

Rx&D Response to the  
Discussion Guide for  
Consultations on the Board's  
Excessive Price Guidelines



***Canada's Research-Based Pharmaceutical Companies***

**August 25, 2006**

## **EXECUTIVE SUMMARY**

- **The PMPRB should only assert its jurisdiction in cases where prices appear to be excessive in the context of the patentee abusing its patent rights;**
- **The notion of “excessive pricing” cannot be tied to an average or median, but rather it is a price that exceeds a threshold beyond which pricing would be considered truly egregious; and**
- **A medicine should only be considered to be priced excessively if it exceeds the prices in all other countries and the CPI adjusted prices of all other drugs in the therapeutic class.**

The PMPRB’s activities, including the Excessive Pricing Guidelines (Guidelines), must better reflect the original intent of Parliament: “to protect consumers and contribute to Canadian health care by ensuring that prices charged by manufacturers for patented medicines are not excessive.”

The PMPRB is authorized and empowered by the *Patent Act*. It must necessarily assert its jurisdiction in situations where a patentee’s prices appear to be truly excessive, such that the patentees’ pricing constitutes an actual abuse of its patent rights.

The PMPRB’s Guidelines and other activities should better reflect the balance of innovation and consumer protection. Injudicious price regulation will have a significant negative impact for patients, the Canadian health care system and on future innovative medicines and vaccines. The PMPRB must not become a barrier to entry for new medicines and vaccines, thereby denying patients and the health care system access to the latest therapies. The PMPRB should also adopt a more enlightened approach to the application of its mandate, allowing market forces rather than direct regulation to control pricing where appropriate.

The PMPRB’s statutory mandate has been incrementally and unjustifiably expanding since the passage of Bill C-91 (for example, by claiming to have jurisdiction over prices of patented medicines before patents even granted). This is inconsistent with Parliament’s original intent and should be reversed.

The PMPRB’s highly mechanistic application of the Guidelines recently has resulted in an unprecedented number of expensive and time consuming Board panel hearings, to the detriment of patients, taxpayers and patentees. In order to be an efficient and effective regulator, the PMPRB needs to exercise reasonable discretion in the application of the Guidelines, provided that such discretion is consistent with its statutory mandate and Parliament’s original intent.

## **INTRODUCTION**

With daily advances in modern medicine, Canada's research-based pharmaceutical companies play an integral role in the health of Canadians by providing new and innovative therapies. Innovative patented medicines are one of the most cost effective means to deliver quality health care to Canadians, representing less than eight cents of every health care dollar spent in Canada.<sup>1</sup> It is imperative therefore, that governments recognize the value of innovative pharmaceuticals in relation to Canada's health care system as a whole when they are considering the impacts of healthcare pricing policy.

The PMPRB defines its mandate<sup>2</sup> as "to protect consumers' interests and to contribute to Canadian health care by ensuring that prices of patented medicines are not excessive". Section 83 of the *Patent Act* supports the PMPRB's latter claim. Protecting consumers' interests also includes ensuring patients have access to innovative new medicines.

Although it is acknowledged that Canada is spending more on pharmaceuticals than in the past, it is also important to note that we're getting more for what we spend. For instance, one dollar spent on cardiovascular drugs results in a savings of nearly nine dollars in disability costs; for mental health drugs, \$5.60 is saved in disability costs for every one dollar in spending on medications.<sup>3</sup> Other studies have demonstrated dramatic reductions in the AIDS death rate<sup>4</sup> over a time period coincident with the introduction of antiretroviral drugs, savings on hospital costs of more than two and a half times the cost of medication for schizophrenia,<sup>5</sup> and potential savings in hospital and societal costs of \$122.4 million for the province of Ontario from a chicken pox vaccination program.<sup>6</sup>

Other studies and reports have confirmed that pharmaceuticals are often substituted for more costly hospital and physician care. A 2005 CIHI health expenditure trend report<sup>7</sup> shows that provinces that provide the greatest access to pharmaceuticals for their patients also spend the least in terms of total health care spending.<sup>8</sup> For example, Quebec provides patients with better access to innovative medicines than most provinces but the province spends the least in terms of total health costs.

A comprehensive research project has found that increased pharmaceutical spending in Canada clearly leads to improved health outcomes and cost savings for Canadians. The study, entitled *The Value of Pharmaceuticals in Canada*,<sup>9</sup> determined that over a 25-year

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<sup>1</sup> Canadian Institute for Health Information, *Health Expenditures by Use of Funds* (2004); PMPRB *Annual Report 2004*.

<sup>2</sup> Section 83, *Patent Act*.

<sup>3</sup> Narine, L. et al., "Economic Contribution of the Canadian Pharmaceutical Industry", PMAC; 1997.

<sup>4</sup> Government of Québec, *Portrait de l'épidémie de VIH/SIDA au Québec*, 2000.

<sup>5</sup> Castilloux, A.M., M. Savoie J. LeLorier, "Costs-benefits of resource utilization in the Quebec welfare recipients population using two atypical drug products", *European Neuropsychopharmacology*; 2000; 10(Supp. 3): 328.

<sup>6</sup> Law BJ, C. Fitzsimon, L. Ford-Jones, et al., "Cost of chickenpox in Canada: Part 2 – Cost of complicated cases and total economic impact", *Pediatrics* 1999; 104: 7– 14; American Academy of Pediatrics, Committee on Infectious Disease, "Varicella Vaccine Update", *Pediatrics* 2000; 105(1): 136–141.

