PUBLIC CONTRACTS REVIEW BOARD

Case 1358 – CT 2276/2019 – Tender for the Supply of Interlukin 17A Inhibitor

Remedy before Closing Date of a Call for Competition

The publication date of the call for tenders was the 4th August 2019 whilst the closing date was extended to the 3rd September 2019. The estimated value of the tender (exclusive of VAT) was € 1,010,202.64

On the 26th August 2019 V J Salomone Pharma Ltd sought a Remedy against the Central Procurement and Supplies Unit as the Contracting Authority requesting that the call for tenders be suspended.

On 27th September 2019 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Mr Lawrence Ancilleri and Mr Carmel Esposito as members convened a public hearing to discuss the objections.

The attendance for this public hearing was as follows:

Appellants – V J Salomone Pharma Ltd

Dr Mario De Marco	Legal Representative
Dr Therese Comodini Cachia	Legal Representative
Ms Lara Cauchi	Representative
Ms Jacqueline Scerri	Representative
Ms Gayle Bugeja	Representative
Mr Adrian Salomone	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Marco Woods	Legal Representative
Dr Alison Anastasi	Representative
Ms Tracy West	Representative

Department of Contracts

Dr Franco Agius	Legal Representative

Interested Parties;

Mr Kenneth Briffa	Representing Vivian Corporation
Ms Lisa Zammit Montesin	Representing Vivian Corporation
Dr Clement Mifsud Bonnici	Representing Charles de Giorgio
Mr Mark Mallia	Representing Charles de Giorgio
Dr Maxine Montanaro	Representing Charles de Giorgio

Dr Anthony Cassar, Chairman of the Public Contracts Review Board, welcomed the parties and prior to inviting submissions noted that the Public Contracts Review Board (PCRB) had already heard all the submissions in this case and had made their decision. There was therefore no need for lengthy representations on the merits of the tender.

Dr Mario De Marco Legal Representative for V J Salomone Pharma Ltd agreed with the Chairman's comments and stated that Appellants were seeking the correct implementation of the PCRB's decision in Case 1279 as this had not been implemented correctly by the Contracting Authority. In the previous case reference was made to the Appellants' suggestions to acquire more than one product so long as it was approved by the Medical Council and that the period of the tender contract not to be too extensive. The Appellants were obviously fully in agreement with this position.

The present tender (227/2019) requests bids solely for Interlukin 17A inhibitor (hereinafter referred to as Interlukin) and was based solely on price as the determining factor. This was not approved by the Medical Council – conversely medical consultants were opposed to the way the tender was issued. Interlukin is made up of two basic active biologic ingredients. Biologics do not have identical characteristics and consequently its use and its results are particular to certain patients and are not interchangeable because of their different reactions. The call is discriminatory against drugs which can treat psoriasis, psoriatic arthritis and ankylosing spondylitis to the advantage of drugs that can treat only psoriasis and psoriatic arthritis.

Medical consultants are totally opposed to this since if they are already treating patients with an existing brand they cannot switch to another product for non-medical reasons since biologics are not interchangeable. The PCRB directed that ideally there should be more than one product to give diversity of choice to consultants and Appellants are now requesting the Authority to follow the suggestions of the Board and the medical people agree this can only benefit the patient. It makes one wonder what held the Authority back from widening the choice of medication?

There is ambiguity in the tender in article 262d as it is assuming the biologics are interchangeable – there is ambiguity in the financial consideration as it appears to have ignored the fact that

different dosages affect the price of a product and there are issues of treatment under various Health Acts. A further issue is that one of the products is not covered by social security provisions and would militate against certain patients. The sensible course would have been to follow the same procedure as in other medications and allow more than one product, thus not limiting treatment to two out of three conditions.

The Chairman recapping the situation said that according to Appellants the tender was not following the PCRB directions. The hearing would deal solely on this point since the merits of the case had been gone into in the previous hearing and were not going to be considered again or changed.

