

# 2.1

## Scheduling and classifying substances

### Key recommendations

- International drug control bodies and national-level policy makers should attain the proper degree of balance between restriction of harm and the medical usefulness of a substance when making a scheduling decision
- The UN drug control regime should urgently review its scheduling processes to ensure that these reflect the latest evidence and the needs of the contemporary drug response. An expert group should be assigned this task, and the resulting advice should be passed on to governments to assist them in re-designing their national scheduling processes
- The role of scientific reviews – conducted by the WHO’s ECDD – should be strengthened and protected as part of international scheduling processes at the UN level, including mandatory periodic reviews of currently controlled substances (including cannabis) to reflect any emerging evidence and make the necessary adjustments to the policy response
- Where they do not already exist, policy makers should establish national advisory committees composed of scientific and social scientific experts to recommend appropriate classifications for substances proposed for control
- Policy makers should be bound by the recommendations of their advisory committees. If governments reject the advice of their expert committees, the grounds for doing so should be systemically and transparently articulated, and must be based upon evidence
- The unique problems presented by NPS should be embraced as an opportunity for better scheduling approaches based on evidence. For example, the approach originally adopted by New Zealand should be re-established and its results monitored and studied to examine the potential of replicating it elsewhere.

### Introduction

Although a complex technical issue, scheduling is at the heart of drug control. Both international law as embodied in the UN drug control conventions and national legislation systems include hierarchical classifications based on the degree of risk and the level of medical usefulness associated with controlled substances.

These hierarchies are often known as *schedules*, and their objective is to assign appropriate levels of control to a given set of substances. They are intended to apply the tightest control measures to those substances considered the most dangerous. Similarly, substances believed to carry the lowest levels of risk are assigned to the least restrictive schedule. The medical utility of drugs is also

factored into the decision to assign a substance to the appropriate schedule in drug laws and policies. Whether these classifications are appropriate in practice is, however, a matter of considerable dispute – often the scheduling is based on unexamined cultural beliefs or historical accidents instead of scientific evidence.<sup>2</sup>

The mandate for scientifically reviewing substances proposed for international control lies with the World Health Organisation (WHO), while at the national level many countries have set up specialised agencies to advise their governments on the appropriate schedules for substances. It is of great importance that the principle of scientific review is maintained, which should be independent of governments, and that its assessment of



Ketamine

substances proposed for control is carried out on a scientific basis. However, governments are often unwilling to take the advice of their own advisory bodies, fearing public reactions to scientific recommendations on drug control or holding ideological positions on substances that run counter to scientific advice.

Scheduling has recently become a more complex issue due to the emergence of large numbers of new psychoactive substances (NPS). These substances have generated a sense of panic among many governments. The proliferation of these new substances – and the dynamic ways in which they are produced and brought to market through the internet and social networking – have led to the conclusion that the customary processes of scheduling involving detailed scientific reviews are too slow and unwieldy to meet the control requirements of this novel situation.

## Legislative/policy issues involved

### Evidence-based hierarchies of harm

Attempts should be made to base scheduling on both hierarchies of harm, and a balance between those harms and medical usage. Figure 1 below represents an alternative pattern of scheduling derived from the work of Professor David Nutt in the UK.<sup>3</sup> It compares an 'independent expert assessment of harm' with the current classification within the international drug

control system administered by the UN. It is notable that the two lists vary widely; cannabis, for example, is included in the most dangerous drugs (and with no medical value) within the UN system, while Nutt's system places it in the low risk category. A similar dissonance applies to LSD and ecstasy.

