or have unnecessarily burdensome licensing procedures that deter pharmacies and medical institutions from stocking controlled medicines, and divert healthcare workers' time from providing medical care.

The licensing system in most of India's states, where healthcare providers must obtain five different licenses from several government agencies, is a prime example. To its credit, the Indian government has recommended partial reform to improve patient access to morphine. Today, 14 states have adopted a new, simple system for morphine that involves obtaining one license from one government agency. In China, hospitals are categorized according to their size, and only larger hospitals are authorized to handle opioids. As a result, people living outside of large cities have to travel much further to obtain opioid medicines than they would if they were available in all hospitals.

## SURVEILLANCE OF PATIENTS AND HEALTH CARE PROVIDERS

- PATIENT SURVEILLANCE

  Prescription tracking systems have a legitimate role in preventing diversion of controlled medications but some countries have instituted much more invasive surveillance of patients. In Georgia, for example, patients are required to visit police stations to fill their opioid prescriptions. Intrusive surveillance deters legitimate use of controlled medicines and may violate privacy rights.

- SURVEILLANCE AND LEGAL SANCTION OF HEALTHCARE WORKERS

  Healthcare institutions that handle controlled substances are required to keep records so that the authorities can monitor their use. However, some countries have created invasive systems of control that may deter or stigmatize prescribing of controlled medicines or violate privacy rights. For example, in Ukraine, staff who handle opioids are subject to blood tests, and empty morphine ampoules must be collected and counted.

## PROVEN TREATMENT ILLEGAL

UNODC, UNAIDS and WHO agree that opioid substitution therapy (OST) using methadone or buprenorphine is one of the most effective treatments for opioid dependence, and critical to HIV prevention and facilitating antiretroviral therapy among people who inject drugs.[8] Yet, methadone for OST is illegal in Russia, Malaysia, the Philippines and Sri Lanka; use of buprenorphine for OST is illegal in Burma; and both are illegal in Bangladesh, Bhutan, Cambodia, Japan and Singapore. In many other countries, including Pakistan, Kazakhstan, Egypt, Argentina and Brazil, large numbers of people inject opioids, but no OST is available.[9]

## INNOVATIVE REGULATION PROMOTING SAFE ACCESS TO CONTROLLED MEDICINES

### COMPREHENSIVE REGULATORY REFORM

Several countries, including Vietnam, Colombia and Romania, have undertaken comprehensive reviews of their drug control regulations, as recommended by the INCB, to ensure that they do not unnecessarily impede access to controlled medicines. As a result, all three countries increased the amount of time that oral morphine can be prescribed for using one prescription to 30 days, from previous limits between 3 and 10 days. Romania also changed its regulations to ensure that all doctors could prescribe opioids and that all patients in pain could receive them, regardless of their underlying disease.[10] Vietnam expanded the types of health facilities that are authorized to prescribe and dispense opioids, and mandated that district hospitals stock opioid medicines if no pharmacy in a district does.

### NURSE PRESCRIBING

Uganda, the United Kingdom and most states in the United States allow nurses to prescribe controlled medicines in certain circumstances. In some cases, pharmacists, clinical officers or physician's assistants may also be licensed to prescribe controlled medicines. For example, in 2008 Vietnam amended its law to allow assistant doctors to prescribe morphine when no doctor is available.[11] Nurse prescribing has the most potential to improve access to controlled medicines in resource-limited settings where there are not enough doctors. The INCB has commended Uganda for its efforts to increase access to controlled medicines.[12]

### EMERGENCY PRESCRIBING

Lithuania and the United Kingdom allow pharmacists and nurses to prescribe controlled medicines when a patient is in severe pain and no doctor is available. They also allow doctors to authorize an emergency prescription by telephone or fax, as do many other European countries.[13]

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# DRUG CONTROL AND ACCESS TO CONTROLLED MEDICINES: A GLOBAL VIEW

Photo: Palliative care nurses and volunteers check up on a 67-year-old woman, who is paralyzed and taking morphine for pain in south Kerala. © 2009 Brent Foster

Ensuring the availability of essential medicines like morphine, methadone and buprenorphine is a core obligation of governments under the right to the highest attainable standard of health. Drug control regulations that restrict the adequate availability of these medications violate that right. Denial of strong opioids to patients in severe pain can also constitute cruel, inhuman or degrading treatment.

