World Health Organization

Opioid Strategy toolkit: Legal module

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Access to Medicines, Vaccines and Pharmaceuticals

Legal Module

developed by UNODC

International Drug Control Conventions

WHO role within the International Drug Control Conventions

1961 Single Convention on Narcotic Drugs
*as amended by the 1972 protocol

1971 Convention on Psychotropic Substances

- **Apply** measures of international control to substances listed in their schedules
- **Obliges** countries that are party to the Conventions to protect public health and welfare
- **Mandate** WHO with the responsibility of reviewing and assessing substances to determine whether they should be controlled under the Conventions and make recommendations to CND
  - Assess risks of abuse, dependence and harm to health
  - Where it is relevant, the ECDD also consider whether the substance is for medical or scientific use.
  - WHO Mandate reinforced by UNGASS & CND Resolutions e.g. 61/8

WHO Procedures for Substance review: Expert Committee on Drug Dependence (ECDD)

- 'Guidance on WHO review of psychoactive substances for international control‘
- Established to operationalize WHO’s mandate within Conventions

- Describes the processes and procedures undertaken by WHO to fulfil its treaty responsibility
  - WHA 33.27 (1980);
  - Revisions approved by WHO Exec. Board 2010
  - Describes phases of review (pre-review, critical review, etc.) and how they are initiated
  - Following a critical review, the ECDD may make a recommendation to CND about scheduling

Data collection for prioritization of substances, surveillance and ECDD review

Scientific evidence is central to ECDD decision making processes

- Published scientific data in relevant fields (e.g. abuse liability testing, epidemiology, toxicology)
- WHO health-related databases on adverse reactions to medicines (Vigibase), substandard and falsified medicines (GSMS)
- Published and unpublished scientific data from UNODC (EWA, ToxPortal), INCB, EMCDDA, CICAD, etc
- Member State data on prevalence and harms
  - ECDD Member State Questionnaire sent to all countries

The collection of robust data on abuse, dependence and harm for the most prevalent and harmful psychoactive substances remains a challenge

The Expert Committee on Drug Dependence (ECDD) composition of experts

- Selected experts - recognised expertise on substance evaluation (e.g. toxicology, pharmacology, psychiatry etc.)

- Independent medical or scientific expertise
  - Not representing a country or a governmental agency
  - Clear of conflicts of interests

- Geographic and gender balance

- Observers: UN agencies e.g. INCB, UNODC

Opioids voted by 62nd CND for scheduling following 41st ECDD (Nov 2018)

Schedule I of the Single Convention on Narcotic Drugs:

- Parafluoro butyrfentanyl
- Ortho-fluorofentanyl
- Methoxyacetyl fentanyl
- Cyclopropyl fentanyl

Opioids to be reviewed at the 42nd ECDD

Fentanyl analogues (critical review): Crotonylfentanyl , Valerylfentanyl

Preparations listed in Schedule III of the 1961 Single Convention on Narcotic Drugs (pre-review)

Preparations of*:

- Acetyldihydrocodeine
- Codeine
- Dihydrocodeine
- Ethylmorphine
- Nicocodine
- Nicodicodine
- Norcodeine
- Pholcodine

*when compounded with one or more other ingredients and containing not more than 100 milligrams of the drug per dosage unit and with a concentration of not more than 2.5 per cent i undivided preparations.

Enhancing WHO's response to increasing public health risks

- WHO holds annual ECDD meetings to review psychoactive substances and make scheduling recommendations

- To increase the number of substances being actively monitored for subsequent review and scheduling, ECDD NPS sub-committee meets twice a year

- The first phase of an NPS surveillance system has been implemented to increase monitoring of NPS and encourage data sharing with Member States
  - The surveillance system complements the ECDD scheduling process and aims at communicating rapidly to countries the dangers and risks associated with particular psychoactive substances e.g. opioids. CND 60/4