

THE IMPACT OF INTERNATIONAL DRUG POLICY ON ACCESS TO CONTROLLED MEDICINES



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02

INTRODUCTION

03

THE INTERNATIONAL DRUG CONVENTIONS AND
AVAILABILITY OF CONTROLLED MEDICINES

05

WHAT THE UN AND INTERNATIONAL BODIES SAY

08

ACCESS TO CONTROLLED MEDICINES AND THE
UNGASS DEBATE

As member states of the United Nations take stock of the drug control system, a number of debates have emerged among governments about how to balance international drug laws with human rights, public health, alternatives to incarceration, and experimentation with regulation.

This series intends to provide a primer on why governments must not turn a blind eye to pressing human rights and public health impacts of current drug policies.



ACCESS TO CONTROLLED MEDICINES

Every year, tens of millions of people suffer disease and pain because they lack access to controlled medicines—that is, medicines of which the distribution and use is regulated under the international drug conventions or national drug-control law.



INTRODUCTION

Every year, tens of millions of people suffer disease and pain because they lack access to controlled medicines—that is, medicines of which the distribution and use is regulated under the international drug conventions or national drug-control law. Among those who lack access to these medicines are 5.5 million terminal cancer patients and 1 million people with end-stage AIDS, as well as women giving birth, patients with chronic illnesses or injuries from violence or accidents, and people recovering from surgery. There is ample supply of raw materials needed to produce the medicines in question, and many are inexpensive to produce. Availability of controlled medicines is limited by the persistence of myths, restrictive regulations, insufficient investment in the training of health professionals—resulting in weak understanding of pain relief and drug dependence—and related failure of supply and distribution systems.

Controlled medicines¹ have critical and diverse applications in modern healthcare—from analgesia, anesthesia and treating drug dependence, to uses related to maternal health, mental health, neurology, and palliative care. These applications are recognized in the international drug conventions, which note that controlled substances are indispensable for medical and scientific purposes. The 1961 Single Convention on Narcotic Drugs goes further, stipulating that states are obliged to make adequate provision to ensure the availability of controlled medicines for such uses.²

The World Health Organization (WHO) considers that a balanced public health approach requires access to controlled medicines for scientifically sound clinical use to be maximized and diversion to non-medical use to be minimized.³

Globally, 5.5 billion people have limited or no access to adequate pain relief—this is 75 percent of the global population.

- 1 Examples of controlled medicines include those to treat pain like morphine and codeine, and those to treat opioid dependence like methadone and buprenorphine. Notably, there are twelve controlled medicines on the WHO Model List of Essential Medicines. See World Health Organization, *WHO Model List of Essential Medicines, 19th List* (amended Aug. 2015), <http://www.who.int/medicines/publications/essentialmedicines/en/>
- 2 The 1961 Single Convention specifically acknowledges the importance of narcotic drugs as analgesic medications, and asserts that governments must ensure the availability of narcotic drugs for relief of pain.
- 3 See generally World Health Organization, *Improving Access to Medications Controlled Under International Drug Conventions* (World Health Org., Access to Controlled Medications Programme, Briefing Note, 2012) [hereinafter WHO Briefing Note], http://www.who.int/medicines/areas/quality_safety/ACMP_BrNote_Genr1_EN_Apr2012.pdf

THE INTERNATIONAL DRUG CONVENTIONS AND AVAILABILITY OF CONTROLLED MEDICINES

The international drug conventions comprise three international treaties:

- the 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol (Single Convention);
- the 1971 Convention on Psychotropic Substances (1971 Convention); and
- the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances.

The conventions are complementary and self-reinforcing with the Single Convention and 1971 Convention codifying the rules of international drug control for narcotic and synthetic psychotropic substances, and the 1988 Convention strengthening state obligations to criminalize illicit production, possession, and trafficking of drugs.⁴ The international drug conventions are part of international law (the rules that govern relations between states and responsibilities of states).

The international drug conventions are founded on the premise of concern for the “health and welfare of mankind” and impose a dual obligation upon signatory states—namely, ensuring the adequate availability of controlled substances for legitimate medical and scientific use, while preventing their diversion and misuse.⁵ This dual obligation also figures in the mandate of the International Narcotics Control Board (INCB)—the independent and “quasi-judicial” monitoring body for the implementation of the international drug conventions. The INCB states that the overall goal of a well-functioning national and international system for managing the availability of narcotic drugs and psychotropic substances should be to provide relief from pain and suffering by ensuring the safe delivery of the best affordable medicines to those patients who need them.⁶

4 Legally, the term “narcotic” includes substances ranging from opioids and cocaine to marijuana.

5 See International Narcotics Control Board, *Report of the International Narcotics Control Board on the Availability of Internationally Controlled Drugs: Ensuring Adequate Access for Medical and Scientific Purposes*, iii, U.N. Doc. E/INCB/2010/1/Supp.1 (2011) [hereinafter *INCB Report*], https://www.incb.org/documents/Publications/AnnualReports/AR2010/Supplement-AR10_availability_English.pdf

6 See *id.* ¶ 132.

The Single Convention and 1971 Convention expressly recognize that narcotic drugs and psychotropic substances are indispensable for medical and scientific purposes. The Single Convention imposes a positive obligation on states to make adequate provision to ensure the availability of these medicines, whereas the 1971 Convention sets out a more limited obligation, requiring that access to psychotropic substances for medical purposes not be unduly restricted.

