

Case No. 11

Advert Notice No CT 59/2002 – Supply of Sulphasalazine 500mg tablets

On 21.01.2002 the Government Pharmaceutical Services formally requested the Director of Contracts to issue a call for offers for the supply, on a period contract basis, of Sulphasalazine 500mg Enteric-Coated tablets. As a result, a formal tender with an estimated contract value of Lm 68,984 was published in the Government Gazette. The closing date for the call for offers was 04.04.2002.

A schedule of offers received dated 20.04.2002 confirmed that three offers had been received.

Subsequently, in the Tender Adjudication Report dated 20.06.2002 submitted by Ms. M. Dowling (Chairperson) and two other members, namely, Ms. M. Azzopardi (Pharmacist) and Ms. B. Brincat (Senior Pharmacy Technician), it was noted that, although the offer submitted by Rodel Limited was in fact the cheapest, yet this was not according to specification requirements and as a consequence the offer submitted by Drugsales Limited was being recommended in view of the fact that the latter was according to tender document specifications.

Yet, this decision was not communicated immediately and another Tender Adjudication Report, this time dated 31.10.2002, was compiled. However, except for minor variations, the contents and conclusions reached were largely the same as the other report compiled previously.

It transpired that the matter needed to be somehow elaborated upon in view of the fact that it was only on the 25th March 2003 that the General Contracts Committee resolved to agree with the recommendations endorsed by the Director Government Pharmaceutical Services and only after being informed by its Secretary “*that stocks of this product were running very low*”.

Upon publication of the award of the tender as recommended by the Adjudication Board, Rodel Limited filed a notice of objection.

The Public Contracts Appeals Board, consisting of Messrs A. Triganza (Chairman) and A. Pavia and E. Muscat (Board Members), met on 01.10.2003 to publicly analyse the objections made by Rodel Limited.

Throughout the hearing the persons mentioned hereunder participated in the proceedings:

- Mr Joseph V. Spiteri (Contracts Department)
- Mr Joseph Meli (Contracts Department)
- Dr Norman Vella (Rodel Limited)
- Dr Noella Grima LLD (Rodel Limited)
- Mr Alfred Gera de Petri (Drugsales Limited)
- Dr Andrea Gera de Petti LLD (Drugsales Limited)
- Ms Miriam Azzopardi (Government Pharmaceutical Services)
- Mr Tonio Cassar (Government Pharmaceutical Services)
- Mr Mark Cilia (Government Pharmaceutical Services)

Dr Noella Grima stated that its client, Rodel Limited, filed an objection on the basis of the fact that the Company was informed that HEYL's offer for the item in question, despite being the cheapest, was not recommended for acceptance in view of:

- the Certificate of Pharmaceutical Product (CPP) not being in the name of the foreign principal
- and
- the language used on the packages not conforming to specification requirements

Dr Grima claimed that Mrs L. Wismayer, Director - Medicine Regulatory Unit (MRU), who was responsible for the sale of medicinal products in Malta, had confirmed in a letter that although Rodel Limited submitted the CPP to MRU and the relative receipt was issued in the name of Rodel Limited, the actual owners of the CPP were the foreign principals. She insisted that Rodel Limited were simply acting as intermediaries because although Rodel Limited presented the tender, the contractor remained the foreign principal (HEYL). In fact, she argued that, if the same CPP's were delivered by a courier service instead of Rodel Limited, the receipt of the CPP would have been issued in the name of the foreign company as the tenderer and marketing authorisation holder.

Dr N. Vella explained that each pharmaceutical product, before being marketed and sold, had to be approved by the Health Authority of that country where it had been manufactured. The issue of a CPP for each particular product granted such approval. With regard to this particular case he said that the receipt for certificate dated 16 May 2002, which was issued by MRU, clearly stated that it was a receipt of CPP to HEYL. He clarified that the receipt was addressed to Rodel Limited simply because the latter physically delivered it on behalf of HEYL.

Rodel Limited's representative declared that they had been dealing with Government Pharmaceutical Services (GPS) for many years. In the past they always followed this same procedure and there had never been any objection from GPS in awarding contracts directly to the foreign tenderers by issuing letters of acceptance and importing the goods directly from them.

Mr Alfred Gera de Petri argued that once it was Rodel Limited who presented the CPP to the MRU, who were the issuing body of the receipt for CPP, this company was the holder of this certificate. He said that the CPP was not transferable unless the local company agreed to transfer its right to the foreign company. He contended that HEYL could not import this product in Malta because it did not possess a valid receipt for the relative CPP because the CPP receipt was issued in the name of Rodel Limited and not in the name of HEYL – the tenderers. He stressed that the tenderer was not the holder of the CPP receipt.

