PUBLIC CONTRACTS REVIEW BOARD

Case 1361 – CPSU 164139N19JP – Request for Participation (Negotiation) for the Supply of Enzalutamide 40mg capsules

Call for Remedy before Closing Date of a Call for Competition

The publication date of the call for participation was the 23rd April 2019 whilst the closing date was the 23rd May 2019 (extended to 30th May 2019).

On the 29th May 2019 A M Mangion Ltd sought a Remedy against the Central Procurement and Supplies Unit as the Contracting Authority requesting that the call for participation be modified.

On 8th October 2019 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Dr Charles Cassar and Mr Carmel Esposito as members convened a public hearing to discuss the objections.

The attendance for this public hearing was as follows:

Appellants – A M Mangion Ltd

Dr Steve Decesare	Legal Representative
Mr Jonathan Mangion	Representative
Mr Ray Vella	Representative
Ms Gaby Ganado	Representative
Mr George Mifsud	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Marco Woods	Legal Representative
Dr Alison Anastasi	Representative
Ms Julia Pirotta	Representative

Interested Parties;

Ms Tanya Formosa

Dr Anthony Cassar, Chairman of the Public Contracts Review Board, welcomed the parties and invited submissions.

Dr Steve Decesare Legal Representative for A M Mangion Ltd said that Appellants' product Aberiterone competes with the molecule referred to in the tender – namely Enzalutamide. The

Central Procurement and Supplies Unit (CPSU) are claiming that the former medicine needs to be used with a daily dose of steroids. This decision was taken by GFLAC but the CPSU could not provide a reply in time to a query raised by Appellants.

Professor Andrew Borg (412362M) called as a witness by the PCRB testified on oath that he was Professor of Medicine and Head of the Government Formulary List since 2013. He described the role of the GFLAC and how assessments are carried out for a medicine to go on the Formulary List. It is finally the Advisory Board for Health Care Benefit which takes the decision. He stated that it is a wrong concept to think that in medicine one size fits all patients. In the case of chemotherapy naive patients with metastatic resistant prostate cancer Enzalutamide is more popular with clinicians. The two drugs under discussion work in entirely different ways and there is a particular niche for each medication.

Questioned by Dr Decesare witness stated that there are financial considerations for not choosing Abiraterone although consultants were in favour of having both treatments.

Dr Decesare tabled Doc 1 showing the use of Aberaterone in several other countries.

Questioned by the Chairman witness confirmed that the use of steroids was necessary in administering Aberaterone.

Dr Nick Refalo (512075M) called as a witness by the PCRB testified on oath that he was a consultant Oncologist at Mater Dei Hospital. He stated that his role was to prescribe medicine for certain types of cancer, and uro oncology was one of his specialities. He prescribes both medicines under discussion as they do not fulfil the same role. In metastatic castration prostate cancer there was a need to have both medicines to give a professional service, however, steroids were not to be used in patients suffering from diabetes.

Dr Marinos Tsiatas called as a witness by Appellants testified on a declaration that he was an Oncologist by profession, and stated that both drugs have similar results for the conditions indicated – in the case of Abiratorone it is to be treated jointly with steroids. He tabled Doc 2 indicating the different side effects of the two drugs.

Dr Decesare said that the Contracting Authority had to abide by Regulation 39 of the Public Procurement Regulations in that specifications have to treat everyone equally and no bidder is excluded. He made reference to PCRB Cases 1028/1116/1135/1155/1104 and 1279 which all support his contention on this point. The PCRB in one instance confirmed that procurement is not limited solely to medicines on the Formulary List. Clinicians should decide on the best treatment for patients.

Dr Marco Woods Legal Representative for the Central Procurement and Supplies Unit said that the Board had the confirmation of the Chairman of the GFLAC that only Enzalutamide is one the Formulary List and the application for Arbiterone was still outstanding. The decision to introduce new medicines was not up to the Contracting Authority and only items on the List could be considered.

Dr Decesare said that Appellants' application was not for their product to go on the List. The Formulary List should not overrule the use of any product for the same kind of treatment or condition. Appellants were requesting the Board to give the necessary instructions to open the tender for competition.

The Chairman thanked the parties for their submissions and declared the hearing closed.

End of Minutes

Decision

This Board,

having noted this 'Call for Remedy Prior to the Closing Date of a Call for Competition' filed by A.M. Mangion Ltd (herein after referred to as the Appellants) on 29 May 2019, refers to the claims made by the same Appellants with regard to the tender of reference CPSU 164139N19JP listed as case No. 1361 in the records of the Public Contacts Review Board.

