

# Ensuring balance in national policies on controlled substances

GUIDANCE FOR AVAILABILITY AND ACCESSIBILITY  
OF CONTROLLED MEDICINES

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# PREFACE

The international drug control treaties came into being to prevent the abuse of substances that can induce dependence. The universal adoption of the treaties and their implementation continue to be highly effective in preventing the diversion of drugs from licit to illicit markets in international trade and in protecting society from the consequences of dependence. However, equal emphasis has not been placed on the other fundamental objective of the treaties of ensuring that controlled substances are available for medical and scientific purposes. As a result, the health benefits that can be derived from medicines containing controlled substances remain inaccessible to the large majority of people around the world.

The majority of substances controlled under the international drug control treaties, notably narcotic drugs and psychotropic substances, have a variety of medical uses. Opioid analgesics, such as codeine and morphine, and antiepileptics, such as lorazepam and phenobarbital, are considered as essential medicines by the World Health Organization. There is broad consensus that opioid analgesics are indispensable for the treatment of moderate to severe pain and some, like methadone and buprenorphine, are increasingly used for the treatment of drug dependence. The widespread recognition of the therapeutic value of controlled substances has led in recent years to a substantial increase in their consumption. However, this increase has occurred predominantly in developed countries. In contrast, the availability of controlled substances has remained very low in most developing countries and is far from adequate to meet the medical needs of their populations. Unless remedial measures are implemented, the gap in the availability of controlled substances, namely opioid analgesics, will widen as the number of patients diagnosed with cancer and AIDS in developing countries rises.

There are many reasons to account for the inadequate availability of controlled substances for medical purposes. Some relate to the economic and social development of a country and affect the supply of medicines in general. Others are specific to controlled substances and operate within the specific regulatory system that exists in some countries for the manufacture, prescription and distribution of such substances. In some countries, laws and regulations intended to prevent the misuse of controlled substances are overly restrictive and impede patient access to medical treatment with such substances. Such situations can arise when insufficient attention is paid to the impact of regulations on the supply of controlled substances for medical purposes. Yet preventing the abuse of controlled substances and ensuring their availability for licit uses are complementary, and not mutually exclusive, objectives of the international drug control treaties. An effective drug control regime that complies with the spirit of the drug control treaties should therefore strike the right balance between the considerations given to these two aims.

Undue regulatory restrictions often have their origins in poor understanding among policy makers about controlled substances and their therapeutic value. Moreover, in many countries, inadequate knowledge and fear of dependence are key reasons behind the unwillingness of health professionals to prescribe controlled substances. To address these issues, policy makers need to go a step further than relaxing regulatory restrictions to availability: they should devise and implement enabling policies that promote widespread understanding about the therapeutic usefulness of controlled substances and their rational use. Health professionals should be trained in prescribing and administering controlled substances. Patients should be informed about the benefits and risks of using controlled substances. Drug control and law enforcement personnel should be sensitized to their medical and scientific necessity. Promoting dialogue among all these sectors is also essential to foster understanding and dispel misconceptions about the medical use of controlled substances. Furthermore, it is by integrating the concerns of all sectors that influence the use of controlled substances that policies can achieve the optimal balance between ensuring access and preventing abuse.



Ensuring that controlled medicines reach those patients who need them most is a multifaceted challenge. As such, it demands a response that is applied on many fronts and that requires the involvement of and cooperation among many sectors of Government and society. This response should be rooted in the recognition that controlled substances are indispensable for medical and scientific purposes. This recognition means that ensuring access to controlled substances should be given due importance on the public health agenda of countries. This recognition should also be at the source of the strong and sustained support that all Governments must provide to the complex task of removing impediments to the availability of controlled medicines and promoting their rational use.

Ensuring the adequate availability of controlled substances for medical and scientific purposes is one of the objectives of the international drug control treaties that has yet to be universally achieved. As the guardian of the international drug control treaties, the International Narcotics Control Board (INCB) has often called upon Governments to give to this treaty objective the attention that it deserves in their drug control policies. It is to assist Governments in this task that WHO, with the support of INCB, developed the first version of the present guidelines ten years ago. Today, controlled substances continue to be important for the relief from pain and suffering and have been recognised to be essential for treating some of the most debilitating diseases and conditions that afflict our societies. It is therefore more than ever an imperative to achieve a balance in controlled substances policies so that these work to protect societies from the misuse of controlled substances without depriving them from their immense medical and scientific benefits.

Hamid Ghodse  
President  
International Narcotics Control Board

# FOREWORD

These new World Health Organization (WHO) policy guidelines *Ensuring balance in national policies on controlled substances: guidance for availability and accessibility of controlled medicines* build on a previous set of guidelines, *Achieving balance in national opioids control policy: guidelines for assessment*, published in 2000.

The 2000 document primarily addressed the need to address pain in cancer patients. However, WHO estimates that every year 5.5 million terminal cancer patients still suffer moderate to severe pain that is not managed at all. There is therefore a continued need for guidance in this area.

Cancer, however, is not the only cause of pain. WHO estimates that tens of millions of people experience unrelieved pain from different diseases and conditions other than cancer, and therefore require access to medicines (many of which are controlled) to relieve pain.

And controlled medicines are not only used to relieve pain. Better access to different controlled medicines could prevent for instance 130 000 new HIV infections among injecting drug users, and around 75 000 cases of maternal death.

The new guidelines cover a wider range of medicines and signal aspects that were previously not covered, but that should be considered while working on improving access: human rights, gender and the public health perspective.

The challenge now is to implement them. WHO commits to helping countries use the guidelines, assisting them in carrying out assessments of legislation and policies and assisting in strategies to overcome the current barriers for access.

Dr Carissa F. Etienne  
Assistant Director-General  
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# EXECUTIVE SUMMARY

*Ensuring balance in national policies on controlled substances: guidance for availability and accessibility of controlled medicines* provides guidance on policies and legislation with regards to *availability, accessibility, affordability* and *control* of medicines made from substances regulated under the international drug control conventions, herein referred to as "controlled medicines". Their scope encompasses "all controlled medicines", but with a specific focus on essential medicines. Controlled medicines play an important role in several areas of medicine, including pain treatment, treatment of opioid dependence, emergency obstetrics, psychiatry and neurology.

The availability, accessibility and affordability of controlled medicines are important issues for all countries, but problematic for most of them. The World Health Organization (WHO) promotes governments, civil society and other interested individuals to strive for the maximum public health outcome of policies related to these medicines. WHO considers the public health outcome to be at its maximum (or "balanced") when the optimum is reached between maximizing access for rational medical use and minimizing substance abuse. Policy-makers, academia, civil society and other individuals whose area of work or interest is drug control or public health may potentially work with these guidelines in order to ensure that better use is made of controlled medicines and that more patients benefit from the advantages that their rational use can offer.

All countries have a dual obligation with regard to these medicines based on legal, political, public health and moral grounds. The dual obligation is to ensure that these substances are available for medical purposes *and* to protect populations against abuse and dependence. Countries should aim at a policy that ultimately achieves *both* objectives; in other words, a "balanced policy".

The core legal basis for this obligation can be found in the international drug control conventions. Legal principles supporting national responsibility to ensure availability for medicinal purposes is also expressed in several legal instruments elaborating the international right to health. The political grounds can be found in various Millennium Development Goals, which cannot be achieved without controlled medicines. From the public health perspective, there are many societal benefits, including cost savings and reduction of transmission of infectious disease. Obviously, there is a moral obligation on governments to prevent people from suffering or dying if this is in any way preventable.

However, WHO estimates that every year tens of millions of people suffer disease, moderate to severe pain and ultimately death due to not having access to controlled medicines, including:

- 1 million end-stage HIV/AIDS patients;
- 5.5 million terminal cancer patients;
- 0.8 million patients suffering injuries caused by accidents or violence;
- Patients with chronic illnesses;
- Patients recovering from surgery;
- Women in labour (110 million births each year);
- Paediatric patients;
- 130 000 preventable new HIV infections and an unknown number of other blood-borne infections;
- 75 000 women who die during childbirth.

After 1986, the total global consumption of morphine increased significantly, but the increase only occurred in a limited number of industrialized countries. Approximately 80% of the world's population does not have access to morphine for pain relief. For the pharmacological treatment of dependence syndrome, only 70 countries have services that are operational, while globally only 8% of injecting drug users receive this therapy.

Controlled medicines may be unavailable, inaccessible or unaffordable for a variety of reasons, including:

- legislation and policy issues;
- lack of knowledge and societal attitude;
- economic aspects.

Governments should therefore work continuously on *all* of these aspects in order to make controlled medicines available, accessible and affordable.

This document provides 21 guidelines for working on the improvement of availability, accessibility and affordability of controlled medicines from a policy perspective. They relate to seven aspects of policy and legislation:

- content of drug control legislation and policy (Guidelines 1 and 2);
- authorities and their role in the system (Guidelines 3 to 6);
- policy planning for availability and accessibility (Guidelines 7 to 10);
- healthcare professionals (Guidelines 11 to 14);
- estimates and statistics (Guidelines 15 to 17);
- procurement (Guidelines 18 to 20);
- other (Guideline 21).

For each guideline, an explanation is provided, as well as the legal background and/or justification for the guideline. A Country Assessment Checklist is also provided that enables users of the guidelines to check the extent to which they are adhered to in a particular country.

The guidelines may be used by governments, health professionals and others as a national policy and legislation evaluation tool, by providing a basis for formulating new policies and legislation or improving existing policies and legislation; they may also be used as an educational tool to inform interested parties about the relationship between national drug control policy and legislation and the availability and accessibility of controlled medicines. Countries who wish to formulate new policy in this area, or improve existing policies and legislation may also want to work with WHO's Access to Controlled Medications Programme (ACMP). The ACMP was jointly developed by the International Narcotics Control Board (INCB) and WHO, and is operated by WHO.

This publication also includes several annexes and a CD-ROM that provide additional documentation.

The use of these guidelines and the Country Assessment Checklist may enable governments to systematically identify and assess policy barriers, and gradually progress towards a situation where controlled medicines are both readily available and accessible.

With the publication of this document, the previous guidelines *Achieving balance in national opioids control policy: guidelines for assessment* (2000) are withdrawn.

# GLOSSARY <sup>a</sup>

**Abuse** is defined by the WHO Expert Committee on Drug Dependence as “persistent or sporadic excessive drug use inconsistent with or unrelated to acceptable medical practice” (1). Abuse of a substance is a term in wide use but of varying meaning. The term “abuse” is sometimes used disapprovingly to refer to any drug use at all, particularly of illicit drugs. Because of its ambiguity, “abuse” is not used in ICD-10, except in the case of non-dependence-producing substances; harmful use and hazardous use are the equivalent terms in WHO usage, although they usually relate only to effects on health and not to social consequences (2). The international drug conventions use the word “abuse” and not “misuse” or “harmful and hazardous use”; therefore, these guidelines use this word frequently, in particular when in relation to the conventions or their objectives.

**Accessibility** is the degree to which a medicine is obtainable for those who need it at the moment of need with the least possible regulatory, social or psychological barriers.

**Affordability** is the degree to which a medicine is obtainable for those who need it at the moment of need at a cost that does not expose them to the risk of serious negative consequences such as not being able to satisfy other basic human needs.

**Agonist** is a substance that binds to a receptor of a cell and triggers a response by that cell. Agonists often mimic the action of a naturally occurring substance.

**Analgesic** is a medicine that reduces pain.

**Antagonist** is a substance that blocks the action of an agonist.

**Availability** is the degree to which a medicine is present at distribution points in a defined area for the population living in that area at the moment of need.

**Consumption statistics** have to be reported by governments to the International Narcotics Control Board (INCB) annually and represent the amounts of narcotic drugs that were distributed in the country to the retail level, i.e. to hospitals, pharmacies and practitioners.

**Controlled medicines** are medicines containing controlled substances.

**Controlled substances** are the substances listed in the international drug control conventions.

**Convention** is a formal agreement between States. The generic term “convention” is thus synonymous with the generic term “treaty”. Conventions are normally open for participation by the international community as a whole, or by a large number of States. Usually the instruments negotiated under the auspices of an international organization are entitled conventions (3, 4).

**Defined Daily Dose (DDD)** is the assumed average maintenance dose per day for a medicine used on its main indication in adults (5).

**Dependence** is defined by the WHO Expert Committee on Drug Dependence as “A cluster of physiological, behavioural and cognitive phenomena of variable intensity, in which the use of a psychoactive drug (or

<sup>a</sup> References to this guidelines document can be found on the CD-ROM and on the internet at [www.who.int/entity/medicines/areas/quality\\_safety/ReferencesEnsBal.pdf](http://www.who.int/entity/medicines/areas/quality_safety/ReferencesEnsBal.pdf)

drugs) takes on a high priority. The necessary descriptive characteristics are preoccupation with a desire to obtain and take the drug and persistent drug-seeking behavior. Determinants and problematic consequences of drug dependence may be biological, psychological or social, and usually interact" (6). Dependence is clearly established to be a disorder. WHO's *International classification of diseases, 10<sup>th</sup> Edition (ICD-10)* (7) requires for **Dependence syndrome** that three or more of the following six characteristic features have been experienced or exhibited:

- (a) a strong desire or sense of compulsion to take the substance;
- (b) difficulties in controlling substance-taking behaviour in terms of its onset, termination, or levels of use;
- (c) a physiological withdrawal state when substance use has ceased or been reduced, as evidenced by: the characteristic withdrawal syndrome for the substance; or use of the same (or a closely related) substance with the intention of relieving or avoiding withdrawal symptoms;
- (d) evidence of tolerance, such that increased doses of the psychoactive substance are required in order to achieve effects originally produced by lower doses;
- (e) progressive neglect of alternative pleasures or interests because of psychoactive substance use, increased amount of time necessary to obtain or take the substance or to recover from its effects;
- (f) persisting with substance use despite clear evidence of overtly harmful consequences, such as harm to the liver through excessive drinking, depressive mood states consequent to periods of heavy substance use, or drug-related impairment of cognitive functioning; efforts should be made to determine that the user was actually, or could be expected to be, aware of the nature and extent of the harm.

The Expert Committee on Drug Dependence (ECDD) concluded that "there were no substantial inconsistencies between the definitions of dependence by the ECDD and the definition of dependence syndrome by the ICD-10" (6).

**Diversion** refers to the movement of controlled drugs from licit to illicit distribution channels or to illicit use.

**Essential medicines (for children)** are those medicines that are listed on the WHO Model List of Essential Medicines or the WHO Model List of Essential Medicines for Children. Both model lists present a list of minimum medicine needs for a basic healthcare system, listing the most efficacious, safe and cost-effective medicines for priority conditions. Annex 1 provides a list of controlled medicines also included on these Lists.

**Estimates** of the requirements for controlled substances for legitimate purposes have to be submitted to INCB by the national competent authority. For narcotic drugs and for certain precursor chemicals, estimates have to be submitted to INCB annually and for psychotropic substances, simplified estimates (known as assessments) have to be submitted at least every three years.

**International drug control conventions** are the Single Convention on Narcotic Drugs of 1953 as amended by the 1972 Protocol, the Convention on Psychotropic Substances of 1971, and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

**Law** refers to a set of rules on a specific topic enacted by the legislative body at the national, state or local level and having binding legal force.

**Legislation** refers to all rules having binding legal force at the national, state or local level.

**Maintenance therapy (or opioid substitution therapy)** with long-acting opioid agonists for the treatment of opioid dependence involves relatively stable doses of the agonists (usually methadone or buprenorphine) prescribed over prolonged periods of time (usually more than six months), which allows stabilization of brain functions and prevention of craving and withdrawal (8).

**Misuse (of a controlled substance)** for the purposes of these guidelines, is defined as the non-medical and non-scientific use of substances controlled under the international drug control treaties or under national law.

**Narcotic drugs** is a legal term that refers to all those substances listed in the Single Convention.

**National authority**, in these guidelines, refers to any government institution involved with the issues discussed in this document. The term applies not just to national government institutions but may equally apply to other relevant institutions in the national territory involved with these issues, such as federal, state or provincial institutions.

**National competent authority**, in these guidelines, refers to any government agency responsible under its national law for the control or regulation of a particular aspect of the country's controlled substances legislation, in particular to issue certificates and authorizations for the import and export of narcotic drugs and psychotropic substances (9).

**Opioid** means literally "opium-like substance". It can be used in different contexts with different but overlapping meanings:

1. Botanical: chemical substances belonging to the class of alkaloids produced by the poppy plant (*Papaver somniferum* L.). They can also be called natural opioids. Some of them (e.g. morphine and codeine) have analgesic properties ("pain killers"); others do not.
2. Chemical: chemical substances having similar structural formulas as morphine, codeine and other natural opioids (the benzylisoquinoline structure). They may be natural or synthetic. An example of a (semi-)synthetic opioid is buprenorphine.
3. Pharmacological: chemical substances having similar pharmacological activity as morphine and codeine, i.e. analgesic properties. They can stem from the poppy plant, be synthetic or even made by the body itself (endorphins), and they may be structurally related to morphine or not. An example of a synthetic opioid not structurally related to morphine is methadone.

