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PMPRB Draft Guidelines Consultation

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In its latest consultation on the Guidelines, the PMPRB has proposed important changes aimed at lowering the cost of patented medicines. What appears to be missing however, is any consideration of the substantial role played by the private drug plan market. In this, the PMPRB is not alone. Neither HESA nor the Advisory Council on the Implementation of National Pharmacare provided any thoughtful analysis of a role for private insurance.

One statement included in the PMPRB Backgrounder stands out as a misrepresentation of the significant role of private drug plans and their many stakeholders:

“Given that the private market for pharmaceuticals in Canada is an offshoot of the public system and cannot function without it, the policy intent in the Amended Regulations is to adopt the perspective of the public health care system...” (p. 6)

This submission will focus on the \$12.7 billion private drug insurance market.¹ A central premise is that national policy decisions should be made only after considering the needs and preferences of all Canadians, not just those covered by provincial or federal drug plans.

1. Why the private drug insurance market matters

Private drug plans, such as those offered to individuals by non-for-profit Blue Cross since 1939 and Green Shield Canada in the 1950s have expanded to become an integral part of prescription drug coverage for working Canadians and their families.

Starting in the 1970s, provinces focused their limited drug benefit funding on seniors and those on social assistance. This provided an opportunity for private drug plans, which then expanded to cover the workforce and their families. Both payer groups have co-existed and provided essential and complementary coverage ever since. As the Board knows, public and private plans currently either cover different beneficiary populations, or different layers of expenditure. History strongly indicates private drug plans are not an “offshoot” of the public system but the primary source of prescription drug coverage for 22 million Canadians.

¹ Canadian Institute for Health Information (CIHI), 2019. *National Health Expenditure Trends, 1975-2019*. Table G.14.1.

Private drug plans provide 37% of prescription drug spending² and cover about 60% of Canadians.³ These plans are sponsored (funded in whole or in part) by over 100,000 employers,⁴ as well as by associations, unions and individuals. Private drug insurance spending has exceeded provincial drug spending since 2017.⁵ Without question, private drug plans have the scale and public popularity⁶ to function without public plans.

This view is supported by doctoral research conducted by one of the authors. Detailed interviews with a number of current and former provincial drug plan managers support private drug plans because they limit the financial, political and to some extent reputational risk of provincial plans.⁷ No province has ever stated a desire to finance the total cost of prescription drugs consumed by their populations. Even the federal Minister of Finance has acknowledged the important role of private drug plans and has suggested they not be eliminated in the federal government's pharmacare planning:

"We need a strategy to deal with the fact not everyone has access, and we need to do it in a way that's responsible, that deals with the gaps, but doesn't throw out the system that we currently have" (Harris, 2018, quoting Bill Morneau).⁸

Some academics have proposed public single payer drug insurance that could eliminate or severely limit private drug plans, but based on the current financial and political climate, this seems unlikely. Even if that perspective eventually prevails, such a change would take several years to properly transition and implement, in part because of the significant financial and human consequences of eliminating private drug plans. In the meantime, the PMPRB ought to pay close attention to millions of citizens, taxpayers, patients, employers and workers who are well-served by the private market.

² CIHI, 2019.

³ Law MR, 2018. *Cost-related barriers to prescription drug access in Canada*. A report prepared for the Advisory Council on the Implementation of National Pharmacare.

⁴ Advisory Council on the Implementation of National Pharmacare, 2019. *A Prescription for Canada: Achieving Pharmacare for All. Final Report* (June). p. 1.

⁵ CIHI, 2019.

⁶ Sanofi Canada Healthcare Survey, 2019. Available at: <https://www.sanofi.ca/en/products-and-resources/sanofi-canada-healthcare-survey>.

⁷ Bonnett C, 2019. Recommendations for the Advisory Council on the Implementation of National Pharmacare. Available at: <https://www.longwoods.com/content/25723/recommendations-for-the-advisory-council-on-the-implementation-of-national-pharmacare>.

