PUBLIC CONTRACTS APPEALS BOARD

Case No. 128

Adv No 324 /2006 - CT 2 280 /2006 - GPS 10008 T05 RZ - Tender for the Supply of Concentrated Bicarbonate Kits

This call for tenders was published in the Government Gazette on 18.08.2006.

The closing date for this call for offers was 101.10.2006 and the estimated contract value was Lm 153,948 (€ 358,591).

Three (3) different tenderers submitted their offers.

Following the publication of the 'Notification of Recommended Tenderers', *Messrs* Pharma-Cos filed an objection on 18.01.2008 against the award of the tender in caption to Associated Equipment 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 04.06.2008 to discuss this objection.

Present for the hearing were:

Pharma-Cos Ltd

Dr Antonio M Tufigno	Legal Representative
Mr Tim Kamradt	Senior Area Manager South East Europe – Fresenius Medical Care GmbH
Mr Gordon Voelksen	Area Manager South East Europe – Fresenius Medical Care GmbH
Mr Claudio U. Martinelli	Senior Product Specialist
Mr James Borg	Product Specialist
Mr Marcel K Mifsud	Director

Associated Equipment Ltd

Mr Charles Mifsud

Government Health Procurement Services (GHPS) – formerly known as *Government Pharmaceutical Services* (GPS)

Ms Anna Debattista	Director
Ms Isabelle Grima	Assistant Director

Adjudication Board

Ms Miriam Dowling	Chairperson
Ms Sharon Zerafa	Member
Mr Anthony Bugeja	Member

After the Chairman's brief introduction, Dr Antonio M Tufigno, legal representative of Pharma-Cos Ltd, the complainants, was invited to explain the motive which led to his clients' objection.

Prior to commencing his intervention Dr Tufigno asked whether it was possible for the hearing to be held in English in view of the presence of his clients' principals who are foreigners. All parties concerned agreed with Pharma-cos Ltd's representatives' recommendation for the proceedings to be held in English.

Dr Tufigno started by stating that his clients decided to file their objection in respect of the tender issued for the supply of 'Concentrates for Bicarbonate Kits' because they failed to understand why their offer was not accepted considering that it was

(i) compliant with all the tender specifications and
(ii) considerably cheaper than the one recommended for award, namely Associated Equipment Ltd.

He claimed that the documentation supplied with their objection clearly showed that if his clients' offer in respect of the 650g cartridges were to be accepted, it would result in savings of € 35,902.57 over a three-year period.

Ms Anna Debattista, Director Government Health Procurement Services (GHPS) responded by stating that they were not contesting that the appellants' offer was cheaper. However, she remarked also that the price was not the sole criterion upon which offers were adjudicated.

At this point Ms Debattista introduced Mr Anthony Bugeja who is the officer in charge of the Renal Unit as well as the technical member on the Adjudication Board. According to Ms Debattista, Mr Bugeja's presence was aimed at providing those present with pertinent reasons as to why the offer submitted by Pharma-Cos Ltd was deemed as not being according to specifications.

On cross-examination by the Chairman, PCAB, the Adjudication Board's technical member testified that the appellants' offer was not according to the tender specifications. He pointed out that this statement was corroborated also by Dr M P Vella, Consultant Physician, and Mr John Caruana, Nursing Officer. He declared that the Adjudication Board was unanimous in its recommendations to reject the appellants' offer.

Mr Bugeja explained that the tender consisted of two items, namely Item 'A' - Acid Solution, and Item 'B' - Sodium Bicarbonate Cartridges. He said that these two items were mixed with specially treated water for use in the kidney machine. The witness explained that they requested Items 'A' and 'B' to be made by the same manufacturer because in the past, when these two items were supplied by different manufacturers and they encountered some problems, the contracting authority could not identify which party's supply was giving rise to the problem.

