



BTC Drug Class in Canada Part II

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National Drug Scheduling Framework

Model offers a provincial “safety net”, and consists of:

- three schedules/four categories of drugs,
- consistent inclusion *factors* for each schedule,
- a standard *process* for scheduling,
- National Drug Scheduling Advisory Committee (NDSAC)
- National Standards of Practice for expected levels of pharmacist intervention (I, II, III)

NDSAC

- Members
- Funding
- Applicants, “Interested Parties”, and the public
- Process for finalizing decisions

Scheduling decisions...

Based on a “cascading principle”

- Drug first assessed against the **Schedule I** factors
- If insufficient factors for Schedule I, then assessed against **Schedule II** factors
 - If insufficient factors for Schedule II, then assessed against **Schedule III** factors
 - Drug not meeting factors for any schedule becomes “**Unscheduled**”

Operational issues.....

- How scheduling recommendations are implemented at the provincial level
- What happens if a “switch” drug is not reviewed by NDSAC?
- Natural Health Products

Schedule I

- Schedule I factors very closely aligned with criteria used by Health Canada
- Includes all federal Rx drugs “+”
- Examples
- Standards of Practice for pharmacists

Schedule II (“BTC”)

- no prescription required
- pharmacist accountable for decision to sell
- no public access – “**behind the counter**”
- Standards of Practice for pharmacists

Schedule II factors

1. Initial need is identified or confirmed by a regulated health professional.
2. Chronic therapy or subsequent re-treatments should be monitored by a pharmacist.
3. Must be readily available under exceptional circumstances when a prescription is not practical.
4. Is intended for administration in a health care setting or under the direction of a regulated health professional, or is an injectable dosage form and not otherwise included in Sch I.
5. Is significant potential for misuse or abuse, due to its inherent pharmacological action or chemical properties.
6. Selection requires intervention by a pharmacist:
 - to confirm that an appropriate self-assessment has been made by the patient; or-for a condition that is new to patient self-assessment; or for a condition that is generally not amenable to patient self assessment.
7. Use may delay recognition or mask the symptoms of serious disease.
8. May cause serious or significant adverse drug reactions or drug interactions that cannot be adequately addressed through product labeling.
9. Safe and appropriate use requires intervention by a pharmacist to reinforce or expand on limited, or complex, information that appears on product labeling.
10. Medicinal ingredient is new or is in a new drug delivery system, for self-medication.

Schedule II drugs: some examples

- **Clobetasone butyrate** (when sold in a concentration of 0.05% clobetasone butyrate in cream preparations for topical use on the skin)
- **Epinephrine and its salts** (in pre-filled syringes intended for emergency administration by injection in the event of anaphylactic reactions to allergens)
- **Insulin**
- **Iron and its salts and derivatives** (in preparations with more than 30mg elemental iron per solid dosage unit or 5ml oral liquid)

Schedule III

- no prescription required
- available in self-selection area of a pharmacy that is under the direct supervision/ “sight & sound” of a pharmacist, “**over-the-counter**”
- Standards of Practice for pharmacists

Schedule III factors

1. Chronic use may delay recognition or mask the symptoms of serious disease.
2. Is a new ingredient for self-selected self-medication and the availability of a pharmacist to provide advice can promote appropriate use.
3. Is used to treat a persistent, chronic or recurring condition and the availability of the pharmacist to provide advice can promote appropriate use.
4. Is potential for misuse or abuse of the drug, due to its inherent pharmacological action or chemical properties.
5. Availability of a pharmacist to reinforce or expand on product labeling, or where product selection is likely to cause confusion, could contribute to the safe and appropriate use of the drug.

Schedule III drugs: some examples

- Polymyxin B and its salts and derivatives (*for ophthalmic use*)
- Nystatin and its salts and derivatives (*in topical preparations for use on the skin*)
- Hydrocortisone. (*when sold as a single medicinal ingredient in a concentration that provides 0.5% hydrocortisone in preparations for topical use on the skin*)

“Unscheduled” drugs

Conditions for sale of non-Rx drugs in other jurisdictions

- UK
- Australia

Stakeholder perspectives (Sch II)

- Public
- Regulators
- Pharmacists
- Other healthcare professionals
- Industry
- Retailers

Future considerations