

Do international model drug control laws provide for drug availability?

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^a The WHOCC is located in the Pain & Policy Studies Group at the University of Wisconsin Carbone Comprehensive Cancer Center, School of Medicine and Public Health. Its terms of reference include providing technical assistance to the World Health Organization and Member States to respond to the World Health Assembly call in 2005 to ensure the medical availability of opioid analgesics for pain relief; to use WHO Guidelines to assess “balance” and barriers in national approaches to opioid analgesic regulation; to cooperate with units of the WHO and national Governments; to develop methods to communicate with health professionals, regulators and policy makers about balanced drug control policy and to develop methods to study national and international policies related to the medical use of opioid analgesics. Since 1996, the WHOCC has been developing methods and resources for evaluating national policies and improving availability and access to opioid analgesics for the relief of pain due to cancer and HIV/AIDS in many countries.

INTRODUCTION

The World Health Organization (WHO) considers opioid analgesics to be essential for the treatment of pain, but there are great disparities in their availability among countries of the world, leading to needless pain and suffering. Over a period of 15 years of study and efforts to rectify these disparities, the Pain & Policy Studies Group (PPSG) has found that national narcotics control laws often do not contain provisions that recognize the dual obligation of governments under the international drug control conventions not only to control narcotic drugs but also to make them adequately available for medical and scientific purposes.

International drug control organizations develop and publish model narcotics laws and regulations for governments to use. If these models convey the dual obligations of governments, the models would be considered “balanced,” and national governments would have model policy language not only for control of licit drugs, but also for their availability. Most governments have already adopted laws to implement the Single Convention, however it is not known if they followed the Single Convention itself or model laws.

The PPSG conducted this preliminary assessment of whether the models published by the United Nations Office on Drugs and Crime are balanced, using as a guide the 1995 recommendations of the International Narcotics Control Board¹ and the 2000 WHO publication *Achieving Balance in National Opioids Control Policies: Guidelines for Assessment*.²

BACKGROUND

Parties to the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs, 1961 (Single Convention), are expected to adopt national laws and regulations to carry out their obligations, including to ensure adequate availability of narcotic drugs for medical and scientific purposes.

“The Parties, Concerned with the health and welfare of mankind, 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...Hereby agree as follows:” (Preamble)³

“...an efficient national drug control regime must involve not only a programme to prevent illicit trafficking and diversion, but also a programme to ensure the adequate availability of narcotic drugs for medical and scientific purposes” (p. 14)¹

The two mechanisms whereby the International Narcotics Control Board (INCB) endeavors, in cooperation with governments, to ensure adequate availability of narcotic drugs for medical and scientific purposes are the estimates system and statistical returns system. Articles 19 and 20 of the Single Convention specify the duties of the Parties and Articles 12 and 13 specify the administrative duties of the INCB with respect to estimates and statistics. Essentially, governments annually are to 1) estimate the amounts of narcotic drugs needed in the coming year to satisfy adequately medical and scientific needs in the country, and 2) report the amounts of narcotic drugs consumed (distributed to the retail level). The INCB’s role is to manage the

system so that there is a sufficient supply to meet demand while preventing diversion. Article 4 specifies that governments are to establish a system of controls so that the distribution and use of the drugs is limited to medical and scientific purposes.

The United Nations Economic and Social Council (ECOSOC)⁴ the INCB⁵ and the World Health Assembly (WHA)⁶ have called for action by national governments to identify and address unmet medical and scientific needs for narcotic drugs.

“Governments should determine whether their national narcotic laws contain elements of the 1961 Convention and the 1972 Protocol that take into account the fact that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering...” (p. 16)¹

According to a survey by the International Narcotics Control Board,¹ a number of countries appear not to have adopted laws to carry out the drug availability obligations of the Single Convention:

- Some governments do not recognize in national policy that narcotic drugs are indispensable for the relief of pain and suffering;^b
- Some governments do not affirmatively recognize the national obligation to ensure adequate opioid availability;^c
- Some governments fail to submit consumption statistics;^d
- Health professionals in many countries continue to be reluctant to prescribe or stock opioids because of unduly strict regulations and concerns about legal sanctions;^e
- Despite recommendations from the international authorities to governments to address these matters; some governments have not examined their methods for assessing medical needs for opioids as requested by international authorities.^f

Based on these findings, the INCB recommended that:

“Governments that have not done so should determine whether there are undue restrictions in national narcotics laws, regulations or administrative policies that impede prescribing, dispensing or needed medical treatment of patients with narcotic drugs, or their availability and distribution for such purposes, and should make the necessary adjustments” (p.15)¹

The purpose of this report is 1) to review the United Nations model laws regarding the drug availability obligations of governments under the Single Convention, and 2) to propose for discussion the elements of a model law that would assist governments to address the inadequate availability of opioids for medical and scientific purposes.

