PUBLIC CONTRACTS REVIEW BOARD

Case 1028 – CFQ 020-8611/2016 – Call for Quotations for the Supply of Anti-Haemophilia Recombinant Factor VIII Octocog Alfa

The Publication Date of the Call for Tenders was 2 August 2016 whilst the Closing Date for Call of Tenders was 30 August 2016. The Estimated Value of the Tender, (Exclusive of VAT) was € 119,615.

Four (4) Bidders have submitted offers for this Tender.

On 6 February 2017, Charles de Giorgio Ltd filed an Objection against the decision of the Central Procurement and Supplies Unit to award the Tender to Drugsales Ltd for the price of € 152,750 (Exclusive of VAT) against a deposit of € 600.

On 7 March 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 – Charles de Giorgio Ltd

Dr Mario Lapecorella	Representative
Ms Alessandra Morrone	Representative
Mr David Stellini	Representative
Dr Antoine Cremona	Legal Representative
Dr Clement Mifsud Bonnici	Legal Representative
Dr Maxine Montanaro	Legal Representative

Recommended Bidder – Drugsales Ltd

Mr Andrew Attard Montalto	Representative
Ms Giulia Attard Montalto	Representative
Mr Vlasis Liakopoulos	Representative
Dr Hionia Mavrommati	Representative
Dr Douglas Aquilina	Legal Representative

Contracting Authority – Central Procurement and Supplies Unit

Mr Tonio Farrugia	Chairperson, Evaluation Board
Ms Sharon Vella	Member, Evaluation Board
Ms Danika A Decelis	Representative
Mr Stephen Tonna	Representative
Mr Joseph Xuereb	Representative
Dr Stefan Zrinzo Azzopardi	Legal Representative

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

Dr Clement Mifsud Bonnici, one of the Legal Representatives present for Charles de Giorgio Ltd opened by submitting that this was an Appeal for Call for Quotations for the Supply of Anti-Haemophilia Recombinant Factor VIII Octocog Alfa. It was issued towards the beginning of August 2016 and had a deadline towards the end of August 2016.

The product in question treats patients who suffer from Haemophilia and they need an agent to help blood corroboration. There was also a distinction between Factor VIII molecules which were the recombinant and the plasma draft. The former do not have any biological material while the latter is completely artificial and synthetic. The reason being that there was a major issue towards the beginning of the 1990s where there was some infected supply of anti-Heamophilia medicine and therefore there was this shift towards the Recombinant Factor VIII molecules.

Dr Mifsud Bonnici continued explaining that his clients were the local agents of Novo Nordisk and their product Novo Eight. This product was refused through a Letter of Rejection issued by the Central Procurement and Supplies Unit on 30 January 2017. On the other hand, Drugsales Ltd, the local representatives of Baxter were recommended for award.

The Appellants then proceeded by making two preliminary pleas. Firstly, they were disappointed by the way the Contracting Authority had conducted the process. This was a Call for Quotations issued under Part II of the Public Procurement Regulations which had a set threshold of € 120,000. However, the Recommended Bidders exceeded this threshold by at least € 30,000 according to Charles de Giorgio Ltd who added that as a point of principle, the Tender should have never been awarded to them since it exceeded the threshold set.

With regards the second preliminary plea, Dr Clement Mifsud Bonnici added that his clients were also disappointed by the fact that from August 2016, the matter went completely dead and they had to chase the Central Procurement and Supplies Unit themselves to see what happened on 23 January 2017. The following day, the call for quotations was awarded to Drugsales Ltd on the Electronic Public Procurement System without notifying any of the Bidders about this development.

The Appellants somehow managed to get to know of this fact themselves and following this they contacted the Contracting Authority about this. It was clear that the standstill period was not respected and that Charles de Giorgio Ltd was not informed as per Regulations with the Letter of Rejection which also gave them the right to appeal. This was rectified a week later on 30 January where the process was rectified and eventually issued.

