Managing drug costs by regulating prices… balancing budget and access risks in the search for sustainability.

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Introduction

There is an unprecedented amount of change occurring in the reimbursement landscape for prescription medicines in Canada. The federal government is consulting widely on a renewed push for national pharmacare[1]. (Editor's note… see the other feature article in this issue). Health Canada and the Patented Medicine Prices Review Board (PMPRB) are implementing the most significant changes to patented drug price regulation since the PMPRB's inception in 1987[2]. The Canadian Agency for Drugs and Technologies in Health (CADTH) is leading the development of a framework to review Drugs for Rare Diseases (DRD).[3] Finally, the pan-Canadian Pharmaceutical Alliance (pCPA) released a "Biologics Policy Directions" paper in September 2018. Along with the earlier "First Principles" document, this policy paper will govern how biologic and biosimilar products are negotiated and considered for reimbursement by public drug plans.[4]

With all these changes afoot, one common theme runs through all of them: growing concern about drug expenditures in Canada.

This article investigates the trends behind drug expenditure growth in Canada and the implications that regulatory changes to patented drug pricing could have on access to innovative therapies.

In a previous version of this article, the editor had added a sentence to the original text which changed the meaning intended by the authors. This has been corrected.

Drug expenditures and the changing mix of reimbursement.

Total prescription drug expenditures are increasing around the globe. IQVIA estimates that the global pharmaceutical market is poised to grow to US$1.5 trillion by 2023.[5] In Canada, public and private drug plans spent CA$33.7 billion in 2018.

High-cost, low volume specialty drugs represent a large share of these expenditures. According to TELUS Health[6], specialty medicines account for an estimated 0.96% of claims, but make up 25.9% of expenditures in private plans. A PMPRB annual report states that, in 2016/2017, high-cost medicines accounted for 27.7% of public spending while comprising only 0.29% of prescriptions.[7] As new drugs become more specialized, there will be increased pressure on drug plan sustainability.

Drug budgets.

One contributor to increases in drug budgets is the entry of high-cost drugs (e.g. next-generation biotherapeutics, gene therapies and stem cell therapies) to the market. From 2016 to 2017, 90% ($1.07 billion) of total growth in patented drug spending in Canada resulted from an increase in the sales of 10 drugs[8] whose annual treatment costs ranged from CA$2,948 to $57,928.

However, despite the entry of more high cost specialty drugs, there are offsets that contain the growth of drug budgets: patent expiries, generic substitutions, price reductions negotiated with public drug plans, and private drug plans' use of plan design elements such as patient deductibles and copayments. (Pharmaceutical companies often offer financial assistance to patients to ensure cost is not a barrier to treatment). The IQVIA study cited above estimated that, by 2023, 18 of the current top 20 branded drugs will face generic or biosimilar competition. Competition in the biologics market will be nearly three times larger than it is today, resulting in an estimated US$160 billion in lower drug spending globally over the next five years. These savings will inevitably be passed on to Canadian payers: CIHI has already reported that introduction of a generic version of duloxetine led to significant savings in the antidepressant drug class in 2018.[9]

Budget risks.

Despite these budget offsets, the possibility that a high cost specialty drug might land within an employer's private drug plan raises concern about how risks and costs can be managed. DRD submissions to the CADTH Common Drug Review (CDR) nearly doubled between 2004 and 2015.[10] And, approximately 7 out of 10 drugs entering pCPA negotiations for the past three years have been specialty products.[11] As high-cost specialty drugs continue to increase in proportion to lower-cost drugs, the risk increases that any given drug plan will end up with a high-cost claim.

In response to growing concerns about budget risk and affordability, attention is turning to drug prices as a means to manage drug expenditures. The thinking goes: drop prices to reduce expenditures. Although it may not be unreasonable to consider drug pricing as a mechanism to manage drug budget growth, plans need to be careful to avoid an unbalanced focus on drug price alone. There are many potential tripwires with such a single-minded focus. A careful examination of the consequences of a proposed overhaul of pricing regulations raises serious concerns about the future of drug launches and access to new therapies in Canada.

The history of drug prices vs. drug expenditures in Canada: from predictability to risk.

Since the PMPRB's inception, prices for patented medicines in Canada have typically been at or below the median of seven countries (United States, United Kingdom, France, Germany, Switzerland, Italy, and Sweden) with economies similar to Canada.[12] PMPRB has a solid track record of meeting its mandate to ensure that patented drug prices are "non-excessive", with drug prices in Canada currently 21% below the international median.[13]

Despite the record of the PMPRB, solutions to drug budget management continue to focus on drug prices.

