PUBLIC CONTRACTS REVIEW BOARD

Case 1135 – RFP: 021-60003/2018 – Request for Participation for the Supply of Sunitinib Preparations

Remedies before Closing Date of a Call for Competition.

The publication date of the call for tenders was the 16th January 2018 whilst the closing date of the call for tenders was the 6th February 2018. The estimated value of the tender (exclusive of VAT) was € 2,798,040.

Alfred Gera and Sons Ltd. filed an application on 24th January 2018 for Remedies before Closing Date of a Call for Competition against the Contracting Authority on the basis that the specifications preclude other bidders from taking part in the tender.

On 20th February 2018 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Mr Carmel Esposito and Mr Lawrence Ancilleri as members convened a public hearing to discuss the objections.

The attendance for this public hearing was as follows:

Appellant – Alfred Gera & Sons Ltd

Dr Antoine Cremona	Legal Representative
Dr Clement Mifsud Bonnici	Legal Representative
Mr Simon Delicata	Representative

Contracting Authority – Central Procurement and Supplies Unit - Health

Dr Stefan Zrinzo Azzopardi	Legal Representative
Dr Danika Camilleri Agius Decelis	Pharmacist – Health Department
Mr Mark Zammit	Representative

In a brief introduction, the Chairman, Dr Anthony Cassar, welcomed the parties and asked Appellant's representative to make their submissions.

Dr Antoine Cremona, Legal Representative for Alfred Gera & Sons Ltd, said that this appeal seeking remedy before the tender award was on a matter of principle. It was not intended to be a comparison of products or to win a tender but to ensure that competition was open to all. The present tender was structured such that only one entity was in the race. Local and European existing legislation enforced openness and determined competition - brand specific tenders created illegality. He referred to two related cases decided by the Public Contracts Review Board-namely Cases 1116 and 1028 where the Board had decided that tendering was not limited to products on the Formulary List.

Dr Cremona referred to the CPSU adhering to the NICE (National Institute for Health and Care Excellence) process which in his view should not be adhered to too rigidly due to the different jurisdictions between the UK and Malta, especially due to the difference in pricing and cost-benefit.

Dr Zrinzo Azzopardi, Legal representative for the Central Procurement and Supplies Unit – Health, intervened to point out that the CPSU was the final step in a long process which involved the GFLAC (Government Formulary List Advisory Committee) and the DPA (Directorate of Pharmaceutical Affairs).

Continuing Dr Cremona said that he was not against having the best funding controls in tenders but doctors must also have a whole range of medications otherwise treatment was restricted

He tabled a set of extensive documents from the European Medicine Agency.

At this stage the Chairman asked the CPSU witness to give her evidence.

Ms Tanya Formosa (373664M) testified on oath that she was the Director of Pharmaceutical Affairs. She outlined the process undertaken for a medicine to be accepted on the Formulary List. She was not involved in the issue of tenders but was aware that Appellants had requested their product (Sorafinib) to be included in the formulary in 2010 but this had been rejected on the basis that in the UK it had been found not to be good value for money. Sunitib had a wider use for renal treatment. Ms Formosa stated that the inclusion of Sorafinib in the formulary will be tackled towards the end of 2018.

Mr Mark Zammit (425874M) under oath testified that tenders are limited to medicines on the formulary, and this is dictated by the DPA. The hands of the Authority were tied by the DPA when the specifications for tenders were being drawn up.

Dr Clement Mifsud Bonnici, Legal Representative for Alfred Gera & Sons Ltd tabled further documents. He then stated that this was not a competition between products. The Contracting Authority should take a step back and approach the matter from a functional therapeutic angle,

by having an open approach tender and then consider if the product is on the formulary. It was not up to the CPSU to determine who tenders.

Both Ms Formosa and Dr Zrinzo Azzopardi made the point that the approach Dr Mifsud Bonnici was advocating takes place before the tender is issued.

The Chairman asked if the CPSU would object if instead of specifying active ingredients in the tender documents they would state what treatment the product was required for. This might meet the objection regarding the lack of competition in public procurement. He then thanked the parties for their submissions and declared the hearing closed.

This Board,

Having noted this Request for Remedies prior to the Closing Date of Call for Competition filed by Alfred Gera & Sons Limited, (hereinafter referred to as the Appellant) on 24 January 2018 refers to the contentions made by the same Appellant with regards to the award of Tender of Reference RFP 021-6003/2018 listed as Case Number 1135 in the records of the Public Contracts Review Board.

