PUBLIC CONTRACTS APPEALS BOARD

Case No. 260

Adv. No. NP 53/2009 - CT 2031/2010 - 10046 T08 RZ
Tender for Supply of Pulmonary Surfactants for Intra-Tracheal Use

This call for tenders was published in the Government Gazette on 28h January 2010. The closing date for this call for offers with a department estimate of € 22,300 was 18th February 2010.

One (1) tenderer had originally submitted their offers.

V. J. Salomone Pharma Ltd, on behalf of Abbott Laboratories filed an objection on 19th November 2010 against the decision by the Contracts Department to disqualify its offer on being found non-compliant and to recommend the cancellation of the tender.

The Public Contracts Appeals Board composed of Mr Alfred Triganza as Chairman and Mr. Edwin Muscat and Mr. Carmel Esposito as members convened a public hearing on Wednesday, 9th February 2011 to discuss this objection.

Present for the hearing were:

VJ Salomone Pharma Ltd

Dr Jonathan de Maria	Legal Representative
Ms Vanessa Said Salomone	Executive Director
Mr Jackie Mangion	Operations Manager

Government Health Procurement Services (GHPS)

Ms Anne Debattista	Director

Evaluation Board

Ms Miriam Dowling	Chairperson

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 Company's objection.

Dr Jonathan de Maria, legal representative of VJ Salomone Ltd, the appellant company, stated that by way of letter dated 19th November 2010 the Department of Contracts informed his client that the company's offer was adjudicated as non-compliant since the shelf-life and delivery period were not according to tender specifications and conditions.

Dr de Maria explained that this product was required for babies born prematurely who did not have their lungs fully developed and functional and the absence of this product could result in infant fatalities. The appellants' legal advisor added that, albeit, there were other suppliers of this product - for which there were no generic alternatives – yet, locally, only his client supplied the volume/dosage required for premature babies born with a weight of 700g and over and that there was only one manufacturer of this product, Abbott Laboratories in the US.

Dr de Maria then referred to a document dated 15th November 2010 which stated, among other things, that:

- *Survanta® is a lung surfactant that is introduced into the lungs of premature infants who cannot produce their own lung surfactant. It is a life-saving drug.*

- *Survanta® is manufactured by Abbott in the US and has 18 months of Shef-life in total.*

- *After manufacture of the primary Active Pharmaceutical Ingredient by Abbott in North Chicago, Survanta® drug product is manufactured in another Abbott site in North Chicago. QA release takes around 2 months, after which product is shipped to Abbott's Central Distribution Centre in the Netherlands.*

- *Between the manufacture of the API and final receipt of finished product in the Netherlands, there are usually around 4 months*

- *For EU markets product still needs to be re-tested after arrival in the EU. Lead time for EU retesting is around 3 months, due to the rat lung activity test. Because of very high cost of testing, Abbott manufactures 1 master lot every 3 months that is used for multiple EU countries.*

- *The above is the reason that the remaining Survanta Shelf-life after EU release is usually around 12 months. Then it takes another 3 months before the next EU released lot is available.*

Dr de Maria remarked that calls for tenders for the supply of this product were being repeatedly cancelled because the supplier could not meet the shelf-life and delivery conditions set out in the tender document. Dr de Maria added that, in the meantime, the contracting authority resorted to a direct order from a wholesaler in the UK who offered the same product at a higher price, namely €448 per vial than that offered by his client in the tender submission, i.e. €350 per vial.

Ms Jackie Mangion, also representing the appellant company, confirmed that the only manufacturer of this product was Abbott Laboratories though there could be more than one supplier. Ms Mangion remarked that since this product was manufactured every 3 months it was important for the supplier to know the approximate order dates so as they could try to obtain the supply from newly manufactured batches. Ms Mangion stated that they could supply even one single vial on demand and if the standby stock were to be availed of in one go they would instantly restock the Government Health Procurement Services with this product but not with the stipulated 5/6 remaining shelf-life.

It was confirmed that the only local client of this product was Mater Dei Hospital, notwithstanding that there were other private hospitals.