<sup>7</sup> CIHI, National Health Expenditure Trends, 1975-2005. accessed at [http://secure.cihi.ca/cihiweb/dispPage.jsp?cw\\_page=media\\_07dec2005\\_e](http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=media_07dec2005_e)

<sup>8</sup> Also see Blomqvist, Åke and Jing Xu, "Pharmacare in Canada: Issues and Options," Working Paper Series, Health Canada, Ottawa, 2001 and Lichtenberg, Frank R., "Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS", *Health Affairs*, September/October, 2001 and "Benefits and Costs of New Drugs: An Update", June 2002, National Bureau of Economic Research, Working Paper Series No. 8996.

<sup>9</sup> Canada's Research-Based Pharmaceutical Companies, 2004.

period, rising pharmaceutical spending is strongly correlated with longer life expectancies and lower infant mortality.

These trends are again reflected in the findings of a recent study completed by Analysis Group Ltd. (Boston), which estimated that provinces could save \$1.35 billion annually in their health care budgets if they increase their per capita drug spending the same way Quebec did since 1980.<sup>10</sup> This study suggests that providing greater access to prescription drugs and encouraging their appropriate use are important elements to any long-term health care cost-containment strategy.

Clearly there is significant value in pharmaceutical therapy both to the quality of life of Canadians as well as the Canadian health care system. In order to continue providing innovative therapies to Canadians, it is important that the achievements and progress provided by Canada's research-based pharmaceutical companies are reflected in the prices of the innovative products that bring about advancements in disease therapy.

## **DISCUSSION**

### **Parliament's Original Intentions for PMPRB**

When Parliament created the PMPRB, its intention was to ensure that there was not excessive pricing as a result of Patent Act amendments that restricted the issuance of compulsory licenses. The purpose of the amendments was to restore some of the patent protection for innovative pharmaceuticals that had been taken away in the 1969 amendments to the Act. By "excessive", Parliament was not seeking to lower prices below what competition and market forces would ordinarily bring about. Rather, Parliament wanted to ensure that, in the absence of competition, patentees did not establish prices that were so excessive they abused their exclusive patent rights – exclusive rights that would not have existed had the compulsory licensing regime remained in place. Accordingly, "excessive" can only refer to some extreme upper limit beyond which prices are clearly abusive and not to an average or median price. Section 85 of the *Patent Act* lists the factors that the PMPRB must take into account, including prices of other medicines in the same therapeutic class, international prices and changes in the Consumer Price Index. In this context, it is clear that the price of a patented medicine can only be considered excessive if it exceeds the prices in all other countries, and the CPI adjusted prices of all other drugs in the therapeutic class.

### **Mandate Expansion**

Parliament's intention was that the PMPRB should focus on the prices of patented prescription medicines for human use. Indeed, virtually all the debate surrounding Bills C-22 and C-91 was concerned with the prices and costs of prescription drugs in the context of the Canadian health care system. Nevertheless, the PMPRB has insisted on regulating the prices of non prescription and veterinary drugs, a practice they are only now reconsidering. They have also claimed jurisdiction over the prices of medical imaging

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<sup>10</sup> Analysis Group, "Does Drug Use Reduce Utilization of Other Health Care Resources?," April 2005, (submitted for publication).

products as well as certain biologic products such as blood products and vaccines that are already subject to government oversight:

- **Blood products and vaccines.** The PMPRB continues to assert jurisdiction over the prices of blood products and vaccines even though these products are typically purchased solely by federal or provincial government (or government funded) agencies through competitive tender processes that result in multiyear contracts. These agencies have a mandate to ensure Canadians have a guaranteed supply of these critical products and that the government receives the best possible value for the products and related services that they purchase. The PMPRB interferes in this process by applying an additional set of price guidelines that take no account of the supply guarantees and value-added services provided through the tender process. The perverse effect of the PMPRB intervention is that manufacturers must structure their bids with PMPRB semi annual price reviews in mind rather than offering the best possible long term value to the agencies purchasing the products. In some cases, given the limited global supplies, manufacturers may even elect not to offer to supply the Canadian market if PMPRB insists on prices that are lower than those in Europe and the United States. It is doubtful that Parliament intended for PMPRB to duplicate the roles served by other government agencies and potentially compromise their ability to fulfill their mandates.

Over the years since the passage of Bill C-91, the PMPRB has sought to expand its mandate beyond that which Parliament originally intended:

- **Dedicated patents.** Patent dedication refers to the process by which a patentee surrenders its proprietary interest in a patent and dedicates that interest to the Canadian public. Through the act of dedication, a patentee relinquishes its exclusive ownership of the patent and its ability to sue other persons for patent infringement. Patent dedication has been practiced in Canada for many years for all types of patents (i.e., not just pharmaceutical).<sup>11</sup> From 1987 through 1994, the PMPRB acknowledged that it had no jurisdiction over drugs with dedicated patents but changed its mind in January 1995 to expand its price review mandate to include products with dedicated patents – a policy that some legal experts believe exceeds the Board’s authority under the *Patent Act*.
- **Jurisdiction in the Patent Application Period Prior to Patent Grant.** In 1995 the PMPRB claimed to have jurisdiction over prices of patented medicines before patents are even granted. This particular issue was litigated and finally settled in 2005 by the Federal Court in *Hoechst Marion Roussel Canada Inc. v. Attorney General of Canada (Nicoderm)*,<sup>12</sup> which ruled that the PMPRB had no jurisdiction in the patent application period. This decision was not appealed by the government. Despite a clear ruling in the Nicoderm case against the PMPRB, the PMPRB continues to claim to have jurisdiction in the patent application period, but retroactively once the patent issues.<sup>13</sup> This further attempt to extend its jurisdiction will likely once again result in a lengthy and expensive court case which many

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<sup>11</sup> Parliamentary Research Branch, November 1995 (<http://dsp-psd.pwgsc.gc.ca/Collection-R/LoPBdP/MR/mr136-e.htm>).

