
Access to Controlled Medicines and WHO mandate to operate the Expert Committee on Drug Dependence

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Medicines 'controlled' by international and national legal instruments

- A medicine that is under control (international or national) due to its psychoactive or mind-altering properties
- **International:** Single Convention on Narcotic Drugs, 1961 and Convention on Psychotropic Substances 1971
- **National:** National laws and regulations



United Nations
Conference for the
Adoption of a Single
Convention on Narcotic
Drugs 24 January - 25
March 1961, New York

Source:

<https://www.un.org/en/conferences/drug/newyork1961>



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Both conventions emphasise the “indispensable” need to maintain access to narcotic and psychoactive substances for medical use

- Limit the possession, consumption, trade, distribution, import, export, manufacture and production of drugs to medical and scientific purposes only
- Fight against drug trafficking through international cooperation
- Protocol amending the Single Convention on Narcotic Drugs in 1972:
 - Treatment and rehabilitation of drug dependence

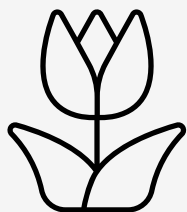


Recognizing that the **medical use of narcotic drugs** continues to be **indispensable** for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes
(1961 Convention)



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
(1971 Convention)

Examples of internationally/nationally controlled medicines listed on the WHO Model List of Essential Medicines



Opioids

codeine
morphine
fentanyl
oxycodone
hydromorphone



Drug Dependence Treatment

buprenorphine,
methadone

NB: Naloxone* NOT under international control



Antiepileptics/ sedatives

phenobarbital



Mental health

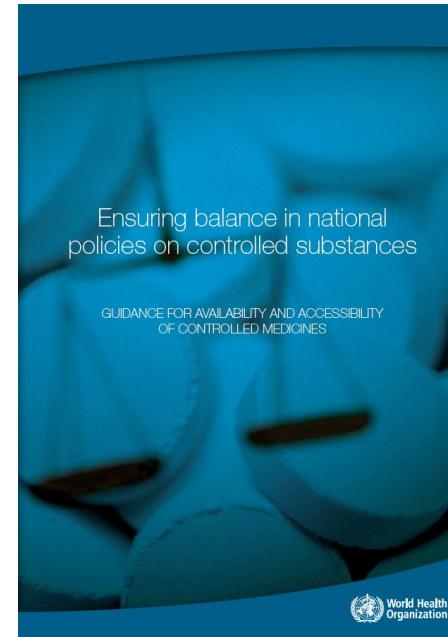
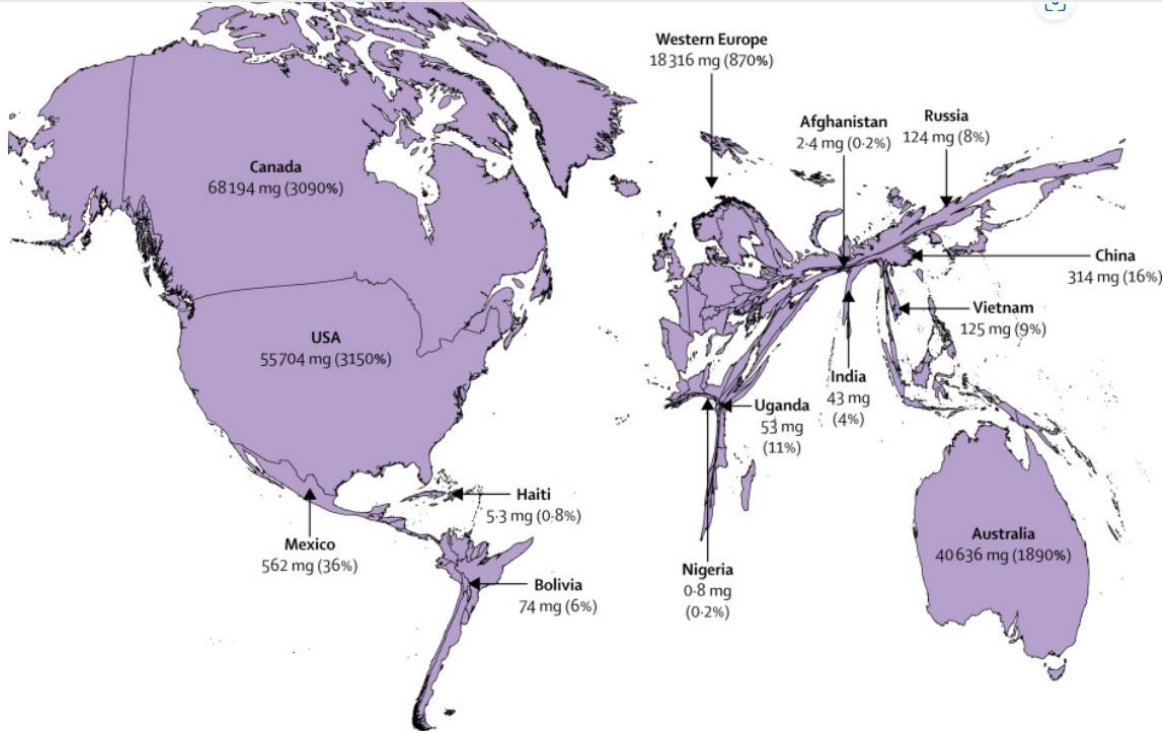
Diazepam,
lorazepam
midazolam

