

PUBLIC CONTRACTS REVIEW BOARD

Case 1470– CT 2323/2019 – Tender for the Supply of Romiplostim 250 Micrograms Injection

Remedy before the Closing Date of a Call for Competition.

The tender was published on the 20th May 2020 and the closing date of the tender was the 21st July 2020. The estimated value of the tender (exclusive of VAT) was € 1,470,000.

On the 22nd June 2020 V J Salomone Pharma Ltd filed a Call for Remedy before the closing date of a call for competition against the Central Procurement and Supplies Unit as the Contracting Authority on the grounds that the tender was restrictive and discriminatory. A deposit of € 7,350 was paid.

On 5th August 2020 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Dr Charles Cassar and Mr Lawrence Ancilleri as members convened a public virtual hearing to discuss the objections.

The attendance for this public hearing was as follows:

Appellants – V J Salomone Pharma Ltd

Dr Arthur Galea Salomone	Legal Representative
Mr Adrian Salomone	Representative
Ms Louisann Caruana Scicluna	Representative
Ms Jackie Mangion	Representative
Ms Janica Mizzi	Representative

Contracting Authority – Central Procurement and Supplies Unit & Directorate of Pharmaceutical Affairs

Dr Alex Sciberras	Legal Representative DPA
Dr Marco Woods	Legal Representative CPSU
Ms Antonia Formosa	Representative DPA
Mr Karl Farrugia	Representative CPSU

Interested Party – Cherubino Ltd

Dr Matthew Paris	Legal Representative
Mr David Cherubino	Representative

Department of Contracts

Mr Mark Mizzi

Representative

Dr Anthony Cassar Chairman of the Public Contracts Review Board welcomed the parties. He noted that since this was a virtual meeting all the parties had agreed to treat it as a normal hearing of the Board. He then invited submissions.

Dr Arthur Galea Salomone Legal Representative for V J Salomone Ltd said that the product requested in the tender – Romiplostim was the only available authorised product in the European Union and this was not contested by the DPA and the tender could only be met by one product and was therefore not an open tender.

Dr Alex Sciberras Legal Representative for the Directorate of Pharmaceutical Affairs intervened to say that both points raised in the letter of appeal are agreed as proven and there was no need to enter into discussions regarding these points.

Dr Matthew Paris Legal Representative for Cherubino Ltd stated that in Clarification Note No 1 the Contracting Authority had made it clear that the medicine was being procured as per licensed indications. Romiplostim is used for the treatment of Chronic Immune thrombocytopenic purpura (ITP) while Eltrombopag is used for the treatment of ITP in primary immune cases. The CPSU already obtains both products and the tender refers to different conditions albeit of the same disorder.

Dr Sciberras said that the product specified in the tender is for unusual and particular conditions and hence the reason why it is referred to by name. Romiplostim is required for only about ten patients; it is still patented and therefore restricted and used exclusively.

Dr Galea Salomone said that in 2019 a small contract was awarded to Appellants through a negotiated procedure. In this instance the call is for an open tender for one product which is exclusive and goes against the Public Procurement Regulations. He made reference to PCRB Cases 1116 and 1397 both of which dealt with discrimination in tenders.

Dr Sciberras quoted EJC Case 328/92 Commission vs Spain wherein it was held that an authority could not go for a negotiated procedure if there was only one supplier.

Mr John Forte (0119866M) called as a witness by Appellants testified on oath that he was employed by the said Appellants as a Regulation Affairs Officer. He had 20 years experience, including holding a Masters, as a pharmacist. He explained the medical conditions needing the use of the product and confirmed that there was an identical product to Romiplostim and also a third product which was licensed only for use on adults. There is no generic product that contains Romiplostim

In reply to a question witness stated that Romiplostim was available in powder form for administering by injection whilst Eltrombopag was available in tablet form and also in powder form for dilution and administering by mouth.

Professor Alex Gatt (152972M) called as a witness by the PCRB testified on oath that he is a Consultant in the Haematology Department at Mater dei Hospital. He explained that the condition when these medicines are used is when there is a bleeding disorder caused by a low level of platelets in the blood. First line treatment was through a combination of medicines whilst about one-third of patients required either one of the medicines under discussion as a second line treatment. A certain percentage of patients do not respond to one or the other so they are offered the alternative. Both products are used for primary ITP and both are used for primary and secondary chronic conditions.

