

2.2

Ensuring access to controlled substances for medical and scientific purposes

Key recommendations

- National drug control regulations should be reviewed using WHO's 2011 guidance³⁵ to ensure that they do not needlessly interfere with the availability and accessibility of controlled medicines, especially opioid analgesics
- The adequacy of annual estimates for medical and scientific needs of controlled substances should be reviewed in accordance with the INCB and WHO's Guide on estimating requirements for substances under international control,³⁶ and estimates should be adjusted as needed
- Adequate training for current healthcare workers should be provided on the use of controlled medicines, and incorporated into undergraduate and graduate curricula for all relevant healthcare workers
- National health strategies should be reviewed, including for cancer, non-communicable diseases and HIV, to ensure that they adequately address the need for palliative care
- More scientific research should be encouraged, conducted and funded on the medical value of cannabis and psychedelics.³⁷

Introduction

Some substances controlled under the international drug control treaties are routinely used in healthcare in diverse fields of medicine, such as anaesthesia, drug dependence, maternal health, mental health, neurology, pain management and palliative care. For example, the World Health Organisation (WHO) has included 12 medicines that contain internationally controlled substances in its Model List of Essential Medicines: buprenorphine, codeine, di-

azepam, ephedrine, ergometrine, hydromorphone, lorazepam, midazolam, methadone, morphine, oxycodone and phenobarbital.³⁸ These represent the 'minimum medicine needs for a basic healthcare system' and 'the most efficacious, safe and cost-effective medicines.'³⁹ A number of countries also apply similar national controls to other essential medicines outside of those proscribed by international law – such as ketamine⁴⁰ (see Chapter 2.1 for more details).

Although ensuring the adequate availability of controlled substances for medical and scientific purposes is one of the fundamental aims of the UN drug conventions, the UN system and UN member states have so far failed at fulfilling this objective. The WHO estimates that 5.5 billion people live in countries with low or non-existent access to controlled medicines, and that tens of millions of people in these countries experience moderate to severe pain without access to treatment every year, including 5.5 million people with terminal cancer and a million people with late-stage HIV/AIDS.⁴¹

The international drug control regime also interferes with scientific research into potential medical uses of controlled substances. An increasing body of evidence suggests that substances such as cannabis and cannabinoids, heroin, ketamine, ketobemidone, LSD and MDMA, have medical uses in the treatment of a variety of conditions, including pain, multiple sclerosis, drug dependence, glaucoma, depression, post-traumatic stress disorder, and Parkinson's disease.⁴² Yet, the fact that these substances are listed in schedules that recognise no medical or scientific use in the drug control treaties creates significant regulatory and financial obstacles to further research and the development of new medications.⁴³

Legislative/policy issues involved

The 1961 Single Convention on Narcotic Drugs and the 1971 UN Convention on Psychotropic Substances articulate a dual obligation for states with respect



Dr. Gloria Dominquez Castillejos, pain clinic director, speaks with a patient in Hospital Doctor Angel Leano in Guadalajara, Mexico

to controlled substances and their medical use: countries must ensure their availability for medical and scientific use, and prevent their use and diversion for other uses (i.e. recreational and non-medical use).⁴⁴ The Single Convention formulates four basic requirements for national regulations of opioid analgesics, which are in the strictest schedule for substances with medical uses:

- Individuals dispensing the medication must be licensed, either by virtue of their professional license or through a special licensing procedure
- Only authorised institutions or people may handle and transfer these medications
- The medications can only be dispensed to a patient upon a medical prescription
- Records on the movement of these medications are kept for no less than two years.⁴⁵

The 1971 Convention contains similar provisions for psychotropic substances. However, both the 1961 and the 1971 conventions explicitly open the door for countries to adopt measures of control stricter or more severe than those provided by the drug control treaties, including a special prescription form for controlled medications, if they deem it necessary.⁴⁶ In contrast, specific operative paragraphs requiring states parties to ensure access to controlled medicines are conspicuously absent.

Many countries have adopted regulations around controlled substances that go far beyond the requirements of the 1961 Convention or the 1971 Convention. Often, these regulations directly interfere with medical practice and make controlled medicines inaccessible for patients. Common barriers in national legislation include:

- requirements for special prescription forms
- limitations on the number of days a prescription can cover

- limitations on which healthcare workers can prescribe controlled substances
- requirements for additional licenses for hospitals, pharmacists and healthcare workers
- additional record keeping or reporting requirements
- limitations on the daily doses that can be prescribed.

Furthermore, the laws on controlled substances of some countries impose harsh criminal punishments for healthcare workers, sometimes even for unintentional errors in handling them.

The WHO,⁴⁷ the International Narcotics Control Board (INCB),⁴⁸ the Commission on Narcotic Drugs (CND),⁴⁹ the United Nations Office on Drugs and Crime (UNODC),⁵⁰ and the World Health Assembly (WHA)⁵¹ have repeatedly called on UN member states to review their regulations on controlled substances to ensure they do not needlessly interfere with medical use. The WHO has also published guidance for countries on reviewing their national policies on controlled substances.⁵²

Implementation issues involved

Regulatory barriers are not the sole reason why the availability of controlled medicines, especially opioid analgesics, is so limited in much of the world. Few governments have put in place effective supply and distribution systems for these medications; they have no relevant health policies or guidelines for practitioners; they do not ensure that healthcare workers get instructions on the use of controlled medicines as part of their training; and they do not make sufficient efforts to ensure that they are affordable.⁵³ Myths about controlled medicines among both healthcare workers and the public, as

