PUBLIC CONTRACTS REVIEW BOARD

Case No. 884

CFT 3126/2015

Framework Contract for the Supply of Povidone Iodine Non Adhering Dressings.

The Tender was published on the 6th March 2015. The closing date was on the 13th April 2015. The Estimated Value of the Tender is €85,799.25 (Exclusive of Vat).

Three (3) offers had been submitted for this Tender.

On the 21st October 2015, Cherubino Limited filed an objection against the rejection of their offer because of technical non-compliance.

The Public Contracts Review Board composed of Dr Anthony Cassar (Chairman), Dr Charles Cassar and Mr Lawrence Ancilleri as members convened a hearing on Tuesday the 5th January 2016 to discuss the objection.

Present for the hearing were:

Cherubino Limited:

Dr Matthew Paris	Legal Representative

AM Mangion Limited:

Mr Desmond Bell	Representative
Mr Ray Vella	Representative

Central Procurement and Supplies Unit:

Ms Marika Cutajar	Chairperson Evaluation Board
Mr Eman Gravina	Secretary Evaluation Board
Mr Mark Spiteri	Member Evaluation Board
Dr Stefan Zrinzo Azzopardi	Legal Representative

The Chairman made a brief introduction and asked the representatives for the Contracting Authority to state clearly the reason why the Appellant's Tender was rejected since the Letter of Rejection was far from clear.

Dr Stefan Zrinzo Azzopardi on behalf of the Contracting Authority admitted that the Letter of Rejection was not very clear. This had stated that *"Tender was not successful since according to declaration of conformity and literature the product is not considered to be in compliance with the relevant legislation."* Dr Zrinzo Azzopardi explained that after the receipt of the Appellant's Declaration of Conformity the documents had been sent to the MCCAA for verification. The result received from the MCCAA had been that the product was not compliant with the relevant legislation and that the authority could not recommend its use by the Health Departments.

Dr Matthew Paris for the Appellant agreed that at this point a representative from the MCCAA should be summoned to be heard as a witness.

Mr Michael Cassar, ID No. 142564M, representing the MCCAA under oath stated that the Contracting Authority had asked the MCCAA to examine the Declaration of Conformity submitted in connection with this Tender. The Declaration of Conformity is a declaration by the manufacturer that the product conforms to the European Directives. This had been examined by another colleague at the Authority who was his underling and which fell under his responsibility.

She had discovered several faults. The document in question appears to have been issued by Meghdoot Pharma of India and states that it conforms to Council Directive 93/42/EEC as amended, and was issued in 2012. The document however, does not state that it had been checked by a recognized body and did not specify the amendments to the legislation. It also lacks to indicate the responsible representative and contains no signature. The document also fails to quote a standard to which the product complies. Mr Cassar said that he personally confirms the assessment his colleague had made and that the product cannot be used in Malta and in Europe. The relative directive is 93/42 EEC.

Replying to questions by Dr Paris, the witness said that the directive became effective in Malta in 2005. It is the responsibility of the MCCAA to ascertain that the Declaration of Conformity and literature submitted by the Appellant were in order. From the literature received from the Contracting Authority it could be seen that the manufacturer is Pharmachem from the UK and not the Indian company which was mentioned in the Declaration of Conformity.

Whenever a product bears the CE mark it has to be accompanied by a Declaration of Conformity by the manufacturer. At this point, the witness was shown a sample package by Dr Paris and the latter confirmed that according to the package the manufacturer was Meghdoot Pharma and has the CE mark. The sample sachet however had a different address, the one of Medical UK. The sachet showed 2 addresses and it states that the product was manufactured by Meghdoot.

The Literature states that it is marketed by Medical UK but manufactured in India. The Indian firm is the subcontractor to the UK firm. The Directive requires that each medical product must have a European representative. From the Declaration of Conformity the product in question cannot be used in Malta because it does not have an authorized European

representative. Replying to questions by Dr Zrinzo Azzopardi, Mr Cassar said that the MCCAA makes its assessments on the Documents of Conformity and not on samples.

Dr Matthew Paris on behalf of the Appellant contended that the Letter of Rejection did not state any of the above. The Appellant had not understood the reasons. The Tender Document does not state that the Declaration of Conformity was mandatory. This Appellant was asked for this document through a clarification after the closing date of the Tender. This was not in order since by that time Appellant had already submitted the Tender. This was a new requirement and not part of the original Tender.

Dr Stefan Zrinzo Azzopardi for the Contracting Authority contended that the witness had explained the reason for disqualification. The clarification was only requested because the certification submitted by the Appellant was not clear and was issued only on what the Appellant had submitted. This was not an additional requirement. The Declaration of Conformity submitted was not according to regulations since it was issued by the manufacturer. The Contracting Authority had examined the document submitted as clarification and this led to the exclusion of Appellant's offer.