**Overly restrictive law or regulation:** In these guidelines, the term "overly restrictive law or regulation" refers to drug regulatory provisions that either:

- a) do not materially contribute to the prevention of misuse of the controlled medicines but do create an impediment to their availability and accessibility; or
- b) have the potential to prevent the misuse of controlled medicines but disproportionately impede their availability and accessibility.

Whether a drug regulatory provision disproportionately impedes availability and accessibility of controlled medicines must be determined in each individual case and will depend on context, the extent of its contribution to preventing the misuse of the medicines, the extent to which it impedes the availability and accessibility of controlled medicines, and the availability of other control measures that could provide a similar prevention but interfere less with the availability and accessibility of the medicine.

**Party or State Party** to a treaty is a country that has ratified or acceded to that particular treaty, and is therefore legally bound by the provisions in the instrument (3).

**Preamble** is an introductory statement (e.g. to a convention) (10).

**Psychotropic substances** is a legal term that refers to all those substances listed in the Convention on Psychotropic Substances.

**Rational (medical) use**, for the purposes of these guidelines, is defined as the appropriate use of a medicine by both health professionals and consumers in their respective roles. Rational medical use aims at meeting the clinical needs of the individual patient by prescribing, dispensing, and administering effective medicines for the medical condition of the patient, at the adequate dose, within the required time schedule and for the

required amount of time to treat or cure the patient's medical condition; it should also enable the patient to adhere to such treatment.

**Regulation** refers to a set of rules on a specific topic with binding legal force at the national, state or local level and enacted by an administrative body to which the authority to issue such rules has been delegated by the national, state or local legislative body.

**Single Convention** refers in this publication to the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs, 1961 (11).

**Tolerance** refers to a reduction in the sensitivity to a pharmacological agent following repeated administration, in which increased doses are required to produce the same magnitude of effect.

**Withdrawal syndrome** is the occurrence of a complex (syndrome) of uncomfortable symptoms or physiological changes caused by an abrupt discontinuation or a dosage decrease after repeated administration of a pharmacological agent. Withdrawal syndrome can also be caused by the administration of an antagonist.



# INTRODUCTION TO THE GUIDELINES

## Purpose, target and scope

The **purpose** of these guidelines is to provide authoritative guidance on policies and legislation with regards to *availability, accessibility, affordability* and *control* of medicines made from substances that are controlled under the international drug control conventions (11–13).<sup>b</sup> In this document, these medicines will be referred to as “controlled medicines”.

The availability, accessibility and affordability of controlled medicines are important issues for all countries, but problematic for most of them. The World Health Organization (WHO) encourages governments, civil society and other interested individuals to strive for the maximum public health outcome of policies related to these medicines. WHO considers the public health outcome to be at its maximum (or “balanced”) when the optimum is reached between maximizing access for rational medical use and minimizing hazardous or harmful use.

It is hoped that these guidelines, by identifying and overcoming the regulatory and policy barriers to the rational use of controlled medicines, will enable governments to achieve better treatment of those patients that require them.

The guidelines' **target audience** (those groups and individuals whom it is envisaged will be encouraged to utilize this document) is:

- policy-makers, regulators (in government, administrative departments, national competent authorities) and politicians;
- academia and civil society;
- healthcare professionals and their organizations;
- individuals (including patients and their families) and organizations whose area of work or interest is drug control or public health.

The **scope** of these guidelines is “all controlled medicines”. These are medicines made from substances controlled internationally under the Single Convention on Narcotic Drugs (further called “Single Convention”) and under the Convention on Psychotropic Substances. It also includes medicines made from precursors regulated under the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. Furthermore, they could also be other substances controlled under national drug laws and regulations.

The guidelines pay special attention to those medicines that are also listed on the WHO Model List of Essential Medicines and on the WHO Model List of Essential Medicines for Children,<sup>c</sup> because these medicines are essential for health and health care. In addition, governments should ensure balance in policies and legislation with regard to other controlled medicines that are not listed as “essential medicines”.

<sup>b</sup> Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol; Convention on Psychotropic Substances, 1971; United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988.

<sup>c</sup> See Annex 1.

## Background

Controlled medicines play an important role in several medical areas. Opioids are used to treat pain (opioid analgesia), and to treat opioid dependence (long-acting opioid agonist therapy). Other controlled medicines are essential in emergency obstetrics (ergometrine, ephedrine) or used as anxiolytics and hypnotics (benzodiazepines) or as anti-epileptics (phenobarbital and benzodiazepines).

There are a number of issues related to balanced policies and legislation that are covered by other documents. For example, guidance for actual treatment is covered by a number of WHO treatment guidelines that have been or will be developed with involvement of a group of international experts through a transparent evidence-based process that aims to ensure their universal applicability. There are WHO treatment guidelines on opioid dependence, cancer pain (including cancer pain in children), emergency obstetrics and HIV/AIDS. Treatment guidelines relevant to this document are listed in Annex 2.

There are also a number of documents addressing practical aspects for implementing the recommendations from this guidelines document, such as the UNODC publication *A 'step-by-step' algorithm for the procurement of controlled substances for substitution treatment*, (practical information on importation of opioids) (14). Furthermore, *Guidelines for the international provision of controlled medicines for emergency medical care* may be applied to disaster relief settings (15). Currently, WHO and INCB are jointly developing guidelines for estimating requirements for controlled substances.

### The central principle of "balance"

*The central principle of "balance" represents a dual obligation of governments to establish a system of control that ensures the adequate availability of controlled substances for medical and scientific purposes, while simultaneously preventing abuse, diversion and trafficking. Many controlled medicines are essential medicines and are absolutely necessary for the relief of pain, treatment of illness and the prevention of premature death. To ensure the rational use of these medicines, governments should both enable and empower healthcare professionals to prescribe, dispense and administer them according to the individual medical needs of patients, ensuring that a sufficient supply is available to meet those needs. While misuse of controlled substances poses a risk to society, the system of control is not intended to be a barrier to their availability for medical and scientific purposes, nor interfere in their legitimate medical use for patient care (16).*

## A dual obligation, a quadruple imperative

Countries have a dual obligation with regard to these medicines based on a quadruple imperative, which is based on legal, political, public health and moral grounds. They must ensure that these substances are available for medical purposes *and* they must protect their populations against abuse and dependence. Indeed, here lies the challenge for both public-health and drug-control authorities. WHO promotes policies that simultaneously strive for minimizing substance abuse and maximizing access for rational medical use. The combination that leads to the maximum public health outcome is the optimum between these two elements, and a policy leading to this optimum can be called a "balanced policy" (See box above, The central principle of "balance"). WHO's work towards balanced policies is supported by the INCB and the Commission on Narcotic Drugs (CND) in its Resolution 53/4 (in paragraph 10 and also in paragraphs 4, 6 and 9) (16, 17).

Moreover, in 2008, the United Nations' Special Rapporteur on the prevention of torture and cruel, inhuman, or degrading treatment or punishment, and the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, jointly wrote a letter to the CND on human rights aspects of drug control, in which they requested that "national drug control laws recognize the indispensable nature of narcotic and psychotropic drugs for the relief of pain and suffering, and guarantee adequate availability of those medicines for legitimate medical uses, including opioid analgesics and opioids for substance dependence programmes" (18).

### **Legal imperative**

The obligation to make controlled medicines available for medical purposes finds its legal basis in the international drug control conventions, which state 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*" (11).<sup>d</sup> Human rights principles supporting the duty to ensure adequate availability of controlled medicines for medicinal purposes are also contained in international legal instruments expressing the international right to health. A key instrument in this regard is the WHO Constitution, the first international legal instrument expressing the right to health. In the WHO Constitution, the right to health is broadly formulated as follows: "*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: Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. 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.*" (19).

Almost all countries worldwide are party to the international drug control conventions and have thus legally committed their governments to making controlled substances available for medical purposes. In addition, most countries are party to the WHO Constitution and/or the International Covenant on Economic, Social and Cultural Rights (20), both of which recognize the right to health. For specific controlled medicines, such as those used in obstetric emergencies, other human rights instruments may be applicable, including the right to life and provisions specifically related to the rights of women to health (21, 22).

### **Political imperative**

In September 2000, the United Nations adopted the United Nations Millennium Declaration (23) urging their nations to reduce extreme poverty and setting out a series of targets with a recommended completion date of 2015. These have become known as the Millennium Development Goals. The eight Millennium Development Goals (MDGs) form a blueprint that has been agreed upon by all of the world's countries and all leading development institutions.

Several MDGs affect essential medicines either directly or indirectly, including controlled medicines that are also listed as essential medicines. In particular, MDGs include:

- "To encourage the pharmaceutical industry to make essential drugs more widely available and affordable for all who need them in developing countries" (MDG 8e);
- "...To have reduced maternal mortality by three quarters, and under-five child mortality by two thirds, of their current rates." (MDG 5a);
- "...To have, by then, halted, and begun to reverse, the spread of HIV/AIDS, the scourge of malaria and other major diseases that afflict humanity." (MDG 6a).

In the MDGs, countries also agreed to "spare no effort to ... strengthen the rule of law, as well as respect for all internationally recognized human rights" and "[t]o strive for the full protection and promotion in all our countries of civil, political, economic, social and cultural rights for all."

### **Public health imperative**

Drug control should not be approached as an objective in itself, but as a tool to optimize public health.

One focus should be the prevention of abuse and dependence; the other to avoid collateral harm. The outcomes should be judged both by the harms from abuse it prevents and the harm it causes through, for example, lack of access.

<sup>d</sup> This wording is from the Single Convention on Narcotic Drugs; the Convention on Psychotropic Substances contains similar wording for psychotropic substances.

Untreated pain may cause losses to society in the form of incapacity to work, caregivers becoming unproductive in society due to their caring role, and pain patients needing further attention if they do not receive adequate pain management. Treatment of dependence syndrome may re-socialize people who previously were incapable of work, and may serve to reduce petty crime and the risk of harmful behaviour by the individual; it may also reduce the transmission of infectious disease through unsafe injection. Programmes that provide long-acting opioid agonist treatment (or "substitution therapy")<sup>e</sup> are cost-effective for a country (24).

Treatment of neurological and psychiatric disorders, including epilepsy, will be more effective if the medicines needed for treatment are readily accessible. For emergency obstetric care, reducing the rate of maternal mortality is an important target which cannot be achieved without making the appropriate medicines available.

### ***Moral imperative***

Aside from a legal and a political obligation and from public health considerations, a moral imperative also exists to prevent suffering by making controlled medicines available and accessible; this is particularly true as suffering can be prevented at a relatively low cost and without too much effort.

Without any efforts for change, the current situation will continue, with every year tens of millions of people suffering from disease, moderate to severe pain or ultimately death (25). These include:

- 1 million end-stage HIV/AIDS patients;
- 5.5 million terminal cancer patients;
- 0.8 million patients suffering injuries caused by accidents and violence;
- patients with chronic illnesses;
- patients recovering from surgery;
- women in labour (110 million births each year);
- paediatric patients;
- 130 000 preventable new HIV infections and an unknown number of other blood-borne infections;
- 75 000 women who die during childbirth.

The consequences of a lack of availability of controlled medicines are severe and the numbers of patients afflicted are at least the same in magnitude as those afflicted by conditions that are recognized as major contributors to the world's burden of disease; in particular HIV, malaria and tuberculosis.<sup>f</sup>

## **Indispensability of controlled medicines in contemporary medical practice**

### ***Analgesia***

Pain is prevalent in almost all medical specialties, including in general practice, palliative care, oncology, internal medicine, haematology and surgery. Patients who are affected include people who have cancer, HIV, sickle-cell disease, or those who have had surgery or accidents.

Cancer patients may need pain relief at every stage of the disease. More than two thirds of patients with advanced cancer and about half of all patients with advanced HIV/AIDS will experience moderate to severe pain (25, 29, 30). In obstetrics, women may need pain relief during labour, surgery and post-surgery.

<sup>e</sup> The wording "substitution therapy" is misleading because it is not just replacing illicit drugs by officially approved drugs; there is evidence now that hormone levels are normalized and because of the slow onset of the medicines used, there is no immediate awarding sensation or "kick". Therefore, the terminology "long-acting opioid agonist therapy" or "opioid agonist therapy" is preferred.

<sup>f</sup> HIV: incidence: 2.7 million/yr, prevalence: 33.4 million/yr, mortality: 2.0 million/yr (2008) (26)

Malaria: incidence: 243 million/yr, mortality: 863 000/yr (2008) (27)

Tuberculosis: incidence: 9.4 million/yr, prevalence: 11.1 million/yr, mortality: 1.3 million (2008) (28)

For all of these patients, pain relief should be part of their overall treatment. Oral opioids are key components for the treatment of moderate to severe pain and several are regarded as essential medicines (25, 31, 32). Paracetamol (acetaminophen), acetylsalicylic acid, non-steroidal anti-inflammatory medicines (NSAIDs) when used alone and weak acting opioids (tramadol, codeine) are usually not effective in the case of moderate to severe pain. NSAIDs can have serious side-effects and should be used with caution on a chronic basis (33, 34). Despite a century of pharmaceutical chemistry, suitable alternatives to strong opioids for treatment of moderate to severe pain have yet to be found.

Unrelieved pain can impair all aspects of a person's life, impacting on emotional, physical and social functioning; unrelieved severe pain can even result in a wish for death to occur (35).

### ***Treatment of opioid dependence syndrome and prevention of HIV***

Globally, there are an estimated 16 million people who inject illicit drugs (36). The number of people who are dependent on opioids who do not inject is much higher. In 2008, UNODC estimated that globally, between 12.8 and 21.9 million people illicitly used opioids over the previous 12 months, with the prevalence ranging between 0.3% and 0.5% of the world's population aged 15 - 64 (37). Of the new HIV infections in Eastern Europe and Central Asia in 2005, 62% were due to injection drug use (38).

There is strong evidence for the efficacy of treatment of opioid dependence with long-acting opioid agonists such as oral methadone and buprenorphine which effectively reduce and prevent injecting drug use and thus contribute to containing hepatitis B and C and the HIV/AIDS epidemic. Treatment with long-acting opioid agonists also reduces mortality from heroin overdose by 90% (39). Moreover, it allows patients with opioid dependence to function more fully in society. Dependence is a disorder associated with neurobiological changes in opioid peptides and other neuropeptides that can be stabilized with long-acting opioid therapy (40); legislation should therefore focus on treatment, not punishment. However, it is estimated that, worldwide, only 8% of injecting drug users have access to treatment for opioid dependence (41).

### ***Other uses of essential controlled medicines***

Opioids are also used in anaesthesia and, additionally, morphine is used for treating dyspnoea and anxiety resulting from dyspnoea. Codeine and some other weak acting opioids are used to treat coughs and diarrhoea.

Ergometrine and ephedrine, two substances frequently diverted for the production of illicit drugs, play important roles in emergency obstetrics and can prevent maternal death. Each year, half a million women die during childbirth (42), about 120 000 of them from post-partum bleeding (43). Many of these lives could be saved if medicines to stop the bleeding were more widely available.

Ketamine is an essential medicine, pivotal for anaesthesia. In rural areas of developing countries in particular, ketamine is the only suitable and safe anaesthetic. Although not listed in the international drug treaties, ketamine is now under national control in approximately 50 countries worldwide. In 2006, the CND called upon governments "to consider controlling the use of ketamine by placing it on the list of substances controlled under their national legislation, where the domestic situation so requires" (44, 45). Ketamine is still under review by WHO's Expert Committee on Drug Dependence (46). National control policies with regard to ketamine should be balanced in order to ensure surgery is available to rural populations (47).

Other medicines are important for neurology and psychiatry, for example in the treatment of epilepsy, anxiety and sleeplessness. In some countries, overconsumption of benzodiazepines as hypnotics and anxiolytics occurs. When used as hypnotics and anxiolytics, they are indicated for use during a brief period in crisis situations only, but are often prescribed for extended periods. On the other hand, controlled medicines for the treatment of epilepsy, such as phenobarbital and benzodiazepines, may scarcely be available. In Africa, 80% of the population affected by epilepsy has no access to essential antiepileptic medicines (48).

Finally, controlled substances are important for scientific purposes, e.g. for medical research (including clinical trials), for research into dependence, and for use in forensic laboratories.