<sup>12</sup> *Hoechst Marion Roussel Canada Inc. v. Attorney General of Canada* 2005 FC 1552.

<sup>13</sup> See <http://www.pmprb-cepmb.gc.ca/english/View.asp?x=539&mp=254>

leading legal experts expect the PMPRB may lose. The issue is presently being considered by the Board panel as part of the Adderall XR pricing hearing.

- **Advance Notification of Prices.** Through the December 31<sup>st</sup>, 2005 proposed amendments to the regulations the PMPRB is seeking to require patentees to file information on introductory prices and price changes in advance despite the clear wording in the Patent Act that limits price reviews to prices at which the medicine is being or has been sold. It has no authority to review prices in advance except in exceptional circumstances as outlined in the Act. Nevertheless, the PMPRB is seeking to extend its mandate to prospective price approvals, which is consistent with its apparent desire to become a full blown price regulator and inconsistent with its statutory mandate with regard to the control of excessive pricing.
- **Patent Register vs. PMPRB definitions of “patented medicine”.** The Health Canada Patent Register was established through the C-91 amendments and the Patented Medicines (Notice of Compliance) Regulations and offers a clear definition of “patented medicine”. Only products listed on the patent register are entitled to full intellectual property protection available under Canadian law. PMPRB’s definition of patented medicine is far more expansive. The PMPRB seeks to claim jurisdiction irrespective of whether the patents have any direct relationship to the product on the market or if they have any commercial value. As a result, there exist inconsistent and even contradictory federal policies respecting patented medicines such that a medicine may be subject to PMPRB price review yet have none of the protection afforded by the Patent Register and may even face generic competition – a situation that is clearly beyond the mandate for PMPRB that was anticipated by Parliament.
- **Non-patented medicines.** The PMPRB now appears to be seeking to expand its mandate to include non-patented medicines. The PMPRB has taken the first step in this process by committing to conduct exhaustive analyses of non-patented drug prices on a quarterly basis despite a huge backlog of patented drug prices to review. There are currently 91 drug products under review and/or investigation or subject to notice of hearing.<sup>14</sup> Former PMPRB officials are on record as advocating that this would be a desirable expansion of its mandate.<sup>15</sup>

## Regulatory Expansion

Not only has the PMPRB taken steps to incrementally extend its mandate, but it has also imposed greater regulation by periodically redefining its definition of “excessive pricing.” In every case the proposed changes have been intended to lower prices below their existing levels.

- In 1992, the PMPRB proposed significant changes to its excessive price guidelines intended to lower prices of patented medicines below the international median. After a protracted consultation process the PMPRB eventually acknowledged that the proposals extended well beyond the definition of excessive, but still managed

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<sup>14</sup> PMPRB *Annual Report*, 2005, P.11, Table 5.

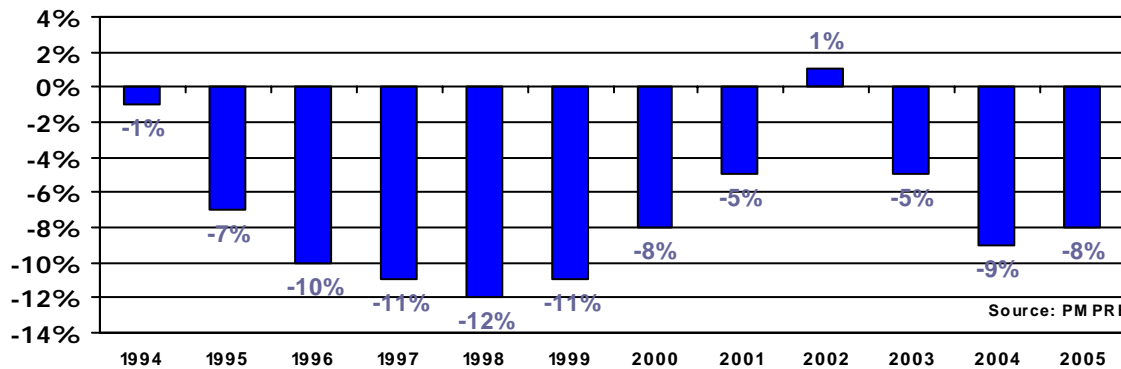
<sup>15</sup> See Wayne Critchley presentation at <http://www.chspr.ubc.ca/hpc/?page=presentations>

to implement changes in 1994<sup>16</sup> that have resulted in Canadian drug prices that are lower than even those anticipated by the PMPRB's overreaching definition of excessive.

- In 2000, the PMPRB decided to change the way it calculates the US price by arbitrarily averaging in the severely discounted price to the US Department of Veteran Affairs, a customer that on average represents only 1.5% of sales in the U.S.<sup>17</sup> Even the US government does not include these prices when they calculate an average selling price for establishing Medicare reimbursement limits. This change by the PMPRB required some manufacturers to lower their Canadian prices even though they were already lower than other drugs in the same therapeutic class and in many cases had never taken a price increase.

