GREEN SHIELD CANADA

SUBMISSION TO PMPRB ON THE BOARD'S EXCESSIVE PRICE GUIDELINES

AUGUST, 2006

1.0 ABOUT GREEN SHIELD CANADA

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. In addition, 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 goal is to serve our clients and the public interest by providing the most efficient and effective benefits programs. We are committed to exceeding our clients' expectations by offering the highest quality of service and can be relied on to be responsive and flexible. You can reach us at www.greenshield.ca or 1 800.268.6613.

1.1 Green Shield Canada and PMPRB

Green Shield has responded to numerous PMPRB initiatives and most recently to the Board's January 2005 Proposed Amendments to the *Patented Medicines Regulations and the March 2005 Discussion Paper on Price Increases*.

We are pleased that the Board has decided to initiate a comprehensive consultation on the Excessive Price Guidelines and are happy to participate in this process.

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2.0 CONTEXT

2.1 Principles

The responses to the questions in the Discussion Guide are informed by a number of principles. These are based on:

- The Green Shield mission to serve the common good and enhance access to quality health benefits.
- Acceptance of the need to reward innovation through the patent system.
- The need for any changes not to cause an undue administrative burden for patentees. Similarly the burden for the Board must be manageable.

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- Recognition that the pharmaceutical market is not a normal "free market" since most drugs are dispensed pursuant to a prescription and the patient may pay little or no money for the prescription. Even where the patient does pay cash he or she usually is not in a position to know the relative cost-effectiveness of the drug and make the same informed buying decision as occurs with other consumer purchases.

- Recognition that the pharmaceutical market grows at a faster rate than most markets. This is due in large measure to public and private subsidization that makes it easier for patentees to sell drugs that may be (a) more costly than some competitors in the same therapeutic class or (b) costly new therapies.

- Recognition that Canada has a publicly funded and administered health system but that with respect to drugs the public and private sectors play complementary funding and policy roles that need to be coordinated.

- Acceptance of the mission and values of the PMPRB, with the exception that Green Shield feels the mission should be expanded to include non-patented drugs

2.2 Recent Green Shield Research

Green Shield published studies of drug claims costs in 1992, 1994, 1998, and 2002. The 2006 edition (in press) examines data for 2000 to 2005 and expands the scope of previous research. Some preliminary results are relevant to this submission.

Over the 2000 to 2005 period aggregate employers' costs rose by 44.5% (7.6% annually) assuming a constant number of plan members. The high level cost drivers were price effect (8%), claim effect (16.4%) (volume used per claimant), drug mix effect (13.4%), and demographic effect (6.7%). The cost drivers were broken down into sub-drivers in the study. The 8.0% price effect, for example, comprised: 9.0% due to price changes, 1.9% due to increased fees, -2.9% due lower cost generics replacing higher cost brand products. The drug mix effect comprised: drug entry effect -2.7%, existing drugs mix effect 14.3%, exit effect 1.8%. The negative effect of drug entry is in dramatic contrast to findings in previous studies where the entry of new drugs had a large positive effect.

Another part of the study examined drug cost per claim exclusive of the pharmacist's fee and showed the average drug cost per claim rose from 39.97 in 2000 to 53.18 in 2005, a 5.8% annual rate of increase. In contrast the 2005 median cost per claim was only 26.80. The difference between the average and median is explained by the large number of low cost claims and the relatively smaller number of high cost claims.

Annual rates of increase in claim cost are lower than in previous Green Shield studies.

Claims were divided into Patented (as defined by PMPRB annual reports), All brand, All non-patented, Non-patented brand and Generic. The table provides the results for 2005.

2005 Patented, All Brand, All Non-Patented, Non-Patented Brand and Generic Shares of Claims and Costs

	Patented	All brand	All non-patented	Non-patented brand	Generic
% claims	33.0	62.3	66.9	29.2	37.7
% claim costs	62.7	84.0	37.3	21.3	16.0
Avg. cost/claim	101.06	71.72	29.63	38.79	22.50

The proportion of patented claim costs has always been similar to PMPRB results, typically 1% less. Until 2003 this continued to be the case. In 2004 65.2% of Green Shield costs were for patented drugs (compared to the 68.6% PMPRB result) and in 2005 62.7% compared to 71.4%.

