PUBLIC CONTRACTS APPEALS BOARD

Case No. 129

CT 2168/2007 – Adv No 263/2007 – GPS 03008 TO7 DC Tender for the Supply of Ceftriaxone 2gr Injections.

This call for tenders was published in the Government Gazette on 13.07.2007.

The closing date for this call for offers was 04.09.2007 and the estimated contract value (36 months) was Lm 310,628 (€ 723,546).

Six (6) different tenderers initially submitted their offers but only two (2) were allowed to proceed to the following stage which related to the opening of the financial proposals.

Following the negative reply received following its request to be granted an extension to obtain the marketing registration of their product from the Medicines Authority which would have qualified its bid to continue participating in this tendering process, *Messrs* EuroPharma Ltd filed an objection in regard on 27.02.2008.

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 04.06.2008 to discuss this objection.

Present for the hearing were:

EuroPharma Ltd
Mr Oliver Scicluna — Manager

V. J. Salamone Ltd
Mrs Jackie Mangion

Government Health Procurement Services
Ms Anna Debattista — Director
Ms Isabelle Grima — Assistant Director

Contracts Department
Mr Mario Borg — Asst Director Post Contracts

Absent

Although Cherubino Ltd were informed about the public hearing no representative attended the hearing.

After the Chairman's brief introduction, Mr Oliver Scicluna, representing EuroPharma Ltd, the appellant Company, was invited to explain the motive which led to his Company's objection.

According to Mr Scicluna, on the 22nd February 2008, EuroPharma Ltd were informed by the Department of Contracts that

(i) their bid for the supply of Cefriaxone 2gr Injections to the Health Department was not among the selected ones as it had been adjudicated not compliant with the tender specifications since the product was not registered

(ii) they had up to the 28th February 2008 to submit an objection.

The same appellants' representative stated that on the 28th February 2008 they lodged their appeal with the Contracts Department explaining that they had submitted an application to the Medicines Authority to register their product and that the approval was due to be issued within a couple of weeks. Moreover, the attention of the Contracts Department was drawn to the fact that in most cases it was rather impossible for product registrations to be granted within six weeks – here one had to consider also the Christmas holidays - and hence they asked for an extension.

Mr Scicluna remarked that this registration should have been quite straightforward as EuroPharma Ltd had already registered the 1gr dosage of the same product and, in fact, this represented what one referred to as a line extension. This registration was not finalised by the time the Government Pharmaceutical Services made its recommendations as to which offers were compliant to move on to the next stage, that is, the opening of the third envelope, which included the 'Financial Offer'. Hence, EuroPharma Ltd requested an extension since the registration of their product was expected to be finalised within a couple of weeks and so their product would have become compliant and, therefore, qualify to the next stage of the tendering process.

To the question put forward by the PCAB as regards the procedure which had to be followed for a product to be registered, Mr Scicluna replied that one had to lodge an application with the Medicines Authority, however, the time limit for the processing of an application by the Medicines Authority was not clear and, in fact, he was aware that there was a backlog of applications for the registration of medicine at the Medicines Authority citing shortage of staff and staff training among the reasons for that state of affairs. He also informed the PCAB that the registration fee for the product in question was Euro 116 (Lm 50) and that the authorisation was renewable after five years.

Ms Anna Debattista, Director GHPS, informed the PCAB that Clause 9.1.2 of the tender conditions stated that:

> *"In the event that at the closing date for the submissions of the offer, the medicinal product being offered does not have:*
>
> *a) a valid provisional marketing authorisation, or*
> *b) a valid market authorisation, or*
> *c) a valid parallel import licence, or*
> *d) a central authorisation by EMEA*

tenderers will be allowed an additional 6-week period from the closing date of the respective tender or from the date of request from the Director General of Contracts/ Director GPS, in order to be able to register the offered medicinal product in terms of prevailing Laws of Malta."

In response to questions put forward by the PCAB, Ms Debattista stated that:

- she was not attached to the Medicines Authority, the regulatory body with regard to medicinal products registration. She added that the clause she had just quoted was inserted in the tender conditions following high level talks between Government and representatives of importers of medicines at the time when the concept of medicine registration was introduced and since then things have settled down. As already indicated, Ms Debattista continued, this clause allowed an additional 6-week period from the closing date of the respective tender, which in this case was the 4th of September 2007, or from the date of request from the Director General of Contracts/ Director GHPS, which in this case was the 4th December 2007;

- the registration of medicines should in no way be attached to the issue of tenders by government as these were two separate issues;

- six offers were received in response to this call for tenders, two were disqualified as no samples were submitted; two, namely Cherubino Ltd and V. J. Salamone Ltd were compliant and were recommended to proceed to the next stage, i.e. the opening of the third envelope; and the other two, EuroPharma Ltd and Borg Barthet Ltd, did not have their product registered by the closing date of the tender;

- the latter two companies were informed on the 4th December 2007 that they had been allowed six-weeks as per clause 9.1.2 to obtain the registration of their product, that is, up to the 15th January 2008. Borg Barthet Ltd did not react whereas EuroPharma Ltd had their product registered on the 9th April 2008, which information she obtained from the website of the Medicines Authority.