## REGULATORY BARRIERS TO MEDICAL ACCESS TO CONTROLLED DRUGS

Access to controlled medicines must be regulated to prevent their misuse. The 1961 Single Convention establishes three basic requirements for such regulations:

- Controlled medicines may be dispensed only pursuant to a prescription;
- A license must be required to manufacture, trade or distribute them, and
- Appropriate records must be kept.[1]

Yet, many countries have enacted regulations that go well beyond what is required by the Single Convention and that impede availability of controlled medications. INCB has repeatedly called on countries to review their drug control regulations to assess whether they unnecessarily impede access to controlled medicines.[2]

### PRESCRIPTION PROCEDURES

- SPECIAL PRESCRIPTION FORMS

  Many countries, like Turkey, require use of a special prescription for controlled medicines. WHO has observed that special multiple-copy prescription requirements "typically reduce prescribing of covered drugs by 50 percent or more." The requirement to use special prescription forms can be particularly burdensome if doctors have to apply to receive the forms, as in Morocco and Germany, or have to pay for them, as in the Philippines, Denmark, Albania and Estonia. Problems accessing enough special prescription forms have been reported in Turkey, El Salvador and Ukraine.

- PRESCRIPTION LIMITATIONS

  Many countries, like Morocco, limit the number of days a prescription for controlled medicines can cover. WHO recommends "decisions concerning…the amount of the prescription and the duration of therapy are best made by medical professionals on the basis of the individual need of the patient, not by regulation."[3] Extreme time limits include Ukraine (1 day), Belarus (3 days), Greece, Lithuania and Russia (5 days). In many other countries, an opioid prescription may be valid for as many as 90 days or there is no limitation at all.[4]

- RIGHT TO PRESCRIBE LIMITED TO CERTAIN SPECIALISTS

  Like Montenegro, some countries limit the right to prescribe opioids to doctors practicing in certain specialties, commonly oncology, pain management or anesthesiology. Such restrictions significantly limit patients' access to opioid medicines. The WHO recommends that "physicians, nurses and pharmacists should be legally empowered to prescribe, dispense and administer opioids to patients in accordance with local needs."[5] Countries with similar restrictions include, among others, Egypt and Ukraine.[6]

### LICENSING REQUIREMENTS

- SPECIAL LICENSES FOR DOCTORS

  In many countries, like Greece, doctors need a special license or registration to prescribe controlled medicines. While in some countries the process for obtaining a license is simple, in others obtaining it requires considerable paperwork or even invasive screening of the doctor. For example, the Philippines requires doctors applying for a license to submit to blood tests. As a result of excessively complex licensing procedures in some countries, including Morocco and the Philippines, very few doctors obtain them.[7]

- LICENSES FOR PHARMACIES, HOSPITALS AND HOSPICES

  The UN drug conventions require that states create a system to license healthcare institutions that handle opioid medications. Some countries arbitrarily exclude certain healthcare facilities from eligibility for a license

## ACCESS TO CONTROLLED MEDICINES AND THE UN DRUG CONVENTIONS

The 1961 Single Convention on Narcotic Drugs obliges states to make "adequate provision… to ensure the availability of narcotic drugs" which continue to be "indispensable for the relief of pain and suffering." The International Narcotics Control Board (INCB) has stated that the Single Convention "establishes a dual drug control obligation: to ensure adequate availability of narcotic drugs for medical and scientific purposes, while at the same time preventing the illicit production of, and trafficking in and use of such drugs." Yet, the President of the INCB observed in July 2009 that access to controlled medicines is "virtually non-existent in over 150 countries."

