VIEWPOINT

HEALTH POLICY

Canada's Amendment to Patented Drug Price Regulation

A Prescription for Global Drug Cost Control?

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The cost of drugs in the United States has emerged as a focal point for reducing overall health care costs.[1,2] Canada, like many countries around the globe, is experiencing rising health care costs (with markedly increasing prescription drug prices as the main driver of cost) and may provide an example for the United States and other countries as an approach to controlling the cost of drugs.[3] The pharmaceutical industry has evolved significantly in recent years, with specialized biologic and genetic therapies among the most rapidly growing drug classes. These therapies are often accompanied by high drug prices, which create an obstacle for patients in accessing innovative treatments. In line with the changing landscape of health technologies, pricing and reimbursement models must evolve to provide patients with access to promising new treatments and ensure the sustainability of health care systems.

Canada's Patented Medicine Prices Review Board (PMPRB) is a quasi-judicial regulatory body that has a mandate from Health Canada to ensure that patent holders do not abuse their rights by charging excessive drug prices during the patent monopoly period.[4] Since its inception in 1987, the PMPRB has carried out this mandate by conducting scientific and pricing reviews to determine the maximum list price (MLP) at which a patented medicine can be sold in Canada. The scientific review determines the primary indication, level of therapeutic improvement, and comparators of the patented medicine. This information subsequently guides the selection of the appropriate price, which involves a comparison with drug prices in 7 countries (Italy, France, Germany, Sweden, Switzerland, United Kingdom, and United States) to determine the MLP. The intent of the price setting is to keep Canadian patented drug prices consistent with those in other countries.

Prices for patented medicine in Canada are outpacing the prices in most of the comparator countries. Canada now has the third highest drug prices among the 31 countries in the Organisation for Economic Co-operation and Development.[4] As Canadian payers are struggling to cope with high-cost pharmaceuticals, many are questioning the effectiveness of the PMPRB in meeting the government's policy objectives.[5] In May 2017, Health Canada proposed an amendment to PMPRB regulations governing patented medicines. The amendment included 5 major changes: (1) introducing economic factors (such as cost-utility analysis [CUA]) to determine whether a pharmaceutical price is excessive; (2) amending the list of countries used for international price comparisons to include 12 countries (Australia, Belgium, France, Germany, Italy, Japan, the Netherlands, Norway, South Korea, Spain, Sweden, United Kingdom) and remove the United States as a comparator; (3) reducing the regulatory burden for generic drugs by removing the requirement to systematically identify and report the price of these drugs, thus allowing the PMPRB to prioritize drugs at higher risk of monopoly pricing; (4) modernizing reporting requirements to establish the information required on price, revenue, and research and development (R&D) expenditures; and (5) requiring patent holders to disclose all third-party discounts and rebates.[6] The purpose of this amendment is to operationalize the PMPRB's policy objective of improving affordability and accessibility by protecting Canadian consumers from excessive drug prices. After a public consultation, this amendment is currently undergoing internal review and is subject to approval by the Government of Canada.

A key, controversial component of the amendment is the introduction of an economic tool, the CUA, to determine whether a patented medicine is being sold at an excessive price. A CUA is a type of economic evaluation that estimates the incremental cost per quality-adjusted life-year gained (sometimes referred to as the incremental cost-effectiveness ratio [ICER]) for a new drug compared with the current standard of care. In the amendment, the PMPRB would adopt an ICER threshold to determine the MLP. However, a positive ICER, often seen for a more effective and expensive new drug compared with an existing one, means paying more to gain additional health benefits.

A key cause of escalating drug costs is that some new drugs offer breakthrough treatment benefits but at high cost. For example, Kymriah (tisagenlecleucel), a chimeric antigen receptor T-cell (CAR-T) therapy for a rare type of pediatric leukemia, was the first gene therapy to be approved by the US Food and Drug Administration in 2017. At a price of US$475 000, a recent CUA conducted from a US health care payer's perspective estimated that Kymriah had an ICER of $61 000, which is well below the threshold typically considered acceptable for rare diseases.[7] Despite the high cost of the drug, the low ICER was driven by important gains in quality-adjusted life-years. The current price of Kymriah may be affordable for many payers, in part because the number of eligible patients is small. However, with the arrival of CAR-T and other gene therapies, potentially with more patients qualifying for treatment, the cost for a payer may increase substantially, and under such circumstances, CUA fails to address the affordability issue.

Although the proposed use of CUAs to address affordability may not be effective, other changes in the

PMPRB's amendment offer a viable means to improve the effectiveness of drug price control. The PMPRB will reevaluate the MLP after 3 years or until the drug is marketed in 12 countries, whichever comes first.[6] As part of this process, the PMPRB would evaluate how the proposed price in Canada compares with public list prices in other markets. If the price in Canada exceeds the international median, that price would be considered potentially excessive and the MLP would be adjusted accordingly. As part of the amendment, the United States will be removed as a comparator. This would effectively serve to lower the international median price because the United States has the highest drug prices in the world. Given that a number of countries will be used as comparators and drug prices are evaluated over time, this amendment by the PMPRB is a recognition that drug price regulation is a dynamic process.

Another important change is that drug patent holders will be required to report third-party discounts or rebates. Pharmaceutical manufacturers are increasingly negotiating product listing agreements (PLAs) that include confidential pricing and rebates tied to drug expenditure, utilization, or health outcomes.[8] Although confidential PLAs can result in otherwise unattainable price discounts to individual payers, they hinder the collective purchasing negotiation on a national scale.[8] They also create significant policy challenges because there is variation in the use of PLAs across jurisdictions (including Canadian provinces), leading to concerns that confidential rebates within PLAs could result in interjurisdictional inequities in drug pricing.[8] Mandatory reporting of discounts and rebates will ensure that the PMPRB is informed of the actual prices paid for patented drugs in Canada. The United States has recently announced similar efforts to bring transparency to prescription drug pricing.[9]

The PMPRB currently requires patent holders to report gross revenue and R&D expenditures in Canada. The pharmaceutical industry often cites high R&D costs and small patient populations as justification for high drug prices—yet these companies do not disclose the true cost of R&D.[10] It is unreasonable for the public and payers to accept a high drug price without knowing the true cost of developing the drug. These reporting requirements make possible an explicit linkage between revenue and R&D costs, which is important in regulating drug prices.[10] However, in the era of globalization, investment and revenue in the pharmaceutical industry rarely occur in isolation within a specific country. Restricting these reporting requirements to Canada may have a limited effect on controlling drug prices. Only knowing the manufacturer's true revenue and R&D costs at the global scale can a price regulation mechanism effectively balance issues of affordability while ensuring reasonable investment returns. This requires an international collaboration and open dialogue with the pharmaceutical industry. While there are challenges due to inequalities of economies and different market sizes, countries need to work together to harness differences to meet common needs and thereby help to make innovative drugs accessible and affordable.

With an increasing number of high-cost, potentially breakthrough drugs being marketed worldwide, there is a need to establish a price regulation mechanism to control drug prices and ensure the sustainability of the Canadian and other health care systems. The proposed amendment to Canadian patented drug price regulation is a first but important step to addressing rising drug costs. An effective approach to controlling drug prices must regulate the amount of profit each pharmaceutical R&D investment dollar can generate and ultimately requires a concerted effort at the international level.

ARTICLE INFORMATION

Published Online: March 29, 2019. doi:10.1001/jama.2019.2280

Conflict of Interest Disclosures: Ms Humphries is a PhD candidate at McMaster University and a Health Technology Assessment and Health Economics associate at PDCI Market Access. No other disclosures were reported.

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