Canada falls behind in new drug submissions compared with the United States and Europe

Description

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ABSTRACT

Canada has experienced much uncertainty about the federal government's intention to regulate lower ceiling prices for patented medicines during the past seven years. This study's objective was to examine how many medicines submitted to the US Food and Drug Administration (FDA) and/or the European Medicines Agency (EMA) between 2006 and 2020 were also submitted to Health Canada by the end of October 2022 and to compare trends before and during the proposed federal regulation changes. New medicine submissions to the FDA and/or the EMA between 2006 and 2020 were identified from publicly available data sources. The number submitted to Health Canada by October 31st, 2022 as a percentage of the number submitted to the FDA or the EMA, whichever came first, was calculated for each year of submission to the first agency (FDA or EMA). Over 80% of new medicines submitted to the first agency in each year between 2006 and 2014 were, on average, also submitted to Health Canada, but the percentage decreased to 44% for medicines submitted to the first agency in 2020. Similar trends occurred in oncology therapies and orphan status medicines. Canada's federal government continues with its intention to regulate reduced medicine prices. Adding any tougher price regulations to barriers that must already be overcome to bring medicines to Canadians will further delay or deny patient access. Canada's policy towards new medicines needs to change from obsessive cost-containment to reviving biopharmaceutical research and manufacturing and ensuring patient access.

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