Independent Review Panel

Decision No.05/19

In the matter of:

A.E Patel & Co Ltd

(Applicant)

v/s

Ministry of Health and Quality of Life

(Respondent)

(Cause No. 05/19/IRP)

Decision

A. History of the case

An invitation for bids was issued by the Respondent, the Ministry of Health and Quality of Live ("Ministry") for the procurement of the "Annual supply of Renal Drugs."

The Applicant, A.E Patel & Co Ltd, submitted its bid on the 21st November 2018.

By way of letter dated 21st February 2019, the Applicant challenged the decision of the Respondent on 26 February 2019. Upon receipt of the said letter, the Applicant challenged the decision of the Respondent.

The Respondent replied to the challenge on the 1st March 2019 explaining the reasons for the non-retention of the Applicant's bid. One of them read: *"The requirement as per our bidding documents for generics of low therapeutic index was the mandatory submission of recent bioequivalence or bioavailability test. Your company has failed to submit such document."*

Being unsatisfied, the Application made an application for review. He prayed that the IRP would:-

(A) Prohibit the Public Body namely the Ministry of Health and Quality of Life from acting or deciding in an unauthorised manner.

(B) Recommend the annulment of the unauthorised act and the unauthorised decision of the said Public Body mentioned above.

(C) Recommend payment of reasonable costs incurred in participating in the bidding process where a legally binding contract has been awarded which, in the opinion of the Review Panel, should have been awarded to the applicant.

(D) Make such other order as may be appropriate in the circumstances.

B. Notification of Award

Through the letter dated 21 February 2019 the Ministry of Health and Quality of Life notified the company A.E Patel & Co that an evaluation of the bids received has been carried out and its bid has not been retained for award for items **RN-A1, RN-A2, RN-A3, RN-A4, RN-A5, RN-A6, RN-A7 and RN-A8.** The particulars of the successful bidders are given in the following annex:

***ANNEX* - MHPQ/PHARM/2018-2019/Q52 OAB**

Item No.	***Description***	***Quantity***	***Successful Bidder***	***Amount (Rs)***
RN-A1	*Azathioprine 50 mg tab*	*1,000,000*	*Unicorn (MSJ Ltd)*	*790,000.00*
RN-A2	*Cyclosporin 25 mg cap*	*125,000*	*Unicorn (MSJ Ltd)*	*3,112,500.00*
RN-A3	*Cyclosporin 50 mg cap*	*145,000*	*Unicorn (MSJ Ltd)*	*7,183,300.00*
RN-A4	*Cyclosporin 100 mg cap*	*18,750*	*Unicorn (MSJ Ltd)*	*1,875,000.00*
RN-A5	*Cyclosporin Oral Solution 100 mg/ml x 50 ml*	*300*	*Unicorn (MSJ Ltd)*	*2,093,700.00*
RN-A6	*Mycophenolate Mofetil 500 mg tab*	*750,000*	*IBL Healthactiv*	*26,955,000.00*
RN-A7	*Calcium Polystyrene Sulphonate powder (454 g)*	*1,300*	*IBL Healthactiv*	*2,038,400.00*
RN-A8	*Tacrolimus 0.5 mg cap*	*70,000*	*IBL Healthactiv*	*275,800.00*

C. The Challenge

On 26 February 2019, the Applicant challenged the procurement on the following grounds:

"The Applicant has submitted the lowest bids as per the criteria required."

D. The Reply to Challenge

On 01 March 2019, the Public Body made the following reply to the challenge and stated that:

"The requirement as per our bidding document for generics of low therapeutic index was the mandatory submission of recent bioequivalence or bioavailability test. Your company has failed to submit such document. I am therefore directed to inform you that your offer for item RN-A6 Mycophenolate Mofetil 500 mg tab/cap could not be retained for award."

E. Grounds for Review

On 07 March 2019, the Applicant seized the Independent Review Panel for review on the following grounds:

1. *Section 40 of the Public Procurement Act 2006 reads as follows:-*

   "(3) A public body in relation to a procurement contract, the value of which is above the prescribed threshold shall notify the successful bidder in writing of the selection of its bid for award and a notice in writing shall be given to the other bidders, specifying the name and address of the proposed successful bidder and the price of the contract.

   Amended by [Act No. 1 of 2009]"

   *1.1 In the letter dated 21st of February 2019, the Employer has failed to inform the Applicant the name of the successful bidder for items *RN-A9 and *RN-A10.*

2. *At page 31, ITB 6.3 (c) of the bidding documents reads as follows:-*

   *"**8.** Recent bioequivalence or availability test for generics of low therapeutic index (Mandatory)"*

2.1 In the bidding documents issued by the Employer, there is no mention of any list whereby stating which items would fall within the list of low therapeutic index.

