The Manitoba Pharmaceutical Association

200 Tache Avenue, Winnipeg, Manitoba R2H 1A7

Phone (204) 233-1411 Fax: (204) 237-3468 E-mail: info@mpha.mb.ca Website: www.mpha.ca

Understanding Drug Schedules

The Scheduling Process

The National Association of Provincial Regulatory Authorities (NAPRA) was established by the provincial regulatory bodies in February 1995, to help provinces take a national approach to addressing common issues. The National Drug Schedule Advisory Committee (NDSAC) was created by NAPRA in August 1995 to advise provincial regulatory authorities on the placement of drugs into the national scheduling model and to help maintain and evaluate the drug scheduling factors and cascading principles used to make scheduling recommendations.

The province of Manitoba follows the NAPRA national drug schedules by reference. Any scheduling amendments made to the National Drug Scheduling System are effective immediately in Manitoba, as provided in provincial legislation. Manitoba was the first province to adopt the National Drug Scheduling System model as the provincial model in September 1998. Some provinces currently require approval by their provincial regulatory body and provincial government prior to implementation of the NAPRA drug schedule recommendations.

The national model consists of three schedules or four categories: Schedule I, Schedule II, Schedule III and Unscheduled, with specific conditions for sale expected for each.

The model for drug scheduling recommendations uses a “cascading principle” in which a drug is first assessed using the factors for Schedule I. Should sufficient factors pertain, the drug remains in that Schedule. If not, the drug is assessed against the Schedule II factors, and if warranted, subsequently against the Schedule III factors. Should the drug not meet the factors for any schedule, it becomes “unscheduled” and may be sold in any retail outlet.

Outline of the Schedules

The scheduling of drugs determines the conditions for sale of the product as well as the pharmacist’s intervention required if any.

Schedule I drugs – Prescription only

The drugs require a prescription for sale and are provided to the public by the pharmacist following the diagnosis and professional intervention of a practitioner. The sale is controlled in a regulated environment as defined by provincial pharmacy legislation. Provincial regulations require that pharmacists provide patient counseling on all prescriptions – new and renewals.

Schedule II drugs – No prescription required, sale from "no public access" area of pharmacy

While less strictly regulated, these drugs do require professional intervention from the pharmacist at the point of sale and possibly referral to a practitioner. While a prescription is not required, the drugs are available only from the pharmacist and must be stored within an area of the pharmacy where there is no public access and no opportunity for patient self-selection (i.e. the dispensary.)

Schedule III drugs – No prescription required, sale from area immediately adjacent to pharmacy

Schedule III drugs may present risks to certain populations in self-selection. Although available without a prescription, these drugs are to be sold from the self-selection area immediately adjacent to the pharmacy which is operated under the direct supervision of the pharmacist, subject to any local professional discretionary requirements which may increase the degree of control (for example, dimenhydrinate placed behind the counter due to local abuse of the product). The pharmacist is available, accessible and approachable to assist the patient in making an appropriate self-medication selection.

Unscheduled Drugs – Sale from any retail outlet

Unscheduled drugs can be sold without professional supervision. Adequate information is available for the patient to make a safe and effective choice and labeling is deemed sufficient to ensure the appropriate use of the drug. These drugs are not included in Schedules I, II or III and may be sold from any retail outlet.

Some medications may be included in more than one schedule; depending on the strength, dosage form or package size of the drug. For example, Ibuprofen is listed Schedule 1 if the concentration is greater than 400mg per dosage unit, Schedule 3 if sold in package size greater than 18,000mg and Unscheduled for package size up to 18,000mg.

To determine which schedule a drug may be listed, visit the www.napra.ca and click Search Drug Schedules.

NAPRA has developed National Standards of Practice for pharmacists corresponding to the level of professional intervention and advice necessary for the safe and effective use of these drugs by consumers, according to each Schedule. The standards were approved by the members in 2006 and are enforceable in Manitoba.