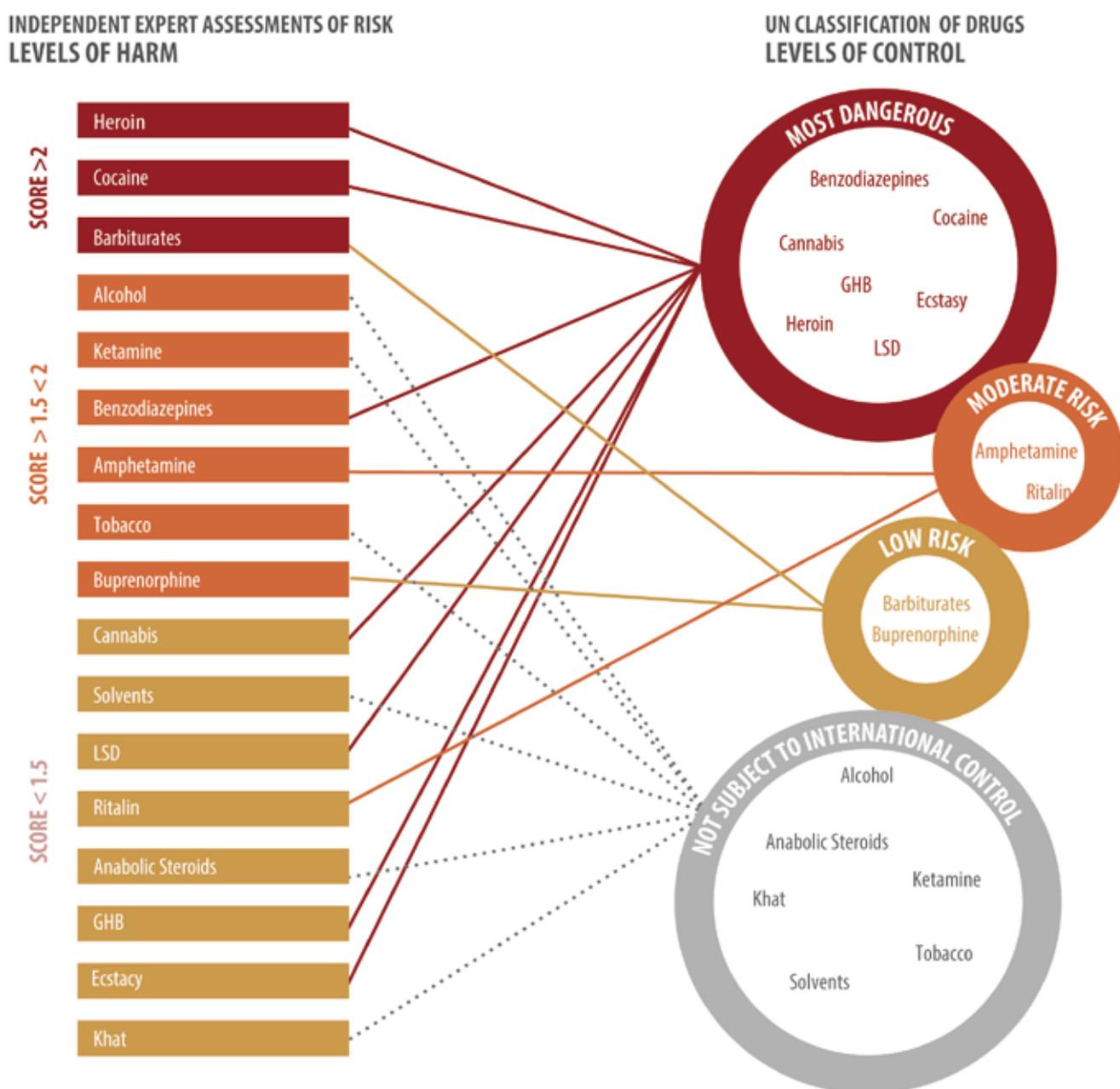
In general, the UN system classifies many more substances as 'most dangerous', which is arguably a result of cultural and historical factors at work during the early and mid-20<sup>th</sup> century, during which period colonial judgements and values, as well as xenophobia and racism, tended to prevail.

In 2007, the Nutt classification placed ketamine very close to the most dangerous drugs in its scale,<sup>4</sup> whereas, for the moment, the substance is not scheduled in the UN system. Proposals to schedule it are being debated, as will be discussed below – but even if these efforts are successful, ketamine will be classified as a low-risk substance because of its high medical value. This demonstrates the difficulty of assigning scientific schedules to psychoactive substances through an objective and evidence-based assessment of both harms and medical benefits. The best practice at the moment involves recommendations made by expert committees of scientists to advise governments based on available evidence, and for governments to base policy decisions on these recommendations.

### Assessing the medical usage of substances

The campaign against the non-medical consumption of controlled substances, which was waged

**Figure 1. Classification of drugs: Levels of control vs. levels of harm<sup>5</sup>**



through much of the 20<sup>th</sup> century, has resulted in a bias against the supply of controlled substances for medical purposes, demonstrating once more the imbalance within the international system and in many countries' domestic policy contexts.

At the 58<sup>th</sup> Session of the Commission on Narcotic Drugs (CND) in March 2015, it was proposed that ketamine be controlled under schedule IV of the 1971 UN Convention on Psychotropic Substances.<sup>6</sup> This move was motivated by the expansion in the recreational use of ketamine, particularly in China and South East Asia, and increases in associated harms such as ketamine bladder syndrome, and patterns of dependence that had not previously been seen among populations using the substance for recreational purposes. A campaign by medical and clinical professionals, drug policy NGOs and some

governments was initiated to resist the proposal to schedule ketamine, because the substance is a vital anaesthetic in both human and animal medicine, particularly in rural districts of low and middle income countries. The restriction on ketamine stemming from international control would probably not adversely affect wealthy countries, but developing states would lack the economic, administrative and technical resources necessary to meet the requirements of international drug control – even if the substance were included in the least restrictive schedule IV of the 1971 Convention.<sup>7</sup> For these developing countries, it would be much cheaper and simpler to effectively ban the substance altogether. Valium and Phenobarbital represent equivalent cases, and are extremely difficult to obtain in rural Asia and Africa, despite being classified under schedule IV of the 1971 Convention.

