PUBLIC CONTRACTS REVIEW BOARD

Case No. 548

CT/2017/2012

Pre-Contractual Complaint - Tender for the supply of Topiramate 100mg tablets

The closing date of the tender which was due on the 26th April 2012 was later extended to the 10th May 2012.

Messrs Rodel Ltd filed a pre-contractual objection on the 9th May 2012 against the decision of the Ministry for Health to issue a call for tenders calling for the supply of these tablet specifying the brand name Topamax ®.

The Public Contracts Review Board composed of Mr Joseph Croker as Acting Chairman with Messrs Carmel Esposito and Paul Mifsud as Members convened a hearing on the 10th May 2013 to discuss the objection.

Present:

Rodel Ltd (representing Accord Healthcare)

Dr Norman Vella	Director

Central Procurement and Supplies Unit – Ministry for Health

Ms Astrid Sammut	Representative
Ms Jennifer Farrugia	Senior Pharmacist

Evaluation Board

Mr Joseph Xuereb	Chairman
Mr Mark Spiteri	Member
Ms Sonya Bonnici	Member
Ms Alison Brincat	Member

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

Dr Norman Vella, on behalf of Rodel Ltd, the appellant, made the following submissions:-

i. by email dated 5th March 2012 he had requested the Contracts Department, the contracting authority, and copying the Ministry of Health, (i) to remove the restriction imposd in Volume 3 'Technical Specifications' at page 46 of the tender document which called for the supply of the Topiramate 100mg specifying the brand Topamax® (Keppra) or (ii) to confirm that should Accord Healthcare Ltd offer its generic Levetiracetam 500 mg tablets, which were being supplied to hospitals in England and Wales, such tender would be considered;

ii. the purpose of his objection was to allow his overseas principals to participate in the tendering procedure which circumstances applied also to about four other prospective bidders who could offer their generic product;

iii. on the 26th April 2012 he even phoned the Director of Contracts and his advice was to wait as no developments had taken place up till then;

iv. his series of emails to the Contracts Department, the last one dated 2nd May 2012, i.e. the day before the extended closing date for the submission of tenders, remained unaswered and therefore he was left with no alternative but to have recourse to the PCRB in terms of Part XIV Reg. 85 (1) (a);

v. Accord Healthcare Ltd confirmed that its generic medicine was registered and marketed in England, the Netherlands and Italy with the appropriate market authorisations in place;

vi. at the hearing he provided a hard copy and a soft copy of the complete dossier of the bioequivalence study in respect of Accord Healthcare's Tipiromate 100 mg tablets, which study had been presented to the Health Authorities of the UK who eventually tested and approved the generic product with regard to its bioequivalence with Topamax®;

vii. he cited various technical quotes to domonstrate the bioequivalence of Accord Healthcare Ltd's generic Topiramate medicine to that of Tiporamate Topmax®, which brand was requested in the tender document; and

viii. besides being in his interest and in the interest of other bidder who would be able to offer similar generic medicines, it was also in the interest of the Ministry for Health and of patients to have as many bidders as possible in order to obtain a product of the same quality but at a cheaper price.

Mr Joseph Xurerb, chairperson of the evaluation board, stated that the specifications for the procurement of such medicinces were provided by the Department of Pharmaceutical Affairs (DPA) and in this case it recommended the procurement of tablets of a particular brand, i.e. Topamax®.

Ms Jennifer Farrugia, senior pharmacist, remarked that:-

a. Dr Norbert Vella, consultant, recommended that a patient should be given the same brand of anti-epileptic drug (AED) and that patients should not be shifted onto generic versions; and

b. this advice was in line with the Royal Pharmateutical Society of Great Britain and the NHS website, which provided practice guidance on epilepsy, which similarly indicated that it was important that, whenever possible, patients with epilepsy always received the same brand of anti-epileptic dug because switching versions could potentially affect seizures control and numerous academic research papers urged caution and recommended further research into the effects of substituting AEDs.

The A/Chairman PCRB remarked that it would appear that it was medically adviseable that patients using tablets of a certain brand should stick to that particular brand however new patients could start on a different generic drug and he therefore asked if any other drug, besides Topamax, has been procured.

Mr Xuereb reported that:-

i. in response to the tender in question only one bidder participated, even though it was an open tender which allowed for parallel trading to take place;

ii. in the meantime there had been a change in the administration of the CPSU and he recalled that the supply of this item was made through a direct order; and

iii. Dr Norbert Vella, consultant, could not attend the hearing because on Fridays he, along with the other neurologists, were detailed on duty in clinics.

Dr. Norman Vella concluded that he could understand a situation where a consultant would advice that a limited number of patients should stay on the brand of AED and therefore a limited stock be kept for such cases but it was not justified that the CPSU should pay a higher price for a particular brand when the same requirement could be satisfied by a cheaper generic drug in the case of new patients or patients who could tolerate a change in brand.

The Board,

- having noted that Messrs Rodel Ltd had by email dated 9th May 2012 submitted a pre-contractual objection in terms of the Public Procurement Regulations whereby it objected that the tender had specified the procurement of a medicinal with a particular brand name;

- having noted the appellant's claim that the generic product he represented was bio-equivalent to the branded originator drug, that the product in question was widely supplied to the NHS hospitals in the UK; that the inclusion of the generic product would be beneficial to the Contracting Authority since it

would increase competition and thus it would be able to procure quality products at an advantageous price;

- having noted that the Contracting Authority's contention that the specifications are drawn up by the Department of Pharmaceutical Affairs and that the consultant recommended that patients be retained on the same brand of pharmaceuticals since changes in brands may cause undue side effects; having also noted that in spite of this recommendation, new patients could be introduced to different brands as long as the use of a particular brand per patient is retained;

came to the following conclusions:

1. that generic products which seem to be bio-equivalent to the originator drug are available on the market;

2. that though there is only one representative for the originator product in Malta, the tender was published on the international market and anyone could participate in the call;

3. that though it is highly recommended that epileptic patients be kept on the same brand of medicine, there is nothing untoward in new patients being prescribed different brands as long as they be kept on the same brand.

In view of the above, the Board finds in favour of the appellant and recommends that the tender be cancelled and replaced by a new tender showing the generic chemical name of the medicine. In order not to jeopardise the well being of patients who are already on a particular brand the Contracting Authority is urged to continue to supplying them with their medicine through alternative procurement procedures.

Joseph Croker	Carmel Esposito	Paul Mifsud
A/Chairman	Member	Member

17 May 2013