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August 11, 2015

Ms. Jacqueline Gonçalves
Director General
Controlled Substances and Tobacco Directorate
Health Canada, Main Statistics Canada Building
150 Tunney's Pasture Drive
Ottawa, ON K1A 0K9

Dear Ms. Gonçalves,

This letter is in response to the pre-consultation notice regarding *Proposed Tamper-Resistant Properties of Drugs Regulations*, as published June 27, 2015 in the Canada Gazette.

The Canadian Pharmacists Association (CPhA) has been vocal in addressing the risks of abuse and misuse of controlled substances, in particular opiates. Canadians continue to die from the inherent risks of these medications, as a result of their purposeful misuse and abuse, as evidenced by regular media reports describing the devastating consequences.

CPhA has spoken to the issue at the House of Commons Standing Committee on Health (December 2013) as well as the Conservative Caucus (April 2014) highlighting the need for the Canadian government to respond quickly and effectively to this growing national crisis. CPhA has also responded to the recent Health Canada consultation on tamper-resistance formulation regulations (March 2015).

The crisis has worsened since Health Canada's approval of generic extended release oxycodone, at a time when a tamper-resistant form of this molecule was being marketed in Canada, for which evidence was growing in the United States of its effectiveness in curbing abuse and misuse. Canada has consistently lagged its international comparators in implementing risk mitigation strategies, despite having a crisis at least as serious as that experienced in other countries. By comparison, the US, fully acknowledging the risks of letting its own opiate drug crisis unfold unabated, has implemented aggressive controls with outcomes that suggest that abuse-deterrent formulations are an important strategy to mitigating the crisis. The US Food and Drug Administration has approved four abuse-deterrent formulations for oxycodone and other opiates with a further three under active review.

Against this backdrop of a growing Canadian crisis, the Canadian Pharmacists Association is supportive of regulations that will mitigate the crisis, but is concerned with the limited scope of the proposed regulations and the lack of urgency in fully implementing their solutions. Anecdotally, pharmacists across Canada have been made aware of how generic oxycodone is being abused, most commonly by crushing the tablets, then either snorting the powder or injecting the liquefied powder. Given the high potency of extended-release oxycodone, and its variable effects when it has been tampered with, Canadians are clearly put at risk when such practices are followed. Since



the introduction of a tamper-resistant extended release oxycodone formulation, we have seen the target of abusers migrate to other drugs such as hydromorphone and fentanyl, drugs that are equally if not more toxic.

Clearly, this underscores the need for regulations that address the entire class if any progress in dealing with this crisis is to be anticipated. **CPhA strongly advocates for the modification of the regulations to encompass all extended-release opiate drugs currently marketed in Canada and not just oxycodone.** In its submission in response to Health Canada's consultation in 2014, CPhA encouraged the government to include stimulant products such as methylphenidate in its list of products to which tamper-resistant properties would be applied. CPhA also suggested that Health Canada consider criteria to determine which controlled substances should require tamper-resistant properties.

While Canada has not accumulated data on the effectiveness of tamper-resistant opioids in mitigating the abuse of prescription opioids, this data exists in the US, via the Researched Abuse, Diversion and Addiction-Related Surveillance System (RADARS). Following the approval of tamper-resistant oxycodone extended release products, RADARS reported a 42.9% decline in intentional abuse exposures as reported by poison centres (as per data at the following site: <http://www.radars.org/>). This data not only highlights the effectiveness of tamper-resistance, but also the inherent risk facing those who abuse opioids in this way.

Prior to the market approval of Oxyneo[®] (tamper-resistant extended release oxycodone) pharmacies were frequently targets of robberies and thefts, specifically for Oxycontin[®]. In fact, many pharmacies would not regularly stock the product, and would post signage indicating that this product was not stocked, in order to deter robberies and theft. While data is not available in this regard, anecdotally it has been often mentioned that criminal activity of this kind has reduced significantly since Oxyneo[®] became available.

One unfortunate outcome is that the target of prescription drug abusers has shifted to other opioids, most notably fentanyl and hydromorphone, with tragic consequences. It is for this reason that CPhA encourages Health Canada to implement a tamper-resistant regulation for all targeted medications, not only oxycodone.

The gradual pace of consultation, regulation development and implementation of the *Tamper-Resistant Properties of Drugs Regulations* runs counterintuitive to the immediacy of the opiate drug crisis and its devastating consequences. Canada is not embarking on an initiative that has no international comparison; this issue is a global one, with other nations showing leadership in addressing it and Health Canada needs to move forward quickly with regulations. **CPhA strongly advocates for tamper-resistant regulations to take force soon, and feels that a three year coming-in-to-force is woefully inadequate in dealing with the crisis.**

More work is also required in the area of education, particularly with respect to the prescribing of opiates. Despite efforts of national strategies such as "First Do No Harm", there is evidence that opiate drugs continue to be prescribed widely, which is contributing to severity of the crisis. Resources need to be made available so that front-line health care professionals have access to a broad selection of alternatives that clearly weigh the proposed



benefits against risks. In its submission to Health Canada further to the 2014 consultation on tamper-resistance, CPhA identified specific actions designed to improve both patient and health care professional awareness, including making public information available in pharmacies and heightening the awareness of physicians and pharmacists as to the common diversion strategies utilized in their communities.

A further risk mitigation strategy described in CPhA's submission was to broaden the use of tools that help identify patients' addiction risk prior to the initiation of opioid therapy through physician and pharmacist education. Access to important patient care information and better integration of electronic health records, including common national standard for a seamless e-prescribing system in Canada, are essential to supporting enhanced clinical decision-making, prescribing, medication management and surveillance.

CPhA also encouraged Health Canada to assume responsibility for the creation, funding and implementation of a national narcotic monitoring system to thwart diversion tactics and identify patients who may be struggling with addiction.

While some progress has been made to address diversion, this has been slow and inconsistent across Canada. It is vital that a national surveillance system be implemented as soon as possible, that is accessible to a broad spectrum of health care professionals who manage patients who use opiate medications.

Tamper-resistance is one strategy in a multi-pronged effort to meaningfully reduce the abuse of prescription opiates. CPhA would urge Health Canada to pursue a holistic approach to dealing with the prescription drug crisis, which incorporates all of the tactics described above.

Opiate drugs have an important role to play in the management of pain. CPhA fully supports the continued efficiency of access for Canadians who require these drugs to manage their pain. We must preserve this treatment modality for patients who need opiates in managing their pain. However, we must remain focused on the risks of these medications when they are used improperly, and protect Canadians who unfortunately choose to use medication in a way for which it is not intended. There is an obligation for regulators to effectively manage the needs of both groups in order to ensure maximal therapeutic benefit and access, while minimizing harms.

The Canadian Pharmacists Association, and pharmacists in general, remain committed to ensuring that Canadians obtain the most benefit from drug therapies, while minimizing the inherent risks that are present. We appreciate the opportunity to provide commentary on these regulations, and appreciate any similar consultations in order to achieve beneficial outcomes in this challenging area.

Sincerely,

Janet Cooper, BSc(Pharm), ACPR
Vice President, Professional Affairs, CPhA