

August 31, 2021

Shoppers Drug Mart and Loblaw Pharmacies comments regarding the Patented Medicine Prices Review Board changes to the coming-into-force date, the definition of Gap medicines, the references to the comparator countries, and the international price tests for Grandfathered medicines and their line extensions

Shoppers Drug Mart and Loblaw Pharmacies are pleased to see the approach taken in July 2021 by the Patented Medicine Prices Review Board (PMPRB) to delay the coming-into-force date of the Regulations Amending the Patented Medicines Regulations (“Regulations”) a further six months, from July 1, 2021, to January 1, 2022.

However, the delay is not nearly enough. The proposed Regulations have a significant impact on pharmacy and the broader pharmacy industry. The dialogue must be broadened to consider and include all impacted stakeholders, and implementation put on hold indefinitely to allow the impacts to be fully recognized, understood, and addressed.

In addition, we were extremely disappointed and concerned to see that the PMPRB has changed the goalposts for the scope of the proposed Regulations again, specifically the definition of Gap medicines, the references to the comparator countries, and the international price tests for Grandfathered medicines and their line extensions.

As a stakeholder that will be significantly impacted by the proposed Regulations, we refer you to our August 4, 2020, submission on the draft Guidelines (Attachment 1), and our November 6 Submission (attachment 2). Our position and concerns remain unchanged however, we draw your attention to the significant increase in impact which the newly revised Regulations would have on pharmacy and on our patients.

Over the past year, guideline changes have increased the negative estimated impact to our pharmacies from an initial \$15M to over \$50M annually. Extending this impact to all community pharmacies and distributors in Canada, our original estimated impact of \$60M - \$75M in August 2020 has now increased to \$140M - \$220M. This is approximately a threefold impact increase with very little explanation and transparency behind the proposed changes.

Note: the exact impact is impossible to determine without significant time and resources being made available, given the complexity and far reaching scope of the proposed Regulations.

We recommend that:

- **The revised Regulations be put on hold indefinitely.**
- **The dialogue must be broadened, to allow the impacts to be fully recognized, assessed, understood. and addressed, as the Regulations will have significant impact on pharmacy, the broader pharmacy sector, and the patients we serve.**
- **Measures must be taken to ensure any future Regulations do not impact the ability of Canadians to access their medications.**

Thank you for considering our input,

Sincerely,

Deb Saltmarche, Senior Director Professional Affairs

Cc:

Ashesh Desai, Executive Vice President Pharmacy
Chris Potter, Senior Vice President, Healthcare Businesses
Perry Martin, Vice President Government Relations

For questions please contact Deb Saltmarche, dsaltmarche@shoppersdrugmart.ca

August 4, 2020

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 lead 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.

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

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

² According to estimates by PDCI Market Access

³ PMPRB Public Webinar, July 8, 2020 slide 13

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.

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 phased 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,

Deb Saltmarche, Senior Director Professional Affairs

Cc:

Tanya Moore, Vice President, Pharmaceutical Partnerships
Chris Potter, Senior Vice President, Healthcare Businesses
Ashesh Desai, Executive Vice President Pharmacy
Perry Martin, Vice President Government Relations

For questions on our submission please contact Deb Saltmarche,
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Attachment 2

November 6, 2020

Submission to the House of Commons Standing Committee on Health by Shoppers Drug Mart and Loblaw Pharmacies Regarding the Patented Medicine Prices Review Board Guidelines

On October 26, 2020, the House of Commons Standing Committee on Health agreed to undertake a study on the Patented Medicine Prices Review Board's (PNPRB) Final Guidelines issued on October 23, 2020. Both the regulatory amendments and the guidelines are set to come into force on January 1, 2021.

As an interested stakeholder, Shoppers Drug Mart and Loblaw Pharmacies refer you to our August 4, 2020, submission on the draft Guidelines (Attachment 1). Our general position has remained unchanged following the release of the final Guidelines, however, we draw your attention to the financial impact which, following a deeper analysis that the time between August and November afforded us, has been revised based on future projections. The estimated impact to Shoppers Drug Mart and Loblaw Pharmacies, through the impact to funding on our community pharmacies and distribution channel, has increased from an estimate in August of \$15M annually to our current estimate of \$31M annually. Extending this impact to all community pharmacies and distributors in Canada, our estimated impact of \$60M - \$75M in August has increased to \$80M - \$100M.

We would like to re-emphasize that the Guidelines will have the unintended consequence of further isolating the Canadian market from the rest of the world. Canada represents a very small percentage of global pharmaceutical sales and is on a slow growth trajectory. The Guidelines will continue to impede Canada's growth relative to other developed markets as manufacturers will be hesitant to launch products in Canada given the continued downward course and even lower prices the Guidelines impose.

We strongly recommend that the revised Guidelines are not implemented until further assessment is done and measures taken to ensure these regulations do not impact the ability of Canadians to access medications, including anticipated COVID-19 vaccines.

The Neighborhood Pharmacies Association of Canada (NPAC) has requested to present at the Committee hearings and is aware of our submissions on this matter.

Thank you for considering our input,

Sincerely,

Deb Saltmarche, Senior Director Professional Affairs

Cc:

Chris Potter, Senior Vice President, Healthcare Businesses

Ashesh Desai, Executive Vice President Pharmacy

Perry Martin, Vice President Government Relations

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