Dr Clement Mifsud Bonnici on behalf of Charles de Giorgio said that his clients agreed that it is better if there is a choice of medication; however the recommendations of the PCRB were not binding. The Contracting Authority has wide powers in framing a tender as long as it follows the Public Procurement Regulations, and in this instance they had opened up competition to a class of medicines rather than a patented medicine. His clients do not agree that treatment is restricted and this is a pre-contractual remedy in reverse in that it is trying to overturn an existing PCRB decision. The tender calls for functional equivalent of the medication that treats psoriasis and psoriatic arthritis, and there is a need to open the market as there are at least four suppliers of this medication. The merits are the same as the previous hearing and one cannot re-open a decided case once there were no appeals. In support of this contention Dr Mifsud Bonnici referred to PCRB case 317 (a case once decided cannot be re-opened) and the Court of Appeal case 115/2013 (re-opening of a case is precluded).

Dr Cecilia Mercieca (33580M) called as a witness by the PCRB testified on oath that for five years she has been a Medicine and Rheumatology Consultant at Mater Dei Hospital. She stated that any request for new medication is passed on to the competent authority to be included in the Formulary List. There are pathways for different treatments which include different ranges of class of medicines to ensure that these agree with the patients. There are four types of TNF (tumour necrosis factor) inhibitors available and they are all used. Two types of Interlukin 17A inhibitors are approved but they should be available to all patients – although in the same class they cater for different needs.

Witness stated that she was not consulted in the case of the Interlukin tender. International recommendations state that in their pathways there should be more than one product in each class of medication.

Questioned by Dr Agius Legal Representative of the Department of Contracts witness stated that she is not *'au fait'* with tender procedures. The procedure in the Health Department is that if the available medication does not agree with the patient he stays without.

In reply to a question from Dr Mifsud Bonnici witness stated that she had no expertise in the treatment of psoriasis and psoriatic arthritis. Since around 2016 the only treatment considered was to prescribe Secukinumab. Since then, no one has been approved for use of Interlukin. There are two pathways for psoriatic arthritis and ankylosing spondylitis for existing patients in future.

Dr De Marco said that the issue is one of considering more than one product. This applies to two scenarios – one of no switching of medication on existing patients and the other one of treating new patients. The pathway has to refer to present and future patients. The Contracting Authority was duty bound to reflect the decision of the Board.

Dr Agius countered by saying that it is the prerogative of the Contracting Authority to decide on how to issue tenders – the directions of the PCRB were to ensure that medical boards were consulted.

Dr Mifsud Bonnici said that it was up to Appellants to seek a judicial review if they disagreed with the PCRB decision. The Board made a non-binding recommendation and it was up to the Authority whether that was taken up. The time to challenge that decision was in March 2019.

Dr Denis Vella Baldacchino (560962M) called as a witness by the PCRB testified on oath that he has occupied the position of Chief Medical Officer since 2014. He explained that medical consultants are regularly consulted before the purchasing of any medicines listed in the Formulary, and that there is a different committee that deliberates on medication for exceptional cases. He confirmed that he is aware that there existed an exchange of e-mails between Ms Antonio Formosa, Profs Andrew Borg, Dr Lawrence Scerri, Mr Karl Farrugia and others related to the execution of the PCRB's previous decision and its implementation and that he is conscious of the directions given in Case 1279 by the PCRB.

Witness was referred to paragraph 3 and the other conclusions of the Board's decision in Case 1279 and asked what extent and level of consultation were undertaken to establish if it would be of benefit to the patients to have a tender covering more than one product. Witness replied that the scope in all instances was to obtain the best cure for patients. When buying this medicine it was essential to ensure it was efficacious and achieves the best results. As far as witness could recall consultants had no objection to having various medications as all meet the different requirements of the patients. Witness was referred to particular e-mails from the exchanges referred to above.

Dr Mifsud Bonnici objected to this since the trail of e-mails was incomplete and therefore not acceptable. He wished to have formally recorded that:

'Dr Mifsud Bonnici requests that correspondence produced by e-mail to the Board Secretary by a person not party to these proceedings is thrown out and should not constitute evidence. Moreover Dr Mifsud Bonnici demands that no reference to such e-mails is made in questioning by legal

counsel. Dr Mifsud Bonnici also notes that the correspondence sent was not complete and that most of the parties involved in that correspondence are not present here for purposes of cross-examination'.

