PUBLIC CONTRACTS REVIEW BOARD

Case 1664 – CT 2242/2020 – Tender for the Supply of Budesonide 100 micrograms Dry Powder Inhaler

27th December 2021

The Board,

Having noted the letter of objection filed by Dr A. Galea Salomone on behalf of Galea Salomone & Associates acting for and on behalf of V.J. Salomone Pharma Limited, (hereinafter referred to as the appellant) filed on the 28th October 2021;

Having also noted the letter of reply filed by Dr Alexia Farrugia Zrinzo and Dr Leon Camilleri acting for the Central Procurement and Supplies Unit (hereinafter referred to as the Contracting Authority) filed on the 8th November 2021;

Having heard and evaluated the testimony of the witness Ms Helen Vella (Director Licensing, Malta Medicines Authority) as summoned by Dr A. Galea Salomone acting for the Appellant.

Having heard and evaluated the testimony of the witness Mr Christopher Treeby-Ward (Tender Business Manager at V.J. Salomone Pharma Limited) as summoned by Dr A. Galea Salomone 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 Leon Camilleri acting for the Contracting Authority.

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 14th December 2021 hereunder-reproduced;

Minutes

Case 1664–CT2242/2020. Tender for the Supply (of) Budesonide 100 Micrograms Dry Powder Inhaler

The tender was published on the 1st October 2020 and the closing date was the 5th November 2020. The value of the tender excluding VAT was € 732,187.50. The tender was awarded on the 22nd October 2021.

On the 28th October 2021 V. J. Salomone Pharma Ltd filed an appeal against the Central Procurement and Supplies Unit as the Contracting Authority objecting to their disqualification on the grounds that the offer was technically not compliant.

A deposit of € 3,660 was paid.

There were two (2) bidders.

On 14th December 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 consider the appeal.

The attendance for this public hearing was as follows:

Appellant – V J Salomone Pharma Ltd

Dr Arthur Galea Salomone	Legal Representative
Ms Vanessa Said Salomone	Representative
Ms Jackie Mangion	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Leon Camilleri	Legal Representative
Dr Ian Ellul	Chairperson Evaluation Committee
Ms Denise Dingli	Representative

Preferred Bidder – Associated Drug Co Ltd

Ms Christina Apap Bologna	Representative
Mr Nicholas Falzon	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.

Dr Arthur Galea Salomone Legal Representative for V J Salomone Pharma Ltd stated that the disqualification was on two points - that paragraphs were left blank and provenance of the medicinal product cannot be identified. This is totally incorrect as no paragraph or box was left blank and it is not a *sine qua non* for a product to be registered at the time of the tender. At the time of submission of the tender bidders were allowed to have the product registered in Malta – in fact the Medicines Authority was encouraging suppliers to obtain full Marketing Authorisation (MA). At the time therefore they could not quote a local registration number and the only way to compete was to indicate eventual registration as they could not quote the MA of another country. No boxes were left blank

Dr Leon Camilleri Legal Representative for the Central Procurement and Supplies Unit said that the bidder was obliged to provide a reason why he was unable to complete the required boxes. The Contracting Authority was expecting MA numbers, country of licensing and such. The Evaluation Committee was not expected to find these things out for themselves.

Ms Helen Vella (77367M) called as a witness by the Appellant testified on oath that she is responsible for the Registration of Medicines. There are two different procedures for registration; either Mutual Recognition Procedure (MRP) or via Article 126A – the latter is different as licences are already issued in another country. In 2020 a policy change led to encouraging registration under the MRP procedure. The foreign MA number is of no interst to the Malta Medicines Authority as a new local number is given to an application. The SPC is common but the name of the product and the MA holder and number are populated nationally by the country of issue.

Mr Christopher Treeby-Ward (488073M) called as a witness by the Appellant testified on oath that he is the Tender Business Manager at V J Salomone Pharma Ltd. He explained that 126A registration refers to a foreign country product whilst in the case of MRP the foreign company registers the product in Malta under a different procedure. If a product is not registered in Malta it is normal to quote the foreign MA and in that case one had to use documents sent by foreign firm. The product in question in this tender is now registered in Malta.

Questioned by Dr Camilleri witness said that at the time of the tender submission they were using a 126A registration but since then they have the MRP registration.

Dr Ian Ellul (296980M) called as a witness by the Contracting Authority stated he was a Chemist by profession and had the role of an evaluator in the tender. Section 2.2 and 2.3 of the Technical Offer form relate to the country of licence and MA number and the evaluators expected to find this information. Both quoted sections were not rectifiable as they came under Note 3 nor was it subject to clarification. Registration under 126A allows better accessibility to the market and is an easier process but where possible suppliers were encouraged to register under MRP procedure. There was no explanation provided by Appellant regarding information supplied in the Sections mentioned and there was no reason why the country of origin could not have been stated. The self limitation restrictions prevented the Authority from taking further action.

