March 19, 2025

Draft Submission – Consultation on Draft Guidelines for PMPRB Staff

Introduction

On behalf of Save Your Skin Foundation (SYSF), Colorectal Cancer Resource & Action Network (CCRAN), Migraine Canada, and Canadian Neuroendocrine Tumour Society (CNETS), we wish to thank the PMPRB for giving us the opportunity to present a submission regarding proposed changes to the PMPRB Guidelines. Save Your Skin Foundation (SYSF) is a national patient-led not-for-profit group dedicated to the fight against non-melanoma skin cancers, melanoma and ocular melanoma through nationwide education, advocacy, and awareness initiatives.

This a very technical document and its contents deal with the implementation of legislation that impacts procedures for industry drug pricing, which in turn implicates access to drugs for patients living in Canada. For that reason, it is of concern to patients and their representatives.

The non- binding Guidelines deal with the steps in the review of proposed prices for drugs entering the Canadian market to ensure the prices proposed are not excessive. They are intended to be seen through the lenses of fairness and consistency for all Rights Holders, by providing the same processes and timelines, which they do.

The factors which the PMPRB can use to determine excessive prices are outlined in the *Patent Act* section 85. In analyzing the Guidelines, which are provided for in section 96(4) of the *Patent Act* and the *Patented Medicine Regulations* these factors must be considered.

The proposed Guidelines are divided into two steps, the initial review which applies to all drugs sold in Canada and the in depth review which only comes into place when determined by the initial review.

First Step

Initial Review

Basket of Scheduled Countries

The basket of eleven countries that has been determined as comparators is reasonable from the patient perspective. It represents a list of countries with which Canada is closely aligned in terms of healthcare delivery and pricing practices.

List Price selection

The selection of the official formularies for the highest international price (HIP) in the basket of countries is appropriate for the starting points for comparison.

HIP should definitely be kept in the Guidelines.

As regards Canadian price comparisons, it is recognized that the provincial formulary price has already generally been reviewed for value by the Canadian Drug Agency and may have been negotiated by the pan-Canadian Pharmaceutical Alliance.

The question is what the PMPRB will do if provinces that have agreed to publicly reimburse the drug have different prices for it. Even though generally they would follow the pan-Canadian Pharmaceutical Alliance negotiated price, they are not required to do so and may reach a different pricing agreement with the Rights Holder.

Annual Review

The process of conducting an annual review of list price for both new and existing medicines is appropriate particularly in the quickly changing environment in which we find ourselves at this time.

Considering the CPI in the annual review is also reasonable.

Exceptions to In-Depth Review Process

The exceptions set out in paragraphs 61, 65, and 66 are reasonable.

Second Step

In-Depth Review Process

Complaints Process

The use of in-depth reviews as exceptional measures based on complaints from the stakeholders in paragraph 67 is reasonable given resource restraints.

We do not support the proposal in the Guidelines to permit insurance companies to file complaints.

In order to avoid vexacious complaints, we propose that the PMPRB state explicitly that it will validate an excessive price complain to ensure that it doers in fact meet the criteria for a complaint *i.e*. it is higher than the HIP.

The identification of TCC based on approved indications or use is reasonable.

Step 1: Qualitative Assessment

Qualitative Assessment class definitions are reasonable.

Human Drug Advisory Panel (HDAP)

The inclusion of external clinical experts in a particular situation is strongly supported. Rights Holders should be permitted to input names for this process, and if feasible, at least one of those names should be accepted among the clinical experts chosen to provide advice. This is also being proposed by CDA for its reimbursement reviews.

Hearing Comparator Prices

It is reasonable that at the hearing stage all prices for the patented medicine and its comparators may be considered by a Hearing Panel, not solely the HIP price.

Domestic TCC (dTCC)

We are concerned that the PMPRB has not described the situations in which the comparators with generics products or biosimilars would be considered appropriate and what evidence would be considered as part of the Scientific Review.

Undertakings

Considerations of undertakings by Rights Holders early in the review process is strongly supported.

Price Hearings

Role of Patient Input in Price Hearings

Given that the PMPRB is a quasi-judicial body, and given that patients and their representatives are interested parties, there should be an opportunity for interested patient representatives and affected patients to address the PMPRB at the hearing Stage.

The *Act* provides a list of factors that the Board must consider when holding a hearing to determine whether a patented medicine is being sold or has been sold at an excessive price in any market.

This does not prohibit the Board from including Guideline processes for obtaining relevant information for a Hearing. In addition to the information provided by the Rights Holder, patients may well also provide relevant information about whether the price being proposed is excessive, given that the *Act* does not define what is excessive.

Thus, relevant patient representatives should be provided notice of the Hearing and be given the opportunity to be heard including affected patients in writing and/or in person if they so request.

Offset of Excess Revenues

We submit that options for redress of excess revenues should not include payment to His Majesty in right of Canada. Excess prices should be retained within the drug portfolio to be used to benefit patients. The first two options provide that result.

Conclusion

Thank you for the opportunity to provide a submission to the PMPRB Guideline changes.

Yours truly,

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