

# Patented Medicine Prices Review Board: Rethinking the Guidelines

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## PATENTED MEDICINE PRICES REVIEW BOARD: RETHINKING THE GUIDELINES

### BACKGROUND

The Patented Medicine Prices Review Board (PMPRB) was formed thirty years ago in response to fears that the discontinuing of the compulsory licensing system would result in a rapid rise in medication prices. At that time, changes to the *Patent Act* were the responsibility of the former Department of Consumer and Corporate Affairs. So it fell to this Department to prepare some form of “consumer protection” with respect to pharmaceuticals.

The decision to discontinue compulsory licensing was made following strong representation from organizations representing pharmacologists, physicians, pharmacists, academics, pharmaceutical firms and patent lawyers. When compulsory licensing was enacted the government promised that it would not affect drug research spending. Industry research expenditures in fact remained steady but those in other countries were growing at a rapid rate. So, relatively, Canada was losing ground. More importantly, the pharmaceutical industry saw Canada as a place that was not supportive of a pharmaceutical industry. This was illustrated by firms such as (then) Smith Kline and French announcing that their recently opened research facility in Canada would be sold and the research ended.

Pharmaceutical investment in Canada dropped substantially. Canada, which had become self-sufficient in pharmaceutical manufacturing, saw that newer drugs and sophisticated dosage forms were now being imported rather than produced in Canada.

Patent legislation in Canada was increasingly at variance with that of other developed countries and the existence of compulsory licensing was a major concern to Canada's trading partners. Trade agreements were hampered by this situation.

Finally, the lower prices of many new drugs made under compulsory licensing were being exported to other countries to the detriment of the pharmaceutical firms there. There were increasing legal and trade irritations with which Canada had to deal. Legislation changing Canada's patent laws was welcomed (Bill C-22) despite Senate foot dragging.

**In this climate the PMPRB was born. The former Department of Consumer and Corporate Affairs had very little expertise in the health and pharmaceutical areas and the legislation was drafted in haste. There was no stakeholder input and only a brief legislative debate. This was a clear case where sunset legislation would have been beneficial, instead the new legislation was implemented and problems accumulated.**

The goal of preventing excessive prices was imprecise and the general perception in Canada continues to be one that sees drug prices as excessive. This perception appears to be held, in particular, by Provincial drug programs. Surrounding this situation is the call for the pharmaceutical industry to make drug prices affordable to patients. If this was taken literally the price levels would have to result in all prescription prices being less than \$50, a figure at which a third of private insurance beneficiaries reported they would consider not purchasing the medication.<sup>1</sup>

## TOWARDS A MODERNIZED FRAMEWORK

In light of the turbulent history of the PMPRB over 30 years it is time for a review of the legislation.

The key issue appears to be clarity of purpose and operating structure. The fuzzy nature of “excessive prices” is evident from the various meanings offered for discussion. The correct answer is “none of the above” and a more nuanced goal would be to ensure that a drug is an accepted product within clinical guidelines. This approach would give consideration to “value for money” and enable comparative effectiveness analysis of a health program.

The questions for discussion within the *Discussion Paper* are narrowly framed in the context of price **even if price is irrelevant**.

For example, Question 1. D. asks if a product which has a price in line with similar products “should be considered potentially excessive if it accounts for a disproportionate amount of overall spending on drugs in Canada”. This situation describes an increase in utilization not price. The situation described is likely due to the product being preferred by physicians and patients. Total expense is the price times the quantity. Why should this be an issue for the PMPRB?

The use of the term “cost” is ambiguous; sometimes it refers to price and sometimes to expense. There appears to be an assumption that if price increases, the total expenditure will increase proportionately. A basic economic concept is that as price

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<sup>1</sup> *The Sanofi Canada Healthcare Survey 2012*

increases the quantity purchased decreases. In drug therapy, as a general rule, very expensive drugs are sold in small quantity.

In Alberta, the Minister of Health recently announced that a new drug cost over \$300,000 and that this was unaffordable. There were only two patients who received the drug as a benefit. If 2,000 patients needed the drug it would be different. So, even though the price remains the same the expenditure can be either affordable or unaffordable.

A rethink is necessary.

A new perspective is needed in which the health system does not revolve around drug price and avoids the concept that one can easily identify and “solve” excessive prices. To a large extent the competitive nature of the market will prevent what is seen as excessive prices and the health system in its use of comparative effectiveness will ration any cases of high prices. This rationing will decrease the total expenditure on the product, the same end point the PMPRB is attempting to do with increasing administrative expenditure on litigation and operational complexity.

