

## **PUBLIC CONTRACTS REVIEW BOARD**

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### **Case 1279 – CPSU 021-60006/19 –Request for the Participation for the Supply of Secukinumab 150mg/ml in 1ml solution for injection**

#### **Call for Remedies before the Closing Date for Competition**

The publication date of the call for tenders was the 18<sup>th</sup> January 2019 whilst the closing date of the call for tenders was 7<sup>th</sup> February 2019. The estimated value of the tender (exclusive of VAT) was € 585,099.90 for 36 months.

On the 6<sup>th</sup> February 2019, Charles De Giorgio Ltd filed a Call for Remedy against the Central Procurement and Supplies Unit as Contracting Authority requesting that the tender be re-issued without a specific reference to Secukinumab.

On 12<sup>th</sup> March 2019 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Mr Carmel Esposito and Mr Lawrence Ancilleri as members convened a public hearing to discuss the objections.

The attendance for this public hearing was as follows:

#### **Appellants – Charles De Giorgio Ltd**

Dr Clement Mifsud Bonnici	Legal Representative
Mr Mark Mallia	Representative

#### **Contracting Authority – Central Procurement and Supplies Unit**

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

#### **Others**

Ms Lara Cauchi	Representative (Novartis)
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Dr Anthony Cassar, Chairman of the Public Contracts Review Board, welcomed the parties and invited submissions.

Dr Clement Mifsud Bonnici Legal Representative for Charles De Giorgio Ltd stated that it is a fundamental point in Public Procurement Regulations that any reference to a specific product is not allowed. Euro directives state that a tender must refer only to an active ingredient. Appellant

is asking for the tender to be re-visited or cancelled so as to open the market for competition by indicating the application of the product. The scope of this call for remedy was not to defend a particular, or the cheapest, product but to open competition.

Dr Marco Woods Legal Representative for the Central Procurement and Supplies Unit (CPSU) said that the technical specifications were drawn up by the Directorate for Pharmaceutical Affairs (DPA) and not by the CPSU. The intention, following the issue of this tender was that the terms might be widened following an internal review.

Dr Alison Anastasi Assistant Director at the CPSU stated that after the remedy was submitted the Chief Medical Officer (CMO) and the DPA examined the points raised as a result of which it transpired that the medication in question was not in the formulary, and two other products offered by the Appellant had also been excluded. The function requirement in the specifications will have to be re-issued after licensing as indicated in previous cases by this Board.

Dr Mifsud Bonnici suggested that the CPSU might consider purchasing more than one product in smaller quantities to offer a wider range of treatments.

Dr Anastasi pointed out that tender was usually issued for three years plus a further one year extension. The CGO and the DPA had stated that there is no evidence that medication cannot be changed on a long term basis. Open competition in tenders was very commendable but it was not an easy task and there are big issues involved.

Dr Mifsud Bonnici said that within the budget concerns indicated by Dr Anastasi there is room for multiple products. A tender for three years plus one was monopolistic and led to lack of competition and was not proportionate.

Dr Woods said that it would not be in the best interest of patients to be switched from one medication to another and then, after one year, to be switched again.

Dr Mifsud Bonnici made reference to PCRB Case 1135 (Alfred Gera & Sons Ltd vs CPSU) where the Board had stated that tendering was not limited to products on the formulary list and which was relevant to this Case. Competition should be opened but not for lengthy periods of time, and it was not always to patients' benefit to choose the cheapest product. He tabled literature from the European Medical Agency and NICE re the functionality of the medical products in question (Doc A). He also tabled documents regarding the effects of different medicines on psoriasis (Doc B).

The Chairman said that the optimal situation would be an open tender with a range of multiple products.

Dr Woods said the CPSU were in favour of opening tenders, but changes in the terms of years need consideration between the medical parties involved in the purchasing of medications.

Dr Mifsud Bonnici in conclusion said that Appellants would appreciate a recommendation by the Board along the lines discussed.

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

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**This Board,**

**having noted this Call for Remedy filed before the Closing Date of Competition by Charles de Giorgio Limited (herein after referred to as the Appellants) on 6 February 2019, refers to the claims made by the same Appellants with regard to the Tender of Reference CPSU 021-60006/19 listed as Case No 1279 in the records of the Public Contracts Review Board and issued by the Central Procurement and Supplies Unit (herein after referred to as the Contracting Authority).**

**Appearing for the Appellants: Dr Clement Mifsud Bonnici**

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

**Whereby, the Appellants contend that:**

- a) their main concern refers to the fact that any reference to a specific product is in breach of the spirit of the directives issued by the European Union. In this regard, the Appellants request the**

**Contracting Authority to reconsider the technical specifications so that, the Tender Document will stipulate the active ingredient of the product and not that of a particular brand, hence broadening the possibility for more participation in the competition.**

**This Board has also noted the Contracting Authority's 'Letter of Reply' dated 19 February 2019 and also its verbal submissions during the hearing held on 12 March 2019, in that:**

- a) **the Contracting Authority contends that, it can only procure medicinal products which are listed in the Government Formulary List, however, the Directorate for Pharmaceutical Affairs confirms that, at present, it is in liaison with prescribers to update specifications so that other medicinal products will be included in the formulary list.**

**This Board, having examined the relevant documentation to this "Call for Remedy" and heard submissions made by the parties concerned, opines that the issue raised by the Appellants and which deservedly merit consideration, is the reference being made in the Tender Document to a particular product rather than the description of the active ingredients of the product being requested.**

- 1. This Board acknowledges and appreciate the fact that, the Contracting Authority can only procure medicinal products which are presently listed in the Government Formulary List so that, in a sense, there exist already a form of limitation for the participations of offers, of other equivalent products. This Board also takes into consideration the fact that these products are medicinal and must be of the highest standards possible for the well being of the patients, so that there must be regulatory authorities to ensure that all medicinal products administered are of the desired and effective standards as duly stipulated, in the medical field.**
- 2. At the same instance and on numerous occasions, this Board notes that, the technical specifications, as in similar Tender Documents, refer to specific active ingredients, rather than to the functional equivalence and main objective of the product. In this respect, this Board would respectfully point out that, although the procedure for a product to be listed on the formulary list is somewhat lengthy, every effort should be made by the Contracting Authority to recommend the inclusion of other available medicinal products in the various branches of the medical field, so that a wider range of medicinal products will be available to the benefit of both the Authority and the end user.**

- 3. With regards to the 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.**
- 4. With regards to the Appellants' claim that the period of three years procurement is too long and suffocates the opportunity for other competing bidders to participate, this Board acknowledges that, sometimes and in certain circumstances, it is not medically wise to switch medication on a patient after a short period of time, however, this Board upholds the decision to shorten the Tender period for medicinal products, the inclusion of which, will not affect the treatment of the end user.**

**In conclusion, this Board,**

- a) upholds Charles de Giorgio Limited's contention in that the technical specifications should not refer to a specific active ingredient of a particular brand;**
- b) upholds the Appellants' suggestions subject to the above mentioned reservations.**

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

- i) upholds the contentions made by Charles de Giorgio Limited;**
- ii) directs that the present Tender is to be cancelled and that a new one is to be issued to reflect the considerations and decisions taken by this Board;**
- iii) directs the Central Procurement and Supplies Unit to transmit this Board's considerations to the Authority responsible for the formulary listing of medicinal products**

Dr Anthony Cassar  
Chairman

Mr Carmel Esposito  
Member

Mr Lawrence Ancilleri  
Member

*25<sup>th</sup> March 2019*