Do national drug control laws ensure the availability of opioids for medical and scientific purposes?

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Objective To determine whether national drug control laws ensure that opioid drugs are available for medical and scientific purposes, as intended by the 1972 Protocol amendment to the 1961 Single Convention on Narcotic Drugs.

Methods The authors examined whether the text of a convenience sample of drug laws from 15 countries: (i) acknowledged that opioid drugs are indispensable for the relief of pain and suffering; (ii) recognized that government was responsible for ensuring the adequate provision of such drugs for medical and scientific purposes; (iii) designated an administrative body for implementing international drug control conventions; and (iv) acknowledged a government's intention to implement international conventions, including the Single Convention.

Findings Most national laws were found not to contain measures that ensured adequate provision of opioid drugs for medical and scientific purposes. Moreover, the model legislation provided by the United Nations Office on Drugs and Crime did not establish an obligation on national governments to ensure the availability of these drugs for medical use.

Conclusion To achieve consistency with the Single Convention, as well as with associated resolutions and recommendations of international bodies, national drug control laws and model policies should be updated to include measures that ensure drug availability to balance the restrictions imposed by the existing drug control measures needed to prevent the diversion and nonmedical use of such drugs.

Abstracts in عربي, 中文, Français, Русский and Español at the end of each article.

Introduction

In a report to the United Nations, the International Narcotics Control Board (INCB) stated:

"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 the rational use of narcotic drugs and psychotropic substances."[1]

Countries that signed the 1961 Single Convention on Narcotic Drugs as Amended by the 1972 Protocol, hereafter referred to as the Single Convention, are expected to abide by the Convention's provisions on the control of certain drugs while ensuring that these drugs are available for medical purposes. The Single Convention established a medicolegal principle of balance: governments have a dual obligation to prevent the diversion and abuse of narcotic drugs and to ensure adequate provision of opioid analgesics for legitimate medical and scientific purposes.[2] In this paper, we use the word "balance" in the way it is used by international organizations, such as the United Nations Economic and Social Council, the INCB,[3] the World Health Organization (WHO)[2] and the Commission on Narcotic Drugs.[4] Drug availability is ensured most effectively in the context of balance and drug control is achieved most effectively when carried out with availability in mind. Table 1 lists the principal measures proposed by the Single Convention to ensure the availability and control of Schedule I drugs in situations in which a closed drug control system has been established to give a government authority over other involved parties, thus preventing the diversion and nonmedical use of these substances. Schedule I drugs belong to one of four schedules of drugs classified by the Single Convention according to their potential for abuse and medical value. These drugs are recognized as being essential for medical and scientific purposes but, since they are also the most susceptible to abuse, are subject to the most stringent control of all medical drugs. Drugs may be added to Schedule I by the Commission on Narcotic Drugs on the recommendation of WHO if they have the same potential for abuse as other drugs on the schedule.[5]

WHO has estimated that tens of millions of people worldwide experience pain associated with late-stage cancer, acquired immunodeficiency syndrome (AIDS) and other painful diseases and conditions.[6] However, despite WHO's long-standing designation of morphine as an essential medicine for the relief of pain, much of the world still does not have access to this drug or to other opioid medications commonly used for the treatment of pain and dependence syndrome,[3] such as hydromorphone, fentanyl, morphine, methadone and oxycodone. Moreover, WHO estimates that over 80% of the world's population lives in countries with little or no access to controlled opioid analgesics.[6–8] Indeed, most patients in developing countries with cancer, AIDS and other painful conditions are not treated with opioid medicines because access to these controlled drugs is severely restricted.[3,7,9,10] According to United Nations' bodies, there are a number of reasons for the poor availability of, or limited access to, essential opioid medicines, such as concerns about patients developing dependence, insufficient training for health-care professionals and problems with procurement, manufacture and distribution.[2,3,11,12] In addition, the availability of these substances for medical use has also been severely limited by administrative requirements that are much stricter than the control measures proposed by the Single Convention (i.e. "regulatory impediments", Box 1).[3,20]

In 2009, the Pain and Policy Studies Group at the University of Wisconsin in the United States of America examined

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Table 1. **Single Convention[a] references to the availability and control of Schedule I drugs[b]**

