

New Patented Medicine Regulations in Canada: Case Study of a Manufacturer's Decision-Making

Description

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ABSTRACT

The Canadian federal government has proposed sweeping changes for the price review guidelines of the Patented Medicine Prices Review Board (PMPRB), the quasi-judicial agency whose role is to ensure that the prices of patented medicines sold in Canada are not excessive. The revisions are due to come into effect in 2019. The objective of this article is to examine the proposed changes in the guidelines and to apply them to a hypothetical case study of the decision-making process that the pharmaceutical manufacturer of a new medication for a rare disorder is likely to go through when assessing whether to seek regulatory approval in Canada under the new PMPRB regulations.

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