Independent Patient Advocacy Groups renew call for strong and effective PMPRB Guidelines that bring down the high cost of patented medicines in Canada

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Submission to the Patented Medicine Prices Review Board

on the Guidelines Consultation

Submitted by

Independent Voices for Safe and Effective Drugs

And

Breast Cancer Action Quebec

The signatories of this brief

Our two organizations, Independent Voices for Safe and Effective Drugs and Breast Cancer Action Quebec would like to thank the Patented Medicine Prices Review Board (PMPRB) for the opportunity to comment on its revised proposed Guidelines. At issue in these Guidelines are the rules that determine whether many Canadians can afford to pay for their prescription drugs. According to the PMPRB itself, prices of patented medicines are the third highest of Western countries, after the United States and Switzerland. As well, Canada is the only Western country with national healthcare that does not include patented medicine. The high price of patented medicines imposes significant economic hardship for Canadians who do not have the necessary health insurance to pay for their prescriptions, generally those people who already have the most limited or precarious incomes. Some are forced to go without certain medicines or skip doses. Even Canadians with health insurance are concerned about the impact of escalating drug prices on co-pays and the health care system. Canadians are not at all familiar with the PMPRB and its guidelines, but they do know there is a major problem with access to affordable medicine in Canada.

The signatories of this brief all work for or with patient advocacy groups that do not receive any funding from pharmaceutical companies. This generally means that our budgets are small or nonexistent, much or all of the work done is on a volunteer basis, and we must cover a wide range of issues. To ensure full transparency, all patient advocacy groups that submit briefs on issues of drug pricing should be required to indicate if they have received funding from the pharmaceutical industry for any of their work. Industry funded patient groups have the means to make themselves heard forcefully, but louder voices should not be mistaken for wide support in the general public.

Because of the complex and remote nature of the Guidelines, it can be difficult to mobilize our members and allies and the situation is even more challenging during the summer and a pandemic. Despite this, more than 2,500 Canadians signed our House of Commons petition in support of these actions: enacting the reforms to the Patented Medicines Regulations as presented in August 2019 as soon as possible; severing the financial links between the drug industry and patient advocacy groups; maintaining the government's commitment to strengthen the PMPRB; and moving quickly to institute universal Pharmacare. As we said, Canadians know there is a serious problem.

The revised reform to the Guidelines

When the first draft of the proposed reform of the Guidelines was released in August 2019, we were all impressed. The Patented Medicine Prices Review Board is officially a consumer protection agency and it appeared that this role would, finally, be fulfilled with the new guidelines. Thus, it was with profound dismay that we read the revised reform released in May 2020. On many fundamental issues, there is serious weakening of the guidelines. What would have created a strong and fair system of pricing regulations has become a series of much weaker measures aimed at reducing some of the worst excesses of the high prices paid in Canada but no longer representing a solid system of consumer protection.

Further, many of the pricing criteria have been skewed significantly upwards towards allowing much higher average comparators. As mentioned in the Backgrounder 2020, independent stakeholders have diametrically opposed positions on many issues from the pharmaceutical industry and the groups they fund. The role of the PMPRB is consumer protection, therefore its role is to come down on the side of consumers, i.e. citizens, and especially disadvantaged citizens who suffer the most from the high price of prescription drugs. The values at the heart of a strong system of drug price regulations are patient protection, transparency and sustainability. In fact, these values reinforce one another. Unfortunately, with the revised Guidelines, they no longer appear to the be guiding force of the proposed reform. We are particularly concerned that in revising the PMPRB's draft guidelines, the agency has significantly weakened key mechanisms of price control. Below, we will outline just three of our major concerns.

