IN THE MATTER OF THE PATENT ACT, R.S.C. 1985, c. P-4, as amended
AND IN THE MATTER OF ELI LILLY CANADA INC.
AND IN THE MATTER OF HUMALOG (INSULIN LISPRO)

REASONS - Voluntary Compliance Undertaking

Introduction

On March 14, 1998 the Patented Medicine Prices Review Board (the "Board") issued a public notice (the "Notice") that it had received a Voluntary Compliance Undertaking (the "VCU") from Eli Lilly Canada Inc. ("Lilly") in respect of the price of the medicine Humalog. The Notice observed that the Staff of the Board recommended the acceptance of the VCU by the Board and provided Ministers of Health in the provinces and territories of Canada and other interested persons with an opportunity to make submissions on the appropriateness of the VCU and its terms and provisions.

Background

Humalog is a rapid-acting analog of human insulin that has been approved by Health Canada for the treatment of patients with diabetes mellitus who require insulin for the maintenance of glucose homeostasis. An application for a Canadian patent pertaining to Humalog, filed in 1990, is still pending but Lilly expects that a patent will be granted in the future.

A history of the review by Board Staff of the pricing of Humalog was set out in the Notice, together with an account of the process which led to the submission of the VCU by Lilly and the reasons for Board Staff's recommendation that the Board accept the VCU. In brief, the VCU provided that Lilly would lower the manufacturer's list price for Humalog by approximately 23%, such that the relationship between the prices of Humalog and regular insulin in Canada would reflect the relationship between the prices of those products in other countries.

In addition, the VCU proposed to offset all excess revenues which had been received by Lilly as a result of charging the higher price through a mechanism intended to provide Humalog at no charge to patients who had previously been treated with it.

The Submissions from Interested Persons

(a) The Price of Humalog

The Board received submissions from or on behalf of Ministers of Health of six provinces: Alberta, British Columbia, Nova Scotia, Prince Edward Island, Québec and Saskatchewan. Submissions were also received from the Canadian Diabetes Association and Novo Nordisk Canada Inc.

Most of the parties agreed with the proposed price reduction and with the methodology for determining the maximum non-excessive (MNE) price. The Ministries of Health for British Columbia and Saskatchewan opposed the basis for calculating the maximum non-excessive price and argued that the price should be lowered still further, to the price of regular insulin, in a manner consistent with the PMPRB's Guidelines.

(b) Offsetting Excess Revenues Already Received

All of the submissions objected to the proposed method of achieving the offset of excess revenues, i.e. the attempted distribution of free Humalog to patients who had used the medicine in the past.

The Amended VCU

On April 24, 1998 Lilly submitted an amended VCU that changed the proposed method of offsetting excess revenues. Pursuant to the amended VCU, Lilly undertakes to make a payment to the Government of Canada for the full amount of excess revenues received up to December 31, 1997, i.e., $666,824. To the extent that any excess revenues may have been received in 1998 prior to the price reduction, they will be offset through further price reductions to ensure that the average price for Humalog in 1998 does not exceed the MNE price of $22.1072.

Decision

Having considered all of the submissions from interested parties and the amendments to the Voluntary Compliance Undertaking made by Lilly on April 24, 1998, the Chairperson on behalf of the Board has decided to accept the amended VCU.

While the Board was sensitive to the submissions of parties who argued for a larger reduction in the price of Humalog, it was considered on balance that the amended VCU is consistent with the provisions of the *Patent Act* and the Board's Compliance and Enforcement Policy. The amended VCU establishes a reasonable

basis for determining the MNE price for Humalog consistent with the factors set out in subsection 85(1) of the *Patent Act*. Furthermore, the amended VCU will result in an immediate price reduction for Humalog, together with the repayment of past excess revenues in a manner consistent with the submissions of interested parties.

The acceptance of the amended VCU is based on the particular circumstances of the medicine Humalog and its context in the international market for analogs of human insulin. This exceptional case does not warrant a review or amendment of the Board pricing Guidelines, which remain applicable to medicines subject to the Board's jurisdiction.

Use of the Funds Paid to the Government of Canada

Under the *Patent Act*, the Board has no authority to order that funds paid to the Government of Canada to offset excess revenues be used for certain purposes. Pursuant to section 103 of the *Act*, the Ministers of Health in Canada have agreed in principle that funds collected as a result of Board Orders and VCUs be distributed to the provinces on a per capita basis. They further agreed that such funds should be used for pharmaceutical objectives.

In this case, the Canadian Diabetes Association recommended that any payment to governments should be directed towards a national diabetes related initiative. The Board wishes to bring that recommendation to the attention of governments and encourage them to give due consideration to it.

Sylvie Dupont-Kirby
Secretary to the Board

April 29, 1998