PUBLIC CONTRACTS APPEALS BOARD

Case No. 172

Adv. No. 88/2009; CT/2142/2008; GPS 01.002.T08AS
Tender for the Supply of Letrozole 2.5mg Tablets/Capsules

This call for tenders covering 3 years' supply was, for a contracted estimated value of € 368,102.72 was published in the Government Gazette on 24.02.2009. The closing date for this call for offers was 21.04.2009.

Two (2) different tenderers submitted their offers.

On 02.10.2009 Messrs Rodel Ltd, acting on behalf of Accord Healthcare Ltd, filed an objection against the intended award of the tender in caption to V J Salomone Pharma Ltd.

The Public Contracts Appeals Board (PCAB) made up of Mr Alfred Triganza (Chairman) with Mr Edwin Muscat and Mr Carmel Esposito, respectively, acting as members convened a public hearing on 18.11.2009 to discuss this objection.

Present for the hearing were:

Rodel Ltd

Dr Hugh Peralta	Legal Representative
Dr Norman Vella	Representative
Mr Manoj Prakash	Representative of Accord Healthcare Ltd

Government Health Procurement Services

Ms Anne Debattista	Director
Mr Chris Treeby Ward	Health Division Representative

Evaluation Committee

Ms Miriam Dowling	Chairperson
Mr David Baldacchino	Member

V J Salomone Pharma Ltd

Mrs Vanessa Said Salomone	Representative

Medicines Authority

Mr Michael Chetcuti	Representative

Department of Contracts

Mr Francis Attard	Director General
Mr Mario Borg	Assistant Director

After the Chairman's brief introduction the appellant Company's representative was invited to explain the motives of the objection. The parties agreed that the hearing be held in English so that Mr Manoj Prakash, representing Accord Healthcare Ltd, would be able to follow proceedings.

Dr Norman Vella, representing Rodel Ltd, the appellant Company, explained that two firms tendered for this contract and he claimed that his client was €60,000 cheaper.

Dr Hugh Peralta, the appellants' legal representative, took up the case and referred to a letter dated 25th September 2009 from Contracts Department which informed the appellant that:

> *…the tender submitted by you was not successful as you have submitted an application for a variation to register the x30 pack size being offered and to include an additional EU batch release site. These variations have not been included in the last MA update dated 30th July 2009. Therefore, product is not acceptable.*

Dr Peralta remarked that the main reason given for exclusion was that this variation was not on the Medicines Authority (MA) website dated 30th July 2009. Dr Peralta explained that, previously, this medicine was presented in a pack of 28 tablets, which had been registered in October 2008 in the UK, the member reference state, which registration automatically applied to the other member states. He added that at the time that Accord Healthcare Ltd submitted its tender, the 28-tablet pack was changed to a 30-tablet pack, which change constituted a variation. Dr Peralta continued that once a variation was accepted in one (Reference) Member State then it was automatically applicable to all the other EU Member States. Dr Peralta said that this variation had not been included in the 30 July 2009 update but that it was issued on the 24th September. He declared that it so happened that on the 21st April 2009, which was also the closing date of the tender the UK had approved this variation, admittedly, an event not known to his client at that time.

Dr Peralta remarked that the tender document submitted by his client did indicate that an application for variation had been filed. Dr Peralta then referred to the email dated 28th September 2009 sent by Ms Helen Vella of the Medicines Authority to his client and to the Health Department which, *inter alia*, stated that:

> *Regarding the below mentioned product Letrozole tablets and variations pertaining to the marketing authorisation of same, I would like to inform you that variations:*
>
> *1. UK/H/112/001/1A.002 – replacement/addition of a manufacturer responsible for batch release*
>
> *2. UK/H/1142/001/1B/001 – to register additional pack sizes including pack x 30,*
>
> *were both finalised positively by the Reference Member State carrying out the assessment, UK, and all Concerned Member States, including Malta in March and May 2009 respectively.*

Dr Peralta claimed that, as a matter of fact, both variations were registered in the UK in May 2009. Dr Peralta stated that in September 2009 the Contracts Department had stated that the variations were not registered after having made reference to the Medicines Authority website update of the 30th July 2009.

Dr Peralta continued by quoting from the email sent by Ms Vella, namely:

> *"In Malta, the national phase has not yet been completed. However, once the variations were positively concluded by the RMS (as per CTS database below, used for Member States to communicate during European procedures), the changes can be implemented by the marketing authorisation holder."*

Dr Peralta claimed that these variations had been approved in the UK and he argued that, if one were to consider the case at that point in time, one would conclude that the reason given for exclusion, i.e. that it did not appear on the last Medicines Authority website update of 30th July 2009, was no longer applicable.