Control measures in the Single Convention[5]	Availability measures in the Single Convention[5]
Governments must adopt legislative and administrative measures to limit exclusively to medical and scientific purposes all manufacture, distribution and possession within the country (Article 4).	Governments must adopt legislative and administrative measures to carry out the provisions of the Single Convention, including to limit exclusively to medical and scientific purposes all manufacture, distribution and possession within the country (Article 4).
All persons and enterprises involved in import, export, production, manufacture, trade and distribution must be controlled under government licence (Articles 29 and 30).	The INCB and governments must cooperate with governments to achieve this purpose (Article 9).
All persons who obtain government licences must have adequate qualifications for effective and faithful execution of laws and regulations enacted to implement the Single Convention (Article 34).	Governments annually must provide the INCB with estimates, as well as the method of estimation, of the quantities of controlled drugs required for consumption for medical and scientific purposes (Article 19).
Quantities manufactured and exported must be within the quantities of drugs required for medical and scientific purposes, as officially estimated by governments and confirmed by the INCB (Articles 12, 19 and 21).	Governments may submit supplementary estimates if requirements change (Article 19).
Possession of drugs is not permitted, except under legal authority (Article 33); therefore, medical prescriptions from duly authorized persons are required for dispensing to individuals, for example patients (Article 30).	The INCB administers the Single Convention estimate system with a view to limiting use and distribution of controlled drugs to an adequate amount required for medical and scientific purposes. The Board shall as expeditiously as possible confirm governments' estimates and supplementary estimates (Article 20).
Governments must report the amounts of opioids imported, exported, manufactured and consumed (distributed to the retail level) to allow the INCB to examine governments' compliance with the Single Convention (Article 20).	The total quantities of each drug manufactured and imported by any country must be within the limit of the relevant estimated requirement (Article 21).
Records of acquisition and disposal are to be kept by governmental authorities, manufacturers, traders, scientific institutions and hospitals (Article 34).	Governments must furnish to the INCB statistics on the quantities of controlled drugs actually imported, exported, manufactured and consumed (Article 20).

INCB, International Narcotics Control Board.
[a] Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs.[5]
[b] Schedule I drugs, such as opioids, cannabinoids and cocaine, are defined in the Single Convention on Narcotic Drugs.

Box 1. **Examples of regulatory impediments to the availability of Schedule I drugs[a] for medical and scientific purposes**

- inadequate national drug availability policy
- limits on the amount of a drug that can be prescribed[13]
- limits on the maximum drug dose[14]
- short time limits on the validity of prescriptions[15]
- prescription of opioids limited to specialists[16,17]
- opioid prescriptions permitted for certain diagnoses only[17]
- barriers to obtaining official prescription forms[18]
- unreasonably severe penalties for inadequate record-keeping[19]
- restrictions on prescribing practices that may seem contrary to medical indications but that may be legitimate[19]

[a] Schedule I drugs, such as opioids, cannabinoids and cocaine, are defined in the Single Convention on Narcotic Drugs.

the model law, model drug regulation and model drug abuse bill proposed by the United Nations Office on Drugs and Crime (UNODC) – the body responsible for preparing national model legislation and regulations – to determine whether these models provide governments with language they can use to implement their obligations under the Single Convention. The Group found that these model instruments did not reflect all the requirements of the Single Convention.[21]

Table 2 compares UNODC model legislation provisions with measures proposed by the Single Convention. Overall, the Group concluded that the UNODC models do not establish an obligation on national governments to ensure the availability of opioid drugs for medical use. In fact, the control recommended by these models is excessively stringent.

Despite their stated intent, UNODC model laws do not provide a framework for ensuring medication availability, as implied by the Single Convention. What is more, implementation of UNODC model legislation is likely to result in unbalanced national regulation of narcotic drugs, which may lead to limited availability of opioids for medical use.[25] An increasing number of experts now recognize that governments are not taking measures to ensure the adequate provision of opioid drugs and it is, therefore, an opportune time to assess the extent to which countries' laws reflect the need for balanced drug control laws encapsulated in the Single Convention.[26] The aim of this study was to examine a sample of national drug control laws to determine whether they contain provisions ensuring that opioid drugs are available for medical and scientific purposes.