Beyond this, the Single Convention and 1971 Convention focus heavily on substance control and provide limited additional guidance on implementing the medical imperative of access to controlled medicines. This emphasis on control in the text of the conventions has contributed to the dominance of control-oriented national policies—in many cases to the detriment of access to controlled medicines.

The Single Convention sets out reasonable minimum regulatory requirements for prescribing controlled medicines at national levels, but it explicitly allows states to impose stricter controls if they deem necessary. Specifically, the Single Convention requires:

- **licenses for manufacture, trade and distribution of controlled substances;**
- **prescriptions for the supply or dispensation of controlled substances;**
- **government authorization for import or export, and transport or transfer of controlled substances; and**
- **governments to provide statistical reports to the INCB, and retain records for a period of not less than two years.**

“In 2010...the Special Rapporteur on the Right to Health urged states to reform domestic laws to increase access to controlled essential medicines, and take a human rights-based approach within a context of reasonable drug control.”

WHAT THE UN AND INTERNATIONAL BODIES SAY

The right to health and access to controlled medicines

The International Covenant on Economic, Social and Cultural Rights (ICESCR) recognizes the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. A state cannot guarantee health in itself—rather this is a right to adequate health care and to the underlying determinants of health. It includes the right to availability, accessibility, acceptability, and quality of a defined set of services, goods, and information, with a corresponding state obligation to take steps to progressively achieve the full realization of this right. Certain core obligations—such as the obligations to ensure access to essential medicines and non-discrimination—must be immediately prioritized.⁷

Multiple human rights bodies, including the Committee on Economic, Social and Cultural Rights (CESCR), the Committee on the Rights of the Child (CRC), and the United Nations Special Rapporteur on the Right to Health have confirmed these obligations, and emphasized the state's specific immediate and continuing obligation to ensure access to essential medicines, including controlled medicines, in fulfillment of the right to health.⁸

In 2010, in recognition of the negative impact of drug policy on the enjoyment of the right to health, the then Special Rapporteur on the Right to Health urged states to reform domestic laws to increase access to controlled essential medicines, and take a human rights-based approach within a context of reasonable drug control.⁹

The prohibition of cruel, inhuman, and degrading treatment, and access to controlled medicines

The International Covenant on Civil and Political Rights and the Convention against Torture provide that no one be subjected to torture or to cruel, inhuman, or degrading treatment or punishment. These provisions are understood to represent a positive obligation on states to prevent such treatment and to protect people in their jurisdiction from such treatment.

⁷ Committee on Economic, Social and Cultural Rights, *General Comment No. 14, The Right to the Highest Attainable Standard of Health*, U.N. Doc. E/C.12/2000/4 (2000) [hereinafter CESCR, *General Comment No. 14*].

⁸ *See id*; see also Committee on Economic, Social and Cultural Rights, *General Comment No. 3, The Nature of States Parties' Obligations*, ¶ 10, U.N. Doc. E/1991/23 (1991). The Committee confirms that states parties have a core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights enunciated in the Covenant, and that the obligation to provide essential.

⁹ Anand Grover (Special Rapporteur on the Right to Health), *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, ¶ 6, U.N. Doc. A/65/255 (Aug. 6, 2010), <http://bit.ly/1NZNZD9>

The UN Special Rapporteur on Torture has specifically addressed the issue of pain treatment, stipulating that “the *de facto* denial of access to pain relief, if it causes severe pain and suffering, constitutes cruel, inhuman, or degrading treatment or punishment.”¹⁰ The Special Rapporteur on Torture has also specifically addressed the denial of opiate substitution therapy as a particular “form of ill-treatment and possibly torture,” recognizing the impact of painful withdrawal symptoms.¹¹ This recognition triggers the obligation of states to protect people from degrading treatment. This obligation is immediate and absolute—meaning that this denial of treatment is never acceptable.

Access to controlled medicines: declarations and resolutions of the UN and other multilateral bodies

Recent years have seen increased recognition of the need for better access to controlled medicines, including by the Commission on Narcotic Drugs, the United Nation’s main drug policy-making body.

In 2009, UN member states adopted a political declaration and plan of action on drugs at a high-level meeting of the Commission on Narcotic Drugs (2009 Declaration). The 2009 Declaration refers to maintaining a balance between the demand for and the supply of narcotic drugs and psychotropic substances in order to ensure the relief of pain and suffering. The 2009 Declaration also advocates for the availability of medication-assisted therapy as part of a comprehensive package of services for the treatment of drug dependence.¹²

In 2010, the Commission on Narcotic Drugs adopted a resolution focused on promoting adequate availability of controlled medicines.¹³ Recognizing that some countries have administrative barriers stricter than the control measures required by the Single

“In 2015 the Organization of American States adopted the first ever human rights treaty to include explicit obligations to ‘ensure that medicines recognized as essential by the WHO, including controlled medicines...are available and accessible for older persons.’”