In 1993, the PMPRB stated that its objective was that prices on average should be at the international median – i.e., that is by definition some prices would be above and some below the international median price. Since that time Canadian drug prices have on average remained below the international median and in 2005 were 8% below the international median on average.

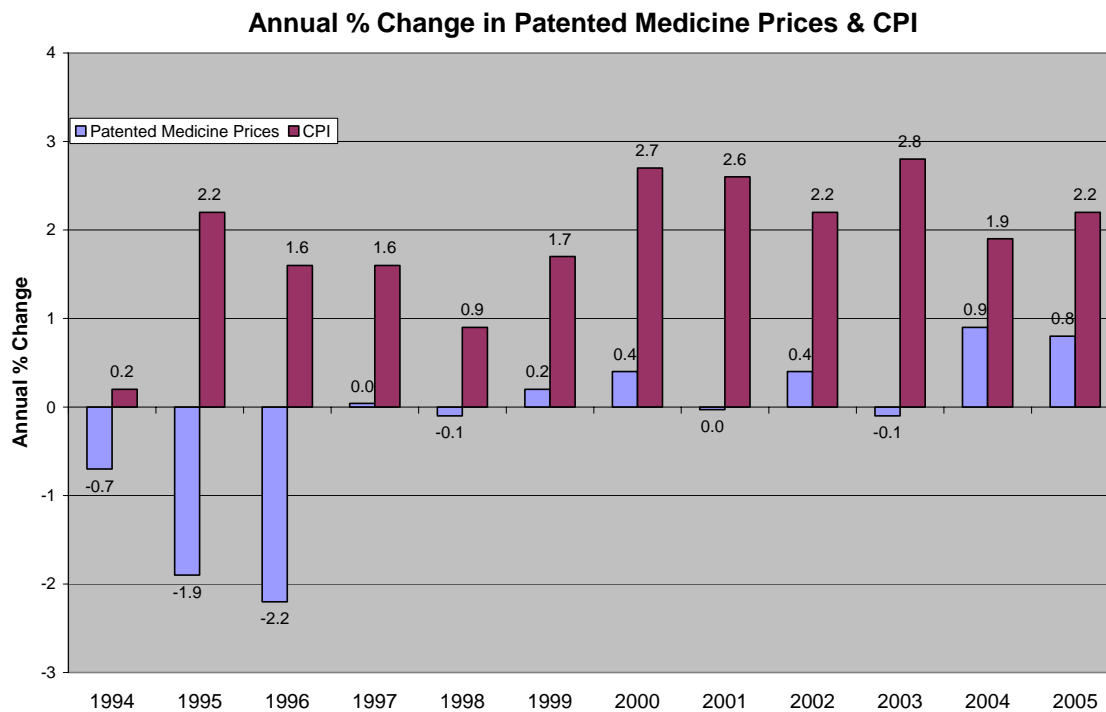
**Canadian Prices vs International Median**



Moreover, price increases have remained well below the inflation as measured by the Consumer Price Index – that is in real terms prices have fallen year after year. The following chart illustrates that prices of patented medicines have never kept up with inflation.

<sup>16</sup> The 1994 changes included changes to the CPI guideline such that permissible increases were limited to three year changes in the CPI (instead over the life of the drug product) and an additional price test was added such that the prices of new and existing patented medicines could not exceed the range of international prices, irrespective of the number of international prices available and the results of the other price tests.

<sup>17</sup> Danzon, P, *Price Comparisons for Pharmaceuticals*, April 1999.



For almost all new patented drugs the introductory price cannot exceed the range of prices in the therapeutic class – prices that have not kept up with inflation –, with the result that new products are also entering at lower prices in both nominal and real terms. This is confirmed by the PMPRB’s figures for category 3 drugs, which indicate that in most years the majority of category 3 drugs are priced more than 10% below the maximum allowable price permitted by the Guidelines. As demonstrated by the PMPRB’s own figures in their 2005 annual report, the market itself is an appropriate moderator for pharmaceuticals.<sup>18</sup> It is therefore difficult to understand why the PMPRB is once again contemplating even lower prices when prices are already well below even their definition of excessive. Indeed the evidence would suggest that, if there are to be changes to the Guidelines, it is time to allow higher prices.

The Guidelines adopt a definition of “excessive” that results in prices being considered as such if they merely exceed the allowable price under the Guidelines. It is important to note that the Guidelines do not have the force of law or regulations. Rather, the Guidelines are merely an administrative tool used by PMPRB staff to conduct an administrative review of patented drug pricing. In effect, they are a kind of “safe harbour” in that, if the price is below the designed acceptable level (based on a calculation made by PMPRB staff with reference to product category), then the price is generally deemed acceptable. However, if the price exceeds that permitted in accordance with the administrative tool, then the matter could result in a hearing before a Board panel. As discussed below, this mechanistic approach is inconsistent with Parliament’s intentions, which were that PMPRB should take action only when the “excessive” pricing is truly abusive in nature, and its application is resulting in expensive and largely unnecessary proceedings.

<sup>18</sup> PMPRB *Annual Report*, 2005.



