

CMA Response:

Regulation of Self-Care Products in Canada

The Canadian Medical Association (CMA) appreciates the opportunity to respond to the Health Canada consultations on the regulation of self-care products in Canada. The CMA is encouraged that Health Canada is proposing a framework for the regulation of self-care products that is reliant on scientific proof to support health claims.

The CMA has over 83,000 physician-members. Its mission is helping physicians care for patients and its vision is to be the leader in engaging and serving physicians, and the national voice for the highest standards for health and health care.

The CMA's comments on the regulation of self-care products, particularly natural health products and non-prescription drugs is based on the CMA Policy on Complementary and Alternative Medicine attached as Appendix 1. Our position is based on the fundamental premise that decisions about health care interventions used in Canada should be based on sound scientific evidence as to their safety, efficacy and effectiveness - the same standard by which physicians and all other elements of the health care system should be assessed. Canadians deserve the highest standard of treatment available, and physicians, other health practitioners, manufacturers, regulators and researchers should all work toward this end.¹ CMA supports a regulatory approach to self-care products such as natural health products that is based on risk assessment and the development of standards.²

Risk Based Approach

As noted above CMA has recommended a regulatory approach that is based on risk assessment. We are troubled that the consultation document does not provide enough information on Health Canada's risk assessment process. We are concerned that the proposal for a risk based approach could place many natural health and homeopathic products in a lower risk category based on whether or not the product makes a health claim which would require no Health Canada review or licensing of these products. As noted in the consultation document all health products have some level of risk and Health Canada's role is to ensure that the benefits of a product outweigh any known risks. CMA does not believe that a determination of risk can be made based on historical use of a product or on the basis of a philosophical system not supported by science.

The CMA has a long standing position that the same regulatory standards should apply to both natural health products and pharmaceutical health products. These standards should be applied to natural health products regardless of whether a health claim is made for the product. This framework must facilitate the entry of products onto the market that are known to be safe and effective, and impede the entry of products that are not known to be safe and effective until they are better understood.³

CMA would recommend that the initial risk assessment of a self-care product should be evidence informed and based on the same standards of proof and efficacy as those for conventional medicines and pharmaceuticals. As such, we are concerned that homeopathic and natural health products are given as examples of lower risk products that would not require Health Canada review or licensing.

Health Claims

The consultation document redefines a health claim to only those that pertain to diagnosis, treatment, prevention, cure or mitigation of disease or serious health condition. These claims will need to be supported by scientific evidence and only these health claims will be allowed and reviewed by Health Canada.

The CMA has recommended that safety and efficacy claims for natural health products, and claims for the therapeutic value of these products should be prohibited when the supportive evidence does not meet the evidentiary standard required of medications currently regulated by Health Canada.⁴ Claims of medical benefit should only be permitted when compelling scientific evidence of their safety and efficacy exists.⁵ Therefore the CMA supports the proposal that two products making similar claims would have to provide the same level of scientific evidence and are held to the same standard. CMA would not be in support of the proposal that products can still make claims “based on traditional systems of medicine or alternate modalities” with only “adequate supporting information” to be maintained by the company without review or licensing by Health Canada.

CMA would also recommend that even those products that do not make health claims are held to the same standard as those established for pharmaceutical products. Since our position is that all self-care products from lower risk to higher risk should be reviewed for safety and quality, all products should undergo review by Health Canada.

Information

It is certainly problematic that, as noted in the consultation document, fewer than 2 in 5 Canadians surveyed rated themselves knowledgeable about the effectiveness of self-care products. Canadians have the right to reliable, accurate information on self-care products to help ensure that choices they make are informed. It is very important that Canadians understand the level of scrutiny a product has undergone by Health Canada. CMA can support the proposal for an authorization number on those products that have been reviewed and approved by Health Canada. Equally, a disclaimer on the product label that indicates that the product has not been reviewed or approved by Health Canada for effectiveness is very important. We must guard against an assumption by the public that if Health Canada did not need to review a product there is no risk associated with the product.

The Information provided on self-care products should be user friendly and easy to access and include a list of ingredients, instructions for use, indications that the product has been proven to treat, contraindications, side effects and interactions with other medications.

In an era when product claims can be spread via social media and the internet and cannot be easily monitored it is important to ensure consistent oversight of product marketing. Health claims can only be promoted if they have been established with sound scientific evidence. This restriction should apply not only to advertising, but also to all statements made in product or company Web sites and communications to distributors and the public. Advertisements should be pre-cleared to ensure that they contain no deceptive messages.

