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Patented Medicine Prices Review Board  
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Submitted electronically to [PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca](mailto:PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca)

Dear Board Members,

### Re: **PMPRB 2020 DRAFT Guidelines**

Thank you for the tremendous amount of work the PMPRB has done so far in considering the feedback received in response to the November Draft Guidelines. We are grateful for this second opportunity to submit responses regarding the 2020 Draft Guidelines.

Since 1976, the [Canadian Society of Intestinal Research](#) and the [Gastrointestinal Society](#) have been advocating for patients with digestive and liver diseases and disorders (everything from gum to bum). This includes, among a host of other conditions, as many as 6 million Canadians with irritable bowel syndrome ([IBS](#)), more than 9 million with functional dyspepsia, as many as 8 million with chronic acid reflux ([GERD](#)), and an additional 270,000 suffering from [inflammatory bowel diseases](#) including [Crohn's disease](#) and [ulcerative colitis](#). We also represent several rare diseases and disorders, including [eosinophilic gastrointestinal disease](#), a condition of unknown cause increasingly prevalent in children and adults, and [gastroparesis](#), a debilitating motility disorder commonly related to diabetes, that only has medications to help alleviate symptoms, but nothing that targets the disease itself. Many of these are chronic conditions that rely heavily on the healthcare systems.

### Considerations for Implementation

We are troubled by the remaining inconsistencies and ambiguity in the proposed Draft Guidelines, several of which we will discuss in further detail below. The Guidelines' high level of uncertainty and unpredictability disincentivizes drug manufacturers and pushes them away from seeing Canada as an attractive market for launching innovative medicines. As a result, we respectfully urge the PMPRB to pause and thoroughly evaluate the effects of the adjusted basket of countries as an especially important first step. Then, calculate its success before taking any further measures. This is a more reasonable proposition since many of the concerns we are bringing forward regarding subsequent processes are shared by other patient group stakeholders.

### Patient Input

While opportunities for consultation and discussion were plentiful in the development of the previous Guidelines, we are deeply concerned with the paradoxical situation for this version of the Guidelines. That said, as a patient member of the Steering Committee, I can attest that the process was not deliberative and, as such, the PMPRB missed out on genuine consultation. We had hoped for meaningful deliberative dialogue between the PMPRB and patient communities. Such conversation is even more crucial at this time due to the complex changes made to the Guidelines and the challenges and revelations the novel coronavirus disease (COVID-19) pandemic has brought to the importance of accessible, timely, transparent, and effective healthcare systems.

We are also discouraged to notice that the revised Guidelines overlook the consideration of direct input from patients themselves in the price review process. Patients are the ideal stakeholder to provide external and real-world evidence on medicines, which is particularly applicable in the Guideline's proposed scientific reviews and in the mandatory factor of determining the pharmacoeconomic value of medicines. Our lack of inclusion in the review process is a stark departure from well-established and renowned Health Technology Assessment agencies in Canada and internationally, as well as processes within provinces. Nowhere in the revised Guidelines is patient input expressly or implicitly mentioned, failing to recognize the significance of our

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involvement or the value of our input. Uppermost in our minds should always be that the main reason the PMPRB exists is because individual Canadians need medications to treat issues such as disease, accidents, or genetic variances.

### Federal Court Ruling

It is unclear how the PMPRB will move forward with the 2020 Draft Guidelines and Regulations, considering that the recent Federal Court ruling found the disclosure of confidential rebates as *ultra vires* the mandate of the PMPRB outlined in the *Patent Act*. This ruling affects a significant portion of the Guidelines, and while the Federal Court has viewed the introduction of the new economic factors as within the PMPRB's jurisdiction, their use in the calculation of the **maximum rebated price are rendered moot**. This leaves the maximum list price (MLP), particularly the change to the basket of comparator countries, as the remaining body in the Guidelines that is in line with the *Act*. Should the PMPRB repurpose the new mandatory factors for the setting of the MLP, we strongly recommend the inclusion of patient input in this process.

