

August 3, 2020

Patented Medicine Prices Review Board
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

RE: PMPRB June 2020 Guidelines Consultation

Dear PMPRB Board Members,

Thank you for the opportunity to provide feedback on the PMPRB guidelines and, more generally, the proposed changes to federal drug price regulation.

The undersigned are cancer care providers and/or cancer researchers from different regions of the country who share a great concern about how the proposed PMPRB guidelines and federal drug price regulations (will and are already) negatively impacting our ability to provide Canadians with the cancer care they need and deserve.

We will be left without the resources we need to treat our patients effectively with the modern breakthrough medications.

The new PMPRB guidelines and price regulations are already limiting the availability of new cancer treatments in Canada and the number of clinical trials of new treatments. This dilemma has been created solely by a policy decision – the excessive reach of the new PMPRB regulations and the carelessness with which they affect patients with cancers and rare diseases (facing unmet needs and dire circumstances) in a large net better suited for other common maladies.

We appreciate the good intentions behind the new regulations to help lower the cost of patented medicines in Canada. Certainly, the costs of cancer medicines can be very high but this occurs for many reasons, including costs of research and development and regulatory costs around complex clinical trials. However, the means by which this price-lowering goal is being pursued, along with the sheer scale and scope of the changes, will have unintended consequences.

It is expected that new oncology medicines coming to Canada will require price reductions of 60% on average. This will impact cancer care in many important ways.

The first involves the *availability* of new treatments. This is an exciting time in oncology -- remarkable new therapies are being developed based on better understanding of the molecular drivers of malignancy and the activation of our own immune systems. However, with such demands on pricing, companies are cancelling plans to launch new treatments in our small market, including (so far) one for breast cancer and one for leukemia. Between 2013 and 2016, well over half (55.4%) of new drugs were approved in Canada before or within one year after their approval in the United States. Last year, however, this dropped to just 15.6%, with the decrease being even greater for new cancer medications.

Without these new treatments – or until their launch years later – some Canadians with cancer will die who didn't have to.

The second impact is on *clinical trials* of new treatments. Canada has a world-class infrastructure supporting clinical research. Thousands of Canadians annually benefit from free access to new and

promising treatments before they become commercially available. However, companies may be more reluctant to initiate clinical studies in Canada if such drugs are unlikely to launch here, since they commit to treating those patients free of charge and offering other patients compassionate access until they are available commercially. The number of new trials registered with Health Canada from November 1, 2019, to March 15, 2020 (during which the new PMPRB guidelines have been under review), fell by 52% compared to the average for the same period in the previous four years, while comparable data for the U.S. show no similar decrease.

We *already* have existing downstream mechanisms to reduce the costs that our governments pay and to ensure that new medicines are used correctly. The pan-Canadian Pharmaceutical Alliance (pCPA) negotiates *confidential* prices that are often massively discounted and we all benefit from those mechanisms. Most global modern medical systems cross-reference prices with other nations when approving their own prices, and companies will not bother to launch in Canada if the *publicly listed* price dramatically lowers the value of their product internationally.

At the least, we need recognition of the special circumstances facing patients with cancers and rare diseases so that they are not mistakenly caught in this indiscriminate net. We need to remember that cancer killed 82,000 Canadians in 2019 – nine times more than have lost their lives so far from COVID-19 – and we need the best possible tools in that struggle.

Therefore, we respectfully request the PMPRB reconsider its new guidelines and regulations to ensure that the more than 225,000 Canadians who will be diagnosed with cancer this year, and those in the years to come, are not unfairly penalized because of PMPRB policies that make new treatments and clinical trials less available to them.

Sincerely,



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