PUBLIC CONTRACTS REVIEW BOARD

Case 1515– CT 2146/2020 – Tender for the Supply of Insulin Preparations in Vials – Lots 1 & 2

The tender was published on the 30th April 2020 and the closing date of the tender was the 19th May 2020. The estimated value of the tender (exclusive of VAT) was € 910,023.75 for Lot 1 and € 988,200 for Lot 2.

On the 30th October V J Salomone Pharma Ltd filed an appeal against the Central Procurement and Supplies Unit as the Contracting Authority objecting to their disqualification on both Lots on the grounds that their bid was not technically compliant and on the cancellation of the tender.

A deposit of € 9,491 was paid.

There were two (2) bidders.

On 20th November 2020 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Dr Charles Cassar and Mr Carmel Esposito as members convened a public virtual hearing to discuss the objections.

The attendance for this public hearing was as follows:

Appellants – V J Salomone Pharma Ltd

Dr Roderick Zammit Pace	Legal Representative
Dr Sharon Pace Gouder	Legal Representative
Ms Jackie Mangion	Representative
Ms Luksa Malgorzata	Representative
Mr Philip Pace	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Marco Woods	Legal Representative
Ms Monica Sammut	Chairperson Evaluation Committee
Ms Julia Pirotta	Secretary Evaluation Committee
Ms Anna Ellul	Member Evaluation Committee
Dr Ian Ellul	Member Evaluation Committee
Ms Kathryn Galea	Member Evaluation Committee

Interested Party – Charles De Giorgio Ltd

Dr Clement Mifsud Bonnici	Legal Representative
Dr Calvin Calleja	Legal Representative
Dr Maxine Montanaro	Representative
Mr Mark Mallia	Representative
Ms Enza Lapira	Representative

Department of Contracts

Dr Daniel Inguanez	Representative
Mr Nicholas Aquilina	Representative

Dr Anthony Cassar 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. He then invited submissions.

Dr Roderick Zammit Pace Legal Representative for V J Salomone Ltd (VJS) said that the basis for Appellants' appeal on both Lots was fully detailed in the letter of objection. The Contracting Authority claim that the offer was not compliant and the tender was subsequently recommended for cancellation, and this point was also being appealed on. Testimony of witnesses will prove that Appellants' products were compliant with the tender requisites.

Dr Marco Woods Legal Representative for the Central Procurement and Supplies Unit (CPSU) said that the Contracting Authority maintains that no formal contestation has been raised in the way the appeal is drafted and the Board should ignore this appeal. In any case the Authority would be objecting if the appeal is based on technical points since it is patently obvious that the technical specifications were not met.

Dr Zammit Pace said that the appeal made it clear that Appellants' bid was technically compliant and they ought to be allowed to prove it.

Dr Clement Mifsud Bonnici Legal Representative for Charles De Giorgio Ltd (CDG) stated that he concurred with Dr Woods when he said that no reasons had been given for the objections raised – they were neither defined nor given. Procurement Regulations lay down that objections have to be detailed, but there were no submissions on this point. He referred to the documents submitted by Appellants in the last few days and queried if the original versions were in the Polish language and if they gave any indication of the market authorisation. He also queried why the Marketing Authorisation number (MA) was not shown on two of the Summary of Product Characteristics (SPC) sheets.

Dr Zammit Pace said that all the points raised will be answered by the witnesses about to be heard. It appeared as if there has been selective reading of the points of the appeal, as there is a clear statement that the offer was technically compliant.

Dr Woods said that the specifications in the tender were very exact – if these are not being contested then there is no point in the appeal. If it is the specifications that Appellants disagreed with then they could have made use of earlier remedies. The evaluation committee decides the merits on what is submitted and since the reasons for rejection are not being contested it follows that they cannot be changed through testimonies.

Dr Zammit Pace stated that the purpose of the appeal was not to attack the specifications. The reason given for disqualification has been given as the technical non-compliance; however through witnesses it

will be proven that in fact they are compliant. The evaluation of a product is an understanding of its characteristics and its functions and its range of actions within the human body and this will be proven.

