PUBLIC CONTRACTS REVIEW BOARD

Case 1155 – RFP 021/14020/2017 - Request for the Participation (Negotiation) for the Supply of Drugs used in the Management of Multiple Sclerosis (MS)

Remedies before the Closing date of a Call for Competition

The publication date of the call for tenders was the 29th September 2017 whilst the closing date of the call for tenders was the 8th March 2018. The estimated value of the tender (exclusive of VAT) was € 2,700,000.

On the 8th February 2018, Pharma.MT Ltd filed a Call for Remedies before the Closing Date of the Competition against the Central Procurement and Supplies Unit

On 12th 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 – Pharma.MT Ltd

Dr Jonathan Thompson	Legal Representative
Dr Celia Mifsud	Legal Representative
Mr Patrick Nicholl	Director, Pharma MT Ltd
Ms Elisa McKenna	Director, Pharma MT Ltd

Contracting Authority – Central Procurement and Supplies Unit – Health

Dr Stefan Zrinzo Azzopardi	Legal Representative
Dr Danica Camilleri Agius Decelis	Pharmacist, Ministry of Health

The Chairman of the Public Contracts Review Board, Dr Anthony Cassar, in a brief introduction requested the Appellant to make his submissions.

Dr Jonathan Thompson, Legal Representative of Pharma MT Ltd stated that there was an exhaustive list of drugs available for the treatment of Multiple Sclerosis (MS), with clinicians prescribing the cheapest available drug and then moving upwards on the list until finding one that works. Despite this, his clients' particular drug – Natalizumab - had been omitted from the list.

He requested the Board to hear his first witness.

Dr Josanne Aquilina (682461M) testified on oath that she was a Consultant at Mater Dei Hospital. When asked if she was aware why Natalizumab had been excluded from the tender list, witness said that the drug had been long available, it was highly efficacious – it has a rate of 63 to 65% efficacy and was used on aggressive cases of MS when other medicines failed. She was treating about five patients with this drug. She mentioned that the drug had certain side effects and one must be cautious in prescribing it and patients should be monitored very strictly. However, it showed an annual relapse rate reduction and other drugs were not as effective. She could see no specific reason as to why it was not on the tender list since if a patient was doing well on it ideally that treatment should continue. Witness was aware that there were protocols in place according to budgets to determine treatment. She had no objection to this product being included in the list since although the side effects were a major concern, prescription was closely monitored by the clinician.

Dr Angus Byars, the next witness testified on oath that he was a medical doctor who worked for Biogen. He explained the effects of MS on the auto immune system and the benefits of Natalizumab in the management of aggressive cases of MS. Extensive research internationally had proved the efficacy of this drug.

Dr Ljubimor Dimitrovski, a medical doctor qualified from the University of St Cyril and Methodius in Macedonia testified that his most recent information indicated that there were 12 patients in Malta on this drug.

Dr Jonathan Thompson said that the drug in question was highly efficacious, it was already in use in extreme cases and should be on the list for open competition. He claimed that the current tender disadvantaged any supplier who wanted to bid for just one item, because in that case capping worked to his disadvantage, because of the average capping system used. Natalizumab's price was in excess of the capping limit and was therefore excluded. Capping limits the availability of medicines to patients, and excluded those already on a particular product. There was inconsistency in the averaging of prices and CPSU had used a figure inconsistent with the evidence heard regarding the number receiving treatment. He also referred to the latest

clarification note (No 13) which indicated that there would be two procurement cycles – which is inconsistent with the tender document.

Dr Stefan Zrinzo Azzopardi, Legal Representative for the CPSU said that there were two objections raised – what was included in the list and capping. With regard to the list he mentioned that the process of what went on that list was thought out scientifically based on the efficacy of products and there were other avenues open to suppliers to have their products included.

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

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This Board,

Having noted this Call for Remedies prior to the Closing Date of a Call for Competition filed by Pharma.MT Limited (hereinafter referred to as the Appellant) on 8 February 2018, refers to the contentions made by the same Appellant with regards to the Tender of Reference RFP 021/14020/2017 listed as Case No 1155 in the records of the Public Contracts Review Board.

