

Understanding Alberta's Drug Schedules

Preface

In May 2002, the provincial drug schedules to the *Pharmaceutical Profession Act* were amended. In April 2007, the Alberta Regulation 66/2007 to the *Pharmacy and Drug Act*, the Scheduled Drugs Regulation, came into force and are amended as necessary with the most recent changes being November 2017. The Alberta provincial schedules are now mostly aligned with the national drug scheduling model developed by the National Association of Pharmacy Regulatory Authorities (NAPRA). Future changes to the schedules will be made by reference to the national model, in accordance with the recommendations of the National Drug Scheduling Advisory Committee (NDSAC).

Drugs which are on the Prescription Drug List to the federal Food and Drug Regulations and in the schedules to the *Controlled Drugs and Substances Act* are included in Schedule 1 of the Scheduled Drugs Regulation.

This guide has been prepared to

- provide pharmacists and pharmacy technicians with information on the drug schedule harmonization process in Canada,
- describe Alberta's drug schedules,
- provide a reference to help pharmacists and pharmacy technicians understand the schedules, and
- describe the standards of practice that apply to Schedules 2 and 3.¹

¹ The standards of practice which apply to the non-prescription drug schedules are the *Health Professions Act* and the Standards of Practice for Pharmacists and Pharmacy Technicians, Standards 3, 4, 8, 9, and 18. These standards are included as Appendix A of this guide, and can be found on the ACP website at abpharmacy.ca/standards-practice.

Alberta's drug schedules - their origin and maintenance

Drug Schedule Harmonization Process²

Alberta's drug schedules are consistent with the national scheduling model described in the May 1995 report from the Canadian Drug Advisory Committee (CDAC), which was approved by the National Association of Pharmacy Regulatory Authorities (NAPRA) in the same year. Included in the CDAC's report was a list of drugs recommended for each schedule. To ensure ongoing review and maintenance of the drugs listed in the model schedules, NAPRA established the National Drug Scheduling Advisory Committee (NDSAC) in August 1995. NDSAC includes drug experts from across Canada as well as a consumer and a physician. NDSAC's mandate is to advise the provincial pharmacy regulatory authorities on matters relating to the placement of drugs within the national scheduling model and to continually evaluate and maintain the drug scheduling factors within the model.

The CDAC model that NDSAC uses for making drug scheduling recommendations embodies a "cascading principle" in which a drug is first assessed using the factors for Schedule 1. Should sufficient factors pertain, the drug remains in that schedule. If not, the drug is assessed against the factors for Schedule 2, and if warranted it is subsequently assessed against the factors for Schedule 3. Should the drug not meet the factors of any schedule, it becomes unscheduled or non-restricted and available for sale from any retail outlet. This process promotes the listing of drugs in schedules corresponding to the conditions of sale, providing for proper drug use and patient safety.

As a result of applying the cascading principle, four categories of drugs resulted:

- **Schedule 1:** Drugs that require a prescription as a condition of sale.
- **Schedule 2:** Drugs that are available only from the pharmacist and without a prescription. There is no opportunity for patient self-selection.
- **Schedule 3:** Drugs that are available without a prescription from the self-selection area of a pharmacy.
- **Unscheduled:** Drugs not listed in Schedule 1, 2 or 3 that may be sold from any retail outlet.

The CDAC report states that the outcome of drug scheduling should serve the patient in the best and most sensible and reasonable manner possible in light of knowledge and practice. Scheduling factors were developed to reflect an assessment of drug use risk to the public and to establish the level of professional control required to provide safe and effective drug use for patients.

However, patients have the ultimate responsibility for their health, and they should have access to self-selected drugs for self-medication or access to the selection of non-prescription drugs, with the assistance of a pharmacist. The safety and effectiveness of non-prescription drugs depends on their appropriate use to treat minor ailments. Consultation must be appropriate in level, scope and

² Allen BE, Suveges LG. *Standards of Practice - Non-prescription Drugs*. A report to the National Association of Pharmacy Regulatory Authorities; endorsed October 1995.

content to the needs of those seeking assistance.

