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Impact on Canada's Pharmacy Sector and Restricted Access to Medicines for Patients from Proposed Amendments to the Patented Medicine Regulations

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Neighbourhood Pharmacy Association of Canada

Introduction:

The Neighbourhood Pharmacy Association of Canada (Neighbourhood Pharmacies) appreciates the opportunity to provide this Submission Brief regarding Health Canada's Notice on the Proposed Amendments to the Patented Medicines Regulations.

Neighbourhood Pharmacies represents Canada's leading pharmacy organizations who deliver high value, quality care to Canadians in all models including chain, banner, long-term care, specialty and independent pharmacies as well as grocery chains and mass merchandisers with pharmacies. Our members are home to the most trusted providers of drug therapies, pharmacy-based patient services and innovative healthcare solutions. We advocate for community based care through our members' high accessibility and proven track record of providing optimal patient care closer to where patients live, work and play. By leveraging the over 10,000 points of care with pharmacies conveniently located in every neighbourhood across Canada, Neighbourhood Pharmacies aims to advance sustainable healthcare for all stakeholders.

Neighbourhood Pharmacies has thoroughly reviewed the following:

- The proposed regulatory changes;
- The Regulatory Impact Analysis Statement (RIAS); and,
- Various Health Canada and Patented Medicine Prices Review Board (PMPRB) consultation documents.

As a key stakeholder in this process, Neighbourhood Pharmacies has repeatedly expressed its members' views regarding significant PMPRB-related policy and regulatory changes. Neighbourhood Pharmacies also provided a detailed and extensive response to the May 16, 2017 consultation on: *Protecting Canadians from Excessive Drug Prices: Consulting on Proposed Amendments to the Patented Medicines Regulations*.

Neighbourhood Pharmacies recognizes the government's desire to modernize the framework for managing the price and costs of patented medicines, since the last comprehensive regulatory changes were implemented nearly two decades ago. However, Neighbourhood Pharmacies would like to point out that this period was one in which amendments and significant revisions to both federal and provincial pharmaceutical policy, pricing and reimbursement were being introduced, with the goal of applying additional measures in the approval and cost-effectiveness of medicines, in making funding decisions, including the following:

- The PMPRB undertook significant changes to its *Compendium of Policies, Guidelines and Procedures*.
- The Canadian Agency for Drugs and Technologies in Health (CADTH) was established which created several national health technology assessment (HTA) programs and services, including the Common Drug Review (CDR) and the pan-Canadian Oncology Drug Review (pCODR).
- The pan-Canadian Pharmaceutical Alliance (pCPA) (to negotiate lower pharmaceutical prices) was created.
- Health Canada reviewed and revised its Notice of Compliance (NOC) processes and its cost recovery program (which it is doing once again).
- Provinces instituted a major series of reforms to their reimbursement policies, with negative impacts for pharmacies and their patients.

Therefore, given the modifications that have occurred over this period, Neighbourhood Pharmacies believes that changes to the regulations have been miscast, given the government's position that prices in Canada have been excessive. We would argue that it is necessary to have a rational evidence-based dialogue that strikes a balance between affordability and accessibility, and focused on value rather than simply cost or prices in isolation, while taking into account the uniquely Canadian pharmaceutical pricing and market access environment. For years both federal and provincial governments have recognized that maintaining this balance is crucial. However, it now appears the policy priority is to simply reduce patented medicine prices to the point where Canadians' accessibility to new and innovative medicines may be threatened, and optimal health outcomes are no longer a priority.

In broad terms, Neighbourhood Pharmacies supports the government's intent of ensuring affordable medicines for all Canadians. What is at issue is properly recognizing the unintended consequences of Health Canada's significant shift away from achieving both goals of affordability and accessibility.

The following sections in this document outlines issues that need to be considered regarding this significant policy/regulatory change. Our comments are based on the December 2, 2017 RIAS, a comprehensive document that provided initial analysis of how the proposed regulatory changes will impact Canadians and the pharmaceutical industry. Neighbourhood Pharmacies does not challenge this analysis; rather what is at issue is the conclusions drawn from the RIAS. There are three areas we wish to focus our comments on:

1. The PMPRB;
2. Increase in the regulatory burden; and,
3. Impact on the industry.

The PMPRB

For more than thirty years, the PMPRB has established a successful track record in its role as national regulatory agency with a mandate to ensure that the prices of patented medicines in Canada are not excessive. It has been able to carry out its mandate with a reasonable budget and it has worked extensively with provincial and territorial governments, Canadians and the industry, whose prices it regulates. In trying to understand the issues regarding today's debate, Neighbourhood Pharmacies has examined all the PMPRB's annual reports since the agency was created.