The mis-use of cost effectiveness to set drug prices: replacing one risk with another.

There are five proposed changes to pricing regulations that the PMPRB could apply to new drugs launching in Canada.

- Changing the basket of countries used for international price comparisons from seven to 12
- Reducing the regulatory burden for generic drugs
- Requiring patentees to disclose all third-party discounts and rebates
- Continually assessing market size/growth, which would permit additional price reductions up to three years post-launch
- Applying a health economic tool, referred to as the "cost-effectiveness threshold", to establish much lower price ceilings for patented drugs

Most of these changes increase the level of uncertainty for manufacturers wanting to launch new drugs. Applying the cost-effectiveness threshold for price setting raises the greatest concern.

A cost-effectiveness analysis calculates the difference in costs and health benefits of a new treatment compared to the current standard of care. It is designed to estimate the relative value of a new treatment. It is not a policy tool to set a drug price.

Cost-effectiveness analyses are based on incremental costs. Therefore, there is an inherent assumption that a drug plan will pay more for a new treatment that results in an improvement in patient health. And here's the rub: new high-cost specialty treatments that have better outcomes than currently available treatments will cost more; they are expected to. As such, a cost-effectiveness analysis does not address affordability. By applying an arbitrary "cost-effectiveness threshold" to drive down drug prices, the PMPRB unilaterally and substantially reduces the value placed upon these new innovative therapies, which Canadian patients need. Policy makers are trading reduced risk to drug budgets for increased risk to patient access.

Innovative Medicines Canada (IMC) published a report in January 2019 on Canada's attractiveness for innovative drug launches. In it, they compared the launch counts of new drugs in 16 comparator countries, placing Canada at eleventh. IMC also found that Canada's median launch lag (relative to the US) for new drugs was approximately 11 months.[14] It is hard to see how a near-obsessive focus on squeezing drug prices even further would improve Canada's global standing with regard to innovative drug launches.

Pharmaceutical companies, especially new ones, have to consider the impact of this increased risk to access when considering a launch in Canada. A case example can highlight the gravity of this risk.

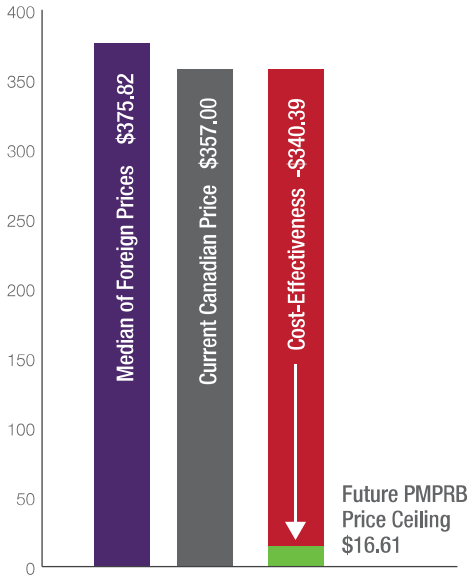
A case study on drug pricing and the risk to drug launches in Canada.

This case study involves a drug that launched in Canada several years ago. It was the first approved therapy effective in treating a life-threatening rare condition. The clinical benefit combined with a small patient population resulted in a high cost - a list price of $357.00 per tablet (or over $250,000 per year). This Canadian price was not out of line with foreign markets - the price ranges from $330.95 to $474.50 per tablet in the PMPRB comparator countries.

At the time of launch in Canada, the PMPRB determined that this product offered a substantial clinical improvement over the standard of care and set a maximum price of $375.82[15].

Had the PMPRB applied the proposed "cost-effectiveness threshold" as a pricing factor, the allowable list price would have plummeted by more than 95% to $16.61 per unit (approximately $12,000 per year.[16] (See Figure 1). A highly innovative treatment such as the one in this case study has large costs of research, development and commercialization (upwards of US$2 billion)[17] that need to be recouped and provide funding for further investment in research and development.

Figure 1.
A rare disease drug launch scenario after proposed PMPRB pricing controls.



The pivotal issue is not whether the launch price under the future scenario is reasonable or not. The issue is that the revised price would be so far out of line with the manufacturer's experience in other international markets that it places Canadian patient access at risk. Consider the substantial gap between the two positions on price (that of the pharmaceutical company and that of the PMPRB). It is unlikely that a price could ever be agreed to for a timely launch in this country; consequently, the drug would not launch in Canada. This case study raises red flags about the trade-off between lower drug prices and a disincentive to launch new specialty drugs in Canada altogether.