Following these preliminary pleas, Dr Clement Mifsud Bonnici, one of the Legal Representatives for Charles de Giorgio Ltd proceeded by explaining the product which his clients have submitted for this Tender. Novo Nordisk was a pharmaceutical company based in Northern Europe. It is a new player in the Maltese market which was supplying insulin with a product called Novo Rapid and it has also been active in the supply of anti-Haemophilia products as well.

The way which similar past Tenders were issued, Charles de Giorgio Ltd's products was excluded for the simple reason that it specified that plasma derived Factor VIII molecules were to be supplied and since Novo VIII was a Recombinant product, it was therefore excluded.

When the Appellants were faced with this call for quotations, they took it for granted that their product was included because it said that it was a Recombinant Factor VIII molecule. It did specify Octocog Alfa but all purchases of public health products in the world, treat both products the same and therefore they submitted their Bid because they had no doubt in their minds that they could qualify for the Tender.

Dr Clement Mifsud Bonnici pointed out that the way which the Central Procurement and Supplies Unit wrote their Reasoned Letter of Reply on 14 February 2017 was a deceitful way. He quoted Paragraph 4 of this letter which stated that,

"*According to medical experts confirm that the submission made by the Appellants that "turoctocog alfa is exactly the same as all other Factor VIII molecules available in the market (octocog" is completely unfounded.*".

Dr Mifsud Bonnici argued that the above statement was completely misquoted since his clients qualified their statement with the words "*upon activation*" in the fifth paragraph of their Letter of Objection dated 6 February 2017. This was also confirmed by the Appellant's other Legal Representative present for this Public Hearing, Dr Antoine Cremona.

Dr Clement Mifsud Bonnici continued that they had other evidence to back their statement and that they have summoned a witness who will get into more detail about this matter. He then proceeded to submit screenshots from the European Medicines Agency relating to Novo VIII, the product which Charles de Giorgio Ltd was submitting and Advate, the product which Drugsales Ltd was submitting. Dr Mifsud Bonnici illustrated that the ATC code is exactly the same for both products. This meant that both products had the same chemical, therapeutic and pharmaceutical properties.

The Appellants continued by explaining the difference between turoctocog and octocog. The word "*tur*" refers to truncated. There was a part in the molecule which was not important and which has been removed but upon activation, when there is the need of blood corroboration, they act in the same way.

In practical terms, the Administration of this product is the same for both. They come in the same units, hence no training is needed and there are no switching issues due to side effects when switching from octocog to turoctocog. All other purchasing Authorities in Europe are treated exactly the same.

Dr Anthony Cassar, the Chairman of the Public Contracts Review Board, asked whether the main issue was the same product or not. This was confirmed by one of Charles de Giorgio Ltd's representative, Dr Clement Mifsud Bonnici who added that this should not have been excluded by the Contracting Authority.

Dr Mifsud Bonnici added also that it was also very important to note that his client's product was significantly cheaper than the one submitted by Drugsales Ltd at least by € 42,000. This sustains one of the preliminary points which he had raised earlier on wherein the threshold limit for this call of quotations was € 120,000.

The Technical Specifications needed to relate to the function equivalence and shouldn't refer to added technology or something specific but they needed to refer to function equivalent criteria.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit submitted that he first wanted to reply to the first preliminary plea raised by the

Appellants with regards to the submissions which are over € 120,000. The process continued to proceed further following authorisation by the Department of Contracts notwithstanding that the offers submitted exceeded the threshold.

With regards to the way that the Bidders were informed of the Award Recommendation, Dr Zrinzo Azzopardi countered that given that the Right of Appeal was in no way affected, no Bidder was prejudiced in this aspect and thus all parties were making their submissions in respect to the Objection raised by Charles de Giorgio Ltd and therefore, there was a rectification but it did not affect the interest of no party involved.

With regards to the product itself, the Central Procurement and Supplies Unit's Legal Representative argued that the Evaluation Board has taken the advice of an expert, Mr Mark Zammit, who when explaining the products and the affects of both products, notwithstanding all the submissions which were been made, there was Literature which would be eventually submitted which show that between the product offered by Charles de Giorgio Ltd and the one requested, there were a number of differences, particularly on the effect and way that they react even in relation to particular patients.

