PUBLIC CONTRACTS REVIEW BOARD

Case 1270 – CT 2151/2018 – Supply for the Mycophenolate Preparations

The publication date of the call for tenders was the 30th June 2018 whilst the closing date of the call for tenders was 2nd August 2018. The estimated value of the tender (exclusive of VAT) was € 852,696.

On the 14th January 2019 Cherubino Ltd filed an appeal against the Central Procurement and Supplies Unit (CPSU) as the Contracting Authority objecting that their bid was found not to be technically compliant. A deposit of € 400 was paid.

There were five (5) bidders.

On 26th February 2019 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Dr Charles Cassar and Mr Carmel Esposito as members convened a public hearing to discuss the objections.

The attendance for this public hearing was as follows:

Appellants – Cherubino Ltd

Dr Victor Axiak	Legal Representative
Dr Francis Cherubino	Representative
Mr Paul Calleja	Representative
Mr David Cherubino	Representative

Recommended Bidder – Charles de Giorgio Ltd

Ms Maxine Montanaro	Legal Representative
Mr Mark Mallia	Representative

Contracting Authority – Central Procurement and Supplies Unit (CPSU)

Dr Marco Woods	Legal Representative
Ms Monica Sammut	Chairperson Evaluation Committee
Mr Danika Agius Decelis	Member Evaluation Committee
Mr Adrian Spiteri	Member Evaluation Committee
Dr Alison Anastasi	Representative
Mr Mark Zammit	Representative

Department of Contracts

Dr Franco Agius Legal Representative

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

Dr Victor Axiak Legal Representative of Cherubino Ltd stated that this appeal was in regard to the tender for the supply of either Mycophenolate Mofetil or Mycophenolate Sodium. He referred to clause 1.2 of the tender and section 4 1.1 of the Technical specifications which gave details in table form of what was required. He explained that Mofetil or sodium are immuno suppressants. Section 3.1 of the tender documents refers to the provision of two tablets of the same brand either of sodium salt or Mycophenolate salt - his clients bid on two completely different brands. The reason for the rejection was that 'prima facie' the same brand was requested in the tender, but this appears to have been caused through an oversight by repeating a 'cut and paste' option from various other tenders issued by the CPSU. He made reference and quoted from several past tenders where both brands were requested.

A public assessment report published by the Medicines and Healthcare Regulatory Agency (MHRA) states that the two medicines offered in this tender Cellcept and Tillomed are bio-equivalent. The Contracting Authority was not justified in requesting the same brand, and it was counterproductive of the Authority to turn down an excellent product at a much cheaper price.

Dr Franco Agius Legal Representative of the Department of Contracts said that there was no oversight and the wording in the tender was intentional. The same brand of medication was required to safeguard patients in case of chemical reaction to the treatment. The Appellants' arguments are not logical as one cannot argue with the tender documents at this stage. The evaluation process was correct – the call for same brands was in the tender and has not been contested, and the fact that bidders' offer was cheaper is not relevant. There was the pre-contract remedy available to them if they disagreed or had difficulty with the terms.

Dr Axiak said that the wording in the tender qualifies the requirements regarding the brand and therefore there was no doubt in Appellants' mind that there was the need to seek pre-contract remedies.

Mr Mark Zammit (425874M) called as a witness by the Contracting Authority testified on oath that he is the Advance Pharmacy Practitioner at the CPSU and a lecturer at the University of Malta in pharmacology and toxicology. It was essential to have same brand product as there is the need to determine if there is any reaction to a particular brand. In case of extreme cases it is important to find out the causative excipients in the medication. He was not involved in the preparation of the tender. Referring to the MHRA report (tabled as Doc 1) he agreed that Cellcept and Tilloomed were equivalent medicines but if two brands were used it makes it difficult to identify which one could be causing problems. He agreed that bio-equivalence was an

important concept and crucial as it led to the opening of competition and the elimination of branded goods as in past tenders. In this instance the same brand was required not because of lack of bio-equivalence but to limit the risk of side effects through excipients. Medicines carried two items of information - one intended for the patient and the other was a summary of product characteristics which listed the excipients which invariably are the cause of side effects. Witness confirmed that Tillomed is bio-equivalent to Cellcept in their clinical effect.

