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Patented Medicines Consultations
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Input Regarding Proposed Amendments to the Patented Medicines Regulations

Introduction:

The Best Medicines Coalition (BMC) is a national alliance of 24 patient organizations with a shared goal of equitable and consistent access for all Canadians to safe and effective medicines that improve patient outcomes. Areas of interest include drug access, approval, assessment and reimbursement along with patient safety and supply concerns. The coalition strives to ensure that Canadian patients have a voice and are meaningful participants in policy development, specifically regarding pharmaceutical care.

As part of our efforts on behalf of Canadian patients, we welcome this opportunity to comment on the draft amendments to the Patented Medicines Regulations as published in Canada Gazette Part 1, December 2017 with a February 14 deadline for comments. This follows input the BMC submitted in June 2017 on Health Canada's proposed amendments, and in October 2016 regarding Health Canada's PMPRB Guidelines Modernization Discussion Paper.

Pricing Regulation: Core Positions

The BMC's input on the draft amendments to the Patented Medicines Regulations, as follows, is focused on those aspects directly related to patient interests and needs.

Please consider the following core positions:

- **Balanced Oversight.** The BMC supports a strong, balanced and fair regulatory framework for pharmaceutical pricing aimed at sustaining the life, health and wellbeing of patients. Such a framework should support early and sustainable access to innovations to meet unmet patient needs while also protecting patients and payers, and supporting current and ongoing effectiveness and sustainability of the health care system.
- **Availability.** A primary goal of pricing regulation, and indeed of all public bodies operating in the realm of pharmaceutical care, must be to contribute to an environment that facilitates the introduction and availability of a comprehensive range of medicines, including newly developed advancements to address unmet needs, and not hinder patient access to clinical trials.

- **Timely Access.** The ability to access necessary medicines in a timely manner is an important cornerstone of protecting and optimizing the health and wellbeing of Canadians. The pricing framework must respect this premise and not deter early introductions. Furthermore, the review process must be efficient and timely, not duplicative and prolonged due to redundant and overlapping administrative mandates. Patients must not be forced to endure extended wait times, in some cases over several years, to access new or improved medicines.

It is the BMC's position that if there is not sufficient clarity on impact on patient care and on system efficiency, value and sustainability reforms must be halted until there is full certainty.

In addition, officials and decision makers must carefully and meaningfully consider the full scope of input and policy options presented by all stakeholders, including the pharmaceutical industry, the broader life sciences community, public and private payers, and health care professionals. Along with patients, individuals and groups from each of these communities are well equipped to provide informed perspectives and expertise and have a legitimate role in determining the next iteration of a pharmaceutical pricing regulation framework, and therefore should be fully engaged.

Proposed Amendments: Issue Review And Discussion

Pharmaceutical pricing is complex with diverse implications for pharmaceutical industry profitability and investments, the Canadian research and innovative infrastructure, and the economy broadly. These implications are significant, and ultimately have downstream impact on the healthcare system and patient care and so warrant full consideration. However, the BMC is primarily focussed on issues with a direct connection to patient care.

From a patient perspective, in reviewing the proposed draft amendments, the following issues are considered critical:

Availability: Pharmaceutical Introductions Into Canadian Market

From our review, there are worrisome indications that Canada is at risk of losing ground in terms of the scope of medicines introduced, compared to other countries, should the proposed regulations be implemented. The realistic possibility of this unintended consequence must be fully understood and addressed.

By many estimations, including the PMBRB's own *Med Entry Watch Report, 2015*, Canada is currently among leading countries within the OECD in terms of percentages of all new drugs globally which are launched here. In examining this report, it can be surmised that Canada would no longer be in the preferred tier as it moves towards pricing in line with OECD median pricing, as proposed, where there are fewer or delayed launches of new/improved drugs.

It is worrisome to consider what impact the proposed regime will have on decisions by global pharmaceutical manufacturers such as how many, when, and which new/improved drugs to launch into the Canadian market. While this is difficult for patient communities to evaluate, the pharmaceutical industry cautions that due to price, process and unpredictability, Canada could be de-prioritized for new drug launches.