***Except where otherwise noted, all information is from Human Rights Watch interviews or correspondence with healthcare professionals in the countries mentioned. These examples are illustrative of regulations that promote or impede access to controlled medicines and do not fully reflect the regulatory environment in the countries mentioned. These examples are not intended to suggest that practices in the countries mentioned are better or worse than those in countries not mentioned. Non-regulatory barriers also contribute to the unavailability of controlled medicines, particularly inadequate training for healthcare workers in their use.** Additional sources of information on reverse: Jordan: Jan Stjernswärd et al., "Jordan Palliative Care Initiative: A WHO Demonstration Project", Journal of Pain and Symptom Management, vol. 33 no. 5, May 2007, 631; Rwanda: International Narcotics Control Board, Narcotic Drugs: Estimated World Requirements for 2009 – Statistics for 2007, E/F/S.09.XI.02 (New York: United Nations, 2009), p. 241; K. M. Foley, "Pain Syndromes in Patients with Cancer," in K. M. Foley, J. J. Bonica and V. Ventafridda, eds., Advances in Pain Research and Therapy, (New York: Raven Press, 1979), 981_994; UNAIDS, "Rwanda: Country Situation", July 2008, http://data.unaids.org/pub/FactSheet/2008/sa08_rwa_en.pdf (accessed February 9, 2010); Singapore: Central Narcotics Bureau, Annual Bulletin, 2007. [1] Single Convention on Narcotic Drugs, 1961, adopted March 30, 1961, 520 U.N.T.S. 151, entered into force December 13, 1964, preamble. [2] International Narcotics Control Board, "Availability of Opiates for Medical Needs: Report of the International Narcotics Control Board for 1995," http://www.incb.org/pdf/e/ar/1995/suppl1en.pdf (accessed February 10, 2010), p. 1. [3] UN Economic and Social Council, "Statement by Professor Sevil Atasoy, President of the International Narcotics Control Board," July 30, 2009, http://www.incb.org/documents/President_statements_09/2009_ECOSOC_Substantive_Session_published.pdf (accessed February 10, 2010), p. 2. [4] UN Committee on Economic, Social and Cultural Rights, "Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights," General Comment No. 14, The Right to the Highest Attainable Standard of Health, E/C.12/2000/4 (2000), http://www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En (accessed February 9, 2010), para. 43. [5] Human Rights Council, Report of the Special Rapporteur on Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, Manfred Nowak, "Promotion and Protection of All Human Rights, Civil Political, Economic, Social and Cultural Rights, including the Right to Development," A/HRC/10/44, January 14, 2009, para. 72. [6] International Narcotics Control Board, Report of the International Narcotics Control Board for 2008, E.09.XI.1 (New York: United Nations, 2009), p. 118. [7] WHO, Cancer pain relief: with a guide to opioid availability, 2nd ed., (Geneva: WHO, 1996). [8] N.I. Cherney et.al, "Formulary availability and regulatory barriers to accessibility of opioids for cancer pain in Europe: a report from the ESMO/EAPC Opioid Policy Initiative", Annals of Oncology, forthcoming, February 2010. [9] Evan Anderson et al., "Closing the Gap: Case Studies of Opioid Access Reform in China, India, Romania & Vietnam" (Centers for Law and Public Health: A Collaborative at the Johns Hopkins and Georgetown Universities, 2008). [10] WHO, UNODC, UNAIDS, Position Paper: Substitution maintenance therapy in the management of opioid dependence and HIV/AIDS prevention, (Geneva: World Health Organization, 2004). [11] Catherine Cook and Natalya Kanaef, Global State of Harm Reduction 2008: Mapping the response to drug-related HIV and Hepatitis C epidemics (London: International Harm Reduction Association, 2008). [12] Daniela Mosoiu, et al., "Romania: Changing the Regulatory Environment," Journal of Pain and Symptom Management, vol. 33 no. 5, May 2007, 610. [13] International Narcotics Control Board, Report of the International Narcotics Control Board for 2004, E.05.XI.3 (New York: United Nations, 2005), para. 196.

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# DRUG CONTROL AND ACCESS TO CONTROLLED MEDICINES: SELECTED EXAMPLES

**MEXICO** few hospitals and pharmacies stock morphine
Mexico City has a population of 18 million people, yet only nine of its hospitals or pharmacies stock morphine, apparently because of burdensome regulatory requirements. This makes pain treatment inaccessible to most of the city's inhabitants.

