PUBLIC CONTRACTS APPEALS BOARD

Case No. 215

Adv. No. 382/2009; CT/2375/2009; GPS 03.039.T09DC

Tender for the Supply of Piperacillin with Tazobactum 2.25g Injections

This call for tenders was published in the Government Gazette on 25.09.2009. The closing date for this call for offers was 5.11.2009.

The estimated budget for this tender was € 51,209.

Three (3) tenderer had originally submitted their offers

Rodel Ltd acting on behalf of Elpen Pharmaceutical Co Ltd filed an objection on the 30.04.2010 following notification received from the Contracts Department wherein the tenderer was informed that its offer was found non-compliant since "product is not locally registered and package inserts are in Greek" and that the intended award of tender to V J Salomone Pharma Ltd.

The Public Contracts Appeals Board composed of Mr Alfred Triganza as Chairman and Mr. Edwin Muscat and Mr. Carmel J Esposito as members convened a public hearing on Wednesday, 11 August 2010 to discuss this objection.

Present for the hearing were:

Rodel Ltd (obo Elpen Pharmaceutical Co Ltd)
Dr Norman Vella — Director

V J Salomone Pharma Ltd
Ms Jackie Mangion — Representative

Government Health Procurement Services (GHPS)
Ms Anna Debattista — Director

Adjudicating Board
Ms Miriam Dowling — Chairperson
Ms Miriam Azzopardi — Member

Department of Contracts
Mr Francis Attard — Director General (Contracts)

After the Chairman's brief introduction the appellant Company's representative was invited to explain the motive/s of the objection.

Dr Norman Vella, representing Rodel Ltd, explained that on the 23rd April 2010 the Contracts Department informed them that the offer they submitted was found non-compliant since the product in question was not locally registered and package inserts were in Greek. Furthermore, the same appellant Company was informed that it was being recommended that the tender be awarded to V J Salomone Pharma Ltd.

At this point Dr Vella contended that the offer submitted by his firm was the cheapest and, in his view, it was also fully compliant.

Dr Vella submitted that, contrary to what it was stated by the Contracts Department, the product was in fact registered locally so much so that the application to register the product was lodged with the Medicines Authority (MA) prior to the closing date of the tender.

Ms Anne Debattista, Director GHPS, furnished the following chronology of events relevant to the product registration:

a) date tender was published
   - 25 September 2009

b) date application for product registration was drawn up by appellant
   - 8 October 2009

c) date application for product registration was received by the MA
   - 13 October 2009

d) closing date of tender
   - 5 November 2009

e) latest date for product registration in terms of Art. 126A and clause 9 of Annex IV of the tender document (6 weeks after the 5th November)
   - 17 December 2009

f) date of MA product registration
   - 2 February 2010

g) date appellants were notified of product registration
   - 12 March 2010

Ms Debattista remarked that this clearly demonstrated that the product was not registered by the closing date of the tender and not even six weeks after that, i.e. by the 17th December 2009.

The Director GHPS stated that this product was registered under the provisions of clause 9 of Annex IV to the tender document, which stated that:

"In the event that the medicinal product being offered does not have a valid Marketing Authorisation, or a valid Article 126 A Authorisation, or a valid Parallel Importation Licence or a Central Authorisation by E.M.E.A. at the closing date for the submission of the offer, I, the Responsible/Qualified Person, accept to undertake

i) to ascertain that the offered medicinal product is duly registered strictly within a 6-week period from the closing date of the respective tender …"

Ms Debattista stressed that the registration of medicines was to be treated independently of and separately from the issue of specific calls for tenders.

Dr Vella explained that, along with Annex IV of the tender submission, his firm had also submitted the English version of the 'Instructions Leaflet' and he added that on the basis of that document, the Medicines Authority had issued the appropriate licence.

Ms Debattista referred to clause 7.1 of Annex VI which, *inter alia*, read as follows:

"The Tenderer must ensure that the following is submitted with each offer:

(iii) original/true copy of the package insert in one of the official languages of Malta."

Ms Debattista remarked that (i) the instruction leaflet supplied with the sample was all in Greek; (ii) in its tender submission the appellant Company furnished a untitled document which she considered to be the 'Summary of Product Characteristics' (SPC); the package insert submitted to the Medicines Authority with the appellant Company's application for product registration was an English translation of the Greek package insert – the GHPS obtained this from the Medicines Authority.

Ms Debattista pointed out that the adjudication board had to carry out its evaluation on the documents presented in the tender submission and that it did not have access to documents that the appellant Company had submitted to the Medicines Authority or elsewhere.

Dr Vella remarked that, at tendering stage, his firm could only submit the translation in English of the package insert since the Greek supplier was not at that time oriented towards the international export market. He added that the Medicines Authority had, nevertheless, approved the licence on the basis of the translation submitted. Dr Vella stated that on the 20th July 2010 they were awarded a tender by GHPS for the supply of this product.

The Chairman PCAB remarked that the adjudicating board had to evaluate the tender under review on the basis of the documentation submitted by the closing date of the tender (and also 6 weeks after that in the case of an Art. 126A licence). He added that it appeared to him that the appellant Company had been awarded a contract on the 20th July 2010 for the supply of this product because by that date the appellant Company had everything in order, including the product registration which was issued

on the 2nd February 2010. He added that it was evident that the appellant Company submitted certain information to the Medicines Authority which it did not submit to the GHPS.

