Waiting for new medicines in Canada, Europe and the United States 2016-2021

Description

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ATTRIBUTION
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CITATION
Canadian Health Policy Institute (CHPI) (2022). Waiting for new medicines in Canada, Europe and the United States 2016-2021. *Canadian Health Policy*, APR 2022. ISSN 2562-9492 https://doi.org/10.54194/SPOS4023 canadianhealthpolicy.com.

INTRODUCTION

Pathway to Access a New Drug in Canada

It takes a long time to successfully develop a new drug that will prove safe and effective for use by patients. A 2016 estimate based on the United States experience found that the time between the start of clinical testing of a novel drug molecule, and submission of a new drug application for marketing authorization was 80.8 months or 6.7 years. However, the end of the research and development phase is just the beginning of the wait for access to new medicines caused by government policies affecting the geographic priority for new drug launches, regulatory approvals, and reimbursement processes.

Getting access to a successfully developed new drug under a public drug plan in Canada is a particularly complex and time-consuming bureaucratic process. Before a new drug can be sold in Canada, it must be authorized for marketing by the federal regulatory agency Health Canada, which reviews the clinical evidence to assess and certify the safety and therapeutic effectiveness of the product.

The prices of new medicines are also federally regulated by a quasi-judicial agency known as the Patented Medicine Prices Review Board (PMPRB). PMPRB reviews the clinical evidence to determine the applicability of price control guidelines and sets the ceiling price for new drugs using international, domestic, and therapeutic reference prices.

Further, new drugs are subject to health technology assessment (HTA) by the Canadian Agency for Drugs and Technology in Health (CADTH), which again reviews clinical evidence to assess the cost-effectiveness of the product and make recommendations regarding reimbursement on behalf of all federal and provincial public drug plans, except Quebec which utilizes its own HTA agency known as the Institut national d'excellence en santé et en services sociaux (INESSS).

Manufacturers of new drugs then enter price negotiation with the pan-Canadian Pharmaceutical Alliance (PCPA), which acts as a monopsony on behalf of every federal and provincial public drug plan. Under the direction of their respective Ministers of Health, public drug plans make the final decision about listing a new drug on the formulary, and the reimbursement price and conditions, within a budget allocated by the Minister.

This complex process determines the availability of new drugs, and how long Canadian patients must wait for insured access to new medicines. Despite its importance, policy makers have failed to scrutinize the impact of the process on access. Access to new medicines should be a higher priority for federal and provincial governments. A literature review published by CHPI in 2019, found 68 studies published in peer-reviewed academic journals from 1990 to 2018 affirming that greater use of innovative pharmaceuticals is empirically associated with improved patient and population health outcomes, reduced potential health system costs, and reduced societal costs like economic productivity losses from untreated or under-treated illness. There is a lot to be gained from improving access to new drugs.

Objective

Inter-jurisdictional comparisons of access to new medicines can provide insights about the impact of policies and regulations, the performance of regulatory agencies, and the adequacy of insurance. This study compares the regulatory and reimbursement experience of new medicines in Canada, the European Union, and the United States. It introduces a novel accrual-based analysis to account for drugs matching Health Canada approvals during the years 2016-2020 that were approved in previous years in Europe or the United States. The analysis comprehensively examines the total wait time for insured access to new medicines, measured from the first global application for marketing authorization to inclusion on a public drug plan formulary.[/vc_column_text][/vc_column][/vc_row][vc_row][vc_column width="1/4?][vc_btn title="GET ARTICLE" link="url:https%3A%2F%2Fwww.canadianhealthpolicy.com%2Fproduct%2Fwaiting-for-new-medicines-in-canada-europe-and-the-united-states-2016-2021%2F"][/vc_column][vc_column width="1/4?][/vc_column][vc_column width="1/4?][/vc_column][/vc_row]