**GREECE** permits required for doctors and patients
Doctors need a special permit to prescribe opioid medicines and patients need one to receive them. Both requirements deter the legitimate medical use of opioids.

**MONTENEGRO** many specialists cannot prescribe opioids
Oncologists may prescribe opioid medicines but many other specialists cannot, severely limiting access to opioid medicines for patients with pain from causes other than cancer.

**ROMANIA** comprehensive regulatory reform
New drug regulations enacted in 2006 significantly improved accessibility of controlled medications, authorizing all doctors to prescribe opioids and allowing patients in severe pain to receive opioids regardless of the underlying disease.

**LITHUANIA** emergency prescribing
Nurses and pharmacists may prescribe opioids in emergencies, meaning patients no longer have to suffer agonizing pain if no doctor is available.

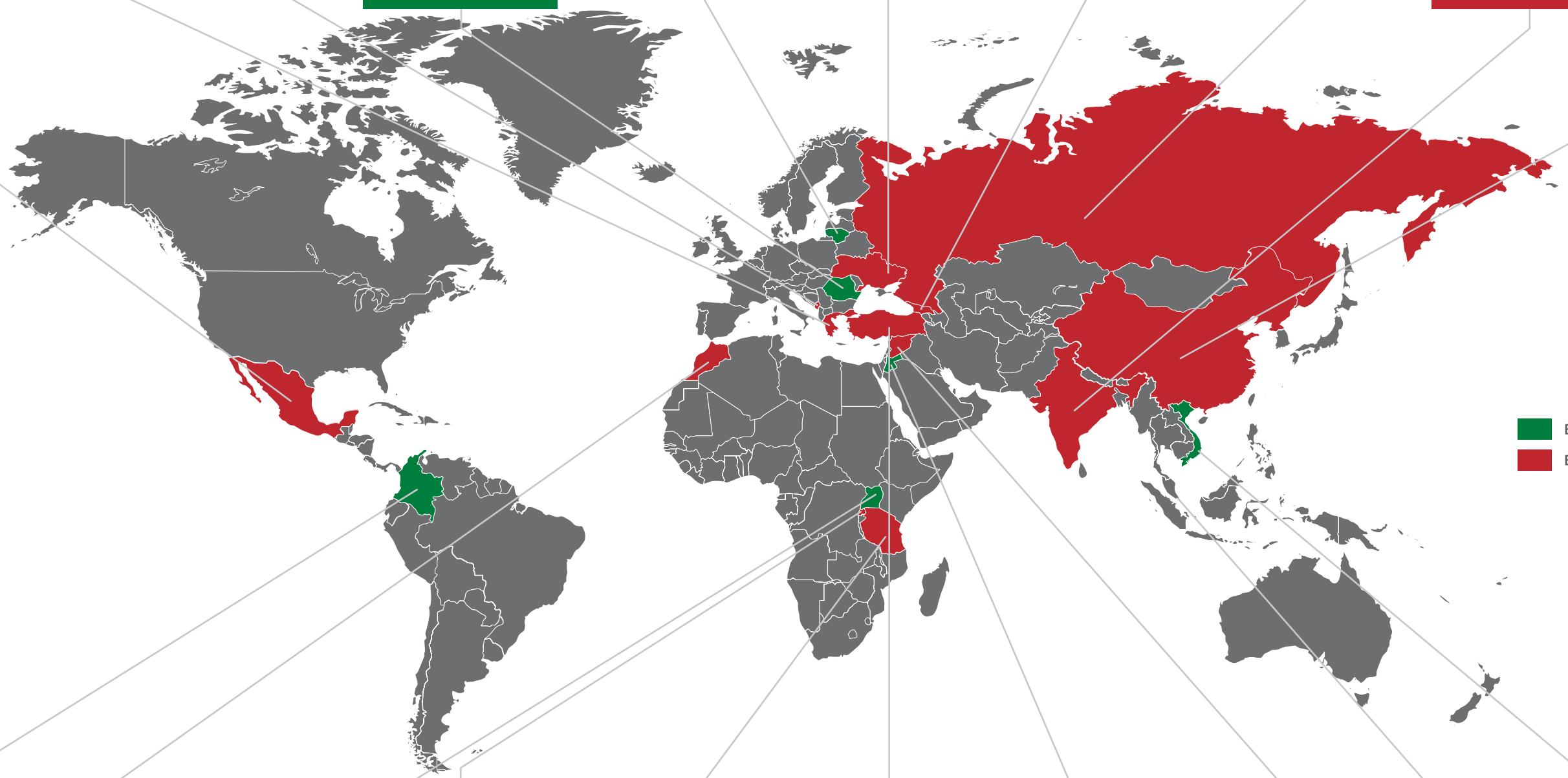
**UKRAINE** unnecessarily complex prescription procedures
Three doctors must sign each morphine prescription. This cumbersome process makes many doctors reluctant to prescribe the medication.