Dr Peralta remarked that a pertinent question was whether the Contracts Department or the contracting authority should have checked with Ms Vella or with his client as to how things stood in actual fact and thus save the government €60,000. Dr Peralta contended that a private company would have checked things out in an effort to save the company a good amount of money – a cost saving exercise - especially when it was dealing with a respected client.

The appellant's legal advisor argued that if one had delved a bit deeper into the matter one would have found out that the variations had, in fact, been approved and, as a consequence, the reason for exclusion would not have applied. Furthermore, his client's product was good and offered at a competitive price and, as a result, it should not have been discarded.

Ms Anne Debattista, Director, Government Health Procurement Services, conceded that the appellant's offer was the cheaper of the two offers submitted but was quick to add that the product offered was in a pack of 30 capsules whereas the local Medicines Authority website displayed the product in a pack of 28 tablets. She explained that albeit, at the closing date of tender, 21st April 2009 (tender published on the 24th February 2009), the appellant Company did indicate in its submission that an application had been submitted to the Medicines Authority in connection with the variation, yet the adjudicating process had to be carried out on the information submitted at the closing date of tender. Ms Debattista said that it was incumbent on the contractor to inform the Contracts Department that the procedure had been terminated because the Government Health Procurement Services was not privy to such information as the Medicines Authority witness would testify later on.

At this point the Chairman PCAB intervened to observe that if one were to solely rely on data / details listed on a website (in this case the Medicines Authority's website), it could well result that the website would not be up-to-date and, hence, not reflect the true state of affairs.

Ms Debattista then referred to Annex VI – Tender Technical and Special Conditions – clause 7.1 Medicinal Products which read as follows:

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

(i) a true representative sample of the product in the pack size as offered ….

Ms Debattista submitted that the appellant Company's sample was not presented in "the pack size being offered."

The Chairman PCAB noted that the sample was not mentioned as one of the reasons for exclusion and, therefore, it was not fair on the appellant for the contracting authority to bring up this issue at that stage.

Ms Debattista remarked that it was true that the appellant was only informed about the licensing issue but called on the PCAB to appreciate that the adjudication board had to consider all the information that had been submitted. She added that, had the product been duly registered, the appellant would have submitted the registered sample but the fact was that the appellant submitted a product that was not registered and that was evident even from the leaflet accompanying the sample which did not indicate the date when it was approved. Ms Debattista claimed that the Government Health Procurement Services listed the licensing issue as the only shortcoming because the other shortcomings were consequential.

Ms Debattista conceded that it would seem that a product registered in the UK or, for that matter, in any other EU State, would be acceptable to the Maltese authorities. However, on this specific issue she preferred to let the Medicines Authority representative elaborate on that as the matter was not that straightforward and the Medicines Authority was the competent entity at that. Ms Debattista stated that at no stage did the appellant contact the Contracts Department to inform it of any developments that had occurred.

The Chairman PCAB remarked that in this case it was very relevant for the contracting authority to be well aware of the workings of the Medicines Authority because, had it been the case, this case would, most probably, not have ended up before the PCAB.

Mr Michael Chetcuti, representing the Medicines Authority, under oath, gave evidence the salient points of which one could highlight as follows – mainly according to Mr Chetcuti …

- not everything that is registered in EU Member States is automatically recognised in Malta;

- there are procedures that allowed for the mutual recognition of medicine licensing and, once such procedures are concluded, then these would be applicable to all EU countries. In this case Malta has been a participant from the beginning in the decentralised procedure, i.e. since it was initially registered in 2008. Also, in this particular instance, there were no grounds for exclusion because Malta was part of the said procedure;

- once a procedure is concluded it has also to be officially concluded in all the Member States;

- the national phase is a phase that varies from country to country depending mostly on the resources available;

- there is a day-to-day procedure together with another type of procedure. With regards top this particular case the first procedure was concluded in March 2009 whereas the second one was concluded in April 2009. The Reference Member State (RMS) procedural level had been concluded with the UK being the Reference Member State, the lead Member State, whereas Malta was the Concerned Member State (CMS), the one that followed although Malta would also contribute to the procedure;