There followed a lengthy discussion between the Board and the parties concerned regarding the failure of significant key witnesses to turn up.

Dr De Marco said that the witnesses should be made to turn up as the lack of testimony by them would prejudice and penalise Appellants' case and suggested that the case be adjourned to a later date.

Dr Mifsud Bonnici quoting Public Procurement Regulation 265 pointed out that hearings must be decided with urgency and concluded in one sitting.

The Chairman directed that he was prepared to grant a recess to enable the witnesses to turn up failing which the Board would decide how to proceed.

Dr De Marco asked that it be officially recorded that:

'Dr De Marco stated that the main thrust of the summoning of Prof Andrew Borg and Ms Antonia Formosa is to determine whether the medical consultants;
(1) Were consulted by the Contracting Authority following the decision of the PCRB in Case 1279;
(2) To determine whether the Contracting Authority should consider procuring more than one product on a particular brand;
(3)What the advice of the medical consultants in this regard was;
(4) If the advice of the medical consultants was to issue the tender in such a way as to purchase more than one product why was the advice discarded;
(5) Whether the option to have more than one product on a particular tender is in the better interest of the patient;
(6) Whether in the case of the treatment of psoriasis, psoriatic arthritis and ankylosing spondylitis it is in the best interest of the patient that the Contracting Authority procures more than one product given that the products for the treatment of such conditions are biologics and not normal medical products or generics;
(7) Whether treatment pathways in respect of such conditions as above indicated have been discussed and approved by the GFLAC and the Advisory Committee on Health Care Benefits and finally to confirm that they were party to the various e-mail exchanges to which reference has been made before the Board today.'

Dr Mifsud Bonnici objected and asked that it be officially recorded that:

'Dr Mifsud Bonnici reserves the right to oppose to any questions made by legal counsel to Appellants to the said witnesses. It is noted that some of the points indicated by legal counsel for the Appellants as a matter of fact and law refer to the Minutes of Case 1279'

At this stage the Chairman proposed a recess to enable witnesses to be contacted.

On resumption the Chairman informed the parties that Prof Borg and Ms Formosa could not be contacted, and the Board intends to fine them for non-attendance.

Dr Agius suggested that the testimonies of witnesses already heard should be taken into account in the other hearings related to this tender. He said that the Department of Contracts was following the policy directives of the Chief Medical Officer who is overall responsible for medical decisions and whose testimony indicated that the necessary consultations had taken place and that should suffice. He was also prepared to ask other witnesses from the Health Department to testify

Dr De Marco said that this suggestion was not acceptable to the Appellant. They require their own witnesses to be heard as allowed by law.

After another short recess to consider this last point the Chairman said that the Board will take the necessary measures against the witnesses who failed to turn up. He then stated that the Board had heard enough submissions to enable it to consider whether it is in a position to reach a decision.

End of Minutes

Second Hearing

A second hearing was convened on the 25th October 2019.

The Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Mr Lawrence Ancilleri and Mr Carmel Esposito as members convened a public hearing.

The attendance for this public hearing was as follows:

Appellants – V J Salomone Pharma Ltd

Dr Mario De Marco Legal Representative

Ms Lara Cauchi	Representative
Ms Jacqueline Scerri	Representative
Ms Gayle Bugeja	Representative
Ms Louisann Caruana Scicluna	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Marco Woods	Legal Representative
Dr Denis Vella Baldacchino	Representative
Eng Karl Farrugia	Representative
Dr Alison Anastasi	Representative

Department of Contracts

Dr Franco Agius	Legal Representative

Interested Parties

Dr Clement Mifsud Bonnici	Legal Representative, Charles de Giorgio
Mr Mark Mallia	Representative, Charles de Giorgio
Dr Maxine Montanaro	Representative, Charles de Giorgio

The Chairman said that before coming to a decision is this Case the Board wished to hear the testimony of a further witness who was unable to be present at the first hearing.

Dr Agius Legal Representative of the Department of Contracts enquired what the relevance of hearing of further witnesses was in relation to this Case.

