PUBLIC CONTRACTS REVIEW BOARD

Case 1440 – 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 5th July 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 the Public Contracts Review Board convened a public hearing to discuss the objections and is decision was published on the 17th December 2019.

On the 27th March 2020 the Court of Appeal directed the Public Contracts Review Board to rescind its decision and to consider in its deliberations the submissions made by V J Salomone Ltd.

On the 30th April 2020 the Public Contracts Review Board composed of Dr Anthony Cassar as Chairman, Dr Charles Cassar and Mr Carmel Esposito as members convened a public virtual hearing to comply with the Court's directive.

The attendance for this virtual meeting was as follows:

Appellant – Cherubino Ltd

Dr Matthew Paris	Legal Representative

Interested Party – V J Salomone Ltd

Dr Therese Comodini Cachia	Legal Representative
Ms Louisann Caruana Scicluna	Representative
Ms Chrystalla Charalambous	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 (PCRB) welcomed the parties and before inviting submissions obtained the consent of all parties to treat this virtual meeting as a normal

meeting of the Board. He then went on to state that following the decision of the Court of Appeal all that the PCRB is now required to do is to take into consideration the letter dated 31st October 2019 from V J Salomone Ltd and to rescind their previous decision in this Case. The Board has already dealt with the technical aspects of this Case and will not consider further submissions on this point.

Dr Therese Comodini Cachia Legal Representative for V J Salomone Ltd (Salomone) said that the Court of Appeal rescinded the Board's decision in its entirety and that the PCRB had failed to consider Salomone's letter and all parts of the previous proceedings were irregular and do not exist. The Board has to start from scratch including the full submissions by Salomone and their witnesses – a full hearing must be heard otherwise any decision taken at this sitting will again end up at the Court of Appeal.

Dr Matthew Paris Legal Representative for Cherubino Ltd (Cherubino) objecting to having a full hearing as the Court had only ordered the letter from Salomone to be considered. He also queried why Novartis were represented at this hearing when they were not a party to the proceedings.

Dr Comodini Cachia said it was up to the Board to decide if Novartis are an interested party – the previous practice of the Board was to allow interested parties to attend and this should continue, to which the Chairman noted that the Board had no objection to the presence of the Novartis representative as she would not be making any submissions.

Dr Paris stated that he had no objections to follow what Dr Comodini Cachia was proposing provided that Cherubino retained the right to put their case first as they were the Appellants. However he insisted that the additional documents submitted by Salomone at the last minute should be disregarded as they were not filed within the statutory time limit imposed by Regulation 264 of the Public Procurement Regulations (PPR).

Dr Comodini Cachia said it was irregular not to admit documentary evidence since Salomone had not had this opportunity at the previous hearing. Should they not have submitted them the other parties would complain that they did not have the documents when reference is made to them during the hearing.

Dr Paris reminded the Board that at this hearing they are not dealing with the technicality or the merits of the products mentioned in the tender but by the terms of the Request for Participation (RfP) and the fundamental point that European Court rulings demand 'equivalent product' obligation.

The Chairman stated that the Board must make it clear that they are considering a precontractual call for remedy to allow full competition. The technical points were not up to the PCRB to decide. The Court of Appeal cancelled the first sentence and it is up to the PCRB to ensure that the RfP is observed. Apologies were extended to V J Salomone Ltd for omitting them from the first hearing, due to an oversight, but the Board was not willing to hear evidence about the quality of the products but simply if the call for participation allows competition in line with PPR and will only consider the contractual rather than the product aspect.

Dr Comodini Cachia objected to this ruling on the grounds that it did not include any decision regarding the presentation of documents.

The Chairman said that documents will be accepted along with the Salomone letter of 31st October only in the context of the precontractual concern.

Dr Comodini Cachia said that the precontractual concern by Cherubino is that their product is medically equivalent to the tender requirements and asked why they were allowed to produce documentation in support of their claim but this was being denied to Salomone.

Dr Paris noted that although the original decision was annulled by the Court, Salomone were using exactly that precise decision to claim to be allowed equal treatment. The Court allowed documents to be submitted - it was the PCRB which claimed product equivalence not Cherubino but in fact it is the European regulations that impose the use of 'equivalent to'. The RfP as it stands is limiting competition which is the basis of Cherubino's appeal.

Dr Woods Legal Representative for the Central Procurement and Supplies Unit (CPSU) said that the appeal by Cherubino was based on the reference to 'active ingredients'. The RfP is used as an indicator to evaluate the market. It appears now that more than one bidder can supply this type of medicine – therefore the RfP will be cancelled and an open tender issued instead.

Dr Comodini Cachia said that she was looking for a decision by the Board if a witness will be allowed to testify if there is a comparable equivalent product and to challenge the equivalence claim. In regard to the CPSU intention to open competition with open specifications this undermines the equivalence concept completely as the tender will be based on the cheapest price without regard to product effectiveness thus completely eliminating equivalence. Since Dr Woods claims that equivalence is not the remit of the PCRB this can only lead to the procuring of the cheapest product.