As you know, the court decision also highlights several key distinctions in the scope and jurisdiction of the PMPRB, further establishing that its mandate is to protect Canadians from excessive pricing instead of setting these prices. [Justice Manson](#), relying on precedent, stated: <sup>1</sup>

*It bears repeating that the Board's mandate under the Patent Act is not to set prices for patented medicines, and the Board does not regulate profits made by patentees. The Board's mandate to control prices is only engaged where it finds a patentee has abused its monopoly by charging excessive prices... a vast majority of patentees' sales are made to drug wholesalers. Patentees generally do not sell medicines to public drug plans or private insurers, and these entities do not purchase or take title of medicines from patentees. Rebates and discounts provided by patentees to third party insurers are unrelated to the "price" at which patented medicines are "sold" within the meaning of paragraph 80(1)(b) of the Patent Act (paras 199 and 205).*

### Ensuring Access to Lifesaving Medicines

We support the goal of the federal government to improve the affordability of medicines in Canada and to ensure financial sustainability for our healthcare systems. However, these should not be pursued at the cost of decreasing access to innovative therapies. We strongly advise the PMPRB to reconsider the Draft Guidelines in the context of its impact on patients and the public, including its unintended consequences. We are extremely concerned that access to important new therapies will be significantly delayed or denied and that the consequential manufacturers' decisions to not launch products in Canada would eliminate access for all patients.

Furthermore, an unintended consequence could be that even those who have private insurance might be affected. Dramatic reductions are also expected in Canada for clinical trials, patient support programs, and compassionate medication releases. If pharmaceutical companies do not consider Canada as a Tier I product launch country and are disincentivized to come to Canada due to the unpredictability of the PMPRB reforms, then they are consequentially very unlikely to conduct the clinical trials needed to achieve licensure in the country, further reducing access for Canadian patients.

These anxieties are not unfounded. [Life Sciences Ontario conducted a survey](#) in late 2019,<sup>2</sup> which revealed that virtually every pharma executive in Canada expects the PMPRB changes to result in 'no launch' decisions and delayed launches in Canada. Senior pharmaceutical and life sciences executives expect oncology, biologics, rare disease, rheumatology, and gene therapy to be the most affected by the changes, many of whom are patients who we represent. They also report that 94-96% of respondent companies predict negative impacts to clinical trial research and employment in Canada. Lastly, about 70% of Canadian pharmaceutical executives predicted 'somewhat negative impact' to patient support programming as well as negative impacts on availability of medicines through compassionate access initiatives.

Changing the basket of comparator countries from the PMPRB7 to the PMPRB11 alone will likely result in a 20% reduction in the number of new drugs coming to Canada. This is a travesty that I don't think the PMPRB actually wants for Canadians, yet it will likely happen. Furthermore, according to a [systematic review conducted by the Canadian Health Policy Institute](#),<sup>3</sup> a large number of studies conclude that there is a significantly negative relationship between drug price controls with research and development and access to new medicines. It is in

the best interest of the PMPRB to contribute to, rather than impede, the facilitation of a vibrant research and development landscape in Canada, as this would complement the federal government's efforts to exponentially grow the health sciences sector.<sup>4</sup> Canada's goal is to be among the top three countries around the globe in health innovation and research but these spots are currently held by the US, UK, and Germany. The federal government's targets include doubling the country's number of exports and firms in the health and biosciences sector. Yet, Canada only makes up 2% of the biopharmaceutical industry's manufacturing process, including active pharmaceutical ingredients (APIs), and the majority of these facilities are located in EU countries and the US.<sup>5</sup> We ask the PMPRB to ensure that their new regulatory approach would not curtail these objectives.

### Timeliness

We ask the PMPRB to provide a clear timeline for the price review process, and how it will operate with CADTH, INESSS, and the pCPA. Furthermore, the Guidelines are vague as to how the PMPRB expects patentees to achieve compliance all along the drug access pathway, since negotiations with provinces via varied product listing agreements and other processes may take years. Many products end up not even being covered by formularies after all that public money is spent on price negotiations.

According to Innovative Medicines Canada,<sup>6</sup> our reimbursement rate is found to be comparable to New Zealand that, sadly, has both the least new drug launches and publicly-reimbursed drugs among the OECD20. While Canada's launch rate is similar to the OECD20 median, its reimbursement rate is remarkably lower and Canadian drug list prices have been consistently and significantly below the median international list prices for countries currently monitored by the PMPRB. New Zealand is not a good comparator and we don't want to mimic its healthcare practices in Canada.

