### PUBLIC CONTRACTS APPEALS BOARD

### **Case No. 132**

CT 2188/2006 – Adv. No. 131/2006 – GPS 07.207.T.05.MM Tender for the Supply of Medical Oxygen to be refilled In Cylinders -Health Division

This call for tenders was, for a contracted value of € 552,373 (Lm 237,141 equivalent) was originally published in the Government Gazette on 18.04.2006. The closing date for this call for offers was 08.06.2006.

A few objections were lodged since the original closing date causing delay in the award of this tender.

Two (2) different tenderers had submitted their offers.

Following the publication of the 'Notification of Recommended Tenderers', Multigas Ltd filed another objection on 31.07.2008 against the award of the tender in caption to Poligas 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 22.08.2008 to discuss this objection.

Present for the hearing were:

### **Multigas Ltd**

Dr Joseph Caruana Scicluna Legal Representative
Mr Vincent Bartolo Technical Representative
Mr Alister Cachia

Mr L.A. Farrugia

## **Government Pharmaceutical Services (GPS)**

Dr John Cachia Director General Health Care Services

**Adjudication Board** 

M Dowling Chairperson

A Camilleri Pharmacist - Member
J Muscat Senior Engineer - Member

C Muscat Clerk - Member

**Medicines Authority** 

Ms Helen Vella Director Pre-Licensing

Mr Mark Cilia Director Inspectorate and Enforcement

**Poligas Ltd** 

Dr George Said Legal Representative

Mr T Polidano

Prof. A Serracino Inglott Consultant

Mr Victor Fenech

**Department of Contracts** 

Mr Francis Attard Director General (Contracts)

After the Chairman's brief introduction, Dr Joseph Caruana Scicluna, representing Multigas Ltd, the appellant Company, was invited to explain the motive of the objection. This was followed by interventions by representatives of the Government Pharmaceutical Services, the contracting authority, and Poligas Ltd, the recommended tenderer, as well as the testimony given by witnesses.

Dr Caruana Scicluna explained that their only objection concerned the fact that Poligas Ltd did not meet the conditions stated in the tender document at the closing date of receipt of offers since it did not have a marketing authorisation or a provisional marketing authorisation. Moreover, Dr Caruana Scicluna requested representatives of the Government Pharmaceutical Services to state whether the authorisation number quoted by Poligas Ltd in its submission corresponded to the number of a marketing authorisation or to a provisional marketing authorisation.

Dr John Cachia, Director General Health Care Services, informed the PCAB that in the absence (due to ill health) of Ms Anne Debattista, Director Government Pharmaceutical Services, he was representing the contracting authority in her stead. Dr Cachia stated that the Declaration Sheet for Medical Products - A (henceforth referred to as *Form A*) submitted by Messrs Poligas Ltd in connection with the tender that had the closing date of 8<sup>th</sup> June 2006, had para. 3a 'Market Authorisation Holder in the country of licensing' blank whereas with regard to para. 3b referring to 'Marketing Authorisation' the following information was given: 59-2003 country of licensing Italy. Dr Cachia explained that that was an indication that the product was licensed in Italy. However, he pointed out that to distribute such a product in Malta one required a market authorisation issued by the Medicines Authority of Malta.

Dr Cachia remarked that apart from the marketing authorisation, at the closing date for the receipt of tenders there was other mandatory information missing in the tender documents submitted by Poligas Ltd and Multigas Ltd such that both tenderers could have been disqualified. Dr Cachia reported that with regard to Multigas Ltd (i) *Form A* was not filled in its entirety and (ii) no proof was given that the cylinders and the valves were compliant with the pertinent Legal Notice 331/2002.

The Chairman PCAB remarked that a clear distinction had to be made between (i) a tenderer not having a mandatory requirement, e.g. not being in possession of a marketing authorisation at the given date, and (ii) seeking clarifications on something which the tenderer was in possession of at the given date, i.e. asking for explanations to render given information more clear.