Anaesthetics & perioperative



Ketamine*
Nitrous oxide*

Inequitable accessibility to controlled medicine

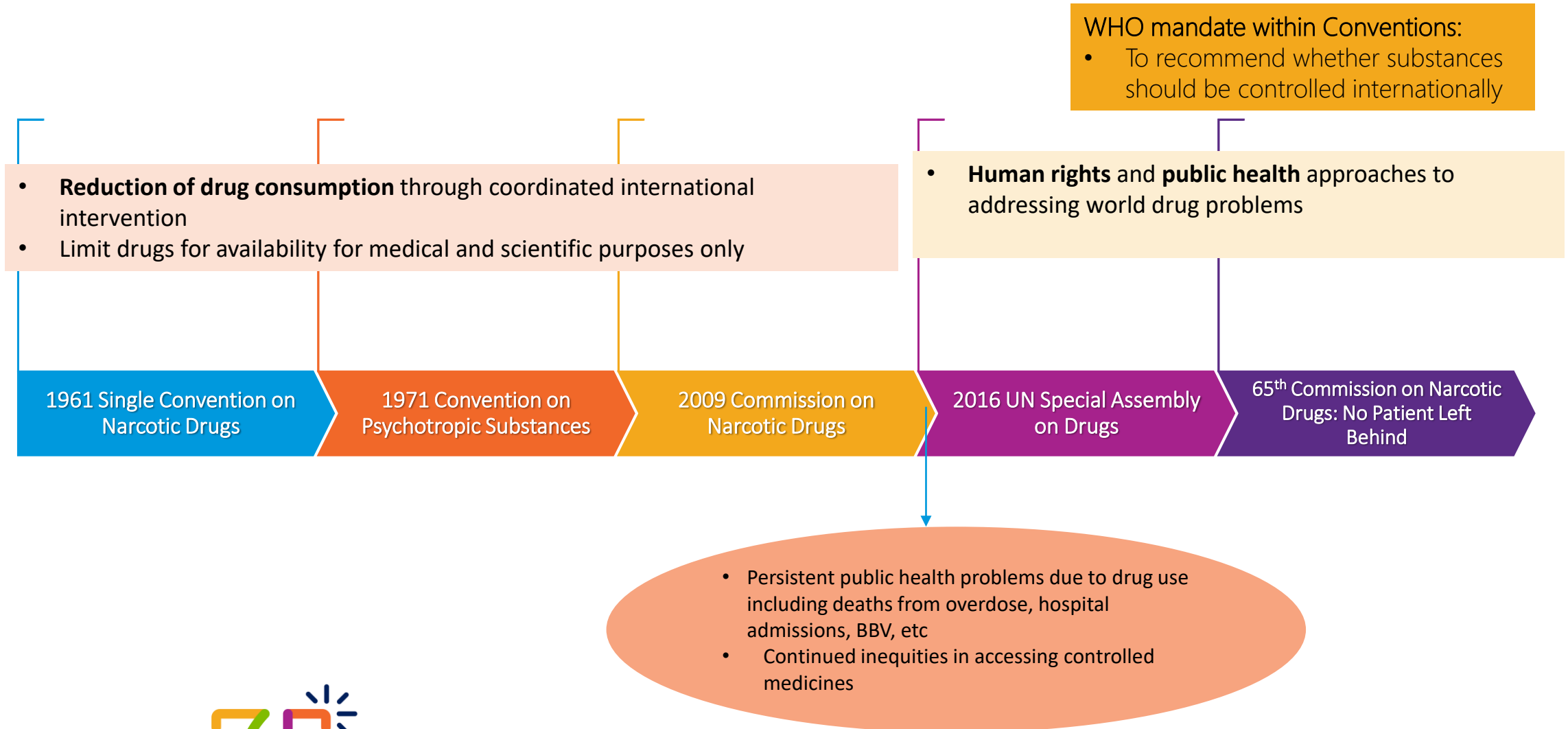


- Most of the world continues to lack affordable access to morphine for **pain and palliative care**
- Low availability and accessibility to medicines also reported for anaesthesia, mental health care, OAT

Under revision

Image Source: Knaul et al.
The *Lancet* Commission on Palliative Care and Pain Relief—findings, recommendations, and future directions (2018)

WHO role and mandate International Drug Control Conventions



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WHO fulfils mandate within Conventions through Expert Committee on Drug Dependence (ECDD)

Critical/pre reviews of psychoactive substances

- Using peer-reviewed published and unpublished data
 - Member State Questionnaire

Other sources of data

- Early warning systems (UNODC & INCB)
- European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)
- Uppsala Monitoring Centre on adverse medicines reactions (WHO)
- WHO Global Surveillance and Monitoring System for substandard and falsified medical products

Consultation process

- Info session includes reports and statements from Member States, Private Sector, Civil Society, etc.
- A special website established to publish reviews and collect public comments

