Case 1177 – 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

SECOND HEARING

The first hearing of this Case appears under Case No 1157 heard on the 14th April 2018.

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.

A first hearing was held on 14th April 2018 when it was agreed by both parties that the CPSU will re-consider the risk-sharing model presented at the hearing.

On 18th June 2018 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Dr Charles Cassar and Mr Lawrence Ancilleri 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 Paul Apap Bologna	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
Engineer Karl Farrugia	Representative

Other Bidding Party – A M Mangion Ltd

Mr Roger Aquilina	Representative
Mr Ray Vella	Representative

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

Dr Alison Anastasi, Representative of the Central Procurement and Supplies Unit, stated that the CPSU had reviewed the original model and had now reduced that number of probable patients from the original 65 to 35. They have also reviewed the risk sharing ratio for the first year as follows:

First Quarter	70% of the cost to be borne by Ministry for Health
Second Quarter	80% of the cost to be borne by Ministry for Health
Third Quarter	90% of the cost to be borne by Ministry for Health
Fourth Quarter	100% of the cost to be borne by Ministry of Health

Mr David Caruana, Representative of Associated Drug Co Ltd said that his Company could not decide on these figures unilaterally and they need to consult the manufacturers who felt that no risk sharing was acceptable in view of the high cost of the product. The dosage factor needs to be reflected in the ultimate price paid by the supplier.

Dr Massimo Vella, Legal Representative for Associated Drug Co Ltd, suggested that the simplest solution would be to amend the SPC to indicate the dosage as this will be reflected in the tender.

The Chairman said that it was essential to establish the basis on which the tender had to be evaluated to which Dr Anastasi said that if a weight of 80 kilos was used as the standard that would give uniformity across the board, and asked if the CPSU were to amend the dosage whether it would be possible to proceed with the tender. Engineer Farrugia said that the Procurement Regulations were being followed and it was not possible to keep amending the terms. The CPSU had amended the controversial points and changed what possible parameters they could.

Mr Caruana said that monitoring was critical to the risk sharing as the number of patients and their performance status were unknown. Their product was only used on tested patients and therefore could be less costly to the CPSU. The Malta Community Chest Fund was currently funding both treatments and the Government should procure both.

Dr Zrinzo Azzopardi stated that the tender refers only to the two indications approved by the Medical Authorities – if the Government takes over those funded by the MCCF then a new tender would be necessary.

The Chairman appealed to both parties to save this tender and not leaving it pending much longer for the sake of patients' well being. He accepted that Appellants have to refer the matter to the manufacturers but said that he expects an answer, if necessary by e-mail, within two days and that it should also be notified to the CPSU. On receipt of that answer the hearing will be resumed.

The Chairman thanked both parties for their submissions and adjourned the hearing.

THIRD HEARING

On 18th July 2018 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Dr Charles Cassar and Mr Lawrence Ancilleri as members convened a public hearing for this adjourned Case.

The attendance of the public hearing was as follows:

Appellant – Associated Drug Co Ltd

Dr Massimo Vella	Legal Representative
Mr Paul Apap Bologna	Representative
Mr David Caruana	Representative
Ms Kimberley Vella	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Stefan Zrinzo Azzopardi	Legal Representative
Dr Marco Woods	Legal Representative
Dr Alison Anastasi	Representative
Engineer Karl Farrugia	Representative
Mr Michael Cassar	Representative

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

Dr Massimo Vella, Legal Representative for Associated Drug Co Ltd referred to the CPSU submission in reply to the Appellants letter of the 19th June, which said that the former were not excluding testing. Testing was mandatory in the use of the Appellants' product which streamlined the number of patients using it thus reducing costs. Their competitors' product did not specify obligatory testing – it simply recommended it - this factor was a fundamental issue, as testing reduces the cost risk to the extent of 30 to 40%. If the CPSU eliminates risk sharing and introduced testing there will be a saving in medicine and costs.
Mr David Caruana, Representative of Associated Drug Co Ltd said that it is important to know the number of patients likely to be treated in the first quarter because of the related burden of costs. Testing brings predictability and therefore budget management.

Dr Stefan Zrinzo Azzopardi, Legal Representative of the CPSU stated that the original objections were to capping and risk sharing; now testing seems to be the main problem. The tender recognises that there might be the need for negotiations. The CPSU has two priorities – the medical factor and the call to examine two medicines and compare them – one needs testing the

other does not; hence testing was omitted to have a level playing field. The Ministry for Health has no experience how the medication is going to work and to be administered– hence the risk sharing model is needed. Capping is necessary for equality of treatment and if testing is necessary in risk sharing model and since cost of testing is negligible compared to the value of the tender, the CPSU will still go for the most effective product.

In reply to a comment by Dr Vella that risk sharing was not necessary the Chairman pointed out that this point had been discussed before and it there will be no change in the tender.

Mr Caruana in a final comment said that unless testing was recommended for both products there will be an imbalance between the bidders.

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

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This Board,

Having noted the Call for Remedies filed by Associated Drug Company Limited, (hereinafter referred to as the Appellants) before the Closing Date of a Call for Competition on 4 April 2018, refers to the contentions made by the same Appellants with regards to the issue of Tender of Reference RFP 021/6011/2018 issued by the Central Procurement and Supplies Unit and listed as Case No 1177 in the records of the Public Contracts Review Board.

