

## **PUBLIC CONTRACTS REVIEW BOARD**

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### **Case 1359 – CPSU 152088P19TW – Request for Quotation for the Supply of Interlukin 17A Inhibitor**

#### **Call for Remedy before Closing Date of a Call for Competition**

The publication date of the call for quotations was the 27<sup>th</sup> August 2019 whilst the closing date was the 28<sup>th</sup> August 2019. The estimated value of the quotation (exclusive of VAT) was € 367,608.22

On the 28<sup>th</sup> 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 quotations be suspended.

On 27<sup>th</sup> 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
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## **Interested Parties;**

Dr Clement Mifsud Bonnici	Representing Charles de Giorgio Ltd
Mr Mark Mallia	Representing Charles de Giorgio Ltd
Dr Maxine Montanaro	Representing Charles de Giorgio Ltd

Dr Anthony Cassar, Chairman of the Public Contracts Review Board, welcomed the parties and stated that since this call for remedy was parallel with that in Case 1360 save for a different Appellant a joint hearing would be held.

This was agreed by all parties. All parties also agreed that testimonies and submissions heard in Case 1358 would also apply to these hearings.

Dr Therese Comodini Cachia Legal Representative for V J Salomone Pharma Ltd said that the lack of implementation of the Board's decisions in Case 1279 and the ambiguities and discrimination in the tender in Case 1358 applied also to this Case. This request for quotations is similar to the call for tender in Case 1358 with the only difference being that it was to cater for 30 patients for a twelve month period. Once the Contracting Authority issued a call for tenders and subsequently issued a call for quotation a conflict arises as it creates a precontractual liability and prejudices all bidders against fair competition as prices are divulged before assessing the call for tenders. The Public Procurement Regulations (PPR) does not allow calls for quotations in excess of € 144,000 and the Authority must prove why they exceeded these criteria.

Dr Woods Legal Representative for the Central Procurement and Supplies Unit stated that the appeal as submitted fails to give the reason for the application and does not contain a formal request and should be dismissed. The justification for issuing this call was that no open call could be issued because of the existing objection and the Authority was duty bound to ensure that treatment to patients was not interrupted. He would produce witnesses to amplify this point.

Dr Clement Mifsud Bonnici Legal Representative for Charles De Giorgio Ltd said that his clients request cancellation of the call for quotations as they were not aware of the original application of the Appellants. According to the PPR this call should have been issued as a tender. The CPSU made a reference to justify a negotiated procedure which does not apply either. This was simply done to resolve an interim supplies problem. The crucial factor, however, is that appellants prejudice themselves since they have to indicate a price for only a one year's supply when for a longer period they can achieve economies of scale and therefore lower prices. This distorts competition and he referred to several cases decided by this Board regarding distortion of competition.

Dr Alison Anastasi (398380M) called as a witness by the PCRb testified on oath that she was the Head of Operations in Procurement at the CPSU. The medicine in current use is not on the Formulary List and is bought on an *ad hoc* basis to treat eleven patients. Since this is purchased on an exceptional basis and only exact quantities are bought there is a risk that an additional patient

cannot be treated. The Director of Contracts in lieu of a direct order issued a request for quotations since the value was over the € 144,000 limit. Two parties appealed the request for quotations.

Questioned by Dr Comodini Cachia witness stated that in this particular instance the instructions from the Policy Unit of the Health Department came from Ms Antonio Formosa, and gave no room for options in specifications as they specified only one particular medication – ILK 17A inhibitor. No alternate options were given – the exact number of patients was specified based on the cheapest technical compliant offer based on one year’s supply on a like for like basis. Ms Formosa indicated the cycle from patient information in her possession on which the financial bid was to be based and between the loading dose and the maintenance dose to be administered for psoriasis and psoriatic arthritis – spondylitis was not included as it is not in the Formulary.

Reference was made to documents ELC1 and ELC2 presented by Appellants Charles De Giorgio Ltd which give a summary of products characteristics and indicating the different dosages and period of application.

