Case 1104 – RFP 021/14020/2017 – Request for Participation (Negotiation) for the Supply of Drugs Used in the Management of Multiple Sclerosis (MS)

The Publication Date of the Call for Tenders was 29 September 2017 whilst the Closing Date for Call of Tenders was 27 October 2017. The Estimated Value of the Tender, (Exclusive of VAT) was € 2,700,000.

On 30 October 2017, VJ Salomone Pharma Limited filed a Call for Remedies before the Closing Date of the Competition against the Central Procurement and Supplies Unit.

On 21 November 2017, the Public Contracts Review Board composed by Dr Anthony Cassar as Chairman, Dr Charles Cassar and Mr Carmel Esposito as members convened a Public Hearing to discuss the Objection.

The Attendance for this Public Hearing was as follows:

Appellant – VJ Salomone Pharma Limited

Ms Lara Cauchi	Representative
Ms Agnes Nagy	Representative
Mr Adrian Salomone	Representative
Mr Michael Sultana Loporto	Representative
Dr Joseph Bugeja	Legal Representative
Dr Mario de Marco	Legal Representative

Contracting Authority – Central Procurement and Supplies Unit

Ms Alison Anastasi	Representative
Ms Danika Agius Decelis	Representative
Ing Karl Farrugia	Representative
Dr Stefan Zrinzo Azzopardi	Legal Representative

Following an introduction by The Public Contracts' Review Board Chairman, Dr Anthony Cassar, the Appellants were invited to make their submissions.

Dr Mario de Marco, the Legal Representative for VJ Salomone Pharma Limited opened by saying that his clients' Objection was based on three grounds. Their call for remedy was based on the fact that the Central Procurement and Supplies Unit issued a Request for Proposals for a number of products based on Multiple Sclerosis which is a serious and complicated illness.

The Request for Proposals requested a number of products which are intended for treatment and which are not necessarily interchangeable. There is a price cap of € 9,000 per patient so one has to calculate how much there is projected for each protocol without exceeding the mentioned cap.

The products indicated make a distinction between First and Second Line therapy. From all the indicated medics, there were two which are second line therapy. The latter line drugs are more specialised than the First Line Drugs and treat the gravest situations of Multiple Sclerosis.

Dr Mario de Marco continued explaining that it was very ambiguous to put both lines of medicines in the same Request for Proposals as if they are interchangeable between them. If the latter was issued as two separate Request for Proposals, VJ Salomone Pharma Limited would not have any Objection because the aim of the two treatments is very different. The Central Procurement and Supplies Unit assumed that both lines of therapy are interchangeable, hence putting them in the same Request for Proposal.

VJ Salomone Pharma Limited's Second Objection regarded Clinical Protocol. Dr Mario de Marco said that the Request for Proposal was misleading and he referred to Page 3 of the same which *inter alia* stated,

"*All technically compliant offers received will be ranked according to the price required to treat each patient annually. It is estimated that 100 patients per year will be benefiting from these treatments. The newly diagnosed patients will be initiated on the cheapest technically compliant product and will have the option to move down the product cascade according to the next higher ranking product until s/he is stabilised on the cheapest yet effective and tolerated product according to published clinical protocols*"

Dr de Marco continued by saying that his clients have brought witnesses to testify on the fact that the patients cannot be started on the cheapest technical compliant offer since there are different degrees of Multiple Sclerosis. There are protocols who request different forms which can lead to the commencement of treatment from the First Line in some cases and from the Second Line in others.

Besides, the Second Line drugs are more advanced, more specialised and more expensive and should help to reach a graver status. In their Reasoned Letter of Reply dated 17 November 2017, the Central Procurement and Supplies Unit wrote that it was the clinicians who had to decide which medicines are to be given to the different patients according to the case in question. On the other hand, the Request for Proposal was stating that the treatment was to be based on the cheapest compliant medicine which does not make sense as this must be seen according to the patient's needs at the moment.

Dr Mario de Marco continued by saying that the issue here was not the price but how much the product was compatible with the patient. He referred to one of the products mentioned in the Request for Proposal, Fingolimod which was a Second Line blood treatment and was the only product which has the ingredient called Gilenya. There was no other product which has this ingredient. Fingolimod was already being given to the Government through the Directorate of Pharmaceutical Affairs at the price of € 58.92 per capsule. In this case, the resultant price calculated for this product was € 55.19.