### Human Cost

There are conflicting sources of data on the rate of drug launches and the availability of clinical trials in Canada in association with the announcement of the PMPRB changes. As a patient organization representing hundreds of thousands of Canadians affected by system-wide transformations in access to necessary care, we do not wish to boil down our conversation to a battle of the data. The bottom line is that there is a real human cost to delaying and barring access to new medicines. The COVID-19 pandemic and the incredible amount of resources needed to respond should have made us realize that access to timely care is no trivial matter. The pandemic has also shown us the many ways in which we can transform healthcare systems and patient access, and of particular relevance surrounding PMPRB, the speed in which regulatory bodies and health agencies have reviewed and approved (where applicable) essential and life-prolonging drugs. We strongly encourage the PMPRB to consider these lessons in timeliness and accessibility moving forward. *It can be done!*

### Impact Assessment

Analysis of the PMPRB's own data shows that there is no health-spending crisis related to the prices of patented medicines that justifies new regulation.<sup>7</sup> In 2018, prices have also declined less than the Consumer Price Index (CPI), adding to the 25 years that prices have remained below the CPI. In fact, the weight of available evidence suggests the Guidelines could lead to higher total healthcare costs by hindering clinical access to efficient innovative pharmaceutical treatment technologies. Furthermore, a detailed examination of the Regulations found the proposed pricing rules to be arbitrary and based on questionable assumptions. It also raised serious technical concerns about the proposed methods for determining price ceilings. As it is patients who will ultimately be affected by these regulatory changes, we want to ensure that they will result in the best outcomes and in a fair and transparent manner.

However, debates still surround the true state of prices and healthcare pharmaceutical spending in Canada and, as a result, we strongly advise the adoption of independent and rigorous review of the Guidelines upon its implementation. This may be pursued in addition to the Guidelines Modernization and Evaluation Process (GMEP). Yet, we remain perplexed about this process as we have little information on how it will operate and specifically what metrics it will use to measure impact. The PMPRB announced that a GMEP proposal will be made available to the public in early 2020.<sup>8</sup> However, its release has been delayed to after the finalization of the Guidelines. Furthermore, there has been no indication provided as to whether patient groups and other stakeholders will be invited to engage in consultations. As a result, we advise the PMPRB that any move toward implementation of the Guidelines should be postponed until the GMEP availability.

Too often, the true cost of delaying or barring access to medicines is overlooked in analysis reports. Therefore, we recommend that the PMPRB include patient engagement in these assessments. We have lived experiences of its impact and the overall cost to the healthcare systems, including the various means in which medicines are made accessible and used in Canada. We also suggest monitoring to be conducted by independent committees and expert stakeholders, in addition to patients and patient groups, with a focus on patient outcomes and comparative analyses with OECD countries. This includes the assessment of clinical trials, new drug launches, and effects (associative and causative) in the economic vitality of the health sciences sector in Canada. To further capture the impact of the PMPRB changes, evaluation should be conducted from the lens of opportunity costs and consequences to patients on the availability and unavailability, as well as delay, of medications and expanded therapeutic options to patient outcomes. Considerations from this approach would entail observations on whether the new PMPRB framework has increased efficiency, timeliness, and accessibility; whether the needs of Canadian patients are being met, especially patients with rare diseases; economic consequences to individuals and the healthcare budget; and rates in number of clinical trials of new drugs, duration and extent of drug trial phases, and study sites, as well as availability of compassionate access programs and patient supports.

### **Transparency and Fairness**

There is a lack of explanation as to how the PMPRB staff determine whether a comparator medicine (patented or non-patented), used in both the domestic therapeutic class comparison (dTCC) and international therapeutic class comparison (iTCC), is believed to be “sold at an excessive [public] price,”<sup>9</sup> with consequential removal from review. This elimination of “excessively priced” therapies will alter the price review by effectively lowering the top or median price points for the drug product in question. With no information provided on how the staff will make these determinations, drug manufacturers are more uncertain in how their products will fare in the Canadian market. As representatives for Canadian patients, on the other hand, we want to ensure that innovative drugs will be given a fair review process, as the cost for barring access are greater losses.