Dr Mario De Marco Legal Representative for V J Salomone Pharma Ltd stated that in the decision of the Public Contracts Review Board (PCRB) in Case 1279 the Board had decided to leave the final decision regarding the acquisition of more than one product in the hands of the medical consultants. Additionally to Ms Antonio Formosa both Dr Lawrence Scerri and Prof Andrew Borg need to be heard as they were medical consultants and had a role in the Government Formulary List Advisory Committee (GFLAC).

Dr Clement Mifsud Bonnici Legal Representative of Charles de Giorgio said that the request for additional witnesses went beyond the Public Procurement Regulations. He wished it to be officially recorded that whilst he relied on the PCRB judgement he was objecting to more than one witness being heard.

Dr Agius again queried the relevance of new witnesses. The testimony which the Chief Medical Officer had given indicated that the views of the consultants had already been taken into consideration and dealt with. He requested that it is officially recorded that he was objecting to the hearing of new witnesses and that he had not had the opportunity at the first hearing of calling his witnesses to testify.

Dr De Marco stated that he wished it to be recorded that once witnesses had been called they should be heard.

The Chairman pointed out that the written request from Dr De Marco was for one new witness to be heard and it is the Board's decision that only that one will be heard.

Ms Antonia Formosa (373667M) called as a witness by the PCRB testified on oath that she has occupied the position of Director of the Pharmaceutical Affairs Directorate (DPA) for five years. Referred to the decision in Case 1279, witness stated that she was made aware that the PCRB had recommended that the tender be issued for more than one product subject to the decision of the medical consultants. No decision on this point was taken by her Directorate because their role was to follow directives. She confirmed that Secukinumab was still not included on the Formulary List.

Personally she did not agree with the use of the word 'equivalent' (as used in tenders) as there were several types of equivalence in medicine. The existing treatment pathways recommended by GFLAC suggest different drugs for different patients with different needs.

The procedure is that GFLAC recommends which drugs are included in the Formulary List in line with the existing pathways and recommended more than one product as not all drugs are equivalent for each condition. There are certain cases which are difficult as the patient is young and needs to have different drugs as some of these do not work over a period of time.

Once GFLAC has made its decision the DPA is no longer involved – they merely prepare the specifications, dosages and quantities which are then sent to the CPSU to formulate the tender. The Advisory Committee on Health Care Benefits (ACHCB) has still not considered alternative drugs recommended by GFLAC pathway. It is normal for tender to be issued before it is dealt with by the ACHCB, although medicines are still administered to certain patients if necessary through the Exceptional Committee.

The open specifications in tender under discussion (1358) were based on Interlukin17A which was meant to follow the PCRB directive – it was an open specification and all relevant medical parties were involved in this decision. It followed a directive given by the Chief Medical Officer that new patients could benefit from the new specifications whilst other had to be dealt with by an alternative specification.

At this stage witness tabled a document (Doc 1) giving a list of patients receiving different drug treatment as directed by the Emergency Committee.

On further questioning witness confirmed that the present tender was limited to one product contrary to the GFLAC pathway which recommends more than one product. Witness said that she saw no contradiction here as for new patients starting treatment there were options available. Medical consultants spoken to confirmed that they were in favour of tenders with more than one product but the final decision to include more than one product had still not been taken.

Witness was referred to a trail of emails dated around the beginning of May 2019 exchanged between her and various medical personnel in which emails Dr Lawrence Scerri confirmed the benefit of having two products and witness confirmed that an open market situation was preferable and the best procurement practice was to find a common policy. She confirmed that the situation was still that the consultants want more than one product whilst the CPSU goes for the one cheapest product. It was the view of the witness that in this tender the CPSU could have opted for more than one product. In the past there were tenders issued which allowed bids for more than one product.

Questioned by Dr F Agius, witness said that the role of her committee was to fulfil what is decided by other committees. By deduction this tender is based on named patients as the product specified is not on the Formulary List. Before the issue of the tender there were consultations which considered the PCRB decision.