Given that this product is used for very rare diseases and rare cases and unless it is very specific to the Technical Specifications that are requested, the product could potentially have an adverse effect on the patients which requires them. Therefore, there is a situation whereby the type of product which has been procured; its effect has to be very specific in order to ensure that the needs of the patients.

Dr Stefan Zrinzo Azzopardi said that in order for a better explanation to be made to the Public Contracts Review Board, he would like to summon Mr Mark Zammit to give his evidence and better explanation. Given that this was also a very technical matter, Dr Zrinzo Azzopardi requested to the same Public Contracts Review Board to allow any eventual experts summoned by the Appellants who were present to testify to be present and vice-versa since here the discussion was about scientific evidence. Dr Antoine Cremona, one of the Legal Representatives for Charles De Giorgio Ltd found no objection to this request.

At this point in time, Dr Roger Houben, a Director for Biopharmaceuticals for Novo Nordisk, who was brought to the Public Hearing by Charles de Giorgio Ltd, was summoned to testify under oath before the Public Contracts Review Board.

Following Dr Houben's testimony, Mr Mark Zammit, an Advanced Pharmacy Practitioner within the Department of Health holding ID Card No 425874 (M) was summoned by the Central Procurement and Supplies Unit to testify under oath before the Public Contracts Review Board.

At the end of Mr Zammit's testimony, Dr Antoine Cremona, one of the Legal Representatives present for Charles de Giorgio Ltd argued that there was something which the Central Procurement and Supplies Unit and their expert were missing. In Public Procurement, contrary to Private Procurement, one cannot buy a specific solution.

Public Procurement is all about the Government buying various solutions that can reach the goal that one wants such as patient treatment and recovery times which were objective criteria. Contrary to a private hospital, the State cannot buy the Octocog solution and completely ignore the Turoctocog. These were public funds and Public Procurement was based on technically objective functional specification.

Dr Cremona continued explaining that there are rules in the choice of a solution because whoever is buying it being a consultant, being a biochemist is not buying is through his funds. These rules relate exclusively to the functional outcome of what is being bought. One cannot buy patent technologies, one cannot even buy tools to go down one route if the other leads you to the same conclusion. That is why there is a rational decor of Public Procurement to open up, to stimulate innovation, to simulate new products, to make the Government go out of its usual channels.

The Appellants continued by saying that both their product and the Recommended Bidder's product are top notch solutions. There is absolute no scientific proof, contrary to what was being alleged by Drugsales Ltd, regarding the truncated part, that had the molecule not been truncated, the full molecule is in any way superior to the truncated one. This is not scientifically correct.

Dr Antoine Cremona submitted also that there was a question of legality since this was an under € 120,000 bid which was being granted to someone who was being in excess of € 150,000 and this cannot happen. There are rules which have to be followed.

Dr Stefan Zrinzo Azzopardi, the Legal Representative for the Central Procurement and Supplies Unit replied that from the Technical Explanation that has been granted one can clearly understand the reason why the product presented by the Appellant was not considered to be technically compliant.

The Contracting Authority's Technical Witness explained the reasons why this happened. There was a technical evaluation which was correct and therefore, in view of the circumstances and based on what was also requested, even by the way that the Tender was drafted, that there was a request for an Octocog. It is clearly indicating, what did the Contracting Authority was requesting.

Furthermore, the conclusion to request and to procure the Technically Compliant Active Substance leads to the fact that the Central Procurement and Supplies Unit was correct in its adjudication given all the circumstances as explained by Mr Zammit.

