PUBLIC CONTRACTS REVIEW BOARD

Case No. 928 – CT 2188/2015: Tender for the Supply of Diagnostic Markers for Immunophenotyping with Equipment on Loan.

The Tender was published on the 27th October 2015. The closing date is on the 15th March 2016. The estimated value of Tender is €1,500,005.

On the 18th February 2016 Cherubino Limited filed another Pre-Contractual concern in terms of Regulation 85 of the Public Contracts Procurement Regulations claiming that in spite of the Public Contracts Review Board's decision the Contracting Authority failed to abide with the Board's decision.

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 19th April 2016 to discuss the Objection.

Present for the hearing were:

Cherubino Limited:

Dr Francis Cherubino	Representative
Dr Marcello Cherubino	Representative
Ms Janet Pace	Representative
Mr Reha Tunc	Representative
Dr Adrian Delia	Legal Representative

Central Procurement and Supplies Unit:

Mr Larkin Bonnici	Representative
Ms Josette Atkins	Representative
Ms Patricia Brincat	Representative
Mr David J Camilleri	Representative
Dr Alexia Farrugia Zrinzo	Legal Representative

Department of Contracts:

Ms Mary Anne Borg	Procurement Manager
Dr Christopher Mizzi	Legal Representative
Dr Franco Agius	Legal Representative

Evolve Limited:

Mr Chris Busuttil	Representative
Mr Mark Mizzi	Representative
Dr Steven Decesare	Legal Representative

The Chairman made a brief introduction and pointed out that the Letter of Objection was filed thirty minutes after the closing date of the Tender and that the same failed to mention the reasons for such Objection.

Dr Adrian Delia contended that the law allowed Pre-Contractual Objections to be raised up to the award of the Tender. This may be through an omission of the law. He continued that when deciding a previous concern the Public Contracts Review Board had ordered the opening of the specifications of the Tender and had also explained that this was to be done through clarifications.

However instead of abiding with the Board's reasonable directives the Contracting Authority had left the restrictions and aggravated the matter. Dr Delia argued that the supposedly revised Technical Specifications, namely Section 4 Point 2 states *"any mention of Euroflow in the published Tender Documents is to be taken as: 'Euroflow or any other consortium or working group which can provide certified, clinically validated and published 8 colour Flow Cytometric protocols for Immunophenotyping of leukaemias and lymhpomas.'"*- left the position as it was before the Board's decision.

The Contracting Authority had understood perfectly why Appellant had filed a new Objection because it replied and tried to give explanations. In the Letter of Reply, the Contracting Authority had defined clinical validation. The present Objection is mainly about this clause above. Dr Delia submitted that:

a) The Appellant contends that no group in the world today carries the CE certification and the term 'certified' in the clarification could not mean the CE marking. The Contracting Authority is to state what it meant by certified;

b) Clinical validation means that the reagent panels have been tested for the diagnosis of leukaemia and lymphomas. This is not just laboratory testing. Clinical validation requires that the necessary tests have been carried out in several places, compared and tallied and so become validated. There is no supplier on the market who has this clinical validation. He contended that the wording certified and clinical validation should be removed from the Tender specifications;

c) What was published has to follow.

Dr Delia said that it is not acceptable to have wording relating to one supplier and that there are several suppliers of the items needed in this Tender including EGIL. Some operators prefer one and others prefer the others. However the wording as is in the document is restrictive while care should be taken not to eliminate bidders at the outset.

Dr Christopher Mizzi on behalf of the Department of Contracts pointed out the lack of motivation in the Letter of Objection by the Appellant. Since no reasons were brought, the Department of Contracts had done the best to pre-empt the reasons when filing the Letter of Reply. He declared that since the matter was a technical one he suggested the hearing of evidence in this regard.

