CMA's Response to Health Canada's Public Consultation Guide to New Authorities in reference to Bill C-17, *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)*

Canadian Medical Association

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ASSOCIATION MÉDICALE CANADIENNE
CANADIAN MEDICAL ASSOCIATION

Helping physicians care for patients
Aider les médecins à prendre soin des patients

The Canadian Medical Association (CMA) is the national voice of Canadian physicians. Founded in 1867, CMA's mission is helping physician care for patients.

On behalf of its more than 80,000 members and the Canadian public, CMA performs a wide variety of functions. Key functions include advocating for health promotion and disease/injury prevention policies and strategies, advocating for access to quality health care, facilitating change within the medical profession, and providing leadership and guidance to physicians to help them influence, manage and adapt to changes in health care delivery.

The CMA is a voluntary professional organization representing the majority of Canada's physicians and comprising 12 provincial and territorial divisions and 51 national medical organizations.

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The Canadian Medical Association (CMA) is pleased to provide its response to Health Canada's public consultation on the Guide to New Authorities (power to require & disclose information, power to order a label change and power to order a recall), in reference to the *Protecting Canadians from Unsafe Drugs Act (Vanessa's Law),* which came into force on November 6, 2014.

The CMA supports a robust legislative framework toward an unbiased, evidence-based system for the oversight of pharmaceutical products, which spans both the pre- and post-approval of these products, with the ultimate goal of patient safety. Prescription medication plays a critical role as part of a high-quality, patient-centred and cost-effective health care system. It is a priority to physicians that all Canadians have access to affordable, safe and effective prescription medications.

Stemming from this perspective, the CMA strongly welcomed the new ministerial authorities established by *Vanessa's Law* as an important contribution to patient safety and the effectiveness of Health Canada's oversight of prescription pharmaceuticals. With these new authorities now in effect, it is critical that implementation is comprehensive, effective and transparent. As such, CMA's response to this public consultation on the new Guide will focus on the need for:

- increased clarity on the thresholds that underpin the use of these new authorities,
- guidance on the notification of public, physicians and other health care practitioners, and
- a commitment to ongoing oversight and revision process of this guidance.

ISSUE 1: PROVIDE INCREASED CLARITY ON THE THRESHOLDS

In CMA's brief[1] to the House of Commons Standing Committee on Health as part of its study of Bill C-17, *Protecting Canadians from Unsafe Drugs Act,* key recommendations included clarification of both ministerial authority and responsibility in support of patient safety. The CMA supported the intent of the expansion of these powers, but expressed concern with the lack of clarity on the threshold required to be met to enable the use of these new authorities.

In order to ensure the consistent and effective implementation of these new ministerial authorities, the CMA considers it essential that the Guide provide more clarity on the threshold that enables the use of the new authorities, including the determination of serious risk.

To determine this threshold, Health Canada relies on experts to analyze scientific information and make a recommendation to the Minister.

[1] Canadian Medical Association (2014) Bill C-17 An Act to amend the Food and Drugs Act - Protecting Canadians from Unsafe Drugs. Submission to the House of Commons Standing Committee on Health. CMA. Retrieved from: http://policybase.cma.ca/dbtw-wpd/Briefpdf/BR2014-09.pdf

The CMA recommends that guidance be expanded to specify a mechanism for experts, external to Health Canada, to submit recommendations for action and the process by which these recommendations would be considered.

As the definition of "serious risk of injury to human health" is not provided in *Vanessa's Law,* it is critical that it be addressed in the Guide. Annex A of the Guide states that "the determination of whether a therapeutic product presents a serious risk is complex and is conducted on a case-by-case basis when new information becomes available", and puts forward a "non-exhaustive" list of elements to be considered. It also states that different weights would be attributed to different elements and suggests further contextual elements. The CMA is concerned that without a clear process for the determination of what constitutes a serious risk that subjectivity may have an undue role in this determination and there is the potential for a lack of consistency from case to case. Further, a detailed process is required to ensure that this threshold does not constrain ministerial authority when action is needed.

The CMA recommends that the elements and process for the determination of "serious risk" be further defined, in order to bring clarity to the determination of a threshold for serious risk, and support reasoned decisions which stand up to legal challenges.