10 Manfred Nowak (Special Rapporteur on Torture), *Report of the Special Rapporteur on Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment*, ¶ 72, U.N. Doc. A/HRC/10/44 (Jan. 14, 2009), <http://www2.ohchr.org/english/bodies/hrcouncil/docs/10session/A.HRC.10.44AEV.pdf>

11 Juan E. Méndez (Special Rapporteur on Torture), *Report of the Special Rapporteur on Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment*, ¶ 73.1, U.N. Doc. A/HRC/22/53 (Feb. 1, 2013) http://www.ohchr.org/Documents/HRBodies/HRCouncil/RegularSession/Session22/A.HRC.22.53_English.pdf

12 United Nations Office on Drugs and Crime High-Level Segment Commission on Narcotic Drugs, *The Political Declaration and Plan of Action on International Cooperation Towards an Integrated and Balanced Strategy to Counter the World Drug Problem, Action Plan* ¶ 2(a), 10(c) (Vienna, Mar. 1112, 2009).

13 Commission on Narcotic Drugs Res. 53/4, *Promoting Adequate Availability of Internationally Controlled Narcotic Drugs and Psychotropic Substances for Medical and Scientific Purposes While Preventing their Diversion and Abuse* (Mar. 12, 2010).

Convention, this resolution requests states to take steps to improve the availability of narcotic drugs for medical purposes, in accordance with the recommendations of the WHO.¹⁴ The resolution also encourages states to ensure that regulators and health professionals understand that opioid-based medicines are indispensable for the relief of pain and suffering.

In 2011, the Commission on Narcotic Drugs passed a resolution requesting UNODC, INCB, and WHO to work together to update UNODC model laws to ensure that they reflect an appropriate balance between adequate access to controlled medicines and the prevention of diversion and misuse.¹⁵ The revised model law has not yet been released.¹⁶

In 2014, the World Health Assembly passed a landmark resolution endorsing the integration of palliative care into healthcare systems. This resolution calls for states to ensure that efforts to prevent the diversion of narcotic drugs and psychotropic substances under international control do not result in inappropriate regulatory barriers to access to medicines. The resolution also urged states to “review, and, where appropriate, revise national and local legislation and policies for controlled medicines...to improve access and rational use of pain management medicines, in line with the United Nations international drug control conventions.”¹⁷

Most recently, in 2015 the Organization of American States adopted the first ever human rights treaty to include explicit obligations to “ensure that medicines recognized as essential by the WHO, including controlled medicines...are available and accessible for older persons.” The Inter-American Convention on Protecting the Human Rights of Older Persons will enter into force when it is ratified by two states.

14 This request is based on the International Narcotics Control Board, Annual Report, Recommendation 40, (2009).

15 Commission on Narcotic Drugs Res. 54/6, *Promoting Adequate Availability of Internationally Controlled Narcotic Drugs and Psychotropic Substances for Medical and Scientific Purposes While Preventing their Diversion and Abuse* (Mar. 25, 2011). The resolution further requests UNODC to develop a technical guide explaining the revised model laws, to ensure that the model laws are accessible and readily understood by States.

16 The 2003 UNODC Model Law provides “opioids such as morphine should be subject to ‘strict’ regulation.” This was addressed in 2009 by the Pain and Policy Studies Group at the University of Wisconsin who found that these model instruments did not reflect all the requirements of the Single Convention. The Group concluded that the UNODC models did not establish an obligation on national governments to ensure the availability of opioid drugs for medical use, and found the controls recommended to be excessively stringent, and may lead to limited availability of opioids for medical use. See S. Asra Husain, Marty Skemp Brown & Martha A. Maurer, *Do National Drug Control Laws Ensure the Availability of Opioids for Medical and Scientific Purposes?* 92 WORLD HEALTH ORG. 108, 108–16 (2013), <http://www.who.int/bulletin/volumes/92/2/13-121558/en/>

17 World Health Assembly, *Strengthening of Palliative Care as a Component of Comprehensive Care Throughout the Life Course*, WHA67.19, (May 24, 2014), http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_R19-en.pdf

ACCESS TO CONTROLLED MEDICINES AND THE UNGASS DEBATE

Notwithstanding the body of international policy and law on access to controlled medicines, the dual obligation of states under the international drug conventions is often poorly understood. Many factors contribute to states' failure to balance adequate availability of controlled medicines with the prevention of abuse, diversion, and trafficking of controlled substances.

Challenges associated with scheduling

The scheduling of substances is the basis of the international drug control system. Scheduling is the classification and listing of a substance according to its potential for abuse against its value for medical purposes and, accordingly, determines the level of regulation applied. In recent decades, an increase in nonmedical use of prescription medicines has raised important questions around scheduling and fear of misuse. However, because scheduling of substances under the most restrictive control can mean significantly heavier regulatory obligations, it is imperative that the medicinal value of a particular substance not be underappreciated or dismissed.

