PUBLIC CONTRACTS APPEALS BOARD

Case No. 173 and Case No. 174

Adv. No. 148/2009; CT/2574/2008; GPS 07.227.T07CA
Tender for the Supply of Venlafaxine 75mg Capsules

This call for tenders was, for a contracted estimated value of € 1,100,537.93 covering a contract period of 36 months, was published in the Government Gazette with the closing date for this call for offers being 09.06.2009.

Four (4) different tenderers submitted their offers.

On 09.10.2009 *Messrs George Borg Barthet Ltd* and on 13.10.2009 *VJ Salomone Pharma Ltd* respectively filed an objection against the decision by the Contracts Department that their offers were non-compliant.

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 25.11.2009 to discuss these objections.

Present for the hearing were:

George Borg Barthet Ltd (GBB Ltd)

Ms Lina Aquilina	
Ms Michelle Chircop	

VJ Salomone Pharma Ltd (VJSP Ltd)

Dr Adrian Delia	Legal Representative
Dr John L Gauci	Legal Representative
Ms Jackie Mangion	V J Salomone Pharma Ltd
Mr Daniel Vella Friggieri	Actavis Malta Ltd
Ms Deborah Campbell	Actavis Malta Ltd
Ms Jo Ann Vassallo	Actavis Malta Ltd

Vivian Corporation Ltd

Ms Denise Borg Manche	Tender Business Manager

Government Health Procurement Services

Ms Anna Debattista	Director
Mr Christopher Treeby Ward	Principal Pharmacist

Evaluation Committee

Ms Miriam Dowling	Chairperson
Mr David Baldacchino	Member

Department of Contracts

Mr Francis Attard	Director General (Contracts)

The Chairman PCAB explained that, since these two objections concerned the same call for tenders, it was decided that a joint hearing be held. However, it was also explained that the two cases would be dealt with and decided upon separately.

Following this brief introduction, the Chairman PCAB then invited the representative of *George Borg Barthet Ltd* to explain the motive of the objection.

Objection raised by Messrs George Borg Barthet Ltd

Ms Lina Aquilina, representing one of the appellant Companies, namely Messrs George Borg Barthet Ltd, explained that by letter dated 7 October 2009, the Contracts Department had informed them that their offer was considered non-compliant because "*the package/insert are in the French language*".

Ms Aquilina informed those present that the sample they submitted, besides having the pack and the insert in French, had also a copy of the insert in the English language.

Ms Anne Debattista, Director, Government Health Procurement Service, displayed the sample presented by George Borg Barthet Ltd which had the pack and the insert in French together with a photocopy of an insert in English. Ms Debattista then referred to Annex VI 'A' Technical Conditions section 3 'Packaging and Labelling' where clause 3.1 'Medical Products' stated that :

> *"The following particulars shall appear on the "outer packaging" (3) of a medical product, or where there is no outer packaging on the "immediate packaging" (4) in one of the official languages of Malta*".

Making particular reference to this clause, Ms Debattista placed emphasis on the fact that, it was common knowledge that the official languages of Malta are Maltese and English.

Then she referred also to section 7 'Samples and Literature' para. 'Medicinal Products' which stated that:

> *"The tenderer must ensure that the following is submitted with each offer:*
>
> *A true representative sample of the product in the pack size as offered …….… Original/true copy of the outer packaging and immediate packing labelling in one of the official languages of Malta Original/true copy of the package insert in one of the official languages of Malta*."

Referring to the said clause, the same contracting authority's representative stated that, for clarity's sake, she had to mention that the appellant Company, whilst submitting an *"Original/true copy of the package insert in one of the official languages of Malta"*, did not do the same as far as the other mandatory request which required a tenderer to submit an *"Original/true copy of the outer packaging and immediate packing labelling in one of the official languages of Malta"*.

Ms Debattista explained that, albeit the package insert was submitted, yet all the official packaging was in French and not in any one of the official languages of Malta.

Furthermore, Ms Debattista quoted Annex IV – 'Declaration Sheet for Medicinal Products' para. 5 which stated "*Pack size: pack of 30 capsules SR – French language only.*"

Ms Debattista concluded that George Borg Barthet Ltd defaulted because it submitted a sample with the outer packaging and labelling all in French when the tender document requested it to be in one of the official languages of Malta, i.e. Maltese or English.

