

## Scheduling in the international drug control system

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While often viewed as an obscure technical issue, the problem of scheduling lies at the core of the functioning of the international drug control system. Scheduling – the classification of a substance within a graded system of controls and restrictions, or 'schedules' – must take place in order for a substance to be included in the international control framework, and determines the type and intensity of controls to be applied. For this reason, the topic is of central importance.

In addition, the issue has become a contemporary flashpoint for strains and tensions surrounding the general orientation of the present regime of drug control and the international Conventions which reside at its heart.<sup>2</sup> These Conventions are organised around two core imperatives – one that is restrictive in nature, and aims to limit access to controlled drugs and to prevent their manufacture, distribution and possession for pleasure, recreation and entertainment; the other is enabling in nature, and aims to ensure the availability of controlled drugs for medical and scientific purposes. The art of good drug control, within the parameters set by the Conventions, is to find an appropriate, humane and effective balance between these twin objectives. Historically, however, it has been the repressive pole that has been prioritised, though present debates are increasingly highlighting the need to modify the balance of the system in order to affirm the importance of the principle of health.<sup>3,4</sup> The scheduling of new substances and proposed changes to the classification of others already scheduled are, in addition to the technical issues involved, providing new contexts for the airing of these wider issues. Moreover, the emergence of multiple new forms of drugs and intoxicants in the shape of New Psychoactive Substances (NPS) has introduced an unprecedented urgency into the problems of scheduling, with many states parties<sup>5</sup> perceiving themselves to be under siege, and finding the current process too slow and too cumbersome to respond to a fast-moving recreational drugs market and the technological developments underpinning it. The Single Convention

### Key points

- Scheduling has become a flashpoint for tensions within the UN drug control regime.
- The WHO, mandated to make scheduling recommendations under the 1961 and 1971 treaties, has been marginalised. This conflicts with the intended re-balancing of the system towards health and human rights.
- Restrictive interpretations of treaty provisions have resulted in poor access to essential medicines. The WHO therefore has advised against scheduling ketamine, in developing countries often the sole anaesthetic available.
- The rapid expansion of NPS has generated a 'regulatory panic', and, for the first time, the provisional controls provided by the conventions have been invoked – these controls should be used with caution since they bypass the scientific review process.
- The role of the WHO's Expert Committee on Drug Dependence in scientifically reviewing substances for scheduling must be respected and adequately funded.
- The INCB oversteps its mandate by recommending controls for essential medicines and other substances like khat that contravene the WHO expert advice. This risks creating a parallel regime with the INCB and the CND calling on governments to schedule substances at national level.
- The broad discretion of the CND to reject the WHO recommendations should either be removed, or the CND should have to justify its decision under explicit and transparent criteria.
- The scheduling of cannabis in the UN system represents a historical anomaly, and should be reviewed at the earliest opportunity.
- The 2016 UNGASS on drugs provides an opportunity to re-examine this issue.

on Narcotic Drugs of 1961, as amended by the 1972 Protocol, and the Convention on Psychotropic Substances of 1971 both possess provisional scheduling measures, which can in theory be initiated in order to meet urgent problems, and which permit controls to be applied pending assessment by the World Health Organisation (WHO). The Single Convention allows for both discretionary and mandatory provisional controls to be applied, while the Psychotropics Convention allows only discretionary scheduling, which countries can decide not to apply. At the 2014 Commission on Narcotic Drugs (CND or Commission), the UK initiated provisional controls under the Psychotropics Convention in respect of mephedrone, citing widespread illicit use and the success of its domestic controls as the primary reasons for doing so.

However, a major problem with provisional scheduling in general is that substances are subjected to controls prior to a thorough scientific, medical and public health examination by the WHO's Expert Committee on Drug Dependence (ECDD), a body composed of specialists in these fields. Such circumstances may pose a potentially serious set of challenges for the health-related pole of the system should substances be inappropriately classified, playing into the sense of regulatory panic that threatens the re-balancing of the UN drug control system. This was much in evidence at the 57<sup>th</sup> CND. The question of provisional controls is further discussed in the following pages.

The approaching United Nations General Assembly Special Session (UNGASS) on 'the world drug problem' of 2016 may provide an opportunity for the re-examination of current theory and practice in relation to scheduling, and to the elaboration of improved arrangements.<sup>6</sup> Amongst the most prominent of present stresses are disputes surrounding the proper role of UN drug control bodies in the scheduling process – especially those of the International Narcotics Control Board (INCB) and the WHO. However, we will suggest that the part played by the CND and states parties is also fraught with difficulties.

### **The marginalisation of the WHO**

The WHO is the body charged by the 1961 Single Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances

with the scientific and medical review of scheduling proposals. It is the one core element of the drug control system mandated to the structures representing the healthcare principle. Recently, however, the INCB – which refers to itself as 'the independent and quasi-judicial monitoring body for the implementation of the United Nations international drug control conventions'<sup>7</sup> – appears to be taking an increasingly active role in discussions around the decision-making process, thereby arguably exceeding its mandate. This INCB expansionism is linked to a general trend toward the marginalisation of the WHO within the system. In recent decades, the WHO has been starved of funding and of human and technical resources to the extent that the WHO's ECDD, which undertakes the detailed work of reviewing scheduling proposals, has been compelled to postpone its regular meetings for a six year stretch; by custom, it should convene biannually. Ironically, certain states parties at the CND have spoken out against the WHO for failing to convene an Expert Committee in a timely manner.<sup>8</sup> Amidst much discussion at the CND of the lack of funds that has sometimes compromised the work of the United Nations Office on Drugs and Crime (UNODC) – the agency responsible for co-ordinating international drug control activities – the equivalent issue impacting upon the WHO has received little attention, with some governments apparently unaware of WHO's financial difficulties. Without the necessary money, the ECDD cannot function, and the CND and states parties have been remiss in permitting the crisis to continue.

However, the marginalisation of the WHO within the drug control system is not new, having begun during the build-up to the 1998 UNGASS. The WHO Programme on Substance Abuse (PSA) was initiated at the start of the 1990s, which the UN designated 'the decade on drug abuse', and was accompanied by a large influx of staff and resources.<sup>9</sup> Six staff were allocated to strengthening the WHO contribution to the field. *Addiction*, amongst the most prestigious of Britain's drug-related journals, welcomed the arrival of the PSA in an editorial entitled *Six horsemen ride out: WHO initiates a new programme on substance abuse*. '(T)he world community has great need of this Programme and wishes those who serve within it much success'.<sup>10</sup> The Programme was very proactive, and conducted important new analysis on issues such as cocaine and cannabis.<sup>11</sup> However, its work proved

controversial, with certain states parties, in particular the United States of America (USA), unhappy with the findings and the PSA was systematically pushed toward the periphery as the preparations for the 1998 UNGASS drew near.<sup>12</sup> A project whose inception was greeted in such glowing terms has now been rendered ineffective, its six staff members reduced to one, who is in fact shared by another WHO programme. Six horsemen rode out: half a horse goes limping on, toward an uncertain destination. Such impoverishment expresses in the most concrete of terms what is meant by 'the marginalisation of the WHO' within the drug control system. The same trend is also apparent in the tensions which have arisen around scheduling, and which are explored in this briefing paper.

### Historical background of the scheduling principle

Since the problems associated with scheduling are to some degree inherent in the Conventions, it is necessary to explore briefly their historical development. In the course of imperial and colonising projects undertaken in the period between the 16<sup>th</sup> and 19<sup>th</sup> centuries, European and North American nation states encountered a patchwork of cultures consuming different intoxicants, many of them in use for centuries, which then entered into trade networks and spread across the globe.<sup>13,14</sup> By the early 20<sup>th</sup> century, the production, distribution and use of drugs were regarded as requiring regulation by a transnational block of interested states. This history of global trade and geopolitical power has indelibly marked our understanding of intoxicating substances and their management, resulting in, for example, the exclusion of alcohol, tobacco, coffee, etc. (the culturally accepted drugs of the USA and Europe) from the drug control treaties. These substances were simply not defined as 'drugs' by the builders of the international control system.<sup>15</sup>

The first legally binding instrument of international drug control was the International Opium Convention ('the Hague Convention') of 1912. Following concerns about mass opium-smoking in China and the advent of drug-using subcultures in the metropolitan West, the Hague Convention sought the 'gradual and effective suppression' of opium use, and the confinement to 'medical and legitimate purposes' of the manufacture, sale and use of morphine, cocaine and heroin. However, all

of these substances were subject to the same set of controls and governed by no pattern of graded classification, or scheduling. The early treaties focused on preventing diversion of drugs from the licit trade, and by the 1930s efforts in this direction met with some success. The illicit market then moved to meet the continuing demand for the non-scientific and non-medical consumption of drugs, reacting to legal and regulatory restrictions by expanding its sphere of activity to include cultivation and production, a strategy which mitigated its early reliance upon drugs diverted from licit sources.<sup>16</sup>



The earliest of the international treaties to include the principle of scheduling was the 1931 Convention for Limiting the Manufacture and Regulating the Distribution of Narcotic Drugs ('the Limitation Convention').<sup>17</sup> A core point in the debates leading up to the Limitation Convention concerned the advisability or otherwise of applying identical controls to all substances covered. The German delegation, manoeuvring on behalf of its pharmaceutical industry, at this time the leading manufacturer of codeine, argued that codeine was a safer therapeutic substance than opium or heroin, and that it should not be subjected to the same stringent restrictions applied to these more powerful opiates. Germany declared itself unable to sign up to the treaty if its provisions did not differentiate between these drugs.<sup>18</sup> Following further discussions, a system of dual scheduling was devised and agreed as a compromise measure, enabling Germany to ratify the treaty while maintaining the restrictive controls on those drugs considered to pose higher levels of risk. The two schedules were:

- Group 1, which included morphine, heroin and cocaine and their salts, and
- Group 2, comprising codeine and ethyl morphine, and their salts.