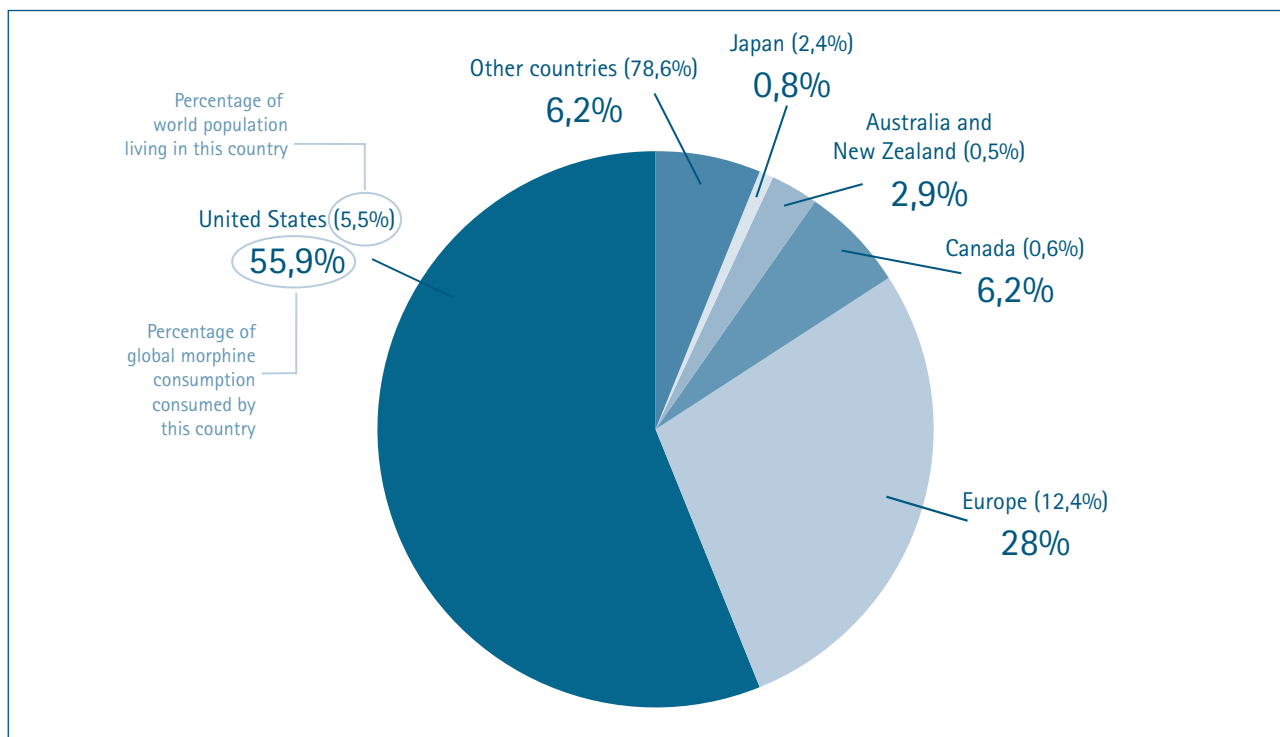
## Safety of controlled medicines

It should be recognized that controlled medicines when used rationally for medical purposes are safe medicines. Opioid analgesics, if prescribed in accordance with established dosage regimens, are known to be safe and there is no need to fear accidental death or dependence. A systematic review of research papers concludes that only 0.43% of patients with no previous history of substance abuse treated with opioid analgesics to relieve pain abused their medication and only 0.05% developed dependence syndrome (49). This may be explained by a postulated neurobiological mechanism (50).

## Current availability

The total global consumption of opioids increased significantly after 1986, when WHO introduced the Analgesic Ladder for cancer pain relief. However, the increase occurred in a limited number of mainly industrialized countries that represent only a small part of the world's population (51, 52). It is estimated that 80% of the world's population does not have access to morphine for pain relief (53).

MORPHINE: DISTRIBUTION OF CONSUMPTION, 2009



Source: INCB

Any statistics contain an inherent inaccuracy (usually from underreporting) and this will be equally true for the statistics on controlled substances. However, the statistics on narcotic drugs and psychotropic substances published by the INCB (53) can be considered as reliable, because the administrative systems provided for by the Single Convention and the 1971 Convention obligate governments to report statistical data to the INCB, which then investigates any inconsistencies.

For the treatment of opioid dependence syndrome, despite the fact that injecting drug use has been reported from almost every country in the world, only 70 countries (out of 193) have services where long-acting opioid agonist therapy is operational, and it is estimated that worldwide only 8% of injecting drug users receive this therapy (compared to 61% in Western Europe, where it is a standard treatment option) (41).

## **Impediments to availability, accessibility and affordability**

It is almost a century since the first international drug control convention came into force (54), and the drug control conventions that established the dual obligation of ensuring adequate availability of controlled medications and of preventing their misuse have existed for almost 50 years. Yet the obligation to prevent abuse of controlled substances has received far more attention than the obligation to ensure their adequate availability for medical and scientific purposes, and this has resulted in countries adopting laws and regulations that consistently and severely impede accessibility of controlled medicines.

The INCB and WHO have highlighted overly restrictive laws and regulations that impede the adequate availability and medical use of opioids (31, 32, 51, 55 - 58). As far back as 1989 (55), the INCB drew attention to some governments' overreaction to the drug abuse problem when "the reaction of some legislators and administrators to the fear of drug abuse developing or spreading has led to the enactment of laws and regulations that may, in some cases, unduly impede the availability of opiates". INCB also stated that "legislators sometimes enact laws which not only deal with the illicit traffic itself, but also impinge on some aspects of licit trade and use, without first having adequately assessed the impact of the new laws on such licit activity. Heightened concern with the possibility of abuse may also lead to the adoption of overly restrictive regulations which have the practical effect of reducing availability for licit purposes".

In each guideline of this document, the type of measures that contribute or do not contribute to the prevention of abuse and dependence and the type of measures that are an impediment to availability and accessibility for rational medical use are explained. Many practical examples of barriers at various levels are provided, including:

- legislation and policy;
- knowledge and societal attitude;
- economic aspects, including affordability.

In order to improve access, governments should work continuously on *all* of these aspects in order to make controlled medicines available, accessible and affordable.

## **Why and how to work with this document?**

### ***The imperative for evaluation of national drug control policies***

For a quarter of a century, attention has been drawn to the fact that the level of consumption of controlled medicines worldwide does not match the needs for health care. In some countries the consumption level has improved over this period, but in most countries there has been little significant change.

In 2010, the INCB stated that "discrepancies in the consumption levels of opioid analgesics in different countries continue to be very significant. Factors such as knowledge limitations and administrative barriers stricter than the control measures required under the 1961 Convention affect the availability of opioid analgesics". The INCB requested "the Governments concerned to identify the impediments in their countries to access to and adequate use" (52). Also, as INCB had done previously, CND and WHO have called on governments to evaluate their healthcare systems and laws and regulations, and to identify and remove impediments to the availability of controlled substances for medical needs (16, 31, 32, 51, 55 - 57).

### ***Using the guidelines***

The guidelines in the next chapter may be used by governments, health professionals and others. The guidelines can be used as:

- a policy and legislation evaluation tool;
- a basis for formulating new policies and legislation or improving existing policies and legislation;
- an educational tool to inform interested parties about the relationship between national drug control policy and legislation and the availability and accessibility of controlled medicines.

Strategies to make controlled medicines readily available and accessible include:

- review of legislation and its subsequent amendment;
- planning for improved availability, through
  - developing good annual estimates and statistics (and submitting them to the INCB);
  - integrating access to controlled medicines into health and disease control policies;
  - establishing adequate services where patients can obtain rational treatment without interruption;
  - education of healthcare professionals and the general public.

The need to evaluate policy is clear, but the process may not be. Several steps are recommended to governments.

- Designate a person or committee (for example, the national competent authority or health professionals) to study the guidelines. Governments may wish to organize a special meeting or workshop of regulators and healthcare practitioners to discuss and complete the Country Assessment Checklist (as some of the questions are legal ones and others are policy ones, in the case of a committee, it may be necessary to establish both a legal and a policy sub-committee);
- Obtain additional information from the key resource materials (see the CD-ROM);
- Obtain up-to-date copies of the national drug control policies and legislation;
- Use the Country Assessment Checklist to assess the legislation and the policies;
- Establish dialogue between policy-makers, academia and civil society to make the necessary changes.

For educational purposes, the guidelines can be distributed to the relevant governmental and nongovernmental organizations, especially to those individuals and groups who are involved in drug control and improvement of pain relief, cancer services, palliative care, treatment of dependence, medical education, etc.

Countries who wish to work on formulating new policy or improving existing policies and legislation may want to work with WHO's Access to Controlled Medications Programme (ACMP). The ACMP was jointly developed by INCB and WHO, and is operated by WHO. In its 2009 Report, the INCB recommended that "the Access to Controlled Medications Programme ... will provide effective assistance to Governments in promoting rational use of opioid analgesics. The Board calls upon Governments to support and cooperate with WHO in the implementation of the Access to Controlled Medications Programme" (52). Furthermore, the WHO Collaborating Centre for Pain Policy and Palliative Care (University of Wisconsin, Madison WI, United States) can assist in various ways and makes relevant resources available on its website.<sup>9</sup>

### ***Using the Country Assessment Checklist***

A Country Assessment Checklist is provided below that enables users to check the extent to which the guidelines in this document are adhered to in a given country. It may be used as a tool for the analysis of national policies and legislation.

The numbering refers to the guidelines and indicates whether a question is on legal or policy issues. This may enhance assessment by teams who want to split their work over policy and legal sub-teams.

For most questions, the answer that is most favourable for ensuring good access and availability to controlled medicines is represented in bold. Thus, for any question where the answer is not presented in bold, there is an opportunity to work on improvement. By working systematically on these issues, a country can gradually improve access and availability of controlled medicines. A systematic approach also necessitates subsequent completion of the Country Assessment Checklist at a later date.

<sup>9</sup> www.painpolicy.wisc.edu (accessed 31 December 2010).





GUIDELINES FOR ENSURING  
BALANCE IN NATIONAL  
POLICIES ON CONTROLLED  
SUBSTANCES

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# Content of drug control legislation and policy

## GUIDELINE 1

National drug control policies should recognize that controlled medicines are absolutely necessary for medical and scientific purposes.

It can be considered as a condition sine-qua-non for enabling and facilitating availability and accessibility of controlled medicines, that national policies are explicit about their objectives. National policies should recognize the necessity of controlled medicines and ensure they put in place policy statements to ensure implementation of the policies. Such statements would include those on improving access to all in need. Moreover, countries may want to establish this in their law, either as an objective or an obligation for the government. This would mirror the imperative stated in the international drug control treaties to make narcotic drugs and psychotropic substances available for medical use.

### Relevant international law<sup>h</sup> and principles

Single Convention on Narcotic Drugs, Preamble, paragraph 2 (11): "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."

Convention on Psychotropic Substances (59) Preamble paragraph 5: "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."

## GUIDELINE 2

Governments should comply with their international legal obligations to ensure adequate availability and accessibility of controlled medicines for all medical and scientific purposes through national legislation and drug control policies.

Governments have an international legal responsibility to comply with all the treaties to which they are a party. This responsibility does not just fall on one agency or sector but on the government as a whole. As such, drug control authorities need to comply not only with the drug control treaties but also with obligations that flow from other treaties, including international human rights instruments. Conversely, other government agencies have to ensure that legislation/regulations under their responsibility comply with international drug control conventions.

The international drug control conventions provide the basic framework for national drug control legislation. In its 2009 annual report, the INCB once again declared that: "One of the fundamental objectives of the international drug control treaties is to ensure the availability of narcotic drugs and psychotropic substances for medical and scientific purposes and to promote access to and rational use of narcotic drugs and psychotropic substances" (52).

International human rights treaties and other instruments provide a further source of guidance related to the availability and accessibility of controlled medicines. The right to health, which is recognized in some form by almost all countries, is secured in a number of treaties and other legal instruments (60). For example, the Constitution of the World Health Organization provides the first legal expression of the international right to health. In addition, Article 12 of the International

<sup>h</sup> For more details: see the original texts of the conventions.

Convention on Economic, Social and Cultural Rights (ICESCR) (61) further articulates the right to health.<sup>i</sup> The Committee on Economic, Social and Cultural Rights, established by ECOSOC, prepared General Comment 14 to further elaborate on the content of the right to health. Although technically non-binding as a matter of international law, the General Comment was designed by the Committee to serve as an authoritative interpretation of Article 12.

The international drug conventions and the principle of the right to health complement each other; the first consideration of the Preamble of the Single Convention reads: "The Parties [to this Convention], Concerned with the health and welfare of mankind ...".

Advocates argue that international human rights principles require that governments must provide essential medicines – which include controlled medicines – as part of their minimum core obligations under the right to health. In addition, other advocates have linked access to controlled medicines to the human rights obligation of governments to take measures to protect people under their jurisdiction from inhuman and degrading treatment (18).

In 2005, the UN's Economic and Social Council (ECOSOC) and the World Health Assembly urged countries to ensure the medical availability of opioid analgesics according to international treaties (62, 63).

In a 2009 report to the Human Rights Council (64), the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment declared that he "wishes to recall that, from a human rights perspective, drug dependence should be treated like any other health-care condition" (paragraph 71), and that "Given that lack of access to pain treatment and opioid analgesics for patients in need might amount to cruel, inhuman and degrading treatment, all measures should be taken to ensure full access and to overcome current regulatory, educational and attitudinal obstacles to ensure full access to palliative care" (paragraph 74(e)).

#### Relevant international law and principles

Single Convention, Article 4: "the parties shall take such legislative and administrative measures as may be necessary ... to limit exclusively to medical and scientific purposes the production, manufacture ... distribution ... use and possession of drugs".

Convention on Psychotropic Substances (59), Article 5, paragraph 2: "Each Party shall ... limit ... as it considers appropriate the manufacture ... distribution ... use and possession of substances in Schedules II, III and IV to medical and scientific purposes"<sup>j</sup>

Single Convention, Article 38, paragraph 1: Countries have an obligation to provide both prevention and treatment of substance dependence. The Article declares: "The Parties shall ... take all practicable measures for the prevention of abuse of drugs and for the ... treatment ... of the persons involved". The Convention on Psychotropic Substances, Article 20, paragraph 1, contains almost identical wording.

International Covenant on Economic, Social and Cultural Rights (ICESCR), Article 12 (61): "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 achieve the full realization of this right shall include ... the ... treatment and control of ... diseases [and] the creation of conditions which would assure to all medical service and medical attention in the event of sickness".

General Comment 14 to Article 12, ICESCR includes (60):

- ▶ The right of ... access to ... appropriate treatment of prevalent diseases, illnesses, injuries and disabilities, preferably at community level; the provision of essential drugs; and appropriate mental health treatment and care (paragraph 17);
- ▶ The importance of an integrated approach ... based on ... attention and care for chronically and terminally ill persons,

i 193 countries are Member States to the World Health Organization; 160 countries are parties to the ICESCR ([http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg\\_no=IV-3&chapter=4&lang=en](http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3&chapter=4&lang=en); accessed 3 January 2011).

j Stricter limitation is required for substances in Schedule I of the Convention on Psychotropic Substances, as is explained in Article 7. These substances are of limited medical use, but if they are needed, even their use can be allowed.

- sparing them avoidable pain and enabling them to die with dignity (paragraph 25);
- The right to healthy natural and workplace environments ... [and] the obligation of States parties ... to provide ... information campaigns ... with respect to HIV/AIDS [and] the abuse of ... drugs and other harmful substances (paragraphs 15 and 36);
- The core obligation ... to provide essential drugs, as from time to time defined under the WHO Action Programme on Essential [Medicines] (paragraph 43d);
- The core obligation ... to ensure equitable distribution of all health facilities, goods and services (paragraph 43e);
- The core obligation to ensure reproductive, maternal ... care (paragraph 44a);
- The core obligation ... to provide appropriate training for health personnel, including education on health and human rights (paragraph 44e).

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: Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. 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" (19).

Other human rights treaties relevant to the right to health exist as well, such as the Convention on the Rights of the Child (3) and others of regional importance, such as the African Charter on the Rights and Welfare of the Child (65), the African Charter on Human and Peoples' Rights (66), the [European] Convention for the Protection of Human Rights and Fundamental Freedoms (67), the European Social Charter of 1961 (68), and the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (69).

## Authorities and their role in the system

### GUIDELINE 3

Governments should designate a National Authority for ensuring adequate availability and accessibility of controlled medicines in health care.

The INCB recommends that "Governments should determine whether their national narcotic laws contain elements ... that take into account...the fact...that adequate provision must be made to ensure the availability of narcotic drugs for such purposes...[and] to ensure that administrative responsibility has been established and that personnel are available for the implementation of those laws." (51). Such an authority could be part of the National Competent Authority or a separate office, whatsoever is the most appropriate in the national situation.

### GUIDELINE 4

Governments should ensure that all authorities involved in developing and implementing policies on controlled substances cooperate and meet as necessary for the promotion of their availability and accessibility for medical and scientific purposes as well as the prevention of abuse, dependence syndrome and diversion.

