

## The International Drug Control Regime and Access to Controlled Medicines

Christopher Hallam<sup>1</sup>

The World Health Organisation estimates that some 5.5 billion people around the globe inhabit countries with low to non-existent access to controlled medicines and have inadequate access to treatment for moderate to severe pain. This figure translates to over 80 per cent of the world's population.<sup>2</sup> Only in a small number of wealthy countries do citizens stand a reasonable chance of gaining adequate access to pain care, though even here room for improvement remains.<sup>3</sup> According to the International Narcotics Control Board, recent data indicate that more than 90 per cent of the consumption of strong opioids takes place in Australia, New Zealand, Canada, the United States and Western Europe.<sup>4</sup>

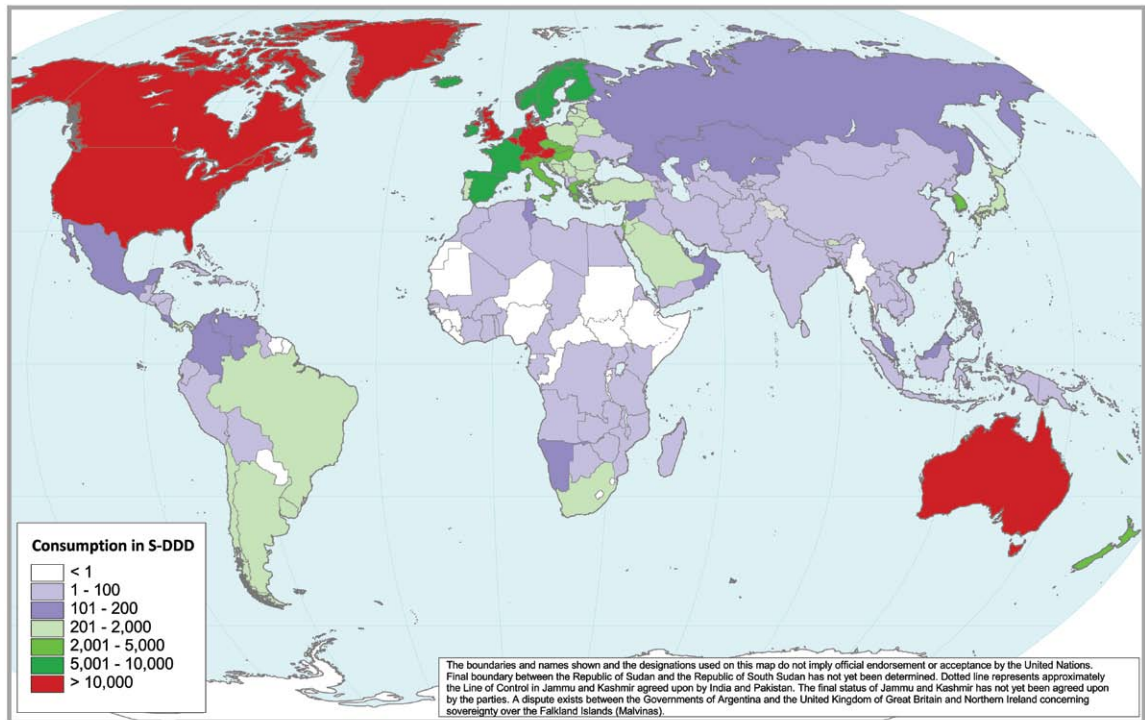
In poor and developing nations, meanwhile, and even in several industrialised states, pain remains largely uncontrolled. Africa is the least well served continent for access to analgesia.<sup>5</sup> The situation affects numerous conditions: pain may go untreated for those with cancer and with HIV/AIDS, for women in childbirth, for numerous chronic conditions, for those in post-surgical settings, those who are wounded in armed conflicts, those who have suffered accidents, and so on. Moderate to severe pain is resistant to ordinary household analgesics such as paracetamol or non-steroidal anti-inflammatory (NSAID) medicines, yet it can be 'easily controlled' by opioids such as morphine, oxycodone and fentanyl;<sup>6</sup> opioids also represent a highly effective and powerfully evidence-informed treatment for heroin dependence, another category of treatment to which access is poor in many parts of the world. Overall, this state of affairs has been rightly called a 'tragedy',<sup>7</sup> and a 'global pandemic of untreated pain'.<sup>8</sup>

Morphine is on the World Health Organisation's Model List of Essential Medicines along with several other opioids;

### Conclusions and recommendations

- The unacceptable situation with respect to access to controlled medicines is another indicator that the time is right to consider the revision of the international drug control treaties in order to achieve a better balance between the twin objectives of restricting nonmedical drug use and ensuring access for medical and scientific requirements.
- While the treaties remain unreformed, the INCB should achieve a better understanding of the manner in which its concerns with restricting diversion and nonmedical use impacts upon the system's public health imperatives, in particular the provision of access to essential medicines.
- With this in mind, the INCB should refrain from interfering in those areas of the system that are mandated to WHO, such as the scheduling of substances under the 1961 and 1971 conventions.
- The WHO has demonstrated courage and leadership in its defence of public health priorities in its scheduling recommendations. It should continue to adopt this position, and should receive the commendation and support of Parties and NGOs in so doing.
- Again, until the treaties are reformed to represent a better balance between their twin objectives, the INCB should consider utilising Article 14 of the Single Convention in relation to those states who fail to progressively establish access to essential medicines. In most cases, the Article should be invoked together with Article 14 *bis*, which would allow supportive technical and financial steps to be taken to assist non-compliant countries.
- Funds to assist governments to comply with their obligation along the lines of Article 14 *bis* could come from individual states with an interest, or from a special group fund dedicated to the purpose.
- NGOs in the field of palliative care and those working to reform the drug control system should cooperate to bring about change.