Dr Mifsud Bonnici asked the witness, who confirmed, that the tender was to cater for new and existing patients. The quantities specified in the tender were outside her remit – she just indicated the number of patients and it was the CPSU who decided on the quantities. Witness confirmed what she had stated earlier that it was not safe to interchange medicines unless it was for a medical reason. This was based on intensive research carried out by her Directorate to ensure the safety of products. Both products under discussion had the same therapeutic indications for the treatment of psoriasis and psoriatic arthritis. In reply to a further question witness stated that the drug Taltz was not on the European Medicines Agency listing which is what the Health Ministry followed.

In reply to a question from Dr De Marco witness confirmed that from research and available literature it had been established that it was not safe to switch medicines for non-medical reasons, and that you could possibly switch for medical reasons when the first medication fails or has adverse effects on the patient.

Dr De Marco stated that the tender as issued was limited and leads to obtaining one product at the cheapest price. Legal provisions exist not to limit tenders to single products hence the decision of the PCRB in tender 1279 that made it clear that more than one equivalent product should be considered so long as it was in the patients' interest. Ms Formosa had testified that the recorded pathways by the GFLAC should make available as a matter of fact more than one product. The

PCRB issued clear instructions to the CPSU, totally ignored by them, not to decide for themselves but to consult with the medical consultants, Section 4 para 1.1 of the technical specifications indicate that the tender is to cater for 60 patients over two years. This is estimated by the CPSU to cater for current and future patients and not just limited to the eleven patients currently undergoing treatment. This shows no respect for either GFLAC or the PCRB recommendations. Here one is dealing with people's lives and one must ensure that they are having the best beyond the bottom line. Patients must be assured that they are having the best product available for their condition without needing exceptional committee procedures.

Dr Agius said that all patients receive the best treatment and the bottom line caters for all patients. The Public Procurement Regulations criteria in regard to the awarding of tenders state that finally the winning bidder must be one – if tender is split into lots it becomes a sham – competition favours patients through best possible price. Both witness Ms Formosa and the Chief Medical Officer confirmed that the process of adding more products is still underway and the tender must therefore address the problem of those who are not yet receiving treatment. The other paragraphs in the decision in Case 1279 should also be considered as they address other just as important points. The points made in the submissions in Case 1360 should also be applied to this case, especially the reference to the Court of Appeal decisions. Witness confirmed that doctors have a free hand to administer medicine as they see fit and to cater for everyone's condition and that is the reason why the system is open for competition.

Dr De Marco pointed out that there are no complications in having a tender open for more than one product; therefore the point made by Dr Agius that there is only one winner is not valid. It was also not correct to claim that no consideration was given to other points in the Board's full decision but not one single reason was given why it was not considered by the Contracting Authority.

Dr Mifsud Bonnici said that despite several hearings by the Board as well as a Court of Appeal hearing on this topic no solution has been offered as to how to deal with multiple products tenders. Witness made it clear that it is possible to cater for different patients with different needs. No studies have been produced regarding switching between medicines for non-medical reasons – contrary wise the studies submitted by Charles De Giorgio (Doc ELC 4 to 8) indicate that there are no harmful effects in switching on medical grounds. Appellants are trying to reverse the decision in Case 1279. The PCRB set a precedent when they moved away from favouring active ingredients in favour of therapeutic classes – there are three previous decisions by the PCRB in favour of this process. In Case 1279 there was a clear PCRB decision and GFLAC, the DPA and the CPSU must comply.

Dr De Marco stated that previous PCRB decisions indicate that they favour the tendering for multiple products. This backs what Dr Mifsud Bonnici himself had stated as the ideal situation.

Dr Agius insisted that the tender document was not prohibiting anyone from bidding thus assuring the best medical treatment.

In conclusion Dr Mifsud Bonnici said the CPSU must not be coerced into buying from only one source. The hands of the medical consultants are not tied as measures are in place to deal with exceptional cases.

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

End of Minutes

Decision

This Board,

having noted this 'Call for Remedy Prior to the Closing Date for Call for Competition' filed by V J Salomone Pharma Ltd (herein after referred to as the Appellants) on 26th August 2019, refers to the claims made by the same Appellants with regard to the tender of reference CT 2276/2019 listed as case No. 1358 in the records of the Public Contracts Review Board.

