PUBLIC CONTRACTS APPEALS BOARD

Case No. 199

Advert No. 325/2009; CT/2360/2009; GPS 07119 T09 BB
Supply of Olanzapine 5mg and 10mg Tablets and Capsules

This call for tenders was published in the Government Gazette on 21.08.2009. The closing date for this call for offers with an estimated value of Euros 4,919,307 was 13.10.2009.

Three (3) different tenderers submitted their offers.

On 09.03.2010 *Messrs Europharma Ltd* filed an objection after its offer had been adjudicated administratively non-compliant because the package inserts were not in the English language.

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 05.05.2010 to discuss this objection.

Europharma Ltd

Mr Michael Peresso	Representative
Mr Oliver Scicluna	Pharmacist/representative

Charles De Giorgio Ltd

Mr Davis Stellini	Representative
Mr Ivan Laferla	Repersentative
Dr Antoine Cremona	Legal representative
Dr Julienne Portelli Demajo	Legal representative

V.J. Salomone Pharma Ltd

Dr John Gauci	Legal Representative
Ms Jackie Mangion	Representative
Ms Deborah Campbell	Representative of Actavis Malta Ltd

Government Health Procurement Services (GHPS)

Ms Anne Debattista	Director

Evaluation Committee

Ms Miriam Dowling	Chairperson
Mr Sonia Bonnici	Member
Mr David Baldacchino	Member
Mr Mark Spiteri	Member

Department of Contracts

Mr Francis Attard	Director General

After the Chairman's brief introduction, the appellant company was invited to explain the motives of the objection.

Mr Oliver Scicluna, representing Europharma Ltd, the appellants, stated that their offer had been adjudicated administratively and technically non-compliant because the package inserts were not in the English language. He explained that:

a. in the tender submission they had clearly indicated that the product they were offering had been registered through the 'Centralised Procedure' and had quoted the relative reference number so that the contracting authority would be able to effect its verifications;

b. the 'Centralised Procedure' was a European Medicines Agency (EMEA) registration which was considered as one of the most costly and rigorous procedures such that a product registered under this particular procedure could be marketed throughout the European Union;

c. one of the requisites of this kind of registration was that the literature accompanying the product had to be in English and even in other languages, including Maltese;

d. in order to obtain the marketing authorization the product's literature had to be in English or in Maltese and the authorization references quoted in the tender submission clearly indicated that they were offering a product in line with EU and Maltese legislation;

e. this was a new product on the Maltese market and, since it was a mass produced product, at that point in time, the manufacturing company could not produce just one sample for Malta but instead his firm submitted a representative sample the literature which was neither in the English nor the Maltese language; and

f. in envelope 2 of the tender submission, they had also submitted in English and in Maltese the 'summary of product characteristics' (SPC), which was a much more technically detailed document than the package insert, to enable the technical officers of the contracting authority to evaluate the product.

Ms Anne Debattista, representing the Government Health Procurement Services, submitted the following:

a. this call for tenders was for the supply of Olanzapine 5mg and 10 mg tablets or capsules and that Europhama Ltd had quoted only for the 10mg, which she considered in line with tender conditons;

b. section 1.5 of the 'Instructions to Tenderers' stated that "*The supplies must comply fully with the technical specifications as indicated above and conform in all respects with the indicative quantities, samples and other instructions"* and section 7 of the Annex VI 'Tender Technical and Special Conditions' provided that "*The tenderer must ensure that the following is submitted with each offer*: *a true representative sample of the product.…… Original/true copy of the outer packaging and immediate packaging labeled in one of the official languages of*

