

OCTOBER 2015

# THE NEGATIVE IMPACT OF DRUG CONTROL ON PUBLIC HEALTH:

## THE GLOBAL CRISIS OF AVOIDABLE PAIN



GLOBAL  
COMMISSION ON  
DRUG POLICY

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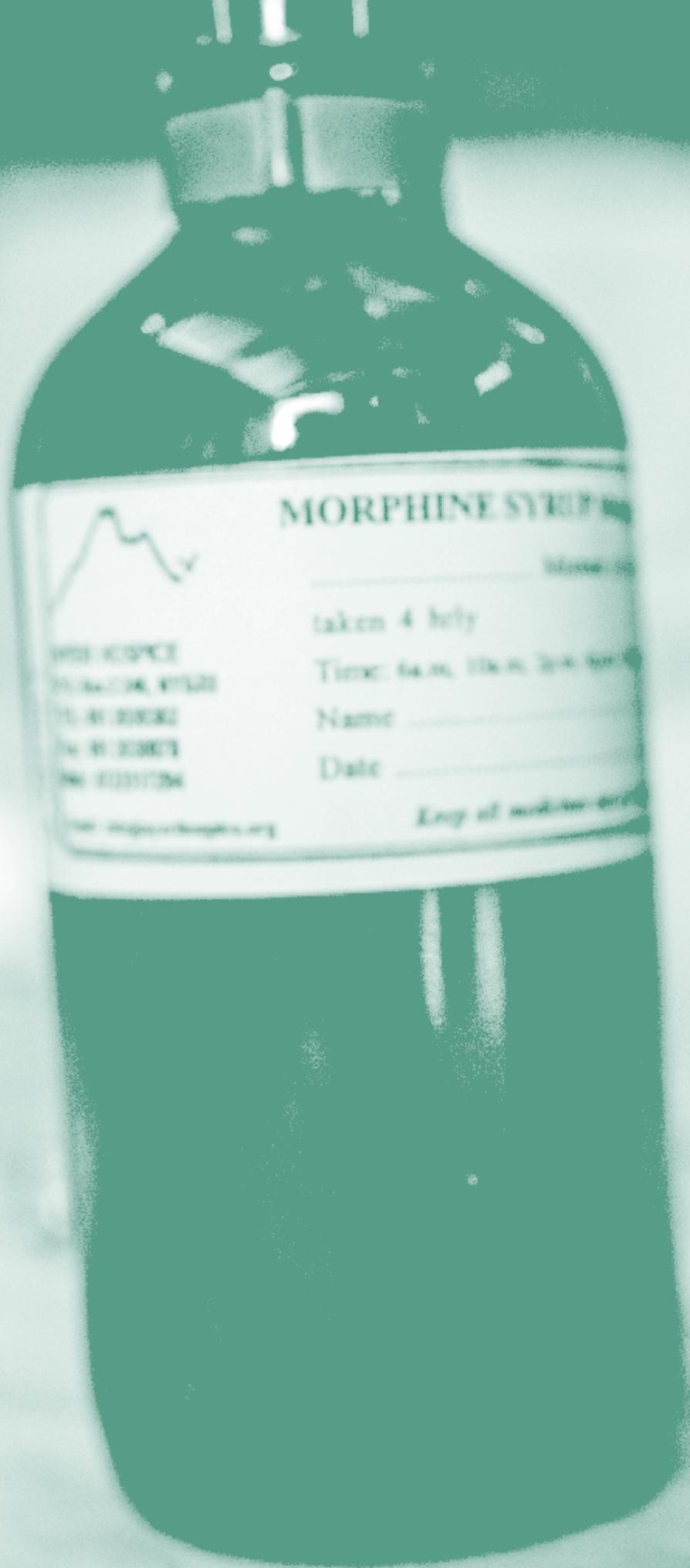
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MORPHINE SYRUP

APPROXIMATE  
CONCENTRATION, 10/1000  
1% BY WEIGHT  
10% BY VOLUME  
1000 mg/100 ml

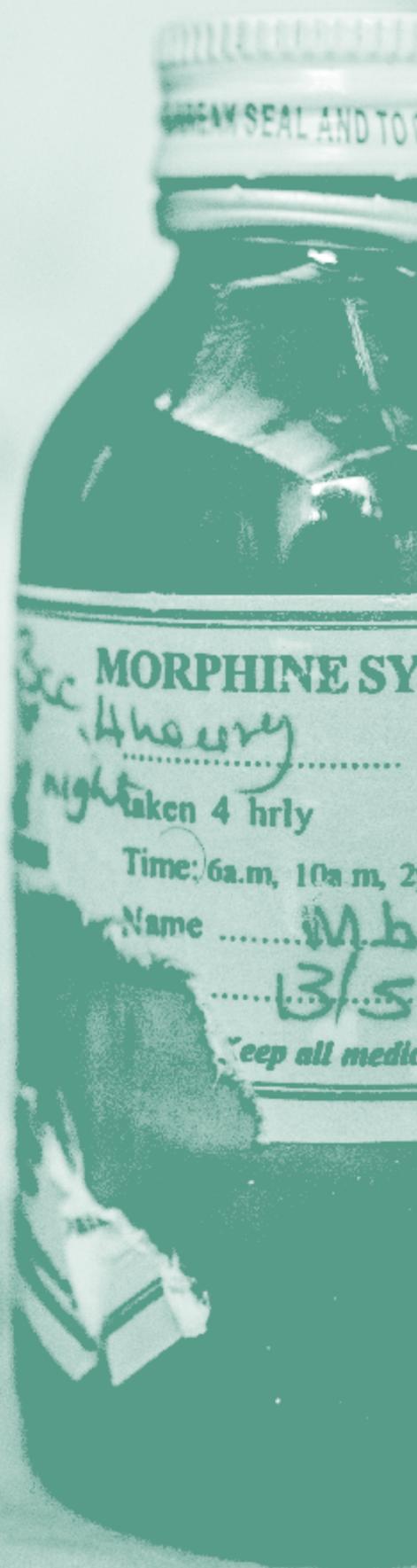
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Keep all medicines safe



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# EXECUTIVE SUMMARY

The international drug control system is stoking a global crisis of inequitable access to controlled medicines. Of the global population, an estimated 5.5 billion have poor to nonexistent access to opioid analgesics, in particular morphine, resulting in the avoidable pain and suffering of people around the world. At the last estimate, 92 percent of the world's supply of morphine was consumed by just 17 percent of the global population, that consumption primarily concentrated in the global north.

Terminal cancer patients, end-stage AIDS patients, and women in labor suffering from uncontrolled pain are among the key impacted groups, with the World Health Organization (WHO) estimating that tens of millions suffer from unrelieved pain annually due to a lack of access to controlled medicines. In addition, only a fraction of people globally who inject drugs are able to access controlled medicines for treating opioid dependence.

Under international drug control law and international human rights law, States have an obligation to ensure controlled medicines are made available to their populations; any restriction of access constitutes a violation of the right to health. Though a number of factors impose barriers to access, including weak healthcare systems and the lack of training of clinicians working on the ground, the international drug control system has been responsible for perpetuating the continual undersupply of controlled medicines.