The Chairman said that the issue before this Board was that the Contracting Authority wanted two medicines of the same type and the appeal should be considered accordingly.

Ms Monica Sammut (42482M) called as a witness by the Contracting Authority testified on oath that she was the Chairperson of the evaluation committee and confirmed that the requirement was for the same brand for both doses. Appellant offered different brands - namely Cellcept and Tillomed.

Dr Axiak said that the two brands were the same; they would have no different effect on patients and offered a very large monetary savings. There was an error in formulating the tender as the technical specifications do not refer to same brand requirement.

Dr Agius in concluding his submissions said that witness had made it clear that there could be side effects caused by excipients. The tender required the same brand to narrow the risks of side effects and was centred on the patients' wellbeing. He reminded the Appellants that when they submitted their offer they declared that they were accepting the terms fully. They had not sought any clarification and there was no pre-contractual concern shown. The same brand could have been offered by Appellants as they have the requisite product.

Dr Axiak concluded by stating that the patient will definitely not be affected by their offer of different brands and this was another attempt to limit competition through same brand limitation.

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

This Board,

having noted this Objection filed by Cherubino Limited (herein after also referred to as the Appellants) on 14 January 2019, refers to the claims made by the same Appellants with regard to the Tender of Reference CT 2151/2018 listed as Case No 1270 in the records of the Public Contracts Review Board,

awarded by the Central Procurement and Supplies Unit (herein after also referred to as the Contracting Authority).

Appearing for the Appellants: **Dr Victor Axiak**

Appearing for the Contracting Authority: **Dr Marco Woods**

Appearing for the Department of Contracts: **Dr Franco Agius**

Whereby, the Appellants claim that:

a) **their main contention refers to the fact that they had offered the appropriate combination of medicinal products and due to the fact that such a combination was not of the same brand, their offer was unfairly discarded. In this respect, the Appellants maintain that, the product which they offered was bio-equivalent to what was requested in the Tender Document. At the same instance, the Appellants insist that it was not justified to request both medicinal products to be of the same brand.**

This Board has also noted the Contracting Authority's 'Letter of Reply' dated 25 January 2019 and its verbal submissions during the Public Hearing held on 26 February 2019, in that:

a) **the Central Procurement and Supplies Unit insists that the Tender Document clearly stipulated that the two medicinal products being**

requested must be of the same brand. In this regard, the Contracting Authority maintains that such a condition was not capriciously dictated, on the contrary, there is a valid medical reason for such an imposition which, in turn, is to the benefit of the well-being of the patient. At the same instance, the Contracting Authority contends that the Appellants had all the remedies to explore such an imposition prior to the submission of their offer.

This same Board also noted the testimony of the following witness summoned by the Central Procurement and Supplies Unit, namely:

1. **Mr Mark Zammit**
2. **Ms Monica Sammut**

This Board has also taken note of the following documents submitted by Cherubino Limited which consisted of:

1. **An article regarding Mycophenolate Mofetil Tillomed 500mg film-coated tablets, also referred to as Doc 1;**
2. **A Public Assessment Report on the Decentralised Procedure of Mycophenolate Mofetil Tillomed 500mg Film-Coated Tablets issued by the Medicines & Healthcare Products Regulatory Agency;**
3. **Tender Document for CT 2219/2017 – Tender for the Supply of Oxaliplatin Injections**

This Board, having examined the relevant documentation to this Appeal and heard submissions made by the parties concerned, including the testimony of the witnesses duly summoned, opines that the issue that merits consideration is whether the request for the medicinal products to be of the same brand, was justified or not:

1. **This Board would respectfully point out that since this Appeal involves a medical issue, it had to rely on the testimony of the technical witness, in arriving at its final deliberations;**

2. **This Board would refer to Clause 1.1 of Section 4 of the Tender Document which clearly specifies that:**

   "*Either*

   Mycophenolate 250mg capsules CPV 33652300-9 Mycophenolate Mofetil 250mg Capsules

   AND

   Mycophenolate Mofetil 500mg tablets CPV 33652300-8 Mycophenolate Mofetil 500mg tablets

   OR

   Mycophenolate 180mg EC tablets CPV 33652300-8 Mycophenolate sodium 180mg enteric coated tablets

   AND

Mycophenolate 360mg EC tablets CPV 33652300-8 Mycophenolate sodium 360mg enteric coated tablets."