1. Risk-based Approach to Determining Category 1 Classifications

Under the PMPRB regulations, drugs that will be subject to the strongest price controls are designated "Category 1." In the previous guidelines, most new drugs were classified as Category 1, but the PMPRB has altered the guidelines so that only 25% of drugs now fit this classification. The rationale given for this change is that the PMPRB staff lack the resources to treat so many new drugs as Category 1. This sidesteps the issue, which is that the majority of new drugs now have shockingly high prices that threaten fair access to these medications and system sustainability. We strongly oppose the more generous thresholds provided in the revised guidelines to determine whether a drug will be classified as Category 1, including the special consideration given to "rare disease" drugs. Classifying a drug as a treatment for a rare disease – a poorly defined designation – has enabled pharmaceutical companies to game the system. From the perspective of price controls, when so many new drugs (including "rare disease" treatments) come with excessive price tags, classifying only 25% of new drugs as Category 1 allows the pricing of many new drugs to escape proper scrutiny. The public interest should drive policy; policy should not be adapted to accommodate the limited resources of the PMPR staff.

Recommendation: All drugs should be eligible for the Category 1 designation. If the PMPRB needs more resources to cope with the influx of new high-priced drugs, the government should provide these resources.

2. Pharmaco-economic value

The pharmaco-economic value (PV) is an important new feature of the PMPRB regulations, designed to provide the patient population with the most health benefit within a limited health budget. The PV allows the PMPRB to take into account the opportunity cost of making cuts elsewhere in the system when a drug is excessively priced, using the standard measure of the QALY (Quality-Adjusted-Life-Year). This is a valuable addition to the PMPRB's powers. The clinical benefit of new drugs is often ambiguous or unknown, which has allowed companies and industry funded patient groups to press for coverage of very expensive drugs that turn out to have limited clinical value and sometimes significant clinical harm. The PMPRB states that patentees (pharmaceutical companies) are "fundamentally opposed to the introduction of PV as a factor." Apparently in response to this opposition, the new guidelines substantially weaken this valuable regulatory tool by revising the guidelines to change the PV threshold from $60,000 per QALY to $200,000 per QALY.

Recommendation: The PMPRB should reinstate the PV threshold of $60,000 per QALY.

3. Market Size Adjustments

Under the regulations, the innovative use of a Market Size Adjustment allows the PMPRB to adjust the price cap of a new drug by taking the company's annual revenues from that drug into account. We welcome this power because it allows the PMPRB to contest a company's often exaggerated claims that a high price is necessary to compensate for a new drug's expected "small market." The shift in the industry's business model, from popular "me too" drugs with large markets to specialty drugs has driven the rise in prices to exorbitant levels. Very often, to justify a high price, companies claim a drug will have

a small market, then significantly expand the market by applying to have multiple indications approved (e.g., Humira, Remicade, Gleevec) and/or by encouraging off-label sales. The resulting prevalence of high prices has reset public expectations so that even drugs with large markets are now priced at levels that threaten system sustainability and promote access injustices (e.g., Sovaldi for Hepatitis C). In the earlier guidelines, the PMPRB proposed imposing a market size price reduction of between 10% and 50% for drugs with annual revenues equal to or over $25 million. The new guidelines raise this level to $50 million, apparently ceding to what the PMPRB describes as intense industry opposition. This concession is counter to the public interest.

Recommendation: The PMPRB should retain $25 million as the revenue figure that justifies a market size adjustment.

Has the PMPRB Forgotten Its Role?

As we have said above, as a consumer protection agency, the role of the PMPRB is to protect the public interest, by determining price caps that will regulate excessive prices. In these revised guidelines, we are dismayed that the agency seems to have forgotten its purpose. When independent stakeholders and industry representatives hold "divergent and even diametrically opposing points of view," the PMPRB's responsibility is not to strike a "balance" between the demands of industry and policies that serve the public interest. The PMPRB's role is to come down firmly on the side of the side of the public. It is not to protect the payers or to come up with a strategy for rare diseases, and it is definitely not to make concessions to an industry that is far too powerful.

During public consultations, members of the PMPRB staff stated that the guidelines are not set in stone. We urge the government to revisit the revised guidelines and to ensure the agency has the powers to do its job: to protect the public from excessive drug prices.

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