**GEORGIA** patient surveillance
Morphine is dispensed to out-patients from special pharmacies in district police-stations, stigmatizing its legitimate medical use and compromising patients' privacy.

**RUSSIA** effective treatment illegal
Opioid substitution therapy with methadone or buprenorphine is illegal, leaving hundreds of thousands of Russians without effective treatment for drug dependence and at high risk of HIV infection.

**INDIA** multiple licenses required to procure opioids
In many states, hospitals require as many as five different licenses to procure and stock morphine and the procurement process can take months. As a result, many hospitals simply do not stock the medication, abandoning countless patients to excruciating pain.

**CHINA** many hospitals are barred from prescribing opioids
Only hospitals with a certain rank, which is based on their size, are authorized to prescribe opioid medications. As a result, hospitals in many cities and towns cannot dispense opioids and people may have to travel long distances in order to be able to obtain them.



EXAMPLES OF GOOD REGULATION
EXAMPLES OF POOR REGULATION

**COLOMBIA** increase in time limit for opioid prescriptions
In 2006, new regulations increased the length of time for which oral morphine can be prescribed using one prescription from 10 to 30 days.

**MOROCCO** prescription limitations
Patients can only get one week's supply of morphine per prescription, meaning that they must pick up a new prescription every week. For patients who are terminally ill or live far from their doctor this is very difficult.

**UGANDA** nurse prescribing
Since 2004, specially trained nurses and clinical officers are authorized to prescribe morphine, significantly increasing its accessibility in a country with a severe shortage of doctors.

**RWANDA** almost no opioids available
UN drug conventions require states to ensure adequate 'availability of narcotic drugs for [medical] purposes.' Yet, between 2003 and 2007, Rwanda used an amount of morphine sufficient to treat only 330 of the more than 40,000 patients who died of cancer during that period, 80 percent of whom are likely to have suffered significant pain.

**TANZANIA** morphine not available in pharmacies
If a hospital wants to offer oral morphine to its patients, a qualified pharmacist has to collect it from the capital city, a trip that can take up to three days. As a result, very few hospitals have oral morphine, leaving most patients with severe pain to suffer.

**TURKEY** special opioid prescription forms
Prescriptions for strong opioids must be made on a special prescription form. Procuring these forms is time-consuming; many doctors do not keep a supply of them and are not able to prescribe opioids to patients in pain.

**JORDAN** reforms to allow all doctors to prescribe opioids
Since 2004, all doctors can prescribe morphine. Previously, only oncologists could, making treatment inaccessible to people with severe pain from causes other than cancer.

**SYRIA** Out-patients must visit the Ministry of Health to obtain morphine
Out-patients can only receive oral morphine after obtaining permission from the Ministry of Health in Damascus. This unnecessarily complicates access to these essential medications, especially for those who live outside the capital city.

**SINGAPORE** effective treatment illegal
Buprenorphine is a banned substance, leaving thousands of people without effective treatment for drug dependence and at high risk of HIV infection.

**VIETNAM** all districts must have strong opioids
Since 2008, regulations require district hospitals to stock opioid medicines if no pharmacy in a district does, considerably improving accessibility.