PUBLIC CONTRACTS REVIEW BOARD

Case 1724 – CT2016/2022 – Tender for the Supply of SARS COV2 Fast Track Detection Assay Kits with Equipment on Loan (Real-Time PCR)

20th May 2022

The Board,

Having noted the letter of objection filed by Dr Matthew Paris on behalf of Dalli Paris Advocates acting for and on behalf of Cherubino Limited, (hereinafter referred to as the appellant) filed on the 8th April 2022;

Having also noted the letter of reply filed by Dr Alexia J Farrugia Zrinzo acting for Central Procurement and Supplies Unit (hereinafter referred to as the Contracting Authority) filed on the 18th April 2022.

Having also noted the letter of reply filed by Dr Clement Mifsud Bonnici, Dr Antoine Cremona and Dr Calvin Calleja on behalf of Ganado Advocates acting for Medlab Imports Limited (hereinafter referred to as the Recommended Bidder) filed on the 12th April 2022;

Having heard and evaluated the testimony of the witness Dr Graziella Zahra (Member of the Evaluation Committee) as summoned by Dr Matthew Paris acting for Cherubino Limited;

Having heard and evaluated the testimony of the witness Dr Scott McKeown (Representative of Randox Laboratories) as summoned by Dr Clement Mifsud Bonnici acting for Medlab Imports 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 17th May 2022 hereunder-reproduced.

Minutes

Case 1724 – CT 2016/2022 – Tender for the Supply of SARS COV2 Fast Track Detection Assay Kits with Equipment on Loan (Real-Time PCR)

The tender was issued on the 29th January 2022 and the closing date was the 10th March 2022. The value of the tender, excluding VAT, was € 1,510,488.

On the 8th April 2022 Cherubino Ltd filed an appeal against the Central Procurement and Supplies Unit as the Contracting Authority objecting to their disqualification on the grounds that their bid was deemed to be technically not compliant.

A deposit of € 7,552 was paid.

There were four (4) bids.

On the 17th May 2022 the Public Contracts Review Board composed of Mr Kenneth Swain as Chairman, Dr Charles Cassar and Ms Stephanie Scicluna Laiviera as members convened a public virtual hearing to consider the appeal.

The attendance for this public hearing was as follows:

Appellant – Cherubino Ltd

Dr Matthew Paris	Legal Representative
Ms Janet Pace	Representative

Contracting Authority – Central Procurement and Supplies Unit

Dr Leon Camilleri	Legal Representative
Mr Charles Borg	Chairperson of the Evaluation Committee
Dr Graziella Zahra	Member Evaluation Committee
Mr Mario Farrugia	Member Evaluation Committee

Preferred Bidder – Medlab Imports Ltd

Dr Clement Mifsud Bonnici	Legal Representative
Dr Calvin Calleja	Legal Representative

Mr Kenneth Swain Chairman of the Public Contracts Review Board welcomed the parties. He noted that since this was a virtual meeting all the parties agreed to treat it as a normal hearing of the Board in line with Article 89 of the Public Procurement Regulations. He then invited submissions.

Dr Matthew Paris Legal Representative for Cherubino Ltd stated that the tender requested specific requirements. Once the Department of Contracts provided information regarding the name and make of product selected it was realised that these did not meet the tender specifications. Section 3 of the Specifications, article 1.1 (ii) specified that the kits offered must target two out of five genes of the SARS COV2. The product offered by the winning bid does not meet at least two of these requirements. The documents tabled by the preferred bidder vary from the offer of Appellant and are not the latest technical data sheets on the product. (Compare Doc MI 1 page 91 table 6 which indicates revision with page 93 submitted by Appellant which indicates kit reserved for research only). It is clear therefore that the evaluation was not carried out on the latest document and does not meet the two requisites specified. There is a difference between kits used for research only and clinical use purposes. Evidence to this effect was provided by Bosch themselves. Dr Paris invited the CPSU to review their decision in view of these new facts.

Dr Leon Camilleri Legal Representative for the CPSU said that the evaluation had been completed and he wished to proceed to hear all the facts. The documents submitted by the bidder show compliance and the product met the requirement of detecting two genes.

Dr Clement Mifsud Bonnici Legal Representative for Medlab Imports Ltd agreed with Dr Paris on the technical specifications aspect but disagreed with the argument regarding the

submissions. Problems would arise with post performance if the product does not target the required genes. The product offered conforms with the tender and targets the genes requested.

At this stage Dr Paris said that he would be relying on the documentary submissions but wishes to hear the testimony of witnesses.

Dr Graziella Zahra (237975M) called as a witness by Appellant testified on oath that she is the Head of Section carrying out Molecular Diagnostics. She had drafted the tender specifications and was part of the Evaluation Committee (TEC). The end use of the product is on suspected Covid sufferers. External research had been carried out both on literature and equipment on more extensive coverage of the market and was separate from the documents submitted. The TEC was not aware that Bosch had issued literature after the technical offer was submitted – had the TEC been aware that the kit was only for research purposes they would not have accepted the offer. The literature provided did not state that the kits were only for research purposes. Witness agreed that the latest literature provided varied from the submitted documents.