The second group was exempted from some of the more onerous regulatory and reporting requirements applying to the first. The scheduling principle was thereby established within the international drug control system.

Importantly, under the provisions of the Limitation Convention, the health agency, which at this time was the Health Committee of the League of Nations, was assigned the decisive role in the scheduling of substances: it decided what was to be controlled and how strict the control measures were to be.

### **Inconsistencies of scheduling under the current drug control Conventions**

With the post-World War Two arrival of the three Conventions that form the current framework for drug control,<sup>19</sup> scheduling became more complex, with four schedules operating in both the 1961 Single Convention and in the 1971 Psychotropics Convention. In addition, the 1988 Trafficking Convention applies schedules to precursors, with two tables classifying direct precursors of psychotropic substances and their salts (Table 1, which includes ephedrine, lysergic acid and others), and reagents, solvents and their salts that can be utilised in the illicit production of narcotic drugs and psychotropic substances (Table 2, comprising acetone, ethyl ether etc.). See Box 1 for more details. A fundamental structural inconsistency in the system derives from the fact that the 1961 Convention included herbal raw materials and other precursors, while the 1971 Convention deliberately excluded these substances. Consequently, the 1988 Trafficking Convention only includes precursors for substances controlled under the 1971 'Psychotropics' treaty (not for 'narcotics'), and reagents/solvents for both. As a result of this division of labour between the Conventions, a corresponding partition arises between the treaty bodies: the WHO recommends on precursors for narcotics and the INCB on precursors for psychotropics.

It should be noted that the 1971 Convention is generally the more lenient in its controls. This came about as a result of the political manoeuvring underlying the treaty's design, which saw the developed countries lobbying on behalf of their domestic pharmaceutical industries; it also reflected their cultural preference for scientifically produced synthetic drugs, as opposed to the more raw and

untreated plant-based materials still in use in the developing world.<sup>20,21</sup> Essentially, while enthusiastic about the imposition of tight restrictions on the drugs of the people of Asia, Africa and Latin America, the industrialised nations wished for more flexible arrangements for their own synthetic drugs. As noted above, those recreational substances that were thoroughly embedded in 'Western' culture were not even classed as drugs, and remained outside the system. This was to cause further problems for the WHO, whose health-driven mandate and scientific ethic has proven difficult to adapt to the licit/illicit structuring of the drug control system.

The basic principle informing the classification of substances under the 1961 and 1971 Conventions is often called the 'similarity principle'. This centres on the proposition that if a substance resembles one that is already controlled under the international conventions, then it too is likely to warrant controlling and should be reviewed with this objective in mind. Scheduling under the 1961 Convention also involves a 'convertibility principle', which turns on the ability of a substance to be easily converted into a drug having equivalent properties to those already under control. In practice, the similarity principle has centred on three substances – a drug must possess morphine-like, cocaine-like or cannabis-like effects to be scheduled under the 1961 Convention. Aside from the difficulties in specifying the precise nature of such a 'similarity', it is important to recall that these three substances have not themselves been reviewed for a very long time (heroin since 1949, cannabis and the coca leaf since 1965).<sup>22</sup> That is to say, the substances that provide the foundation for the entire scheduling edifice, and operate as templates for substances requiring control, themselves remain unanchored by contemporary evidence.

### **The Expert Committee on Drug Dependence**

The Conventions of 1961 and 1971 mandate the WHO with responsibility for reviewing any substance proposed for inclusion within their schedules, or changes to the scheduling of a substance already controlled. A review may be initiated by a member state or by WHO itself; when it is arrived at, WHO's recommendation goes to the CND for acceptance or otherwise. WHO's general role is to assess, within a public



# Schedules under the UN drug control conventions

## 1961 Single Convention on Narcotic Drugs

SCHEDULE I	SCHEDULE II	SCHEDULE III
Substances that are highly addictive and liable to abuse, and precursors readily convertible into drugs similarly addictive and liable to abuse (e.g. <i>cannabis, opium, heroin, methadone, cocaine, coca leaf, oxycodone</i> )	Substances that are less addictive and liable to abuse than those in Schedule I (e.g. <i>codeine, dextropropoxyphene</i> )	Preparations containing low amounts of narcotic drugs, are unlikely to be abused and exempted from most of the control measures placed upon the drugs they contain (e.g. <i>&lt;2.5% codeine, &lt;0.1% cocaine</i> )
↓		
SCHEDULE IV		
Certain drugs also listed in Schedule I with "particularly dangerous properties" and little or no therapeutic value (e.g. <i>cannabis, heroin</i> )		

## 1971 Convention on Psychotropic Substances

SCHEDULE I	SCHEDULE II	SCHEDULE III	SCHEDULE IV
Drugs presenting a high risk of abuse, posing a particularly serious threat to public health with little or no therapeutic value (e.g. <i>LSD, MDMA, cathinone</i> )	Drugs presenting a risk of abuse, posing a serious threat to public health, which are of low or moderate therapeutic value (e.g. <i>dronabinol, amphetamines</i> )	Drugs presenting a risk of abuse, posing a serious threat to public health, which are of moderate or high therapeutic value (e.g. <i>barbiturates, buprenorphine</i> )	Drugs presenting a risk of abuse, posing a minor threat to public health, with a high therapeutic value (e.g. <i>tranquillizers, including diazepam</i> )

## 1988 Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances

TABLE I	TABLE II
Precursors of psychotropic substances, such as ephedrine, piperonal, safrole, phenylacetic acid, lysergic acid; and a few key reagents such as acetic anhydride used in the conversion of morphine into heroin and potassium permanganate used in the extraction of cocaine	A wide range of reagents and solvents that can be used in the illicit production of narcotic drugs and psychotropic substances, but also have widespread licit industrial uses, including acetone, ethyl ether, toluene and sulphuric acid

health orientation and on the basis of the best available evidence, the medical properties of a substance and its liability for unauthorised use ('abuse'). It must attempt to balance the need for the medical availability of a substance

against the adverse health consequences of its unauthorised use. The 1988 Convention is different in this respect; it mandates the INCB to provide scheduling recommendations on precursor substances to the CND. Under the

1961 and 1971 Conventions, however, the WHO is assigned unambiguous responsibility for providing scheduling recommendations (see Appendix 1 for a flow-chart of the review process).

The detailed work of reviewing substances for scheduling by the WHO is undertaken by the ECDD. The ECDD was established following a resolution at the first World Health Assembly in 1948, and acquired its present title in 1968. Its membership is chosen by the Director General of the WHO, and it meets as required, but should do so at least every second year. The Expert Committee is responsible for undertaking the review of a substance proposed for scheduling, and advises the Director General of the WHO on his or her recommendation to CND.

The ECDD carries out two types of review in order to make its recommendations: the pre-review and the critical review. The pre-review is a preliminary exercise, carried out in order to decide on the necessity or otherwise of a critical review. This will depend on whether the pre-review indicates that a substance may require scheduling under the Conventions, though no recommendation can be arrived at by a pre-review. If no such information is identified, the ECDD will recommend that insufficient data exists to necessitate a critical review.

A critical review is initiated when: (1) a party to the 1961 or 1971 Convention requests the scheduling of a substance, or the modification of its existing scheduling; (2) an explicit request for a review is made by the CND; (3) the ECDD's pre-review has recommended a critical review, or (4) the WHO is informed that a substance is subject to clandestine manufacture, or represents a serious risk to public health, and has no recognised therapeutic value. The critical review process is a detailed one, and includes consideration of a substance's chemistry, pharmacology, toxicology, dependence and 'abuse' potentials, therapeutic applications, presence on the WHO model list of essential medicines, industrial use, trade, public health impacts, dependence and unauthorised use, illicit production and trafficking, and other factors within a general public health and medical perspective. The WHO Secretariat is responsible for collecting the necessary data for the critical review document, requesting information from ministers of health in the member states and, when required, from ad hoc working groups.