The importance of non-patented claims is illustrated in the chart. Although they only comprise 37.3% of costs they comprise 66.9% of the claims. Stated another way, the PMPRB mandate and activity affect 33% of 2005 Green Shield prescription drug claims and 62.7% of drug costs.

2.3 Recent Ontario Legislation and Policy Changes

The Transparent Drugs System for Patients Act 2006 and its associated regulations and policies are likely to have profound effects on drug pricing in Ontario and throughout Canada. With respect to Brand prices it is proposed that special discounts and competitive arrangements will lower costs for drugs supplied through the public ODB plan but the published drug benefit prices (DBPs) will not reflect these price concessions. If there is no change in this policy the "net public prices" and the prices available to wholesalers and pharmacies will diverge. This effect may be compounded over time as manufacturers attempt to offset price concessions to government with higher prices in the non-government market generally.

The 2005 PMPRB Annual Report began reporting the patented prices by customer type and by province. This data is likely to become increasingly important in view of Ontario's changes.

For generic drugs Ontario is similarly proposing to have concessions for government (50% of brand prices) but higher listed DBPs (70% or 63% of brand prices). Published prices will continue to overstate the true prices being realized by generic manufacturers. The PMPRB work on comparing non-patented prices to international prices will become increasingly relevant. It will also be important to find ways of getting access to the net Canadian prices.

From the public policy perspective manufacturers' net prices should be transparent and available broadly.

2.4 Multiple Pricing Concerns

According to the May 2006 CIHI Drug Expenditure in Canada report (Table 2, page 13) 54% of Canadian prescribed drug expense is privately funded. Public policies that cause increased prices for individuals without coverage and for employer sponsored plans are worrying. We expressed our concern about multiple prices in our May 2005 submission on price increases as follows:

"As the market moves to having greater negotiation between manufacturers and large buyers and payers multiple prices with lack of transparency will potentially create unfairness where those without power in the market may pay higher prices than currently to offset the lower prices manufacturers give to large buyers, especially government. This will create challenges for the Board to ensure that there is some transparency in market prices and to ensure that maximum non-excessive prices reflect the universe of prices and the associated unit sales volumes."

This remains a concern and is even more apposite with the Ontario proposals.

2.5 Excessive Price Factors in the Act

Section 85 (1) of the *Patent Act* states, "…the Board shall take into account **the following factors**…" (emphasis added). This should be interpreted as applying not just a single factor but all the factors that are relevant in particular circumstances.

3.0 ISSUE 1 IS THE CURRENT APPROACH TO THE CATEGORIZATION OF NEW PATENTED MEDICINES APPROPRIATE?

3.1 Question 1 Are the new patented drug categories and their definitions appropriate?

In an ideal world a drug presented to the PMPRB for an assessment of its maximum non-excessive (MNE) price would come with data comparing it to other drugs in terms of effectiveness and safety.

Newly marketed drugs approved by Health Canada are evaluated for safety and efficacy, typically on the basis of clinical trials in controlled settings that are not representative of the way the drugs are used in the "real world". There is no assessment of their role in relation to drugs already marketed. It is therefore difficult to distinguish between "moderate" improvement and "little or no" improvement at the time of marketing and at the time the Board determine MNE prices.

It is important to recall that all patented drugs receive some reward by virtue of their lack of competition from generic products.

With respect to Category 1 (new strength or dosage form) the Reasonable Relationship test continues to be appropriate. Currently the Board uses the Therapeutic Class Comparison test (TCC) where the drug has a different therapeutic use or dosage regimen. Where the new DIN is the same chemical in either a different physical form (e.g. crystal size, optical isomer, delayed release) or chemical form (e.g. salt, ester, base) the manufacturer often makes claims of improvement (convenience, safety, efficacy) and the TCC would be the appropriate test. We support the approach for Category 1 subject to ensuring the TCC is used for physical and chemical modifications to a drug.

