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Natural and Non-prescription Health Products Directorate
Health Products and Food Branch
Health Canada
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Consultation regarding proposed NHP Compounding and Raw Materials Policy

Thank you for the opportunity to review the updated Natural Health Product Raw Material Policy and for your continued engagement with stakeholders. We acknowledge Health Canada's efforts to clarify the distinction between raw materials and finished natural health products (NHPs). However, after a detailed review, several core concerns remain unresolved and, in some cases, have become more pressing under the revised framework—particularly with respect to homeopathy, patient access to prescribed remedies, and the ability of regulated practitioners to obtain, prepare, dispense, or use essential remedies within an established practitioner-patient relationship.

We ask for an exemption for homeopathic remedies from the proposed NHP Compounding and Raw Materials Policy and for further dialogue as a regulator to discuss public safety.

The updated policy's expectation that imported substances must *"clearly require further manufacturing or modification"* before use places homeopaths in an untenable position. In homeopathic practice, a remedy may appropriately be dispensed in its purchased form or may be further prepared depending on the needs of the individual patient. Requiring a practitioner to physically alter a remedy solely to satisfy a regulatory definition would create an artificial requirement that provides no additional benefit to patient safety, quality assurance, or therapeutic care.

Regulation should not require unnecessary clinical procedures simply to fit a practice model designed for conventional manufacturing processes. The relevant question should be whether the remedy is being used within a regulated healthcare practice, not whether it has been altered before being dispensed.

Homeopathic single remedies such as Pulsatilla start off in the raw form as the homeopathic mother tincture and through a process carried out in the laboratory, or under the supervision of a regulated homeopath, are compounded by serial dilution and succussion, as per the Organon of Medicine, and brought to potency, Decimal, Centesimal, LM, etc., which are generally understood to be low risk when used appropriately.

Homeopathic remedies must be differentiated from pharmaceutical products which require strong regulation because they potentially may pose risk of toxicity. Safety in homeopathic practice is supported by both product oversight and professional regulation. Health Canada reviews homeopathic products for safety, quality, and evidence before authorizing sale; while Ontario's professional framework requires homeopaths to practice safely, ethically and competently within established standards. This is particularly important because homeopathic remedies are often used by members of the public seeking gentle forms of care, where qualified practitioner guidance and clear professional accountability are essential.

As stated in the document, *"It must be left to the homeopath to decide whether a remedy will be given to the patient in its original form... or compounded further for the patient."* This clinical discretion is essential to safe, competent practice within a defined patient-practitioner relationship.

Background and Regulatory Context

The Natural Health Products Regulations establish requirements for the manufacturing, packaging, labelling, importation, distribution, storage, and sale of NHPs in Canada. Importantly, the practice of complementary, alternative, or traditional medicine—including homeopathy—is outside the scope of these Regulations and is not regulated by Health Canada.

Jurisdictional concern: The revised policy should be careful not to transform federal product oversight into indirect regulation of a provincially regulated health profession. In Ontario, homeopathy is governed through the provincial health-profession framework, with public protection achieved by ensuring that practitioners are trained, competent, ethical, accountable, and practicing within a practitioner-patient relationship.

Health Canada's legitimate role is to regulate commercial NHP activity, including manufacturing, importation, packaging, labelling and sale. It should not extend that role into decisions about individualized assessment, remedy selection, potency, dispensing, clinical instructions, or whether a regulated practitioner's use of a remedy is appropriate for a particular patient. Those are matters of professional practice and provincial oversight.

The concern is not simply that Health Canada is regulating products. The concern is that, by controlling the conditions under which practitioners may obtain, prepare, dispense, or use remedies, federal policy begins to determine the manner in which a provincially regulated profession operates. Questions about whether a remedy has been sufficiently individualized, whether a practitioner-patient relationship exists, whether preparation is clinically appropriate, whether remedies may be prepared in advance based on prescribing history, or whether a remedy should be dispensed directly or further modified are questions of professional practice, not product regulation.

In **Ontario**, the regulation of homeopaths is grounded in two core principles articulated in the **Regulated Health Professions Act, 1991** and the **Homeopathy Act, 2007**:

· **Protection of the public**, and

· **Ensuring access to treatment by well trained, competent, and ethical homeopaths**.

Homeopaths are regulated by the **College of Homeopaths of Ontario** (CHO) primarily for public protection and to ensure access to qualified, ethical practitioners. Without reliable access to remedies, homeopaths cannot fulfill their legislated mandate.

Nature of Homeopathic Remedies

Homeopathic remedies originate from naturally occurring substances that are diluted and succussed through a series of steps to achieve the required potency e.g. Pulsatilla 200C. These remedies do not present a risk of toxicity and may be used empirically, applied to sugar pellets, or further compounded for patient specific use.

The clinical reality is that these remedies function as practitioner-use materials within a practitioner–patient relationship, even when they appear in dosage forms that could be misinterpreted as finished products under the updated policy. A homeopathic remedy may be prepared by a pharmacy, placed in pellet or liquid form, and physically appear to be a finished product. However, within a practitioner-patient relationship, its clinical significance is not determined solely by physical form. The remedy's potency, timing, frequency, and directions for use are selected by the homeopath through the practitioner-patient relationship.