The above mentioned stipulated condition clearly dictates what is being requested by the Contracting Authority and in this regard, this Board would also refer to the full text of clause 3.1 of the "Instructions to Tenderers", as follow:

"*3.1 This tender is not divided into lots, and tenders must be for the whole of quantities indicated. Tenders will not be accepted for incomplete quantities.*

***This item is an immunosuppressant and patient can require a smaller dose than the regular dose and therefore a combination of the two tablet doses might be required so same brand doses will be needed. We are hence requesting either both doses of the sodium salt or the two doses of the Mycophenolate salt of this medication*.**"

From the above clauses stipulated in the Tender Document, it was clearly dictated that the combination of medical products being requested must be of the same brand, so that the Appellants were well aware of what they had to offer. At the same instance, this Board notes that the Appellants' had the remedies to clarify any dubious interpretation of the stipulated requirements prior to the submission of

their offer and in this respect, this Board is aware that such remedies were not availed of by Cherubino Limited.

3. With regards to the Appellants' claim that such a condition was not justified, this Board would respectfully refer to the credible testimony of Mr Mark Zammit, who amplified the reason why the combination of the requested medicine had to be of the same brand, as follows:

"*Xhud:* ***Ikun hemm cirkostanzi speċjlament meta' jkollok mard li huwa serju ħafna bħal ma hu dan il-każ u huwa kruċjali li wieħed jiddetermina u jinduna jekk xi ħadd kellu xi reazzjoni ħażina għal* particular brand *li ġieli jiġri kemm minħabba li l-*brands *ivarjaw mil-lat ta'*excipients*. Li jfisser l-ingredjenti l-oħrajn li m'humiex l-*active ingredients*. Fil-mediċina bażikament it-tabib ser jiktiblek il-mediċina li trid. Imma fil-verita' meta' ser nieħdu l-mediċina, mhux ser ikun hemm biss dik il-mediċina li kitiblek it-tabib. Imma biex issir it-*tablet*, biex issir il-*capsule*, jintużaw sustanzi oħra, kuluri,* fillers, stabilising agents*. Issa ġieli jkun hemm sitwazzjonijiet fejn xi ħadd ikollu xi reazzjoni ħażina jew allerġija għal xi wieħed minn dawn l-ingredjenti u allura speċjalment f'*diseases *li huma verament kruċjali. F'din il-każ din it-tip ta'mediċina tintuża f'pazjenti li jkollhom* renal transplant*. U tintuża għax***

***min ikollu* renal transplant *importanti li ma jkollux* rejection *għat*-transplant *u allura tbaxxi l-immunita'. Allura jekk inti f'ċirkostanzi partikolari pero', jekk inti ser ikollok* two tablets, *inti jekk ser ikollok reazzjoni ħażina għaliha, huwa importanti li tidentifika liema hu l*-causative brand. *Jekk ikunu* two brands, *ser tkun diffiċli ħafna biex wieħed jidentifika kinetx waħda jew l-oħra. Jekk ser ikunu l-istess* brand, *it-tabib ser jgħid isma, din il*-brand *tidher li ma taqbilx miegħu mela ser ikolli nordnalu biex jieħu* brand *differenti. Allura ser ikun jista' jasal iktar faċilment għal dik. Allura dan huwa* a standard requirement *f'ħafna mis-sitwazzjonijiet fejn għandek dożi differenti tal-istess mediċina*."

From the testimony of Mr Zammit, this Board is comfortably convinced that for medical reasons and for the benefit of the well being of the patient, the condition in the Tender Document to procure this combination of medicine having the same brand, is well and truly justified.

