Rx&D Submission re:
Patented Medicines Regulations,
1994 (the Regulations)

Canada's Research-Based Pharmaceutical Companies

April 2005

Introduction

In February 2005 the Patented Medicine Prices Review Board (PMPRB) issued proposals to amend the *Patented Medicines Regulations, 1994* (the *Regulations*) and invited comments from stakeholders. The following comments represent the position of Canada's Research-Based Pharmaceutical Companies (Rx&D).

Background

The *Regulations* were first issued in 1988 and amended in1994 and outline the filing requirements for patentees pursuant to sections 80 and 88 of the *Patent Act*.[1] The filing provisions include filing of the identity of the medicine, ex-factory prices in Canada and reference countries, volumes of units or packages sold, net revenues or average price for each patented medicine. The *Regulations* require that patentees file extensive details on the pricing information reported to the PMPRB such that the price and sales data are broken out by package size, province and class of customer. The data are provided semi-annually for existing drugs and for the first 30 days of sales for new products. The *Regulations* also outline the strict deadlines within which the information must be filed.[2]

The *Regulations* also contain filing requirements for patentees' research and development expenditures and list the PMPRB reference countries however these latter items are not the subject of the PMPRB's proposed changes to the Regulations.

The plan to proposed changes was announced in the PMPRB's January 2005 Newsletter (released in February 2005) and portrayed in a manner that would lead the reader to believe that the proposed amendments were of a "housekeeping nature" when in fact some of the changes would represent a significant departure from the PMPRB's existing policies and in our view appear to extend beyond the authority granted by the relevant provision of the Patent Act. Moreover, the Timelines Project which is referenced in the Notice and Comment as the genesis of the current proposals was intended to be a consultative initiative with industry to improve the timeliness and efficiency of the price review process, but instead became a unilateral PMPRB process that has resulted in certain proposals that are not only impractical but may also be unlawful.

PMPRB Proposed Amendments to the Regulations

The Notice and Comment document published by the PMPRB outlines six proposed changes to the *Regulations*; these and Rx&D's position are outlined below.

[1] Section 80 refers to the identity and price and sales of patented medicines that are being marketed and to those that are no longer patented ("former patentees"), and s. 88 refers to research and development expenditures. The text of these sections can be found in the appendix

[2] Section of 76.1 of the Patent Act provides for severe penalties (fines, imprisonment) for patentees that fail to file information in accordance with the Regulations

1. Notification of proposed price

The PMPRB proposes to add a new section to the *Regulations*:

> 5. (1) In addition to the information referred to in paragraph 4(1) and for the purpose of section 82(1) of the Act, the patentee shall provide prior to the sixtieth day preceding the date on which the patentee first offers the medicine for sale, the price at which the medicine is intended to be sold.

The PMPRB's rationale is that it needs proposed prices to increase efficiency of the price review process of new patented medicines.

Rx&D's position is that the proposed amendment to require filing of proposed introductory prices prior to 60 days before the first sale:

- ***is unlawful,***
- ***threatens to delay patient access to new therapies,***
- ***adds inefficiencies to the PMPRB price review process and***
- ***is not practical,***

The PMPRB has adequate mechanisms under the current regime to conduct its mandate to review introductory prices in an efficient and timely manner.

- Regulations must be passed in accordance with the enacting statute. While the Patent Act, section 96, provides the PMPRB with authority to make rules regulating its practice and procedure, to make by-laws concerning its internal management and to issue guidelines on any matters within its jurisdiction, it has no power to make or amend regulations nor is it given any role in the regulation making process. Section 101 confers the authority to make regulations on the Governor in Council. It further provides that certain regulations, including those creating duties on the part of the PMPRB in relation to the introductory price of any medicine, or the powers to carry out any such duties, may only be made on the recommendation of the Minister following consultations with the provinces and such representatives of consumer groups and the pharmaceutical industry as the Minister considers appropriate. While the process the PMPRB is currently engaged in may result in recommendations for regulatory change being made to the Minister, it is not the consultative process that will have to take place prior to the Minister making any recommendations to the Governor in Council.
- Furthermore, even assuming the correct procedure is followed, the Governor in Council does not possess unlimited discretion to pass regulations. The regulations must be as contemplated by Parliament in furthering the purposes of the relevant parts of the enabling Act and must not be in contradiction to provisions of the enabling Act. As is noted in the PMPRB's discussion paper, section 82(1) of the Act already provides the Board with the authority to request proposed prices by Board order. The fact that this provision is embodied in the legislation rather than in regulation is important in assessing the scope of the regulatory power. Indeed there are a number of grounds for challenging the validity of the proposed regulation.
    i. In enacting section 82, Parliament made clear that a requirement to provide pricing information in respect of a medicine that is not being, and has not been, sold in Canada, is outside the scope of the regulation making power granted by Parliament under the Act.