Ms Anne Debattista, Director Government Health Procurement Services, gave the following explanations:

- she categorically dismissed the notion that the present state of affairs with regard to the availability of this product was putting the lives of infants in danger but confirmed that the department had an adequate stock at all times;

- this specific product was being supplied for two instances, namely for premature babies born with a weight under 700g and over 700g;

- the Government Health Procurement Services, acting on the advice of Mater Dei Hospital, kept a relatively small standby stock of this product so much so that, as at the end of 2010, they kept 16 vials. Moreover, besides consumption having an irregular pattern, it was emerging that the use of this product was on the decrease because the recent trend was that premature babies were weighing less than 700g and so the issue of the expiry date was assuming more relevance;

- over the past few years consumption was as follows: in 2006 - 77 vials, 2007 – 73 vials, 2008 – 56 vials, 2009 – 23 vials and in 2010 – 44 vials;

- the document referred to earlier on and issued by Abbott Laboratories was the result of a specific request made by the Government Health Procurement Services because the Government Health Procurement Services had suspected that something might have changed in the supply chain and it had to be noted that the document was issued in November 2010 when the closing date of the said tender was February 2010;

- the Government Health Procurement Services expected suppliers to keep it informed with (a) regulatory changes, (b) developments in the production process or (c) changes to the product profile that, inevitably, affected the supply and delivery of medicines so that the contracting authority would give it due consideration;

- although the manufacturer's declaration stated that the product could not be supplied with a remaining shelf-life in excess of 12 months, on three previous occasions the appellant

company had supplied this same product from the same manufacturer with a 15 month remaining shelf-life, which worked out at 5/6 remaining shelf-life as per tender conditions and there were other instances when the remaining shelf-life varied from 13 months 3 weeks to 6 months 3 weeks;

- the appellant company was offering this product on the following conditions, 6 to 8 weeks delivery period with 30 to 65 % remaining shelf-life or 6 to 26 weeks delivery period with 65 to 75% remaining shelf-life when the tender conditions as per clause 11 'Shelf-life' read as follows:

  > *"The shelf life of the product must be clearly indicated in the Tender documents submitted. Goods received at Government Health Procurement Services must not have their shelf-life expired by more than one-sixth of their total declared shelf-life. Any infringement in this respect will render the tenderer liable to a penalty of 5% of the value of the consignment, together with any other damages suffered by the Government Health Procurement Services.*
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  > *When five-sixths of the total shelf-life is less than 2 years, the tenderer must clearly state this on the tender documents. Products with a longer shelf-life will be given preference."*

- whilst it was a practice that suppliers who delivered products with a remaining shelf-life different from that stipulated in the tender document would replace expired items or else issue credit notes, yet, if the product was supplied according to specifications then the Government Health Procurement Services would not expect the supplier to replace expired items or to refund the relative cost;

- the appellant company was refusing to replace expired stock which was not supplied according to tender specifications;

- in other European countries the delivery of medicines was carried out within 2 to 3 or 7 days with a 2/3 remaining shelf-life whereas in Malta the Government Health Procurement Services was requesting 6 to 8 weeks with a 5/6 remaining shelf-life - keeping in view that there were frequent flights to most European destinations;

- Government was reviewing on an on-going basis the procurement procedures with regard to various products and, late in 2010, it was decided that, with regard to medicines with a total shelf-life exceeding 2 ½ years, a 2/3 remaining shelf-life was being requested whereas, in the case of products with a shelf-life of less than 2 ½ years, a 5/6 remaining shelf-life was still being requested;

- the week before the hearing an order of this product - but of the smaller volume/dosage - was issued on a Thursday and delivered on a Saturday and, still, the supplier undertook to replace any unused stock or to issue a credit note and that was the norm followed when deliveries did not respect tender conditions;

- previously the Government Health Procurement Services used to store the 1.5 mls volume, yet, the volume purchased was of 3 mls in which case a vial could be used by two patients if that case arose; and

- on being contacted with regard to a recent request for the supply of this product, the appellant company had informed the Government Health Procurement Services' chemist that it could not supply the product in accordance with the requested conditions, namely with the product having a 5/6 remaining shelf-life or to replace expired stock that had not been supplied according to stipulated conditions.