A recent example of the challenges associated with scheduling substances is the deliberation over the proposed scheduling of ketamine. Health systems rely heavily on ketamine, an anesthetic, for basic surgical procedures in some countries of the global South. It is on the WHO Model List of Essential Medicines. However, based on reports from China, Indonesia, Australia, and the U.S., among other countries, ketamine is also used as a recreational drug.

At the request of member states, the WHO Expert Committee on Drug Dependence (ECDD) reviewed the evidence around the potential for nonmedical use of ketamine, its potential public health impacts, and the importance of ketamine in medical practice. The ECDD concluded that “based on accumulated evidence and data on nonmedical use, diversion and trafficking, and evidence of ketamine’s therapeutic value” it should not be scheduled.¹⁸ Despite this finding, in early 2015, China asked the Commission on Narcotic Drugs to consider placing ketamine under the most restrictive control possible under the 1971 Convention—Schedule I. Several member states, and many civil society actors, strongly opposed the proposal on the basis that it would significantly reduce medical access to ketamine for millions of people. Ultimately, China asked that the Commission on Narcotic Drugs postpone a decision on scheduling ketamine to allow more information to be gathered.¹⁹

Challenges associated with estimates

The Single Convention imposes a system of estimates with a view to ensuring adequate supplies of controlled medicines. States are required to submit annual estimates of their need for controlled medicines (sometimes referred to as “quotas”) to the INCB; these estimates should specify the amount of each substance necessary to satisfy the medical and scientific needs of their populations. However, due to many factors, many states lack the data to adequately estimate their annual needs. Consequently, states either submit estimates well below actual medical needs (often based on the inadequate level of consumption the previous year) or fail to submit estimates at all. For many years, there was little pressure on countries to improve their estimates or assistance to enable them to improve their practices.²⁰ A 2011 Human Rights Watch report concluded that thirteen countries of the global South (Burkina Faso, Burundi, Cambodia, Central African Republic, Chad, Côte d’Ivoire, Ethiopia, Haiti, Malawi, Mali, Niger, Nigeria, and Rwanda) did not set aside or consume enough opioids to treat even one percent of their terminal cancer and HIV/AIDS patients.²¹

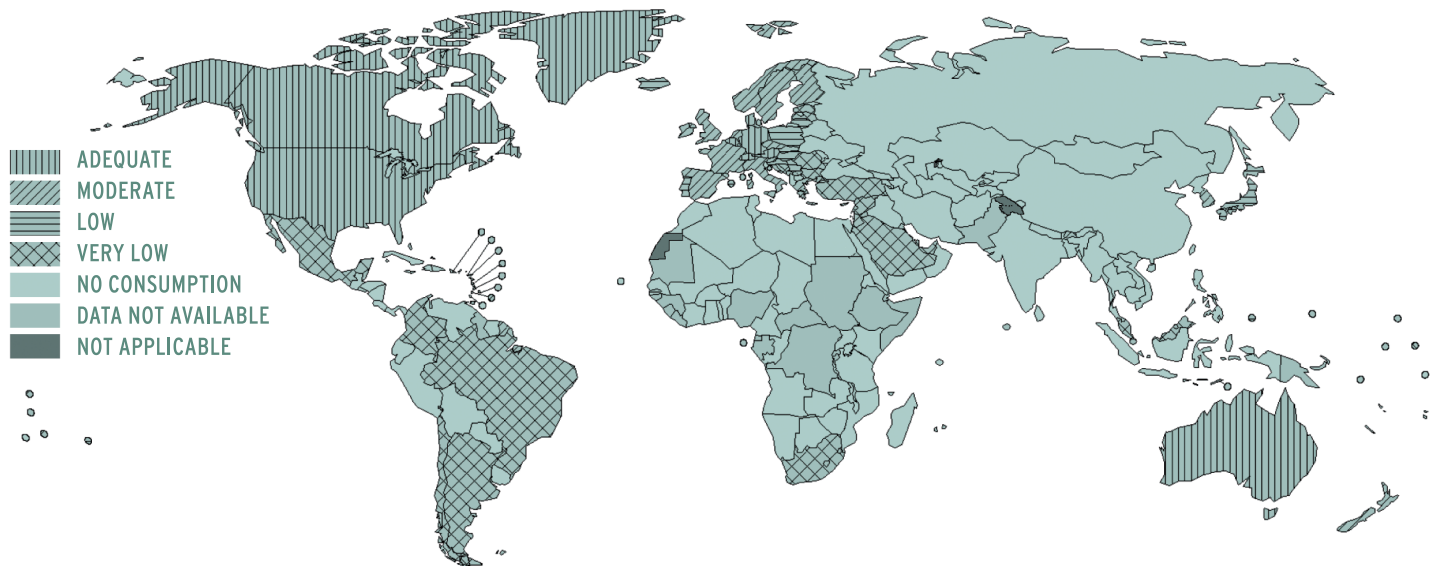
18 See World Health Organization, *Reports of Advisory Bodies: Expert Committee on Drug Dependence*, ¶ 6, U.N. Doc. EB136/48 (Dec. 19, 2014), http://apps.who.int/gb/ebwha/pdf_files/EB136/B136_48-en.pdf

19 International Drug Policy Consortium, *The 2015 Commission on Narcotic Drugs and its Special Segment on Preparations for the United Nations General Assembly Special Session on the World Drug Problem* (2015).