Methods

This pilot study involved a convenience sample of laws from 15 countries. Countries were selected on the basis of our experience and contacts and because their drug laws were available in English. Four policy evaluation criteria were de-

Table 2. **Model legislation and Single Convention[a] references to the availability and control of Schedule I drugs[b]**

Model legislation	Single Convention
UNODC Model Civil Law (2003)	
"… opioids such as morphine should be subject to 'strict' regulation".[22]	"… a party is not precluded from adopting more restrictive control measures if, in its opinion, such regulation is necessary or desirable to protect public health or welfare" (Article 39).[5]
UNODC Model Regulation (2002)	
An interministerial commission for the coordination of drug control, led by the prime minister or the minister of justice, should be established to coordinate all drug control policy[23] (the minister of health is not mentioned).	The Single Convention recommends only the creation of the Commission on Narcotic Drugs, the INCB and a special administrative body for carrying out the provisions of the Convention (Articles 5 and 17).[5]
UNODC Model Drug Abuse Bill (2000)	
The Bill recommends using several exclusively harm-related terms to describe controlled drugs, such as "drugs of abuse", "high-risk drugs" (which specifically includes morphine) and "risk drugs".[24]	The Single Convention uses the terms "narcotic", "drug" and "opioid".[5] It does not include the terms mentioned in the Model Drug Abuse Bill.
The Bill uses a definition of a "drug-dependent person" that is obsolete according to international standards.	No definition of a "drug-dependent person" is included in the Single Convention.
The Bill proposes that governments prohibit prescribing to "drug-dependent persons" without regard to whether the person may need opioids for relieving pain from diseases such as cancer and AIDS.[24]	The preamble to the Single Convention states that narcotic drugs are "indispensable for the relief of pain and suffering, and that their adequate provision must be made to ensure the availability of narcotic drugs for [medical use]".[5] There is no limit on their use by non-drug-dependent persons.
Specific medical practices are recommended. For example, prescribing an "unusual or dangerous dose" of a drug should be avoided[24] when international bodies have noted that the correct dose varies from person to person and that there is no typical dose.	No specific medical practices are mentioned.

AIDS, acquired immunodeficiency syndrome; INCB, International Narcotics Control Board; UNODC, United Nations Office on Drugs and Crime.
[a] Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs.
[b] Schedule I drugs, such as opioids, cannabinoids and cocaine, are defined in the Single Convention on Narcotic Drugs.

veloped in consultation with the Center for Health Law, Policy and Practice at the Temple University Beasley School of Law in the United States. Previous Pain and Policy Studies Group analyses emphasized that evaluations of policy and legislation should have a clear rational basis that is derived from authoritative sources.[27,28] Consequently, the criteria we developed used the plain language of the Single Convention and were based on interpretations of the Convention and recommendations made by competent international authorities, such as this statement from a report by the INCB:

"Governments should determine whether their national laws include 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 and 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…"[20]

Our four criteria concern: (i) recognition that the medical use of opioid drugs is indispensable for the relief of pain and suffering; (ii) government responsibility for ensuring adequate provision of opioid drugs for medical and scientific purposes; (iii) designation of a special administrative body with responsibility for implementing international drug control conventions; and (iv) a government's intention to implement international drug control conventions, including the Single Convention (Table 3). The first three criteria directly reflect relevant objectives within the Single Convention, whereas the fourth relates to whether or not a country's laws express the intention to conform to the provisions of the Single Convention.

Several members of the Pain and Policy Studies Group with experience in evaluating legislation reviewed each national law. We evaluated only statutory drug control legislation that had been adopted by the country's law-making body and which was currently in force. We excluded sections relating to drug classification, scheduling or penalties as well as commentaries and footnotes. For inclusion in this evaluation, a provision had either to use wording that was substantially the same as that used in the criterion or to express clearly the main intent of the criterion.

