PUBLIC CONTRACTS APPEALS BOARD

Case No. 211

Adv. No. 234/2009; CT/2339/2009; GPS 02.095.T09MH

Tender for the Supply of Statin Preparation – Simvastatin Tablets/Capsules (10mg, 20mg, 40mg and 80mg)

This call for tenders was published in the Government Gazette on 19 June 2009. The closing date for this call for offers was 11 August 2009.

The estimated budget for this tender was € 2,417,531.

Nine (9) tenderers had originally submitted their offers

Rodel Ltd acting on behalf of Accord Healthcare Ltd filed an objection on the 12 February 2010 following notification received from the Contracts Department wherein the tenderer was informed that its offer was being rejected for being non-compliant since the product is not locally registered and the bank stamp was not included in Annex IX with the consequence that the tender was being recommended for cancellation.

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.

Rodel Ltd

Dr Norman Vella	Director
Dr Simon Galea Testaferrata	Legal Representative
Mr Manoj Prakash	Representative of Accord Healthcare Ltd
Mr Samrat Kamdar	Representative of Accord Healthcare Ltd

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 as to how the hearing was going to be conducted, the appellant was invited to explain the motive/s of the objection.

Dr Norman Vella, representing Rodel Ltd, the appellant Company, explained that by letter dated 5 February 2010, the Department of Contracts informed his firm that the tender was recommended for cancellation and that his firm's offer was found non-compliant because the 'product is not locally registered' and 'in Annex IX bank stamp is not included'. Dr Vella added that his firm had reacted to these two issues raised by the Department of Contracts in the reasoned letter of objection dated 18 February 2010.

Dr Vella pointed out that clause 11 of Annex IV to the tender document 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*
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> *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, or otherwise …."*

Dr Vella added that in the covering letter dated 7 August 2009, submitted with envelope 2, it was stated that 'we can confirm that we have started procedures to register this product in Malta within 6 weeks under article 126A'. He stated that the Medicines Authority issued the licences on the 5 October 2009 to *Accord Healthcare Ltd* in respect of the 10/20/40/80mg tablets, which licences were forwarded to the GHPS and to the Contracts Department on the 9 December 2009.

Dr Galea Testaferrata, legal representative of Rodel Ltd, submitted that his client had done its part in time to obtain the necessary licences within the 6 week period but the responsibility to issue licences for medicines rested solely with the Medicines Authority . He argued that his client could not be penalised because the Medicines Authority failed to issue the licences within the required 6-week period.

Mr Anthony Pavia, PCAB member, noted that the tender document was quite clear in the sense that the medicinal product offered had to be registered strictly within a 6-week period from the closing date of the respective tender and he, therefore, asked for a chronology of relevant events and the following was established (even following some verifications carried out there and then by Mr Samrat Kamdar - a representative of the foreign principals which Rodel Ltd represents locally - over the phone with officials of his firm):

- Closing date of tender: 11 August 2009
- 6 weeks after that date: 22 September 2009
- Date when licences were issued by Medicines Authority: 5 October 2009
- Date on which the application

was sent to MA: 17 August 2009
(*this was confirmed by Mr Samrat Kamdar even though it was stated in the appellant's tender submission that action started being taken on the 7 August 2009 and received by MA on 19 August 2009*)

Mr Manoj Prakash, representing Accord Healthcare Ltd, explained that most companies did not use to register their products in Malta because of the small size of its internal market and, as a result, the Maltese authorities had introduced the 6-week registration period so as to allow for both better competition and better prices. He added that the grant of a licence within a 6-week period applied to a medicinal product in respect of which a marketing authorisation had already been issued in the UK or in another EU member state.

