

Fact Sheet on the Proposal to Discuss International Scheduling of Ketamine at the 59th CND (March 2016)

Introduction

Ketamine is an essential medicine used for anaesthesia. It is the only available anaesthetic for essential surgery in most rural areas of developing countries, home to more than 2 billion of the world's people. Scheduling ketamine will leave these populations with no alternative anaesthesia for essential surgery, and will further deepen the already acute crisis of global surgery.

Last year, in its 58th session, the Commission on Narcotic Drugs (CND) was asked to review a proposal to place ketamine in Schedule IV (initially proposed to be Schedule I) of the 1971 *Convention on Psychotropic Substances* ([E/CN.7/2015/CRP.5](#) and [E/CN.7/2015/7](#)). A wide range of national and international civil society organizations, including medical associations, such as those endorsing this fact sheet, have voiced concern about the proposal. Recognizing these concerns, the 58th Session of the CND voted to defer the vote on placing ketamine under international control. While this was an important development, concern remains that at subsequent sessions, attempts may once more be made to place ketamine under international control, with the potential to again threaten access to safe anesthetic and surgical care for billions of people.

As per the terms of the 1971 Convention, the WHO Expert Committee on Drug Dependence (ECDD) critically evaluated ketamine in 2006, 2012 and 2014 and updated the 2014 review in November 2015. Based on accumulated evidence and data on non-medical use, diversion and trafficking, and evidence of ketamine's therapeutic value, the ECDD has consistently recommended against placing ketamine under international control, and in November 2015 emphasized that doing so could generate a "public health crisis" in developing countries where ketamine is the anesthetic of necessity.¹

This basic fact sheet provides compelling legal, medical and social arguments against placing ketamine in any schedule of the 1971 Convention. Section I covers definitions and substantive issues; Section II, procedural issues. Section III provides a resource list for further reading.

For any questions on this fact sheet, please contact Dr. Jason Nickerson (jason@jasonnickerson.ca).

Section I: substantive issues

What is ketamine? And how important is ketamine in human and veterinary medicine?

Ketamine is a medication used as an anaesthetic in human and veterinary medicine. Because it is readily available, easy to use and inexpensive, ketamine is one of the most commonly used anaesthetic agents in developing countries. It is also used recreationally in some countries as a "party drug." The World Health Organization considers ketamine an "essential medicine" and does not recommend scheduling it under the international substance control conventions. The Secretariat of the WHO Executive Board, writing in support of World Health Assembly resolution 68.15 to strengthen emergency and essential surgical care and anesthesia as a component of universal health coverage, noted that ketamine must be accessible in all facilities where anaesthesia is needed, in order to ensure safe and affordable surgical care.²

¹ http://www.who.int/medicines/access/controlled-substances/recommends_against_ick/en/

² http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_31-en.pdf

Ketamine is also the primary anaesthetic used in veterinary practice. Scheduling ketamine would restrict access and lead to losses in the agricultural economy.

How harmful is non-medical use of ketamine?

The non-medical use of ketamine has limited harmful effects. After a notification by China suggesting that ketamine be placed in Schedule I of the 1971 Convention, the ECDD critically reviewed it in 2014, and updated this review in 2015. The ECDD considered peer reviewed reports and data regarding ketamine's recreational use in some urban areas, the likelihood of its potential to cause dependence if used non-medically, epidemiological evidence of morbidity and mortality rates, as well as records of police seizures of illicit supplies. After weighing all the reports, this international expert panel concluded that "ketamine abuse currently does not appear to pose a sufficient public health risk of global scale to warrant scheduling" and recommended that "ketamine not be placed under international control at this time".² The World Health Organization has now reviewed ketamine four times since 2006, and has consistently recommended against scheduling for this reason.

Why does the WHO ECDD recommend against international control of ketamine?