Results

Table 4 lists the policy evaluation criteria that were fulfilled by the laws of each of the 15 countries. Two of the 15 countries (13%) had a drug control law that recognized that the medical use of opioid drugs continues to be indispensable for the relief of pain and suffering. Australia is unique because its drug control law includes the entire Single Convention verbatim.[31] Consequently, the term "indispensable" appears just as it does in the preamble to the Single Convention. In the United States, the term "indispensable" does not appear but the preamble to the Controlled Substances Act states:

"The Congress makes the following findings and declarations: (1) Many of the drugs included within this subchapter have a useful and legitimate medical purpose and are necessary to maintain the health and general welfare of the American people."[32]

Three countries (20%) had a drug control law that established the government's responsibility for ensuring adequate provision of opioid drugs for medical and scientific purposes:

Table 3. **Criteria for evaluating national drug laws**

Criterion	Single Convention[a] text[5]	Rationale for criteria
Indispensability[b] National law should recognize that the medical use of opioid drugs continues to be indispensable for the relief of pain and suffering.	"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)	A government's responsibility for assuring adequate availability of opioid medicines is enhanced when national policies are in agreement with the Single Convention's assertion of the indispensability of these medicines for public health in general and for the relief of pain and suffering in particular.
Adequate provision[b] National law should acknowledge that it is the government's responsibility to ensure adequate provision of opioid 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)	Legislative authority to establish government responsibility for adequate drug availability can provide support for health-care professionals who are attempting to convince members of government agencies of the need to increase access to medications, especially when those individuals believe that access to pain medicines should be severely restricted.
Special administration National law should designate an administrative body with responsibility for implementing international drug control conventions in the country.	"The Parties shall maintain a *special administration* for the purpose of applying the provisions of this Convention." (Article 17)	The administrative body is usually referred to as the National Competent Authority (NCA), which is responsible for managing the government's obligations under the Single Convention, including the submission of estimates of the amount of opioid drugs that will be required to satisfy medical and scientific needs in the country.[c]
Intention to implement the Single Convention National law should acknowledge an intention to implement international drug control conventions, particularly Article 4 of the Single Convention.	"The Parties shall take such legislative and administrative measures as may be necessary: (a) to give effect to and *carry out the provisions of this Convention* within their own territories…" (Article 4)	National laws that did not specifically invoke international drug control conventions were regarded as not meeting this criterion. Although not required by the Single Convention, acknowledging an intention to be bound by the Convention is important because it demonstrates that the country is aware of the duties the treaty confers upon its parties.

[a] Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs.

[b] The indispensability and adequate provision criteria both rely on the preamble to the Single Convention, which, although not legally binding, does offer an insight into the intent of the Single Convention and the goals that should be achieved by enacting the treaty. Consequently, the preamble text served as the basis for evaluation because it represents the spirit of the law. Further justification for using the preamble text comes from international authorities that have recognized its importance for defining the overarching purpose of the treaty and which have repeatedly called for its inclusion in national laws.[2,20,29]

[c] The 2010 resolution from the Commission on Narcotic Drugs accorded a very high priority to this responsibility: "underscoring the fact that the submission of estimates and statistical returns by Governments is critical to the actions taken by the International Narcotics Control Board for the implementation of treaty provisions regarding the adequate availability of internationally controlled licit drugs for medical and scientific purposes".[30] The critical nature of this designated responsibility was also exemplified as a specific guideline in recent World Health Organization (WHO) guidelines for ensuring balance when enhancing the availability and accessibility of controlled medicines: "Guideline 3: Governments should designate a National Authority for ensuring adequate availability and accessibility of controlled medicines in health care. Such an authority could be part of the National Competent Authority or a separate office, whatsoever is the most appropriate in the national situation."[2]

Australia, Georgia and Uganda. The national drug control law in Uganda clearly states:

"A Statute to establish a National Drug Policy and a National Drug Authority to ensure the availability, at all times, of essential, efficacious and cost-effective drugs to the entire population of Uganda, as a means of providing satisfactory health care and safe-guarding the appropriate use of drugs."[33]

Five of the 15 (33%) national drug control laws acknowledged that government had an administrative responsibility for implementing international drug control conventions. India's law, which states that "the International Conventions" include the Single Convention, is an example:

"Chapter II Authorities and Officers... the measures which the Central Government may take...include...(b) obligations under the International Conventions."[34]

National drug control laws in 7 of the 15 countries (47%) specifically acknowledged that the government intends to implement international drug control conventions. As noted above, Australia clearly accepted its obligations under the Single Convention. In addition, the law in Uganda states:

"The National Drug Policy shall be… (h) to comply with the international regulations on drugs including the conventions on Narcotic Drugs and Psychotropic Substances under International Control…"[33]

In the United States, the Controlled Substances Act fulfils this last criterion by acknowledging that the country accepts the Single Convention:

"The United States is a party to the Single Convention on Narcotic Drugs, 1961, and other international conventions designed to establish effective control over international and domestic traffic in controlled substances."[35]

Table 4. **Policy evaluation criteria on the availability and control of Schedule I drugs[a] satisfied by country laws**

Country	Criterion[b] satisfied			
	Indispensability	Adequate provision	Special administration	Intention to implement the Single Convention[c]
Armenia	No	No	Yes	Yes
Australia	Yes	Yes	Yes	Yes
Georgia	No	Yes	No	No
India	No	No	Yes	Yes
Jamaica	No	No	No	No
Jordan	No	No	No	No
Kenya	No	No	No	No
Nepal	No	No	No	No
Nigeria	No	No	No	No
Philippines	No	No	No	No
Serbia	No	No	Yes	Yes
Sierra Leone	No	No	No	No
Uganda	No	Yes	Yes	Yes
United States	Yes	No	No	Yes
Viet Nam	No	No	No	Yes
Percentage of countries whose laws satisfied the criterion	13	20	33	47

[a] Schedule I drugs, such as opioids, cannabinoids and cocaine, are defined in the Single Convention on Narcotic Drugs.
[b] The criteria are defined in Table 3.
[c] The Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol Amending the Single Convention on Narcotic Drugs.

The other countries whose laws met the last criterion were Armenia, India, Serbia and Viet Nam. Often the language used in legislation was unclear. In Viet Nam, for example, the relevant statute mentioned drug control conventions without specifically naming the Single Convention.

Discussion

Once ratified by national governments and incorporated into national law, treaties such as the Single Convention gain substantial legal force.[36] To date, 184 countries have ratified the Single Convention.[37] The results of this pilot study support the conclusions of the INCB and WHO that there is a need for more balanced model and national laws on drug control and availability. Although the Single Convention and interpretations of the Convention made by competent international authorities are clear about national governments' obligation to ensure that opioid drugs are available for medical and scientific purposes, balanced legal provisions were scarce among national laws. Less than half the countries we studied had laws that acknowledged an intention to implement international drug control conventions. Even fewer acknowledged responsibility for ensuring drug availability. Several countries had laws that seemed to reflect the balanced intent of the Single Convention but placed no obligation on government to ensure that drug availability and control measures were balanced. Without laws that ensure the availability of controlled medicines, countries may not have a balanced drug control policy that can guide the actions of agencies that control drugs and satisfy the expectations of patients and caregivers.

Among the few national laws that did fulfil Single Convention criteria on drug availability, there was little uniformity in the language used or the intent expressed, which underlines the need for appropriate legislative models on balancing drug availability and control. It is likely that a systematic evaluation of laws and regulations from around the world would uncover similar impediments to drug availability. The Pain and Policy Studies Group is currently developing criteria that can be used to perform a more complete assessment of national laws. One aim is to provide guidance to governments on how to align national policies with the balanced approach to drug availability and control implicit in the Single Convention, thereby helping ensure adequate opioid availability.

Even though a country may have ratified the Single Convention, the absence of legislation establishing the government's responsibility for ensuring drug availability means that health professionals may find it difficult to convince government agencies that drugs should be made available for medical needs, especially if government officials believe that, for example, pain medicine should be strictly controlled. In contrast, drugs are readily available in some countries without clear legislative authority. Many government representatives do accept the need for balanced legislation on drug availability and control and have pursued this objective in national workshops and United Nations meetings.[38,39] However, other government representatives are more familiar with drug control, which has sometimes prompted resistance to balanced legislation. Encouragingly, once governments become aware of WHO and INCB recommendations on improving drug availability, change can, and often does, take place (EL Krakauer, personal communication, 2013). Recently, United Nations drug control bodies have been examining the need for model policies and national drug control laws that deal with both preventing the diversion and abuse of controlled medicines and ensuring the availability of these medicines for medical and scientific purposes. With the passage of Resolutions 53/4 and 54/6 by the Commission on Narcotic Drugs in 2010 and 2011, respectively,[4,40] and with the drafting of a document on ensuring drug availability, UNODC has an opportunity to become a central force in establishing balanced legislation in this area. Resolution 53/4 on drug availability encourages Member States to work with the INCB and UNODC to "update policies and legislative frameworks, as appropriate, to ensure adequate availability of internationally controlled substances"[40] in addition to preventing diversion and abuse. Resolution 54/6 provides similar encouragement and requests UNODC to create a technical guide to help Member States incorporate

model legislation into their own national laws. The Commission on Narcotic Drugs also supported the INCB's call for Member States, as a priority, to promote the availability, accessibility and rational use of drugs for medical purposes[4] and to identify impediments to opioid availability and access for pain relief, as recommended by WHO.[2,12]

