

PUBLIC CONTRACTS REVIEW BOARD

Case No. 515

CPSU/CPU/2061/12

Tender for the Supply of High Protein Powder

This call for tenders was published in the Government Gazette on the 3rd February 2012. The closing date for this call with an estimated budget of €31,350 was the 5th March 2012.

Four (4) tenderers submitted their offers.

A.T.G. Company Ltd filed an objection on the 25th October 2012 against the decision of the Ministry for Health, the Elderly and Community Care to disqualify its offer as non-compliant because the sample submitted upon request was not gluten free.

The Public Contracts Review Board composed of Mr Alfred Triganza as Chairman, Mr Joseph Croker and Mr Carmel Esposito as members convened a public hearing on Wednesday, 16th January 2013 to discuss this objection.

Present for the hearing were:

A.T.C. Company Ltd

Mr Oliver Attard	Managing Director
Mr Andrew Corrieri	Chemist/food handler
Mr Hans Wolfe	Representative

Cherubino Ltd

Dr Francis Cherubino	Representative
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Central Procurement and Supplies Unit – Ministry for Health, the Elderly and Community Care

Mr David Baldachino	Representative
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Evaluation Board

Ms S Zerafa	Pharmacy Technician/Member
Dr M Caruana	Dietician/Member
Mr M Spiteri	Pharmacist/Member
Ms B. Briscoe	Secretary

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

Mr Oliver Attard, representing ATG Ltd, the appellant company, made the following submissions:

- i. by email/letter dated 18th October 2012 the appellant company was informed that its offer was not successful since, according to the sample submitted on request, the item in question was not gluten free;
- ii. the information displayed on the packet containing the product offered was in line with EU directives;
- iii. the proposed product was gluten free and, in any case, if the contracting authority had any doubt in this regard it could have asked the firm for a clarification/confirmation as to whether the product was gluten free.

Mr David Baldacchino, representing the contracting authority, submitted that:-

- a. the sample of the product submitted had printed on its package: *Produced in a factory that handles products containing milk, egg, soy and gluten*;
- b. the product could well have been contaminated with gluten once it was not manufactured in a gluten free environment;
- c. gluten free products usually carried a label clearly stating that the product was gluten free;
- d. in this case it was evident that the manufacturer printed this warning so as not to shoulder any responsibility in case the product would be contaminated with gluten;
- e. the tender specifications stated that the product had to be '*high protein powder for the dietary management of patients with proteinaemia as a protein supplement for those unable to meet their protein requirements from normal food and drink or for patients with increased protein requirements, e.g. burns, wound healing etc*';

and

- f. the proposed product also carried a label which stated that '*this product is not intended to diagnose, treat, cure or prevent any disease or illness.*'

Mr Andrew Corrieri, a pharmacist, representing the appellant company, submitted that:-

- i. the proposed product was not a medicinal product and that explained why it was labelled that it did not provide cure to disease and so forth - in fact this was a food product and, by legislation, it had to have that information;

- ii. the European Food Labelling Directive provided no requirement to indicate that the product was gluten free in respect of 14 or so allergies;
- iii. the tender requested high protein powder and it specified that it had to be gluten free and, as a consequence, the product offered was 'whey protein' which naturally was gluten free and over 90% pure and there was no chance that it contained gluten;
- iv. gluten was a product from plants, like wheat and barley, and to be gluten free a product had to have less than 20 parts per million.

Dr Mario Caruana, a dietician and a member of the evaluation board, stated that:-

- a. the product requested in the tender represented food for special medical purposes;
- b. the fact that the product offered displayed the warning which read '*Produced in a factory that handles products containing milk, egg, soy and gluten*' meant that the product was manufactured in an environment that was exposed to gluten and, therefore, the manufacturer could not guarantee that the product was gluten free;
- c. the contracting authority had to be sure that the product was gluten free so that it could safely give to celiac patients and other patients requiring this high protein powder;
- d. for persons with celiac disease the maximum safe level of gluten in a finished product was as little as 20 parts per million, namely it only took a very small amount of gluten to contaminate the product;
- e. there would have been no problem with the product offered by the appellant company had it not been for the label which clearly stated that the product was manufactured in an environment that contained gluten and could, as a result, be contaminated;

and

- f. although after testing the product it could be found gluten free, still, as presented, that product could not be said to be gluten free as requested in the tender document;

At this point Mr Corrieri intervened and:

- a. reiterated that 'whey protein' did not contain gluten;
- b. stated that if a product contained wheat protein then it would be treated to have the gluten removed and it would still need to have both the statement that it was manufactured in a factory that handled gluten and also the label that it was gluten free;

and

- c. expressed the view that if the contracting authority had any doubt as to whether the product offered was gluten free or not, then it should have asked for a clarification from the tenderer.

