

February 14, 2020

Patented Medicine Prices Review Board  
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## **SUBMISSION ON PMPRB DRAFT GUIDELINES**

### **BACKGROUND**

The Better Pharmacare Coalition (BPC) has been effectively advocating for appropriate and timely access and coverage to evidence-based prescription medications through the BC PharmaCare program since 1997. Today, as a coalition of 30 chronic disease-specific not-for-profit organizations and charities, we work collectively towards maintaining and improving access to medications, medical technologies and treatments as well as ensuring that health policy decisions focus on patient needs: the pursuit of cost-effectiveness should not cause harm to people. The BPC's current member organizations represent more than two million patients and their caregivers in BC. The BPC is also a member of the Best Medicines Coalition (<https://bestmedicinescoalition.org>), a national alliance of patient organizations also with a shared goal of equitable and consistent access for all Canadians to safe and effective medicines that improve patient outcomes.

On behalf of the members of the Better Pharmacare Coalition (BPC), we welcome the opportunity to provide a written submission sharing our views on the Patented Medicine Prices Review Board (PMPRB) Draft Guidelines and provide considerations for implementation. We recognize the importance of maintaining and ensuring fair prices for medicines which are affordable for Canadians, however, we also emphasize the importance of ensuring a healthcare landscape that attracts global companies to bring useful medicines to Canada so Canadians may benefit from new medicines which improve quality of life and extend life expectancy of Canadians.

### **VIEWS AND CONSIDERATIONS**

As a Coalition, we support and endorse the submission and input provided by the Best Medicines Coalition, see attached enclosure.

In addition, we would like to further emphasize the concerns that these PMPRB Draft Guidelines (PMPRG-DG) may have on the future introduction of useful medicines, those that safe and effectively address unmet needs, to Canada and their availability to and accessibility by Canadians. The PMPRG-DG may have unanticipated or unintended consequences such as reducing the number and delaying the entry of novel medicines being introduced and marketed in Canada, particularly those medicines

that would help improve quality of life and extend life expectancy of Canadians. There is concern that global manufacturers may overlook drug and related treatment launches in Canada as a result of these PMPRB-DG since Canada is a small percentage of the worldwide pharmaceutical market. Patients in Canada have a desire for lower and fair prices, but it should not result in the loss of new useful medications being studied and submitted for approval in Canada. The current rate of launches of new medicines in Canada and the recent history prior to PMPRB changes should be a baseline to compare impact of PMPRB-DG. Safeguards, surveillance and monitoring should be put in place to ensure early detection of changes that may lead to worsened access to medicines in Canada. This may be measures related to reduced investment in this sector leading to economic impact and reduction in GDP, reduced clinical research in health, and negative impact to overall resources for healthcare for Canadians, this includes the loss of jobs and private health insurance for people who are working.

Modeling should be done, based on real and recent decision-making principles to anticipate what may be lost and what is gained as a result of these changes so a better-informed process can be exercised for implementation of PMPRB-DG. The implementation of the PMPRB-DG should be cautious and recognize risks that may reduce access to useful medications, both to those treatments which are currently available in Canada as well as those that are yet to be marketed or submitted to Health Canada for approval. Worldwide comparison of medicine availability should be included to ensure Canadians do not lose out on important and useful therapies that are available in developed countries which do not get introduced to Canada to due the parameters in the PMPRB-DG.

Consideration should be given to recent data and decisions which have been made as a result of the anticipation of PMPRB-DG. There are reports which have identified the withdraw or removal of drugs from review processes claiming the anticipated impact of PMPRB-DG is the reason. This may require further investigation to better understand the actual reasons of these withdrawals.