Appearing for the Appellants: **Dr Mario De Marco**
Dr Therese Comodini Cachia
Appearing for the Contracting Authority: **Dr Marco Woods**
Appearing for the Department of Contracts: Dr Franco Agius

Whereby, the Appellants contend that:

a) **Their main concern refers to the fact that the Contracting Authority in the present tender of Ref. CT 2276/2019, did not follow the Public**

Contracts Review Board's decision in Case No. 1279, wherein, it was decided that more than one product should be procured so long, as these were approved by the medical consultants. In this regard, Appellants maintain that the present tender is discriminatory against other drugs that can affect treatment to the benefit of the well-being of the patient.

b) Appellants also contend that the technical specifications as stipulated in the tender document were not approved by the medical consultants as duly directed in the Public Contracts Review Board's decision in case No. 1279.

This Board also noted the Contracting Authority's 'Letter of Reply' dated 12 September 2019 and a 'Letter of Reply' dated 5 September 2019 from Charles de Giorgio Ltd an interested party, followed by submissions during the hearings held on 27 September and 25 October 2019, in that:

a) The Authority maintains that it is the Contracting Authority's prerogative as to how the technical specifications of the tender are formulated. In this regard, the Authority insists that the Public Contracts Review Board's decision directed that Medical Boards were consulted, and such directions were duly applied.

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

Dr Cecilia Mercieca, duly summoned by the Public Contracts Review Board

Dr Denis Vella Baldacchino, duly summoned by the Public Contracts Review Board

Ms Antonia Formosa, duly summoned by the Public Contracts Review Board

1. **This Board, after having examined the relevant documentation to this 'Call for Remedy' and heard submissions made by all the interested parties, including the testimony of the witnesses duly summoned during the hearings held on 27 September and 25 October 2019, opines that, the issue that merits consideration is the adherence by the Contracting Authority to the directions given by the Pubic Contracts Review Board's decision in case No. 1279, in the issuance of this tender of reference CT 2276/2019.**

2. **In its decision, in case No. 1279, this Board recommended the availability of more than one product, always after consulting the medical consultants, as follows:**

"3. With regard to Appellants' suggestion that the Contracting Authority should consider procuring more than one equivalent product on a particular tender, this Board, although in agreement with such a recommendation, would respectfully leave such a decision to be approved by the Medical Consultants, taking into consideration the fact as to whether such an option is in the interest of the patient."

In this regard, Appellants are insisting that the above-mentioned recommendations were not adhered to by the Authority, since Medical Consultants were not consulted.

3. **This Board would refer to an extract from the testimony of Ms Antonia Formosa who confirmed that more than one product was taken onto consideration in the formulation of the technical specifications, as follows:**

"Avukat : Ha nispjega ruhi ahjar. Mela il-GFLAC irrakkomanda pathways illi kienu jkopru iktar minn prodott wiehed ghax essenzjalment dawn il-prodotti mhux dejjem huma interchangeable jekk fhimtek sew

Xhud : Iva f'dan il-kaz mhumiex interchangeable

Avukat : *Mela la darba mhux interchangeable, il-GFLAC hareg b'dan il-pathway. Il-pathway allura jitkellem dwar aktar minn prodott wiehed ghal pazjenti li qeghdin ibatu minn psoriasis jew psoriatric arthritis*

Xhud : *Yes"*

Furthermore, same witness re-affirmed the fact that this is an open tender where more than one product is being tendered for as duly testified. Viz:

"Avukat : *It-tender li nhareg issa li qeghdin fuqu hawn hekk illum mhux miftuh ghal aktar minn prodott wiehed ghax filwaqt li kif inhu miktub, filwaqt li iva iktar minn prodott wiehed jistghu jittenderjaw, pero l-ghazla ser tkun limitata ghal prodott wiehed li huwa l-irhas. F'dan il-kaz tender li huwa essenzjalment ser jintghazel one product based on x'inhu l-irhas, qieghed jirrifletti l-pathway rakkomandata mill- GFLAC?*

Xhud : *Dawk l-open specs ta' dan it-tender kienu qeghdin immirati biex niffolowjaw il-PCRB decision li kienet ittiehdet qabel din fejn ahna gejna gwidati wkoll mill-procurement illi ma stajniex nohorgu tender illi kien jismu Secukinumab imma kellu jkun an open spec."*

Through the credible testimony of Ms Formosa, this Board establishes that the tender specifications conformed with the recommendation of the Public Contracts Review Board's decision in that, more than one equivalent product should be considered in formulating the specifications of the new tender.