Availability of opioids for pain management (2010-2012 average)  
 Consumption in defined daily doses for statistical purposes (S-DDD) per  
 million inhabitants per day. (Map courtesy of INCB)



\*Codeine, dextropropoxyphene, dihydrocodeine, fentanyl, hydromorphone, ketobemidone, morphine, oxycodone, pethidine, tilidine and tramperidine.

methadone and buprenorphine are also included for the treatment of opioid dependence. Essential medicines are those that satisfy the priority healthcare needs of the population, and access to treatment with these substances is regarded as a human right. 'Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford,' as the World Health Organisation (WHO) puts it.<sup>9</sup> The major human rights treaties dealing with health are discussed in Box 1.

Alongside their status as WHO essential medicines, to which access is in theory protected by the right to the highest attainable state of health (see Box 1), opioid medicines are 'controlled medicines' under the international drug control system administered by the United Nations. The system is underpinned by three international treaties to which most of the countries in the world are currently signed up. The first of the three treaties to be devised was the Single Convention on Narcotic Drugs of 1961, under whose terms morphine is governed. Morphine is at the very heart of analgesic treatment. Over a century of pharmaceutical-chemical research failed to discover

alternative classes of medicines to replace opioid analgesics for the control of moderate to severe pain. The international drug control treaties recognise the importance of these substances, and the *Preamble* to the Single Convention begins as follows:

*The Parties,*

*Concerned* with the health and welfare of mankind,

*Recognising* that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes...'

Given such a bold statement of intent in the opening declaration of its founding text, and thus a core principle in understanding its objectives, how is it that the drug control system has failed so signally to match its performance to its rhetoric? This briefing paper examines that question, reviewing the international drug control conventions and the system built upon them, which is responsible for both ensuring the availability of medicines and the suppression of nonmedical drug use. It explores the most important impediments to access, and the roles of the various actors involved in the

supply and its regulation. Finally, it makes recommendations for improving the present position, in which most of the world's population is compelled by circumstances beyond their individual control to endure unnecessary pain.

### **International drug control**

The key impediments to achieving satisfactory access to controlled medicines are linked to laws and legal over-regulation, itself driven by an exaggerated fear and loathing of addiction; lack of training amongst health personnel; the absence of

properly functioning systems for assessing medical need, a shortage of economic and financial resources, and sometimes the high prices of medicinal products. At the core of these issues, and interwoven with most or all of them, is the international drug control system, which requires signatory countries to devise domestic legal arrangements according to the parameters laid out in the three international drug control conventions.

While the international system has a lengthy history, and is usually considered to have been initiated by the International Opium Convention (the Hague Convention) composed in the Netherlands in 1912,

#### **Box 1. Health, Human Rights and Access to Essential Medicines**

'Health is a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity. The right to the enjoyment of the highest attainable standard of physical and mental health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition' stated the preamble to the Constitution of the WHO in 1946.

The 1948 Universal Declaration of Human Rights reiterated the right to health.<sup>10</sup>

These provisions do not refer to an abstract 'right to be healthy', which the state is somehow supposed to guarantee to individuals, but rather to the 'highest attainable state of health', in which states provide, according to their resources, the pre-conditions for health, 'a variety of goods, facilities, services and conditions necessary for its realisation'.<sup>11</sup> At the same time, a country's lack of resources does not excuse it from taking these steps to realise the right to health.

The International Covenant on Economic, Social and Cultural Rights of 1966 (ICESCR) provides the most comprehensive account of the right to health in international human rights law. The Committee on Economic, Social and Cultural Rights (CESCR), the treaty body that monitors the ICESCR, recognises that it is difficult for all states to realise such a right all at once, and has

elaborated the concept of progressive realisation. This requires states to dedicate as much of their resources as they are able toward realising the right to health, as rapidly as they can. In practice, this means establishing specific objectives and a timeframe for their achievement, and the monitoring of progress against benchmarks, as enshrined in the Committee's General Comment 14. The latter provides four criteria for the realisation of the right to health as it impacts on access to essential medicines: availability, accessibility, acceptability and quality.<sup>12</sup>

The implementation of the WHO's guidelines for improving access to essential medicines is an appropriate example of what a state is required to do to progressively realise its health-related obligations under these human rights treaties. Indeed, according to CESCR, the effort to improve the provision of essential drugs, including opioids, is one of the core minimum human rights obligations placed on states.<sup>13</sup>

The offices of the Special Rapporteur on the Right to the highest attainable standard of health and on the Right to protection from torture were established by the Human Rights Council to monitor abuses. The two Rapporteurs were sufficiently exercised over a number of drug control issues to write to the Chair of the Commission on Narcotic Drugs (CND) in 2008; one of these issues was access to essential medicines for pain relief. They called for the problem, 'a global human rights issue', to be 'addressed forcefully' in the next ten year drug strategy.<sup>14</sup>

as mentioned above there are three international treaties that currently underpin the functioning of global drug control. They are the Single Convention of 1961 as amended by the 1972 protocol, the Convention on Psychotropic Substances of 1971, and the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988. The Single Convention imposes a set of controls on opium, morphine, heroin, cocaine and cannabis and substances similar to these; the 1971 Convention deals with synthetic substances such as tranquillisers, the entheogens such as LSD and MDMA, and stimulants such as amphetamine. In general, we can say that the 1961 treaty sets out to control plant-based drugs, though there are numerous exceptions to this rule, such as methadone, pethidine etc. The 1971 treaty, meanwhile, was concerned with the drugs produced by industrial societies, though, similarly, it contains many anomalies such as the plant-based entheogens DMT (the main active ingredient in *ayahuasca*), mescaline and psilocybin.<sup>15</sup> Both include controls over many substances that are used as medicines. Finally, the 1988 treaty places controls on a number of drug precursors (substances used in the production of controlled drugs), some of which also have medicinal uses. For the purposes of this briefing paper, we will focus mainly on the drugs controlled under the 1961 treaty, for these embrace the gold standard of pain relief – morphine.

