PUBLIC CONTRACTS APPEALS BOARD

Case No. 212

Adv. No. 226/2009; CT/2153/2009; GPS 02.021.T09MH

Tender for the Supply of Trimetazidine 20mg Tablets

This call for tenders was published in the Government Gazette on 12 June 2009. The closing date for this call for offers was 4 August 2009.

The estimated budget for this tender was € 824,868.55.

One (1) tenderer had originally submitted their offers

Rodel Ltd acting on behalf of Labormed Pharma Ltd filed an objection on the 26.02.2010 following notification received from the Contracts Department wherein the tenderer was informed that its offer was found non-compliant since delivery period was not as required in the tender specifications and conditions and product was not locally registered.

The Public Contracts Appeals Board composed of Mr Alfred Triganza as Chairman and Mr. Anthony Pavia and Mr. Carmel J Esposito as members convened a public hearing on Wednesday, 28 July 2010 to discuss this objection.

Present for the hearing were:

Rodel Ltd

Dr Norman Vella	Director
Dr Simon Galea Testaferrata	Legal 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 was invited to explain the motives of the objection.

Dr Norman Vella, representing Rodel Ltd, explained that on the 19 February 2010 the Contracts Department informed them that the adjudicating board had recommended the rejection of their bid because the delivery period was not as required in the tender specifications and conditions and because the product was not locally registered with the consequence that the tender was being recommended for cancellation - since it turned out that there were no other participating tenderers.

Dr Vella remarked that, in terms of Annex II, delivery was to be effected within 6 to 8 weeks from confirmation of order at GHPS whereas his firm had indicated at section 9 of Annex IV 'Delivery Period': 60 days after receipt of notification on adjudication. The 'notification on adjudication' was interpreted by Dr Vella to mean the moment the Contracts Department's notice board and GHPS website would display the recommended tenderer for the award of the contract. He argued that given (i) that tenderers were allowed 10 days to appeal with regard to the recommended award, i.e. from 19 February to 1 March 2010, and (ii) another few days would be required to issue the letter of acceptance and for GHPS to place the first order, the 4 day difference between the maximum 8 week period (56 days) from confirmation of order indicated in the tender document and the 60 days from the date of the recommended award indicated in his firm's submission were more than compensated for and hence the delivery period proposed in his submission was well within the period stipulated in the tender. Dr Vella added that, indeed, a supply would be made only following the placing of an order by the contracting authority, however, the supplier was undertaking the tenderer would be in a position to make deliveries as from 60 days following the tender award recommendation by the contracting authority.

Dr Vella conceded that perhaps the terminology used by his principals when compiling the tender submission was not the most appropriate one but he felt that the tender requirements with regard to the delivery period were nevertheless satisfied.

Mr Anthony Pavia, a PCAB member, noted that in the tender document the date of confirmation of order was directly related to the date of delivery, whereas in the appellant Company's submission there was no such link between the order confirmation and the actual delivery but, as Dr Vella was interpreting it, the appellant Company had set a date, i.e. 60 days after the date of tender award notification, following which the contractor would be in a position to start effecting deliveries.

The Chairman PCAB remarked that he could not make any connection between the terms 'notification on adjudication' and the 'confirmation of order'. He added that an adjudication board should not be expected to decipher what the tenderer had in mind.

Mr Pavia expressed the view that it would appear that the appellant, when compiling the tender submission, had mixed up the delivery period with what was stated under section 8 'Period of Validity' sub-section 8.3 where it was stipulated that:

> *"The successful tenderer will be bound by his tender offer for a further period of* 60 days following receipt of the notification *that he has been recommended for award."*

Dr Vella reiterated that in his opinion what happened was that his principals had related the delivery period to the 'notification on adjudication' rather than to the 'confirmation of order'.

Ms Anne Debattista, Director GHPS, informed those present that in the tender document the contracting authority indicated the previous annual consumption of the same medicinal so that the contractor would have a good idea of the quantities involved – in this case the annual consumption was put at 2,990,460 units.

Ms Debattista remarked that the appellant Company's submission was non compliant in this regard, namely since all deliveries were to be effected upon specific orders raised by GHPS whereas the appellant was referring to the delivery period as being 60 days after receipt of notification on adjudication.

Mr Francis Attard, Director General (Contracts), explained that on the department's notice board one would only display the fixed rate that the contracting authority would pay for the product and not the global value of the contract.

Dr Vella submitted that the application to register the product was made on the 20 July 2009 and, therefore, well ahead of the closing date of the tender which fell on 4 August 2009. Dr Vella remarked that it was up to the Medicines Authority (MA) to issue the licence and that the appellant had no say as to the time taken by the Medicines Authority to process the registration.