With reference to the documents presented by Rodel Limited, he said that Mrs Wismayer's statement, that '*the Marketing Authorisation Holder is currently equivalent to that entity submitting a CPP for a particular product*', was a confirmation that it was Rodel Limited who submitted the CPP. However, Dr. Vella intervened stating that it was the practice of MRU to issue such certificates in that

manner. He argued that the fact that the foreign principal, as the tenderer and market authorisation holder, had sent the certificate to Rodel Limited for the latter to physically deliver it to MRU, did not make Rodel Limited the owners of the CPP and the product.

In giving his views on the matter, Mr Joseph Spiteri, DG Contracts, said that in this particular case a procedural impasse arose with regard to the tender submitted by Rodel Limited. He said that such impasse was not created as a result of poor quality of the medicine supplied by Rodel Limited's principals as this had always been found to be acceptable. According to DG Contracts, the impasse was brought about by the fact that Rodel Limited were tendering in contravention of DH Circular 10/2002 dated 15 January 2002 as well as a letter circular dated 2 September 2002. Mr. Spiteri claimed that the Director GPS interpreted this circular in a way that it automatically excluded the tenders being submitted by Rodel Limited. It was, however, quite evident, even considering the praxis adopted until then, that Rodel Limited were presenting the CPP on behalf of their suppliers, acting solely as messengers with the tender being submitted in the name of their overseas suppliers.

However, DG Contracts stated that, rightly so, the GPS wanted somebody to be responsible for the delivery of the medicine. The latter had contended that the Qualified Person (QP) nominated by Rodel Limited was not performing his/her duties accordingly. Amongst other duties, a QP was responsible for ensuring that the importation of every medicinal product was covered by a valid CPP and that the medicine, which was released, conformed to what was accepted by Government. The Director GPS objected to assume responsibility for the correctness of the medicine when it was released from Customs and so they wanted Rodel Limited to carry out this job.

Mr Spiteri stated that the problem that gave rise to this appeal was that, when a circular was issued, the tender conditions were not being changed to reflect that circular. As a consequence, Rodel Limited continued to submit their tenders under the conditions appearing in the particular tender even though the conditions of tender ought to have been changed following the issue of the internal circular.

DG Contracts also remarked that, in the past, contracts awarded to Rodel Limited did not create problems since it was accepted that Rodel Limited were just representatives who were providing a service.

However, in an attempt to solve this anomalous situation once and for all, the Contracts Department and Rodel Limited's representatives formally discussed the issue and an agreement was reached aiming at establishing a level playing field for all possible tenderers in similar future tenders.

Ms. Miriam Azzopardi (Adjudication Board) confirmed that although the offer was according to specifications, the tender could not be recommended for acceptance because the receipt of the CPP was in the name of Rodel Limited and not HEYL, who were the tenderers, and therefore not according to the circular.

Mr Mark Cilia from the Health Department said that the circular was issued to all stakeholders and they had to abide by the legal implications thereof since suppliers of

medicinal products should ensure a number of requisites in connections with the safety and efficacy of the drugs delivered.

As regards the CPPs, he said that since they had no access to them because they were submitted to MRU, they had to rely on the receipt, which had always been issued on the person who was submitting the CPP (in this case Rodel Limited). He said that HEYL's offer was not according to the tender conditions as HEYL, the tenderer, did not possess a valid receipt for the relative CPP, since the CPP receipt was in the name of Rodel Limited (the Maltese commission agent) and not in the name of HEYL who signed and submitted the tender. He declared that since the introduction of CPPs, it was an established principle that a CPP was not transferable.

In reply to Dr Grima's question, Mr Tonio Cassar, also representing the Health Department, confirmed that the practice had always been for the CPP receipt to be issued in the name of the local company, that is, Rodel Limited.

To specific questions by Dr Andera Gera de Petri, Mr Mark Cilia replied that the CPP holder was Rodel Limited and the tenderer was HEYL. When Mr Spiteri asked about the importance of a CPP, it was stated that this was indispensable because it certified that a product was safe and efficacious.