Questioned by Dr Galea Salomone witness said that the country of origin can vary from the MA country of registration.

This concluded the testimonies.

Dr Galea Salomone said that witnesses confirmed that if a bidder gave a foreign MA number it would be misleading. The MA licence would be applicable in Malta but would not be effective at that stage as it was still being processed. When the Appellant indicated that registration is to take place it was clear that the process would be completed through the MRP. The boxes were filled in correctly in the only way possible and the bidder was following the instructions of the Medical Authorities.

Dr Camilleri stated that in his testimony Mr Treeby-Ward that this was one of the first registrations under MRP as normally in Malta registration is under the 126A process. This was a Note 3 matter and therefore not rectifiable. Once the country of licensing was requested it was up to the bidder to give an explanation as to why it was omitted, more so since it was available. The Evalaution Committee was bound by self limitation.

Dr Galea Salomone pointed out that the fact that it was stated that registration was to follow meant that the explanation was there. It is clearly stated that there will be national registration.

Dr Camilleri concluded by saying that since the usual registration was under 126A process there was no indication given that this bid was different.

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 14th December 2021.

Having noted the objection filed by VJ Salomone Pharma Ltd (hereinafter referred to as the Appellant) on 28th October 2021, refers to the claims made by the same Appellant with regards to the tender of reference CT 2242/2020 as case No. 1664 in the records of the Public Contracts Review Board.

Appearing for the Appellant:	Dr A Galea Salomone
Appearing for the Contracting Authority:	Dr Leon Camilleri

Whereby, the Appellant contends that:

a) Whereas by means of a communication dated 22nd October 2021, VJ Salomone Pharma was informed that the offer submitted was found to be technically non-compliant for the following reasons;

"Section 8 of the SmPC [MA number] has been left empty. Likewise section 2.2 [country of licensing] and section 2.3 [MA Number] of the technical offer have been left empty. Both documents are not rectifiable as per tender conditions. In view of the fact that [1] sections detailed above have been left empty, [2] documents are not rectifiable and consequently [3] provenance of the registration details of the medicinal product which is being offered cannot be identified, offer cannot be recommended."

b) The first statement made, that is, *"Section 8 of the SmPC [MA number] has been left empty"* is factually incorrect. As is evident from the copy of the SmPC submitted, Paragraph 8 was not left blank but was completed with the wording "To be completed nationally".

c) The second statement made that is, "Likewise section 2.2 [country of licensing] and section 2.3 [MA Number] of the technical offer have been left empty" is also factually incorrect. As is evident from the Technical Offer, sections 2.2 and 2.3 were not left empty. They were completed with the wording "item will be registered in Malta within 90 days of award".

According to the tender conditions, it is not a *sine qua non* for a product to be registered at the time of tender. Once it is not registered a registration number cannot be provided. Article 9.11 of the Tender Document, under the Heading Registration of Medicinal Products' specifically states

"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: ……."

d) Not only are the statements made in the tender outcome notification dated 22nd October factually incorrect, as clarified in paragraphs 2 and 3 above, but the conclusions and reasons for the disqualification are a non sequitur and do not follow from the factually incorrect statements made. The reasons for disqualification are stated as follows:

"Both documents are not rectifiable as per tender conditions. In view of the fact that (1) sections detailed above have been left empty, [2] documents are not rectifiable and consequently [3] provenance of the registration details of the medicinal product which is being offered cannot be identified, offer cannot be recommended."

Firstly as indicated above the above detailed sections have not been left empty. Secondly, nobody has requested rectification of the documents nor is rectification necessary as both documents have been completed in a technically compliant manner. Thirdly, ascertainment of provenance entails identification of the Marketing Authorisation Holder and registration number.

The Marketing Authorisation holder was clearly indicated in Para 7 of the SmPC as Orion Corporation of Orionintie 1, FI-02200 Espoo, Finland. The registration number could not have been provided as the product was not registered in Malta nor was there the necessity for it to be so registered at that stage. The offer by VJ Salomone Pharma was for a country specific (Malta) pack. There was no need to reference any other product in any other country. The registration number was not yet available since the product was not registered in Malta at the time of tendering. The latest version of the SmPC provided as part of the tender was eventually used to register the product in Malta and was considered acceptable for registration purposes by the Malta Medicines Authority. The MA has now been available since 20th January 2021 and in terms of Article 9.11 of the Tender Document, VJ Salomone Pharma may submit a copy of the registration certificate to the CPSU within 90 days from signing of the contract.

