PUBLIC CONTRACTS APPEALS BOARD

Case 97

CT 2215/2006 - Advert No 231/2006; GPS 99.005.TO6.CA - Supply of Ipratropium Bromide Nebuliser Solution

This call for tenders was published in the Maltese Government Gazette on 06.06.2006 and was issued by the Contracts Department following a request transmitted to the latter by the Government Pharmaceutical Services (GPS) on 09.02.2006.

Two (2) different tenderers originally submitted their offers.

The closing date for this call for offers was 27.07.2006 and the global estimated value of the total contract covering three years was Lm 98,556.

Following the publication of the *Notification of Recommended Tenderers*, Messrs Drugsales Ltd filed an objection on 20.12.2006 against the intended award of the said tender to Messrs Vivian Corporation Ltd.

The Public Contracts Appeals Board (PCAB) made up of Mr Alfred Triganza (Chairman) with Mr Anthony Pavia and Mr Edwin Muscat, respectively, acting as members, convened a public hearing on 02.02.2007 to discuss this objection.

Also present for the hearing were:

Drugsales Ltd

Prof Ian Refalo	Legal Representative
Mr Alfred Gera de Petri	
Ms Giulia Gera de Petri	
Dr Andrea Gera de Petri	

Vivian Corporation Ltd

Dr Albert Grech	Legal Representative
Dr Stephania Zerafa	Legal Representative
Ms Joanna Cremona	
Ms Maria Formosa	

Government Pharmaceutical Services (GPS)

Ms Anna Debattista	Director GPS

Following the Chairman's brief introduction, Prof Ian Refalo, legal representative to Drugsales Ltd, the appellants, started by stating that his clients' offer was cheaper than that submitted by the recommended tenderer, namely Vivian Corporation Ltd, by about Lm17,000. He pointed out that their product was registerable in terms of the current regulations.

The appellants' lawyer argued that, in view of the fact that

a. the product offered by his clients was in accordance with specifications and registered in the United Kingdom, and

b. his clients had specifically declared that they were going to register the product if awarded the tender,

the said product was fully qualified to be considered and should not have been excluded on the basis of its lack of registration.

Furthermore, the appellants' legal representative insisted that the regulations for this type of registration should have been put in place before the tender was issued in June 2006.

Prof Refalo remarked that the new regulations that came into force provided for the possibility of the registration of a product even if, when offered to the authorities, it was still unregistered. He pointed out that there were instances where medicinal products were even registered after award of contracts.

Dr Albert Grech, legal representative of Vivian Corporation Ltd, responded by stating that tenderers were obliged to abide by the conditions of this particular tender which stipulated that the product had to be registered. At this stage he made reference to paragraph 3b in the *Declaration Sheet for Medicinal Products – A* wherein tenderers were required to indicate that the product was effectively registered under 'PMA/MA/EU (delete where applicable)' and also it was stipulated that '*If this is not completed in ALL respects, where applicable, offer will not be considered*'. Dr Grech said that it was clear that the appellants did not fulfil the tender requirements.

Ms Joanna Cremona, also representing Vivian Corporation Ltd, explained that the Medicines Authority introduced a system whereby all medicinal products that were registered with a valid Certificate of a Pharmaceutical Product (CPP) prior to November 2002 were granted a Provisional Marketing Authorisation (PMA) after submission of the necessary dossiers. When the required documentation was positively assessed, a full Marketing Authorisation (MA) was then issued for such products. She contended that the appellants' product could not be registered at tendering stage in view of the regulations that were in force at that time.

Mr Alfred Gera de Petri, representing the appellants, clarified that, prior to the accession to the EU, Malta did not have registration procedures of medicinal products. He said that Malta was given a derogation for the introduction of such procedures and that during the

transition period there were many problems due to the different types and complexity of registrations and the small size of the island, which were sorted out only some time before the end of the derogation period. Mr Gera de Petri declared that they included the above mentioned condition in their bid because the tender was issued during the transition period and the regulations were not yet defined.

Mr Gera De Petri further explained that there were three types of procedures recognised for a Marketing Authorisation to be granted as well as for the said product to be able to be placed on the Maltese market, namely

(i) the National Registration which was very expensive;
(ii) Mutual Recognition Process which could be achieved by asking other Member States to mutually recognise the Marketing Authorisation granted by the Reference Member State; and
(iii) Article 126a.

He contended that albeit their overseas suppliers wanted to register their product under Article 126a, yet they could not submit such an application because, at tendering stage, discussions on this type of registration were not yet concluded.

