

August 26, 2014

Mr. Robert Ianiro
Director General
Controlled Substances and Tobacco Directorate
150 Tunney's Pasture Driveway,
Main Statistics Canada Building
Address Locator: 0302A
Ottawa, ON K1A 0K9

**RE: Tamper Resistance under the Controlled Drugs and Substance Act: Canadian Gazette
Part I, June 28, 2014**

Dear Mr. Ianiro:

The Canadian Pain Society Board of Directors appreciates that Health Canada aims to “establish and maintain prescription drug accessibility, while decreasing the risk of abuse associated with certain drugs” (Ianiro, Nov 6. 2013). We will first describe the Canadian Pain Society and its position on opioid misuse and addiction before responding to the proposal regarding the *Tamper Resistance under Controlled Drugs and Substance Act published on the Canada Gazette, June 28, 2014*

A- Canadian Pain Society

The Canadian Pain Society (CPS) is a multidisciplinary, non-profit, independent organisation that represents 800 clinicians and researchers from across Canada working to improve pain management. One in five Canadians experience chronic pain and the CPS works with patient advocacy organisations, including the Canadian Pain Coalition and *Association Québécoise de la douleur chronique*.

Our mission is to promote research, education, prevention and management of pain for all Canadians.

Facts:

Chronic Pain is reported by about 20% of the Canadian adult population that is in the moderate to severe range for 3 out of 4 people. [1, 2] About 20% of non-cancer chronic pain patients are using prescription opioids and, close to 5% of them do report non-medical use of opioids.[3] The median prevalence of addiction in chronic pain patients is 4.5% and its median incidence is 0.5% .[4] Prevention strategies are essential to reduce the harmful consequences of opioid misuse and addiction. [4-8] Furthermore, suicidal ideation is present in ¼ of chronic pain patients and it is 5 times higher if an illicit drug has been self-used to manage pain.[9]

Promotion of educational and research initiatives related to opioid addiction and effectiveness in pain control is mandatory. The government is to be congratulated for two recent initiatives: Health Canada's educational grant program in July 2014 and Canadian Institutes of Health Research's Canadian Research Initiative on Substance Misuse (CRISM). Specialists in pain management and addiction management are working closer than ever. We all share concerns about the appropriate and safe use of analgesics including opioids, and want to prevent their abuse. However, abuse-deterrent formulations do not necessarily prevent addiction and can limit effective options for patients in severe pain who need them.

Canadians have the fundamental human right to have effective options for pain relief. However, it is obvious that opioid misuse and addiction are also critical issues that need to be addressed. All stakeholders (e.g., patient, law enforcement personnel, health care providers, Health Ministry, educators) need to develop a concerted action plan to balance the control of risk of addiction and misuse with the needs of patients to control pain.

Before responding to your request of comments, we will like to highlight the following:

- Evidence from high-quality nationwide Canadian surveys (*CADUMS 2009-2012; Canadian Alcohol and Drug Use Monitoring; Survey 2012: Microdata User Guide; Health Canada; September 2013*) indicates that the non medical use of prescription opioids is significantly decreasing.
- Most individuals using opioids without a prescription are actually using them for the treatment of pain and have obtained them from a friend or family member [10].
- The use of prescription opioids to get high was 0.4% in 2009 and has decreased to 0.3% in 2012 (CADUMS).
- CADUMS 2012 added a question about tampering with opioids and this was 0.3% of those who had used an opioid.
- There has been a significant decline in the rates of substance abuse and the rates of substance dependence [10].

B- Our commentary regarding the proposed regulations on Tamper-resistant products, opioid analgesic:

The CPS is very concerned about the misuse of prescription analgesics, sedatives and tranquilizers, which frequently in combination have resulted in untoward deaths for people with mental health issues including addiction as well as naïve, experimenting youth. Our pain curriculum survey of health professional faculties [10] pointed to the urgent need for increased pain education, a new fellowship for medical residents and advanced training for clinicians in practice is now available in many provinces. Also, CPS is encouraging the dissemination of the *Canadian Guideline for Safe and Effective Use of Opioids for Chronic Non-Cancer Pain*, [11] which promotes appropriate screening and adequate medication storage so essential to safe practices. An update of this document with a more active action plan is in progress.