Ms Debattista informed those present that Elpen Pharmaceutical Co. Ltd was not new to the GHPS and that it was well versed in the procedures adopted in Malta. She confirmed that the bridging contract for the supply of this product was awarded to the appellant Company in July 2010 by which time the appellants were fully compliant. She explained that, with regard to an Art. 126A licence, the Medicines Authority usually sought clarifications from the regulatory body from where the appellant Company had already obtained a licence for the product. Ms Debattista remarked that the information furnished by the same appellants to the GHPS was different from what it had submitted to the Medicines Authority. Ms Debattista concluded that the onus to submit a compliant tender rested with the tenderer and that, in this case, there was another participating bidder who furnished a fully compliant submission.

At this point the hearing was brought to a close.

This Board,

- having noted that the appellants, in terms of their 'reasoned letter of objection' dated 5 May 2010 and also through their verbal submissions presented during the public hearing held on 11 August 2010 had objected to the decision taken by the General Contracts Committee;

- having taken note of Dr Vella's (a) contention that the offer submitted by his firm was the cheapest and, in his view, it was also fully compliant, (b) statement that contrary to what it was stated by the Contracts Department, the product was in fact registered locally so much so that the application to register the product was lodged with the Medicines Authority (MA) prior to the closing date of the tender, (c) reference to the fact that, along with Annex IV of the tender submission, his firm had also submitted the English version of the 'Instructions Leaflet' adding that, on the basis of that document, the Medicines Authority had issued the appropriate licence, (d) remark that, at tendering stage, his firm could only submit the translation in English of the package insert since, at the time, the Greek supplier was not oriented towards the international export market and (e) reference to the fact that the Medicines Authority had approved the licence on the basis of the translation submitted;

- having also taken note of Ms Debattista's reference to the (a) chronological sequence of events relevant to the product registration, (b) the fact that it was amply clear that the product supplied by appellant Company was not registered by the closing date of the tender and not even six weeks after that, i.e. by the 17th December 2009, (c) fact that the registration of medicines was to be treated independently of and separately from the issue of specific calls for tenders, (d) fact that the appellant Company's instruction leaflet supplied with the sample was all in Greek, (e) the fact that the package insert submitted to the Medicines Authority - the GHPS obtained this from the Medicines Authority - with the appellant Company's application for product registration was an English translation of the Greek package insert, (e) fact that the

adjudication board had to carry out its evaluation on the documents presented in the tender submission and that during the evaluation stage it did not have access to documents that the appellant Company had submitted to the Medicines Authority or elsewhere and (f) fact that the bridging contract for the supply of this product was awarded to the appellant Company in July 2010 by which time the appellants were fully compliant;

reached the following conclusions, namely:

1. The PCAB opines that with regards to the registration of the medicinal product within 6 weeks from the closing date of the tender as stated in the tender document, one could be tempted to favour the point raised by the appellant Company wherein it was argued that the said Company had applied in time. However, one has to consider all holistically and this approach provides the PCAB with further food for thought in so far as, whilst one could extend the argument in a way as to state that as long as one applies within the six week time frame all is fine then this Board will have to accept the argument that even if one were to apply for such registration on the last day prior to the expiration of the six week time frame then all should be considered in accordance with the tender document's requirements. This Board feels that, all things being equal, the spirit of the clause governing this condition, as reflected in the tender document, is definitely not contemplating such a scenario. The PCAB has no doubt that the time frame envisaged in the tender document aims at establishing that the said registration is actually in place by the expiry of the six week time frame. Nevertheless, in this particular instance, the Board notes that, whilst it may be considered to be quite bureaucratic, yet one has to note that whilst there is a six week time frame and the appellant Company was well within the said period of time considering that it had submitted the application for registration quite well prior to the closing date of the tender, yet, this Board agrees with the argument raised by Ms Debattista that, in similar circumstances, there is no direct link between the time the application to register a product in Malta is submitted and the participation in a tendering process as the two procedures have to be kept distinct from one another. If this Board were to accede to appellant Company's request it could be technically accepting the idea that a tenderer will commence the procedure on the last day preceding the expiry of the six week time frame and this is unacceptable and against the scope of the condition imposed by the tender document itself.

2. The PCAB feels that the adjudicating board had to evaluate the tender under review on the basis of the documentation submitted by the closing date of the tender (and also 6 weeks after that in the case of an Art. 126A licence). Whilst acknowledging that the appellant Company had been awarded a contract on the 20th July 2010 for the supply of this product (because by that date the appellant Company had everything in order, including the product registration which was issued on the 2nd February 2010), yet one had to acknowledge that all this happened after the adjudication process had been brought to a close.

3. The PCAB recognises the fact that it was evident that the appellant Company submitted certain information to the Medicines Authority which it did not submit with its offer.

4. The PCAB feels that the appellant Company's representative's own admission during the hearing wherein he stated that, at tendering stage, his firm could only submit the translation in English of the package insert since, at the time, the Greek supplier was not oriented towards the international export market, is enough proof that the Company was not compliant with the tender specifications at the time it submitted its offer.

As a consequence of (1) to (4) above this Board finds against the appellant Company.

In view of the above and in terms of the Public Contracts Regulations, 2005, this Board recommends that the deposit submitted by the said appellants should not be reimbursed.

Alfred R Triganza Chairman	Edwin Muscat Member	Carmel J Esposito Member

13 August 2010