20 See Global Commission on Drug Policy, *The Negative Impact of Drug Control on Public Health: The Global Crisis of Avoidable Pain*, 16-17 (2015), <http://www.globalcommissionondrugs.org/reports/>. The Global Commission noted that the INCB has historically failed to press governments to scale up their estimates to meet the “obvious medical need”

21 See generally Human Rights Watch, *Global State of Pain Treatment: Access to Palliative Care as a Human Right* (2011), <https://www.hrw.org/sites/default/files/reports/hro511W.pdf>

Figure 1: Global Analgesic Consumption 2010



The boundaries and names shown and the designations used on this map do not imply the expression or any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city, or area or its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement. Data source: WHO²² © WHO 2012

In 2012, the INCB and WHO partnered to produce a *Guide on Estimating Requirements for Substances under International Control*, with a view to assisting “governments of countries with low levels of consumption of controlled medicines in calculating their requirements,” to improve the efficacy of the system of estimates. While such guidance was much needed, it will take resources and commitment to put in place the coordination mechanisms and processes required for a functioning estimates system. In the past, public health experts have criticized INCB’s ability to manage its conflicting mandates of control and supply, and called for WHO to be granted greater authority in the estimate process.²³ This joint effort by INCB and WHO may be a step in the right direction.

²² Béatrice Duthey, et al., *Adequacy of Opioid Analgesic Consumption at Country, Global, and Regional Levels in 2010, its Relationship with Development Level, and Changes Compared with 2006*, 47 J. OF PAIN & SYMPTOM MGMT. 283, 283-97 (2014).

²³ See *The Negative Impact of Drug Control on Public Health*, supra note 20, at 12.

WHO estimates that around 80 percent of cancer patients will experience moderate to severe pain at the end of life and will require morphine for an average period of 90 days before death.

The 2015 Human Rights Watch Report on palliative care in Armenia describes the suffering resulting from inadequate opioid pain treatment for people with cancer and the emotional strain placed on their families. Data collected by Human Rights Watch from nine polyclinics in Armenia shows that less than 8 percent of individuals who died of cancer in 2011 received strong opioids before they died.²⁴ Armenia consumes just 1.1 kg of morphine per year—an amount sufficient to adequately treat moderate to severe pain in just three percent of Armenian patients with terminal cancer or AIDS.²⁵



24 Human Rights Watch, "All I Can Do Is Cry" *Cancer and the Struggle for Palliative Care in Armenia* (2015), <https://www.hrw.org/report/2015/07/14/all-i-can-do-is-cry/cancer-and-struggle-palliative-care-armenia>

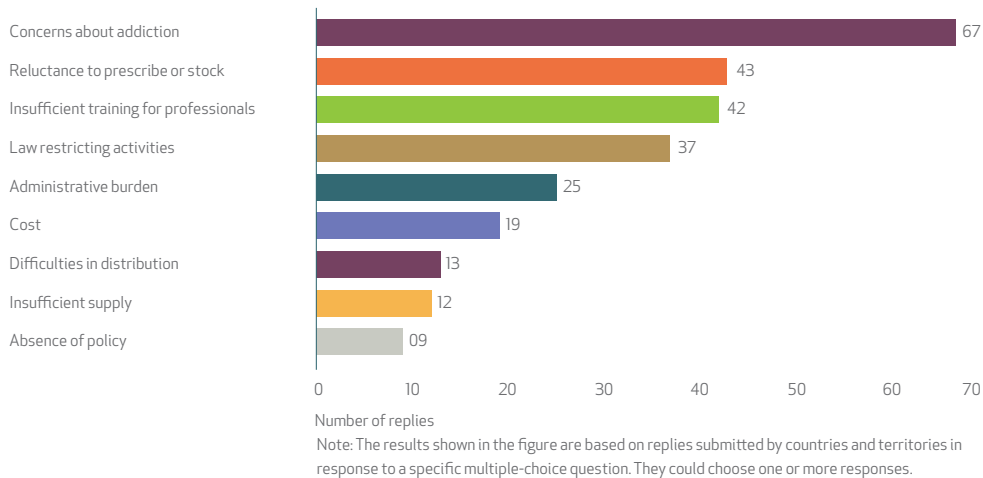
25 *A Country Snapshot: Armenia, Treat the Pain*, American Cancer Society (Apr. 8, 2015) <http://www.treatthepain.org/Assets/CountryReports/Armenia.pdf>

In order to effectively improve their estimates for controlled medicines, states must ensure that drug control and health authorities coordinate to make such estimates, that an adequate number of health professionals are authorized and trained to prescribe controlled medicines, and that exaggerated fears of addiction or misuse are appropriately countered.