ii. In enacting section 82, Parliament expressly confined the requirement to provide pricing information before the first sale in Canada to exceptional cases where the Board was empowered to require the information by individual order. A regulation requiring the production of such information in all cases contradicts the intention of Parliament expressed in section 82.

iii. In enacting section 82, Parliament expressly recognized the practical difficulties of setting a first sale date. A notice of intent to sell is not required in accordance with any general time frame but only 'as soon as practicable after determining the date'. The proposed regulation by replacing the flexibility contained in the statute with a standard, and arbitrary, time requirement contradicts the intent of Parliament expressed in the Act.

iv. In enacting Section 82, and specifically 82(3), Parliament requires patentees to provide introductory price information within the time that the Board may specify in its order but that, as provided by 82(4), no patentee is required to comply with such an order, or supply introductory price information 'prior to the sixtieth day preceding' the date of first sale. In section 82, Parliament thus expressly contemplates that introductory price information will be required within sixty days of the first sale and stipulates that it shall never be required prior to the sixtieth day preceding first sale. The proposed regulation requires all introductory price information to be provided 'prior to the sixtieth day preceding' the first sale. The regulation is in direct conflict with the intention of Parliament as expressed in the statute.

v. The purpose of the relevant provisions of the *Patent Act* that govern the regulation making power in issue is to assess prices being charged in the context of the time that they are being charged, as measured in part by the prices of other medicines in the same period in Canada as well as the prices of the same medicines in the same period in other countries. There is no basis in the Act for gathering information on proposed Canadian prices prior to sixty days before the first Canadian sale. Indeed the effect of the proposed regulation will be to delay the introduction of new medicines to the Canadian market as, in the normal course, it will not be until the issuance of a Notice of Compliance that patentees will be able to determine the first sale date. The regulation will then impose a sixty day delay before sale of the medicine. The imposition of such a delay is not within the contemplated purposes of the relevant sections of the *Patent Act.* From a broader policy perspective, this additional delay is contrary to the political will expressed by the Government to reduce drug approval times in Canada. The additional 60 days will de facto constitute a new form of pre-market approval and force the manufacturer to wait two months post Notice of Compliance (NOC) before making its product available to Canadian patients.

- As a practical matter, patentees generally begin marketing a new medicine as soon as is practicable after Health Canada issues a NOC, the date of which, if granted, is determined by Health Canada and not by the patentee. Even drugs first sold through the Special Access Program (SAP) are initiated by physicians and not the patentee who cannot determine in advance when the first sale will be. Regardless of the authority for so doing, requiring a proposed price sixty days before the first sale would have the effect of delaying introduction of new

patented medicines for sixty days after NOC further impeding patient access to new therapies. Further, in cases where the NOC is not granted, it would create unnecessary work for both the PMPRB and the patentee.

- Under the existing Regulations, patentees file introductory price data of new patented medicines within 60 days of the first sale reflecting the first 30 days of sales. Under its existing practices the PMPRB staff conduct an initial review of these 30 day prices and then again at the end of the semi annual period (June or December) to complete the introductory price review. By adding a pre-marketing review, the PMPRB will review the same price three times adding regulatory burden, with further and unnecessary use of the Board's scarce resources, and creating further inefficiencies in the price review process. This is contradictory to the Board's stated intention of improving timeliness of review and appears inconsistent with the Smart Regulation Initiative.
- The reality of the competitive pharmaceutical market is that prices are often established at the last possible opportunity to reflect changing market conditions. For example, the introduction or price changes of competing products, changes in the reimbursement policies of government drug benefit programs, and shifts in clinical practice can all impact on pricing decisions such that a Canadian price is often only established within a few days of first sale.

2. Notification of a proposed price increase

The PMPRB proposes to modify section 4 of the *Regulations*:

> (4) Notwithstanding subsection (2), any proposed increase to the price of the medicine, for any class of customers in any market in Canada, shall be communicated to the Board at least 120 days before the effective date of the intended price increase.

