INDEPENDENT VOICES FOR SAFE AND EFFECTIVE DRUGS

REPRESENTING CANADIAN ACADEMICS, RESEARCHERS, PATIENT AND CONSUMER ACTIVISTS

February 8, 2020

Patented Medicine Prices Review Board
Consultation on Draft Guidelines

To the Patented Medicines Prices Review Board:

We are academics, researchers, and patient and consumer advocates with no ties to the pharmaceutical industry. We are able to speak directly to the research evidence on drug costs, safety and efficacy and to take into account the health care needs of all Canadians.

We welcome the opportunity to comment on the Draft Guidelines to the newly amended Patented Medicines Regulations that will come into force July 1, 2020. These amendments are intended to strengthen the PMPRB's role in protecting Canadian consumers from the excessive costs of patent medicines by introducing new requirements for determining and monitoring patented drug price ceilings.

We strongly support the mandate of the PMPRB in terms of researching, monitoring and setting price ceilings for patented drugs. Canada's patented drug prices are the third highest among OECD countries and much of this cost burden is carried by 23% of Canadians who pay out of pocket for their medications. The high cost of patented medicines not only affects patients directly but also draws money out of the health care system that could be used to enhance access to medically necessary health care services that are vital to Canadians.

In addition to these direct opportunity costs, unseen ripple effects have an impact on access to prescription medicines. For example, high drug costs are pushing insurance premiums up and extended health benefits out the door. Up to 80% of the cost of extended health benefits are going to pharmaceuticals, and as drug costs increase many small and mid-sized employers have cancelled coverage. Both public and private employers have moved to outsourcing, contract and part-time jobs to avoid the high costs of employer-funded health benefit plans. One group that has felt the full weight of cancelled benefits are seniors: a majority of employers no longer provide benefits to retirees at all.

We support many of the regulatory amendments proposed by the PMPRB, including benchmarking prices against countries more akin to Canada, requiring information from the pharmaceutical industry about actual prices (including rebates and discounts) paid in Canada,

and incorporating a pharmacoeconomic lens to determine the therapeutic value of drugs in the context of other public health needs. We believe that these amendments lend positive support to plans for a National Pharmacare program which will need access to fairly priced essential medicines.

However, we feel that some of these amendments do not go far enough. The "basket" of countries that will be used to help set prices in Canada has been changed and the number of comparator countries has increased, but they still spend above the OECD average. And we are concerned that the PMPRB will continue to use the highest list price for the purpose of the Maximum List Price comparison.

We are also uncertain about how – or whether – prices of patented drugs will be weighed in relation to their impact on total population health needs and our health care system as a whole. For example, the population of elderly Canadians is increasing and we must consider how we will respond to the growing need for home support and home care. As the population ages, we have seen an increased need for other non-pharmaceutical services such as dental and vision care, audiology and other essential services. Even without taking into account these growing needs, expenditures on patented medicines already take a disproportionate share out of every health care dollar, a fact that is felt across the entire health care system where Canadians are often waiting in long queues to access services. Our health care system is already strained.

We believe that the PMPRB is an essential tool in Canada's efforts to effectively control the cost of prescription medicines. As the Minister's office has stated before, the regulatory changes will help "lay the foundation for National Pharmacare," something that Canadians are anxious to see. However, we believe there are additional tools that Canada needs to support the work of the PMPRB and the potential role it can play in a National Pharmacare program. One of these is compulsory licencing.

Beginning in 1923, Canada's patent laws allowed compulsory licensing of pharmaceuticals. After amendments in 1969, compulsory licencing saved Canadians an estimated $100 million dollars a year ($679 million in 2020 dollars) and created the conditions for a thriving domestic generic drug manufacturing industry. Under this system, Canadians paid among the lowest drug prices for prescription medicines in the world.