Ms Anne Debattista, director GHPS, remarked that:

- besides the dates indicated above, one had to add that the call for tenders was issued in the Government Gazette and on the department's website on the 19 June 2009;

- the information she obtained from the Medicines Authority was that the appellant Company had lodged its application to register all four doses of this medicine on the 19 August 2009;

- 6 weeks from the 11 August 2009 would be the 22 September 2009 and the GHPS was informed of the product registrations on the 9 December 2009;

- she agreed with what Mr Prakash had stated that Malta had adopted the 6-week registration period following Malta's accession to the EU because there was a shortage of registered medicines in Malta, a situation that has improved by time and that it was reflecting itself in wider competition and cheaper prices – e.g. this call for tenders elicited 9 offers;

- one of the offers received, that by S.C. Labormed Pharma S.A., was in fact found to be compliant in all respects by the closing date of the tender and, consequently, recommended for award with regard to item 1 - 10mg capsules/tablets;

- it had been made amply clear to operators in the medicines sector that there should be no direct link between the time the application to register a product in Malta was submitted and the participation in a tendering process but that the two procedures had to be kept distinct from one another; and

- the fee to register a product in terms of Art. 126A was €116.46 (Lm 50).

Dr Galea Testaferrata raised the issue that in the letter of rejection dated 5 February 2010, the Contracts Department had indicated that 'the product is not locally registered' when the product was in fact registered on the 5 October 2009, i.e. well before the 5 February 2010. He argued that one might consider that as a very fine line but still it was a very pertinent point so much so that he could not accept the reason for disqualification as presented. Dr Galea Testaferrata stated that he would perhaps

have accepted a reason for rejection stating that the product had not been registered as per Art. 126A.

Ms Debattista replied that the adjudicating board assessed the submission according to the specifications and conditions set out in the tender document and when the adjudicating board made that remark it meant that the product was not registered as requested in the call for tenders.

Dr Galea Testaferrata remarked that in previous PCAB decisions it was stated that the GHPS had all the opportunity to carry out its own verifications and that, although it was not a legal obligation on the part of the contracting authority to do that, it was certainly a moral obligation on the part of the contracting authority to check with the applicant or with the Medicines Authority whether the product was in fact registered.

The Chairman PCAB commented that each case had to be considered on its own merits as there were instances when seeking clarifications was either not considered necessary or even not permitted.

Mr Carmel Esposito, a PCAB member, observed that the GHPS did not trace this product on the 28 October 2009 list of product registrations in terms of Art 126A on the Medicines Authority website when the product was in fact registered on the 5 October 2009.

Ms Debattista reiterated that, first of all, the product was not registered as on 22 September 2009, as laid down in the tender conditions, and that, albeit the product was registered on 5 October 2009, it appeared on the Medicines Authority website for the first time on 30 November 2009 and, moreover, the appellant Company had stated that it had informed the GHPS of this registration on 9 December 2009.

Ms Debattista remarked that there has been a development in this respect in the sense that competition has been on the increase in this sector and, as a consequence, it was decided to do away with the clause whereby tenderers could register their product within 6 weeks from the closing date of the tender. Instead, proceeded Ms Debattista, the department was insisting in the tender document that the medicinal product had to be registered as at the closing date of the tender and was being asked that a copy of the registration certificate should be attached. Ms Debattista, however, pointed out that the scenario was different when this call for tenders was issued.

Dr Galea Testaferrata insisted that the hearing had to stick strictly with the reasons for rejection, one of which clearly stated that 'the product is not registered' and he claimed that that referred on 5 February 2010. He added that this same kind of medicine was already being supplied to GHPS and, as a result, he questioned why the contracting authority was going to disqualify a good and relatively cheap product for the sake of formalities.

Ms Debattista insisted that the adjudicating board had to evaluate the offer on the documentation submitted. She informed that Government had issued calls for the supply of small quantities of this medicine until such time that the tender under reference was adjudicated and she confirmed that the GHPS did place orders for this

product, supplied by the appellant Company since it was duly registered on the closing date and it was the cheapest.

Mr Prakash noted that the other seven tenderers had been found non-compliant at some stage of the tendering process and it appeared that his firm remained the only participating tenderer with regard to items 2 to 4, i.e. 20/40/80 mg tablets and so he questioned the rationale behind the cancellation of this tender for a mere few additional days taken to have the product registered, i.e. from 22 September to 5 October 2009.

Ms Debattista remarked that the other tenderers were rejected for a number of reasons ranging from the delivery period, not quoting for all dosages, product registration, the shelf life and missing information.