To formulate and implement coherent drug control policies, countries need to ensure that relevant government agencies work in cooperation with each other and that their policies and regulations are closely aligned. In order to be effective, such meetings should be held as necessary, depending on national circumstances. Relevant agencies include drug control legislators, healthcare authorities, customs officials, police, and members of the judiciary. Their cooperation will allow for all participants to be more effective, and ensure synergy between their policies. Agencies will also develop a better understanding of each other's concerns, constraints and challenges, resulting in opportunities to collaborate jointly to achieve controlled medicines' availability for rational medical use and to decide on and implement the necessary measures for balancing national control policies. The National Authority referred to in Guideline 3 should be actively involved.

## **GUIDELINE 5**

Governments should ensure that there is a forum where drug control authorities and public health authorities cooperate and meet as necessary with health professional organizations and other stakeholders for the promotion of the availability and accessibility of controlled medicines for medical and scientific purposes, as well as the prevention of abuse, dependence syndrome and diversion.

Communication between relevant national authorities (including the National Authority to be designated under Guideline 3), health workers and other stakeholders is essential in order to ensure that each understands the other's aims and mandate. In order to be effective, such meetings should be held as necessary, depending on national circumstances. This will enable health workers and their associations to provide information on needs for controlled substances and to be aware of the concerns of regulators. In turn, regulators will be able to learn in more detail about the effects of legislation and policy on medical care and the importance of controlled medicines for both individual patients and public health in general.

Such cooperation could take the form of a National Advisory Board of relevant stakeholders, including government authorities, medical boards, representatives of health professionals, patients and health insurances, and those parts of the administration responsible for public health care requiring controlled medicines, including drug control enforcement officials and legislators. If appropriate, this could also include police, customs officials and members of the judiciary.

The overall mandate of the National Advisory Board would be to advise on how to achieve the balance between availability of controlled medicines for medical use and prevention of substance abuse and dependence. The work of the National Advisory Board, depending on composition and mandate, could comprise the following aspects:

- ▶ to assist the needs assessment for controlled medicines and to report on the degree of access;
- ▶ to advise on the promotion of rational use of controlled medicines, implementation of best practices, development of national treatment guidelines and implementation of international treatment guidelines.

## **GUIDELINE 6**

All government agencies, depending on their roles and obligations, should ensure that in the fulfilment of their duties, they do not impede health policies and access to legitimate treatment with controlled medicines. Health authorities should provide relevant information on treatment principles to drug law enforcement and other relevant agencies.

The conventions require prohibition of drug possession if not "under legal authority". As health workers "while performing therapeutic functions" do not need a license or a prescription, the professional possession of controlled medicines should be considered "under legal authority" and is therefore not prohibited. Similarly, patients who obtained controlled medicines on medical prescription from authorized dispensing pharmacies and health facilities possess such medicines "under legal authority".

The conventions place an obligation on governments to provide education to people who work on drug control. All agencies involved with drug control (for example, customs officials and the police), should therefore have sufficient knowledge of the government's health policy with regard to treatment with controlled medicines. Their knowledge should be sufficient to understand when it is lawful for patients and health professionals to be in possession of medicines and that they should not exert excessive control measures. This principle also applies to treatment of opioid dependence; law enforcement should not prevent such patients from undergoing treatment. Provision of information and education about treatment and use of controlled medicines should not be considered as promotion of illegal drugs and not lead to prosecution.

#### Relevant international law and principles

Single Convention, Article 38, paragraph 3, requires that governments "shall assist persons whose work so requires to gain an understanding of the problems of abuse of drugs and of its prevention". The Convention on Psychotropic Substances, Article 20, contains almost identical wording.

Single Convention, Article 33: prohibits "the possession of drugs except under legal authority". Article 30, paragraph 1.a: in case of distribution, a license is required, but (Article 30, paragraph 1.c) this "need not apply to persons duly authorized to perform and while performing therapeutic or scientific functions". Similarly, the supply or the dispensing of medicines to individuals requires a prescription (Article 30, paragraph 2.b.i) and therefore any patient who obtained his medicines with a prescription can be considered to possess his medicines under legal authority as mentioned in Article 33. Article 30, paragraph 2.b.i also declares that "this requirement need not apply to such drugs as individuals may lawfully obtain, use, dispense or administer in connexion with their duly authorized therapeutic functions".

Convention on Psychotropic Substances, Article 8, paragraph 1 requires licensing of distribution of substances listed in Schedules II, III and IV, but "licensing or other similar control measures need not apply to persons duly authorized to perform and while performing therapeutic or scientific functions" (Article 8, paragraph 3). Possession is also allowed "under legal authority", e.g. healthcare workers using the medicines professionally, or patients to whom medicines were prescribed (Article 5, paragraph 3).

Convention on Psychotropic Substances, Article 10, paragraph 2: "Each Party shall, with due regard to its constitutional provisions, prohibit the advertisement of such substances to the general public". (Note that this is limited to advertising).

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## Policy planning for availability and accessibility

### **GUIDELINE 7**

Governments should include the availability and accessibility of controlled medicines for all relevant medical uses in their national pharmaceutical policy plans. They should also include the relevant controlled medicines and relevant services in specific national disease control programmes and other public health policies.

Planning for availability through the formulation of policy plans is essential for defining and realizing the health policy objectives of a country. It is also essential for the realization of a country's international obligations with respect to the international drug conventions and human rights conventions.

The objective to make controlled medicines available and accessible for all medical and scientific purposes in the national medicines policy plan should be stipulated at the outset. Policies should also address availability of controlled medicines for scientific purposes, as research with these substances may be necessary for such use.

Only after establishing this general policy should specific policy plans be developed for individual diseases. As a minimum, countries should ensure that availability and accessibility of controlled medicines is addressed for the following disease-specific policies:

DISEASE PROGRAMME	ITEMS TO INCLUDE IN THE PROGRAMME
Cancer control	<ul style="list-style-type: none"> <li>• access to and availability of strong opioid analgesics (70)</li> <li>• integrated hospice and palliative care services (71)</li> </ul>
HIV/AIDS	<ul style="list-style-type: none"> <li>• access to and availability of strong opioid analgesics (70)</li> <li>• integrated hospice and palliative care services (71)</li> <li>• prevention of HIV transmission through availability and accessibility of opioid agonist therapy (72, 73)</li> </ul>
Mental health (substance abuse and dependence syndrome)	<ul style="list-style-type: none"> <li>• prevention of substance abuse and dependence syndrome (74)</li> <li>• treatment of dependence syndrome through availability and accessibility of opioid agonist therapy (24)</li> </ul>
Mental health (other psychiatric and neurological disorders)	<ul style="list-style-type: none"> <li>• availability and accessibility of anxiolytics, hypnotics and antiepileptics</li> </ul>
Maternal health	<ul style="list-style-type: none"> <li>• availability and accessibility of oxytocin (not-controlled) and/or ergometrine and of ephedrine for emergency obstetric care (75 - 77)</li> </ul>

However, all governments should ensure that patients have pain relief in accordance with national and international treatment guidelines, and access to controlled medicines should not be restricted to the above groups only. When developing and implementing policies on availability and accessibility of controlled medicines, it is important to avoid introducing rights for certain patient groups that could be construed as withholding this right to other patient groups. Similarly, there should not be a geographical restriction of availability within the country. The continuum of care from the family and community level to the highest levels of specialization, such as university hospitals, should also be ensured.

It is essential that government policies ensure that patients are able to continue their treatment with controlled medicines when they are hospitalized in health facilities that normally do not use such medicines.

Governments should identify and establish a List of Essential Medicines, modeled after the WHO Model List of Essential Medicines and the WHO Model List of Essential Medicines for Children, which include controlled medicines needed to cover the most pressing needs of the population.

Moreover, general policies should be developed that address the rational use of controlled medicines. Such policies could include an information campaign, or campaigns to address myths and stereotypes about opioids. Patients and their families should be informed about the treatment of pain and treatment of dependence. Involving the patient and the patient's family will lead to a better understanding and "ownership" of the issue.

#### Relevant international law and principles

General Comment 14 to ICESCR: the Right to Health "must be understood as a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health" (paragraph 9). "While the Covenant provides for progressive realization and acknowledges the constraints due to the limits of available resources, it also imposes on States parties various obligations which are of immediate effect. States parties have immediate obligations in relation to the right to health, such as ... the obligation to take steps towards the full realization of article 12. Such steps must be deliberate, concrete and targeted towards the full realization of the right to health" (paragraph 30). "[P]rogressive realization means that States parties have a specific and continuing obligation to move as expeditiously and effectively as possible towards the full realization of article 12" (paragraph 31).



## GUIDELINE 8

Governments should ensure that all population groups without discrimination equally benefit from their policies on the availability and accessibility of controlled medicines for rational medical use and the prevention of diversion, abuse, and dependence syndrome.

Non-discrimination is a fundamental principle that runs throughout the entire body of international human rights law.

When developing policies and establishing treatment services, governments should not only guard against deliberate discrimination, but also ensure that the policies do not unintentionally lead to discrimination against vulnerable groups. A number of groups, including women, children, the elderly, people in lower income classes, ethnic minorities, prisoners, people living with HIV, sex workers, men who have sex with men, and injecting drug users, are particularly vulnerable and may require a special effort to ensure realistic access to controlled medicines. When designing policies, it should be ensured that such policies and resultant services allow for equal access and availability for these groups and are both gender sensitive and culturally appropriate.

Patients who have a history of substance abuse have as much right to be treated for their pain as anybody else, and regulations should not limit their access to essential medicines. It is a medical decision to consider the advantages and disadvantages of different treatment options. The fact that someone has or had opioid dependence syndrome is not a reason to withhold adequate pain management from that person.

In some countries, only HIV-positive patients are allowed access, in other countries only HIV-negative patients (78). Yet access to treatment of opioid dependence syndrome should be equal for both HIV-positive and HIV-negative patients. There is no medical reason to distinguish between the two groups and it is best practice to allow all patients access to treatment (79).

It is also important that treatment continues for people requiring controlled medicines when they are arrested or imprisoned, regardless of whether they are on pain treatment, treatment for dependence syndrome or for other diseases. Prisons should have functioning treatment programmes for opioid dependence. The use or threat of painful withdrawal to coerce confessions from people with opioid dependence may constitute torture, cruel, inhuman or degrading treatment or punishment and would therefore be prohibited under international human rights law (30, 74, 79 - 81).

The availability of treatment facilities in prisons also helps to diminish the illicit drug problem within them (79). The INCB declared in its 2007 annual report that: "Governments have a responsibility to reduce the availability of illicit drugs in prisons, [and] provide adequate services for drug offenders (whether in treatment services or in prison)" (45).

In countries where long-acting opioid agonists are available for the treatment of heroin dependence syndrome, pregnant women are frequently denied this option as doctors fear for the health of the unborn child. Evidence shows that while a child may be born with opioid withdrawal syndrome, it can be weaned off shortly after birth. If abstinence from heroin is not an option for a woman during her pregnancy, she may avoid visiting medical services, and this may result in a much more complicated birth and even greater threats to the child's health (24, 82).

### Relevant international law and principles

The Universal Declaration of Human Rights, Article 2: "Everyone is entitled to all the rights and freedoms set forth in this Declaration, without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status. Furthermore, no distinction shall be made on the basis of the political, jurisdictional or international status of the country or territory to which a person belongs, whether it be independent, trust, non-self-governing or under any other limitation of sovereignty" (83).

ICESCR, Article 2, paragraph 2: obligates countries "to guarantee that the rights enunciated in the present Covenant will be exercised without discrimination of any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status".

General Comment 14, paragraph 34: "In particular, States are under the obligation to respect the right to health by, inter alia, refraining from denying or limiting equal access for all persons, including prisoners or detainees, minorities, asylum seekers and illegal immigrants, to preventive, curative and palliative health services".

## GUIDELINE 9

Governments should examine their drug control legislation and policies for the presence of overly restrictive provisions that affect delivery of appropriate medical care involving controlled medicines. They should also ensure that provisions aim at optimizing health outcomes and take corrective action as needed. Decisions which are ordinarily medical in nature should be taken by health professionals.

In many countries, national legislation includes provisions stricter than the international drug control conventions require. This is allowed for by the conventions, as far as it is in the opinion of the government "necessary or desirable for the protection of the public health or welfare". However, in practice, many stricter provisions do not contribute to a better public or individual health. Therefore, it is important to analyze the effects of any stricter rules on the prevention of diversion, abuse and dependence syndrome and on the availability and accessibility of controlled medicines. Rules (and policies) that do not contribute to the protection of public health or welfare should be eliminated or changed. Rules violating any other international obligation, regardless whether originating from the drug conventions or any other treaty, should be guarded against.

Such an analysis should be undertaken rule by rule, and cover both legislation and official policy. If a rule provides a barrier for availability and accessibility, but does not contribute to the prevention of abuse, diversion and dependence syndrome, this rule does not contribute to the protection of public health or welfare, and should therefore be either eliminated or changed. In the case where a rule both contributes to prevention and constitutes a barrier for medical use at the same time, alternative ways of providing the same level of prevention without posing a barrier to rational medical use should be explored. This publication provides a check list that may be used for assessing which rules are overly restrictive and may therefore be in need of correction.

Many examples of overly restrictive laws and policies are provided in the existing literature (84 - 89). They may affect the healthcare worker and the way controlled medicines can be used, but they may also affect the patient in a negative manner.

- ▶ The conventions do not define the length of a medical prescription or the amount of medicines to be prescribed by a health worker. If a prescription covers only the amount of medicines needed for a limited time span, or if the validity of prescriptions is limited, the patient will need to go frequently to the physician and the pharmacy.
- ▶ Some countries require a system of registration and authorization for patients to render themselves eligible to receive a prescription for a controlled medicine. There is no requirement for such a system by the drug control conventions. This system may be a barrier for accessing treatment and delay the onset of or adherence to treatment.
- ▶ Registration of patients treated with opioids for opioid dependence (in particular central registration of patients) can provide more accurate data on treatment numbers and prevent patients from receiving methadone or buprenorphine from more than one source. Registration may result in a breach of patient privacy. This may deter some patients from entering treatment and it can delay the commencement of treatment. This can be aggravated if registration also

results in refusal of a driver's license, government employment, housing, or denial of child custody, for example. Such registries may severely interfere with public health policies to provide treatment for dependence and HIV prevention. Safe and effective treatment of opioid dependence can be achieved without registration. Because such registration could cause harm if privacy is breached, it should only be used if government agencies have effective systems for maintaining privacy.

- ▶ Requirements for duplicate prescriptions and special prescription forms increases the administrative burden both for healthcare workers and drug control authorities. The problem is compounded if forms are not readily available, or if health professionals need to pay for them. The conventions allow for duplicate prescriptions and special prescription forms if countries consider them necessary or desirable. Governments should ensure that this system does not impede the availability and accessibility of controlled medicines.
- ▶ In many countries, retail and hospital pharmacies and dispensaries are allowed to procure, stock, and dispense controlled medicines by virtue of their general license; however, some countries require them to obtain a special license. In some cases, application procedures for such licenses dissuade healthcare institutions from obtaining them; for example, through overly burdensome bureaucratic procedures, unnecessary levels of paperwork, excessive screening of staff authorized to handle controlled medicines, or overspecification of special storage facilities.
- ▶ Some countries maintain severe punitive provisions for errors or problems in the prescribing and dispensing of controlled medicines that deter healthcare workers from legitimated prescribing and dispensing of these medicines. The INCB has stated: "Health professionals ... should be able to ... [provide opiates] without unnecessary fear of sanctions for unintended violations [including] ... legal action for technical violations of the law ... [that] may tend to inhibit prescribing or dispensing of opiates"(55). Unintentional errors that do not result in diversion of controlled medicines or serious health consequences should not be subject to criminal penalties.

#### Relevant international law and principles

Single Convention, Article 39: "Notwithstanding anything contained in this Convention, a Party shall not be, or be deemed to be, precluded from adopting measures of control more strict or severe than those provided by this Convention and in particular from requiring that preparations in Schedule III or drugs in Schedule II be subject to all or such of the measures of control applicable to drugs in Schedule I as in its opinion is necessary or desirable for the protection of the public health or welfare".

Article 30, paragraph 2 (b ii): "The Parties shall also ... [i]f the Parties deem these measures [of requiring medical prescriptions for the supply, or dispensation of drugs to individuals] necessary or desirable, require that prescriptions for drugs in Schedule I should be written on official forms to be issued in the form of counterfoil books by the competent governmental authorities or by authorized professional associations".

Convention on Psychotropic Substances, Article 23: "A Party may adopt more strict or severe measures of control than those provided by this Convention if, in its opinion, such measures are desirable or necessary for the protection of the public health and welfare".

See also the obligations and principles stemming from the right to health discussed above.

## **GUIDELINE 10**

**Terminology in national drug control legislation and policies should be clear and unambiguous in order not to confuse the use of controlled medicines for medical and scientific purposes with misuse.**

Drug control legislation and policy have sometimes contributed to stigmatization of controlled medicines because of the use of inappropriate terminology. Confusion and discrimination relating to terminology can deter doctors from prescribing controlled medicines when it is legitimate to do

so; it can also confuse authorities who wish to discriminate between legitimate and illegitimate use. Countries should therefore take steps to review policies to ensure the consistent use of medical terms and remove stigmatizing terminology from their legislation. These guidelines specifically recommend the use of non-stigmatizing terminology.

