Fewer new drug approvals in Canada: early indication of unintended consequences from new PMPRB regs?

Description

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Abstract

In July 2020 the Canadian federal government plans to introduce sweeping changes to the price review guidelines of the Patented Medicine Prices Review Board, the agency whose role is to set ceiling prices for patented medicines sold in Canada. The changes were first proposed by the government in 2016, with new regulations released in 2018 followed by the publication of guidelines in 2019. This has led to much concern among the pharmaceutical industry, patients, health care providers, researchers and many others. The objective of this analysis is to investigate whether the development and introduction of the new regulations and guidelines are associated with changes in the pattern of new drugs being approved in Canada between 2013 and 2019. Although reasonable consistency existed across the years and between jurisdictions in the median review times and inter-quartile ranges, the percentage of new drugs approved in Canada before or within a year after approval in the United States decreased substantially from an average between 2013 and 2016 of 55.4% to 15.6% in 2019. The decrease was even greater for new cancer medications and was substantial for new drugs for rare disorders, although small numbers make the pattern less obvious. In contrast, the percentage of new drugs approved in Canada before or within a year after approval in Europe remained stable. The results suggest that the pharmaceutical industry has taken note of the impending changes and begun to view Canada as a less attractive market when compared with the United States.

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