The following timeline was established:

a)	date tender was published:	12 June 2009
b)	closing date of tender:	4 August 2009
c)	latest date for product registration in terms of Art. 126A and clause 11 of Annex IV of the tender document (6 weeks after 4 August 2010):	15September 2009
d)	date application for product registration submitted to MA:	20 July 2009
e)	date of MA product registration:	23 December 2009
f)	date product registration notified by MA:	February 2010

Ms Debattista remarked that, occasionally, the Medicines Authority might have to seek information, e.g. from other regulatory bodies overseas, and that could explain the variation in the time taken to conclude the registration of one medicinal from another.

Dr Simon Galea Testaferrata, legal advisor of Rodel Ltd, raised the issue that the tenderer could only undertake to register the product within 6 weeks from the closing date of the tender and that the tenderer's obligation was therefore to submit the application to register the product prior to the closing date of the tender since the actual registration process was outside the control of the bidder. Dr Galea Testaferrata observed that, apparently, the contracting authority had noted this anomaly and in subsequent calls for tenders it had decided to do away with the provision at clause 11 of Annex IV. Dr Galea Testaferrata argued that, as far as the bidder was concerned, the words 'to register' (a product) should mean 'to apply' (for

product registration) because the bidder had no say as to the procedure of product registration as that was within the realm of the Medicines Authority . He added that should the PCAB accept this argument then it had only to ascertain whether the tenderer had submitted the application to register the product in a timely manner since the registration process itself lied beyond the bidder's control and therefore the bidder should not be punished for a shortcoming on the part of the Medicines Authority .

Ms Anne Debattista remarked that the registration of medicines should not be correlated with the issue of specific calls for tenders and she stressed that this point had been made very clear by the Medicines Authority during meetings held on the topic of product registration, i.e. product registration had to be treated as separate from any specific tendering process. She added that that was all the more so in the case of the medicine that featured in this call for tenders which was one that the GHPS procured on a regular basis.

Ms Debattista pointed out that the tender document clearly indicated that within 6 weeks from the closing date of the tender, the bidder had to have the product registered and not that he had to submit an application to register the product. Ms Debattista remarked that the adjudicating board had to evaluate the offers on the information submitted by the bidders.

The Chairman PCAB could not help note that, in this particular case, it took the Medicines Authority from 20 July 2009 to 23 December 2009 to register this product, a good 5 months, which was well beyond the 6 weeks after the closing date of tender. He added that in this case even if the tenderer had applied on the date the tender was issued, i.e. the 12 June 2009 the licence would have been issued in November, which, again, was well after the 15 September 2009. The Chairman PCAB remarked that, whereas one was imposing stringent timeframes on the tenderer, the Medicines Authority seemed to be left at liberty as to the time it took to issue such licences. The Chairman PCAB observed that this failure on the part of the Medicines Authority could lead to the exclusion of valid offers from bidders who would decide to participate upon noting GHPS's intention to procure the medicine following the publication of the relevant call for tenders. The Chairman PCAB conceded that medicine registration should not, as a rule, be related to the issue of specific tenders but, on the other hand, perhaps one should not entirely exclude the possibility of having new bidders who would decide to participate on noting that a call for tenders had just been published.

Dr Galea Testaferrata remarked that the tender document did contemplate the possibility of bidders offering a product that was not registered at the closing date of the tender and specifically referred to the provisions of clause 11 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 remarked that the provision referred to by the appellant Company was no longer featuring in tender documents and that that provision was included at a time when the situation was such that medicinal product registration in Malta was rather limited. Ms Debattista added that the standard system for medicinal registration was the market authorisation and that the procedure outlined at Art. 126A was an 'ad hoc' arrangement worked out between the EU and Malta for the circumstances prevailing in Malta at that particular time.

Dr Galea Testaferrata contended that the system introduced by Art. 126A was meant to be a 'fast track' registration system in the case of products already registered in other EU member states. Dr Galea Testaferrata remarked that, unfortunately, the way the Medicines Authority sometimes went about this licensing procedure did not turn out to be a fast track registration system.

Dr Vella stated that a 'Mutual Recognition Procedure' (MRP) was registered within a given period whereas there was no time limit for registration in terms of Art. 126A. Dr Vella also questioned why, in the case of grey areas, the contracting authority did not avail itself of the opportunity given in the tender document to seek clarifications, such as on the issue of the delivery period, which, according to him, did satisfy the requirements set out in the tender document even though the wording used was not the most appropriate. Dr Vella also pointed out that, from the outset, the tenderer had undertaken to accept all tender conditions.

