



## Naturopathy and Homeopathy Act Amendments Submission from the OAND

### Prescribing, Selling, Dispensing and Compounding

#### Summary of Need for Change:

- Access to this controlled act is necessary for naturopathic doctors (NDs) to be able to maintain their current scope and to preserve access to required natural substances while federal classification of these substances continues to undergo changes.
- The change in Schedule L of Bill 171 deeming that Natural Health Products (NHPs) are not considered drugs is insufficient because this only addresses that subset of natural substances (Natural Health Products) intended for “Over The Counter” self-care selection by consumers. There are many natural substances traditionally used in naturopathic medicine that do not fall within the definition or purview of the *Natural Health Products Regulations* (such as higher dosages of folic acid) or are presently listed in restricted schedules (i.e. Schedule F) or are combination products cross-listed as drugs.
- Compounding, as well as dispensing and selling, are necessary in order to continue to provide the individualized preparations that are integral to naturopathic care.
- Access to this controlled act was recommended by HPRAC and is currently part of the scope of practice of NDs in Ontario under the *Drugless Practitioners Act* (DPA).
- NDs are prepared to work with the Transition Council to develop a schedule of natural substances designated as drugs suitable for use by NDs.
- Without this controlled act, NDs and their patients will lose access to natural substances that are currently available, effectively limiting the ability of NDs to practice to their full scope and likely resulting in a loss of care for patients.

#### Proposed Wording:

4. (1) In the course of engaging in the practice of naturopathic medicine, a member is authorized, subject to the terms, conditions and limitations imposed on his or her certificate of registration, to perform the following:

Prescribing, dispensing, selling and/or compounding prescribed substances that are consistent with the practice of naturopathic medicine.

## **Rationale:**

NDs are trained to practice to their full scope, and have been safely and effectively working to full scope under the *Drugless Practitioners Act*. The regulator, the Board of Directors of Drugless Therapy-Naturopathy (BDDT-N), has stated that “it is crucial that the diagnostic, therapeutic and emergency substances requested by NDs be available for use in the care of their patients.”

HPRAC recommended that NDs be granted the controlled act of prescribing, dispensing, selling and/or compounding drugs based on the recognition that NDs need access to restricted or controlled natural health products. This includes botanical medicines and other NHPs that should only be used under the advice and supervision of a healthcare provider who is educated and trained in their use.

Providing individualized patient treatment is a core principle of naturopathic medicine, and prescribing, dispensing, selling and/or compounding natural substances have long been recognized as a part of the scope of practice of naturopathic doctors.

Being granted the right to prescribe is the trend in other healthcare professions in Canada, including professions who have less training than NDs. NDs in most other regulated jurisdictions, with similar education, training and licensing requirements, continue to safely use substances which would become unavailable to Ontario NDs and their clients.

Changes in the federal *Food and Drugs Act* to regulate natural substances will make many of these substances unavailable to the patients of NDs unless NDs have the ability to prescribe, dispense, sell and compound these substances. Bill 50 and now Bill 171 have attempted to address this by establishing that natural health products are deemed to not be drugs for the purposes of provincial legislation, but this only addresses a subset of natural substances used by NDs, specifically those natural substances intended for “Over The Counter” self-care selection by consumers. It does not address natural substances that should only be used in naturopathic treatment or administered by NDs, and it does not address natural substances that are cross-listed as scheduled drugs but are traditionally used in the practice of naturopathic medicine. Without prescribing, many natural substances will not be available to the patients of NDs.

Ensuring continuing access to natural substances is particularly important for maintaining the ability to provide parenteral therapy. These are patients with some of the greatest health challenges, including cardiovascular disease, chronic fatigue, autism, HIV, and cancer, where naturopathic medicine’s unique approach to care is an essential complement to the care available from medical doctors. Losing the ability to prescribe, dispense, sell or compound natural substances that become restricted would mean that a significant number of very ill patients will lose access to safe and effective naturopathic therapies that are available to them in other regulated jurisdictions.

A more detailed discussion of the impact of the federal regulation of natural substances and the need for prescribing is in the appendix to this document.

In addition to prescribing, NDs also require the ability to compound, dispense and sell natural substances that are consistent with naturopathic practice. Compounding is the preparation of a unique formula, delivery method or concentration for an individual patient. Compounding is recognized by Health Canada as forming part of the practice of a number of healthcare practitioners including but not limited to Naturopathic Doctors, Doctors of Traditional Chinese Medicine, Herbalists and Homeopaths.