Additional Powers

In its submission on Bill C -17 An Act to amend the Food and drugs Act – Protecting Canadians from Unsafe drugs the CMA recommended that the ministerial authorities and measures to address patient safety risks should extend to natural health products.⁶ We would therefore suggest that Health Canada explore the need for additional powers and tools to require a company to change labels, or order a recall of an unsafe product and institute new penalties to address patient safety issues.

Canada's physicians are prepared to work with governments, health professionals and the public in strengthening Canada's regulatory framework for self-care products to ensure that the health related products Canadians receive are safe and effective.



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¹ Canadian Medical Association. *CMA Policy Complementary and Alternative Medicine (Update 2015)*. Ottawa: The Association; 2015. Available: <http://policybase.cma.ca/dbtw-wpd/Policypdf/PD15-09.pdf>

² Canadian Medical Association. *Brief BR1998-02 - Regulatory framework for natural health products*. Ottawa (ON): The Association; 1998.

³ Canadian Medical Association. *CMA Policy Complementary and Alternative Medicine (Update 2015)*. Ottawa: The Association; 2015. Available: <http://policybase.cma.ca/dbtw-wpd/Policypdf/PD15-09.pdf>

⁴ Canadian Medical Association. Policy resolution GC08-86 - Natural health products. Ottawa (ON): The Association; 2008.

⁵ Canadian Medical Association. Policy resolution GC10-100 - Foods fortified with “natural health” ingredients. Ottawa (ON): The Association; 2010.

⁶ Canadian Medical Association. *Brief BR2014-09 - Bill C-17 An Act to amend the Food and Drugs Act*. Ottawa: The Association; 2014.



COMPLEMENTARY AND ALTERNATIVE MEDICINE (Update 2015)

This statement discusses the Canadian Medical Association's (CMA) position on complementary and alternative medicine (CAM). CAM, widely used in Canada, is increasingly being subject to regulation. The CMA's position is based on the fundamental premise that decisions about health care interventions used in Canada should be based on sound scientific evidence as to their safety, efficacy and effectiveness - the same standard by which physicians and all other elements of the health care system should be assessed. Patients deserve the highest standard of treatment available, and physicians, other health practitioners, manufacturers, regulators and researchers should all work toward this end. All elements of the health care system should "consider first the well-being of the patient."¹ The ethical principle of non-maleficence obliges physicians to reduce their patient's risks of harm. Physicians must constantly strive to balance the potential benefits of an intervention against its potential side effects, harms or burdens. To help physicians meet this obligation, patients should inform their physician if the patient uses CAM.

CAM in Canada

CAM has been defined as "a group of diverse medical and health care systems, practices and products that are not presently considered to be part of conventional medicine."ⁱ This definition comprises a great many different, otherwise unrelated products, therapies and devices, with varying origins and levels of supporting scientific evidence. For the purpose of this

analysis, the CMA divides CAM into four general categories:

- *Diagnostic Tests*: Provided by CAM practitioners. Unknown are the toxicity levels or the source of test material, e.g., purity. Clinical sensitivity, specificity, and predictive value should be evidence-based.
- *Products*: Herbal and other remedies are widely available over-the-counter at pharmacies and health food stores. In Canada these are regulated at the federal level under the term *Natural Health Products*.

ⁱ Working definition used by the National Center for Complementary and Alternative Medicine of the U.S. National Institutes of Health.

- *Interventions*: Treatments such as spinal manipulation and electromagnetic field therapy may be offered by a variety of providers, regulated or otherwise.
- *Practitioners*: There are a large variety of practitioners whose fields include chiropractic, naturopathy, traditional Chinese and Ayurvedic medicine, and many others. Many are unregulated or regulated only in some provinces/territories of Canada.

Many Canadians have used, or are currently using, at least one CAM modality. A variety of reasons has been cited for CAM use, including: tradition; curiosity; distrust of mainstream medicine; and belief in the “holistic” concept of health which CAM practitioners and users believe they provide. For most Canadians the use is *complementary* (in addition to conventional medicine) rather than *alternative* (as a replacement). Many patients do not tell their physicians that they are using CAM.

Toward Evidence-Informed Health Care

Use of CAM carries risks, of which its users may be unaware. Indiscriminate use and indiscriminating acceptance of CAM could lead to misinformation, false expectations, and diversion from more appropriate care, as well as adverse health effects, some of them serious.

