



The Chairman explained that in the light of the Court of Appeal decision, the Board intended to ask the parties involved to prepare any questions that they wanted to make to the expert appointed by the Board, Peter W Mullen. These would be transmitted by the Board through its legal advisor to Professor Mullen who would also be asked to provide answers to the said questions. He remarked that the matter had to be decided since nearly five years had passed since the issue of the Tender.

Dr Stefan Zrinzo Azzopardi on behalf of the Contracting Authority filed a letter of reply and said that he wanted to hear some witnesses before the questions were submitted.

Dr Francis Cherubino for the Appellant declared that Appellant had no issues regarding the submission of questions to the expert. However he said that Appellant was apprehensive about the length of time this Tender was going to take to award.

The Chairman asked who was supplying the medicine in question during these five years and was informed by the Contracting Authority's representative that VJ Salomone Pharma Limited was doing so.

Dr Arthur Galea Salomone on behalf of VJ Salomone Pharma Limited explained that his client was an interested party and agreed to submit questions to the expert but reserved the right to produce witnesses and make further submissions after the replies were received.

Dr Stefan Zrinzo Azzopardi contended that the court of Appeal had directed that the Board had to hear these submissions and any necessary witnesses "in the light of the expert's report".

The Chairman directed that the parties should submit in writing the questions they wanted to ask of the expert by the 30<sup>th</sup> March 2016. These questions would be distributed to all interested parties.

At this point the hearing was closed.

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The Chairman explained that the Board, as agreed with the parties had written to the expert Peter W Mullen and referred the questions submitted by the parties to him and asked him to reply as necessary. This expert, however, has asked that to do so he should be paid a fee of six thousand Canadian dollars. This was the normal praxis when experts are appointed to give their professional opinion. The Public Contracts Review Board is not to pay out this fee out of its own funds and therefore a just remedy would have to be found between the parties involved to have the sum in question provisionally deposited in order to pay the expert fees.

Dr Adrian Delia pointed out that the law gave the PCRFB the faculty to appoint experts to help on matters it was not cognizant and he does not see how anyone could expect to question such experts, and did not agree. If anyone wanted to question the expert he should bear the costs.

Dr Arthur Galea Salomone on behalf of VJ Salomone Pharma Limited said that the Court of Appeal had decided the matter and suggested that the costs should be provisionally shared between all the parties involved, a third each by his client, Cherubino Limited and the Contracting Authority.

Dr Adrian Delia on behalf of Cherubino Limited does not agree. He contends that the costs should be borne by whoever raised the questions made to the expert, that is, VJ Salomone Limited. This was the praxis of the Court procedure. After all, the expert was an independent person.

Dr Arthur Galea Salomone on behalf of the Recommended Bidder reiterated that the costs should be shared.

The Chairman declared that the parties had three days in which to decide how the fees to the expert are to be paid. The Board would then decide the matter itself. He showed the voluminous documents submitted by VJ Salomone together with the desired questions and said that it was obvious that the expert would expect payment for going through all that material before giving his reply.

Dr Adrian Delia for the Appellant Cherubino pointed out that it is clear that the Recommended Bidder had enclosed an ex-parte report by Professor Johnson together with the questions. This should not have been done and was not admissible. The Court decision had made it clear that only questions on the existing expert report should be made. New evidence could not be submitted at this stage and he objected to this.

Dr Arthus Galea Salomone for the Recommended Bidder stated that he had submitted a number of questions and enclosed a report made by another expert. He had given a copy to all parties.

The Chairman asked those present if they objected if only the questions were submitted to Dr Mullen.

Dr Adrian Delia for the Appellant insisted that the costs be borne by the Recommended Bidder who had raised the matter that necessitated the submitting of the questions to the expert.

Dr Arthur Galea Salomone for the Recommended Bidder claimed that the need had arisen because of the Public Contracts Review Board decision. Thus he reiterated his suggestion that the costs be shared provisionally but stated that his client would accept the Board's

decision on this point, but would reserve the right to submit the extra report.

At this point the hearing was closed and adjourned to a future date.