Witness confirmed that for evaluation purposes the maintenance dosages will be taken and this will require a clarification. She confirmed that no clarification request had been received from Appellants.

It was pointed out to witness that nowhere in the call for quotations is it mentioned that this was a negotiated procedure. It was confirmed by the Chairman that there is no indication that this was a negotiated procedure.

At this stage Dr Comodini Cachia reminded the Board that as agreed at the start of this hearing the evidence and submissions heard in this case apply also to Case 1358.

Dr Mifsud Bonnici pointed out that the question of dosages was first raised at this hearing. The criteria of the Contracting Authority was based on price per annum per patient not on dosages. The tender and the request for quotations are to be treated differently.

Resuming her testimony Dr Anastasi said that the request for quotations was issued on the basis of the cost of treatment not on individual dosages.

Dr Comodini Cachia commented that no details of dosages or of patients were supplied either in the tender or in the request for quotations. One had to bear in mind that dosages may change with the age of the patient.

Dr Mifsud Bonnici said that there were three reasons for cancelling these calls:

1. They went against the decision in Case 1279 which was for a tender not a request for quotations
2. This was a request for quotation not a negotiated procedure

### 3. The procedure adopted distorted the market

His clients were requesting that their position is not prejudiced by having to divulge prices based on only one year's supply.

Mr Karl Farrugia (24774M) called as a witness by the PCRB testified on oath that he is the Managing Director of the CPSU. He stated that there was an urgent need for this medicine and occasional direct orders had been issued for the same amount and the same period as the current request. The tender had been issued on the basis of previous tender but had been stopped on appeal. As an alternative a direct order was issued but it too was stopped. All methods had been tried so the CPSU was now asking for a quotation for supply. He confirmed that the request for quotation was a negotiated procedure but regretfully this had not been notified to the parties concerned. He saw no difference, except in the title, between a request for quotation and a negotiated procedure. The previous direct order was for Secukinumab. He saw no reason to buy through direct orders for new patients.

Dr Comodini Cachia said that the Contracting Authority has not shown that it had fulfilled the terms of the criteria it set or of the PPRs. There was ambiguity as there was no like for like comparison – the characteristic of the product in relation to patients, their ages, dosages indicated that it was not the same or equivalent. Bidders were not informed that it was a negotiated procedure and the Authority had issued a request for quotation whilst a tender for the same product was still outstanding. A witness had even confirmed that there was need for clarification. All these missing factors were prejudicial to bidders.

Dr Franco Agius Legal Representative of the Department of Contracts stated that the stopping of the process and eventual cancellation is merely a ploy to protect the financial interest of bidders. It is the Government prerogative to choose which product it wishes to acquire and he referred to Court of Appeal Case (on 27.7.2007) which confirmed the buyer's right to choose. The Authority requested quotations on a price per patient – there was therefore no discrimination as it was open to all offers. The call for quotations meets the Board's directions and procurement regulations. The Board's directions in Case 1279 had been scrupulously followed. The statements by the Chief Medical Officer demolished the argument that the Authority was breaking the law since he stated that four different medicines were being prescribed and it was not tying itself to buying from one single source. No proof had been supplied that there was any discrimination between suppliers. He referred to Article 34 of the European Directive on Procurement and to a publication by Graells (Public Procurement and EU Competition Rules) both stressing that the Contracting Authorities have unlimited discretion in tender requisites.

Dr Mifsud Bonnici said the appeal was abusive as it was finding obstacles to opening the market – a further two products were now available. The present supplier has market dominance and

therefore special obligations. PCRB Case 1328 had established the principle of precedent on different products. On new patients there was no need to restrict direct orders to one product – this will remove the present abuse.

Dr Comodini Cachia said that discrimination and skewering of competition existed as the Social Security Act does not cover psoriatic arthritis. The decision by the Board in case 1279 should be upheld and effectively implemented and it was unjust to ignore patients’ consideration. The Chief Medical Officer’s advice and that of other witnesses was that there should be more than one medication available as that is in the patients’ interest.

Dr Agius said that he differed on the Chief Medical Officers’ testimony with the version quoted by Dr Comodini Cachia.

