GREEN SHIELD CANADA

October 3, 2008.

Ms. Sylvie Dupont
Secretary of the Board
Patented Medicine Prices Review Board
Box L40,
Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Dear Ms. Dupont,

Green Shield Canada is pleased to be given the opportunity to respond to the August 2008 Patent Medicine Prices Review Board *Notice and Comment* document entitled "Draft Revised Excessive Price Guidelines."

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 March 2008 to the discussion document *Options for possible changes to the Patented Medicines Regulations, 1994 and the Excessive Price Guidelines.*

Green Shield Canada has advocated for equitable access to affordable health care at the local, provincial and federal level since our inception in 1957. We have taken active roles in public policy discussions and have provided input to many committees, commissions and legislative reviews. We believe that only through active participation will we ensure that all Canadians continue to have access to affordable health care.

Section 1: Issue-- Underlying Principles

Green Shield Canada is in agreement with other stakeholders regarding the underlying principles guiding the Board's interpretation of the *Patent Act*. We support the Board's inclusion of language reinforcing a consumer protection focus in the Compendium.

Section 2: Issue-- Levels of Therapeutic Improvement

We believe that the Working Group on Therapeutic Improvement should be commended for their recommendations regarding the assessment of therapeutic improvement. Additionally, Green Shield Canada agrees with the Board's positions regarding the consideration of acute care and institutional health care costs (and the difficulty of attributing their impacts), as well as the differentiation of considering patient/caregiver convenience from simple preference. We also support the consideration of compliance improvements only if linked to therapeutic efficacy.

Section 3: Issue-- International Therapeutic Class Comparison

Green Shield Canada agrees with the Board's position that in most cases, the ITCC may not be reliable and not always useful in terms of the interests of Canadian consumers. We also agree that the test may be of occasional use in cases of dispute, and recognize the ongoing requirement of this test.

Section 4: Issue—Introductory Price Tests

Green Shield Canada supports the principle of incremental reward commensurate with the level on innovation shown by new patented medicines.

However, we also believe that the allowance of the *top* of the TCC test for new drug products that show little or no therapeutic improvement over existing drug products may be rewarding mediocrity.

To illustrate, consider a hypothetical new proton pump inhibitor. In 2007, the Canadian Agency for Drugs and Technologies in Health's COMPUS group published findings that "there are no clinically important differences among standard doses of PPIs in treatment of symptomatic GERD, ENRD and esophagitis." (available at http://cadth.ca/index.php/en/compus/current-topics/ppis). Similar findings were published by the U.S.-based Agency for Healthcare Research and Quality in 2005. Assuming the hypothetical new PPI also offers no therapeutic improvement over other available agents, one could reasonably assume that the TCC test would allow a price of approximately $2.20 (the current Ontario price of Losec 20mg tablets), although equally efficacious PPIs are available for less than $1.00 per day.

As an alternative, we would propose that for products that show little or no improvement over existing products in the class, that the allowance of the median of the TCC test be used. This could ensure that such products are introduced at a price that is truly competitive with the rest of the class. We recognize, however, that such an approach could create a disincentive to the pharmaceutical industry. Clearly further analysis is required to develop a methodology acceptable to both consumers and the pharmaceutical industry.

Section 5: Issue—Modified Guidelines for Certain Patented Generic Drug Products

The Board's position on this issue notes that "generally Canadian consumers already benefit from the fact that patented generic bioequivalent drugs fall under public plan pricing rules that make them **significantly** cheaper than the reference brand drug." This assumption by the Board, in our opinion, is incorrect.

Since Ontario's passage of the Transparent Drug System for Patients Act (2006), generic manufacturers have created a two-tiered pricing system whereby the same drug product is available to the Ontario Drug Benefit program at one price (usually 50% of the price of the brand name equivalent), and is sold to the private sector at a higher price. In most cases this price has been 70% to 75% of the brand name product, but has been as high as 85% (in the case of Apo-Perindopril 8mg). Theoretically, there is no ceiling to this two-tiered system, and generics could potentially be introduced to non-public payers at only a slight (if any) discount from the brand equivalent.

While no longer under the jurisdiction of PMPRB, the current price of generic ranitidine products in Ontario is $0.4042 per tablet. The current price of the reference brand product (Zantac 150mg) is $0.1800, *less than half the price of the generic products*. To date, generic manufacturers have not shown a willingness to be price-competitive with the reference ranitidine brand product in any fashion that clearly benefits consumers.

Yet another example is seen in the case of Diamicron MR 30mg (gliclazide). Effective October 1, 2008, the manufacturer of Diamicron MR has reduced the price of their product from $0.3513 per tablet to $0.1405 per tablet. At the time of the announcement of this price change, the price of generic gliclazide MR was $0.2794. The generic manufacturer has matched this brand price, thus making the products cost-neutral.

The traditional assumption that generics are *significantly* cheaper than their reference brand drugs is increasingly becoming a fallacy (especially for the private sector).

Such pricing practices by the generic pharmaceutical industry are clearly counter to the underlying principles perceived by stakeholders of Lowest Reasonable Price, Simplicity/Transparency and International Parity/Consistency. They also run counter to the Board's mandate of protecting the interests of consumers.

The Competition Bureau's October 2007 *Generic Drug Sector Study* noted that private sector drug plans "do not appear to be obtaining competitive prices from manufacturers." Patented generics should be held to the same standard as patented brand name pharmaceuticals, with consideration given to the international prices of generic versions of the drug as well as their reference brand equivalent.