Confusion may occur between "abuse" (or "misuse") on the one hand, and long-term medical use on the other. The 1961 and 1971 Conventions do not define the terms "misuse" or "abuse". However, "abuse" is defined by the WHO Expert Committee on Drug Dependence as "persistent or sporadic excessive drug use inconsistent with or unrelated to acceptable medical practice" (1). This definition excludes the long-term use of controlled medicines concurrent with rational medical practice.

A further confusion relates to the definition of "dependence" and "dependence syndrome". Reference is also made to the glossary. The WHO definition of "dependence syndrome" requires the presence of at least three out of six symptoms, including a strong desire or a sense of compulsion to take the drug and also the neglecting of interests and daily activities because of devotion to the use of psychoactive substances. It is clear that a patient requiring increasing doses of an opioid for pain relief because of pharmacological tolerance due to prolonged treatment does not normally fall into this category. Neither does a patient who develops withdrawal syndrome.

Furthermore, it is recommended to avoid the use of stigmatizing terms like "dangerous drugs", "addiction", etc. for controlled medicines in legislation. Distinction should be made between the legal terms "narcotic drugs" and "psychotropic drugs" referring to substances controlled under both conventions, and medicine classes such as opioid analgesics, long-acting opioid agonists, etc.

Patients should be referred to in a respectful way; WHO does not therefore recommend the use of "addict" for a patient living with dependence syndrome, as the term is considered to be stigmatizing.

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## Healthcare professionals

### GUIDELINE 11

Appropriately trained and qualified physicians, and, if applicable, nurses and other health professionals, at all levels of health care should be allowed to prescribe and administer controlled medicines, based on their general professional license, current medical knowledge and good practice without any further license requirements.

All healthcare professionals should be trained appropriately for the professional activities they actually perform, and this applies equally to the prescription of controlled medicines. The competence to prescribe controlled medicines, including strong opioids, should not be restricted to a small number of medical specialties, e.g. oncologists only, and controlled medicines should be available at all appropriate levels of care.

Requirements for physicians to obtain a license for prescribing controlled substances may lead to limited access and availability (see also Guideline 6). In all countries, all physicians should be sufficiently trained to treat pain and hence be allowed to prescribe opioid analgesics if necessary. Training for treatment of other conditions depends on whether a condition occurs or not within their specialty.

In some countries, other healthcare workers, such as nurses, can specialize in a specific area and are then allowed to prescribe within the area of their specialization as well. Nurse prescribing can

be useful e.g. for mitigating pain in a number of circumstances; for example, during a shortage of physicians or to improve the quality of care.

When balancing drug *control* legislation and policies, it is wise to leave *medical* decisions up to those who are knowledgeable on medical issues. Therefore, the amount of medicine prescribed, the appropriate formulation and the duration of treatment should be the practitioner's decision, based on individual patient needs and on sound scientific medical guidance (e.g. national or WHO treatment guidelines). An example of how this rule may sometimes be violated is the legal restriction on the maximum daily dosage of strong opioids. Another example is the limitation of the use of strong opioids only to certain conditions such as cancer pain or terminal cancer pain, while other moderate to severe pain remains unaddressed.

#### Relevant international law and principles

Single Convention, Article 30, paragraph 2 (b): "[Governments shall] ... (i) Require medical prescriptions for the supply or dispensation of drugs to individuals. This requirement need not apply to such drugs as individuals may lawfully obtain, use, dispense or administer in connection with their duly authorized therapeutic functions; and (ii) If the Parties deem these measures necessary or desirable, require that prescriptions for drugs in Schedule I should be written on official forms to be issued in the form of counterfoil books by the competent governmental authorities or by authorized professional associations" (see also under Guideline 6).

## **GUIDELINE 12**

Appropriately trained and qualified pharmacists at all levels of health care should be allowed to dispense controlled medicines, based on their general professional license, current medical knowledge and good practice without any further license requirements.

As the need for controlled medicines can be present at all levels of health care, all pharmacists should be trained appropriately for the dispensing of these medicines. Requirements for pharmacists to obtain a license for prescribing controlled substances may limit access and availability (see also Guideline 6).

Some countries allow for the correction of technical errors by pharmacists. In order to start the prescribed therapy in a timely manner, legislation should address the pharmacist's ability to correct technical errors in prescriptions and to dispense small amounts of controlled medicines in case of emergencies.

Paragraph 43 of the INCB special report of 1989, states: "While sanctions are necessary to deal with persons who transgress the law, they should not, as such, constitute an impediment to the prescription or dispensation of opiates in accordance with existing regulations. The vast majority of health professionals exercise their activity within the law and should be able to do so without unnecessary fear of sanctions for unintended violations. Occasions may still arise when a health professional could nevertheless be exposed to legal action for technical violations of the law. This possibility may tend to inhibit the prescribing or dispensing of opiates."

#### Relevant international law and principles

The Convention on Psychotropic Substances, Article 9, paragraph 3 permits that countries allow authorized licensed pharmacists or other licensed retail distributors to supply, at their discretion and without prescription, for use for medical purposes by individuals in exceptional cases, small quantities of substances in Schedules III and IV: "Notwithstanding paragraph 1, a Party may, if in its opinion local circumstances so require and under such conditions, including record-keeping, as it may prescribe, authorize licensed pharmacists or other licensed retail distributors designated by the authorities responsible for public health in its country or part thereof to supply, at their discretion and without prescription, for use for medical purposes by individuals in exceptional cases, small quantities, within limits to be defined by the Parties, of substances in Schedules III and IV."

The drug control conventions provide no guidance on correction of errors in prescriptions by pharmacists.

## GUIDELINE 13

Governments should promote that medical, pharmaceutical and nursing schools teach the knowledge and skills for the treatment of pain, substance use disorders in the context of medical use of controlled medicines, and other health conditions that need treatment with controlled medicines.

In all countries, including those where the use of controlled medicines is not yet common, it is important that all healthcare schools teach their use. Although controlled medicines and in particular strong opioids can be applied safely, basic knowledge is essential and an opportunity to practice their application under supervision of an experienced peer is important. In its 2006 annual report, the INCB encouraged all Governments to ensure that "the rational use of narcotic drugs and psychotropic substances for medical purposes and the risks associated with drug abuse are included ... in university curricula" (17).

Current best practices should be derived from WHO treatment guidelines and other international and national evidence-based guidelines for the various diseases that need treatment with controlled medicines. Annex 2 lists a selection of WHO guidelines related to treatment with controlled medicines.

### Relevant international law and principles

Under both conventions, there is an obligation to the countries to "promote the training of personnel in the treatment ... of abusers of drugs ... as far as possible".<sup>k</sup> (Single Convention, Article 38, paragraph 2; the Convention on Psychotropic Substances, Article 20, paragraph 2 has almost identical wording).

General Comment 14, (paragraph 12 (a): "[The right to health...contains the following...elements...] Functioning public health and health-care facilities, goods and services, as well as programmes, have to be available in sufficient quantity within the State party. The precise nature of the facilities, goods and services will vary depending on numerous factors, including the State party's developmental level. They will include, however, the underlying determinants of health, such as ... trained medical and professional personnel receiving domestically competitive salaries."

Paragraph 35: "The right to health, like all human rights, imposes three types or levels of obligations on States parties: the obligations to *respect*, *protect* and *fulfil* (paragraph 33)". "Obligations to *protect* include, *inter alia*, the duties of States to ... ensure that medical practitioners and other health professionals meet appropriate standards of education, skill and ethical codes of conduct."

## GUIDELINE 14

In countries where controlled medicines become available and accessible for the first time, governments should organize education initiatives for healthcare professionals to ensure their rational use.

It is important while introducing policies on accessibility and availability of controlled medicines to provide the relevant healthcare staff with the knowledge and skills for using these medicines appropriately; training courses should therefore be provided throughout the country. This also applies to some degree when a new substance becomes available or a new indication is approved.

<sup>k</sup> Remark on the word "abusers": note that dependence is a disorder that needs treatment, occasional abuse is not necessarily a disorder, as can be concluded from the ICD-10 criteria described under Guideline 10 and in the glossary.

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## Estimates and statistics

### GUIDELINE 15

Governments should develop a practical method to estimate realistically the medical and scientific requirements for controlled substances, using all relevant information.

### GUIDELINE 16

Governments should furnish to the INCB estimates and assessments of the quantities of controlled substances required for legitimate medical and scientific purposes (estimates annually for narcotic drugs and certain precursors; assessments at least every three years for psychotropic substances). Governments should furnish supplementary estimates or modified assessments to the INCB if it appears that the availability of controlled substances for legitimate purposes will fall short because of initial underestimation of regular demand, emergencies or exceptional demand.

The Single Convention provides for a system of estimates of requirements for narcotic drugs that enables INCB, in cooperation with governments, to support the balance between the supply of and demand for these drugs. The system allows countries to manufacture and/or import narcotic drugs provided that the total estimated amount is not exceeded, and prevents from manufacturing and/or importing more narcotic drugs than required for legitimate purposes, which could lead to the diversion of the excess to illicit markets. During the course of a year, governments can submit supplementary estimates at any time. Governments should establish estimates using the recommendations and methods proposed by WHO and INCB. These methods recommend including a certain surplus amount in order to minimize chances that the estimates prove to be insufficient towards the end of the year.

While no such system is foreseen for psychotropic substances by the 1971 Convention, a system of assessments (simplified estimates) was established by Economic and Social Council Resolutions 1981/7 and 1991/44. By adopting Resolution 49/3, the Commission on Narcotic Drugs requested governments to also provide INCB with estimates of their legitimate requirements for certain precursors frequently used in the manufacture of amphetamine-type stimulants.

#### Relevant international law and principles

Single Convention, Article 19, paragraph 1: "The Parties shall furnish to the Board each year for each of their territories, in the manner and form prescribed by the Board, estimates on forms supplied by it in respect of the following matters: (a) Quantities of drugs to be consumed for medical and scientific purposes; (b) Quantities of drugs to be utilized for the manufacture of other drugs, of preparations in Schedule III, and of substances not covered by this Convention; (c) Stocks of drugs to be held as at 31 December of the year to which the estimates relate".

Single Convention, Article 19, paragraph 4: "The Parties shall inform the Board of the method used for determining quantities shown in the estimates and of any changes in the said method".

Single Convention, Article 12, paragraph 3: "If any State fails to furnish estimates in respect of any of its territories by the date specified, the Board shall, as far as possible, establish the estimates. The Board, in establishing such estimates, shall to the extent practicable do so in co-operation with the Government concerned."

Single Convention, Article 12, paragraph 5: "The Board, with a view to limiting the use and distribution of drugs to an adequate amount required for medical and scientific purposes and to ensuring their availability for such purposes, shall as expeditiously as possible confirm the estimates, including supplementary estimates, or, with the consent of the Government concerned, may amend such estimates".

Single Convention, Article 21, paragraph 4 (b): "Parties shall not during the year in question authorize any further exports of the drug concerned to that country or territory, except: (i) In the event of a supplementary estimate being furnished

for that country or territory in respect both of any quantity over imported and of the additional quantity required, or  
(ii) In exceptional cases where the export, in the opinion of the Government of the exporting country, is essential for the treatment of the sick".

## GUIDELINE 17

Governments are required to submit statistical reports to the INCB on narcotic drugs and psychotropic substances in accordance with the respective provisions of the international drug control conventions and relevant resolutions of the Economic and Social Council.

Besides having to submit estimates and assessments in advance, countries also have to report to the INCB on actual activities involving controlled substances, such as their production, manufacture, import and export, utilization, consumption and stocks. The reporting requirements for narcotic drugs are more detailed than for psychotropic substances. Statistics are useful for the national competent authority, the INCB and others to evaluate, inter alia, the consumption levels of narcotic drugs and psychotropic substances, the quality of previous estimates and assessments and the methods to establish them, as well as to evaluate and improve the quality of accessibility and availability of controlled medicines, their supply and the services using them.

The conventions and resolutions require that reports be submitted by the national competent authorities to the INCB, including quarterly statistics of imports and exports of narcotic drugs; quarterly statistics of imports and exports of psychotropic substances in Schedule II of the 1971 Convention; annual statistics of narcotic drugs; and annual statistics of psychotropic substances. Quarterly reports have to be furnished four times a year by the end of the month following the quarter to which they relate, while annual reports have to be submitted by 30 June following the year to which they relate.

### Relevant international law and principles

Single Convention, Article 20, paragraph 1: "The Parties shall furnish to the Board for each of their territories, in the manner and form prescribed by the Board, statistical returns on forms supplied by it in respect of the following matters:

- a) Production or manufacture of drugs;
- b) Utilization of drugs for the manufacture of other drugs, of preparations in Schedule III and of substances not covered by this Convention, and utilization of poppy straw for the manufacture of drugs;
- c) Consumption of drugs;
- d) Imports and exports of drugs and poppy straw;
- e) Seizures of drugs and disposal thereof;
- f) Stocks of drugs as at 31 December of the year to which the returns relate; and
- g) Ascertainable area of cultivation of the opium poppy."

Convention on Psychotropic Substances, Article 16, paragraph 4: "The Parties shall furnish to the Board annual statistical reports in accordance with forms prepared by the Board:

- a) In regard to each substance in Schedules I and II, on quantities manufactured, exported to and imported from each country or region as well as on stocks held by manufacturers;
- b) In regard to each substance in Schedules III and IV, on quantities manufactured, as well as on total quantities exported and imported;
- c) In regard to each substance in Schedules II and III, on quantities used in the manufacture of exempt preparations; and
- d) In regard to each substance other than a substance in Schedule I, on quantities used for industrial purposes in accordance with sub-paragraph b) of article 4.

The quantities manufactured which are referred to in sub-paragraphs a) and b) of this paragraph do not include the quantities of preparations manufactured."



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## Procurement

### GUIDELINE 18

Governments should ensure, in cooperation with companies and agencies managing distribution, that the procurement, manufacture, and distribution of controlled medicines are accomplished in a timely manner with good geographical coverage so that there are no shortages of supply, and that such medicines are always available when they are needed while maintaining adequate controls to prevent diversion, abuse, or dependence syndrome.

As part of a government's obligation to ensure the adequate availability and accessibility of controlled medicines, it is essential that the procurement, manufacturing and distribution of these substances are well organized. This is based on the assumption that there is a list of controlled medicine formulations which received marketing authorization within the country. The WHO Model List of Essential Medicines and the WHO Model List of Essential Medicines for Children can serve as a model to determine a minimum set of medicines for which substances and dosage forms are needed (Annex 1) (84, 90).

The provision of adequate availability of controlled medicines is part of a country's obligation under international treaties and subject to monitoring by INCB.

Similar to any other medicine, a controlled medicine needs to be in stock in order for it to be continuously dispensed, as interruption of supply will also interrupt the patients' treatment. Such interruption may entail serious consequences for patients.

Abrupt discontinuation of treatment with opioid analgesics may cause the return of the patient's pain (if the underlying cause continues to be present) and withdrawal syndrome, with symptoms including hypertension, nausea and vomiting, painful abdominal cramps, diarrhoea and muscle pain.

In the case of interruption of treatment with long-acting opioid agonists for dependence syndrome, the interruption may also cause withdrawal syndrome. Patients with dependence syndrome are familiar with this syndrome and know that it can be treated with (illicit) opioids. In such a case they may drop out of the programme and relapse. Periods without access to medication compromise the results from prolonged periods of programmes for dependence treatment and HIV prevention.

With regards to the occurrence of withdrawal syndrome, it should be noted that this is not necessarily a sign that patients have dependence or dependence syndrome as explained under Guideline 10. Withdrawal syndrome can usually be avoided by gradually decreasing the dosage. For other controlled medicines, interruption poses serious problems for patients, whether the return of epileptic seizures, psychiatric crises, or maternal death (in case of unavailability of ergometrine and ephedrine).

If controlled medicines are to be accessible at the appropriate level of health care (please see explanation under Guideline 7), there is a requirement for them to be widely available in pharmacies and at the required health services. Almost all controlled medicines are also used at the primary care level and their availability should not therefore be solely limited to hospital pharmacies. Patients and their families should not need to incur high costs in terms of travel time and money in order to reach pharmacies dispensing controlled medicines.

Preferably, the distribution of controlled medicines should be combined with that of other non-controlled medicines through reliable medicine distribution systems. A state monopoly on controlled

medicines is not required by the conventions and will, in many cases, pose additional barriers for accessibility and availability of these medicines. This is often the case where a state monopoly coincides with the centralization of delivery; for example, where delivery is limited to one location in the nation's capital or to a limited number of locations in provincial capitals, or where pharmacists need to appear in person to collect their order for controlled medicines.

Relevant international law and principles

Guideline 18 is a consequence of Guidelines 2 and 7. Also other Guidelines are related (e.g. 8, 9, 11, 12, 15, 16 and 17). Relevant international law is presented under these Guidelines.

