

POSITION PAPER

GOVERNMENT'S ROLE IN ADDRESSING PRESCRIPTION DRUG ABUSE

Governments across Canada are concerned about the abuse of prescription drugs, with recent policy discussions focused on mitigating abuse of pain medications in particular. Innovative Medicines Canada has developed the following position on the non-medical use of prescription medicines and public policy approaches to addressing prescription drug abuse in Canada.

PREVENTION AND PRESCRIBING OF PAIN MEDICATIONS

Innovative Medicines Canada believes that it is in the best interests of patients to support and promote preventive health strategies that mitigate the need for prescription medicines to treat pain. Such strategies should seek to first identify and then treat the root causes of pain. Non-pharmaceutical treatments that have been scientifically demonstrated to be safe and effective alternatives or complements to prescription medicines should be utilized by the medical community to treat pain among vulnerable patient populations whenever possible.

Prevention efforts and non-pharmaceutical treatments do not entirely eliminate the need for safe and effective prescription pain medicines. Many people will require the use of pharmaceutical products to improve their health outcomes. The safe use of prescription pain medicines by patients starts with proper diagnosis and consequent prescribing by health professionals.

Innovative Medicines Canada supports efforts to develop and administer professional guidelines for prescribing of pain medicines by organizations such as the Royal College of Physicians and Surgeons of Canada and the National Pain Centre and McMaster University (NOUGG). These guidelines are disseminated through professional education programs designed to improve awareness of the proper prescribing, use, risks and related social issues involved with non-medical abuse. Healthcare professionals should be encouraged to follow-up and monitor the progress of patients using prescribed pain medications and work with provincial systems – especially in pharmacy settings – which have been implemented to address this issue. Innovative Medicines Canada also supports the strategy by the Canadian Centre for Substance Abuse through its “First Do No Harm” report to reduce prescription drug abuse in Canada.

The pharmaceutical industry is one of the most regulated industries in the world and fully supports mechanisms that ensure Canadians have timely access to safe, effective, and high quality medicines and vaccines. Health Canada reviews medicines on the basis of scientifically demonstrated safety and efficacy. Medicines are approved on the basis of a positive benefit-risk profile for their approved use.

The approved use is outlined in specific terms in the product monograph and labels approved by Health Canada. This labeling information determines the representations that can be made about a medicine and guides prescribing and dispensing practices. It also provides information to support proper use and adherence by patients.

Innovative Medicines Canada and our members have long been active participants in discussions and efforts to modernize Health Canada's regulatory regime. We strongly support the policy objectives of the



government's recent efforts, as outlined in Bill C-17, to ensure federally approved, up-to-date and accessible information is available for patients and is clearly understandable. Better informed patients and healthcare professionals are important elements of a successful strategy to reduce non-medical use of prescription pain medicines.

MONITORING

Experts on the abuse of prescription medicines believe that the unused supply of legitimately prescribed products is a key source of the illicit trade in prescription medicines. Innovative Medicines Canada supports the development of an electronic record system or better integration of present provincial efforts into a pan-Canadian system that would make it easier to monitor and control the unused supply of prescription medicines.

Experts also have determined that abusers of prescription medicines will often seek to obtain multiple prescriptions for pain medicines from separate prescribers who may be unaware of previously issued prescriptions. An electronic record system would make it easier to mitigate against patients 'shopping around' for prescribers in an attempt to fill multiple prescriptions.

LAW ENFORCEMENT

The problem of non-medical use of prescription medicines is encouraged and facilitated by illegal trafficking of what are otherwise legitimately-produced, responsibly-prescribed and safely-used medicines that effectively treat pain and improve health outcomes for millions of people. Law enforcement agencies need the support of the life sciences community in their ongoing efforts to stop the illicit trade in prescription medicines.¹

Innovative Medicines Canada members, through their membership in the Health Products Stewardship Association and their own company initiatives, such as take-back programs for expired and/or unused pharmaceutical products, work with the pharmacy community and law enforcement agencies to support efforts to reduce trafficking in prescription drugs.

STREAMLINE THE REGULATORY SCHEDULING OF NEW CONTROLLED SUBSTANCES

Innovative Medicines Canada encourages policy decisions that streamline the regulatory process at Health Canada through the Office of Controlled Substances. Innovative Medicines Canada believes it makes sense for Canada to ensure that new entity narcotics and controlled substances are rapidly scheduled at or in

¹ Ontario Association of Chiefs of Police (2012). Media Release. Ontario's Police Leaders Call on the Federal Government to Keep "Generic" Oxycodone out of Canada: Police Chiefs Warn of Threat to Community Safety. Toronto. July 11, 2012. URL: <http://www.oacp.ca/content/news/article.html?ID=1231>.



advance of Notice of Compliance (NOC). Rapid scheduling of controlled substances can help guide prescribing and assist law enforcement efforts.

PUBLIC HEALTH AND SOCIAL SERVICES

Non-medical use of prescription medicines should be defined as a public health problem and it should be recognized that there are social factors and mental health challenges that are often associated with drug abusers. Federal and provincial health authorities should be allocated the necessary budget resources to create strategies and programs that mitigate the abuse of prescription medicines. Experts have identified that some communities and regions are particularly vulnerable and require special attention.

The efforts of social services, mental health and public health agencies to identify vulnerable populations and to develop strategies for intervention should also be supported by the Federal Government.

PHARMACEUTICAL INNOVATION

Pharmaceutical innovation is a part of the solution and should be part of any policy to reduce prescription drug abuse. Innovative Medicines Canada believes that policies that encourage the development and adoption of abuse deterrent products can be expected to encourage abuse-deterrent formulations (ADFs) for other medicines, and this could multiply the societal economic savings estimated from the impact of technology substitution.