The CMA recommends that federal, provincial and territorial governments respond to the health care needs of Canadians by ensuring the provision of clinical care that continually incorporates evidence-informed technological advances in information, prevention, and diagnostic and therapeutic services.² Physicians take seriously their duty to advocate for quality

health care and help their patients choose the most beneficial interventions. Physicians strongly support the right of patients to make informed decisions about their medical care. However, the CMA’s Code of Ethics requires physicians to recommend only those diagnostic and therapeutic procedures that they consider to be beneficial to the patient or to others.³ Until CAM interventions are supported by scientifically-valid evidence, physicians should not recommend them. Unless proven beneficial, CAM services should not be publicly funded. To help ensure that Canadians receive the highest-quality health care, the CMA recommends that CAM be subject to rigorous research on its effects, that it be strictly regulated, and that health professionals and the public have access to reliable, accurate, evidence-informed information on CAM products and therapies. Specific recommendations are provided below:

a) **Research: Building an Evidence Base**

To date, much of the public’s information on CAM has been anecdotal, or founded on exaggerated claims of benefit based on few or low-quality studies. The CMA is committed to the principle that, before any new treatment is adopted and applied by the medical profession, it must first be rigorously tested and recognized as evidence-informed.⁴ Increasingly, good-quality, well-controlled studies are being conducted on CAM products and therapies. The CMA supports this development. Research into promising therapies is always welcome and should be encouraged, provided that it is subject to the same standards for proof and efficacy as those for conventional medical and pharmaceutical treatments. The knowledge thus obtained

should be widely disseminated to health professionals and the public.

b) An Appropriate Regulatory Framework

Regulatory frameworks governing CAM, like those governing any health intervention, should enshrine the concept that therapies should have a proven benefit before being represented to Canadians as effective health treatments.

i) *Natural Health Products.* Natural health products are regulated at the federal level through the Natural Health Products Directorate of Health Canada.

The CMA believes that the principle of fairness must be applied to the regulatory process so that natural health products are treated fairly in comparison with other health products.⁵ The same regulatory standards should apply to both natural health products and pharmaceutical health products. These standards should be applied to natural health products regardless of whether a health claim is made for the product. This framework must facilitate the entry of products onto the market that are known to be safe and effective, and impede the entry of products that are not known to be safe and effective until they are better understood. It should also ensure high manufacturing standards to assure consumers of the products' safety, quality and purity. The CMA also recommends that a series of standards be developed for each natural health product. These standards should include:

* manufacturing processes that ensure the purity, safety and quality of the product;

* labelling standards that include standards for consumer advice, cautions and claims, and explanations for the safe use of the product to the consumer.⁶

The CMA recommends that safety and efficacy claims for natural health products be evaluated by an arm's length scientific panel, and claims for the therapeutic value of natural health products should be prohibited when the supportive evidence does not meet the evidentiary standard required of medications regulated by Health Canada.⁷ Claims of medical benefit should only be permitted when compelling scientific evidence of their safety and efficacy exists.⁸

The Canadian Medical Association advocates that foods fortified with "natural health" ingredients should be regulated as food products and not as natural health products

The CMA recommends that the regulatory system for natural health products be applied to post-marketing surveillance as well as pre-marketing regulatory review. Health Canada's MedEffect adverse reaction reporting system now collects safety reports on Natural Health Products. Consumers, health professionals and manufacturers are encouraged to report adverse reactions to Health Canada.

ii) *CAM Practitioners.* Regulation of CAM practitioners is at different stages. The CMA believes that this regulation should: ensure that the services CAM practitioners offer are truly efficacious; establish quality control mechanisms and appropriate standards of practice; and work to develop an evidence-informed body of competence that develops with evolving knowledge.

Just as the CMA believes that natural health products should be treated fairly in comparison with other health products, it recommends that CAM practitioners be held to the same standards as other health professionals. All CAM practitioners should develop Codes of Ethics that insure practitioners consider first the best interests of their patients.

