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Mr. Stephen Norman, Director
Natural and Non-Prescription Health Products Directorate
Health Products and Food Branch
Health Canada
2 Constellation Dr, PL 2607A
Nepean, ON K1A 0K9

Email: nnhpd.consultation-dpsnso@hc-sc.gc.ca

Dear Mr. Norman,

Thank you for your response dated Thu 2025-01-02.

The College of Homeopaths of Ontario (CHO) is regulated by the Government of Ontario under the *Regulated Health Professions Act (RHPA), 1991*. The mandate of the CHO is essentially two-fold. One, to protect the public from harm and two, to ensure that the public have access to well qualified, competent and ethical homeopaths.

The scope of practice of homeopathy is defined as "...the assessment of body system disorders and treatment using homeopathic techniques to promote, maintain or restore health."

To carry out the CHO mandate, members of the CHO must have access to homeopathic remedies.

Thank you for confirming that homeopathic remedies are not subject to the NHPR and are considered raw materials:

> "As outlined in the Natural Health Product Raw Material Policy, the importation or sale of a substance not manufactured, sold or represented for use as a natural health product (NHP) for further processing by manufacturers, which can include processing during compounding, is not subject to the *Natural Health Products* Regulations (NHPR) and is considered a raw material."

Registered homeopaths provide remedies (which are considered raw materials), that can be further compounded, for therapeutic purposes to their patients.

> "NHPs compounded within a patient-practitioner relationship as per the NHP Compounding Policy, require no authorizations in Canada for the activities undertaken to compound, package, label and sell it."

Note that shipments of imported remedies are made to registered homeopaths, who declare their educational credentials and designated place of practice. The intended use of the remedy will always

be for therapeutic purposes based on homeopathy principles. You state that imported remedies must be addressed to the registered homeopath by name, including professional credentials, and to their registered place of practice. The shipment should include a description of the intended use for the imported products.

Health Canada inspectors may contact the importer/practitioner to gather additional information when necessary, such as to determine if compounding is occurring as opposed to sale or further manufacturing of the imported product.

Delays at the border can impact the health of the patient. Queries must be posed and addressed expeditiously.

See below the various issues that need to be addressed a priori. In the interests of simplicity, I provide a summary of the key points put forward within this letter. The references highlighted and italicized were taken directly from the Health Canada website.

In summary:

1. Homeopaths are regulated in Ontario under the *RHPA, 1991* and the *Homeopathy Act, 2007*.
2. Homeopaths have the legal right to compound homeopathic remedies which are designated as raw materials.
3. Homeopathic remedies are regulated by Health Canada and are appropriately labelled with HN-DIN numbers.
4. Homeopathic remedies are safe and pose no risk to the public.
5. The public is at risk when homeopathic remedies prescribed by a registered homeopath are not available.
6. Homeopathic remedies ordered by some registered homeopaths for further compounding have been stopped at the border. This is troubling.
7. While the impact of Bills C-47 and C-368 have yet to play out, there is concern that the increased costs they may impose will reduce the range of remedies that continue to be manufactured in Canada. The only option in this case will be importation, which makes it all the more important that clear and effective rules are in place that allow for timely acquisition of materials vital to patient care.

Homeopathic remedies are legally available in Canada. They can be purchased by the public and by Homeopaths in Ontario.

> *"The Natural Health Products Regulations (the NHPR) require all homeopathic medicines to have a licence before being sold in Canada. Licence holders are issued a product number, which must appear on the label of their product. The product number for homeopathic medicines is preceded by a DIN-HM. To obtain a DIN-HM, a Product Licence Application (PLA) form must be completed by applicants. These applications are assessed by the Natural and Non-prescription Health Products Directorate (NNHPD), which is responsible for issuing product licences for all natural health products (NHPs). The NNHPD uses evidence submitted by applicants to critically assess the safety, efficacy and quality of NHPs prior to approving them for sale in Canada."*
>
> ***Homeopathic Products Information on Homeopathic Products - Canada.ca***

"Homeopathic products come in many forms such as pellets, oral droplets, syrups, creams and ointments. These products are made up of substances that come from plants, minerals, or animals. These products are generally low risk.

Health Canada reviews homeopathic products to make sure that they are safe and that the health claims (what the product claims to do) are supported by textbooks and other references used in the practice of homeopathy (e.g., pharmacopoeia, Materia medica).

Health Canada has approved more than 8,500 homeopathic products. There is a database on the Health Canada website that lists these approved products."