Appearing for the Appellants: Dr Massimo Vella

Appearing for the Contracting Authority: Dr Stefan Zrinzo Azzopardi.

Whereby the Appellants contend that:

a) **Although the risk sharing agreement (RSA) has been substantially improved from the original version, the Contracting Authority is still applying an additional reduction over an already capped treatment cost per year, thus driving the entry price to a level well below the average EU Price;**

b) **The stipulated dosage should be aligned with the latest approved Summary of Product Characteristics;**

c) **There should be included a biomarker testing against a Risk Sharing Agreement.**

This Board has also noted the Contracting Authority's "Reasoned *Letter of Reply*" dated 2 July 2018 and its verbal submissions during the Public Hearing held on 18 June 2018, in that:

a) **The Central Procurement and Supplies Unit contend that after conducting a market research, the Risk Sharing Agreement has been revised to the benefit of all potential Bidders, so that a level playing field is being maintained;**

b) Although the Contracting Authority will update the dosage in accordance with the latest Summary of Product Characteristics, it should be pointed out that, at the time of publication of the RFP, the stipulated dosage was the then updated dosage;

c) The Contracting Authority insists that bio-marker has not been included as its inclusion would cause discrimination between potential Bidders.

This Board, after having examined the relevant documentation to the concerns brought forward by Associated Drug Company Limited and heard submissions made by the parties concerned during the three sittings held on 14 April 2018, 18 June 2018 and 18 July 2018, would respectfully note that these concerns relate to a particular medical treatment which is being administered for the first time, in Malta, so that great emphasis is being placed on the well-being of the patient.

1. **<u>Risk Sharing Agreement</u>**

With regards to Associated Drug Company Limited's first contention, this Board, after having requested the Contracting Authority to reconsider the original model of the "*Risk Sharing Agreement*" (RSA)

and after being presented with a revised version, opines that, upon examination of the RSA model, duly amended, the latter offers much more advantageous conditions to all the economic operators. This Board acknowledges and appreciates that this medicinal product is being applied for the first time, so that there is no known history as to the success of such treatment and in this respect, one has to accept the fact that, after the first year of application of the treatment, both the Authority and the successful Economic Operator will be in a wiser situation to assess the outcome. In this regard, this Board notes that the Authority is also willing to discuss with the Economic Operator any needed negotiations which will be necessary for the second year of the Tender period.

In this particular case, this Board opines that, an element of goodwill and trust has to prevail between the Central Procurement and Supplies Unit and the successful Economic Operator, in that, after the first year of application of this medicinal product, which is of great benefit and relief to the patients to whom such treatment is to be administered, some form of statistical parameters can be objectively established on which possible objective negotiations, (if any), can be agreed upon. In this context and perspective, this Board opines that the revised model of the "*Risk Sharing Agreement*" is a reasonable module on which the risk

factor is projected in the first year of application of this particular treatment and therefore, in this regard, this Board confirms the following module:

Year 1	Price Paid by the CPSU	Price Paid by EO
Q1	70% of the Quoted Price	30% of the Quoted Price
Q2	80% of the Quoted Price	20% of the Quoted Price
Q3	90% of the Quoted Price	10% of the Quoted Price
Q4	100% of the Quoted Price	0% of the Quoted Price
Year 2	100% of the Quoted Price	0% of the Quoted Price

This Board also opines that through the above module, the Economic Operator will only be exposed to a minimal fraction of the risk factor and only for a period of nine months when compared to the Tender Period of Two Years which can also be extended by an additional two years.

With regards to the Appellants' claim that the Authority is still applying an additional reduction over an already capped cost per year, thus driving the price below EU levels, this Board would respectfully point out that such a capped price has already been revised and uncontested, apart from the fact that the Contracting Authority,

through a market survey is confident that such capped price will be attained and in this regard, this Board does not consider this issue as relevant, at this particular stage.

2. **<u>Dosage</u>**

With regards to Associated Drug Company Limited's second concern regarding an updated dosage, this Board would point out that at the time of publication of the Tender, the Central Procurement and Supplies Unit stipulated the then current dosage and it is an obvious fact that, since considerable time had passed since then, the applicable dosage will be administered, in accordance with the most recent Summary of Product Characteristics' approval.

3. **<u>Bio-Markers</u>**

With regards to the Appellants' Third Contention, this Board upholds the Central Procurement and Supplies Unit's credible argument in that, by the inclusion of this test, the same Authority would have caused discrimination between prospective Bidders. However, this Board was made aware that the non-inclusion of this test in the RFP does not necessarily imply that the Contracting Authority will not carry out such

tests, if necessary, through a separate procurement procedure. In this regard, this Board does not find any justifiable reason to merit consideration on this issue.

In view of the above, this Board,

i) **Upholds the last version of the "*Risk Sharing Agreement*" module;**

ii) **Does not uphold the contentions made by Associated Drug Company Limited with regards to the alleged effect of the capping price over the revised risk sharing schedule;**

iii) **Instructs the Central Procurement and Supplies Unit to resume the Tendering Process without further delay, taking into consideration the issues concluded herein.**

Dr Anthony Cassar	Dr Charles Cassar	Mr Lawrence Ancilleri
Chairman	Member	Member

10th August 2018