Dr Mifsud Bonnici said that the reason for objections had to be in line with Article 270 of the Public Procurement Regulations (PPR). This appeal does not give a clear reason for the objection and the grounds given cannot be considered since they do not meet the tender specifications. As no reason has been given for appeal there is no room for manoeuvre and the Board should make a decision on this point.

The Chairman said that it was important for the Appellants to clarify the basis of their appeal so that the Board can understand what is being contested and this without reference to previous tenders.

Dr Woods concurred with the Dr Mifsud Bonnici's statement and pointed out that the evaluators were bound by the principle of self limitation. The product offered was not compliant as it did not fall within the range of specifications denoted in the tender.

Dr Zammit Pace stated that the appeal was based on proof of technical compliance. Appellants submitted documents regarding two Emergency Response Unit (ERU) competitive calls which were awarded on the same technical and specific criteria and the same offer documents as those specified in the tender. At the least the Contracting Authority should have followed the clarification on this point since it tied the specifications to the previous two cycles. Since the appeal is dealing with technical specifications there is therefore the need on the part of Appellants to establish if the evaluation of the product meets the technical requirements.

Dr Woods disagreed with the above statement. Previous tenders and calls cannot be considered in an appeal on this tender. The Appellants submissions did not include the clarification in the reply and therefore it cannot be taken into consideration. The technical evaluation was carried out by technically qualified persons who understood clearly the requirement of the tender – the evaluation committee cannot be expected to delve into the characteristics of the products, and if this was not clear to the Appellants they had the chance to seek a clarification. The action range of a product cannot be changed, not even by witnesses.

Dr Mifsud Bonnici said that the point at issue is that the reasons for the appeal have not been stated and the Authority could not deal with them as they were not raised in the first place and the Board in applying the level playing field principle cannot thus allow these last minute arguments.

Dr Zammit Pace said that there was no need to refer to the clarification as this was part of the tender documents and was not referring to previous cycles and therefore it referred to products in the same cycle.

Dr Woods pointed out that the clarification had been included in Appellants reply and hence the Board was aware of it whilst Dr Mifsud Bonnici commented that it had not yet been established what the clarification referred to in the procurement cycle.

At this stage the Chairman proposed a short recess to enable the Board to consider the points raised by both parties.

After the resumption the Chairman said that the Board directs that:

- In line with PPR no reference shall be made to previous tenders
- That Appellants had produced no specific reasons in their appeal to justify their product characteristics and had confirmed that what they offered was different to the tender document
- Appellants had failed to submit any proof of equivalence of their product and the Board will not hear any submissions regarding equivalence.

He then asked the hearing to proceed in line with this ruling.

Dr Zammit Pace asked for witnesses to be heard.

Dr Ian Ellul (296980M) called as a witness by Appellants testified on oath that he was one of the evaluators on this tender. He stated that that Appellants' offer did not meet the specifications of the tender as dictated by the Department of Pharmaceutical Affairs (DPA) in Lot 1 A and B and in Lot 2 as the product they offered did not meet the required peak action effect on the human physiology. Item A was a quick acting insulin (2 to 4 hours); item B was an intermediate acting insulin (4 to 12 hours) whilst Lot 2 was a combination of both insulins. What was offered was totally different. Apart from the different peak actions Appellants' offer gave no indication in the literature supplied that that product could be offered intravenously and some other issues such as the lack of an MA number on the SPCs.

In reply to several questions from Dr Zammit Pace witness stated that the terms of the tender were dictated by the Department of Pharmaceutical Affairs but issued by the Central Procurement and Supplies Unit (CPSU). The MA was not shown on Lot 1 Item B and on Lot 2. This was required from the country of origin (normally a European one) but there is the possibility of registering the product in Malta after the adjudication stage. The Summary of Product Characteristics (SPC) was essential in the tender submissions as it was the key to the assessment and should include the identifier number, which however was not included in Appellants' submissions.

Dr Woods asked for the testimony to be interrupted as he wished to object to the line of questioning. Witness had confirmed that the SPC did not have an MA number but Dr Zammit Pace has now asked witness a question on certificates of origin.