⁸ Harris K, 2018. *Pharmacare won't be free for all Canadians, Bill Morneau says*. February 28. Available at: <https://www.cbc.ca/news/politics/morneau-budget-2018-pharmacare-1.4555186>.

2. Questions of Process

It has been a decade since the last PMPRB changes were implemented. In today's rapidly evolving market, strategy must be reviewed much more frequently. For the Board, this will ensure faster recognition and response to emerging issues that can be more quickly communicated and addressed. For others, this will allow quicker response, more effective engagement and less chance of prolonged uncertainty. Similar recommendations were made by Chris Bonnett, one of the authors of this submission, over three years ago in his October 2016 Submission on PMPRB Guidelines Modernization.

The Good and Bad

Confidential submission of actual, net market prices to the Board is necessary for effective surveillance. We also support the introduction of the PMPRB11. We suggest however that submitting the entire basket of grandfathered patented medicines to repricing commensurate with the mean international price (MIP) of the PMPRB11 should be staggered over a period of two to three years. As proposed, this is to be done over the last half of 2020. This rushed schedule presents two major problems.

Based on ratios included in the PMPRB's "civil society" presentation deck,⁹ new Canadian prices should on average be 0.83 of current prices. Based on the most recent figures available, this is a cost reduction of \$2.9 billion per year¹⁰ a very significant part of the \$13 billion in total proposed savings over a ten-year period. This significant reduction will initially be welcomed by plan sponsors, but this will also commensurately reduce insurance broker compensation as well as insurer administration revenue and profit. About \$1.1 billion in drug plan premium and sales taxes collected by the provinces will also be negatively affected.¹¹

Repricing is perhaps the easiest to understand of all the new cost control measures to be introduced. In total, these changes are complex and it is perhaps not clear to anyone exactly what the bottom-line impacts will be for each future drug and the pharmaceutical industry at large. Possible risks include the opportunity cost of new therapies that may not be released here, Canada's place in the launch sequence of new drugs, fewer opportunities for Canadians to access clinical trials, loss of Canadian jobs in the pharmaceutical industry and foregone investments in drug research and development. All of these affect industries, health research patient access and health status. For these reasons, we strongly urge PMPRB to measure,

⁹ Foreign-to-Canadian price ratios, patented medicines, OECD Countries, 2017 (Slide 15). Available at: <https://www.canada.ca/content/dam/pmprb-cepmb/documents/consultations/draft-guidelines/presentation-dec10-en.pdf>.

¹⁰ PMPRB, 2018. *Annual Report 2017*, p. 21.

¹¹ Personal communication. CLHIA July 22, 2019.

evaluate against projections and publicly report the impact of changes at least annually over the next five years.

The Uncertain

Drug program sustainability is a serious concern in many markets, and pharma companies will need to adapt here as they have elsewhere.

Drug plan administration in private markets relies on a complex mix of stakeholders and administration systems, including third party administrators, pharmacy benefit managers, pharmacies, specialized pharmacy networks and product listing agreements. The transition (time and complexity) to new prices for several thousand DINs must be carefully considered for both private and public payers. A six-month grace period is proposed, but this should not be set until consultation has occurred with the CLHIA's 23 health insurers that provide drug benefit plans, third party administrators, as well as the three largest pharmacy benefit managers,¹² in addition to provincial and federal drug plan managers.

Specifically, PMPRB should be aware that drug price changes will have to be effectively communicated to tens of thousands of insurer clients plus their intermediaries (advisors and Third Party Administrators).¹³ Many small advisors are unaware of the details of PMPRB drug price reform. There must be adequate time to prepare and respond to questions which may also require PMPRB direction and comment. It is also highly likely that the terms of many private Product Listing Agreements will require review and renegotiation. Six months may not be enough to effect all these changes.