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### **Third Public Hearing:**

The Public Contracts Review Board composed of Dr Anthony Cassar (Chairman), Dr Charles Cassar and Mr Lawrence Ancilleri as members convened a hearing on Tuesday the 6<sup>th</sup> September 2016 to continue hearing the Objection.

Present for the hearing were:

#### **Cherubino Limited:**

|                      |                      |
|----------------------|----------------------|
| Dr Francis Cherubino | Representative       |
| Dr Adrian Delia      | Legal Representative |

#### **VJ Salomone Pharma Ltd.:**

|                            |                      |
|----------------------------|----------------------|
| Mr Michael Sultana Loporto | Representative       |
| Dr James Bannister         | Legal Representative |

#### **Central Procurement and Supplies Unit:**

|                            |                         |
|----------------------------|-------------------------|
| Mr David Baldacchino       | Member Evaluation Board |
| Mr Mark Zammit             | Representative          |
| Ms Sharon Vella            | Representative          |
| Mr Tonio Farrugia          | Representative          |
| Ms Alison Anastasi         | Assistant Director      |
| Dr Stefan Zrinzo Azzopardi | Legal Representative    |

The Chairman explained that during the present stage of the proceedings, questions made by the parties involved to the expert that had been appointed were about to be delivered to the said expert. Problems had cropped up about the payment of the fees to be paid to the expert, but the matter had to be settled and the final decision delivered.

Dr Adrian Delia on behalf of Cherubino pointed out that he does not remember any instance where the expert appointed by the Board was paid by the parties. The expenses for such appointments have always been paid by the Board. He contended that the question arose mainly because of VJ Salomone Limited who instead of just asking questions had practically filed a new report by another ex-parte expert. The Public Procurement Regulations have no structure whereby the decision about the expenses when experts are appointed can be regulated. He contended that the fees payable to the expert had increased because the Recommended Bidder had filed a new report. His clients were not avoiding paying their share capriciously but because they feel that whoever was the cause of the extra expenses, should carry the onus for payment.

Dr Stefan Zrinzo Azzopardi for the Contracting Authority said that the present was a unique case. The case did not deal with the usual technical compliance; there were different thesis and views on the products submitted by the parties that are used for the treatment of transplant patients. In this Tender the evaluation board had decided. Even experts on the matter disagree among themselves on the benefits of the two products. The Contracting Authority had accepted to pay a third part of the fees due to the expert in order to expedite matters. The Board had given parties the opportunity to file questions to be submitted to the expert, but it is finally up to the Board to decide who should bear these expenses.

Dr Adrian Delia for Cherubino nearly agreed with this but insists that the Contracting Authority should not bear any expenses related to questions to be put to the expert about his report. He contended that the difficulty arose because Salomone had filed another report with the questions entailing new decisions. The Board had been satisfied with the report submitted by the expert and therefore should order the removal of the new report as prepared by Salomone's expert. The law at present does not cater for similar situations, and the Board should decide the matter.

Dr James Bannister on behalf of VJ Salomone Limited at this point declared that only the set of questions prepared by his clients need be forwarded to the expert for answering; the new report should not be forwarded.

Dr Stefan Zrinzo Azzopardi for the Contracting Authority said that the Contracting Authority had prepared some questions regarding the matter of equivalence of the two submitted products to be forwarded to the expert.

The hearing was closed at this point.

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## **Fourth Public Hearing**

On 18 April 2017, the Public Contracts Review Board composed by Dr Anthony Cassar as Chairman, Mr Lawrence Ancilleri and Mr Carmel Esposito as members convened a Public Hearing to discuss the Objection.