It is worth noting that many of the hearings and investigations occupying the PMPRB and its staff are linked to the jurisdictional issues outlined above and the application of the Guidelines. These cases are taking so long (several years in some cases) to resolve that the PMPRB is unable to review prices of subsequent drugs that must reference the prices of the initial drug. As a result there can be a significant delay in the price review process. For example, the PMPRB states in its most recent Annual Report (released in June 2006) that it had not completed or resolved reviews for almost one quarter of the products introduced in 2005. The Annual Report also states that 14 products from 2004 and 3 from 2003 were still under investigation or subject to a hearing.<sup>19</sup>

Hearings are a complex court-like proceeding whereby the Board considers allegations by Board staff that the price of a particular patented medicine may be excessive. Hearings are conducted over several months or even years and are extremely costly in terms of legal fees and staff resources for both the PMPRB and the patentee. In the first 16 years of its mandate the PMPRB issued 5 notices of hearing, approximately one every three years. Since 2004, the PMPRB has issued 7 notices of hearing. As of July 2006 the Board had six hearings on its docket in various stages of the hearing process (two almost completed, while the other four will likely continue into 2007 and beyond).

Prior to 2004, the PMPRB recognized that the guidelines are not a rigid set of decision making rules but rather a starting point for reviewing prices of patented medicines. In recent years the PMPRB has done the opposite – the guidelines are applied inflexibly even if the outcome is illogical or unreasonable. As a result the PMPRB is now conducting hearings into products that have prices that are well below the median international price and/or are within the range of therapeutic class comparators. This rigid application of the present Guidelines without any reasonable discretion is contrary to Parliament's original intent with respect to the control of excessive pricing, negatively impacts potential investment by innovators, and also has a deleterious effect on Canadians' access to medicines.

In summary, the PMPRB has extended its jurisdiction far beyond that intended by Parliament, and is exercising its powers in a manner contrary to the interests of patients, taxpayers and patentees. Its policies and guidelines have evolved such that the PMPRB threshold defining excessive pricing has fallen year after year and that the underlying premise of excessive pricing equating to "patent abuse" has been completely lost.

### **Impact of Mandate & Regulatory Expansion on Patients and the Health Care System**

From its inception, PMPRB has had a consumer protection role: "To protect consumers and contribute to Canadian health care by ensuring that prices charged by manufacturers for patented medicines are not excessive."<sup>20,21</sup> However, the day-to-day functioning of the PMPRB has seen significant deviation in recent years from the original mandate established by Parliament.

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<sup>19</sup> PMPRB *Annual Report*, 2005.

<sup>20</sup> PMPRB Mandate and Jurisdiction. Accessed at <http://www.pmprb-cepmb.gc.ca/english/View.asp?x=175&mp=87> .

<sup>21</sup> PMPRB "Discussion Guide for the Consultations on the Board's Excessive Price Guidelines", May 2006. Accessed at <http://www.pmprb-cepmb.gc.ca/english/view.asp?x=271&id=56> .

The impact on restrictive price regulation is that new medicines are often introduced later in Canada than in other countries, or not at all. Moreover, the decline in R&D means that patients, physicians and allied health care professionals do not get to participate in clinical trials. Trials that provide patients earlier access to the latest medical advances that allow Canadian physicians and researchers to develop expertise in leading edge clinical practice.

One of the unintended effects of price regulation is that it creates deterrents for price competition. Price review policies that link prices of new products to prices of old products discourage manufacturers from lowering prices of the older products, even in the face of generic competition. The result is that the health care system not only fails to benefit from lower priced branded products, but generic prices also remain high. This is one of the factors contributing to generic prices in Canada that, according to the PMPRB's own assessment, are among the highest in the world.

### **Impact of Mandate & Regulatory Expansion on the Innovative Pharmaceutical Industry**

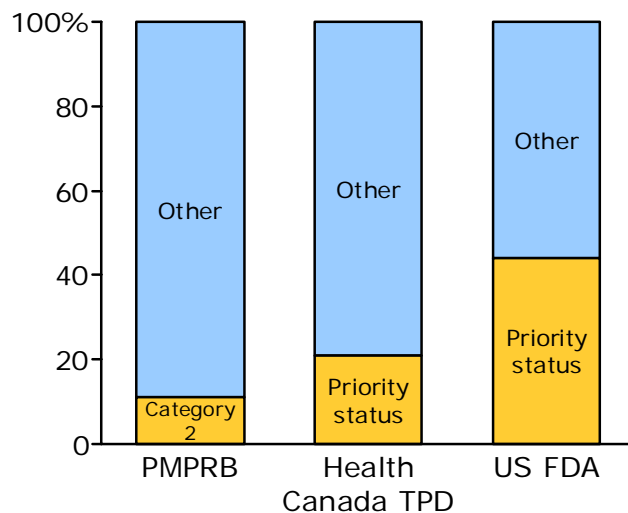
The patented pharmaceutical industry spent \$1.2 billion on R&D in 2005. Despite this significant expenditure, the R&D to sales ratios have on average been lower in recent years relative to the highs seen in the late 90's. This relative decline is the result of a deterioration in the investment climate in Canada, which in turn is the product of a pricing environment that makes Canada unattractive for marketing new drugs and for investment in the research and development that would typically precede and follow the introduction of these drugs. Indeed, it is unclear why manufacturers would invest in the basic research and clinical trials in Canada for innovative new therapies when it is apparent that the PMPRB will not allow the prices necessary to fund these investments.