While generally applauded in direction and scale by colleagues in the private insurance industry, changes to the Guidelines have created significant anxiety among colleagues in the pharmaceutical industry. Pharma is resistant to any changes that will lower prices and consequently their revenues and profits, and potentially their footprint in the Canadian market. The lengthy process itself has allowed anxiety to fester in Canadian pharmaceutical operations and in global offices. Our discussions indicate that business decisions are already being hampered and introduction of new products deferred. This creates patient anxiety and affects access for patients.

Roles for all Parties

Slow processes, minimal consultation, overt mistrust, alarmist language, huge and complex changes and limited process and price transparency are not conducive to successful

¹² The 23 members of the CLHIA-controlled Canadian Drug Insurance Pooling Corporation are noted at: <http://cdipc-scmam.ca/who-is-cdipc/>. The three PBMs are Telus Health, Express Scripts Canada and ClaimSecure.

¹³ Third Party Administrators may be consulted through TPAAC: <https://www.tpaac.ca/>.

stakeholder relations. This should not be seen as a zero-sum game. Drug manufacturers need investment returns that encourage innovation, and Canada must acknowledge the crucial role played by this industry in overcoming disease, sustaining life and improving quality of life. The industry's patient support programs fill human service and education gaps left by a health care system that is too often transactional and bureaucratic. The pharma industry invests heavily in research and development, but Canada does not appear to be getting its fair share despite our exceptional resources. Certainly, the forecasts of missed opportunity for clinical trials and new drug launches are important threats to Canadian patients and investment. Both pharma and the PMPRB must mutually appreciate the need for socially responsible prices, sustainable drug plan funding and an attractive investment climate.

3. The Opportunity

The PMPRB, the pharmaceutical industry, medical researchers, all payers and patients are facing a complex and uncertain world moving at unprecedented speed. The drivers of these changes are well-known and yet each party works in relative isolation until after problems have already developed. Rapid change and isolated expertise create fragmented and clearly inadequate governance for prescription medicines, within a health system that performs poorly in international comparisons.¹⁴

Moving forward and proposed earlier to be applied at the system level,¹⁵ a standing forum is needed to provide expert input to the PMPRB and help the Board manage the complexity of the entire Canadian patented drug market. It would also create the relationships and trust needed to solve complex problems that have both singular and interactional effects. We recommend an Advisory Board that includes public, insurer, advisor, plan sponsor and patient representatives, the brand and generic pharmaceutical industries, the pharmacy industry and relevant health professionals (medicine, pharmacy, nursing, dentistry, veterinary). This would eliminate or at least mitigate the need for ad hoc or situational consultations and help the Board stay abreast of the market.

Beyond monitoring the process and real-world impacts of the new Guidelines, the Board should commission frequent and focussed studies that could inform policy. One need is to develop and release comparative system research that illustrates international changes to drug regulation in comparison to key economic indicators, including GDP, average industrial

¹⁴ Schneider EC, DO Sarnak, D Squires, A Shah, MM Doty, 2017. Mirror, Mirror 2017: International Comparison Reflects Flaws and Opportunities for Better U.S. Health Care. Commonwealth Fund. Available at: <https://www.commonwealthfund.org/publications/fund-reports/2017/jul/mirror-mirror-2017-international-comparison-reflects-flaws-and>.

¹⁵ Bonnett, 2019.

wage, industry/service mix and demographic profiles. This would not only guide PMPRB actions, but encourage pharma and payers to keep Canadian changes current, and in context.

4. Concluding Comments

This submission has highlighted the crucial role of private payers and the need to actively and routinely consult them in policy and operational decisions that affect them, over 100,000 employers and over 22 million Canadians. Improved communication, trust and transparency are needed to reduce uncertainty for pharmaceutical manufacturers and patients. We have identified important improvements needed in the Board's consultation process in order to allow these important changes to be properly communicated and implemented by all stakeholders.

We argue there is a mutual dependency among and between the Board, pharma, patients and other payers and recommend creation of a standing consultative and collaborative forum to create the relationships, trust, transparency and policy options to help inoculate the PMPRB from unintended outcomes of a rapidly changing and complex market.

Thank you for this opportunity to provide input into the Board's regulations and guidelines.