Other UN bodies, including UNODC and the INCB, may be invited to attend Expert Committee meetings as observers, as may appropriate NGOs 'in official relations with WHO'.<sup>23</sup> The review process has been subject to periodic changes in its guidelines, the latest version having been adopted by the WHO Executive Board in January 2010. The new rules included a specific requirement that reviews must be evidence-based, and increased the transparency of the process, with meeting documents being published on the WHO website prior to the meeting, along with the ECDD's subsequent reviews of substances under scrutiny and peer-reviews of these documents.

### **Conceptual and classification problems**

There are numerous structural conflicts in the scheduling system as inscribed in the Conventions. Some of these relate to underlying philosophical assumptions, and are highly unlikely to be broached within the UN system or by delegates of states parties; nonetheless, they continue to exist and have important effects on the way the system is designed and operated.<sup>24</sup>

The historical development of the 1961 Convention, for example, remains embedded in its title and the conception of the class of drugs it is meant to regulate: 'narcotic' drugs. This term is understood in medicinal vocabulary to refer to drugs that induce drowsiness or sleep, yet cocaine (a stimulant) and cannabis (a hallucinogen) are scheduled under this Convention. The term 'psychotropic' drug as used in the 1971 Convention is, if anything, still more elusive in its claims to pharmacological meaning. While it is sometimes argued that psychotropic substances are those that affect the central nervous system, such a criterion would also apply to those controlled under the 1961 Convention. 'Psychotropic' drugs regulated by the 1971 Convention include buprenorphine (a narcotic), amphetamine (a stimulant) and LSD (an entheogen). Essentially, these are merely administrative terms, possessing conflicted and uncertain reference outside the Conventions.<sup>25</sup> As stated by the UN Drug Control Programme in 2000: 'the international classification into narcotic drugs and psychotropic substances according to whether the substance is governed by the 1961 or by the 1971 Convention has no conceptual basis. The legal definition of many

psychotropic substances is entirely applicable to narcotic drugs, and in many cases, the reverse is true'.<sup>26</sup>

Beyond this circularity, perhaps the most important element to distort the coherence and application of these treaties is the conception of drugs they embody, which is based on a notion of pharmacological determinism. This implies that the effects of drugs stem simply and unproblematically from their pharmacological properties, and are fixed, stable and universal in character. It is, however, becoming increasingly clear to sociological, historical, cultural and other analysts of intoxicants that the effects of these substances are not caused solely, or perhaps even primarily, by their chemical makeup, but are powerfully influenced by the dosage and mode of administration, by cultural beliefs and suppositions surrounding their use, the legislative and enforcement context, the policy setting, surrounding social attitudes toward drug consumers, the age, the physical and psychological makeup of the user, the subcultural setting and the role of the drug in identity formation, and so on.<sup>27</sup> As noted, these topics may remain outside the arena of discussion for the foreseeable future, but their impact is felt in the present and should be acknowledged.

The incoherence of the current framework is of practical and immediate policy relevance in its influence on scheduling decisions. There are multiple problems in this respect, not least for the body charged with producing scheduling recommendations to the CND – the WHO. When the ECDD convened for its 33<sup>rd</sup> meeting in 2003, it noted that its first task in reviewing substances, based on the 1961 Convention, is to satisfy the similarity principle – to ascertain whether substances possess 'morphine-like', 'cocaine-like' or 'cannabis-like' effects, or can be converted into a substance that does. 'However', the report of the meeting states, 'no specific guidance is given in the Guidelines as to how similar to the original drug a substance must be for it to be considered as morphine-like, cocaine-like, or cannabis-like'.<sup>28</sup> It adds that this impacts powerfully on the Committee's work when a drug under review has some similarity to both narcotic and psychotropic substances. The ECDD describes the decision as to whether to control stimulants and analgesics under the 1961 or the 1971 treaties as 'a major problem'. In terms of central nervous system stimulants, for example, 'cocaine is under the 1961 Convention, whereas amphetamines are

under the 1971 Convention. Thus, the criteria for choosing between the two Conventions are ambiguous for these classes of drug'.<sup>29</sup> There are in fact numerous inconsistencies in the scheduling of substances; cannabis, for example, is controlled under the 1961 Convention, while its most active ingredient, THC, is controlled under the 1971 treaty. The classification of cannabis in the most restrictive schedules of the 1961 treaty, Schedules I and IV, has represented a topic of often heated debate for almost half a century,<sup>30</sup> and growing numbers of governments are currently considering adopting an alternative set of regulatory controls at the national level.

### Unhealthy schedules?

As mentioned above, there is a growing trend toward a rebalancing of the international drug control system toward the health principle, which has moved from a discourse of civil society into parts of the drug control system itself. UNODC, for example, urges parties to '(u)se the upcoming high level review as an opportunity to reconfigure responses to the world drug problem, so as to balance the drug control system focusing on health and respect for human rights'.<sup>31</sup> However, with its focus as a UN specialised health agency, the WHO has for some years been the leading advocate among the drug control bodies of a reconfigured drug control system where the imperatives of health override those of repressive enforcement. In its Access to Controlled Medicines Programme (ACMP), it has urged national governments to ensure that their domestic laws 'recognise the indispensable nature of narcotic and psychotropic drugs for the relief of pain and suffering, and guarantee adequate availability of those medicines for legitimate medical uses, including opioid analgesics and opioids for substance dependence programmes'.<sup>32</sup> The WHO argues that international drug controls are often interpreted in an overly restrictive fashion, leaving an estimated 5.5 billion people living in countries without adequate pain relief.<sup>33</sup> The WHO's contention, while entirely in harmony with its mandate and the ethic of the international drug control treaties, is not always well-received at the CND, or by those member states who adopt a repressive approach to drug policy.<sup>34</sup> The INCB, while mandated to administer the estimates and requirements system for licit uses and vocally supportive of enhanced access to controlled medicines,<sup>35</sup> is generally an advocate of the restrictive rather

than the enabling principles of the Conventions; its stance on the problem of providing access to medicines is thus ambivalent. Tensions between the WHO and the INCB are frequent, and exacerbated by INCB's mandate to recommend on scheduling under the 1988 Convention, which can have such a deleterious effect on the ACMP. The negative impact of controls on the availability of medicines is illustrated by examples such as that of ephedrine, which is listed as an essential medicine by the WHO yet controlled as a precursor under the 1988 Trafficking Convention. Those materials, like ephedrine, listed in Table 1 of the 1998 Convention, are direct chemical precursors of psychotropic substances. Primarily, it is the substances listed in Table 1 of the 1988 Convention that cause problems for the access to essential medicines.

### **Towards a 'public health crisis'? The INCB and ketamine**

The debates surrounding the scheduling of ketamine illustrate clearly both the marginalisation of the WHO and the 'mission creep' of the INCB, and arguably the CND, in relation to their mandates. Ketamine is an anaesthetic used in both veterinary and human surgical and diagnostic procedures, such 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 clinical controlled conditions are unavailable; 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>36</sup>



It is also consumed recreationally as a hallucinogen, a form of consumption that has grown in recent years, prompting moves to control the substance under international law. Following a pre-review at its 33<sup>rd</sup> meeting in 2003, a critical review of ketamine was undertaken by the ECDD in 2006. This followed calls by the INCB in its Annual Report for 2004 for the 'international community to give serious consideration to initiating the procedure' for placing the substance under international control<sup>37</sup> and coincided with a recommendation from the INCB for the WHO to 'expedite' its review of the substance in light of what it identified as 'widespread abuse'.<sup>38</sup> While animal studies had provided some evidence of dependence, the 2006 review noted that 'reports of such dependence in humans are very limited'.<sup>39</sup> The Committee also found that ketamine is a widely employed anaesthetic, with therapeutic use in 70 of the 74 countries responding to the WHO questionnaire. Moreover, it should be recalled that it is included in the WHO Model List of Essential Medicines.<sup>40</sup> Within this context, the critical review concluded that there was insufficient evidence to schedule ketamine, and the Expert Committee asked the WHO secretariat to produce an updated version of the critical review document.<sup>41</sup> However, during its 34<sup>th</sup> meeting in March 2006, the ECDD received news that the 49<sup>th</sup> Session of the CND had adopted a resolution calling for controlling the use of the substance via national legislation.<sup>42</sup> While acknowledging the concerns of states regarding illicit use, at its 35<sup>th</sup> Meeting in 2012 the Expert Committee nonetheless repeated its previous recommendation against scheduling. The ECDD reported that concerns were raised at this 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>43</sup>

Despite being fully in accord with the Expert Committee's role under the Conventions, this proved to be a controversial decision. For much of the previous decade, the INCB had been using its annual reports and associated statements and correspondence to express alarm regarding the 'abuse' of ketamine, avoid substantive discussion of its medical utility<sup>44</sup> and in so doing build pressure on the WHO via member states to bring the substance under national, and ultimately, international



control. To be sure, despite (and arguably because of) the ECDD's 2006 recommendation against scheduling, the INCB and various states parties had campaigned strongly to control ketamine through a network of national legislation, effectively by-passing the WHO's recommendation – even though the WHO is the agency mandated by the relevant conventions to issue scientific and medically based recommendations on scheduling questions.

