PUBLIC CONTRACTS REVIEW BOARD

Case 1852 – CT2329/2022 – Supplies – Measles, Mumps and Rubella Vaccine

20th March 2023

The Board,

Having noted the call for remedies filed by Dr Clement Mifsud Bonnici and Dr Calvin Calleja on behalf of Ganado Advocates for and on behalf of Associated Drug Company Limited, (hereinafter referred to as the appellant) filed on the 16th February 2023;

Having also noted the letter of reply filed by Dr Leon Camilleri and Dr Alexia Farrugia Zrinzo acting for the Central Procurement and Supplies Unit (hereinafter referred to as the Contracting Authority) filed on the 22nd February 2023;

Having also noted the letter of reply filed by Dr Mark Anthony Debono acting for the Department of Contracts (hereinafter referred to as the DoC) filed on the 21st February 2023;

Having heard and evaluated the testimony of the witness Dr Alison Anastasi (Representative of the Central Procurement and Supplies Unit) as summoned by Dr Clement Mifsud Bonnici acting for Associated Drug Company Limited;

Having taken cognisance and evaluated all the acts and documentation filed, as well as the submissions made by representatives of the parties;

Having noted and evaluated the minutes of the Board sitting of the 9th March 2023 hereunder-reproduced.

Minutes

Case 1852 – CT 2329/2022 – Supplies – Measles, Mumps and Rubella Vaccine

Application for pre-contractual remedy (Regulation 262)

The tender was issued on the 28th January 2023 and the closing date was the 28th February 2023. The estimated value of the tender excluding VAT, was € 277,200.

On the 16th February 2023 Associated Drug Co Ltd filed an application for a pre-contractual remedy against the Central Procurement and Supplies Unit as the Contracting Authority on the grounds that a technical specification is unduly estrictive. .

A deposit of € 1,386 was paid.

On the 9th March 2023 the Public Contracts Review Board composed of, Mr Kenneth Swain as Chairman, Dr Charles Cassar and Ms Stephanie Scicluna Laiviera as members convened a virtual public hearing to consider the appeal.

The attendance for this public hearing was as follows:

Appellant – Associated Drug Co Ltd
Clement Mifsud Bonnici Legal Representative

Ms Kimberley Vella	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Leon Camilleri	Legal Representative
Dr Alison Anastasi	Representative
Ms Denise Dingli	Representative

Department of Contracts

Dr Mark Anthony Debono	Legal Representative

Mr Kenneth Swain Chairman of the Public Contracts Review Board welcomed the parties and invited submissions.

Dr Clement Mifsud Bonnici Legal Representative for Associated Drug Co Ltd said that the reason for the appeal was a cautionary step to nip in the bud the possibility of future action. The vaccine in question is currently a world-wide issue but with a very limited supply. The point at issue in this appeal is that the product being offered by Appellant is a recombinant version of human albumin, which process historically included human blood albumin. In a PCRB hearing on the same product in 2019 an expert witness confirmed that there were minute traces of blood in the product but there were no health risks and the appeal was upheld. With a copy and past submission of the previous tender the matter now is a question of price and Appellant is seeking clarification that it will not be eliminated on the human blood

issue.

Dr Leon Camilleri Legal Representative for the CPSU mentioned that the Appellant's objection stated that the Authority failed to reply to a request for clarification but explained that this clarification could not be answered differently as otherwise it would have been tantamount to an evaluation of the tender at that stage. In a previous post-award case it has already been decided that the product offered by Appellant is not incompatible.

Dr Mifsud Bonnici said that the clarification was sought to reassure the economic operator and to ensure market competition and to ensure that a product approved by the European Medicines Agency (EMA) is acceptable.

Dr Alison Anastasi (398380M) called to testify by the Appellant stated on oath that she is the Head of procurement at CPSU and that the product in use since 2019 is the MMRVAXPRO vaccine offered by Associated Drug Co. No health problems have been encountered in its use. The terms in the present tender are similar to the ones in the 2018 tender. The Summary of Product Characteristics (SPC) indicate that the product contains human albumin recombinant and hence there is an issue.