Challenges associated with attitudes, stigma, and lack of knowledge

In 2010, the INCB surveyed governments on factors they deemed to influence the availability of opioids for medical needs and found that 67 of 70 respondents indicated concerns about addiction to be a barrier.²⁶ Health professionals, policy makers and the general public may have exaggerated and unfounded concerns about the potential for dependency on opioid medications and the side effects of their medical uses.²⁷

Figure 2: Main factors affecting the availability of opioids for medical needs, INCB 2010²⁸



With respect to healthcare workers, adequate training and information on the appropriate use of controlled medicines—including training on recognizing and managing pain—is critical to rectify these concerns and avoid inappropriate prescribing practices. Without reliable information, fear and uncertainty will result in healthcare workers continuing to underutilize controlled medicines—to the detriment of patients.²⁹ Health professionals must also be supported to overcome stigma about addiction. For example, even where a person has a clinical history of opioid dependence appropriate use of opioids for pain management may be clinically indicated.³⁰

²⁶ See *INCB Report*, *supra* note 5, ¶ 97.

²⁷ See WHO Briefing Note, *supra* note 3, at 2; Vanessa Adams, *Access to Pain Relief: An Essential Human Right*, HELP THE HOSPICES FOR THE WORLDWIDE PALLIATIVE CARE ALLIANCE, 23 (2007).

²⁸ See *INCB Report*, *supra* note 5, ¶ 97, fig. 29.

²⁹ United Nations Office on Drugs and Crime, *Ensuring Availability of Controlled Medications for the Relief of Pain and Preventing Diversion and Abuse: Striking the Right Balance to Achieve the Optimal Public Health Outcome*, 9-10 (2011) [hereinafter UNODC Discussion Paper].

³⁰ WHO Briefing Note, *supra* note 3, at 2; (“[A]s almost all pain patients are able to stop opioid medication at the end of their treatment, with no long-lasting effects”); Lynn R. Webster & Rebecca M. Webster, *Predicting Aberrant Behaviors in Opioid-Treated Patients: Preliminary Validation of the Opioid Risk Tool*, 6 *PAIN MED.* 432, 432–42 (2005).

Many factors influence the perceptions of policy makers and the general public of controlled medicines, including cultural values. Fear of addiction and stigma—often unfounded—may result in patients not reporting their pain or refusing to be treated with opioid analgesics.³¹ Stigma fueled by the war on drugs also affects the availability and accessibility of opioid substitution therapy for the treatment of drug dependence.

Challenges associated with regulation

WHO recommends that “decisions concerning the type of drug to be used, the amount of the prescription, and the duration of therapy are best made by medical professionals on the basis of the individual needs of each patient, not by regulation.”³² Yet, many countries have regulations that unnecessarily restrict the decisions of medical professionals and exceed the minimum control measures recommended in the drug conventions.

A 2011 INCB survey found laws and regulations that unduly restrict access to and use of controlled medicines, including:³³

Limitations on prescription authority and handling—for example, allowing only specialist medical doctors to prescribe opioids and other controlled medicines;³⁴ imposing arbitrary restrictions on the number of pharmacies permitted to dispense opioids; and arduous requirements relating to the storage of opioids.

Limitations on prescription period or quantity—including limitation on the number of days’ supply that may be provided in a single prescription, or the number of doses or tablets that may be prescribed in a single prescription.

Special prescription procedures for opioids—such procedures may include additional paperwork, special prescription pads, or a requirement that health facilities keep copies of prescription records. WHO has observed that special multiple-copy prescription requirements typically reduce prescribing of covered drugs by 50 percent or more.³⁵

31 David E. Joranson et al., *Opioid Policy, Availability and Access in Developing and Non-Industrialized Countries*, in BONICA’S MGMT. OF PAIN 194, 199 (Scott M. Fishman et al. eds., 2010).

32 World Health Organization, *Cancer Pain Relief: A Guide to Opioid Availability*, 10–11 (2d ed., 1996) [hereinafter *WHO Cancer Pain Relief*].

33 Nathan I. Cherny et al., The Global Opioid Policy Initiative (GOPI) Project to Evaluate the Availability and Accessibility of Opioids for the Management of Cancer Pain in Africa, Asia, Latin America and the Caribbean, and the Middle East: Introduction and Methodology, 24 *ANNALS OF ONCOLOGY* xi7, xi7–xi13 (2013).

34 Most States do not provide for nurse prescription despite the WHO recommendation that “physicians, nurses and pharmacists should be legally empowered to prescribe, dispense and administer opioids to patients in accordance with local needs.” *WHO Cancer Pain Relief*; *supra* note 32, at 57.

35 *WHO Cancer Pain Relief*; *supra* note 35, at 10.

Patient eligibility—for example, a requirement that patients register or seek special permission before being permitted to receive opioid prescriptions.³⁶

Disproportionate or excessive penalties for health professionals—including penalties and prosecutions for unintentional errors in prescription or mishandling of controlled medicines, and/or minor infractions.

For example, prior to a law reform in 2014, India’s strict laws required healthcare institutions in many states to obtain five different licenses, from two different government agencies, in order to purchase morphine. The licenses each had a unique application procedure and did not necessarily have the same period of validity. Over seven years, after the law was enacted in 1985, morphine consumption dropped 97 percent as hospitals and pharmacies simply stopped stocking it.³⁷ Since 2014, India has worked to set up a simpler one-license system for obtaining morphine.