Appearing for the Appellant: Dr Jonathan Thompson

Appearing for the Contracting Authority: Dr Stefan Zrinzo Azzopardi

Whereby, the Appellants contend that:

a) **Although the published drugs listed in the Tender Document are exhaustive, the product "*Natalizumab*", which is one of the drugs for the treatment of Multiple Sclerosis, has been omitted;**

b) **Pharma.MT Limited also insist that the current Tender, through its capping system, disadvantaged any supplier who wants to bid for just one item and which is priced over the capped price.**

This Board also noted the Contracting Authority's "*Letter of Reply*" dated 26 February 2018 and its verbal submissions during the Public Hearing held on 12 April 2018, in that:

a) **The Central Procurement and Supplies Unit contends that the reason why the Appellants' product was not included in the published list, was simply due to medical reasons relating to side effects;**

b) **The Contracting Authority also maintains that it had abided by the decision taken by the Public Contracts Review Board and in no way limits the scope of participation.**

This same Board also noted the testimonies of the witnesses duly summoned by Pharma.MT Limited, namely:

1. **Dr Josanne Aquilina**
2. **Dr Angus Byars**
3. **Dr Ljubomir Dimitrovski.**

This Board, after having examined the relevant documentation to this Appeal and heard submissions made by the parties concerned, including the testimony of the witness, the latter on which great emphasis were placed, in its adjudications, opines that the issues which are to be considered on their merits are twofold:

i) **The noninclusion of the Appellants' product in the published list of drugs;**

ii) **The capping issue so dictated in the Tender Dossier, followed by a revision of the same in the Clarification note.**

i) **<u>The non-inclusion of the "*Natalizumab*" drug</u>**

With regards to this issue, Pharma.MT Limited are maintaining that this drug is efficient and is being administered in extreme cases for the treatment of this condition of multiple sclerosis and yet it was not included in the list of drugs in the Tender Dossier.

On the other hand, the Central Procurement and Supplies Unit insist that such non-inclusion of the drug "*Natalizumab*" was based on medical reasons as the same drug has severe side effects.

As can be appreciated and acknowledged, this Board has to rely substantially on the knowledge and submissions of medical experts in this field of medicine and in this regard, this Board would refer directly to the testimony of Dr Josanne Aquilina, a consultant neurologist, as follows:

"***Dr Jonathan Thompson: Jekk insemmilek il-mediċina Natalizumab, l-ewwel nett x' taf tgħidilna fuqha u jekk hix qegħda f' din il-lista jew jekk hemmx xi ħaġa ohra ekwivalenti u li tagħmel l-istess ħaġa f'***

din il-lista u jekk tistax tgħidilna ukoll jekk tafx għalfejn ġiet eskluża minn din il-lista.

Xhud: Bħala mediċina ilha available għal numru ta' snin. Hija waħda mill-ewwel mediċini li hija konsiderata bħala high efficacy l-ewwelnett jiġifieri hija effettiva ħafna fuq pazjenti b' multiple sclerosis li għandhom marda aggressiva.

L-annualized relapse rate titnaqqas b' mod sostanzjali jiġifieri qegħda 63 jew 65% efficacy. Titnaqqas l-annualized relapse rate. Normalment nużawha f' pazjenti li għandhom multiple sclerosis li hija aggressiva.

Il-problema li għandna b' Natalizumab hija side effect profile tagħħa. Kulħadd jaf li waħda mill-complications hija dik li ngħidulha il-progressive multifocal leukoencephalopathy li hija virus fil-brain li jista' jkun fatal. Allura hemm ċertu proċeduri li nkunu rridu niffolowjaw biex intawlu l-effetti kemm nistgħu fuq il-pazjenti, għax jistgħu jkunu fatali.

Dr Jonathan Thompson: Bħala droga tiġi prescribed in certain situations hawn Malta?

Xhud: Iva bħala droga nużawha. Bħala mediċina nużawha fuq dawk il-pazjenti li għandhom marda aggressiva tal-MS li diġa iffailjaw mill-mediċini l-oħra li huma in low jew moderate efficacy pero' aħna dejjem niċċekkjaw rutina il-JC Virus li huwa dan il-virus li jikkaġuna l-PML fil-pazjenti.