If one had to make an estimate on the number of capsules indicated in this Request for Proposal, each patient would cost the Government about € 20,000. This price was not only established by the same Directorate but was also established in 11 EU countries. This means that the € 9,000 cap imposed by the Request for Proposals was going to be exceeded by over twice as much, apart from the fact that there is a sentence in the Award Process at this Request for Proposal which said that,

"*Current Procured Products will not be assessed if the price is higher than the cap provided*"

Dr Mario de Marco was wondering what would happen to those twenty patients who currently use Gilenya if these were to be stopped. The Appellant's Legal Representative was insisting that these drugs cannot be changed since they are specialised. This was not a case of monopoly but was a case of a specialised drug which was launched into the market after a lot of research. The Central Procurement and Supplies Unit could not ask for a product to be offered with half the price which is currently being offered.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit, opened by saying that at this stage he wanted to introduce his clients' case in order for everybody present to understand the aim which this Procurement wanted to deliver. One had to frame the discussion on the basis of the Public Procurement Regulations and whether there were any clauses of the Request for Proposals which were breaking the same, once there was this Call for Remedies prior to the Closing Date of the Competition.

Dr Zrinzo Azzopardi explained that VJ Salomone Pharma Limited based their Objections on two grounds referring to ambiguous terms which go against Clause 262(d) of the Public Procurement Regulations and discriminatory grounds which go against Clause 262 (c) of the latter. The debate must be directed on these two grounds.

These medicines are specialised on this type of illness which was difficult to everybody, let alone technical people in this area, to explain. There is a list of medicines which every Bidder could have applied for. It was true that the Multiple Sclerosis was divided into two different Lines of therapy which distinguish different factors. These will be explained by a witness brought by the Contracting Authority who will explain that the Request for Proposal was going to disadvantage no body since the treatment was going to be evaluated on its own.

The Central Procurement and Supplies Unit was contending the argument brought forward by VJ Salomone Pharma Limited that the fact that both lines of therapy were issued together since these were not going to discriminate any Bidder. It will be the clinicians who will decide what treatment should be given at the end of the day. The Request for Proposals system was being adopted because in this situation there isn't a Tender which can plan how

many pills the Contracting Authority can buy like in other situations since this type of illness was more patient specific.

With regards to Dr de Marco's argument on the way with which the Central Procurement and Supplies Unit was going to buy these capsules, Dr Stefan Zrinzo Azzopardi referred to Page 3 of the Request for Proposals which *inter alia* said that,

"*This process is being done so that the patients who will be initiating treatment after this Tender is awarded, will be offered treatment with the cheapest technically compliant medicine. Thereby it is through clinical consensus that this cycle will be used to establish the clinical protocol*."

The Contracting Authority was looking for the most efficient way to buy the medicine and therefore they were finding the most efficient way on how to buy them. The fact that the Central Procurement and Supplies Unit was binding itself with these treatments, their buying price and the fact that these were going to be chosen according to the patients' needs, they were giving a chance to whoever was offering this medicine to be chosen as long as the price does not exceed € 9,000.

It was the clinician's responsibility to decide whether the patient was going to be started on the First or Second Line of Therapy. The Central Procurement and Supplies Unit has the modality to agree on a parameter of price products according to the requests needed.

With regards the Fingolimod Capsules, Dr Stefan Zrinzo Azzopardi, wanted to submit that the price mentioned by Dr Mario de Marco was established in 2013. The fact that the Contracting Authority wanted to be more price efficient doesn't mean that the latter was seeking lesser quantity since all the Bidders who will submit eventual offers will be treated equally

The a patient who is being given a type of pharmaceutical with less than € 9,000 will not be denied the current treatment given because a new Tender was being enforced. There are cases in the Public Procurement Regulations which protect these medicines and patients and there are policies established on how this is to be made. The Contracting Authority's obligation towards the patient is to continue.

Dr Stefan Zrinzo Azzopardi continued by saying that one had to look to three points when talking about totality since every Bidder can submit an offer within a specialised price brand. The final choice will depend on clinical decisions but the Central Procurement and Supplies Unit was bound to choose with people who can make offers in a particular time.

