Vernon Chiles,
Green Shield Canada

Memo

To: Patented Medicine Prices Review Board (sdupont@pmprb-cepmb.gc.ca)

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: May 9, 2005

Re: Green Shield Canada's Comments on the March 2005 *PMPRB Discussion Paper on Price Increases for Patented Medicines*

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*.

We are pleased that the Board has released the discussion paper on price increases.

This initiative by the Board is timely as illustrated in the paper's discussion on price stability in Section 3.0 and its review of the Current Environment in Section 4.0.

2.0 Signs of Change in Price Stability (Section 4.3 of the Discussion Paper)

This section highlights recent price increases for patented and non-patented drugs, cross border sales and supply issues and the Quebec response to the unprecedented number of price increase requests.

It concludes by asking whether we are seeing signs of the weakening of the price stability of the past decade. This question is even more apposite if one considers the trend to multiple prices and a lack of transparency in pharmaceutical pricing.

Multiple prices and lack of transparency in the U.S. market were reviewed by the Board's Working Group on Price Review Issues. It is not in the interest of Canadians to move to a U.S. style of pharmaceuticals market.

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. (See the Green Shield submission on the January 2005 proposed changes to the guidelines.)

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'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 (restricted formulary, influence on drug utilization patterns outside hospitals, buying group arrangements).

New types of competitive price arrangements are appearing. The drug Pantoloc®, for example, which has a price in the ODB Formulary of $1.90 is supplied to the Department of National Defense (DND) at $0.45. (See Report of the Auditor General of Canada November 2004 page 9 Section 4.77.) PMPRB may have more data on this type of multiple pricing and perhaps further data is available from DND.

The Auditor General's comments on the prices paid by NIHB will cause greater public and private focus on obtaining competitive prices and perhaps lead to more tiered pricing.

►The J&J drug Pariet® is an interesting case of tiered pricing. The 20mg tablet has a price comparable to its proton pump inhibitor competitors (e.g. Losec®). Two 10mg tablets however, cost much less than a single 20mg tablet and even less than the generic version of Losec® (omeprazole). As a result Pariet® has been able to get a full listing in the Ontario Drug Benefit Formulary whereas other PPIs have limited use restrictions.

►Reference pricing is likely to spread from British Columbia to public drug benefit plans in other provinces. Private sector plan administrators will imitate this cost containment approach for their employer (public and private sector) clients. Reference pricing leads to special prices in specific areas (e.g. geographic, drug plan managers). Plan managers are anxious to have as many products as possible available at the reference price. Manufacturers, in turn, are anxious not to lose market share where a reference price arrangement is in place for a therapeutic class.

►The prices of generic products listed in provincial formularies are often much higher than the prices actually charged ("price spread"). They may be the prices invoiced but "free goods" may substantially lower the true prices. Generic fluoxetine, for example, has a list price in the Ontario Drug Benefit formulary of $1.0112 but is supplied to larger pharmacy groups (chains, wholesalers) for less than $0.40. This data is anecdotal and the whole matter of generics pricing is opaque and varies with the pharmacy group (chain, solo operator or wholesaler) and the generic manufacturers. These special concessions are often arranged through a chain's central office and individual branch managers may be unaware that true generic prices are much lower than those published in provincial formularies.

►Saskatchewan's Standing Offer Contract system has resulted in strategic behaviour among generic suppliers. Smaller generic companies rely on larger generic companies to supply generics with the smaller companies' labels and DINs. The smaller generic companies then quote and win the contracts in the Saskatchewan formulary but do not sell in other provinces. This avoids scrutiny in other provinces on the discrepancy between the "list" large generic manufacturer's prices and lower prices for the same product packaged using the smaller generic manufacturer's label.

►Green Shield has been informally approached to list a drug with a high price to the pharmacy in exchange for a rebate given to Green Shield to then be passed on to the employer plan sponsor.

It is possible to administer such rebates for clients whose funding mechanism is Administered Services Only (ASO). In this funding method the client pays Green Shield a fixed charge or percentage per claim. For clients (typically smaller employer groups) whose funding is on a premium basis with a risk component built into the price it would be more difficult to return rebates to employers in a fair way. Thus rebate arrangements could be unfair for smaller groups with premium based funding; this is the funding mechanism for about 25% of our 1.2 million plan participants.

We are loathe to participate in such rebate arrangements unless they are transparent and disclosed in the market.

►Green Shield has also been informally approached to give favourable consideration to listing a non-patented drug at close to the U.S. price in exchange for a substantial rebate (~50%) as an inducement to list.

2.1 Price Increases and Usage for Non-patented Drugs

The proportion of patented drug expense (PMPRB 2003 Annual Report), BC data, Green Shield data) has risen dramatically to ~67%; this seems to be stabilizing.

The *2002 Green Shield Claims Cost Analysis* shows that for 2001, 65.1% of all claims cost is for patented drugs. Although total non-patented drug (brand and generic) costs are only 34.9% their proportion of total claims is 66.3%. The following table illustrates this.

