Submission on PMPRB Guidelines Modernization – October 2016

Introduction

My comments will focus on the role of the Patented Medicine Prices Review Board (the Board) relative to private payers – insurance plans sponsored and paid primarily by employers, and personal out-of-pocket expenses. Traditionally the dominant focus of the PMPRB has been on public drug plans funded by federal, provincial and territorial governments.

In 2014, private drug plans funded over $10 billion (36%) of prescription drugs – almost equivalent to provincial governments – and individuals paid another $6.4 billion (22%) out-of-pocket.[1] Though contentious to academics advocating a single payer system, the crucial funding role played by private payers ought to ensure their participation in all prescription drug policy and program discussions.

Response to Board Questions

I would like to submit four recommendations to modernize the Guidelines aligned primarily with discussion questions 2, 4, 5, 8 and 9.

1. Update Guidelines regularly.
2. Improve transparency in drug pricing.
3. Integrate private payers as "customers" of the Board.
4. Change the comparator countries to all OECD nations.

These points will be discussed below.

1. Review and update the Guidelines regularly

These comments are in partial response to Discussion **Q8**. The PMPRB Strategic Plan 2015-2018 notes that since its establishment in 1987, "…many other developed countries with public health care systems have introduced measures to address affordability issues, maximize value for money and keep pace with a rapidly evolving pharmaceutical market (p. 2)."

I have assessed the German model in my doctoral research. Its laws and regulations are regularly revised, which stands in stark contrast to those of Canada and the provinces.

[1] Canadian Institute for Health Information, 2015. *Prescribed Drug Spending in Canada, 2013: A Focus on Public Drug Programs*. See page 9.

Germany – Recent Drug Policy Legislative History	
Year	**Legislation Name**
1989	Reference pricing introduced (Henschke, Sundmacher and Busse, 2013).[2]
1993	Health Care Structure Act
1998	Act to Strengthen Solidarity in Statutory Health Insurance [SHI]
2001	Pharmaceutical Budget Redemption Act
2002	Pharmaceutical Expenditure Limitation Act
2004	SHI Modernization Act
2006	Act to Improve Efficiency in Pharmaceutical Care
2007	Act to Strengthen Competition in SHI
2010	SHI Reform Act
2011	Pharmaceutical Market Restructuring [Reform] Act[3]

Source: Generally compiled from information in Busse and Blümel (2014).

I believe this is the first time the Board has considered Guidelines Modernization since its establishment in 1987. In that year, Canada spent just $3.3 billion on prescription drugs. If that figure was adjusted solely for changes in the Consumer Price Index, spending would have increased to $6.0 billion by 2015.[4] But in 2014, Canada spent a forecasted $28.8 billion on prescription drugs (CIHI, 2014). Notwithstanding the pan-Canadian Pharmaceutical Alliance (pCPA) negotiation of 118 products,[5] the provinces have made few major changes in their legislation and regulations pertaining to prescription drugs.

The Board must have a regular schedule to review and revise its pricing responsibilities and overall mandate. This could be aligned with its strategic planning cycle and would therefore much better reflect the dynamics of the pharmaceutical market.

2. Improve transparency in drug pricing

Responding to Discussion **Q2**, yes, the Board needs to immediately move beyond public list prices to determine what is a non-excessive price. Confidential Product Listing Agreements (PLAs) increasingly manage pricing and costs for all new drugs expected to have a material impact on provincial and, in recent years, private drug plans.[6] List prices for new drugs have become largely irrelevant.

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[2] According to Henschke et al., patented medicines were originally included in reference pricing along with their approved generic or therapeutic substitutes. In 1996, patent drugs were excluded to encourage innovation, but then included again in 2004 because so many drugs without clear additional benefits had been introduced.

[3] The PMPRB refers to this law as: "Act on the Reform of the Market for Medical Products" in its Strategic Plan 2015-2018 (2015b), p. 13.

[4] Statistics Canada reported the CPI at 69.7 in January 1988, and 126.5 in December 2015. $3.293 billion x 126.5/69.7 = $5.977 billion.

[5] See: http://www.pmprovincesterritoires.ca/phocadownload/pcpa/2016/pcpa_completed_negotiations_sept30_2016.pdf.

[6] PDCI Market Access Inc. and H3 Consulting have collaborated to survey PLAs in the private market, first in 2015, and again in 2016 (forthcoming). See: http://www.pdci.ca/manulife-drugwatch-private-payer-product-listing-agreement-pla-series/.

Canada and all other jurisdictions have accepted that confidentiality is a necessary feature of PLA contracting. However, Germany may be unique in publishing a list of patented drug prices set by the Deutsches Institut für Medizinische Dokumentation und Information (DIMDI).[7] The current price list runs for 938 pages, with thousands of drugs listed.[8] This occurs despite Germany being the third largest pharmaceutical manufacturer and the fourth largest consumer market in the world (Busse and Blümel, 2014). This suggests Canada should require greater price transparency and need not be worried about losing our disproportionately small amount of remaining research and development.