At this point, Dr Ivaylo Simeonov, a Chief Scientific Officer within Novartis, holding ID Card Number 6468762, was summoned by VJ Salomone Pharma to testify under oath before the Public Contracts Review Board.

At the end of Dr Simeonov's testimony, Mr Robert Palmer, a Head Patient Access in Central & Eastern Europe for Novartis, holding ID Card 067468234001 was summoned by VJ Salomone Pharma to testify under oath before the Public Contracts Review Board.

Following Mr Palmer's testimony, Dr Mario de Marco, the Legal Representative for VJ Salomone Pharma Limited requested the Testimony of Ms Antonia Formosa, a Director

within the Directorate of Pharmaceutical Affairs but informed the Public Contracts Review Board that she was not present for the Public Hearing.

Dr Stefan Zrinzo Azzopardi, the Legal Representative of the Central Procurement and Supplies Unit replied that instead of her, the Contracting Authority has brought Dr Dennis Vella Baldacchino who is the Chief Director Officer of the Director of Pharmaceutical Affairs and Ms Formosa's direct superior.

Dr Mario de Marco, the Legal Representative for VJ Salomone Pharma Limited while insisting on Ms Formosa's presence for cross examination requested for a deferment in order to Ms Antonia Formosa to testify.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board warned that the process was going to lengthen itself but that he was accepting the Appellant's request for deferment and bring in the Contracting Authority's Witness for Cross-Examination.

At this point, Dr Denis Vella Baldacchino, the Chief Medical Officer for the Ministry for Health, holding ID Card Number 560962 M, was summoned by the Central Procurement and Supplies Unit to testify under oath before the Public Contracts Review Board.

At the end of Dr Vella Baldacchino's testimony, the Public Hearing was adjourned to Thursday 23 November 2017 at 13:00 wherein the testimony of Ms Antonia Formosa and of another clinician brought in by the Central Procurement and Supplies Unit will be heard.

Second Public Hearing

On 23 November 2017, the Public Contracts Review Board composed by Dr Anthony Cassar as Chairman, Dr Charles Cassar and Mr Carmel Esposito as members convened a Public Hearing to discuss the Objection.

The Attendance for this Public Hearing was as follows:

Appellant – VJ Salomone Pharma Limited

Ms Lara Cauchi	Representative
Ms Agnes Nagy	Representative
Mr Michael Sultana Loporto	Representative
Dr Joseph Bugeja	Legal Representative
Dr Mario de Marco	Legal Representative

Contracting Authority – Central Procurement and Supplies Unit

Ms Alison Anastasi	Representative
Ms Danika Agius Decelis	Representative
Ing Karl Farrugia	Representative
Dr Stefan Zrinzo Azzopardi	Legal Representative

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board opened by saying that this Public Hearing was convened in order to cross examine a witness brought in by VJ Salomone Pharma.

At this point, Ms Antonia Formosa, a Director within the Directorate of Pharmaceutic Affairs, holding ID Card Number 373667 M was summoned by VJ Salomone Pharma to testify under oath before the Public Contracts Review Board.

At the end of Ms Formosa's testimony, Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit, said that they wanted to bring a Consultant for this Public Hearing as a Witness but since the date for the Second Public Hearing was given at a short notice, he was not in a position to attend.

Therefore, the Central Procurement and Supplies Unit were to propose two dates where the Public Hearing for this case was to resume following an agreement with the Appellants.

Third Public Hearing

On 7 December 2017, the Public Contracts Review Board composed by Dr Anthony Cassar as Chairman, Dr Charles Cassar and Mr Carmel Esposito as members convened a Public Hearing to discuss the Objection.

The Attendance for this Public Hearing was as follows:

Appellant – VJ Salomone Pharma Limited

Ms Lara Cauchi	Representative
Ms Agnes Nagy	Representative
Ms Jacqueline Scerri	Representative
Dr Joseph Bugeja	Legal Representative
Dr Mario de Marco	Legal Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Alison Anastasi	Representative
Ms Danika Agius Decelis	Representative
Ing Karl Farrugia	Representative
Dr Stefan Zrinzo Azzopardi	Legal Representative

Following an introduction by The Public Contracts' Review Board Chairman, Dr Anthony Cassar, Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit said that he has brought two witnesses for cross-examination.