The Chairman PCAB expressed the view that the case for a clarification did not arise with regard to the delivery period because the statement made by the appellant Company in its tender submission was quite clear, even though, one might argue that the appellant Company used the wrong terminology to communicate its intentions. He added that one had to be careful to use the right terminology when compiling the tender submission because, in the case of an award, that terminology would be binding when one would come to the settlement of disputes. The Chairman PCAB opined that, the way the appellant Company put it in its tender submission, it could well mean that it would supply the whole consignment within 60 days from the date it received the notification that it was the recommended tenderer. He remarked that although it was true that the tenderer accepted all tender conditions, in this case the tenderer inserted an explicit statement that the delivery period would be 60 days after receipt of notification on adjudication which was not in line with the tender conditions.

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 25 February 2010 and also through their verbal submissions presented during the public hearing held on 28 July 2010 had objected to the decision taken by the General Contracts Committee;

- having taken note of Drs Vella and Galea Testaferrata's interventions, especially those relating to the fact that (a) the adjudicating board had recommended the rejection of their bid because the delivery period was not as required in the tender specifications and conditions and because the product was not locally registered with the consequence that the tender was being recommended for cancellation - since it turned out that there were no other participating tenderers, (b) delivery was to be effected within 6 to 8 weeks from confirmation of order at GHPS whereas his firm had indicated at section 9 of Annex IV 'Delivery Period': '60 days after receipt of notification on adjudication', (c) the appellant Company had interpreted the phrase 'notification on adjudication' to mean the moment the Contracts Department's notice board and GHPS website would display the recommended tenderer for the award of the contract, (d) according to the appellants, albeit it was stated that a supply would be made only following the placing of an order by the contracting authority, yet, the supplier was also undertaking that the tenderer would be in a position to make deliveries as from 60 days following the tender award recommendation by the contracting authority, (e) in their opinion, what happened was that the tenderer's principals had related the delivery period to the 'notification on adjudication' rather than to the 'confirmation of order' and (f) a tenderer could only undertake to register the product within 6 weeks from the closing date of the tender and that the tenderer's obligation was therefore to submit the application to register the product prior to the closing date of the tender since the actual registration process was outside the control of the bidder;

- having also taken note of Ms Debattista's reference to the fact that (a) the appellant Company's submission was non compliant due to the fact that all deliveries were to be effected upon specific orders raised by GHPS whereas the appellant was referring to the delivery period as being 60 days after receipt of notification on adjudication, (b) occasionally, the Medicines Authority might have to seek information, e.g. from other regulatory bodies overseas, and that could explain the variation in the time taken to conclude the registration of one medicinal from another, (c) the registration of medicines should not be correlated with the issue of specific calls for tenders and she stressed that this point had been made very clear by the Medicines Authority during meetings held on the topic of product registration, i.e. product registration had to be treated as separate from any specific tendering process, (d) the tender document clearly indicated that within 6 weeks from the closing date of the tender, the bidder had to have the product registered and not that he had to submit an application to register the product and (e) the adjudicating board had to evaluate the offers on the information submitted by the bidders;

- having taken into consideration the fact that the appellant Company had submitted the application for the product to be registered on the 20 July 2009 and, therefore, well ahead of the closing date of the tender which fell on 4 August 2009;

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 arguments raised by the appellant Company, namely that it had done so and what happened thereafter was beyond its control. This could be a correct interpretation if the argument were to be dealt with 'per se' and, especially, when one considers that it took the Medicines Authority from 20 July 2009 to 23 December 2009 to register this product, a good 5 months, which was well beyond the 6 weeks after the closing date of tender. Furthermore, the PCAB could also consider 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 finds comfort in knowing that similar tender specifications have been updated in a way as to reflect a more precise and unequivocal way of interpretation of the said clause which now states that now the department is insisting in the tender document that the medicinal product has to be registered as at the closing date of the tender and that a tenderer is being asked that a copy of the registration certificate be attached with the submission.

3. The PCAB feels that, albeit it was true that the tenderer accepted all tender conditions, in this case, the tenderer inserted an explicit statement that the delivery period would be 60 days after receipt of notification on adjudication which was not in line with the tender conditions. The PCAB maintains that the said clause was misinterpreted by the appellant Company in spite of the fact that, in its opinion, it was more than evident as to what the contracting authority was really after.

As a consequence of (1) to (3) 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	Anthony Pavia Member	Carmel J Esposito Member

11 August 2010