Dr Cachia remarked that the first paragraph (in italics) of *Form A* stated that:

... Where the Tenderer and the Pharmaceutical Wholesale Dealer/Importer are the same both Part II and III must be completed. If this is not completed in ALL respects, where applicable, offer will not be considered.

Dr Cachia stated that Part II and III of *Form A* submitted by Multigas Ltd had been left blank and that the filling in of *Form A* was a mandatory requirement.

Mr Vincent Bartolo, technical representative of Multigas Ltd, quoted from section 9.1 of the 'Tender Technical and Special Conditions':

A tenderer established in Malta must be duly licensed as a pharmaceutical wholesale dealer by the competent authority in Malta. When the tenderer is not established in Malta he must appoint a pharmaceutical wholesale dealer duly licensed by the competent authority in Malta in order to act on his behalf to import the medicinal product in Malta and to deliver the product to the Government Pharmaceutical Services. In this respect, Part II and Part III of Form A are to be duly filled in.

Mr Bartolo argued that this applied to a tenderer who was not established in Malta. Mr Bartolo added that if one were to refer to Part II of *Form A* one would find that this had to be filled in by a pharmaceutical wholesale dealer/importer. He stated that Multigas Ltd had a manufacturing authorisation and consequently Multigas Ltd did not require a wholesaler's license.

At this point, Dr Caruana Scicluna quoted from the email dated 19<sup>th</sup> August 2008 sent by Mr Mark Cilia, Director Inspectorate and Enforcement at the Medicines Authority, in reply to a query raised by Multigas Ltd:

The manufacturing authorisation covers also the distribution of those products manufactured under the said manufacturing authorisation. Obviously you will still need the marketing authorisation/s for products to be put on the relative market/s.

Dr Caruana Scicluna stated that this was a confirmation from the competent authority that once you had a manufacturing authorisation you did not need a wholesaler's licence and that was the reason why Part II of *Form A* was not filled in by Multigas Ltd.

With regard to Part III of *Form A*, Mr Bartolo explained that Multigas Ltd did not fill it in because Part III stated, among other things, as follows:

As a tenderer who is not established in Malta I hereby appoint the pharmaceutical dealer/importer ...

and, therefore, Part III was not applicable in the case of Multigas Ltd as it was established in Malta.

The Chairman PCAB remarked that, ideally, the contracting authority should have carried out things properly from the very beginning and thus the need for this hearing would not have arisen.

Dr Cachia said that one had to appreciate that he took over responsibility for this sector as from April 2008; however, he had gone through all the paperwork relative to this case.

The Chairman PCAB remarked that it was pointless for the contracting authority to indicate in the tender forms that certain requirements were mandatory and then allow the Adjudication Board to start making allowances for deficiencies on the part of tenderers. The PCAB argued that the way forward should have always been whether

a tenderer qualified or not because if one were to start making compromises with one party then one had to make similar compromises with the other party and then that could lead to further complications. He added that a fundamental role of the PCAB was to ascertain that the tendering process was fair with all parties concerned, which meant, that the process had to be in line with the specifications issued by the contracting authority.

Dr Cachia remarked that according to the ruling of the PCAB delivered on 26<sup>th</sup> June 2008, the contracting authority was directed to proceed with the adjudication according to the facts known at the time and not as things stood at the closing date of tender. He argued that as things were at the closing date of tender, both tenderers should have been disqualified.

Dr Caruana Scicluna made it clear that on that occasion the PCAB had ruled that the tender issued in 2006 had to be adjudicated and not cancelled.

The Chairman PCAB remarked that in its decision of the 26<sup>th</sup> June 2008, the PCAB, besides showing its dissatisfaction at the manner in which the tendering process was handled and that the decision taken by the PCAB in August 2005 had been ignored, recommended:

that the contracting authority cancels the call for quotations published in the Government Gazette on the 29<sup>th</sup> May 2008 (as per the addendum to decision on Case 127); and

that the contracting authority proceeds with the adjudication rather than the cancellation of the call for quotations whose closing date was the 8<sup>th</sup> June 2006.