Dr Zammit Pace replied that the offer did not consist solely of the SPCs and certificates were also relevant and the Board should have cognisance of the certificates existence. There is no requirement for an MA number in the tender let alone for it to be included in the SPC.

Dr Mifsud Bonnici pointed out that the bidder has an obligation to adduce information required by the tender – if the MA is not shown it created doubts.

Dr Zammit Pace said that the confines of an appeal are dictated by the evaluation committee's decisions and tender did not specify that the MA number had to be shown. The evaluation committee had before it several documents which should have been looked at, and the MA number was available in these other documents.

Dr Woods stated that the witness had just confirmed the importance and relevance of the MA number in the SPC which in this case was not available and hence authenticity could not be proven. It was crucial for the evaluation committee to be sure of what had been submitted.

Dr Mifsud Bonnici stated that compliance with the tender terms is achieved by the submission of an SPC which has to look authentic. An SPC with numbers and dates missing straightaway casts doubts as to its authenticity. The fact that a number was shown on a separate certificate means that the SPC cannot be treated as evidence in the technical evaluation. He made the further point the tender documents have to be in the English language and that the submitted translations should have had the original documents attached to ensure authenticity and to remove any doubts thereon.

Dr Zammit Pace replied that translations submitted were certified as true and complete and that issue was not contested, to which Dr Mifsud Bonnici said that the Authority was not adding reasons for rejection but merely clarifying the value of the MAs – in any case further reasons can always be added (C of A Case 103/17).

The Chairman said that the objections to the line of questioning was upheld and requested that the witness proceeds with his testimony.

Dr Ellul proceeded to say that the whole point of requesting the SPC was to establish the registration of the product. In reply to questions from Dr Zammit Pace he stated that in the case of Gensulin 30 the product licence issued in 2018 by the Medicines Authority had been submitted but since there was no reference to it in the SPC and no tying up of identification numbers it was difficult to prove it was valid as there was no correlation with the licence. The evaluation committee must be left in no doubt as to the genuineness of documents.

In reply to further questions by Dr Zammit Pace witness agreed that the specifications stated that Lot 1 A and B had to be the same brand and they were therefore linked. There were certain shortcomings in the SPCs which indicate that the injections could be given intravenously only whereas the tender stipulated both intravenous injection and intravenous infusion. This was a non-rectifiable item and hence no clarification was sought.

As a matter of observation Dr Mifsud Bonnici noted that no original documents in Polish had been submitted with the SPCs translations and that only one SPC (that of Gensulin R) out of the three submitted showed MA number and dates; the other two had blank boxes in items 8, 9 and 10. The text in boxes 8, 9 and 10 of SPC in the case of Gensulin R was in a font that was different to the rest of the text in the SPC.

Ms Antonia Formosa (373667M) called as a witness by Appellants testified on oath that she is the Director of Pharmaceutical Affairs at the Ministry of Health. She stated that the time of action requirements of the product was dictated by her department which was asked in April 2019 to review the specifications regarding the cartridge situation. After consultation with the medical authorities they eventually simplified the system equating delivery of the medicine by cartridge and by vial. These details were passed on to the CPSU in May or June 2020. The terms of the current tender were published before that and could not be changed. The ERUs referred to were issued prior to the updating of the

specifications. The DPA was aware of the clarification included in the tender by the Contracting Authority.

Ms Jackie Mangion (31370M) called as a witness by the Appellants testified on oath that she is the Operations Manager at V J Salomone Pharma Ltd and that she was responsible for submitting the tender on the EPPs. Prior to submission the tender had been discussed within the Company to ensure compliance with the terms. She stated that it was noted that the specifications regarding the time ranges in this tender were the same as previous ones, and the product offered was already on the market having been supplied twice previously, in July and September 2020 on a competitive bid basis and with the same documentation as offered in this tender. On Lot 1 A and B and on Lot 2 the Company had supplied product mock-ups, packaging and patient information leaflets, CPSs and product licences which indicated the MA number on it. She confirmed that in Lot 1 A and B no MA number was shown on the CPS.