The frame of reference for PMPRB is legislatively narrow and cannot meet the objective of substantially reducing prescription prices for patients. It can have some impact on health care expenditures on medication but this involves a wider scope that better meets the needs of the Provinces rather than those of patients, and the activities of the PMPRB are increasingly distorted in this direction.

**The PMPRB works on assumptions that are no longer valid, if they ever were. Based on the assumptions below, PMPRB cannot meet expectations of Canadians with minor renovation alone. There is a need for reconstruction or replacement.**

## PMPRB LEGISLATIVE ASSUMPTIONS

1. Pharmaceuticals are consumer products to be purchased by individuals.
2. Pharmaceuticals are not part of the health system.
3. Comparators selected in Europe are closely matched to Canada.
4. Price controls will have a positive impact on prescribing.
5. Reductions in drug prices will result in lower health care costs.
6. PMPRB is part of an overall government strategy to stimulate research.
7. Monitoring of drug prices provides valuable information for governments.

The above legislative assumptions are explicit, as stated in the legislation and supporting arguments, and implicit in the operation of the PMPRB. The added activities of PMPRB, reporting on prices and research, are supportive in nature. It is time to rethink these assumptions.

## 1. PHARMACEUTICALS ARE CONSUMER PRODUCTS PURCHASED BY INDIVIDUALS

It is estimated that 10% of Canadians, or 3.5 million Canadians, are without a drug benefit program and pay for their medication out of pocket.<sup>2</sup> This group is predominantly people who work in the private service sector or have part time jobs. For those with incomes below the national average this figure rises to 20%.<sup>3</sup> So, what price level for prescriptions would be affordable?

The reality is that most Canadians have drug benefit coverage through employer-based private insurance or government programs. These are the major beneficiaries of the price reduction activities of PMPRB. This is illustrated by the disposition of the \$7 million in “excessive prices” charged in 2015 which went mainly to hospitals and medical clinics (undefined) described as “Canadian customers”. It is unlikely that the patients who paid out of pocket received any money.

What is surprising is that PMPRB, since 1993, has accrued \$150 million from these “excessive price” charges for their own operations, money that should have gone to the people who paid an “excessive” amount for pharmaceuticals. **That a “consumer protection program” would adopt a “user pay” approach is fundamentally wrong.** The purpose of the program is to protect all Canadians so the funding should come from general revenue of the federal government. The justification that this allows the PMPRB to be “revenue neutral” is political posturing.<sup>4</sup>

The reality is that the PMPRB returns most money collected to the Provincial drug programs and that the “excessive prices” clawed back is basically a tax on the firms. Only the Provincial governments benefit from the lower price in lieu of tax payments.

This hardly reflects a consumer protection program that reduces drug prices to individuals. **The reality is that individuals can no longer afford to buy necessary medications and that publicly funded universal programs are required. This is the future context for PMPRB.**

<sup>2</sup> Law MR, *et.al.* The effect of cost on adherence to prescription medications in Canada. *CMAJ* 184(3). doi: 10.1503/cmaj.111270

<sup>3</sup> <http://www.oecd-library.org/docserver/download/8115071e.pdf?expires=1474391826&id=id&accname=guest&checksum=D758DA1AE13C8CFFF4A08FA496E2E7E1>. Accessed 9/20/16.

<sup>4</sup> Letter from the Minister of Health, Ottawa, dated July 25, 2016.

## 2. PHARMACEUTICALS ARE NOT PART OF THE HEALTH SYSTEM

Pharmaceuticals are the glue that link physicians, community health, residential and long term care facilities and hospitals. Availability or shortage of a drug has an impact throughout the system. If a firm decides that the Canadian market will not generate enough revenue, compared to other markets, due to slow regulatory processes<sup>5</sup>, delays in reaching the public market due to the assessment of cost effectiveness by the Common Drug Review, and further delays in negotiating with each Province and Territory, as well as the newly imposed pan Canadian purchasing negotiations, it is likely that new, expensive specialty products will not be marketed in Canada. Period. This will result in patients having less effective care and the health system having increased costs and longer wait times. Instead of easing the problems of access and inequity the unavailability of products will exacerbate them. This is not taken into account in the current system. Only the drug price is considered.