- at the moment the administrative phase undertaken in Malta could take a number of months to be concluded because of the workload at the Medicines Authority;

- once a product is approved, procedurally, the Medicines Authority is allowed to implement, as was demonstrated in this instance by the email dated 28th September 2009 sent by Ms Helen Vella of the Medicines Authority which had been quoted earlier on during the hearing by Dr Peralta;

- Ms Vella sent the said email in September 2009 because the Medicines Authority was not asked to give any information in that regard prior to that date;

- to his knowledge, this was the first case of its type;

- the only source of information currently available publicly for local approvals was the Medicines Authority website which is updated regularly. Mr Chetcuti could not recall if the website was updated every two weeks or every two months because such updating does not fall within the realms of his responsibility;

- whilst it could happen that a product would have been approved without being displayed on the website, yet, that was rather remote as, once the procedure would have been brought to a close, it would be uploaded on the Medicines Authority's website which process, admitted Mr Chetcuti, could take up to two weeks or so;

- the website is the only means for the Medicines Authority clients to obtain licensing information unless they made a specific request to the Medicines Authority;

- he was not aware as to whether other entities, such as contracting authorities like the Government Health Procurement Services, could ask the Medicines Authority for licensing information;

- the administrative process, with regard to this product, was still in progress because of the workload on the part of the Medicines Authority; ***and***

- he worked for the licensing department of the Medicines Authority which was an autonomous body set up by government.

Ms Debattista explained that, during the adjudication process, she had queried in the beginning of September as to whether the Medicines Authority's website had been updated and it resulted that up until September 2009 and, even up to that same day, the website had not been updated. When asked by the PCAB to confirm this statement Mr Chetcuti could not confirm or deny it.

Ms Debattista stressed that the contracting authority was not allowed to make any queries that would, in any way, alter the original offer submitted at the closing date of tender and added that any queries had to be made through the Contracts Department.

Ms Debattista showed comprehension as to the way this case developed but she insisted that there were two factors which could not be overlooked, namely the (a) Medicines Authority's website had not been updated and (b) tenderer failed to inform the Contracts Department that its product had, in the meantime, been approved in the UK.

The Chairman PCAB conceded that the contracting authority could not and should not go beyond certain limits but added that the PCAB had to take into account the interests of all the parties concerned. The Chairman PCAB failed to understand why the Medicines Authority's website was not continuously updated.

Moreover, the PCAB's Chairman expressed concern that, even if the workload at the Medicines Authority was, in this instance, a matter of fact, a genuine case, still, in other circumstances one could not entirely exclude the possibility that there could be ulterior motives behind a delay in the approval to a product.

The Chairman PCAB disagreed completely with the notion that a tenderer should be penalised because of the workload on the part of any public entity. The Chairman opined that it did not take much time to update a website, irrespective of the workload, and that one should not expect a client to wait for months on end to obtain an approval, in this case a market authorisation.

Ms Debattista summed up what in her opinion were the three main issues in this case: (a) the Government Health Procurement Services was not allowed to make queries which in any way could lead to a change in the original offer, (b) the approval granted by the Reference State was not available to the Government Health Procurement Services and (c) the contractor, at no point in time, did officially inform the Director of Contracts that the variation for the product that was submitted in its offer had been positively concluded by the Reference Member State, the UK. Ms Debattista declared that the contractor was required to offer a product with a marketing authorisation issued in Malta and that the appellant Company had acted correctly because it had indicated in its tender submission that it did not possess the marketing authorisation but that it had lodged an application with the Medicines Authority for that purpose. She added that the tenderer was not obliged to inform the contracting authority that the product had been approved in the UK - the Reference Member State.

On his part Dr Peralta refused the accusation that his client had not contacted the contracting authority about the authorisation of the product as he contended that it was not proper for tenderers to embark on private communications with the contracting authority. He claimed that it was the responsibility of the contracting authority to seek clarifications from tenderers and moved on to quote from section 20.3 under 'Instructions to Tenderers' which read as follows:

> *"To facilitate the examination, evaluation and comparison of tenders, the evaluation committee may ask each tenderer individually for clarification of his tender …"*

Dr Peralta stated that the fact was that the contracting authority failed to find out if the product had actually been registered in the meantime.

Dr Peralta also opined that the answer to the first question put to Mr Chetcuti, which he answered in the negative, was subsequently a 'yes' answer, i.e. that a product registered in the UK was recognised in Malta if the required action had been taken.