In reply to questions from Dr Camilleri witness outlined the difference between the recombinant and human serums stating that the former has a safety profile. Either product offer is acceptable so the final decision will be on price.

Questioned by Dr Debono the Legal Representative for the Department of Contracts, witness said that the specifications on the current call were similar to the one in the 2018 tender.

At this stage there was a discussion between the parties on the best way of accepting the appeal without changing the terms of the tender. The Board directed that on the submissions made a clarification is to be issued by the Authority that recombinant human albumin is not a human blood product and that Clause 2.5 in the technical specifications of the tender document is to be evaluated against the product's characteristics approved by the EMA.

There being no further submissions the Chairman thanked the parties for their contributions and declared the hearing closed.

End of Minutes

Hereby resolves:

The Board refers to the minutes of the Board sitting of the 9th March 2023.

Having noted the call for remedies filed by Associated Drug Company Limited (hereinafter referred to as the Appellant) on 16th February 2023, refers to the claims made by the same Appellant with regard to the tender of reference CT2329/2022 listed as case No.1852 in the records of the Public Contracts Review Board.

Appearing for the Appellant:	Dr Clement Mifsud Bonnici & Dr Calvin Calleja
Appearing for the Contracting Authority:	Dr Leon Camilleri & Dr Alexia Farrugia Zrinzo
Appearing for the DoC:	Dr Mark Anthony Debono

Whereby, the Appellant contends that:

a) Over the course of the past 3 years, the Applicant has supplied MMRVAXPRO to the Contracting Authority and the same MMRVAXPRO has been administered to patients in Malta with no adverse incidents or issues. In the current case, the Applicant, faced with the same technical specification present in the 2018 Tender, is concerned that its bid for this Tender may be rejected yet again by the Contracting Authority.
b) The Applicant, having exhausted its right to request clarifications from the Contracting Authority, submits that it is being compelled to submit the present application in terms of Regulation 262 of the PPR to address this issue.
c) The Applicant submits that the technical specification 2.5 is unduly restricting competition on the market, discriminatory in nature, and further, it is disproportionate.
d) While a contracting authority is afforded a margin of discretion when drafting tender conditions, that margin of discretion cannot be misused and it is curbed by the general principles of public procurement.

e) This technical specification is at odds with the Contracting Authority's duties in Regulation 39 of the PPR to *"treat economic operators equally and without discrimination";* to design the procurement model in such a way that *"artificially narrows competition"* and to act *"in a proportionate manner"*. These duties emanate from the fundamental general principles of public procurement law as developed by the EU Directives and case-law of the Courts of Justice of the European Union.

f) The Applicant submits that the principle of competition is of constitutional importance to public procurement and it is important that competition on the market is fostered. If there is no or limited competition, it is the contracting authority which suffers by obtaining higher offers, bad quality supplies or services or possibly no offers at all.

g) The Applicant further submits that the principle of proportionality is also of constitutional importance to public procurement, and that the technical specifications ought not exceed what is necessary to achieve the objectives of a procurement procedure, in particular, where such specifications may exclude an incumbent product which is being purchased and administered without issue.

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 22nd February 2023 and its verbal submission during the virtual hearing held on 9th March 2023, in that:

a) Clause relates to albumin or blood products derived from humans -

CPSU primarily submits that although each and every evaluation is independent from the any subsequent evaluation on the same or different products and what is established in one evaluations does not constitute a fact in any other evaluation, the applicant is the incumbent contractor and was awarded the contract following a tender where the same specification at dispute (2.5) was included - it is therefore difficult to understand the reason why the applicant is claiming that this same clause, this time is discriminatory against him. CPSU submits that specification 2.5 gives preference to products which do not contain human albumin or other human blood products for valid and important health reasons as will be explained during the sitting. Human albumin or other human blood products only relate to products which are derived directly from the human body and clearly do not refer to any recombinant human albumin. This is being submitted because in case number 1337 of the 30th of August 2019 which the applicant mentions in the application, it was minuted that applicant's witness Dr. Oliver Wicht explained that *"this process meets the tender specifications as the manufacturers are using the recombinant version of human albumin and the vaccine is therefore free of human products"*

b) Clarification Request made by Applicants -

The applicant seems also to imply that the contracting authority did not or did not want to give a substantive reply to its request for clarification, however CPSU submits that the request/question

was worded in a way that it could not have ever received a different answer. The applicant did not request for further information on a particular clause but requested a confirmation of whether their product is compliant to a particular specification, at pre-evaluation stage! The question asked is a matter of evaluation and thus CPU could have never provided a different answer.