This pilot study has a number of limitations. Regulations and other administrative decrees were not evaluated. However, ordinarily these policies implement statutory laws and neither exceed nor broaden them. Although achieving a balance between opioid drug availability and control is arguably a goal of the Single Convention, it is an implied goal since the Convention does not use the term. However, bodies with the authority to interpret the Single Convention have repeatedly discussed the need for balance. The study did not aim to identify provisions in national laws that were overly restrictive (i.e. regulatory impediments), though knowledge of these provisions is essential for obtaining a complete picture of all factors affecting drug control and availability. Moreover, we did not investigate how model and national laws were developed, reviewed, approved or promulgated. Hence, we are unable to explain why they appear so unbalanced. Finally, although a country's laws may have satisfied our four study criteria, there is no guarantee that opioids will be available for medical purposes in sufficient quantities. Actions must also be taken to improve access to medications within the health-care system, for example, through national workshops, physician training and public education.

The findings of our analysis of national legislation can be used by countries to adjust their laws to ensure they fully embrace the Single Convention's goals of preventing the diversion and abuse of opioid drugs while ensuring their availability for medical and scientific purposes. In particular, government ministers and their staff can assess their own national laws using the criteria proposed in this study and can ask UNODC to provide model laws that would help increase drug availability.

The study's findings also indicate directions for additional policy research, such as determining whether the Single Convention's provisions on drug availability have been applied in a larger sample of national legislation, regulations and administrative policies. Another area of inquiry is to investigate the extent to which governments are able to manage policies and systems that prevent the diversion and abuse of controlled medicines without interfering with their availability for medical purposes. The results would provide the evidence needed for guiding the assessment, planning and systematic improvement of drug control and availability policies and for consolidating our understanding of how such policies affect medication availability and patient care. Research could also be carried out on why United Nations' guidance on ensuring drug availability has not been accessible to governments until recently, whereas guidance on the strict control of drugs has been thoroughly investigated. In addition, it would be useful to understand why ensuring the adequate availability of narcotic drugs was included in the preamble to the Single Convention after it was amended by the 1972 Protocol but was not mentioned in the original version of the Convention.

The limited availability of opioid medications combined with the increasing number of people with cancer and other noncommunicable diseases has widened the gap between the amount of medication available for the relief of pain and suffering and the amount needed.[30,41,42] United Nations' bodies and civil society have expressed deep concerns about this gap. However, the necessary progress cannot be achieved within the current weak and contradictory international drug control policy framework. There is an urgent need to reform United Nations' model drug legislation. This would require the INCB and UNODC to expand their work with governments for a number of years in order to increase drug availability within the constraints of existing drug control policies.[4] Otherwise, generations of patients may continue to suffer.

We propose a number of goals for revised model drug legislation. First, revised model legislation should carefully follow international drug control conventions and should provide specific language that governments can use in updating relevant laws and regulations while bearing in mind the need to adapt legislation to national conditions. Second, new model drug legislation should offer commentaries on the purpose of the legislation, the meaning of balancing control and availability, the obligation to ensure that drugs are available, safeguards for supply chains, the identification of unduly strict provisions and ways of estimating the amount of drugs needed for medical and scientific purposes. Finally, after a Member State has requested model drug legislation, the resulting national legislation should be developed collaboratively with the INCB, WHO and civil society, including individuals involved in health care, patient care and drug control. The adoption and promulgation of UNODC model laws, which are effective in establishing a balance between drug control and availability, can lead to a drug regulatory system that takes into account public health needs. However, without the commitment of governments to enact laws that ensure the drugs they control are available for medical purposes, it will be difficult to improve access for those with legitimate medical needs and set-backs are likely. ■

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ملخص

هل تضمن القوانين الوطنية لمكافحة المخدرات توفر المواد أفيونية المفعول للأغراض الطبية والعلمية؟

الغرض تحديد ما إذا كانت القوانين الوطنية لمكافحة المخدرات تضمن توفر العقاقير أفيونية المفعول للأغراض الطبية والعلمية، وفق المقصود في بروتوكول عام 1972 المعدل للاتفاقية الوحيدة للمخدرات لعام 1961.

