Opioid Strategy toolkit: Legal module

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Access to Medicines, Vaccines and Pharmaceuticals
WHO role within the International Drug Control Conventions

- **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- Published and unpublished scientific data from UNODC (EWA, ToxPortal), INCB, EMCDDA, CICAD, etc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 62\textsuperscript{nd} 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 in 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