Prescribing Drugs, Natural Health Products and Medical Devices

DEFINITIONS

"Medical Device" as per the federal *Medical Device Regulations,* and *Food and Drugs Act*, medical device is any instrument or component used to treat, diagnose or prevent a disease or abnormal physical condition. Medical devices do not include those used for animals or for veterinary purposes.

Note: Also referred to as a "device" in *The Pharmacy and Pharmacy Disciplines Act* (PPDA) and SCPP Regulatory Bylaws. Identified through a device name or other identifier listed in the Health Canada's Medical Devices Active Licence Listing. If the item does not appear on Health Canada's list of devices, see text box below "Scope of Practice: Prescribing Health Care Aids."

"Drug" as per *The Pharmacy and Pharmacy Disciplines Act* means a substance or combination of substances included in Schedule I, II or III of *The Drug Schedules Regulations, 1997* and for the purposes of Part K, also includes the "Unscheduled" category of NAPRA's National Drug Schedules. Identified through a Drug Identification Number (DIN) on the product label.

"Natural Health Product" as per the *Natural Health Products Regulations* means a substance set out in Schedule I of the *NHP Regulations*, a homeopathic medicine, or a traditional medicine that is sold for the uses described in the *NHP Regulations*. Includes vitamins, minerals, probiotics. Identified through a Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM) on the product label.

ACRONYMS

DIN – Drug Identification Number
DIN-HM – Homeopathic Medicine Number
NHP – Natural Health Product
NPN – Natural Product Number

1. PURPOSE

Drugs, natural health products and medical devices are all regulated differently. This document outlines **pharmacist's** authority to prescribe drugs, natural health products and medical devices and applicable requirements.

Documentation in the Pharmaceutical Information Program (PIP)

For information on PIP data entry requirements see the Pharmaceutical Information Program (PIP) FAQs and text box "Documentation in PIP as Required in *The Prescriptions Drugs Act"* in General Provisions for Prescribing Authority.

Public and Private Coverage Program Benefits:

Drug, NHP or medical device coverage benefits are determined by the patient's private or public coverage program. Pharmacists should work with patients to confirm:

- their individual eligibility for coverage;
- whether the program recognizes pharmacists as prescribers for the purposes of coverage; and
- the program's billing process.

2. PHARMACIST PRESCRIBING DRUGS

Scope of Practice: Prescribing Drugs

Drugs are regulated federally under the *Controlled Drugs and Substances Act* and its Regulations, the *Food and Drugs Act* and the *Food and Drug Regulations*.

Drugs are also regulated provincially under *The Pharmacy and Pharmacy Disciplines Act* and *Drug Schedules Regulations, 1997*.

A pharmacist is authorized to prescribe drugs as per s. 23(3)(a) of *The Pharmacy and Pharmacy Disciplines Act:*

> ***23*** *(3) A licensed pharmacist who meets the qualifications set out in this Act and the bylaws, may, subject to the terms, conditions and restrictions on that licensed pharmacist's licence, perform all or any of the following practices:*
>
> *(a)* ***prescribe*** *and administer* ***drugs*** *in accordance with the bylaws … and the regulations …..;*

See section 9.1 of *The Drug Schedules Regulations, 1997* and The SCPP Regulatory Bylaws (Part K – Prescribing Drugs).

Note: Part K of the SCPP Bylaws are specific to prescribing drugs and are not applicable to NHPs as they are not classified as drugs. See section 3 for prescribing NHPs.

2.1. All SCPP bylaws, policies, guidance and standards pertaining to prescribing drugs must be taken together as whole. See General Provisions for Prescribing Authority, Level I Prescribing Authority documents (Practitioner-initiated; Pharmacist-initiated; and Structured), and Level II Prescribing Authority documents in the SCPP Reference Manual.

Note: The scheduling of drugs in Saskatchewan is largely based on the NAPRA National Drug Schedules with exceptions as noted in the SCPP Administrative and Regulatory bylaws. See the following for a complete explanation of Saskatchewan drug scheduling:

- SCPP Administrative Bylaws for Drug Schedule I and Drug Schedule II.