The Chairman PCAB stated that this meant that one had to adjudicate on the basis of the documentation submitted on the closing date of tender, that is, 8<sup>th</sup> June 2006.

Dr Cachia referred the PCAB to the adjudication report dated 4<sup>th</sup> July 2008 wherein the Adjudication Board listed the shortcomings on the part of both tenderers, then it presented the action taken to rectify those shortcomings and, lastly, submitted the award recommendation. Dr Cachia argued that if the PCAB wished to focus only on the shortcomings of the tenderers listed in page 2 of the 'Adjudication Report', then the solution was for the PCAB to cancel the tender and to issue a fresh call for tenders.

The Chairman PCAB reiterated the view that (i) a tenderer either qualified or else it did not qualify and (ii) seeking a clarification on something that was submitted or that the tenderer possessed at the closing date of tender was one thing whereas the case of a tenderer not having had a mandatory requirement at the closing date of tender was another issue altogether.

At this point, Mr Bartolo stated that with regard to *Form A* having been submitted incomplete by Multigas Ltd, a clarification was made on the 7<sup>th</sup> March 2007 wherein Multigas Ltd stated that it did not have to fill in Part II and III of *Form A*. However, once the contracting authority kept insisting, then Multigas Ltd re-submitted *Form A* completely filled in.

The Chairman PCAB questioned how was it then that in its report dated 4<sup>th</sup> July 2008 the Adjudication Board was still referring to *Form A* as submitted incomplete by Multigas Ltd when this matter had in fact been clarified way back in March 2007. He further asked whether the clarification submitted by Multigas Ltd in this respect was satisfactory or not.

At this point the PCAB called the following witnesses to take the stand. All witnesses gave their testimony under oath.

Ms Helen Vella, Director Pre-Licensing at the Medicines Authority, declared that according to EU legislation one required a marketing authorisation from the country where the product was going to be stored and distributed. Ms Vella confirmed that Poligas Ltd did not have this marketing authorisation at the closing date of the tender.

Mr Francis Attard, Director General Contracts, in reply to a specific question by Dr Cachia stated that the direction issued by the Contracts Department to the Health Division was that, in adjudicating this tender, account had to be taken of all the clarifications made during the period in question. He added that the Contracts Department did not go into the merits of these clarifications but instructed that such clarifications had to be considered.

Mr Mark Cilia, Director Inspectorate and Enforcement at the Medicines Authority, stressed that one should not use abbreviations such as 'MA' as that might refer to a marketing authorisation or to a manufacturing authorisation.

On cross-examination by Dr Cachia, Mr Cilia explained that (i) a manufacturing authorisation authorised an establishment to manufacture the product and also to distribute that product and (ii) a wholesaler's licence authorised an establishment to distribute product/s that it did not produce itself. Mr Cilia confirmed that a manufacturing authorisation was in itself a wholesaler's licence for the product/s manufactured under that authorisation. Mr Cilia confirmed that in June 2006 Multigas Ltd had a manufacturing authorisation and, consequently, a wholesaler's licence for the medicinal products that it manufactured. Mr Cilia confirmed that in this regard he had replied to a query by Multigas Ltd by way of email dated 19<sup>th</sup> August 2008.

Ms Amanda Camilleri, Pharmacist, Government Pharmaceutical Services and Adjudication Board Member, in reply to the question by the PCAB as to why *Form A* submitted by Multigas Ltd was considered as incomplete, stated that she was aware that Multigas Ltd had a manufacturing authorisation and therefore a wholesaler's licence, however, she still requested that *Form A* be entirely filled in by Multigas Ltd for completion purposes only. She added that completely filled in forms would have been useful in case a problem arose in the future and one needed to refer to the documentation submitted by tenderers. Ms Camilleri confirmed that the details submitted by Multigas Ltd in its clarification related to the product manufactured by Multigas Ltd and not to an imported product.

