Canadian Society of Hospital Pharmacists
Société canadienne des pharmaciens d'hôpitaux

Patented Medicines Regulations Consultations
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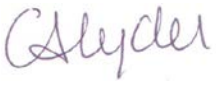
Re: Proposed amendments to the Patented Medicines Regulation

The Canadian Society of Hospital Pharmacists (CSHP) is grateful for the opportunity to provide feedback on the proposed amendments to the Patented Medicines Regulation.

In response to the invitation, CSHP invited select members to provide feedback. Very little feedback has been received, but what is received is supportive of the proposed amendments. Please see the collated responses attached to this letter.

Please do not hesitate to contact me if you have any questions in regard to the information provided.

Sincerely,



Cathy Lyder, BScPharm, MHSA
Director, Members and Programs

CC Myrella Roy, Executive Director, Canadian Society of Hospital Pharmacists

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Feedback received from select members of CSHP

June 2017

Proposal	Response
1 1. Do you agree that a pharmacoeconomic evaluation is an important factor for the PMPRB to consider when determining whether a drug is priced excessively? If so, how should the evaluation be considered? 2. Do you agree that the size of the market for the drug in Canada and other countries is an important factor for the PMPRB to consider when determining whether a drug is priced excessively? If so, how should the size of the market be considered? 3. Do you agree that Canada's GDP and GDP growth are important for the PMPRB to consider when determining whether a drug is priced excessively? If so, how should GDP be considered? 4. Are there any other factors that should be considered by the PMPRB when determining whether a drug is priced excessively? How should the factor(s) be considered and what information should be required from patentees?	▪ In today's context, using pharmacoeconomic evaluation as one of the basis for comparing drugs makes sense and is important. This change would signal to the industry the need to demonstrate value for the drug products they are seeking to market in Canada. The notion of value here indicates the need to go beyond a limited definition of innovation, e.g. new mechanism of action, and demonstrate that the introduction of the new drug product leads to improved clinical and economic outcomes in order to be able to seek higher price for the drug product. To the question of how should the evaluation be considered, there may be several answers depending on the possible multiple interpretations of this question. One important element to consider would be that the pharmacoeconomic evaluation framework uses key perspectives reflecting the Canadian context, e.g. public payer (i.e. provincial ministry of health/drug programs/hospitals) as well as private and out-of-pocket payers (many Canadians do not have private drug coverage and are not eligible to the publicly funded drug programs because of either where they reside in Canada or due to age restrictions of publicly-funded drug programs). ▪ Size of the market may be an important consideration but drug adoption also depends on insurance coverage. As such, comparing market sizes between countries should also account for reimbursement practices in those countries. ▪ GDP and GDP growth may be relevant considerations but likely secondary compared to evidence of value of the drug products (please refer to first bullet above). ▪ Although it may be difficult to correctly quantify the impact on drug uptake, and it may not be aligned with regulatory evaluation, it could be relevant to consider the potential for off-label uses of the drug product as sometime such uses can significantly expand the size of the market of the drug product (e.g. off label uses of certain anti-epileptic drugs for chronic pain management). Perhaps the latter could be considered in supplemental analyses. In addition, given the potential for expansion of personalized medicine in the coming years, the new price evaluation framework may need to consider the cost of

	other/parallel interventions, for example the price of companion diagnostic tests that need to prescribed in order to decide whether to prescribe, or not, the drug product.
	Agree with the price to reflect the value of the drug product based on a pharmacoeconomic evaluation: this is long overdue. The size of the market is an important factor, but it might be difficult to quantify. Two factors come to mind: ▪ Use of the drug may change over time as the drug is used in a larger population than initially intended and approved for. Projections could reflect growth patterns in other countries where the drug is approved for use and use is established in the "real world", having moved from use in patients who are very similar to those in clinical trials to establish the approved indication. ▪ Use of the drug may change depending on the patient (or organization's) ability to pay for it.
2 1. Are there other countries that should be considered in revising the Schedule? 2. Are there other criteria that should be considered in revising the Schedule? 3. Please provide any other comments you may have on the Schedule of comparator countries.	Consideration should be given to including New Zealand as well.
	No comments.
	Agree with the approach taken.
3 1. Do you agree that patentees of generic drugs, i.e. drugs that have been authorized for sale by Health Canada through an ANDS should only report information about the identity of the	Reducing requirements for generic drugs would make sense but there may still be a need to remain vigilant. For example, although not strictly considered generic products, the new framework would need to account for emerging drug products such as biosimilars. These would typically be priced at a lower level than brand name products but their price may still be important for consumers/payers.

drug and its price in the event of a complaint or at the request of PMPRB?	
	The approach appears sensible, but it relies on the market playing out as assumed. Having a patent for a generic drug does not necessarily imply a competitive market for the drug as over time other patent holders may leave the market, and prices may increase. It's important to periodically review the prices. If the proposal is accepted, is PMPRB still obliged to review the pricing information, at whatever period it selects?
4 1. Is the information sought in relation the new factors relevant and sufficient? 2. Is this information generally available to patentees?	If the cost-utility analysis is prepared and submitted by the patentee, the framework should include a provision for PMPRB to conduct a critical appraisal of the economic evaluation, and the economic model used, in order to ascertain the relevance of effectiveness assumptions used by the patentee. Indeed, these may be a source of bias which could potentially result in favourably depicting the patentee's drug products.
5 1. Are there any reasons why patentees should not be required to disclose to the PMPRB information on indirect discounts and rebates provided to third party payers?	There are no reasons why patentees should not disclose to PMPRB information on discounts and rebates. There may however be a need to submit such information in a confidential manner in order to not negatively impact patentees' pricing and marketing strategies.
General comments	
I think the recommendations of the PMPRB are sound, and I agree with them. I'm most impressed with the expansion of the comparator countries list, and the requirement of companies to submit their "other deals".	