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Overhaul to Drug Pricing Regime Proposed in Canada

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On May 16, the Patented Medicine Prices Review Board (PMRPB) published the consultation paper "Protecting Canadians from Excessive Drug Prices: Consulting on Proposed Amendments to the Patented Medicines Regulations." The PMPRB is seeking feedback on its proposal to amend the *Patented Medicines Regulations* under the *Patent Act*, with the underlying purpose to equip "the PMPRB with more relevant and effective regulatory tools to better protect Canadians from excessive prices for patented drugs."

What You Need To Know

Background

The proposal followed Health Minister Philpott's announcement on May 16, 2017 where she declared the government's goal of lowering "unacceptably high drug costs." The proposal is unlikely to be a surprise to stakeholders, as the PMPRB sought input on how to modernize pricing rules through its *Rethinking the Guidelines* consultation in 2016, which included many of the same themes as the proposal. It appears that after receiving feedback from multiple stakeholders who said the suggested changes could not be made via a simple Guidelines update, Health Canada is ready to begin the process for a formal regulatory amendment.

Proposed Regulations

The consultation paper describes five proposals that PMPRB intends to incorporate into the regulations:

- **Introducing new factors into the determination of whether a drug price is "excessive."** Under the current regime, therapeutic contribution and international pricing are key factors that determine if a price is excessive. Under the proposal, the new regulations would contemplate a payer's "willingness and ability to pay" by considering a pharmacoeconomic evaluation of the drug, the size of the market for the drug in both Canada and other countries, and the GDP of Canada.

- **Amending the "basket" of countries for international pricing comparison.** Under the current regulations, the pricing of seven countries, including the United States and Switzerland, is used to assess whether the Canadian price is excessive. The proposal would revise this to a list of 12 countries and would remove the U.S. and Switzerland from this assessment. The removal of the U.S. and the inclusion of other lower-priced jurisdictions are significant: as the U.S. price is generally the highest of the original seven and as the additional countries all have lower prices than Canada, the overall effect will be to drive the median price of a drug down

- **Lessening reporting requirements for generic drugs.** Like branded products, the PMPRB has jurisdiction over a generic drug product if there is a patent that "pertains" to the drug (e.g., method patent) including where the drug is subject to a licensing agreement. The proposal would require reporting to PMPRB only if there is a complaint about a particular generic drug; so generic manufacturers will not be subject to the regulatory burden of reporting launch and ongoing sales information to PMPRB.

- **Requiring the reporting of additional information.** In order for PMPRB to assess the new factors noted above, the proposal contemplates submission of additional information, including a pharmacoeconomic evaluation for the drug and for other drugs in the same therapeutic class, and estimated uptake of the drug per approved indication. It is not clear whether this information would be provided only at launch, or whether patentees would have to report updated information through the product life cycle.

- **Introducing further monetary reporting requirements**. PMPRB has previously signaled its intention to have a better understanding of the "transparent" price (i.e., actual price after applying a manufacturer's volume discount). To this end, the proposal would require reporting of "all indirect price reductions, given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefit in Canada."

Impact and Implications

The proposed introduction of "willingness and ability to pay" to the assessment of whether a price is excessive is in stark contrast to the current statutory text—as well as the current regime that essentially permits "breakthrough" drugs (i.e., drugs that inherently involve more investment to come to market) to have a higher non-excessive price than "me-too" drugs. If passed, a challenge for the regulator in implementation of the proposal will be ensuring that its assessment of a non-excessive price ceiling respects the fundamental purpose of the *Patent Act* in incentivizing innovation. It is not clear from the proposal how the new factors will be practically incorporated into pricing tests under the Guidelines.

Case law interpreting the current regulations has limited PMPRB's ability to gather information on volume discount paid to provincial drug plans under product listing agreements (PLAs) as the courts has indicated that the provinces are not "customers" of a patentee: they do not purchase the drug, but rather provide reimbursement. Proposal 5 is attempting to overcome this case law through explicit regulation. The scope of this proposal is likely to be scrutinized as PMPRB is bound by constitutional limitations and attempting to regulate beyond the "factory-gate" price could be deemed interference with provincial jurisdiction.

The proposal indicates that the required pharmacoeconomic evaluation would be consistent with information that a manufacturer currently submits to CADTH and other bodies that provide recommendations to the provinces on formulary price. Thus, PMPRB is considering reviewing the very same information that is provided to the provincial authorities tasked with delivery of health care and budgeting, and are seemingly best equipped to make decisions about value and "willingness" to pay for a given product.

Next Steps

Consultation on the proposal is open until June 28, 2017. Stakeholders are invited to submit comments to Health Canada. Following the consultation, it is expected that draft regulations will be published with another opportunity for stakeholder feedback.

To discuss these issues, please contact the author(s).