Case 1089 – CFT 021-6348/2017 – Tender for the Supply of Aqueous Cream BP

The Publication Date of the Call for Tenders was 12 May 2017 whilst the Closing Date for Call of Tenders was 1 June 2017. The Estimated Value of the Tender, (Exclusive of VAT) was € 107,165.50.

Nine (9) Bidders have submitted offers for this Tender.

On 14 September 2017, Reactilab Limited filed an Objection against the decision of the Central Procurement and Supplies Unit to award the Tender to Vivian Corporation Limited for the price of € 112,111.60 (Exclusive of VAT) against a deposit of € 540.

On 5 October 2017, the Public Contracts Review Board composed by Dr Anthony Cassar as Chairman, Dr Charles Cassar and Mr Carmel Esposito as members convened a Public Hearing to discuss the Objection.

The Attendance for this Public Hearing was as follows:

Appellant – Reactilab Limited

Mr Lyon Xuereb	Representative
Dr John Gauci	Legal Representative

Recommended Bidder – Vivian Corporation Limited

Ms Denise Borg Manche	Representative
Mr Corinne Zaffarese Elbourne	Representative

Contracting Authority – Central Procurement and Supplies Unit

Ms Denise Dingli	Chairperson, Evaluation Board
Mr Stephen Martin	Secretary, Evaluation Board
Ms Corinne Bowman	Member, Evaluation Board
Mr Mark Zammit	Representative
Dr Stefan Zrinzo Azzopardi	Legal Representative

Following an introduction made by the Chairman of the Public Contracts' Review Board Dr Anthony Cassar, the Appellants were invited to make their submissions.

Dr John Gauci, the Legal Representative for Reactilab Limited, opened by saying that his clients submitted the required offer for this Tender. On the 4th September 2017, they received a Letter of Rejection from Central Procurement and Supplies Unit saying, that they were "*technically non compliant*" the Appellants also asked unsuccessfully for an extract from the Evaluation Report.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board asked why the Appellants asked for an extract from the Evaluation Report. Dr John Gauci, the Legal Representative for Reactilab Limited replied that, the request was made in order to see why their Bid was being rejected.

Dr Gauci continued by saying that, there was an exchange of e-mails between his clients and the Central Procurement and Supplies Unit regarding the matter, he referred to an e-mail dated 5 September 2017, where the Contracting Authority were requesting for a mock up and a medical device.

The Appellant's Legal Representative continued to explain, that the Tender was for the supply of Aqueous Cream which could be found at the supermarket. The Tender justifiably made a distinction between the requirements needed for a medicinal product and a medical device.

Dr John Gauci explained that in their offer, Reactilab Limited submitted the necessary inscription on the packaging, which was clear and legible as per Tender Requirements. The Appellants felt that the Evaluation Board could have been erroneously incorrect, by saying that, no mock up was submitted.

Dr John Gauci explained that Section 2.1 of the Tender Document that, the mock up had to be submitted only for medicinal products. With regards to the medical devices there were fewer requests, as stated in same: "*a clear and legible copy of the packaging including the labelling of the product being offered*", the requirements submitted by Appellant in his offer.

Reactilab Limited pointed out that, there was no need to present a mock up since it was a medical device. The Contracting Authority agreed with the Appellant's statement and added that, what the latter submitted was presumed to be the wording to be found on the label of the product.

Dr John Gauci continued that, the wording presented was found on the outside of the medical device, however the Central Procurement and Supplies Unit insisted on excluding them from the race since in their opinion, a clear and legible copy of the packaging was the same as mock up. The Appellant sustained the argument that whenever a mock up was required, in the Tender Document, the latter has always submitted it, in their offer.

The Appellants felt that in their opinion, their Bid, who had the second cheapest offer, were technically and more compliant than that of the Recommended Bidder, who had the fourth cheapest offer. The Appellants also confirmed that, all the wording submitted, will be found in the actual packet and thus their exclusion from the Tender is an unfair one.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit said that the main point of contention was whether the document which was exhibited in the submission made by the Appellants was enough for what was requested in the Tender Document. On the other hand, he wanted the Public Contracts Review Board to appreciate the particular circumstances for this case.