The following referenced data and reports are provided for consideration as PMPRB-DG are implemented because these represent concerns and unintended consequences that may have negative impacts to people and patients in Canada:

- PDCI reports that future launches of innovative medicines in Canada will be at risk due to significant price reductions associated with the PMPRB-DG to Category I new medicines, including an 82.8% price reduction for rare disease medicines and a 60.8% price reduction for oncology medicines. Although lower prices and a sustainable healthcare system is needed, these should not pose a barrier for new drugs in these categories coming to Canada [PDCI. Impact analysis of the draft PMPRB excessive price guidelines. February 12, 2020]
- Innovative Medicines Canada (IMC) reports that seven planned drug launches have been delayed or suspended, including rare disease and oncology medicines due in part to the anticipated impact of PMPRB-DG. [Anne Babineau, Director (Western Canada/Prairies), IMC, verbal communication, Feb 7, 2020].
- The number of new drugs submitted for approval to Health Canada has been lower since the announcement of the PMPRB-DG. Health Canada data shows there were 44 per cent fewer new drug submissions between August and December 2019 compared to the same time period in 2018, and 30 per cent fewer than the same time period in 2017 and 2016. After

implementation of the new regulations and PMPRB-DG, it should be investigated if the reduced number of new drug submissions is due to these proposed PMPRG-DG and which sections or requirements may be the cause of potential negative impact to people and patients in Canada. We recommend that parameters and regulations that are identified as presenting a barrier to submission of new drugs to Health Canada or making them available to patients once they receive a Notice of Compliance be addressed. We emphasize the need to find solutions which provide value to Canadians with respect to patented pharmaceuticals and balance health system sustainability with patients in Canada losing access to important therapies. [Health Canada (2020). Drug and Health Product Submission Under Review. Accessed Feb 6, 2020. Available at: [https://www.canada.ca/en/health-canada/services/drug-health-product-review-approval/submissions-under-review.html# Supplemental\\_new\\_drug\\_1](https://www.canada.ca/en/health-canada/services/drug-health-product-review-approval/submissions-under-review.html# Supplemental_new_drug_1) ]

- A survey conducted by Research Etc. commissioned by Life Sciences Ontario (LSO) was aimed at gaining better understanding of the impact of PMPRB-DG on the pharmaceutical industry and life sciences organizations. Patient organizations are concerned that reduced investment by these companies will result in reduced clinical trials carried out in Canada as well as reduced medicine options for patients. This survey of senior executive level decisions makers from pharmaceutical companies and life sciences organizations found that the PMPRB-DG would have a “significant negative impact” to the following decisions for their Canadian operations:

<b>Specific aspects of pharmaceutical business plans impacted</b>	<b>Response Rate for Somewhat Negative and Significant negative impact combined</b>	<b>Response Rate for Significant negative impact</b>
Product launches, commercialization and supply of current products to the Canadian market	97%	74%
Compassionate access programs	70%	55%
Clinical research	91%	44%
Employment	97%	40%
Patient support programs	73%	35%
Manufacturing	37%	23%

Patients are concerned that one or more of these decisions are likely to result in delayed or abandoned product launches which may be a new medicine that changes the course of their disease or enables them to survive until they are able to access a breakthrough therapy. We call on Health Canada to further analyze the impact of the PMPRB-DG to guard against such unintended consequences and to monitor for detriments to the health of Canadians and patients. [Research etc (2020). Impact of PMPRB Pricing Changes Final Research Report. Accessed Feb 7, 2020. Available at: <https://lifesciencesontario.ca/wp-content/uploads/2020/02/Research-Etc.-PMPRB-Survey-02-03-20.pdf>]

