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Consultation regarding Importation of Homoepathic Remedies

Dear Mr. Norman,

Thank you for providing us with this opportunity to dialogue and to explain about the principles of Homeopathy and how they relate to the definition of "Raw Materials". It is even more important for us to explain the importance of getting these remedies to the homeopaths and their patients and the difficulties that can arise when patients do not receive their medicines timeously.

Homeopathic remedies in whatever form (globules, medicating potencies, liquid potencies, etc.) must be understood to meet the definition of "raw material" as set out by Health Canada. Additionally, every form of homeopathic remedy preparation can be used for compounding purposes as per the guidelines provided by Health Canada: https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription/legislation-guidelines/policies/compounding-policy.html

As such, it is imperative that the authorization standards and importation rules and guidelines established by the NNHPD, the CBSA and Health Canada remain in alignment with this fact and are implemented accordingly.

In what follows we will discuss why homeopathic remedies that are purchased from international pharmacies for use in a clinical context (practitioner - patient relationship), as well as for individual use, must be recognized as raw materials, as per the definition established by Health Canada. The international manufacturing pharmacies themselves also support the understanding that homeopathic remedies are raw materials. This is in accordance with global homeopathic standards.

Understanding "Raw Material" in context means processed, manufactured or otherwise, into a finished product that does not differ materially from the original. These raw materials typically retain their natural, unrefined, or minimally altered or changed state, and are used as the starting point for further compounding resulting in a more dilute and materially the same substance.

Homeopathic medicines are compounded from original raw materials (substances) which can include plant or animal extracts, minerals, or any homeopathic stock solutions (the original tinctures or

potencies), which can subsequently be made into remedies as individually prescribed for patients. The raw material is not a finished product meant for direct retail, but rather as a foundational component that must be tailored by the homeopath for their patients and must potentially be available for further compounding, or dispensed by a homeopath according to the individualized requirements, defined by the totality of symptoms, reflected by each patient based on the principles of Similia Similibus Curentur. Simply put, "Like cures Like". This is the foundational principle of homeopathy. If a substance can cause a set of symptoms in a healthy person, then a very small amount of that same substance (sequentially agitated and diluted) can be used to **treat** those same symptoms in a sick person.

The abovementioned aphorism posits that a substance capable of evoking symptoms in a healthy person, can, when administered in minute amounts, treat a person who is unwell and whose health profile reflects a similar set of symptoms.

This tenet guides remedy selection facilitated by the recorded observation of a person's response to the remedy in a proving or previous cases recorded in Materia Medica, and which supports its natural tendency toward healing. In essence the remedy selected acts as a catalyst to provoke the body's natural healing potential i.e. the immune system or the vital energy, towards a healing response.

Remedies are prescribed based on the patient's totality of symptoms which include the individual's characteristic physical and mental-emotional symptoms revealed through the personal health history; there is no one-size-fits-all approach.

Another central tenet is the use of potentization—a process of serial dilution and vigorous shaking (succussion) which, according to homeopathy theory, releases the remedy's therapeutic properties absent of toxicity. Each process of dilution and succussion is compounding.

Homeopaths also emphasize the minimum dose principle, believing that the smallest possible dose, when properly selected, stimulates the body's vital force without causing adverse effects. Finally, the holistic philosophy of homeopathy considers the whole person, not just the disease, seeking to restore overall balance and well-being.

A raw material in the homeopathic context needs to be differentiated from all other branches of medicine. Homeopathic medicines are ultra-high, agitated dilutions of raw materials. At the 12C dilution, Avogadro's number is exceeded and there are no longer molecules of the raw material observable within the solution, and as such, there are no active ingredients within the solution. Rather, there appears to be a mechanism whereby the molecular information from the original raw material in solution is retained in proportion to the level of dilution and degree of agitation.

When a homeopathic remedy is grafted, it is simply copied or replicated. A single remedy may be grafted without changing its qualities.

It is imperative that homeopaths be allowed to import remedies for their patients without having to compound them, as it is understood that a homeopathic remedy is always already a raw material. Every remedy in-potency, no matter the medium, in which it is prepared (I.e. liquid, pellet, medicating potency, etc.) is a raw material. Even so, when homeopaths import products for re-sale, this is not for

the general public but specifically for the patient in question. Registered Homeopaths do not sell remedies to the public, nor do they market remedies for any specific purpose whatever. The homeopathic remedies that are being imported into Canada are purely for use in the context of the practitioner-patient relationship.

There is no quantitative or qualitative difference when it comes to grafting by a homeopath. Grafting is the transfer of the idiosyncratic properties of the original remedy by means of using alcohol as a solvent to facilitate the transfer from the original to the duplicate resulting in the production of an exact copy of the remedy. The grafted remedy is intrinsically the same as the original remedy purchased from the pharmacy which in its original form may also be given directly to their patient. The medicine remains the same, both are raw materials.

Registered Homeopaths do not engage in the sale of products directly to the public, i.e. in cases where the public decides independently of the homeopath which items they wish to purchase. The homeopath's remedy selection for a patient is highly individualized, meaning that it is based on the totality of symptoms as determined by the homeopath and which fits each individual patient. For example, 10 patients, each of whom have as their chief complaint "headache", each could receive different remedy prescriptions. Some patients could have their headache on the vertex, others on the temples, and yet others in the occipital area, and in addition, the sensations and intensity of the headache can vary in each case, as well as the time frames as to when the pain may be experienced. In summary, homeopathic prescribing works on the basis of individualization and patient totality of symptoms. In addition to all of this, the potency and frequency of administration is also individualized and based on the homeopaths assessment of the patient's need.