This scarcity is due to the prioritization, by governments and UN bodies alike, of preventing the diversion of controlled substances for illicit purposes over ensuring access for medical and scientific needs. For example, both the International Narcotics Control Board (INCB) and United Nations Office on Drugs and Crime (UNODC) have a dual obligation

to maintain a balance between preventing diversion and ensuring access, yet have historically favored the former. This has translated to the national level where some governments continually emphasize a criminal justice approach to drug control, rather than a public health one, all to the detriment of providing access to controlled medicines.

In some countries, overly burdensome regulations for prescribing controlled medicines, something that can be linked to the UN drug conventions, create a situation where physicians must operate in a climate of fear and legal uncertainty, real or perceived. As a result, many are afraid of prescribing controlled medicines due to the risk of prosecution, or of being charged with professional misconduct for failing to adhere to stringent regimes. What's more, this environment contributes heavily to broader societal attitudes and the stigmatization of people who use controlled substances, licit or otherwise.

The INCB and UNODC have begun to take steps to rectify this gross inequity of access around the world, and WHO's increasing involvement in the issue over the past decade is a key step in the right direction. However, there is considerable work to do to amend the damage caused by decades of placing a primacy on anti-diversion measures in drug control.

With an increasing number of States and UN bodies drawing attention to the lack of access to controlled medicines, we are reaching a critical juncture, particularly with the United Nations General Assembly Special Session on drugs approaching in 2016. The time for concrete action on the issue is now. A new global initiative must be explored and greater power and funds must be handed to WHO, to lead on tackling inequitable access to controlled medicines. Without action, millions of people will continue to suffer unnecessarily.

# RECOMMENDATIONS

- 1 States and UN bodies must utilize the United Nations General Assembly Special Session (UNGASS) on drugs in 2016, to both acknowledge and begin to forcefully address the major gap in access to controlled medicines, particularly opioids for pain relief. More than 75 percent of the world's population has little or no access to such medicines, leading to the avoidable pain and suffering of millions. There must be an admission that the international drug control system represents a barrier to accessing controlled medicines.
- 2 States must recognize they have an obligation under international law to ensure access to controlled medicines for their populations. This obligation is implied in the cornerstone treaty of the international drug control system, the Single Convention on Narcotic Drugs, and is firmly rooted in the right to the highest attainable standard of health in international human rights law.
- 3 UN drug control bodies and States must recognize that drug policies at both national and international levels are imbalanced, with emphasis on preventing diversion of controlled substances holding primacy over ensuring their access for medical use. This has profound implications for public health and human rights around the world.
- 4 A high priority must be given to the treatment of physical and mental pain by ensuring access to controlled medicines, including opiates, for pain relief, palliative care, anesthesia, dependency, and all other forms of suffering. While States have the obligation to ensure the production and/or import of sufficient quantities of such medicines—especially those that are on WHO's *Model List of Essential Medicines*—WHO, UNODC, and INCB must provide governments with the necessary technical and financial support.
- 5 Governments should provide the necessary funding for a renewed international program to be overseen by WHO, in partnership with UNODC and the INCB, to ensure adequate and affordable access to controlled medicines where they are unavailable.

6 Priority must be given to expanding the spectrum of treatment for opioid dependence, while respecting human dignity and offering the possibility of prescription of controlled medicines such as methadone and buprenorphine (included in WHO's *Model List of Essential Medicines*) or diamorphine. This can be done in line with the WHO-UNODC-UNAIDS Technical Guide: for countries to set targets for universal access to HIV prevention, treatment and care for injecting drug users. States and the relevant UN bodies must work together to address the failure of many countries to adequately implement opioid substitution therapy (OST) for opioid-dependent people.

7 Governments should establish clear plans to remove the barriers to ensuring access to controlled medicines, including: national drug policies anchored in a criminal justice approach, rather than a public health and human rights approach; burdensome domestic regulatory frameworks; stigmatized societal attitudes driving a fear of prescribing opioids for pain relief and the treatment of opioid dependence; poor knowledge of these medicines by health professionals and regulators; and overpricing.

8 The INCB must take more assertive steps in working with countries that consistently fail to ensure adequate access to controlled medicines, and should work increasingly with governments and national health authorities to ensure they provide evidence-based estimates of the need for controlled medicines.

9 Governments and UN drug control bodies should acknowledge and address the gaps and lost opportunities in relation to the medical use of, and medical research into, controlled substances, including cannabis. They should review the 1961 and 1971 drug conventions' schedules in light of scientific evidence and prioritize exploring the medical benefits of controlled substances, based on WHO's Expert Committee on Drug Dependence recommendations.

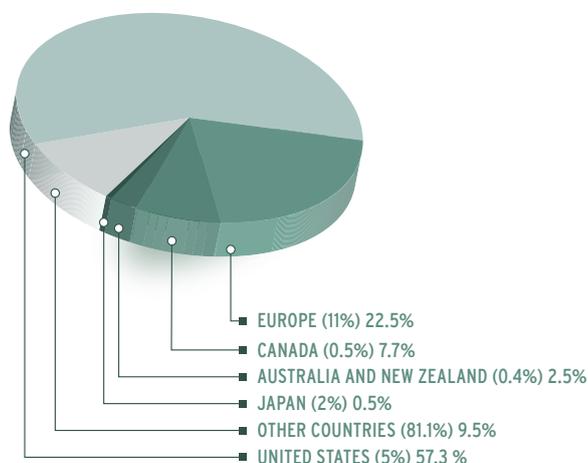
10 The United Nations and the international community must urgently address inadequate access to controlled medicines as a global health priority. Demand for these medicines is driven not by political expediencies, but by the universal human susceptibility to illness and pain. It is not acceptable to wait for a consensus from States on broader drug policy reform. It is time for action.

## There is an urgent need to ensure greater access to controlled medicines around the world

The international drug control system is stoking a global crisis of inequitable access to controlled medicines, resulting in the avoidable pain and suffering of people around the world. Controlled medicines are used in fields as diverse as neurology, psychiatry, and anesthesia. This report will examine in depth the situation as it pertains to access for the treatment of pain and opioid dependence.

An estimated 5.5 billion people—over 75 percent of the global population—have low to nonexistent access to opioid analgesics,<sup>2</sup> which are controlled under the cornerstone treaty of the drug control system, the 1961 United Nations (UN) Single Convention on Narcotic Drugs (Single Convention). In the case of morphine, one of the most vital analgesics for treating moderate-to-severe pain, 92 percent of the world's supply is consumed by just 17 percent of the world's population, that consumption primarily concentrated in the global north. As of 2014, strong opioids and opiates were virtually unavailable in over 150 countries.<sup>3</sup>

FIGURE 1:  
**MORPHINE:  
DISTRIBUTION OF CONSUMPTION 2013**



Note: Percentages in parentheses refer to share of the world population (i.e. total population of all reporting countries).

Source: INCB

Medicines made of or containing opioids are essential, not only in the treatment of pain, but also in treating opioid dependence. Methadone and buprenorphine are primarily used in opioid substitution therapy (OST), a medical treatment for people suffering from opioid dependence, and are both controlled under the UN drug treaties.<sup>4</sup> These, along with morphine, are included in the WHO's *Model List of Essential Medicines*,<sup>5</sup> which serves as the key guide for national governments and institutions in determining what medicines they should make available in their healthcare systems.