Generalising a little, we can say that the substance that originally prompted the building of the international control system was opium; used as a medicine all over the world, it was also consumed for recreational purposes on a mass scale in China and much of South East Asia.<sup>16</sup> The essential point of the first treaties was to allow opium and its fast-expanding set of derivatives to be utilised for medical purposes while restricting their nonmedical uses.<sup>17</sup> This twin objective has remained central to the international control system now in place. However, the Single Convention and its predecessors grew out of a context in which the licit trade in drugs was considered to function well enough in providing for those who wished to purchase them; the reason that the trade was seen to require regulating was to ensure that the drugs in question were for medical and scientific uses and not for pleasure and

recreation. Consequently, the major focus was on *preventing diversion* rather than *ensuring access*. In a sense, it was felt that the trade worked *too well* – drugs everywhere were too freely available. It is worth recalling that the countries whose diplomats negotiated the detailed provisions of the conventions and the bureaucrats who drafted them were overwhelmingly from economically liberal countries, and possessed an implicit faith in the workings of the market. This, combined with the widespread alarm regarding the effects of unrestricted drug consumption, meant that the treaties contained many provisions detailing what should happen in cases of diversion into the illicit market, but little about what should happen when populations did not receive sufficient supplies of analgesics.

### The Single Convention of 1961

As we saw in the introduction, the preambular paragraphs of the Single Convention open with a resounding endorsement of the medicinal value of narcotic drugs. According to the relevant UN bodies, the obligation for states who have signed this instrument to ensure the availability of medicines is clear. The INCB states that: 'The objective of the international drug control conventions is to ensure adequate availability of narcotic drugs and psychotropic substances for medical and scientific purposes while ensuring that such drugs are not diverted for illicit purposes'.<sup>18</sup> The UN Office on Drugs and Crime (UNODC), meanwhile, observes that 'the control provisions of the Conventions are designed to (a) ensure that controlled medications are prescribed for legitimate medical purposes and safely reach patients through a controlled distribution chain and (b) combat illicit manufacture, trade and distribution'.<sup>19</sup>

The WHO, finally, notes that 'the obligation to make controlled medicines available for medical purposes finds its basis in the international drug control conventions'.<sup>20</sup> There can be little doubt in view of such statements that the drug control conventions do place an obligation on parties to make certain that citizens are provided with analgesics, including those forms of powerful opioid pain relief necessary for

controlling moderate to severe pain. The Single Convention is not in any general sense 'prohibitionist', as is sometimes argued.

However, upon entering into the operational paragraphs of the treaty, it becomes clear that there is a deep-lying imbalance in the text. There are several provisions that require parties to criminalise various acts (see Article 36, 'Penal Provisions'), and to suppress traditional practices such as opium-smoking, cannabis consumption and the chewing of coca leaves within a set timeframe (Article 49). It also allows countries to enact national control measures that are 'more restrictive' than those required by the convention (Article 39)

are scheduled or rescheduled under the Single Convention can be tremendously burdensome and, at times, can outstrip the capacity of poor countries.<sup>24</sup> Putting in place the control requirements of the Single Convention is a problem requiring considerable administrative, legal, financial and technical capacity that poor countries often do not possess. 'It is widely appreciated', says one commentator, 'that because of the regulatory burden imposed by the Single Convention, many poor states simply ban a medicine that may have important public health purposes'.<sup>25</sup> Even in cases where medicines are not simply banned, major regulatory obstacles may be placed in the way of medical professionals: limits on what

**'... a party is not precluded from adopting more restrictive control measures if, in its opinion, such regulation is necessary or desirable to protect public health or welfare' (Article 39).**

On the other hand, when it comes to the enabling function of the treaty, that which deals with ensuring access to drugs for medicinal and scientific uses, there are no such provisions, only the requirement that parties submit annually to the INCB a set of estimates of their needs for drugs for medical and scientific use (Articles 12 and 19), and sets of statistical returns containing data on production, consumption, imports, exports, etc. (Article 20).<sup>21</sup> The strategic goal of these measures stems originally from the League of Nations, which administered the international control system during the interwar period; the objective was to match production to global medical and scientific need, thereby leaving no excess supplies to be diverted.<sup>22</sup> The provisions may guide countries in the administration of medical provision for their citizens, but do not answer what is to be done in situations in which these supplies are inadequate or entirely lacking, which is the present scenario. At the same time, while the focus of the earlier treaties was largely on the regulation of the licit supply chain, illicit production then being relatively minor in scale, it has been plausibly argued that the Single Convention represented a break with this focus and enshrined a more repressive orientation.<sup>23</sup>

Moreover, it has been observed that, 'The regulatory requirements for drugs that

doctors can prescribe, fixed maximum doses, time-limits on the validity of prescriptions, prescribing restricted to particular specialisms, restrictions on the number of pharmacies permitted to dispense certain drugs, the use of special prescription forms, severe penalties for minor or inadvertent infractions (such as for record-keeping), and so on. Such measures can make clinicians unwilling to devote the necessary time to satisfy such requirements or to take the risk of legal and/or professional regulatory problems should honest mistakes occur.<sup>26</sup>

As a result of these and other factors, it is fair to say that the Single Convention itself, along with the other treaties, has pushed policies in a direction which has negatively affected the availability of essential medicines, and that it shares, consequently, the responsibility for the pandemic of untreated pain. The treaties place upon parties an obligation to criminalise aspects of the market and to impose sanctions on citizens, but they do not oblige countries in any similar way to guarantee adequate availability of controlled drugs for medical and scientific uses. They are in this sense, as has been remarked, 'lopsided'.<sup>27</sup> That said, it should be recalled that the international drug control conventions do not impose obligations on governments that stop them from ensuring adequate supplies to their populations if they utilise the

system effectively. However, superimposed on the problematic balance that exists within the texts of the treaties themselves are the difficulties associated with their implementation.