Dr Vella remarked that the small format of Annex IX 'Financial Identification' as presented in the tender document did not allow for legible printing of the tenderer's details and so the requisite information was printed on an Accord Healthcare Ltd letterhead, which information was certified as 'all correct and in order' by Ms Joanna Lewis, Senior Commercial Manager of HSBC plc and attached thereto were (a) a copy of Ms Lewis's business card and (b) the bank statement of account no. 68021189. Dr Vella contended that this kind of authentication by the bankers of Accord Healthcare Ltd was by far superior to a bank rubber stamp with no certification.

Dr Galea Testaferrata claimed that the form at Annex IX was rather small for it to be filled in properly and, as a consequence, it was decided that they would submit it, admittedly, in a different format but still with all the requested information. He added that although the letter did not bear the bank's stamp still there were the certification by Ms J Lewis, HSCB senior commercial manager, and her business card. Dr Galea Testaferrata remarked that it was no justification to disqualify a tender on mere grounds of formality when the things that mattered were in fact submitted.

Ms Debattista remarked that at tender opening stage the Contracts Department had clearly indicated that, with regard to the appellant Company's submission, Annex IX 'Financial Identification' had been found blank.

The Chairman PCAB observed that the adjudicating board did not raise any issue as to the information submitted in the letter but simply stated that the bank's stamp was not on the document.

Mr Manoj Prakash stated that his firm was informed that it was not the practice at HSBC to issue such information on its letterhead or to stamp such documents because the current practice was to do that electronically.

Dr Galea Testaferrata considered that the certification made by Ms J. Lewis and the reproduction of her business card were adequate substitutes to the bank's stamp. He continued that his client had adopted this same approach when participating in other tendering processes and no objections had been raised by the contracting authorities.

Ms Debattista emphasised that on Annex IX 'Financial Identification' it was clearly indicated that 'the bank stamp plus signature of bank representative' and the 'date plus signature of the account holder' were all obligatory requirements.

The PCAB noted that with regard to the 'Financial Identification' form the appellants submitted the following (a) in the tender submission, a letter bearing the letterhead of Accord Healthcare Ltd signed and dated by the account holder along with the certification by Ms Joanna Lewis HSBC bank manager together with a photocopy of Ms Lewis's business card and certification and (b) with the reasoned letter of objection dated 18 February 2010, they submitted the 'Financial Identification' form on a letterhead of HSBC and signed by Ms Joanna Lewis.

Dr Galea Testaferrata reiterated that one of the reasons why his client lodged the appeal was the statement made on the 5 February 2010 by the Contracts Department that the 'product is not registered' and that no mention was made that the product was not registered within 6 weeks from closing date of tender. After pointing out that (i) the product had in fact been registered on the 5 October 2009, (ii) his client had satisfied all the other conditions and (iii) his client was already supplying this medicine to GHPS, Dr Galea Testaferrata questioned the wisdom behind the recommendation of the adjudicating board to reject his client's offer which would consequently lead to the cancellation of the tender.

As for the missing bank stamp, Dr Galea Testaferrata considered that the requisites stipulated in Annex IX were adequately satisfied even if in a different format.

On his part, Mr Prakash remarked that, due to a few days' delay in the issue of the product registration, the contracting authority was contemplating the rejection of his tender which would lead to the cancellation of the tendering process and the initiation of a fresh process which would take months to conclude. Mr Prakash, therefore, appealed to the authorities to assess the situation not only from the point of view of the documentation presented but also from a wider perspective.

Ms Debattista highlighted the following facts:

- the call for tenders was published on the 19 June 2009;

- the product had to be registered either by the closing date of the tender, i.e. the 11 August 2009, or, at most, 6 weeks after that date, i.e. 22 September 2009;

- the adjudicating board had to evaluate according to the published tender conditions and it could not take into account the developments that took place at later stages; and

- one tenderer was in fact found entirely compliant with regard to item 1.