The Chairman Public Contracts Review Board remarked that in this case the label was quite clear and left no room for any diverging interpretations. He asked whether the same factory could produce products with gluten and gluten free.

Mr Attard stated that it was difficult for a factory to limit its production exclusively to gluten free products and what happened was that when shifting production from gluten products to gluten free products the factory had to follow an established procedure to clean up the place from gluten and still, in that case, although the product would be gluten free it had to bear the label stating that it was manufactured in a factory that handled gluten. Mr Attard remarked that every batch delivered would be accompanied by an appropriate certificate of analysis that it was gluten free.

The Chairman Public Contracts Review Board opined that the label represented a commercial disclaimer and that the end user was guided by the instructions that featured on the pack and not by the information that might be available on websites or in departmental files.

Dr Caruana remarked that legislation had been introduced precisely to protect patients who suffer from certain allergies, including celiac patients, because, in the past, no indications were displayed on products with regard to gluten content to the detriment of these patients. He added that the label on this product made it clear that the manufacturer could not guarantee that the product was gluten free and that rendered the product unsafe for use and hospital staff would decline to prescribe and hand out such a product to patients. Dr Caruana stated that the product offered was not indicated as food for special medical purposes.

Dr Francis Cherubino, representing the recommended tenderer, submitted that:-

- a. that label was displayed on the product precisely because it could have been contaminated by gluten because other products, like the one offered by the recommended firm, which were manufactured in a sterilised environment, did not have to bear that label since it would be 100% free of gluten so much so that the container displayed the wording 'gluten free';
- b. the product offered by the recommended firm was termed as food for medical purposes and gluten free;
- c. it was questionable how the appellant company's product could have satisfied the tender requirement as per LN 209 of 2001 that it had to be certified a dietary food for specific medical purposes;

and

- d. if the product was totally gluten free then, according to legislation, there was no need for any disclaimer as that appearing on and applicable to the appellant's product.

Mr Hans Wolfe, also representing the appellant company, submitted that:-

- i. the certification mentioned by the recommended bidder applied to special medicinal foods;
 - ii. the tender requested a high protein powder and not a special medicinal food and the product offered did meet the tender requirements in that regard;
 - iii. the product offered was a general consumer product and that was why it displayed those statements by way of disclaimers;
 - iv. although the product offered was a general consumer product, in the tender document it was clearly stated that each and every batch delivered would be accompanied with a certificate of analysis which would clearly demonstrate that the supply was gluten free and that would satisfy the gluten free requirement at clause 1 of Volume 3;
- and
- v. albeit legislation was very strict on manufacturers to display information in the case of general consumer products, yet dedicated supplies such as in this one could be issued with a specific certificate attesting that the product was gluten free.

The Chairman Public Contracts Review Board observed that it could be that the contracting authority might be covered contractually with the required paperwork that the product was gluten free but the fact remained that pharmacists and nurses who would be distributing this product, as well as the users themselves, would only have the instructions on the package to go by and that label did not state that it contained gluten but, on the other hand, it did not provide the peace of mind that the product was gluten free.

Mr Corrieri contended that clause 1 of Volume 3 stated that this protein powder was meant to supplement protein requirements from normal food and drink and that did not render the item a medicinal product.

Dr Caruana maintained that this product was required for dietary management of patients and so it was legally termed as food for special medical purposes. Dr Caruana added that the product offered was marketed as a 'sports nutrition product' and not as food for special medical purposes and the evaluation board adjudicated on the sample provided which represented the product that would eventually be supplied and which had to be consumer friendly.

Mr Mark Spiteri, a member of the evaluation board, explained that, whilst non medicinal products represented products which were not pharmaceuticals/drugs, yet there were food preparations which were meant to treat medical conditions.

Mr Wolfe pointed out that the tender did not request a product for the treatment of medical conditions but what it requested was a high protein powder for dietary management of patients and the product offered satisfied that purpose. He maintained that the appellant company's product was equivalent to that of the recommended tenderer and up to tender specifications but at a better price and if the contracting authority wanted something different then it should have reflected those requirements in the tender specifications.

