

Regulatory Guidance

Prescription and Non-prescription Drugs and Substances Information

Naturopathic doctors in Ontario can recommend supplements and natural remedies for patients as well as prescribe specific drugs once they have met the standard of practice for prescribing. Confusion can sometimes arise when trying to determine if a drug or substance requires a prescription, if it is a natural health product and if it is available in Canada. For example, some drugs can only be acquired through a prescription from an authorized regulated health professional. Others can be acquired without a prescription but must be dispensed by a pharmacist. Still, other drugs are available for self-selection as are supplements and remedies; however, the same drug or supplement may need a prescription depending on the dosage and/or route of administration.

The following resources can help registrants find the drug and substance related information they are looking for. Please see the bottom of the page for links to all referenced documents and websites.

Prescription Drug List (PDL) and Schedules of the *Controlled Drugs and Substances Act, 1996* (CDSA)

The Prescription Drug List (PDL) has been established by Health Canada under the Food and Drugs Act (Canada). The PDL "is a list of medicinal ingredients that when found in a drug, require a prescription. It does not include medicinal ingredients that when found in a drug, require a prescription if those ingredients are listing in Controlled Drugs and Substances Act Schedules"¹. In addition to listing the medicinal ingredient, the PDL will also set out any inclusions as well as any qualifiers.

Naturopathic Doctors in Ontario are permitted to prescribe some drugs that include medicinal ingredients listed on the PDL. These drugs are designated in the *General Regulation* made under the *Naturopathy Act, 2007*, and are listed on the tables in the Regulation.

In order to be permitted to prescribe, dispense, compound or sell a drug, or administer a substance by injection or inhalation, an ND in Ontario must first have met the standard of practice for prescribing by successfully completing the Canadian Prescribing and Therapeutics course and the Ontario Prescribing and Therapeutics examination

¹ The Prescription Drug List, Health Canada, Drugs and Health Products. 2023-10-27

The *Controlled Drugs and Substances Act, 1996 (CDSA)* and its schedules, set out medicinal ingredients contained in drugs whose use (prescription and distribution) is controlled. Where a medicinal ingredient on the schedules is permitted for use, it establishes a distinct list of regulated health professionals who may issue a prescription for the drug containing that medicinal ingredient. Naturopathic Doctors are not included under the CSDA as health professionals who can prescribe a drug that contains a medicinal ingredient on the CSDA Schedules.

National Association of Pharmacy Regulatory Authorities (NAPRA)

The National Association of Pharmacy Regulatory Authorities (NAPRA) includes as its members all pharmacy regulators across Canada to facilitate collaboration and take a national approach to common issues in pharmacy. Among its many roles, NAPRA creates and maintains the National Drug Schedules which address how drugs are to be accessed and distributed. There are four schedules developed by NAPRA:

- Schedule I: drugs that require a prescription from an authorized prescriber and that may only be distributed (sold, dispensed) by an authorized person.
- Schedule II: drugs that are available without a prescription but must be distributed under the supervision of an authorized person. These are drugs that are located in the area of the pharmacy "behind the counter", where there is no public access and no opportunity for patient self-selection.
- Schedule III: drugs that do not require a prescription nor the intervention of an authorized person for them to be distributed and sold. These are drugs that are available for self-selection from the area of the pharmacy under the direct supervision of the pharmacist, i.e., directly in front of the pharmacy.
- Schedule U: drugs that are unscheduled and that may therefore be purchased from any retail outlet, such as a grocery store.

When searching the NAPRA database and other resources, be aware of the medicinal, generic and brand names that can be used for a drug. For example, a search on the NAPRA database for Tylenol produces no results, while a search for acetaminophen produces six listings for the drug.

The NAPRA National Drug Schedules are of high importance because every province and territory in Canada incorporates these schedules into their provincial drug regulatory regime. For example, in Ontario, the *Drugs and Pharmacies Regulation Act* incorporates the NAPRA schedules into law meaning that any drug that requires a prescription according to NAPRA requires a prescription in Ontario. Similarly, the *Drugs and Pharmacies Regulation Act* also incorporates the *Controlled Drugs and Substances Act (Canada)* schedules into the drug regulatory regime in Ontario.

An ND in Ontario may incorporate into their practice any drug that is listed on Schedules II, III and U of the NAPRA Schedules; however, with respect to Schedule I drugs, an ND may only prescribe, dispense, compound or sell those Schedule I drugs that appear on the tables to the *General Regulation* made under the *Naturopathy Act*, 2007.

Compendium of Pharmaceuticals and Specialties

Table 3 of the *General Regulation* lists the drugs or "medicinal ingredients" exactly as they are listed on the PDL. To find additional names that can be used for drugs, the Compendium of Pharmaceuticals and Specialties (CPS) is a valuable resource. The CPS can be used to identify the generic and brand names of a drug in addition to the medicinal name used in the PDL and Table 3.

The CPS can be accessed through the Canadian Pharmacists Association.

Health Canada Drug Product Database

It is important to determine whether or not the drug has been approved for use in Canada. The Health Canada Drug Product Database is an up-to-date list of all such human pharmaceuticals and biological drugs.

Licensed Natural Health Product (LNHP) Database

The Natural and Non-prescription Health Products Directorate of Health Canada maintains the Licensed Natural Health Product Database. This database contains information about natural health products that have been issued a product license by Health Canada. These products have been assessed and found to be safe, effective and of high quality under their recommended conditions of use.

The majority of substances found in the LNHP Database do not need a prescription to distribution and sale by a regulated health professional. However, there are exceptions when a natural health product becomes a "drug" set out in the Prescription Drug List (including NAPRA Schedule I and Schedule I under the *Drugs and Pharmacies Regulation Act*).

Several of the natural health products typically used by NDs will meet these exceptions. For example:

Medicinal Ingredient	It is an NHP	It is a Drug	Notes
Vitamin A	10,000 IU or less	10,001 IU or more	Dosages above 10,000 IU require a prescription
Vitamin D	2,500 IU or less	2,501 or more	Dosages above 2,500 IU require a prescription
Vitamin K	When sold for external use in humans or oral dosage in humans of 0.120 milligrams or less	When sold for internal use (injection) or oral use in humans of 0.121 milligrams or more.	Prescription is required when sold for intramuscular injection or in oral dosage for humans of more than 0.120 milligrams.
Folic acid	1.0 milligrams per day or less.	1.1 milligrams per day or more	Dosage above 1.0 milligrams per day requires a prescription.

How would an ND or Patient Know?

Fortunately, the *General Regulation* made under the *Naturopathy Act, 2007* includes tables setting the substances that may be administered by injection (including IVIT) or inhalation, as well as the drugs that may be prescribed, dispensed, compounded or sold. Before recommending a natural health product, an ND should reference these tables to ensure the product is not listed as a drug at a specific dosage.

Ultimately, it is each registrant's responsibility to determine whether they have the legal authority to access a given drug or substance in Canada. Therefore, it is important to use all available resources to make a thorough search for drug and natural health product-related information.

Additional resources:

Prescription Drug List (PDL)

Controlled Drugs and Substances Act (CDSA)

National Association of Pharmacy Regulatory Authorities (NAPRA)

Compendium of Pharmaceuticals and Specialties

Health Canada Drug Product Database

Licensed Natural Health Product (LNHP) Database

Natural Health Products Ingredients Database