The Attendance for this Public Hearing was as follows:

### **Appellant – Cherubino Ltd**

|                      |                      |
|----------------------|----------------------|
| Mr David Cherubino   | Representative       |
| Dr Francis Cherubino | Representative       |
| Dr Danica Caruana    | Legal Representative |
| Dr Adrian Delia      | Legal Representative |

### **Recommended Bidder – VJ Salomone Pharma Ltd**

|                            |                      |
|----------------------------|----------------------|
| Ms Jacqueline Scerri       | Representative       |
| Mr Michael Sultana Loporto | Representative       |
| Dr Arthur Galea Salomone   | Legal Representative |

### **Contracting Authority – Cherubino Ltd**

|                             |                      |
|-----------------------------|----------------------|
| Ms Danika Agius Decelis     | Representative       |
| Ms Marica Sammut            | Representative       |
| Ms Federica Spiteri Maempel | Representative       |
| Ms Sharon Vella             | Representative       |
| Mr Mark Zammit              | Representative       |
| Dr Stefan Zrinzo Azzopardi  | Legal Representative |

The Chairman of the Public Contracts Review Board, Dr Anthony Cassar, opened by saying that this Board has decided to send all the questions without any additional reports to Dr Peter W Mullen, the expert appointed by the latter on the matter and whoever loses the Appeal will have to cover all expenses.

Dr Adrian Delia, the Legal Representative for Cherubino Ltd asked what would happen afterwards for which Dr Anthony Cassar, the Chairman of the Public Contracts Review Board replied that all parties concerned will have the chance to see the answers given. A final Public Hearing will be eventually held and the final decision on this case will be issued.

Dr Arthur Galea Salomone, the Legal Representative for VJ Salomone Pharma Ltd said that with regards to the matter of the expenses his clients were going to accept the decision taken by the Public Contracts' Review Board but he did not understand why the report which they have sent was not going to be sent to the expert since the questions were mainly based on it.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board replied that it was agreed that only a set of questions were going to be sent.

Dr Arthur Galea Salomone, the Legal Representative for VJ Salomone Pharma Ltd replied that without the report, the questions were going to be out of their context. He felt that it was essential for the expert to see this report and it was precisely the reason why the Court of Appeal has sent back the decision to the Public Contracts Review Board, so that the latter can hear the relevant witnesses.

VJ Salomone Pharma has already reserved the right to summon clinical experts and Dr Galea Salomone was insisting on this. According to the Recommended Bidders' it was essential for the Public Contracts Review Board to hear the clinical experts as per recommendation of the Court of Appeal.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board replied that the latter as diversely composed did not gave the parties the chance to see Dr Mullen's report but took the decision based on it.

Dr Arthur Galea Salomone, the Legal Representative for VJ Salomone Pharma referred to the decision issued by the Court of Appeal issued on 29 April 2015 wherein *inter alia* it was stated that,

*“Għal dawn il-motivi, l-Appell qed jiġi milqugh, id-deċiżjonijiet tal-Bord dwar ir-Revizjoni tal-Kuntratti Pubbliċi tat-30 ta' Lulju 2012 u tal-14 ta' Novembru 2012 qed jiġu revokati. Tirimetti l-atti lura quddiem il-Bord sabiex jisma' s-sottomissjonijiet u jekk ikun il-każ anke il-provi, mill-partijiet kollha interessati u dana fid-dawl tar-rapport sottomess mill-espert Peter W Mullen, jgħaddi għad-deċiżjoni tiegħu skond il-liġi”*

Dr Galea Salomone suggested whether at this stage it was the case to summon a Public Hearing where the testimony of the witness was to be heard.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board asked whether these were already heard for which Dr Adrian Delia, the Legal Representative for Cherubino Ltd said that these were already heard and closed. Dr Arthur Galea Salomone, the Legal Representative for VJ Salomone Pharma Ltd disagreed with the previous statements since they wanted to summon a clinical expert. Dr Anthony Cassar, the Chairman of the Public Contracts Review Board replied that the evidence had to be sent to the same person who

made the report.

Dr Adrian Delia, the Legal Representative for Cherubino Ltd agreed with the decision taken by the Public Contracts Review Board. He added that there was no stage where the evidence was not allowed to be put forward. The sentence of the Court of Appeal was a similar one to rental cases. The Public Contracts Review Board had the right to take expert advice. What happened then was that the decision was issued on the report.