### **The ambivalent role of the INCB**

The text of the Single Convention makes explicit the fact that the INCB is responsible for overseeing the implementation of the treaty, restricting the 'cultivation, production, manufacture and use of drugs to an adequate amount required for medical and scientific purposes (and) to ensure their availability for such purposes...'.<sup>28</sup> The convention assigns to the INCB the task of cooperating with Parties to ensure that its medical and scientific objectives are met. Further to the stipulations of the Single Convention, the Psychotropics Convention of 1971 in its Preamble recognises that 'the use of psychotropic substances for medical and scientific purposes is indispensable and that their availability for such purposes should not be unduly restricted'.<sup>29</sup>

In 1989, the INCB was 'among the first to issue a warning that availability of narcotic drugs was not ensured by a majority of countries'.<sup>30</sup> In partnership with WHO, the Board assessed the global medical need for opioids and found that these were not being met, particularly with respect to cancer. It published a supplement to its 1989 annual report detailing the situation regarding unmet analgesic need, and requested governments to examine national systems for assessing their medical requirements, their healthcare services, and their domestic regulatory environments in order to attempt to identify obstacles to achieving the treaties' medical objectives. Subsequently, the Board included the problem repeatedly in its annual reports, and has continued to raise it periodically through the intervening years; it discusses access to controlled medicines in all of its country visits, of which there are about twenty each year.<sup>31</sup> From 1999, the INCB began approaching countries with low estimates of medical need for drugs in order to initiate or continue dialogue on the problem, and in 2004, four countries whose supplies had increased from a very low base were invited to make their policies known for the guidance of other Parties with very low

consumption levels. The Board's 2010 Annual Report contains another supplement devoted to the topic.

The obligation to ensure the availability of drugs for medical and scientific purposes has been reinforced by resolutions adopted by a range of UN bodies, including the World Health Assembly (WHA) and ECOSOC. The CND has also turned its attention in this direction, expressing in its 2010 Resolution 53/4<sup>32</sup> the intention to promote adequate levels of availability of drugs for medical and scientific requirements, revisiting and reaffirming the objective in the following year in Resolution 54/6.<sup>33</sup> In the latter, the Commission called for the UNODC to update its model laws to reflect this rebalancing toward ensuring access to medicines, a process that the Office has since begun. The INCB has made its voice heard on all these platforms over two and half decades, and has therefore an extensive and honourable history of raising awareness of this topic.

Nonetheless, it is necessary to state that the INCB has had an ambivalent impact in this area of human suffering. This is for a number of reasons, but they are all linked to the institution's overarching orientation to the duties assigned to it by the drug control conventions. The INCB is widely and correctly regarded as the most conservative of the UN drug control bodies, repeatedly emphasising the repressive principles of the treaties over and above their enabling principles. This balance in favour of repression has been at its clearest in recent decades in the debates around harm reduction, which the Board has only gradually and grudgingly accepted.

As described previously, the fact that vast numbers of people around the world lack adequate access to pain is linked to an overly restrictive regulatory environment driven by anxieties about the diversion of drugs to the illicit market; the lack of a rigorous and balanced education amongst healthcare professionals – particularly around the use of opioids; the failure to submit accurate or appropriate estimates of need for controlled medicines to the INCB, and so on. The INCB accepts these factors as impediments to access, but appears to view them as operating solely at the national level, effectively

divorced from the drug control conventions and the institutions they established. Yet not only are those national systems guided by the conventions, but the Board's own actions and public pronouncements regarding 'drug abuse' continually inflame the very fears that are in large part responsible for the problem.

According to the WHO, 'the drug control conventions that established the dual obligation of ensuring adequate availability of controlled medications and of preventing their misuse have existed for almost 50 years. Yet the obligation to prevent abuse of controlled substances has received far more attention than the obligation to ensure their adequate availability for medical and scientific purposes, and this has resulted in countries adopting laws and regulations that consistently and severely impede accessibility of controlled medicines'.<sup>34</sup>

Such an imbalance is readily apparent in the public discourses and actions of the INCB, which offers many other examples of its orientation toward the repressive pole of the conventions. In its regular response to the Board's Annual Reports, the International Drug Policy Consortium has noted the 'selective reticence' of the INCB: that is, it is usually willing to condemn publicly the actions of states who experiment with policies that operate at the limits of tolerance allowed by the conventions; Uruguay, which has recently established a legal, regulated market for cannabis is a good example, and has drawn much criticism from the INCB.<sup>35</sup> However, countries that transgress the conventions in a repressive direction, such as Russia, which has banned the use of methadone for drug dependence treatment (a drug which is on the WHO list of Essential Medicines), rarely if ever warrant a mention in the Board's annual reports. Perhaps this is a consequence of the Single Convention's explicit permission (in Article 39) for countries to be more restrictive than the terms of the treaty require, or perhaps it reflects the Board's interpretation of its mandate.

Whatever the reason in this specific case, in general the position of the Board is often ambiguous and confusing for Parties. Its good work in advocating greater access to controlled medicines is often simultaneously and subtly undermined by its repressive

tendencies. The INCB has to recognise its own role in tackling this imbalance of priorities. Anand Grover, former UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, has drawn attention to the lack of access to adequate pain medication, finding this and other drug-related human rights violations to be 'traceable ultimately to a disproportionate focus on criminalisation and law enforcement practices at the expense of the enjoyment of the right to health and reduction of harms associated with drugs'.<sup>36</sup> As IDPC and others have pointed out, there has historically been a clear tension between the INCB's rigid interpretation of the drug control treaties, which tends to reinforce the 'climate of fear' surrounding the application of controlled drugs in therapeutic practice, and the very worthwhile work it is doing in its advocacy of more reasoned and evidence-grounded approaches with regard to these substances.