Dr Mifsud Bonnici said that the Board’s recommendation was not binding; there was a need to find a workable solution to incorporate more than one medication.

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

End of Minutes

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## **Decision**

**This Board,**

**having noted this ‘Call for Remedy Prior to the closing date of Call for Competition’ filed by V.J. Salomone Pharma Ltd (herein after referred to as the Appellants) on 28 August 2019, refers to the claims made by the same Appellants with regard to the Request for Quotation of reference CPSU 152088P 19TW listed as case No. 1359 in the records of the Public Contracts Review Board.**

**Appearing for the Appellants:**

**Dr Mario Demarco**

**Dr Therese Comodini Cachia**

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

**Whereby, the Appellants contend that:**

- a) **The request for quotations for a product similar to that being included in a tender, which at present, is under appeal, will create a conflict and prejudices all bidders against fair competition as prices are made known to all, prior to the assessment of the call for tenders.**
  
- b) **The Public Procurement Regulations does not permit Calls for Quotations for Procurement in excess of €144,000 so that, the Authority must provide justifiable evidence as to why it exceeded such criteria.**

**This Board also noted the Contracting Authority's 'Letter of Reply' dated 6 September 2019, in that:**

- a) **The Authority took into consideration that, since no Open Call could be issued and in order to safeguard the well-being of the patients, there was no other option but to obtain supplies through a Call for Quotations. This procurement is essential for the continuity of the treatment of patients.**

**b) The Authority also insists that, there was no discrimination as the offer was open to all bidders and at the same instance, the Public Contracts Review Board's directions in case No. 1279 had been scrupulously followed and adhered to.**

**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**

**Ing. Karl Farrugia duly summoned by the Public Contracts Review Board**

**Dr Allison Anastasi duly summoned by the Public Contracts Review Board**

**This Board, after having examined the relevant documentation to this 'Call for Remedies' and heard submissions made by all the interested parties, including the testimony of the witnesses duly summoned, opines that the issues that merit consideration are three-fold namely:**

- Whether such a call for quotations will create a disruption in the competitive process of the offers intended for the tender, presently under appeal,**

- **whether such a call will induce discrimination among prospective bidders for the tender under appeal and**
- **whether the Authority adhered to the decision of case No. 1279 issued by this Board.**

### **Disruption in the Competitive Process**

1. **This Board appreciates and acknowledges the fact that, the treatment of patients is a continuous and never-ending process so that, the supply of this medicine must not be interrupted. At the same instance, this Board understands the Authority's situation when it comes to procuring such medical products, in that, in this particular case, a new tender was issued and was appealed thereon during which period, the Authority required supply and in this regard, a 'Call for Quotation' was issued for the supply of Interleukin 17A Inhibitor for a period of 12 months. This Board also notes that the estimated value of such a call exceeds €144,000.**
2. **This Board also acknowledges that, since the tender has been appealed, there exists an uncontrollable gap of time between the publication of this Board's decision and the evaluation and finalisation of the tender so that,**



during such an interim period, patients have to be served the necessary medication. In this regard, this Board was made aware that previous 'Calls for Quotations' were issued and the last RFQ was issued in August 2019 and awarded to Appellants' company.

3. The 'Call for Quotation' under review was issued to all prospective bidders so that there was no hindrance to open competition. At the same instance, the Authority wanted to avoid a direct order to the incumbent economic operator.
  
4. With regards to Appellants' contention in that, the Authority is prejudicing the objector in seeking the disclosure of commercial sensitive information, mainly the price, while the tender is still open for the same product, this Board would respectfully point out that, it is the duty and obligation of the Authority to secure supplies of this particular medicine and to ensure that the ongoing treatment of the patients carries on uninterrupted. At the same time, the Authority must also ask for the price in the 'Call for Quotation' (RFQ) moreover, if this RFQ is cancelled, to secure supplies, the Authority will have no other option but to keep on issuing direct orders to the incumbent supplier and such a

