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Kelly Grant: Health Canada taking longer to approve generic drugs, data show

Beyond regulatory delays: How patent misuse impacts access to affordable medications

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Health Canada's growing delays in approving generic drugs, as reported by *The Globe and Mail* this week, are deeply concerning. Slower reviews mean patients wait longer for lower-cost treatments, while public and private drug plans spend more on expensive original-brand medications. But if we want to solve the affordability crisis in Canadian prescription medications, we must dig deeper. Regulatory bottlenecks are only one side of the story. Another less visible but significant contributor is the way some pharmaceutical companies exploit Canada's system of intellectual property (IP) protections to extend drug patents far beyond their original intent.

For many Canadians, access to life-changing medications comes down to one question: when will a more affordable version arrive? Generic and biosimilar medications can cost up to 95% and 50% less than their original-brand versions, respectively. They are becoming the cornerstone of a sustainable Canadian healthcare system. Yet too often, they are kept out of the market for years. How? Strategies such as filing new patents for minor changes like a new coating or delivery device or stacking dozens of overlapping patents on a single drug are routinely used to maintain exclusivity.

The result? Misuse of patent protection keeps healthcare costs high by forcing public and private drug plans to pay for original-brand medications at the "patented price" rather than at lower post-patent prices for generics or biosimilars. Take the example of Humira (adalimumab), one of the world's top-selling inflammatory arthritis medications. Its primary patent expired in 2017, but its manufacturer filed more than 130 additional patents in North America, delaying biosimilar competition in Canada until 2021. The cost to Canadian drug plans? More than $1 billion in unnecessary spending.

These actions have real, measurable consequences for patients. Higher medication prices force many to choose between their medications and rent, groceries, or utilities. They lead to skipped doses, treatment gaps, and worsening health outcomes, particularly for those managing chronic

diseases like rheumatoid arthritis, cancer, or diabetes. Delayed access to affordable generics or biosimilars can mean months or years of avoidable disease progression and disability.

For our health system, the stakes are enormous. Every year an original-brand medication monopoly is extended costs public drug plans hundreds of millions of dollars in savings that could instead be reinvested on drug plan sustainability, surgical wait times, and long-term care. Drug spending is the fastest-growing health expenditure in Canada, and delays, whether caused by Health Canada delays or misuse of patents, are fueling the crisis.

We recognize that patents are critical to driving innovation. Developing a new medication is expensive. On average, it takes 10 years and costs more than $1 billion. But when patents are misused to protect profits rather than patients, they undermine trust in the system and harm those who can least afford it.

We believe change starts with education and that includes shining a light on both the visible delays at Health Canada and the hidden delays caused by patent extensions.

The federal government is taking steps to address drug affordability, from pharmacare discussions to pan-Canadian bulk purchasing agreements. It now needs to look at speeding up generic approvals and curbing the misuse of IP laws that allow companies to stretch their monopolies past their original term. Policymakers, regulators, and courts must work together to ensure patent protection is a reward for real innovation, not a loophole to keep affordable medicines out of reach of patients who need them.