At this point, Dr Josanne Aquilina, a Consultant Neurologist at Mater Dei Hospital, holding ID Card Number 682461, M was summoned by the Central Procurement and Supplies Unit to testify under oatch before the Public Contracts Review Board.

Following Dr Aquilina's testimony, Dr Norbert Vella, the Clinincal Chairperson in the Neurosciences Department at Mater Dei Hospital, holding ID Card Number 93362 M, was summoned by the Central Procurement and Supplies Unit to testify under oath before the Public Contracts Review Board.

At the end of Dr Vella's testimony, Dr Alison Anastasi, an Assistant Director within the Central Procurement and Supplies Unit, holding ID Card Number 398380 M, was summoned by the same Contracting Authority to testify under oath before the Public Contracts Review Board.

At the end of Dr Anastasi's testimony, Dr Mario de Marco, the Legal Representative for VJ Salomone Pharma said that their Call for Remedy was based on Article 262 of the Public Procurement Regulations wherein they were requesting the Public Contracts Review Board to correct a number of ambiguities which were found in the Request for Proposals and to remove those clauses which they felt that they were discriminatory.

Dr de Marco would have been more satisfied with the Request for Proposals had the Central Procurement and Supplies Unit issued the document by themselves without anyone interfering in the protocol issue, where the Contracting Authority was mistaken. The latter had every right to buy whichever product it pleases but they went beyond their remit since anything beyond had to be decided by the clinicians.

Dr Mario de Marco quoted Page 3 of the Request for Proposals which *inter alia* said,

"*All Technically Compliant offers received will be ranked according to the price required to treat each patient annually*".

The Appellant's Legal Representative continued to explain that this was wrong since the ranking should have been determined by the product's efficiency rather than the price. The way that the Request for Proposal was formulated was a wrong and discriminatory one.

VJ Salomone Pharma Limited was going to talk only about what there was written on the Request for Proposals and the Central Procurement and Supplies Unit was wrong in binding the consultants who at the end of the day were responsible to cure the patients under their care.

With regards to the price, Dr Mario de Marco, was wondering how come they determined a capping of € 9,000 when the Fingolimod alone costed € 20,000. This could not be done since the products were different. The average concept, with reference to the different efficiencies available in this Request for Proposal, does not make sense unless one was comparing like with like. Despite their good intentions, the Central Procurement and Supplies Unit worked with the wrong parameters.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit said that the reasons why there was this Call for Remedies were in the Appellant's Letter of Objection. With regards, the Maximum Reference Price, this was installed in order to provide a ceiling for the Contracting Authority on how much they can spend. The Government indicates this for audit purposes.

The basic rules which one had to respect were the technical compliance and the price issue. The Appellants, according to Dr Zrinzo Azzopardi, were requesting that two separate Requests for Proposals, one for First Line Drugs and another one for Second Line Drugs were to be issued. This could not be done and besides, neither clinician found a problem in making a Single Request for Proposal for both drugs.

A basic point when it comes to the medicines available in Public Health was the Formulator of Medicines that the Government approves. The Central Procurement and Supplies Unit have a complicated and particular Procurement Protocol when it comes to the buying of medicines.

Dr Stefan Zrinzo Azzopardi said that this Request for Proposals was giving more tools for the consultants with which to work, gives a wider choice of medicines available and increases competition. A proposal was being made to see whether the Contracting Authority can manage to buy the medicines with € 9,000 and the latter was neither doing wrong nor creating an ambiguity in doing so.

Dr Mario de Marco, the Legal Representative for VJ Salomone Pharma Limited insisted that Dr Vella himself testified against the proposal to go for the cheapest medicine available. His clients were making a request to separate the First Line Drugs from the Second Line Drugs because the element of Public Tenders can only compare like with like. One cannot base everything on the price.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit, concluded that every offer was going to be evaluated in the correct way. A whole list of items was going to be bought and the clinicians will buy according to the medical protocol. One cannot say that there is a like with like comparison when the products will be evaluated individually.

At this stage, the Public Hearing was adjourned to Tuesday 9 January 2018 at 09:00 wherein the Public Contracts Review Board will transmit the decision taken for this Objection verbally and then distribute a hard copy of the same to all parties concerned.