The contended product, which was a cream, had to be deemed to be either a medical product or a medical device, according to how it was declared by the manufacturer. If one had to see the submitted documentation, there are products which were to be declared to be a medical product from the manufacturers but the latter, who is a non-EU registered company, consider it to be a medical device.

The fact that originally the part of the medical device was quoted to be a medical product and vice-versa, comes also from the fact that the offer was classified to be a different one from different manufacturers. Having said that, one had to see what does the package contents say if one had to see what Section 2.1 of the Tender Document.

Dr Stefan Zrinzo Azzopardi continued by saying that the Evaluation Board felt that what was presented by the Appellants were not the full details which there will be in the package for this product. This was also bound to the fact that this product was classified as a medical device since the latter means that it is an apparatus which was going to be used.

Dr Stefan Zrinzo Azzopardi referred also to the EU Directive 1993/42/EEC issued on 14 June 1993 where one had to see what type of information there should be on the packaging. The submitted document was not equivalent to what would be required in such circumstances and therefore the Evaluation Board, rightly so felt that what Reactilab Limited presented was not what was requested and therefore they had to deem their offer as technically non-compliant.

Dr Stefan Zrinzo Azzopardi made this explanation in view of the fact that Dr John Gauci has referred to the correspondence which there was between the Appellant and the Contracting Authority but should the need arises, there were members of the Evaluation Board who were available for further explaining.

At this point, Ms Corinne Bowman, a Principal Pharmacist who was also a member of the Evaluation Board, holding ID Card 114674 M was summoned by the Central Procurement and Supplies Unit to testify under oath before the Public Contracts Review Board.

Following Mr Bowman's testimony, Dr John Gauci, the Legal Representative for Reactilab Limited said that from the submissions heard from both parties and Witness during this Public Hearing, it resulted that there is an agreement that Reactilab Limited has offered a medical device.

Therefore, the Section which was communicated to the Appellant by the Contracting Authority, wherein the reference for the mock-up was made, Section 2.1, was not applicable. The Evaluation Board member justly said that it was clear that the apparatus submitted by the Appellant was a medical device but couldn't delve into the correspondence which was made since she was not involved in it but the Witness has confirmed that the quoted Section was not applicable for medical devices.

Dr John Gauci continued by saying that an allegation was made where somehow Document C was presented as a leaflet. No such evidence to support this allegation was presented and there was no such indication in the presented document.

The Witness has mentioned two further things, the weight issue where it was confirmed that in their Bid, Reactilab Limited will offer the 100g and that there was no Batch number. When one is giving an indication of a product which is going to be presented, one cannot give *a priori* the product's batch number. These two things are to be seen in a logical way.

Dr John Gauci continued questioning whether the issue of 50g and 100g and what the batch number was were hindering the establishment of whether the product was idoneous or not. The Appellants have confirmed that they will be submitting the 100g product. If one had to see all the other things stated in this Document, the ingredients, usage, storage and warning items were all present an in accordance with the Regulations.

The Appellants' Legal Representative continued by saying that had the Central Procurement and Supplies Unit had a particular complaint on one of the items, then there would have been a valid reason for his client's bid to be excluded but from what was submitted, it resulted that a decision was taken on the basis of a small error of valuation and then one has to stand by what was said.

Dr John Gauci continued by saying that from what was submitted in this Public Hearing he was sure that the product offered by his clients satisfies completely not only the Tender Document but also all applicable Regulations because if there was something serious which could have raised some concerns about it, the reason of exclusion would have been another one. Reactilab Limited was once again declaring that the actual wording which there will be on the product was submitted in their offer.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board, asked why the Contracting Authority asked for the Batch Number.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit replied that first and foremost the Appellants were making an assumption about the Medical Products Clause which was being referred to. This was subsequently was rectified. There were companies which considered the product to be a medical device and others which did not.