It is obvious that all stakeholders in pain and addiction have two priorities: access to appropriate pain management options and prevention of prescription medication abuse. As we understand from actions by Health Canada, addiction and chronic pain management must both be considered. Individuals suffering with these conditions must be treated ethically and equitably.

In our opinion the proposed regulations under the Controlled Drugs and Substances Act to require tamper-resistant properties in specified controlled substances is premature, this is mainly due to lack of evidence supporting the clinical efficacy and effectiveness of these preparations in relieving pain and in preventing addiction as described below. Moreover, the Canadian Pain Society supports the current regulatory process for drug approval and feels there is no need for an additional level of approval at the Ministerial level. *Further, regulation is not the solution and will exacerbate the under treatment of pain while failing to solve the problem of inappropriate use of opioids by the 0.3%.*

The Health Canada questions on tampered formulations raised to guide input are important, and our responses are outlined below:

Questions 1-5. Tamper-resistant formulations may play a role in future but at this time there is no clear evidence on the impact of this on drug efficacy and effectiveness. Preliminary research is minimal, and decisions need to be based on solid science which is not currently available for this proposal. Moreover, the recently developed tamper-resistant oxycodone (e.g., OxyNEO) has not necessarily prevented addiction. Some addicts have found ways of using it or have switched to heroin or other substances. [12-14]

Unfortunately for some patients with severe pain, reports from health professionals and patients indicate that the abuse-deterrent coating has limited the effectiveness of these agents as analgesics [in comparison to the regular formulation]. Therefore, the tamper-resistant formulation, using oxycodone as an example, has not met the pain relief needs of people with severe pain.

Pursuing and developing research in this area is important to collect sufficient data. While several pharmaceutical companies are at the development stage, this will take time for rigorous testing unless funding is rapidly available and ideally also from independent source such as CIHR.

Question 6. Efficacy trials comparing these formulations with those not coated are critical and in chronic pain samples versus healthy volunteers. To our knowledge, no head-to-head trials with pain patients were performed to support the decision to allow only tamper resistant formulations. Analgesics, including opioids, are an important option for people with intractable severe pain and patients need access to various options that are known to be effective.

Question 7. Authorizing marketing of any tamper-resistant formulation, without adequate testing with pain populations to provide the necessary science, will not address the challenge of balancing appropriate pain management and prescription drug abuse prevention. As stated in

#6, rigorous head-to-head analgesic trials with patients experiencing severe pain are required before this type of formulation can be authorized as the unique source of opioid.

Questions 8-10. Both appropriate pain management and prevention of prescription drug abuse, including opioids, are public health priorities and also a Canadian Pain Society priority. Education of prescribing health professionals, funding for research for clinical trials to find effective management options, and raising the public's awareness of the issue are all strategies the Society supports as part of the National Pain Strategy and recent initiatives for the Federal government are welcome.

Moreover, access to optimal pain management strategies has been designated as a human right by our Society as well as the World Health Organization and other international pain societies. [15]

It is noteworthy that the U.S. FDA recently approved a drug called Zohydro, a long-acting form of hydrocodone *without a hardened coating*, despite the opinion of their expert panel to not approve it. [16, 17] The FDA stated that chronic non-cancer pain patients had the right to all options, which should be a major consideration in its approval. The Governor of Massachusetts' legal challenge to prevent the use of Zohydro in his state was overturned, with the judge ruling on the grounds that patients suffering with chronic non-cancer pain had a right to access any opioid that held promise of relief.

The U.S. FDA concluded that " the complex public health challenge of opioid abuse and misuse requires a comprehensive and science-based approach".

In summary, as described above, the Canadian Pain Society does not support, at this time, the proposal from Health Canada on *Tamper Resistance under the Controlled Drugs and Substance Act* until there is more evidence supporting its effectiveness in pain control and prevention of addiction-abuse and misuse. Specialists in pain, pharmacology and addiction need to work together on solutions; it is important to balance the human right to pain relief with protecting our population from drug misuse and risk of addiction.

Please feel free to contact us if you wish further discussion on this important issue.

Yours sincerely

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