

Clinical Trials in Canada: Worrying Signs Remain Despite PMPRB's Superficial Response

Description

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ABSTRACT

The federal government is introducing changes in July 2021 in the price review guidelines of the Patented Medicine Prices Review Board (PMPRB), the tribunal that sets ceiling prices for patented medicines sold in Canada. The changes will lead to price reductions being required for new medicines and are causing much concern and uncertainty. In a report published in this journal in February 2021, Health Canada's clinical trials database was used to identify pharmaceutical company-sponsored trials approved in the first half of each year between 2015 and 2020 and posted by mid-January 2021. The analysis was limited to the first half of each year to provide an evaluation of trends in research unbiased by the five-to-six-month lag time previously shown to delay the recording of trials in the database. The PMPRB responded with a Twitter post indicating that the number of approved trials in the second half of 2020 was consistent with the number in the first half. An implication of the post was that the backlog in posting trials had been eliminated in the month between the data extraction for the February 2021 article and the Twitter post. Unlike the February article, which focused on trends in pharmaceutical company-sponsored research, the data reported by the PMPRB covered all trials regardless of whether sponsored by a company or an academic institution. The aim of the present report is to update the February article by analyzing numbers of manufacturer-sponsored clinical trials approved in each year between 2015 to 2020. At 15%, the reduction in the number of phase III/IV trials of oncology medicines between 2015 and 2020 is somewhat less than that in the previous report, but the 25% decrease in the number of phase III/IV trials of non-oncology medicines is the same. When drug developers perform fewer clinical trials in Canada, investment in research is reduced and employment opportunities are lost. It may also be a sign that manufacturers do not intend to launch new medicines here. Further detailed investigation into how and why developers invest in Canada and the benefits of such investment is required but should be performed by an independent organization external to government and not by the PMPRB, which currently plans to "self-audit" the impacts of its own regulatory reforms.

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