In the context of the health system the definition of excess price is relative to alternative therapy. If drugs cost less than other therapies they are not excessive. This is the basis of cost effectiveness approaches now in use by CADTH. It is clear that the concept of excessive price is a relative term and depends on context. In some cases the same price may be excessive and not excessive.

## 3. COMPARATORS SELECTED IN EUROPE ARE CLOSELY MATCHED TO CANADA

European pharmacare systems are national systems that have universal coverage and include most drugs. Their systems cover more medications, and often at higher prices, as they pay much less for physician services (just over half) and have a better system of social services that results in fewer patients with mental illness, dementia and disability, due to age, moving into the health care system.<sup>6</sup>

Pharmaceutical firms find it much easier to enter EU countries as there is only one regulatory review of a medication before it can be sold in all member countries. This makes for a simple, effective system in comparison with Canada.

The other comparator is the United States, wherein published prices do not reflect the myriad of discounts given to large purchasers.

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<sup>5</sup> For example, over a year for notice of compliance (NOC) to market the drug in Canada compared to 6 months maximum in most other jurisdictions.

<sup>6</sup> For a good case of higher value for money in health expenditure see, <http://www.cameroninstitute.org/2012/10/03/finding-canadas-healthcare-equilibrium/>

For Canada to find other “similar” systems it would likely be necessary to go to developing countries.

The PMPRB's *Discussion Paper* refers to Canada's ranking as being third from the top and third from the bottom. With the few comparators used this means either being in 3<sup>rd</sup> position or 5<sup>th</sup> position. This is not an important distinction. **More importantly for patients in medical need, Canada ranks 17 of 19 comparator OECD countries in terms of access to medication.**<sup>7</sup> Shifts between 3<sup>rd</sup> and 5<sup>th</sup> are more likely to be due to Canada's widely fluctuating exchange rate. Even the PMPRB's attempt to downplay this by using a 6 month average fails to materially affect the ranking when the Canadian dollar drops markedly compared to the US dollar or Euro. This is certainly more influential than company pricing policies.

Placing Canadian pricing in the mix of comparators with the view that they always be in the bottom is more mechanistic than realistic. There are a lot of factors at play in all countries and even if pricing was correct at the time of the decision it may not be in a later time period. Also, the concept that a country should try to have lower prices than other countries runs afoul of the notion that not all countries can be at the top or bottom.<sup>8</sup> The price that is targeted as a maximum will also become the minimum as firms have no incentive to have a lower price.

#### 4. PRICE CONTROLS WILL HAVE A POSITIVE IMPACT ON PRESCRIBING

Given the narrow scope of PMPRB legislation, clinical evaluations are now included in the review of medication to ensure that drugs likely to be valuable in treating diseases are made available. Thus more scope for the evaluation of price is provided. As a result some drugs are given a faster review because of their overall benefit.

The determination of price based on a small number of selected international comparisons (for controlling costs) is faulty. **The Canadian Institute for Health Information (CIHI) has determined that utilization is the major driver of total drug spend, not price.**<sup>9</sup> CIHI states that access to appropriate medication, quality of care and safety are more important considerations than drug prices.

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<sup>7</sup> [http://innovativemedicines.ca/wp-content/uploads/2016/05/20160524\\_Access\\_to\\_Medicines\\_Report\\_EN\\_Web.pdf](http://innovativemedicines.ca/wp-content/uploads/2016/05/20160524_Access_to_Medicines_Report_EN_Web.pdf). Accessed 9/20/16.

<sup>8</sup> Pharmaceutical manufacturers, like almost all consumer product firms that sell products globally, price their products using differential pricing, also known as Ramsey pricing, in which a firm charges a market/country/economy what it can bear related to mall others. Price controls in any one country have the unintended effect of raising or lowering prices in other countries.

<sup>9</sup> Canadian Institute for Health Information. *Drivers of Prescription Drug Spending in Canada*. Ottawa, ON: CIHI, 2012; also, [http://www.benefitscanada.com/wp-content/uploads/2014/03/03.14\\_DrugReport.pdf](http://www.benefitscanada.com/wp-content/uploads/2014/03/03.14_DrugReport.pdf) Accessed 9/21/16.

Many countries have health systems that improve the quality of care using pharmaceuticals. A search for best practices in pharmaceutical management would be more valuable to governments than simplistic price evaluations based on international price comparisons.