The PMPRB's rationale is that there is currently no provision in the *Regulations* that requires patentees to notify the PMPRB of price increases between reporting periods. In between reporting periods, the PMPRB must obtain this information from third party sources. Making notification of a proposed price increase a mandatory reporting requirement under the *Regulations* would purportedly ensure that the PMPRB receives this information in a timely manner thereby allowing the prompt review of any price increase. The PMPRB also asserts that it would allow it to notify patentees sooner if there appear to be pricing issues. The PMPRB acknowledges that the proposed amendment does not call for prior approval of a price increase, but rather seeks to ensure that the PMPRB has sufficient information between reporting periods on the state of prices.

Rx&D's position is that the proposed amendment to file price increases 120 days in advance:

- ***Is unlawful,***
- ***is not practical,***
- ***creates inappropriate profit seeking opportunities in the supply chain, and***
- ***adds inefficiencies to the PMPRB price review process.***

The PMPRB has adequate mechanisms under the current regime to conduct its mandate to review price increases in an efficient and timely manner.

- As noted above the power to make regulations is circumscribed by the relevant provisions of the Patent Act. These authorize the PMPRB to review only the prices of patented medicines that are being or have been sold – the PMPRB has no authority to regulate prices that will be established in the future. Requiring through regulation, notice of price increases and the imposition of a 120-day delay before they can be introduced is a restriction on the commercial activities of patentees that does not appear to be within the scope of regulatory authority of the relevant sections of the Patent Act.
- Given that the Patent Act authorizes the PMPRB to regulate actual prices and not proposed prices or price increases, the application of the PMPRB's compliance and enforcement polices with respect to these prices would be an inappropriate and inefficient use of the Boards resources.
- The reality of the competitive pharmaceutical market is that price increases are often established at the last possible opportunity to reflect changing market conditions. For example, the introduction or price changes of competing products, changes in the reimbursement policies of government drug benefit programs, and shifts in clinical practice and the timing of introductions in PMPRB reference countries can all impact on pricing decisions such that Canadian price increases are often only established at the last possible moment. Notification of price increases 120 days in advance is simply not practical.
- Notwithstanding the confidentiality provisions of section 87 of the Patent Act, Rx&D has no guarantee that pricing information provided to the PMPRB will remain confidential given the agreements in place between PMPRB and provincial drug plans, federal / provincial / territorial (FPT) committees, and the PMPRB's reliance on external consultants. Indeed, as a practical matter, once a price change is communicated to any third party it has to be assumed that it is public knowledge and that affected parties will adjust accordingly. Prior knowledge of price increases (or decreases) can result in profit seeking activities by wholesalers and pharmacies and other manufacturers will use the information to advantage and to the detriment of the Canadian consumers and the health care system. For example wholesalers with prior knowledge of a price increase will stockpile at the lower price but sell to pharmacies at the higher price once the increase becomes effective.
- Under the existing Regulations, patentees file price and sales information on a semi annual basis and the PMPRB conducts price reviews of these data. Given that PMPRB has acknowledged the information on inter-period price changes is already publicly available and that it does not intend to seek prior approval of price increases, it is not clear why the PMPRB wishes to add a significant additional regulatory burden on patentees. Moreover by requiring pre-notification of price increases the PMPRB will review the same price twice doubling the current PMPRB workload which will not contribute to the stated objective of timely review.

3. Details on the calculation of net price and net revenues

The PMPRB proposes to add the following sentence to paragraph 4(4) and (5) of the *Regulations*:

For the purpose of this paragraph, any amounts used in the calculation must be identified and reported on the appropriate form.

The PMPRB's rationale is that the *Regulations* and (PMPRB recommended) reporting forms require patentees to file net price or net sales, but that there is no requirement for patentees to provide information on how net revenues or net prices are calculated. To have a more complete picture of how the average price per package or the net revenue is calculated by the patentee, the PMPRB is proposing that the *Regulations* be amended to require patentees to file further particulars on the calculation of net prices and net revenues. The PMPRB asserts that this information is necessary for the PMPRB to have a better understanding of how the patentee arrived at its calculation of the average price per package for a particular medicine.

Rx&D's position is that the proposed amendment to file details on the calculation of net price and net revenue is:

- ***vague,***
- ***unnecessary,***
- ***adds to the already significant regulatory burden on patentees, and***
- ***creates inefficiencies to the price review process.***

The PMPRB has adequate mechanisms under the current regime to access details on the calculation of net price and net revenue.