Such a move consists, arguably, in the creation of a parallel regime of international control, established via mechanisms other than those provided by the Conventions for this purpose. On this point it is worth recalling comments within the ECDD's *Ketamine: Critical review report* from its 35<sup>th</sup> meeting. Then, under the heading 'Current international controls and their impact' the Report noted: 'It may be argued that de facto over the years a situation of international control has emerged without any scientific assessment of the situation, due to both CND resolutions and the INCB continuous pressure (sic) on Member States.' The Committee goes on to say, 'It should be mentioned that according to the international drug control conventions the CND has no mandate to conclude to international control without a WHO recommendation and the INCB has no mandate at all'.<sup>45</sup> This position is strengthened by an expert peer review of the critical report. Among other things, it notes that, 'Strict procedures required for procurement following international control are likely to create a public health crisis in [African] countries. Many of the countries facing problems due to abuse or illicit trade, manufacture or diversion of ketamine have *already taken control measures based on the suggestion by the INCB* (emphasis added). It may be advisable for other countries to review their national situation and come up with control measures based on reports of abuse/diversion/illicit trafficking and need for therapeutic use rather than international control'.<sup>46</sup>

Indeed, in its Annual Reports for 2007,<sup>47</sup> 2008<sup>48</sup> and 2009,<sup>49</sup> each time with reference to the 2006 CND resolution, the INCB has repeatedly urged parties to control the drug at the national level. It is likely that this stance had much to do with the introduction and acceptance of reinforcing CND resolutions on that issue in 2007<sup>50</sup> and, as is discussed below, again in 2014. Behind the scenes, in 2005 the

INCB also sent letters to the WHO concerning the misuse and trafficking of ketamine, particularly with regard to East and South East Asia; regions frequently highlighted within its annual reports.<sup>51</sup> Responding to the INCB's 2006 Report, the ECDD spokesperson at the CND declared the WHO 'astonished' that the INCB should call on states to control ketamine in this way. In view of ketamine's critical significance in parts of the developing world where it is practically irreplaceable, and of the restrictive impact scheduling would have on its availability, 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>52</sup>

The INCB, as it is accustomed to doing, continued in its course. Its actions were defended by the US delegation at the CND, which described its overall performance in 2007 as 'outstanding'.<sup>53</sup> Further, the 2009 Annual Report saw the INCB proclaiming that it has 'repeatedly drawn the attention of Governments to the widespread abuse of ketamine, particularly among youth'. Again calling on governments to introduce national controls, it went on to claim that ketamine is a substance 'most often used for the commission of crime'.<sup>54</sup> No reference was provided for this particularly dubious assertion; the debilitating effects of ketamine would surely place it among the most unsuitable of drugs to employ in the commission of a crime – at least, for any crime that required one to be able to stand up, walk or perform practical cognitive functions. Such a claim is best viewed as a rhetorical device calculated by the INCB to further inflame the anxieties of those governments it wished to influence. If so, it worked. Not only did concern within the CND over ketamine 'abuse' continue to grow but the plenary witnessed sharp criticism of the WHO's recommendation against scheduling, with certain delegations seemingly unaware of the public health basis upon which the ECDD conducts its critical reviews.<sup>55</sup> The same year also saw the INCB continue to place pressure on the WHO to recommend scheduling. In its Annual Report for 2012, published in March 2013 a few weeks before the Commission session, the INCB noted that it 'shares the opinion of the Governments concerned that national control

measures alone may not be sufficient to enable law enforcement cooperation between countries involved.<sup>56</sup>

In light of the nature and direction of the debate within the CND, it was not surprising that a third substantive resolution on ketamine was negotiated and a final version agreed at the 57<sup>th</sup> session of the CND in 2014. Initiated by Thailand, and co-sponsored by Egypt, Indonesia, China, Sweden and the USA, the resolution explicitly cites previous resolutions on the issue and consequently contains familiar themes concerning diversion and control at the national level. Nonetheless, as the title 'Preventing the diversion of ketamine from legal sources, while ensuring availability for medical use'<sup>57</sup> reveals, the resolution is different from its predecessors in that it pays attention to medical uses of the substance. While there was clearly no appetite within the CND to block the resolution (in relation to either the lack of need for enhanced controls or the circumvention of the WHO process), the more balanced approach to the issue appears to have been the result of committed engagement within the negotiations of a number of states, including France, Germany, Switzerland and the Netherlands. Explicit inclusion of the medical usefulness of ketamine may have tempered the restrictive urge from some members of the CND, but the resolution is unlikely to satisfy proponents of international control. Indeed, amongst numerous calls within the 2014 plenary for control of tramadol, a synthetic opioid that seems destined soon to be subject to the same processes as ketamine, China remained outspoken. During discussions on scheduling matters, the Chinese delegate noted that 'With all due respect...China finds it hard to agree with the WHO's conclusion' on ketamine.<sup>58</sup> Having submitted a large amount of documentation concerning ketamine 'abuse' in China to the Expert Committee, the Chinese delegation seems determined to assist the WHO in considering the substance at the ECDD's next meeting in June 2014, and announced at the CND that it has formally notified the Secretary General regarding the control of ketamine under Schedule I of the 1971 Convention.<sup>59</sup> Widespread dissatisfaction with the proposal to internationally control ketamine has been registered by the medical profession, especially amongst anaesthesiologists working in developing countries.<sup>60</sup>

The CND is allowed considerable flexibility with respect to the WHO scheduling

recommendations. As the secretariat has acknowledged in a paper on scheduling published shortly before the 57<sup>th</sup> CND in 2014, the Commission has 'broad discretionary powers' when it comes to its acceptance or otherwise of WHO recommendations.<sup>61</sup> Clearly, the right to reject a recommendation, allowed under both treaties, is the key issue. Otherwise, the degree of discretion varies between the 1961 and 1971 Conventions. Under the 1961 Convention, the CND must accept or refuse the WHO's recommendation as a whole, though it can decide to place a substance in Schedule I and not in Schedule IV where the WHO has recommended inclusion in both. The CND should, in principle, accept the scientific findings of the WHO; if it rejects the recommendation, this must be on 'social or administrative' grounds. Under the 1971 Convention, the CND is given still more flexibility; it can accept a recommendation by the WHO and yet decide to place it in an alternative schedule. It is supposed to accept the WHO's scientific advice, but may take into account legal, administrative, economic, social and other factors in coming to a decision. While the guidelines for the ECDD review are clearly stated and have been considered at some length,<sup>62, 63</sup> the social, administrative and other grounds on which the CND may reject WHO recommendations are given little further elaboration in either the treaties or their commentaries. While all involved must act 'in good faith', the social, administrative and other grounds are open to broad differences of interpretation, and constitute an opening for ideological themes of all kinds.

The voting regulations also differ between the 1961 and 1971 Conventions. Under the former, a simple majority of the CND member states is sufficient; under the latter, a decision of two-thirds is required. In addition, the CND may decide 'by consensus' not to vote, which stalls the scheduling process without issuing any explicit rejection; this was the action undertaken by the 2007 CND in the case of a WHO recommendation to change the scheduling status of dronabinol from Schedule II to the less restrictive Schedule III.<sup>64</sup> Finally, there is another important difference between the two Conventions, which concerns the degree to which the parties are bound by the CND decisions. Both treaties include a facility to appeal a scheduling decision to the Economic and Social Council (ECOSOC), whose review is final. However, while under the 1961 treaty the parties are bound by the

decision, 'and the Parties shall thereupon take such action as may be required under this Convention', the 1971 treaty contains a 'principle of non-acceptance'. Article 2 paragraph 7 states that if a Party, 'in view of exceptional circumstances...is not in a position to give effect with respect to that substance to all of the provisions of the Convention', it may submit a written explanation of reasons why it is unable to implement all the provisions of the decision. The right of non-acceptance applies to any decision adding or transferring a substance to a schedule of the 1971 Convention. It should be noted, in addition, that should the INCB conclude that the Convention's objectives are threatened by such a non-acceptance, it can apply the sanctions detailed in Article 19. These can, at their most serious, entail the suspension of imports and exports of psychotropic substances to and from the country involved.

