International drug control systems

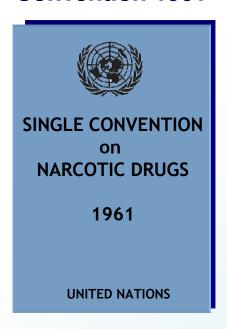
Control of narcotic drugs, psychotropic substances and precursor chemicals

Vienna, March 2009

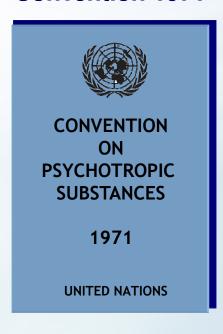
Historical development in international treaty law in drug control

Current international Conventions:

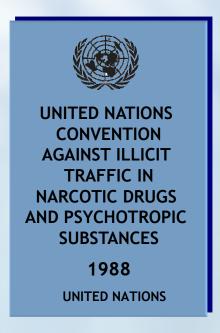
Convention 1961



Convention 1971



Convention 1988



International Narcotics Control Board

- Established by the Single Convention of 1961

INCB



- Elected by ECOSOC
- Independent treaty body
- 13 members; 3 nominated by WHO, 10 nominated by Governments
- Predecessors at the time of League of Nations

Role of INCB

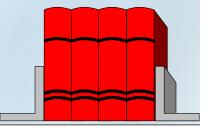
Overall treaty function:

- To monitor and promote treaty compliance
- To encourage dialogue with Governments



Function:

- To administer international control systems;
- To ensure balance between supply and demand;
- To endeavor, in cooperation with Governments, to prevent illicit activities.



OBJECTIVES OF THE CONTROL SYSTEM

- Limit the use of narcotic drugs and psychotropic substances to legitimate medical and scientific purposes
- Ensure that narcotic drugs and psychotropic substances are available for medical and scientific purposes
- Two complementary, not mutually exclusive, aims (Report of the International Narcotics Control Board for 1999, Chapter I, "Freedom from pain and suffering")

INCB Annual Report

- ✓ Analyses global drug control situation
- ✓ Draws attention of Governments to any weaknesses in national drug control and treaty compliance
- ✓ Suggests possible improvements at both national and international levels.

2006 Annual Report

Chapter I - Internationally controlled drugs and the unregulated market

Some features of unregulated markets:

- Unlicensed individuals and/or entities trade in drugs
- Licensed individuals/entities trade in drugs that they are not authorized or entitled to deal with in contravention of the applicable laws

Internationally controlled drugs and the unregulated market (continued)

Sources of drugs available on unregulated markets

- Thefts or unauthorized sales from licensed manufacturers, wholesalers, distributors, health-care institutions and/or health-service providers
- Expired drugs/ substandard drugs that have been recalled by the manufacturer
- Individuals who have legally obtained drugs and sell them for profit
- Counterfeit drugs

Internationally controlled drugs and the unregulated market (continued)

Factors driving the unregulated market

- Limited access to health-care facilities
- Cost of drugs
- Lack of public awareness
- Inadequate drug control regulations and weaknesses in enforcement
- Consumer demand for illicit drugs

Internationally controlled drugs and the unregulated market (continued)

Emerging issues

- Counterfeit drugs
 - An estimated 25-50 per cent of the medicines used in developing countries are believed to be counterfeit
- Internet orders
 - Large majority of Internet pharmacies are unlicensed and unregulated and sell internationally controlled drugs (benzodiazepines -84 %; opioids - 68 %)
 - Most accept prescriptions by fax (high risk of falsification)
 - Risks:
 - Lack of proper medical supervision;
 - Higher price than in legal pharmacies;
 - Buyer's medical and financial data may be compromised.

Internationally controlled drugs and the unregulated market (concluded)

Requirements of a regulatory system

- Adequate legal framework (according to WHO, drug regulation is non-existent in a significant number of countries)
- Drug regulatory authorities must assess the efficacy, safety and quality of drugs before allowing them to be imported, manufactured or marketed;
- Drug regulatory authorities must have adequate human and financial resources;
- Health-care professionals should receive training on the promotion of rational use of drugs;
- Procurement, storage, distribution and dispensing of medicines must follow strict standards to minimize the risk of such drugs being diverted into illicit channels.

Provisions of Conventions

Control Measure	1961	1971	1988
Licence to deal in controlled substances	Article 30.1.(a)	Article 8	
Licence to import-export controlled substances	Article 31.3(a)	Article 8	
Prescription requirement	Article 30.2.(b)(i)	Article 9	
Advertisement to general public		Article 10	
Adequate labelling			Article 16.2
Shipments by mail-parcels			Article 19
Trade requirements (import-export authorization system)	Article 31.4.	Article 12	
Lack of proper documentation of export			Article 16.1
National laws and regulations	Article 31.1 (a)		
Estimates for narcotic drugs	Article 31.1 (b)		
Suppress mail for illicit trafficking			Article 19
Prohibition of export to P.O.Box	Article 31.8	Article 12	
Penal provisions under national law	Article 36.1	Article 22	

Recommendations

Governments should:

- Establish a comprehensive legal framework and rigorously enforce existing legislation
- ✓ Conduct inspections (in accordance with article 15 of the 1971 Convention)
- Correctly assess requirements for narcotic drugs and psychotropic substances
- Build capacity of staff of drug regulatory authorities
- Implement effective policies to combat counterfeit drugs

Recommendations

International organizations

- ✓ World Health Organization (WHO) should consider studying the dynamics of the unregulated market;
- ✓ WHO should consider developing a guide on best practices in dealing with the unregulated market;
- ✓ UNODC and WHO should provide technical assistance to Member States to build capacity in drug regulatory authorities.

Private sector

✓ Pharmaceutical industry should notify drug regulatory authorities of any attempts to manufacture and distribute counterfeit drugs

Counterfeit Medicines

- Public Health challenge
- WHO response (IMPACT)
- International collaboration (GS1, WCO, WTO, Healthcare associations, pharmaceutical industry etc...)
- Awareness raising
- Global solution

THANK YOU

More information at www.incb.org

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