With regard to the problem of the language used on the package, Dr Grima stated that on 27 March 2002 her client had submitted a sample of the outer pack in English. The DG Contracts confirmed that the date of the receipt of the sample and instructions for use in English indicated that it was received before the closing date of the tender. However, the sample demonstrated by Ms Miriam Azzopardi was not in English but in German. She referred to an internal circular dated 27 June 2001 which stipulated that they had *'to enforce the condition for submission of samples with offers. This would imply that from now onwards offers without a sample which is not a true representative of the consignment to be delivered, will not be considered, that is, samples submitted have to be exactly as the item being offered even in respect of pack size.'* Dr De Petri stated that Clause 6 specified that the outer pack had to be in English.

However, Health officials confirmed that the product submitted by Rodel Limited was according to specifications.

In his concluding remarks, Mr Spiteri stated that the Contracts Committee always opined that if the contents of such circulars were to be enforced they should be incorporated in the tender conditions. He said that they had never received a reply when they asked the Health Department to seek legal advice as to whether contents of the Department of Health circulars overruled or otherwise the conditions issued in the tender documents.

Finally, he said that irrespective of the outcome of this particular appeal, Rodel Limited must now abide by the new agreement.

Mr Gera De Petri insisted that once the required certification for the importation of pharmaceuticals into Malta was not in HEYL's name and the sample of the outer

package was not as requested in the tender conditions (in English), tender could not be awarded in favour of this company.

Dr Grima stated that her client had abided by tender conditions and that the issue of the receipt was a question of an internal policy. She insisted that, once the tender conditions were not amended according to circulars issued by the Health Department, her client should not be penalised. She said that it had been proved that the product was covered by a valid CPP and that the owner of the CPP and tenderer was HAYL.

The Public Contracts Appeals Board, having gone through facts submitted and arguments raised during the hearing, deliberated on the following issues:

- the DG Contracts rightly stated that if the contents of circulars were to be enforced they should be incorporated in the tender conditions in order to ensure that all parties concerned know precisely what the specifications are all about. It is generally felt that circulars are predominantly an internal mode of communication and one should not rely solely on their presence. One has to bear in mind that potential new tenderers would never have a chance of knowing the right specifications were such internal circulars not incorporated in the formal tender document;
- the DG Contracts has confirmed that in order to ensure that Rodel Limited are aware of all the specification requirements an agreement was reached by which the Company is now fully aware of the Department of Health's exigencies. Whilst agreeing with the initiative taken by the Department of Contracts in regard, this Board also insists that the contents of circulars should still be incorporated in future tender documents as otherwise there could still be a possibility that similar anomalies are encountered with other parties;
- Rodel Limited had acted in good faith and in line with what the known praxis was until then;
- Rodel Limited had also submitted an offer that fully complied with conditions of the tender as issued;
- Dr Grima's statement that her client had abided by tender conditions and should not be penalised;
- both the DG Contracts and Health officials had confirmed that the quality of the product supplied by Rodel Limited's principals was according to specifications and that in the past the same product had been accepted by local authorities and no problem was ever encountered;
- the sample originally submitted by Rodel Limited is deemed to amply meet the Department of Health's requirements. Furthermore, the comment made by DG Contracts with regard to the timeliness of the submission of sample was found to be highly apposite by this Board;

- the ambiguous scenario wherein the Adjudication Board had to decide basing its findings on different parameters (including internal circulars) from those actually listed in the Tender Documents;
- the difficulty encountered by the Contracts Committee to ensure a level playing field amongst tenderers, but, at the same time, quite rightly, depending on the recommendations made by the Adjudication Board even though the Committee had on several occasions drawn the attention of the Adjudication Board to submit its report as well as recommending the latter to seek legal advice in order to clarify certain pertinent issues.

This Board, having considered that:

- Rodel's offer was fully compliant with the tender conditions as confirmed by the Adjudicating Board in their final recommendation;
- the reason given for Rodel's non-recommendation was that the tenderer did not "*..... possess a receipt for a valid CPP, since CPP receipt is in the name of the Maltese commission agent and not the entity who signed and submitted the tender offer (memo dated 2nd September (2002) refers).*

and

- this latter requirement resulting from internal instructions was not specified in the tender documents,

decides that Rodel Limited was fully compliant with the published tender conditions and therefore should be awarded the contract.

Furthermore, the Board strongly recommends that in future the Department should ensure that all defined requirements relating to any procurement should be expressly stated in the tender documents, since prospective bidders are only bound by these documents.

Alfred R. Triganza
Chairman

Anthony Pavia
Board Member

Edwin Muscat
Board Member

Date: 24.11.2003