Ms Debattista explained that the situation in Malta was changing both with regard to product availability/competition and to prices, which were going down as far as medicine supplied to government was concerned (she also explained that the prices of medicine procured by government were significantly cheaper from prices of medicine purchased from private pharmacies).

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 18 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 and Mr Prakash's interventions, particularly, wherein these (a) stated that in their letter dated 7 August 2009, submitted with envelope 2, it was stated that they could confirm that they had started procedures to register this product in Malta within 6 weeks under article 126A, (b) stated that the Medicines Authority issued the licences on the 5 October 2009 to *Accord Healthcare Ltd* in respect of the 10/20/40/80mg tablets, which licences were forwarded to the GHPS and to the Contracts Department on the 9 December 2009, (c) remarked that the responsibility to issue licences for medicines rested solely with the Medicines Authority and that they could not be penalised because the Medicines Authority failed to issue the licences within the required 6-week period, (d) raised the issue that in the letter of rejection dated 5 February 2010, the Contracts Department had indicated that 'the product is not locally registered' when the product was in fact registered on the 5 October 2009, i.e. well before the 5 February 2010, (e) remarked that the small format of Annex IX 'Financial Identification' as presented in the tender document did not allow for legible printing of the tenderer's details and so the requisite information was printed on an Accord Healthcare Ltd letterhead, which information was certified as 'all correct and in order' by a Senior official of HSBC plc in England, with the appellant Company's representative claiming that such document was by far superior to a bank rubber stamp with no certification and that it was no justification for the contracting authority to disqualify a tender on mere grounds of formality when the things that mattered were in fact submitted and (f) informed those present that they had been told that it was not the practice at HSBC plc to issue such information on the Bank's letterhead or to stamp such documents because the current practice was for all to be carried out electronically;

- having taken into consideration the points raised by Ms Debattista, particularly those relating to the fact that (a) the information she obtained from the Medicines Authority was that the appellant Company had lodged its application to register all four doses of this medicine on the 19 August 2009, (b) six weeks from the 11 August 2009 would have been the 22 September 2009 and the GHPS was informed of the product registrations on the 9 December 2009, (c) the product was not registered by 22 September 2009, as laid down in the tender conditions, and that, albeit the product was registered on 5 October 2009, it appeared on the Medicines Authority website for the first time on 30 November 2009 and, moreover, the appellant Company had stated that it had informed the GHPS of this registration on 9 December 2009,

(d) it had been made amply clear to operators in the medicines sector that there should be no direct link between the time the application to register a product in Malta was submitted and the participation in a tendering process but that the two procedures had to be kept distinct from one another, (e) the adjudicating board assessed the tenderers' submissions according to the specifications and conditions set out in the tender document and that, in the case of the appellant Company's submission, the product on offer had not been registered as requested in the call for tenders and (f) the adjudicating board had to evaluate the offer on the documentation submitted;

- having also noted Ms Debattista's remark which referred to the fact that, since competition had increased in this sector, central authorities decided to do away with the clause whereby tenderers had to register their product within 6 weeks from the closing date of the tender and that now the department was insisting in the tender document that the medicinal product had to be registered as at the closing date of the tender and was being asked that a copy of the registration certificate should be attached;

- having also reflected on Ms Debattista's statement that Government had issued calls for the supply of small quantities of this medicine until such time that the tender under reference was adjudicated and she confirmed that the GHPS had placed orders for this product, supplied by the appellant Company, since it was duly registered on the closing date and it was the cheapest;

- having noticed that the adjudicating board did not raise any issue as to the information submitted in the letter but simply stated that the bank's stamp was not on the document

reached the following conclusions, namely:

1. The PCAB feels that as regards the rubber stamp required, considering that all information was submitted in the appellants' original tender submission, albeit in a different format, yet this still included the HSBC plc's official's details and certification. This, the PCAB argues, should have instigated at least a request for a formal confirmation by the evaluation board. This Board is aware of the mandatory requirements but it opines that, in this particular instance, there was sufficient scope for a minimal clarification process to be followed by the evaluation board.

2. 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'. 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 one week after 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.

3. 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.

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	Anthony Pavia	Carmel J Esposito
Chairman	Member	Member

11 August 2010