Because drug scheduling using the cascading principle is based on factors of relative risk associated with taking medications with or without the advice of a health care professional, the standards of practice also reflect this concept. The standards of practice for Schedule 2 drugs include activities that must be undertaken by the pharmacist interacting with a patient desiring to self-medicate with one of these products. As patients may self-select Schedule 3 drugs, it is essential for pharmacists to be available for consultation. Patients should be encouraged to seek consultation on any concerns regarding the safety and/or effectiveness of either Schedule 2 or Schedule 3 drugs. Although the required activities may vary for Schedule 2 and 3 drugs, the consultation process on all non-prescription drugs is very similar.

The Alberta College of Pharmacy will follow NDSAC's recommendations to maintain its provincial drug schedules.

For more information about NDSAC recommendations, please refer to the NAPRA website at www.napra.ca.

Federal and Provincial Regulations

Drugs in Canada are both federally and provincially regulated.

Federal Regulations

Federally scheduled drugs include

- **narcotics** in the Schedule to the Narcotic Control Regulations;
- **controlled substances** in Part I, II, and III of the Schedule to Part G of the Food and Drug Regulations;
- **benzodiazepines and other targeted substances** in the Schedule to the Benzodiazepines and Other Targeted Substances Regulations; and
- drugs on the Prescription Drug List to the Food and Drug Regulations.

The Prescription Drug List of the Food and Drug Regulations is divided into two separate lists:

1. A list of medicinal ingredients that, when found in a drug, require a prescription for **human use**
2. A list of medicinal ingredients that, when found in a drug, require a prescription for **veterinary use**

If a veterinary drug product is not on the "veterinary use" section of the List, it is considered a non-prescription drug for veterinary use.

Provincial Regulations

Since January 1, 1995, Alberta has had three provincial drug schedules.

Schedule 1

The drugs included in Schedule 1 require a prescription as a condition of sale, and in a pharmacy must be stored and sold only in the dispensary. Drugs in this schedule include all federally scheduled drugs and certain others, some of which are specific to Alberta. The latter may appear to be non-prescription drugs (as there will be no symbol directly on the drug product label). Pharmacists must be aware of these products to prevent possible sale without a prescription.

Drugs listed in Schedule 1 of the Scheduled Drugs Regulation are subject to all the same considerations as drugs on the Prescription Drug List to the Food and Drug Regulations (Canada).

The standards of practice that apply to drugs in this schedule are the same standards that apply to all prescription medications.

Schedule 2

The drugs listed in Schedule 2 do not require a prescription as a condition of sale. These drugs may be sold **only** from a licensed pharmacy or an institution pharmacy by a pharmacist, or under the direct supervision of a pharmacist. Schedule 2 drugs must be stored and sold only in the dispensary. Standards of practice for assessment of therapy (Standard 3 and 4)³, patient **counselling** (Standard 8) and **documentation** (Standard 18) apply to Schedule 2 drugs.

Schedule 3

The drugs listed in Schedule 3 do not require a prescription as a condition of sale. These drugs may be sold **only** from a licensed pharmacy or an institution pharmacy. Schedule 3 drugs must be stored and sold only in the patient services area⁴ of the pharmacy. A pharmacist must take reasonable steps to offer assistance to a patient who wishes to purchase a Schedule 3 drug (Standard 9.)

3 Standards of Practice for Pharmacists and Pharmacy Technicians, July 2011

4 Standards for the Operation of Licensed Pharmacies, Standard 4.6

Appendix A - Standards of Practice for Pharmacists and Pharmacy Technicians

The Standards of Practice can also be found at <http://abpharmacy.ca/standards-practice>.

- STANDARD 3: Pharmacists must consider appropriate information for each patient.
- STANDARD 4: Pharmacists must determine whether a patient has or is likely to have a drug therapy problem.
- STANDARD 8: Each time a pharmacist or a pharmacy technician dispenses a Schedule 1 drug or blood product pursuant to a prescription, or sells a Schedule 2 drug:
 - a.) the pharmacist or the pharmacy technician must confirm the patient's identity, and
 - b.) a pharmacist must provide the patient with sufficient information to enable the patient to receive the intended benefit of the drug therapy.
- STANDARD 9: A pharmacist or a pharmacy technician must take reasonable steps to offer assistance to a patient who wishes to purchase a Schedule 3 drug or a health care product, aid or device.
- STANDARD 18: A pharmacist must create and maintain patient records for pharmacist services provided by that pharmacist.

A pharmacy technician must create and maintain patient records for pharmacy technician services provided by that technician.