In reply to a question from Dr Mifsud Bonnici as to the reason why only the Gensulin R out of three CPSs had the MA number witness stated that this was what the supplier had provided. She agreed that there was a discrepancy but said that the MA number was not part of the specifications and hence they had not contacted the supplier regarding this shortcoming. Questioned further witness stated that the SPCs had not been physically altered or manipulated in any way and no text had been added to the document.

Dr Alison Anastasi (398380M) called as a witness by the Central Procurement and Supplies Unit testified on oath that she is the Head of Operations, Procurement, at the CPSU. She stated that after the last appeal regarding the cartridges the CPSU checked to see if the competition could be opened up and updated specifications were received from the DPA. In the meantime there has been three procurement cycles. Witness stated that she was informed that till today there has been no further correspondence with the DPA.

In reply to question from Dr Zammit Pace witness confirmed that one of the direct suppliers provided a product called 'Novo'.

Questioned by Dr Mifsud Bonnici witness said that the communications with the DPA were held only after the close of the tender and she had advised that Department not to discuss or correspond on this matter whilst the tender adjudication was in process.

Dr Zammit Pace stated that the Board had heard from witnesses that the tender specifications were the same as those used in two previous cycles – one was a direct order for the supply of product Novo from the interested party in this appeal. The offer of both products Bioton and Novo are considered to meet the technical specification of the direct order and the ERU, as are the specifications in this tender and therefore VJS's Bioton offer meets the specifications; one therefore cannot argue that it does not meet the specifications as the short and intermediate action time requirements are fulfilled.

Nowhere in the specifications does the tender state that the SPCs have to show the MA number, but what the tender states quite clearly in item 9.11 in Section 2 is that a copy of the registration certificate must be submitted within 90 days of the signing of the contract – there is no reference to an MA and therefore there is no need for an MA and all that is stipulated is that the product need not be registered. The product

brand is Bioton and despite what is claimed in the disqualification letter it meets the specifications. Despite the claim on the purified monocomponent aspect standards the attention of the Board is directed to tender item 3.1.1 in Section 3 which makes it clear that the European Pharmacopoeia is the standard required. Since the product is registered in Europe it follows that it meets the required standard and it is not a matter for the SPC. The possibility for intravenous fusion is clear in item 4.2 of the SPC and hence this point is also fulfilled.

CPSU claim that they did not seek clarifications as there were other points meriting disqualification. This argument is not justified as the Authority has an obligation to seek clarifications and it could have saved everyone's time had they done so.

In conclusion, said Dr Zammit Pace, Appellants' offer should not have been disqualified nor the tender cancelled and the evaluation committee should have gone on to the financial evaluation to the benefit of the Government and the public.

Dr Woods said that on the basis of the arguments heard it is clear that the disqualification was justified. Several references were made to previous calls but following the direction of the Board these should not be considered. Appellants are trying to convince the Board that Appellants' offer was technically compliant but they are ignoring the fact that each call is separate from other calls and does not give rise to claims of legitimate expectations of compliance– there is simply no justification in adopting this line of argument. Appellants are not contesting the disparity in the peak action time aspect which they seem to have accepted but are claiming that the bid was technically compliant due to having been awarded previous calls – this does not make sense and the evaluation committee can only decide an offer based on submissions.

It has been confirmed by witnesses that the SPCs did not show the MA number. This is a primary evaluation document and is the official description of the product, and enables the Authority to be certain that they are procuring the best product available at the best price. The evaluators expressed serious doubts about the SPC documents – the fact that the MA number may have been shown on certificates but not on the SPCs cannot be accepted. After going through this full hearing the Authority still feels that both their decisions are right and the Board should confirm them.