At a conceptual level Category 2 appears to be designed to preferentially recognize and reward true innovation (breakthrough) and substantial improvement; Category 3 seems to be designed to provide the price reward due to a patented product but with no special recognition or "premium".

At the conceptual level we support these categorizations.

3.2 Question 2 Is it important to distinguish a medicine that offers "moderate therapeutic improvement" from a medicine that provides "little or no therapeutic improvement?" If yes, why is it important? If not, why not?

At the conceptual level it is valid to distinguish medicines offering "moderate therapeutic improvement" from those offering "little of no therapeutic improvement". This encourages innovation by facilitating the implementation of a mechanism to reward moderate improvement.

There are difficulties in achieving this:

- At the time that MNE price determinations are made there is usually insufficient data to asses the relative value of the medicine (See response in Section 3.1)

- After marketing some drugs are found to have greater value than may have seemed the case initially; similarly some are found to have less value and may even be withdrawn from the market due to lack of effectiveness or adverse effects

- Moderate improvement may only be for a small subset of patients with a given condition. A premium price that recognizes this could be an excessive price for the majority of users where lower cost alternatives work as well

Another approach is to recognize moderate improvement by assuming that medicines that receive priority review, or establish a new therapeutic class, or become available for a new indication or as a new dosage form are moderate improvements. This approach is based on "novelty" with an "implicit" assumption that novelty is associated with improvement. Green Shield feels that novelty is already recognized in the granting of a patent. Further reward, in the form of a price premium, in the absence of evidence of moderate improvement is not appropriate.

One could argue that it is not important to recognize "moderate improvement" since it is rarely, if ever, possible to demonstrate this at the time of determining the MNE price. However, there are likely cases where evidence of moderate improvement is available. Green Shield argues that it is useful to make provision for rewarding moderate improvement where it is demonstrated.

3.3 Question 3 If the answer to question 2 above is yes, on what basis would a new medicine that offers "moderate improvement" be distinguished from a new medicine that provides "little or no therapeutic improvement"?

Moderate improvement would be demonstrated by showing "clinically significant improvement" in health outcomes and/or decreases in adverse effects. This improvement should apply to a "substantial proportion" of the persons likely to be treated with the medicine.

To develop a framework for defining "clinically significant improvement" and "substantial proportion" the Board would need to solicit expert advice.

A medicine rewarded with a "moderate improvement" rating based on evidence available at the time of its MNE price determination should be automatically reviewed at a later date based on "real world" experience and if the advantageous rating is later found to be unwarranted the MNE price should be reassessed, without retroactive penalty, based on only "little or no therapeutic improvement".

4.0 ISSUE 2 IS THE CURRENT APPROACH USED TO REVIEW THE INTRODUCTORY PRICES OF NEW PATENTED MEDICINES APPROPRIATE?

Previous Green Shield submissions have argued that the Therapeutic Class Comparison (TCC) price test is overly generous in that it allows medicines with no proven incremental value to price at the level of the highest price comparator. This means that the "innovation premium" awarded to the highest priced comparator is continually applied to more patented drugs that offer no incremental value.

Until the current Discussion guide there has been no data available to demonstrate the scatter of actual prices compared to the MNE price calculated using the TCC. As well it has not been possible to assess the implicit assumption that the International Price comparison (IPC) test is more generous than the TCC test. Thus the data provided on pages10 to 12 of the Discussion Guide is very helpful in dealing with Issue 2.

Our assessments on Issue 2 are based on:

- Category 2 drugs should be rewarded with a price test that is more generous than Category 3.
- Category 3 drugs should not normally be rewarded with a MNE price that equals the highest priced comparator using the TCC test.

4.1 Question 1 Are the price tests currently used to review the prices of new medicines in the various categories appropriate to that category? Why? Why not? If not how could these tests be amended to improve their appropriateness?