The Board has opted to exempt generic products from PMPRB's "golden rule" that the price of a Canadian patented product cannot be the highest in the world. Green Shield Canada is extremely disappointed in this decision. Many Canadian consumers cannot benefit from public drug plan pricing rules for generic drugs. The generic drug industry has taken great efforts in the last two years to break the link between the prices paid by the public and private sectors. As we have seen, we can no longer depend on generics to be significantly cheaper than reference brand drugs. We strongly urge the Board to reconsider their decision exempting patented generic bioequivalent drugs from the "golden rule," and to consider these products on the same playing field as their reference brand equivalents.

Section 6: Issue—Impact of Reporting Benefits (De-linking of the ATP from the MNE price)

Green Shield Canada support's the Board's position balancing consumer protection without creating a disincentive to manufacturers.

We recognize the uniqueness of the "DIP" and "GAP" phenomena described by the Working Group, and accept the proposed methodology for handling "DIP" situations. However, our support is contingent on the availability of "Any Market Price Reviews" to ensure that markets not receiving a benefit are not encumbered by excessive costs that would fund such benefits.

With respect to "GAP" situations, we believe that the Working Group may have developed an acceptable methodology for which to handle such situations. We appreciate the Board's concern regarding potential price increases; however, we also recognize that patentees must be able to recover from "GAP" situations within a reasonable time frame. We believe that the methodology proposed by the Working Group on Price Tests presents a solution that can be acceptable to both patentees and consumers.

For price increases beyond the "DIP" and "GAP" situations, Green Shield Canada is greatly concerned by the potential implications of the Working Group's first option. By retaining 3-year banking and eliminating the one-year cap of 1.5 times the forecast change in the annual CPI, we are concerned about potential excessive single-year price increases that would be detrimental to Canadian consumers.

Given the choices provided by the Working Group, Green Shield Canada must support the allowance of only simple CPI increases. The *status quo* of three year banking with a one-year cap is also acceptable to Green Shield Canada.

Section 7: Issue—Any Market Price Reviews

Green Shield Canada is pleased by the Board's belief "that it is important to ensure that introductory prices are not excessive for *any class of customer* or in any province/territory," and that reviews should be carried out on existing drug products on a case-by-case basis.

We are, however, disappointed at the definition of "class of customer" used by the Working Group on Price Tests. The definition used in the *Notice and Comment* document limits "customers" to "pharmacy, hospital and wholesaler" without recognizing individual payers (public or private) and consumers. It is critical that those parties most affected by potentially excessive prices be recognized as "customers" within their respective market(s).

While we agree with the Criteria for Commencing an Investigation described in Schedule 9 to the *Notice and Comment* document, we are concerned that the current criteria open Board Staff to potentially frivolous complaints. We would suggest that Maximum Non-Excessive (MNE) prices be communicated in some fashion to all classes of customers so that each customer can independently assess their market and avoid unwarranted complaints.

Green Shield Canada strongly feels that when calculating excessive revenues as part of an Any Market Price Review, that excess revenues should be calculated based only on the market in which the price was excessive.

Stakeholders have expressed concern that benefits offered to some classes of customers could result in excessive prices for other customers. Stakeholders clearly fear that "foregone revenues in markets where benefits were offered" will be not fully foregone, but simply shifted to other markets. The calculation of excess revenues based on national ATP will do little to allay this concern of stakeholders.

Within the generic drug sector, benefits offered to some classes of customer have been anecdotally reported to be well in excess of 100% of the list price of the drug. While such

generic drug products may not always fall under the jurisdiction of PMPRB, such reports raise the possibility of the national ATP for the product approaching zero (if benefits exceed the cost of the drug for a significant customer class). Calculating excess revenues based on ATP in this case clearly does little to protect consumers in other markets.

Green Shield Canada is concerned about the potential overlap between the Delinking of the ATP from the MNE price and Any Market Price Reviews. We urge the Board to consider methodologies that will protect patentees from being in a position of unintentionally exceeding the MNE price in some markets due to the expiration of a benefit in another.

We are also very concerned that existing PMPRB regulations do not permit the recovery of excess revenues by an aggrieved market. Voluntary Compliance Undertakings are payable to Her Majesty in Right of Canada with those in markets that have overpaid having no opportunity for redress.

Section 8: Issue—Re-setting the MNE Price

Green Shield Canada recognizes the need for periodic re-setting of MNE prices.

We are concerned by the Board's position accepting the recommendation giving a patentee until *the end of the following calendar year* to ensure that their price does not exceed the new MNE. If an MNE is reset in the month of January, a patentee is then permitted to maintain a price in excess of the MNE for up to 23 calendar months. Green Shield Canada strongly objects to such an excessive time window. We would suggest that in the event a price is re-set downward, a patentee should have one full year from the date the MNE is re-set to reduce its price to the new MNE price without the commencement of any investigation.

Closing Comments

There is an ongoing 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).

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 is concerned that existing PMPRB regulations do not permit the recovery of excess revenues by an aggrieved market. We believe 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.).

With respect to benefits and the calculation of ATP, we are greatly concerned by the potential implications of the fact that the Board has no discretion to differentiate whether free goods are of a compassionate nature (or other benefits to consumers), or a simple marketing allowances to increase market share (benefit only to non-consuming customers). Future legislative and regulatory changes are clearly needed in order to protect consumers in this regard.

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. We applaud the PMPRB for your ongoing efforts in protecting the interests of both Canadian patentees and their customers.

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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