Ms Debattista asked Mr Scicluna if he could produce proof, such as, the receipt for payment effected on the submission of the application with the Medicines Authority, to demonstrate when they actually lodged their application.

Mr Scicluna reacted by saying that

(i) they did not register this dosage before because the manufacturer did not intend to export it to Malta due to marketability and it was only after this tender was issued that its registration became necessary and so, in his opinion, there was a relation between submitting bids for tenders and product registration;

(ii) the Medicines Authority did not issue them with a receipt and later added that they paid through internet banking but he could not recall the exact

date of the statement relevant to this payment but that the date was in January 2008, and

(iii) the product registration process involved paperwork and licences on the part of the supplier itself, which is a Greek firm, and on the part of EuroPharma Ltd as the middleman and that they had started the process at an early stage of the tendering procedure.

Mr Scicluna argued that this case moved at a relatively fast pace because from his experience in dealing with government tenders for the supply of medicinal products the tendering process usually took much longer to conclude and therefore they felt that it was not unreasonable to request an extension of a few weeks to enable them to obtain the registration of their product. He added that if they were to be allowed to continue participating in this tendering process it would be beneficial since there would be more competition.

In response to questions put by the PCAB regarding the marketing authorisation process of medicines, Ms Debattista said that although this process was not her responsibility she was aware that the law provided for time limits within which the Medicines Authority had to issue its authorisations.

The PCAB remarked that:

(i) it was pertinent to point out that the tender was issued in July 2007, the closing date was the 4th September 2007, the clock for the six-week period in terms of clause 9.1.2 started ticking on the 4th December 2007, which period lapsed on the 15th January 2008 and therefore, in effect, EuroPharma Ltd did not have six weeks but six months to register its product. The PCAB considered that ample time was granted to tenderers to register their product even if one considered the pace at which the Medicines Authority processed this application, i.e. 3 months from January 2008 to 8th April 2008;

(ii) it could have been the case that the Greek principals took a lot of time to submit the necessary paperwork leaving the Maltese representative with little time to do its part in which case this appeal should have been addressed to the Greek supplier;

(iii) one had to appreciate that there had to be a cut off date and that the contracting authority could not be expected to grant extensions beyond the concessions already available. The PCAB argued that, once the appellant Company was interested in participating in this tendering process, it should have taken the necessary steps to register the product from the very beginning once this registration was required for the bid to qualify for all the stages of the tendering process;

(iv) ultimately, the onus was on the tenderer to see to it that the tender documentation submitted was all in order; and

(v) one had also to be fair with the other two tenderers that were compliant with the tender specifications.

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 'letter of objection' and also through their verbal submissions presented during the public hearing held on the 04.06.2008, had objected to the decision taken by the General Contracts Committee;

- having taken note that the appellants were claiming that they had submitted an application to the Medicines Authority to register their product and that the approval was due to be issued within a couple of weeks;

- having also taken note of the fact that the appellant Company was claiming that in most cases it was rather impossible for product registrations to be granted within six weeks and that is why they were asking for a two-week extension which will enable them to become compliant and, therefore, qualify to the next stage of the tendering process;

- having established the procedure which had to be followed for a product to be registered;

- having taken cognizance of Ms Debattista's statements especially those referring to (a) the actual time frames allocated, and (b) the fact that the registration of medicines should in no way be attached to the issue of tenders by government as these were two separate issues;

- having established that the appellant Company did not register this dosage before because the manufacturer did not intend to export it to Malta due to marketability and it was only after this tender was issued that its registration became necessary;

- having also noted that, ironically, Mr Scicluna claimed that this case moved at a relatively fast pace because from his experience in dealing with government tenders for the supply of medicinal products the tendering process usually took much longer to conclude and therefore they felt that it was not unreasonable to request an extension of a few weeks to enable them to obtain the registration of their product;

reached the following conclusions, namely, the PCAB:

1. agrees with Ms Debattista that the registration of medicines should in no way be attached to the issue of tenders by government as these were two separate issues;

2. cannot take seriously the comment made by the appellants' representative who, *inter alia*, stated that this case moved at a relatively fast pace because, from his experience in dealing with government tenders for the supply of medicinal products, the tendering process usually took much longer to conclude and, therefore, they felt that it was not unreasonable to request an extension of a few weeks to enable them to obtain the registration of their product;

3. argues that ample time was granted to tenderers to register their product considering that although the original time frame envisaged was six weeks, yet, one cannot but notice that, in actual fact, six months were made available for a potential tenderer to regularise one's product's registration, namely, between July 2007 and January 2008. The PCAB argues that, once the appellant Company was interested in participating in this tendering process, it should have taken the necessary steps to register the product from the very beginning considering that this registration was required for the bid to qualify for all the stages of the tendering process;

4. appreciates that there has to be a cut off date and that the contracting authority cannot be expected to grant extensions beyond the concessions already available;

As a consequence of (1) to (4) above this Board finds against appellants.

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 not be refunded.

Alfred R Triganza	Anthony Pavia	Edwin Muscat
Chairman	Member	Member

25 June 2008