PUBLIC CONTRACTS REVIEW BOARD

Case 1397 – CPSU164048N19JP– Request for Participation for the supply of Lot 1: Dabrafenib 75mg capsules and Lot 2: Trametinib 2mg tablets

Remedy before Closing Date of a Call for Competition

The publication date of the request for participation was the 17th September 2019 whilst the closing date was the 17th October 2019 (extended to 29th October 2019). The estimated value of the tender (exclusive of VAT) was not stated.

On the 28th October 2019 Cherubino Ltd sought a Remedy against the Central Procurement and Supplies Unit as the Contracting Authority because they felt aggrieved that the tender did not allow competition.

On 3rd December 2019 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman Dr Charles Cassar and Mr Richard Matrenza as members convened a public hearing to discuss the objections.

The attendance for this public hearing was as follows:

Appellants – Cherubino Ltd

Dr Matthew Paris	Legal Representative
Dr Francis Cherubino	Legal Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Marco Woods	Legal Representative
Dr Alison Anastasi	Representative
Ms Julia Pirotta	Representative

Dr Anthony Cassar, Chairman of the Public Contracts Review Board, welcomed the parties and invited submissions.

Dr Matthew Paris Legal Representative for Cherubino Ltd asked, before making his submissions, what type of negotiated procedure this request for participation was and the value of the tender.

Dr Alison Anastasi Representative of the Central Procurement and Supplies Unit (CPSU) said that this request for participation (RFP) is with publication within the contracts threshold and is issued for participation because the medicine was introduced in the Formulary List two years ago and is

still under a valid patent and if it transpires that there is competition the CPSU will issue a tender. The value of the tender was not known.

Dr Paris stated that the tender called for two specific products but the RFP does not give much information. However, in the reply to Clarification Note 2 the CPSU indicated that the two mentioned products were *Dabrafenib* and *Trametinib* and were used jointly for the treatment of melanoma with a BRAF V600 mutation. The Appellants are aggrieved that these active ingredients as stipulated can only be procured from one source since they are patented.

Dr Paris tabled two documents (Doc 1 and Doc 2) and directed the Board's attention to the respective documents which state that *Dabrafenib* and T*rametinib* are produced by Novartis Ltd. It is obvious therefore that the product can only be obtained from one source and the concept of the Formulary List is at this stage irrelevant. European Medicines Agency (EMEA) documents indicate that there is another active ingredient that meets the call.

Further documents (Doc 3 and Doc 4) were tabled by Dr Paris which respectively indicate that medications by the name of *Cotellic* and *Zelboraf* are produced by a different manufacturer to treat the same medical condition despite the fact that the Contracting Authority restricted the tender to only one product. Reference was made to the European Union directives to contracting authorities regarding the obligation in tenders for procurement equivalence. Reference was also made to PCRB Case 1135 which dealt with an identical scenario to the present case. Once again the Board must ensure that the Contracting Authority opens up the tender to competition.

Dr Marco Woods Legal Representative for the Central Procurement and Supplies Unit stated that the Contracting Authority had to abide by the self limitation obligations, in that they must follow the Formulary List. The process to include a new product in the List is lengthy and the indicated medicines in the RFP are the only ones in the List. Clarification 3 makes it very clear that the evaluation process has to follow the specifications issued by the Directorate for Pharmaceutical Affairs.

Dr Paris said that if one followed the directive in Case 1135 it was clear that at this stage of the tender process the Contracting Authority must ensure that no bidder is given an advantage. The RFP restricts competition and it must follow the Board's directive to denote clearly the objective of the tender.

In reply to a question from Dr Woods asking if Appellants had applied for the mentioned medicines to be included in the Formulary List, Dr Paris said that the question was irrelevant as the objective is to open the tender to competition. He also referred to PCRB Case 1116 which also dealt with the principle of free and open competition.

The Chairman pointed out that the PCRB is only interested in following the Public Procurement Regulations (PPR) and what is and what is not on the Formulary List is not of concern to those Regulations.

Dr Woods contended that the CPSU cannot ignore the Formulary List which they must scrupulously follow. The suggested medication was not on the List and the Health Authority had a procedure to buy medicines for exceptional cases.