2001 Green Shield Canada Drug Costs per Claim

	Patented	Total Non-patent	Brand Non-patent.	Generic
% of claims	33.7	66.3	29.7	36.6
% of claims costs	65.1	34.9	19.8	15.1
Avg. drug cost/claim	84.36	22.94	28.91	17.97

The 66.3% share of claims underlines that the discussion paper is correct in drawing attention in Section 4.3 to the importance of price increases for non-patented drugs.

3.0 Perspective and Principles in Responding to Price Increases

Before responding to the questions listed in the discussion paper Green Shield would like to identify the perspective and principles that underlay our approach.

3.1 Board's Mandate

The Board's mandate is "to ensure that the manufacturers' prices of patented medicines sold in Canada are not excessive." Prices should continue to be non-excessive after the initial evaluation of a patented medicine price as market conditions and the Canadian health system change. An assessment of the reasonableness of price increases should be considered in the context of high rates of increase in total pharmaceutical expenditures (Section 4.1 of the discussion paper) and increased market share for patented drugs (43.2% in 1990, 67.1% in 2003 [PMPRB 2003 Annual Report]).

The discussion should also examine the need for an expanded PMPRB mandate to assess the prices of both patented and non-patented medicines.

3.2 Administrative Efficiency

It is important that any changes not cause an undue administrative burden for patentees. Similarly the burden for the Board must be manageable.

3.3 Primacy of Excessive Price Factors in the Patent Act

The factors listed in the *Patent Act* include (a) prices of the medicine in Canada, (b) prices of other medicines in the same therapeutic class in Canada, (c) prices for the medicine and other medicines in the same therapeutic class outside Canada, (d) Consumer Price Index, and (e) other factors that may be specified by regulation.

It is not in Canadians' interest where an initial price which is determined to be non-excessive subsequently becomes excessive due to successive CPI increases. Thus all factors should come into play when considering requests for increases.

3.3.1 Other Factors

It may be that in Board's deliberations some other factor is identified that should be added by regulation. Examples worth exploring include (a) the proportion of a patentee's revenues spent on marketing and sales and (b) the proportion of R&D spent on demonstrating the value of a drug (e.g. comparative trials) in relation to other drugs in the same therapeutic class. Such changes by regulation would require PMPRB to enter into discussion with the government, presumably after a consultation process.

We would not support adding an economic argument as a criterion. An economic argument for a specific patentee's product would be difficult to justify since patentees' cost structures differ and one would not want to allow a price based on an economic argument for an inefficient manufacturer that would not be required by a more efficient manufacturer. Furthermore it is very difficult for the Board to determine operating costs given the international nature of the pharmaceutical industry.

3.4 Rights of Patentees

The *Patent Act* provides patent protection while ensuring that prices must not be 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.

4.0 Questions

Before addressing the discussion paper questions we make the following general comments:

►Patented drugs are protected from competition from generic manufacturers. Market exclusivity should diminish the economic need to raise prices in comparison with products that experience price competition.

►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 often does not reflect a balanced assessment of the market in a therapeutic class.

►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.

►The pharmaceutical market grows at a much 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 many of their competitors in the same therapeutic class or (b) costly new therapies in a new therapeutic class.

►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 multiple prices for different classes of customer issue 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.

►The pharmaceutical market is comprised of patented and non-patented drugs. It is not appropriate to consider either sector in isolation. Patented drugs become non-patented drugs when the patents expire. Patented drug manufacturers also market branded non-patented drugs that may never have been patented. Some own or have an interest in generic manufacturers. Both patented and non-patented drugs are in competition for formulary listings and prescriber and pharmacist patronage. It is inconsistent that there is no mechanism to prevent excessive prices for non-patented drugs.

4.1 Should the Guidelines allow for automatic (i.e. without prior approval) price increases?

We would agree with automatic price increases in accordance with guidelines provided they are submitted to the Board in advance of their effective dates in line with the January 2005 proposed amendments to the *Patented Medicines Regulations*. This minimizes administrative work for patentees and the Board.

To ensure that these automatic increases are in compliance with the guidelines however, it may be necessary for the Board to provide more information to stakeholders to assist them in ensuring that their price increases are not excessive.

4.2 Are there considerations other than, or in addition to, CPI that should be used to review price increases?

In addition to CPI the guidelines for price increases should require that the other factors mentioned in the *Patent Act* be considered.

Recommendation #1

All factors listed in Section 85 (1) of the *Patent Act* should be considered when assessing whether a proposed price increase results in an excessive price.

4.2.1 Excessive Price Factor 85 (1) (a) The prices at which the medicine has been sold in the relevant market

We are concerned that multiple pricing will create economic pressure on manufacturers that would result in their requesting higher "list prices" to enable them to accommodate requests from large payers and buyers for lower prices. These requests from governments, their ministries and agencies will be much more common pursuant to the September 2004 First Ministers' National Pharmaceuticals Strategy and in particular point 5 in the Strategy, "Pursue purchasing strategies to obtain best prices for Canadians for drugs and vaccines".