Ms Anna Debattista, Director Government Pharmaceutical Services (GPS), when cross examined by the PCAB, gave some background information about the registration procedures of medicinal products. She said that prior to EU accession medicinal products were placed on the Maltese market by the submission of a valid Certification of Pharmaceutical Products (CPP). During the negotiations for accession, Malta was granted a transition period on the registration of pharmaceuticals up to December 2006 since all products placed on the Maltese market had to be registered before they could be sold in Malta. According to Ms Debattista, medicinal products with a CPP were first granted a PMA, subsequently proceeding to a full MA in line with EU requirements. She said that, given a number of factors, there were various problems and the end result was a drop in the number of medicines available on the market.

The same witness declared that in this particular tender's conditions it was stipulated that the product had to be registered up to the closing date of tender. She said that when they assessed the two bids it resulted that the product offered by Drugsales Ltd was cheaper and according to specifications but it did not fulfil the registration criterion while that submitted by Vivian Corporation Ltd was registered under the PMA procedure and complied with the specifications. Ms Debattista emphasised that the offers could only be adjudicated on the basis of the tender conditions as at closing date of tender.

In reply to a specific question by the PCAB, Ms Debattista declared that the regulatory conditions did not preclude anyone from applying for the registration of medicinal products provided that applicant/s complied with the local regulations of the Medicines Authority. The appellants' product could be registered under the MA procedure subject to all appropriate documentation being presented. When asked about the number of days

taken for an application to be processed from the date it is submitted, the witness replied that these were specified in the legislation.

In his concluding remarks Prof Refalo invited the PCAB to look at Article 126a. He explained that according to EU law, as reflected in the Treaty, they had a right for a Marketing Authorisation under Article 126a but, in practice, it was not possible because the discussions concerning the registration procedures were not yet concluded. The appellants' lawyer reiterated that this type of registration was put in place only in December 2006 following agreement reached by the Malta Chamber of Pharmacists and the Health Authorities. Prof Refalo pointed out that his clients had since submitted an application for the registration of their product. However, he insisted that the state was obliged to make the registration possible under this article before the tender was issued.

When asked to state whether any clarifications had been sought on the matter from the tendering authority, Mr Gera de Petri replied in the negative and the reason given was that any queries raised could not be answered in view of the fact that discussions were still underway and too complicated to be addressed at the time. Nevertheless, he added that, during the tender adjudication process they could have been contacted about the alternative offered in their tender.

Dr Stefania Zerafa, also acting as legal representative to Vivian Corporation Ltd, contended that her clients' offer was submitted in accordance with all the conditions and requirements of the tender.

On her part, Ms Cremona concluded by remarking that in other instances, whenever Vivian Corporation Ltd did not submit tenders which were not in order with terms and conditions, these were rejected.

At this stage the hearing came to a close and the PCAB members proceeded with their deliberations before reaching their decision.

This Board,

1 having noted that the appellants, in terms of their 'reasoned letter of objection' dated 21.12.2006, and also through their verbal submissions presented during the public hearing held on 02.02.2007, had objected to the decision taken by the General Contracts to award the tender to Messrs Vivian Corporation Ltd;

2 having noted that appellants' arguments against them being unjustifiably excluded on the basis of lack of registration of product offered;

3 having considered Vivian Commercial Ltd's legal advisor's claim regarding the fact that tenderers were obliged to abide by the conditions of this particular tender which stipulated that the product had to be registered, as well as the fact that in not being duly registered, appellants did not fulfil the tender requirements;

4 having also noted Mr Gera de Petri's chronological rendition of facts, as well as, the explanation given relating to the three types of procedures recognised for a Marketing Authorisation to be granted;

5 having also noted the evidence given by the Director GPS, especially her statement regarding the fact that in this particular tender's conditions it was stipulated that the product had to be registered up to the closing date of tender and that, according to the same witness, offers could only be adjudicated on the basis of the tender conditions as at closing date of tender

concludes, that

a. the Director, Government Pharmaceutical Services' explanation and description of facts are considered credible enough;

b. the decision taken by the appellants' foreign suppliers to only, conditionally, register the product is to be construed as a legitimate administrative decision which, albeit may have been regarded as commercially viable and appropriate, yet implied a non-observance of the tender's specific requirements;

c. the appellants had enough time to seek clarification or draw the attention of the pertinent authorities as regards the anomalous scenario applicable at the time of issue of this particular tender and corresponding submission of respective offer/s and, yet, no similar initiative was taken by the said appellants simply because the latter's foreign suppliers simply wanted to participate according to their own commercially-inclined rules.

As a result of the above-mentioned points, this Board decides against the appellants and in terms of the Public Contracts Regulations, 2005, this Board recommends that the deposit submitted by the appellants in terms of regulation 83, should not be refunded.

Alfred R Triganza	**Anthony Pavia**	**Edwin Muscat**
Chairman	Member	Member

26 February 2007