

## **PUBLIC CONTRACTS APPEALS BOARD**

### **Case No. 35**

#### **CT 2018/04 Advertisement 37/2004, GPS 70.672 T03 PT Analysis of Human Pathological Samples**

The call for offers (estimated cost of tender, Lm 464,890) covering a three-year period was published in the Government Gazette (closing date 06.04.2004) following a request received by the Contracts Department from the Government Pharmaceutical Services (GPS) on 15.01.2004.

Following analysis of seven (7) offers received, the Contracts Committee decided to 'inter alia' reject the offer submitted by Messrs E. J. Busuttil Ltd on behalf of Centro Analisi Fleming SpA on the basis that it was considered not in compliance with tender specifications and therefore could not qualify for the third stage, namely, the opening of their financial proposal.

The Public Contracts Appeals Board constituted of Mr Alfred Triganza (Chairman), Mr Anthony Pavia (Member) and Mr Edwin Muscat (Member), held a public hearing on 6 July 2005 at the Department of Contracts, Floriana, to discuss the objection lodged by Messrs E. J. Busuttil Ltd against the decision by the Contracts Committee, which albeit filed on 31.01.2005, was subsequently followed by various correspondence between interested parties, giving vent to the delay in the public hearing being formally convened.

During the public hearing, the following entities were represented as follows

#### **Centro Analisi Fleming SpA**

Dr Josette Attard – Legal Representative

#### **E. J. Busuttil Ltd**

Mr Edwin Busuttil

#### **Government Pharmaceutical Services/ Adjudication Board**

Ms Miriam Dowling - Chairperson

Dr Gerald Buhagiar – Consultant Biochemist, Board Member

Dr Christopher Barbara – Consultant Virologist, Board Member

Dr Alicja Grochowska – Consultant Haematologist, Board Member

Ms Rosette Spiteri – Department of Health

#### **Witnesses**

Ms Carmen Buttigieg – Health Procurement Section

Dott.sa Maria Grazia Marine – Centro Analisi Fleming SpA

Dott. Filippo Monteleone – CEO Centro Analisi Fleming SpA

The Chairman commenced proceedings by inviting the appellant's representatives to explain the motivation behind their objection.

Dr Josette Attard, Centro Analisi Fleming's Legal Representative, stated that the Department of Contracts had informed her clients that their tender was rejected on the basis that it was considered not in compliance with tender specifications. She claimed that from the Adjudication Board's report it clearly transpired that the tender was rejected by the Contracts Committee following the recommendations made by the Health Department relating to the Company's past performance. As a consequence, she argued that Centro Analisi Fleming should not be impeded from proceeding to the following stage, namely the opening of the third envelope stating that the Adjudication Board should consider issues solely relating to this tender and not allow itself to be influenced by other unrelated matters.

Dr Attard said that, according to their records, the whole of 2004 and in 2005, up to the month of May, Centro Analisi Fleming SpA had carried out 8,062 and 3,974 tests respectively. Furthermore, according to statistics, non delivery results amounted to 1.2% which meant that they obtained 98.8% compliance performance. On the other hand, the Health Department's officials, when specifically requested to confirm such statement, declared that they did not have any records. However, Dr Gerald Buhagiar stated that the service provided was sub-optimal and Ms Carmen Buttigieg remarked that they had encountered problems with every shipment.

While Dr Buhagiar was criticising Centro Analisi Fleming's *Vademecum*, Dr Attard drew the attention of those present that whilst being so stringent with her client's supporting literature material, yet the Adjudication Board had accepted one of the other tenderers' literature which was, ironically enough, remarked Dr Attard, submitted in the German language. Furthermore, the same Board decided to recommend that this particular tenderer proceed to the next stage of the tender evaluation.

At this stage, Dr Attard tabled a written report to rebut the Health Department's grievances mentioned in the Adjudication Board's report and the Consultants' attached statements regarding their past performance.

In her concluding remarks Dr Attard reiterated that after taking into consideration the fact that their tender was according to specifications, Centro Analisi Fleming should not be stopped from the opening of the financial package.

During their submissions, Drs G Buhagiar, C Barbara and A Grochowska recounted their experience as regards Centro Analisi Fleming SpA's performance over the last two years. All of them claimed that this tenderer was not up to the level of efficiency they required. From their testimony it transpired that the most recurring problem was the lack of communication such as misinterpretation of names, performing the wrong tests and not adhering to the turn-around time stated in the *Vademecum*.