Strict or excessive regulatory requirements for controlled medicines result in fear of legal sanctions among doctors and healthcare workers.³⁸ Ambiguous rules for the prescription and handling of opioids, and harsh punishments for mistakes in handling them, impede legitimate prescribing and undermine patients’ right to health.³⁹ A majority of key informants in a 2011 Human Rights Watch survey reported that doctors were hesitant to prescribe opioids because of fear of repercussions—such as criminal sanctions or license revocation.⁴⁰ This is despite widespread recognition that 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.”⁴¹

This issue is not limited to countries with constrained resources or limited training of medical professionals. A 2009 study of the knowledge, beliefs, attitudes, and prescribing practices of doctors in the U.S. state of Wisconsin found that responding physicians held many misconceptions about the prescribing of opioids. The study concluded that these

36 UNODC Discussion Paper, *supra* note 29, at 9.

37 Human Rights Watch, India: *Major Breakthrough for Pain Patients: Amendments to Drug Act Simplify Access to Pain Medicines* (2014), <https://www.hrw.org/news/2014/02/21/india-major-breakthrough-pain-patients>

38 See Nathan I. Cherny et al., *supra* note 33, at xi8.

39 Human Rights Watch, *Global State of Pain Treatment*, *supra* note 21, Part II. (“Criminalizing unintentional mistakes in opioid prescription is not consistent with the right to health”).

40 Informants from 34 of 40 countries said that doctors were hesitant to prescribe opioids because of fear of legal sanction for mishandling them, such as criminal sanctions or professional sanctions such as license revocation. *Id.*

41 World Health Organization, *Ensuring Balance in National Policies on Controlled Substances: Guidance for Availability and Accessibility of Controlled Medicines* (2011) (citing International Narcotics Control Board, Demand for and Supply of Opiates for Medical and Scientific Needs, 15 [1989]).

misconceptions, coupled with a lack of knowledge about laws and regulations governing the prescribing of controlled substances, have the potential to result in inadequate prescribing of opioids with resultant inadequate management of pain.⁴²

Challenges associated with financing and procurement

Attempts to implement obligations under the international drug control system frequently result in states imposing extensive controls on the import, distribution, sale, and transport of controlled medicines. Such regulation tends to exacerbate the realities of resource constraints, weak supply chains, inadequate infrastructure and/or weak monitoring and oversight—creating significant obstacles to the availability of controlled medicines.⁴³ Supply chains and infrastructure limitations may be felt most acutely in rural areas and small towns.

Additionally, though most opioid analgesics are off-patent and, accordingly, can be produced and sold cheaply—they often cost significantly more in low- and middle-income countries than in high-income countries. This disparity is often because national and international drug control requirements increase the cost of importing, distributing, and selling these medicines, while at the same time reducing their use so that it is unattractive for pharmaceutical companies to enter these markets. High prices result from the lack of competition in such cases.⁴⁴

Until recent reforms, Mexico’s centralized approach to regulating the stocking and prescribing of controlled medicines was so burdensome that it greatly suppressed prescription outside state capitals. Strict regulation meant few doctors beyond state capitals sought licenses to prescribe opioid medicines for pain, forcing patients and family members to travel long distances to obtain and fill their prescriptions. Doctors were required to use special prescription forms, as well as unique barcoded stickers that could be obtained at only one distribution point in every Mexican state. Doctors were required to collect the barcoded stickers in person, a costly and arduous burden.

In June 2015, Mexico introduced a new electronic system for prescribing and dispensing strong prescription pain medicines. This electronic system will relieve the burden on doctors by allowing them to download barcodes for opioid prescriptions from a secure website.⁴⁵

42 Marla Z. Wolfert et al., *Opioid Analgesics for Pain Control: Wisconsin Physicians’ Knowledge, Beliefs, Attitudes, and Prescribing Practices*, 11 PAIN MED. 425, 425–34 (2010).

43 Human Rights Watch notes the impact of the failure of states to put in place functioning drug supply systems, weak government authority, limited financial resources, and inadequate infrastructure—upon access to controlled medicines. Human Rights Watch, *Global State of Pain Treatment*, *supra* note 21, Part II (“Criminalizing unintentional mistakes in opioid prescription is not consistent with the right to health”).

44 Commission on Narcotic Drugs, *Ensuring Availability of Controlled Medications for the Relief of Pain and Preventing Diversion and Abuse: Striking the Right Balance to Achieve the Optimal Public Health Outcome*, ¶ 46, U.N. Doc. E/CN.7/2011/CRP.3 (Mar. 25, 2011). The broader impact of pharmaceutical producers, bilateral contracts, and global trade agreements will not be dealt with in this paper.