## **GUIDELINE 19**

**Governments should minimize the negative impact of control and safety measures on the affordability and availability of controlled medicines.**

On the world market, morphine and methadone are relatively cheap substances and many other opioid raw materials are also relatively inexpensive. Yet although drugs as such are not expensive, they may be restricted as a result of safety measures, and in many countries there are control measures that affect pricing. Many of these measures are not required in the conventions and are not necessary to prevent diversion.

The challenge for many countries with current low consumption of controlled medicines is to make and keep them affordable during the period of transition to better access and availability. In situations with low turnover, the cost of licenses and registration can prove prohibitive for marketing these medicines. In production and distribution, the cost of packing a batch of 100 tablets is not much different from packing a batch of 10 000 tablets and the same is true for the cost of transportation. A pharmacy that is required to make high investments in safety measures in order to be allowed to dispense controlled medicines may decide not to procure and stock them; these factors can make controlled medicines artificially expensive and may be a barrier to increased consumption.

Countries should perform a review of their control and safety measures and the impact on controlled medicines pricing. In particular, attention should be paid to ensuring that any safety measure and the cost related to that measure is proportional to the actual risk of diversion. Countries should take adequate steps to remedy any problems found.

Relevant international law and principles

Guideline 19 is a consequence of Guidelines 2 and 7. Also other Guidelines are related (e.g. 8, 9, 11, 12, and 18). Relevant international law is presented under these Guidelines.

## **GUIDELINE 20**

**Drug control authorities should be aware of the existence of the *WHO model guidelines for the international provision of controlled medicines for emergency medical care*, which provide a simplified procedure for importation and exportation of controlled medicines into a country where disaster disrupted the functioning of the drug control authorities. They should apply them when necessary.**

Both natural and man-made disasters can cause an increased demand for controlled substances, but can also disrupt national drug control authorities and result in them not being able to issue import licenses for controlled medicines. The INCB, in its report for 1994, recommended that control obligations could be limited to the authorities of exporting countries in emergency situations (15). This principle was endorsed at the UN Commission on Narcotic Drugs and the World Health Assembly (91, 92).

When such a disaster situation occurs, other competent authorities should be aware that the *WHO model guidelines for the international provision of controlled medicines for emergency medical care* may be applicable (15). These model guidelines assist national authorities with simplified regulatory procedures. In cases where there is doubt in relation to their applicability, it is recommended that the International Narcotics Control Board is consulted.

#### Relevant international law and principles

The general principle from the international drug control conventions is that controlled medicines are indispensable and that adequate provision must be made to ensure their availability. (See under Guideline 1 for the text of the conventions' preambles).

General Comment 14, paragraph 40: "States parties have a joint and individual responsibility, in accordance with the Charter of the United Nations and relevant resolutions of the United Nations General Assembly and of the World Health Assembly, to cooperate in providing disaster relief and humanitarian assistance in times of emergency".

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## Other

### GUIDELINE 21

Governments that decide to bring medicines under national control that are not controlled under the international drug control conventions should apply these guidelines equally to those nationally controlled medicines.

At times, governments may feel compelled to bring substances that are not internationally controlled under national control if they are perceived to pose serious risk of misuse and harm to public health. Under the international drug conventions, countries have the authority to do so. Yet, where such decisions concern substances that are also medicines – and particularly when they are essential medicines – and thus may have a significant impact on the availability and accessibility of these substances for medical and scientific uses, they must be made only with restraint and care.

If governments do decide to consider national scheduling, they should do so only after a careful and transparent process involving all relevant stakeholders that weighs the costs and benefits of such step. In particular, they should examine:

- ▶ the evidence of risk of hazardous and harmful use;
- ▶ the extent of the threat for public health and society;
- ▶ the significance of the substance for medical care;
- ▶ the impact on availability and accessibility of scheduling the substance.

Before deciding whether the substance should be scheduled or not, governments should take into account a scientific assessment of its dependence liability by WHO's Expert Committee on Drug Dependence, if available.<sup>1</sup>

If a government decides that both the risk of hazardous and harmful use and the threat for public health and society are so significant that national scheduling is appropriate, it should develop and implement a plan of action with guidelines that are capable of ensuring that the availability and accessibility of the substance for medical and scientific purposes is not interrupted after scheduling or negatively affected over time.

<sup>1</sup> For all documentation related to the Expert Committee on Drug Dependence, please see: [http://www.who.int/medicines/areas/quality\\_safety/ECDD/en](http://www.who.int/medicines/areas/quality_safety/ECDD/en) (accessed 9 January 2011).

The above recommendations are particularly important given the fact that, for example, the national scheduling of ketamine and tramadol has led to reduced availability and accessibility of these medicines in many countries. Ketamine is an essential medicine used for anesthesia in resource-poor settings and is frequently the only anesthetic available for surgery. Tramadol is a weak opioid that is used in many countries to manage moderate pain, reviewed by the 34<sup>th</sup> WHO Expert Committee on Drug Dependence in 2006. The Committee "considered that, even after recent major increase in the extent of its use because of its therapeutic usefulness, tramadol continues to show a low level of abuse. Hence the Committee concluded that there was not sufficient evidence to justify a critical review". National scheduling has resulted in reports of unavailability of these medicines, with serious consequences for patients (93, 94).

Relevant international law and principles

ICESCR, Article 12, paragraph 2 and its General Comment 14 (See Guideline 2).



# COUNTRY ASSESSMENT CHECKLIST<sup>m</sup>

Governments and other interested groups, including healthcare professionals, may use the following checklist to guide their analysis of national drug control policies and the extent to which the guidelines are adhered to in their country. At the country level, it may be a taskforce or working group that may be put in charge of this task. Please note that some further enquiry may be required prior to answering the questions contained in this checklist.

The numbering of the 67 questions corresponds with the numbering of the guidelines. In some cases a question may refer to more than one guideline; in such a case its number refers to the most relevant guideline. For each question, the checklist indicates whether it is a question on legal issues ("L": 11 questions), policy issues ("P": 53 questions) or both ("L/P": 3 questions). This may enhance assessment by teams who want to split their work over both policy and legal sub-teams.

For most questions, the answer that is most favourable for ensuring good access and availability to controlled medicines is represented in bold. Thus, for any question where the answer is not presented in bold, there is an opportunity to work on improvement. By working systematically on these issues, a country can gradually improve access and availability of controlled medicines. A systematic approach also necessitates completion of the Country Assessment Checklist at a later date.

## CONTENT OF DRUG CONTROL LEGISLATION AND POLICY

Number (refers to related Guideline)	Legal issue (L) or Policy issue (P)	Question	Action required? (please tick if yes)
1	L/P	Is there a provision in the legislation or in official national policy documents that controlled medicines are absolutely necessary for medical and pharmaceutical care?  <input type="checkbox"/> <b>yes, please list:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
2	P	Is there a provision in the legislation that establishes the government's obligation to make adequate provision to ensure:	
		<ul style="list-style-type: none"> <li>▶ the availability of controlled medicines for medical and scientific purposes, including the relief of pain and suffering?   <input type="checkbox"/> <b>yes, please list:</b>  <input type="checkbox"/> no  <input type="checkbox"/> unknown</li> </ul>	<input type="checkbox"/>
		<ul style="list-style-type: none"> <li>▶ the prevention and treatment of substance dependence?   <input type="checkbox"/> <b>yes, please list:</b>  <input type="checkbox"/> no  <input type="checkbox"/> unknown</li> </ul>	<input type="checkbox"/>
3	P	Has the government established a national authority for implementing the obligation to ensure adequate availability of controlled medicines for medical and scientific purposes, including licensing, estimates and statistics?  <input type="checkbox"/> <b>yes, please list agency/agencies:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>

Number (refers to related Guideline)	Legal issue (L) or Policy issue (P)	Question	Action required? (please tick if yes)
4	P	a) Is there a mechanism (such as a regular meeting) among government agencies to coordinate drug control policies and to concert all sub-policies?  <input type="checkbox"/> <b>yes, please describe mechanism: how often are such meetings held? .... /year</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
4	P	b) Does the mechanism involve the agencies responsible for the following functions:	
		▶ drug control legislation?  <input type="checkbox"/> <b>yes, please list agencies:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		▶ anti-drug diversion policies?  <input type="checkbox"/> <b>yes, please list agencies:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		▶ healthcare policies (pharmaceutical, cancer, HIV policies, etc.)?  <input type="checkbox"/> <b>yes, please list agencies:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		▶ customs?  <input type="checkbox"/> <b>yes, please list agencies:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		▶ police?  <input type="checkbox"/> <b>yes, please list agencies:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		▶ judiciary?  <input type="checkbox"/> <b>yes, please list agencies:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>



Number (refers to related Guideline)	Legal issue (L) or Policy issue (P)	Question	Action required? (please tick if yes)
4	P	c) Does the mandate of the mechanism involve:	
		<ul style="list-style-type: none"> <li>▶ the promotion of the availability and accessibility of controlled medicines for medical purposes?</li> </ul> <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		<ul style="list-style-type: none"> <li>▶ the prevention of abuse and dependence?</li> </ul> <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		<ul style="list-style-type: none"> <li>▶ the prevention of diversion?</li> </ul> <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
5	P	a) Is there a mechanism for cooperation between the government and healthcare professionals to ensure the availability and accessibility of controlled medicines for medical and scientific purposes, including for the relief of pain, treatment of opioid dependence and other medical illness, as well as the prevention of abuse, dependence and diversion?	
		<input type="checkbox"/> <b>yes, please describe the mechanism:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
5	P	b) Does the cooperation involve the agencies responsible for the following functions:	
		<ul style="list-style-type: none"> <li>▶ drug control legislation?</li> </ul> <input type="checkbox"/> <b>yes, please list agencies:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		<ul style="list-style-type: none"> <li>▶ anti-drug diversion policies?</li> </ul> <input type="checkbox"/> <b>yes, please list agencies:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>

Number (refers to related Guideline)	Legal issue (L) or Policy issue (P)	Question	Action required? (please tick if yes)
		▶ healthcare policies (pharmaceutical, cancer, HIV policies, etc.)?  <input type="checkbox"/> <b>yes, please list agencies:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		▶ customs?  <input type="checkbox"/> <b>yes, please list agencies:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		▶ police?  <input type="checkbox"/> <b>yes, please list agencies:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		▶ judiciary?  <input type="checkbox"/> <b>yes, please list agencies:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		▶ medical boards?  <input type="checkbox"/> <b>yes, please list:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		▶ representatives of health professionals?  <input type="checkbox"/> <b>yes, please list organizations:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		▶ representatives of patients?  <input type="checkbox"/> <b>yes, please list organizations:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		▶ representatives of health insurances?  <input type="checkbox"/> <b>yes, please list organizations:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>

Number (refers to related Guideline)	Legal issue (L) or Policy issue (P)	Question	Action required? (please tick if yes)
5	P	c) Does the mandate of the cooperation involve:	
		▶ the promotion of the availability and accessibility of controlled medicines for medical purposes?  <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		▶ the prevention of abuse and dependence?  <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		▶ the prevention of diversion?  <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
5	P	d) Does the cooperation comprise the following aspects	
		▶ to assist the needs assessment for controlled medicines and to report on the degree of access?  <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		▶ to advise on the promotion of rational use of controlled medicines?  <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		▶ implementation of best practices, development of national treatment guidelines and implementation of international treatment guidelines?  <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		▶ to advise on lifting overly-restrictive barriers for access to controlled medicines?  <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>

Number (refers to related Guideline)	Legal issue (L) or Policy issue (P)	Question	Action required? (please tick if yes)
		<p>▶ to advise on improving prevention and control of substance abuse and dependence without establishing new barriers for accessibility and availability?</p> <p><input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown</p>	<input type="checkbox"/>
6	P	<p>Did the government make adequate provision to ensure education of government officers and others whose work requires an understanding of the problems of abuse of drugs and of its prevention, including the relation to health policies and legitimate treatment with controlled medicines?</p> <p><input type="checkbox"/> <b>yes, please describe the mechanism:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown</p>	<input type="checkbox"/>
<p><b>Policy planning for availability and accessibility</b> <i>National medicines policy plan:</i></p>			
7	P	<p>a1) Is there an approved national medicines policy plan that includes the availability and accessibility of controlled medicines for all relevant medical and scientific uses?</p> <p><input type="checkbox"/> <b>yes, please reference: when was the last update of the plan?</b> <input type="checkbox"/> no <input type="checkbox"/> unknown</p>	<input type="checkbox"/>
7	P	<p>a2) Does the national medicines policy plan (or any government policy) make provision for a List of Essential Medicines, modeled after the WHO Model List of Essential Medicines and the WHO Model List of Essential Medicines for Children?</p> <p><input type="checkbox"/> <b>yes, please reference:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown</p>	<input type="checkbox"/>
7	P	<p>a3) Does this List of Essential Medicines include all medicines currently on, or equivalent to the controlled medicines on, the WHO Model List of Essential Medicines and the WHO Model List of Essential Medicines for Children?</p> <p><input type="checkbox"/> <b>yes</b> <input type="checkbox"/> no, please list missing medicines: <input type="checkbox"/> unknown</p>	<input type="checkbox"/>

Number (refers to related Guideline)	Legal issue (L) or Policy issue (P)	Question	Action required? (please tick if yes)
7	P	a4) Does the national medicines policy plan (or any government policy) make provision for policies that address the rational use of controlled medicines by the general population, including that patients and their families should be informed about the treatment of pain and treatment of dependence?  <input type="checkbox"/> <b>yes, please specify:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
7	(P - Refers also to Guidelines 11 and 12)	a5) Does the national medicines policy plan (or any government policy) provide for the availability of the relevant medicines at appropriate levels of care, including both the availability of strong opioid analgesics at all levels and the authority of prescribing by all relevant medical specialties?  <input type="checkbox"/> <b>yes, please specify:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
7	P	a6) Does the national medicines policy plan (or any government policy) make adequate provision that patients who are hospitalized for other reasons are able to continue their treatment with controlled medicines?  <input type="checkbox"/> <b>yes, please specify:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
7	P	a7) Does the national medicines policy plan (or any government policy) make adequate provision that treatment continues for people on controlled medicines when arrested or imprisoned, regardless whether they are on pain treatment, treatment for dependence or for other diseases?  <input type="checkbox"/> <b>yes, please specify:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
<i>Disease specific policy plans:</i> - Cancer:			
7	P	b1) Is there an approved national comprehensive cancer control program that includes access to and availability of strong opioid analgesics for treatment of moderate to severe pain and for services like hospice and palliative care where patients can obtain such treatment?  <input type="checkbox"/> <b>yes, please reference: when was the last update of the plan?</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>

Number (refers to related Guideline)	Legal issue (L) or Policy issue (P)	Question	Action required? (please tick if yes)
7	P	<p>b2) Has it been verified that no provisions in the policy plan granting rights to one patient group could be explained as withholding this right to other patient groups?</p> <p><input type="checkbox"/> yes  <input type="checkbox"/> no  <input type="checkbox"/> unknown</p>	<input type="checkbox"/>
7	P	<p>b3) Are sufficient resources available for the implementation of the policy?</p> <p><input type="checkbox"/> <b>yes, please specify budget:</b>  <input type="checkbox"/> no  <input type="checkbox"/> unknown</p>	<input type="checkbox"/>
<i>- HIV/AIDS:</i>			
7	P	c1) Is there an approved national HIV/AIDS policy programme that:	
		<p>▶ includes the treatment of moderate to severe pain through availability and accessibility of strong opioid analgesics and of services like hospice and palliative care where patients can obtain such treatment?</p> <p><input type="checkbox"/> <b>yes, please reference:</b>  <input type="checkbox"/> no  <input type="checkbox"/> unknown</p>	<input type="checkbox"/>
		<p>▶ includes the prevention of HIV transmission through availability and accessibility of opioid agonist therapy and treatment centers where patients with opioid dependence can obtain such treatment?</p> <p><input type="checkbox"/> <b>yes, please reference:</b>  <b>when was the last update of the plan?</b>  <input type="checkbox"/> no  <input type="checkbox"/> unknown</p>	<input type="checkbox"/>
7	P	<p>c2) Has it been verified that no provisions in the policy plan granting rights to one patient group could be explained as withholding this right to other patient groups?</p> <p><input type="checkbox"/> yes  <input type="checkbox"/> no  <input type="checkbox"/> unknown</p>	<input type="checkbox"/>