"1.0 General information - Evidence for homeopathic medicines - Canada.ca

1.1 Definition of a homeopathic medicine

To be considered a homeopathic medicine, a product must meet two criteria. It must be:

1. *Manufactured from, or contain as medicinal ingredients, only substances referenced in a homeopathic monograph in one of the following homeopathic pharmacopoeias, as they are amended from time to time:*
    - *Homeopathic Pharmacopeia of the United States (HPUS)*
    - *Homöopathisches ArzneiBuch (HAB) or German Homeopathic Pharmacopoeia (GHP)*
    - *Pharmacopée française or French Pharmacopoeia (PhF)*
    - *European Pharmacopoeia (Ph.Eur.)*
    - *Encyclopedia of Homeopathic Pharmacopoeia (EHP)*
2. *Prepared in accordance with the methods outlined in one of the homeopathic pharmacopoeias listed above, as they are amended from time to time."*

Sources of homeopathic remedies are varied, and they can be made from any substance including animal, mineral, or plant. Potency and frequency remain the responsibility of the Registered Homeopath who follows the principles of homeopathic prescribing. Remedies have been imported into Ontario since 1859 when the Ontario legislature first recognized the profession. Disrupting the importation of homeopathic remedies is unacceptable as it poses a significant threat to the health of patients seeking care from a regulated profession.

According to Health Canada, homeopathic remedies are considered raw materials. This applies to homeopathic remedies either manufactured within Canada or imported into Canada. DIN-HM numbers have been created by Health Canada for a considerable number of homeopathic remedies.

Natural Health Product (NHP) Compounding Policy (cite source)

II. Background

"Compounding is generally understood as a process whereby a health care practitioner mixes, or prepares health products (natural, medicinal, etc.) to an exact specification tailored to a patient's needs, and in a vehicle desired (cream, lotion, gel, drops, capsules, pellets, etc.).

Compounding is an activity performed by a health care practitioner in the context of a practitioner-patient relationship. It is an activity that generally falls under provincial or territorial jurisdiction. A site license is therefore not required to compound, and the compounded product does not require a product license to be sold. Responsibility for the safety, efficacy and quality of the compounded product is assumed by the health care practitioner."

It is not uncommon for Registered Homeopaths to import remedies and other raw materials from other parts of the world to compound, potentize and use in the treatment of patients. It is common for homeopaths to search for remedies outside of the *Pharmacopoeias* listed earlier in this letter since any substance could in fact be considered as a remedy provided it contains the healing attributes identified by the homeopath.

New remedies are constantly being discovered all over the world. Homeopaths need to import remedies without restriction to serve their patients' needs. Patients must not be put at risk just because these new remedies are not available locally. Remedies have been held at the border because of restrictions placed on importation and these actions can have tragic implications for patients in Ontario and elsewhere in Canada.

The importation of remedies follows College of Homeopaths guidelines, whereby homeopaths have a pre-existing relationship with a patient and provide informed consent for treatment.

"Importation or sale of material not manufactured, sold or represented for use as an NHP for compounding by health care practitioners does not trigger PL and SL requirements; instead, these materials are treated as raw materials." – Health Canada.

Natural Health Product Raw Material Policy - Canada.ca

3.0 Policy Statement - General notes about raw materials: Raw materials are not NHPs.

Under this policy, those products that are manufactured, sold or represented for use as NHPs are regulated as NHPs. Those products that are manufactured, sold or represented for use as foods are regulated as foods. Those products that are clearly neither foods nor finished NHPs are considered raw materials.

Importation or sale of material not manufactured, sold or represented for use as an NHP for compounding by health care practitioners does not trigger Product Licence and Site Licence requirements; instead, these materials are treated as raw materials.

Examples of the Regulation of Various Materials

#4 - Importation or sale of herb, tincture, medicating potency, medicated pellet or freeze-dried extract (e.g., of chamomile) for further processing by manufacturer (i.e., not manufactured, sold or represented for NHP use). Treated as Raw Materials

#6 - Importation or sale of herb, tincture, medicating potency, medicated pellet or freeze-dried extract (e.g., of chamomile) for compounding by health care practitioner (i.e., not manufactured, sold or represented for NHP use). Treated as Raw Materials

Schedule 2 (Subsection 1(1))

Excluded Natural Health Product Substances

1. *A substance set out in Schedule C to the Act*
2. *A substance set out in Schedule D to the Act, except for the following:*
   - ***a.*** *a drug that is prepared from any of the following micro-organisms, namely, an alga, a bacterium or a fungus; and any substance set out on Schedule D when it is prepared in accordance with the practices of homeopathic pharmacy"*

A medicating potency is often further diluted, compounded, potentized or applied to blank globules or used as an olfactory application. Remedies that are purchased from international pharmacies in the form of globules and liquid potencies can be compounded and given to a patient.