In reply to a question from Dr Paris witness stated that the administration of these products is different – there is a preference for the use of tablets for reasons of convenience. The Medical Authorities cannot do without either of these products.

Dr Paris said several new points were raised at this hearing which had not been in the appeal letter and these should be discarded. There should also not be any limit on the number of economic operators as on previous tenders there was a multiplicity of bidders.

Dr Galea Salomone stated that the Consultant in his testimony had confirmed that the products were identical. Romiplostim should be procured not on an open tender as this does not satisfy the PPRs.

Dr Sciberras said that it was clear that there were only two medicines of this type with Eltrombopag the one mainly in use – both medicines were patented and there was no generic equivalent and both were needed as they were complementary in use. An open tender was needed to encourage more economic competition.

Dr Marco Woods Legal Representative of the CPSU asked for it to be recorded that Dr Sciberras was appearing on behalf of the DPA and not the CPSU.

The Chairman thanked the parties for the submissions and declared the meeting closed.

End of Minutes

Decision

This Board,

having noted this ‘Call for Remedy Prior to Closing Date of a Call for Competition’ filed by VJ Salomone Pharma Ltd (hereinafter referred to as the Appellants) on 22nd June 2020, refers to the claims made by the same Appellants with regard to the tender of reference CT 2323/2019 listed as case No. 1470 in the records of the Public Contracts Review Board.

Appearing for the Appellants: Dr Arthur Galea Salomone

Appearing for the Directorate of Pharmaceutical Affairs (DPA): Dr Alex Sciberras

Appearing for Central Procurement and Supplies Unit: Dr Marco Woods

Whereby, the Appellants contend that:

- a) **Their main concern refers to the fact that, the product being requested in this particular tender is ‘Romiplostim’ which can be procured only from one supplier. Since, this is an open tender, no reference was made to other equivalent products on the market and such an omission goes against the spirit of the Public Procurement Regulations.**

This Board also noted the Contracting Authority’s ‘Letter of reply’ dated 9th July 2020 and its verbal submissions during the virtual hearing held on 5th August 2020, in that:

- a) **The DPA contends that, the product being specified in the tender document is being procured for unusual and particular conditions of a limited number of patients, hence the exclusivity.**

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

Mr John Forte duly summoned by VJ Salomone Pharma Ltd

Prof Alex Gatt duly summoned by the Pubic Contracts Review Board

This Board, after having examined the relevant documentation to this ‘Call for Remedy’ and heard the submissions made by all the interested parties, including the testimony of the technical witnesses opines that, the issue which is being contested relates to the omission of participation in the tender document, of other equivalent or similar products.

- 1. This Board noted the testimony of Prof Alex Gatt who explained in vivid terms the application of this particular product. In this regard, this Board was made aware that, there is another product for the treatment of the same condition however, it was also pointed out that, in cases where one of the available products is not suitable for the particular patient, the other available product is applied.**
- 2. This Board is also aware of the exceptional circumstances where a particular medicinal product is required for the treatment of a particular condition of a particular patient. This Board would also point out that, since there is only one alternative product, a negotiated procedure cannot be used so that, an open tender was issued.**
- 3. Once an open tender has been issued, the DPA had to include the word ‘or equivalent’ after the name of the mentioned product ‘Romiplostim’, to adhere to the Public Procurement Regulations.**

In conclusion, this Board opines that:

- a) The medical reasons given by the medical experts for the procurement of the specific product ‘Romiplostim’ are truly justified and will allow the treatment of patients with a particular condition.**
- b) Appellants are not disputing the product being procured however, quite appropriately, they are contesting the limitation of an open competition, in this open tender.**
- c) The tender document, with particular reference to the technical specifications, should never limit the scope of competition in an open tender.**

In view of the above, this Board,

- i. upholds Appellants’ contention,**
- ii. directs the DPA to include the word ‘or equivalent’ after the specific mentioned product ‘Romiplostim’, through a clarification note.**
- iii. directs that the tendering process be resumed as soon as possible.**
- iv. directs that the deposit paid by Appellants be fully refunded.**

Dr Anthony Cassar
Chairman

Dr Charles Cassar
Member

Mr Lawrence Ancilleri
Member

10th August 2020