ISSUE 2: INCLUDE GUIDANCE NOTIFICATION TO PUBLIC, PHYSICIANS AND OTHER HEALTH CARE PRACTITIONERS

The CMA is supportive of the guiding principles that should govern all decisions made by Health Canada acting as a regulatory decision-maker, i.e., that power is exercised in a process that is free from bias, based on evidence and in a transparent manner.

In order to support transparency, the CMA recommends that the guidance be expanded to include the notification of the public, both by companies[2] and by Health Canada, when these new authorities are exercised.

Access to accurate, unbiased information is essential for people to make decisions about their own health.. A clear elaboration and articulation of the process and timelines for how and when public notification is issued in relation to the exercise of the new ministerial authorities is critical to ensure their comprehensive, effective and transparent implementation.

Also, when new information is discovered about a prescription medication, it is important that health professionals be informed as quickly and efficiently as possible.

As part of Health Canada's commitment to transparency, the CMA recommends that the guidance should be expanded to include public disclosure of Health Canada's usage of the guidance: how the thresholds are applied on a case by case basis and the outcomes of decisions, even when the process results in no action being taken.

[2] Note: Throughout this submission, "companies" refers to whom the new ministerial powers apply outside of the regulator – as explained in the consultation document, in the case of s. 21.1 it is a "person" (can include an individual, a research institution, a corporation or an authorization holder), in the case of 21.2 it is the therapeutic product authorization holder, and in the case of s.21.3 it is a "person".

The U.S. Food and Drug Administration (U.S. FDA), for example, provides guidance and instructions on their public notification expectations in a situation where a product may pose a significant health hazard.[3] In addition, there are different mechanisms of public notification, including 'mobile web' and alerts.

Finally, also consistent with the guidance of the U.S. FDA, the CMA recommends that the guidance be expanded to require evaluation by companies and Health Canada of the use of the power for collection of information, label change or recall and public reporting on the effectiveness of the action taken.

ISSUE 3: SPECIFY THE OVERSIGHT AND REVISION OF THE GUIDANCE

As part of its public consultation outreach with stakeholders on this new guidance, Health Canada officials have described the Guide as an evergreen document that will be continually updated. The CMA is supportive of Health Canada's efforts to engage stakeholders and the public in the development and revision of this guidance.

To ensure clarity on how or when the revision process will be undertaken, the CMA recommends that the guidance include a timeline for revision, a mechanism for stakeholders to identify issues with the guidance, and the circumstances that would trigger an early review, possibly leading to a revision.

CONCLUSION

The CMA welcomed this opportunity to submit recommendations on how Health Canada may improve the Guide to New Authorities, which is critical to the comprehensive, effective and transparent implementation of the new authorities established by *Vanessa's Law*. The CMA looks forward to continued and ongoing collaboration with Health Canada on its implementation of these important new powers.

Overview of Recommendations

1. The CMA recommends that the guidance be expanded to specify a mechanism for experts, external to Health Canada, to submit recommendations for action and the process by which these recommendations would be considered.
2. The CMA recommends that the elements and process for the determination of "serious risk" be further defined, in order to bring clarity to the determination of a threshold for serious risk, and support reasoned decisions which stand up to legal challenges.

[3] U.S. Food and Drug Administration (2015) Guidance for Industry: Product Recalls, Including Removals and Corrections. Retrieved from: http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm

3. In order to support transparency, the CMA recommends that the guidance be expanded to include the notification of the public, both by companies and by Health Canada when these new authorities are exercised.
4. The CMA recommends that the guidance should be expanded to include public disclosure of Health Canada's usage of the guidance: how the thresholds are applied on a case by case basis and the outcomes of decisions, even when the process results in no action being taken.
5. The CMA recommends that the guidance be expanded to require evaluation by companies and Health Canada of the use of the power for collection of information, label change or recall and public reporting on the effectiveness of the action taken.
6. To ensure clarity on how or when the revision process will be undertaken, the CMA recommends that the guidance include a timeline for revision, a mechanism for stakeholders to identify issues with the guidance, and the circumstances that would trigger an early review, possibly leading to a revision.