

Prescription Drug Abuse and Canada's Lagging Regulatory Framework

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In Budget 2016, the Trudeau government was true to its campaign word. It will negotiate a new Health Accord with the provinces and territories and invest in mental health, palliative care, vaccination uptake and population health interventions with First Nations communities. However, notably absent was mention of Canada's National Anti-Drug Strategy which includes tactics to address prescription opioid misuse, abuse and diversion along with the broader utilization of abuse-deterrent/tamper-resistant formulations by pharmaceutical manufacturers. The Canadian heads of two leading innovative and generic pharma companies are of one mind on this issue.

At the risk of paraphrasing Finance Minister Bill Morneau's Budget speech, it was replete with soaring phrases about the importance of meeting the challenges of today, and tomorrow, with tempered judgment leading to wise choices buttressed by strategic investments. And it clearly echoed the Liberals' 2015 winning election narrative themed around an innovative, inclusive, transparent and collaborative approach to governing.

Budget 2016 builds on these themes laying out leadership roles for the government in middle class economic growth, infrastructure renewal, climate change, reconciliation with our indigenous communities, and a more expansive role in international affairs, to name a few.

In terms of healthcare policy, the government was true to its campaign word. It will negotiate and finance a new Health Accord with the provinces and territories and its commitments to invest in mental health, palliative

care, vaccination uptake and population health interventions with First Nations communities were honoured.

However, there was no mention of Canada's National Anti-Drug Strategy or long-awaited regulations to mandate that all pharmaceutical manufacturers of prescription opioids (aka: powerful pain medications) convert their product portfolios to formulations that are abuse-deterrent/tamper-resistant.

Given that Budget 2016 was tabled just two weeks after Prime Minister Trudeau's successful visit to Washington with President Obama, the importance of these specific regulations has only grown. Just prior to this visit, a bi-partisan congressional delegation representing nine states released an open letter to Health Minister Jane Philpott urging greater regulatory cooperation on the prescription drug abuse file. They specifically urged Canada to move ahead with its own abuse-deterrent/tamper-resistance regulations.

For context, in 2011, the current Obama Administration, as part of the *National Drug Control Strategy*, directed the U.S. Food and Drug Administration (FDA) to give priority reviews to pain treatments with the potential to deter abuse, misuse and diversion and to encourage the development of abuse-deterrent formulations (ADFs) of opioid medications. Fast forward five years and the benefits of this approach are self-evident. The FDA has approved five ADF products for prescription by American healthcare professionals to their patients and reports that 30 more ADF products—from brand-name and generic pharma companies—are in various stages of development.

This news is very important as Canada currently finds itself in the midst of two related public health crises: the under-treatment of pain and the challenges of prescription drug abuse, misuse and diversion. Pain affects one in five Canadians as well as their families and caregivers. Patients can experience debilitating pain during end-of-life care, cancer treatment, and post-surgical recovery or by suffering from unrelenting, severe and often progressive non-cancer pain conditions. Prescription opioids remain a safe and effective treatment for appropriately diagnosed, selected and monitored patients.

However, these medicines do have a risk profile when incorrectly prescribed, misused by patients and/or abused by and diverted to non-patient populations. Prescription drug abuse has disproportionately affected young Canadians and our First Nations communities. It has also resulted in large expenditures of healthcare, social services and law enforcement resources. As well, the stigmatization of those who struggle with addiction

alongside those who responsibly prescribe, dispense, and use these medicines cannot be ignored.

In several areas of pharmaceutical policy, brand-name (innovative) and generic companies are often on opposite sides of public policy debates. However, our two companies—Purdue and Teva Canada Limited—as the respective brand-name and generic industry leaders with a combined 110 years' experience in pain product education, research and development and working with physicians and pharmacists, are in complete agreement that opioid analgesic products manufactured with ADF properties that are intended to reduce misuse, abuse and diversion are an important contribution by industry to the broad multi-pronged, multi-stakeholder strategy to address prescription drug abuse.

Moreover, our joint commitment to abuse-deterrence is driven and continues to be bolstered by the abundance of published evidence supporting the positive impact these technologies can have on public health.

[ADFs are not a “silver bullet” for addressing the complex societal issues of prescription opioid abuse, but they are an important and available ‘upstream’ tool to help deter misuse, abuse and diversion of these medicines. However, they are an upstream tool to complement other “harm reduction” interventions such as prescription drug monitoring programs, prescriber education, revising clinical practice guidelines, national surveillance programs, patient and family education, responsible storage and disposal programs, law enforcement and the provision of naloxone to first responders and addiction outreach workers.]

Fortuitously, much of the groundwork has been laid for the health minister to move forward—robust public consultation and research occurred during the last Parliament. Both the Senate Social Affairs, Science and Technology (November 2013) and the House of Commons Health (April 2014) committees recommended that Health Canada amend the *Controlled Drugs and Substances Act* regulations to make abuse-deterrent/tamper-resistant products a Canadian reality. These recommendations were informed by experts from the fields of medicine, pharmacy, public health,

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law enforcement, and addiction.

Then, just before the 2015 election call last summer, Health Canada gazetted regulations to incorporate abuse-deterrent/tamper-resistant properties into all controlled-release oxycodone products. While positive, it was a timid first step as evidenced in criticism from the addiction, public health and pharmacy communities, due to its lengthy implementation timing and limited scope. Nonetheless, both of our companies strongly urged Health Canada then, and Minister Philpott now to require controlled release oxycodone to be tamper-resistant.

Looking to the future, our ideal goal should be that abused opioids (and preferably any opioid product) should be converted to abuse-deterrent formulations whenever possible, provided that the formulation does not hinder the intended delivery characteristics of the product for the benefit of the patient (e.g., rapid onset formulation for severe breakthrough pain), as all opioids have the potential for abuse.

To achieve this policy objective, Health Canada, needs to work in concert with industry, the FDA, regulatory bodies, and other stakeholders as ADF technologies continue to evolve. The ultimate goal should be to transition today's opioid products to ADF products in an orderly manner, while ensuring no undue disruption for patients who are stabilized on existing therapies. This collaboration will help generate the appropriate evidence base, which will in turn allow regulators to approve products, and companies to obtain product monograph claims as to the abuse-deterrent properties of their products to better inform prescribers and patients.

The pressing need of the current crisis of prescription drug abuse combined with the fact that Canadian prescribers, pharmacists and patients have limited access to these technologies provides ample political and public health rationale for action.

Moreover, the bulk of a regulatory impact assessment work has already been conducted by Health Canada officials and awaits ministerial direction. Finally, the U.S. pressure and attention on the gap between our two countries on this file will only intensify in the months ahead so alignment of our respective national regulatory approaches makes eminent sense.

Health Minister Philpott recently wrote that she has a “moral imperative” to respond to “staggering mortality rates from suicide and substance abuse.” This eloquence conveys her deep understanding of the issue and compassion for the lives, families and communities affected. In this task she has our full support and we firmly believe the regulatory approach we advocate is the right thing to do as a positive, evidence-based contribution to improving public health. **P**

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