^b In a 1995 INCB survey of governments, only 48% of responding governments reported that their laws recognize that narcotic drugs are indispensable for the relief of pain and suffering.

^c The INCB survey found that only 63% of responding governments said there was a provision in national policy regarding the obligation to ensure availability of narcotic drugs for medical purposes.

^d See INCB Technical Report for Narcotic Drugs http://www.incb.org/incb/narcotic_drugs_reports.html

^e The INCB survey showed that 47% of responding governments identified health professionals' fear of legal sanctions as an impediment to opioid availability.

^f The INCB survey showed that 59% of responding governments said they had not examined their methods for assessing medical need for opioids.

ARE CURRENT MODEL LAWS BALANCED?

Model law is a traditional vehicle that governments use to draft national laws and regulations, consistent with national constitutions, in order to establish the legal framework and administrative infrastructure that is necessary to put into practice a government's international treaty obligations.

UNODC Model Laws

The United Nations Office on Drugs and Crime (UNODC) has issued several model laws.[§] One is considered current, the Model Law on the Classification of Narcotic Drugs, Psychotropic Substances and Precursors and on the Regulation of the Licit Cultivation, Production, Manufacture and Trading of Drugs (Model Law), dated January 2003.⁷ This Model Law addresses drug classification, prohibition and regulation of licit activities involving controlled drugs. Annexes include the drug classification schedules as well as definitions.

The introductory material in the Model Law says that it presents “provisions of the Single Convention on Narcotic Drugs, 1961...which States are required or recommended to introduce into their domestic legislation,” and that preparation of the model law was guided by “the desire to ensure the availability of drugs used in medicine.” However, the Model Law does not contain such provisions, but it does contain non-Single Convention language that appears to be ambiguous and possibly inappropriate by today's medical and scientific standards.

- The Model Law does not contain a provision that parallels the Preamble of the Single Convention recognizing that narcotic drugs are indispensable for relief of pain and suffering, or that there are dangers with respect to addiction to narcotic drugs.
- The Model Law does not recognize that Parties have an obligation to ensure that medical needs are adequately met, which was strengthened by the 1972 Protocol,
- Although a commentary mentions that the Single Convention requires governments to estimate requirements and report statistics, the Model Law does not recommend the specific provisions that governments could adopt in order to carry out these obligations. The Model Law does establish a domestic requirement that enterprises authorized in the country to handle controlled drugs must furnish information about their stocks and distributions of drugs to the Competent Authority. The Competent Authority is to establish the maximum allotments that entitle designated enterprises to manufacture, acknowledging the need for stocks of controlled drugs to be sufficient to allow smooth functioning of business within the country. A brief commentary states that the purpose of allotments is to distribute among the authorized enterprises the amount of drugs needed for manufacture and import each year in accordance with Articles 19 and 21 of the Single Convention. However, setting allotments for individual enterprises in a country to allow smooth functioning of business does not establish the obligation of the government itself to estimate adequately the amounts of

[§] A “Model Law for the application of the Single Convention on Narcotic Drugs, 1961” from 1969, although not considered to be current, was reviewed; no drug availability provisions were found.

narcotic drugs that will be needed for all medical and scientific purposes in the country.

- The section on classification of opioids such as morphine states that these drugs should be “subject to strict regulation.” (p. 8)⁷ The meaning of “strict regulation” is not discussed and is not balanced by language recognizing the need to ensure adequate availability for medical and scientific purposes.
- Several terms are defined in an Annex, although they do not seem to be used in the Model Law, such as ‘drug dependence,’ and ‘drug addict.’ ‘Drug addict’ is defined as “a person in a state of physical and/or psychic dependence on a drug.” Such a definition is outdated and allows confusion of pain patients as addicts merely by their physical dependence on opioids. This definition would not meet the standard for balanced national drugs control policy established by the WHO.²

In conclusion, this Model Law appears not to contain the specific provisions which, if adopted by a Party, would satisfy its obligation to adopt laws, regulations and administrative procedures to carry out the provisions of the Single Convention to ensure adequate availability of narcotic drugs for medical and scientific purposes. Furthermore, it contains outdated and incorrect definitions that could confuse pain patients with drug addicts.

UNODC Model Regulation

The UNODC Model Regulation Establishing an Interministerial Commission for the Coordination of Drug Control (Model Regulation)⁸ provides language for a government to consider in establishing a Commission to be responsible for defining, promoting and coordinating all drug control policy in the country. The Commission is to be led by the Prime Minister or the Minister of Justice. The Commission membership is to be comprised of many Ministries, including the Director of Pharmaceutical Services of the Ministry of Health, the Drug Control Commission, and the central drug enforcement agency.

