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Ms. Sylvie Dupont
Secretary of the Board
Patented Medicine Prices Review Board
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Dear Ms. Dupont,

Green Shield Canada is pleased to be given the opportunity to respond to the discussion document *Options for possible Changes to the Patented Medicines Regulations, 1994 and the Excessive Price Guidelines*.

Green Shield Canada feels strongly that the PMPRB needs to hear concerns voiced from the private sector with regards to drug pricing. Our positions on the proposals, which are contained in this submission, can be summarized as follows:

- All changes made to the *Patented Medicines Regulations 1994* should recognize the Canadian market which is approximately 60% private and 40% public. Access to non-excessive prices for employer-sponsored drug insurance plans and for those individuals with no coverage is a fundamental aspect of the PMPRB mandate.
- Green Shield Canada believes in a transparent pricing system and recommends that the PMPRB should make the average transaction price (ATP), or the maximum non-excessive (MNE) prices, publicly available. Publication of the ATP fulfills a role that cannot be played by others such as private sector marketing companies and better complies with achieving the roles of the Board.
- Mechanisms are needed to ensure that the price of a costly drug introduced for a rare disease does not automatically become the price when the drug is approved for use for more common diseases.
- Benefits, such as free goods, need to be considered when calculating ATPs, and we would like to see further work on the mechanisms required to appropriately and consistently incorporate these.

Background Information

Green Shield Canada specializes in group and individual health and dental benefits programs and administration. We are recognized as a leader and innovator in the provision of health and dental benefits administration to a growing number of plan members in a variety of industries from

manufacturing, public service, education, union and other employer and association groups. We also provide health and dental adjudication for a number of insurance companies. As Canada's only national not-for-profit health and dental benefits carrier, our mission is to serve the public interest by providing the most efficient customer service and the most effective benefits programs.

Green Shield Canada has responded to numerous PMPRB initiatives in the past, the most recent being a detailed response in August 2006 on the *Submission to PMPRB on the Board's Excessive Price Guidelines*. We are pleased that the Board has released the discussion paper addressing issues raised by stakeholder consultations in the past.

Section 111 Overall Guidelines Review

Proposed Scenarios for Consultation

a) Any market price review

Green Shield Canada **generally** supports the proposals suggested on page 4 of the document, however;

In the absence of specific knowledge of ATPs, how can other customers (and other groups within the customer population) have a basis to complain? If the "average price for Canada appears to exceed the MNE", PMPRB has still not addressed the issue of some customers paying higher prices than those who are able to negotiate lower prices. Transparency of pricing is needed to recognize when excessive pricing is occurring for different customers and within classes of customers, as well as to facilitate price competition. We suggest that substantiated complaints of alleged excessive prices should trigger **ALL** classes of customers and each province/territory to be investigated. As well, the alleged complaint should be posted so that the other specific classes of customers are aware of the complaint, and able to check and compare their pricing as well. From the public policy perspective, manufacturer net prices should be transparent and available broadly.

b) Resetting the MNE price

Proposal 1

i) How would the Board be able to establish whether the drug product had been sold upon introduction at an artificially low price? If this price could be identified upon introduction (e.g. a true introductory price vs. an artificially low price upon introduction), it would be helpful. Before allowing higher pricing, data concerning the efficacy and safety of the drug should also be reviewed. We would hope that a lower introductory price would not be established to garner market share, and once market share obtained, the price increased.

ii) We would need more information before commenting on this proposal.

iii) We currently see this happening – a raw ingredient is either not available, or the cost has increased significantly for the procurement. In the case of a raw ingredient being unavailable (e.g. contaminated product, not meeting standards, etc.) and alternate sources are sought, we suggest that the manufacturer be allowed to sell this product at a price exceeding MNE for a specified period of time, after notifying PMPRB of the situation, without resetting the MNE [similar to (b)]. In the case where the acquisition cost has increased, this would probably be an international issue and the MNE should be reset based on PMPRB's criteria of setting the MNE [similar to solution (a)].

Proposal 2

We agree that the MNE should be reset when new evidence or new indications are available that affects the category of therapeutic improvement of the medicine. This could, in some instances, reset the MNE to a **lower** point. Consideration should be given to medicines that were approved for one indication (e.g. a rare cancer) and then found to have broader application for more common conditions. The MNE was set high because of a narrow entry market, but as market share increases and the indications for treatment expands; the MNE should be reduced, making the product more affordable. We believe this to be within the purview of the PMPRB.