At this point, the Chairman PCAB remarked that in the adjudication report of the 4<sup>th</sup> July 2008 *Form A* should not have been referred to as being still incomplete because following clarifications it was established that at the closing date of tender Multigas

Ltd in fact possessed a manufacturing authorisation and consequently a wholesaler's licence for the same product and hence the filling in of Part II and III of *Form A* was just a matter of formality for completion purposes only. At this stage, Ms Camilleri further clarified that Part II and III of *Form A* referred to cases where the tenderer was a pharmaceutical dealer/importer and that no reference was made to the manufacturer because the manufacturer assumed also the responsibilities pertaining to a wholesaler/importer since a manufacturing authorisation was in itself also a wholesaler's licence as had been explained earlier on.

The Chairman PCAB remarked that with regard to *Form A* submitted by Multigas Ltd it was emerging that it was not a case of incompleteness as such but rather a matter that required clarification.

At this point in time, there was general agreement that on the 8<sup>th</sup> June 2006, the closing date of tender, Poligas Ltd did not possess a marketing authorisation and/or a manufacturing authorisation and that it was only on the 14<sup>th</sup> June 2007 that Poligas Ltd obtained the marketing authorisation. By that time, Poligas Ltd had also obtained a manufacturing licence.

With regard to the second shortcoming attributed to Multigas Ltd, namely that of proving that the cylinders and the valves complied to LN 331/2002 as requested in Clause 3 of the General Conditions for the Supply of Medical Gas, Mr Joseph Muscat, Senior Engineer and Technical Member of the Adjudication Board, stated that a clarification was sought from Multigas Ltd in this respect and that this clarification was in fact submitted. Mr Muscat explained that they had to request certain certificates and declarations from both tenderers with regard to cylinders and valves as requested by the Malta Standards Authority and added that these certificates and declarations were not originally requested in the tender.

Mr Bartolo explained that paragraph 2.3 of LN 331/2002 provided that cylinders placed on the market before 1<sup>st</sup> July 2001 shall be outside the scope of these regulations. A Malta Standards Authority letter, dated 5<sup>th</sup> March 2007, addressed to Multigas Ltd on this issue was also referred to.

Mr Muscat explained that on the 14<sup>th</sup> March 2007 two meetings were held between representatives of the Government Pharmaceutical Services (GPS), the Contracts Department, the Foundation for Medical Services, the Health Division and the two bidders wherein the latter were requested to submit a declaration assuming responsibility for compliance with LN 331/2002 (equivalent to the Transportable Pressure Equipment Regulations of the EU) and to furnish the requested documentation as far as that was possible. Mr Muscat stated that, following these meetings, Multigas Ltd furnished the Department with the requested documentation related to the cylinders and the valves that Multigas Ltd had at the closing date of tender, confirming in the process that Multigas Ltd did not change the cylinders it had at the closing date of tender.

Mr Victor Fenech, representing Poligas Ltd, during his intervention noted that Part I para. 3a of *Form A* related to 'Marketing Authorisation Holder in the country of licensing' and that para. 3b related to 'PM/MA/EU No.' and asked whether 'MA'

under para. 3b referred to a Manufacturing Authorisation or to a Marketing Authorisation.

Mr Fenech added that, in his opinion, Poligas Ltd was compliant in 2006 because at that time Poligas Ltd intended to import the product and that their Italian supplier had authorisation from the competent Italian authorities to export and to distribute the product. At this point, the attention of Mr Fenech was drawn to the fact that it had already been established at this hearing that to market a medicinal product in Malta one required a marketing authorisation issued by the competent authority in Malta. Mr Fenech conceded that at the closing date of tender Poligas Ltd did not have that authorisation from the Maltese authorities.