The Single Convention affirms in its preamble that the medical use of substances controlled under the treaty "continues to be indispensable for the relief of pain and suffering," and that "adequate provision must be made" to ensure their availability.<sup>6</sup> Yet, many countries have failed to fulfill this objective. Instead, fears over the dependency on controlled opioids and their diversion into the illicit market have trumped concerns for their medical availability. This is despite the fact that research, while limited, has shown that among patients with no history of substance misuse who were treated with opioid analgesics, only 0.43% misused their medication, while just 0.05% developed dependence.<sup>7</sup>

In the United States, the world's largest consumer of opioid analgesics, there has been alarm about the rise in deaths from 1999 to 2011 related to their misuse,<sup>8</sup> which may suggest that widespread availability contributes to misuse. However, recent research into this trend has found that the only common predictor of pain relief medication misuse is past-year illicit drug use disorder.<sup>9</sup> These findings underscore that if there is no history of substance misuse then the likelihood of developing dependence or misusing opioid analgesics will be low.

Sadly, this means that patients with a history of drug use or misuse often find it difficult to access opioid pain relief medications, partly as a result of the fear that they are more susceptible to developing dependence. This fear should never be a reason for withholding treatment and opioid analgesics should be prescribed when there is a clinical need.<sup>10</sup>

## What are essential controlled medicines?

Substances controlled under international law are routinely used in healthcare in such diverse fields of medicine as analgesia, anesthesia, drug dependence, maternal health, mental health, neurology, and palliative care. The World Health Organization (WHO) has included twelve medicines that contain internationally controlled substances in its *Model List of Essential Medicines*; these medicines should be available to anyone who needs them.

## The lack of access to controlled medicines has created a public health and human rights crisis, resulting in the suffering of millions

Pain relief through the use of controlled medicines is an essential component of medical care for a number of groups, among them: terminal cancer patients, women in labor suffering from uncontrolled pain, end-stage AIDS patients in pain, and people suffering injuries caused by accidents or violence. More than two-thirds of cancer patients and half of patients with advanced HIV/AIDS,<sup>11</sup> including many who either have no access to antiretroviral treatment (ART) or access it very late, will experience moderate-to-severe pain. Pain relief may also be required during labor, or in surgery and post-surgery settings.

WHO estimates that each year tens of millions of people suffer from unrelieved pain arising from a lack of access to controlled medicines,<sup>12</sup> in particular opioids.

Access to palliative care—a medical specialty that seeks to alleviate suffering and improve quality of life for people with life-limiting illnesses—and opioid analgesics is of particular importance for cancer

patients in low- and middle-income countries, as they are often diagnosed when the disease is in its advanced stages,<sup>13</sup> or may not have access to chemotherapy and radiotherapy because of weak healthcare infrastructure.<sup>14</sup> The lack of palliative care services on offer in these countries means that nine out of 10 people around the world in need of such care are not receiving it.<sup>15</sup>

The severe deficit in the availability and access to pain relief medicines has broader physical, societal, and economic implications than the immediate failure to alleviate suffering; for example, patients deprived of access to controlled medicines can suffer from a subsequent loss of strength and mobility.<sup>16</sup> In terms of social and economic impacts, failure to secure access to pain relief medication can result in the future inability to work or care for children properly, and cause undue distress for family members. In certain severe cases, some patients deprived of controlled medicines for pain relief have resorted to taking their own lives.<sup>17</sup>

There are additional benefits that can be derived from administering opioid analgesics beyond pain relief. At the 2015 World Health Assembly, Australia's Chief Medical Officer, Professor Chris Baggooley, shared his professional experience, highlighting that providing pain relief "not only gave comfort to...patients but it also expedited the ability to more accurately and more quickly diagnose and treat their afflictions."

"The evidence is clear: around the world, we see that countries which integrate public health into drug control work achieve greater health effects and greater social benefits, while at the same time indeed improving the rule of law and security. Our priority must be to promote health-based responses which offer care for drug users. We must ensure access to essential controlled substances for legitimate medical purposes."<sup>1</sup>

Jan Eliasson, UN Deputy Secretary-General, 2015

Inadequate access to controlled medicines and the ensuing public health implications are not limited to pain relief; OST for treating opioid dependence is only available in 80 countries and territories.<sup>18</sup> Worse still, recent global estimates suggest that just 6–12 percent of people who inject drugs receive OST,<sup>19</sup> despite the proven efficacy of this treatment in curtailing the spread of HIV and hepatitis C.

In spite of medical advances over the past century, no alternatives to strong opioids for treating moderate-to-severe pain have been found so far. This underlines the importance of scaling up their global provision to tackle the inexcusable suffering of some of the most vulnerable populations. The international community has the capacity to overcome the serious deficit in availability of medicinal opioids throughout the globe, yet has to date been unable to because of myriad factors. While acknowledging the importance of these dynamics, this report explores the international drug control system's role in limiting access to controlled medicines and the undue focus on upholding components of it that frequently contravene human rights recognized in international law.

## States have an obligation under international law to ensure access to controlled medicines

As stated in its preamble, the Single Convention promotes access to controlled medicines, recognizing that "adequate provision must be made to ensure the availability of narcotic drugs for [medical] purposes."<sup>20</sup> This principle is operationalized within the treaty through the creation of obligations and mechanisms designed to ensure that adequate supplies of controlled medicines are available to States.

The preamble of the Single Convention implies an obligation not only to have supplies of controlled medicines available to States, but also for States to make those medicines available to their populations. This implied obligation within international drug control law is explicit within international human rights law: the UN Committee on Economic, Social and Cultural Rights has clarified that access to "essential drugs" is an element of the right to the highest attainable standard of physical and mental health (hereinafter "the right to health") under Article 12 of the International Covenant on Economic, Social

and Cultural Rights (ICESCR).<sup>21</sup> Under the right to health framework, first articulated in the 1946 Constitution of the WHO,<sup>22</sup> States Parties have a clear obligation to ensure the realization of the right to health,<sup>23</sup> including making medicines available. This includes those which may also be substances controlled pursuant to the drug control conventions and national laws implementing those conventions; the fact that a substance is scheduled under a drug control convention does not oust a state's obligations to ensure access to it for medical purposes.

Indeed, the obligations under the Single Convention and the ICESCR are complementary and mutually reinforcing.<sup>24</sup> However, these obligations are not being met by far too many States, thus violating the right to health and providing an example of rights abuses being perpetuated in the name of drug control.

Such abuses are well documented, from forced detention in so-called rehabilitation centers,<sup>25</sup> which offer little in the way of medical care for drug treatment (and are replete with other forms of torture or other cruel treatment),<sup>26</sup> to continued use of the death penalty for drug offenses, a sanction that violates international law.<sup>27</sup> The Single Convention, though expressing in its preamble a concern for the "health and welfare of mankind," has been criticized for failing to include mention of the 1948 Universal Declaration of Human Rights—an absence that has in part allowed drug control to supersede the human rights obligations of States.<sup>28</sup> Indeed, this is exacerbated by Article 39 of the Single Convention, which allows States to "adopt measures of control more strict or severe than those provided by the Convention."<sup>29</sup>

Observers and UN bodies alike have continually highlighted the clear violation of human rights in restricting access to controlled medicines, yet to little avail. In 2008, for example, two Special Rapporteurs appointed by the UN Human Rights Council sent a joint letter to the Commission on Narcotic Drugs (CND),<sup>30</sup> the policy-making body of the United Nations on drug control issues, reminding governments of their "minimum core obligations under the right to health" to provide controlled medicines, and called for the issue of lack of access to be "addressed forcefully in the next ten-year drug strategy."<sup>31</sup> Progress, however, while made incrementally in the years since 2008 by some States, has been slow to nonexistent in many countries.