By way of a final example, we can turn to the issue of ketamine, which is illustrated in Box 2. In this case, the INCB has over an extended period attempted to exert pressure on the CND, on Member States and on the WHO, which has the sole legal responsibility for recommending substances for inclusion in the schedules of the 1961 and 1971 international control conventions. The Board has sought to impose its own bias toward issues of abuse and diversion, at the expense of the public health and scientific focus of the WHO. In addition to ketamine, further drugs such as tramadol have been invested by the same process.<sup>37</sup>

### **The World Health Organisation and the Access to Controlled Medicines Programme**

With its public health remit, the WHO is equipped to provide a corrective to balance the more overtly politicised manoeuvrings of the INCB and CND. In 2005, the WHA and ECOSOC adopted resolutions calling for WHO to become involved in efforts to improve access to controlled medicines.<sup>38</sup> This led to the setting up of the Access to Controlled Medicines Programme (ACMP), with the Dutch government seconding staff from its Health Ministry to assist the

## Box 2. **Ketamine and public health: An INCB blind spot**

Ketamine is an anaesthetic used in both veterinary and human surgical and diagnostic procedures, its use being of central importance across large areas of the developing world, where it is often the sole anaesthetic agent available. Ketamine is easy to use, especially in undeveloped and emergency settings where controlled, clinical conditions are often not available; it does not suppress the respiratory function, and is safe in terms of overdose when used under medical guidance. It has been authoritatively described as, 'for sedation of both children and adults...perhaps the most widely used agent in the world'.<sup>40</sup>

In recent years ketamine has also been consumed recreationally as a hallucinogen, and this has prompted moves to control the substance under international law. The WHO's Expert Committee on Drug Dependence (ECDD) undertook a critical review of ketamine in 2006 in order to examine the scientific evidence in this regard. It followed calls by the INCB for the 'international community to give serious consideration to initiating the procedure' for placing the substance under international control<sup>41</sup> and coincided with a recommendation from the INCB that WHO should 'expedite' its review in the light of what the Board identified as 'widespread abuse'.<sup>42</sup> The WHO, which in its scheduling decisions balances the potential harms of recreational use against medical benefits, found that ketamine is a widely employed anaesthetic, especially in the developing world. It is included in the WHO Model List of Essential Medicines.<sup>43</sup> Within this context, the WHO review concluded that there was insufficient evidence to schedule ketamine. However, in the same year the CND had adopted a resolution calling for controlling the use of the substance via national legislation.<sup>44</sup> While acknowledging the concerns of states regarding illicit use, in 2012 the WHO Expert Committee again subjected ketamine to a critical review and repeated its previous recommendation against placing ketamine under international controls. The Committee reported that concerns were raised at the meeting 'that if ketamine were placed under international control, this would adversely affect its availability and

accessibility. This in turn would limit access to essential and emergency surgery, which would constitute a public health crisis in countries where no affordable alternative anaesthetic is available'.<sup>45</sup>

The INCB's role in the debates around ketamine has consistently focused on controlling the substance in order to prevent abuse and diversion, with apparent disregard for the immense medical utility of the substance in developing countries where it is, in practical terms, irreplaceable. The general thrust of the INCB's position here seems to be in direct opposition to its stated concerns about increasing access to pain relief. Indeed, bearing in mind the restrictive impact that national and international controls would have on the availability of ketamine in the developing world, the WHO stated that: 'The call by INCB could easily lead to the impossible choice for physicians not to give surgery or to give surgery to patients in full consciousness. Who would be so heartless', asked the spokesperson, 'to wish doctors to make such a decision?' He urged States Parties to ignore the INCB call for scheduling and the remarks made on ketamine in its 2006 Report.<sup>46</sup>

At the 2014 CND, a further Resolution (57/10) called for action to prevent the diversion of ketamine,<sup>47</sup> and China, as is required by the conventions, formally notified the UN regarding its wish that Ketamine be placed under international control (Schedule 1 of the 1971 Psychotropics Convention). In response, the WHO updated its latest review of ketamine and the issue was put once again on the agenda of the ECDD in June 2014.<sup>48</sup> Numerous organisations of anaesthesiologists from around the world submitted letters to the ECDD expressing their opinion that placing ketamine under international control would have 'catastrophic' consequences. The resulting reduction in the availability of the drug could lead to surgery being performed without anaesthetics and 'force anaesthesia and surgery back to unsafe practices from past centuries'. It would be 'disastrous for patients, surgeons and anaesthesia providers in countries where ketamine is the most common – and sometimes the only – anaesthetic available'.<sup>49</sup> Reviewing the available evidence, the update did not lead the ECDD to change its previous recommendation not to schedule ketamine.



programme in its implementation phase commencing in 2007.<sup>39</sup>

As described in its preliminary phase on the WHO website, the 'Access to Controlled Medications Programme will address the main causes for impaired access. These causes are essentially an imbalance between the prevention of abuse of controlled substances and their use for legitimate medical purposes.'<sup>50</sup> The WHO implements the programme, and is partnered by the INCB, which provided its expertise. The differing mandates of the two institutions reflected in their objectives within it. The improvement of access to opioid medications has been the consultative focus of the Board, while WHO, whose objective is the attainment of the highest possible level of health, took on the wider remit of supporting the provision of all essential medicines, including methadone and buprenorphine for Opioid Substitution Therapy (OST). It has also targeted the provision of controlled medicines for mental illnesses and for obstetric usage. The programme has run and partnered in a series of workshops attended on a voluntary basis by representatives of national regulatory authorities, law enforcement agencies and healthcare services, and provided a varied range of technical assistance to developing countries. Countries have been invited to review their national drug control and regulatory systems and identify, in collaboration with WHO experts, impediments to achieving adequate access to essential medicines, and to devise and implement improved arrangements.