The Witness testified under oath that she considered the product as a medical device because the manufacturer declared it as such. The person, who made the Evaluation, was correct in thinking that the product submitted by the Appellants was a Medical Device and was supported in her considerations by the relative Clauses.

Dr Stefan Zrinzo Azzopardi continued by saying that with regards the medical device, Document A was being mentioned. If one had to see this Document, the person who evaluated it said that this was not the label but it was a leaflet and gave its reasons.

With regards the submissions made, Dr Zrinzo Azzopardi invited the Public Contracts Review Board to see once again the list of the things which have to be presented on the label and see that in the Appellant's offer, this was not to be found according to the testimony made under oath by the Witness.

The Contracting Authority's Legal Representative continued by saying that if one had to see the list presented in Clause 13 of the EU Directive 1993/42/EEC issued on 14 June 1993, one sees that there are other things which in the Document submitted, which the Appellant is insisting that was the label, were not present.

Dr John Gauci, the Legal Representative for Reactilab Limited, interrupted Dr Zrinzo Azzopardi's submission to point out that the reason of exclusion was that the Appellant did not submit the leaflet and not the label. The Contracting Authority's Legal Representative continued by saying that according to the Directive, what the Appellant was submitted could not be considered as a label.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit invited the Public Contracts Review Board to study the Clause in question to see why his clients were making the argument that Reactilab Limited did not supply a label.

Dr John Gauci, the Legal Representative for Reactilab Limited said that when he asked the Witness what they did found missing in their offer with respect to the Regulations, the Witness replied that she was not in a position to reply. Therefore, there is a situation, where an allegation was made but was not supported by the Technical Person in the Evaluation Board.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit concluded that the document speaks for itself.

At this stage, the Public Hearing was adjourned to Thursday 19 October 2017 at 09:00 wherein the Public Contracts Review Board will transmit the decision taken for this Objection verbally and then distribute a hard copy of the same to all parties concerned.

This Board,

Having noted this Objection filed by Reactilab Limited (herein after referred to as the Appellant) on 14 September 2017, refers to the Contentions made by the latter with regards to the award of Tender of Reference CFT 021-6348/2017 listed as Case No 1088 in the records of the Public Contracts Review Board, awarded by the Central Procurement and Supplies Unit (herein after referred to as the Contracting Authority).

Appearing for the Appellant: Dr John Gauci

Appearing for the Contracting Authority: Dr Stefan Zrinzo Azzopardi

Whereby, the Appellant contends that:

a) **He was denied a copy of the extract of the Evaluation Report and that such request was made so that he will be made aware of the specific technical reasons why his offer was discarded;**

b) **The alleged reasons that he had submitted only a "*leaflet*" and not a "*label*" is incorrect. In this regard, the Appellant insists that he had submitted all the information necessary in accordance with Section 4, Article 2.3 of the Tender Document.**

This Board also noted the Contracting Authority's "*Letter of Reply*" dated 25 September 2017 and its verbal submissions during the Public Hearing held on 5 October 2017, in that:

a) **The Central Procurement and Supplies Unit contends that, although the "*Letter of Rejection*" did not indicate the specific technical**

reasons for why the Appellant's offer was discarded, later correspondence was transmitted to the latter specifying the technical deficiency in his offer;

b) In accordance with Section 4, Para 2.3 (iii) of the Tender Document, Reactilab Limited had to submit a "*clear and legible copy of the packaging including labelling of the product being offered*" and in this respect the Appellant failed to abide by this mandatory condition.

This same Board also noted the Testimony of the witness namely, Ms Corinne Bowman duly summoned by the Central Procurement and Supplies Unit.

This Board, after having examined the related documentation and heard submissions made by both parties to the Appeal, including the testimony of the Technical Witness, opines that the main contention of this Appeal is whether Reactilab Limited's submissions included what was requested in Section 4 Article 2.3 (iii) of the Tender Dossier, that is "*a clear and legible copy of the packaging including labelling of the product being offered*".