الطريقة بحث المؤلفون ما إذا كانت نصوص عينة ملائمة من قوانين المخدرات من 15 بلداً: (1) أقرت أن العقاقير أفيونية المفعول لا غنى عنها لتخفيف الألم والمعاناة؛ (2) اعترفت بأن الحكومة مسؤولة عن ضمان التوفير الملائم لهذه العقاقير للأغراض الطبية والعلمية؛ (3) حددت هيئة إدارية لتنفيذ الاتفاقيات الدولية لمكافحة المخدرات؛ (4) أقرت بعزم الحكومة على تنفيذ الاتفاقيات الدولية، بما في ذلك الاتفاقية الوحيدة.

النتائج تم اكتشاف أن معظم القوانين الوطنية لا تتضمن تدابير تضمن التوفير الكافي للعقاقير أفيونية المفعول للأغراض الطبية والعلمية. علاوة على ذلك، لم يضع التشريع النموذجي الذي قدمه مكتب الأمم المتحدة المعني بالمخدرات والجريمة التزاماً على الحكومات الوطنية لضمان توفر هذه العقاقير للاستخدام الطبي.

الاستنتاج لتحقيق الاتساق مع الاتفاقية الوحيدة، وكذلك مع قرارات وتوصيات الهيئات الدولية ذات الصلة، ينبغي تحديث القوانين الوطنية لمكافحة المخدرات والسياسات النموذجية بحيث تتضمن تدابير تضمن توفر العقاقير وذلك للموازنة بينها وبين القيود المفروضة من خلال التدابير القائمة لمكافحة المخدرات والمطلوبة لمنع الانحراف والاستخدام غير الطبي لتلك العقاقير.

摘要

国家禁毒法律可确保医学和科学用途阿片类药物的供应吗?

目的 确定国家毒品控制法律是否如《1961 年麻醉品单一公约》1972 年草案补正的预期可确保医学和科学用途阿片类药物的供应。

方法 作者研究来自 15 个国家禁毒法律便利样本的文本是否：(i) 承认阿片类药物对缓解疼痛和痛苦是不可或缺的；(ii) 确认政府有责任为医学和科学用途确保这类药物充分供应；(iii) 指定贯彻国际禁毒公约的行政机关；(iv) 认可政府贯彻包括单一公约在内的国际公约的意向。

结果 发现大多数国家法律没有包含确保医学和科学用途阿片类药物充分供应的措施。此外，联合国毒品和犯罪办公室提供的公示法案并没有确定各国政府在确保在医疗用途上提供这类药物的义务。

结论 要与单一公约以及国际组织的相关决议和建议保持一致，就应该更新国家药物控制法律和公示政策，以包括确保药物供应的措施，从而平衡现有毒品控制措施为防止此类药物流失和非医疗使用所需而施加的限制。

Résumé

Les législations nationales de lutte contre la drogue assurent-elles la disponibilité des opioïdes à des fins médicales et scientifiques?

Objectif Déterminer si les législations nationales de lutte contre la drogue permettent que les opioïdes soient disponibles à des fins médicales et scientifiques, comme le prévoit l'amendement au protocole de 1972 à la Convention unique sur les stupéfiants de 1961.

Méthodes Les auteurs ont examiné si les textes d'un échantillon de commodité de lois de lutte contre la drogue dans 15 pays: (i) reconnaissent que les opioïdes sont indispensables pour soulager la douleur et la souffrance; (ii) reconnaissent que le gouvernement est chargé d'assurer l'approvisionnement suffisant de ces drogues à des fins médicales et scientifiques; (iii) désignent un organisme administratif pour l'application des conventions internationales de lutte contre la drogue; et (iv) reconnaissent l'intention d'un gouvernement de mettre en œuvre les conventions internationales, y compris la Convention unique.