The WHO has been very active in the field of access to controlled medicines generally, and has produced useful guidelines for countries to achieve a balanced set of policies and control measures. 'Balance' is in this sense an accommodation between the two core objectives of the conventions, limiting nonmedical use while ensuring adequate availability to meet medical and scientific needs. It is a concept of great importance in the 2011 revised WHO Guidelines on achieving balanced national drug control policies.<sup>51</sup> As the introduction states: 'the system of control is not meant to be a barrier to their (i.e. controlled drugs) availability for medical and scientific purposes, nor interfere in their legitimate use for patient care'.<sup>52</sup> It also notes, importantly, that 'drug control

should not be approached as an objective in itself, but as a tool to optimise public health'.<sup>53</sup> The introduction makes a powerful case for improving the access to essential medicines, and is followed by a set of twenty-one guidelines which are recommended to governments. There is considerable evidence that international institutions are capable of generating changes in the way states behave.<sup>54</sup> This means that the WHO, UNODC and the INCB are well placed to achieve a great deal if they work in a consistent fashion toward improving access.

### **Assessment of needs for controlled medicines**

In a Supplement to its Annual Report of 2010 that deals with the problem of untreated pain, the INCB maps the global state of availability of controlled drugs, and notes that there is currently no universally agreed level of adequacy of medicinal consumption. (This, incidentally, is largely because there is no standard dose of morphine, for example, that will control pain for everybody; appropriate dosage must be individually tailored). In view of the absence of consensus, 'the Board has internally, for administrative purposes, set some minimum standards to use when examining estimates of annual requirements for narcotic drugs submitted by countries'.<sup>55</sup> These minimum measures, however, are problematic in view of their possible insufficiency, as discussed below. The INCB uses these standards to represent the distribution of the consumption of controlled drugs for medical purposes, finding a strong correlation between the consumption of controlled medications and the Human Development Index (HDI) - a United Nations Development Program statistical frame of reference for both social and economic development.<sup>56</sup>

Concerns have been expressed amongst some palliative care experts that the Board's figure of 200 S-DDD<sup>57</sup> represents a low base, and whether it is in fact an appropriate level at which to benchmark adequacy of access. If we examine an actual example of consumption data, the INCB's rough adequacy level is provided with a context. For example, the S-DDD per million inhabitants per day for the United States (2007-2009) was 39,487; for Australia it was 8,013; for Germany it was

19,319; for the United Kingdom it was 3,655; for Japan it was 1,023, and for South Africa it was 600. The great disparity between these actual levels of consumption in the developed world and the INCB's 'rough measure of adequacy' is clear. It is remarkable that South Africa was the single country on the African continent to exceed the Board's adequacy figure of 200, with 6 countries having less than 1 defined daily dose per million inhabitants per day.<sup>58</sup>

A 2011 research paper sets out to address the lack of a method of assessing the total population need for pain medications to deal with moderate to severe pain at national, regional and global levels. This is attempted via the development of an 'Adequacy of Consumption Measure (ACM)'.<sup>59</sup> Making use of three major indicators of pain-producing morbidity – cancer, HIV and injury – the researchers estimated per capita requirements of controlled pain medications for 188 countries. Their calculations were based on an adequacy level derived from the top twenty countries of the HDI on the assumption that these countries would most likely have 'an opioid analgesics consumption that is more or less adequate to their need'. The study generates some startling figures. If we examine the global picture using the method established by these authors, the dimension of unmet need is dramatic. 'In 2006', they report, 'the world used a total of 231 tons of morphine equivalents. If all countries increased their consumption to adequate levels, the required amount would be 1,292 tons, or almost 6 times higher'.<sup>60</sup>

The method has been employed in a more recent study. It found that between 2006 and 2010, a total of 67 countries had increased their adequacy of opioid consumption per capita. While this provides some encouragement, they also found that 66 per cent of the global population continues to have 'virtually no' opioid consumption; for 10 per cent of the population consumption is 'very low', for 3 per cent 'low', for 4 per cent 'moderate', and only 7.5 per cent have adequate access (with insufficient data for the remainder).<sup>61</sup>

### **An improving situation?**

Despite the extremity of a situation in which

numerous people are condemned to suffer and die without access to pain relief, progress has been made in a number of countries, and not just those that have high levels of income and resources, such as France. The French government recognised in the late 1980s that its consumption of opioids was unduly low, and introduced changes in policy and drug control legislation before implementing a national action plan to improve access to pain relief. This included the removal of regulatory impediments that had blocked the supply chain at all levels.<sup>62</sup>

In terms of countries with less resources, Colombia, Jordan, Romania, Georgia, Serbia, Panama, Guatemala, Vietnam and India have all introduced reforms aimed at improving access to essential medicines for pain relief. In sub-Saharan Africa, probably the world's worst affected region, there is encouragement in the example of Uganda (see Box 3). Despite these positive developments, there remains a gulf between need and access that urgently requires addressing. Beyond the measures already indicated, how might this be achieved?