In 1987, the government passed Bill C-22, limiting compulsory licensing and creating the Patented Medicine Prices Review Board to ensure prices of patented medicines were not excessive as a consequence of the new law. But six years later compulsory licencing was eliminated altogether, a move that had a dramatic and negative impact on domestic generic drug manufacturing and on our ability to control the cost of drugs. Today, brand-name pharmaceuticals account for just under 80% of domestic sales in Canada[1], up from 43.9% in 1995.[2] Canada's trade deficit in pharmaceuticals has also skyrocketed, from $1.6 billion in 1993, to $4 billion in 2000[3] and $8.5 billion by 2018.

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[1] Industry Canada, Pharmaceutical industry profile. Available at https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01703.html.

[2] Canadian Drug Manufacturers Association, "PMPRB Annual Report shows increase in market share for Big Pharma as Canadians' drug costs continue exponential rise," in Drug Costs News Update, July/August 2001

[3] Canadian Drug Manufacturers Association, "PMPRB Annual Report shows increase in market share for Big Pharma as Canadians' drug costs continue exponential rise," in Drug Costs News Update, July/August 2001

As Sean Flynn, Aidan Hollis and Mike Palmedo have pointed out, "The right of countries to use compulsory licenses to promote access to medicines has been repeatedly reaffirmed in international law, including through the Doha Declaration on the TRIPS Agreement and Public Health, issued at the 2001 WTO Ministerial Meeting."[4] Since it was introduced, the "Doha Declaration solution," has only been used once. This occurred in 2007 when Apotex was granted a compulsory licence by Canada to export antiretroviral drugs to Rwanda.[5]

Canada is facing growing pressures to manage the costs of Expensive Drugs for Rare Disease (EDRDs), including biologics, which in 2018 comprised 26.2% of Canada's pharmaceutical sales. Lower cost strategies, including the use of less expensive biosimilars, have had limited success in Canada and lag far behind European countries. We believe that compulsory licencing within the terms permitted by the WTO under the Doha Declaration is possible and would support access to cost-effective biosimilars in Canada. It also would complement the regulatory mandate of the PMPRB, contributing to a strong foundation for a cost-effective National Pharmacare program.

We therefore urge the PMPRB to explore the viability of using compulsory licencing, possibly in alliance with other countries such as The Netherlands who may also be interested in developing policies that meet population needs while upholding obligations undertaken in the WTO. Compulsory licensing – or even the possibility of compulsory licencing – would shift the power over price from the patent holder to government while at the same time protecting the patent holder's right to make a profit. This would strengthen negotiations with manufacturers over bulk purchasing of essential medicines and strengthen the role of the Patented Medicine Prices Review Board in medicine pricing.

We congratulate the PMPRB for including a range of voices and backgrounds in their recent consultation processes. We are disturbed, however, by the dominant role that patient groups funded by the pharmaceutical industry have played within the PMPRB, most notably when three individuals, all from organizations heavily funded by the drug industry, were named to represent patients on a steering committee of the Review Board. At the same time, members of patient and health advocacy organizations independent of the industry were entirely missing from the same committee.

We have to wonder on what basis individuals were chosen to sit on the steering committee, since the selection criteria are not, to our knowledge, on the record. Furthermore, some of the views of these committee members on drug prices and related drug policy matters are contested within the patient and health advocacy community. In future, we recommend that individuals selected to represent patients and the public interest on drug policy agencies be chosen through a transparent process, grounded in a system accountable to patients and to the public interest. This would help ensure that the range and diversity of views and experiences among Canadians better informs public policy.

Many countries are grappling with the dilemma of industry-funded patient advocacy organizations. The process of implementing a new drug policy regimen is an opportunity for Canada to establish a system of "best practices" for engaging with patient and public interest

[4] S. Flynn, A. Hollis, and M. Palmedo, "An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries," Journal of Law, Medicine & Ethics 37, no. 2 (2009): 184-209

[5] Ooms Gorik, Hanefeld Johanna. Threat of compulsory licences could increase access to essential medicines BMJ 2019; 365 :l2098

groups. A good starting point, we believe, would be to require independence from the pharmaceutical industry.

We look forward to working in the future with the PMPRB to achieve our common goals of an effective patented medicines pricing regime and a National Pharmacare program.

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