The "New Drug" Phenomenon
Update from Canada

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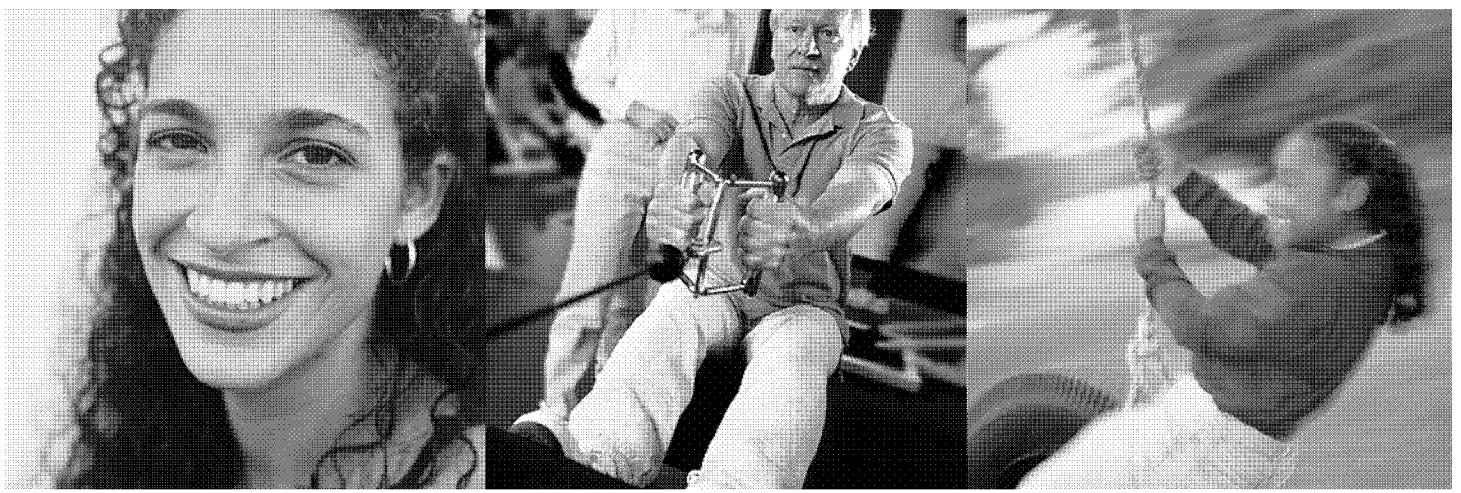

Outline

- Canadian Legislative Framework for Controlled Substances
- Scheduling Process
- Current Scheduling Initiatives
- Challenges/Potential Improvements

Legislative Framework

Canadian Legislative Framework

International Conventions

Single Convention on Narcotic Drugs 1961

Convention on Psychotropic Substances 1971

United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988

Controlled Drugs and Substances Act (CDSA)

- Narcotic Control Regulations (NCR)
- Food and Drug Regulations-Part G (FDR-G)
- Food and Drug Regulations-Part J (FDR-J)
- Benzodiazepines and Other Targeted Substances Regulations (BOTSR)
- Precursor Control Regulations (PCR)
- Marihuana Medical Access Regulations (MMAR)
- Industrial Hemp Regulations (IHR)
- Qualifications for Designations as Analysts Regulations
- Police Enforcement Regulations
- Regulations Exempting Certain Precursors and Controlled Substances From the Application of the *Controlled Drugs and Substances Act*

Scheduling Process (1)

1. Substance Identification

- United Nations decision to schedule substance under international drug control conventions; or
- Domestic and international information on abuse/addiction liability/other risks of substance

2. Info Collection and Preliminary Review

- Info collected from a variety of sources
- Determination of whether sufficient info exists for full CDSA scheduling assessment

Scheduling Process (2)

3. Scheduling Assessment

- Factors considered:
  - Overall risk to public health and safety posed by the substance
  - Chemical and pharmacological similarity to other substances already regulated under the CDSA
  - Legitimate uses of the substance (i.e., therapeutic, industrial or commercial)
  - Potential for abuse and risk of addiction associated with the substance
  - Extent of actual abuse of the substance in Canada and internationally
  - International requirements and trends in international control
- Development of final Issue Analysis Summary
- Review by Departmental WG

Scheduling Process (3)

4. Notice to Interested Parties in *Canada Gazette*, Part I

5. Scheduling Decision

- Scheduling recommendation to senior management for approval

6. Federal Regulatory Process

- Pre-publication of proposed regulation in *Canada Gazette*, Part I with comment period (min. of 30 days)
- Development of final regulation and publication in *Canada Gazette*, Part II

Emerging Substances

	2005	2006	2007	2008	2009	2010
2C Family	6	66	53	103	187	272
Salvia	0	9	8	4	20	36
Tryptamine Family	11	5	124	239	148	40
BZP/TFMPP	0	8	151	1161	2366	1921
Synthetic Cannabinoids	0	0	0	0	2	88

Current Scheduling Initiatives

- tramadol
  - Draft regulation published in June 2007
- BZP/TFMPP
  - NOI published in December 2008
- Salvia and Salvinorin A
  - NOI published in January 2011
- tapentadol
  - NOI published in February 2011
- L-phenylacetylcarbinol (LPAC)
  - Scheduling assessment in progress

Future Scheduling Initiatives?

- synthetic tryptamines, e.g., 5-MeO-DIPT, 5-MeO-DALT, etc.
  - Only N,N-DMT and N,N-DET and their salts are currently included in Schedule III to the CDSA
- synthetic phenylethylamines, e.g., 2C-I, 2C-E, etc.
  - Only 4-bromo-2,5-dimethoxybenzeneethanamine (2C-B), its salts, isomers or salts of isomers is currently included in Schedule III to the CDSA

Potential Improvements (1)

- Publication of a Scheduling Policy
  - Objective is to respond to stakeholder demands for greater openness and transparency, and to foster greater accountability within Health Canada
  - Policy will define scheduling factors, set out a process map and explain all steps of the process in a single clear and concise document

Potential Improvements (2)

- Establishment of an External Advisory Committee on Scheduling
  - To enhance science-based decision-making by providing Health Canada with an established, formal mechanism to request external expert scientific/ medical advice when needed
  - Membership would include experts on abuse, addiction, pharmacology of substances of abuse and epidemiology
  - Ad hoc representation from law enforcement, criminology, social work fields as required