Clinical Trials in Canada: Worrying Signs that PMPRB Changes will Impact Research Investment

Description

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ABSTRACT

The Canadian federal government is introducing changes in the price review guidelines of the Patented Medicine Prices Review Board (PMPRB), the tribunal whose role is to set ceiling prices for patented medicines sold in Canada, which are due to come into effect in July 2021. The changes will lead to severe price reductions being required for new medicines and are causing much concern and uncertainty in patients, health care providers and pharmaceutical companies. An earlier analysis demonstrated that the number of new clinical trials in the Health Canada's clinical trials database between November 2019 and mid-March 2020 was much lower than the numbers in the same time period in previous years. However, a lag time of five to six months has been shown to affect the recording of trials in the database. The objective of this research was to provide a more comprehensive evaluation of clinical trials approved in Canada by analyzing the number of trials by trial development phase in the first six months of the years 2015 to 2020. The numbers of phase I and II trials with No-Objection-Letters in the first six months of 2015 to 2020 showed little variation across the years. The number of phase III/IV trials was also consistent between 2015 and 2019 but decreased by 26% in 2020. A similar picture occurred in both oncology and non-oncology trials. When drug developers perform fewer clinical trials in Canada, investment in research is reduced and employment opportunities are lost. It can also be a sign that manufacturers do not intend to bring new medicines here. Examining numbers of clinical trials only provides a limited view of trends in private-sector pharmaceutical investment in research in Canada. Further investigation into how and why developers invest in Canada and the benefits of such investment is required.

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