For Category 2 drugs the median IPC price is reasonable since it complies with the intent of 85 (1) c) of the Patent Act to consider international prices. We see no reason to change current practice.

For Category 3 drugs the TCC test as presently used is generous. This is the case since:

- Between 1999 and 2004 18% to 35% of Category 3 MNE prices using the TCC test would have been higher than the median IPC (used for Category 2) if the patentee had chosen to use the maximum allowable TCC price (Figure 2).

- In 2003 and 2004 65% of Category 3 DINs could have achieved a "price premium" above what have been allowed for a category 2 drug by pricing at the maximum allowable TCC price (Figure 3).

- Between 1999 and 2005 from 24% to 44% of category 3 DINs achieved a Canadian price premium compared to what would have been allowed if it were a Category 2 drug (Figure 4).

- Allowance of a price equal to the highest in the class increases societal costs, especially since new drugs (up to the highest priced comparator) replace older drugs in the class which are often the lower priced comparators and often generic versions.

Nevertheless the TCC can still be an appropriate test by amending its application to allow a lower amount than the price of the highest comparator.

One alternative to using the highest priced comparator is the use of the median comparator price. This would be consistent with the Patent Act requirement to consider the prices of other medicines (plural) in the same therapeutic class. This approach could be problematic however where there is only a single comparator and where each new comparator enters the market at about the same price. Another approach is to allow new Category 3 products a MNE price that is less than 100% of the price of the highest comparator. (See Section 4.2)

The median IPC and the highest IPC should continue to override the TCC price where it is higher.

4.2 Question 2 If you think that medicines that offer "moderate therapeutic improvement" should be distinguished from medicines that provide "little or no therapeutic improvement" what would the appropriate new price test be?

The price test for drugs that offer moderate therapeutic improvement should be the TCC (except where impossible or inappropriate to identify comparable drugs in Canada). Medicines with demonstrated moderate improvement should receive a premium above those with little or no improvement.

Further research to refine the comparison of the TCC test with the IPC test may be needed to determine the appropriate magnitude of the premium. The IPC, in principle, should be a more generous measure to reward breakthrough and/or substantial improvement.

Options

(a) Allow the median price for little or no improvement and a percentage premium above the median for moderate improvement.

(b) Base the determination of the MNE price on a proportion of the highest priced comparator –say 100% and 80%-- of the highest priced comparator respectively for moderate improvement and little or no improvement. Alternatively comparisons with the IPC may indicate that lower proportions to be appropriate say –90% and 70%-- respectively.

(c) An alternative to the above is to define the MNE price for Category 3 drugs as the lesser of the TCC and the median IPC price (as proposed in 1993). (The median IPC is already used for Category 3 where the TCC is impossible or inappropriate.)

(d) Options (a) plus (c).

(e) Options (b) plus (c)

4.3 **Question 3 For price review purposes, "comparable medicines" are medicines that are clinically equivalent. Do you have any suggestions as to the principles or criteria that should be used in determining how to identify "comparable medicines" for the purpose of inclusion in the above price tests?**

We concur with the current practice which is based primarily on the World Health Organization's Anatomical Therapeutic and Chemical (ATC) classification system at the 4th level sub-classes.

4.4 **Under the current Guidelines, Board Staff compares the Canadian average transaction price of the new medicine to the prices of the same medicine sold in the seven countries listed in the Regulations. However, Section 85 (1) of the *Patent Act* states that the Board should take into consideration "the prices of other comparable medicines in other countries". Should the Guidelines address this factor? If so, how could this factor be incorporated into the price tests for new medicines?**

The Patent Act provision to consider prices "in countries other than Canada" should be the primary directive for the Board. Obviously it would be cumbersome and onerous if too many countries were considered.. Also the countries chosen must be reasonably comparable industrialized nations.