Although the suppliers of Items 'A' and 'B' of Associated Equipment Ltd's were from Sweden and Germany respectively, Mr Bugeja confirmed that both items were from the same manufacturer. It was also established that for these last years these

products were always supplied by Associated Equipment Ltd, however, in previous years they used to have other suppliers.

In reply to a specific question by the PCAB, Mr Bugeja testified that Pharma-Cos Ltd's offer was rejected due to the storage temperature and the formulations. He claimed that while the tender specifications requested a storage temperature of up to 40˚ C without losing consistency, the label on the samples and package insert submitted by the appellants specified a temperature of up to 30˚ C.

Mr Bugeja declared that (i) the appellants did not have all the formulations (7 out of 15) requested within the specifications and (ii) Messrs Associated Equipment Ltd gave all the formulations required. He explained that they requested different formulations for the kidney machines in order to meet the requirements of all patients since each individual required a specific formulation. Mr Bugeja said that the formulations were calculated according to the type of blood of each patient.

The same witness added that, in the past, there were instances where companies indicated that they could produce custom made formulations.

When the PCAB questioned whether the appellants were asked to state whether they were in a position to provide all the required formulations, Ms Debattista said that, once the adjudication board declared in its technical report that they were not according to specifications, they did not see the scope of seeking clarifications.

Dr Tufigno remarked that in view of the fact that the only reasons mentioned by the witness for the rejection of his clients' offer were the storage temperature and the formulations, then they understood that the other reason, namely that there were no parking holders did not apply. Furthermore, he pointed out that the tender specifications did not require parking holders for the 650g cartridges but only for the 700-750g and 1100-1200g cartridges.

Mr Bugeja said that no parking holder was required for the 650g cartridge because this was totally consumed on one patient within 4 hours. According to the same witness, only the bigger cartridges were required to be equipped with removal caps with parking holders for further use.

Dr Tufigno intervened by stating that this was irrelevant as only the 650g cartridges were recommended for award and that the latter two were not considered.

Ms Debattista said that the specifications under Item B – 'Sodium Bicarbonate Cartridges' stipulated that:

> *'Item b (700 to 750g) and Item c (1100 to 1200g) require to be equipped with removal caps with parking holders to reduce spillages and drippings for use between treatments.'*

When Mr Tim Kamradt, who said that he was representing the manufacturing company *Fresenius* and not *Pharma-Cos Ltd*, intervened to cross-examine Mr Bugeja, the PCAB drew Mr Kamradt's attention that any clarifications on the composition of the 'Dialysate', as well as the specifications of the tender documents, should have been sought before submitting the tender and not after. The PCAB emphasised that it

was not permissible to question the specifications after the closing date of the tender and that prospective tenderers had every right to dispute and to challenge what was written in the tender document before participating in the game because once they were participating in the game they were accepting the rules. The PCAB continued by stating that the onus of ascertaining that the needs of the customer were being satisfied did not fall on the Contracting Authority or the Department of Contracts but on who was submitting the tender. At this stage the PCAB saw it pertinent to point out that the PCAB's role was to establish whether the proper procedure had been followed and, in the prevailing circumstances, prospective tenderers had two choices, namely, either to seek clarifications on the tender specifications before the closing of the tender or else, if they were not satisfied that they could meet them, not to submit their bid.

Mr Kamradt claimed that, although he understood the PCAB's arguments in regard to the timing of clarifications, they still felt that their offer was compliant since variations between the products they offered and those requested in the tender document were minimal. He explained that the questions were not related to the design of the tender but were intended to prove that small tolerances in the composition of the Dialysate occurred anyhow due to the daily changes in the nutritional status of each dialysis patient.

At this point Mr Kamradt asked Mr Bugeja to confirm whether in every *Dialysis* machine, when mixing ready-to-use 'Dialysate', there were slight tolerances which had to be taken into consideration. Albeit the witness's reply was in the affirmative yet, he contended that the formulations had to be as accurate as possible.