Malta. Original/true copy of the package insert in one of the official languages of Malta";

c. the samples submitted by the appellant company, both in respect of the tablets and the disintegrating ones, had their literature not in any one of the official languages of Malta but, presumably, in Slovenian, the country of manufacture. No translation thereof had been submitted;

d. as stated by the appellants themselves, the product was properly registered and that an English and Maltese version of the 'summary of product characteristics' (SPC) had been submitted, which was a much more detailed document from the technical point of view than the package insert which was meant for the consumer;

e. that, whilst confirming that, once registered, the product had to respect the local language requirements with regard to product literature, yet, she insisted that the tender *dossier* contained two specific conditions requesting a true and representative sample and that the sample submitted by the appellant company did not conform to those two conditions. She added that the adjudication board had to evaluate the tender submissions according to the conditions laid down in the tender *dossier*;

f. the product 'Zalasta' offered by the appellants was new to the Health Department;

g. this was a 3 package tender and the adjudication process was at package 2 stage and that the estimated value of this supply over a period of 36 months was put at €4.9 million; and

h. the last page of the package insert did indicate the countries where the product was registered but under the heading 'Malta' the address given read: 'KRKA' – which stood for the manufacturing company, namely, Pharma Dublin Ltd

At this point the Chairman PCAB intervened to acknowledge the fact that it was rather difficult for one to ask the manufacturer to produce a single sample in Maltese. However he queried why the appellant company failed to submit a translation of the inserts in any one of the official languages of Malta. The Chairman PCAB held that, after all, the responsibility for submitting a compliant tender rested with the bidder and that the adjudication board was bound to evaluate according to the tender conditions and specifications.

Mr Scicluna remarked that he dealt with the manufacturing company which was based in Slovenia and explained that the reference to Dublin was in terms of being the holder of the marketing authorisation and not in terms of commercial representation. He explained that the manufacturer had registered this product in all EU countries and that the file in respect of Malta had been deposited in Dublin. Mr Scicluna stressed that the fact that the product was registered meant that it had satisfied all the requirements both at local level and at EU level.

Mr Michael Peresso, also representing the appellant company, supported Mr Scicluna's contention, namely that, once the product was registered under the 'Centralised Procedure', then the product had to be delivered in Malta accompanied with the relative literature in the English or Maltese languages.

The Chairman PCAB remarked that, apparently, the language requirement with regard to the package insert was overlooked by the appellant company because he took it for granted that once the product was centrally registered the product would eventually be delivered in Malta with all relative literature in our official language/s, adding that tenderers were expected to abide by all tender requirements and that any deviations had to be exhaustively explained.

Mr Scicluna remarked that his supplier in Slovenia had informed him that, at that point in time, they did not have a sample of the product with all the packaging in English. He reiterated that the registration reference number quoted in the tender submission was verifiable on the websites of the competent authorities and that he expected that one of the basic verifications that the adjudication board would carry out as part of its evaluation exercise was to check that the product was registered as per reference number quoted. Mr Scicluna found it odd that his offer was being excluded for administrative and technical grounds when, for technical evaluation purposes, they had submitted the 'summary of product characteristics' in English and in Maltese which was far more detailed than the package insert.

On her part, Ms Debattista agreed that the 'summary of product characteristics' (SPC) was a highly technical document meant for specialised professionals whereas the patient information leaflet (package insert) was meant for the man-in-the-street. However, she also remarked that when a product was registered in a country it was a basic requirement that the package of that product had to be in the official language/s of that same country.

Dr John Gauci, representing Messrs V.J. Salomone Pharma Ltd, an interested party, referred to Case No. 174 CT 2574/08 where a tenderer had been excluded for submitting the sample in the French language and the package insert in the English language because that was considered in conflict with the tender conditions.

Replying to a question raised by the PCAB, Ms Debattista informed the PCAB that a tenderer could bid either for the 5mg or for the 10mg or for both dosages in which case each dosage had to be provided in the same formulation, i.e. both had to be in the form of a tablet/capsule or in the form of an orally disintegrating tablet.

Dr Antoine Cremona, legal advisor of Messrs Charles de Giorgio Ltd, a tenderer which had, similarly, lodged an appeal on this same tender, while acknowledging that this issue did not directly concern his client's case, argued that Annex II 'Item Description' indicated 'Olanzapine 5mg and 10mg tablets/capsules or orally disintegrating tables' which meant that the tenderer did not have the option to bid for one of the two dosages but the said tenderer had to bid for both dosages and that the option applied only as to the formulation, i.e. whether in tablet/capsule form or in a disintegrating tablet form.