There has already been a decision made by Hoffmann-La Roche Limited to withdraw its submission under review at pan- Canadian Oncology Drug Review (pCODR) and the Institut National d'excellence en Santé et en Services Sociaux (INESSS) for TECENTRIQ® (atezolizumab), a treatment used in combination with chemotherapy (nab-paclitaxel) for the treatment of adult patients with unresectable, locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumours express PD-L1, and who have not received prior chemotherapy for metastatic disease. This decision is *"based on the anticipated impact of draft guidelines issued by the Patented Medicines Pricing Review Board (PMPRB) on November 21, 2019, which propose changes to the ways in which the PMPRB assesses the price of a medicine"*, see attached letter enclosure which was sent to healthcare practitioners. This is significant since this is the first and only approved cancer immunotherapy agent in Canada in unresectable, locally advanced or first-line metastatic TNBC. This demonstrates that manufacturers are already making decisions as a result of anticipated impact of PMPRB-DG. Monitoring of such occurrences is needed, which are tremendously difficult if the decisions are made not to submit to Health Canada at all. As such, there is a need to analyze the barriers which result in such negative outcomes which in turn has negative impacts to patients in Canada as PMPRB-DG are implemented. [Letter to Healthcare Professionals informing them of the withdraw of the product submission, dated Feb 5, 2020]

The Better Pharmacare Coalition also echoes the input of the Best Medicines Coalition and encourages the PMPRB to consider methods to monitor and carry out surveillance in a holistic manner to measure the overall impact on access to medicines in Canada. We would be pleased to be involved in the development and implementation of these mechanisms.

Thank you for your consideration,



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Encl.



February 14, 2018

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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

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February 5, 2020

Dear Dr. Low,

We are writing to advise that on Tuesday January 28, 2020, Roche Canada **withdrew its submissions under review** at the pan-Canadian Oncology Drug Review (pCODR) and the Institut National d'excellence en Santé et en Services Sociaux (INESSS) for TECENTRIQ® (atezolizumab) in combination with chemotherapy (nab-paclitaxel) for the treatment of adult patients with unresectable, locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumours express PD-L1, and who have not received prior chemotherapy for metastatic disease.

This decision is **based on the anticipated impact of draft guidelines issued by the Patented Medicines Pricing Review Board (PMPRB)** on November 21, 2019, which propose changes to the ways in which the PMPRB assesses the price of a medicine. The draft guidelines introduce three new pricing factors - pharmacoeconomic value, market size, and GDP per capita - that generate significant uncertainty and complexity, making it extremely challenging for manufacturers to reliably estimate an acceptable price at launch and throughout a product's life cycle. Canada's innovative pharmaceutical companies, including Roche, have advised the PMPRB and the federal government throughout the guideline development process that this uncertainty will force companies to delay launch decisions or forego launching new medicines in Canada.

TECENTRIQ in combination with chemotherapy (nab-paclitaxel) marks the first and only approved cancer immunotherapy agent in Canada in unresectable, locally advanced or first-line metastatic TNBC. Roche Canada strongly believes in the clinical benefit of this regimen as

evidenced by approvals from Health Canada and other international regulatory agencies. **We have decided to withdraw the TECENTRIQ TNBC pCODR and INESSS submissions at this time while we seek certainty regarding the impact of the PMPRB guidelines, and await additional evidence to further inform payer decision-making, with the goal of optimizing patient access to this important therapy.** We will communicate regarding developments on this submission as available.

Roche Canada continues to stand behind the value of TECENTRIQ in this difficult to treat and well-defined population and remains committed to TNBC patients. **As such, we are continuing to provide TECENTRIQ free of charge through our OnCare™ program and explore all coverage options for patients for ABRAXANE® (nab-paclitaxel) in order to support access to this combination for patients. In addition, to ensure efficient and rapid identification of patients who could benefit from this regimen, Roche Canada will continue to provide access for patients to PD-L1 testing.** Physicians who have made the decision to prescribe TECENTRIQ for their TNBC patients and who are interested in information about our patient support services should contact the Roche OnCare™ program at 1-833-651-2047.

We would like to express our sincere appreciation to those clinicians and patients who provided input to the pCODR and INESSS evaluations.

Should you have any questions, please contact Elodie Reydet at [elodie.reydet@roche.com](mailto:elodie.reydet@roche.com) or 647-643-6520.

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