PMPRB comparator countries. While certainly there are various aspects to consider, analysis indicates that those countries with lower price ceilings are faced with later or fewer pharmaceutical introductions. A careful reconsideration of the proposed PMPRB price comparator countries is warranted.

The draft regulations propose to remove the USA and Switzerland from the list of price comparators and replace them with Australia, Belgium, Japan, the Netherlands, Norway, South Korea and Spain. If PMPRB is correct in stating that the new list of comparators will likely mean a reduction in the median price of drugs in Canada of about 20 per cent, then it is perhaps foolhardy to assume there will be no unintended or unanticipated consequences for patients in terms of access. PMPRB's own data from the 2015 Med Entry Watch Report shows that in Australia and South Korea, only 65 per cent and 54 per cent (respectively) of new drugs launched globally were available. These facts are worrisome for patients.

This issue is of vital importance to current patients with unmet or poorly-met needs, as well as future patients who could benefit from the introduction and availability of medications that are yet to be discovered. Canadian patients with life-threatening, debilitating or difficult to treat diseases expect to have access to the same treatments as patients in other advanced countries. We believe that Canadian officials and decision makers have an obligation to make certain that timely availability is not eroded, and therefore ask that the federal government *not* proceed until this has been publicly assessed and fully resolved.

Clinical trial access. Many patients volunteer for and rely on access to clinical trials as an avenue to much-needed treatments prior to Canadian approvals. A complex mix of factors determine whether these trials will be held in a country, including level of quality care, research expertise and infrastructure which is closely related to pharmaceutical investments. Canada's status as a worthy centre for trials must not be compromised as an unintended side effect of drug pricing re-regulation. The list of comparators should not include any jurisdictions which have less access to clinical trials than Canadians have at present because, we reiterate, clinical trials are vital to patients with unmet needs.

Timely Access: Delayed Introductions and Regulatory Processes

Under the current regulatory structure, Canada currently benefits from early launches of new pharmaceuticals compared to other countries, including several of those countries in the proposed additions to the PMPRB "basket" of comparators. Again, the Canadian pharmaceutical industry has expressed concerns that this situation could change under a more restrictive regulatory regime. For patients with critical illnesses awaiting treatments, and for all future patients for whom medicines have yet to be discovered, this is a critical issue. Officials and decision makers must work cooperatively with the pharmaceutical industry to understand and assess risks and develop solutions. If there is a chance that the regulatory changes will increase the likelihood that companies will move Canada down their list of countries when they market a new drug, this must be addressed.

Extended review times. Also related to timely access, care must be taken to ensure that a more complicated regulatory process does not result in extending the entire review process, encompassing the time between when a pharmaceutical is initially submitted for approval and when decisions are made on reimbursement.

In the current system, patient groups identify wait times for treatment as a significant barrier to patient care, and policy makers must be diligent in not adding additional steps or redundancies to approval processes. It is appropriate that a pharmaceutical pricing framework be implemented by a national body, and that it operates in concert with and reflect the realities of other national and regional bodies which play a role in pricing, thereby avoiding duplication. For example, implications of the regulations on the role and effectiveness of the panCanadian Pharmaceutical Alliance (pCPA) must be understood to ensure that its effectiveness in managing prices through negotiations is not compromised.

Role of duplication in delays. Currently, pharmaceutical regulatory and program delivery frameworks are often described as convoluted and duplicative, a labyrinth which is itself a barrier to timely access to necessary care. This situation must not be exacerbated and must be improved. Quite simply, patients need the right drug at the right time and the current system falls considerably short of this. There is reason to believe that these proposed regulatory changes will further complicate systems and contribute to delays with no benefit in terms of patient care and outcomes.

Patients are concerned about the duplication and overlap of administrative responsibilities among Health Canada, PMPRB, the Canadian Agency for Drugs and Technology in Health (CADTH), Institut national d'excellence en santé et en services sociaux (INNESS), and the pCPA. The proposal to expand the work of PMPRB to include a cost-effectiveness test, and to elevate this test to special status within the draft regulations, would take PMPRB beyond its original scope of protecting consumers from excessive pricing. Essentially, it would be duplicating the work of assessing, and then negotiating, the value of medicines of established and publicly-funded organizations such as: CADTH/INNESS and pCPA. Canadians do not need another taxpayer-funded organization examining cost effectiveness; we need the existing organizations to do a better and faster job of negotiating value arrangements with pharmaceutical companies.