*2.2 In fact, the Applicant invites the Independent Review Panel to consider the article written by Prof. Dr. Teun van Gelder (marked as **Annex A**). In the said article, at page 508 quote: - "Although neither is considered to be a narrow therapeutic index drug, this should not lead to careless switching between the innovator drug and generic formulations, or between one generic formulation and another".*

F. The Hearing

The hearing of the case was held on 26th March 2019. The Applicant was represented by Mr Malleck together with Mr Oozeerally of Counsel whereas the Respondent was represented by Mr Beeharry, Principal State Counsel.

G. Findings

In the present application, the central issue the Panel has to determine is whether the renal drugs proposed to be supplied by the Applicant is of such low therapeutic index that it was necessary, or 'mandatory', for the bid to include a recent bioequivalence or bioavailability test.

The Applicant's contention is that the drug it proposed to supply is not of low therapeutic index. In support, it produced no less than four articles from medical journals written from expert of high calibre, one dated 2015, another dated 2017 and the remaining two as recently as 2019. One can read that Mycophenolate mofetil generics can now barely be considered a drug with narrow (or low) therapeutic index.

The Respondent, on whose behalf Principal Pharmacist, Mr F. Elyhee, gave evidence gave the Panel an overview of the implications of a drug having low or narrow therapeutic index on its administration to patients. He then contended that Mycophenolate generics are of low therapeutic index and to buttress his argument, he also produced articles from renowned medical journals, one from 2015 and the other from a decade ago.

The Applicant replied that this drug has been produced in generic form for a number of years now and has improved so that now it does not have a low index.

What ensued was a number of exchanges about the strengths and number of articles each side could have produced but such exchanged offered little help to the case in point which is, is Mycophenolate mofetil generic a drug low therapeutic index.

However, the Panel then queried Mr F. Elyhee on a number of issues and three matters came to light that we believe are of the utmost relevance to the issue. First, it appears that he (and the Ministry) keeps a list of drugs they somehow deem to be of low therapeutic index but, quite surprisingly, this list is not made available to bidders nor is it in anyway referred to or hinted at in the bidding documents. This list was made available to us on 27 March 2019 following the hearing – Mycophenolate mofetil generic is included but there was simply no way for the Applicant to have known that fact at bid submission stage and it, rightly one may say, proceeded on the basis that this drug is now deemed to have a higher or larger index.

Secondly, originator/innovator drugs as opposed to generic drugs that came about after the originator's patent expired have an 'edge' of sorts in the subjective element of his evaluation process because of the 'known doses'/administration methods. Finally, and most surprisingly of all, to cater for use of generics, not only is equivalence needed for some (those with low index) but such equivalence tests may be requested by the Ministry at contract implementation stage.

We will refrain, in the circumstances, from making observations on the apparent impropriety that we have witnessed in this case for an item worth north of Rs 25 million of public funds. Yet, we feel compelled to state that the Public Procurement Act requires that government departments call for bids in a fair and open manner aiming to get responsive bids for the best price, not to hedge bets, so to speak, and have some items floated in case the 'preferred' items are not available. Should it be the case, the bidding documents should **openly and expressly** reflect that so that bidders would then be well advised and act accordingly instead of expending money to submit bids only to find out that they had no chance *ab initio*. Furthermore, obscure or highly subjective evaluation criteria applied randomly as well as unpublished 'lists' do not have their place in public procurement proceedings and we are confident that the Central Procurement Board and the Procurement Policy Office will agree with this observation of ours.

Be that as it may, we find, on balance, that the generic Mycophenolate mofetil generic does not have a low therapeutic index, does not require a bioequivalence test to be submitted at bid submission stage, and we declare the bid of the Applicant valid and should the Ministry need such

bioequivalence, it would be able to avail itself of the mechanism provided in the contract.

IBL was selected on the basis of 750,000 units for Rs 26,955,000 when the bid was for 600,000 – which was a permissible 25% increase in quantity. All things being equal, IBL's total price for 600,000 units would have been Rs 21,564,000. The Applicant gave two options in its quote: one for Rs 18,150,000 and the other for Rs 17,250,000.

Accordingly, we recommend a prompt re-evaluation of the bids in the knowledge that the Applicant's bid was substantially lower than the bid of the successful bidder, IBL, by at least Rs 3.4 million. Such re-evaluation to be done by a differently constituted Bid Evaluation Committee.

Chairperson
(H. Lassemillante)

Member
(A. Gathani)

Member
(A.K. Namdarkhan)

Date: 03 April 2019