4. **With regards to Cherubino Limited's contention that their offered combination is bio-equivalent, this Board has to resort to the vivid explanation given by Mr Zammit as follows:**

"*Xhud:* **Bio equivalence** ***huwa kunċett kruċjali u fil-fatt il*-bio equivalence** ***wassal biex l-i*specifications** ***ħarġu kif ħarġu. Ejja ma ninsewx, sa dan*** **the past tender kien unbranded,** **brand** ***partikolari waħda biss kienet. L-i*specs** ***kienu jissejħu*** **Mycophenolate Mofetil** ***jew inkella*** **Mycophenolate Mifortic.** ***Kienu*** **branded.** ***Il-kunċett tal*-bio equivalence** ***tant huwa kruċjali li wassal li aħna verament niftħu għall*-competition.** ***Din il*-call, *il*-brands** ***telqu. M'għadx hemm*** **brand** ***fl-i*specs,** ***fis-sens irrid karozza Mercedes jew BMW. Hawnhekk ftaħnieha li għandek l*-indication** ***qegħdin għal*** **Mycophenolate Mofetil** ***u*** **Mycophenolate Acid** ***u*** **competition** ***bejniethom. Ifisser il-fatt li huwa*** **bio equivalent,** ***kieku ma kellniex evidenza li hemm*** **bio equivalence** ***f'dawn il-prodotti ma konniex nagħmlu dan il-pass. Dan huwa dokument kruċjali. Pero' li semmejt jien huwa differenti. Li semmejt jien huwa dan. Mhux qed ngħid li Cellcept u Tillomed m'humiex*** **bio equivalent.** ***Hawnhekk qed ngħidu li kieku m'għandniex sigurezza li*** **they are bio equivalent,** ***ma konniex nistgħu niftħu l-i*specs** ***b'dak il-mod li jista' jkun hemm*** **competition** ***bejn dawk il*-brands.** ***Għax kieku kienet tfisser li ser tkun traġedja fil-pazjenti kollha li***

ser jaqilbu minn **brand** ***għal ieħor. Li qed ngħidu hawn hija xi ħaġa differenti pero'. Hawnhekk qed ngħidu din: Li anke jekk ser jinfetaħ u ser ikun hemm*** **a healthy competition** ***kif kien hemm bejn ħafna*** **bidders** ***u ħafna prodotti, aħna qed ngħidu li*** **the two doses iridu jkunu of the same brand** ***mhux minħabba l-*****issue** ***ta'*** **bio equivalence** ***imma minħabba l-*****issue** ***li semmejt qabel jien illi l-*****clinician** ***irid ikollu*** **clear visibility** ***tal-pazjent fuqhiex inhu biex jekk ikun hemm xi*** **reactions,** ***hawnhekk mhux qed ngħidu li l-*****clinical effect** ***mhux ser ikun l-istess. Il-*****clinical effect** ***f'*****bio equivalence** ***ser ikun l-istess. Jekk il-pazjent huwa prodott milli*** **he rejects the kidney,** ***jekk ser naqilbu fuq*** **brand** ***oħra ser ikun protett. Hekk tfisser*** **bio equivalent.** ***Ifisser li fil-ġisem ser ikun available fiċ-ċirkolazzjoni biex jaħdem, ser ikun l-istess daqs tal-*****originator,** ***il-*****brand** ***normali. Pero' aħna rridu li t-*****two brands** ***ikunu l-istess biex il-*****clinician** ***ikollu*** **visibility** ***ta' xi brand il-pazjent qed jieħu biex jekk il-pazjent ikollu xi*** **allergic reaction** ***li tista' tkun minħabba l-*****excipients** ***tal-prodott, aħna nkunu nafu.*****"**

In conclusion, this Board opines that:

a) **the technical specifications stipulated in the Tender Document were clearly dictated to mean that the medicinal combination should be composed of tablets of the same brand;**
b) **Cherubino Limited were well aware of what was requested and if in doubt had the opportunity to seek remedies;**
c) **the condition that the combination had to be of the same brand was fully justified.**

In view of the above, this Board,

i) **upholds the Central Procurement and Supplies Unit's decision in awarding the Tender;**
ii) **does not upholds the contentions made by Cherubino Limited;**
iii) **directs that the deposit paid by the Appellant should not be refunded.**

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

7th March 2019