HLS Therapeutics

February 14th, 2020

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 Draft Guidelines Consultation

Dear PMPRB:

HLS Therapeutics Inc. thanks you for the opportunity provided to stakeholders to offer comments on the PMPRB draft guidelines. We wish to voice our grave concerns on a number of aspects that, if the guidelines are adopted as drafted, will have a significant and potentially devastating negative impact on patentees, innovation, and ultimately the health of Canadian patients.

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.

1. Degree of Innovation

We find it highly unfortunate that consideration of the degree of innovation previously used by PMPRB has been totally evacuated from the proposed guidelines. Thus, the assessment of excessive price will no longer take into account the innovative value of the new product. This is contrary to the original mission of PMPRB which recognized and valued innovation as part of a strategy to support the development of health technologies, improve the health of Canadians and favorably position Canada on the international scene. We believe that this will have serious consequences and result in the same price test being applied to all products, regardless of their value or level of therapeutic improvement. We request that the assessment of improvement over existing technologies be re-introduced into the process.

2. Using the Median Therapeutic Class Comparison

Similarly, we are extremely concerned that the proposed therapeutic class comparison uses median values instead of maximum ones, regardless of the value of the product. This will have dramatic consequences in calculating the maximum list price, particularly in cases where the therapeutic category includes one or more older and sometimes very old drug.

For example, acetylsalicylic acid (ASA), which received its patent in 1899, is still extensively used in cardiovascular medicine. Any new medication used to treat a similar condition will thus be assessed using the median of the category containing ASA.

It is illogical as well as totally unfair to compare the price of new innovative medicines developed in the 21st century to the price of drugs of the 19th century like ASA. Since PMPRB proposes to abolish the assessment of therapeutic improvement, using the median of the therapeutic class will apply to all new drugs and will therefore never result in a fair price that reflects the true value of an innovation. We believe that PMPRB must link price to value and innovation, and therefore abandon this proposed price test.

3. Setting the Maximum List Price

As stated above, using the median of a therapeutic class will most likely result in setting the price of new innovative drugs below other, older drugs in that category, and most likely below the price of the same drug in other countries. Hence, by setting the Maximum List Price at the lower of the Median International Price and the Median Therapeutic Class, the price of a new drug in an existing category will de facto be lower in Canada than anywhere in the world.

We believe that this is contrary to the wishes of Canadians, and definitely against the best interest of Canada. Indeed, the objective of the PMPRB must remain to ensure Canadians not pay more than they should for new drugs, an objective we share, but it must not be to drive the price of these drugs to the lowest level in the world.

4. Factors related to market size

Again, we find it completely illogical and unfair to decrease the price of a product as sales go up. From our point of view, an arbitrary reduction in price solely based on level of success that product attains is a serious deterrent to innovation and success. In fact, this approach based on market size essentially penalizes success and is a disincentive to the introduction of new dosage forms, new indications, etc.

In addition, as competition increases in a given segment, the patentee will not be allowed to adjust its price in cases where sales fall below the set threshold. This is a further disincentive to maintain products on the market and will limit therapeutic choices.

Furthermore, the arbitrary nature of this rule completely obliterates the notion of value. This approach is also irrational; if a product meets the cost-effectiveness criteria set in the guidelines, then its sales should be encouraged as its use makes the system comparatively more efficient. Greater sales bring greater value to society. Instead, the proposed rules penalize the manufacturer and will make many innovations unsustainable from a business point of view.

5. Price review as of August 2019

We are also extremely concerned that by grandfathering drugs that received their DIN prior to August 21, 2019, the PMPRB essentially uses that date to begin implementing the Guidelines. Essentially, this provision makes the process retroactive to August 2019. The PMPRB should put in place attenuation measures for product receiving Notice of Compliance between August 2019 and June 2020 as patentees planned on introducing products to market based on the previous set of rules. We understand that PMPRB has already recognized the problems inherent to this provision. We strongly encourage you to exclude these products from the new guidelines.

6. Considering the maximum dose instead of the usual dose

We are concerned that by considering the maximum dose instead of the usual dose in calculating the cost of treatment may result in erroneous calculations as the maximum dose does not reflect in market reality. These calculations should be based on usual dosage and duration of treatment as determined by Health Canada based on the results of the clinical trial program.

Using the highest possible utilization is also inconsistent with typical pharmacoeconomic analyses which use the recommended dose used in the trials.

7. Comparable dosage forms

We believe that grouping dosage forms into categories does not differentiate sufficiently between dosage forms and is a deterrent to innovation in developing new dosage forms that can be more effective, cause fewer side effects, ensure better compliance and ultimately more effective treatment, etc.

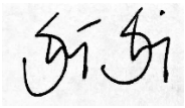
For example, in the topical category, a formulation of a product provided as a patch would be considered comparable to a powder or a tincture. This ignores advances in dosage forms. Similarly, various aerosols in the Nasal/Pulmonary category may have different properties and inherent advantages. Once again, the proposed guidelines do not recognize the value of innovation in this area and will discourage the introduction of new and improved dosage forms.

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.

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, and will hurt patients by diminishing the attractiveness of the Canadian market, thus limiting access to important new technologies. In short, the proposed Guidelines will be bad for Canada.

Sincerely,

HLS THERAPEUTICS INC.



Gilbert Godin
President and Chief Operating Officer