### A dangerous precedent: the move to bring ketamine under international control

Ketamine, a substance on the WHO's *Model List of Essential Medicines*, is the only available anesthetic for essential surgery in most rural areas of low- and middle-income countries, home to more than 2 billion people.<sup>34</sup> Unlike other essential medicines discussed in this report, it is not controlled under the UN drug conventions. However, ahead of the 58th Session of the CND in 2015, China—concerned about domestic misuse of the drug—pushed for ketamine to be controlled under the 1971 Convention on Psychotropic Substances.

Bringing ketamine under international control, as opioids are, would create a public health and human rights crisis that would reverberate throughout many developing countries. The WHO Expert Committee on Drug Dependence (ECDD) has recommended on three separate occasions—2006, 2012 and 2014—that the CND *not* bring ketamine under international control, noting in its 2014 review that scheduling "would limit access to essential and emergency surgery...in countries where no affordable alternative anesthetic is available."<sup>35</sup> China finally withdrew its proposal and a CND vote on the issue has, at least for now, been delayed.

The fact that a vote could still take place, however, is of concern. Firstly, if a decision were taken to control ketamine, this would perpetuate the imbalance in the UN drug treaties, allowing fears of misuse and prioritization of preventing diversion to supersede much-needed access for medical and scientific purposes. Secondly, the refusal by certain States to properly consider WHO's recommendations on ketamine sets a worrying precedent, highlighting the need for issues of global access to essential medicines—controlled or otherwise—to be placed firmly within the mandate of WHO.

The international drug control system does not operate outside of international human rights law. Rather, these legal regimes operate concurrently, as part of a broad range of international legal commitments. Therefore, fulfilment of State obligations under the drug treaties must be done in conformity with these concomitant human rights obligations.<sup>32</sup>

The International Narcotics Control Board (INCB), the body of independent experts established to monitor the three international drug control treaties, has continually defended the drug conventions as being compliant with human rights norms, and recommended that States give "due consideration" to both human rights norms and their obligation to ensure access to controlled medicines.<sup>33</sup> However, such language lacks the force it should carry in ensuring States comply with their obligations under international law, and is at the heart of the problems with the international drug control system and those

tasked with upholding it: the implicit prioritization of restricting availability, rather than ensuring access for public health purposes.

### The international drug control system contains a "deep-lying imbalance" that favours punitive approaches over ensuring access to controlled medicines

In practice, drug control law has made promoting access to controlled medicines a secondary consideration to that of preventing the diversion of these substances.<sup>36</sup> During the drafting process of the Single Convention, much of the focus was on tackling the illicit trade in narcotics and "addiction," described

in the preamble of the Single Convention as “a serious evil.” This focus on preventing diversion is evident in the treaty obligations requiring States to penalize various acts, including the cultivation, manufacture, sale, and possession of controlled substances. Conversely, specific provisions such as these are conspicuously absent when it comes to ensuring access to controlled medicines. Thus, there is “a deep-lying imbalance in the text [of the Convention].”<sup>37</sup>

Recognition from UN drug control bodies of this imbalance, and of their implicit roles in propagating it, has been seriously lacking, as have been efforts to address it. For one, the CND has historically been inactive on the issue of access, with resolutions on promoting adequate availability not adopted until 2010 and 2011.<sup>38</sup> While these were certainly welcome steps, the decades of silence on the matter highlight the ingrained prioritization of drug control elements within the conventions.

With regards to the 2011 resolution, the United Nations Office on Drugs and Crime (UNODC) was requested to review, and update where necessary, its model laws to ensure that the appropriate balance between ensuring access and preventing diversion is achieved. These laws had been described as “excessively stringent” and criticized for failing to provide sufficient focus on encouraging domestic laws to ensure access.<sup>39</sup> Revision of the UNODC’s model legislation on drug control is thus welcome; yet, four years after the CND’s request, it is still to be finalized and there is concern that the proposed amendments—based on indications during the drafting process—may not address previous failings. This ultimately leaves a considerable void in the provision of assistance to States in implementing balanced domestic laws.

When it comes to the INCB, since 1989 the body has played an important part in highlighting the lack of availability of controlled medicines; however, its statements have not been matched by concrete actions to alleviate the problem. The INCB has often placed the onus solely on national governments for failing to ensure access, doing so in isolation from a critique of the barriers created by the international drug control system as a whole. Thus, there has been a failure to acknowledge its role in perpetuating the imbalanced focus through an historical prioritization of law enforcement and drug control.<sup>40</sup> The emphasis placed by many national governments on

overregulation stems from the very prohibitionist elements instilled in them by the Single Convention and key UN bodies.

At the operational level, the INCB has failed to adequately use its influence to reduce systemic barriers contained within the Single Convention. The principal obstacle here is the “estimates” system the INCB manages, whereby countries are required to submit annual figures on their needs for controlled substances for scientific and medical purposes, before they can import. (This system will be critiqued later in the report.)

The INCB’s record on drawing international attention to the issue is commendable. However, it is failing to use its influence maximally to promote an effective, balanced approach and as such has contributed to the many barriers that exist in ensuring the adequate availability of controlled medicines.

## **Access to controlled medicines is seriously hindered by a number of key factors alongside the international drug control system**

In addition to the international drug control system, there are a number of other factors that significantly impede access to controlled medicines. Weak healthcare systems that lack funding and resources are a fundamental problem, inevitably impacting the availability of controlled medicines.

Furthermore, the lack of clinical education and training for health professionals is a serious obstacle to the proper provision of controlled medicines, in particular opioid analgesics. Millions of physicians, nurses, pharmacists, and drug control officials have little understanding about, or formal training in, pain management or palliative care. The World Health Assembly’s Resolution WHA 67.19 acknowledged this gap and recommended that States scale-up the training of health professionals in relation to palliative care and those working with patients with life-threatening conditions; this includes ensuring access to controlled medicines for pain management.<sup>41</sup>



Photo: Nyeri Hospice, part of KEHPCA, Kenya Hospices and Palliative Care Association.  
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### Pain Free Hospital Initiative in Kenya

"Pain is real and I will not fear morphine if my patient is in severe pain," was the comment of one health worker attending Kenya's Pain Free Hospital Initiative (PFHI). Kenya is a country that has made significant efforts to scale-up access to opioid analgesics. The PFHI addresses the knowledge and training gap through an education course aimed at patients and staff. This course aims to ensure that clinicians receive regular training sessions to assist them in their knowledge of pain management. In addition, the program makes sure that there is an adequate supply of controlled medicines for pain relief.<sup>42</sup>

Many of these impediments cannot be seen in strict isolation of a country's drug laws as they are in part influenced by the fact that the use and/or possession of illicit versions of controlled medicines are criminalized in most countries. This conflation of licit medicinal products with illicit substances contributes to an anti-drug environment where controlled medicines are demonized despite their necessity in healthcare settings. One explanation for this conflation may be that controlled medicines are categorized in certain countries as "poisons,"<sup>43</sup> or "dangerous drugs,"<sup>44</sup> by the governmental bodies charged with controlling and dispensing them. This can influence the practices and view of health professionals, family members and patients, and can result in fear of prescribing, a family member withholding, or a patient refusing pain relief medication.<sup>45</sup>