Dr Arthur Galea Salomone, the Legal Representative for VJ Salomone Pharma said that the report issued by Professor Atholl Johnson was to be submitted to Dr Peter W Mullen together with their questions and that his clients are requesting to summon a clinical expert prior to the final decision being taken by the Public Contracts Review Board, in line with the recommendation given by the Court of Appeal.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board asked for a suspension of five minutes so that the latter Board could deliberate on Dr Galea Salomone's request.

Following the recommencement of the Public Hearing, Dr Anthony Cassar, the Chairman of the Public Contracts Review Board quoted the Minutes of the Third Public Hearing held on 6 September 2016 where *inter alia* it was stated that,

*“Dr James Bannister on behalf of VJ Salomone Limited at this point declared that only the set of questions prepared by his clients need be forwarded to the expert for answering; the new report should not be forwarded.”*

In view of this, the Public Contracts Review Board has decided to send the questions to Dr Peter W Mullen and when the answers arrive, these will be distributed and a Final Public Hearing will be heard on Thursday 19 October 2017 at 09:15. On the other hand, the opportunity for the final witness to be heard was not to be closed but this would all depend on the expert's answer.

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Dr Anthony Cassar, the Chairman of the Public Contracts Review Board opened by saying that he received an application from the Central Procurement and Supplies Unit whereby it was requested that all parties are to submit all their submissions in writing so that each party can give their own comments on the replies submitted by Dr Peter Mullen.

The Public Contracts Review Board was also going to accede to the request made by VJ Salomone Pharma to defer the Public Hearing for Tuesday 14 November at 09:30 so that a Witness can be summoned.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit said that at this point all parties had received the replies to all questions submitted by all parties by an expert chosen by the Public Contracts Review Board. At the same time there is a request by the Recommended Bidders for a Witness to be summoned to make his comments on the questions concerned.

Dr Arthur Galea Salomone, the Legal Representative for VJ Salomone Pharma Limited agreed with the latter statement and added that the request was made once an expert was found to testify on the matter and that no further questions over and above the report will be permitted.

Mr Carmel Esposito, a member of the Public Contracts Review Board, said that the Witness will be asked questions exclusively on the replies submitted by Dr Mullen.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit added that his clients were on the receiving end. He was asking for this point to be clarified since the lawyers were uncomfortable to debate scientific terms and it was clearer for all parties to make their submissions in writing. Further than that, once a Witness will be summoned to testify, Dr Zrinzo Azzopardi asked whether further submissions can be made after the testimony.

Dr Danica Caruana, the Legal Representative for Cherubino Limited said that the important thing was that the questions asked to the Witness will be exclusively on the replies submitted.

Dr Arthur Galea Salomone, the Legal Representative for VJ Salomone Pharma Limited asked whether it was possible to send to the Witness the replies submitted by Dr Pieter W Mullen to have cognizance of the report.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board replied in the negative to the request made by VJ Salomone Pharma Limited.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit said that this was a Tender about a particular medicine which has been suspended from 2011. Besides, his clients had to regularize their position as a Contracting Authority since they had to take interim measures for six years since there was a pending Objection on it.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board asked whether there was anybody from the Contracting Authority who could answer a question regarding a particular statistic regarding the purchasing of this medicine.

At this point, Ms Alison Anastasi, a Pharmacist at the Central Procurement and Supplies Unit holding ID Card Number 398380 M, was summoned to testify under oath before the Public

Contracts Review Board.

Following Ms Anastasi's Testimony, Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit suggested that during the next Public Hearing, all questions are to be made to the witness. All parties agreed with the submission made by the Contracting Authority.

Dr Arthur Galea Salomone, the Legal Representative for VJ Salomone Pharma Limited suggested that the Public Contracts Review Board should summon the Witness for the next Public Hearing.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit said that since everybody was in agreement about what questions the expert was going to be asked, he appreciated if all parties were to know what will be discussed and these Terms of Reference were to be clear both in the minutes of this Public Hearing and in the Summons for the Witness which will be sent to the expert.