Furthermore, the proposed PMPRB regulation changes allow no room for patient input into the matter of value or cost-effectiveness. PMPRB needs to develop a meaningful, ongoing patient input process to be in step with current practice.

Conclusion: Moving Forward

The PMPRB is not just a body to protect from excessive pricing, but it also has a broad role, along with other bodies, of contributing to an improved health care system. Specifically, to be an effective and relevant part of the entire framework, the PMPRB must play a positive role in maintaining and enhancing a high level of quality care and contributing to improved outcomes for all patients. Pharmaceutical spending is generally viewed as a cost to the system, but there must also be a recognition that it is an investment in the lives of Canadians through reduction of suffering and improved health.

In addition, introducing greater system-wide efficiency, including alignment and avoidance of duplication and overlap, must also be considered goals of this specific regulatory initiative and indeed broader reform. In this context, the pricing regulation package as drafted can be evaluated by asking these questions:

- Does it ultimately contribute to improved patient care and outcomes?
- Does it reduce duplication, improve efficiency, and contribute to value and sustainability of the health care system?

At this juncture, following review and discussion, it is the position of the BMC that there is not sufficient clarity and understanding of all implications to definitively answer yes to the above questions. It is unwise to think that a 20 per cent reduction in the median price of medicines is achievable, without any negative impact on patients. There is a demonstrable risk that patient care will be diminished, not improved, and that aspects of the proposed framework are duplicative and redundant. Therefore, it is the position of the BMC that immediate changes to the Patented Medicines Regulations, as drafted, should not be implemented. Further analysis, meaningful discussion and consultation is required. An appropriate balance must be found so that levels of patient care are improved, and not compromised.

In addition, we urge ongoing monitoring of pricing regulation and a rigorous evaluation of outcomes. This must include full understanding of patient impact, analysis of real savings, and analysis and evaluation of how savings are invested in improved patient care. Patient values and perspectives must be incorporated throughout monitoring and evaluation, including consideration of impact on timely access, availability of a range of treatment options, and system efficiencies such as alignment and reduction of duplication.



About the Best Medicines Coalition

The Best Medicines Coalition is a national alliance of patient organizations with a shared mission of equitable and consistent access for all Canadians to safe and effective medicines that improve patient outcomes. Areas of interest include drug approval, assessment and reimbursement issues, as well as patient safety and supply concerns. The BMC strives to ensure that Canadian patients have a voice and are meaningful participants in health policy development, specifically regarding pharmaceutical care. The BMC's standing goals are as follows:

- Drug programs which deliver high standards of equitable and consistent access to medications for all Canadians.
- Drug review and post-marketing surveillance systems to address patient safety; knowledge of risks and benefits throughout drug lifecycle.
- Effective models for meaningful and equitable patient participation in drug reviews and policy development.

Through issue education, consensus building, planning and advocacy, patient-driven positions are communicated to decision makers and stakeholders. Formed in 2002 as a grassroots alliance, the BMC was registered under the Not-for-profit Corporations Act in 2012 and is governed by a Board of Directors elected from member organizations.

Best Medicines Coalition Members

Alliance for Access to Psychiatric Medication
Arthritis Consumer Experts
Asthma Canada
Better Pharmacare Coalition
Brain Tumour Foundation of Canada
Canadian Arthritis Patient Alliance
Canadian Breast Cancer Network
Canadian Council of the Blind
Canadian Epilepsy Alliance
Canadian Hemophilia Society
Canadian PKU & Allied Disorders
Canadian Psoriasis Network
Canadian Skin Patient Alliance
Canadian Society of Intestinal Research
Canadian Spondylitis Association
Canadian Treatment Action Council
Crohn's & Colitis Canada
Foundation Fighting Blindness
Gastrointestinal Society
Health Coalition of Alberta
Kidney Cancer Canada
Lymphoma Canada
Ovarian Cancer Canada
Parkinson Canada