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Mr. Stephen Norman, Director
Natural and Non-Prescription Health Products Directorate
Health Products and Food Branch
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Dear Mr. Norman,

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 and the ability of practitioners and patients to access essential remedies made from these materials.

The updated policy's expectation that imported substances must "clearly require further manufacturing or modification" before use places homeopaths in an untenable position. As noted in the original submission, "many remedies—though clinically considered raw materials—may be interpreted as finished products if dispensed without additional alteration." This interpretation does not reflect the realities of homeopathic practice, where remedies may be dispensed as purchased or further compounded depending on the clinical needs of the patient.

Homeopathic remedies are nontoxic, highly diluted, and have never caused harm. They must be differentiated from pharmaceutical products, which require strong regulation precisely because they do pose toxicity risks. 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.

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.

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 processed into highly diluted preparations. The juice of the flowering plant Pulsatilla is diluted and succussed through a series of steps to achieve the required potency (e.g., C30, C200), and such remedies are not toxic. These preparations may be used empirically, applied to sugar pellets, or further compounded for patient specific use.

The clinical reality is that these remedies function as raw materials within a practitioner–patient relationship, even when they appear in dosage forms that could be misinterpreted as finished products under the updated policy.

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.

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. Recognition 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."

This divergence creates a regulatory mismatch. Remedies that are clinically raw materials may be classified as finished products under the federal definition, even though they are not sold commercially as finished NHPs and are intended solely for practitioner guided therapeutic use.

2. Dosage Form and Clinical Use

The policy's emphasis on dosage form and "readiness for consumption" does not align with homeopathic practice. Remedies dispensed as pellets or liquids are individualized for each patient and do not constitute standardized products with fixed indications.

3. Therapeutic Intent and Classification

The policy's reliance on therapeutic intent as a determinant of NHP classification introduces subjectivity. Homeopathic prescribing is based on the totality of symptoms, not on condition specific indications. This creates a risk of inconsistent enforcement and misclassification.

4. Importation and Compounding Pathways

The narrowing of importation pathways to substances requiring further manufacturing or modification poses significant challenges. Many remedies that function as raw materials in clinical practice may be deemed finished products under the policy, disconnecting regulation from real world use.

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

5. Patient Access

The absence of explicit exemptions for personal importation of prescribed remedies creates uncertainty for patients. Many patients import remedies for personal use under the guidance of a qualified homeopath. Delays or restrictions in this process directly impact continuity of care.

6. Repackaging and Relabelling

Treating practitioner level repackaging or relabelling as licensable commercial activities does not reflect clinical reality. These activities are part of individualized dispensing, not commercial distribution.

7. Increased Regulatory Uncertainty

The combined effect of multiple overlapping criteria—dosage form, therapeutic intent, manufacturing status, and importation pathways—creates uncertainty for practitioners, importers, and patients. This increases the likelihood of inconsistent interpretation and enforcement.

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. Practitioners and patients continue to face barriers to timely, reliable access. As the document states, "Ultimately, it is the public that suffer when homeopaths are unable to provide remedies to their patients."

We respectfully request further dialogue to develop a regulatory approach that:

- Reflects the realities of homeopathic practice
- Ensures patient access to essential remedies
- Recognizes the non toxic nature of homeopathic preparations
- Maintains Health Canada's commitment to safety and quality
- Supports the continued effectiveness of a regulated health profession

Respectfully,

Basil Ziv, HOM
Registrar and CEO

cc: Dr. Karima Velji, Assistant Deputy Minister and Chief of Nursing and Professional Practice

Allison Henry, Director, Health Workforce Regulatory Oversight Branch