Dr Arthur Galea Salomone, the Legal Representative for VJ Salomone Pharma Limited said that was the reason why he suggested that the witness was to be notified that there were going to be questions on the report which will not be available to him. He added that the Recommended Bidders were going to accept any decision taken by the Public Contracts Review Board.

## **Sixth Public Hearing**

On 14 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 – Cherubino Limited**

|                      |                      |
|----------------------|----------------------|
| Dr Francis Cherubino | Representative       |
| Dr Danica Caruana    | Legal Representative |

### **Recommended Bidder – VJ Salomone Pharma Limited**

|                            |                      |
|----------------------------|----------------------|
| Ms Agnes Nagy              | Representative       |
| Ms Jacqueline Scerri       | Representative       |
| Mr Michael Sultana Loporto | Representative       |
| Dr Arthur Galea Salomone   | Legal Representative |

### **Contracting Authority – Cherubino Limited**

|                            |                      |
|----------------------------|----------------------|
| Ms Alison Anastasi         | Representative       |
| Dr Stefan Zrinzo Azzopardi | Legal Representative |

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board opened by saying that in this Public Hearing, a witness brought by the Recommended Bidders was going to be cross-examined strictly with regards to the reports presented by Dr Peter W Mullen.

At this point, Professor Emanuel Farrugia, a consultant on Kidney Transplants at Mater Dei Hospital holding ID Card Number 163 G, was summoned by VJ Salomone Pharma Limited to testify under oath before the Public Contracts Review Board.

Following Professor Farrugia's testimony, all parties concerned have agreed to submit their final written submissions by not later than Tuesday 12 December at 12:00 (noon) in order for the Public Contracts Review Board to issue a final decision on this case.

**This Board,**

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**Having noted this Objection filed by Cherubino Limited (herein after referred to as the Appellant) on 22 December 2011, refers to the Contentions made by the latter with regards to the award of Tender of Reference GHPST 410/2011 listed as Case No 914 in the records of the**

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

**Appearing for the Appellant: Dr Adrian Delia**

**Dr Danica Caruana**

**Dr Francis Cherubino**

**Appearing for the Contracting Authority: Dr Stefan Zrinzo Azzopardi**

**Dr Kim Zarb**

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

- 1. Dr Alison Anastasi duly summoned by the same at the Public Hearing held on 19 October 2017;**
- 2. Profs Emanuel Farrugia duly summoned by VJ Salomone Pharma Limited at the Public Hearing held on 14 November 2017;**

**This Board has also taken note of the documents submitted by Profs Peter W Mullen which consisted of a report called, “*A Review of the Bioequivalence of the Cyclosporin Formulations Deximune (Generic Product) and Neoral (Reference Product)*”.**

**This Board, would respectfully remind the parties concerned to this Appeal that five Public Hearings were held after the decision of the Court of Appeal during which the report compiled by Prof Peter W Mullen was duly distributed to allow the parties concerned to make any submissions on the contents therein. At the same instance, this Board would refer to the decision of the Court of Appeal to confirm and emphasize the remit of this Board, in this particular case as follows:**

*“Ghal dawn il-mottivi, l-Appell jigi milqugh, id-deċiżjonijiet tal-Bord dwar ir-Revizjoni tal-Kuntratti Pubbliċi tat-30 ta’ Lulju 2012 u tal-14 ta’ Novembru 2012 qed jigu revokati. Tirremetti l-Atti lura quddiem il-Bord sabiex wara li jisma s-sottomissjonijiet, u jekk ikun il-każ anke provi, mill-partijiet kollha interessati u dana fid-dawl tar-rapport sottomess mill-espert Peter W Mullen, jghaddi għad-deċiżjoni tiegħu skond il-Liġi”.*

**In this regard, this Board gave the opportunity to the parties concerned to submit their submissions after asking the relevant questions to the same Profs Mullen and the replies thereto are being also taken into consideration.**

**This Board opines that the main contention has always been the “Bio**

***Equivalency***” issue and in this regard, since the matter is of a highly technical medical nature, this same Board would refer to the replies of Prof Mullen as follows:

*“Given that the bioequivalency of these two products has been demonstrated, there is no convincing reason why organ transplant recipients and other patients in Malta could not be readily switched from “Neoral” to “Deximune”*

Again, Profs Mullen emphasizes the existence of equivalency between the two medical products as follows:

*“Based on the available evidence, I see no reason why “Deximune” should not be prescribed to patients in Malta. “Deximune” appears to be well-accepted by the various Authorities, Organizations, Knowledgeable Health Care Professionals and other individuals you cite.”*

This Board also notes that when Profs Mullen was confronted by one of the interested parties with regards as to whether the opinion he expressed in 2012, was still valid in 2017, he replied:

*“Since, I have seen nothing over the past five years which would convince me otherwise, I could still draw the same conclusions as stated in my 2012 report.*

*Thus to reiterate, it is my considered opinion that there is sufficient evidence to conclude that “Deximune” is bioequivalent to “Neoral”.*

In this regard, this Board also considered Profs Mullen’s final remark, which is:

*“Additionally, studies published since 2012 have indicated that other equivalent generic formulations of “Cyclosporin” can be successfully interchanged with “Neoral” in organ transplant patient.”*

In this regard and at this particular stage of consideration of the merits of this Appeal, this Board has to rely on the expert’s convinced confirmation that *“Deximune”* is bioequivalent to *“Neoral”*. At the same instance, this Board was not presented with any credible medical proof that *“Deximune”* is not bioequivalent to *“Neoral”*

From the testimony of the Local Specialist, namely Profs Emanuel Farrugia, this Board notes that one of the cardinal issues indicated during the Public Hearings was the question of switching from one type of medicine to another on patients who progressed well on *“Neoral”*. In this regard, reference is being made to extracts from the testimony of Profs Farrugia as follows:

*“Generics huma units kbar. Jiena naqbel li l-aktar post li jagħmel sens għall-generics huma f’ pazjenti ġodda u mhux li toqghod tagħmel il-bidliet”.*

At the same instance, this Board recognizes the fact that the final decision rests with the Specialists and it is their professional opinion that will decide the type of drug that is most suitable for the patient. However, it also credibly transpired that “*Deximune*” is bioequivalent to “*Neoral*”, but it has also been established that switching the treatment from one drug to another will require more monitoring of the patient, yet at the same time, it was also confirmed that “*Deximune*” can be administered on new patients, so that there exists bioequivalency. Profs Mullen also confirms that:

*“Of course, any possible increase in Blood Drug Concentration monitoring is essential, a consideration only in instances where a switch from one cyclosporine formulation to the other drug has occurred during treatment.”*

This Board would also refer to Profs Mullen’s final remark, which is:

*“Additionally, studies published since 2012 have indicated that other Bioequivalent generic formulations of Cyclosporin can be successfully interchanged with “Neoral” in organ transplant patient”.*

**This Board opines, that from Profs Mullen’s report and from his replies to questions put forward by the interested parties, there is enough evidence provided, to establish that “*Deximune*” is bioequivalent to “*Neoral*” and at the same instance, no medical proof was presented to indicate that “*Deximune*” cannot be administered on patients who underwent organ transplant.**

**This Board also noted, that from submission made and also from Prof Mullen’s report, there exists an issue of increased monitoring by the clinician when a patient is switched from one particular drug to another. However, in this regard, it was also established that such monitoring will be minimal or negligible if the new drug “*Deximune*” is administered on patients from the very start of their treatment.**

**In view of the above, this Board:**

- i) Confirms that “*Deximune*” is bioequivalent to “*Neoral*”;**
- ii) Confirms the decision taken by this Board as differently composed on 14 November 2012, in that “*Deximune*” is bioequivalent to “*Neoral*” and can be used interchangeably;**

**iii) Confirms that this Tender of reference GHPST/410/11 should not have been cancelled and at the same instance, this Board revokes the decision to cancel the tender and orders that Cherubino Limited is to be reintegrated in the Evaluation Process;**

Dr Anthony Cassar  
Chairman

Dr Charles Cassar  
Member

Mr Carmel Esposito  
Member

*30 January 2018*