PUBLIC CONTRACTS REVIEW BOARD

Case 1157 – RFP 021/60011/2018 - Request for the Participation (Negotiated) for the Supply of Treatment Service of PD1 Inhibitors

Remedies before the Closing Date of a Call for Competition

The publication date of the call for tenders was the 6th March 2018 whilst the closing date of the call for tenders was the 11th April 2018. The estimated value of the tender (exclusive of VAT) was € 6,000,000 with possibility of a two year extension.

On the 4th April 2018, Associated Drug Co Ltd filed a Call for Remedies before the Closing Date of the Competition against the Central Procurement and Supplies Unit

On 17th April 2018 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:

Appellant – Associated Drug Co Ltd

Dr Massimo Vella	Legal Representative
Mr Andreas Yerasimou	Representative
Ms Eria Nicolaou	Representative
Ms Christina Meli Bugeja	Representative
Mr David Caruana	Representative
Ms Kimberley Vella	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Stefan Zrinzo Azzopardi	Legal Representative
Dr Alison Anastasi	Assistant Director
Dr Danica Camilleri Agius Decelis	Pharmacist

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

Dr Massimo Vella, Legal Representative of Associated Drug Ltd, said that remedy was being sought regarding the supply of PD1 used for the treatment of cancer patients. This was an innovative medication which prevents cancer from switching off the immune system; it was different and gave better results than conventional chemotherapy. The proposal was for two particular products – Nivolumab (Nivo) and Pembrolizumab (Pembro). Associated Drug Co Ltd was the importers of Pembro. The concern was in regard to Sec. 1.1 of the tender specifications capping the price through specifying a particular dose of medication tied to the weight of the patient.

Dr Vella stated that by limiting the dosage to a weight based approach it was eliminating fixed dosage treatment. The medicine was used in the treatment of melanoma, Hodgkin lymphoma, urothelial carcinoma and lung cancer. The technical specifications should not exclude fixed dosage treatment as this limits competition apart from leaving a set of patients without treatment.

Another issue, raised by Dr Vella, was the risk-based approach through which the supplier had to bear the major part of the cost on a sliding scale. By capping the maximum price and the testing of patients prior to the prescribing of treatment supplier might be unable to bid because of the shifting of the major part of the cost onto to him. The way the tender is worded the supplier would be in a position where they are unable to price the product because the dose cannot be administered.

Dr Stefan Zrinzo Azzopardi, Legal Representative of the CPSU, provided some background to the tender process. The dosages indicated related to only two types of cancer and the Request for Proposal was purposely drafted as such. There was no question of exclusion. PD1 inhibitors were a new medicine being introduced and there were medical reasons for procuring these medicines for only two particular situations – namely skin melanoma and second line cancer. With regard to a point made by Dr Vella that Keytruda was approved by the European Agency for treating a wider range of cancers than the two decided locally, Dr Zrinzo Azzopardi made the point that the Advisory Health Care Benefits Committee decides what conditions are to be treated if a drug is to be provided, and the product limited to what is approved. They were not limiting the use of the drug - they were merely limiting the public procurement.

Mr Andreas Yerasimou, Representative of the manufacturer of Keytruda, said that the tender was vague in what the obligations of the supplier were in the second year, and further clarification was required. In the risk-sharing proposal there was no indication that it was linked to performance; one needed to know who starts on the treatment and what state they were in when the treatment was started to enable a tenderer to assess the risk. It was necessary to have a revision of the risk sharing scheme by revising the estimated rate of survival of an individual and

to the patients' response to the treatment. He also felt that the number of patients estimated to be treated was high.

Dr Vella re-iterated this last point and said that his clients had three requests – clarification of the Request for Proposal to indicate that there were only two situations in consideration; another look by the Contracting Authority at the number of patients estimated to be treated and that the risk model needs to be reassessed as it is in reality bias.

Dr Alison Anastasi, Assistant Director, CPSU, said that the risk model approach was non-outcome based – the treatment does not cure but prolongs life, therefore outcomes difficult to capture. The model was based on first year and second year because of the outcomes approach which was difficult to predict. The preferred bidder would be offering a service by helping to achieve certain outcomes.

After thanking both parties for their submissions the Chairman declared the hearing closed.

This Board,

Having noted this Call for Remedies filed prior to the Closing Date of Call for Competition by Associated Drug Company Limited, (hereinafter referred to as the Appellant) on 4 April 2018, refers to the contentions made by the same Appellant with regards to the Tender of Reference RFP/021/6011/2018 listed as Case No 1157 in the records of the Public Contracts Review Board.

Appearing for the Appellant: Dr Massimo Vella

Appearing for the Contracting Authority: Dr Stefan Zrinzo Azzopardi.

Whereby, the Appellant contends that:

a) **When referring to clause 1.1 of the Tender Specifications, wherein, by limiting the dosage to a weight based approach, this factor is in fact eliminating products with a fixed dosage treatment;**

b) **With regards to capping a maximum price and the testing of the state of the patients prior to prescribing of treatment, suppliers might find difficulty in participating due to the fact that the major part of the cost has to be taken by bidders.**

This Board also noted the Contracting Authority's "*Letter of Reply*" dated 9 April 2018 and its verbal submissions during the Public Hearing held on 17 April 2018, in that

a) **The Central Procurement and Supplies Unit maintains that the dosage was solely indicated for the purpose of an evaluation and not to limit competition. In this regard, the Contracting Authority confirms that dosage in the case of other indications, will be treated at the same**

treatment price awarded within the Request for Proposals, whatever the dosing;

b) With regards to the "*Risk Sharing Agreement*", the Contracting Authority contends that this was based on the principle that the same Authority pays for this service whilst taking into account the results achieved in the patients' condition and the quantity of drug that has been administered.