Mr Kamradt declared that the storage temperature put on the label of the 'Bicarbonate Cartridge' was according to the European *Pharmacopoeia* which is a manufacturing practice/standard for medicinal devices. In this instance this listed a range between 30˚ C and 40˚ C for 'bicarbonate cartridges' to be stored. However, Mr Bugeja said that in the tender specifications they requested a storage temperature of 40˚ C because they had to ensure that the product would not fail them while stored in Malta as it was a life saving product. At this stage, Ms A Debattista intervened to textually quote from the tender specifications which stipulated that:

> *'Tenderer should provide certification that bicarbonate offered is for use in haemodialysis and that it can be stored up to a temperature of 40 c without losing consistency.'*

On examining the sample which was exhibited by the appellant Company during the hearing, the Director GHPS said that the label specified a temperature of up to 30˚ C. When she asked Mr Kamradt to state why their product was not labelled accordingly if they were stating that it could be stored up to 40˚ C, he said that this was not necessary and insisted that in any case the content of the bicarbonate always remained stable up to a temperature of 40˚ C.

Whilst *Fresenius'*s representative maintained that the storage temperature was not a justified reason for Pharma-Cos Ltd's offer being rejected, the Director GHPS claimed that only the principal company knew this because they were the manufacturers, stating that, if the Department's clinical people were to use their product, they would only see a maximum storage temperature of 30˚ C as clearly

indicated on its label. She claimed that, apparently, the policy of the said manufacturing company was to have the same standard label irrespective of the area where the product was marketed. The Director GHPS questioned if there was any problem for their company to label the product specifically for Malta's climatic conditions. The Chairman PCAB remarked that rather than labelling, this was a question of guaranteeing a product's quality.

In his intervention, Mr Marcel Mifsud, one of Pharma-Cos Ltd's representatives, said that although the label on the sample submitted had a range of +5˚ C and +30˚ C (which was according to the *Medical Devises Directive*), they also had a confirmation that the compound could be stored up to 40˚ C. When asked by the PCAB to state whether they corroborated such confirmation with documentation in their tender offer, the reply given was in the negative. Dr Tufigno intervened to stress the fact that when his clients supplied the sample they did not supply just the label but the component itself.

At this stage the PCAB pointed out that the bidder did not provide any comfort to the adjudication board at adjudication stage as it had supplied a sample which was not corroborated by documentation.

Mr Claudio Martinelli, acting on behalf of Pharma-Cos Ltd, intervened by stating that 'Sodium Bicarbonate', as a chemical component, remained stable up to 40˚ C and that such information was not taken from the label but from the component itself. The 30˚ C which was shown on the label of the package was a norm that had to be met because of the European *Pharmaceupoeia*. He said that irrespective of what was written on the label, 'Sodium Bicarbonate' was a 40˚ C product.

Dr Tufigno added that 'Sodium Bicarbonate' withstood the temperature of 40˚ C, naturally.

Another issue raised by Dr Tufigno during the hearing was that the information appearing on the *Schedule* of the decision published on 11 January 2008 by the Department of Contracts indicated that only *Item B* was recommended for award even though the call for tenders was issued for the supply of *Items A* and *B* together.

Ms Debattista rebutted by declaring that the Department of Health had recommended the award of both *Items A* and *B* respectively.

Mr Francis Attard, Director General (Contracts), testified under oath that, unfortunately, the schedule of the decisions published on the Department's *Notice Board* had some missing information in respect of which items were recommended for award and this might have given the impression that only one item was being procured. However, he declared that the General Contracts Committee had concurred with the Adjudication Board's recommendations (also endorsed by the Director, GHPS) for the purchase of both items from Associated Equipment Ltd.

Dr Tufigno responded by stating that the perception received was that there was no recommendation for award in respect of *Item A*.