- The proposed regulation is vague and makes reference to "appropriate forms" which are not referenced anywhere in the *Regulations*. The current practice is that patentees use the forms from the 1988 *Regulations* or electronic files (e.g., Excel) that provide the relevant information required by the *Regulations*. Given that the PMPRB has not provided details of the information to be provided or an exemplar of the proposed form, the PMPRB has offered inadequate information to justify the proposed amendment.
- Under existing practices, Board staff request additional information from patentees in cases where there is some uncertainty regarding the calculation of net revenues or net price and patentees provide the requested information in a timely manner. In the extraordinary event that a patentee does not voluntarily provide the information the Board can issue an order (under section 81) compelling the patentee to provide all relevant information.
- The PMPRB has offered no evidence that the current practice is not adequate to carry out its mandate in a timely and efficient manner. Indeed, requiring further information potentially adds a significant regulatory burden on patentees for no appreciable benefit to the price review process. This is explicitly contrary to the objectives of the Smart Regulation initiative, which aims to make regulation a source of competitive advantage not a burden.
- Indeed, by requiring the detailed information for all patented medicines the proposed amendment could increase significantly the workload of PMPRB creating inefficiencies in the price review process. For example, in 2003 the PMPRB monitored 1044 drug products (PMPRB Annual Report Table 3). When this number is multiplied by class of trade and 10 provinces, it yields 41,760 calculations for the PMPRB to review and check. This volume of work will not help the PMPRB meet its timeliness objectives

4. Product monograph / draft monograph

In section 3(1), which reads:

> 3. (1) For the purposes of paragraphs 80(1)(a) and 80(2)(a) of the Act, information identifying the medicine shall indicate

The PMPRB proposes to add:

> i) a product monograph, or draft monograph if a notice of compliance has not yet been issued;

The PMPRB's rationale is that the PMPRB uses the product monograph (or draft monograph in cases where the medicine has not received its Notice of Compliance) in the scientific review component of the price review process. Since it is not currently required under the *Regulations*, if a patentee does not submit a product monograph, the PMPRB must request it. As such, the *Regulations* should be modified to indicate that the product monograph/draft monograph automatically be submitted to the PMPRB for each new patented medicine.

Rx&D's position is that the proposed amendment to file product monographs is unnecessary. The PMPRB has adequate mechanisms under the current regime to access the product monograph of a new patented medicine. Moreover, there are confidentiality concerns with respect to the filing of draft monographs. Finally, draft monographs may change forcing PMPRB to repeat work based on the final monograph, compromising efficiency.

- The PMPRB's Guidelines and scientific review procedures require patentees to file a product monograph as part of its new medicine price review submission. To our knowledge all patentees file product monographs in a timely manner with the PMPRB. Indeed, the PMPRB has offered no evidence that patentees are not providing product monographs in a timely manner. Furthermore, in most cases product monographs are publicly available on company websites and the web site maintained by the Canadian Pharmacists Association (eCPS). Moreover, the PMPRB announced in its January 2005 Newsletter that filing a product monograph within specific timelines is a requirement to have a product reviewed by the Board's Human Drug Advisory Panel (HDAP). Finally, in the extraordinary event that a patentee does not voluntarily file a product monograph, the Board can issue an order under section 81. Accordingly, it is evident that the PMPRB has sufficient mechanisms through its Guidelines and the Act to ensure filing of product monographs in a timely manner.
- With respect to draft monographs there are confidentiality concerns. When a patentee files a draft monograph with the PMPRB, the Board shares it with its consultants (HDAP and drug information centres) and there are significant concerns that this proprietary confidential information is being disseminated without due consideration to the confidentiality provisions of section 87.
- Furthermore, Health Canada has an expectation that these draft monographs be kept confidential. This regulation may force us to go against Health

Canada's intentions. This is the kind of situation that the Smart Regulation Initiative explicitly wants to avoid. "We want to avoid situations where a new regulation or policy is introduced, only to find that it conflicts with that of another department or jurisdiction," said Minister Alcock in his March 24 press release.

- Finally, since draft product monographs are by definition drafts, they may change before NOC is granted. These changes could result in the HDAP or PMPRB having to redo their analysis and duplicate work. Thus increasing inefficiency and further harming timeliness

5. Recognition of electronic signatures

The PMPRB proposes to add the following new sections to the *Regulations*:

> 9. Any signature that is required by these Regulations to be shown on a record or document may be an electronic reproduction of the required signature.
>
> 10. Any information that is required to be maintained or filed with the Board by these Regulations may be maintained or filed with the Board in any electronic format from which a printed copy of the record can be produced.