Proposal 3

We would agree that the number of countries and the threshold of 3 years are arbitrary. The suggestion to align to the timeframes of Health Canada's proposed Progressive Licensing Initiative seems reasonable.

Options to Address Issues Arising from the Federal Court of Canada Decision

A. Regulatory Options

Option 1 – Maintain the current Regulations and respect the outcome of the FCC decision.

We would **not** support this option as we would be concerned that some pharmaceutical companies who currently offer programs such as compassionate use programs would stop such programs if this was calculated into their average price. Processes need to be put in place to ensure that pharmaceutical-funded compassionate use programs remain viable and that the concerns of "patients and their advocacy groups" are taken into consideration. **We could support this option if compassionate use drugs were excluded.**

Option 2 – Amend the Regulations to exempt patentees from the requirement to report benefits to third party payers.

In our April 10, 2005 response to the Proposed Amendments to the Patented Medicines Regulations (January 2005), Green Shield Canada stated that it supported the recommendation to require more information in the calculation of net price. In this submission, we stated that "due to market pressures, patentees have an increasing variety of prices for different customers…".

"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 our submission to the March 2005 PMPRB Discussion Paper on Price Increases for Patented Medicines, Green Shield Canada stated:

"The following points focus on some examples of market activity where there are multiple prices and/or lack of transparency. These examples are drawn from Green Shield Canada's experience and knowledge of the Canadian pharmaceutical market; the list is not exhaustive. Some brand/patented manufacturers have lower prices where they can augment their market share. Hospitals have long been able to get lower prices through the exercise of their market power (e.g. restricted formulary, influence on drug utilization patterns outside hospitals, buying group arrangements, etc.)…".

Manufacturers generally attempt to offset price concessions to governments with higher prices in non-government markets. Manufacturers have also started to offer rebates to various sectors in return for formulary listings.

We would not support this option where payments provided to third party payers (F/P/T drug plans and potentially private insurers) were not included in the calculation of Average Price.

Green Shield Canada strongly believes in a transparent pricing system. ATPs should be publicly disclosed by the Board so that various classes of customers can know whether prices are less than the normal publicly available prices (e.g. as published in provincial formularies). Although the Board does not publish the MNE prices, the formulary prices are often close to the MNE prices. Publication of the ATP fulfills a role that cannot be played by others such as private sector marketing groups and better complies with achieving the roles of the Board:

- *"protect consumers….by ensuring that prices charged…for patented medicines are not excessive"*

- *"..ensuring that the prices patentees charge wholesalers, hospitals, pharmacies and others for prescription and non-prescription patented drugs are not excessive"*

In this option, some classes of customers would be paying higher prices due to concessions to government. This applies to employer-sponsored groups and to citizens with no drug coverage. PMPRB is the only agency that has the legal authority to access this data and publish it.

We are already seeing provincial governments negotiating "preferred pricing" while other constituencies pay a higher price. Again, a reference from our 2005 submission:

"The increasingly common practice in the Canadian market of selling patented medicines at multiple prices must be considered since it does not make sense to allow an increase over the so-called "list price' when the patentee commonly sells the product to some customers at lower than the requested increased price. The issue of multiple prices for different classes of customers could itself be a motivation for asking for an increase since discounts to customers like governments might precipitate pressure to offset these lower prices with price increases for customers lacking the same bargaining power."

We would also agree that reporting the trends in pharmaceutical pricing would become less representative of the pharmaceutical market if these payments to third party payers are excluded.

Publishing the ATP would provide transparency of pricing and facilitate price competition.

Option 3 – Amend the Regulations with respect to free goods.

i) Amend the regulation to exclude all free goods from the calculation of the Average Price

We would **NOT** support this recommendation as we strongly believe that free goods should be included in the ATP with the exclusion of compassionate use drugs as we recognize the need for these types of programs.

ii) Amend the regulations to exclude free goods from the calculation of the average price when only free goods are provided to a particular customer class.

We would **not** support this recommendation since goods distributed for compassionate use are a class of customer too granular for PMPRB to evaluate. We would only support the exclusion of free goods for compassionate use being calculated into the ATP**. This change would not benefit the private sector nor those Canadians with no drug coverage.**

iii) Amend the regulations to exclude free goods in "non saleable" or "sample" package sizes that are provided to those legally able to receive such goods pursuant to the Food and Drugs Act, from the calculation of the Average Price.