Dr Mifsud Bonnici stated that the first grievance that the appeal was not detailed has already been dealt with by the Board and can be ignored. The claim that Appellants had a legitimate expectation has also been dealt with by the Board in directing that award of previous tenders cannot apply and the Board can take comfort that that decision has been applied in several past cases. Further the Court of Appeal in Case 306/15 rejected the notion of legitimate expectation. There cannot be equal treatment of all parties if by considering legitimate expectations one goes against something written in the tender which is sacrosanct. On this point one cannot go against the decisions of EJC Cases 55/91 (para 67), C 54/95 (para12) and C 339/00 (para 81 and 82) which lay down the principle that if mistakes were made in the past one should not expect the mistakes to be repeated and on grounds of fairness were irregularities were tolerated the Commission should not expect them to be repeated subsequently. Article 39 (1) of the PPR ensures that everyone, including interested parties, are guaranteed equal treatment.
On the matter of clarifications Dr Mifsud Bonnici said that there is no obligation to clarify so long as parties are dealt with properly by the evaluation committee. The evaluators have to rely on the SPCs as

a guarantee on the product that is being offered. The SPC translations submitted had no MA number and no date and certain text seems to have been added in the case of SPC for the Gensulin R therefore creating doubt on the genuineness of the document which should be discarded. No one of the bidders was compliant and hence the cancellation of the tender was justified.

Dr Zammit Pace said that no evidence has been put before the Board that mistakes have happened in the past and hence the argument put to disregard the point on legitimate expectation has no basis. Similarly no evidence has been produced that the SPC is not an authentic document and lack of authenticity cannot now be claimed. From the evidence of Ms Formosa it can be adduced that the Contracting Authority had an interest that the tender should not be adjudicated as the specifications were not available in time and this is the real reason for the decision to cancel the tender. Without prejudice the Appellants request that the deposit should be refunded.

Dr Woods stated that the Appellants were now trying to put doubts about the evaluation and to ridicule it – the fact is that it had already been completed at the time of the proposed changes and therefore the point is futile. It is the bidders' obligations not to leave any doubts on the offer and the evaluation committee is limited to consider only what is made available to it. The submissions were not technically compliant unlike the ERUs previously submitted and hence they failed.

Dr Mifsud Bonnici objected to the deposit being refunded as he claimed the appeal was frivolous and vexatious and was doomed to fail from the start as the Appellant did not attack the reason for disqualification.

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

Decision

This Board,

having noted this objection filed by VJ Salomone Pharma Ltd (hereinafter referred to as the Appellants) on 30th October 2020, refers to the claims made by the same Appellants with regard to the tender of reference CT 2146/2020 listed as case No. 1515 in the records of the Public Contracts Review Board.

Appearing for the Appellants: Dr Roderick Zammit Pace

Dr Sharon Pace Gouder

Appearing for the Contracting Authority: Dr Marco Woods

Appearing for Charles de Giorgio Ltd: Dr Clement Mifsud Bonnici

(Interested Party)

Whereby, the Appellants contend that:

a) **Their offer was technically compliant and should not have been rejected by the Evaluation Committee in that, the objective of this appeal is to provide the necessary evidence to PCRB to justify their claim regarding the technical compliance of the product which they are offering.**
b) **Appellants also maintain that the tender should not be cancelled.**

This Board also noted the Contracting Authority's 'Letter of reply' dated 9th November 2020 and its verbal submissions during the virtual hearing held on 20th November 2020, in that:

a) **The Contracting Authority insists that, the technical reasons for the rejection of Appellants' offer are not being contested.**
b) **The issues being raised by the Appellants are totally irrelevant and groundless as they represent a baseless attempted justification of their product's technical compliancy.**

This same Board also noted the testimony of the witnesses namely:

Dr Ian Ellul duly summoned by VJ Salomone Pharma Ltd

Ms Antonia Formosa duly summoned by VJ Salomone Pharma Ltd

Ms Jackie Mangion duly summoned by VJ Salomone Pharma Ltd

Dr Alison Anastasi duly summoned by Central Procurement and Supplies Unit

On a preliminary note, the Contracting Authority maintains that, since no formal contestation has been filed by Appellants, in the 'Letter of Objection' with regard to the technical specifications, as stipulated in the tender document and made no reference, in any form whatsoever, to any clear justification to their objecting to the Authority's decision, such an appeal should be rejected. The Authority also insists that Appellants' 'Letter of Objection' is purely an attempt to justify technical compliance of their product without justifying their claims against the Contracting Authority's decision in this respect.