On Dr Cachia's request, Mr Cilia was called again to explain the difference between a marketing authorisation and a wholesaler's licence. The witness testified that (i) the marketing authorisation related to the product and that it was issued by the country where that product was going to be distributed, in this case, Malta, (ii) a wholesaler's licence certified that the holder had all the procedures in place to store and to distribute the medicinal product and (iii) a manufacturing authorisation related to an establishment being authorised to manufacture a medicinal product and to distribute that same product.

Mr Cilia stated that he could not tell what the 'MA' under para 3b specifically referred to as that document was not drawn up by the Medicines Authority and that was why he stressed in his evidence given earlier that it was imperative for one to avoid using abbreviations such as 'MA' as this could refer both to a 'marketing authorisation' as well as a 'manufacturing authorisation'.

Prof A. Serracino Inglott, representing Poligas Ltd, explained that the process to obtain the authorisations required to manufacture and distribute a medicinal product was a lengthy and an expensive one. Prof Serracino Inglott argued that he had advised Poligas Ltd to take the acquisition of the required authorisations as 'work-in-progress' but to obtain them as expeditiously as possible. He added that he tendered this advice because it appeared to him that Poligas Ltd had not been disqualified as otherwise the relative official notice would have been issued to that effect.

The Chairman intervened to clarify that the professional advice of Prof Serracino Inglott at this stage had to be seen in the light that, at the closing date of the tender, the other tenderer, i.e. Multigas Ltd, was in possession of the tender requirements whereas Poligas Ltd did not have the marketing authorisation which was a mandatory requirement. The Chairman emphasised that the PCAB had the responsibility to look into the procedural issues of the tendering process under review.

Prof Serracino Inglott observed that this process had been dragging on for almost three years and had things taken their proper course one would have arrived at the stage of issuing another tender at which time Poligas Ltd would have had everything in place.

Dr George Said, also representing Poligas Ltd, argued that (i) mandatory requirements were self-explanatory, (ii) in this case there were shortcomings on the part of both tenderers and this issue had to be taken into consideration when deliberating and (iii)

during the whole process there was a continuous flow of correspondence between Poligas Ltd and the contracting authority.

On his part, Dr Caruana Scicluna concluded that during the hearing it resulted that, on the closing date of the tender, Poligas Ltd did not have the marketing authorisation, which was a mandatory tender requirement, and that the shortcomings attributed to Multigas Ltd in the adjudication report of the 4<sup>th</sup> July 2008 did not involve the omission of mandatory requirements but they only involved clarifications.

Dr Cachia, representing the contracting authority, stated that he stood by the report drawn up by the Adjudication Board on the 4<sup>th</sup> July 2008 in the sense that it took into account all the clarifications made up till then and that he left it up to the PCAB to deliberate on this case.

At this stage the public hearing was brought to a close and the PCAB proceeded with the deliberation before reaching its decision.

# This Board,

- having noted that the appellants, in terms of their 'motivated letter of objection' dated 05.08.2008, and also through their verbal submissions presented during the public hearing held on the 22.08.2008, had objected to the decision taken by the General Contracts Committee;
- having taken note of Dr Cachia's comments in connection with information supplied by both bidders relating to *Form A*, particularly those concerning the 'market authorisation', the 'manufacturing authorisation' and the 'wholesaler's licence' respectively;
- having observed that seeking a clarification on something that was submitted or that the tenderer possessed at the closing date of tender was one thing whereas the case of a tenderer not having had a mandatory requirement at the closing date of tender was another issue altogether;
- having considered Dr Cachia's comment relating to the fact that at the closing date for the receipt of tenders there was other mandatory information missing in the tender documents submitted by both Poligas Ltd and Multigas Ltd such that both tenderers could have been disqualified;
- having noted Mr Bartolo's statements;
- having acknowledged Dr Caruana Scicluna's argument relating as to the reason why Multigas Ltd did not fill Part III of *Form A* which was fully corroborated during the hearing by Mr Bartolo himself;
- having questioned how, in its report dated 4<sup>th</sup> July 2008, the Adjudication Board was still referring to *Form A* as submitted incomplete by Multigas Ltd when this matter had in fact been clarified way back in March 2007;