Dr Gerald Buhagiar, Consultant Biochemist, said that the Adjudication Board judged Centro Analisi Fleming's tender on their past and present performance because they were concerned that in future they would encounter the same problems. He said that this tenderer was the most problematic when compared with the previous ones and that the Department had not received the service they had been accustomed to. Dr Buttigieg said that the *Vademecum* was not appropriately detailed as it should be. The Department had reasons to believe that samples were not all analysed at Centro

Analisi Fleming's laboratories but were forwarded to other laboratories. According to the Department's representative, the fact that many tests were not done in-house was considered as a very serious concern because by the time the samples reached the ultimate point of destination, the quality of such samples could be adversely affected thus resulting in inaccurate scientific conclusions being reached. Dr Buhagiar expressed his concern about instances where samples which carried a name of a certain patient ended up being sent back to Malta after having been analysed in foreign laboratories bearing a patient's name totally different from that it would have originally been dispatched on from Malta.

He said that the contract had originally been awarded for two years and that it was subsequently extended twice (6 months each on both occasions). Although they were not happy with this supplier Dr Buhagiar stated that they were compelled to continue using their service because of the lengthy tendering procedure to be followed, which would constitute huge difficulties in the procurement processes involved.

Dr Christopher Barbara, a Consultant Virologist, said that, once they were dealing with patients, on many occasions they required results very urgently. He said that complaints about the length of time taken for samples to be analysed and the receipt of relative results were regularly raised with *Centro Analisi Fleming* through the Procurement Section of the Health Department. There were instances when they had to send couriers to expedite delivery of results. Dr Barbara pointed out that the service provided by the previous two suppliers, namely *Bio Scientia* of Germany and *Laboratoire Marcel Merieux* of France, was excellent and they received a lot of feedback on tests performed.

Dr Barbara also remarked that when his department discussed medical issues with *Centro Analisi Fleming*, very often, they had communication problems. He said that on many an occasion, despite the fact that they even invited Dott.sa Maria Grazia Marini to deliver a lecture to improve communication between the two sides, communication remained an issue which raised a few concerns.

Dr Alicja Grochowska, a Consultant Haematologist, said that they complained about the service provided by Fleming Laboratories because this was not up to the level of standard that was expected from a foreign reference laboratory. She said that the problems encountered were related to difficulties in communication, lack of appropriately detailed *Vademecum* and diagnostic approaches. Dr Grochowska said that they had problems with the detection of *Philadelphia Chromosome*, which they requested to be performed by PCR technique since this was a very useful tool for early diagnosis. At first, samples were refused for Ph chromosome detection, even though the test was listed in *Vademecum* (Item Ref. No 210). The Department's Consultant Haematologist stated that by the time the matter was solved a lot of time had been wasted! Although it was thought that this item did not feature in the list of this tender, it was later established that it was included under Item No 158 as Genetic Philadelphia Chromosome PCR.

Dr Grochowska said that the problem relating to the Factor II DNA testing was more serious considering the possible adverse diagnostic consequences erroneously attributed to a patient following the receipt of the wrong results. For example, explained Dr Grochowska, in 2003 the Department had sent a batch of samples, randomly taken from 12 patients for the detection of Factor II and they received 12

positive results. From a scientific point of view, this was very unlikely because the percentage of mutation of this particular factor was very low. All patients had to be called to repeat tests and on this occasion the results were different, that is, not showing abnormal mutation. Undoubtedly, such anomalies tend to cast serious doubts on the reliability of such tests, emphasised Dr Grochowska.

In her testimony, Ms Carmen Buttigieg, from the Health Procurement Section, declared that the list included in the tender documentation was based on the present annual consumption and that, at the end of the list, an option was included stipulating that the supplier might be required to carry out any other *ad hoc* tests.

When she was asked by this Board to state whether the problems the Department was encountering with this tenderer were ever referred to the Department of Contracts, the reply given was in the negative.

Dott.sa Maria Grazia Marini, representing Centro Analisi Fleming, testified that with regards to the Factor II DNA problem referred to by Dr A Grochowska, it came also as a surprise to the Italian Company. As a matter of fact, they double-checked the results in another laboratory, which in turn produced the same results! At this point, Dr Grochowska intervened and insisted that in such instance the report should have never been issued.

Dott. Filippo Monteleone, Chief Executive Officer of Centro Analisi Fleming Spa. and member of the Board of Directors of *Générale de Santé*, testified that he had been occupying the post of CEO with the Company since January 2005. He informed those present that Centro Analisi Fleming has since been taken over by Générale de Santé Group giving in the process some information about the profile of this Group which was one of the largest health service providers in France and in other European countries. Dott. Monteleone claimed that Générale de Santé catered for 1.5 million patients every year, including testing.

