COMMENTARY

Regulator or regulatory shield? The case for reforming Canada's Patented Medicine Prices Review Board

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Prescription drug prices in Canada are regulated by a federal agency. In 1987, the Patent Act introduced a major overhaul that strengthened patent protection for drugs to encourage more pharmaceutical research and development in Canada.[1] The act also created the Patented Medicine Prices Review Board as an arm's-length agency with a mandate "to ensure that prices charged by patentees for patent medicines sold in Canada are not excessive," which included powers to order price reductions and to monitor spending on research and development by pharmaceutical patentees. The results have been discouraging, and drug pricing in Canada remains a major problem. We examined the role of the board and other factors that affect drug pricing in Canada and found that, far from achieving its mission of protecting Canadians from high drug prices, the agency has become a regulatory shield raised by the pharmaceutical industry to legitimize its pricing strategies. We argue that current legislation needs reform by the federal government.

Seven countries were identified by the Patented Medicine Prices Review Board for pricing comparisons under the board's regulations: France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States. From 1998 to 2013, research and development investment in Canada declined relative to sales from 11.5% to 4.5%, which is lower than the 2013 comparator country average of 21.7%.[2] In addition, Canada's expenditures involving patented drugs have increased by 184% as a share of gross domestic product (GDP) since 2000, which is higher than in all of the comparison countries.[3] Prescribing patterns contributed to this increase, but pricing is the major issue. From 2005 to 2014, prices of patented drugs in Canada went from being equal or lower than those in five of six European comparator countries to higher than prices in five of six.[4]

Why is this happening? Two factors drive drug prices: negotiations with suppliers and regulatory oversight of pricing. Canadian provinces have taken some steps to improve negotiations with suppliers, but the timetable for definitive action is not clear. This means that regulatory oversight is in play, and all Canadians have a stake in reforms to the Patented Medicine Prices Review Board.

Other countries have contained pharmaceutical prices by instituting national processes to identify which drugs are eligible for coverage and negotiating what prices will be paid.[5] In contrast, Canadian purchasing power has been fragmented for decades. Provincial and territorial governments purchased drugs separately and entered into confidential price-listing agreements with pharmaceutical companies that precluded sharing information across provincial boundaries. Starting in 2010, Canadian provincial and territorial governments made a foray into collectively purchasing drugs through the pan-Canadian Pharmaceutical Alliance. However, public purchasers represent only about 40% of the Canadian market; evidence from other countries suggests that the alliance leaves considerable savings on the table, and Canadian per capita spending on drugs has continued to rise since the inception of the alliance, now ranking second in the Organisation for Economic Co-operation and Development (OECD).[6]

Over the long term, a consortium approach to purchasing drugs is likely to yield more savings. Universal "pharmacare," in whatever way it is constituted, would reinforce that strategy. In the interim, questions remain: Why has the Patented Medicine Prices Review Board failed, and what can be done to reform it?

The board's benchmark that Canadian prices for patented drugs should be less than the median of prices in selected comparison countries is a key drawback. It puts Canada well above the OECD average by aligning Canada with countries that spend more from the outset (35% higher in 2014).[7] In contrast, some OECD countries more robustly benchmark prices for patent drugs against countries with middle to low pricing.[3] This change alone seems appropriate, long overdue and could drive massive savings.

KEY POINTS

- The Patented Medicine Prices Review Board is not meeting its mandate to curb patented drug prices.
- The board appears to have become a regulatory shield raised by industry to legitimize its pricing strategies.
- The legal and regulatory framework for the board is outdated.
- The board should update Canada's pricing benchmarks, address the increasing impact of costly specialty drugs and implement broader surveillance of pricing and procurement practices.

The board also relies on comparison prices that are further inflated because of confidential discounts and rebates patentees provide to their international customers.[3] It would be of greater value to set prices closer to what comparator countries actually pay for their drugs as opposed to the "sticker" prices that most commonly represent the starting point for confidential negotiations. The confidentiality of these price listing agreements is gradually being overcome, however, and even the international comparisons made by the OECD report prices adjusted for "possible rebates."[6] Yet Canada does not take this into account in its pricing decisions for patented medicines.

The board has been cautious about exercising its reporting mandate to call out suboptimal purchasing and pricing. With criticism mounting in the fall of 2016, the board finally highlighted adverse pricing trends in the fast-growing area of biologics.[2] However, the board has no role in pricing of "biosimilars," the less expensive forms of biologics marketed after patents expire. A closely coordinated approval and national pricing strategy for biosimilars could save Canada hundreds of millions of dollars annually.

One signpost of the board's compromised position is that the lobby group for the Canadian pharmaceutical industry now invokes it to argue that prices are not an issue. For example, Innovative Medicines Canada lauded the effectiveness of the board in a 2016 statement to a House of Commons Standing Committee,[8] arguing that, rather than concerning themselves with drug prices, policy-makers should address the "challenging access, regulatory and intellectual property environments"[9] present in Canada.

This situation is hard to characterize. The label "regulatory capture" is commonly applied when a public regulator ends up advancing the interest of the industry it is tasked with regulating rather than the public interest.[10] The Patented Medicine Prices Review Board has not been captured so much as hobbled by its own legislation. The result is a more insidious phenomenon, which might be termed "regulatory shielding": a regulated industry uses the existence of an ineffective regulator to protect itself from criticism and interventions that might better advance the public interest.

The board itself recently started a year-long process of strategic planning process to "reaffirm the organization as an effective check on the patent rights of pharmaceutical manufacturers and a valued source of market intelligence for policy makers and payers."[3] However, we do not see a way for the Patented Medicine Prices Review Board to shed the shackles of the 1987 Patent Act. Definitive legislative reform by the Government of Canada is urgently needed. This legislation should include new price benchmarks that reflect an active mandate to obtain value for the public purse, and a mandate that strengthens oversight of costly specialty drugs, extends to biosimilars, and includes guidance to the public and policy-makers about pricing and procurement practices. Canadians deserve a better deal on drugs and biologics now.

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