Box 1 Mexico reviews its prescribing and dispensing system for opioid analgesics

On 15 June 2015, Mexico introduced a new system for prescribing and dispensing opioid analgesics in response to concerns that the old system was so cumbersome that it deprived people with advanced illnesses of access to essential pain medicines. The new system allows physicians to download special prescriptions from a secure website with bar codes required for prescribing opioid pain relievers. It also introduces electronic record keeping for pharmacies.⁵⁴

Before June 2015, physicians had to travel in person to state capitals to obtain the bar-code stickers that Mexican law requires for prescriptions of opioid analgesics. This highly time-consuming requirement discouraged many physicians from prescribing these medicines. Moreover, pharmacies had to record all transactions involving these medicines in multiple log books, posing a significant bureaucratic burden. A 2014 Human Rights Watch report found that Mexico's regulations were so burdensome that the vast majority of doctors, especially those living outside state capitals, simply did not prescribe these medications and that very few pharmacies kept them in stock.⁵⁵

Apart from simplifying the prescription of opioid analgesics, the electronic system also improved

government oversight of their use. Previously, pharmacies were unable to scan the bar-code stickers on prescriptions for opioid analgesics to authenticate them because they were not linked to a central system. Thus, the requirement for bar codes, which was intended to allow close monitoring of prescribing and dispensing opioid analgesics, did not actually help prevent their misuse, but did create a major barrier to legitimate medical use.

Under the new system, pharmacies will be able to authenticate prescription forms using the bar code, and scripts will be automatically cancelled once they have been scanned. The new system for prescribing opioid analgesics is one of a series of measures by the Mexican government to improve access to palliative and end-of-life care. Pain treatment is an important component of this kind of healthcare.

In December 2014, the Ministry of Health issued guidelines to its healthcare system to put into effect provisions on end-of-life care as outlined in Mexico's 2009 health law and created a department to advance palliative care. In January 2015, the government adopted an inter-agency agreement on palliative care, which made it mandatory and instructed medical schools to include it in their curricula.



Credit: Ed Kashi/VII / Human Rights Watch

Doña Remedios and her daughter, Orlanda Hernandez Ramirez, 44, take a very early morning journey to receive palliative care at the National Cancer Institute in Mexico City, 2014

Box 2 Kenya's improved access to opioid analgesics

Kenya has made significant progress in improving access to opioid analgesics in the last five years, with morphine consumption jumping more than three-fold over that period. In 2010, access to opioid analgesics was very limited and available in just a few Kenyan hospitals. According to a 2010 Human Rights Watch report, Kenya recognised oral morphine as an essential medicine but its central pharmaceutical supplier – the Kenya Medical Supplies Agency, which procures essential medicines for public hospitals – did not purchase or stock oral morphine. Hospitals therefore had to negotiate individually with pharmaceutical companies to obtain the medication. Moreover, the government levied an import tax on morphine powder pushing up the price.⁵⁶ As Kenya's drug law prescribed heavy prison sentences for illicit possession of morphine and provided no detailed guidelines on lawful possession for healthcare workers and patients, many healthcare providers viewed morphine as a dangerous substance rather than as an essential medicine for pain.

Since 2010, Kenya has taken significant steps toward improving access to opioid analgesics. It has integrated palliative care into the public health system, developed clinical guidelines, and introduced multiple training curricula that include the use of opioid analgesics. In 2013, the Kenya Medical Supplies Agency began to procure morphine centrally for public hospitals, and the government removed the tax on morphine powder. As a result, 43 public hospitals offered palliative care by late 2014, and all had a steady supply of morphine.⁵⁷

well as often unfounded fears of diversion for illicit purposes, are key factors blocking improved access to controlled medicines.

In the case of pain management and palliative care, these factors combine to create a vicious cycle of under-treatment in many countries. Because pain treatment and palliative care are not policy priorities, healthcare workers do not receive the necessary training to assess the medicines necessary to treat moderate to severe pain. This leads to widespread under-treatment and to low demand for opioid analgesics. Similarly, the complex procurement

and prescription regulations, as well as the threat of harsh punishment mentioned above, discourage pharmacies and hospitals from stocking these medicines, and healthcare workers from prescribing them, again resulting in low demand. This, in turn, reinforces the low priority given to pain management and palliative care. This low prioritisation is not a function of low prevalence of pain, but of the invisibility of its sufferers.

To break out of this vicious cycle, governments and the international community should:

- take a multipronged approach that focuses on eliminating regulatory barriers and criminal sanctions for legitimate medical uses of controlled medicines
- develop health policies, such as national strategies on cancer or on non-communicable diseases, that identify palliative care as an objective, and integrate such services into the healthcare system
- overcome gaps in training on the use of controlled medicines for healthcare workers
- take action to ensure an adequate supply and distribution system.

Key resources

- Duthey, B. & Scholten, W. (2014), 'Adequacy of opioid analgesic consumption at country, global and regional level in 2010, its relation to development level and changes compared to 2006', *Journal of Pain and Symptom Management*, **47**(2): 283-97, doi:10.1016/j.jpainsymman.2013.03.015
- Global Commission on Drug Policy (October 2015), *The negative impact of drug control on public health: The global crisis of avoidable pain*, <http://www.globalcommissiondrugs.org/reports/>
- Hallam, C. (December 2014), *The international drug control regime and access to controlled medicines* (International Drug Policy Consortium & Transnational Institute), <http://idpc.net/publications/2015/01/the-international-drug-control-regime-and-access-to-controlled-medicines>
- International Narcotics Control Board & World Health Organisation (2012), *Estimating requirements for substances under international control*, https://www.incb.org/documents/Narcotic-Drugs/Guidelines/estimating_requirements/NAR_Guide_on_Estimating_EN_Ebook.pdf
- World Health Organisation (2011), *Ensuring balance in national policies on controlled substances*, http://apps.who.int/iris/bitstream/am/10665/44519/1/9789241564175_eng.pdf