## Box 1 The UK and the Dutch approaches to khat

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>8</sup>

Another report was requested, from the Trimbos Institute, to look into the social impact of khat in the Somali migrant community, stories of public nuisance in some cities around the khat trade and 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 Dutch government sent the Trimbos study to the parliament with the announcement that it had decided to put khat on List II, despite neither the Trimbos report nor the CAM making such a recommendation.<sup>9</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’.<sup>10</sup> However, UK Home Secretary Theresa May decided six months later to ban it, saying the risks posed might have been underestimated.<sup>11</sup>

In November 2013, 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 the UK becoming a regional hub for illegal onward trafficking to those countries.<sup>12</sup> The ban took effect on 24<sup>th</sup> June 2014.<sup>13</sup>

At the 2015 CND, the proposal to schedule ketamine was deferred owing to the controversy over its effect on the availability of this important anaesthetic. However, the proposal is likely to return at the next CND session. The WHO, which has the mandate to recommend on scheduling within the international regime, has critically reviewed the substance four times and found that it does not need to come under international control. Furthermore, the WHO has stated that the scheduling of ketamine would constitute a ‘public health crisis’.<sup>14</sup> The WHO position recognised that there are far more effective ways than scheduling to address the harms associated with ketamine use while avoiding restrictions in access for this vital anaesthetic substance.<sup>15</sup>

The controversy of the scheduling status of ketamine, which is on the WHO’s Model List Of Essential Medicines,<sup>16</sup> goes beyond the particular substance. If the UN drug control system is to meet its

rhetorical claims to be a more health- and human rights-focused regime, it needs to demonstrate its new orientation by shifting the balance toward medical applications in the field of scheduling, as well as listening to the advice of its expert committee. Individual countries should take similar steps to assign proper importance to the medical and therapeutic capacities of substances proposed for scheduling.

### Implementation issues involved

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 both at national levels and in the international, UN-administered system. The following case studies, on cannabis, khat

and new psychoactive substances (NPS), illustrate these frictions. A similar case on the coca leaf is discussed in Chapter 4.3.

### Scheduling controversies around cannabis

This has been particularly the case for discussions around the scheduling of cannabis. For example, the UK's Misuse of Drugs Act 1971 established the Advisory Council for the Misuse of Drugs (ACMD) – an independent expert scientific group which advises the government on scheduling matters.<sup>17</sup> In 2007, when cannabis had been re-scheduled as a 'Class C' drug (the least harmful category) under the 2001 Misuse of Drugs Regulation, the government requested the ACMD to review this classification based on reports of severe mental health effects from high-strength 'skunk' preparations of the substance. The government wished to return cannabis to its earlier 'Class B' classification, but after extensive review the ACMD recommended that the drug remain in 'Class C'.<sup>18</sup> Nevertheless, in 2008, cannabis was re-scheduled as a 'Class B' substance.

Then, in February 2009, the UK government once more rejected an ACMD recommendation, this time that ecstasy be downgraded from 'Class A' to 'Class B'. The government's justification for this decision at the time was: '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>19</sup>

The UK government is legally entitled to reject the ACMD recommendations, as the statutory framework only requires conscientious consultation by the government with the ACMD on classification decisions, not that its recommendations be followed. However, relations between the government and the ACMD, and parts of the scientific community more generally, became further strained following the sacking of the ACMD Chair, Professor David Nutt, over his views on the relative safety of ecstasy and cannabis compared to alcohol and tobacco.<sup>20</sup> 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>21</sup> A total of six members of the ACMD resigned over the sacking and the issues it raised. Later in 2010, the UK government once again discarded the ACMD recommendations when it announced its ban on mephedrone.