In reply to a question from Dr Camilleri witness stated that the Bosch literature submitted was not dated but it did not include the clause that it was only for research purposes.

Questioned by Dr Mifsud Bonnici witness said that the external research carried out was to check if the literature submitted made sense compared to the market. She agreed that the tender was compliant.

Dr Scott McKeown (PP No 504849168) called as a witness by the Preferred Bidder testified on oath that he was a Scientist with a Ph.D. qualification and had worked for over twelve years for Randox Laboratories. Medlab Imports has been a distributor for Randox for 26 years and the product offered by them was manufactured by Bosch Healthcare Division. Randox imports products from Bosch and acts as distributor for sales. Witness explained how the product is a testing kit for targeting the E and N1 genes associated with SARS Covid. The February version of the Instructions for Use (IFU) supplied to a particular client did not supersede the version supplied to Medlab. Witness confirmed that there were no restrictions on professional use on the version offered.

Questioned by Dr Paris witness stated that he works for Randox and has no connection with Bosch and that the latter had not confirmed to him that the revision in the literature had been made for a particular purpose.

This concluded the testimonies.

Dr Paris said that in the case of medical equipment more care is required in public procurement. Equipment intended for research purposes cannot be used on patients and that alone is enough to exclude it. Bosch is the only manufacturer of this product and it is

not up to Randox to interpret documents issued by the former – documents supplied by the Appellant shows date when revision was issued on 1st February. If the two versions are compared it is obvious that they are different and that the kit was issued only for research and cannot be used on patients. The declaration by the manufacturer overcomes the evidence of the witness. The second version of the documents is different and provides no comfort that it meets the tender specifications. There are doubts and therefore danger to patients. The solution facing the PCRB is to order a re-evaluation of this tender.

Dr Mifsud Bonnici stated that it has not been contested that the winning bid is compliant as it targets the two genes. The allegation is that there is some document which states that the kit can be used only for research. Witness clearly stated that the product can be safely used for professional purposes. Dr Zahra confirmed that from public information available the Bosch product is compliant for professional use. The Board cannot stand in the shoes of the TEC and carry out the evaluation themselves. The question of the product literature is a Note 2 matter but the technical literature is Note 3 where Appellant confirms that the product conformed at the time and still conforms till this day. It is illogical to think that the wrong product will be offered – besides the witness who is a specialist in this field confirmed that the product is suitable for professional use. One also had to consider the principle of proportionality.

Dr Camilleri said that the TEC evaluated on the submitted documents and followed the correct procedure. It is up to the Board to decide having heard the new submissions.

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

End of Minutes

Hereby resolves:

The Board refers to the minutes of the Board sitting of the 17th May 2022.

Having noted the objection filed by Cherubino Limited (hereinafter referred to as the Appellant) on 8th April 2022, refers to the claims made by the same Appellant with regard to the tender of reference CT2016/2022 listed as case No. 1724 in the records of the Public Contracts Review Board.

Appearing for the Appellant:	Dr Matthew Paris
Appearing for the Contracting Authority:	Dr Leon Camilleri & Dr Alexia J Farrugia Zrinzo
Appearing for the Preferred Bidder:	Dr Clement Mifsud Bonnici & Dr Calvin Calleja

Whereby, the Appellant contends that:

a) ***Recommended bid is not technically complaint (sic)***

Following the publication of the manufacturer by DOC, it is clear that the product on offer is not technically complaint (sic) and does not meet the minimum standards specifications indicated in Section 3 of the tender document. The specifications/terms of reference, which are subjected to Note 3, clearly determine precise and detailed specifications, which must be strictly adhered to.

Provision 1.1 [ii] states, *"Kits offered must target two of the following genes of the SARS CoV2:*

1) ORF 1ab

2) RdRp

3) N1

4) N2

5) E"

Thus and thereby, the specifications are mandatory and non-derogable. Publicly available documents in relation to the product on offer by Messrs. Medlab Imports Limited confirm that it is in breach of inter alia of the above mentioned provision.

b) ***Strict adherence principle***

This Board has already been called upon to decide and determine in similar situations. In the PCRB decision - Case 1356 [CFT 019-0326/19], it has been held that *"the equipment being procured by the Authority will be applied under a 'Life or Death' situation and also understands that, such equipment should be as user friendly as possible, having the best of real time feedback facility, for the benefit and well-being of the patient"*

In so determining, whilst in each and every tender, specifications are to be fully adhered to, wheresoever the context permitted, this board and the Court of Appeal applied the principle of proportionality and favoured competition over strict adherence - the very fact that this product is of an important nature within the context of the pandemic, creates an obligation of strict adherence and self limitation, thus no deviation from the rigours standards may be or should be permitted.