It is entirely possible that a homeopath may purchase a remedy for an individual patient and may never need to use the remedy in question again for any other patient, because of the high degree of individualization that is required for accuracy in prescribing. As such, it must be understood that homeopathic remedies do not have predetermined usages and do not come with instructions for their administration. These factors are all variable depending on each case before the homeopath.

Many international pharmacies have thousands of remedies available, and many more are created every year to meet the demands of the advancement in homeopathic prescribing. The majority of these new remedies are simply not available in Canada because the Canadian market is small compared to these bigger populations. In addition, homeopaths are under pressure to serve their patients in a timely manner. Many of our patients rely exclusively on homeopathic treatment, and as such, access and availability of remedies is a public health issue. There have been cases where patients have suffered because of delays attributed to remedies being held up at the Canadian border.

Homeopaths prescribe single remedies (simples). Complex or combination remedies (containing two or more substances) are not commonly used in classical homeopathic prescribing. The homeopathic remedies that are being imported from international pharmacies by registered homeopaths are in the vast majority single remedies. They are not labelled with having pre-determined uses, and the labels have no claims about how they are to be used. For example, labels from Helios Pharmacy may only contain the remedy name, potency, best before date, and pharmacy contact information. The

international homeopathic pharmacies clearly state on their customs labels that the package contains raw materials for use by a qualified practitioner or their patient.

Homeopathic remedies that are coming through the border have been **misinterpreted** as finished products by CBSA/Health Canada, and not as raw materials. However, we already know that Health Canada has determined that homeopathic remedies are raw material. It has been determined that any homeopathic remedy in any form can be used for the purpose of compounding. There is not a single homeopathic remedy preparation that cannot be used for compounding purposes.

If a homeopath has ordered a medicine (remedy) for a specific patient and then sells it to the patient to recover costs of importation, this is different from buying a product as a retail item (hence an item that may require an NHP).

Regulations and border operations often follow rigid policies and consequently can have unintended consequences on homeopathic practice. Working within the regulatory framework, there are many players involved. NNHPD may want to follow rules, but if there needs to be clarity of interpretation of the rules, this needs to be done fairly with due consideration since we are sometimes dealing matters of life and death, the patients' health, which can be critical. We need to ensure that homeopathic remedies will not be held at the border ever again. This is too big a risk for NNHPD to take. If there is ever any uncertainty, it should be obligatory to call the registered homeopath.

Homeopathic medicines are raw materials. Raw materials are the same, no matter how they are used. Homeopaths may be required to compound for the sake of the patient, but it is senseless to force them to compound just to satisfy a rule. This issue is not about homeopaths making a business out of selling remedies, but rather about homeopaths treating their patients within their scope of practice. There is a tremendous burden on healthcare workers throughout Canada, homeopaths should be encouraged to do their work and to relieve some of the pressure. This surely must be in the public interest.

A homeopathic remedy is not like a common manufactured product, I.e., where various manufactured parts are put together to make up the completed product. They are also not like herbal formulas, where various herbs are mixed together and the completed item is then marketed for certain specific health conditions. Single homeopathic remedies from international pharmacies are not marketed for a specific use. Homeopaths do not prescribe remedy X for condition Y. Homeopaths treat their patients as individuals, each with their unique totality of symptoms, which require the homeopath to select an appropriately matching remedy in the patient's treatment.

<u>Explanation of how homeopathic remedies are produced</u>.
Potentization is a process to reveal the healing or curative powers of substances.

Liquid substances are diluted 1 drop of mother tincture to 99 drops of alcohol and succussed 100 times. This produces 1C dilution is 1:100.
One drop of 1C is mixed with 99 drops of alcohol and succussed 100 times, this produces 2C, dilution is 1:10,000.
One drop of 2C is mixed with 99 drops of alcohol and succussed 100 times, this produces 3C, dilution is 1:1,000,000

At the dilution of 12C, Avogadro's number is exceeded, and this means that there are no longer any molecules of the original substance contained with the dilution. Beyond 12C the dynamic energy of the substance becomes the curative property of the substance. 30C, 200C, 1M, 10M, CM, and beyond are commonly used by homeopaths to treat their patients.

Solid substances are first triturated in a mortar and pestle with milk sugar. The substance is triturated to 3C and then diluted and succussed as described above.

There are a number of different potency scales used by homeopaths and these include the following: X, D, C, CH, LM (Diluted to 50,000)

Once the liquids have been potentized to the desired level of dilutions and successions, they can be used in liquid form, or they can be used to coat little sugar balls, which come in different sizes, and allowed to dry.

Some homeopaths further dilute the dry dose (globules) into water and alcohol and use these as a stock bottle from which to administer the remedy dosage.

The remedies work on the basis of the molecular imprint of the original raw material being retained in the solution of water and alcohol.

Remedies are ordered for patients. Homeopaths may import remedies and compound them, but it is important to remember that the purpose is to help patients.

Importation for personalized medicine/personal use. Patients are sometimes required to purchase medicines for themselves which have been prescribed by a registered homeopath. We have to ensure that patients are able to do this without their prescriptions being held at the border for an indefinite period of time. The timely delivery of homeopathic remedies is essential for successful treatment outcomes, and as such this is a public health matter.

There is no national body overseeing homeopathy. Homeopathy is a regulated healthcare profession only in Ontario. There are membership organizations in other provinces.

It has been understood that if an international company/pharmacy has form 7, this is the recognized quality control standard.

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