Innovation originally led to the development of extended release technologies for pain medicines. These products contain higher dosage strengths of the active ingredient compared to the strengths available in immediate release products. When taken as prescribed, the controlled-release properties of these products allow doses to be administered safely to users over longer periods of time, safely providing more effective and extended pain relief. These unique properties have made extended release medicines a popular choice for pain management by prescribers, but immediate release opioid products can also similarly be abused and misused.

Individuals who abuse pharmaceutical products have learned to modify these products by chewing, crushing tablets for inhaling or dissolving tablets in fluid for injecting, which defeats the time release property that moderates the dosage and causes higher doses of the active ingredient to be released immediately. Policies designed to reduce abuse must avoid the unintended consequence of jeopardizing the health benefits gained by millions of legitimate users of these safe and effective prescription pain medicines.

In response, the life sciences community has invested in and developed abuse deterrent technologies that make it much harder to chew, crush, inhale or dissolve tablets for injection. These technologies are successfully mitigating the abuse of prescription medicines where it has been adopted.



According to a review of the literature published by the Canadian Health Policy Institute (CHPI)², recent studies of the effectiveness of abuse-deterrent formulations for prescription opioid drugs suggest a promising potential for these innovative technologies to reduce abuse.

In one experimental study abusers were tested on their ability to manipulate an abuse-deterrent formulation of a prescription opioid and interviewed about the results.³ According to the study, most participants were not willing to inhale (92%) or inject (84%) the tampered products.

A second study published in the *New England Journal of Medicine* surveyed a sample of opioid abusers in the United States, about the effectiveness of abuse-deterrent technologies.⁴ The study found that, the selection of the formerly abused product as a primary drug of abuse decreased from 35.6% of respondents before the release of the abuse-deterrent formulation to just 12.8%, 21 months later.

In an earlier study, researchers conducted a hypothetical analysis of the expected budgetary savings to private insurers from market adoption of abuse-deterrent formulations of prescription opioid drugs.⁵ Stated in 2006 US dollars, the study estimated, "Potential cost savings to third-party payers from introducing an abuse-deterrent opioid for the United States could range from approximately \$US0.6 billion to \$US1.6 billion per year".

An analysis published by CHPI in 2012⁶ calculated that permanent replacement of one abused opioid product with its innovative abuse-deterrent version in Canada could potentially reduce the societal economic costs of prescription opioid abuse related to the product, without causing the loss of health benefits accruing to legitimate users of the medicine. Potential savings from the wholesale substitution of the abuse-deterrent product for its previous version exceeded the expected savings from generic supply of the previous version by a net difference of between 232% and 467% for Canada and between 199% and 516% for Ontario.

Importantly, the study concluded that a policy that encourages the adoption of abuse deterrent products could be expected to encourage a proliferation of new abuse-deterrent formulations for other drugs. The

² Skinner BJ (2012). *Net societal economic impact in Canada from withholding regulatory approval for generic OxyContin®*. Canadian Health Policy, September 12, 2012. Toronto: Canadian Health Policy Institute.

³ Vosburg, SK., JD Jones, JM Manubay, JB Ashworth, IH Benedek, SD Comer (2012). *Assessment of a formulation designed to be crush-resistant in prescription opioid abusers*. *Drug and Alcohol Dependence*, June 19, 2012 (Epub ahead of print).

⁴ Cicero TJ, Ellis MS, Surratt HL (2012). *Effect of Abuse-Deterrent Formulation of OxyContin*. *New England Journal of Medicine*, 367;2 July 12, 2012.

⁵ White, Alan G., Howard G. Birnbaum, Dov B. Rothman, Nathaniel Katz (2009). *Development of a Budget-Impact Model to Quantify Potential Cost Savings from Prescription Opioids Designed to Deter Abuse or Ease of Extraction*. *Applied Health Economics and Health Policy* 2009; 7(1): 61-70

⁶ Skinner BJ (2012). *Net societal economic impact in Canada from withholding regulatory approval for generic OxyContin®*. Canadian Health Policy, September 12, 2012. Toronto: Canadian Health Policy Institute.



subsequent adoption of abuse-deterrent technologies across other products will multiply the health benefits and socio-economic savings.

Innovative Medicines Canada believes that existing and ongoing pharmaceutical innovation offers the realistic potential to deter non-medical use of prescription medicines, while preserving the normal availability of safe and effective treatments for legitimate medical use by patients.

OTHER CONSIDERATIONS

Innovative Medicines Canada believes that it is not just narcotic types of prescription drugs that are abused. Other medications should also be under consideration for the benefits of adopting abuse deterrent technologies, potentially including for example ADHD medicines (i.e. stimulants) and anabolic steroids/testosterone.

Innovative Medicines Canada also recognizes that the adoption of abuse deterrent formulations of abusable drugs is associated with an incremental cost. These formulations are much more expensive to produce/manufacture than simple compressed tabs or capsules. However, abuse-deterrent technologies add significant value to the health system and a reduction of the societal costs and human impact of abuse that far outweigh the incremental costs.

CONCLUSION

Innovative Medicines Canada members are committed to the discovery and development of safe and effective medicines and vaccines for Canadians. Our members wholeheartedly support efforts to improve patient safety and we believe that the recommendations contained in this position paper will inform government policy to address and reduce the non-medical use of prescription medicines.

ABOUT INNOVATIVE MEDICINES CANADA

Innovative Medicines Canada is the national voice of Canada's innovative pharmaceutical industry. We advocate for policies that enable the discovery, development and commercialization of innovative medicines and vaccines that improve the lives of all Canadians. We support our members' commitment to being valued partners in the Canadian healthcare system.