### **The case of dronabinol: a medicine haunted by the 'Dope Fiend'**

While cannabis is listed in the 1961 Convention, and tetrahydrocannabinol (THC) in Schedule I of the 1971 Convention, dronabinol – an isomer of THC – has been subject to debate as to its proper scheduling. Originally listed in Schedule I of the 1971 Convention, dronabinol was moved into the less stringent Schedule II in 1991. By accepting WHO's recommendation to reschedule, after its initial rejection in 1989, the CND has recognised the medical utility of the substance. More recently, the ECDD again critically reviewed dronabinol and, at its 34<sup>th</sup> meeting in 2006, recommended that the substance be reassigned from Schedule II to Schedule III of the 1971 Convention, chiefly on account of its therapeutic applications in the treatment of nausea amongst HIV/AIDS and cancer patients undergoing chemical treatments. Reduced restrictions would enhance access to, and medical utility of, this substance. The ECDD noted further that dronabinol is a promising material whose medical uses appeared likely to expand in the future. The CND, however, requires a two thirds vote to approve such a move under the 1971 Convention, one of the very few topics on which a vote is required, and in this case the Commission decided *not* to vote, effectively blocking the move. The Conventions allow the Commission to refrain from voting on a scheduling recommendation; moreover, unlike its other scheduling decisions,

the decision not to vote is not subject to ECOSOC review. In this case, the CND resolved to request the WHO, 'in consultation with the International Narcotics Control Board, as appropriate, to undertake, for consideration by the Commission, a review of dronabinol and its stereo isomers when additional information became available'.<sup>65</sup> This resolution is curiously phrased: as discussed earlier, review of substances proposed for scheduling resides in the mandate of the WHO, and there is nothing particularly 'appropriate' about doing this in consultation with the INCB, though it can consult if it so chooses.

The grounds for the CND's position appear to relate tenuously to its mandate. The ECDD had previously concluded that a rescheduling of dronabinol to Schedule IV of the 1971 Convention was appropriate, but in a step considered 'highly unusual', the then Executive Director of UNODC Mr. Antonio Maria Costa intervened and asked the WHO to reconsider its recommendation, which accordingly never reached the CND.<sup>66</sup> At its 2006 meeting, the Expert Committee considered reiterating its recommendation, but, acting more cautiously this time, advised that Schedule III would be appropriate for dronabinol. At its 2012 meeting, the Expert Committee revisited its critical review; finding no new evidence, it decided that the recommendation should stand.

While it is perfectly within its rights not to vote, the CND's reluctance appears in this instance to have involved the symbolic impact of cannabis; the history of drug policy is saturated with the symbolic valences that drugs acquire in the course of their social and cultural representation. The Secretary of the ECDD spoke at the CND, reminding states parties that dronabinol is subject to very little illicit use, and that '(W)e should...



not forget that there is an alternative that is abundantly available almost everywhere and that is called cannabis'.<sup>67</sup> Moreover, delegates were informed, the proposed rescheduling would not affect their national control arrangements. Gesturing toward its medical uses, the Secretary continued: 'Impeding its (dronabinol's) development by choosing an overly strict regimen should therefore be regarded as unethical'.<sup>68</sup> Nonetheless, it was evident that certain countries continued to link dronabinol with the vexed question of cannabis, long considered by reformers as a historical anomaly within the international control system's scheduling arrangements. In particular, the WHO recommendation came at a time when the issue of medical cannabis was a politically charged topic in the USA, and the US authorities feared that any lessening of controls over dronabinol would 'send the wrong signal' with respect to it. It was the USA that suggested a consensus decision rather than the vote demanded by protocol, after contending that the WHO recommendation was not sufficiently based on medical evidence – a claim that was itself backed by little reasoned argument, and that is in violation of the terms of the treaties, which oblige the Commission to accept the medical and scientific data deployed by the WHO.<sup>69</sup> On the basis of his impression of 'a lot of nodding' in the room, the CND Chair assented to the US proposal. As IDPC's observer at the 2007 CND concluded: 'The applause following the decision sounded like a fundamental undermining of the expert authority of the WHO, an outburst of relief that in the CND political considerations still prevail over science and evidence'.<sup>70</sup>

At the 57<sup>th</sup> CND in 2014, the Netherlands prompted a vote on the rescheduling of dronabinol from Schedule II of the 1971 convention to Schedule III in accordance with the WHO's recommendation, submitting a draft decision to this effect.<sup>71</sup> The Netherlands explained that it was taking this course of action in order to obtain acknowledgement of the substance's medical value, and to ease the restrictions that impede therapeutic access. In order to be successful, the vote required a two thirds majority of CND Members (i.e. 36 out of 53) to vote for it. In the event, this did not happen. In the pre-vote debate, a number of countries had argued that the data on which the Expert Committee had relied was outdated; several times, countries declared their support for the work of the ECDD, but

declined to accept its recommendation, and then went on to criticise the quality of the scientific evidence used – something which the CND is not supposed to do. A large majority of member states voted against, the result being that dronabinol remains in Schedule II of the 1971 Convention. Nine states voted in favour of rescheduling and, while the vote was unsuccessful, their actions reaffirmed the importance of the health principle and the place of scientific evidence in the drug control system.

### **The relationship with national scheduling systems**

Conflicts between expert groups assembled to provide guidance on the classification of substances on the one hand and those making the political decisions on the other have arisen at national levels as well as in the UN system. Debates featuring these terms have occurred in both the international context and in countries such as the Netherlands and the United Kingdom (UK) around the use of khat and cannabis.

### **The rescheduling of cannabis in the UK**

The UK's legal framework for drug control centres on the Misuse of Drugs Act, 1971, which established the Advisory Council on the Misuse of Drugs (the ACMD), a body of independent experts with whom the UK Government must consult on the classification of drugs.<sup>72</sup> The Government had traditionally followed the advice of the ACMD, but in 2007, a time when cannabis was scheduled as a Class C drug – the least harmful category – it requested the ACMD to review this classification. Alarmed by reports of severe mental health effects from high-strength 'skunk' preparations, the Government wished to return cannabis to its earlier Class





B classification. The ACMD carried out an extensive review, and recommended that the drug remain in Class C. The recommendation was rejected, and in 2008 cannabis was re-scheduled as a Class B substance. Then, in February 2009, the Government rejected the ACMD's recommendation that ecstasy be downgraded from the most harmful category – Class A – to the lesser category, Class B. It also rejected the ACMD's recommendation that a national scheme be created for the purpose of testing MDMA with a view to providing harm reduction advice and developing monitoring data.

The Government is legally entitled to reject the ACMD recommendations; the statutory framework only requires conscientious consultation by the Government with the ACMD on classification decisions, not that its recommendations be followed. The ecstasy decision was justified as follows: 'It is our view that the system should be based on evidence, but it should also be based on the considered view of those responsible for policy making, and should take into consideration the impact that changes in classification are likely to have on the use of, and harms caused by drugs and the impact that that has on the criminal justice system. That is why it will remain the case that our advisers will advise us, and we will decide.'<sup>73</sup>

Relations between the UK government and the ACMD, and parts of the scientific community more generally, became very strained following the sacking of the ACMD chair, Professor David Nutt, over his views on the safety of ecstasy and cannabis relative to alcohol and tobacco. The Home Secretary wrote to the Professor explaining that, 'it is important that the government's messages on drugs are clear and as an advisor you do nothing to undermine public understanding of them'.<sup>74</sup> A total of six members of the ACMD resigned over the sacking and the issues it raised. As a result of the dispute between scientific advisors and the UK Government, the regulations governing the role of expert advisory bodies and governments were reviewed, and a new set of guidelines established. Initially, these carried no reference to academic freedom, and included the objective of expressing a 'shared position' between Government and advisors. Following a campaign by scientists, these measures were respectively added and removed. However, unease remains in the academic and scientific communities over a principle stipulating that

neither side should act in ways that undermine 'mutual trust', which remained in the final version of the principles, and are included in the resulting Ministerial code. It appears that such phrasing could once again facilitate the expulsion of troublesome advisors such as David Nutt.

### **Scheduling controversies around khat at national and international levels**

Khat is not subject to international control at present. The Advisory Committee on the Traffic in Opium and Other Dangerous Drugs of the League of Nations first discussed khat in 1933 and it has appeared on the international agenda several times since then. At the request of the CND, the WHO Expert Committee reported in 1962 that clarification on the chemical and pharmacological identification of the active principles of khat was needed before a sound medical appraisal of the chronic use of khat could be made. Several studies, including by the UN Narcotics Laboratory, subsequently identified a number of phenylalkylamine alkaloids as the major psychoactive compounds in the khat plant: cathinone and cathine (norpseudoephedrine), and to a lesser degree norephedrine. Cathinone is unstable and undergoes decomposition rapidly after harvesting and during drying of the plant material, which is the main reason why fresh khat leaves are preferred by chewers. Dried leaves, with much lower levels of cathinone, are more often used to make tea, known as Abyssinian or Arabian tea.