The PMPRB consultations on its price guidelines combined with provincial initiatives (e.g., Bill 102 in Ontario) are creating considerable uncertainty for the innovative pharmaceutical industry and threatening investment and in-licensing opportunities. With several jurisdictions contemplating changes to their pricing policies, there is a significant risk associated with any investment in new product introductions in Canada. In other words, even if one jurisdiction accepts a particular price as cost effective, there is no certainty that it will be accepted by PMPRB or vice versa. Moreover, if a discount is provided to one drug plan as part of a listing agreement or similar arrangement, there is a risk that the policies of the PMPRB or other jurisdictions may undermine these agreements. This is already the case for products offered to federal or provincial governments under long term tender contracts.

An important factor in the deteriorating pricing environment is the failure of the PMPRB guidelines to recognize innovation. Whereas Health Canada and the FDA have recognized the importance of certain new therapies through the priority review system, the PMPRB, with few exceptions, has failed to recognize innovation and, as a result, has unreasonably limited prices. The following graph compares the percentage of products recognized as innovative by PMPRB, Health Canada and the FDA and illustrates that the

PMPRB's approach could be better informed with reference to other accepted standards of innovation.<sup>22</sup>

Classification of new active substances (1998-2003)



A recent study examined the relationship between drug price regulation and pharmaceutical R&D, finding that that price controls R&D by one-quarter and one-third, on average.<sup>23</sup> The US Department of Health and Human Services estimated that a one-percent reduction in drug prices led to a reduction in R&D spending of 0.68 percent.<sup>24</sup> The cumulative effect of each successive expansion in the PMPRB's powers has propelled it towards a role that diverges significantly from Parliament's original intended mandate. By significantly influencing drug pricing in Canada, the PMPRB can have a significant negative impact on future drug innovations, and reduce access to medicines for Canadian patients.

In a major study for the European Commission, Charles River and Associates demonstrated that the growth in R&D expenditures in the US has far outpaced R&D expenditures in Europe and Japan, where price controls exist.<sup>25</sup> This trend was noted despite the fact that many of the costs associated with development and bringing pharmaceuticals to market are much higher in the United States than in European countries.

In 2004, Bain and Company conducted a major review of the pharmaceutical R&D investment climate in Canada.<sup>26</sup> Their analysis revealed that in the decade from 1992 to 2002, there was a massive outflow of R&D investment activity from Europe and Asia to

<sup>22</sup> Bain and Company, *The Impact on Canada of Pharmaceutical Regulations and Pricing Policies*, 2004.

<sup>23</sup> Vernon, J.A. (2005) "Examining the Link Between Price Regulation and Pharmaceutical R&D Investment", *Health Economics*; 14:1-16.

<sup>24</sup> US Department of Health and Human Services quoted in Troyer, Jennifer and Alexander Krasnikov, "The Effect of Price Regulation on Innovation in the Pharmaceutical Sector", *Journal of Applied Business Research*; 18:4, Fall 2002.

<sup>25</sup> Charles River Associates (2004). *Innovation in the Pharmaceutical Sector: A Study Undertaken for the European Commission* (London: Charles River).

<sup>26</sup> Bain and Company, *The Impact on Canada of Pharmaceutical Regulations and Pricing Policies*, 2004.

the United States. Furthermore, in 2002, pharmaceutical R&D spending per capita in Canada stood at less than 1/3 the US', 1/3 the UK's and less than 1/2 of Japan's. Since almost all pharmaceutical companies invest in Canada at lower rates than their global average, it was concluded that the gap in R&D spend is due to structural causes. This cannot be attributed to a lack of an educated work force, higher wages, tax treatment of R&D, or infrastructure - in all such respects, Canada rates as well if not better than competing countries. The major driver of Canada's inability to attract its fair share of R&D investment is its commercial environment with respect to pharmaceuticals, including price regulation. By addressing the shortcomings in the commercial environment (of which the restrictive pricing guidelines of the PMPRB are an important component) the Bain study concludes that significant increases in R&D expenditures could be realized. It is estimated that achieving US levels of R&D spend per capita would add \$3.2B per year in R&D investment in Canada.

## **Proposed Solution**

### *Key Recommendations*

- *The PMPRB should only assert its jurisdiction in cases where prices appear to be excessive in the context of the patentee abusing its patent rights;*
- *The notion of "excessive pricing" cannot be tied to an average or median, but rather it is a price that exceeds a threshold beyond which pricing would be considered truly egregious; and*
- *A medicine should only be considered to be priced excessively if it exceeds the prices in all other countries and the CPI adjusted prices of all other drugs in the therapeutic class.*

Rx&D proposes that the PMPRB's guidelines better reflect the original intent of Parliament: "To protect consumers and contribute to Canadian health care by ensuring that prices charged by manufacturers for patented medicines are not excessive."<sup>27</sup> When the *Patent Act* was amended in 1987, Parliament's intention was to foster increased pharmaceutical research and development in Canada, while at the same time ensuring that prices of patented medicines are not excessive. The sensitivity of this balance was confirmed by the Standing Committee on Industry in 1997, when they wrote that, "[i]t is absolutely essential that everyone recognizes that to change one component is to set in motion a new balance, because so many issues are interrelated."