Dr Mathew Paris for the Appellant cited Clause 7.1 of the Tender Document which stated that rectification was not allowed. The Tender had not asked for the Declaration of Conformity but only that the product carries the CE mark. The Contracting Authority went against the Regulations when Appellant was asked to produce the Declaration of Conformity.

Dr Zrinzo Azzopardi insisted that the Appellant had agreed when signing the Tender Document that the Declaration of Conformity would be submitted if and when requested.

Mr Ray Vella on behalf of the Recommended Bidder remarked that the Declaration of Conformity is used to verify the CE mark.

At this point the hearing was closed.

This Board,

Having noted the Appellant's complains, in terms of the "*Letter of Objection*" dated 21 October 2015 and also through the Appellant's verbal submissions during the Public Hearing held on 5 January 2016, had objected to the decision taken by the Pertinent Authority, in that:

a) The Appellant Company maintains that the "*Letter of Rejection*"

dated 14 October 2015 did not state the valid and explicit reasons why the Appellant's offer was rejected. In this regard, they are also contending that the "*Declaration of Conformity*" represented an additional requirement to the original Tender conditions;

b) The Appellant contends that since, according to clause 7.1 of the Tender Document, no rectifications were allowed, the "*Declaration of Conformity*" was an additional mandatory condition which changed the requirements of the original Tender, leading to a "*Rectification*".

Having considered, the Contracting Authority's "*Letter of Reply*" dated 27 October 2015 and also their verbal submissions during the Public Hearing held on 5 January 2016, in that:

a) The Contracting Authority contends that it had requested the MCCAA to assess the "*Declaration of Conformity*" submitted by the Appellant Company. In this regard, the MCCAA confirmed that the "*Declaration of Conformity*" was not in line with the EU directive as it lacked the representative responsible in either Europe or Malta;

b) The Contracting Authority maintains that although the documents submitted by the Appellant should have a CE mark, this did not

abide by the EU directive, that is that the medical product must have a European Representative and he should be the one to issue such certificate of "*conformity*" and not the manufacturer of the product.

Reached the following conclusions:

1. **With regards to the Appellant's First Grievance, this Board, explicitly and strongly would like to emphasise Regulation 84 (i) of the "*Public Procurement Regulations*", which clearly state that:**

   "***The Communication to each Tenderer of the proposed award shall be accompanied by a summary of the relevant reasons relating to the rejection of the Tender as set out in Regulation 44 (3), and by a precise statement of the exact standstill period.*"**

   This Board justifiably notes that the "*Letter of Rejection*" dated 14 October 2015 was devoid of any particular reason as to why the Appellant's offer was discarded. In fact, this same letter mentions only that "*The Letter of Conformity and the Literature of the product was not considered to be compliant with the relevant legislation.*"

   This Board credibly points out that not only did the "*Letter of*

***Rejection*" not specify the relevant reason why the Appellant's bid was rejected but even complicated the issue by referring to a "*relevant legislation*" which was not at all specified in the same *"Letter of Rejection*".**

This Board, on numerous occasions emphasised the important issue for the Contracting Authorities to state the specific reasons as to why an offer has been rejected. In this regard, this Board upholds the Appellant's contention that the Contracting Authority failed to give the specific reasons why they have rejected the Appellant's bid.

2. **With regards to the "*Letter of Conformity*", this Board would like to point out that the purpose of the latter is to verify the CE mark of the particular product. The fact that the Contracting Authority did not mention the "*Letter of Conformity*" as a mandatory requirement does not exempt the latter from seeking clarifications of any manner to ensure that the product being offered by the Appellant is in compliance with EU Directive 93/42 EEC and this directive entails that "*Each medical product must have a European Representative*".**

This Board credibly opines that the Clarifications sought by the Evaluation Committee formed part of the Tender Conditions and it

did not, in any credible way, reflect a "*Rectification*".

In this regard, this Board justifiably noted that the reasons why clarifications are sought by the Evaluation Committee were well founded and at the same time, this same Board opines that the "*Letter of Conformity*" submitted by the Appellant Company, as certified by MCCAA was not in compliance with EU Directive 93/42 EEC.

This Board does not uphold the Appellant's contention that "*The Letter of Conformity, so requested by the Contracting Authority, was an additional requirement by the latter and that this Clarification requested did not constitute a "Rectification" to the original Tender Conditions*"

In view of the above, this Board finds against the Appellant Company and recommends that the deposit paid by the latter should not be reimbursed.

Dr Anthony Cassar Chairman	Dr Charles Cassar Member	Mr Lawrence Ancillieri Member

18 January 2016