The Chairman again made the point that there was the need for things to change and to come into line. The PPR cannot be changed to fit into the Formulary requirements – where alternatives exist the tender must be open to competition.

Dr Paris said that the choice facing the CPSU was between either breaking the PPR or sticking to the Formulary List.

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

End of Minutes

Decision

This Board,

having noted this 'Call for Remedy Prior to the Closing Date of a Call for Competition' filed by Cherubino Ltd (herein after referred to as the Appellants) on 28 October 2019, refers to the claims made by the same Appellants with regard to the tender of reference CPSU 164043N19JP listed as case No. 1397 in the records of the Public Contracts Review Board.

Appearing for the Appellants: **Dr Matthew Paris**

Dr Francis Cherubino

Appearing for the Contracting Authority: Dr Marco Woods

Whereby, the Appellants contend that:

a) **The request for participation (RFP) as duly published refers to a particular product which can only be obtained from one supplier and in this regard, Appellants maintain that since there are other products which would attain the objective of this procurement, the RFP should provide for the inclusion of other equivalent products so that, there will be no restrictions to an open competition.**

This Board also noted the Contracting Authority's 'Letter of Reply' dated 28 November 2019 and its verbal submissions during the hearing held on 3 December 2019, in that:

a) **The Authority contends that, it is restricted to the formulary list so that, only medicines listed therein can be tendered for and in this regard, the evaluation process must follow the specifications as duly issued by the Directorate for Pharmaceutical Affairs.**

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

Documents No.1 & 2 – Respective Documents showing Products being tendered for, can only be supplied from One Source Only.

Documents No. 3 & 4 – Indications that the name 'Cotellic' and 'Zelboraf' are produced by a Different Manufacturer.

1. **This Board, after having examined the relevant documentation to this 'Call for Remedies', with particular reference to the stipulated specifications in the tender dossier, also took into consideration the submissions made by the parties concerned. In this regard, this Board opines that the issue that merits consideration, is the limitation imposed upon the Authority to procure medicines from products listed in the formulary list only.**

2. **It must be made clear, from the start, that the Authority's procurement is financed from Public Funds so that such Public Procurement is governed by the Public Procurement Regulations.**

3. **The technical specifications, as stipulated in the RFP promotes the supply of a product that can be obtained from one manufacturer only and such an eventuality limits the scope of open competition.**

4. **This Board would respectfully point out that the formulary list should not override a main principle in Public Procurement i.e. the duty and obligation of the Contracting Authority, in its stipulated technical specifications in a particular tender, must never allow a restriction in the participation of bidders in an open competition. At the same instance, the Authority should never formulate technical specifications in a manner as to give an advantage to a particular economic operator.**

5. **In this particular case, this Board acknowledges the fact that the technical specifications were dictated by the Directorate for Pharmaceutical Affairs and not by the Contracting Authority itself and in this regard this Board, as it has opined in other similar cases, does not uphold the fact that the Authority, which is the entity that identifies its objective, is not involved in the formulation of the technical specifications in its procurements.**

6. **It must also be mentioned that, the procedure for the inclusion of a particular product in the formulary list is a lengthy process, so that other alternative and equivalent medicines are not all included. In this respect, this Board after hearing so many cases of similar eventualities, request**

the competent Authorities to align the procedure of the formulary list to the Public Procurement Regulations, to avoid unnecessary suppression of open competition.

In conclusion, this Board opines that:

a) **The manner in which the technical specifications in the RFP are stipulated suppresses the spirit of open competition where available equivalent products are restricted from participating.**

b) **Credible evidence was provided to confirm that there exist other equivalent products, which although not included in the formulary list, render the same effective objective.**

c) **The Authority should have the responsibility for the formulation of the technical specifications in their procurement requirements.**

d) **The Authority responsible for the administration and processing of the formulary list should endeavour to abide, as much as possible, with the Public Procurement Regulations.**

In view of the above, this Board,

i. **uphold Appellants' concerns,**

ii. **directs the Authority to cancel the RFP,**

iii. **directs the Authority to issue an open tender including technical specifications which do not breach the principles of Public Procurement Regulations,**

iv. **directs the Authority to include this Board's findings in the formulation of the technical specifications of the tender.**

Dr Anthony Cassar Chairman	Dr Charles Cassar Member	Mr Richard A Matrenza Member

17 December 2019