- Among the terms of reference listed for the Commission is the task of “implementing the provisions of the United Nations conventions of 1961, 1971 and 1988.” However, all the references are to drug abuse and trafficking and there are no references to licit drug availability.

This Model Regulation appears not to address the obligation of Parties to establish a special administrative structure (Article 17) to carry out the provisions of the Single Convention to ensure adequate availability of narcotic drugs for medical and scientific purposes, in particular the estimates and statistics (Articles 19 and 20). Although the General Secretariat is tasked with the responsibility to “ensure or facilitate the transmission of information and data to the competent international bodies as required by the treaties,” this general language would not provide specific direction to governments regarding their obligation to estimate requirements and report statistics. In addition, there is no reference to narcotic drugs being indispensable as stated in the Preamble to the Single Convention, nor is there any reference to medical use of drugs, or the obligation to ensure adequate availability, or whether the Commission is the Competent Authority under the Single Convention.

UNODC Model Drug Abuse Bill

The UNODC also has on its website a Model Drug Abuse Bill (Model Bill)⁹ that governments with common law legal systems can use as a guide to establishing a comprehensive drug control law that will “ensure full and effective implementation of obligations under the international drug control conventions.” The objective of the Bill is “to ensure that certain drugs are available only for medical, scientific purposes, while preventing their abuse.”

However, the Model Bill does not include provisions that would:

- Recognize that narcotic drugs are indispensable for the relief of pain and suffering.
- Establish the national obligation to ensure adequate availability for medical and scientific purposes
- Establish the government’s obligation for estimating requirements and reporting statistics
- Establish a competent authority to administer licit drug obligations under the Single Convention.

Furthermore, the Model Bill contains several terms and provisions that appear to be inconsistent with the Single Convention.

- The Model Bill contains terms not found in the Single Convention to describe the drugs controlled under the conventions, such as “drugs of abuse,” “high-risk drugs” (which includes morphine), and “risk drugs.”
- The Model Bill contains a legal definition of “drug dependent person” which is outdated and medically incorrect by today’s standards: Drug dependent person means a person in whom: “administration of the drug to him or her results in the person demonstrating impaired control in relation to the use of that drug, or drug seeking behaviour suggesting impaired control, or cessation of the administration of the drug is likely to result in the person experiencing symptoms of mental or physical distress or disorder.” The third clause has the potential to confuse drug dependence (which is a complex biopsychosocial condition that can be difficult to treat) with physical dependence (a normal physiologic effect of the use of opioid analgesics for pain relief that can be successfully medically managed if the drug is no longer needed).
- The Model Bill prohibits prescribing to “drug dependent persons” without regard to whether the drug dependent person may have severe pain from a disease such as cancer or HIV/AIDS. Together with the outdated definition of “drug dependent person,” the Model Bill may suggest that prescribing even to a physically dependent pain patient may be unlawful.
- The Model Bill defines “drug abuser” as one who uses drugs of abuse without a medical prescription for other than a medical purpose, apparently neglecting the possibility that some persons with a medical prescription may be abusers.

- The Model Bill, without citing the Single Convention or offering a medical rationale, cautions against issuing prescriptions in “an unusual or dangerous dose.” Terms such as “unusual” or “dangerous” when applied to dosing are ambiguous. For example, excessive caution about dosing morphine can lead to under treatment of pain. An expert committee of the WHO indicated that opioids such as morphine do not have a ceiling dose, that the dose should be increased until pain is relieved or side effects are not tolerated; the expert committee cautioned against governmental regulation of dosage, which is a medical decision that should be based on the patient’s needs.¹⁰

CONCLUSIONS

Current UN model laws do not provide sufficient guidance to governments to implement drug availability under the Single Convention. Furthermore they recommend some provisions that appear to be inconsistent with the Single Convention and advice from international authorities such as the World Health Organization. The models concentrate on the abuse potential of narcotic drugs to the exclusion of the medical value of narcotic drugs. They do not contain provisions that convey the obligation to ensure the adequate availability of narcotic drugs or provisions to establish a Competent Authority to carry out the specific licit drug regulatory responsibilities of the Single Convention.^h

RECOMMENDATION: REVISE THE MODELS

The following suggestions are offered as a starting point to encourage broader discussion and exploration of the measures that should be included in a revised model law and regulation and to generate discussion about how governments can improve their national drug control policies with respect to drug availability. The proposed language follows the Single Convention but would need to be adapted to the constitutional and legal systems of individual governments, existing law, and the appropriate application of law vs. administrative regulations. For example, provisions designating the Competent Authority could appear in both law and regulations.