Number (refers to related Guideline)	Legal issue (L) or Policy issue (P)	Question	Action required? (please tick if yes)
7	P	c3) Are sufficient resources available for the implementation of the policy?  <input type="checkbox"/> <b>yes, please specify budget:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
<i>- Opioid dependence:</i>			
7	P	d1) Is there an approved national mental healthcare programme on opioid dependence that includes prevention of substance abuse and dependence, treatment of substance dependence through availability and accessibility of opioid agonist therapy and treatment centers where patients with opioid dependence can obtain such treatment?  <input type="checkbox"/> <b>yes, please reference: when was the last update of the plan?</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
7	P	d2) Has it been verified that no provisions in the policy plan granting rights to one patient group could be explained as withholding this right to other patient groups?  <input type="checkbox"/> <b>yes</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
7	P	d3) Does the mental healthcare programme on opioid dependence make adequate provision that treatment continues for people on controlled medicines when arrested or imprisoned, regardless whether they are on pain treatment, treatment for dependence or for other diseases?  <input type="checkbox"/> <b>yes, please specify:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
7	P	d4) Does the mental healthcare programme on opioid dependence make adequate provision that prisons have functioning treatment programmes for the treatment of opioid dependence?  <input type="checkbox"/> <b>yes, please specify:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>

Number (refers to related Guideline)	Legal issue (L) or Policy issue (P)	Question	Action required? (please tick if yes)
7	P	d5) Are sufficient resources available for the implementation of the policy?  <input type="checkbox"/> <b>yes, please specify budget:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
<i>- Psychiatric and neurological disorders:</i>			
7	P	e1) Is there an approved national mental healthcare programme on other psychiatric and neurological disorders that includes the availability and accessibility of anxiolytics, hypnotics and anti-epileptics?  <input type="checkbox"/> <b>yes, please reference: when was the last update of the plan?</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
7	P	e2) Has it been verified that no provisions in the policy plan granting rights to one patient group could be explained as withholding this right to other patient groups?  <input type="checkbox"/> <b>yes</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
7	P	e3) Are sufficient resources available for the implementation of the policy?  <input type="checkbox"/> <b>yes, please specify budget:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
<i>- Maternal health:</i>			
7	P	f1) Is there an approved national maternal healthcare programme that includes the availability and accessibility of oxytocin (not-controlled) and/or ergometrine and of ephedrine for emergency obstetric care?  <input type="checkbox"/> <b>yes, please reference: when was the last update of the plan?</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
7	P	f2) Has it been verified that no provisions in the policy plan granting rights to one patient group could be explained as withholding this right to other patient groups?  <input type="checkbox"/> <b>yes</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>



Number (refers to related Guideline)	Legal issue (L) or Policy issue (P)	Question	Action required? (please tick if yes)
7	P	f3) Are sufficient resources available for the implementation of the policy?  <input type="checkbox"/> <b>yes, please specify budget:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
8	P	a) Has it been verified that the national medicines policy plan and the national disease specific policy plans:	
		▸ are gender sensitive and culturally appropriate?  <input type="checkbox"/> <b>yes</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		▸ allow for equal access and availability and do not discriminate, or result in being unintentionally discriminatory to:	
		women?  <input type="radio"/> <b>yes</b> <input type="radio"/> no <input type="radio"/> unknown	<input type="checkbox"/>
		children?  <input type="radio"/> <b>yes</b> <input type="radio"/> no <input type="radio"/> unknown	<input type="checkbox"/>
		the elderly?  <input type="radio"/> <b>yes</b> <input type="radio"/> no <input type="radio"/> unknown	<input type="checkbox"/>
		people in lower income classes?  <input type="radio"/> <b>yes</b> <input type="radio"/> no <input type="radio"/> unknown	<input type="checkbox"/>
		ethnic minorities?  <input type="radio"/> <b>yes</b> <input type="radio"/> no <input type="radio"/> unknown	<input type="checkbox"/>
		prisoners?  <input type="radio"/> <b>yes</b> <input type="radio"/> no <input type="radio"/> unknown	<input type="checkbox"/>

Number (refers to related Guideline)	Legal issue (L) or Policy issue (P)	Question	Action required? (please tick if yes)
		<p>pain patients with a history of substance abuse?</p> <p><input type="radio"/> <b>yes</b></p> <p><input type="radio"/> no</p> <p><input type="radio"/> unknown</p>	<input type="checkbox"/>
		<p>people living with HIV?</p> <p><input type="radio"/> <b>yes</b></p> <p><input type="radio"/> no</p> <p><input type="radio"/> unknown</p>	<input type="checkbox"/>
		<p>sex workers?</p> <p><input type="radio"/> <b>yes</b></p> <p><input type="radio"/> no</p> <p><input type="radio"/> unknown</p>	<input type="checkbox"/>
		<p>men who have sex with men?</p> <p><input type="radio"/> <b>yes</b></p> <p><input type="radio"/> no</p> <p><input type="radio"/> unknown</p>	<input type="checkbox"/>
		<p>injecting drug users?</p> <p><input type="radio"/> <b>yes</b></p> <p><input type="radio"/> no</p> <p><input type="radio"/> unknown</p>	<input type="checkbox"/>
8	P	<p>b) Do patients with opioid dependence have equal access to treatment regardless of:</p>	
		<p>▶ age?</p> <p><input type="checkbox"/> <b>yes</b></p> <p><input type="checkbox"/> no</p> <p><input type="checkbox"/> unknown</p>	<input type="checkbox"/>
		<p>▶ gender?</p> <p><input type="checkbox"/> <b>yes</b></p> <p><input type="checkbox"/> no</p> <p><input type="checkbox"/> unknown</p>	<input type="checkbox"/>
		<p>▶ HIV-status?</p> <p><input type="checkbox"/> <b>yes</b></p> <p><input type="checkbox"/> no</p> <p><input type="checkbox"/> unknown</p>	<input type="checkbox"/>

Number (refers to related Guideline)	Legal issue (L) or Policy issue (P)	Question	Action required? (please tick if yes)
		▶ length of substance abuse?  <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		▶ history of attempts at abstinence or unsuccessful treatment attempts?  <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		▶ psychiatric conditions?  <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
8	P	c) Do pregnant and lactating women have equal access to treatment of opioid dependence as other patients?  <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
9	L	a) Has the government conducted an examination to determine if there are provisions in the national and lower legislation and in the official policies that are stricter than the international drug control conventions require?  <input type="checkbox"/> <b>yes, please specify which laws or regulations have been checked and which relevant laws and regulations still need examination:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		b) If such provisions are present, are they necessary or desirable for the protection of the public health or welfare and do they contribute to a better public health (as composed of the availability and accessibility to controlled medicines for rational medical use, and the prevention of abuse, diversion and dependence)?  <input type="checkbox"/> <b>yes, please specify outcomes by provision:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>

Number (refers to related Guideline)	Legal issue (L) or Policy issue (P)	Question	Action required? (please tick if yes)
9	L	<p>c) If provisions were identified that are not necessary or desirable for the protection of the public health or welfare and do not contribute to a better public health, were they either removed or replaced by alternative ways to provide the same level of prevention without posing a barrier to rational medical use?</p> <p><input type="checkbox"/> <b>yes, please specify:</b>  <input type="checkbox"/> no  <input type="checkbox"/> unknown</p>	<input type="checkbox"/>
9	(L - Refers also to Guideline 11)	<p>d) In particular, indicate if the legislation or the policies contain the following provisions that are stricter than required by the drug control conventions that impede prescribing, dispensing and distribution for rational medical use:</p>	
		<p>▶ is the time span for which controlled medicines may be prescribed more limited than for other medicines?</p> <p><input type="checkbox"/> <b>yes, please specify maximum duration and difference with other medicines:</b>  <input type="checkbox"/> no  <input type="checkbox"/> unknown</p>	<input type="checkbox"/>
		<p>▶ is the validity of prescriptions for controlled medicines more limited than for other medicines?</p> <p><input type="checkbox"/> <b>yes, please specify maximum validity and difference with other medicines:</b>  <input type="checkbox"/> no  <input type="checkbox"/> unknown</p>	<input type="checkbox"/>
		<p>▶ is the practitioner allowed to determine the appropriate pharmacological treatment (choice of medicine, formulation, strength, dosage and duration) based on individual patient needs and on sound scientific medical guidance?</p> <p><input type="checkbox"/> <b>yes</b>  <input type="checkbox"/> no; please specify restrictions and difference with other medicines  <input type="checkbox"/> unknown</p>	<input type="checkbox"/>
		<p>▶ is there a limitation on the use of strong opioids in moderate to severe pain to one or more specific diseases (e.g. cancer pain), while moderate to severe pain from other causes remains unaddressed?</p> <p><input type="checkbox"/> <b>yes, please specify restrictions:</b>  <input type="checkbox"/> no  <input type="checkbox"/> unknown</p>	<input type="checkbox"/>

Number (refers to related Guideline)	Legal issue (L) or Policy issue (P)	Question	Action required? (please tick if yes)
		<ul style="list-style-type: none"> <li>▶ is permission required for the patient to render him/her eligible to receive a prescription for a controlled medicine?               <ul style="list-style-type: none"> <li><input type="checkbox"/> yes</li> <li><input type="checkbox"/> no</li> <li><input type="checkbox"/> unknown</li> </ul> </li> </ul>	<input type="checkbox"/>
		<ul style="list-style-type: none"> <li>▶ can controlled medicines be prescribed on a single copy of regular prescription paper?               <ul style="list-style-type: none"> <li><input type="checkbox"/> yes</li> <li><input type="checkbox"/> no; please specify what is needed and at what cost:</li> <li><input type="checkbox"/> unknown</li> </ul> </li> </ul>	<input type="checkbox"/>
		<ul style="list-style-type: none"> <li>▶ is there a registration of patients treated with opioids for opioid dependence?               <ul style="list-style-type: none"> <li><input type="checkbox"/> yes if yes, please specify if there are any such consequences as the refusal of a driver's license, government employment, housing, or denial of child custody, that will cause patients not to seek treatment; if yes, please specify the period for which the registration is kept; if yes, please specify what warrants are in place that ensure the privacy of the patient will not be breached</li> <li><input type="checkbox"/> no</li> <li><input type="checkbox"/> unknown</li> </ul> </li> </ul>	<input type="checkbox"/>
		<ul style="list-style-type: none"> <li>▶ are health workers with general prescribing authority, while performing their professional duties, allowed to prescribe controlled medicines without an additional license?               <ul style="list-style-type: none"> <li><input type="checkbox"/> yes</li> <li><input type="checkbox"/> no</li> <li><input type="checkbox"/> unknown</li> </ul> </li> </ul>	<input type="checkbox"/>
		<ul style="list-style-type: none"> <li>▶ are pharmacists with general dispensing authority, while performing their professional duties, allowed to dispense controlled medicines without a license?               <ul style="list-style-type: none"> <li><input type="checkbox"/> yes</li> <li><input type="checkbox"/> no</li> <li><input type="checkbox"/> unknown</li> </ul> </li> </ul>	<input type="checkbox"/>

Number (refers to related Guideline)	Legal issue (L) or Policy issue (P)	Question	Action required? (please tick if yes)
		<p>▶ is providing information about treatment with and use of controlled medicines allowed and can people providing such information be free from fear of prosecution?</p> <p><input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown</p>	<p><input type="checkbox"/></p>
10	L	<p>a) Is there terminology in the legislation that has the potential to confuse the medical use of controlled medicines with substance abuse?</p> <p><input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown</p>	<p><input type="checkbox"/></p>
10	L	<p>b) Does a definition of "abuse" (or "misuse") exclude the long-term medical use of controlled medicines concurrent with accepted medical practice, and is it clear that medical use of controlled substances, whether long-term or not, and whether adverse drug reactions (including "drug dependence") occur or not, is not "drug abuse"?</p> <p><input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown</p>	<p><input type="checkbox"/></p>
10	L	<p>c) Does a definition of "dependence" require the presence of a strong desire or a sense of compulsion to take the drug and is it clear from this definition that the mere occurrence of tolerance or withdrawal symptoms does not warrant such a diagnosis?</p> <p><input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown</p>	<p><input type="checkbox"/></p>
10	L	<p>d) Does the legislation contain stigmatizing terms for controlled medicines, such as the use of the legal terms "narcotic drugs" and "psychotropic drugs" for medicines beyond their legal meaning related to the international drug conventions?</p> <p><input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown</p>	<p><input type="checkbox"/></p>
10	L	<p>e) Does the legislation refer to patients in a respectful way and in particular, does it avoid stigmatizing terminology such as use of the word "addict" for a patient with dependence?</p> <p><input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> unknown</p>	<p><input type="checkbox"/></p>

Number (refers to related Guideline)	Legal issue (L) or Policy issue (P)	Question	Action required? (please tick if yes)
<b>Healthcare professionals</b>			
11/12	L	a) Can health professionals be free from fear of investigation, prosecution and disproportionate punishment for minor or unintentional breach of drug control rules?  <input type="checkbox"/> <b>yes</b> <input type="checkbox"/> no; please specify <input type="checkbox"/> unknown	<input type="checkbox"/>
12	L	b) Are pharmacists allowed to correct technical errors in prescriptions and to dispense small amounts of controlled medicines in case of emergencies?  <input type="checkbox"/> <b>yes</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
13	P	a) Is there a government policy that urges medical, pharmaceutical and nursing schools to teach the medical use of controlled medicines, including the use of opioid analgesics and pain management?  <input type="checkbox"/> <b>yes, please specify:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
13	P	b) Are relevant WHO treatment guidelines or other international or national evidence-based guidelines for the various diseases and disorders that need treatment with controlled medicines implemented throughout the country, including for:	
		▶ pain management?  <input type="checkbox"/> <b>yes, please specify:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		▶ treatment of opioid dependence?  <input type="checkbox"/> <b>yes, please specify:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>
		▶ prevention of HIV/AIDS?  <input type="checkbox"/> <b>yes, please specify:</b> <input type="checkbox"/> no <input type="checkbox"/> unknown	<input type="checkbox"/>

Number (refers to related Guideline)	Legal issue (L) or Policy issue (P)	Question	Action required? (please tick if yes)
		<ul style="list-style-type: none"> <li>▶ psychiatric and neurological disorders, in particular on the use of anxiolytics, hypnotics and anti-epileptics?</li> <li><input type="checkbox"/> <b>yes, please specify:</b></li> <li><input type="checkbox"/> no</li> <li><input type="checkbox"/> unknown</li> </ul>	<input type="checkbox"/>
		<ul style="list-style-type: none"> <li>▶ maternal health?</li> <li><input type="checkbox"/> <b>yes, please specify:</b></li> <li><input type="checkbox"/> no</li> <li><input type="checkbox"/> unknown</li> </ul>	<input type="checkbox"/>
14	P	<p>If the country is in a transition towards improved access and availability of controlled medicines, are training courses for physicians, pharmacists and nurses to teach the rational use of these medicines given throughout the country?</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> <b>yes</b></li> <li><input type="checkbox"/> no</li> <li><input type="checkbox"/> unknown</li> </ul>	<input type="checkbox"/>
<b>Estimates and statistics</b>			
15	P	<p>a) Does the government have a method to realistically estimate the medical and scientific requirements for controlled substances?</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> <b>yes, please specify:</b></li> <li><input type="checkbox"/> no</li> <li><input type="checkbox"/> unknown</li> </ul>	<input type="checkbox"/>
15	P	<p>b) Does this method include a certain surplus in order to minimize chances that the estimates are insufficient towards the end of the year?</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> <b>yes</b></li> <li><input type="checkbox"/> no</li> <li><input type="checkbox"/> unknown</li> </ul>	<input type="checkbox"/>
15	P	<p>c) Has the government critically examined this method and validated it against the methods recommended by WHO and INCB?<sup>n</sup></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> <b>yes</b></li> <li><input type="checkbox"/> no</li> <li><input type="checkbox"/> unknown</li> </ul>	<input type="checkbox"/>

<sup>n</sup> WHO/INCB Manual on estimates in preparation at the moment of publication of this document.



