



# BTC Drug Class in Canada

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# Presentation Outline

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- Overview of the National Association of Pharmacy Regulatory Authorities (NAPRA)
- Part I - Canada's Drug Scheduling Framework
  - Federal
  - Provincial/Territorial
  - NAPRA
- Part II - National Drug Schedules Framework will be presented by Barbara Wells



# Overview of NAPRA

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- Founded in February 1995, voluntary, not-for-profit corporation based in Ottawa, Canada
- Currently represent 10 provincial and 1 territorial pharmacy regulatory authorities (PRA) and the Canadian Forces Pharmacy Services
- Total number of pharmacists practicing in Canada (2008) – 31,011  
[www.napra.ca](http://www.napra.ca)



# Role and Responsibilities

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- Vision

“NAPRA facilitates the adoption and implementation of best regulatory practices in all pharmacy regulatory authorities in Canada”

- Mission

NAPRA enhances the activities of the pharmacy regulatory authorities by:

- Being a forum to discuss regulatory issues
- Serving as a national voice
- Serving as a national centre for knowledge and awareness
- Facilitating the adoption and implementation of its core programs and best regulatory practices

- One of NAPRA’s Core Programs is the maintenance of the National Drug Schedules



# Federal Role in Drug Scheduling

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- Health Canada administers the *Food and Drugs Act and its Regulations* and manages a wide range of activities/programs. In particular, Health Canada is responsible for:
    - Drug review and issuance of market authorization
    - Determination of whether a drug will be prescription or non prescription
      - Prescription drugs are classed as either Schedule F drugs or controlled substances
    - Post-market drug surveillance
    - Compliance and enforcement
  - Changes to drug substance status require approval by one of the Government of Canada's Cabinet Committees (regulatory process)
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# Federal Role – Switch from Prescription to Non prescription Drugs

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- Review triggered by the filing of a drug submission
- Undertake evaluation of information against a series of factors (listed on the next two slides)
- Make recommendation on proposed scheduling (Drug Schedule Status Committee - an internal, multi-organizational committee)
- Consult on proposal via a published Letter of Intent in Canada Gazette, the government's official newspaper
- Finalize the proposed scheduling by seeking approval by the appropriate Government of Canada Cabinet Committee



# Factors for listing drugs in Schedule F

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Schedule F to the *Food and Drug Regulations* is a listing of chemical entities or classes of drugs which, with exceptions, are required by regulation to be sold under prescription. The following are the factors used by Health Canada to determine whether this level of control over the sale of these drugs is appropriate.

**Drugs will be listed in Schedule F if:**

- (a) individualized instructions and/or direct practitioner supervision, adjunctive therapy with scheduled drugs or routine laboratory monitoring are required;
- (b) there is a narrow margin of safety between the therapeutic and toxic doses, especially in populations such as geriatrics, children and pregnant or nursing mothers;
- (c) there are potential or known undesirable or severe side effects at normal therapeutic dosage levels;
- (d) they are known by experimental data to induce toxicity in animals but have not been in clinical use long enough to establish the pattern or frequency of long-term toxic effects in humans;
- (e) they are used in treatment of a serious disease easily misdiagnosed by the public;
- (f) their use may mask other ailments;
- (g) they have contributed to, or are likely to contribute to, the development of resistant strains of micro-organisms in humans;



# Factors for listing drugs in Schedule F (continued)

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- (h) they possess a dependence or abuse potential that is likely to lead to harmful non-medical use;
- (i) they possess a high level of risk relative to expected benefits; or
- (j) they have a therapeutic effect based on recently elucidated pharmacological concepts, the consequences of which have not been established.

**Exceptions will be considered for drugs which:**

- (a) are required to be readily available under emergency circumstances where it is not practical to obtain a prescription (such as adrenalin in insect bite kits);
- (b) are rarely used without a practitioner's supervision, and where the need for free availability outweighs the need for protection under Schedule F (such as insulin and nitroglycerin); or
- (c) have potential to produce dangerous interactions with other drugs or food constituents but effective labelling can minimize the risk.

Source: Health Canada, TPD Policy on Factors for Listing Drugs in Schedule F, August 1999.  
[http://www.hc-sc.gc.ca/dhp-mpps/prodpharma/applic-demande/pol/schf\\_annf\\_fact\\_pol-eng.php](http://www.hc-sc.gc.ca/dhp-mpps/prodpharma/applic-demande/pol/schf_annf_fact_pol-eng.php)



# Provincial/Territorial Role – Non prescription drugs

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Once the federal government decides on non prescription status, the provinces/territories will:

- Determine the conditions of sale and ensure their implementation
  - May schedule with more restrictions than the one imposed at the federal level but not fewer, i.e., Rx federally must be Rx provincially, but provinces/territories may elevate a non-Rx drug (federally) to Rx provincially
- Adopt Standards of Practice to guide pharmacists' intervention with drugs placed in schedules



# NAPRA Role – Non prescription Drugs

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- Over ten years ago, established a national drug scheduling model known as the National Drug Schedules (NDS)
- Responsible for the management of the NDS (approximately 1700 records) and its associated activities
- Develop model national guidelines such as Standards of Practice for pharmacists which correspond to the NDS
- Link with other national/provincial/territorial organizations
- Monitor implementation of NDS scheduling placement decisions among participating provinces/territories

*NB - Québec does not use the NDS but has a very similar system*



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**Thank you!**

Part II of the presentation follows:

Barbara Wells, Founder and Consultant,  
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