This ultimately feeds into the broader social attitudes that play a major role in limiting access. Patients, families, and prescribers are often reluctant for such

medicines to be prescribed because of the stigma associated with their use and the fear that use will inevitably lead to dependency, despite evidence to the contrary.<sup>46</sup>

Finally, the pricing and procurement of controlled medicines, while a complex area to explore due to the many factors contributing to high prices for what are ostensibly cheap medicines, has proven to be an impediment, with countries with low consumption levels often facing the highest prices.<sup>47</sup> Although morphine is off-patent, and cheap to manufacture and produce, national overregulation, burdensome and overly complicated import/export systems, lack of an assured market in countries where medical opioids are largely unavailable, and anticipated low profit margins result in high prices to consumers in countries that do not subsidize imports or produce the medicine themselves. In the Philippines, for example, one month's supply of immediate-release oral morphine is the equivalent of one month's salary at minimum wage.<sup>48</sup> Although many governments subsidize

"A predominant focus on criminalizing drug use has resulted in severely limited access to, or a complete lack of, opiates in some States because of concerns they may be diverted for illicit uses....Failure to offer access to opiates for legitimate medical treatment is a violation of the right to health, and needs to be addressed as such in States that have eliminated, or severely limited, their use."<sup>51</sup>

Navi Pillay, former High Commissioner for Human Rights, 2014

### Human Rights Watch: "All I can do is cry": Cancer and the Struggle for Palliative Care in Armenia

Armenia has one of the most restrictive prescribing regimes for opioids in Europe. Oral morphine is not available, with only injectable forms dispensed. Furthermore, use of such controlled medicines is limited to those who have cancer and whose diagnosis must be confirmed by biopsy. Only oncologists can issue a prescription and no prescription can be issued without the case being presented to a Standing Commission made up of numerous individuals, who will not agree to the dispensing of opioids until they have seen the patient in their own home. The prescription has to be stamped by four different agencies and will usually only provide enough opioids for 24–48 hours. In addition, prescribers are required to share their patient's confidential details with the police, breaching a person's right to privacy and their right to confidentiality, both of which are core principles of the right to health. The system leaves thousands of people in unnecessary pain and for those cancer patients who are entitled to access opioids, the burdensome nature means many die before they can access pain relief medication.<sup>57</sup>

- In Georgia, pharmacies dispensing opioid medications are based in police stations where patients have to go to collect their medication.<sup>61</sup>
- Ten African countries limit prescriptions of opioid analgesics to no more than two weeks at a time; in Ghana specifically it is just two days.<sup>62</sup>

more expensive medications and formulations, only a few—those that have committed to the availability of controlled medicines for pain relief and palliative care—subsidize morphine imports and distribute the medicine themselves.<sup>49</sup>

The Global Commission acknowledges that these factors are serious impediments to access, and encourages national governments and UN bodies to take a coordinated approach to overcome them. WHO's *Policy Guidelines for Controlled Substances*, which provide direction for governments on policies and legislation with regards to availability, accessibility, and affordability,<sup>50</sup> and WHA Resolution 67.19, should serve as resources in this process.

## Governments limit access to controlled medicines by taking a criminal justice approach rather than an evidence-based, human rights-oriented public health approach

For decades both the INCB and UNODC have provided very little comment on States' failure to implement their legal obligation to ensure access to controlled medicines, rather focusing overwhelmingly on the duty to prevent diversion of substances for illicit purposes.<sup>52</sup> This is evident in INCB's annual reports and UNODC's annual *World Drug Report*. The 2015 *World Drug Report*, for example, continues to frame the "world drug problem" solely as a matter of production, supply, and use of illicit substances, with the lack of access to controlled medicines being given only a fleeting mention in the preface.<sup>53</sup> Of the 12 *World Drug Reports* published since its inception in 2004, the issue of access to controlled medicines is absent in nine of them.

Only recently has the INCB begun to take steps to address the imbalance that exists, despite their mandate to monitor compliance with the dual obligation contained in the treaties of ensuring access and preventing diversion.<sup>54</sup> In light of this historic disparity, many commentators have referred to a "lopsided" focus of the INCB, UNODC, CND, States,

and to some degree the conventions themselves, where a concern over the medical use of certain controlled substances has been lacking.<sup>55</sup>

It is against the backdrop of this imbalanced focus that national governments have implemented overly burdensome regulatory frameworks for the provision of controlled medications, with measures in many cases going beyond what is required in the international drug treaties.<sup>56</sup>

National regulatory barriers vary greatly among nations and directly influence availability and accessibility to controlled medications, in particular opioid analgesics. These can include: <sup>58 59 60</sup>

- limits on the number of days' supply that can be provided in a prescription;
- limits on doses;
- limitations on who can prescribe, with some countries only allowing certain classes of doctors to issue a prescription;
- "special" procedures for prescribing opioids making the process more onerous, including "specific" forms that are difficult to obtain, or a requirement that multiple forms be completed;
- patients either needing to "register" or "receive special permission" to ensure eligibility;
- "excessive penalties" for prescription errors or "mishandling of opioids";
- limited number of pharmacies being able or willing to dispense opioids;
- unreasonable storage requirements.

These are both unacceptable and unnecessary practices creating an environment of fear for physicians, many being afraid of failing to adhere to such a stringent regime and thus risking prosecution. For patients, these highly restrictive practices can be exacerbated by other factors in low- and middle-income countries such as living in a rural area where travel to a city for opioids is required and may not be possible due to a scarcity of money and/or transport.

A number of countries not only impose onerous conditions for the manufacture and distribution of controlled medicines but also subject license holders to harsh punishments even for minor breaches, such as in record keeping. As a result, pharmaceutical companies avoid dealing in controlled medicines, thereby limiting access for patients.

FIGURE 2:  
ADEQUACY OF OPIOID ANALGESIC CONSUMPTION (2010)



The boundaries and names shown and the designations used on this map do not imply the expression of 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: WHO.

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Many States have national bodies appointed to oversee their dual obligation under the international drug treaties. However, in a number of countries the imbalanced focus, stemming from the international drug control system, results in resources and personnel being concentrated on combating the illicit market in controlled substances.

As these national bodies are overwhelmingly focused on managing all aspects of the trade in controlled substances through a criminal justice lens, States should establish a public health-focused body, under the control of the Ministry of Health or other relevant ministry, to take over the role of ensuring access to controlled medicines. International drug control and relevant UN bodies should aid this process through the promotion of an evidence-based public health model, with technical assistance provided by WHO and in-country or regional UNODC staff. States must ensure that their national laws are consistent with obligations under international law to uphold the right to health.

## The global estimates system has failed to ensure adequate access to controlled medicines. The INCB must take further assertive steps to amend its deficiencies

The imbalanced nature of the international drug control system comes to light in the operational paragraphs of the Single Convention that place an emphasis on acts to penalize and prohibit, while neglecting to provide specific guidance on how countries should ensure access to controlled medicines. The only provisions that deal with the latter principle are Articles 12, 19 and 20, and are related to the "estimates" system and the requirement to report consumption of controlled medicines.<sup>63</sup>

Many countries regularly submit estimates to the INCB that do not reflect their medical needs, while some do not submit figures at all. The system itself has failed to achieve the purpose of ensuring adequate supplies to States, as new annual estimates are often based on consumption of controlled medicines within the country the previous year, meaning low and inadequate provision continues in many countries. Historically, the INCB has not pressed governments

sufficiently to scale-up their estimates in order to meet the obvious medical need, thus ensuring an endless cycle of underestimation.

