

# ***International Law and Access to Controlled Medications***

**Advocacy for Palliative Care in Africa  
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# **Millions have a drug problem**



photo: WHO/Marko Kokic



## Illicit drug use

### Worldwide

- Injecting drug users: 13.1 million
- Opioid abusers: 15,5 million (0.4% of 15-64yrs)
- Heroin abusers: 11 million (0.3% of 15-64yrs)
  
- Mortality: 0.4% (of all death causes)

→ Protection against abuse and dependence useful



## Drug trade

### *World illicit drug market*

- \$ 45 - 280 billion <sup>1</sup>
- \$ 332 billion <sup>2</sup>

### *World car market*

69 million vehicles (2006, Wikipedia)

if average value \$ 30,000 → \$ 207 billion

1. Peter Reuter, unpublished, quoted by Francisco Thoumi (2003) - *The Numbers' Game: Let's All Guess the Size of the Illegal Drugs Industry!* Paper  
TNI Seminar 5-6 December 2003  
Accessed at <http://www.tni.org/crime-docs/numbers.pdf>

2. UNODC, World Drugs Report 2005,  
[http://www.unodc.org/pdf/WDR\\_2005/volume\\_1\\_chap2.pdf](http://www.unodc.org/pdf/WDR_2005/volume_1_chap2.pdf)



## Drug Control

Currently 3 conventions:

- Single Convention on Narcotic Drugs (1961)
- Convention on Psychotropic Substances (1971)
- Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988)

"Single" in *Single Convention* refers to unification of multiple treaties (1925-1931-1936-1946-1948-1953)



## National implementation

All countries that signed the conventions are obliged to implement them in their national legislation\*

- All measures from the conventions to be implemented in national legislation
- All substances in the conventions to be included in national controlled drugs legislation

\* All countries in this workshop are signatories to all three drug conventions, except that Namibia did not accede to the 1988 Convention



## Conventions' principles

1961 and 1971 Conventions:

- Prohibition (basic principle)
- Licensing possible for scientist, manufacturers and trade
  - Not required for health-care workers and patients



## Latitude

- Countries may apply stricter measures
  - Examples:
    - Licence requirement for community and hospital pharmacies
    - Dispensing restricted to major hospitals
    - Government monopoly on morphine trade
    - Special prescription forms
- However, countries may not apply more lenient measures



## Convention principles

1961 and 1971 Conventions:

- Both have 4 lists of substances: "schedules"
- Each schedule is related to a set of control measures



## Role of the World Health Organization

- The WHO Expert Committee on Drug Dependence (ECDD) reviews substances (since 1949)
- Can recommend to add/change/delete a substance
- WHO recommends in scientific and medical matters

WHO has programmes related to public health and substances of dependence



## Medical Uses of Controlled Substances

- Non-medical substances
- Opioid analgesics  
moderate to severe pain
- Opioids for substitution treatment  
opioid dependence
- Ergometrine and ephedrine  
emergency obstetrics
- Benzodiazepines  
anxiolytics, hypnotics,  
anti-epileptics
- Phenobarbital  
anti-epileptic
- Some other uses

WHO recognized a number of controlled medicines as "essential" through its **WHO Model list of Essential Medicines**



## Opioid analgesics

Used for all moderate to severe pain due to:

- Cancer
- AIDS/HIV
- Chronic pain
  - Some exceptions
- Traffic and other accidents
- Myocardial infarction
- Sickle cell anaemia
- Surgery



## Substitution therapy

- Methadone Maintenance Therapy (MMT)
- Other modalities (e.g. buprenorphine)

Methadone *oral* solution  
Supervised

*Among the most evidenced based treatments*



## Substitution therapy acts through:

- No needles required (oral therapy)
  - No transmission of blood-borne disease
- Pharmaceutical quality
  - No overdosing
- At no or moderate cost (for the patient)
  - Money for food
  - Regular application: no withdrawal episodes
  - No need to steal for buying drugs
- Social re-integration



## Substitution therapy effects

- Prevents transmission of HIV and Hepatitis C
  - Reduction HIV seroconversion in IDU's: approx 85%
- Reduces death rate of dependence patients to about normal
  - Reduction 90 – 95%
- Reduces public nuisance and petty crime
  - \$ 1 investment yields \$ 5 for society