We **could** support this proposal since it would allow access to new drugs on a sample/trial basis and could also be used for compassionate use. However, we would caution that some sample drugs are new "me too" drugs which offer minimal or no benefit to the patient compared to existing therapies.

Option 4 – Amend the regulations to change "free services" to "services free or partially subsidized" in the calculation of Average Price.

Green Shield Canada could only support this concept if these free services are better defined and transparent.

Option 5 – Amend the Regulations to exclude "gifts" from the calculation of the Average Price.

[in the context of subsection 4(4) (determining the average transaction price) and 4(5) (calculating net revenue), gifts related to the purchase/sale of a specific DIN]

"Gifts", when they occur to prescribers, do not relate to the purchase/sale of specific DINs. A gift in the context of the Regulation comprises the provision of different drug products or gifts like equipment or attendance at conferences in relation to the sale/purchase of specific DINS. A broader interpretation of the term "gifts" is needed than that which is currently used. Understood this way, **"gifts" should be included** in the calculation of ATP.

Option 6 – Amend the Regulations to permit the Board to disallow any or all benefits which it determines, pursuant to a public hearing, were implemented by a patentee for the purpose of reducing its liability in regard to excessive pricing in terms of the calculation of excess revenues.

If previous options were not implemented, then this option would not be needed. If the Regulations recognized the Federal Court of Canada ruling, and made only the exceptions of sample or trial size products, this occurrence would not happen. We would support this option, only if the previous options were implemented. Not considering "free goods" in the calculations of average price could cause the price to be "artificially" high.

We agree with the last paragraph on page 15, which is why we do not support most of the options for amending the Regulations. "This practice of "dumping" free goods to avert liability under the Regulations could have implications for the Canadian Consumer, since some markets might end up paying higher and even excessive prices, while the distribution of free goods to another market effectively reduces the overall Average Price for Canada to a non-excessive level."

B. Guidelines Options
Possible changes to the CPI Adjustment Methodology for Determining the MNE Price

Option 1 – Amend the methodology in the Guidelines for the establishment of the MNE price by using in the CPI adjustment methodology the highest previous non excessive Average Price, if the actual average price declines due to a new or increased benefit.

A price increase should be limited so that any increase in price of the medicine does not exceed the maximum non –excessive price as determined using the International Price Comparison (IPC) test. A price increase should be limited so that any increased price of the medicine does not exceed the sum of the average price at which the medicine is being sold in Canada and the applicable CPI factor.

Option 1 tries to maintain a level of MNE regardless of market factors reducing the average price, which seems contrary to its mandate and a competitive market place.

Average prices below the MNE prices could be comprised of low prices for public plans and higher prices for the private sector. Furthermore, the lower public prices may be provided in part to establish market share through full public formulary listings. Such listings also provide market share in the private sector. The Board must consider not only average prices, but also whether prices to different classes of customer are excessive.

Option 2 encourages manufacturers to have a high introductory MNE price, but enter the market for an introductory period to gain market share, and then increase their price to the MNE price, regardless of market/competitive factors. Reduced prices may also be used at introduction to get listing on provincial and private formularies. Once market share is secured, prices could be increased up to the MNE levels plus CPI. Governments may be able to control this with their strong “buying power”, but private sector groups and individuals have less market power.

For these reasons, we **do not agree** with either of the two options.

Closing Comments

There is a need to consider the changing pharmaceutical landscape since the Patent Act was amended and whether additional factors should be provided for by regulation in Section 85(1)(e).

When a drug with moderate, little or no advantage (Category 3) has its price approved as non-excessive, it is allowed a price up to the level of the highest priced drug in the therapeutic class. In our view, this is generous and does not always reflect a balanced assessment of the market in a therapeutic class.

Although not discussed in this document, in the case of VCU and penalty payments, the penalties are paid to the Federal Government, and the customers who have paid the excessive prices are not reimbursed. Green Shield Canada believes that consideration should be given to the refund of the difference between the excessive price paid and the MNE to those customers where it can be calculated (governments, employer-sponsored benefit plans, etc.).

The Patent Act provides patent protection while ensuring that prices are not excessive. Although guideline changes with respect to price increases must be in the interest of Canadians, they should not inadvertently infringe on the rights of patentees as provided in the legislation.

Thank you for your consideration of our comments. We would be pleased to offer any further clarification of our submission as needed. Please contact us at either of the e-mail addresses listed below.

Sincerely,

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