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 09.03.2010 and also through their verbal submissions presented during the public hearing held on 5.05.2010, had objected to the decision taken by the General Contracts Committee;

- having taken note of Mr Scicluna's (a) reference to the fact that in its submission the appellant Company had quoted the relative reference number so that the contracting authority would be able to effect its verifications, (b) reference to the fact that the 'Centralised Procedure' was a European Medicines Agency (EMEA) registration which was considered as one of the most costly and rigorous procedures such that a product registered under this particular procedure could be marketed throughout the European Union and that one of its requisites was that the literature accompanying the product had to be in English and even in other languages, including Maltese, (c) argument that in order to obtain the marketing authorization the product's literature had to be in English or in Maltese and the authorization references quoted in the tender submission clearly indicated that they were offering a product in line with EU and Maltese legislation, (d) statement that in envelope 2 of the tender submission, they had also submitted in English and in Maltese the 'summary of product characteristics' (SPC), which was a much more technically detailed document than the package insert, to enable the technical officers of the contracting authority to evaluate the product;

- having also taken note of Mr Scicluna's statement that this was a new product on the Maltese market and that, since it was a mass produced product, at that point in time, the manufacturing company could not produce just one sample for Malta and that his firm submitted a representative sample the literature of which was neither in the English nor in the Maltese language;

- having considered Ms Debattista's intervention especially the emphasis placed on the content of section 7 of the Annex VI 'Tender Technical and Special Conditions' of the tender dossier which, *inter alia*, states that, with each offer, a tenderer must submit an "…… *Original/true copy of the outer packaging and immediate packaging labeled in one of the official languages of Malta. Original/true copy of the package insert in one of the official languages of Malta"*;

- having taken into consideration the fact that the samples submitted by the appellant company, both in respect of the tablets and the disintegrating ones, had their literature not in any one of the official languages of Malta but, presumably, in Slovenian, the country of manufacture and that no translation thereof had been submitted;

- having also considered Ms Debattista's argument relating to the fact that , whilst confirming that, once registered, the product had to respect the local language requirements with regard to product literature, yet, she insisted that the tender *dossier* contained two specific conditions requesting a true and representative sample and that the sample submitted by the appellant company did not conform to those two condition;

- having taken particular cognizance of the fact that the adjudication board had to evaluate the tender submissions according to the conditions laid down in the tender dossier including the possibility to assess the product 'per se' as well as the extent of consumer information being provided with a view that the latter's protection is guaranteed, especially considering that the product being offered, namely 'Zalasta' was new to the Health Department;

- having also considered the appellants' claim that (a) the manufacturer had registered this product in all EU countries and that the file in respect of Malta had been deposited in Dublin and (b) the fact that the product was registered meant that it had satisfied all the requirements both at local level and at EU level

reached the following conclusions, namely:

1. The PCAB, albeit being highly aware of the difficulty that one could encounter when asking a manufacturer to produce a single sample in Maltese or English (Malta's official languages), yet is equally aware of the fact that tender specifications, terms and conditions should be observed and, in this instance, the PCAB feels that the tender dossier's content was unequivocal, namely, that a tenderer should have submitted an "…… *Original/true copy of the outer packaging and immediate packaging labeled in one of the official languages of Malta"* as well as an *"Original/true copy of the package insert in one of the official languages of Malta"*.

2. The PCAB agrees with contracting authority's representative that although the product was properly registered and that an English and Maltese version of the 'summary of product characteristics' (SPC) had been submitted which was a much more detailed document from the technical point of view than the package insert which was meant for the consumer, yet, technically, it is a fact that the appellant company did not deliver what was expected as far as the ultimate consumer is concerned, an issue more than adequately covered by the phrase … *"Original/true copy of the package insert in one of the official languages of Malta"*.

3. The PCAB fails to understand why the appellant company did not submit a translation of the inserts in any one of the official languages of Malta arguing that, contrary to what had been submitted by the appellant company's representative, the responsibility for submitting a compliant tender rests with the bidder and that the adjudication board should never be expected to carry out verifications which go beyond its remit.

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	Edwin Muscat
Chairman	Member	Member

18 May 2010