Dr David J Camilleri ID No. 172M under oath testified that he was the Contracting Authority's clinical technical expert. Having been shown clarification number 6, he explained that the clarification contained 4 questions and 4 answers:

i) The first regarded the optical specifications were band ranges were explained and there were any problems. Validated 8-colour panels meant a combination of reagents to be used in an instrument that read 8 colours;

ii) The second regarded fluidics, another term for the way the machine works and the consumption of reagents. Here again there were no problems;

iii) The third item was about information technology software. Again there were no problems because the original Infinicyt had been changed to include any other software having the same characteristics. (When Dr Adrian Delia pointed out that this was not so, the witness corrected himself). Dr Camilleri explained that there was no alternative software to Infinicyt because this gave three dimensional patterns. Infinicyt is made by a company and is validated in several countries and has certain characteristics that were desired by the Contracting Authority. It has advantages in acquiring information and giving better explanations about the patients. It is superior. Infinicyt was chosen because it gave more useful results and has more advantages. Anyone can purchase this software and offer it because it is freely available;

iv) The reply to question 4 was that the offered system had to be Euroflow or any other consortium or working group which can provide certified, and clinically validated. Certified means that the consortium knows that the cocktail of reagents can be used for diagnosis and certifies that this works. It has nothing to do with CE marking. The panel of reagents can also be certified by the consortium or work group itself. Clinically validated involves the patient. Patients have to be identified reproducibly in a certain timeframe.

Normally this validation is made after say 200 cases of patients where the same results are obtained. This is very difficult to in Malta because of the relatively low number of cases. If a bidder can offer a clinically validated panel it is preferable. Certification alone is not enough. Clinical validation is obtained by extrapolation of information from a laboratory for a clinical purpose to make a diagnosis. Without clinical validation diagnosis of patients could be disastrous since the samples would have to been sent oversees for analysis. This takes time and usually results in best fit treatment and this is not acceptable. 'Published' gives weight to clinical validated and certified protocol. The laboratory at Mater Dei hospital is not ISO accredited. Euroflow is not a product but a consortium that had made clinical validation of panels and that had published. This goes beyond mere certification.

On being shown also clarification number 5, the CPSU witness continued that this clarification updated the Tender's Technical Specifications. Point one identified the fluochromes, that is, the type of antibody, clones that is the origin and the combinations of their use. Some recipes exist but not exact quantities for the fluorochromes and we need specific recipes, and this was what was explained in point 1.

Point 2 opened up by allowing any other consortium provided that it provided certified, clinically validated and published protocols. The third section provided that the equipment had to include calibration material and instrument setting protocols for the panels offered. Point 4 explained the need for quality assurance.

Replying to Dr Chris Mizzi, Dr Camilleri said that the Contracting Authority desired a plug and play system and not one that needed validation. Presently a four colour system is being

used on aging equipment that sometimes does not give results.

Replying to questions by Dr Delia witness said that anyone who is not accredited cannot certify. Certification has to be given by a body. He could not state whether Euroflow is an accredited certification body. Certification body means a scientific consortium having ISO certification that it can recommend and give guidelines.

Dr Adrian Delia for the Appellant contends that Euroflow is not certified and therefore cannot supply certifications. CE marking means certification. Only one body in Malta can issue certificates.

Dr David J Camilleri continued that none of the consortia mentioned by Dr Delia – GEIL, ALN, or Harmonia are certified. The Contracting Authority wants panels that are certified to work. He agreed that other consortia or working groups can provide these. The Tender mentioned Euroflow specifically because this stated specifically which fluorchrome to use and gave the quantities – it gave the exact recipes or formulas to use.

At this point Dr Delia for the Appellant exhibited a document that showed that each panel supplied by Euroflow had to use BD fluorochromes. This means that the conditions had reverted to the original position in that only BD products were admissible.

Dr David J Camilleri, witness stated that BD products are available to all bidders. In fact the Appellant firm had won previous Tenders offering BD products. The other workgroups, ELN, GIAL and Harmonia would in fact be excluded if they did not supply the clones. As far as he knew the others did not provide recipes.

That was the reason why Euroflow was chosen. Clinical validation meant that the tests had been made extensively on diverse patients around the world and the result was universally usable. He was certain that Euroflow supplied clinical validation, the diagnosis. Anyone can publish panels that are clinically validated. To clinically validate takes a long time and thus Euroflow was chosen. The other working groups can publish results and they could have them clinically validated.

Dr Steve Decesare on behalf of Evolve Limited contended that letters of Objection are required by law to give specific reasons. Cherubino Ltd had tried to attack the choice of Infinicyt but then this was found to be an off the shelf product. Furthermore the Letter of Objection was filed after the Tender closing time limit and the list of prices offered had been published when the Objection was filed.