The Italian Company's CEO stated that they were very concerned with the level of communication issues raised to date and that he would be committed to improve the relationship with Malta.

Dott. Monteleone said that they were carrying out a reorganisation exercise and investing in IT and communications. As a consequence, he placed emphasis on the fact that, considering that problems being encountered were predominantly related to communications, through such investment currently being undertaken by the Company, many issues could be resolved within a few seconds or not cropping up at all.

When Dr Filippo Monteleone was specifically asked by this Board about the Factor II DNA issue he declared that such things were unacceptable to them as much as they were to any client and, more so, the ultimate patient and that it was not permissible to issue such reports.

Following the submissions of the Health Department's Consultants, Dr Attard said that although she understood their concern, the comments passed regarding carelessness were not justified. She said that the mistakes concerning both the misinterpretation of names as well as that relating to the foreign laboratories

performing the wrong tests, were attributable to proper recognition of names because of handwriting; patients' names and codes were not clearly written and, in some cases, were totally unrecognisable. Dr Attard placed major emphasis on the fact that the documents referred to by Dott.sa Maria Grazia Marini showed that delays and mistakes were made by the laboratories as much as the local government department.

After Dr Monteleone's testimony, Dr Buhagiar declared that they were not aware that Centro Analisi Fleming had been taken over by a new company. He was of the opinion that this could only lead to an improvement of the services provided.

During the sitting the PCAB stated that it found it strongly inadmissible for anyone to be dealing with human life and, despite the fact that the supplier is regularly underperforming, sometimes in a supposedly dangerous manner, yet the pertinent competent authority decides to continue with the relationship, regardless! It was also inconceivable how, despite the disgruntlement about the level of service being provided they continued extending the contract to the detriment of patients and how no alternative measure was found, or remotely sought, to remedy the situation. This Board is of the opinion that, if a supplier is not delivering according to the agreed contract terms and conditions, the matter should be immediately referred to the Contracts Department with the latter considering, if felt necessary and based on sufficient grounds being present, to cancel the tender altogether.

This Board also remarked that, needless to say that the issue of direct orders may occasionally be a better temporary alternative.

Having considered all that was submitted and argued, the Public Contracts Appeals Board

- a. takes note of the concern expressed by Dr Grochowska in respect of Factor II DNA testing and opines that the arguments sustained by Dott.sa Marini leave very much to be desired. However, at the same time, this Board also reflects on the way Dott. Monteleone provided personal assurances regarding the non-repetition of similar anomalies happening in the future;
- b. considers the fact that statistics supplied by Appellant have identified a non delivery rate of 1.2% which, according to those present in the hearing, is normally considered to be a minimal deviation;
- c. notes the different approaches given by the Department with respect to the *Vademecum* presented by different companies taking into consideration the arguments raised in the hearing as well as the evidence given in regard;
- d. takes into consideration the testimony given by Dott. Monteleone which gave an update about Centro Analisi Fleming SpA's future following the take-over of the Company by *Générale de Sante'*, a development of which the Adjudication Board was totally unaware of and which is considered by the same Board members as a positive issue;
- e. considers the fact that the question of communication was not properly managed and that new developments as highlighted by Dott. Monteleone and the total disposition shown by the latter to ensure absolute flow of

communication amongst all interested parties are to be favourably considered;

- f. gives due importance to the fact that issues raised by the pertinent authority as to carelessness demonstrated by the Italian laboratory in question may not have all been justified following viewing of documentation during hearing which amply demonstrated that mistakes concerning the misinterpretation of names were also attributable to proper recognition of codes and so forth (as dispatched by local authorities) and this was due to handwritten notes and markings on relative documents not being recognisable. This Board observes how this is being allowed to happen when similar documentation should usually be typewritten to ensure clarity and avoid possible misinterpretation of facts;
- g. reflects on documentation viewed during the hearing and is of the opinion that delays experienced in the process are occurring due to non-observance of time frames on both sides (local client and foreign supplier)

As a consequence, the Public Contracts Appeals Board considers that the objection raised by Messrs E. J. Busuttill Ltd on behalf of Centro Analisi Fleming SpA is justified.

Hence, this Board finds in favour of Appellant.

This Board recommends that the award of this tender should now proceed with the reinstatement of Appellant's offer for further consideration.

Furthermore, the Public Contracts Appeals Board recommends that the Appellant should be reimbursed the deposit paid when filing the said objection.

**A. Triganza**  
Chairman

**A.Pavia**  
Member

**E. Muscat**  
Member

*27 July 2005*