Cathinone and cathine are alkaloids with effects on the central nervous system similar to amphetamine, though less potent. Since, in the early 1980s, all amphetamine-like substances were placed as a group under international control, cathinone and cathine were – based on a 1985 recommendation of the WHO Expert Committee – added to the list of controlled substances of the 1971 Convention on Psychotropic Substances, respectively to Schedule I and III.<sup>75</sup> Norephedrine was subsequently included in the list of precursors controlled under the 1988 UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, as it was often used in the illicit manufacture of amphetamine.

The WHO Expert Committee concluded in 2006 on the basis of a critical review of khat that scheduling of the plant itself was not

required: 'The Committee reviewed the data on khat and determined that the potential for abuse and dependence is low. The level of abuse and threat to public health is not significant enough to warrant international control. Therefore, the Committee did not recommend the scheduling of khat. The Committee recognized that social and some health problems result from the excessive use of khat and suggested that national educational campaigns should be adopted to discourage use that may lead to these adverse consequences'.<sup>76</sup>

The conclusion of the WHO Expert Committee blocked the option of bringing khat under UN control, clearly to the frustration of the INCB. The INCB had started to report on khat under the heading of 'substances not under international control' in its Annual Reports, expressing concern and calling on the WHO to expedite its review to determine whether it recommended placing khat under international control.<sup>77</sup> After the WHO recommended against it, the INCB continued to call 'upon the authorities to consider taking appropriate measures to control its cultivation, trade and use'.<sup>78</sup> In its report for 2010, in a special topic on "Plant material containing psychoactive substances" the INCB drew attention to the fact that 'although some active stimulant or hallucinogenic ingredients contained in certain plants are controlled under the 1971 Convention, no plants are currently controlled under that Convention or under the 1988 Convention'.<sup>79</sup> This, the INCB argued, is in contrast to the 1961 Single Convention under which 'plants that are the sources of narcotic drugs, such as cannabis plant, opium poppy and coca bush, are subject to specific control measures'.<sup>80</sup> Aware that recommendations for scheduling under the UN Conventions is a unique mandate given to the WHO, the INCB instead – similar to what it has done in the case of ketamine – 'recommends that Governments should consider controlling such plant material at the national level where necessary', thereby contradicting the advice of the WHO experts who favoured educational measures over criminalisation.<sup>81</sup>

The section on 'substances not under international control' first appeared in the INCB report for 2005 and has since become a permanent feature, where now data are also provided on khat seizures in the increasing number of countries that placed it under national control. 'Seizures of khat by customs

authorities in Western Europe in 2012 increased from 54.1 tons in 2011 to 60.6 tons in 2012', according to the report for 2013.<sup>82</sup> In Europe, khat was already on the list of controlled substances in 14 countries: Belgium, Denmark, Germany, Finland, France, Greece, Ireland, Italy, Latvia, Lithuania, Norway, Poland, Slovenia and Sweden.<sup>83</sup> In the USA, the Drug Enforcement Administration classified khat as a Schedule I substance already in 1993, and controls on khat in Canada were introduced under the Controlled Drugs and Substances Act of 1996. Two recent national scheduling decisions, in the Netherlands and the UK, mirror the disregard of scientific advice the INCB shows at the UN level.

In the Netherlands, a risk assessment was undertaken in 2007 by the Co-ordination Centre for the Assessment and Monitoring New Drugs (CAM), the official government advisory body for such matters, which concluded that 'khat poses little risk to the health of the individual user, and it presents no appreciable risk to Dutch society as a whole. There is therefore no reason to prohibit its use in the Netherlands'. According to the CAM, a ban would stigmatise the Somali community, without any prospects of a significant reduction in demand. Discouraging use through education was considered sufficient to increase the awareness to the potential negative social consequences and adverse health effects of excessive use.<sup>84</sup> Another report was requested, from the Trimbos Institute, to look into the social impact of khat in the Somali migrant community, into stories of public nuisance in some cities around the khat trade and into the international context, since the Netherlands had also become an important hub for European imports and Scandinavian countries that had banned khat started to complain. In January 2012, the Government sent the Trimbos study to the Parliament with the announcement that it decided to put khat on List II, even though the Trimbos report had not made such a recommendation.<sup>85</sup> Under the Dutch Opium Law, List II contains drugs with 'an acceptable degree of addictiveness or physical harm', such as cannabis. This allows for prosecutorial discretion when it comes to use and possession, but it does make the importation and domestic trade of khat illegal and subject to active law enforcement.

In the case of the UK, where khat is estimated to be used by around 90,000 people from the Somali and Yemeni communities, the ACMD

concluded in January 2013 'that the evidence of harms associated with the use of khat is insufficient to justify control and it would be inappropriate and disproportionate to classify khat under the Misuse of Drugs Act 1971. In summary the ACMD considers that the harms of khat does not reach the level required for classification'.<sup>86</sup> But UK Home Secretary Theresa May decided six months later to ban it, saying the risks posed could have been underestimated.<sup>87</sup> In November 2013, however, the Home Affairs Committee found that the ban on khat was not based on any evidence of medical or social harm and must be stopped before it becomes law. The parliamentarians concluded that the potential negative effects, both on the diaspora communities in the UK, and on the growers who cultivate it in Africa, outweighed any possible benefits of the ban. The Home Secretary continued to justify the ban by stating that most European Union (EU) countries had already banned khat so there was a danger of Britain becoming a regional hub for illegal onward trafficking to those countries.<sup>88</sup> The ban will take effect from the 24th June 2014.<sup>89</sup>

### **New psychoactive substances: Apocalypse now?**

As observed above, the proliferation of NPS has given a new urgency to the question of scheduling. UNODC observed in its 2013 *World Drug Report* that it had been notified of 166 such substances, the figure rising to 251 by mid-2012.<sup>90</sup> It also noted rightly that the problem of dealing with a raft of new drugs was one that the international system had faced before, for example in the post-Second World War with the emergence of various synthetic opioids.<sup>91</sup> However, the sheer quantity of NPS is unprecedented, and there is every reason to suppose that the numbers will continue to grow. In a phrase attributed to Joseph Stalin: 'Quantity has a quality all its own'. The international drug control system is certainly faced with a challenge of a different order as it contemplates the bringing of this tide of new intoxicants into its regime of classification and control.

As the CND Secretariat acknowledges, the rapid proliferation of NPS, their turnover and global and local circulation makes prioritisation for risk assessment extremely difficult.<sup>92</sup> It also presents problems for the collection of data on whose basis to reach scheduling

decisions, challenges the timeliness of the process and its demand for resources, and highlights the varying capacity for countries to impose realistic controls while ensuring appropriate medical access.<sup>93</sup> The application of provisional controls allowed by the 1961 and 1971 Conventions offers a theoretical way forward from this impasse, but the fact that such measures have only been invoked on one previous occasion indicates that there may be difficulties involved in their practical application. Provisional controls were seriously mooted in the case of the opioid analgesic pentazocine in 1981, under the mandatory provisional measures of the 1961 Convention. In the event, it was decided against their application, and the substance was scheduled in the normal way in 1984.<sup>94</sup> In 2013, UNODC expressed the opinion that failure to make use of provisional scheduling measures stemmed from the fact that in the 1971 treaty there is no role for the CND to impose such controls, it being left instead to parties to unilaterally apply provisional measures. At most, observed the Office, 'the Commission on Narcotic Drugs could adopt a resolution asking Member States to implement such a measure'.<sup>95</sup> Some attempts to deal with the arrival of NPS by other countries and transnational groupings are examined below.

Despite countries' past reluctance with respect to the use of provisional measures, at the 57<sup>th</sup> CND in 2014 the UK announced that it had submitted a proposal to schedule mephedrone under the provisional controls of the 1971 Convention. Describing NPS as 'the challenge of the twenty-first century', the UK stated that mephedrone is one of the most widely used NPS on the illicit market, while lacking any current medical application. The UK delegation made reference to an untenable claim in support of its decision, contending that its domestic controls had been successful in reducing reported illicit use, which had dropped by two thirds between 2010/11 and 2012/13. While reported use may indeed have fallen, it is another matter entirely to conclude that this was as a result of legislation.<sup>96</sup> The UK market for NPS is complex and rapidly changing, tightly interwoven with trends in youth cultures; shifts in consumption of one drug must be seen in the context of the entire market. Nonetheless, there was considerable support for the UK's action at the CND, and it is highly likely that further substances may be proposed as suitable for the application of provisional controls.