Mr Reha Tunc on behalf of the Appellant, is a sales manager with Beckman Coulter and an engineer. He stated that Euroflow is a kind of working group. There are other similar groups like Harmonia that are not only tied to only one brand. There are only two companies on the market at the moment. There is no difference between Harmonia and Euroflow – they are both working groups of customers. He understood that ‘certification’ to mean that it has to bear the CE mark and he does not think that anyone has such certification. If you have certification you can work on your own without further validation.

Clinical validation means that the product could be used for any customer in all laboratories. To use Euroflow you need to get reagents just from one brand. Harmonia are trying to find solutions for the customer and not for the company and are going to publish. He disagreed with Dr Franco Agius that a company could certify its own product for use or that the list exhibited today amounts to certification.

Dr Adrian Delia for the Appellant said that his clients had publications that would be submitted with the Tender to prove equivalence. The point is that the Public Contracts Review Board had given a decision ordering the widening of the Tender specifications to allow more bidders. The Contracting Authority however insisted on Euroflow which meant that only reagents manufactured by BD could be offered.

This is not acceptable – there are enough equivalents on the market. The Appellant contested the use of the words "certified", "clinically validated" and "published" as used in the clarifications. He contended that the Public Contracts Review Board had to be consistent and re-order the widening of the Tender specifications.

Dr Chris Mizzi on behalf of the Department of Contracts said that the Contracting Authority had in fact widened up the specifications as ordered by the Public Contracts Review Board. Those bidders who can satisfy the desired conditions may Tender. However there are certain conditions that cannot be changed but are fundamental.

The Contracting Authority has the right to insist on these three basic principles of certification, validation and publishing because it has reasons for such insistence. The Contracting Authority did not close the market with the clarifications.

Dr Steven Decesare on behalf of Evolve Limited contended that although Regulation 85 was intended to protect the interests of bidders, the late submission of the Objection was prejudicial to all bidders since the financial offers have now been published.

Dr Franco Agius for the Department of Contracts said pre-contractual concerns were intended to remove any decision that could be prejudicial. This made no sense once the decision became final. The Objection had been filed after the time closed and thus the decision became final. He also said that the Contracting Authority wanted ease of mind that the product would give satisfactory results. That was the reason for asking for certification, validation and publication. Certified meant certified by the consortium and not CE marking.

At this point the hearing was closed.

This Board,

Having noted the Appellant's Pre-Contractual Concern, in terms of the "*Letter of Objection*" dated 18 February 2016 and also through their verbal submissions during the Public Hearing held on 19 April 2016, had objected to the fact that the Pertinent Authority had failed to abide with this Board's decision published on 21 January 2016.

This Board is pre-occupied by the fact that the Law and Regulations does not clearly identify the time limit by which a "*Pre-Contractual*" concern is to be submitted. At the same instance, this Board opines that although a Pre-Contractual concern indicates a "*Concern*" prior to the contractual stage, the main purpose of this remedy is to raise any concern prior to the closing date and time of the Tender Submissions.

The logical reason behind this Board's opinion is obviously to save precocious time in the process and at the same instance any concerns presented and approved will be included in the Tender Document by way of clarifications prior to the closing or extended closing time and date of the Tender. The "*Pre-Contractual Concern*" would also remove any decision that could be prejudicial.

Although the wording "*Pre-Contractual Concern*" may mean to indicate that these can be presented by any prospective Appellants up to Contractual Stage, its spirit is mainly available to any bidder so that any adjustment to the Tender Specification, if approved, can be amended through Clarifications so that there will be substantial minimisation of unnecessary appeals, once the Evaluation Board decides and publishes the Award.

The Board is also taking into consideration that if the Appellant Company is then not in agreement with the Award, the Appellant can object in the manner as prescribed in the Public Procurement Regulations.

In this regard, this Board opines that it was knowledgeable to the Appellant Company that the closing date and time of the Tender was 18 February 2016 at 10:00 i.e. 30 minutes after the closing time of the Tender.

In view of the above, this Board justifiably opines that the Objection filed by Cherubino Ltd was submitted beyond the closing time of the Tender and this same Board cannot treat this Objection any further, so that this Board recommends that the Tendering Process be continued.

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

17 May 2016