International conventions require ECDD to recommend control for:

- Individual substances only (unlike some national controls)



Harms to health
(e.g. overdose,
deaths, A&E
admissions)

Need for drug for
medical and
scientific
purposes

Recommendations for:

- Scheduling in Conventions (if critical review)
 - Scheduling under 1961 Convention on Narcotic Drugs (Schedules I – IV)
 - Scheduling under 1971 Convention on Psychotropic Substances (Schedules I-IV)
- Further evaluation / critical review (if pre-review)
- No action
- Surveillance

ECDD international control recommendations

1961 Single Convention on Narcotic Drugs:

- Similarity
- Convertibility

Schedules	Harmfulness	Degree of control	Examples of listed drugs
I	Substances with addictive properties, presenting a serious risk of abuse	Very strict; 'the drugs in Schedule I are subject to all measures of control applicable to drugs under this Convention' (art. 2.1)	Cannabis and its derivatives, cocaine, heroin, methadone, morphine, opium
II	Substances normally used for medical purposes and given the lowest risk of abuse	Less strict	Codeine, dihydrocodeine, propiram
III	Preparations of substances listed in Schedule II, as well as preparations of cocaine	Lenient; according to the World Health Organisation, these preparations present no risk of abuse	Preparations of codeine, dihydrocodeine, propiram
IV	The most dangerous substances, already listed in Schedule I, which are particularly harmful and of extremely limited medical or therapeutic value	Very strict, leading to a complete ban on 'the production, manufacture, export and import of, trade in, possession or use of any such drug except for amounts which may be necessary for medical and scientific research' (art. 2.5.b)	Heroin

1971 Convention on Psychotropic Substances:

- Produces state of dependence and CNS stimulation/depression
- Sufficient evidence that use constitutes public health & social problem

Schedules	Harmfulness	Degree of control	Examples of listed drugs
I	Substances presenting a high risk of abuse, posing a particularly, serious threat to public health which are of very little or no therapeutic value	Very strict; use is prohibited except for scientific or limited medical purposes	LSD, MDMA (ecstasy), mescaline, psilocybine, tetrahydrocannabinol
II	Substances presenting a risk of abuse, posing a serious threat to public health which are of low or moderate therapeutic value	Less strict	Amphetamines and amphetamine-type stimulants
III	Substances presenting a risk of abuse, posing a serious threat to public health which are of moderate or high therapeutic value	These substances are available for medical purposes	Barbiturates, including amobarbital, buprenorphine
IV	Substances presenting a risk of abuse, posing a minor threat to public health with a high therapeutic value	These substances are available for medical purposes	Tranquillisers, analgesics, narcotics, including allobarbital, diazepam, lorazepam, phenobarbital, temazepam

Source: European Monitoring Centre for Drugs and Drug Addiction
[Classification of controlled drugs – topic overview | www.emcdda.europa.eu](https://www.emcdda.europa.eu)

Role of WHO in International drug control process



1. Reports from countries and international agencies



2. Robust scientific review & recommendations for control by WHO Expert Committee on Drug Dependence



3. Vote by UN Commission on Narcotic Drugs (53 Member States)



4. Countries are obliged to enforce national control measures to monitor the manufacture, distribution, trade, etc



International Narcotics Control Board
Monitoring and supporting Governments' compliance with the international drug control treaties

5. Oversight of treaty compliance by INCB



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Some international organizations working alongside WHO



Addressing the problem of illicit drug use and transnational crime and is mandated to assist Member States in their struggle against illicit drugs, crime and terrorism.



Promote policies rooted in human rights



Independent and quasi-judicial monitoring body for the implementation of the UN drug control treaties



The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) is the **leading authority on illicit drugs in the European Union.**



INTER-AMERICAN DRUG ABUSE CONTROL COMMISSION (KNOWN BY ITS SPANISH LANGUAGE ACRONYM, CICAD) is the **consultative and advisory body of the OAS on the drug issue.**



WHO's work on access to controlled medicines is guided by WHA resolutions

covenants, resolutions, and principles endorsed by the United Nations Human Rights Council and the United Nations General Assembly

Public health

Human Rights

Universal health coverage

Primary health care



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SIXTY-SEVENTH WORLD HEALTH ASSEMBLY

WHA67.19

Agenda item 15.5

24 May 2014

Strengthening of palliative care as a component of comprehensive care throughout the life course