This Board,

Having noted this Call for Remedies prior to the Closing Date of Competition filed by VJ Salomone Pharma Limited (herein after referred to as the Appellant) on 30 October 2017, refers to the Contentions made by the latter with regards to the issue of Tender of Reference RFP 021-14020/2017 listed as Case No 1104 in the records of the Public Contracts

Review Board, issued by the Central Procurement and Supplies Unit (herein after referred to as the Contracting Authority).

Appearing for the Appellant: Dr Mario de Marco

Dr Joseph Bugeja

Appearing for the Contracting Authority: Dr Stefan Zrinzo Azzopardi

Whereby, the Appellant contends that:

a) **The list of drugs as contained in the "*Request for Participation*" lacks the distinction between first line drugs and second line drugs and in this regard, VJ Salomone Pharma Limited contend that such a mode of publication will limit the scope of free competition and creates ambiguity.**

b) **The Appellants also refer to the capping of the average maximum cost of € 9,000 per patient, per annum whereas, such capping will determine the treatment of patients which might be detrimental to the well-being of the latter.**

This Board also noted the Contracting Authority's "*Letter of Reply*" dated 17 November 2017 and its verbal submissions during the Public Hearings held on 21 November 2017, 23 November 2017 and 7 December 2017 in that:

a) **The Central Procurement and Supplies Unit contends that the list of drugs as dictated in the "*Request for Participation*" and which includes first line drugs and second line drugs without any particular distinction between them, does not, in any way, limit the scope of competition or creates ambiguities, as any Bidder can opt to submit an offer for any of the listed drugs;**

b) **The Contracting Authority also maintains that the choice of drugs to be administered on a patient suffering from Multiple Sclerosis will be determined by the clinician and not the cost of the drug which the patient requires. In this regard, the Central Procurement and Supplies Unit insist that the capping of € 9,000 per patient per annum is a targeted guideline and is to be considered as a controlling cost for budgeting purposes and not to limit the treatment of patients.**

This same Board also noted the Testimonies of the witness namely:

1. **Dr Ivaylo Simeonov duly summoned by VJ Salomone Pharma Limited;**

2. **Mr Robert Palmer duly summoned by VJ Salomone Pharma Limited;**

3. **Dr Dennis Vella Baldacchino duly summoned by the Central Procurement and Supplies Unit;**

4. **Ms Antonia Formosa duly summoned by VJ Salomone Pharma Limited;**

5. **Dr Josanne Aqulina duly summoned by the Central Procurement and Supplies Unit;**

6. **Dr Norbert Vella duly summoned by the Central Procurement and Supplies Unit;**

7. **Dr Alison Anastasi duly summoned by the Chairman of the Public Contracts Review Board**

This Board, would respectfully state that, in assessing the grievances presented by the Appellants, it has given substantial importance and weight to the testimonies of the Technical Witness, in considering the issues relating to this concern. Although most of the technical submissions related to medical matters, this Board's main concern is to ensure the best of treatment and well-being of patients suffering from Multiple Sclerosis. In the regard, this Board noted carefully the numerous testimonies of the witnesses duly summoned by both VJ Salomone Pharma Limited and the Central Procurement and Supplies Unit, during the Public Hearings held on 21 November, 23 November and 7 December 2017.

This Board opines that, from submissions made, the two main concerns are the "*Composition of the List*" as contained in the Request for Participation and whether the "*capping of € 9,000 per patient per annum*", will restrict the administration of the most suitable drug which the patient will require and in this regard, these two issues will be considered as follows:

1. **<u>Classification of Drugs</u>**

   First of all, one has to bear in mind that the reason why such a "*Request for Participation"* is being issued, is to have an established list of drugs available for patients suffering from "*Multiple*

***Sclerosis*", which will eventually aid in the clinical treatment of this decease. The Appellants' concern, in this respect, is that the list should differentiate between first line drugs and second line drugs, as otherwise, the list, as presented will limit the scope of competition.**

From the various testimonies, it was glaringly noted that there seems to be a difference of opinion as to what can be classified as a first line drug and a second line drug, however, this issue should not deter this Board from considering the Appellants' concerns. From credible submissions, this Board notes that the well-being of the patient does not depend upon the class of drug but rather on the administration of the proper drug by the Clinician, so that it is the latter who dictates the type or classification of the drug.