Dr Paris said that the appeal in this case is by Cherubino and at this stage only the RfP is to be considered. By widening the appeal Salomone is requesting the PCRB to transgress the law. At no stage has Cherubino asked for mandatory equivalence; they only sought the direction of the PCRB to ensure healthy competition. The CPSU are now requesting cancellation of the RfP and issue of a tender. The Board should decide the relevance of the evidence and past cases 1116, 1135 and 1279 were cited as parallel cases for the guidance of the Board on this question. If the PCRB were to follow Salomone's line of reasoning and omit the principle of equivalence they would be acting ultra vires. The decision regarding choice of product comes at evaluation stage.

Dr Woods regretted the fact that this process has been drawn out over seven months whilst stocks of the medicine were getting low to the detriment of patients. He requested the Board to allow an urgent interim order to be placed to enable the ordering of stock from a third party.

The Board acceded to this request.

Dr Comodini Cachia rebutted the assertion that her clients were against equivalence as has been claimed in this case. The Contracting Authority must not use competition and the claim of equivalence as a form of disguise to end up with cheaper products – a point that is becoming a regular feature of appeals. Regrettably the PCRB had accepted Cherubino's product as equivalent without any in depth analysis.

The Chairman pointed out that the Board was concerned that the RfP did not allow open competition and their decision was not based on the premise that some party or other had proved equivalence. However Dr Comodini Cachia said that what actually transpired was that the precontractual challenge started because one party claimed to have an equivalent product – if that had not been the case they would not have had any locus standi.

Dr Paris stated that some of the claims made were not substantiated as equivalence is not a choice but an imposition. It has been mentioned that the RfP will be withdrawn and a fresh call made and one cannot determine in advance how that tender will be worded. Salomone have an interest in reducing competition and prolonging the procedure. The situation is that it is the European Medicines Agency which determines which are the products that save life. If a new tender is issued Cherubino will examine the terms and technical specifications and then decide on their course of action. Salomone are demanding that decisions are made at this stage.

Dr Jadranka Strugar Sujica called to testify by V J Salomone Ltd stated on oath the she is the Novartis oncology medical head for Central Europe. Asked to comment on the equivalence of the two products offered she said that in her expert opinion the pharmacokinetics of the two products are different in their efficacy, safety and dosing. The Dabrafenib and Trametenib combination is the more potent.

Dr Paris objected to this testimony which he said was on purely technical matters and not on competition.

Dr Comodini Cachia stated that it had been clearly indicated to the Board what the subject matter of the witness' testimony would be about and Dr Paris had accepted to hear the witness.

The Chairman made it clear that the Board does not want to hear technical details in an attempt to prove equivalence or otherwise.

Dr Comodini Cachia insisted that it be minuted that the Board had now changed direction and was giving different directives. She then asked the witness to give her opinion on the statement made by Cherubino that as compatible products of an equivalent nature exist the specifications of the RfP fail to denote clearly the objective and utilization of the product, but however dictated only the ingredients.

Witness said that in the context of this case the two medications are not equivalent. The combination of Dabrafenib and Trametinib is more potent meaning a lower concentration is required resulting in less adverse effects on the patient's body. The tolerability profile between the products differs as well as certain side effects like photosensitivity and in some patients rashes and blisters.

Dr Paris interjected saying that the testimony was out of context and clearly biased as it was coming from a representative of the manufacturers of the product.

The Chairman asked the witness two questions to which she replied that the product she represented was not the only type of that medicine available in the world and there are others, although in some aspects their effects differ. Asked to explain this last point witness stated that efficacy and tolerability varied.

Dr Comodini Cachia said that the main submissions had already been made. Witness stated that there is no equivalence in the products as there are different modes and treatments. The PCRB must be convinced of the equivalence of the products before applying the rules of competition otherwise it will be a futile exercise. Cherubino had failed to substantiate their claim.

Dr Woods noted that part of the evidence had indicated that there is more than one product to treat this type of melanoma illness.

Dr Paris said that the RfP as drawn up limited competition as only one supplier met the specifications with a subsequent clarification stating what was required to cure patients. One must bear in mind in considering the testimony given that the witness worked for Novartis and it stands to reason that different medicines lead to different circumstances to obtain the final result. The EMA confirms that there is more than one product to satisfy the required treatment. The RfP requested two ingredients which lead to one product. All that Cherubino requested was openness of the market and that was crucial and fundamental.

The Chairman thanked the parties for their 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 (hereinafter referred to as the Appellants) on 28 October 2020, refers to the claims made by the same Appellants with regard to the tender of reference CPSU 164048N19JP listed as case No. 1440 in the records of the Public Contracts Review Board.

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

Dr Francis Cherubino

Appearing for the Contracting Authority: Dr Marco Woods

Appearing for VJ Salomone Ltd: **Dr Therese Comodini Cachia**

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 2020 and its verbal submissions during the hearing held on 30 April 2020, 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 specifications as duly issued by the Directorate for Pharmaceutical Affairs.**

And

The 'Letter of Reply' dated 31st October 2019 from VJ Salomone Ltd to the application filed by Cherubino Ltd on the 28th October 2019.