## New approaches to new psychoactive substances: The European Union

Throughout the late 1990s, and the early years of this century, governments became aware of a small number of NPS being used in some European countries. However, the major focus of policy and programmes remained plant based drugs. The first formal European action to respond to this growing problem was the creation, in 2005, of the EU 'early warning system' and structures that went with it. Through this, member states could register new substances of concern. Their risks were then assessed by the EU institutions (principally the European Monitoring Centre on Drugs and Drug Addiction), and a decision made on whether or not to recommend the substance for control measures. In practice, this process was only fully used with a small number of substances.<sup>97</sup> Furthermore, in most cases it took a long time and considerable resources to produce a recommendation. This naturally led to concerns about how in reality the process could respond to the growing number of substances coming on to the market from around 2008-2009. As a result, the European Commission (EC) initiated a process to evaluate the existing early warning mechanism. And at the beginning of 2010, amidst the emergence of mephedrone and the reports of deaths associated with its use – particularly in the UK and Ireland – the Commission started the preparatory work.

In July 2011, the Commission published its assessment<sup>98</sup> and concluded that there were three major shortcomings when it came to submitting NPS to Europe-wide control measures. First, the existing system is unable to tackle the large increase in the number of NPS on the market because it addresses substances one by one, through a lengthy process. Second, it was seen to be overly reactive since substances brought under control measures are quickly replaced with new ones with similar effects, often through small modifications of their chemical composition. And third, it lacks a range of effective options for control measures that would allow for rapid and targeted action. Driven by these conclusions, and coinciding with discussions of the issue in the Informal Council on Justice and Home Affairs, the Commission engaged in a process of consultation to propose to EU member states a mechanism to replace a system that was deemed 'no longer fit for purpose'.<sup>99</sup>

The Commission's proposal aims to speed up the 'Union's ability to fight'<sup>100</sup> NPS by providing for:

- **A quicker procedure:** It currently takes a minimum of 2 years to ban a substance in the EU. Under the new structure, the Union will be able to act within 10 months. In some cases, the procedure would be shorter since it will also be possible to *withdraw a substance immediately* from the market for a year. This measure is intended to ensure that the substance is no longer available to customers while a full risk assessment is being conducted. The current system does not allow temporary measures, with proposals to restrict substances having to wait for a full risk assessment.
- **A more proportionate system:** It is intended that the new system will allow for a graduated approach where substances posing a moderate risk will be subject to consumer market restrictions and substances posing high risk to full market restrictions. Only the most harmful substances posing severe risks to consumers' health will be submitted to criminal law provisions, as in the case of illicit drugs. This is a significant departure from the current system since it only provides for binary options – taking no action at EU level or imposing full market restrictions and criminal sanctions. This lack of options means that at present, the Union does not take action in relation to some harmful substances.<sup>101</sup> It is hoped that the new system will allow the Union to tackle more cases and deal with them more proportionately, by tailoring its response to risks involved and taking into account legitimate commercial and industrial uses.<sup>102</sup>

The proposals now need to be adopted by the European Parliament and by EU member states in the EU Council in order to become law. This may not be a straightforward process since it is becoming clear that, as is often the case within the EU, there is not universal agreement on the issue. For example, in January 2014, the UK announced it would opt out of the proposed system ostensibly because it strongly disputes the EU claim that 20 per cent of 'legal highs' have 'legitimate commercial and industrial uses'.<sup>103</sup> Beyond this, it remains likely that EU institutions and national governments will continue to lag behind drug



designers and the changing nature of the NPS market.<sup>104</sup> Moreover, introducing the concept of proportionality and the option of regulating, rather than prohibiting, NPS within the new system raises interesting questions about the relative harm of organic substances, such as cannabis, that are currently under the strictest controls within the UN-based international scheduling framework. This is an issue also raised by the recent legislation passed in New Zealand.

### **New approaches to NPS: The New Zealand Psychoactive Substances Act**

Faced with a flood of NPS that lay beyond the scope of existing, and dated, drug control legislation,<sup>105</sup> the New Zealand Parliament passed what then appeared to be the ground breaking Psychoactive Substances Bill in July 2013.<sup>106</sup> The resultant Act set up a legal framework for the testing, manufacture, sale and regulation of previously uncontrolled psychoactive products, placing the responsibility on manufacturers to prove a product 'low risk' before it can be sold. To this end, it established a Psychoactive Substances Regulatory Authority within the Ministry of Health. In an attempt to minimise the politicisation of the issue, the Authority was advised by the Psychoactive Substances Expert Advisory Committee, and was responsible for ensuring that products met appropriate safety standards before they could be distributed in New Zealand. It also considered applications and granted licences to those who wished to manufacture, import or sell psychoactive substances.

Each new product was required to undergo clinical testing to determine potential harms and the result of the tests were made publically available to inform health professionals and other interested parties about its content and possible effects. There were specific restrictions in the legislation that required licences to be obtained by any company wishing to import, export, manufacture or sell psychoactive substances. Consequently, according to an analysis of the Act made shortly before the New Zealand government changed course, 'The law will apply some of the best harm reduction tools from tobacco and alcohol control to these products'.<sup>107</sup> Among these was a provision allowing the Authority to recall products that turned out to cause harm not detected in the clinical trials. This mechanism would not

require further legislation; rather the licence was simply to be revoked.

Underpinned by a belief in pragmatism, evidence and the protection of health, the Act acknowledged the demand for psychoactive substances and consequently focused on attempting to ensure that this was met in a low-risk manner. Unlike earlier legislation, it provided alternatives to a criminal justice approach and sought to protect the health of the user 'without undue emphasis on illegality and punishment'.<sup>108</sup> As such, offences within the Act predominantly focused upon illegal manufacture and/or supply. It also contained an inbuilt five-year review mechanism to allow for aspects of the legislation to be revisited if it was felt that they were not operating as intended. Furthermore, while the legislation removed the onus of proof regarding level of risk away from the Government and placed it with manufacturers, authorities retained oversight by being able to remove rapidly a product from the market. It was the intention that the legislative framework would also incentivise manufacturers to make low-risk products rather than constantly seeking to circumvent the law by producing chemical variants of unknown harm potential. Approved products would only be available in certain outlets, would come with health warnings and be subject to restricted advertising at the point of sale only.

New Zealand has since undergone what is known in sociology as a 'moral panic', in which multiple authority figures and media commentators seize on a topic and portray it as both cause and symptom of wider problems in the surrounding society. At the centre of this particular moral panic lies the Psychoactive Substances Act. Under the Act, 41 of the lowest-risk substances were assigned temporary approval; in April 2014, the Government suspended these approvals. According to Health Minister Peter Dunne, this sudden reversal in policy was prompted by increased reports of harmful side-effects of the substances in question. The terms of the Act were subsequently amended, bringing to an end the interim or provisional product approvals that had enabled certain substances to be sold prior to full testing. All interim licences to retail NPS have been revoked, and it is now illegal to supply and possess the products.

The crux of these developments is that, owing to the kind of anxieties that have emerged and re-emerged throughout the history of illicit

drug use, a bold and far-sighted attempt to regulate the market has been stopped in its tracks. The reversal in New Zealand's policy was driven by fears of an underground economy and mass drug use and an attempt to prevent harm through the application of controls. Ironically, the Act probably represented the best available method of regulating the market, and its amendment – which is effectively an abandonment of its principles – means that in reality the state has little, if any, control over the market, which has, after a promising start, reverted to criminals.

## Concluding discussion

In the light of the sense of growing anxiety, bordering at times on what we have referred to here as a *regulatory panic*, it is vitally important that the proliferation of NPS should not be allowed to derail the process of re-balancing the international drug control system away from punitive measures and toward public health and human rights objectives. The reviews carried out by the Expert Committee of the WHO represent a key aspect of the system – not merely for the technical reason that these reviews are an integral component of applying controls, but because they assign to the health principle the important task of assessing the risks associated with the use of particular substances and allocating measures that are appropriate to the degree of risk involved. Where this risk assessment is not properly carried out – as in the case of cannabis, which represents a glaring historical error – it brings the entire system into disrepute. In the previous international control system administered by the League of Nations, the 1931 Limitation Treaty and the 1948 Paris Protocol assigned the decisive role in the allocation of controls to the WHO or its predecessor, the Health Committee of the League of Nations.<sup>109</sup> While it appears highly unlikely that the CND would be willing to relinquish its deciding role under the current conventions, some way must nevertheless be sought to support the principle of scientific evidence and the public health objectives it underpins. In practice, this means shoring up the role of the ECDD in the face of ongoing political pressures emanating from the CND and the INCB.

This is a complex question. There are valid arguments that the CND should continue to play a part in the scheduling process in order to take into account social, cultural and political

factors – not least in mitigating the potential social effects of criminalisation. If this is to remain the case, however, the CND and the states parties should seek to thoroughly educate themselves in the intricacies of the scheduling process, and not only at the technical level. The states parties need to take ownership of the system and to take a much more active role within it; this in turn provides an educational function for the drug control bodies, who possess the technical knowledge the parties require in order to play a more meaningful role.<sup>110</sup> But for such engagement to be effective, it must take place within the context of the overall reorientation of the drug control system mentioned previously. The greater involvement of states parties could reverse the gains of recent years if those parties are driven by a sense of panic to opt for harsh repressive measures.