SIXTY-SEVENTH WORLD HEALTH ASSEMBLY

WHA67.22

Agenda item 15.4

24 May 2014

Access to essential medicines

SIXTY-EIGHTH WORLD HEALTH ASSEMBLY

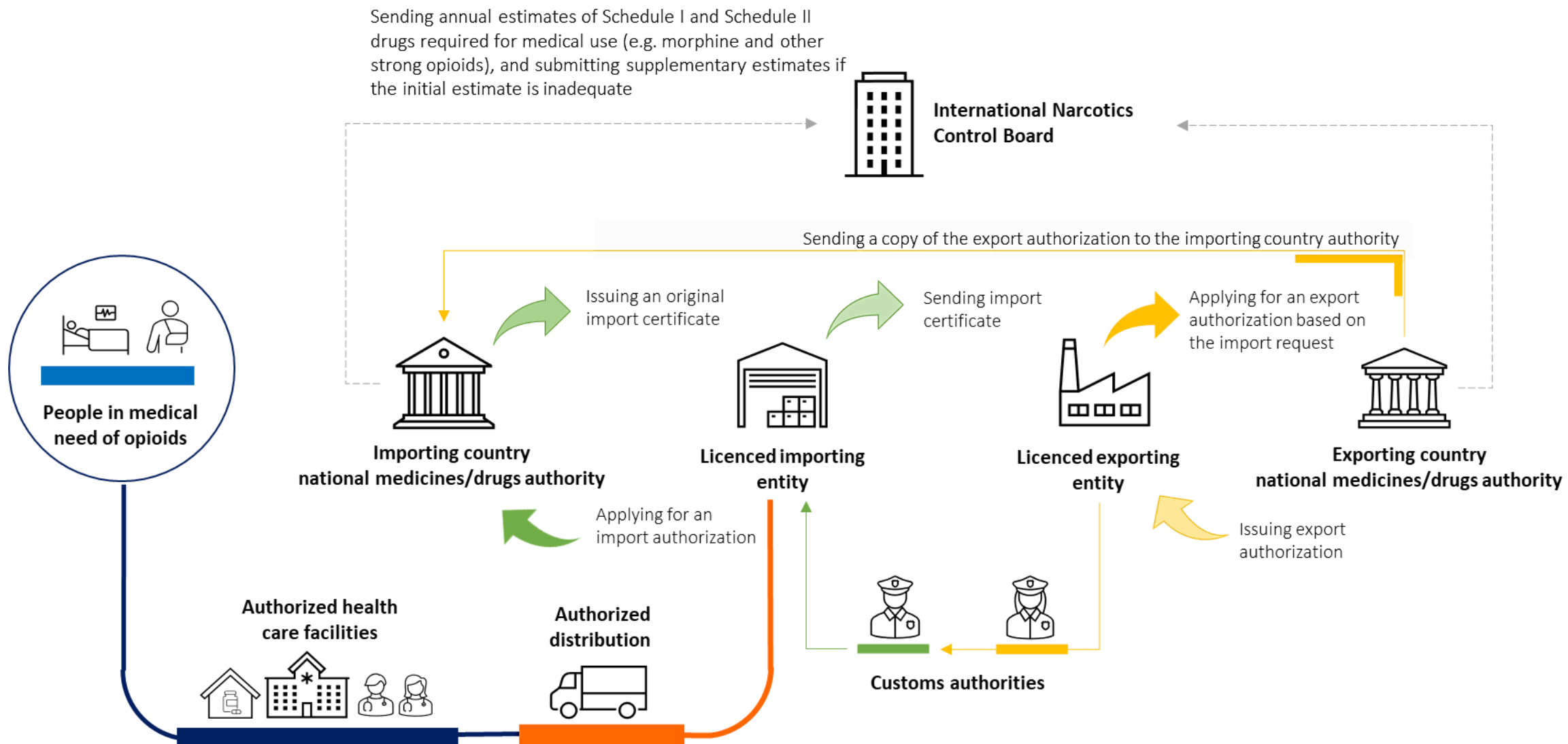
WHA68.15

Agenda item 17.1

26 May 2015

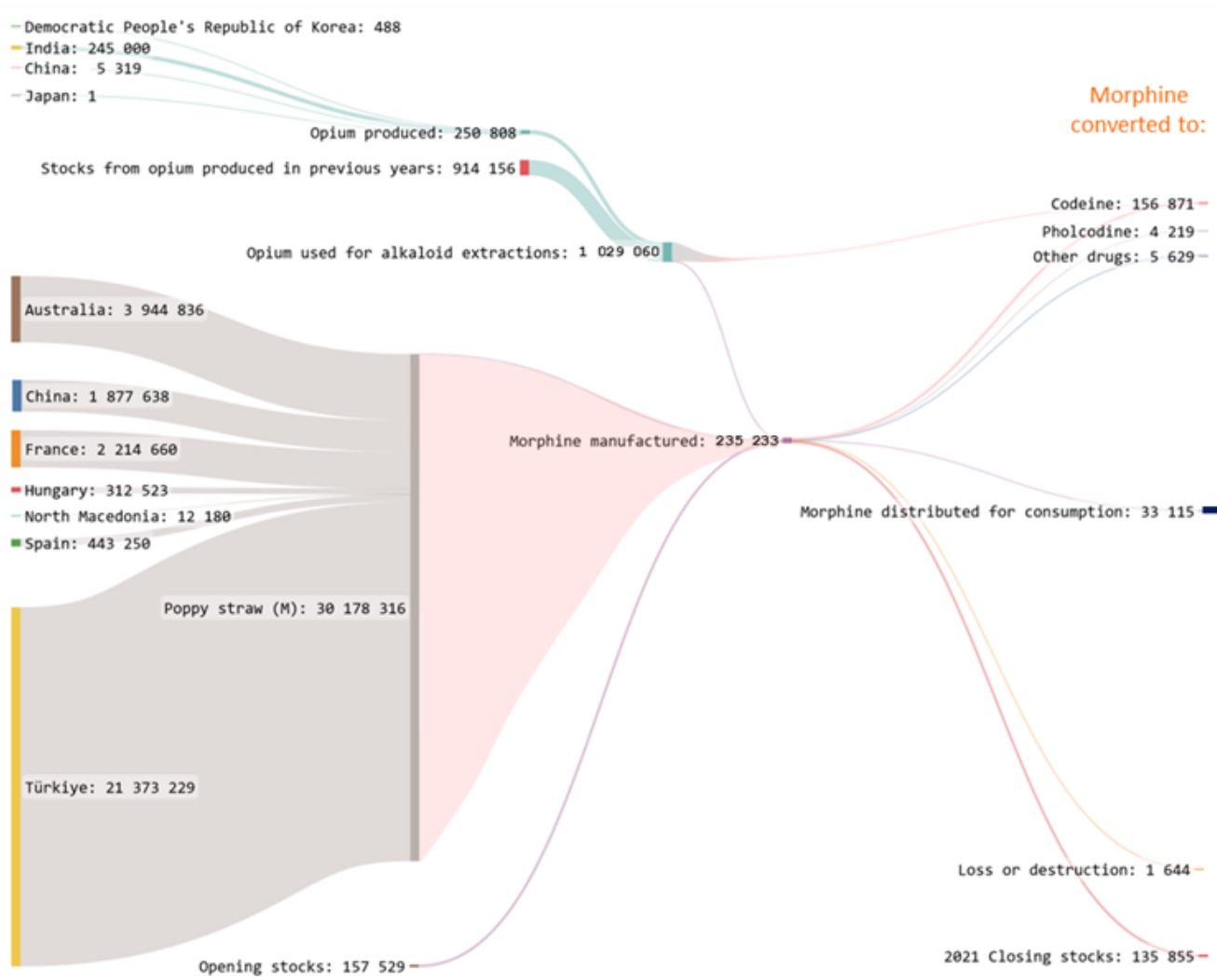