Dr Adrian Delia, *VJ Salomone Pharma Ltd*'s legal representative, intervened to say that this requirement did not emerge only from the tender document but also from the *Medicines Act* and, therefore, even if it were not requested in the tender dossier, it had to be submitted anyway because the law so stipulated. He added that the *Medicines Act* also laid down that the product had to have the outer packaging in Maltese or English and even any inner literature had to be in Maltese or English because, if the capsules were not given out in full packages but individual capsules were handed out, then any inner packaging/foil had to be in Maltese or English so that the patient would be able to read and understand it.

Ms Michelle Chircop, also representing George Borg Barthet Ltd, under oath, conceded that the packaging was all in French. However, she added that there were other instances – she even mentioned one specific product - when they supplied the Government Health Procurement Service with products that had the packaging in French and the insert in English.

Ms Debattista submitted that the public hearing concerned this specific call for tenders and not other calls for tenders and if there was an instance or instances like Ms Chircop mentioned it did not mean that the Government Health Procurement Service was bound to accept such products when the tender specifications clearly requested otherwise. She added that the Government Health Procurement Service procured thousands of items and she could not recall the example mentioned by Ms Chircop.

The Chairman PCAB remarked that the tender conditions were very clear in this respect and expressed his concern as to how there might have been instances when these requirements were overlooked.

Objection raised by Messrs VJ Salomone Pharma Ltd

Dr Adrian Delia, legal representative of VJ Salomone Pharma Ltd, explained that on the 7 October 2009 his client was informed by the Contacts Department that their offer was declared administratively/technically non-compliant because the "*product is not listed in the MA* (Market Authorisation*) list updated by MA* (Medicines Authority) *on 30/07/09*".

The appellant Company's legal representative declared that one had to establish whether a firm had the market authorisation not by simply checking the website of the Medicines Authority but by ensuring that an entity actually had that marketing authorisation. He claimed that the wording used to justify the exclusion of his client's offer did not refer to his client not having the marketing authorisation but that the Medicines Authority website did not display the market authorisation of his client.

The Chairman PCAB recalled another case that had been brought before the Board a few days previously and remarked that a representative of the Medicines Authority had testified that:

a. the Medicines Authority website which indicated that an entity was the holder of a marketing authorisation was not frequently updated;

b. no consultation took place between the entities concerned, i.e. between the contracting authority, which happened to be the Government Health Procurement Service as in this case and the Medicines Authority, and

c. the Medicines Authority had a backlog of work such that the same Medicines Authority was not in a position to issue such authorisations in a timely manner

The Chairman PCAB reiterated what he had said in that case in the sense that the backlog of work that the Medicines Authority had should not be allowed to jeopardise the position of the contractor concerned.

At this point the Chairman PCAB asked the parties concerned to furnish the PCAB with the dates relevant to the case, which read as follows:

21 July 2008	date when the appellant, *VJ Salomone Pharma Ltd*, applied to the Medicines Authority for the market authorisation
9 June 2009	closing date of tender
21 July 2009	when the 6-week period after the closing date of tender lapsed
28 July 2009	the date when the Medicines Authority issued the market authorisation to *VJ Salomone Pharma Ltd*

Ms Debattista explained that, in its tender documentation, the appellant Company, *VJ Salomone Pharma Ltd*, had indicated that it did not have the market authorisation. At this point Dr Delia intervened to confirm that, by the 9th June 2009, his client did not have the requested market authorisation.

Ms Debattista then quoted section 9.1.2 under section 'B Special Conditions' of Annex VI;

> *"In the event that at the closing date for the submission of the offer, the medicinal product being offered does not have:*
>
> *a) a valid Provisional Marketing Authorisation, or*
> *b) a valid Marketing Authorisation, or*
> *etc*
>
> *… tenderers will be allowed an additional 6-week period from the closing date of the respective tender or from the date of request from Director of Contracts/Director GPS, in order to be able to register the medicinal product in terms of prevailing Laws of Malta."*

Ms Debattista pointed out that, in this case, the 6-week period started from the closing date of tender since the tenderer had declared that he had an application pending with the Medicines Authority.

Ms Debattista and Dr Delia agreed that *VJ Salomone Pharma Ltd* had eventually obtained the marketing authorisation on the 28 July 2009 when the 6-week period had lapsed on the 21 July 2009.

The Chairman PCAB remarked that it appeared that, on one hand, the contracting authority had taken note that the appellant obtained the market authorisation 6 days or so after the stipulated time and, consequently, decided to disqualify the latter's offer but, on the other hand, the contracting authority failed to take into account the fact that the same appellant had lodged an application with the Medicines Authority in July 2008, i.e. one year before!

