The “New Drug” Phenomenon
Update from Canada

First International Multidisciplinary Forum on New Drugs
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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
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

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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-phenylacetylcarnbinol (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