PUBLIC CONTRACTS REVIEW BOARD

Case 1154 – 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, V J Salomone Pharma 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 – V J Salomone Pharma Ltd

Dr Mario De Marco	Legal Representative
Dr Joseph Bugeja	Legal Representative
Ms Agnes Nagy	Representative
Ms Jacqueline Scerri	Representative
Mr Jacov Cordina	Representative

Contracting Authority – Central Procurement and Supplies Unit (Health)

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

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

Dr Mario De Marco, Legal Representative for V J Salomone Pharma Ltd opened by stating that in the Request for Proposal there were two issues the Appellant was objecting to – the first related to the batching of first and second line drugs used in the treatment of MS, and this arose because the bulk of the medicines were in the first line. The ranking of prices and existing protocols meant that treatment starts on the cheapest drug – efficacy of the product not price should be the determining factor. The second and main objection was the issue of 'capping' originally set at € 9,000 but now revised to € 11,000. This placed his clients' product Fingolimod, average individual treatment € 20,000 per annum, outside the tender price range. This squeezed his clients' product out of the tender process creating an unrealistic barrier to trade.

At the first hearing of this case the PCRB decision was that capping restricts competition and excludes certain products by creating obstacles. Through Clarification Note 9 the CPSU had raised the limit but Fingolimod was still excluded as the price was higher than the new limit. What the Board had intended was that there should be no capping of prices.

The Chairman stated that the Board in clarifying the objection regarding capping wanted to remedy an ambiguity in that through capping not all products were included in the tender.

Continuing, Dr De Marco said that the issue was not 'average capping' but a realistic capping. In their Reasoned Reply, paragraph 2, the CPSU had accepted that the procurement is limited to a maximum price at which procurement can occur. This was not realistic as it was advantageous to lower priced medicines and excluded products of higher values. The CPSU's revised capping did not reflect the Board's intentions and was still excluding Fingolimod. He repeated that this created barriers to trade, distortions to competition and discrimination. He suggested that there should, at least, be two cappings to cover different prices.

The Chairman proposed that witnesses be heard at this stage to establish how many MS patients were receiving treatment, whether any supplier of medicines was being excluded and how the capping averages were worked out.

Dr Alison Anastasi (398380M), Consultant Neurologist at the Ministry of Health, testified on oath that currently there were 250 MS patients being treated. She confirmed that the average was worked out by dividing the number of patients by the type of drug (high or low value) they were being administered. To a question as to why there could not be two separate cappings covering different prices, witness stated that this would exclude the introduction of new medicines, which were regularly coming on the market. Witness agreed that the capping system created problems because of budget restrictions.

The next witness was Dr Josianne Aquilina (682461M) who testified on oath that she was a Consultant Neurologist at Mater Dei Hospital. She stated that in administering drugs there were three factors to consider – the burden of the disease, the efficacy of the drug and the side effects. She mentioned that new patients could not be prescribed Fingolimod because of the price capping and a substitute medication would be used. In reply to a question, witness stated that prices were constantly changing as new products came on the market, and in cases where a particular medication was prescribed but it was not on the list the clinicians resorted to a mechanism referred to as 'exceptional treatment'.

Ing Karl Farrugia (24774M), Chief Executive Officer, Ministry of Health, testified on oath that through the capping mechanism the Ministry was able to introduce new medicines thus giving an a opportunity to all firms to compete. He outlined the procedure when it was necessary to obtain medicines not covered by a tender and they had to resort to price negotiations. He accepted the comment made by the Chairman that there were two clauses in the tender document that excluded products above a certain price, and witness said that if necessary these clauses would be clarified.

The final witness was Ms Lara Cauchi (309275M). Under oath she testified that she was the Head of Business Operations and Market Access for Novartis in Malta. She tabled a document showing that the average price of Fingolimod in European countries was € 20,730, and that in none of these countries could the product be obtained at the capped price of € 11,000. The market price in Malta was the cheapest of the European countries.

The Chairman said that the issue arose because of price limitation and the clauses in the tender document that restricted items that are currently not being provided from being procured.

Dr De Marco claimed that the Ministry's argument was financial not medical. Treatment of patients is not a matter of price limitations which created an artificial barrier to trade and conflicted with European Union regulations. Firms were indirectly being told not to tender.

In his closing remarks, Dr Stefan Zrinzo Azzopardi, Legal Representative for the CPSU said that the case of the Appellant was a commercial argument dressed as a medical one. The CPSU's view is that resistance to capping is an excuse not to lower prices. The Board's decision had been respected since the capping had been revised upwards.

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

This Board,

Having noted this Call for Remedies prior to the Closing Date of a Call for Competition filed by VJ Salomone Pharma 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 1154 in the records of the Public Contracts Review Board.