Dr Stefan Zrinzo Azzopardi concluded that the fact that there was an authorisation from the Department of Contracts, there was nothing which can stop the procedure to be awared

At this stage, the Public Hearing was adjourned to Tuesday 14 March 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 Charles de Giorgio Ltd (herein after referred to as the Appellant) on 6 February 2017, refers to the Contentions made by the latter with regards to the award of Tender of Reference CFQ

020-8611/16 listed as Case No 1028 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 Antoine Cremona

Dr Clement Mifsud Bonnici

Appearing for the Contracting Authority: Dr Stefan Zrinzo Azzopardi

Charles de Giorgio Ltd made two preliminary pleas, in that:

i) **The Call for Quotations had a set threshold of € 120,000 and the offer of Drugsales Ltd exceeded this threshold by € 30,000; yet still, the Central Procurement and Supplies Unit awarded the Tender at a much higher price the stipulated threshold;**

ii) **The procedure adopted by the Contracting Authority did not respect the standstill period, in that, from August 2016 and 23 January 2017, no communication was forthcoming from the Contracting Authority and it was only on the initiative of the Appellants that the procedures were rectified and eventually issued.**

This Board would like to treat the above preliminary pleas as follows:

1. **It is a common occurrence that when the second cheapest yet fully compliant offer exceeds the set threshold, the Contracting Authority seeks authorisation to proceed with the award of the offer being recommended.**

   In this particular case, this Board, after examining the relevant documentation, justifiably confirms that the request to proceed was properly conducted and approved.

   In this regard, this Board does not consider the plea to be detrimental to the award procedure adopted by the Evaluation Board.

2. **With regards to Charles de Giorgio's second preliminary plea, this Board opines that although there was a rectification, the latter did not prejudice the right of Appeal of the Appellants.**

   In this regard, this Board opines that, again, this plea should not affect the procedure to treat the merits of this Appeal.

This Board would like now to consider the merits of this case whereby, it is being contested that:

a) **Charles de Giorgio Ltd firmly maintains that his product was exactly the same as that requested in the Tender Document. The product has the same application and gives the same end result. In this regard, the Appellant contends that "*upon activation*" the end result is what the Tender requested, apart from the fact that their product is cheaper and within the set threshold of € 120,000.**

   In this regard, the Appellant contends that his product should not have been excluded since it has the requested chemical, therapeutic and pharmaceutical properties.

b) **Charles de Giorgio Ltd contends that the Tender Document requested a "*specific solution*" which is not acceptable in Public Procurement. In this regard, the Central Procurement and Supplies Unit have requested a solution which would render the desired end result without being specifically earmarked for a particular product.**

This Board also noted the Contracting Authority's "*Letter of Reply*" dated 14 February 2017 and its verbal submissions during the Public Hearing held on 7 March 2017, in that:

a) **The Central Procurement and Supplies Unit maintains that there were differences between the product offered by Charles de Giorgio Ltd and the one offered by Drugsales Ltd, particularly on the effect and way that they react in relation to one particular patient.**

This product is used on very rare cases of disease and the Technical Specifications of the product must conform exactly to the requested Technical Specifications as dictated in the Tender Document, the latter of which was prepared on the advice of medical experts in the field.

This same Board also noted the Testimonies of the witness namely:

a) **Dr Roger Houben duly summoned by Drugsales Ltd;**

b) **Mr Mark Zammit duly summoned by the Central Procurement and Supplies Unit**

This Board has also taken note of the documents submitted by Charles de Giorgio Ltd which consisted of:

a) **A Document relating to the full length sequence of the Factor VIII;**

b) The Article "*Turoctocog Alfa (Novo Eight) – From Design to Clinical Proof of Concept*" by Mirella Ezban, Knud Vad and Marianne Kjalke;

c) The Article "*Interim Results from a Large Multinational Extension Trial (Guardian 2) using Turoctocog Alfa For Prophylaxis and Treatment of Bleeding in Patients With Severe Haemophilia A*" by S.R. Lentz, M. Cerqueira, D. Janic, C. Kempton, I. Matytsina, M. Misgav, J. Oldenburg, M. Ozelo, M. Recht, A. Rosholm, A. Savic, T. Suzuki, A. Tiede and E. Santagostino;

d) The Document *"Bioequivalence Between Two Serum-Free Recombinant Factor VIII Preparations (N8 and Advate) – An Open-Label Sequential Dosing Pharmacokinetic Study in Patients With Severe Haemophilia A"* by U. Martinowitz, J. Bjerre, B. Brand, R. Klamroth, M. Misgav, M. Morfini, E. Santagostino, A. Tiede and D. Viuff;

e) The Document *"Purification and Characterization of a New Recombinant Factor VIII (N8)"* by I. Thim, B. Vandahl, J. Karlsson, N.K. Klausen, J. Pedersen, T.N. Krogh, M. Kjalke, J.M. Petersen, L.B. Johnsen, G. Bolt, P.L. Norby and T.D. Steenstrup;