Ensuring compliance of the industry it regulates is a key factor in determining its effectiveness. And on average, according to the PMPRB's own statistics, it has managed to ensure a compliance level of close to 90% to 95%. That is, ensuring prices of patented medicines are not excessively priced in Canada.

However, the RIAS asserts that Canadians have the highest priced patented medicines in the world. This is a bit perplexing given the overall compliance rate published in the PMPRB's annual reports and the fact that the international tests employed by the PMPRB for existing medicines must be at the international median of the basket of countries.

The rational conclusion is that the PMPRB does not have the proper tools to carry out its mandate, given the significant changes that have occurred over the last thirty years within the industry and marketplace. However, it appears Health Canada has concluded that such changes have only resulted in higher prices without improved health outcomes.

The RIAS does not reflect the fact that during this period there have been significant breakthroughs in medicines used to treat some of the most dreaded illnesses. For example, three decades ago it could not even be contemplated that unmet medical needs could be met by medicines that manage the devastating effects of HIV/AIDs. Today, these medicines do exist, resulting in improved health outcomes and quality of life for those who have this disease. Significant new advances have been made in the treatment of cancer, including oral take home therapies, as well as rheumatoid arthritis, psoriasis, and hepatitis C.

Understandably, the current basket of countries the PMPRB uses can be expanded to reflect a more robust comparison and perhaps the result will be lower prices. However, if a policy change is to have any merit, evidence needs to be provided as to why Health Canada is choosing to include certain countries over others. In our opinion, this has not been adequately demonstrated.

What seems very clear is that the government wants to ensure a basket of countries for the PMPRB's international price tests that result in lower prices. For example, the exclusion of the United States from the basket of countries and the inclusion of other lower European priced countries and Australia, without a well articulated rationale for selecting comparator countries, supports this argument. Indeed, Canada and the USA are very similar among OECD countries in having a healthcare system for pharmaceuticals that has a large proportion of non-public payors. The absence of a transparent methodology for comparator selection, and the secretive process for selecting the basket of countries, suggests that the government does not wish to engage in a true consultation with stakeholders.

Many of the countries Health Canada is proposing to include in the basket are already experiencing difficulty in accessing new innovative therapies because they are simply not being introduced given their restrictive reimbursement regimes. Health Canada's proposal heavily skews the results in favour of creating a regime that severely limits prices without adequately considering accessibility to new and innovative medicines.

This situation is even more confounding given the RIAS does recognize that pricing information is not as robust as it should be, given reimbursement plans in Canada, and the United States actually negotiates lower prices than the PMPRB's ex-factory gate price. Nor does the RIAS recognize the pan-Canadian Pharmaceutical Alliance which has, since its inception in 2010 as a negotiating body, on average claimed annual savings of \$410 million.

Therefore, the issue would seem to be the actual pricing information in Canada is imperfect, and that this issue should be solved first before changing the basket of countries so that policy makers/regulators have a clear picture of the market in Canada.

Increase in the Regulatory Burden – Duplication of Effort

Neighbourhood Pharmacies would agree that more analysis and understanding is required when examining the Canadian and global market regarding innovative medicines. Improved information translates into better policy decisions. Indeed, as Health Canada knows, such therapies are complex and require a large amount of data to determine efficacy, effectiveness and value.

To that end, the government and provinces and territories jointly established the Canadian Coordinating Office for Health Technology Assessment, now known as CADTH. Since the early 1990's, this agency has developed into a world-leading health technology assessment organization.

Why then would the same responsibilities and powers be given to the PMPRB to conduct the same work as CADTH?

This seems to be the intent in the proposed regulations. Both organizations approach the value of innovative medicines differently and, of course, have diverse capacity and resources required to undertake their work. The PMPRB's mandate is about determining excessive prices as opposed to CADTH's which assess the cost-effectiveness, i.e. the value of a therapy, and to make recommendations to participating pCPA jurisdictions about whether to either fund or not fund these medicines on their formularies.

