

August 11, 2015

Jacqueline Gonçalves
Director General
Controlled Substances and Tobacco Directorate
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RE: Proposed Tamper-Resistant Properties of Drugs Regulations under the Controlled Drugs and Substance Act: Publication notice of June 26, 2015 – Canada Gazette

Dear Ms. Gonçalves,

The Canadian Pain Society Board of Directors sent a letter in 2014 in response to the first call published by the *Canada Gazette, June 28, 2014*. We were fortunate to read the new notice that came out on June 26, 2015.

In this letter we are highlighting a few points following our 2014 series of comments.

First, 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). Furthermore, we fully support that *tamper resistance is a part of a comprehensive strategy to address prescription drug abuse* as cited in your June 26 WEB document.

Second, as you know, 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, Association Québécoise de la douleur chronique and other Canadian patient groups.

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

Third, we recently revised our position on opioids as follows:

Position Statement on Opioid Analgesics in Pain Management – 2015 Update

The Canadian Pain Society is a chapter of the International Association for the Study of Pain and supports the Declaration of Montreal. <http://www.iasp-pain.org/DeclarationofMontreal>
This declaration recognizes the *intrinsic dignity of all persons and states that withholding of pain treatment is profoundly wrong, leading to unnecessary suffering which is harmful and further recognizes the right of all people to have access to pain management without discrimination.*

The Canadian Pain Society:

1. Recognizes that essential tools for managing moderate to severe pain comprise pharmacotherapy, which may include opioids among other analgesics, in combination with physical and psychological approaches.
2. Emphasizes that a strategy aiming to prevent diversion or misuse of opioid analgesics is essential, but must contain measures to assure that they remain available to those patients for whom they are required.
3. Encourages better education for health professionals and patients about the appropriate and safe use of opioid analgesics for the treatment of pain, based on the best research evidence.
4. Endorses the Canadian Guideline for the safe and effective use of opioids for chronic non-cancer pain. <http://nationalpaincentre.mcmaster.ca/opioid/>.

Fourth, we have a few comments related to the regulatory proposal on Tamper-resistant opioid analgesic products:

- We agree that the Controlled Drugs and Substances Act on tamper-resistant properties for specific controlled substances is one of the approaches that may be effective in reducing inappropriate use. The other measures include, as listed in your document of June 26: an awareness campaign for the public, education for the public and health professionals on better use of controlled drugs as well as alternatives for pain management, a more user friendly guideline on addiction and pain management, etc.
- CPS is highly concerned about misuse of the opioid analgesic oxycodone. However oxycodone is only one of many analgesics that are not always used as prescribed. There is a major concern that focusing on oxycodone will lead to substitution and/or other misuse of other related substances.
- Health Canada is aware about the risk of substitution of oxycodone users to e.g., heroin, in the United States.[1-3] There is little data available in Canada, but we suspect it is similar based on comments we received from clinicians (movement from the west toward the east coast seems to be ongoing).

- Health Canada is certainly aware of the misuse of mixtures of prescription analgesics, sedatives and tranquilizers. The fact these are frequently used in combination seems to result in an increased risk of death for people with mental health issues that include persons with addiction as well as naïve, experimenting youth. The Health issue is larger than opioid analgesics.[4]
- It is obvious that health and community professionals who treat pain and substance misuse need to work together in the prevention and management of addiction.
- In our country, alternative methods to manage acute and chronic pain are not broadly available and/or accessible to many patients. These include, as example, physical therapy after trauma and some surgeries, psychological treatment when risk of addiction is suspected, etc.
- Pharmaceutical companies involved in the production of opioid analgesic drugs should have an obligation to develop other non opioid analgesics and promote other methods of pain control with better and safer analgesic profiles. For example, glial cells have been shown to be involved in the development and maintenance of chronic pain, and their activity can be controlled by drugs, such as minocycline, an antibiotic, which has a very low abuse potential suggesting that this is an avenue of great promise in the future.[5] The safe use of combination therapy, such as acetaminophen and ibuprofen, for post-operative pain, is a currently available approach to control acute pain [6] and may prevent transition to chronic pain while minimizing the risk of addiction in otherwise healthy individuals. Innovative and patient oriented research is mandatory to develop new avenues of pain management and addiction prevention.

Fifth, at this time, we are concerned about the lack of independent evidence (RCT and meta-analysis) supporting the clinical efficacy and effectiveness of tamper-resistant formulations in relieving pain compared to the regular formulations they are replacing. Health Canada needs to make a decision based on solid evidence.

- To our knowledge, no independent meta-analysis is available on efficacy and efficiency of tamper-resistant opioid products in pain relief (the lack of studies that compare regular and tamper resistant preparations are surprising).
- To our knowledge, no independent meta-analysis is available on tamper-resistant efficacy and efficiency for preventing misuse. We recognize that such products are one of many approaches that may reduce misuse, however, they are not the only method.

In summary, as described above, the Canadian Pain Society supports the initial proposal from Health Canada on *Tamper Resistance under Controlled Drugs and Substance Act*. We insist that such regulation should be accompanied by more evidence supporting its effectiveness in pain control and a strong/valid measure to control addiction-abuse and misuse. The development of *tamper resistant opioid formulations* is only one step however. The focus should not be the opioid drugs, the problem is much larger and the approach must be comprehensive and include

enhanced care for people with addictions and a national strategy aimed at improved care for people with pain conditions.

Finally, it is important to balance the human right to pain management with the best standards of care and prevention for addiction and medication misuse in Canada.

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

Yours sincerely,

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