4. **With regard to Appellants' contention that the Medical Consultants and the relative Authorities were not involved in the recommendations given by this Board in its decision in case No 1279, same Board would again refer to an extract from the testimony of Ms Formosa, who stated specifically that:**

> *"Dan gie diskuss bejn kulhadd, bejn il-konsulenti u c-CMO, kulhadd kien involut fiha din id-decizjoni u d-direzzjoni li nghatajt jiena minghand is-CMO kienet illi ghal dawk il- kazijiet generali fejn pazjent jista jgawdi minn medicina jew ohra, jigifieri pazjent gdid qed nghidu, a new patient, jista jibbenefika kemm minn medicina u kemm minn ohra, ghal dawk kien hemm din l-ispec. Ghal pazjenti ohra li ma jaqghux within the spec, ser ikollu jkun hemm spec ohra*

Avukat : *Tista tkun iktar cara?*

Xhud : *Nista naghti ezempji. Jekk inharsu lejn l-ewwel table il-kbira fejn hemm hafna pazjenti fuqha, dawn huma l-pazjenti, ovjament bdiltilhom l-initials u nehhejt l-informazzjoni kollha li hija relatata mal-pazjent u hallejt biss l-informazzjoni li tista twassal ghal decizjoni. Jekk inharsu lejn patient AB, dawn huma decizjonijiet li ttiehdu mill-exceptional committee. Patient AB perezempju ibati minn psoriasis u ghal dak id-decizjoni ttiehdet li dak jaqa fil-kategorija ta' IL 17A inhibitor li huwa l-open spec u therefore it-tender jghodd ghal dan il-grupp ta' pazjenti. Jekk immorru lejn patient QP li jbati minn rheumatoid arthritis, l-istess, IL17A inhibitor gie approvat u ghaliex ukoll il-psoriasis u r- rheumatoid arthritis jaqghu taht din l-ispec. Fejn ghandna pazjenti bl-spondylo arthritis, dawn mhux iz-zewg medicini in question huma licenzjati ghalihom u sa issa ghadu licenzjat biss is- Secukinumab u f'dan il-kaz id-decizjoni li ttiehdet mill-kumitat kienet li jridu jivverifikaw ezattament il-licensing status u nimxu minn hemm. Jigifieri f'dan il-kaz huma ma rawx illi is-17A inhibitors huma adattati ghalihom pero se imorru ghal medicina partikolari"*

5. **This Board will not enter into the merits which have already been treated in the first hearing, however, it must be noted that the motive of the Board's decison in case No. 1279, was to ensure that there will be available more than one type of drug, so as to provide treatment for already existing patients with such a condition and also a choice of treatment for new patients. This Board opines that the Medical consultants should have the opportunity to choose the proper treatment for the particular patient.**

In conclusion, this Board opines that:

a) **The technical specifications of the new tender take into consideration this Board's recommendation with regard to an open tender where more than one type of drug should be tendered for.**

b) **The technical specifiations were discussed with the Medical Specialists as directed in this Board's decision in case No. 1279.**

c) It cannot identify any justifiable reason as to why the technical specifications as stipulated in the tender, should be regarded as ambiguous or discrminatory.

In view of the above, this Board,

i. does not uphold Appellants concerns,

ii. directs that the tendering process be resumed,

iii. directs that the closing date of the tender be 20 December 2019 at 12.00 noon.

Dr Anthony Cassar	Mr Lawrence Ancilleri	Mr Carmel Esposito
Chairman	Member	Member

21 November 2019