Alignment of Federal and Provincial Regulations

Federal NHP Regulations are designed to ensure public safety, while Ontario's regulatory framework ensures competent practice within a defined scope. Homeopaths prescribe homeopathic remedies as part of their regulated healthcare role. Without reliable access to these remedies, homeopaths cannot fulfill their legislated mandate in Ontario.

The practical line should be clear: Health Canada may regulate commercial product activity, but when a regulated homeopath obtains or dispenses a remedy for an identified patient within the scope of practice, the central issue is patient care, not commercial manufacturing.

If Health Canada blurs that line, it risks stepping into an area reserved for Ontario's health-profession regulator.

The compounding exemption should be read in that light. It recognizes that individualized practitioner activity is not the same as commercial manufacturing. For homeopathy, that distinction is essential because the remedy, potency, timing and directions are selected through the practitioner-patient relationship.

Global Practice and Standards

Homeopathy is practiced worldwide, and remedies are manufactured under stringent quality standards in multiple jurisdictions. Canadian practitioners depend on these global supply chains. Given the relatively small Canadian market, many remedies—especially new or less common ones— are not manufactured domestically. As the document notes, *"**the opportunity to obtain new remedies for their patients can only be satisfied through importation**."*

Concerns with the Updated Policy

1. Credit of Homeopathic Remedies

Health Canada defines a raw material as a substance intended to be used in the manufacturing process to produce a finished NHP of different composition or form. In contrast, the CHO considers a substance a raw material when it is "prepared, combined, or modified by a practitioner to produce a patient specific final product."

Health Canada should not allow the federal definition of "raw material" to override the clinical reality recognized in provincial regulation. A homeopathic remedy may be ready to administer and still function as a practitioner-use material because its significance depends on individualized selection, potency and patient-specific direction.

The concern is therefore not merely definitional. If the policy treats practitioner-use remedies as finished commercial products, it may restrict the tools of the profession and interfere with Ontario's ability to protect the public through regulated, competent homeopathic care.

2. Dosage Form and Clinical Use

The policy's reliance on dosage form and "readiness for consumption" is not a reliable test in homeopathy. Pellets and liquids may look finished, but their use is individualized; they are not standardized consumer products with fixed indications.

The distinction between a raw material and a finished product cannot be based solely on the appearance or dosage form of the preparation. The clinical context in which the remedy is selected and used must be recognized as the determining factor.

3. Therapeutic Intent and Classification

Therapeutic intent is also an unsafe criterion for inspectors to apply in this context. Homeopathic prescribing is based on the assessment of the totality of individualized symptoms (mental, emotional, physical and general), not condition-specific labelling such as remedy X for health condition Y. Federal inspectors should not be placed in the position of second-guessing clinical judgment.

If there are concerns about competence, ethics, records, dispensing practices or the existence of a practitioner-patient relationship, those concerns should be referred to the provincial regulator.

Turning those concerns into federal import or licensing barriers would be a serious jurisdictional overreach.

4. Importation and Compounding Pathways

The proposed importation approach is too narrow if it depends on further visible manufacturing or modification. In homeopathy, the clinical use of a remedy may be determined by practitioner assessment rather than by whether the substance is physically altered before being dispensed.

The proper question should be whether the remedy is being imported or held for use within a regulated practitioner-patient relationship. Where that is the case, restricting access would not advance public safety; it would impair the ability of qualified homeopaths to practise responsibly.

Patients who independently import remedies prescribed by a regulated homeopath should also be explicitly protected. These patients are not engaging in commercial importation, retail purchasing, or self-selection of therapeutic products. They are accessing individualized care within an established practitioner-patient relationship. A regulatory framework that creates uncertainty for these patients risks unnecessary delays, border refusals, and interruptions in care.

New remedies not currently available in Canada may face import restrictions, placing patients at risk. This is one of the biggest challenges that homeopaths and the public face.

5. Patient Access

Patient access should be expressly protected. When remedies are obtained under the guidance of a qualified homeopath, the practitioner-patient relationship provides the relevant safeguard: assessment, individualized selection, directions for use, follow-up, and accountability to the provincial regulator. This protection should apply both where regulated practitioners import remedies for identified patients and where patients obtain prescribed remedies directly from international pharmacies based on the recommendation and guidance of a regulated healthcare practitioner.

This concern is significant because homeopathy is not a marginal issue for Canadians.

Survey research according to Hill & Knowlton has reported that nearly **10.3 million** Canadians use homeopathy with a satisfaction rate of eighty-three per cent. If access to remedies is restricted, a substantial number of Canadians may be deprived of practical access to the healthcare modality they have chosen.

6. Repackaging and Relabelling

This is a matter of public choice. If the availability of remedies is limited, the result is not only a restriction on practitioners; it is a restriction on the public's ability to choose the healthcare modality they consider appropriate for themselves and their families.