To also ensure procedural fairness of accessibility for the ultimate benefit of patients, we emphasize to the PMPRB the absence of transparency in the discretionary decisions of staff in the additional review of filings for the investigation process. The proposed Guidelines state that staff may use the price review tests and modify them however they perceive to be most appropriate for the product in question. The inclusion of test modifications may be appropriate in some cases but there is still a lack of transparency surrounding the extent of these discretionary decisions. Thus, we note that test modifications should be practiced reasonably and appropriately, and the PMPRB should provide further clarity on these processes.

Furthermore, the Draft Guidelines are vague as to whether the process of submitting a complaint provides confidentiality or anonymity, and whether the reporting individual or organization will be disclosed to the patentee in question. Of more concern is how the PMPRB staff will address the potential for backlog and whether complaints will be addressed and investigated timely and given due process, especially when they require no evidence and can come from any source. We question how your staff can manage this in addition to their new mandatory factors. Again, for patients, timeliness is of utmost priority in these regulatory changes sought by the PMPRB.

### **Health Technology Assessment and Scientific Reviews: Necessity versus Duplication**

We respectfully highlight that the PMPRB, as empowered by the *Patent Act*, is mandated to protect Canadians from excessive pricing and this body is only one mechanism among many in how drug prices are controlled in Canada. Since the PMPRB's inception in 1987, the drug approval and reimbursement process regime has grown in complexity and has built ways to increase affordability for Canadians. With the creation of a new regulatory approach toward rebated prices via conducting HTA for the calculation of the MRP/MRP[A], it leads us to question the impetus behind the PMPRB requiring additional reviews and expanded jurisdiction; whether this is a result of a need for further competency and robustness to current HTA bodies and reimbursement processes in Canada and whether the PMPRB sees these existing bodies as redundant. CADTH and the pCPA already undertake much more rigorous clinical and health economic evaluations of medicines and have a more direct impact on the actual price that patients and provinces are charged. Therefore, it is unclear how and to what extent the necessity of the PMPRB's additional regulatory approaches of pharmacoeconomic value assessments and scientific reviews, both of which are already plagued with gaps in transparency and accountability.

## Looking Ahead

On July 24, 2020, President Donald Trump of the United States of America signed the Executive Order<sup>10</sup> to allow the importation of drugs sold in Canada for American patients. This exacerbates Canadian patients' current and future supply of access to drugs. This is extremely concerning, and we ask the PMPRB if these potential circumstances were considered in the drafting of the proposed changes to the Guidelines. In particular, we are troubled by the potential shock to Canadian supply of patented medicines, which includes new patented medicines, line extensions, and gap medicines, as the Draft Guidelines have added the size of the market for the medicine in Canada as a factor in its price review determinations.

The Gastrointestinal Society and Canadian Society of Intestinal Research are members of the Medicine Access Coalition - BC (formerly the Better Pharmacare Coalition), which is a member of the Best Medicines Coalition. We endorse the submissions of these coalitions. We encourage the Board to consider their input as it provides complex evaluation of the potential impacts of the Draft Guidelines.

With outstanding questions surrounding the 2020 Draft Guidelines, pending judgment from the Quebec Superior Court on the constitutional validity of provisions of the *Patent Act* and the Regulations with the *Constitution Act (1867)*, as well as the potential for an appeal to the Federal Court ruling, we respectfully urge the PMPRB to reconsider the implementation of the amended Regulations and to provide more opportunities for consultation with patients and other stakeholders on the revised Guidelines.

There are also various other systems-wide changes occurring at this time in Canada's healthcare systems, as such, and with the limitations brought on by the pandemic, we recommend that the PMPRB further analyze whether these new mechanisms will successfully achieve sustainability for healthcare and research and development in Canada while, most importantly, providing timely access to lifesaving and life-prolonging innovative medicines. We welcome further discussions with the Board Members on this submission, should there be interest and points of inquiry.

Yours sincerely,



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