This Board also noted the Contracting Authority's Reasoned Letter of Reply filed on 10th April 2022and its verbal submission during the virtual hearing held on 17th May 2022, in that:

a) ***Recommended bid is not technically compliant***

The offered product by the recommended bidder detects the E genes and the N genes. The N1 and N2 genes are subunits of the N gene, as per peer reviewed literature, copy of which are being

attached. Therefore the product offered by the recommended bidder is in fact compliant with technical specifications/terms of reference and the recommendation of the evaluation committee should be confirmed whilst the objector's grievance rejected.

b) ***Strict adherence principle***

Whilst CPSU submits that this grievance is very general and does not expressly refer to any part of the evaluation process, CPSU submit that the evaluation committee has adjudicated the tender in line with all general principles of public procurement including the principle of self-limitation, but also the principles of equal treatment and proportionality. The scope of having technical members in the evaluation committees is to be able to properly evaluate the offers in line with the tender requirements. In the present case this has been done in conformity with all the general principles of public procurement.

This Board also noted the Preferred Bidder's Reasoned Letter of Reply filed on 12th April 2022and its verbal submission during the virtual hearing held on 17th May 2022, in that:

a) The Appellant's objection is grounded in the allegation that the product offered by the Recommended Bidder does not comply with the technical specifications, specifically, that the product does not target at least 2 of the genes of the SARS CoV2 indicated in the technical specifications. This allegation is untrue and unfounded, and therefore, the appeal ought to be rejected.

b) The Recommended Bidder has offered the following product "Vivalytic SARS-CoV-2 2 genes array 15 cartridges per kit" which is manufactured by Randox Laboratories and Bosch Healthcare Solutions. This product is the "kit" required by the Tender. The Recommended Bidder also offered the following product "Vivalytic Analyser" which is also manufactured by Randox Healthcare and Bosch. This product is the "free equipment on loan" required by the Tender and which is the "integrated cartridge based system" required by the Tender.

c) The kit offered by the Recommended Bidder targets the E-gene and N-gene of SARS Coronavirus-2, and therefore, meets the technical specifications. This is corroborated by the technical literature submitted by the Recommended Bidder and by the confirmation provided by the same in the Technical Offer.

d) The Appellant might be basing its appeal on another kit manufactured by Randox Laboratories and Bosch Healthcare Solutions, which targets the E gene sequence only. However, that is not the kit which was offered by the Recommended Bidder for this Tender.

e) On a concluding point, the Appellant's submission that there is a "strict adherence principle" in public procurement is incorrect and unfounded in law. There is no such principle in EU public procurement law. The starting point is for a contracting authority to abide by the general principles of public procurement law, including, equal treatment, transparency, self-limitation, but also,

proportionality and promotion of genuine competition. There is no hierarchy or order of preference. These general principles which emanate from the EU Treaties are to be applied holistically and each is of equal importance.

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 witnesses duly summoned, will now consider Appellant's grievances.

a) This Board will immediately state from the outset that the Evaluation Committee, *prima facie*, followed due and proper public procurement praxis in evaluating this tender procedure.
b) Reference is now made to the testimony under oath of Dr Graziella Zahra where she stated:
    i. *"The Evaluation Committee was not aware that Bosch had issued literature after the technical offer was submitted – had the evaluation committee been aware that the kit was only for research purposes they would not have accepted the offer"*
    ii. *"the Bosch literature submitted was not dated"*
c) Reference is also made to the testimony under oath of Dr Scott McKeown where he stated:
    i. *"the product is a testing kit for targeting the E and N1 genes associated with SARS Covid. The February version of the Instructions for Use (IFU) supplied to a particular client did not supersede the version supplied to Medlab"*
d) This Board notes that the 2 versions of the Instructions For Use ("IFU") presented as documentary evidence in these proceedings, vary in their content. Specific reference to pages 2, 5 and 91 of such document. Due to the fact that the version as presented by the Preferred Bidder as part of its bid is not dated (reference to Dr Zahra's testimony), whilst the other version presented by the appellant is dated February 2022, i.e. prior to the Closing date of the call for tenders, it cannot be ascertained which version is in fact final. More doubts arise from the testimony of Dr Scott McKeown who stated one does not supersede the other.
e) When one considers, that no testimony and proof was provided by the end supplier, i.e. Bosch, doubts remain as to the technical compliance of the product offered. This Board opines, that bearing in mind the sensitivity of the product being procured, i.e. health purposes, it would be in the best interests of the evaluation committee to ascertain the product's technical literature at the point of the Closing date of the call for tenders, i.e. 10th March 2022. Technical Literature is a note 2 document and rectifications are possible, if need be.

Hence, this Board upholds the Appellant's grievances.

The Board,

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

a) To uphold the Appellant's concerns and grievances;
b) To cancel the 'Notice of Award' letter dated 29th March 2022;
c) To cancel the Letter of Rejection dated 29th March 2022 sent to Cherubino Ltd;
d) To order the contracting authority to re-evaluate the bids received in the tender procedure whilst also taking into consideration this Board's findings;
e) after taking all due consideration of the circumstances and outcome of this Letter of Objection, directs that the deposit be refunded to the Appellant.

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