The PMPRB indicates that approximately 87% of patentees are currently filing their price and sales information with the PMPRB electronically. Where the *Regulations* require that the information sent to the PMPRB be accompanied by a signature, patentees wishing to file electronically must also send a signed hard copy of the print out. As such, the potential for efficiency of electronic filing is not fully realized at this time. A change to the Regulations to formally recognize electronic filings would be appropriate.

Rx&D supports this amendment.

6. Filing requirements for veterinary patentees

Propose adding new text to section 4(3) so that it reads as follows:

> 4. (3) The information referred to in subsection (2) shall be provided:
> (a) within 30 days after the end of each period referred to in that subsection where the medicine is for human use; and
> (b) within 30 days following receipt of a written request made by the Patented Medicine Prices Review Board where the medicine is for veterinary use.

In September 2003, the PMPRB implemented a full complaints-driven approach for the regulation of patented veterinary drug prices. This decision was communicated to stakeholders in the January 2004 NEWSletter. Since the *Regulations* do not distinguish between the filing requirements for human drug patentees and veterinary drug patentees, the *Regulations* need to be amended.

Rx&D supports this amendment.

Appendix- Relevant Sections of the Patent Act

Pricing information, etc., required by regulations

80. (1) A patentee of an invention pertaining to a medicine shall, as required by and in accordance with the regulations, provide the Board with such information and documents as the regulations may specify respecting

(*a*) the identity of the medicine;

(*b*) the price at which the medicine is being or has been sold in any market in Canada and elsewhere;

(*c*) the costs of making and marketing the medicine, where that information is available to the patentee in Canada or is within the knowledge or control of the patentee;

(*d*) the factors referred to in section 85; and

(*e*) any other related matters.

Idem

(2) Subject to subsection (3), a person who is a former patentee of an invention pertaining to a medicine shall, as required by and in accordance with the regulations, provide the Board with such information and documents as the regulations may specify respecting

(*a*) the identity of the medicine;

(*b*) the price at which the medicine was sold in any market in Canada and elsewhere during the period in which the person was a patentee of the invention;

(*c*) the costs of making and marketing the medicine produced during that period, whether incurred before or after the patent was issued, where that information is available to the person in Canada or is within the knowledge or control of the person;

(*d*) the factors referred to in section 85; and

(*e*) any other related matters.

Limitation

(3) Subsection (2) does not apply to a person who has not been entitled to the benefit of the patent or to exercise any rights in relation to the patent for a period of three or more years.

1993, c. 2, s. 7.

Pricing information, etc. required by Board

81. (1) The Board may, by order, require a patentee or former patentee of an invention pertaining to a medicine to provide the Board with information and documents respecting

(*a*) in the case of a patentee, any of the matters referred to in paragraphs 80(1)(*a*) to (*e*);

(*b*) in the case of a former patentee, any of the matters referred to in paragraphs 80(2)(*a*) to (*e*); and

(c) such other related matters as the Board may require.

Compliance with order

(2) A patentee or former patentee in respect of whom an order is made under subsection (1) shall comply with the order within such time as is specified in the order or as the Board may allow.

Limitation

(3) No order may be made under subsection (1) in respect of a former patentee who, more than three years before the day on which the order is proposed to be made, ceased to be entitled to the benefit of the patent or to exercise any rights in relation to the patent.

1993, c. 2, s. 7.

Notice of introductory price

82. (1) A patentee of an invention pertaining to a medicine who intends to sell the medicine in a market in Canada in which it has not previously been sold shall, as soon as practicable after determining the date on which the medicine will be first offered for sale in that market, notify the Board of its intention and of that date.

Pricing information and documents

(2) Where the Board receives a notice under subsection (1) from a patentee or otherwise has reason to believe that a patentee of an invention pertaining to a medicine intends to sell the medicine in a market in Canada in which the medicine has not previously been sold, the Board may, by order, require the patentee to provide the Board with information and documents respecting the price at which the medicine is intended to be sold in that market.

Compliance with order

(3) Subject to subsection (4), a patentee in respect of whom an order is made under subsection (2) shall comply with the order within such time as is specified in the order or as the Board may allow.

Limitation

(4) No patentee shall be required to comply with an order made under subsection (2) prior to the sixtieth day preceding the date on which the patentee intends to first offer the medicine for sale in the relevant market.

1993, c. 2, s. 7.