Given that PMPRB and CADTH regularly work together, so they can both fulfill their objectives, the policy rationale for such a change to the PMPRB's mandate seems illogical and unpersuasive, given that CADTH is already fulfilling their mandate. It is concerning that Health Canada would determine that the PMPRB now needs to undertake similar work. Not only will industry have to submit duplicate information/documentation, thus prolonging approval times and delaying access to innovative medicines, but the additional work undertaken by PMPRB will undoubtedly incur significant incremental costs.

Given the limited funds of the government, it is not clear how it can justify increasing expenditures in an area that is all already clearly and adequately resourced. In addition, the government, on several occasions, has stated that it wants to, as much as possible, reduce "red tape". Unfortunately, it is doing the exact opposite in this situation.

The government has committed to the development of a series of strategies in order to attract investment for research, so that Canada can become an innovative hub for the development of new technologies. Such a direction is at risk since there would now be two separate agencies undertaking the same work.

Policy/regulatory changes of this magnitude requires solid evidence as to the issue, the need and why the solution proposed is appropriate. Nowhere in any of the documentation that has been provided throughout this process has Health Canada demonstrated the need to increase the PMPRB's mandate to undertake health technology assessment.

Impact on the Industry

The RIAS has undertaken an initial analysis on determining the benefits and costs of the proposed regulatory changes. It is estimated that the net benefit is to be \$12.7 billion over ten years, from 2019 to 2028. However, the cost to the industry is approximately \$8.6 billion over ten years, from 2019 to 2028.

This will result in an annual loss to the pharmaceutical industry of about \$860 million in net margin. It is not at all clear how the industry in Canada will react to the economic impact of these changes if the total value of the Canadian marketplace only represents 2% of the global market.

However, what is even more concerning to Neighbourhood Pharmacies is the potential impact that these proposed amendments will have on the patient care delivered by our members. If patented medicine prices are reduced to levels that make manufacturers decide that a business case cannot be made for launching a new drug in Canada, there will inevitably be a spillover effect on the 36 million Canadians who rely on our members' pharmacies to receive the highest quality innovative products and pharmacist-delivered services. That means more patients and caregivers potentially waiting longer for therapies and potentially diminished survival rates – realities that will confront them in conversation at their pharmacy and other healthcare practitioners as they wade through the journey of diagnosis to treatment.

Furthermore, there are consequences that extend to all parts of the pharmaceutical supply chain which have not been considered in the RIAS. Pharmaceutical distribution is priced as a percent of the drug cost, and so drug wholesalers can anticipate a loss of more than \$100 million over ten years. Pharmacies are also compensated, in part, through markups that are based on a percent of the drug cost. Most concerning to Neighbourhood Pharmacies is the anticipated loss to pharmacy of approximately \$900 million in net margin over ten years. Combined, there is an additional \$1 billion impact to the supply chain that delivers vital medicines from manufacturer to patient. There is no doubt that the initial RIAS has not considered all of the factors which will impact the pharmaceutical supply chain and that Canadians need a more thorough assessment.

Conclusion

Neighbourhood Pharmacies understands the need for Health Canada to manage both human and financial resources responsibly on behalf of all Canadians. However, Canadians also deserve access to innovative medicines that are affordable for private and public drug plans and individuals. If the system is to be sustainable for future generations than government and stakeholders must work together to ensure this is feasible.

The concern than is that in this rush to limit the prices of innovated medicines, the research and development that is conducted in Canada will disappear, and that Canada will no longer have access to current and future therapies that offer real hope in combatting chronic and life ending illnesses. This situation will be compounded when Canadians examine the availability of such medicines in other countries and question why they are not available in this country.

For more than a decade, despite countless reforms to pricing and reimbursement policies by public and private payors, our members have maintained the highest levels of medication management services that ensure optimal health outcomes. This is particularly the case with high cost specialty, biologics and cancer therapies. If these proposed amendments are adopted in their current forms, and the flow of new products into Canada begins to diminish, the clear signal to Canadian will be that the PMPRB is not particularly concerned that patients' access to new therapies will be restricted, and that older, less effective medicines are adequate to meet their unmet medical needs.

Therefore, it is critical the government demonstrate it understands the delicate balance between accessibility and affordability. What is evident in this iteration of the proposed changes to the regulations and in the RIAS, is that maintaining this balance is no longer a policy goal. Surely the government recognizes that limiting access to medicines that reflect emerging technologies and advances in health research and development will not help Canadians maintain and improve their health.