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Natural and Non-prescription Health Products Directorate Consultation Health Canada, Government of Canada

Homeopathy Product Labelling and Risk Considerations

The College of Homeopaths of Ontario (CHO) regulates Homeopaths to ensure safe, ethical and competent homeopathy care for the people of Ontario. The College does this by setting requirements to enter the profession, establishing comprehensive standards, and administering quality assurance programs. Acting in the public interest, the College holds Ontario's regulated Homeopaths accountable for their conduct and practice. Within the framework of Ontario's *Regulated Health Professions Act, 1991*, and the *Homeopathy Act*, 2007, the CHO adopts a risk-based approach in the regulation of members' practises in so far as it relates to public protection.

Homeopathy remedies/medicines are regulated by Health Canada within its mandate to ensure that "Canadians have access to natural health products, including homeopathy products. These products should be safe, effective and of high quality. Canadians should have freedom of choice and philosophical and cultural diversity should be respected." ¹

Health Canada has acknowledged that evidence for Homeopathy can include materia medica and provings; however there are many other legitimate sources of evidence including meta analyses, systematic reviews, randomized clinical trials, cohort studies, case controlled studies, case reports, traditional references, HPUS pharmacopoeia (as well as European and Indian) and expert opinions.

Homeopathy is practised in almost every country in the world. In many countries it is still practised by medical doctors. Worldwide, it is estimated that between 200 to 300 million people are using homeopathy and that there are approximately 300,000 homeopaths. It is important to acknowledge that homeopathy has always been part of the medical system. In Ontario it was first recognized in the Ontario Legislature in 1859, and then became part of the College of Physicians and Surgeons of Ontario (CPSO) in 1869. Homeopathy was regulated together with medical doctors for 100 years, becoming regulated as a separate profession in 2015 after a period of unregulated practice. Since that time more than 600 practitioners have been registered with the CHO.



Homeopaths and members of the public have access to both single and complex remedies, some of which are OTCs. To ensure access to care, it is imperative that public access to these products be maintained.

In many cases, use of an OTC homeopathic product is the health care consumer's first experience with the effectiveness of homeopathic remedies. The introduction may be by a trained homeopath, retail access to products or a variety of other avenues which may lead to an individual's purchase. Positive outcomes may lead to consultations for acute or chronic conditions. It is important to understand that homeopathic remedies may be instrumental in stopping the progression of disease at its onset, thereby reducing the need for further treatment and the burden on the broader health care system.

The safety of homeopathic products is not in question. There have been no demonstrated incidents of harmful effects since 1859 or earlier. A recent study by Hill & Knowlton provides clear evidence that homeopathy continues to be increasingly popular in Canada with 2.9 million people over the age of 18 identifying as frequent users². Those people who have used homeopathy products have more positive views of homeopathy, particularly frequent users. These results were similar to those found in the 2016 survey conducted by Health Canada where those who used homeopathic medicines were more likely to have knowledge of these products. Most Canadians interviewed in the study want current levels of access to homeopathy remedies to be maintained.

Health claims by some manufacturers for combination medicines have been based on pharmacopoeias, materia medica, provings, clinical trials, historical data, etc. The focus has been on the predominant characteristics of each medicine which collectively cover the main cluster of the symptoms of a complaint, e.g. cough symptoms. No medicines can be curative or relieve symptoms in 100% of patient experiences. These kinds of medicines are focused on acute manifestations of disease i.e. self-resolving conditions.

In most cases, homeopathy products are packaged in small containers, which means there is limited amount of space on the packages for patient information. What is most important on the outside of the package is actionable product information, specifically the purpose of the product, ingredients, cautions and directions as to how to take it.



A bolded bordered rectangle with a symbol together with an enclosed statement has strong negative connotations. This appears to be symbolic of a warning statement. Using such a label must be reserved for potentially harmful drugs which can result in injury or death. The rectangle and symbol become the focal point on the very small label that overwhelms the essential product information.

The information provided within the warning label does not reflect actual risk. There are definitions that need to be substantiated. All considered, this appears to be an extraordinary requirement for low risk homeopathic products. All other products, where risk of injury is far higher, warning labels on the front of the package are not required (e.g. acetaminophen which can cause liver damage). In a review of requirements in the USA (where homeopathic remedies are considered as drugs), Europe, South America, and Africa, there does not appear to be another country that requires a warning label on the front package of a homeopathic product.

A statement such as, "Based on homeopathic principles" or simply "Homeopathic" (as occurs in the USA) may be acceptable. Any statement that reflects negatively on the profession or the health benefits derived from the product or homeopathic care would not be appropriate or in the public's interest. Changing labels to introduce a false sense of risk has a potential to cause harm if it calls into question the recommendations of a regulated health professional.

The need to provide a link to web information about the product is extraordinary, especially since this is not a requirement for other alternatives therapies such as Ayurvedic Medicine, Traditional Chinese Medicine and Acupuncture, and First Nations medicine. There is little chance that the public would have a better understanding of the tenets of these therapies compared to homeopathy.

In addition, the likelihood of consumers availing themselves of this web information at the point of purchase is extremely low. Other contentious issues to consider include the website location, under whose jurisdiction will it reside, and of course who will be responsible for providing and overseeing the content.

The principles and practice of Homeopathy are well documented on the CHO website. It is important to establish consistency for the definition of homeopathy since the CHO regulates homeopaths in Ontario.

http://collegeofhomeopaths.com/about-homeopathy.html



The key elements of safety, patient outcomes and the assurance of production quality are vital to the health and trust of the many patients who choose to include homeopathy and OTC homeopathic products in their health-care strategies. There must be standards for operating procedures for manufacturers in respect of manufacturing including dilution, potentization (or dynamization), provings and dispensing, and there is benefit and increased trust when the public understands that these standards exist and manufacturers comply with the standards.

There, must, in the public interest, also be a careful balance of not overregulating the manufacturers. There must be room to produce and market less frequently used homeopathy remedies which maybe more expensive to produce, which evidence and experience show creates positive patient health outcomes. Patients benefit from having reasonable access to the homeopathic products which will best address their health issues. Today, many homeopaths have only limited access to remedies produced in Canada, and the selection of OTC remedies is smaller still. The result impacts the health care available to Canadians who seek homeopathic care.

Health Canada needs to consider worldwide regulatory practices and employ a willingness to consult with subject matter experts, including the CHO, to gain a transparent, objective, impartial and fair perspective. To ensure the integrity of homeopathic practice, we believe that there should be no unintended consequences from the government's proposals that could negatively impact either the profession or the care patient's received under the direction of their regulated homeopath.

Patients must always have the right to choose their health-care modality and to seek care from the providers they most trust. Ensuring the ongoing availability of products needed to ameliorate their symptoms and potentially reduce the need for more invasive, costly and treatment with greater propensity of risk is vital to the integrity of our health care system and patient protection.

Respectfully,

Basil Ziv, Hom, RSHom, B Com

Registrar & CEO

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1 Health Canada Proposed Approach to Homeopathic Products September 2020 2 Hill & Knowlton Strategies (2019). Behaviours and Attitudes Towards Homeopathic Medicine: A Survey of Canadians.

