



HLS Therapeutics

December 2nd, 2022

Patented Medicine Prices Review Board
Box L40 Standard Life Centre
333 Laurier Avenue West Suite 1400
Ottawa, Ontario K1P 1C1

Sent via email: PMPRB.Consultations.CEPMB@pmprb-cepmb.gc.ca

Re: PMPRB 2022 Draft Guidelines Consultation

Dear PMPRB:

HLS Therapeutics Inc. wishes to voice its concerns that, if they are adopted as drafted, the proposed Guidelines will have a significant and potentially devastating negative impact on patentees, innovation, and ultimately the health of Canadian patients.

Hence, the concerns expressed in this letter should be viewed in addition to the comments and concerns expressed in our letters of February 14, 2020, and August 20, 2020.

Removal of innovation considerations

We are particularly concerned by the fact that the degree of innovation is no longer considered in determining the price of a medicine. By removing innovation from the equation, PMPRB *de facto* considers all medicines as “me-toos”. This results in the inability to reward the incremental efficacy and safety that innovation brings to patients and sends a very negative message that Canada does not support innovation.

Use of lowest priced drug as comparator in a therapeutic class

We are also extremely concerned by the proposal to compare a new medicine in a given therapeutic class to the lowest priced drug in the class, including generics. PMPRB will therefore no longer use the ceiling of a class to determine if the price of a new medicine is excessive, but rather it will now use the floor of that class. In doing so, PMPRB completely negates a policy that has been in place since its creation in 1987.

This is a dramatic departure from the core mission of the PMPRB, which has always been and should remain to ensure that the price of medicines in Canada not be excessive. Instead, the PMPRB is now focused on reducing prices, which will have the unintended consequence of resulting in less access to innovation as it renders it unsustainable.



HLS Therapeutics

As stated in our 2020 letters, we sincerely hope that the PMPRB will significantly amend its proposed Guidelines. As stated above, HLS Therapeutics is extremely concerned that while attempting to ensure that the price of medicines in Canada not be excessive, the proposed Guidelines sacrifice accessibility and jeopardize the very survival of Canadian companies such as HLS, focused on innovation for the benefit of patient needs.

In the long term, we believe these measures will discourage research and innovation, endanger the sustainability of Canadian companies and cost many Canadians their jobs. Most importantly, those measures will be very detrimental to patients by diminishing the attractiveness of the Canadian market and limiting the introduction of new technologies. In short, the proposed Guidelines will be bad for Canada.

Sincerely,

HLS THERAPEUTICS INC.

A handwritten signature in black ink, appearing to read 'G. Godin', written in a cursive style.

Gilbert Godin
Chief Executive Officer

About HLS Therapeutics

Formed in 2015, HLS is a specialty pharmaceutical company focused on the acquisition and commercialization of late-stage development, commercial stage promoted and established branded pharmaceutical products in the North American markets. HLS's focus is on products targeting the central nervous system and cardiovascular therapeutic areas. Headquartered in Toronto with a significant presence in Montreal, HLS employs some 83 Canadians.