Dr Caruana concluded that the case hinged on the fact that the contracting authority requested a gluten free product whereas the product offered by the appellant company, evidently, did not provide the comfort that it was gluten free. He added that the fact was that a food for special medical purposes would have the indication that it was 'gluten free' whereas a general consumer product, like the one offered, would display a disclaimer.

At this point the hearing came to a close.

This Board,

- having noted that the appellant company, in terms of its 'reasoned letter of objection' dated 25th October 2012 and also through its representatives verbal submissions presented during the hearing held on the 16th January 2013, had objected to the decision taken by the pertinent authorities;
- having noted all of the appellant company's representative's claims and observations, particularly, the references made to the fact that (a) by email/letter dated 18th October 2012 the appellant company was informed that its offer was not successful since, according to the sample submitted on request, the item in question was not gluten free, (b) the information displayed on the packet containing the product offered was in line with EU directives, (c) the proposed product was gluten free and, in any case, if the contracting authority had any doubt in this regard it could have asked the firm for a clarification / confirmation as to whether the product was gluten free, (d) the proposed product was not a medicinal product and that explained why it was labelled that it did not provide cure to disease and so forth - in fact this was a food product and, by legislation, it had to have that information, (e) the European Food Labelling Directive provided no requirement to indicate that the product was gluten free in respect of 14 or so allergies, (f) the tender requested high protein powder and it specified that it had to be gluten free and, as a consequence, the product offered was 'whey protein' which naturally was gluten free and over 90% pure and there was no chance that it contained gluten, (g) gluten was a product from plants, like wheat and barley, and to be gluten free a product had to have less than 20 parts per million, (h) 'whey protein' did not contain gluten, (i) stated that if a product contained wheat protein then it would be treated to have the gluten removed and it would still need to have both the statement that it was manufactured in a factory that handled gluten and also the label that it was gluten free, (j) expressed the view that if the contracting authority had any doubt as to whether the product offered was gluten free or not, then it should have asked for a clarification from the tenderer, (k) it was difficult for a factory to limit its production exclusively to gluten free products and what

happened was that when shifting production from gluten products to gluten free products the factory had to follow an established procedure to clean up the place from gluten and still, in that case, although the product would be gluten free it had to bear the label stating that it was manufactured in a factory that handled gluten, (l) remarked that every batch delivered would be accompanied by an appropriate certificate of analysis that it was gluten free, (m) the certification mentioned by the recommended bidder applied to special medicinal foods, (n) the tender requested a high protein powder and not a special medicinal food and the product offered did meet the tender requirements in that regard, (o) the product offered was a general consumer product and that was why it displayed those statements by way of disclaimers, (p) although the product offered was a general consumer product, in the tender document it was clearly stated that each and every batch delivered would be accompanied with a certificate of analysis which would clearly demonstrate that the supply was gluten free and that would satisfy the gluten free requirement at clause 1 of Volume 3, (q) albeit legislation was very strict on manufacturers to display information in the case of general consumer products, yet dedicated supplies such as in this one could be issued with a specific certificate attesting that the product was gluten free, (r) contended that clause 1 of Volume 3 stated that this protein powder was meant to supplement protein requirements from normal food and drink and that did not render the item a medicinal product, (s) the tender did not request a product for the treatment of medical conditions but what it requested was a high protein powder for dietary management of patients and the product offered satisfied that purpose and (t) the appellant company's product was equivalent to that of the recommended tenderer and up to tender specifications but at a better price and if the contracting authority wanted something different then it should have reflected those requirements in the tender specifications;

- having considered the contracting authority's reference to the fact that (a) the sample of the product submitted had printed on its package: *Produced in a factory that handles products containing milk, egg, soy and gluten*, (b) the product could well have been contaminated with gluten once it was not manufactured in a gluten free environment, (c) gluten free products usually carried a label clearly stating that the product was gluten free, (d) in this case it was evident that the manufacturer printed this warning so as not to shoulder any responsibility in case the product would be contaminated with gluten, (e) the tender specifications stated that the product had to be '*high protein powder for the dietary management of patients with proteinaemia as a protein supplement for those unable to meet their protein requirements from normal food and drink or for patients with increased protein requirements, e.g. burns, wound healing etc*', (f) the proposed product also carried a label which stated that '*this product is not intended to diagnose, treat, cure or prevent any disease or illness.*', (g) the product requested in the tender represented food for special medical purposes, (h) the fact that the product offered displayed the warning which read '*Produced in a factory that handles products containing milk, egg, soy and gluten*' meant that the product was manufactured in an environment that was exposed to gluten and, therefore, the manufacturer could not guarantee that the product was gluten free, (i) the contracting authority had to be sure that the product was gluten free so that it could safely give to celiac patients and other patients requiring this high protein powder, (j) for persons with celiac disease the maximum safe level of gluten in a finished product was as little