c) Discrimination -

A fundamental principle before all judicial and quasi-judicial bodies is that who alleges must prove, thus the applicant should present the necessary evidence to substantiate the claim that this condition is limiting competition and, in any way, discriminating. The contracting authority has a limited discretion to choose what it wants to buy, and in this case as this Honourable Board is well aware, CPSU uses this discretion to choose what is best for the patients. This choice is reflected in the specifications of the particular tender. It is being submitted that unless proven that these specifications were designed as to narrow the choice to a particular product or to deliberately restrict competition, the request of the applicant could not be upheld.

This Board also noted the DoC's Reasoned Letter of Reply filed on 21st February 2023 and its verbal submission during the virtual hearing held on 9th March 2023, in that:

a) As a general rule, in accordance with regulation 53(6) of the Public Procurement Regulations, 2016 technical specifications are to afford equal access of (sic) economic operators to the procurement procedure and not create unjustified obstacles. Furthermore, the DoC submits that for an action in terms of regulation 262(1)(c) of the Public Procurement Regulations, 2016 to be acceded by the Public Contracts Review the applicant should prove, with reference to Regulation 39(3) of the Public Procurement Regulations, 2016, that the design of the procurement is *"made with the intention of excluding it from the scope of the Regulations or of artificially narrowing down competition."*

b) Therefore, the applicant is bound to substantiate its legal submissions by the presentation of satisfactory evidence. The DoC refers to a decision of the Public Contracts Review Board where it had been stated that: *"Whilst the Board notes that the grievance by the appellant of the tender unduly restricting competition on the market and discriminatory in nature, it also notes that according to market research carried out by both the appellant and the contracting authority, there are multiple firms which are in the business of supplying both types of categories."*

c) The applicant refers to a decision delivered by the Public Contracts Review Board where it is submitted that the precise specifications of previous tender are reproduced in the present call. The DoC submits that should the principle of *res iudicata*, may not be applicable since the subject matter of the present call for tenders is limited to one supply, not extensive as the previous tender, the quantity of supplies and the period of the public contract also differing from the previous tender.

This Board, after having examined the relevant documentation to this appeal and heard submissions made by all the interested parties including the testimony of the witness duly summoned, will consider Appellant's grievances as follows:

a) With regards to the clarification request made by the Appellant to the Contracting Authority, it is noted that the Contracting Authority responded in the correct manner. A more direct response by the Contracting Authority would have been construed as taking a decision on technical compliance prior to the start of the actual evaluation process. The question as posed by the Appellant company, in the wording chosen, could not be properly replied to by the Contacting Authority at that stage of the tender process.
b) Reference is now made to the testimony under oath of Dr Alison Anastasi whereby she confirmed that:
    i. *"the specifications on the current call were similar to the one in the 2018 tender"*
    ii. *"Either product offer is acceptable so the final decision will be on price."*
c) At this point, this Board refers to the minuted discussion. This Board directs that a clarification note is to be issued by the Contracting Authority stating that the recombinant human albumin is not a human blood product and that Clause 2.5 in the technical specifications of the tender document is to be evaluated against the product's characteristics approved by the EMA.

Therefore, this Board upholds the Appellant's grievance.

The Board,

Having evaluated all the above and based on the above considerations, concludes and decides:

a) To order the Contracting Authority to issue a Clarification note as per point (c) of this Board's deliberations;
b) after taking all due consideration of the circumstances and outcome of this Call for Remedies, directs that the deposit be refunded to the Appellant;
c) To order the Contracting Authority to amend the closing date of the call for tenders at its discretion whilst keeping in line with the public procurement regulations.

Mr Kenneth Swain	**Ms Stephanie Scicluna Laiviera**	**Dr Charles Cassar**
Chairman	**Member**	**Member**