## Obstetrics



Photo WHO/Antonio Suárez Weise

## Obstetrics

- Ergometrine
  - stops post-partal heamorrhage
  - used in LSD production
- Ephedrine
  - if blood pressure falls during anaesthesia in giving birth
  - used in methamphetamine production
- Can be life saving
- 1988 Convention



## Precursors

- Ergometrine
  - stops excessive bleeding after giving birth
  - used in LSD production
- Ephedrine
  - if blood pressure falls during anaesthesia in giving birth
  - used in methamphetamine production
- 1988 Convention
- Can be life saving



## Why drug control?

Drugs are bad  
Why are drugs bad?  
Because they are bad...  
They can harm...  
Drug control is  
to prevent harm  
to protect public health



## Drug conventions are part of International Public Health Law

1961 and 1971 Conventions:

Two goals:

1. Prevention of harm from drug dependence
2. Availability for rational medical use

Public health interests are best served if all control measures aim at the **optimum between medical availability and abuse prevention**



## Drug conventions

*Recognizing* that the medical use of narcotic drugs continues to be **indispensable for the relief of pain and suffering** and that adequate provision must be made to **ensure the availability** of narcotic drugs for such purposes ...

*(Preamble Single Conv. on Narcotic Drugs)*



## Drug conventions

*Recognizing* that the use of psychotropic substances **for medical and scientific purposes is indispensable** and that their **availability** for such purposes **should not be unduly restricted...**

*(Preamble Psychotropic Substances Convention)*



## Consequence of signing a treaty

- Treaties are signed on behalf of the nation
- Therefore:
  - Entire government is responsible, not one ministry or one officer only
  - All ministries should cooperate to achieve all public-health and other obligations from any treaty



## More international law:

There are many more conventions that confirm that countries, *including the countries present in this workshop*, agree that patients should have access to medicines (including controlled medicines)



## Universal Declaration of Human Rights (UDHR)

### Article 25:

Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing *and medical care*...



## Constitution of the World Health Organization

### Preamble:

The *States Parties to this Constitution declare*, in conformity with the Charter of the United Nations, that the following principles are basic to the happiness, harmonious relations and security of all peoples:

(...) The *enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being* without distinction of race, religion, political belief, economic or social condition.



## International Covenant on Economic Social and Cultural Rights (ICESCR)

### Article 12:

1. The States Parties to the present Covenant recognize **the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.**
2. The **steps to be taken** by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:  
(...) **the creation of conditions which would assure to all medical service and medical attention** in the event of sickness.



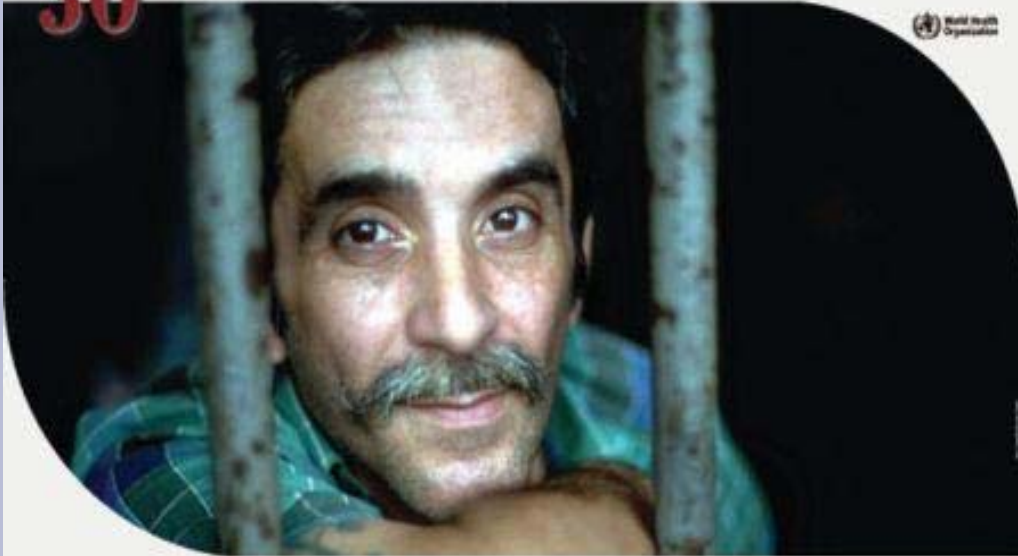
## Right to Health includes:

- Access to Essential Medicines
- Chronically and terminally ill
  - Spare avoidable pain
  - Die with dignity
- Non-discrimination
  - Women, **children**, prisoners, HIV-patients, drug dependents et cetera
- Protection against drug abuse
- States, treaties and UN-bodies should promote right to health internationally

*General Comment 14 to the International Covenant on Economic, Social and Cultural Rights*



**30** Years of Essential Medicines



World Health Organization

**Essential medicines are for everyone**

Los medicamentos esenciales son para todos

Des médicaments essentiels pour tous

## The African Charter on Human and People's Rights (1979)

### Article 16

Every individual shall have the right to enjoy the best attainable state of physical and mental health. States Parties to the present Charter shall take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick.

## UN Convention on the Rights of the Child (1989)

### Article 24

States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services. (...)



## African Charter on the Rights and Welfare of the Child (1990)

### Article 14

Every child shall have the right to enjoy the best attainable state of physical, mental and spiritual health. (...)



# What did a century of drugs control do to public health?

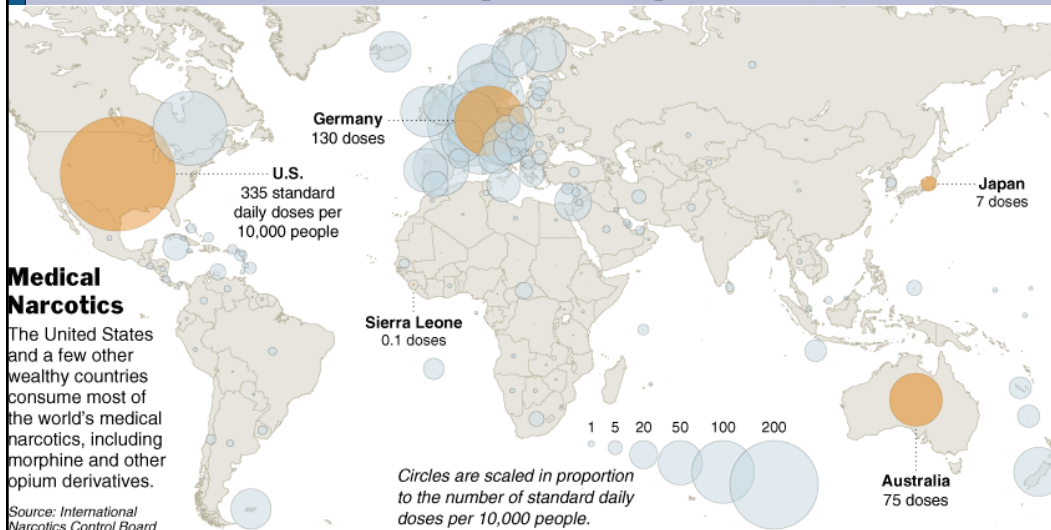
Millions have a drug problem



photo: WHO/Marko Kokic

**They can't get any**

## Morphine consumption per capita



Graphic: New York Times

## Untreated pain patients (annually, globally)

Cause	Number of untreated pain patients
Cancer	4.3 million
HIV/Aids	1.4 million
Emergencies	8 - 40 million
Surgery	8 - 40 million (overlap with emergencies)
Other	10 million (estimated)
<b>Total</b>	<b>30 – 86 million</b>

*All avoidable with controlled medications*



## Number of IDU related new HIV infections

### HIV and its transmission

- 1,400,000 new infections annually (2005; excl. sub-Saharan Africa)<sup>1</sup>

### Injecting Drug Users:

- 30% of all new HIV cases = 420,000 annually (outside sub-Saharan Africa; lowest country: 20%, highest: 90%)

*Treatment of dependence w/ contr. medications prevents many (55-85%=231,000 - 357,000) new HIV cases*

<sup>1</sup> Source: UNAIDS Global Facts and Figures 06



## Maternal mortality preventable by oxytocics

### Maternal deaths (annually)

Total: 500,000

Of which from post-partal heamorrhage:  
125,000

Of which preventable by oxytocics:  
75,000

*Oxytocin is drug of choice,  
but can be replaced by ergometrin  
(oxytocin is not a controlled drug)*