Under the January 2005 proposed amendments to the *Patented Medicines Regulations* manufacturers will provide details of the calculation of net price and net revenues. This would disclose the number of units or packages of a medicine sold at various prices to different customers. A "Net Price" is

determined which reflects the sum of the revenues divided by the number of packages or units. This "Net Price" should be the price to which any CPI related increase is applied.

Recommendation #2

A price increase should be limited so that any increased price of the medicine does not exceed the sum of the "Net Price" at which the medicine is being sold in Canada and the applicable CPI factor.

4.2.2 Excessive Price Factor 85 (1) (b) The prices at which other medicines in the same therapeutic class have been sold in the relevant market

Recommendation #3

A price increase should be limited so that any increased price of the medicine does not exceed the maximum non-excessive price as determined using the Therapeutic Class Comparison (TCC) test for medicines in the same therapeutic class sold in Canada.

For patentees to be able to comply with this requirement it will be necessary to continue and expand the Board's initiative to provide information on therapeutic class comparisons.

The discussion paper draws attention on page 11 to higher than CPI price increases for non-patented drugs. In considering the prices of other medicines in the same therapeutic class PMPRB is obliged to consider the costs of non-patented brand and generic medicines. Legislation does not grant PMPRB authority to determine whether non-patented drugs are sold at excessive prices. Legislation does however, prescribe a role for the Board in monitoring and using non-patented medicine prices in its work and certainly PMPRB could play a role in ensuring that non-patented drugs are not excessive. (See also the final general comment in Section 4.0 on page 5 above.)

Recommendation #4

PMPRB should explore with government and stakeholders whether it is appropriate for it to assume an expanded role in ensuring that non-patented medicine prices are non-excessive.

4.2.3 Excessive Price Factor 85 (1) (c) The prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada

Recommendation #5

A price increase should be limited so that any increased price of the medicine does not exceed the maximum non-excessive price as determined using the International Price Comparison (IPC) test.

For patentees to be able to comply with this requirement it will be necessary for the Board to provide information on international price comparisons.

4.3 How often should the price increase occur? (e.g. every year, once every 3-5 years, only after a certain introductory period, when justified)?

We offer no specific suggestions on frequency but would err on the side of allowing flexibility provided there is a minimum (such as the current one year).

4.4 If justification is required, what criteria should be considered?

Justification of a price increase is accomplished by demonstrating that the resulting increased price is in compliance with the factors listed in Section 4.2 above and the CPI guidelines.

4.5 Given that the CPI is established in the *Patent Act* as a factor to be considered by the PMPRB, do you have any comments on its appropriate application in future guidelines?

Considerations in using CPI are:

CPI is one factor listed in the *Patent Act* and is listed along with other factors. The Act implicitly leaves it up to the PMPRB to determine how to use CPI and whether to consider it in isolation or in concert with the other factors listed.

If the Green Shield approach of using all the factors listed in the *Patent Act* is taken this would be a more restrictive approach than the current CPI provisions and this may be adequate without changing to a lesser allowance than the full rate of CPI increase.

4.0 Frameworks

Three frameworks are outlined in the discussion paper. These are:

- Allow automatic price increases up to the maximum established guidelines. PMPRB review is after the fact with a readjustment of the price when determined to be excessive.
- Allow automatic price increases up to the maximum established guidelines but only after application to the Board and receipt of its approval.
- Require advance application and justification of proposed increases.

It is difficult to comment on these frameworks when one does not know what will be decided concerning other factors, proportion of CPI allowed, frequency of allowed increases and justification.

5.1 Automatic Increases with Review Later

If the Green Shield recommendations to use the factors in the Patent Act are adopted there should be sufficient data available to enable patentees to asses what would constitute an excessive price. In this case it may be possible to continue to allow for automatic increases in accordance with new Guidelines. This would minimize administrative efforts for both patentees and the Board.

5.2 Automatic Increases with Prior PMPRB Review

If major changes are made to the guidelines it will be difficult to anticipate whether patentees would be able to adapt to the new guidelines without having an inordinate number of excessive price increase requests. It may be appropriate to adopt the guideline changes and allow automatic price increases with review after the fact with the proviso that a large number of price roll backs after review would necessitate a further change in the guidelines to require advance approval before allowing price increases.

A large number of price roll backs would be of concern to Green Shield and its employer clients since there is no mechanism to recover excessive changes.

5.3 Justification

If the Green Shield approach is adopted compliance with the excessive price factors in the *Patent Act* constitutes adequate justification.

6.0 PMPRB Communications with Green Shield

Green Shield is pleased to submit these comments in response to the Board's discussion paper on price increases for patented medicines.

Any communications from PMPRB related to the content of this submission should be directed to Vernon Chiles, Vice Chair of the Board.

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