Solutions require collaboration.

The dilemma facing manufacturers, patients and drug plans is essentially the same: how do we ensure patient access to new medicines that often have high price tags, while maintaining the sustainability of drug plans? Research conducted by PDCI shows that taking a sledge hammer to high-priced medicines may have serious, undesired consequences.

Solutions can be found by focusing on points of intersection: drug prices in relation to acknowledged or expected value; performance-based agreements; evidence generation in the clinical setting; and integrated health information sharing. At the moment, there appears little transparent coordination among policies being considered for drug reviews, pricing, and National Pharmacare.

A concerted, coordinated effort can create a drug reimbursement system that builds partnerships based on both value and cost. A start would be to focus our attention on how payers (public and private drug plans) can move toward a system of reimbursement that pays for demonstrated value, rather than the proposed system based on modeling and simple assumptions that bring larger risks to plans and patients alike.

1. Health Canada. Towards Implementation of National Pharmacare: Discussion Paper. Ottawa, ON: June 20, 2018.
2. Patented Medicine Prices Review Board. About PMPRB, 2018. [cited February 2, 2019]. Available from: http://www.pmprb-cepmb.gc.ca/about-us/
3. PDCI Market Access. Expensive Drugs for Rare Diseases - Provincial Working Group Consultation - Winter 2019, 2019. Available from: http://www.pdci.ca/sharing-responses/
4. pan-Canadian Pharmaceutical Alliance. Biologics Policy Directions & pCPA Negotiations, 2018. [cited February 8, 2019]. Available from: http://www.canadaspremiers.ca/wp-content/uploads/2013/12/EN_pCPA_Negotiation_Guidelines_for_Biologics.pdf
5 Aitken M, Kleinrock M, Simorellis A, Nass D. The Global Use of Medicine in 2019 and Outlook to 2023. Parsippany, NJ: IQVIA; January 29, 2019
6. Presentation by TELUS Health. Presented at: Connex Health Benefits Breakfast Club Meeting; June 2017.
7. Patented Medicine Prices Review Board. Annual Report 2017. [cited February 8, 2019]. Available from: http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1380&lang=en.
8. Epclusa®, Eylea®, Zepatir®, Humira®, Eliquis®, Keyruda®, Genvoya®, Adynovate®, Stelara®, Revlimid®
9. Canadian Institute for Health Information. Prescribed Drug Spending in Canada, 2018: A Focus on Public Drug Programs. Ottawa, ON: CIHI; November 2018.
10. Drugs for rare diseases: a review of national and international health technology assessment agencies and public payers' decision-making processes. Ottawa: CADTH; 2018. (Environmental scan; no. 77).
11. Specialty products include oncology drugs, biologics, rare disease drugs, and those costing more than $10,000 annually. The number of specialty products entering initial pCPA negotiations were counted out of the total initial negotiations. Biosimilars and renegotiations were excluded. 52/77 (68%) in 2018, 45/67 (67%) in 2017, and 46/62 (74%) in 2016. As of January 31st, 2019, 45 negotiations are underway at the pCPA, 30 of which are specialty products, or 29 excluding biosimilars. Numbers were determined from internal PDCI Market Access pCPA database based on monthly pCPA updates published at http://www.canadaspremiers.ca/pcpa-archives/ .
12. The list was established in 1987.
13. Op cit
14. Innovative Medicines Canada. An assessment of Canada's current and potential future attractiveness as a launch destination for innovative medicines, 2019. Available from: http://innovativemedicines.ca/wp-content/uploads/2019/02/2019_01_29_-IMC_PhRMA_LaunchSequencing_vFINAL3.pdf
15. Despite the high annual cost, the pCPA was able to negotiate a deal on behalf of the provincial drug plans and the drug was listed as a benefit for many public drug plans.
16. PMRPB will limit prices to a cost effectiveness threshold of $60,000 per Quality Adjusted Life Year. PMPRB will rely entirely on CADTH to calculate the price reductions required to achieve this threshold. The main output of a CADTH review is an Incremental Cost-Effectiveness Ratio (ICER), which is the additional cost required to buy one additional Quality Adjusted Life Year (QALY).
17. DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: New estimates of R&D costs. Journal of Health Economics. 2016;47:20-33. doi: https://doi.org/10.1016/j.jhealeco.2016.01.012