**procedure will not only restrict competition but will, most drastically, breach all the principles of Public Procurement. In this respect, this Board would strongly oppose and deplore if such an action is forcefully imposed upon the Authority to enable same to secure the supplies of the requested medicine. Moreover, such an unwarranted situation would distort completely the scope of an open competition among prospective bidders.**

- 5. With regard to the price being quoted in the RFQ, this Board takes onto account the very basic fact that, prices quoted for short term supplies do not reflect same for a much longer period of supplies so that, bidder's offered prices for an RFQ do not reflect the same intended price for the period of supplies as dictated in the tender.**
  
- 6. Taking all the above considerations into account, this Board opines that the RFQ is the only tool available to the Authority to obtain supplies in a just and transparent manner during the interim period that is, until the tender is evaluated and finalised. At the same instance, this Board opines that the RFQ should be limited for supplies for a period of six months with an option for an extension of another six months.**

**Discrimination for Potential Bidders for Tender (Under Appeal)**

7. With regard to discrimination, this Board noted that, first and foremost the RFQ was issued in accordance with the Public Procurement Regulations and secondly, the ‘Call for Quotations’ was open to all potential offers and in this respect, the Board cannot identify any form of discrimination in the issue of this RFQ. At the same instance, through submissions and testimony of witnesses, no evidence was provided to prove such a contention. This Board would also direct the Authority to inform the bidders that the RFQ will be processed through a ‘Negotiated Procedure’.

**Adherence to the Instructions given in decision of case No. 1279**

8. This Board would respectfully refer to this Board’s decision, case No. 1279, regarding the cancellation of the previous tender and the issuance of a new one, in that, this Board directed that:

- i) The technical specifications should not refer to a specific active ingredient of a particular brand: From documentation made available to this Board and submissions made by the parties concerned, same Board confirms that the RFQ did not refer to

**ingredients of a particular brand but stipulated that the item being requested by the authority, as follows:**

*“Recombinant Human Monoclonal Antibody that selectively binds to Interlukin – 17A, indicated for the treatment of moderate to severe plaque psoriasis, as well as psoriatic Arthritis”*

**From the above description of the medical product being requested, this Board is justifiably convinced that the RFQ is in line with the decision and instructions, given by this Board in case no. 1279.**

- 9. From the testimony of Dr Alison Anastasi, this Board was made aware of the fact that, the Authority has to indicate to bidders, the inclusion of the maintenance dose in the RFQ, however, it is also being confirmed that the price to be quoted is a price per patient for the six months duration.**

**In conclusion, this Board opines that:**

- a) The RFQ is the only fair and transparent procedure to be adopted by the Authority for the temporarily procurement of this medicine, until the tender under appeal is evaluated and finalised.**
- b) The RFQ should be issued for a supply period of six months with an option of an extension of a further period of six months.**

**c) The present RFQ should be amended to indicate:**

- That the Evaluation procedure to be adopted is through a negotiated procedure.**
- The inclusion of maintenance dose, to enable prospective bidders to reflect such an issue in their quotation.**

**d) The RFQ is open to all prospective bidders without any limitation for participation and in this respect this Board does not detect any discrimination among bidders, in the RFQ being issued by the Authority.**

**e) The conditions and technical specifications as stipulated in the RFQ are in Accordance with the instructions and decision, as concluded by this Board in case no 1279.**

**f) The RFQ does not create any conflict or prejudice with regard to commercial information being divulged in the RFQ in relation to that which prospective bidders might include in their offer for the tender under appeal.**

**g) The RFQ was properly issued by the Authority and conforms with the Public Procurement Regulations. At the same instance, this Board would also point out that this transitory procurement is essential for the continuity of the ongoing treatment of the patients and in this respect, urgent processing of the Negotiated Procedure of this procurement is of the utmost importance.**

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

- i) Does not uphold Appellants contentions,**
- ii) Directs the Authority to issue the necessary clarifications to reflect this Board's decision and to resume the Negotiated Procedure to finalise this urgent requirement.**

Dr Anthony Cassar  
Chairman  
*17 October 2019*

Mr Lawrence Ancilleri  
Member

Mr Carmel Esposito  
Member