Canada's misguided changes to drug regulation could fast-track unproven medications, divert funds from health needs

June 27 2023, by Steven G. Morgan, Aidan Hollis, Christopher McCabe Matthew Herder and Mike Paulden

Credit: Unsplash/CC0 Public Domain

The Canadian government is proposing a new "Agile Licensing"

framework to expedite pre-market regulation of pharmaceuticals. While Health Minister Jean-Yves Duclos claims this is part of the government's strategy to offer Canadians "access to quality and affordable medicines," the policy is likely to cause more harm than good.

Adoption of Agile Licensing would allow companies to market drugs up to six months earlier than under the current system. Fewer pre-market clinical trials would be required as long as firms continue studying their drugs' effectiveness after they are already in use.

The government suggests this new approach will significantly improve Canadians' quality of life, estimating the value of this improvement at $302 million over ten years. However, the assumptions behind this estimate are flawed.

Flawed assumptions

By design, Canada will have less information about the risks of new medicines if those drugs enter the market with less pre-market clinical data. This will become a problem if a company fails to conduct promised post-market studies or if Health Canada does not remove unsafe or ineffective medicines from the market.

Unfortunately, the experience in the United States shows that many fast-tracked drugs are not adequately studied after they are approved for sale and few are removed from the market, even if evidence shows they do not perform as suggested by their "promising" but incomplete pre-market trials.

Fast-tracking market approval for new, less-studied medicines is not only potentially wasteful in the first instance; it will inevitably divert money away from other uses in the health-care system to pay for costly but unproven drugs.

New medicines are (and have long been) the primary driver of increasing spending on prescription drugs, for both private and public drug plans. In terms of budgets, new drugs do not simply replace older ones; they increase the overall drug budget, which necessarily means foregone opportunities to use those funds in other sectors of health care, such as improving access to joint replacements, nursing homes or mental health care.

There is a major flaw in Health Canada's cost-benefit analysis of Agile Licensing: it overlooks the fact that accelerated access to—and therefore spending on—"promising" new medicines means less money for other forms of health care that Canadians need.

Affordability

Despite the Minister of Health's assertions, the proposed framework contains no mechanism for making fast-tracked medicines "affordable." This is extremely worrisome given the drugs that will be fast-tracked by this policy are patented, specialized medicines likely to be priced at levels that are unaffordable and arguably indefensible.

Patents are government-granted time-limited monopolies that can stimulate innovation. However, they can also enable manufacturers of specialized medicines to charge exorbitant prices due to the life-or-death situations faced by patients who need such treatments. Pharmaceutical companies are using this market power to charge extraordinarily high prices with increasing frequency.

Before 2006, only four drugs approved in Canada had annual prices above $50,000 per patient—which is clearly a lot of money. Today, however, 67 medicines carry such a price tag, costing Canadians over $3 billion per year in total. Seven drugs now available in Canada are priced at an astonishing $1 million per patient.

Higher drug prices do not guarantee more value or improvements to health and well-being. Studies show it typically costs around $30,000 to produce a measurable improvement in the health of one person, for one year in health-care systems like ours. However, new patented medicines often require hundreds of thousands of dollars for the same benefit.

The harms of high drug prices

This discrepancy between reasonable prices for generating health benefits and the prices charged for many new patented medicines indicates a failing system. It directly harms Canadians by preventing access to therapies due to prohibitive pricing, and it indirectly harms them by diverting funds from more effective investments that would yield greater health benefits per dollar spent.

Before fast-tracking drug approvals so that manufacturers can increase sales, policymakers should develop and enforce measures to ensure the prices charged will fall within reasonable limits. Unfortunately, the Canadian government recently backed down from reforms that would have done just that.

Without a policy to ensure reasonable pricing of fast-tracked medicines, the government's proposed Agile Licensing regulations will only hasten access to unproven therapies while drawing resources away from other forms of health care that Canadians need and that offer better value for money spent.

Provided by The Conversation