The Chairman PCAB remarked that the contracting authority was allowed to seek clarifications so long as such clarification was carried out in a transparent manner and through the Department of Contracts.

The Chairman PCAB …

(i) remarked that one could not condone a situation where a contractor got penalised because a public entity entrusted with the issue of such authorisations had a backlog of work

and

(ii) welcomed the comment made by Mr Chetcuti that after this case cropped up the Medicines Authority has been exploring ways how to avoid the recurrence of such events

At this stage the public hearing was brought to a close and the PCAB proceed with the deliberation before reaching its decision.

This Board,

- having noted that the appellants, in terms of their 'motivated letter of objection' dated 07.10.2009 and also through their verbal submissions presented during the public hearing held on the 18.11.2009, had objected to the decision taken by the General Contracts Committee;

- having taken note of the fact that the main reason given to appellant Company for exclusion was that this variation was not on the Medicines Authority's website dated 30th July 2009;

- having also taken note of the correspondence entered into with Ms Helen Vella of the Medicines Authority;

- having heard Ms Debattista state that (a) albeit the appellant Company did indicate in its submission that an application had been submitted to the Medicines Authority in connection with the variation, yet the adjudicating process had to be carried out on the information submitted at the closing date of tender and (b) the appellant Company's sample was not presented in "the pack size being offered.";

- having also noted that (a) it had to consider the fact that despite the contracting authority's representative's reference to the said sample, such issue was not mentioned as one of the reasons for exclusion and (b) as stated in its defence, the contracting authority claimed that the Government Health Procurement Services listed the licensing issue as the only shortcoming because the other shortcomings were consequential;

- having taken full cognizance of all of Mr Chetcuti's comments and observations;

- having also taken particular note of the fact that (a) it was publicly confirmed that up until September 2009 and, even up to that same day, the Medicines Authority's website had not been updated, a matter which gains considerable importance considering that the Government Health Procurement Services would only consider those products which would be duly listed on the said website, (b) the Government Health Procurement Services maintained that, albeit not obliged to do so, the onus remains on the tenderer to inform the Contracts Department that its product had, in the meantime, been approved in another Reference Member State (RMS), in this particular instance the UK and (c) with reference to (b) the appellant Company's legal representative claimed that it was not proper for tenderers to embark on private communications with the contracting authority and that, as stated in section 20.3 under 'Instructions to Tenderers', "*the evaluation committee may ask each tenderer individually for clarification of his tender …*" to "*facilitate the examination, evaluation and comparison of tenders*";

- having taken note of Mr Chetcuti's comment regarding the fact that Ms Vella sent the said email in September 2009 because the Medicines Authority was not asked to give any information in that regard prior to that date;

- having heard Ms Debattista's comments relating to the fact that the contracting authority was not allowed to make any queries that would, in any way, alter the original offer submitted at the closing date of tender, adding that any queries had to be made through the Contracts Department;

- having reflected on its own (i.e. the PCAB's) remarks stated during the hearing, namely, (a) the fact that it failed to understand why the Medicines Authority's website was not continuously updated and (b) that, even if the workload at the Medicines Authority was, in this instance, a matter of fact, a genuine case, still, in other circumstances one could not entirely exclude the possibility that there could be ulterior motives behind a delay in the approval to a product;

reached the following conclusions, namely:

1. The PCAB feels that if one were to solely rely on data / details listed on a website (in this case the Medicines Authority's website), it could well result that the website would not be up-to-date and, hence, not reflect the true state of affairs.

2. The PCAB disagrees completely with the notion that a tenderer should be penalised because of the workload on the part of any public entity, especially when it is more than obvious that it does not take much time for one to update a website, irrespective of the workload.

3. The PCAB contends that, regardless of the workload, one should not expect a client to wait for months on end to obtain an approval, in this case a market authorisation.

4. Contrary to what has been stated by the contracting authority's representative, the PCAB argues that a contracting authority is allowed to seek clarifications so long as such clarification is carried out in a transparent manner and through the Department of Contracts.

5. The PCAB considers that proper liaison between the contracting authority and the Medicines Authority would have avoided many an issue which emanated from the lack of proper shouldering of responsibilities to ensure that all remains transparent but also without injustices being experienced by any of the tenderers participating in this tender.

As a consequence of (1) to (5) above this Board finds in favour of 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 appellants should be reimbursed.

Alfred R Triganza Chairman	Edwin Muscat Member	Carmel Esposito Member

7 December 2009