- having, through Ms Vella's testimony, established that at the closing date of the tender, Poligas Ltd did not have the 'marketing authorisation' as required in the tender specifications;
- having taken note of the DG Contract Department's reply given during the hearing relating to the fact that the Adjudication Board had to take account of all clarifications made during the period in question, namely, following the original closing date of the tender;
- having also taken note of the fact that in June 2006 the appellant Company had a 'manufacturing authorisation' and, consequently, a wholesaler's licence for the medicinal products that it manufactured;
- having heard Ms Camilleri state that she was aware that, at the time of the appellant Company's submission, Multigas Ltd had a 'manufacturing authorisation' and therefore a wholesaler's licence and that, despite this, she still requested that *Form A* be entirely filled in by Multigas Ltd for completion purposes only;
- having confirmed that on the 8<sup>th</sup> June 2006, the closing date of the tender in question, Poligas Ltd did not possess a 'marketing authorisation' and/or a 'manufacturing authorisation' and that it was only on the 14<sup>th</sup> June 2007 that Poligas Ltd obtained the 'marketing authorisation', a point which was corroborated by Mr Fenech during the hearing;
- having also noted Prof Serracino Inglott's comments and observations made relating to the procedure followed to date in connection with this particular tender;

# reached the following conclusions, namely:

- 1. the claims made in the Adjudication Board's report that the appellant Company's bid was flawed in view of the fact that this had refrained from providing mandatory information, was an error of judgement, especially, when one takes both Mr Muscat's as well as Ms Camilleri's respective testimony into consideration;
- 2. so much productive time had been wasted, especially when one considers (a) the time that the Contracting Authority, the Adjudication Board and the Contracts Committee had so far wasted in mishandling the adjudication process of this particular tender including omissions of an earlier sentence given by this Board relating to a previous appeal lodged in connection with this same tender, (b) an immense confusion as regards to what constitutes a 'clarification process' which, unfortunately, following the summoning of various witnesses during the said public hearing, it transpired that proper common sense was not resorted to resulting in a scenario wherein all that could have been clarified within a few days ended up being formally acknowledged over two years later, i.e. from closing date of tender which was 8<sup>th</sup> June 2006 when a public official claimed that *Form A* as submitted by appellant Company was already acceptable except for a few clarifications

which, in this Board's opinion, should have taken a few minutes to sort out and not over two years;

- 3. the PCAB is of the opinion that had all interested parties, namely the Contracting Authority, the Adjudication Board and the Contracts Committee acted in a more professional manner, (i) the adjudication process would have taken place within a more acceptable time frame, perhaps some couple of years ago, which, ultimately, could have avoided the taxpayer so much waste of human and financial resources, as well as, (ii) mitigated the costs incurred and administrative work which had to be attended to by the bidders in order to ensure possible compliance;
- 4. from the evidence given during the hearing the PCAB is satisfied that, albeit a few clarifications may have been required, yet the documentation as presented by the appellant Company when submitting their bid way back in June 2006 was in conformity with tender document specifications.

As a consequence of (1) to (4) above, this Board finds in favour of the appellant Company and that the tender be formally awarded to Multigas Ltd.

However, it being cognisant of the unnecessary delay in awarding this tender and considering the fact that the same appellant Company was, during this time, still supplying the contracting authority with the said medical oxygen to be refilled in cylinders, this Board suggests that the contracting authority would fulfil its obligations for the remaining months of the contracted term as if it had awarded the tender to the same appellant when it was supposed to do so, over two years ago, and for fairness sake, allow other bidders to compete in a fresh call for offers in say, twelve to eighteen months from the date of this sentence.

Finally, the PCAB recommends that the deposit paid by the said appellants when lodging this claim be refunded in its entirety.

Alfred R Triganza Chairman Anthony Pavia Member

Edwin Muscat Member

11 September 2008