While German prescription prices do not appear to be much lower than Canada's ($741 Germany vs. $772 Canada[9]), German prices typically include a 19% Value Added Tax (Busse and Blümel, 2014).

Germany also enforces reimbursement limits. Limits were first negotiated between 2007 and 2010 for new drugs not subject to reference pricing. To avoid the price ceiling, the manufacturer had to establish: (i) product development costs, (ii) that the drug was cost-effective, and (iii) that it had no alternative treatment. Additionally, the Sickness Funds had to consider "the suitability and reasonableness of having the insured community take on the costs of reimbursement" (Busse and Blümel, 2014, p. 211). Following legislation enacted in 2011, drug manufacturers set the price for drugs containing new active substances for the first year but unless the product is deemed to provide additional benefits by the FJC,[10] the price is then limited to that of an older reference drug (Busse and Blümel, 2014).

As noted previously, private payers are beginning to contract with brand drug manufacturers for price reductions in Product Listing Agreements, but these are done separately from those of the pCPA. Combining volume from both payer groups would likely help lower prices and costs for beneficiaries from both camps, and improve administrative efficiency.

However, these changes leave an important gap, since history has demonstrated that individuals without the benefit of insurance are left paying the highest prices of all.[11] The out-of-pocket share of drug costs borne by patients has increased in recent years: 22% in 2014, versus 20% in 2012, 19% in 2010, and 18% in 2008 (CIHI, 2013; CIHI, 2014).

3. Integrate private payers – insurers, employers and patients – as "customers" of the Board

This section responds to Discussion **Q9**. Private drug plans pay more for drugs than provincial plans, and patient prices are even higher. For example, as more new drugs are subject to Product Listing Agreements confidential to the provinces, private payers are almost certainly targeted by manufacturers compensate for prices given to public plans. This is true also in the pharmacy fee limits imposed or negotiated by provincial plans; it appears that pharmacies shift costs to private payers.

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[7] The website is: https://www.dimdi.de/static/de/amg/festbetraege-zuzahlung/festbetraege/index.htm.

[8] I note at least some specialty drugs are not listed under their Canadian generic name, e.g., Avastin (bevacizumab), Lucentis (ranibizumab), Humira (adalimumab), and Remicade (infliximab).

[9] Op cit. OECD, 2014 pharmaceutical pricing data.

[10] Reimbursement decisions are made by the Federal Joint Committee (FJC / *Gemeinsamer Bundesausschuss, G-BA*) which includes voting representatives of sickness funds and health providers, with patient organizations attending as observers (Gress et al., 2007).

[11] The responsibility for this rests with the pharmacy industry which is not within the PMPRB's mandate. Still, it is important context for broader consideration of how the Board can have optimal impact on costs and prices.

This is not fair and constitutes excessive pricing for the majority of Canadians covered under private insurance plans. As employer fiduciaries, private insurers are beginning to more aggressively manage drug prices, but Canadians – especially those without insurance – still need the PMPRB to do all it can.

The simplest way to manage this issue is to require a single transparent price for a given product, regardless of region or payer. While the PMPRB could encourage or even require this, the pCPA could manage the price/cost negotiations and the implementation of the PLA.[12]

The crucial role played by private payers means they should be included in all national drug policy deliberations. The PMPRB Discussion Paper recognises its future Guidelines may consider the entire market. At stake is a justice consideration – all Canadians should benefit from federal policy, not just those whose insurance is provided by provincial governments. In addition to broader policy changes, the impact of excessive prices (or whatever new requirements arise from Guidelines Modernization) affects the private market – especially individuals without insurance. All Canadians buying prescription drugs have an interest in the Board's excessive pricing reviews (*Patent Act*, s. 83) and this would require a mechanism to ensure excess revenues also benefit private drug plans (perhaps according to market share) and even individual patients (perhaps implemented through a pharmacy's price files as a patient discount on subsequent purchases of the subject drug).

Private insurers, through their industry association, have previously requested a place on the PMPRB governing Board (CLHIA, 2013), which is currently limited to five members. The PMPRB may also consider including private payers in the Advisory Panel (*Patent Act*, s. 92(1)). It should be noted again that private payers include employers and patients in addition to insurers. In the main, private insurers administer but do not insure drug plans for larger employers where the majority of Canadians work. For these plans, decisions on formulary, eligibility, cost-sharing and other operational matters are made by the employer (and sometimes a union) and implemented by the insurer contracted to manage the plan. Since smaller employers have less risk tolerance, insurers take the risk and make these decisions.

The distinction between insurers and other private payers is important because to date only insurers have an organized – if occasional – voice in advocating an expanded role for its industry. Employers have not similarly organized on drug insurance but have a more direct interest in lower drug prices and reduced drug insurance costs because they pay the price passed on by insurers. Further, since private insurer administration costs are typically set as a percentage of premiums, insurers have less interest in slowing drug inflation because it also reduces their future revenues (Law, Kratzer and Dhalla, 2014).