#### 5. REDUCTIONS IN DRUG PRICES WILL RESULT IN LOWER HEALTH CARE COSTS

The focus on a system that is “affordable” and “sustainable” based primarily on price does not assess the impact of availability and drug utilization on the affordability of the health system. Sustainability, as always, is undefined and is more a veiled threat than an operational concept.

Pharmaceuticals account for only 8% of public health care expenditures. The notion that this has a major impact on total health expenditure is unrealistic. Even the use of expensive drugs has offsets in reducing/avoiding other health care expenditures.

#### 6. PMPRB IS PART OF AN OVERALL GOVERNMENT STRATEGY TO STIMULATE RESEARCH

Research-based pharmaceutical firms have modified their research programs so that they no longer have major wet lab establishments conducting basic research. Instead they link to major academic research centres that have cutting edge research and a strong intellectual property portfolio. In this context, Canada is poorly positioned. Public funding of biomedical research is lower than that of comparative countries with the Canadian Institute for Health Research (CIHR) providing only about \$1 billion with little increase over the years.<sup>10</sup> In comparison, research-based pharmaceutical firms in Canada spend an equal amount, but primarily in clinical research which, in part, is in response to regulatory compliance requirements.

With respect to patents of new chemical entities (NCEs) Canada has a poor record.

Canada has an equally poor record in harmonizing its drug patent regime with the rest of the world. Court challenges to drug patents have removed patent protection for 25 products. One generic firm invests hundreds of millions of dollars in litigation on patents rather than on research, product discovery and clinical improvements.<sup>11</sup> This sends the wrong message to research-based firms that Canada wishes to attract.

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<sup>10</sup> <http://www.oecd.org/innovation/inno/researchanddevelopmentstatisticsrds.htm>. Accessed 9/20/16.

<sup>11</sup> Grootendorst P, *et.al.* Canada’s laws on pharmaceutical intellectual property: the case for fundamental reform. *CMAJ*. 184(5): 543–549. doi: 10.1503/cmaj.110493 PMID: PMC3307559

Clinical research requires strong support from major hospitals and Provincial governments. This has not been forthcoming. Organizers of major clinical research sites have had great difficulty in securing the needed support. It has fallen to individual researchers to work with firms to initiate clinical research studies. As a result Canada is losing clinical trials.

Initially, province-wide purchasing programs were developed to include an option for a firm to conduct research or commit to product development within a Province in return for listing a product as an insured benefit. With the initiation of a pan-Canada wide purchasing initiative this option has been dropped. Now it is just about money.

Overall, the disincentives for research in Canada are greater than the incentives. The contribution of PMPRB to this is little more than recording research expenditures. There should be absolutely no surprise, then, when the PMPRB in 2015 reported that research expenditures by research-based pharmaceutical manufacturers in Canada was half of the targeted annual amount and 25% of that spent in the PMPRB's seven comparator countries.<sup>12</sup>

Furthermore, the research of pharmaceutical firms in Canada is narrowly defined by Statistics Canada and the PMPRB. A recent analysis of pharmaceutical research expenditures in Canada by KPMG indicated that the amount of research conducted in Canada is understated by a significant amount.<sup>13</sup> It is not clear whether other countries use similar measures.

## 7. MONITORING OF DRUG PRICES PROVIDES VALUABLE INFORMATION FOR GOVERNMENTS

**Quite simply, it does not. If governments move toward universal coverage of medication in health care, as they should, it would make sense to shift the emphasis from price, and the need for expenditure control, to methods of managing utilization since utilization is more important than price to overall costs.**

**The most appropriate role for PMPRB in the above situation would be setting out clinical guidelines based on international comparisons and best practices. Without losing its acronym, the PMPRB could be transformed into the Pharmaceutical Management Policies Review Board. There is a dire need for this sort of information by the Provinces which would complement their desired move toward integrated care and electronic medical records.**

<sup>12</sup> <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1273#a8>. Accessed 9/20/16.

<sup>13</sup> [http://innovativemedicines.ca/wp-content/uploads/2015/05/2014-06-20\\_RxD\\_RD\\_Report\\_FINAL\\_EN.pdf](http://innovativemedicines.ca/wp-content/uploads/2015/05/2014-06-20_RxD_RD_Report_FINAL_EN.pdf). Accessed 9/20/16.

If something is not worth doing,  
it is not worth doing well.

*T. B. Newman, 2005*

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