In the regard, this Board was not presented with justifiable evidence to merit a segregation of first line drugs from second line drugs by issuing two separate "*Request for Participation*". The list as published in the RFP contains the available medicine for this type of decease and any classification of the drugs will not make any difference whatsoever, either to the Clinician who will dictate the particular drug or the patient as long as he is administered with the suitable drug. At the same instance, this Board would note the

following testimony given by Dr Dennis Vella Baldacchino, the Chief Government Medical Officer, whereby he is contesting the importance of classification of drugs into first line and second line drugs as follows:

"*Lili kienet tagħmilli differenza. Meta jiena rajt dan il-metodu, jiena hawnhekk rajt lill-Pazjenti tagħna ħa jibbenefikaw aħjar, ħa nsemmi fi ħdan tal-qafas tal-baġit li għandna. Il-Baġit Finanzjarju huwa dejjem limitat u allura aħna rridu nippruvaw nimmassimiżżaw, dak li nistgħu nottjenu għall-pazjent mill-Baġit li għandna.*

Meta jien rajt lill-Kliniċi jgħidulna li hawnhekk huma lesti li qegħdin jaraw fl-istess keffa, jew fl-istess kejl, jien jekk joħroġx RFP wieħed jew tnejn, dik ma nkunx dħalt fiha jien u ma nidħolx fiha. Jiena rrid nagħti opportunita' lill-pazjenti li jekk hemm min seta' jibbenefika, qed insemmu droga partikolari, l-Fingolimod, għalfejn bniedem m' għandux jingħata l-opportunita' li jużaha?"

This Board would also refer to the testimony of Ms Antonia Formosa, a Pharmacist and Director of Pharmaceuticals Directorate who, when asked about the difference between First Line Drugs and Second Line Drugs, replied as follows:

**"*Le, mhux eżatt. Hawnhekk ma ttieħditx il-linja ta' x' inhu First Line u Second Line. Il-First Line u s-Second Line meta' jkollna każijiet bħal dawn, fejn int għandek ħafna varjazzjoni f' dal-każ wieħed minnhom, inti għandek kull pazjent li jista' jirrispondi tajjeb fuq mediċina partikolari.*

Hawnhekk għandna kundizzjonijiet oħrajn li huma ċari. Dan huwa First Line. Dan Second Line. Dan Third Line. Pero fl-MS għandek grupp ta' drogi li kull konsulent jipprova wieħed wara wieħed sakemm isib dak li jkun addattat għall-pazjent."

This Board would also refer to the confirmation of the single list as published in the RFP, made by the same witness, wherein she stated that:

"*Dik konna qed nieħdu d-deċiżjonijiet fuq gwida li kienet ħarġet l-Association for British Neurologists bi qbil man-Newroloġisti Maltin.*"

This Board also considered the testimony given by Dr Josanne Aquilina, a Consultant Neurologist, who explained, in a very lucid

way, the mode of clinical classification of the drugs so dictated in the list, as follows:

"*Jiddependi lil min ħa tikkwota bħala First Line u Second Line. Meta qed ngħidu First Line, irid ikun hemm definizzjoni għal First Line. Jiġifieri jekk ser nitkellmu fuq First Line minn Assoċjazzjoni partikolari u korp regolatorju partikolari, qed nitkellmu fuq l-EMEA, tikklassifika First Line u Second Line iva.*

Pero' linji gwida li joħorġu mis-Soċjetajiet tal-iSklerożi Multipla, kif għedtlek, qegħdin jinbidlu u l-kliniċi jużaw skond is-sitwazzjoni klinika, skond kif qed jinbidlu l-linji gwida għax peress li ħerġin linji gwida ġodda sal-aħħar ta' din is-sena u anke First Line u Second Line trid teħodha ukoll, jekk per eżempju għandek pazjent fejn il-marda tiegħu hi attiva ħafna, ma toqgħodx tqis x' inhu First Line jew Second Line imma tmur għall-ogħla effikaċja mill-ewwel.