Strengthening emergency and essential surgical care and anaesthesia as a component of universal health coverage

Main steps in the supply chain of morphine and other opioids



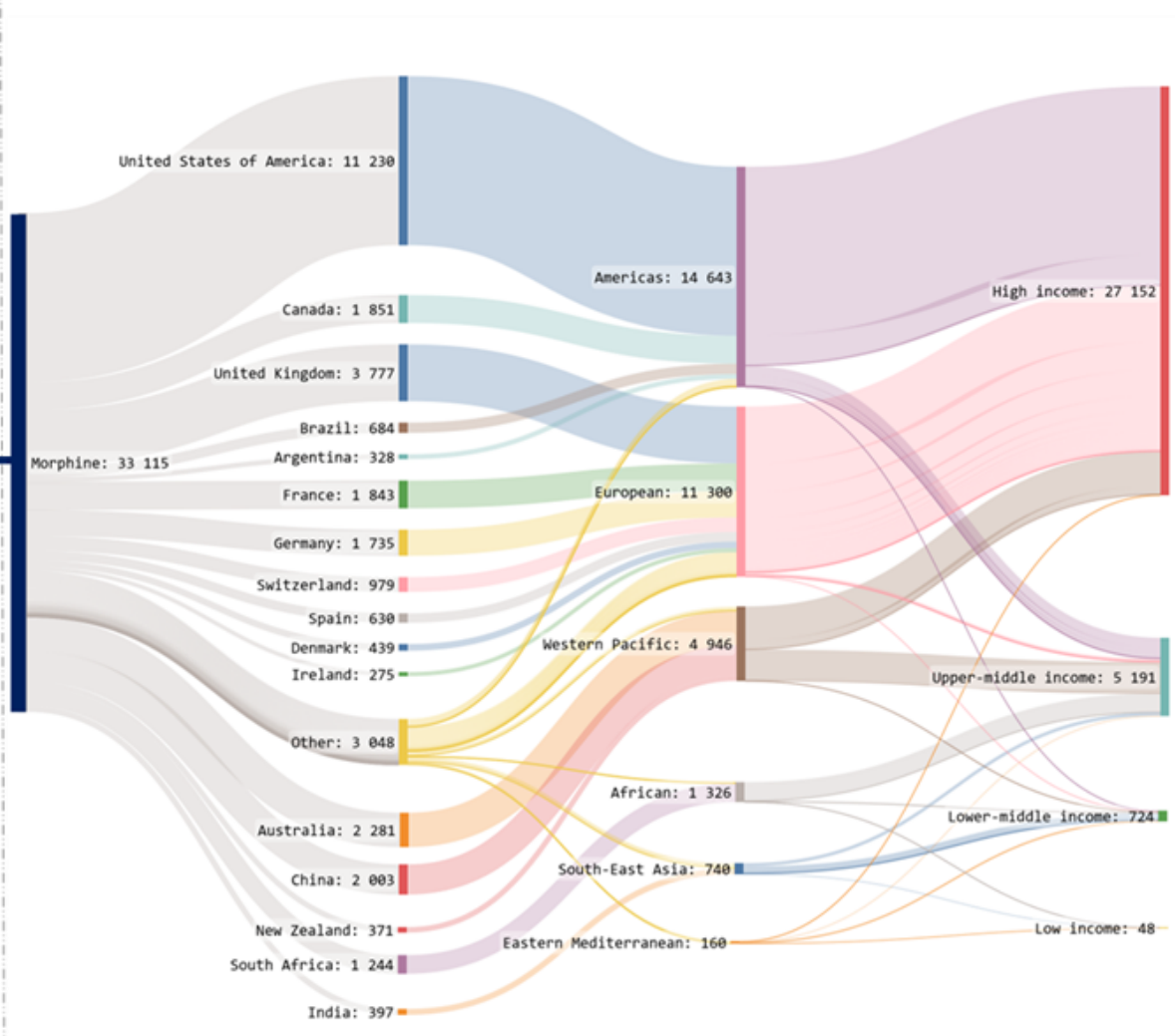
Supply (kg)