For example, 2006 figures on global consumption of morphine equivalents found that six times the actual amount consumed that year would be required to ensure adequate global supply.<sup>64</sup> This striking deficit, while not prevalent to the same degree as 2006, persists today and must be addressed.

The INCB, working with WHO, has taken steps to tackle this issue in recent years, in 2012 releasing its comprehensive *Guide on Estimating Requirements for Substances under International Control*.<sup>65</sup> This publication intends to help the relevant national authorities better calculate and prepare estimates to submit to the INCB of controlled substances required for medical and scientific purposes. The Commission urges the INCB, in collaboration with WHO and UNODC, to continue to take assertive steps encouraging States to submit estimates that accurately reflect the medical need of their populations. If this action does not materialize, there is a very real risk that continuous underestimation will persist.

## Treatment for opioid dependence with controlled medicines improves public health and is cost-effective. Access to them must be scaled-up

Methadone and buprenorphine are the most commonly used controlled medicines for OST and are included in the WHO's *Model List of Essential Medicines*; however, some countries also provide

alternatives such as slow-release morphine and codeine, or heroin-assisted treatment.

OST decreases or eliminates injecting practice among people who use drugs, thus significantly reducing HIV and hepatitis C transmission in this group, an outcome for which there is a well-established evidence base.<sup>66</sup> Based on the efficacy of this treatment, access to it is endorsed by UN bodies, scientific research bodies, and many governments around the world.<sup>67</sup>

Beyond combating the spread of HIV and hepatitis C infection, when OST has been implemented to scale, reductions in overdose, drug-related deaths, and crime can be observed.<sup>68</sup> Moreover, it has been shown to be a critical component in increased adherence to antiretroviral therapy and tuberculosis treatment,<sup>69</sup> while the benefit return for OST is estimated to be four times the treatment cost<sup>70</sup>; according to the National Institute on Drug Abuse in the United States, methadone treatment is "among the most cost-effective treatments, yielding savings of \$3 to \$4 for every dollar spent."<sup>71</sup>

Despite the overwhelming evidence in support of OST, global coverage is extremely low, with the treatment only available in around half of the countries reporting injecting drug use. What is more, this global snapshot does not capture the quality of national-level coverage of OST; in some countries OST is available only within the context of detox or rehabilitation facilities, and adequate provision is typically concentrated in high-income countries, replicating the scenario seen with inequitable access to controlled medicines for pain relief.

In many countries OST coverage levels fall far below the levels recommended by international guidance<sup>73</sup>; for example, in Asia, five countries—Afghanistan, India, Myanmar, Sri Lanka and Vietnam—report coverage levels of less than 20 percent, very low by international guidance standards.

"The existence of national policy on harm reduction [including OST] does not inevitably equate to provision of an adequate response in either scope or quality."<sup>72</sup>

Harm Reduction International, 2014

## The Success of Heroin-Assisted Treatment in Switzerland

In 1988, 74 percent of the Swiss population named illicit drugs as the second-most pressing problem in the country. As a reaction to the open drug scenes, Switzerland conducted a scientific study on the medical prescription of heroin (today known as heroin-assisted treatment or HAT) with the aim of assessing:

- the suitability of this treatment method for people suffering from heroin addiction who had been failed by other treatments, and;
- the impact of such treatment on health and social outcomes.

Consequently, patients should become healthier, return to work, refrain from consumption of nonprescribed substances, and abstain from delinquency.

In response to the International Narcotic Control Board's (INCB) recommendations, Switzerland requested WHO to set up a group of independent international experts for evaluation.

The main conclusions of the abovementioned study and evaluation were:

- Health: Meaningful improvements in patients' health status and high retention rates in HAT are among the most striking results.
- Public safety and security: Significant positive changes regarding employment and criminal behavior were achieved. The evaluation showed an overall drop of 68 percent in contacts with police.
- Cost-effectiveness: Benefits overcompensate the costs of HAT with clear return on investment in the area of legal behavior (i.e., decrease of days of imprisonment, and improved health status of participants).

In 1998 HAT became available as a regular but restricted treatment with the following admission criteria:

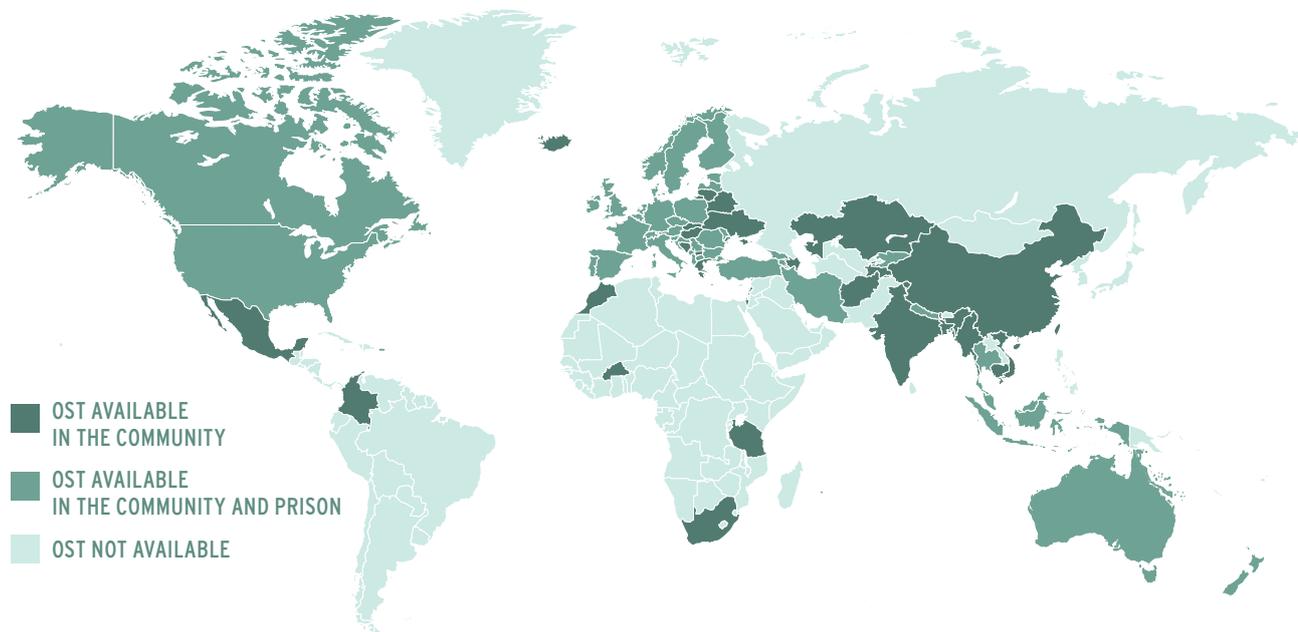
- minimum age of 18 years;
- at least two years of opiate addiction;
- at least two unsuccessful treatment attempts;
- medical, psychological, or social deficiencies caused by the addiction.

In a nationwide referendum, HAT was confirmed by the majority (54.4 percent) of the Swiss electorate in 1999.

In 2008, after another nationwide referendum, the Swiss electorate accepted—with a majority of 68.1 percent—to anchor HAT as a treatment option into the Swiss federal law on narcotic drugs.

