Vernon Chiles,
Green Shield Canada

Memo

To: Patented Medicine Prices Review Board

From: Vernon Chiles, Vice Chair of the Board, Green Shield Canada (vchiles@ebtech.net)

CC: David Garner, President and CEO, Green Shield Canada (david.garner@greenshield.ca)

Date: July 20, 2005

Re: Green Shield Canada Comments on Proposed Amendments to the *Patented Medicines Regulations*, January 2005

Proposed Amendments for Consultation, 3.1 Notification of Proposed Price

Green Shield supports this change to require notification of the proposed price in advance of marketing.

This would allow the Board to begin the price review process sooner.

It might, in some cases, allow the Board to communicate with the patentee in advance of sale where it appears likely that the proposed price may ultimately be found to be excessive.

This could be more efficient for both the Board and the patentee. It might prevent some voluntary compliance undertakings.

For public and private sector plan sponsors plan it is advantageous to have the minimum number of voluntary compliance undertakings. This is the case since there is only provision in law for recoveries to be paid to government and not for recoveries related to usage by individuals and employer sponsored drug plans (public and private).

Proposed Amendments for Consultation, 3.2 Notification of a Proposed Price Increase

Green Shield supports this change to require notification of price increases in advance of the effective date of the intended increase.

From the public interest perspective and from the Board's perspective in fulfilling its mandate it seems bizarre that it does not receive notice of increases in advance of their effective dates. With implementation of this proposed amendment it will be possible to address issues in a timely way and detect market trends that require study.

Although prior approval is not part of this proposed change, there could be cases where it seems highly likely that a proposed increase is outside the guidelines. Such excessive price increases could well be inadvertent and related to error or a misunderstanding of the guidelines. The Board could communicate with the patentee promptly and this would lead to efficiencies for both Board and patentee.

Where patented drug price increases are implemented that are outside the Board's CPI guidelines and subsequently determined to be excessive it is unfair to employer sponsored plans (public and private) and individuals who have no recourse to recovery of excessive payments. It is thus advantageous if excessive price increases can be prevented and all increases limited to what is allowed by the guidelines.

Proposed Amendments for Consultation, 3.3 Details on the Calculation of Net Price and Net Revenues

Green Shield supports the recommendation to require more information in the calculation of net price.

Due to market pressures patentees have an increasing variety of prices for different customers. For example, the patented medicine Pantoloc® is listed in provincial formularies at $1.90 but, according to the Auditor General, is supplied to NIHB for $0.45. With moves to find purchasing efficiencies as part of the First Ministers National Pharmaceuticals Strategy the use of multiple prices for different customers is likely to expand.

It is important for the Board to have the ability to determine the true prices at which patented medicines are being sold.

The proliferation of multiple prices can lead to an opaque pricing milieu similar to that in the U.S. In the U.S., customers with little buying power pay relatively high prices while governments, pharmacy benefit managers, HMOs and others with bargaining power pay relatively low prices.

In determining how to apply the publicly available U.S. Veterans Affairs prices the Board's Working Group on Pricing Review Issues and the Board struggled with determining the extent to which lower prices should apply in estimating true U.S. market prices (for purposes of international comparisons). Detailed data on revenues at different prices is needed so that such approximations will not be needed in the Canadian market.

As market forces lead to a greater variety of prices it will be necessary for employer drug plan sponsors (public and private) to ensure that their employee claims are adjudicated based on reasonable prices and avoid paying higher prices due to patentee price concessions to governments. To make this possible it will be an important service if the Board is able to make these true prices publicly available.

An additional advantage of having more information on prices and revenues occurs when calculating the maximum non-excessive price of a new patented medicine using the therapeutic class comparison test. If accurate price and revenue data is not available the prices of comparative medicines may be inaccurately high and thus the allowed MNE price of a new patented drug may higher than would be the case with a true price reflecting the variety of prices and related revenues in the Canadian market.

Proposed amendments for consultation, 3.4 Product Monograph

Green Shield supports the change to require the monograph or draft monographs as part of the price review process.