## Undue medical effects of drug control

Untreated pain patients	30 – 86 million
Preventable HIV infections	> 250,000
Preventable maternal mortality	75,000
Effect on mortality among patients with opioid dependence	2-3% → 0.2–0.3%

(first three: annual prevalence)



## Estimated needs for analgesics (morphine)

- Hypothetical requirements
- Calculated from
  - cancer mortality + HIV mortality + injury mortality
  - Not included: pain from surgery and other causes
  - Rough indicator only
- Compared with: actual use (2001)

Source: S. Gelders, WHO, 2007 (In preparation)



## Estimated needs for analgesics (morphine)

Selected African countries:

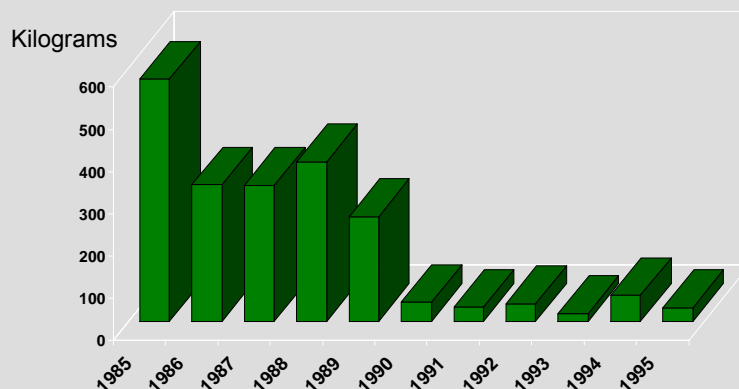
	Hypothetical requirement (mg/capita)	Actual consumption (2005; mg/capita)	ratio
Senegal	9.0	0.09	1.0%
Tanzania	8.2	0.21	0.9%
Zambia	33.2	0.08	0.2%
Rwanda	16.6	0.01	0.1%
Ivory Coast	20.8	0.002	0.1%
Ethiopia	13.5	0.0003	0.003%

Source: S. Gelders, W. Scholten, H. Hogerzeil, WHO, 2008  
(In preparation)



## Consequence of scheduling

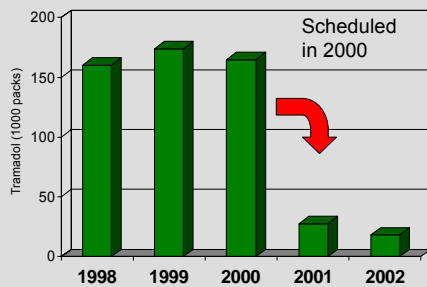
Morphine in India



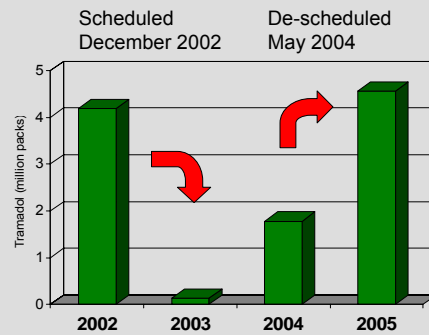
Source

# Consequence of scheduling

Tramadol (INN) units in Jordan before and after scheduling



Tramadol (INN) units in Egypt before, during and after scheduling



What can you do?

## Ensuring access

### **Governments:**

- Check legislation for undue rules
- Submit estimates and statistics to INCB
- Make licensing procedures work fast

### **Health-care professionals:**

- Ensure uninterrupted supply
- Be informed on proper use of these medications
- Proper pain assessment
- Both home care and at the hospital



## WHO's Access to Controlled Medications Programme

- To assist countries to improve access to controlled essential medicines
- Building forth on the experience of the WHO Collaborating Centre for Policy and Communications in Cancer Care (Madison WI, USA) (since 1987)

See [www.who.int/medicines](http://www.who.int/medicines)  
under: [controlled substances](#)



## WHO's Access to Controlled Medications Programme

Access and Control Newsletter

To subscribe send message to  
[accessandcontrol@who.int](mailto:accessandcontrol@who.int)

(and ensure that your spamfilter sees this address  
as safe)

See [www.who.int/medicines](http://www.who.int/medicines)  
under: [controlled substances](#)



## INCB

- Will call on all governments to cooperate with WHO in the implementation of the Access to Controlled Medications Programme
- Will call on governments to provide resources to WHO for the implementation of the programme



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