Source: Diane Steber Büchli, Swiss Federal Office of Public Health

**FIGURE 3:  
GLOBAL AVAILABILITY OF OPIOID SUBSTITUTION THERAPY IN THE COMMUNITY AND IN PRISONS**



Source: HRI

A key contributor to this lack of access is the stigmatizing environment created by the drug treaty regime, which, as stated above, emphasizes the need to suppress "addiction," described in the Single Convention's preamble as a "serious evil" that States have a "duty to prevent and combat."<sup>74</sup> This fear of addiction, and the resultant stigmatization of people who use drugs, has led to an overreliance on regulatory models at the domestic level that prioritize the prevention of diversion rather than ensuring access to OST. Indeed, some countries have tended to create a "hierarchy" among patients in need of controlled medicines, prioritizing those with cancer pain over patients with opioid dependence—the latter being seen as blameworthy, suspicious, and less deserving of pharmacological treatment.

Even in the scenario where access to OST is permitted, people using these services may still face the threat of police harassment or arrest around treatment centers and therefore stop engaging with OST programs. For some groups such as women and young people, additional barriers have been reported such as age restrictions,<sup>75</sup> a lack of gender-sensitive services, and a fear of loss of legal custody of children.<sup>76</sup>

As with access to controlled medicines for pain relief, weak healthcare systems significantly impact the availability of OST. This is exacerbated by a lack of dedicated funding for these services, leading to a situation where it is estimated that USD \$160 million, or just 7 percent of what is required, is currently invested in harm reduction programs globally. Given that this estimate includes additional elements of comprehensive harm reduction package interventions,<sup>77</sup> the total amount invested in OST alone is likely to be far lower than this. Conversely around USD \$100 billion is invested in punitive responses to drugs.<sup>78</sup> A rebalancing of spending whereby there is a concrete move away from law enforcement and toward a public health approach is thus vital.

The INCB has rarely—if ever—criticized States for failing to ensure proper medical access to OST, despite the clear obligation to do so under both international drug control and human rights law.<sup>79</sup> The INCB, along with UNODC, should play a key role in ensuring States provide access to an adequate supply of OST for medical purposes as, to date, the INCB's enthusiasm for this element of their mandate has been lukewarm at best.

## Where Conflict Hinders Access: The Scaling Back of OST in Eastern Ukraine

The delivery of controlled medicines to Donbass, Ukraine, became more difficult due to security restrictions and regulatory controls established by the Presidential Decree of November 2014 (n°875) on "urgent measures to stabilize the socioeconomic situation in Donetsk and Luhansk regions." The government has cut funding to all health facilities (including staff salaries) that have remained in the Non-Government Controlled-Area (NGCA) territory for fear that national budget funds would fall into the hands of the armed groups. Methadone and buprenorphine, in particular, were considered as "narcotic medicines" and "potential weapons," and therefore subjected to specific and complex regulatory procedures. Despite the repeated efforts of the international community, including the suggestion made by Médecins Sans Frontières in Donetsk to monitor the distribution and utilization of methadone to address concerns from the Government of Ukraine, these medications were not allowed to be delivered by UN Humanitarian Convoys. Based on data collected by the International HIV/AIDS Alliance in Ukraine, as of July 2015, over 1,000 patients residing in Donbass had lost access to OST due to a lack of medical supplies and the closure of OST administering sites.

## Under the current framework UN drug control bodies must take a more balanced, proactive, and coordinated role in helping countries ensure access to controlled medicines

For decades the INCB has been perceived as being overly concerned with any potential weakening of the international drug control system, and until recently has often been silent on human rights abuses committed in the name of drug control,<sup>80</sup> thus contributing to the current situation in relation to access to controlled medicines.

Its refusal to criticize countries like Russia, whose human rights abuses of people who use drugs are evident, is just one example. Russia actively prohibits OST, which, along with the absence of needle and syringe programs, has led to a situation where the number of HIV cases in the country increased 80 percent between 2004 and 2014.<sup>81</sup> Within the next five years, 3 million people in the country could be HIV positive.<sup>82</sup> The INCB's silence is a failure to acknowledge a significant breach of the right to health recognized in international human rights law—including in the ICESCR, which Russia has ratified and hence pledged to uphold.

There are mechanisms to address these issues; Article 14 of the Single Convention enables the INCB to: initiate a process of consultation; require explanations; and provide recommendations to States Parties to adapt their policies if the "aims of this Convention are being seriously endangered by reason of the failure of any Party, country, or territory to carry out the provisions of this Convention."<sup>83</sup>

Yet, the INCB has never used this mechanism to address any country's failure to provide adequate estimates, or outright refusal to ensure access to controlled medicines for their population. The INCB should invoke Article 14 in conjunction with Article 14 *bis*, which would provide technical and financial assistance to countries that have repeatedly failed to meet their obligation under international law.<sup>84</sup>

What is more, the INCB should recognize the important role it can play in highlighting human rights abuses as part of the international drug control system, including, but not limited to, the failure to provide controlled medicines.

The UNODC, which has more resources than INCB and in-country or regional staff on the ground, could arguably play a more active role in helping scale-up access to controlled medicines by providing technical support for countries to help them assess whether their domestic laws impede access. While it is currently difficult to assess existing levels of

support on this issue, anecdotal evidence suggests that resources—human, technical, and economic—disproportionately focus on building the capacity of law enforcement agencies in relation to interdiction. In light of this, UNODC should provide transparent data on what field operations are focused on and where resources are positioned. Furthermore, the UNODC, which houses the secretariat to CND, should ensure that resources are deployed to support countries to meet *all* of their obligations under the drug control treaties and international human rights law.

The INCB and UNODC must ensure that they are fulfilling the requirements of their mandates and that their work focuses equally on preventing diversion and ensuring access to controlled medicines, while adhering to international human rights obligations. This has to be central to all aspects of their work, in all arenas including in-country or regional UNODC offices. Both bodies, in collaboration with WHO, must implement a balanced, proactive, and coordinated approach to ensuring access to controlled medicines.

## **Governments should fund a renewed international program led by WHO to ensure equitable access to controlled medicines.**

WHO's clear acknowledgement of the need to work toward a more balanced model for ensuring access, in conjunction with its stated belief that drug control should be used to optimize public health, underscores the necessity for its involvement on the issue. Indeed, over the past decade its role has expanded with the launch in 2007 of the Access to Controlled

Medicines Program (ACMP), a joint initiative with the INCB aimed at providing technical assistance to governments in identifying and removing key barriers to access.

However, while the ACMP was instrumental in a number of key developments—notably developing the aforementioned WHO *Policy Guidelines for Controlled Substances* and WHO/INCB *Guide on Estimating Requirements for Substances Under International Control*—its work has been severely hindered by a lack of funding in recent years. Since 2008, WHO has been unable to fund the program itself, and though interim funding was provided by the European Commission and Dutch Government, the ACMP's work has effectively ground to a halt in recent years.

The Global Commission reiterates the recommendation of its 2014 report, "Taking Control: Pathways to Drug Policies That Work," that WHO, in cooperation with UNODC and INCB, take the lead in ensuring access to controlled medicines.

Currently, WHO does not have the resources or manpower to oversee a new international initiative; this must be addressed as a matter of urgency with a view toward scaling up the agency's capacity to ensure access to controlled medicines. Governments need to commit funds and establish a clear plan with timelines outlining specific goals, which would see the removal of domestic and international obstacles to provision. This could include regional WHO/UNODC offices assisting national governments' move towards a public health approach that addresses all obstacles in ensuring access for controlled medicines.