### **Legal measures for improving access**

Do the international drug control treaties themselves offer any further opportunity to redress this global lack of essential pain control medicines? The Single Convention establishes inspection and monitoring measures to facilitate the carrying out of its objectives, and the INCB is responsible for monitoring the compliance of Parties. It has been pointed out by Taylor, however, an academic specialising in global health law, that inspections have 'not generally been conceived or used as a tool to advance equitable access to desperately needed pain medication'.<sup>63</sup> She argues nonetheless that it would be a 'reasonable and appropriate interpretation of the text of the provision' to do so. The reference here is to Article 14 of the Single Convention (there in a roughly equivalent Article 19 in the 1971 Psychotropics Convention). Article 14 is usually invoked in cases where large scale cultivation and/or trafficking is taking place within a country; the Article was activated by the Board with reference to Afghanistan in 2000.<sup>64</sup> It allows a set of remedial measures of increasing severity to be invoked, if the

**Box 3. Best practice in improving access: The example of Uganda**

Over the last decades, Uganda has made changes to its drug control system in order to begin moving it in the direction of the WHO's 'balanced' model. Uganda is presently the leader of this process of change on the African continent. The government, working in cooperation with the WHO and NGOs, determined to prioritise pain relief, putting in place a palliative care plan and implementing the reforms necessary to realise its objectives.<sup>65</sup> These included modifying the country's drug control legislation in order to permit nurse-prescribing of opioids, and educating health care professionals in pain relief and the use of morphine. It has also developed a more effective system of distribution, and a morphine product designed for oral administration. Nurse-prescribing, which is only lawful in a few other countries including the UK and most US states, proved crucial in the Ugandan setting, where most people live rural lives and have little or no access to doctors.<sup>66</sup> Palliative care is now taught in all undergraduate medical programmes, and is a choice available to all medical postgraduate students.

Hospice Africa Uganda is an innovative palliative care institution established in

1993.<sup>67</sup> One of the challenges that remains is the occasional interruptions to the supply of opioids in the country. The government's stocks ran out completely in 2010; the authorities collaborated with Hospice Africa Uganda and palliative care NGOs to initiate a public-private partnership which began cost-effectively producing the country's own oral morphine solution. The process began, allegedly using a kitchen in 1993, but is a more sophisticated process now. Nonetheless, costs are kept down by using local supplies (buckets, whisks, plastic bottles etc) purchased from a market wherever possible, and bought-in morphine powder is converted into an oral preparation for local use. According to one observer, the cost of ten days' pain treatment is roughly equivalent to the price of a loaf of bread.<sup>68</sup> Between 2000 and 2008, opioid consumption for the Ugandan population rose from under 0.2 mg per person to almost 0.8 mg per person, a fourfold rise.<sup>69</sup>

While it still has very large challenges to face in order to continue these improvements, it is encouraging that Uganda has been able to make steady progress toward expanded access to essential medicines for pain control. It provides an example of what can be achieved if the political will exists and relatively modest resources can be identified and utilised.

INCB ' has objective reasons to believe 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>70</sup> As one of the primary aims of the treaty is to make available controlled drugs for medical and scientific use, Taylor's argument is a coherent one.

Under Article 14, the INCB has the power to propose consultation with the country in question, to request explanations and recommend policy changes. If the Party does not respond to its satisfaction, the Board may make public the non-compliance, taking the issue up with other Parties, the CND and ECOSOC. It may publish a report on the issue. As an ultimate sanction, the INCB may recommend that countries stop the import and/or export of narcotic drugs to and from the errant Party – though that would clearly

be a perverse response in a case where the issue is lack of access to controlled medicines. Taylor contends that the mere threat of the Article's invocation is likely to persuade a non-compliant country to alter its behaviour. As another, more appropriate course of action, the provisions of Article 14 *bis* could be utilised; this Article permits the INCB to recommend, as an alternative or in addition to the measures outlined in Article 14, that technical and financial resources be directed toward to offending country in order to assist it in complying with the treaty.<sup>71</sup> Such a course of action combines the exercise of pressure from the international community (via the INCB) with practical measures to assist the country – obviously it would be preferable to use these as an alternative to the more draconian potentials of Article 14 itself.

Since most countries in the world are signatories to at least one of the Human

Rights treaties, the question has arisen as to whether access to essential medicines is enforceable through the court system. In 2006, a research article appearing in the *Lancet* sought to study the evidence on this question. The authors identified and analysed 71 cases in 12 low-income and middle-income countries in which groups or individuals had sought access to essential medicines through the courts, under the rubric of the right to health. They found that in 59 of those 71 cases, access to essential

medicines 'could indeed be enforced through the courts'.<sup>72</sup> Most of the successful cases were fought in Latin America, with success linked strongly to the existence of constitution provisions referencing the right to health, supplemented by human rights treaties. These researchers noted that: 'Skilful litigation can help to ensure that governments fulfil their constitutional and international treaty obligations. Such assurances are especially valuable in countries in which social security systems

#### **Box 4. Intellectual Property Rights and Access to Essential Medicines**

The problem of access to essential medicines lies at the intersection of trade and human rights, as has become clear since the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), negotiated between 1986 and 1994.<sup>73</sup> Administered by the World Trade Organisation (WTO), TRIPS established detailed minimum standards for the protection and enforcement of intellectual property rights, safeguarding patents, trademarks, data etc. As applied to pharmaceutical products such as medicines, the agreement is intended to encourage companies to invest in technological research and development by permitting them a minimum twenty year period during which competitors are prevented from reproducing or selling a medicine that a given company has researched and brought to market. During this period, the profits obtained from marketing the medication accrue solely to the company that developed it. It is only after the patent protection expires that others may produce generic versions of the drug, which are usually considerably cheaper.

