Waiting for New Medicines

How Does Canada Compare to the United States and Europe?

by Nigel S.B. Rawson

The process of obtaining authorization to market a new medicine in Canada is similar to that in other industrialized countries. However, new medicines are approved in Canada later than in the United States and the European Union because drug developers submit applications later in Canada. For example, Barua, Westcott, and Vo (2021) found that the median difference between submission in Canada and the United States was 170 days, and between submission in Canada and the European Union was 123 days. The question is: why are medicines submitted later in Canada than in the United States and the European Union?

This study explores factors such as population size, geography, and the attractiveness of its pharmaceutical environment that lead to delayed submissions in Canada. Although it has a population similar to some European countries, Canada is an isolated, geographically huge market with a relatively small population and, therefore, a low population density.

Although population size and geography matter, they are only part of a manufacturer's decision-making when deciding where to launch new medicines. A favourable pharmaceutical environment is imperative. This includes incentives to encourage manufacturers to submit new medicines for regulatory review, strength of intellectual property rights, processes for health-technology assessment, price negotiation and price regulation, and policies and criteria put in place by insurance providers for coverage and patients' access to medicines.

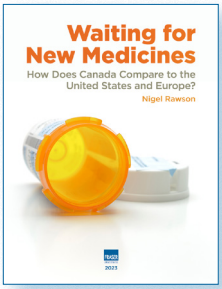
Health technology assessment processes in Canada are a major impediment to getting new medicines to patients. Despite claims of independence, the Canadian Agency for Drugs and Technology in Health (CADTH) is owned, funded, and managed by the governments to whom CADTH reports, a clear conflict of duty. CADTH reimbursement recommendations frequently include overly restrictive clinical criteria that patients must satisfy to obtain insurance coverage. These criteria can be questionable and, in some cases, harmful.

Government drug plans also own, govern and fund the pan-Canadian Pharmaceutical Alliance (pCPA), which negotiates drug prices with manufacturers on behalf of all federal, provincial, and territorial drug plans. CADTH and the pCPA have been aligning their processes for several years. Although not its role, CADTH's reviews regularly include a recommendation for a price reduction to achieve cost effectiveness, which allows CADTH to set up an initial negotiating position for the pCPA if it chooses to negotiate with the manufacturer. When there is no negotiation or an unsuccessful one, the chance of gaining coverage in government drug plans is low and, even when successful, coverage by the government drug plan is not guaranteed.

Added to these disincentives is the federal government's intention to regulate significantly reduced drug prices in Canada. This led to an extraordinary degree of uncertainty following the government stating its intention in 2015 to change the regulations of the Patented Medicine Prices Review Board (PMPRB), the government's quasi-judicial agency tasked with preventing time-limited drug patents from being abused. The proposed changes roused much opposition among drug developers and profound concern among patients. However, they have been scaled back with the principal remaining change being in the countries included in the PMPRB's international price comparison test.

Although the federal government has stayed further changes at this time, it has not relinquished its objective of reducing drug prices. Consequently, it seems highly likely that manufacturers will continue to wait and see before launching new medicines in Canada. If this is a common occurrence among manufacturers, submissions of new medicines in Canada will, at best, be delayed longer than they already are and, at worst, not happen, affecting all Canadians.

Delays in medicines being submitted for marketing authorization in Canada place Canadians' access to innovative medicines at risk. It is essential for government policy towards new innovative medicines to change from its present focus on price control and other access-restricting actions to reviving biopharmaceutical innovation, research and manufacturing, and ensuring patient access. Further delays in access or complete denials of access to innovative medicines will hurt even more Canadians with unmet or poorly met health needs that could be helped by new medicines.



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How much earlier are drugs approved in the U.S. and E.U. before they're approved in Canada?

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	All drugs	Priority review drugs	Standard review drugs
U.S.A.	289 DAYS EARLIER	245 DAYS EARLIER	356 DAYS EARLIER
E.U.	154 DAYS EARLIER	122 DAYS EARLIER	246 DAYS EARLIER