Ms Debattista contended that, in this case, the adjudication board had only acted according to the tender conditions.

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' (Messrs George Borg Barthet Ltd - dated 09.10.2009 and Messrs VJ Salomone Pharma Ltd – dated 16.10.2009) and also through their verbal submissions presented during the public hearing held on the 25.11.2009, had objected to the decision taken by the General Contracts Committee;

in the appeal lodged by Messrs George Borg Barthet Ltd …

- having particularly taken note of the fact that, whilst the appellant Company stated that the sample they submitted, besides having the pack and the insert in French, had also a copy of the insert in the English language, yet Annex VI 'A' Technical Conditions section 3 'Packaging and Labelling' specifically stated, *inter alia*, that the "*following particulars shall appear on the "outer packaging" (3) of a medical product, or where there is no outer packaging on the "immediate packaging" (4) in one of the official languages of Malta*";

- having also taken note of the fact that in section 7 'Samples and Literature' para. 'Medicinal Products', whilst there was specifically stated that "*A true representative sample of the product in the pack size as offered …….… Original/true copy of the outer packaging and immediate packing labelling in one of the official languages of Malta Original/true copy of the package insert in one of the official languages of Malta*", yet all the official packaging on the sample submitted was in French and not in any one of the official languages of Malta, as conceded by Ms Chircop, a representative of the same appellant Company;

in the appeal lodged by Messrs VJ Salomone Pharma Ltd …

- having heard the appellant Company's legal representative declared that one had to establish whether a firm had the market authorisation not by simply checking the website of the Medicines Authority but by ensuring that an entity actually had that marketing authorisation;

- having also given particular attention to its own remarks which remained unchallenged in this hearing, namely that (a) the Medicines Authority website which indicated that an entity was the holder of a marketing authorisation was not frequently updated, (b) no consultation took place between the entities concerned, i.e. between the contracting authority, which happened to be the Government Health Procurement Service as in this case and the Medicines Authority and (c) the Medicines Authority had a backlog of work such that the same Medicines Authority was not in a position to issue such authorisations in a timely manner;

- having taken full cognizance of timeline of events leading to the issue of the market authorisation to the appellant Company by the Medicines Authority;

- having also taken note of the fact that Ms Debattista placed major emphasis on the fact that the appellant Company had eventually obtained the marketing authorisation on the 28 July 2009 when the 6-week period had lapsed on the 21 July 2009;

- having taken note of the PCAB's own reflection expressed during the same hearing that, whilst, on one hand, the contracting authority had taken note that the appellant Company obtained the market authorisation 6 days or so after the stipulated time and, consequently, decided to disqualify the latter's offer, yet, on the other hand, the same contracting authority failed to take account of the fact that the same appellant had lodged an application with the Medicines Authority in July 2008, i.e. one year before;

- having heard Ms Debattista's comments regarding the fact that the adjudication board had only acted according to the tender conditions;

reached the following conclusions, namely:

1. The PCAB feels that in the appeal lodged by *Messrs George Borg Barthet Ltd* the appellant did not abide by tender specifications which were amply clear.

2. With regards to the other appeal which was lodged by *Messrs VJ Salomone Pharma Ltd*, the PCAB maintains its position publicly expressed during the hearing, namely that the general public (in this case the tenderers) cannot be expected to suffer the consequences of any public entity's work backlog or unnecessary delays.

3. The PCAB feels that, in this instance, the contracting authority should have acted more sensibly by demonstrating more pro-activity, pragmatism and common sense. .

4. The PCAB opines that it is indeed crucial for certain Government departments or particular divisions to demonstrate more accountability and a higher degree of concern towards the general public.

As a consequence of (1) to (4) above

a. in Case Ref. No. 173 (appeal lodged by *Messrs George Borg Barthet Ltd)* this Board finds against appellant Company

b. in Case Ref. No. 174 (appeal lodged by *Messrs VJ Salomone Pharma Ltd)* this Board finds in favour of appellant Company

In view of the above and in terms of the Public Contracts Regulations, 2005, this Board recommends that

- in Case Ref. No. 173 (appeal lodged by *Messrs George Borg Barthet Ltd)* the deposit paid by the appellants to lodge this claim should not be reimbursed;

- in Case Ref. No. 174 (appeal lodged by *Messrs VJ Salomone Pharma Ltd)* the deposit paid by the appellants to lodge this claim should be reimbursed.

Alfred R Triganza Chairman	Edwin Muscat Member	Carmel Esposito Member

7 December 2009