Further considerations taken by this Board with regards this case are the following:

1. **With regards to Reactilab Limited's First Grievance, this Board has, on numerous occasions in its deliberations, emphasized the obligation which the Contracting Authority, in this case the Central Procurement and Supplies Unit, has to render the specific reasons for rejection of an offer, as it is only through such information on which a Bidder can object.**

   Many a times, appellants appear before this Board to find out what were the reasons why their offer was being rejected, which should not be the case, as the merits of this Board is to review the procedure adopted by the Contracting Authority in its Evaluation Process and not to establish the deficiencies in the Appellants' offers.

   In this particular case, the "*Letter of Rejection*" issued by the Central Procurement and Supplies Unit on 4 September 2017 indicated that the reason why Reactilab Limited's offer was rejected was due to the fact that their offer was technically non-compliant without specifying in which technical area the offer failed.

   On the other hand, this Board was made aware of a later correspondence wherein the Appellant was informed of the

particular section of the Tender Dossier, where his offer was deficient and this was that the Appellant had failed to submit a clear and legible copy of the label of his product. In this regard, this Board opines that the details submitted by the Central Procurement and Supplies Unit through the later correspondence should have been included in the "*Letter of Rejection*" dated 4 September 2017, in the first place. In this respect, this Board upholds Reactilab Limited's First Grievance.

2. **With regards the Appellant's Second Contention, this Board would respectfully refer to Section 4, para 2.3 (iii) of the Tender Document, wherein it was stated that "*a clear and legible copy of the packaging including the labelling of the product being offered*", was requested. This Board justifiably noted that this particular condition applied to "*Medical Materials and Devices*" and in this case, the product was appropriately classified as a "*Medical Device*" and as duly declared by the Manufacturer; so that Section 4, Article 2.3 (iii) is applicable.**

   In this regard, Reactilab Limited's Contention is that it had submitted all the requested information which falls under Section 4, Para 2.3 of the Tender Document. This Board is fully aware that the packaging had to include a copy of the label of the product being

offered by the Appellant and in this respect, this same Board noted the submissions made by the latter.

This Board is aware of the "*Labelling Requirements*" when placing Medical Devices in the EU markets and as a general principle, each "*Medical Device*" must be accompanied by as much information as is necessary for the public to use it safely and adequate "*Directions for Use*" which the layman can understand and use the device safely. In this regards, details which are to be clearly denoted and included are:

a) **Quantity of dose for each use and usual quantities for persons of different ages and physical conditions;**

b) **Frequency of Administration;**

c) **Duration of Application;**

d) **Time of Administration in relation to other factors;**

e) **Route or method of Application and any preparation necessary for use.**

This Board credibly opines that the Appellant's submission does not contain the details which a label for a "*medical device*" should contain. In fact, Reactilab Limited's submission in this regard, consisted of a general information sheet about the product "*Aqueous Cream*", showing the various weights under which it is provided on the market.

In this regard, this Board also noted the Technical Witness's Testimony, confirming that the Appellant's submission, with regards to labelling, did not represent what was requested in the Tender Dossier, as a "*Packaging Product Label*", should refer to a particular dose of one weight only.

This Board justifiably opines that the Appellant's submission with regards to "*label*" did not meet the required standard. In fact, this Board credibly affirms that Reactilab Limited's submission consisted of a general information leaflet and in this regard, this Board does not uphold the Appellant's Second Contention.

In view of the above, this Board finds against Reactilab Limited, however, due to the fact that insufficient information, regarding the reasons for the

Appellant's offer rejection were given by the Central Procurement and Supplies Unit, this same Board recommends that the deposit paid for this Appeal should be refunded.

Dr Anthony Cassar Chairman	Dr Charles Cassar Member	Mr Carmel Esposito Member

24 October 2017