Accordingly, the PMPRB should only assert its jurisdiction in cases where prices appear to be excessive in the context of the patentee abusing its patent rights. After all, it is the *Patent Act* that empowers the PMPRB, and its excessive pricing mandate can only be exercised within a framework of patents and patent abuse. The present Guidelines do not reflect the factors set out in the Act. The notion of "excessive pricing" cannot be tied to an average or median, but rather it is a price that exceeds a threshold beyond which pricing would be considered truly egregious. This concept should be clearly reflected in the Guidelines. Section 85 of the *Patent Act* lists the factors that the PMPRB must take into

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<sup>27</sup> PMPRB Mandate and Jurisdiction. Accessed at <http://www.pmprb-cepmb.gc.ca/english/View.asp?x=175&mp=87> .

account, including prices of other medicines in the same therapeutic class, international prices and changes in the Consumer Price Index. In this context, a medicine might be considered to be priced excessively if it exceeds the prices in all other countries and the CPI adjusted prices of all other drugs in the therapeutic class. Even if more appropriate Guidelines are introduced, the PMPRB will need to apply them using reasonable discretion in order to ensure that all of their determinations truly reflect Parliament's original intent with respect to the control of excessive pricing.

Rx&D proposes that the PMPRB's Guidelines and the definition of excessive pricing be consistent with Parliament's intentions for the PMPRB and reflect the balance of innovation and consumer protection. The PMPRB's "regulatory expansion" of recent years has seen the PMPRB asserting its powers well beyond the original its parliamentary vision with respect to the control of excessive pricing. This ever expanding, and to a large extent, self-generated mandate has contributed to negative impacts to Canadian health care, particularly by stifling the development and introduction of innovative new medicines in Canada. These consequences are contradictory not only to the expressed intentions of Parliament, but also to the best interests of patients and the Canadian health care system.

## **APPENDIX - ISSUES RAISED IN THE DISCUSSION GUIDE**

### **Issue 1. Is the current approach to the categorization of new patented medicines appropriate?**

#### ***Question 1.1: Are the new patented drug categories and their definitions appropriate?***

Rx&D believes that the current system of categories employed by PMPRB for new patented medicines is unworkable and unnecessary. Moreover, a single definition of excessive pricing can be applied to all new patented medicines (see section 2 below).

The current categories for new patented medicines and their definitions do not adequately recognize the incremental improvements in clinical benefit offered by new, state of the art medicines. Many new therapies go unrecognized by the PMPRB because they are not considered “substantial improvements” or “breakthrough” medications. As a result, they are lumped into a third category for new medicines providing “moderate, little or no” therapeutic improvement over current treatment options. This is often the result of unrealistic criteria for category 2 classification. For example, many groundbreaking biological and antineoplastic agents were brought to market over the past three years, yet only six new medicines have been reviewed as category 2 new medicines since 2002. While the Board may be of the opinion that there simply have not been any substantial improvements or breakthroughs in medical therapy over that time, reviews of the same medicines by Health Canada and the US FDA suggest otherwise.

Rx&D believes that if PMPRB is to maintain a system of categories, it must establish realistic criteria for category 2 new medicines. The current criteria do not adequately recognize the value of the innovative new therapies that pharmaceutical manufacturers bring to the Canadian health care system.

#### ***Question 1.2: 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?***

No. As outlined above, there is no need for a system of categories. The establishment of a new “4<sup>th</sup>” category of new medicines that offer “moderate therapeutic improvement” is not necessary as it has no relationship to the concept of excessive pricing. A 4<sup>th</sup> category could offer yet another mechanism for PMPRB to seek even lower prices rather than develop a system that considers a true definition of excessive in the context of abuse of patent rights as intended by Parliament.

### **Issue 2. Is the current approach used to review the introductory prices of new patented medicines appropriate?**

No. The PMPRB’s guidelines need to reflect a true definition of excessive – that is where prices appear to be excessive in the context of the patentee abusing its patent rights. Accordingly, the notion of “excessive pricing” cannot be tied to an average or median, but rather can only mean a price that exceeds a threshold beyond which pricing would be considered truly egregious.

In the background analysis for this Issue, the Discussion Guide places considerable emphasis on the relationship of category 3 new medicines and the median international price. The analysis suggests that certain category 3 new medicines enjoy a price premium above the prices they could have charged had they been classified as category 2 new medicines. In fact, to clarify, the analysis appears to confuse price tests with category. While the TCC test may in some cases allow a price that is higher than the international median price test, a category 3 new medicine can never achieve a higher price than if it were a category 2 new medicine. That is because the pivotal test for category 2 new medicines is the “higher of” the TCC and the median international price tests.

There is also an underlying theme that somehow the international median price test should be reserved for category 2 new medicines because this is what the Board really intended. Indeed, the inference from these analyses is that prices of category 3 new medicines should never exceed the international median price. However this question was the subject of exhaustive analysis and consultation by the Board in 1992 and 1993. As a result of these consultations, the Board concluded that in fact it is anticipated that prices of some category 3 new medicines would exceed the international median but that “on average” prices would not exceed the international median. This formed the basis of the following “General Principle” outlined in the Board’s Bulletin 11:

The Board wishes to affirm the principle that the prices of patented medicines should not, in general, exceed prices in other countries. To this end, the effect of its Guidelines should be to ensure that the introductory prices of new patented medicines in category iii do not, on average, exceed median international prices.<sup>28</sup>

The principle clearly indicates that the Board expects some introductory prices of category 3 new medicines to be above the median and others below. The obvious implication of this principle is that it would be acceptable to the Board if 50% of category 3 new medicines had prices that are above the international median. That only 25% of category 3 new medicines had prices higher than the median in 2004 is confirmation that the Board’s Guidelines have limited price levels even more than was anticipated by the Board in 1993. Furthermore, in its reasons, the Board confirmed that limiting category 3 new medicines to prices that were the lower of the international median and the TCC test would be inconsistent with its mandate and its definition of excessive.