45 Human Rights Watch, *Mexico: Breakthrough for Pain Treatment Modernized System for Prescribing Strong Medicines* (2015), <https://www.hrw.org/news/2015/06/15/mexico-breakthrough-pain-treatment>



CONCLUSIONS AND RECOMMENDATIONS

Considering the significant impact of the international drug conventions on access to controlled medicines, the following measures are recommended:

1. UN General Assembly Special Session on Drugs

Governments and civil society should use the UN General Assembly Special Session on Drugs in April 2016 to highlight the negative impact of overregulation, and misunderstanding of drug dependence on access to controlled medicines, and should seek commitment to concrete action to address imbalance in the system.

2. Role of health authorities

WHO should have the resources and authority to play an important role in technical assistance to national governments in their estimates of controlled medicine needs. At the national level, controlled medicine policy, like all drug policy, should be overseen by a multisectoral body that includes high-level representation of health authorities. Correspondingly, it would be useful for national delegations to the Commission on Narcotic Drugs and other UN drug discussions to include high-level health officials, which should provide informed consideration of the recommendations of WHO about the scheduling of medicines. Civil society should encourage this rebalancing of health and security at all levels of drug policy-making.



3. Regulation

States should review and reform national law, policy, and practices that undermine balanced drug policy; with particular sensitivity towards:

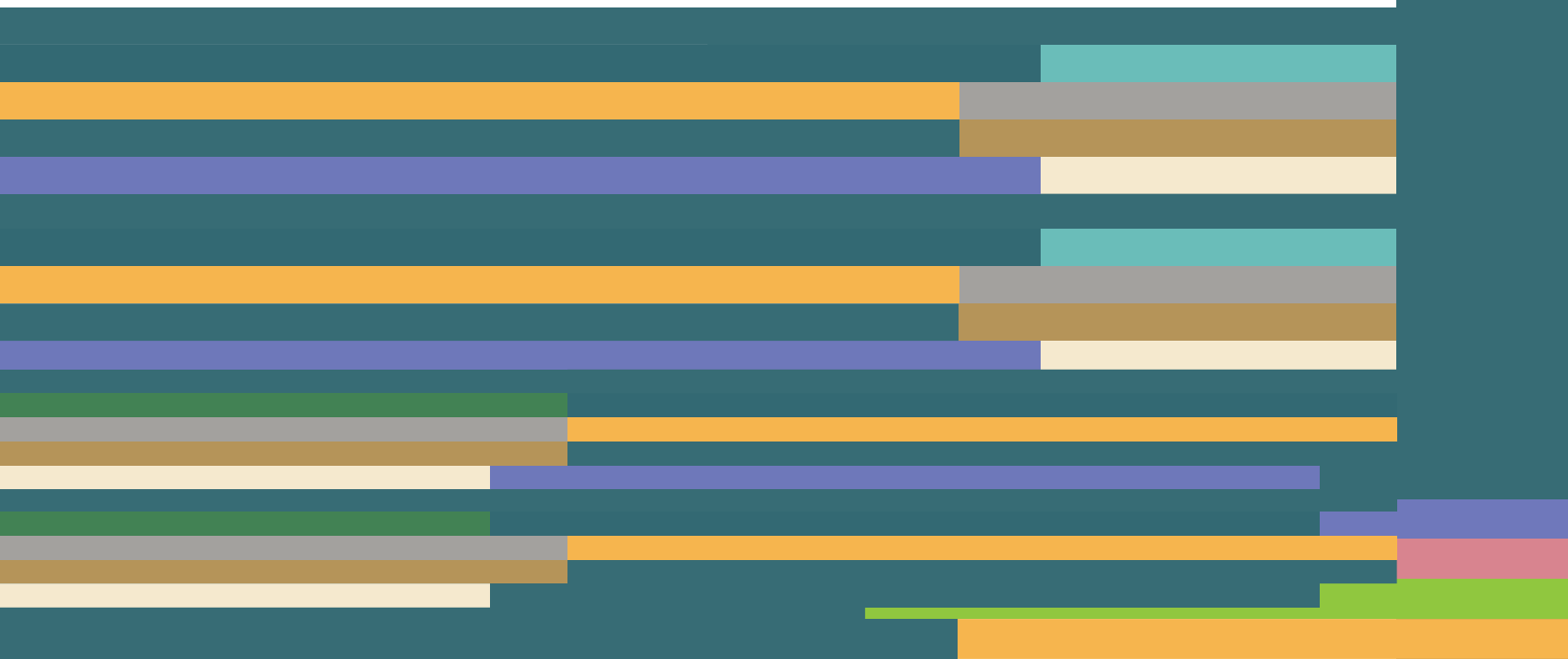
- law, policy, and practice that impose disproportionate penalties on doctors and healthcare workers for mishandling controlled medicines; and
- regulations related to logistics, transport, stocking, prescribing, and dispensing of controlled medicines that undermine access to controlled medicines, especially outside major urban centers.

4. Attitudes, knowledge, and stigma

States should take action to ensure that health professionals at all levels have scientifically sound training on the importance and use of controlled medicines, including the nature of drug dependence.

Civil society should contribute steps to:

- counter misinformation and misconceptions with scientifically sound evidence about controlled medicines, pain, and drug dependence.
- address the stigma faced by people who use drugs and advocate for greater access to evidence-based treatment for drug dependence, including medication-assisted treatment.



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