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 8th November 2021 and its verbal submission during the virtual hearing held on 14th December 2021, in that:

a) <u>On the missing Marketing Authorisation number in the Summary of Product Characteristics (SmPC) –</u> Primarily the CPSU and the DOC submit that the document presented as 'Doc 1' with the objection letter is not the SmPC which was presented with the offer as the one presented with the objection included the Maltese MA number from the Medicines Authority of Malta (MA624/00301) whilst as admitted by the objectors, the one presented with the offer had the words 'to be completed nationally'. The objector contends that the reason given in the rejection letter, that section 8 of the SmPC has been left empty was incorrect because in reality they have written to be completed nationally. The CPSU and the DOC humbly submit that the for the tender's purposes, leaving a blank space or simply saying that 'this has to be completed' is

substantially and fundamentally the same as being left blank, since the information that should be provided, is not there.

From its very nature, an SmPC has to be approved, as otherwise it would be a draft of an SmPC and would have, little or no value for the evaluation committee to decide on. The medicine being offered is certainly licensed in some other country and it is that SmPC which should have been provided and not an incomplete one because the medicine is not yet registered in Malta.

Moreover, the Technical Specifications do not provide that the SmPC has to be approved by the Medicines Authority of Malta. In their technical offer Form and even in paragraph 7 of the SmPC, it is being indicated that the Orion Corporation of Finland is the Marketing Authorisation Holder in the Country of Licensing and thus a Marketing Authorisation number must exist and should have been included in the approved SmPC which had to be submitted. If a marketing authorisation number did not exist at that time a clear explanation should have been given.

b) Country of Licensing and MA/QL/PI/EU No: - The CPSU and the DOC humbly submit once again that the for the tender purposes, leaving a blank space or simply saying that 'Item will be registered in Malta within 90 days of award' is substantially and fundamentally the same as being left empty, since the information requested was not provided.
The objector is focusing his argument on the fact that the tender allowed for a product to be registered in Malta post award. That is not disputed. However the fact that in the Marketing Authorisation Details section in the technical offer form, one is being requested the MA/QL/PI/EU No: clearly indicated that what the contracting authority is after is not the Maltese MA number but some form of Product Identification or Marketing Authorisation number, which could be a Maltese MA number, but not necessarily so.

c) Clarifications - After all, if the contracting authority requested the objector for a clarification on the missing information, that would still not make the objector technically compliant since for the objector to be technically compliant what was required was a ratification(sic). The Contracting Authority submit that the objector and this Honourable Board are well aware, that rectifications are prohibited in Note 3 Documents such as the SmPC (since being part of the specifications) and the Technical Offer.

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:

Reference is made to the following:

a) The testimony under oath of Ms Helen Vella whereby she stated that:
    i. There are two different procedures for registration, either through Article 126A or through the Mutual Recognition Procedure (MRP).
    ii. During 2020 a policy change led to encouraging registration under the MRP procedure.
b) The testimony under oath of Mr Christopher Treeby-Ward whereby he stated that:
    i. The Appellant's bid was for a medicine to be registered under the MRP procedure, hence the offer of V.J. Salomone Pharma Ltd was for a country specific (Malta) pack.

The Board opines that:

a) Since the Appellant's prospective offer was for a country specific (Malta) pack and was duly being registered under the MRP procedure, as encouraged by the Medicines Authority, the Appellant could not have provided a foreign MA number and country of licensing as this would have been misleading.
b) Since the product was not registered in Malta at the time of tendering, the registration number was not yet available.
c) Since the Appellant's product was being licensed under the MRP procedure, the way the Appellant's bid was structured is deemed allowable by the tender document, reference to paragraph 9.11 of Section 2 – Special Conditions.

At this point the Board refers to the testimony under oath of Dr Ian Ellul where he stated *"Both quoted sections were not rectifiable as they came under Note 3* ***nor was it subject to clarification****. Registration under 126A allows better accessibility to the market and is an easier process but where possible suppliers were encouraged to register under MRP procedure. There was no explanation provided by Appellant regarding information supplied in the Sections mentioned and there was no reason why the country of origin could not have been stated. The self limitation restrictions prevented the Authority from taking further action."* (Bold & underline emphasis added).

The Board strongly disagrees with such a statement emphasised in bold & underline. Such a clarification is allowed under the Public Procurement Regulations and with this tool, had it have been used, it would have emerged that the Appellant's bid was for a country specific (Malta) pack which was undergoing a licensing process under the MRP procedure.

Therefore, the Board upholds the 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 22nd October 2021;
c) To cancel the Letters of Rejection dated 22nd October 2021 sent to V.J. Salomone Pharma Ltd;
d) To order the contracting authority to re-evaluate the bid received from V.J. Salomone Pharma Ltd 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**	**Mr Lawrence Ancilleri**
Chairman	**Member**	**Member**