***F' dawk li huma JC Virus Negative għandhom inqas riskji li jiżviluppaw dil-marda għalkemm inkunu rridu nibqgħu niċċekkjaw il-livell tal-virus every six months*"**

From the above testimony, it is being confirmed that the drug, "*Natalizumab*", is being used in extreme cases where intense monitoring is administered on the patients' progress due to the side effects caused by such a drug. However, it was also noted that the use of such a drug, in extreme cases, has its advantages, as duly explained by the consultant neurologist as follows:

"*Dr Jonathan Thompson: Ngħid sew li per eżempju wieħed mill-effetti ta' din il-mediċina huwa li min ma jkunx jista' jimxi, jista' saħansitra anke jibda jimxi bis-saħħa ta' dil-mediċina?*

Xhud: Din il-mediċina hija waħda minn dawk il-mediċini li tista' tirranġa ftit, jiġifieri jkun hemm ftit improvement mid-diżabilita' li kien hemm qabel. Jien personalment qatt ma kelli esperjenza ta' din il-ħaġa jiġifieri li jekk ikunu kompletament ħżiena f' wheelchair imbagħad jistgħu iqumu jimxu pero' kien hemm xi każijiet li bdew jirranġaw.

Dr Jonathan Thompson: Saqsejtek ukoll jekk tafx għalfejn mhix qegħda nkluża f' din il-lista. Ma nafx jekk tafx, jekk ma tafx ma jimpurtax.

***Xhud: Le ma nistax nagħti raġuni speċifika.*"**

From the above testimony, this Board was not presented with a justifiable reason as to why the drug "*Natalizumab*" should not be

included in the published list of drugs for the treatment to the condition, in extreme cases, of multiple sclerosis.

i) <u>Capping of € 11,000</u>

With regards to Pharma.MT Limited's second concern, this Board refers to its previous decision in this regard, whereby it was decided that the Central Procurement and Supplies Unit should rectify the "*award criteria*" to allow the introduction of all available drugs for the treatment of this disease without any impairment of such inclusion through an average capping amount per patient per annum.

The spirit behind such recommendations was to allow, as much as possible, the availability of modern drugs without any restrictions. The capping element, in itself, does limit the application and procurement of high value drugs (Second Line). Such limitation is also indicated in the Tender Document with particular reference to page 3, wherein it is clearly dictated that,

"*Currently procured products will not be processed further if offered at a cost higher than the capped price provided*"

In this case, although the capped price has been revised to € 11,000, it is still precluding drugs for second line treatment as such products do exceed the capped price of € 11,000. And again, the tender dossier continues to stipulate that,

"*Items that are currently not being provided will only be procured if these are within the capped price*".

In this regard, this Board opines that the capping of such procurement is limiting the availability of specialised/advanced medicine to treat the various stage of this disease.

This Board strongly opines that the first priority which must be taken into consideration in this procurement, is the patient's interests and well-being and after having heard lengthy submissions from the professional and technical witnesses, this Board recommends that the present tender is to be cancelled

and a new one is to be issued taking the following factors into consideration for inclusion in the new Tender Document:

a) **There is no justifiable requirement to segregate first line from second line drugs;**

b) **The list of products in the Tender Dossier should include all the possible available drugs on the market, without any restrictions or limitations, unless there exists proven medical reasons that such drugs are not beneficial to the patient;**

c) **There should be no average capping price for the procurement of the listed drugs unless such capping will realistically and factually reflect the inclusion of high value available drugs;**

d) **To avoid any misunderstandings, the Tender Document should clearly indicate that prospective Bidders can submit an offer for any one particular drug from the published list;**

e) There should not be included any clause which might be ambiguous or misinterpreted;

This Board would respectfully point out that most of the clarifications and recommended rectifications to the contents of this Tender Dossier have been discussed and hopefully exhausted so that this same board does not envisage any insurmountable problems which cannot be easily ironed out to issue a new Tender for this procurement without any undue delay.

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

3 May 2018