

August 4, 20

Submission by Shoppers Drug Mart and Loblaw Pharmacies Regarding the PMPRB Draft Guidelines Consultation

Shoppers Drug Mart and Loblaw Pharmacies appreciate the opportunity to comment on the Patented Medicines Prices Review Board's (PMPRB) Draft Guidelines consultation.

Our comments are focused on the potential impact of the Guidelines to the Canadian healthcare system, specifically the availability of medications to patients and their appropriate use to optimize health outcomes. We were pleased to see some positive movement in the Guidelines in this regard, however, we firmly believe that further revisions are warranted if unintended consequences are to be avoided.

The revised Guidelines create unpredictability in pricing for new medications. Innovative Medicines Canada has stated it remains deeply concerned about the impact of the amended regulations and Guidelines on Canadians' access to affordable, innovative medicines¹. It is reasonable to expect that uncertainty in price may lead to a decrease in the launch of innovative medicines in Canada, with a direct impact on the future health and quality of life for Canadians.

We can learn from experience in the generic drug manufacturing industry, where price compression over many years led to a pricing regime that made the feasibility of manufacturing in Canada economically unviable. Further, the COVID-19 pandemic has highlighted the risk of a lack of competitiveness on the ability to acquire products from international markets, and the need to further increase the security of the drug supply chain in Canada. We submit that creating price uncertainty in this environment is not in the best interest of Canadians, or their healthcare system.

We are pleased to see that the approach on the previous draft Guidelines, to apply the Median International List Price (MIP) test to Grandfathered medicines, has been revised to an approach that applies a Highest International Price (HIP). This is a step in the right direction.

This approach decreases potential impact from a reduction in Maximum List Price (MLP) by an average of 20%² to an average of 5%. However, PMPRB analysis demonstrates that approximately one third of Grandfathered drugs, 20% of sales, will experience a significant price decrease of 25% or more³.

Pharmacy reimbursement is based on cost recovery for the medication, a dispensing fee to compensate for associated costs, and a markup on the drug price to compensate for inventory handling and associated costs. Pharmacy distributor revenue is based on allowable distribution fees based on drug price.

¹ <http://innovativemedicines.ca/revised-pmprb-guidelines/>

² According to estimates by PDCI Market Access

³ PMPRB Public Webinar, July 8, 2020 slide 13

We estimate that the impact of the original Guidelines to community pharmacies in Canada was \$160M to \$220M and that the revised guidelines lessened the impact to between \$40M - \$55M, and that the original impact across both pharmacy and distributors was \$216M - \$284M and that the revised guidelines have lessened the impact to between \$60M - \$75M annually across the industry⁴. The estimated impact to Shoppers Drug Mart and Loblaw alone, through the impact to funding on our community pharmacies and distribution channel, is estimated to be \$15M annually.

As the current regulatory structure would allow for distributors to pass financial impact on to pharmacies in the form of increased fees for distribution, we are concerned that there is potential for pharmacies to see an impact of the full \$60-\$75M annually. Either situation, a contained impact, or an exacerbated impact, will negatively affect patient care and health outcomes.

These cuts would compound significant funding cuts to our sector through unrelenting provincial and federal drug reform. Clearly, continued and exacerbating cuts will negatively impact the ability to provide care and medications to Canadians.

Medications for complex conditions, rare diseases, and for many chronic conditions, are high cost specialty medications which require Patient Support Programs (PSP's) to assist patients through their healthcare journey. PSP's are funded by the manufacturer of the medication that the patient is taking. It can be expected that with decreased revenue manufacturer ability to invest in PSP's will be diminished, to the detriment of patients.

Many pharmacies that stock these medications and participate in PSP's have made significant investments in the infrastructure required to support specialized patient care. These pharmacies have already been subjected to decreased revenue due to drug reform, and any additional negative financial impact will further curtail their ability to continue to support PSP's, and their patients.

We recommend that funds spent on PSP's by manufacturers are applicable as an offset to the MLP for Grandfathered drugs.

The increased threshold in the Guidelines to determine if a medication is in Category 1 is also a step in the right direction, as it will exclude many medications that would have originally been caught in that category. However, the proposed system is complex, and we believe it will exacerbate price uncertainty, and therefore the impact on PSP's.

We recommend that PMPRB continue to work with industry stakeholders to find a balanced framework that would meet policy objectives while ensuring patient access to medications.

The proposed approach to pricing for existing medicines will negatively impact access to medications for Canadians. The current model funding model for both community pharmacy and pharmacy distributors is a function of drug cost. Removal of funding from both sectors will challenge sustainability and therefore the supply of care and medications to Canadians.

⁴ The range of the estimate considers the PMPRB estimate and our analysis

It is our understanding that it was not the intent of the Guidelines to impact the viability of pharmacy or distributors and as such we firmly believe that more time, and a phrased in approach, is required to determine the full impact of the Guidelines on the healthcare system, and on the health and well-being of Canadians.

Thank you for considering our input and recommendations,

Sincerely,

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