Appearing for the Appellants: Dr Steve Decesare
Appearing for the Contracting Authority: Dr Marco Woods

Whereby, the Appellants contend that:

a) **The technical specifications of the tender restrict open competition and the Authority must abide by Regulation 39 of the Public Procurement**

Regulations, so that procurement of medicine should not be restricted to those products indicated on the formulary list only.

This Board also noted the Contracting Authority's 'Letter of Reply' dated 19 June 2019 and its verbal submissions during the hearing held on 8 October 2019, in that:

a) **The Authority maintains that the type of medicine which can be procured is regulated by the Government Formulary List Advisory Committee (GFLAC). In this regard, Appellants' product is not on the list, so that the technical specifications are aligned to the products on such list.**

This same Board also noted the testimony of the witnesses namely:

Prof Andrew Borg duly summoned by the Public Contracts Review Board
Dr Nick Refalo duly summoned by the Public Contracts Review Board
Dr Marino Tsiatas duly summoned by A.M. Mangion Ltd.

This Board has also taken note of the documents submitted by A.M. Mangion Ltd which consisted of:

Doc1 – Data showing use of Aberaterone in several countries,
Doc 2 – Data showing different side effects of Aberaterone and Enzalutamide.

This Board, after having examined the relative documentation to this Call for Remedy and heard submissions made by the parties concerned, including the testimony of the witnesses duly summoned, opines that the issue that merits consideration is the availability of choice of medicines.

1. **First and foremost, this Board would emphasize that technical specifications should not be limited or inclined towards a particular product. Such fundamental maxim must be adhered to at all times and whenever a particular product is indicated, directly or indirectly, the word 'Or Equivalent' has to be incorporated, so that open competition is preserved.**

2. **In this particular case, this Board regretfully notes that the Authority is somewhat restricted as to which product it can procure. Same Board was made aware that, any request for a new-product, in cases of medicine, has to be addressed to the 'Government Formulary List Advisory Committee', same request is then referred to the 'Advisory Committee for Health Care Benefits (ACHCB), the latter Committee will advise as whether to accept or reject such a request, for the particular medicine to be included in the formulary list.**

3. **This Board also noted that the Department of Pharmaceutical Affairs is responsible for the drafting and issuance of the technical specifications to be issued in the tender document, so that, the Authority, at this particular stage of the procurement process, has no control over the drafting of the technical specifications of such medicines.**

4. **In this particular case, it was contended by the GFLAC that the medicine presently in use can be applied without the use of steroids whilst Appellants' product requires a daily dose of steroids, hence the reason why it is not listed in the formulary list.**

5. **In their testimony Prof Andrew Borg and Dr Nick Refalo, both specialists in the application of both drugs, confirmed, with credible consistency that, both medicines give the desired results and Appellants' product necessitates the use of steroids which cannot be used on patients suffering from diabetes. Both witnesses also confirmed that they were in favour of having both treatments available and reference in particular was made to 'Metastatic Castration Prostate Cancer' where there was the need to have both medicines in order to provide a professional service to the patient. In this regard, from these specialised technical statements made**

by medical specialists, this Board finds no justifiable cause as to why Appellants' product should not be on the formulary list.

6. **This Board acknowledges the fact that both the 'GFLAC' and the 'ACHCB' are important and necessary regulating committees which ensure that the medicine being prescribed and applied is in accordance with the highest of standards and this Board commends their contribution towards the well-being of the patient; however, this Board is somewhat concerned about the rigid process applied in the introduction of new available medicine on the formulary list and the complete control in stipulating technical specifications in procurement tenders issued by the Authority.**

7. **It should be acknowledged and appreciated that the more medicine is listed in the formulary, the better is the availability of alternative medicine which will be needed for different types of treatments which the specialists deem fit for the particular patient. On the other hand, the formulary list should not be a hindrance for the application of a type of treatment not presently included in such a list and at the same instance, promoting a breach in public procurement by defying the scope of competition.**

In conclusion, this Board opines that:

a) **The technical specifications, as stipulated in the tender dossier, breaches the principle of open competition in public procurement.**

b) **The Authority should have more control over the drafting of the technical specifications of the medicine to be procured, after consulting with specialists involved in the particular field of medicine.**

c) **The formulary list should be updated more often so as to contain, as much as possible available novel products, which in the end, would reap benefits for the well-being of the patient.**

In view of the above, this Board:

i) **Directs the Authority that, through a clarification note, to modify the technical specifications by removing reference to specific molecule and dosage, in order to allow economic operators to offer other novel anti-androgen therapies.**

ii) **Directs the Authority to indulge itself in drafting the actual requirements after consultation with the specialists involved in the application of such medicine.**

iii) **The closing date for the tender document is being established to be 20 November 2019, at 12.00 noon.**

Dr Anthony Cassar Chairman	Dr Charles Cassar Member	Mr Carmel Esposito Member

25 October 2019