Perhaps including private payers in ongoing consultations (s. 96.5) and as a stakeholder consulted for recommendations (s. 101.2) may be possible even without changes to the Patent Act because these payers represent "consumer groups" (employees covered by group drug plans) as described in the Act. While insurers and other parties may be given "intervener" status, their participation should not be incidental.

[12] Note the CLHIA has called for its inclusion in the pan-Canadian Pharmaceutical Alliance. I fully support this request as a principle of justice and for practical reasons to reduce duplication and fragmentation in our pharmaceutical market.

4. Change the Comparator Countries to all OECD Countries

Responding to Discussion **Q4**, I will assume for the moment that the PMPRB continues its mandate of non-excessive pricing and the current basket of seven comparator nations. Under these conditions, the price for new drugs should be set at the lowest price among those seven.

I recommend consideration be given to identifying other countries with lower prices. If the Board is already drawing comparisons to all OECD nations (Figure 2 in the Discussion Paper), then it should consider using that ready-made basket of nations and aiming at the median OECD price. Prices in the Netherlands indicate we could do even better. There, retail per capita pharmaceutical prices were just over half of those in Canada in 2013: $397 vs. $713 (USD, PPP. OECD, 2015). Drug manufacturers use several factors to set their prices in Canada, but 'unofficially', one factor must be willingness to pay. Why would Canada be willing to pay anything other than the lowest price?

Clearly there is some justification for pricing a product higher in a wealthier nation, assuming that governments or private insurers are willing to reduce or eliminate the price to lower income citizens. I have no personal problem with high-income nations subsidizing drug prices in less wealthy nations. However, OECD data indicate Canada's drug prices were the second highest among member states in 2014,[13] considerably out of line with our relative wealth which was ranked 14th in 2015.[14]

5. Pricing and R&D

Regarding Discussion **Q5**, I need a better understanding of why pharmaceutical R&D has declined for so many years. It is clear that the Canadian units of international drug manufacturers have been generally unable to achieve a reasonable level of investment here. The current evidence is overwhelming.

The PMPRB (2015 Annual Report) reported the R&D investment pool has declined in Canada in absolute terms by 44% from its peak of $1,325 million in 2007 to $739 million in 2014, just 4.4% of industry sales revenue.

Further, at 5.3% in 2012, Canada had the lowest R&D:Sales ratio of any of the PMPRB's seven comparator countries. Next lowest was Italy (6.1%) and then France at 16.1%. Canada's ratio was only one-quarter of the aggregate ratio (21.8%) of all seven nations in 2012. This dismal performance deserves thoughtful investigation.

My statements should not be interpreted as a condemnation of drug manufacturers. They frequently drive innovation and their products are as essential as hospitals and physicians. They operate in Canada according to current laws and regulations as they do elsewhere in the world. Many still invest significant sums in R&D in Canada and employ thousands of Canadians in well-paying jobs.

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[13] OECD (2016), Pharmaceutical spending (indicator). doi: 10.1787/998febf6-en (Accessed on 29 October 2016). Rankings by USD per capita, 2014 (the most recent year available). Available at: https://data.oecd.org/healthres/pharmaceutical-spending.htm.

[14] OECD (2016), Gross domestic product (GDP) (indicator). doi: 10.1787/dc2f7aec-en (Accessed on 29 October 2016) Rankings by GDP per capita, USD, 2015 (the most recent year available). Available at: https://data.oecd.org/gdp/gross-domestic-product-gdp.htm.

Specifically responding to **Q8**, in general it seems reasonable to expect pharmaceutical prices to fall with the advent of multiple indications and new competitors, rather than increase with other consumer prices. However, I suggest that individual manufacturers that exceed median levels of pharmaceutical R&D in Canada qualify for somewhat higher prices as an investment incentive.

Conclusions

In general, updating the Guidelines is long overdue. However, we now have the benefit of greater impetus to make changes given the end of the patent cliff, the resumption of drug price and cost increases, and a more robust new drug pipeline that promises important innovations and better patient outcomes, but at much higher prices. These circumstances will not improve the financial sustainability of private drug plans, nor the personal affordability of essential medicines. Equally important, governments have important trade-offs to make in choosing how much of their budgets should be dedicated to the health system, and how much to more important social determinants of health.

In general brand manufacturers have not fulfilled their R&D commitments for many years, and there is an increasingly small domestic drug manufacturing industry to protect. Therefore, I believe we are left with a sole focus on price and cost, which is unfortunate given this country's potential as a much more important pharmaceutical research and development centre.

Fundamentally, I believe the PMPRB – Board and Advisory Committees – should be mandated to protect all Canadians from excessive prices that must be defined differently now than in 1987. Greater pricing transparency must be mandated and private payers – insurers, employers, patients – ought to be equally protected whether they have third-party insurance for medicines or they pay out-of-pocket. Private payer representatives should also play a commensurately larger role in system governance.

Thank you for providing an opportunity to respond to the Guidelines Modernization initiative.

Text References

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