***Din qegħda ukoll fir-regolament tal-EMEA li inti tista' ma tużax First Line pero' taqbeż f' mard attiv ħafna għas-Second Line Drugs.*"**

After having considered all the submissions made by the Technical and Medical Experts in the field of "*Multiple Sclerosis*", this Board

does not find proof or evidence to justify the issue of two separate RFPs, i.e. one for First Line Drugs and another for Second Line Drugs. Through the experts' submissions, this Board was comfortably assured that the type of drug administered on patients does not depend upon its classification but rather on the condition and severity of the decease. At the same instance, this Board was not provided with justifiable evidence that the single list of drugs as published in the RFP, will in some way, limit the scope of competition as there is no restriction for the Appellants to submit their proposal for any of the listed drugs. In this regard, this Board does not uphold VJ Salomone Pharma Limited's First Grievance.

2. **<u>Effect on Treatment due to Capping</u>**

With regards to the Appellants' Second Contention, this Board would like to respectfully refer once again to the submissions made by the experts, wherein it was amply emphasized that the mode of treatment and the application of drugs is at the discretion of the Clinician and the latter's concern will be the type of medicine which is most suitable to the patient's condition and not the alleged capping of € 9,000 per patient per annum. This Board acknowledges the fact that, as in all Public Procurements, a Budget has to be laid out which

will act as a guideline with regards to costs to the particular department, however, in this particular case, this should not imply that if a patient requires a particular medicine which goes beyond the capped amount, will not be made available for the patient's well being. This Board also took notice of the submissions made by the Chief Government Medical Officer, Dr Dennis Vella Baldacchino, who confirmed that, even if the required drug is not on the list of available drugs, other means of procuring the specialised medicine, are available. In this regard, this Board has been comfortably assured that the treatment of patients will not be effected through the capping of € 9,000 per patient, per annum. This Board would also refer to the extracts from testimonies of the technical witnesses, as follows:

a) Extract from the Testimony by Dr Dennis Vella Baldacchino, Chief Government Medical Officer:

"Dr Anthony Cassar: Imma il-kliniku ser ikun ikkundizzjonat mill-kundizzjoni tal-prezz?

Xhud: Le. Assolutament le. Il-kliniku ħa jiddeċiedi liem mediċina minn dawn ħa juża.

Dr Anthony Cassar: Anke jekk jista' jkun li jkun hemm distinzjoni ta' prezz?

Xhud: Jiena min-naħa tiegħi, il-kliniku ma naħsibx li ser jara l-prezzijiet. Il-kliniku ħa jara l-mediċini li hemm għad-disposizzjoni tiegħu fil-Formularju li nkunu daħħalna u hu skond il-pazjent ħa jiddeċiedi.

Dr Stefan Zrinzo Azzopardi: Meta jkun hemm bżonn ta' deċiżjonijiet għal dawn il-mediċini li mhux fil-formularju jew hemm xi ħaġa straodinarja li trid tinbidel, min jagħti l-awtoriżżazzjoni?

***Xhud: Fl-aħħar mill-aħħar inkun jien li nevalwa ċ-ċirkostanza jew l-evidenza u minn hemm nieħu d-deċiżjoni.*"**

b) Extract from the Testimony by Dr Josanne Aquilina, Consultant Neurologist:

"Dr Anthony Cassar: Fil-prattika, Dr Aquilina, jekk inti qed ittini tip ta' mediċina għal din it-tip ta' marda, dik ħa tibdilieli?

Xhud: Le. Jekk qed intik mediċina u qed taħdem u sejjer tajjeb biha, m' hemm ebda raġuni għala titbiddel u għandha titkompla."

Having considered the above issues, this Board opines, that although it has been emphasized that such capping will not effect the well being of the patient, the Tender Document, due to its wording, still precludes a drug which eventually will go beyond the average of over € 9,000 per annum from being listed in the formulatory. In this regard, this Board recommends that the average capping per patient per annum should be based on the inclusion of all the possible drugs available for the treatment of this disease and in this regard, the Award Criteria should take this factor into account.

In view of the above, this Board:

i) **Acknowledges the fact that the "*Capping Issue*" as dictated in the Tender Dossier, does create ambiguities in the selection and award**

process. In this regard, this same Board recommends that, through a clarification note, 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;

ii) Recommends that, during the Evaluation Process, the Central Procurement and Supplies Unit always bear in mind, the treatment and well-being of the patient;

iii) Recommends that after such Clarification Note as recommended in i) above is issued, the "*Request for Participation*" process is to be continued.

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

9 January 2018