Among other things, associations representing CAM practitioners should develop and adhere to conflict of interest guidelines that require their members to:

- Resist any influence or interference that could undermine their professional integrity;⁹
- Recognize and disclose conflicts of interest that arise in the course of their professional duties and activities, and resolve them in the best interests of patients;¹⁰
- Refrain, for the most part, from dispensing the products they prescribe. Engaging in both prescribing and dispensing, whether for financial benefit or not, constitutes a conflict of interest where the provider's own interests conflict with their duty to act in the best interests of the patient.

c) Information and Promotion

Canadians have the right to reliable, accurate information on CAM products and therapies to help ensure that the treatment choices they make are informed. The CMA recommends that governments, manufacturers, health care providers and other stakeholders work together to ensure that Canadians have access to this information. The CMA believes that all

natural health products should be labeled so as to include a qualitative list of all ingredients.¹¹ Information on CAM should be user-friendly and easy to access, and should include:

- Instructions for use;
- Indications that the product or therapy has been convincingly proven to treat;
- Contraindications, side effects and interactions with other medications;
- Should advise the consumer to inform their health care provider during any encounter that they are using this product.¹²

This information should be provided in such a way as to minimize the impact of vested commercial interests on its content.

In general, brand-specific advertising is a less than optimal way of providing information about any health product or therapy. In view of our limited knowledge of their effectiveness and the risks they may contain risks, the advertising of health claims for natural health products should be severely restricted. The CMA recommends that health claims be promoted only if they have been established with sound scientific evidence. This restriction should apply not only to advertising, but also to all statements made in product or company Web sites and communications to distributors and the public. Advertisements should be pre-cleared to ensure that they contain no deceptive messages. Sanctions against deceptive advertising must be rigidly enforced, with Health Canada devoting adequate resources to monitor and correct misleading claims.

The CMA recommends that product labels include approved health claims, cautions

and contraindications, instructions for the safe use of the product, and a recommendation that patients tell physicians that they are using the products. If no health claims are approved for a particular natural health product, the label should include a prominent notice that there is no evidence the product contributes to health or alleviates disease.

The Role of Health Professionals

Whether or not physicians and other health professionals support the use of CAM, it is important that they have access to reliable information on CAM products and therapies, so that they can discuss them with their patients.

Patients should be encouraged to report use of all health products, including natural health products, to health care providers during consultations. The CMA encourages Canadians to become educated about their own health and health care, and to appraise all health information critically.

The CMA will continue to advocate for evidence-informed assessment of all methods of health care in Canada, and for the provision of accurate, timely and reliable health information to Canadian health care providers and patients.

¹ Canadian Medical Association. *CMA code of ethics* (update 2004). Ottawa: The Association; 2004.

² Canadian Medical Association. *Policy resolution GC00-196 - Clinical care to incorporate evidence-based technological advances*. Ottawa (ON): The Association; 2000. Available: <http://policybase.cma.ca/dbtw-wpd/CMAPolicy/PublicB.htm>.

³ Canadian Medical Association. *CMA code of ethics* (update 2004). Ottawa: The Association; 2004. Available: <http://policybase.cma.ca/dbtw-wpd/CMAPolicy/PublicB.htm>.

⁴ Canadian Medical Association. *CMA statement on emerging therapies* [media release]. Ottawa (ON): The Association; 2010. Available: www.facturation.net/advocacy/emerging-therapies.

⁵ Canadian Medical Association. *CMA statement on emerging therapies* [media release]. Available: www.facturation.net/advocacy/emerging-therapies.

⁶ Canadian Medical Association. *Brief BR1998-02 - Regulatory framework for natural health products*. Ottawa (ON): The Association; 1998.

⁷ Canadian Medical Association. *Policy resolution GC08-86 - Natural health products*. Ottawa (ON): The Association; 2008.

⁸ Canadian Medical Association. *Policy resolution GC10-100 - Foods fortified with "natural health" ingredients*. Ottawa (ON): The Association; 2010. Available:

⁹ Canadian Medical Association. *CMA code of ethics* (update 2004). Ottawa: The Association; 2004. Paragraph 7. Available: <http://policybase.cma.ca/dbtw-wpd/CMAPolicy/PublicB.htm>.

¹⁰ Canadian Medical Association. *CMA code of ethics* (update 2004). Ottawa: The Association; 2004. Paragraph 11. Available: <http://policybase.cma.ca/dbtw-wpd/CMAPolicy/PublicB.htm>.

¹¹ Canadian Medical Association. *Brief BR1998-02 - Regulatory framework for natural health products*. Ottawa: The Association; 1998.

¹² Canadian Medical Association. *Brief BR1998-02 - Regulatory framework for natural health products*. Ottawa: The Association; 1998.