Model law

1. [Name of State], recognizing that the medical use of narcotic drugs is indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the adequate availability of narcotic drugs, hereby enacts this law to carry out the obligations of the government of [name of State] to give effect to and carry out the provisions of the Single Convention on Narcotic Drugs, 1961, as amended, to limit exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of drugs, and to ensure their adequate availability for medical and scientific purposes;

^h The UNODC does publish a “check list” of the Main Mandatory Requirements on Parties which includes establishing a “special licit drug regulatory administration” to, inter alia, “maintain forward estimates and *ex-post* statistics of domestic licit drug demand, communicate them to the INCB” but does not mention the governmental obligation to ensure adequate availability. See United Nations Office on Drugs and Crime. *UN Drug Control Conventions Checklist: Main Mandatory Requirements on Parties*. Vienna, Austria: United Nation Office on Drugs and Crime; 2002. Available at http://www.unodc.org/pdf/lap_checklist_convention.pdf.

2. *The [name of government agency, within the ____ Ministry] is designated as the Competent Authority for administering the obligations of [name of State] under the Single Convention on Narcotic Drugs, 1961, as amended, and shall have the following responsibilities¹*

3. *The (Name of Competent Authority) may issue administrative regulations regarding (statement of scope of authority).*

Model regulation

A model regulation can assist governments to designate the Competent Authority (if the law does not name an agency) and assign specific responsibilities to assure full adherence to international conventions and the advice of international authorities. Guidelines for National Competent Authorities are available from the INCB.¹¹ The INCB has training materials about the administrative aspects of preparation and submission of estimates¹² and statistics.¹³ Budgetary matters such as the assignment of sufficient personnel and resources to the Competent Authority are not included in this report, but have been recognized by the INCB as essential to achieving and sustaining adequate availability of opioids.¹

Model regulation

1. The (name of Competent Authority) is designated as the focal point for administering the following licit drug control functions under the Single Convention, limiting the use of opioids to medical and scientific purposes while ensuring their adequate availability for such purposes, including the relief of pain and suffering and shall have the following responsibilities:

a. Estimates of requirements.

1) Develop, in cooperation with relevant organizations and experts, a system to collect information and methods to estimate realistically all medical and scientific needs for opioids controlled under [name of law];

2) Furnish to the International Narcotics Control Board each year in the manner and form prescribed by the Board, estimates of the adequate quantities of drugs that will be required to be consumed for medical and scientific purposes, and to furnish supplemental estimates if the medical need exceeds the estimate in order to prevent interruptions in satisfying the treatment needs of patients;

b. Statistics.

1) The (Competent Authority) shall furnish to the Board in the manner and form prescribed by the Board, statistical returns on forms supplied by

¹ The reporting requirements listed here are abbreviated to include only those regarding the estimate of medical and scientific needs and consumption; to be complete, the other reporting requirements should be added during the drafting of new model policies.

it in respect of the production, manufacture and consumption of narcotic drugs.

2) The [Competent Authority] shall inform enterprises and individuals authorized to use drugs controlled under [national drug control law] about the legal requirements;

c. Other duties. In cooperation with national governmental and non governmental organizations including cancer and HIV/AIDS control and individuals and enterprises authorized under [the drug control law], the [Competent Authority] may:

1) conduct periodic critical examination of the methods for assessing requirements for opioids and the systems for obtaining information about medical needs to ensure adequate availability;

2) identify and recommend ways to correct problems that interrupt procurement and distribution of opioids;

3) assess national [and applicable provincial or state] laws and regulations for appropriate balance in preventing abuse of and ensuring availability of opioids;

4) recommend changes in regulatory requirements that interfere in prescribing and dispensing opioids to patients;

5) make recommendations to improve nationwide patient access to controlled opioid medications.

The drafting of national laws should take into consideration the relevant conventions and advice from international authorities including the INCB and the WHO. A revised model should encourage the repeal or amendment of provisions that are unduly restrictive, for example restrictions on patient care decisions that are medical in nature. The WHO has issued Guidelines, endorsed by the INCB, to guide the examination of national laws.² Revised drug control model laws will enable Parties to establish the balanced drug regulatory infrastructure that was envisioned by the Single Convention so that future generations can benefit not only from the prevention of abuse, but finally, from the adequate availability of medicines that are essential for medical and scientific purposes, including for the relief of pain and suffering.^j

In addition to revising the models, a renewed international effort to improve availability of drugs under control should include the activities proposed by the WHO's Access to Controlled Medicines Program, activities of relevant WHO Collaborating Centers, a re-survey of governments about drug availability policies and practice by the INCB (similar to the 1995 survey), an examination of a sample of national laws and their administration, as well as enhanced monitoring and consultation from UN drug control organizations to support governmental efforts to improve control and availability.

^j Complete analysis of international and national policy with respect to drug availability should include other conventions as well as other legitimate medical purposes for drugs (in addition to pain treatment).

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