as 20 parts per million, namely it only took a very small amount of gluten to contaminate the product, (k) there would have been no problem with the product offered by the appellant company had it not been for the label which clearly stated that the product was manufactured in an environment that contained gluten and could, as a result, be contaminated, (l) although after testing the product it could be found gluten free, still, as presented, that product could not be said to be gluten free as requested in the tender document, (m) that legislation had been introduced precisely to protect patients who suffer from certain allergies, including celiac patients, because, in the past, no indications were displayed on products with regard to gluten content to the detriment of these patients, (n) the label on this product made it clear that the manufacturer could not guarantee that the product was gluten free and that rendered the product unsafe for use and hospital staff would decline to prescribe and hand out such a product to patients, (o) the product offered was not indicated as food for special medical purposes, (p) this product was required for dietary management of patients and so it was legally termed as food for special medical purposes, (q) the product offered was marketed as a 'sports nutrition product' and not as food for special medical purposes and the evaluation board adjudicated on the sample provided which represented the product that would eventually be supplied and which had to be consumer friendly, (r) whilst non medicinal products represented products which were not pharmaceuticals/drugs, yet there were food preparations which were meant to treat medical conditions, (s) the case hinged on the fact that the contracting authority requested a gluten free product whereas the product offered by the appellant company, evidently, did not provide the comfort that it was gluten free and (t) the fact was that a food for special medical purposes would have the indication that it was 'gluten free' whereas a general consumer product, like the one offered, would display a disclaimer;

- having also considered the recommended tenderer's representative's reference to the fact that (a) that label was displayed on the product precisely because it could have been contaminated by gluten because other products, like the one offered by the recommended firm, which were manufactured in a sterilised environment, did not have to bear that label since it would be 100% free of gluten so much so that the container displayed the wording 'gluten free', (b) the product offered by the recommended firm was termed as food for medical purposes and gluten free, (c) it was questionable how the appellant company's product could have satisfied the tender requirement as per LN 209 of 2001 that it had to be certified a dietary food for specific medical purposes and (d) if the product was totally gluten free then, according to legislation, there was no need for any disclaimer as that appearing on and applicable to the appellant's product,

reached the following conclusions, namely:

1. The Public Contracts Review Board opines that the label, as provided by the manufacturer through the appellant company, represented a commercial disclaimer. In this case the disclaimer provided by the manufacturer is, seemingly, more intended towards warning the ultimate user / consumer so as the said manufacturer would not shoulder any responsibility in case the product would be contaminated with gluten. At least this is, *prima facie*, the

perception of such claimer considering that, normally, gluten free products carry a label clearly stating that the product is gluten free.

2. This Board observes that it could be that the contracting authority might be covered contractually with the required paperwork that the product was gluten free but the fact remains that pharmacists and nurses who would be distributing this product, as well as the users themselves, would only have the instructions on the package to go by and that, although the label did not state that it contained gluten, yet, on the other hand, it did not provide the peace of mind that the product was gluten free, especially when the label provided on the sample of the product submitted had the following printed on it, namely *'Produced in a factory that handles products containing milk, egg, soy and gluten.'*
3. The Public Contracts Review Board concurs with the contracting authority's claim namely that there would have been no problem with the product offered by the appellant company had it not been for the label which clearly stated that the product was manufactured in an environment that contained gluten and could, as a result, be contaminated. One has to bear in mind that legislation was introduced precisely to protect patients who suffer from certain allergies, including celiac patients, because, in the past, no indications were displayed on products with regard to gluten content to the detriment of these patients.

In view of the above this Board finds against the appellant company and recommends that the deposit paid by the same company for the appeal to be lodged should not be reimbursed.

Alfred R Triganza
Chairman

Joseph Croker
Member

Carmel Esposito
Member

29 January 2013