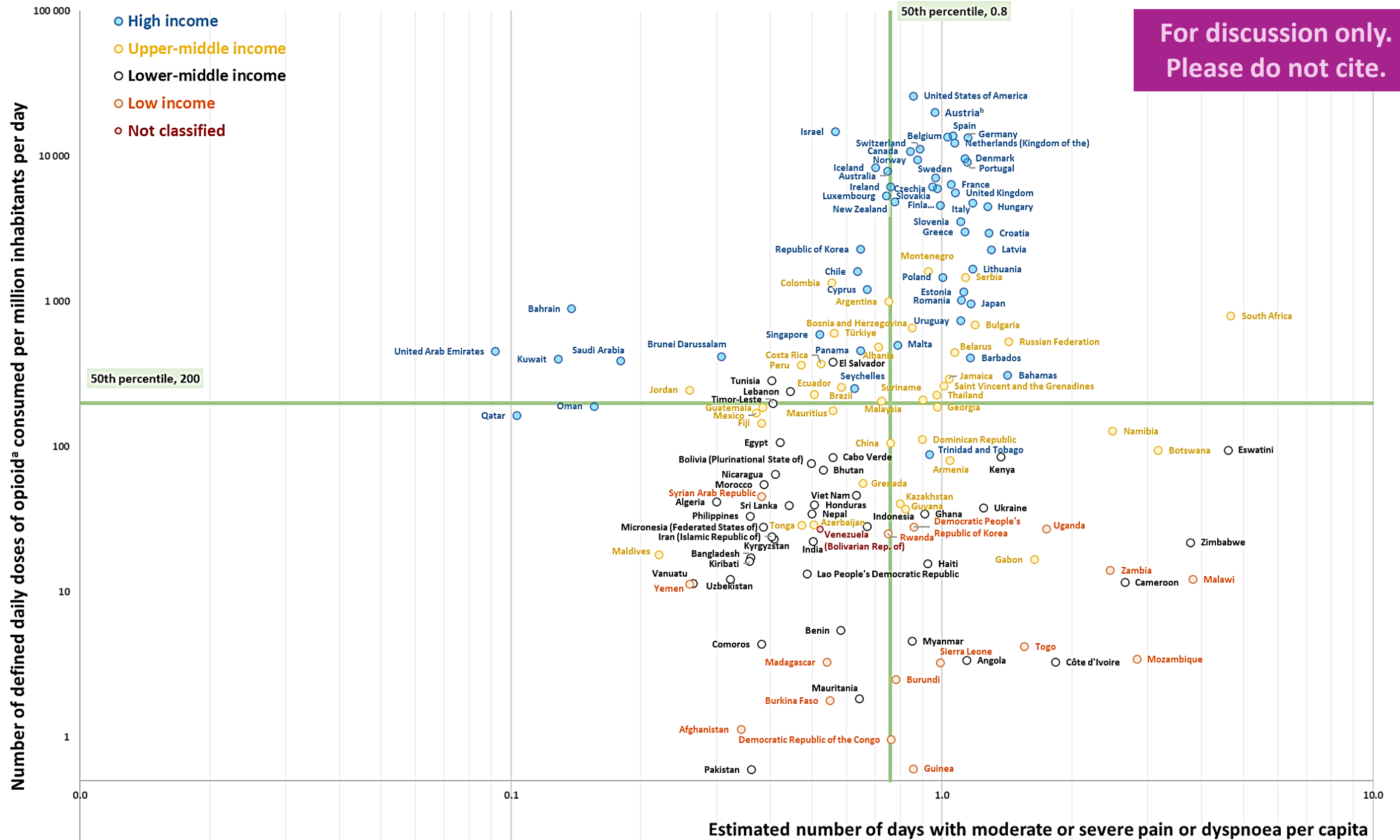
Cultivation^a Production of active pharmaceutical ingredients