This Board has also taken note of the documents submitted by Cherubino Ltd on 3 December 2019, which consisted of:

Documents No. 1&2 – respective documents showing products being tendered for with the specifications, which can be supplied from only one Source.

Documents No. 3&4 – indications that the medication 'Cotellic' and Zelboraf' are produced by a different Manufacturer and are used for the treatment of the same illness.

and

Documents submitted by V J Salomone Ltd, on 27 April 2020, consisting of:

Document No. 5 – short note showing dosage 'Trametinib'

Document No. 6 – comparative study by Hauschild and others, between 'Dabrefenib' and 'Trametinib', versus 'Vermufenib' plus 'Cobimetinib' in the treatment of metastatic melanoma patients

Document No. 7 – study by Hauschild and others on the longer benefit survival with 'Dabrefenib' and 'Trametinib'in mutant stage lll melanoma.

Same Board also noted the testimony of the witness namely:

Dr Jadranka Strugar Sujica duly summoned by V J Salomone Ltd

This Board, after having examined the relevant documentation to this 'Call for Remedies', with particular reference to the technical specifications as stipulated in the RFP and heard submissions made by the interested parties including the testimony of the witness duly summoned opines that, the issue that merits consideration is, whether the technical specifications in the RFP are restricting the scope of competition.

1. **This Board would respectfully point out that, the Authority's intended procurement, which will be financed from Public Funds, must be governed by the Public Procurement Regulations which in turn, must provide for free and open competition at all times.**

2. **It is imperative to point out, at this stage of consideration that, the technical specifications in Public Procurement offers should:**
    - **be precise in the way it describes the requirements,**
    - **be easily understood by the prospective bidders,**
    - **have clearly defined, achievable and measurable objectives,**

- **not mention any brand names or requirements which limit competition or if brands are mentioned to include the term 'or equivalent'.**

3. **In this particular case, the Authority is maintaining that such specifications were dictated by the Directorate for Pharmaceutical Affairs, whilst Appellants are contending that such technical specifications would lead to the availability of only one brand of product, thus suffocating the principle of an open competition.**

4. **Through submissions and explanations given by the Authority, this Board was made aware of the fact that technical specifications are not formulated by the Authority but by the Directorate for Pharmaceutical Affairs and as such are based on the available products so included in the formulary list.**

   In this respect, this Board would point out that, in Public Procurement, the formulary list should not override the principle of an open competition or create a situation where other potential bidders cannot compete. At the same instance, the Authority itself should not allow technical specifications which give an advantage to a particular economic operator.

5. **With regard to the technical specifications, these should be formulated and dictated by the Authority itself, after having all the necessary consultations**

with the professional medical specialists in their particular field and not by the Directorate so that, the Entity which identifies the objectives of the particular procurement is directly involved in the formulation of the technical specifications. It must also be acknowledged that the procedure for the inclusion of a particular product in the formulary list, is a lengthy process in itself, so that, other alternative and equivalent medicines are not all included, however, the Authority should always prevent unnecessary suppression of 'Open Competition'.

6. **This Board must emphasize the fact that this appeal constitutes a 'Call for Remedy Prior to the Closing Date of Competition' so that, the remit of this Board is to ensure that the technical specifications as duly stipulated in the RFP are not restrictive or suppressing open competition.**

7. **This Board would also refer to an extract from the testimony of Dr Jadranka Strugar Sujica, confirming that there is more than one product to treat the disease for which this procurement is being issued, as follows:**

"Chairman : I am going to ask the witness two questions and that is it.

Dr Paris : By all means

Chairman : *In your professional opinion, do you think that there is more than one medicine to do this treatment in the world ?*

Witness : *No*

Chairman : *Only one?*

Witness : *No no there are many*

Chairman : *And in your professional opinion, would you say that the other medicines, the alternative medicines, does give the same result?*

Witness : *Not in all aspects. It is not so easy. We have melanoma which is very wide area. So it includes also in immunooncology, immunotherapy, includes different combinations. So if we are talking about these two treatments, then stick to these two treatments*

Chairman : *So we are talking about these two treatments. So we established that there is not only one medicine for these two treatments. There is more than one, am I right?*

Witness : *Yes*

Chairman : *Will all the medicines give the same result?*

Witness : *No*

Chairman : *Of course not. Nothing gives the same result*

Witness : *Yes*

Chairman : *But it does not mean that for this type of treatment there is only one brand of medicine, am I right?*

Witness : *No, I mean this is the fact. You can list what is approved for the melanoma treatment*

Chairman : *Ok thank you very much."*

8. **On a concluding note, this Board cannot but note that such a procurement process has been going on for quite a lengthy period of time and in this regard, same Board appeals for co-operation and due consideration among the potential bidders so that the tendering process will materialise for the sole benefit of patients awaiting such medication, in such a terrible moment of their lives.**

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 and 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 and must ensure that equivalent products are allowed to participate.

d) The Authority responsible for the administration and processing of the formulary list should also 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	Dr Charles Cassar	Mr Carmel Esposito
Chairman	Member	Member

15th May 2020