

PUBLIC CONTRACTS REVIEW BOARD

Case No. 382

GHPS/569/2011

Tender for the Supply of Docetaxel 20 mg and 80 mg

This call for tenders was published in the Government Gazette on the 3rd June 2011. The closing date for this call with an estimated budget of € 119,988.53 was the 20th June 2011.

Four (4) tenderers submitted their offers.

Charles de Giorgio Ltd filed an objection on 24th October 2011 against the decisions of the Government Health Procurement Services (GHPS) to disqualify its offer as technically non-compliant and to recommend the award of the tender to Accord Healthcare Ltd.

The Public Contracts Review Board composed of Mr Alfred Triganza as Chairman, Mr. Carmel Esposito and Mr Joseph Croker as members convened a public hearing on Monday, 20th February 2012 to discuss this objection.

Charles de Giorgio Ltd

Dr Antoine Cremona	Legal Representatives
Mrs Margot Pisani	Representative
Mr Ivan Laferla	Representative

Accord Healthcare Ltd

Dr Norman Vella	Representative
Mr Samrat Kamdar	Representative

Government Health Procurement Services

Ms Stephanie Abela	Procurement Manager
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Evaluation Board

Ms Miriam Dowling	Chairperson
Ms Allison Brincat	Member
Ms Miriam Azzopardi	Member

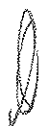


After the Chairman's brief introduction, the appelland company was invited to explain the motives of his company's objection.

Dr Antoine Cremona, legal representative of Charles de Giorgio, the appelland company, made the following submissions:-

- i. by letter dated 18th October 2011, the contracting authority had informed his client that his company's offer was not successful "*since products offered are not compliant with published specifications since even though overall concentration of vial is 20mg & 80mg respectively, the specifications call for 40mg/ml in 0.5 vials (20mg dose) and 40mg/ml in 2ml vials (80mg dose). Agent is offering 20mg/ml.*"
 - ii. despite the fact that his client, the present supplier of this product, was offering the originator drug and the recommended tenderer was offering the generic drug, yet, strangely enough, the latter was about €30,000 more expensive than that offered by his client;
 - iii. notwithstanding the reason for rejection, the product offered by his client presented no functional difference when compared to the published specifications;
 - iv. 'docetaxel' was administered diluted to patients with breast cancer in an infusion bag;
 - v. half way through the current contract (September 2010), the supplier of this product, his client, had informed the Government Health Procurement Services that it was no longer possible to provide the 2 vial preparation, namely 20mg in 0.5ml vial and the 80mg in 2ml vial, but instead the company was going to supply a new preparation of 1 vial and the Government Health Procurement Services had accepted the new preparation and, in practice, this proved to be more convenient;
 - vi. the product that his client was offering in this tender was the one presently being supplied to the health authorities, namely the 1 vial preparation;
 - vii. EU directives dictated that tender conditions and specifications had to have functional requirements and, as a consequence, in this case, since his client's offer contained the same doses, 20mg and 80mg, and it was likewise administered diluted to the patient by drip, it could not be rejected;
 - viii. referred to European Court of Justice cases which upheld that procuring entities cannot exclude products that meet their exact functional requirements;
- and
- ix. as a result, his client's offer should not have been excluded on technical non-compliance and, all the more, when the price was much cheaper.

Ms Margot Pisani, also representing the appelland company, explained that, under the current contract, Charles de Giorgio had supplied the initial two orders with the 2 vial



preparation and the subsequent seven deliveries with the 1 vial preparation. She further explained that, if anything, the one vial preparation was more convenient – it did not involve pre-mix, less needle contact and it saved time - and dilution was more accurate since there was no foaming.

Ms Stephanie Abela, procurement manager representing the Government Health Procurement Services, made the following remarks:-

- i. the adjudicating board evaluated the offers received in response to this call for tenders according to the published conditions and specifications which read as follows:-

Docetaxel 20 mg injections: Docetaxel 40mg/ml powder for reconstruction or solution for injection in 0.5ml vials, for IV use;

and

Docetaxel 80 mg injections: Docetaxel 40mg/ml powder for reconstruction or solution for injection in 2ml vials, for IV use;

NB It is of utmost importance that both the 20mg and 80mg preparations are of the same brand.


- ii. according to those specifications the appellant company's offer was found to be technically non-compliant as stated in letter dated 18th October 2011;
 - iii. admittedly, from the practical point of view, the product offered by the appellant company did meet the actual requirements of the Government Health Procurement Services;
- and
- iv. what happened was that the specifications of the tender document under review had not been updated to take into account the developments that had taken place in the supply of this medicine such that it was issued with the specifications that featured in the previous calls for tenders, but, nevertheless, the tender specifications have since been updated.

Dr Cremona called upon the Public Contracts Review Board to reintegrate his client's offer in the tendering process for further evaluation, including the aspect of price.