The CND secretariat has itself recently recommended some measures intended to improve the scheduling process. These comprised the continued attention to scheduling in forthcoming sessions; the consideration of options such as provisional scheduling, which is now, indeed, being explored; improving the data collection and distribution process and avoidance of duplication on the national, regional and international scales; the production of guidance materials by the secretariat, drawing on in-depth research in the UN archives; capacity-building at the national level in order to participate in the identification of NPS; improvements in data collection and circulation in order to permit risk-assessments of NPS by the WHO and national and regional bodies; a clarification and more effective timetabling of the scheduling process, and last but not presumably least, Member States to deploy resources to enable UN agencies to perform their mandated tasks.<sup>111</sup> The secretariat is right to draw attention to the lack of resources, something that currently cripples the ECDD, and the WHO's drug control engagements more broadly. The CND and states parties continually press the Expert Committee to meet its workload and to do so ever more rapidly, but this cannot realistically be expected without the necessary funding. Increased resources concomitant with the ECDD's growing burden of reviews represent a critically important element in more effective scheduling.

The secretariat's paper is a useful contribution to a discussion which is becoming ever more urgent. The document remains, however, a

technical discussion, locked securely within the constraints of present arrangements and the diplomatic codes standing guard against too much critical interrogation. The problems underlying the present confusion and conflict over scheduling go deeper, resulting in many ways from the structures of the drug control conventions themselves. Moreover, the secretariat's text does nothing to address what is perhaps the core problem, not only at the international level but also at national levels: the difficulty of balancing the analyses of expert bodies such as the ECDD against the often overtly political imperatives in play at the CND. As we have seen, the WHO's treaty-mandated scheduling recommendations are frequently rejected or stymied by the CND, which, as the policy-making body of the international drug control system, is invested with decision-making powers. These powers are, of course, limited by treaty; however, the CND often transgresses the rules that should govern its decisions. For example, in the 2007 Session where the rescheduling of dronabinol was debated, several delegations, as noted earlier, questioned the scientific basis of the WHO recommendation.<sup>112</sup> Such an action is expressly forbidden by both the 1961 and 1971 Conventions, which call on governments to accept in good faith the scientific evidence and conclusions presented by the WHO.<sup>113, 114</sup> In the case of ketamine, the WHO scientific evidence was again strongly criticised at the recent 57<sup>th</sup> CND, in flagrant transgression of the various institutional mandates involved.

An alternative or complementary way forward might entail the CND being called upon to justify its scheduling decisions, especially when these go against the advice of the WHO. In those circumstances, a transparent set of criteria covering precisely and explicitly the social and other grounds on which the CND may reject or modify a WHO recommendation should be constructed in order to impose some rigour and accountability on the reasoning processes involved. Such a protocol would govern the CND's scheduling decisions in an equivalent fashion to the protocols regulating the WHO reviews, though in a social and political register as befits the CND's mandate. As a final note upon this point, it should be borne in mind that in the unlikely event that the WHO were to take a deciding role in scheduling, the ECDD would itself require some restructuring, as its current analysis is based too much upon the presumptions of pharmacological determinism, and

consequently underplays the complexity and reflexivity of drug consumption.<sup>115</sup>

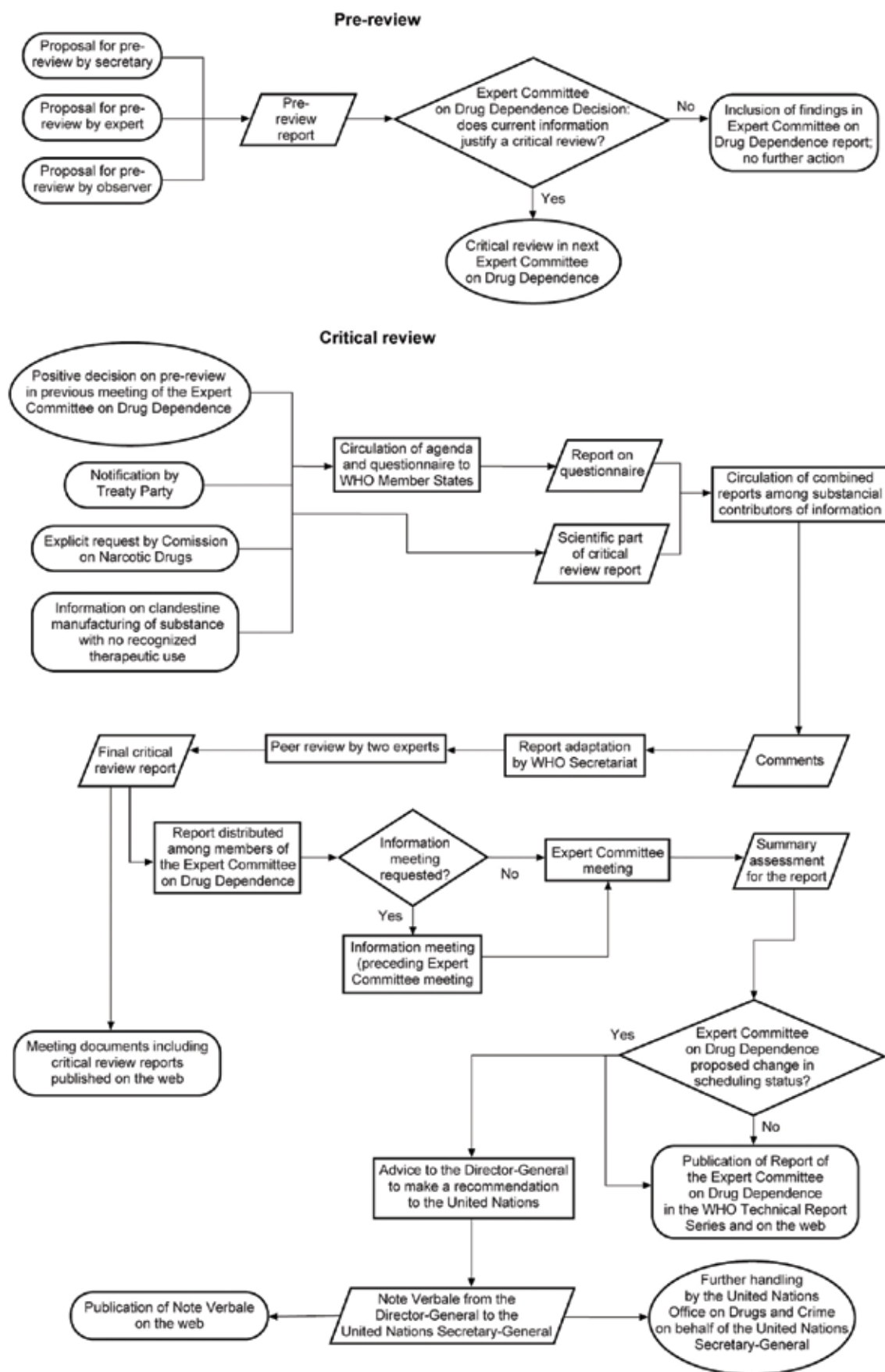
One of the most problematic aspects of recent scheduling debates, which is likely to be confusing for parties, has been the repeated intrusion of the INCB into matters which lie outside its mandate and within that of the WHO. The cases of ketamine, tramadol, dronabinol and khat have been explored or mentioned above; disapproval of ECDD's recommendations in respect of poppy straw and oripavine has also been expressed by the INCB. UNODC, the lead agency of the international drug control system, has increasingly called for a shift in the balance of the regime away from repressive enforcement methods and toward a perspective more informed by evidence, public health and human rights.<sup>116</sup> Despite this, the characteristic tone and much of the content of the INCB public discourse continues to be repressive and belligerent, as exemplified in its recent attacks on Uruguay over its decision to regulate its domestic cannabis market.<sup>117</sup> The INCB is not mandated to carry out reviews for scheduling purposes under the 1961 and 1971 Conventions, only for the scheduling of precursors under the 1988 Convention. The repeated transgression of its mandate in this area is the cause of considerable conflict and confusion in the global context, where the proliferation of NPS is already alarming states parties and a lucid and reasoned analysis of the health and social issues surrounding new intoxicants is especially important.

The present moment represents a point of uncertainty, as political responses to the ever-expanding range of NPS threaten the shift in emphasis we have witnessed in the UN drug control system over the last decade. As the next UNGASS approaches, it will be of central importance not only to defend the gains of recent years, but to extend them into the domain of scheduling in order to ensure that substances are properly risk-assessed and assigned the appropriate levels of control. The only way to achieve this is to make certain that the reviewing process remains within the remit of the WHO.

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## Notes

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### 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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