The work that the Board has recently undertaken to investigate the prices of non-patented drugs illustrates additional countries (Australia, Finland, Netherlands, New Zealand and Spain) that could be considered in addition to those in the Regulations (France, Germany, Italy Switzerland, United Kingdom, United States, Sweden).

The non-patented study relied on data provided by IMS and it would be necessary to determine how comparable the IMS results are with the current average transaction price methodology. The mean and weighted mean foreign prices for 11 countries found in the non-patented drug prices study are very useful for validating the effectiveness of the current Board methodology and for fulfilling the Board's mandate under the Patent Act to consider the prices of comparable medicines in other countries".

If it is determined that it would be too onerous to study all 12 countries instead of the current 7, data could be considered on an occasional or ad hoc basis to confirm that the seven countries mentioned in the Regulations are meeting the directive of the of the *Patent Act*.

5.0 ISSUE 3 SHOULD THE BOARD'S GUIDELINES ADDRESS THE DIRECTION IN THE *PATENT ACT* TO CONSIDER "ANY MARKET"?

The National Pharmaceuticals Strategy aims to achieve lower prices. This may result in lower prices for government and higher prices for others. The Ontario changes mentioned in Section 2.3 illustrate how this may occur in Ontario. Other jurisdictions may adopt comparable strategies.

This is a major change that requires the Board to focus on the "any market" direction of the *Patent Act*.

Provinces and territories will rely on the Board to provide Average Transaction Prices (ATPs) by jurisdiction to ensure that they are getting reasonable prices in their respective jurisdictions.

Perhaps an additional discrete class of customer (government) should be considered with appropriate weighting. This would also assist employer sponsors to ensure that they are getting reasonable prices.

Page 13 of the Discussion Guide describes that the ATP for a DIN is determined by dividing the number of units sold into the total revenues. The method of calculating total net revenues described on page 13 needs to be revised. It should be made clear that the reference to "value of rebates, discounts, refunds, free goods, free services, gifts and other such benefits" should apply both where concessions are provided to the purchaser and also to cases where concessions are provided to others including to "governments in respect of publicly funded benefit plans, employers (public and private) in respect of employee benefit plans, and administrators of these plans (pharmacy benefit managers, insurance companies, others).

An additional service that the Board should provide is to publish on its website the up-to-date MNE prices. In this way purchasers would know when a price exceeds the MNE price and strategies could be considered to secure competitive prices.

5.1 Question 1 Given the price variation by provinces/territories and classes of customer illustrated in the previous figures, is it appropriate for the Board to only consider an ATP calculated based on the total revenues from the sales for all provinces/territories and all classes of customer? Why? Why not?

The percentage of 2004 new drug DINs deviating from the MNE price by province and territory and also by customer class (Figures 7 and 8) are significant in some cases; however the majority of prices equal the MNE price. Similar observations can be made for all DINs sold in 2004 (Figures 9 and 10). This is useful data and needs to be monitored over time.

Based on the data presented in Figures 7 to 10 one could argue that it continues to be appropriate to consider an ATP based solely on total revenues. Current trends and government policies indicate that the extent of the deviations is likely to increase; modifications to the total revenues approach may be needed.

5.2 Question 2 If the current ATP calculation is not appropriate, should the Board review the prices to the different classes of customer and/or the different provinces and territories for all DINs? Or should this level of review be done on a case by case basis, where there is a significant variation in the prices charged?

At a minimum ATP calculations should reflect concessions given to public benefit plans (e.g. for seniors and persons on social assistance and certain agencies (e.g. Department of National Defence). If concessions spread to employer payers and their administrators they should also be reflected in the ATP.

In addition ATPs for patented drug products should be publicly available in as timely a way as possible to provide transparency and facilitate price competition.

If deviations from MNE prices expand then ATPs should calculated by jurisdiction and by class of customer. Even in the current context the Board could announce its intention to monitor ATPs and publish comparative data by jurisdiction and by customer class.

With respect to classes of customer it may be time to add government as an additional class of customer. If concessions spread to employer payers and their administrators they may also need to be considered a separate class of customer.