This Board, after having treated the merits of this case, arrived at the following conclusions:

1. **All interested parties agreed that since this Appeal relates to a highly specific medical product, the Testimonies of both Technical Witnesses plays a most important role in arriving at the Decisions of this Board;**

2. **With regards to Charles de Giorgio Ltd's First Contention, this Board, after hearing the Testimonies of both witnesses, opines that the product of both the Appellant and that of the Recommended Bidder give the same end result.**

   However, according to the explanation given by witness Mr Mark Zammit, this medical product is intended for a very specific patient who is burdened with inhibitors so that the patient's reaction to the initial molecule may be different.

   The product is to be applied on a patient who has been sent abroad and who was diagnosed with lots of inhibitors, hence the patient needing to be stabilised on one molecule which is the Octocog Alfa, the un-truncated molecule.

The Technical witnesses explained in detail the main difference in the products being offered by both Charles de Giorgio Ltd and Drugsales Ltd, in that, although both offers render the same end-result, the product of the latter, which is Octocog Alfa, contains one complete molecule which is referred to as the "*Big Molecule*" and which is the sort of substance that this particular patient requires, due to his condition.

This Board justifiably noted the fact that it was established and agreed that the molecule Turoctocog Alfa is of a different type than that of Octocog, the latter of which is more suited for this type of rare medical condition.

This Board also notes that the Tender Document requested "*Anti-Haemophilia Recombinant Factor VIII Octocog Alfa*", so that the molecular feature of the product was specified. On the other hand, this Board, was informed through the testimony of witnesses, that the Appellant's product is not as per published specifications, it is not Octocog and this difference is not suitable for this patient. In other words, on activation of the molecule, the patient's reaction to other types of molecule may be different.

In this regard, this Board is credibly convinced that for the patient's benefit and good health, the only molecule which is safer, on activation, is the Octocog Alfa. This Board notes that Charles de Giorgio Ltd's offer was discarded for a credible medical reason which justifies the choice of award of this Tender to Drugsales Ltd who, in turn, offered what was required by the Central Procurement and Supplies Unit.

This Board acknowledges the fact that the Appellant's product renders the same function, however, this same Board had to consider the fact that this particular patient required a specific Treatment, due to his condition and which this Board cannot but agree and accede to this Procurement.

The medical condition of the patient on which the substance is to be applied credibly necessitates the application of Factor VIII Octocog Alfa, the Big Molecule.

In this regard, this Board justifiably notes that Drugsales Ltd's offer complied with the Technical Specifications of the Tender and this Board maintains that in this particular case, enough evidence was presented to substantiate the fact that this particular patient required this type of substance i.e. Octocog Alfa.

3. **With regards to Charles de Giorgio Ltd's Second Grievance, this Board would like to justifiably point out that, certain procurements, especially in the medical field do tend to dictate Technical Specifications which perhaps tend to advantage a particular supplier. However, in medical procurement, one has to also consider the application of the same and which type of medicine is most suited for the medical state of the patient in question.**

   In this particular case, the patient for whom the product is requested has been diagnosed to suffer from inhibitors and it has been credibly proved that the most suitable and safest medicine for the patient is that with the molecule Octocog Alfa.

   In this regard, this Board, in arriving at its adjudication, has placed the greatest emphasis on the patient's well being, after hearing credible evidence of the importance of this specific type of medicine required.

In view of the above, this Board opines that although Charles de Giorgio Ltd's offer does render the same end treatment, in this particular case and in these particular circumstances, taking into account the medical condition of the patient, upholds the decision of the Central Procurement

and Supplies Unit to award the Tender to Drugsales Ltd. However, it recommends that the deposit paid by Charles de Giorgio Ltd is to be fully reimbursed.

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

14 March 2017