Appellant for the Appellant: Dr Antoine Cremona

Dr Clement Mifsud Bonnici

Appearing for the Contracting Authority: Dr Stefan Zrinzo Azzopardi

Whereby,

a) **The Appellants' concern is that the tender dossier stipulates ingredients and the other specific components of the product which limits the scope of fair competition and the participation of prospective bidders whose product does not have the same specific formulae but renders the same result. In this regard, Alfred Gera & Sons Limited maintain that the Tender Document should state the purpose of the product being requested by the Contracting Authority without stipulating specific specifications relating to one particular brand.**

This Board also noted the Contracting Authority's "*Letter of Reply*" dated 24 January 2018 and its verbal submissions during the Public Hearing held on 20 January 2018, in that:

a) **The Central Procurement and Supplies Unit contend that the technical specifications, as stipulated in the Tender Document, were compiled after all the necessary procedures and approvals were obtained from the "*Government Formulary List Advisory Committee*" and the "*Directorate of Pharmaceutical Affairs*". In this regard, the drafting of the technical specifications was carried out in accordance with all the**

regulations which, in turn, control the quality and type of the product which is available for procurement.

This same Board also noted the testimony of the witness, namely Ms Tanya Formosa, Director of Pharmaceutical Affairs, who was duly summoned by the Central Procurement and Supplies Unit.

This Board has also taken note of the documents submitted by Alfred Gera & Sons Limited which consisted of:

1. **Document by the European Medicines Agency on Sorafenib;**

2. **Document by the European Medicines Agency on Sunitinib;**

3. **Document by the National Institute for Health and Care Excellence regarding the Guidance on Bevacizumab, Sorafenib, Sunintinib and Temsirolimus for the treatment of advanced and/or metastatic renal cell carcinoma;**

4. **Document by the National Comprehensive Cancer Network Clinial Practice Guidelines in Oncology for Kidney Cancer Version 2.2016;**

5. **Article by B. Escudier called, "*Renal Cell Cardinoma: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up*"**

This Board, after having examined the relevant documentation and heard the submissions made by the interested parties, including the testimony of the technical witness, opines that the issue to be considered in this appeal, is the mode of drafting the technical specifications.

This Board would like to respectfully refer to the guidelines issued by the European Union and the directive in respect of the drafting of the technical specifications in a tender document which should respect the following principles in that such specifications should:

a) **Be precise in the way it describes the requirements;**

b) **Be easily understood by the prospective bidders;**

c) **Have clearly defined, achievable and measurable objectives;**

d) **Not mention any brand names or requirements which would limit competition or if brands are mentioned, include the term "*or equivalent*";**

e) **Provide sufficient detailed information that allows bidders to submit realistic offers.**

The above mentioned basic principles should feature in all tender documents and in this particular case, this Board justifiably notes that the actual specifications, as stipulated in the tender document, does not conform with the guidelines in points c) and d) as follows:

- **The tender document specifies the product but does not stipulate the objective or the purpose for the procurement of the same;**

- **The tender document specifies the specifications of a particular brand of product without inviting equivalent products to compete, thus limiting the scope of competition.**

In this "*call for remedies*", the Appellants are not contesting a disqualification of their offer or asserting their product's technical compliance but rather expressing their concern with regards to the mode of the drafting of the technical specifications, in that such specifications will not allow prospective bidders to compete. In this regard, this Board is credibly convinced that the

way the technical specifications are stipulated, does, in fact, limit the scope of competition and even bars a prospective bidder to compete, as such specifications favour a particular brand which means one particular supplier has the advantage over all prospective bidders. This Board also noted that the technical specifications did not allow for alternative equivalency of the product and at the same instance, no mention is made of the objective of the product itself.

This Board acknowledges the fact that, being a medical product, the specifications thereto must conform to all the medical regulations and protocol under the control of other regulatory bodies and, in fact, this Board was made aware that such specifications represent the end product, after another process which is beyond the control of the Contracting Authority itself. However, in Public Procurement, the Principle of allowing an initial opportunity for a prospective Bidder must prevail and be respected.

From the testimony of the witness, this Board was informed that other compatible products do exist on the market so that the technical specifications can be formulated so as to denote clearly the objective and utilisation of the product rather than dictate ingredients which indirectly gives an advantage to a particular supplier, from the very start of the tendering procedure. In this regard, this Board opines that every opportunity should be given to

prospective bidders to participate and although constricted by medical protocols and formulary, the Central Procurement and Supplies Unit should do its utmost to allow as many bidders as possible to compete, which in the end will be to the benefit of the latter. At the same instance, this Board would like to emphasize that the prime factor to be considered, in the whole process, is the well-being of the patient.

In view of the above, this Board:

i) **Upholds Alfred Gera and Sons Limited's concern, in that the technical specifications, as stipulated in the tender dossier, do in fact favour a particular brand and suppresses the scope of fair competition;**

ii) **Recommends that the technical specifications are to be revised as follows in order to:**

- **Avoid specifications which relate to a particular type of product;**

- **Dictate the objective and utilisation of the product being requested;**

- **Formulate technical specifications which are generally mandatory and yet in such a way, as to allow compatible products to participate;**

- **Recommends that such modifications to the technical specifications are to be notified through a clarification note, so as to avoid unnecessary delay in the procurement process.**

Dr Anthony J Cassar Chairman	Mr Carmel Esposito Member	Mr Lawrence Ancilleri Member

6st March 2018