"Drug control should not be approached as an objective in itself, but as a tool to optimize public health. One focus should be the prevention of abuse and dependence; the other to avoid collateral harm. The outcomes should be judged both by the harms from abuse it prevents and the harms it cause through, for example, lack of access."

WHO, 2011<sup>85</sup>



### UN drug conventions contribute to the limitations in research into the potential medical benefits of other controlled substances

LSD, MDMA, cathinone, and psilocybin are all substances that are subject to the strictest control under the 1971 Convention on Psychotropic Substances. Under Schedule I they are deemed to present "a high risk of abuse, posing a particularly serious threat to public health with little or no therapeutic value."<sup>93</sup>

This is reflected in many countries whose domestic laws deem these substances to have no therapeutic effect. As such, research is limited by regulatory hurdles, and makes them extremely expensive to buy in medical-grade form. For example, UK regulations permit hospitals to have a license for Schedule II substances—morphine, cocaine etc.—but those wishing to research Schedule I substances have to obtain a Home Office license<sup>94</sup>; a 2013 study highlighted that only three out of thousands of hospitals in the UK had such a license.<sup>95</sup>

This experience is not limited to the UK; it took researchers in Canada four years to import MDMA from Switzerland for a study looking at its therapeutic use for PTSD.<sup>96</sup> In addition to the regulatory restrictions, the cost of these substances makes them prohibitive for research purposes. For example, one company supplying a gram of psilocybin was charging US\$12,000 per gram.<sup>97</sup>

The medicinal benefits of these substances are starting to come to light as a result of minimal but groundbreaking research. Studies have explored the use of MDMA to assist psychotherapy, with one study in the US conducted in relation to patients suffering from "treatment-resistant PTSD."<sup>98</sup> The results were impressive, with 80 percent of patients showing clinical benefits compared to only 20 percent in the control group.<sup>99</sup> Other potential conditions where MDMA could have a positive effect include autism and Parkinson's disease.<sup>100</sup>

Photo: Nyeri Hospice, part of KEHPCA, Kenya Hospices and Palliative Care Association.  
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## The international drug control system contributes to the criminalization of people who use cannabis for medicinal purposes

Millions use cannabis for medicinal purposes globally, and, although not a controlled medicine, it has been synthesized by pharmaceutical companies for medical use. These pharmaceutical products have seen many domestic legislators stretch the law in relation to cannabis, with the products themselves being controlled as a class of substance that is distinct. In a large number of countries cannabis is scheduled as having "no therapeutic effect,"<sup>86</sup> a result of its scheduling under the Single Convention.

The Single Convention categorizes substances across three schedules,<sup>87</sup> which, based on risk of harm and/or misuse and therapeutic value, would be subject to varying degrees of control. Schedule I contains substances considered to be "highly addictive and liable to abuse"<sup>88</sup> and are subject to "**all** [emphasis added] measures of control applicable to drugs under this Convention."<sup>89</sup> Additionally, some substances that are controlled in Schedule I are included in Schedule IV where they are considered to be "particularly dangerous"<sup>90</sup> and are thought to have "little, or no therapeutic value."<sup>91</sup> Cannabis is both a Schedule I and Schedule IV substance.

Cannabis has significant value for its potential to treat a range of medical conditions. Researchers have suggested that various active ingredients in the substance could be beneficial for a number of conditions including: pain, spasticity (Multiple Sclerosis [MS]), anxiety disorders, seizure disorders including epilepsy, psychosis, addiction, post-traumatic stress disorder (PTSD), and attention-deficit hyperactivity disorder (ADHD).<sup>92</sup>

Many users of cannabis for medicinal purposes confirm that it is effective at reducing their pain and significantly alleviates the symptoms of conditions like MS and epilepsy. While some are able to access pharmaceutical cannabis-based medication, the vast majority of those medicating themselves have no choice but to risk criminalization, either by growing their own plants or purchasing it from the illicit market. It is a tragedy that people who are in need of medication have to risk imprisonment in order to alleviate their suffering.

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## ADDITIONAL RESOURCES

### Count the Costs

[www.countthecosts.org](http://www.countthecosts.org)

### Cupihd

[www.cupihd.org](http://www.cupihd.org)

### Drug Policy Alliance

[www.drugpolicy.org](http://www.drugpolicy.org)

### Global Commission on HIV and the Law (convened by UNDP)

[www.hivlawcommission.org](http://www.hivlawcommission.org)

### Harm Reduction International

[www.ihra.net](http://www.ihra.net)

### Human Rights Watch

[www.hrw.org](http://www.hrw.org)

### Igarapé Institute

[www.igarape.org.br](http://www.igarape.org.br)

### Intercambios

[www.intercambios.org.ar](http://www.intercambios.org.ar)

### International Centre for Science in Drug Policy

[www.icsdp.org](http://www.icsdp.org)

### International Doctors for Healthier Drug Policies

[www.idhdp.com](http://www.idhdp.com)

### International Drug Policy Consortium

[www.idpc.net](http://www.idpc.net)

### International Network of People who use Drugs

[www.inpud.net](http://www.inpud.net)

### International Narcotics Control Board

[www.incb.org](http://www.incb.org)

### Talking Drugs

[www.talkingdrugs.org](http://www.talkingdrugs.org)

### Transform Drug Policy Foundation

[www.tdpf.org.uk](http://www.tdpf.org.uk)

### Transnational Institute; drug law reform resources

[www.druglawreform.info](http://www.druglawreform.info)

### The Beckley Foundation

[www.beckleyfoundation.org](http://www.beckleyfoundation.org)

### UN Office on Drugs and Crime

[www.unodc.org](http://www.unodc.org)

### Washington Office on Latin America - Drug Policy program

[www.wola.org/program/drug\\_policy](http://www.wola.org/program/drug_policy)

### West Africa Commission on Drugs

[www.wacommissionondrugs.org](http://www.wacommissionondrugs.org)

### World Health Organization: Access to

### Controlled Medications Program

[http://www.who.int/medicines/areas/quality\\_safety/access\\_to\\_cmp/en/](http://www.who.int/medicines/areas/quality_safety/access_to_cmp/en/)

### World Health Organization: Essential Medicines

[http://www.who.int/topics/essential\\_medicines/en/](http://www.who.int/topics/essential_medicines/en/)

## REPORTS BY THE GLOBAL COMMISSION ON DRUG POLICY

- War on Drugs (2011)
- The War on Drugs and HIV/AIDS:  
How the Criminalization of Drug Use Fuels the Global Pandemic (2012)
- The Negative Impact of the War on Drugs on Public Health:  
The Hidden Hepatitis C Epidemic (2013)
- Taking Control: Pathways to Drug Policies That Work (2014)

<http://www.globalcommissionondrugs.org/reports/>

## GLOBAL COMMISSION ON DRUG POLICY

The purpose of the Global Commission on Drug Policy is to bring to the international level an informed, science based discussion about humane and effective ways to reduce the harm caused by drugs to people and societies.

### GOALS

- Review the base assumptions, effectiveness and consequences of the 'war on drugs' approach
- Evaluate the risks and benefits of different national responses to the drug problem
- Develop actionable, evidence-based recommendations for constructive legal and policy reform