Homeopathy is a regulated health profession in Ontario. As such, professional homeopaths need to ensure that their patients receive their prescribed remedies within a reasonable time frame. Access to care is a key component of public protection. We have received several reports from homeopaths in Ontario who have had their parcels of remedies seized or significantly delayed because of examination by Health Canada/CBSA. One homeopath recently had to wait over 4 months to receive a package containing medicating potencies from Helios Pharmacy, London, U.K. This is unacceptable and poses a threat to public health.

The inquiry ID assigned to a case where two parcels from Helios pharmacy were recommended for refusal was 28098. The shipments in question were labeled: UQ947934305GB and UQ944165008GB. In addition, there are other reports that we have received from our professional members. This case was reviewed over a period of several months, and Health Canada deemed that the products (medicating potencies) met the definition of raw materials. The package was delivered to the Registered Homeopath in question, but this was more than 6 months after the time of purchase. This is unacceptable. Health Canada needs to establish clear guidelines such that our members do not face these obstacles any further.

Is Health Canada/CBSA aware that Homeopaths are regulated in Ontario? Are there any efforts to ensure that the remedies imported by our members are delivered in a timely manner, and not subjected to the same regulatory scrutiny as items which can legitimately be considered NHPs? Registered Homeopaths understand the laws concerning the importation of remedies for compounding and the need to establish a system whereby shipments for their clinical practice are not delayed or hindered.

In your letter you write:

> "Note that the presence of the statement 'for compounding by a practitioner' on the product label or invoice accompanying a shipment on its own is not sufficient to determine whether regulatory requirements surrounding licensing apply."

The College of Homeopaths of Ontario requests that clear guidelines be provided to international homeopathic pharmacies regarding customs labels or package inserts to avoid future problems. The member whose case was cited above was told by a representative at Health Canada that instructing

pharmacies to write “Raw materials for compounding by healthcare practitioner” on their customs forms would be sufficient to facilitate clear passage of the remedies to the homeopath. An audio recording of this conversation exists if further proof is required. This is an urgent matter, and we need clarity on this issue. If this issue is not resolved in a timely manner, it poses a serious threat to the health of our patients and violates the legal right of our members to import remedies for compounding purposes.

In general, homeopaths purchase remedies from manufacturers and distributors of homeopathic remedies. Should the impact of Bill C47 be felt by the suppliers of homeopathic remedies, this would undoubtedly impact homeopaths’ ability to treat patients. The costs of manufacturing, distribution, and importation of homeopathic remedies will be adversely affected because of increased expenses, including site licensing and product licenses (DIN-H), together with the threat of harsh penalties.

Changing rules for NHPs will negatively impact patients let down by changes that prevent them from having access to needed health care services. Should these changes be implemented, they may limit the ability of homeopaths to provide care for those who require it, particularly if acquisition of remedies from outside Canada is hindered by the absence of clear and timely rules.

Patient protection depends on having in place a reliable system that ensures homeopaths can access needed remedies in a timely manner. We ask that you consider this matter urgent and provide a means by which delays at the border can be avoided. If this involves labelling by the manufacturer, everyone involved in the importation process must be made aware of what is acceptable so that consistent rules can be recognized and applied.

Respectfully,

Basil Ziv, HOM
Registrar and CEO

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

Allison Henry, Director, Health Workforce Regulatory Oversight Branch, Ontario Ministry of Health

Response from Health Canada

Dear Basil Ziv,

Further to the previous correspondence, we have been in active discussions with our partners in the Regulatory Operations and Enforcement Branch regarding the challenges that some health care practitioners are encountering when importing substances/products for the purposes of compounding within their practice.

These challenges have also recently been raised by other stakeholders and we recognize the need to clarify Health Canada's Natural Health Product Compounding Policy and Natural Health Product Raw Material Policy. We intend to bring a common understanding among Government and external stakeholders that a substance imported by a health care practitioner, for compounding in the context of the practitioner-patient relationship, is considered to be a raw material and not a finished NHP subject to the licensing requirements of the *Natural Health Product Regulations*.

We are developing a plan to update these policies and intend to consult with implicated organizations, including the College of Homeopaths of Ontario, to gather input and ensure that all points of view and concerns have been taken into consideration. We will be organizing a meeting in the coming weeks to update stakeholders and seek feedback.

We look forward to discussing this issue with you at the meeting.

Sincerely,

Stephen Norman

Director General

Natural and Non-Prescription Health Products Directorate