This Board, after having examined the relevant documentation and heard submissions made by the parties concerned, opines that the two issues that merit consideration, in this particular case are:

i) The Dosage Issue;

ii) The Risk Sharing Agreement

i) <u>The Dosage Issue</u>

This Board would respectfully refer to Clause 1.1 of the Tender Specifications which stipulates that the dosage formula is established as follows:

<u>Nivolumab Vials</u>	**<u>Pembrolizumab Vials</u>**
3mg/kg Administered IV Over 60 Minutes Every 2 Weeks	**2mg/kg by IV Infusion over 3 Weeks**

The above dictated formula clearly indicates that the dosages which are requested represent a dosage relating to the weight of the patient. At the same instance, this Board notes that Clause 1.2 states that:

"*Bidders who participate need to have a Technical Compliant offer as per 1.1 (Table Above) and a Financial Bid as per 1.2. If not compliant to both 1.1 and 1.2 they will be disqualified*."

At this stage of consideration, the fact that the dosage for the mentioned drugs in the Tender Document is directly related to the weight of the patient, is definitely excluding products whose dosage are fixed and not

related to the weight of the patient. This Board's priority is the well being and the best treatment possible for the patient. At the same instance, the relativity between dosage and weight is automatically excluding other available drugs which carry a fixed dosage.

From the submissions, this Board was made aware that the requested drug is for the treatment of two types of cancer and the dictated dosage was particularly targeted for these particular conditions. At the same instance, this Board was given to understand that products with fixed dosage and not related to the weight of the patient, do exist, such as the product being offered by the Appellants.

Given that the product submitted by Associated Drug Company Limited does provide an equivalent medical treatment for the two types of cancers, then this Board would strongly uphold the fact that the Appellants' product should be considered as an equivalent for the treatment of such cancers and in which case, clause 1.2 of the tender document needs to be amended to accommodate similar or equivalent products which render the same objective as that so requested by the Central Procurement and Supplies Unit. It is appreciated and

acknowledged that the determination of whether the Appellants' product can deliver the same results or not, should rest on the medical expertise of the clinicians, whilst at the same time, bearing in mind that the patient with such medical condition deserves the best of treatment.

In this regard, this Board opines that, under no circumstances, technical specifications or conditions should be stipulated which limit or precludes similar equivalent products to participate in an offer so that, once it is established that the Appellants' product can deliver the medical results for the treatment of the patients' condition, such an allowance for participation should be reflected in the Tender Dossier.

ii) <u>Risk Sharing Agreement</u>

From the submissions made, it is evident that the table as shown in Clause 1.3 of the Tender Dossier will allow the Central Procurement and Supplies Unit to introduce special treatment for two types of cancer, based on performance and efficacy of the treatment. In this regard, this Board notes that for the first year of treatment, the Central Procurement and Supplies Unit felt the necessity to gauge and monitor

the drug's performance every three months so that the risk factor is apportioned as to:

Cost	Share of Supplier	Share of Contracting Authority
1st 3 Months	100%	0%
2nd 3 Months	75%	25%
3rd 3 Months	50%	50%
4th 3 Months	25%	75%
After	0%	100%

This Board will not enter into the merits as to whether such an apportionment of costs is appropriate, but rather raise the fact that, during the submissions, this Board was made aware that the results of treatment, through the application of Associated Drug Company Limited's product, will usually be evident after a period of more than three months, so that the first three months will not give a fair and just indication of the efficacy of the Appellants' product. In this regard, this Board would opine that the first period of application of drugs for this condition can perhaps, be extended to such a period so that the efficacy and performance of the medicine used in the treatment of this condition

can be more accurately assessed. These recommendations should be always adopted on the premise that such applications are beneficial to the patients, so that, in the end, the decision of the clinician will prevail.

iii) <u>Number of Patients</u>

With regards to the above issue, this Board is comfortably convinced that the estimated figure stipulated in the Tender Dossier has been credibly and justifiably established by the Contracting Authority after having consulted with the Oncology Department as well as the local Epidemiology Department. At the same instance, this Board would recommend that such statistical number of patients to be treated, are to be confirmed once more, by the same Authority.

In view of the above, this Board:

a) Recommends that Associated Drug Company Limited's product is to be included in the list of drugs for the treatment of this medical condition, provided, upon consultation with the clinicians, the Appellants'

products' dosage is certified to achieve the equivalent results which are requested by the Contracting Authority;

b) Recommends that the first period of three months as shown in Clause 1.3 of the Tender Dossier is to be extended to a period whereby the Appellants' product can be fairly assessed;

c) Recommends that the Central Procurement and Supplies Unit will revise the number of patients as indicated in Clause 1.4 of the Tender Dossier, (if necessary), to reflect a more realistic picture of the number of patients to be treated annually.

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

3rd May 2018