The Chairman Public Contracts Appeals Board argued that if one were to work out a programmed forecast as to when the orders for this product would be made then the supplier would make deliveries during the year in a staggered manner and, perhaps, the expiry date would not remain a crucial issue given that a new batch was manufactured every 3 months.

Dr de Maria remarked that things have changed with the introduction of EU rules whereby this product had to undergo tests that took a 3 month period and, as a consequence, his client could only guarantee a remaining shelf-life of not more than 12 months. The appellant company's legal advisor added that, with regard to this product, his client wished to engage with the contracting authority on an exercise detailing an annual order placement schedule.

Ms Debattista stated that the Government Health Procurement Services had entered into discussions with the suppliers of this product to sort out problems that were being encountered, which talks were still in progress.

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 25th November 2010 and also through their verbal submissions presented during the hearing held on 9st February 2011, had objected to the decision taken by the pertinent authorities;

- having noted the appellant company's representatives' (a) reference to the fact that the company's offer was adjudicated as non-compliant since the shelf-life and delivery period were not according to tender specifications and conditions, (b) reference to the fact that the absence of this product could result in infant fatalities, (c) claim that only the company supplied the volume/dosage required for premature babies born with a weight of 700g and over and that there was only one manufacturer of this product, Abbott Laboratories in the US, (d) explanation relating to timeline involved between manufacture of product in North Chicago – QA release prior to dispatch to the Netherlands (+ 2 months) - final receipt of finished product in the Netherlands (+ 4 months) – EU market testing of non EU manufactured product (+ 3 months), (e) reference to the fact that calls for tenders for the supply of this product were being repeatedly cancelled because the supplier could not meet the shelf-life and delivery conditions set out in the tender document, (f) claim that , in the meantime, the contracting

authority resorted to a direct order from a wholesaler in the UK who offered the same product at a higher price, namely €448 per vial than that offered by his client in the tender submission, i.e. €350 per vial and (g) reference to the fact that, with regard to this product, the company wished to engage with the contracting authority on an exercise detailing an annual order placement schedule;

- having considered the contracting authority's representative's reference to the fact that (a) besides consumption having an irregular pattern, it was emerging that the use of this product was on the decrease because the recent trend was that premature babies were weighing less than 700g and so the issue of the expiry date was assuming more relevance, (b) reference to the fact that although the manufacturer's declaration stated that the product could not be supplied with a remaining shelf-life in excess of 12 months, on three previous occasions the appellant company had supplied this same product from the same manufacturer with a 15 month remaining shelf-life, which worked out at 5/6 remaining shelf-life as per tender conditions, (c) whilst it was a practice that suppliers who delivered products with a remaining shelf-life different from that stipulated in the tender document would replace expired items or else issue credit notes - the appellant company was refusing to replace expired stock which was not supplied according to tender specifications - yet, if the product was supplied according to specifications then the Government Health Procurement Services would not expect the supplier to replace expired items or to refund the relative cost and (d) the Government Health Procurement Services had entered into discussions with the suppliers of this product to sort out problems that were being encountered, which talks were still in progress,

reached the following conclusions, namely:

1. The Public Contracts Appeals Board opines that, logically, the appellant company's arguments brought forward in this hearing make more than sense. Existing stock turnover of product in question should pose no difficulty in being serviced by the appellants' foreign supplier. Nevertheless, it is also a fact that no tenderer is allowed to change terms and conditions as one deems fit and this solely with a view to accommodate the parameters within which such tenderer needs to operate. Furthermore, no contracting authority is at liberty to change the terms and conditions of a tender which should always remain applicable to all potential participants within the same level playing field. As a result, this Board decides against the appellant company in view of the fact that, for whatever reason, whether justified or not, it has fallen short from promising delivery of product within the parameters as stipulated in the said tender conditions as published by the contracting authority.

2. The Public Contracts Appeals Board, however, feels that, in the foreseeable future, specifications of similar tenders should be revised in order to ensure that such anomalies will not recur and more pragmatism and common sense prevails in procurement exercises of this nature.

In view of the above this Board finds against the appellant company and also recommends that the deposit paid by the appellants should not be reimbursed.

Alfred R Triganza Chairman	Edwin Muscat Member	Carmel Esposito Member

16 February 2011