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Description

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ABSTRACT: Over the past five years, Canada's federal government has attempted to force through radical changes to the regulations of the Patented Medicine Prices Review Board (PMPRB), the quasi-judicial agency that has performed its role of preventing time-limited drug patents from being abused for the last 35 years. Legal challenges led to the federal Cabinet cancelling most of the changes. The only one retained is in the PMPRB's external reference pricing test, where Switzerland and the United States will be replaced by six countries with generally lower list prices, which came into effect on July 1st, 2022. The government has said that, for the next few months, the "status quo" will be maintained, but how the amended regulations and guidelines will work subsequently is unknown. The objective of this article is to assess what the change in comparator countries might mean by using a case study of a highly-specialized, rare disease medicine approved in Canada within the last five years. The results are considered from the perspective of a global pharmaceutical executive in Europe or the United States deciding whether it is sensible from a business perspective to launch a similar innovative medicine in Canada in the next 12 to 18 months. Our global pharmaceutical executive faces a set of complex and difficult questions. The most fundamental are: will the PMPRB use its external reference pricing test with the new countries in the same way as it has in the past, and will the company's target list price that would be compliant using the old reference pricing test be compliant under the new rules? With so much unknown, the executive's decision seems highly likely to be wait-and-see. If companies commonly make this decision, launches of new medicines in Canada will, at best, be delayed and, at worst, not happen. Canada's attractiveness as a marketplace for new medicines has already diminished as a result of uncertainty about the PMPRB changes; the uncertainty will persist while new guidelines are drafted. Canadians need the PMPRB to become more creative and adaptable in setting maximum prices to encourage developers to launch new medicines in Canada. Further delays in access or complete denials of access to innovative drugs will hurt even more Canadians with unmet or poorly met health needs that could be helped by these medicines.

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