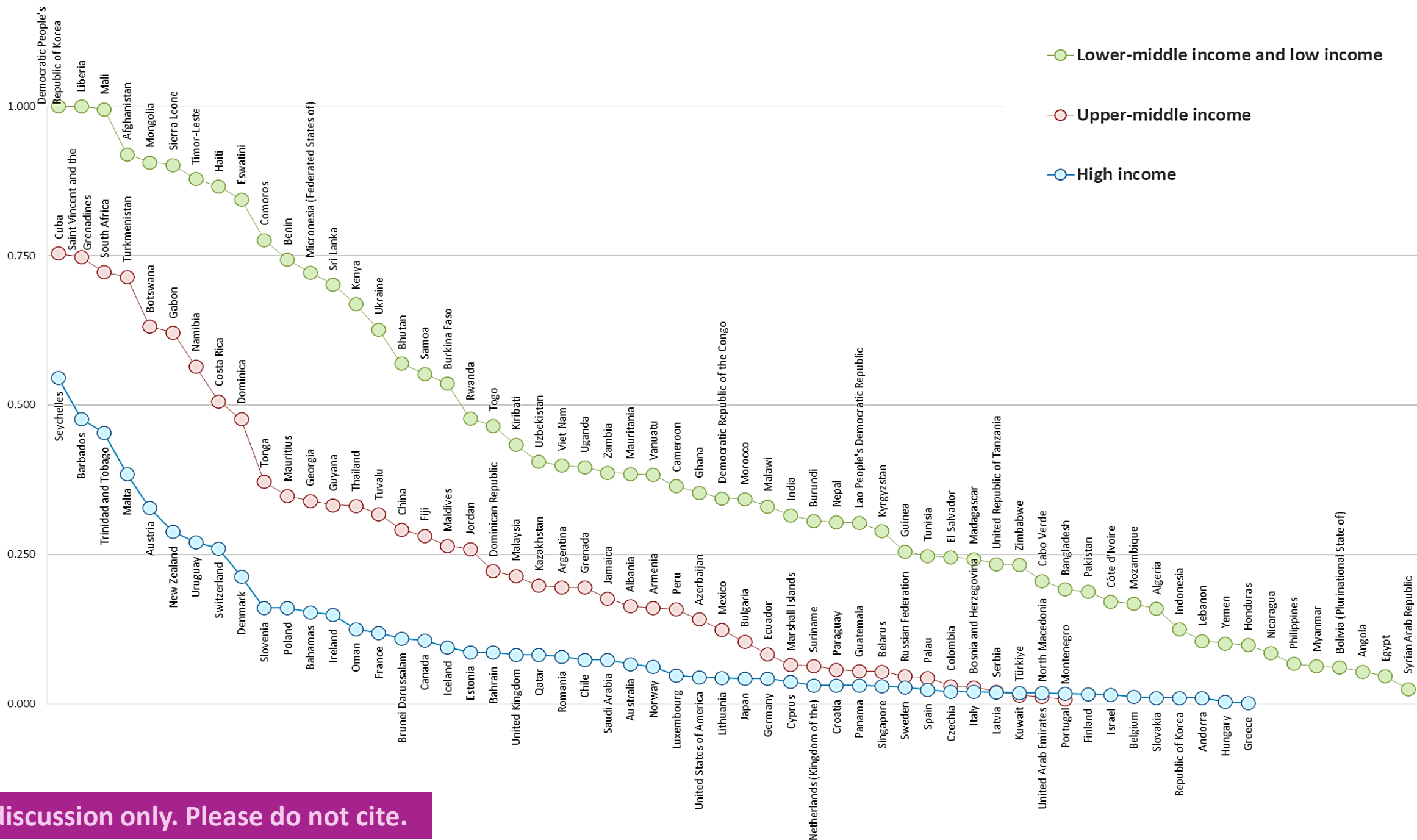
Distributed for consumption (kg)

By country^b By WHO region By World Bank country income group





Proportion of morphine to total consumption of opioids^a



For discussion only. Please do not cite.

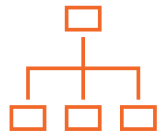
Enablers and barriers to access are often “two sides of the same coin”

Enablers



Barriers

Good governance



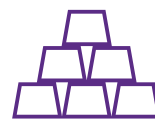
- Regulations or policies
- Medicines/therapeutics committees
- Clinical supervision, formal audit and feedback

Legislative or policy related factors



- Overly focused on preventing non-medical use
- Prescribing/Dispensing restrictions and administrative reqs

Adequate resources



- Predictable, stable and adequate funding
- Medicines and equipment to support the safe use

Service-related barriers



- Irregular availability
- Lack awareness of the availability
- Unaffordable price and costs
- Long distance or poor transportation