Résultats La plupart des législations internationales se sont révélées ne pas contenir de mesures qui assurent l'approvisionnement suffisant des opioïdes à des fins médicales et scientifiques. En outre, le modèle de législation fourni par l'Office des Nations Unies contre la drogue et le crime n'établissait pas d'obligation pour les gouvernements nationaux d'assurer la disponibilité de ces drogues pour un usage médical.

Conclusion Pour demeurer cohérent avec la Convention unique, ainsi qu'avec les résolutions associées et les recommandations des organismes internationaux, les législations nationales de lutte contre la drogue et les modèles de politique doivent être mis à jour pour inclure des mesures qui puissent assurer la disponibilité des drogues afin d'équilibrer les restrictions imposées par les mesures existantes de lutte contre la drogue, qui sont nécessaires pour empêcher le détournement et l'utilisation non-médicale de ces drogues.

Резюме

Обеспечивают ли национальные законодательства по контролю за лекарственными средствами доступность опиоидных препаратов для медицинских и научных целей?

Цель Определить, обеспечивают ли национальные законодательства по контролю за лекарственными средствами доступность опиоидных препаратов для медицинских и научных целей, как определено в поправке 1972 года к Единой конвенции о наркотических средствах 1961 года.

Методы Авторы исследовали тексты законодательства по контролю за лекарственными средствами 15 случайно выбранных стран с целью проверить, удовлетворяют ли они следующим условиям: (i) они подтверждают, что опиоидные препараты являются незаменимыми для облегчения боли и избавления от страданий; (ii) признают, что государство несет ответственность за надлежащее обеспечение этих препаратов для медицинских

и научных целей; (iii) определяют назначение административного органа для реализации международных конвенций по контролю за лекарственными средствами; и (iv) признают намерение государства по выполнению международных конвенций, включая Единую конвенцию.

Результаты Большинство национальных законов не содержало механизмов по надлежащей реализации положений по опиоидным препаратам для медицинских и научных целей. Более того, предоставленная Управлением ООН по наркотикам и преступности модель законодательства не содержит обязательства для национальных правительств обеспечить доступность этих препаратов для использования в медицинских целях.

Вывод Для достижения соответствия положениям Единой конвенции, а также соответствующим резолюциям и рекомендациям международных органов, национальные законодательства по контролю за лекарственными препаратами и модели политик должны быть обновлены таким образом, чтобы включать в себя механизмы по обеспечению доступности опиоидных препаратов для медицинских целей, в целях сбалансирования существующих ограничений, введенных механизмами по контролю за лекарственными средствами и направленных на предотвращение использования таких препаратов в немедицинских целях и не по назначению.

Resumen

¿Garantizan las leyes de control nacional de drogas la disponibilidad de opiáceos para fines médicos y científicos?

Objetivo Determinar si las leyes de control nacional de drogas garantizan la disponibilidad de opiáceos para fines médicos y científicos según lo previsto por la enmienda del Protocolo de 1972 de la Convención única de 1961 sobre estupefacientes.

Métodos Los autores examinaron si el texto de una muestra de conveniencia de leyes sobre drogas procedentes de 15 países: (i) reconocía que los opiáceos son indispensables para el alivio del dolor y el sufrimiento; (ii) reconocía que el gobierno era responsable de garantizar la prestación adecuada de estas drogas para fines médicos y científicos; (iii) designaba a un órgano administrativo para la aplicación de las convenciones de fiscalización internacional de drogas; y (iv) reconocía la intención de los gobiernos de aplicar las convenciones internacionales, incluyendo la Convención única.

Resultados Se halló que la mayoría de las legislaciones nacionales no contienen medidas que garanticen la prestación adecuada de opiáceos para fines médicos y científicos. Por otra parte, la legislación modelo que proporcionó la oficina de Naciones Unidas contra la droga y el delito no obligaba a los gobiernos nacionales a asegurar la disponibilidad de estas drogas para uso médico.

Conclusión Para lograr la coherencia con la Convención única, así como con las resoluciones asociadas y las recomendaciones de organismos internacionales, deben actualizarse las leyes de control nacional de drogas y las políticas del modelo, a fin de incluir medidas que garanticen la disponibilidad de las drogas para equilibrar las restricciones impuestas por las medidas de control de drogas actuales, necesarias para prevenir el uso desviado y no médico de tales drogas.

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