Number (refers to related Guideline)	Legal issue (L) or Policy issue (P)	Question	Action required? (please tick if yes)
15	P	<p>Has the government established a satisfactory system to collect information about requirements for controlled medicines from relevant facilities?</p> <p><input type="checkbox"/> <b>yes, please specify:</b>  <input type="checkbox"/> no  <input type="checkbox"/> unknown</p>	<input type="checkbox"/>
16	P	<p>a) Does the government furnish estimates to the INCB of the requirements for narcotic drugs and certain precursors for the next year in a timely manner?</p> <p><input type="checkbox"/> <b>yes, please provide date of latest submission:</b>  <input type="checkbox"/> no  <input type="checkbox"/> unknown</p>	<input type="checkbox"/>
16	P	<p>b) Does the government furnish assessments (simplified estimates) to the INCB of the requirements for psychotropic substances at least every three years?</p> <p><input type="checkbox"/> <b>yes, please provide date of latest submission:</b>  <input type="checkbox"/> no  <input type="checkbox"/> unknown</p>	<input type="checkbox"/>
16	P	<p>c) If it appears that the medical need for narcotic drugs (mainly opioid analgesics and long-acting opioid agonists for treatment of dependence) will exceed the estimated amount that has been confirmed by the INCB, is it government policy to furnish a supplementary estimate to the INCB?</p> <p><input type="checkbox"/> <b>yes</b>  <input type="checkbox"/> no  <input type="checkbox"/> unknown</p>	<input type="checkbox"/>
17	P	<p>Does the government submit to the INCB in a timely manner the required quarterly and annual statistical reports on narcotic drugs and psychotropic substances?</p> <p><input type="checkbox"/> <b>yes, please provide submission dates for the last year:</b>  <input type="checkbox"/> no  <input type="checkbox"/> unknown</p>	<input type="checkbox"/>

Number (refers to related Guideline)	Legal issue (L) or Policy issue (P)	Question	Action required? (please tick if yes)
<b>Procurement</b> (See also the questions for Guideline 7)			
18	P	a) Has the government established a satisfactory system that ensures, in cooperation with the distribution channels, that the procurement, manufacture, and distribution of controlled medicines are accomplished in a timely manner so that there are no shortages of supply, and that such medicines are always available to patients when they are needed?  <input type="checkbox"/> <b>yes</b> <input type="checkbox"/> <b>no</b> <input type="checkbox"/> <b>unknown</b>	<input type="checkbox"/>
18	P	b) Is there a sufficiently geographical coverage of pharmacies and/or dispensaries all over the country, not limited to hospital pharmacies, where patients and their families can obtain controlled medicines without spending considerable amounts of time on travel, nor needing to make high expenses for such travel?  <input type="checkbox"/> <b>yes</b> <input type="checkbox"/> <b>no</b> <input type="checkbox"/> <b>unknown</b>	<input type="checkbox"/>
19	P	a) Does the government promote the availability of controlled medicines at affordable cost?  <input type="checkbox"/> <b>yes, please specify methods:</b> <input type="checkbox"/> <b>no</b> <input type="checkbox"/> <b>unknown</b>	<input type="checkbox"/>
19	P	b) Are there any fees for licenses for the market admission, procurement, manufacture, and distribution of controlled medicines in addition to those licenses required for medicines not under control?  <input type="checkbox"/> <b>yes, please specify which licenses and fees:</b> <input type="checkbox"/> <b>no</b> <input type="checkbox"/> <b>unknown</b>	<input type="checkbox"/>
20	P	Are the drug control authorities responsible for issuing export permits aware of the existence of the <i>WHO model guidelines for the international provision of controlled medicines for emergency medical care</i> , and did they ever apply them?  <input type="checkbox"/> <b>yes, but not applied</b> <input type="checkbox"/> <b>yes and applied; please specify:</b> <input type="checkbox"/> <b>no</b> <input type="checkbox"/> <b>unknown</b>	<input type="checkbox"/>

Number (refers to related Guideline)	Legal issue (L) or Policy issue (P)	Question	Action required? (please tick if yes)
<b>Other</b>			
21	L/P	<p>a) If the country considers enacting for any national drug control measures on any substance or medicine not under international control, is there a procedure to assess the real risk of abuse, the harm caused by such abuse, and its medical usefulness in decision-making and is it ensured that any drug control measure does not affect medical availability and accessibility?</p> <p><input type="checkbox"/> <b>yes, please specify methods:</b></p> <p><input type="checkbox"/> no</p> <p><input type="checkbox"/> unknown</p>	<input type="checkbox"/>
21	L/P	<p>If the country applies any national drug control measures on any substance or medicine not under international control, does it equally apply the relevant guidelines from this document on such a substance?</p> <p><input type="checkbox"/> <b>yes</b></p> <p><input type="checkbox"/> no</p> <p><input type="checkbox"/> unknown</p>	<input type="checkbox"/>
21	P	<p>If ketamine and/or tramadol is a controlled substance in the country, is medical availability and accessibility ensured throughout the country by applying the relevant guidelines from this document?</p> <p><input type="checkbox"/> <b>yes</b></p> <p><input type="checkbox"/> no</p> <p><input type="checkbox"/> unknown</p>	<input type="checkbox"/>

# ACKNOWLEDGEMENTS

These policy guidelines were produced by the World Health Organization, Department of Essential Medicines and Pharmaceutical Policies, Access to Controlled Medicines Team, as an update of the WHO guidelines *Achieving balance in national opioid control policy*. The original version was developed for WHO by the WHO Collaborating Centre for Policy and Communications in Cancer Care at the Pain and Policy Studies Group, University of Wisconsin, Madison WI, United States of America in 2000.<sup>o</sup>

The initial guidelines were derived from the international drug control conventions and from recommendations from authoritative bodies, such as the International Narcotics Control Board. For this update, other aspects of international law and research on the impediments for availability were also considered.

The update was prepared by Barbara Milani and Willem Scholten, in collaboration with Lauren Koranteng (all three Access to Controlled Medicines, World Health Organization), Saskia Jünger, Universitätsklinikum Aachen, Germany and Tom Lynch and Anthony Greenwood, both Lancaster University, Lancaster, United Kingdom.

A panel of international experts identified topics to address and commented on a first draft in a two-round Delphi study. The resulting final draft was discussed by a Guidelines Development Group that convened in Geneva, 22 – 24 November 2010.

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## Guidelines Development Group

### Members

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## Donors

See page iii (beginning of the document)

DECLARATIONS OF  
INTEREST OF THE  
GUIDELINES DEVELOPMENT  
GROUP MEMBERS



The Guidelines Development Group Members and other external participants were requested to provide a Declaration of Interest following the current WHO format.

Azizbek Boltaev reported that he served as an international expert for the United Nations Office on Drugs and Crime for training Turkmen drug treatment specialists and for preparing a report on quality standards of drug dependence treatment in Central Asia. He received an honorarium for his work. For the Eurasian Harm Reduction Network he provided technical assistance in a workshop on opioid substitution therapy and co-authored a review of the state of opioid substitution therapy in the Central Asian region, for which he receive US\$ 1000 and reimbursement of his expenses. Currently, he serves as the principal investigator of a US NIH funded project at Bukhara State Medical Institute that focuses on the analysis of cost-effectiveness of harm reduction strategies in Uzbekistan, including opioid substitution therapy. From 2006 to 2009 he served as a Regional Harm Reduction Advisor to DFID-funded Central Asian Regional HIV/AIDS Programme at GRM International that supported the range of services targeting injecting drug users, including opioid substitution therapy.

He receives reimbursement from the European Commission, 7<sup>th</sup> Framework Programme, for the cost of his participation in the Guidelines Development Group meeting.

Snezana Bosnjak is an International Pain Policy Fellow and the President of the National Palliative Care Commission in Serbia. In both functions she provided expert opinion and gave public statements on the need and methods to improve availability of opioids for pain and palliative care through education and policy. As Commission President, she also provided guidance to the government regarding a new bill on controlled substances. For the International Pain Policy Fellowship she received a US\$ 12 000 honorarium and US\$ 2000 per year for expenses (2006 - 2008) and US\$ 6000 per year for honorarium and expenses (2009 - 2010) from the Open Society Foundation. She received minor remuneration at various occasions for presentations on the use of opioid analgesics from Jansen and Hemofarma; for preparing brochures on the proper use of Duragesic patches; and for training staff of Merck on the appropriate use of morphine drops. She received a travel grant from Jansen to participate in the EAPC 2009 Congress. For the International Association for the Study of Pain, her team received research support to develop a brochure on opioiphobia for patients and professionals (US\$ 7940). She receives reimbursement from the European Commission, 7<sup>th</sup> Framework Programme for the cost of her participation in the Guidelines Development Group meeting.

Jim Cleary reported to be Director, Pain and Policies Study Group at the Paul C. Carbone Comprehensive Cancer Center, University of Wisconsin, Madison WI, United States. He also reported to be an independent member of the Data, Safety and Monitoring Committee for pain medicine of Wex Pharma (annual remuneration US\$ 3500). He also reported to be the institutional principal investigator for two studies by Archimedes (2008) and Wyeth (current). For both studies the University received a remuneration of US\$ 7000 per patient. He spoke at medical grand rounds and a conference at which he has discussed increased access to opioids for pain control (honorarium of US\$ 2500 - US\$ 7500). He also reported he has participated in a documentary film by WhyteHouse on access to pain medicines with no honorarium.

Saskia Jünger declared that the unit where she is employed is one where colleagues received funding from various pharmaceutical companies, including the opioid producing companies Grünenthal, Mundipharma and Janssen. She received reimbursement from the European Commission, 7<sup>th</sup> Framework Programme, for the cost of her participation in the Guidelines Development Group meeting.

Liliana de Lima reported being employed as the Executive Director of the International Association for Hospice and Palliative Care (IAHPC) for the past ten years. One of the areas of work of IAHPC is improving access to opioid medications for medical treatment. She provides expert advice to the Governments of Colombia, Peru and Panama related to access to controlled medicines.

Diederik Lohman declared that Human Rights Watch receives funding for his employment from the Open Society Foundation to conduct policy research and advocacy on accessibility of controlled medicines.

Aukje Mantel-Teeuwisse receives reimbursement from the European Commission, 7<sup>th</sup> Framework Programme for the cost of her participation in the Guidelines Development Group meeting.

David Prail reported that he is the CEO of Help the Hospices – the national UK charity representing UK hospices. Help the Hospices receives government funding for three programmes: one in Sierra Leone, one with the African Palliative Care Association, and one on the development of palliative care for children in India and Malawi. He sits on the board of the Worldwide Palliative Care Alliance, and the board of the Indian Association of Palliative Care. Help the Hospices shares an interest in this area in as much as it is keen to see, and does all that it can to support, activities that promote appropriate access to pain control medicines and other medicines required by palliative care physicians across the world. He receives reimbursement from the European Commission, 7<sup>th</sup> Framework Programme for the cost of his participation in the Guidelines Development Group meeting.

Lukas Radbruch reported being the President of the European Association for Palliative Care (EAPC) since 2007, with involvement in activities to develop and implement palliative care in Europe, including media activities and projects to survey and improve the access to opioid medications in Europe, with no personal honorarium for this work. He receives reimbursement from the European Commission, 7<sup>th</sup> Framework Programme for the cost of his participation in the Guidelines Development Group meeting. He has given presentations at medical conferences for Archimedes and Cephalon on the development of medicines, receiving honorariums of 1000 - 2000. He is a Member of the Board of the Worldwide Palliative Care Alliance.

Allyn Taylor reported that she wrote a paper on access to pain medicine for the International Union against Cancer (UICC) as a consultant and received a honorarium of US\$ 10 000. She has received funding for travel.

Tom Lynch receives reimbursement from the European Commission, 7<sup>th</sup> Framework Programme for the cost of his participation in the Guidelines Development Group meeting. He attended a conference by the Pain and Policy Studies Group and received reimbursement for his travel from the Open Society Foundation.

Most declared interests coincide with the World Health Organization's objective of balancing controlled substances policies. They are not considered to be conflicting. Declarations that included involvement with the pharmaceutical industry are all considered minor. Moreover, the current guidelines do not make any recommendation on products or treatment methods.



# ANNEX 1

**CONTROLLED MEDICINES ALSO LISTED AS WHO ESSENTIAL MEDICINES OR WHO ESSENTIAL MEDICINES FOR CHILDREN (95, 96)**

Substance	Dosage form	Strength	Indications	For Children	For Adults
buprenorphine	not specified	not specified	used in substance dependence programmes	-	x
codeine	tablet	15 mg (phosphate)	opioid analgesic	x	x
		30 mg (phosphate)	1. opioid analgesic 2. (indication under review) antidiarrhoeal (symptomatic) medicines in adults	-	x
diazepam *	injection	5 mg/ml in 2ml ampoule	preoperative medication and sedation for short-term procedures	x	x
	oral liquid	2 mg/5 ml	generalized anxiety	x	-
	rectal solution or gel	5 mg/ml in 0.5 ml tube	anticonvulsant/ antiepileptic	x	x
		5 mg/ml in 1 ml tube		x	-
		5 mg/ml in 2 ml tube		x	x
		5 mg/ml in 4 ml tube		x	x
	tablet	2 mg	generalized anxiety	x	x
		5 mg	1. generalized anxiety 2. preoperative medication and sedation for short-term procedures	x	x
		10 mg	generalized anxiety	x	x
ephedrine	injection	30 mg (hydrochloride)/ ml in 1 ml ampoule	spinal anaesthesia during delivery, to prevent hypotension	-	x
ergometrine *	injection	200 micrograms (hydrogen maleate) in 1 ml ampoule	oxytocic	-	x
lorazepam *	parenteral formulation	2 mg/ml in 1 ml ampoule	anticonvulsant/ antiepileptic	x	x
		4 mg/ml in 1 ml ampoule		x	x

Substance	Dosage form	Strength	Indications	For Children	For Adults
methadone *	concentrate for oral liquid	5 mg/ml (hydrochloride)	used in substance dependence programmes	-	x
		10 mg/ml (hydrochloride)		-	x
	oral liquid	5 mg/5 ml	used in substance dependence programmes	-	x
		10 mg/5 ml		-	x
midazolam	injection	1 mg/ml	anticonvulsant/antiepileptic	x	-
		5 mg/ml		x	-
morphine	granules (modified release) (to mix with water)	20 mg	opioid analgesic	x	-
		30 mg		x	-
		60 mg		x	-
		100 mg		x	-
		200 mg		x	-
	injection	10 mg/ml (sulfate or hydrochloride) in 1 ml ampoule	1. preoperative medication and sedation for short-term procedures 2. opioid analgesic	x	x
	oral liquid	10 mg (morphine hydrochloride or morphine sulfate)/5 ml	opioid analgesic	x	x
	tablet (immediate release)	10 mg (morphine sulfate)	opioid analgesic	x	x
	tablet (prolonged release)	10 mg (morphine sulfate)	opioid analgesic	x	x
		30 mg (morphine sulfate)		x	x
60 mg (morphine sulfate)		x		x	

Substance	Dosage form	Strength	Indications	For Children	For Adults
phenobarbital	injection	200 mg/ml (phenobarbital sodium)	anticonvulsant/antiepileptic	x	x
	oral liquid	15 mg/5 ml (phenobarbital)	anticonvulsant/antiepileptic	x	x
	tablet	various strengths: 15 mg to 100 mg	anticonvulsant/antiepileptic	x	x
thiopental	powder for injection	0.5 g (sodium salt) in ampoule	general anaesthetic	x	x
		1 g (sodium salt) in ampoule		x	x

\* The listed medicine should be the example of the class for which there is the best evidence for effectiveness and safety.

Remark: Ketamine injection 50 mg (as hydrochloride)/ml in 10ml vial is listed for general anaesthesia. Ketamine is not under *international* control. However, in some countries it is under *national* control. Therefore according to Guideline 21, the guidelines in this document should be equally applied to ketamine (95, 96).

# ANNEX 2



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## Selected WHO treatment guidelines

### Pain treatment

World Health Organization. *Cancer pain relief with a guide to opioid availability*, 2nd ed. Geneva, 1996. Available in Chinese, English<sup>p</sup>, French\*, Russian, Spanish\* and Thai\*.

WHO Bookshop: <http://apps.who.int/bookorders/anglais/detart1.jsp?sesslan=1&codlan=1&codcol=15&codcch=2247> (accessed 3 January 2011)

Downloadable from the WHO Library at: <http://whqlibdoc.who.int/publications/9241544821.pdf> (accessed 3 January 2011)

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<sup>p</sup> Language versions marked with an asterisk are on the enclosed CD-ROM.

<sup>q</sup> ISBN Numbers refer to English version. For ISBN numbers for other language versions please consult the links provided.

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[http://whqlibdoc.who.int/paho/2010/9789275331132\\_spa.pdf](http://whqlibdoc.who.int/paho/2010/9789275331132_spa.pdf) (accessed 3 January 2011)



# ANNEX 3

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## Contents of the CD-ROM *Ensuring balance in national policies on controlled substances*

- Reference list to *Ensuring balance in national policies on controlled substances: guidance for availability and accessibility of controlled medicines*
- Country Assessment Checklist (version in Word format)
- Barriers to opioid analgesic availability test (BOAT) (Adapted version)
- *WHO model list of essential medicines*, 16<sup>th</sup> ed. Geneva, March 2009. (Multiple languages)
- *WHO model list of essential medicines for children*, 2<sup>nd</sup> ed. Geneva, March 2009 (Multiple languages)
- Full texts of guidelines mentioned in Annex 2; Selected WHO treatment guidelines (Multiple languages)
- World Health Organization, *Model guidelines for the international provision of controlled medicines for emergency medical care*. Geneva, 1996. (English and French)
- Further reading
  - Access to Controlled Medicines
  - Barriers
  - Human rights
  - Injecting Drug Use
  - Logistics
  - Maternal mortality
  - Pain management
  - Palliative care

### International Conventions:

- The international drug control conventions, their schedules and their official commentaries (English)<sup>r</sup>
- ICESCR (English, French) and its General Comment 14 (Multiple languages)
- WHO Constitution (Multiple languages)
- Other conventions that involve access to medicines and to health
  - Convention on the Elimination of All Forms of Discrimination against Women (English)

<sup>r</sup> For other language versions (Arabic, Chinese, French, Russian and Spanish): [www.incb.org](http://www.incb.org) (accessed 9 January 2011).

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