Sufficient capacity



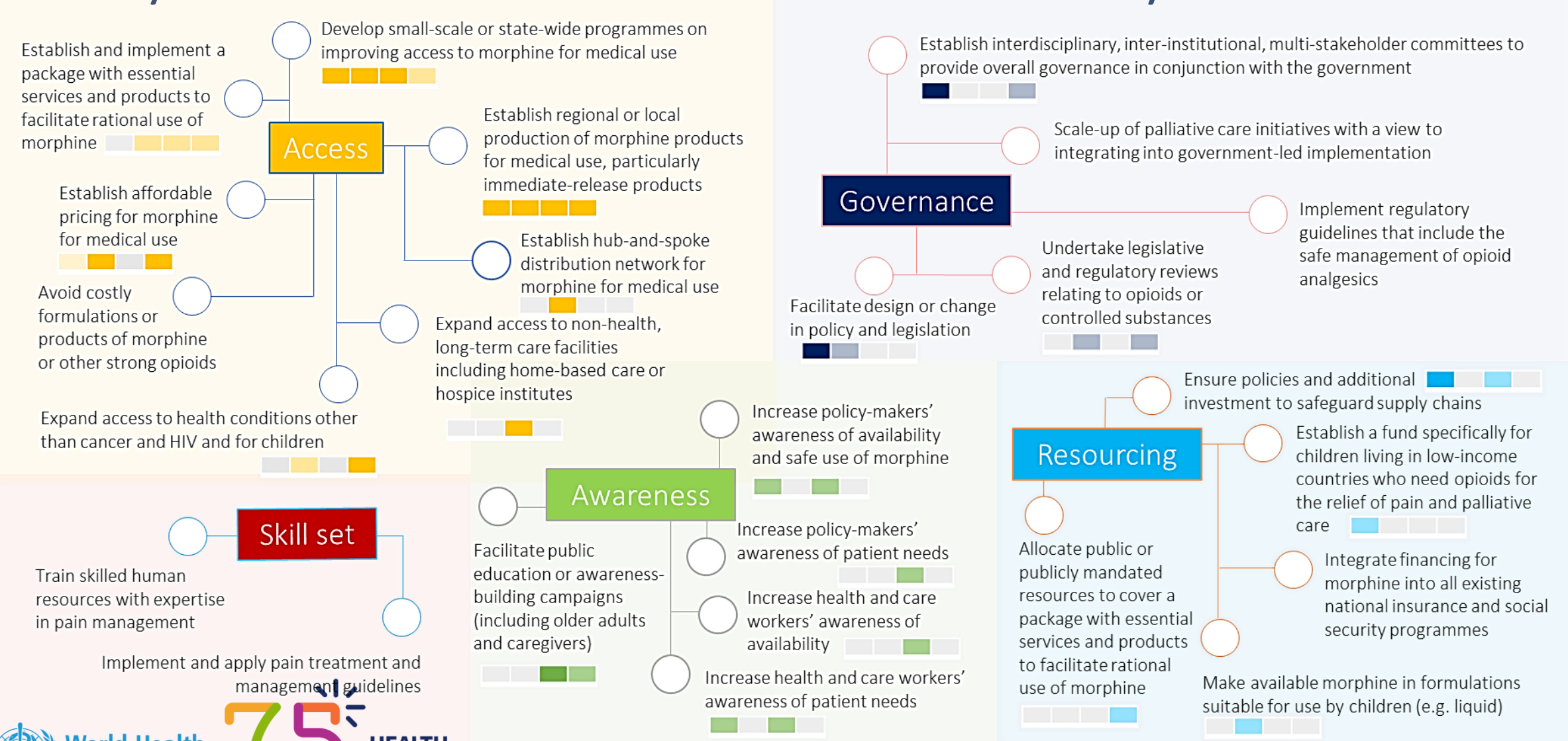
- Skilled workforce
- Training, patient and public education

Attitudes and perceptions



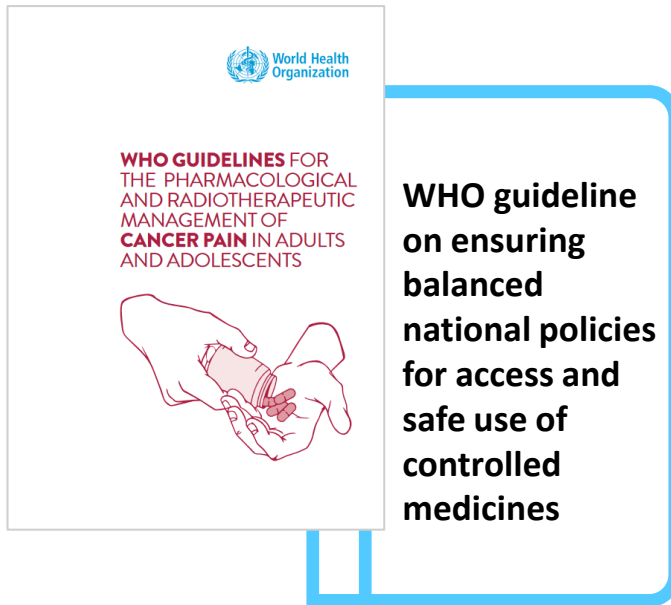
- Fearful of risks
- Associate morphine use only at the end of life, general social stigma
- Low trust

Priority areas for action identified in a WHO survey



WHO work to improve safe access to controlled medicines

Technical Guidance



Policy

WHO Expert Committee on Drug Dependence (ECDD)



Country support

Extent and causes of global variations in access to morphine for medical use and actions to improve safe access through balanced policy

Joint UNODC-WHO Programme on Drug Dependence Treatment and Care

Country support



World Health Organization





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