This situation can impact in powerfully negative ways on access to medicines. In poor countries, the population may not be able to access drugs whose high prices are effectively defended by legal patents. There was some recognition of potential negative effects included within the text of the TRIPS agreement, which permitted WTO states to protect public health by authorising a third party to manufacture and sell medicines without the permission of the patent holder, subject to the payment of a reasonable fee.<sup>74</sup> Paul Hunt, former UN Special Rapporteur

on the Right to Health, argues that such flexibility only benefits those countries possessed of a developed pharmaceutical industry, and thus exclude many developing states. However, he welcomes a related WTO decision made in 2003,<sup>75</sup> which clarified paragraph 3 of the Doha Declaration of 2001, which itself acknowledged the public health imperative and its potential conflict with TRIPS and reaffirmed that the agreement should not prevent states from taking measures to protect public health. Effectively, the 2003 decision operated as a waiver to allow countries producing pharmaceuticals under the compulsory licensing allowed by TRIPS to export to those countries unable to produce the medicine themselves, thus providing a way out of the impasse noted by Hunt.

Countries that have signed up to human rights treaties, especially the ICESCR, are obliged under international law to the progressive realization of the right to health, including to make essential medicines available (see Box 1). While TRIPS sets up an uneasy relationship between this and the defence of intellectual property rights, there may now be sufficient flexibility in the WTO and TRIPS system for states to exercise their human rights obligations. There are also signs that the pharmaceutical industry is responding to public pressure and introducing more of a public-health ethic into its conduct. According to a recent commentary from several academic authors, which draws on the Access to Medicines Index,<sup>76</sup> 'the top 20 research-based pharmaceutical companies are moving in the right direction in their commitments and activities to promote access to essential medicines in low-income and middle-income countries'.<sup>77</sup>

are still being developed. However, redress mechanisms through the courts should be used as a last resort. Rather, policy makers should ensure that human rights standards guide their health policies and programmes from the outset.<sup>178</sup>

### Forward movement?

This year, the WHA adopted Resolution 67.19, 'Strengthening of palliative care as a component of comprehensive care throughout the life course'.<sup>79</sup> The new president of the INCB, Dr Lochan Naidoo, has expressed strong interest in the issue of access to controlled medicines, and INCB is planning to update its 2010 supplement on ensuring access for the 2016 UNGASS. As mentioned in the foregoing, the CND has also supported resolutions reflecting a greater awareness of this problem, and a growing sense of urgency in addressing it. As many countries do not submit realistic assessments of need to the INCB, that organisation has, in partnership with the WHO, published guidance on the appropriate assessment of needs, and if countries make use of the guidance it will contribute to the solution of the problem.

If, as has been suggested, Articles 14 and 14 *bis* of the Single Convention were to be utilised in a positive way, in order to both motivate countries and to assist them with the technical and financial means to act, additional funding would clearly be necessary. This could be made available by individual states with a particular interest in the issue, or by a special group fund.

The imaginative use of the international drug control conventions, human rights treaties and national constitutional principles can all contribute to improving access to pain relief and other essential medicines. In addition, it is likely that the growing number of palliative care NGOs and their increasing links with drug policy NGOs will maintain the momentum that this issue is gathering, ideally working in cooperation with the relevant UN agencies. The WHO has shown courage and leadership in its defence of public health imperatives in the face of considerable pressure both from countries who continue to maintain a repressive orientation in relation to drug control,

and from the INCB, whose ambivalence in this area may perhaps be mitigated by the arrival of a new president at the helm whose commitment to improved access to pain relief is evident.

The approach of the 2016 UNGASS should provide an opportunity to examine the performance of the system with regard to essential medicines. It is unarguable that the rebalancing of the international drug control regime towards health must involve a radical improvement in ensuring access to narcotic drugs and psychotropic substances. A thorough review of the imbalances and inconsistencies embedded in the drug control conventions and the functioning of the INCB should be a core part of that process, even though much can be done to improve access within the constraints of the existing arrangements. If the fundamental objective of the treaties is to enhance human health, the system cannot continue to fail in its obligation to ensure access to drugs for scientific and medical purposes.

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### Transnational Institute (TNI)

De Wittenstraat 25  
1052 AK Amsterdam  
The Netherlands  
Tel: +31-20-6626608  
Fax: +31-20-6757176  
E-mail: [drugs@tni.org](mailto:drugs@tni.org)  
[www.tni.org/drugs](http://www.tni.org/drugs)  
 @DrugLawReform  
 Drugsanddemocracy



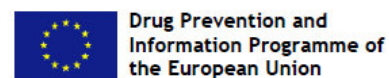
### Transnational Institute

TNI's Drugs & Democracy programme has been analysing trends in the illicit drugs market and in drug policies globally. The programme has gained a reputation as one of the leading international drug policy research institutes and as a critical watchdog of UN drug control institutions, in particular the CND, the UNODC and the INCB. TNI promotes evidence-based policies guided by the principles of harm reduction, human rights for users and producers, as well as the cultural and traditional uses of psychoactive substances. The strategic objective is to contribute to a more integrated and coherent policy where drugs are regarded as a cross-cutting issue within the broader development goals of poverty reduction, public health promotion, human rights protection, peace building and good governance.

### IDPC

The International Drug Policy Consortium (IDPC) is a global network of NGOs and professional networks that focus on issues related to drug production, trafficking and use. IDPC promotes objective and open debate on drug policies at the national and international level, and supports evidence-based policies that are effective at reducing drug-related harm. We produce briefing papers, disseminate key resources on drug policy, build the advocacy capacity of our members and partners, and offer expert advice to policy makers and officials around the world. Our global membership has expertise and experience on the wide spectrum of drug policy issues.

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### International Drug Policy Consortium (IDPC)

124-128 City Road  
London, EC1V 2NJ  
United Kingdom  
Tel: +44 (0)20 7324 2975  
E-mail: [contact@idpc.net](mailto:contact@idpc.net)  
[www.idpc.net](http://www.idpc.net)  
 @IDPCnet  
 International Drug Policy Consortium

