU number was not indicated. If this is the case, the Marketing Authorisation number for the product in Malta is indeed missing, since the product (as permitted in the Tender Document) is not yet registered locally. In view of the above, Pharma stated in its technical offer that the "Product will be registered if tender is awarded". The Tender Document permits the registration of the medicinal product after award of the contract. It is obvious therefore that it is not possible for Pharma to specify an MA/QL/PI/EU number for the product being offered by Pharma in the Tender Procedure, as the relevant product is not yet registered locally.

b) ***The note in DOC Letter re MA number -*** Separately from the reason for disqualification, the DOC Letter also notes the following: *"Also section 2.2 details that the country of licensing is Netherlands but the SmPC submitted details an MA number which relates to Ireland"*. This does not relate to the technical offer form and does not appear to be a reason for disqualification. In any case, Pharma is clarifying this note. The DOC correctly notes that the country of licensing of the product is the Netherlands. However, the Tender Document also required in Section 2.1 of Section 3, that a Summary of Product Characteristics ("SmPC" or "SPC") of the product being offered. An SPC is a specific legal document which is approved as part of the market authorisation of each medicine. It can be found on the European Medicines Agency ("EMA") and the Malta Medicines Authority website. The SPC acts as a basis of information on the use of medicines and forms part of the Marketing authorization of every medicine, the structure of which is defined by European Pharmaceutical legislation. In particular, the SPC includes reference to i) Marketing Authorisation Holder ii) Marketing Authorisation Number iii) Date of First Authorisation / Renewal of the Authorisation. In view of the fact that an SPC has not been issued for the product in Malta, as the product is not yet registered in Malta and no Market Authorisation has been issued in favour of the relevant proposed Market Authorisation Holder in Malta. Pharma (or any other tenderer submitting a tender with a product which is not yet registered, as expressly permitted in the Tender Document as explained above) was not in a position to submit an SPC showing a Market Authorisation number from the Malta Medicines Authority. Since an SPC for the product, in the English language, was required Pharma submitted the SPC used by Tiofarma B.V. for the same product in Ireland, which is one of the EU Member States in which Tiofarma B.V. has a Market Authorisation. The reason for this is obvious; the SPC used in Ireland is in English, one of the official Languages of Malta, and therefore abides by the requirements in Section 2.1 of Section 3 of the Tender Document, as herein mentioned. Therefore, while the DOC's statement that "section 2.2 details that the country of licensing is Netherlands but the SmPC submitted details an MA number which relates to Ireland" is factually correct, this does not result in any breach of the requirements in the Tender Document.

c) ***Duty to seek clarifications*** - While Pharma contends that, on the basis of the above, there is no room for any ambiguity or uncertainty on Pharma's reply in Section 2.3 of its Technical Offer form and the SPC, it submitted that should the Contracting Authority have had any doubt on the same, it had an obligation to seek a clarification from Pharma in these circumstances. Pharma notes that both the Technical Offer form and the SPC are indicated in the Tender Document as being Note 3, meaning that while no rectification may be made in their respect, the Contracting Authority is allowed to make clarifications thereon.

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 19th August 2021 and its verbal submission during the virtual hearing held on 19th October 2021, in that:

a) ***Disqualification due to missing information -*** Referring to the first reason, that being that Section 2.3 of the Technical Offer Form is missing. CPSU contend that the Technical Offer Form was clear and unambiguous, wherein it clearly stated "MA/OU/PI/EU No _____". The Appellant instead opted to indicate "product will be registered if is awarded" therefore referring to the process where a product may be registered within 90 days from signing of the Contract. Evidently, the appellant in his appeal is insisting on this line of argument, however the appellant fails to note that the Technical Offer Form did not request the Maltese MA number, but merely requested "MA/QL/PI/EU No". Therefore, although the Tender stipulates that an unregistered product may be submitted as long as it is registered within 90 days from the date of signing of the Contract the Technical Offer Form did not request the Market Authorisation Number for Malta, but merely requested a Market Authorisation Number. In view of this, the argument being raised by the appellant is entirely unfounded at fact and at law.