Practitioner-level repackaging and relabelling should not be treated as commercial manufacturing.

In clinical practice, these activities support individualized dispensing and safe patient instructions; they are part of professional care, not market distribution.

Accordingly, patient-specific directions, remedy identification, potency and practitioner instructions should remain matters for professional standards and record-keeping under provincial oversight.

7. Increased Regulatory Uncertainty

The combined effect of the policy's criteria—dosage form, therapeutic intent, manufacturing status and importation pathway—creates uncertainty for practitioners, importers and patients. That uncertainty is not simply administrative; it risks pushing federal enforcement into areas where Ontario has already established a public-protection framework.

8. Border Enforcement and CBSA Interpretation

Policy interpretation occurs at the border. Even if Health Canada's intent is to recognize practitioner use and compounding, unclear criteria may result in inconsistent decisions by border authorities. Border officials are not healthcare regulators and do not have the professional mandate or expertise to determine whether a remedy represents legitimate clinical practice within a practitioner-patient relationship.

The policy should include clear operational guidance to prevent individualized remedies from being delayed, refused, or incorrectly classified. In particular, Health Canada should distinguish between commercial manufacturing, retail distribution, and unrestricted sale from individualized patient care delivered within a regulated healthcare relationship.

9. Lack of Identified Safety Concern

The primary issue is not product safety but regulatory classification and jurisdiction. Health Canada has not identified a specific safety concern arising from homeopathic remedies imported and used within regulated practitioner-patient relationships. The proposed restrictions therefore risk creating barriers to care without demonstrating a corresponding public health benefit.

If concerns relate to professional competence, ethical conduct, record keeping, prescribing practices, or the legitimacy of a practitioner-patient relationship, these matters are already addressed through provincial regulatory mechanisms and should be referred to the appropriate provincial regulatory authority.

Conclusion and Request

While the revised policy aims to provide clarity, it does not resolve the fundamental mismatch between homeopathic remedies and the conventional raw material/finished product distinction. More importantly, it risks turning federal product regulation into indirect supervision of a provincially regulated profession. That is thin constitutional ice. Public protection in Ontario is achieved through

regulations of the practitioner: training, competence, ethics, accountability, and the practitioner-patient relationship. Health Canada should not interfere with those safeguards by restricting access to the safe tools of the profession.

We respectfully request further dialogue to facilitate the regulatory approach that will protect access by the public to regulated healthcare practitioners and the remedies they need to treat their patients.

We specifically request that the policy expressly state that it does not apply to or restrict the clinical practice of regulated homeopaths, including individualized remedy selection by regulated homeopaths; dispensing of remedies within a practitioner-patient relationship; practitioner-level preparation, dilution, or modification of remedies; practitioner-level repackaging and relabeling for patient care; importation of remedies by regulated practitioners for identified patients; and patient importation of prescribed remedies where a practitioner-patient relationship exists.

The central principle should be clear: Health Canada regulates commercial products. Provincial regulators regulate healthcare professionals. Access to the tools required for regulated healthcare practice must not be restricted through federal product policies that effectively govern professional practice.

Where Health Canada has a concern about scope of practice, competence, ethics, records, dispensing practices, education, training, or the existence of a practitioner-patient relationship, the appropriate response is referral to the relevant provincial regulator. In Ontario, the College of Homeopaths of Ontario already has the regulatory tools to address these concerns through complaints and discipline processes, standards of practice, guidelines, a quality assurance program, and approval processes for educational institutions. These mechanisms are designed to ensure that registrants have the qualities expected of well-trained, competent, ethical practitioners who practise safely. Preserving access to homeopathic remedies helps preserve the public's freedom to seek care from qualified homeopaths and to make informed choices about their own health.

If Health Canada's concern is truly public protection, the answer is not federal interference with access to remedies; it is reliance on, and cooperation with, the provincial regulatory framework that already exists. Federal enforcement should be reserved for true commercial manufacturing, importation, sale, or distribution outside a regulated practitioner-patient context. It must do the following:

· **Distinguish commercial distribution from professional regulated healthcare practice**

· **Reflect the realities of regulated homeopathic practice**

· **Ensure patient access to essential remedies**

· **Explicitly protect patient importation of prescribed remedies within a practitioner-patient relationship**

· Preserve public choice by ensuring Canadians can continue to choose homeopathic care and access the remedies needed for that care

· Recognize the non-toxic nature of homeopathic preparations

· Maintain Health Canada's commitment to safety and quality

· Support the continued effectiveness of a regulated health profession

We propose that Health Canada review in detail our observations and comments to the NHP Compounding and Raw Material Policies and we look forward to receiving your response as soon as possible.

Respectfully,

Registrar and CEO
College of Homeopaths of Ontario

cc:
Honourable Marjorie Michel - Minister of Health, Government of Canada
Honourable Sylvia Jones - Minister of Health & Deputy Premier, Government of Ontario
Dr. Karima Velji, Assistant Deputy Minister and Chief of Nursing and Professional Practice
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