### Scheduling controversies around khat

Khat – a plant with leaves that are chewed for their mild stimulant properties – 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 the substance has appeared on the international agenda repeatedly since then. 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

Credit: Creative Commons Eestl



Khat leaves

## Box 2 The European Union's approach to NPS

In Europe, the first formal action to respond to the growing problem of NPS was the creation, in 2005, of the EU 'Early Warning System' and structures that went with it. Through this, EU 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, EMCDDA), and a decision made on whether or not to recommend the substance for control measures. In practice, this process was only fully used in a small number of substances.<sup>22</sup> Furthermore, in most cases it took a long time and considerable resources to produce a recommendation. This naturally led to concerns about how the process could respond to the growing number of substances coming onto the market. As a result, the European Commission (EC or Commission) initiated a process to evaluate the existing early warning mechanism. 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 EC published its assessment,<sup>23</sup> concluding that there were three major shortcomings when it came to submitting NPS to Europe-wide control measures. First, the existing system was 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 were quickly replaced with new ones with similar effects, often through small modifications of their chemical composition. And third, it lacked 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 consultation process to propose to EU member states a mechanism to replace a system that was deemed 'no longer fit for purpose'.<sup>24</sup>

The Commission's proposal aims to speed up the 'Union's ability to fight'<sup>25</sup> NPS by providing for:

- **A quicker procedure:** It currently takes a minimum of two years to ban a substance in

the EU. Under the new structure, the EU 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. 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>26</sup> It is hoped that the new system will allow the EU 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>27</sup>

The proposal now needs 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 no universal agreement on the issue.<sup>28</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>29</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.

### Box 3 New Zealand's Psychoactive Substances Act

On the other side of the planet, New Zealand was faced with a flood of NPS that lay beyond the scope of existing drug control legislation.<sup>30</sup> New Zealand passed what appeared to be the ground-breaking Psychoactive Substances Bill in July 2013.<sup>31</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 poses a 'low risk' before it can be sold. To this end, it established a Psychoactive Substances Regulatory Authority within the Ministry of Health, responsible for ensuring that products met appropriate safety standards before they could be distributed in New Zealand.

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>32</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 the level of risk away from the government and placed it with manufacturers, authorities re-

tained oversight by being able to quickly remove 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.

Under the Act, 41 of the lowest-risk substances were assigned temporary approval; however, 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 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 into the hands of criminals.

the plant material. This is the main reason why fresh khat leaves are preferred by chewers. Dried leaves, which contain much lower levels of cathinone, are more often used to make tea, known as Abyssinian or Arabian tea.

Cathinone and cathine are alkaloids with similar effects on the central nervous system to those of amphetamine, though less potent. In the early 1980s, all amphetamine-type stimulants (ATS) have been placed as a group under international control. Cathinone and cathine were, based on a 1985 recommendation of the WHO Expert Committee on Drug Dependence (ECDD), added to the list of controlled substances of the 1971 UN Convention

on Psychotropic Substances, respectively to Schedules I and III.<sup>33</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 amphetamines.

The WHO ECDD 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>34</sup>

### Scheduling controversies around new psychoactive substances

By December 2014, the United Nations Office on Drugs and Crime (UNODC) had received notice of 541 different NPS, compared to just 126 in 2009. This proliferating class of drugs has resulted in panic among many national governments, and put immense strain on the traditional methods of review and classification that take place prior to scheduling. NPS can be developed extremely rapidly, and are often marketed via the internet and social networks. Once one substance is scheduled, chemical variations of it can often be produced and marketed which are not covered under the scheduling decision, and therefore circumvent the law. It is problematic – and often impossible – for governments and law enforcement agencies to keep up. A number of new approaches have therefore been attempted, in particular at EU level (see Box 2) and in New Zealand (see Box 3).

### Key resources

- Advisory Council on the Misuse of Drugs (2013), *Khat: A review of its potential harms to the individual and communities in the UK*, [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/144120/report-2013.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/144120/report-2013.pdf)

- European Monitoring Centre on Drugs and Drug Addiction (2015), *Legal approaches to controlling new psychoactive substances*, <http://www.emcdda.europa.eu/topics/pods/controlling-new-psychoactive-substances>
- Hallam, C. Bewley-Taylor, D. & Jelsma, M. (2014), *Scheduling in the international drug control system* (International Drug Policy Consortium & Transnational Institute), <http://idpc.net/publications/2014/06/scheduling-in-the-international-drug-control-system>
- Scholten, W. (2014), *Factsheet on the proposal to discuss international scheduling of ketamine at the 58<sup>th</sup> CND*, <http://idpc.net/publications/2015/01/fact-sheet-on-the-proposal-to-discuss-international-scheduling-of-ketamine-at-the-58th-cnd>
- McCullough, Wood, J. & Zorn, R. (September 2013), *New Zealand's psychoactive substances legislation* (London: International Drug Policy Consortium & New Zealand Drug Foundation), <http://idpc.net/publications/2013/09/idpc-briefing-paper-new-zealand-s-psychoactive-substances-legislation>

Credit: Jessamine Bartley-Matthews, WOLA



Cannabis at a Colorado dispensary