b) ***The note in DOC Letter re MA number -*** Moreover, the second reason as to why the offer was rejected is that the Country of Licensing is indicated as Netherlands in the Technical Offer Form whilst the SmPC indicates Ireland as the Country of Licensing. CPSU contend that the SmPC is the official document of the product, which Product outlines all the characteristics of the product as well as the licensed country of the product. Therefore, if the Country of Licensing is listed as Ireland in the SmPC, then the objector ought to have indicated Ireland as the Country Of Licensing in the Technical Offer Form, and not Netherlands. The argument being brought by the appellant that they submitted the Irish SmPC due to being published in the English Language can never justify this mistake on the part of the objector. The Contracting Authority must always act in line with the provisions of the law and in the best interest of the patient Moreover. the Evaluation Committee is bound by the principle of Self-Limitation. Therefore, the Evaluation Committee must carry out its Evaluation on the documentation and information as submitted at tendering stage. In evaluating the Technical Offer Form and the SmPC of the product being offered, the Evaluation Committee noticed that the Country of Licensing listed in the Technical Offer Form and that listed in the SmPC of the product as submitted, differed from each other. Therefore, the information given in the Technical Offer Form and that resulting from the SmPC submitted did not corroborate with each other. Consequently, for the reason outlined above, and due to the fact that the Technical Offer Form is a Note 3 Document (Non-rectifiable as per tender conditions), the Evaluation Committee could not validate the offer as submitted.

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) ***Disqualification due to missing information –*** The Board makes reference to Section 4 of the Tender Dossier, whereby Marketing Authorisation (MA) is defined as follows: "is the licence for medicinal products to be placed on the market in Malta granted by the Medicines Authority in accordance with the Medicines Act, 2003 (Act No III of 2003 and subsidiary legislation) and for Centrally Authorized products, by the European Medicines Agency (EMA)……". Reference is also made to the fact that 'if a product is not registered in Malta a copy of the registration must be submitted within 90 days'. Therefore, the Appellant is not deemed to have breached his Technical Offer submission of Section 1 Sub-section 2.3 when he declared "Product will be registered if tender is awarded".

   This Board upholds Appellant's first grievance.

b) ***The note in DOC Letter re MA number –*** In relation to this specific grievance, the Board notes that the:
   i. Technical Offer (Note 3 document) of the Appellant company stated in Section 1 Sub-section 2.2 – "Country of licensing Netherlands".
   ii. Summary of Product Characteristics (SPC) provided within the tender bid, which was requested as per the Tender Document paragraph 2.1 of Section 3, refers to an Irish SPC.

   The Board also notes that the respective European Union Directive has within it a 'template' for SPCs' which has as one of its main objectives, that of harmonisation. As per testimony under oath of Dr Ian Ellul, *"SPC relates to each particular country and had a particular number. European regulations insist on harmonisation of products and the product and authorisation should be from the same country. There might be some small differences between SPCs from different countries but following harmonisation they basically follow the same template."* Therefore, it is the specific and respective country SPC which is the official document upon which one has to base his / her evaluation. Therefore, this Board opines when the Appellant listed "Netherlands" in Section 1 Sub-section 2.2 – Country of licensing, within the Technical Offer, then he should have substantiated his technical documentation with an SPC from the Netherlands. This to be duly translated into an approved language of Malta. It is further noted, that the Evaluation Committee, in this instance, correctly observed the principle of 'Self-Limitation'.

This Board does not uphold Appellant's second grievance.

The Board,

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

a) To uphold the Appellant's concerns with regards to the first grievance entiteld "Disqualification due to missing information" but does not uphold Appellant's concerns with regards to the second grievance (and second reason for technical non-compliance) entitled "The note in DoC Letter re MA number" ;
b) Upholds the Contracting Authority's decision in the recommendation for the award of the tender,
c) Directs that the half the deposit paid by Appellant to be reimbursed.

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