The mandate of the Patented Medicine Prices Review Board is to ensure that the prices of patented medicines are not excessive. **Its Guidelines, therefore, should be consistent with that standard, neither exceeding it nor falling short.**<sup>29</sup>

It is unfortunate for the consultation process that some stakeholders may inadvertently assume from reading the Discussion Guide that it was the Board’s intention that the prices of category 3 new medicines should never exceed the international median when in fact the Board concluded that such a guideline would overstep its mandate, and base their responses in whole or in part on the analyses provided.

***Question 2.1: Are the price tests currently used to review the prices of new medicines in the various categories appropriate for that category? Why? Why not? If not, how could these tests be amended to improve their appropriateness?***

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<sup>28</sup> PMPRB Bulletin 11, page 8, July 1993.

<sup>29</sup> PMPRB Bulletin 12, page 4, September 1993.

No. There is no need for new medicine categories and a single definition of excessive can be applied to all new patented medicines. Rx&D believes that the current system of categories and price tests goes well beyond Parliament's original intent with respect to preventing excessive prices. Under a true definition of excessive, the price of a patented medicine would only be considered excessive if it exceeds the prices in all other countries and the CPI adjusted Canadian prices of all other drugs in the therapeutic class.

**Question 2.2: 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?**

See 2.1 above. The price of a patented medicine would only be considered excessive if it exceeds the prices in all other countries and the CPI adjusted Canadian prices of all other drugs in the therapeutic class.

**Question 2.3: For price review purposes, “comparable medicines” are medicines that are clinically equivalent. Do you have any suggestions as to principles or criteria that should be used in determining how to identify “comparable medicines” for the purpose of inclusion in the above price tests?**

Comparable medicines should include medicines with an approved indication that is the same as the primary indication of the new medicine and/or evidence that the medicine is used in clinical practice to treat that indication. Comparable medicines may or may not be in the same ATC class but should be seen as alternatives to the new medicine in clinical practice. PMPRB should adopt an expansive definition of comparator as opposed to the increasingly restrictive ATC based approach that has been adopted in recent years. Indeed, the World Health Organization (WHO) (the agency responsible for maintaining the ATC system) has cautioned that it is a misuse of the ATC system to use it as a basis of specific pricing decisions.<sup>30</sup>

**Question 2.4: 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?**

We support the consideration of the prices of comparable medicine in other countries in cases where the initial price tests (as outlined in 2.1 above) suggest that a price may exceed the Board's guidelines. Indeed, the PMPRB has used this approach in the past when it approved (after public consultation) prices for Humalog and Viread that took into account the international relationship of the prices of these products to their comparators in the PMPRB reference countries.<sup>31 32</sup> This approach can also be considered in the context of the recommendation in 2.1 above. That is, if the Canadian price is higher than

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<sup>30</sup> WHO [http://www.whooc.no/atcddd/use\\_misuse.html](http://www.whooc.no/atcddd/use_misuse.html)

<sup>31</sup> PMPRB Humalog VCU

<sup>32</sup> PMPRB Viread Advanced Ruling Certificate



the range of international prices and the range of prices in the therapeutic class but the Canadian ratio of the price of the new product to a key comparator is in line with comparable international ratios, this would be evidence that the Canadian price is not excessive.

**Issue 3. Should the Board's Guidelines address the direction in the Patent Act to consider "any market"?**

***Question 3.1: Given the price variations by provinces/territories and class 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?***

Yes, it is most efficient to review prices at the Canada total aggregate level. As illustrated by the data presented under Issue 3 of the discussion guide, the current system of review is already adequate. As outlined in Figures 9 and 10, the vast majority of drug prices run up to 5% below the established MNE whether reviewed by province or customer classes. Clearly there is no need to review the ATP at every possible combination of province and class of customer. Such a system would only introduce new and unjustifiable inefficiencies into an already burdensome price review process.

Moreover, regulating the ATP within individual markets could ultimately eliminate preferred pricing to institutional and government purchasers. For example, many products sold to hospitals and public health systems are sold on a tender or contract basis that may include significant discounts for large orders. This is illustrated by the findings presented in Figures 9 and 10 of the Discussion Guide, which show hospitals as having the greatest proportion of discounts at levels greater than 10% below the MNE. If the PMPRB chooses to review the ATP within individual markets, it could foster a system that discourages preferential pricing to large buyers, thus undermining the abilities of large organizations such as hospitals and governments to negotiate pricing based on their purchasing power.

***Question 3.2: If the current ATP calculation is not appropriate, should the Board review the prices to the different classes of customers and/or the different provinces and territories for all DINs? Or should this level of review be done on a case-by-base basis, where there is a significant variation in the prices charged?***

In exceptional cases, PMPRB staff can review prices in individual regions or classes of customer. For example if the initial price review suggests that a price might exceed the CPI guideline, a sub-analysis may reveal that the apparent increase is the result of a shift in sales from class of customer to another and that in fact no customer experienced a price increase greater than CPI. Another example would be in the case of a complaint filed with the Board concerning a price increase – the sub-analysis at the province / class of customer level would be helpful in determining if the price increase did in fact exceed the PMPRB CPI guideline. However, it should be reiterated that this should only be necessary in truly exceptional cases, and that for the most part (as demonstrated by the Board's own data) reviewing prices at the Canada total aggregate level is preferable.