At this point the hearing was brought to a close.


This Board,

- having noted that the appellants, in terms of their 'reasoned letter of objection' dated 24th October 2011 and also through their verbal submissions presented during the hearing held on 20th February 2012, had objected to the decision taken by the pertinent authorities;



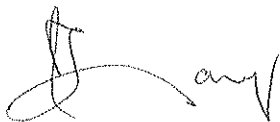
- having noted all of the appellant company's representatives' claims and observations, particularly, the references made to the fact that (a) by letter dated 18th October 2011, the contracting authority had informed the appellant company that its offer was not successful "*since products offered are not compliant with published specifications since even though overall concentration of vial is 20mg & 80mg respectively, the specifications call for 40mg/ml in 0.5 vials (20mg dose) and 40mg/ml in 2ml vials (80mg dose). Agent is offering 20mg/ml*", (b) albeit the present supplier of this product, was offering the originator drug and the recommended tenderer was offering the generic drug, yet, strangely enough, the latter was about €30,000 more expensive than that offered by his client, (c) notwithstanding the reason for rejection, the product offered by the appellant company presented no functional difference when compared to the published specifications, (d) 'docetaxel' was administered diluted to patients with breast cancer in an infusion bag, (e) half way through the current contract (September 2010), the supplier of this product, the appellant company, had informed the Government Health Procurement Services that it was no longer possible to provide the 2 vial preparation, namely 20mg in 0.5ml vial and the 80mg in 2ml vial, but instead the company was going to supply a new preparation of 1 vial and the Government Health Procurement Services had accepted the new preparation and, in practice, this proved to be more convenient, (f) the product that the appellant company was offering in this tender was the one presently being supplied to the health authorities, namely the 1 vial preparation, (g) EU directives dictated that tender conditions and specifications had to have functional requirements and, as a consequence, in this case, since the appellant company's offer contained the same doses, 20mg and 80mg, and it was likewise administered diluted to the patient by drip, it could not be rejected, (h) various European Court of Justice cases have, to date, upheld that procuring entities cannot exclude products that meet their exact functional requirements, (i) the appellant company's offer should not have been excluded on technical non-compliance and, all the more, when the price was much cheaper, (j) under the current contract, Charles de Giorgio had supplied the initial two orders with the 2 vial preparation and the subsequent seven deliveries with the 1 vial preparation and that, if anything, the one vial preparation was more convenient – it did not involve pre-mix, less needle contact and it saved time - and dilution was more accurate since there was no foaming and (k) the Public Contracts Review Board should reintegrate the appellant company's offer in the tendering process for further evaluation, including the aspect of price;
- having considered the contracting authority's representative's reference to the fact that (a) the adjudicating board evaluated the offers received in response to this call for tenders according to the published conditions and specifications, (b) according to those specifications the appellant company's offer was found to be technically non-compliant as stated in letter dated 18th October 2011, (c) admittedly, from the practical point of view, the product offered by the appellant company did meet the actual requirements of the Government Health Procurement Services and (d) what happened was that the specifications of the tender document under review had not been updated to take into account the developments that had taken place in the supply of this medicine such that it was issued with the specifications that featured in the previous calls for tenders, but, nevertheless, the tender specifications have since been updated,

reached the following conclusions, namely:

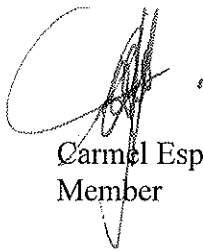




1. The Public Contracts Review Board agrees with the argument raised by the appellant company wherein the latter claimed that, notwithstanding the reason for rejection, the product it offered presented no functional difference when compared to the published specifications especially since the appellant company's offer contained the same doses, namely, 20mg and 80mg respectively, and it was likewise administered diluted to the patient by drip. Furthermore, this Board takes additional comfort by the statement made by the contracting authority's representatives wherein, during the hearing, these stated that, from the practical point of view, the product offered by the appellant company did meet the actual requirements of the Government Health Procurement Services.
2. The Public Contracts Review Board argues that, considering that the product that the appellant company was offering in this tender was the one presently being supplied to the health authorities, the 1 vial preparation was, *sui generis*, a proof of the validity of the product's functionality. This line of thought is corroborated by the fact that during the hearing it was revealed that what happened was that the specifications of the tender document under review had not been updated to take into account the developments that had taken place in the supply of this medicine such that it was issued with the specifications that featured in the previous calls for tenders. This Board has taken full cognizance of the fact that during the hearing the same contracting authority's representatives informed those present that the tender specifications have since been updated.

In view of the above, this Board finds in favour of the appellant company and recommends that (a) the appellant company's offer should be reintegrated in the evaluation process and that (b) the deposit paid by the latter should be reimbursed.



Alfred R Triganza
Chairman



Carmel Esposito
Member



Joseph Croker
Member

5 March 2012