Many of the products used by naturopathic doctors are not available on the open market due to dosage, formula or route of administration.

Compounding natural substances is currently part of the scope of NDs under the DPA, and an integral part of the training and practice of NDs. Where compounding is done by pharmacists, they may not be able to continue compounding on behalf of NDs unless NDs are granted this controlled act.

Dispensing is required because many natural substances are not widely available commercially, particularly in smaller communities, or not intended for commercial sale.

A number of other professions combine prescribing and dispensing, including opticians and dentists. More effective regulation under the RHPA will allow potential conflict-of-interest to be addressed, as with other professions.

## Appendix

### **Background on the Federal Regulation of Natural Health Products**

A natural health product is defined as a substance, or combination of substances, described in Schedule 1 of the *Natural Health Product Regulations*, a homeopathic medicine or a traditional medicine, that is intended to provide a pharmacological activity or other direct effect in:

- Diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physiological state or its symptoms in humans;
- Restoring or correcting organic functions in humans; or
- Modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

Natural Health Products (NHPs) must be safe for consideration as over-the-counter products, be available for self-care and self-selection and not require a prescription to be sold. Products requiring a prescription will continue to be regulated under the *Food and Drug Regulations*.

Accordingly, products with ingredients required to be sold pursuant to a prescription (i.e. listed in Schedule F to the *Food and Drug Regulations*) are not NHPs, except for homeopathic medicines.

Section 7(d) of the *Natural Health Products Regulations* states that Health Canada will not approve products that may injure the health of consumers. In developing the Regulations, Health Canada's intent was to cover products that consumers can select and use themselves without the need to consult a healthcare practitioner and obtain a prescription.

### **Impact of the NHP Regulations on the Practice of Naturopathic Medicine**

The Regulations provide self-care products for **consumers** that are safe, effective and of high quality, and have resulted in the return to the marketplace of some natural products. However, exclusion of many natural substances (Schedule 2), restrictions placed on route of administration, dosage, potency, and concerns of risk to consumers in self-care have resulted in the withdrawal and/or restricted scheduling of products historically used safely and effectively by naturopathic doctors.

For example, although Schedule 1 of the Regulations stipulates that an amino acid is included as a NHP, L-Carnitine, a single amino acid used by naturopathic doctors, remains on Schedule F requiring a prescription. Without the ability to prescribe, naturopathic doctors are unable to access a substance they have the training and education to administer thereby impeding their ability to effectively treat patients. This is but one example as there are a number of natural substances utilized by naturopathic doctors that currently appear on restricted access schedules such as Schedule C, D, F, to the *Food and Drug Regulations* and Schedules I to V of the *Controlled Drugs and Substances Act*.

As the NHPD continues to assess and license NHPs and as more products are found to be unacceptable for self-care, more of the substances currently utilized by naturopathic doctors and consistent with naturopathic practice will be transferred to restricted schedules. These include botanicals, nutritional substances, homeopathic medicines and natural substances like bio identical hormones. It is therefore imperative that naturopathic doctors be granted the right to prescribe.

### **Examples of Impact on Patient Access to Care**

- After doing a series of diagnostic tests (blood work, nutrient profile, genetics, etc.) an ND can currently develop a customized Amino acid/Vitamin/Mineral powder for a patient. The customized formula is based on the results of the aforementioned tests.

Part of the formula could include:

Niacin - 2500mg  
Arginine - 1500mg  
5HTP - 300mg  
Folic Acid - 10mg  
B-complex compound of 50mg and a trace mineral complex.

Prescription sent to manufacturer to compound the customized product for the patient or compounded by ND.

This naturopathic care would not be possible in the absence of prescribing because the dosage exceeds the level of an NHP intended for direct sale to consumers, and pharmacies would not be able to accept a prescription from an ND.

- A patient may require a custom remedy compounded ingredient-by-ingredient in order to avoid retriggering an allergic response, such as may be the case due to elevated sensitivity after poisoning with solvents.
- A patient may require daily changes to their remedies as may be the case with an acute gallbladder incident as the situation ameliorates.
- A patient whose condition is best diagnosed in the TCM tradition may need a range of TCM remedies, modified as the patient comes into balance, and may need a personalized constitutional TCM remedy.
- A patient with chronic allergic and infectious sinusitis may need a range of specific remedies combining lymphatic and sinus drainage actions, anti-infectious agents, and immune balancing and antihistaminic preparations.