In his concluding remarks Dr Tufigno made specific reference to the above-mentioned latter issue and said that Article 83 (2) (a) of the Public Contracts Regulation 2005 stipulated that:

> *'Any decision of the General Contracts Committee (or a Special Contracts Committee) and by a contracting authority, shall be made public at the Department of Contracts or at the office of the contracting authority prior to the award of the contract.'*

The appellants' legal representative argued that due to the fact that the decision made by the General Contracts Committee regarding *Item A* was never published as specifically requested by the regulations and since the lack of procedure in the decision taken in regard to *Item A* did materially affect that of *Item B* (both items had to be from the same manufacturer), the entire process was rendered null. He also submitted that his clients did not file a specific appeal on *Item A* because this item did not feature in the 'Schedule' exhibited on the Contracts Department's Notice Board and some items thereof were only mentioned because of their relation to *Item B.*

The PCAB took note of what had been stated on this issue and informed the appellants' legal representative that all such comments would be taken into consideration during the ensuing deliberations.

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' dated 28.01.2008, 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 of Mr Bugeja's full explanation of proceedings, as well as, the justification for the Adjudication Board's ultimate recommendations;

- having also noted that during the hearing Ms Debattista, Director Government Health Procurement Services (GHPS), stated that whilst they were not contesting that the appellants' offer was cheaper, yet they simply wanted to remark that 'price' was not the sole criterion upon which offers were adjudicated;

- having heard Mr Bugeja confirm that, with regards to Items 'A' and 'B' respectively, for these last years these products were always supplied by Associated Equipment Ltd;

- having established that, according to Mr Bugeja, Pharma-Cos Ltd's offer was rejected due to the storage temperature and the formulations;

- having also noted Mr Kamradt's arguments, particularly, with regards to (i) storage temperature as stated on the label vis-à-vis the storage temperature variances allowable by the same manufacturer and (ii) the fact that his Company still maintained that their offer was compliant;

- In the tender specifications the Contracting Authority had specifically requested a storage temperature of 40˚ C ("that it can be stored up to a temperature of 40 c without losing consistency");

- having also taken cognizance of the issues raised during the hearing by Dr Tufigno relating to the information appearing on the *Schedule* of the decision published on 11.01.2008 by the Department of Contracts which indicated that only *Item B* was recommended for award even though the call for tenders was issued for the supply of *Items A* and *B* together and that in view of the fact that since the lack of procedure in the decision taken in regard to *Item A* did materially affect that of *Item B* (both items had to be from the same manufacturer), the entire process was rendered null;

reached the following conclusions, namely:

1. The PCAB argues that any clarifications on terms, conditions as well as, general specifications of the tender documents, should be sought before submitting the tender and not after;

2. Albeit the manufacturers' representative had placed emphasis on the fact that the content of the bicarbonate always remained stable up to a temperature of 40˚ C, yet, Mr Kamradt acknowledged that the maximum storage temperature of 30˚ C was specifically indicated on the label of the sample submitted by the appellant Company and that no other indication had been given in their offer as regards the capability to store at the higher temperature. As a consequence this Board feels that this lack of corroboration between the manufacturers' guarantee of quality and the storage level actually stated on the label may, in a potential adverse scenario in the future, possibly lead to a distorted legal interpretation of facts;

3. It remains the prerogative of the contracting authority to decide its own tender specifications and terms and conditions as long as these allow for a level playing field as well as a realistic interpretation of what is professionally acceptable and materially available;

4. This Board cannot agree with Dr Tufigno with regards to his interpretation of the incident which emanated as a result of the Department of Contracts' oversight to include both Items ('A' and 'B') on the Department's *Notice Board*, which was fully corroborated under oath by the DG Contracts wherein the latter declared that the General Contracts Committee had concurred with the Adjudication Board's recommendations for the purchase of both items from Associated Equipment Ltd. The PCAB does not feel that the appellant Company's case for appeal was in any way rendered less strong in its legal recource. In the PCAB's opinion, there still remains the fact that the said Company refrained to abide by the rules of the tender requirements.

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