Appearing for the Appellant: Dr Mario Demarco

Dr Joseph Bugeja

Appearing for the Contracting Authority: Dr Stefan Zrinzo Azzopardi

Whereby, the Appellants contend that:

a) **Their first contention is that the mode of batching first line drugs with second line drugs under one list will give an advantage to the suppliers of the first line medicine since the latter are administered more and are cheaper than the second line drugs;**

b) Although the capping has been increased to € 11,000, there still exists an automatic disqualification for offers for second line drugs, the value of which exceeds the capping limit.

This Board also considered the Contracting Authority's "*Letter of Reply*" dated 23 February 2018 and its verbal submissions during the Public Hearing held on 12 April 2018, in that:

a) The Contracting Authority maintains that through clarifications, it had abided by the recommendations as instructed by the Public Contracts Review Board in the latter's decision dated 9 January 2018;

b) The Central Procurement and Supplies Unit also insist that the capping price was reviewed, as instructed by the same Public Contracts Review Board, after taking into consideration the number of patients being administered on low and high value drugs. At the same instance, the Contracting Authority points out that the capping is a necessary measure due to budget restrictions.

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

1. **Dr Alison Anastasi duly summoned by the Public Contracts Review Board;**

2. **Dr Josanne Aquilina duly summoned by the Public Contracts Review Board;**

3. **Ing Karl Farrugia duly summoned by the Public Contracts Review Board;**

4. **Ms Lara Cauchi duly summoned by VJ Salomone Pharma Limited.**

This Board, after having examined the relevant documentation and heard submissions made by all the interested parties, including the testimony of the technical witnesses, the latter of which has been given great importance, opines that the issues to be considered are:

i) **The batching of first line drugs with second line drugs;**

ii) Capping of € 11,000

i) <u>The batching of first line drugs with second line drugs</u>

This Board would respectfully point out that, after hearing the testimony of the witnesses, the segregation of first line from second line drugs will not solve the issue of limitation and, in this Board's opinion, neither the possibility of establishing separate capping limits will provide a solution. In this regard, this Board has been made aware that new drugs for the treatment of this medical condition are being made available on the market and the objective of the Contracting Authority is to make as many drugs available as possible to the clinicians, to treat this condition. At the same instance, it has been established that prospective Bidders can participate to submit an offer for any one particular drug published in the list of drugs in the tender dossier, although the latter consideration was not indicated in the Tender Document. In this regard, this Board refers to an extract from the testimony of Ing Karl Farrugia, as follows:

"***Chairman: Inġinier, jekk jogħġbok. X' differenza tagħmel għas-CPSU jekk il-lista tinqasam fi tnejn, low u high level of medicine u joħroġ average għall kull wieħed separat?***

Xhud: Issa jekk aħna ħa naqsmuhom fi tnejn, dak ifisser li meta l-persuna klinika ħa jiġi biex jiddeċiedi x' tip ta' mediċina ħa jagħti lil pazjent partikolari, irid jara li l-ewwel ħa jibda fil-low u mbagħad jaqleb fuq il-medium, ejja ngħidu medium biex ma nużawx il-high għall-istess terminoloġija.

Aħna dik il-barrier xtaqna neliminawh, u xtaqna neliminawh biex nagħtu opportunita' lill-kumpaniji jiżdiedulhom in-numru ta' pazjenti li ħa ninqdew bihom għax ovvjament iktar ma jiżdied il-volum, iktar il-prezz jonqos. Hekk taħdem l-industrja.

U jekk ħa nissegregaw minn xulxin, erġajna splitjajna r-realt'a li l-clinician ma jistax jibda fuq wieħed jew fuq l-ieħor, ikollu jibda fuq dak li huwa low u mbagħad jibqa' tiela."

From the above testimony, this Board establishes that the Central Procurement and Supplies Unit's main purpose for publishing one list containing both first line and second line drugs, was purely to provide a wider opportunity for the availability of drugs for this medical condition. At the same instance, this Board's prime concern is the well-being of the patient so that the best of treatment available for this condition can be at the disposal of the clinician. In this regard, this Board does not find that segregation of first line from second line drugs will be of any benefit to the patient but rather that all available drugs, whether first line or second line, are made available without any restriction whatsoever to safeguard the administration of the best of treatment to the patient. In this respect, this Board would refer to part of the testimony of Dr Josanne Aquilina wherein she said:

"***Jiġifieri l-ħin kollu tinbidel l-istampa tal-multiple sclerosis għax joħorġu mediċini ġodda, joħorgu mediċini with different efficacies and different profiles, jiġifieri dan iktar ma jkollok mediċini fil-basket, iktar ħa jkollok fejn tagħżel.***"

In this regard, this Board does not find any justifiable medical reason as to why there should be segregation between first line and second line drugs in the tender dossier, as long as all the available drugs are so listed in the technical offer.

ii) <u>Capping of € 11,000</u>

With regards to VJ Salomone Pharma 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	Dr Charles Cassar	Mr Carmel Esposito
Chairman	Member	Member

3 May 2018