- SCPP Regulatory Bylaws for Drug Schedule III.
- NAPRA's National Drug Schedules for Unscheduled drugs.
- Disease Prevention and Travel Health Services Framework for information on vaccine scheduling.

3. PHARMACIST PRESCRIBING NATURAL HEALTH PRODUCTS

Scope of Practice: Prescribing Natural Health Products

NHPs are products which are used and marketed for a variety of health purposes, such as for the prevention or treatment of an ailment or condition, the reduction of health risks, or the maintenance of good health.

All NHPs are regulated under the *Natural Health Product Regulations*, which is a separate and distinct regulatory framework from prescription drugs. See Health Canada's website for more information.

Although NHPs do not require a prescription for sale to the public, a pharmacist is authorized to prescribe NHPs as per s. 23(3)(b) of *The Pharmacy and Pharmacy Disciplines Act*:

> ***23*** *(3) A licensed pharmacist who meets the qualifications set out in this Act and the bylaws, may, subject to the terms, conditions and restrictions on that licensed pharmacist's licence, perform all or any of the following practices:*
>
> > *(b)* ***prescribe treatments*** *and health care aids and devices* ***related to the practice of pharmacy in Saskatchewan****;*

Bylaws have not been created for the prescribing of NHPs, therefore, it is the SCPP/NAPRA Standards of Practice that apply.

Also see:

- Health Canada's Information Kit – Regulation of NHPs
- Health Canada's "About Natural Health Products"
- Health Canada's Licensed Natural Health Products Database to search for licensed NHPs

3.1. In keeping with the SCPP/NAPRA Standards of Practice approved by Council, including sections 1.1.8, 1.2.4b, 1.3.14b, 2.2.1, when a pharmacist prescribes a treatment with a NHP, they:

3.1.1. must follow reputable clinical tools (e.g. NATMED PRO or "Minor Ailments - Nutritional Supplements" in the Canadian Compendium of Pharmaceutical Specialties);

3.1.2. may refer to the SCPP/NAPRA Supplemental Standards of Practice for Schedule II and III Drugs for additional guidance if needed.

4. PHARMACIST PRESCRIBING DEVICES

Scope of Practice: Prescribing Medical Devices

Medical devices are regulated by Health Canada under the authority of *Food and Drugs Act*, and *Medical Devices Regulations*. See Health Canada's website for more information.

Although medical devices do not require a prescription for sale to the public (i.e. sale to an end-user for their own personal use), a pharmacist is authorized to prescribe devices as per s. 23(3)(b) of *The Pharmacy and Pharmacy Disciplines Act*:

> ***23*** *(3) A licensed pharmacist who meets the qualifications set out in this Act and the bylaws, may, subject to the terms, conditions and restrictions on that licensed pharmacist's licence, perform all or any of the following practices:*
>
> *(b)* ***prescribe*** *treatments and health care aids and* ***devices related to the practice of pharmacy in Saskatchewan****;*

The SCPP Regulatory Bylaws Part M further states:

> ***2*** *A licensed pharmacist may:*
>
> *(e) prescribe treatments and devices approved by Council, which are related to the practice of pharmacy in Saskatchewan.*

4.1. When prescribing medical devices, pharmacists must follow the terms, conditions and standards established by Council. See Laboratory Tests and Medical Devices (Accessing, Ordering, Performing, Using or Interpreting).

See Health Canada "What are Medical Devices" for more information.

Also see Health Canada's Medical Devices Active Licence Listing to search for licensed medical devices.

Scope of Practice: Prescribing Health Care Aids

Under section 23(3)(b) of the PPDA, pharmacists are also authorized to prescribe health care aids.

The SCPP considers health care aids as those items that are not drugs, NHPs, nor devices that appear on Health Canada's Medical Devices Active Licence Listing (e.g. incontinence underwear). Health care aids do not have DINs, NPNs, DIN-HMs or device identifiers in Health Canada's database. Many health care aids may be purchased over-the-counter by the public without a prescription, and may be covered by private or public coverage programs.

Bylaws have not been created for the prescribing of health care aids, therefore it is the SCPP/NAPRA Standards of Practice that apply, (e.g. see sections 1.1.8, 1.2.4b, 1.3.14b for guidance when needed).