This Board takes into consideration the fact that Appellants, in their 'Letter of Objection', do not include or mention any reasons to justify their claims against the Authority's decision for the refusal of their offer. Moreover, Appellants' 'Letter of Objection' represents an attempt to justify their offer. This Board also notes that Appellants are referring to previous tenders and this regard, as it has on so many occasions, will disregard such inferences. Needless to point out, if Appellants are now referring to the 'Equivalency' of their product, such an issue should have been dealt with in their original offer accompanied by the necessary documentation, in accordance with the regulations of Public Procurement.

In this regard, this Board directs that:

i. **no refences to previous tenders will be considered,**

ii. **Appellants admitted that their offer's technical specifications were different from those stipulated in the tender document, so that, technical specifications will not be treated by this Board,**

iii. **if Appellants want to prove equivalency, they had all the opportunities to prove such an issue in their original submission.**

In this regard, this Board upholds the Preliminary Plea raised and will only consider other issues raised in Appellants' 'Letter of Objection' dated 30th October 2020.

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 opines that, the issues that merit consideration are:

a) **Marketing Authorisation Number and**

b) **Cancellation of Tender**

1. **<u>Marketing Authorisation Number</u>**

1.1. This Board would refer to clause 4.2 of section 4, whereon the importance of the MA is denoted as follows:

"Marketing Authorisation (MA): is the licence for medical 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). Currently the three main types of procedures recognized for

granting of a marketing authorization and to place a product on the market in Malta are the National Procedures, European Procedures (Mutual Recognition and Decentralized Procedures), and Centralized Procedure."

1.2. Although Appellants are maintaining that they had submitted the MA numbers, the documentation uploaded by the Authority contained no such information. At this stage of consideration, this Board would point out that such an MA reference is most important and the Evaluation Committee, through the principle of self-limitation, cannot accept a 'Summary of Product Characteristics' (SPC), without such an Authorisation reference. At the same instance, this Board notes that other technical specifications were not compliant with those stipulated in the tender dossier.

1.3. This Board would also point out that the MA is purely a licence to place the product on the market and the data and information contained in such a document assures the drug's quality, safety and efficacy. Such an MA reference has to be shown on the SPC, which, in this particular case, was lacking.

1.4. From the testimony of Ms Jackie Mangion, it was clearly established that, Appellants submitted the documentation as supplied by the manufacturer and she also admitted the fact that, there was a discrepancy through the lack of the MA numbers. This Board would also point out that, the inclusion of the MA reference on the SPC gives the guarantee to the Authority that it is being offered the best product on the market at an

advantageous price and the Evaluation Committee has to rely on the SPC and Appellants' submission which in this regard, lacked such an important data.

2. <u>Cancellation of the Tender</u>

2.1. First and foremost, it must be mentioned that, the Authority, in accordance with Article 18.3 (a) of the General Rules Governing Tenders, can cancel the tender in cases where no compliant bids are offered. In this particular case, the Authority received two offers both of which were not technically compliant.

2.2. This Board would also respectfully point out that, under such circumstances, it was the duty of the Authority to cancel the tender as the process was unsuccessful due to the fact that no qualitative offers have been received.

In conclusion, this Board opines that:

a) The Preliminary Plea raised by the Authority and the interested party are being upheld.

b) The MA number is an important reference to the SPC of the medical product being offered. Appellants failed to submit such information and the Evaluation Committee quite appropriately, applied the principle of self-limitation.

c) **The Authority has every right to cancel a tender in cases where no qualitative offers are received. In this particular instance, both offers submitted were technically non-compliant and the Evaluation Committee was correct in recommending the cancellation of the tender.**

d) **After having considered all the submissions made by all the interested parties, this Board finds that such an appeal was made by Appellants to justify the equivalency of their product, without having provided the necessary justification in their original submissions.**

In view of the above, this Board,

i. **does not uphold Appellants' contentions,**

ii. **upholds the Contracting Authority's decision in the cancellation of the tender,**

iii. **directs that the deposit paid by Appellants should not be refunded.**

Dr Anthony Cassar	Dr Charles Cassar	Mr Carmel Esposito
Chairman	Member	Member

4th December 2020