Further to the above, the ECDD considered evidence submitted from all over the world that ketamine is widely used as an anaesthetic in human and veterinary medicine, especially in low- and middle-income countries, as well as in emergency situations. Ketamine is easily administered by trained providers. Compared to anaesthetic gases, which require costly equipment and appropriately trained specialists, it is inexpensive and safe to administer. Recent peer-reviewed evidence has confirmed this safety profile.³ Since many countries have no appropriate or affordable alternatives, scheduling ketamine would force patients in those regions to forego lifesaving essential surgery, further compromising realization of the health-related Sustainable Development Goals.

What would be the public health impact of a placing ketamine in Schedule I?

Under the terms of the 1971 Convention, medicines in Schedule I have "very limited medical usefulness". Parties to the Convention are obliged to prohibit any medical use of a Schedule I substance except by "persons directly under control of the government," and even use for and by those persons is very restricted (Art. 7). Providers in non-government institutions and clinicians in remote areas, especially in resource poor settings, will be unable to use ketamine if it is placed in Schedule I.

The control stipulated for Schedule I substances would be wholly inappropriate for ketamine, given its critical use in developing countries and in zones of armed conflict where high-tech resources, labs, operating rooms etc. are unavailable. People living in rural areas of low-resource countries will not have access to essential surgery if ketamine is less available, or completely unavailable. International restrictions could potentially affect the health of an estimated 2 billion or more people, living mainly in Africa, Asia and Latin-America.

What about placing ketamine in another schedule?

The WHO ECDD recommended against placing ketamine in any schedule. Hypothetically, however, placing ketamine in any other schedule (including Schedule IV, as was proposed in 2015) would also limit its availability and accessibility, both of which are mandatory criteria for essential medicines. The cumulative evidence from over fifty years of international drug control shows that restrictive regulatory requirements imposed by scheduling essential medicines create costly burdens for low resource countries. Strict scheduling requirements result in decreased clinical use or abandonment altogether.⁴ In the words of the 1971 Convention, "the use of psychotropic substances for medical and scientific purposes is indispensable and [...] their availability for such purposes should not be unduly restricted".

³ Burke T, Manglani Y, Altawil Z, Dickson A, Clark R, Okelo S, et al. A Safe-Anesthesia Innovation for Emergency and Life-Improving Surgeries When no Anesthetist is Available: A Descriptive Review of 193 Consecutive Surgeries. *World J Surg.* 2015 Sep;39(9):2147–52.

⁴ See 10 in "Further Reading", below, for low availability of morphine in a majority of countries.

Is there a way to limit misuse and diversion of ketamine?

Ketamine is difficult to synthesize and does not lend itself to large scale illicit manufacture. UNODC reports that China is the source of much of the world's illicitly consumed ketamine, which has either been diverted from legitimate pharmaceutical manufacture, or illicitly produced and then domestically or internationally trafficked.⁵ The NGOs endorsing this letter call on the government of China to take the necessary steps to prevent the diversion, illicit manufacture and export of ketamine beyond its national frontiers, rather than to promote international scheduling.

Section II. Procedural Issues

Can the 59th CND decide to schedule ketamine under the 1971 Convention?

Article 2, paragraph 5, of the 1971 Convention states that the Commission may add a substance to a schedule only following an explicit WHO recommendation to do so. As per the official Commentary to the Convention (p. 46): “the phrase ‘recommendations on control measures,’ means ‘recommendations on the schedule in which the substance in question should be placed’”. Since the WHO recommended in 2014 and 2015 that ketamine not be placed in any of the schedules, there is no extant recommendation that could legally serve as the basis of a scheduling decision by the CND.

Under these circumstances, placing a scheduling proposal for ketamine on the CND agenda would contravene the terms of the 1971 Convention.

Can the CND disregard a WHO recommendation to schedule or not to schedule a substance?

No. As discussed above, the CND can consider scheduling a substance only if the WHO has recommended that the substance be placed in a schedule. In such a case, State Parties can select a schedule other than the schedule recommended by WHO based on relevant economic, social, administrative or other factors. Article 2, paragraph 5 of the 1971 Convention states, however, that the WHO’s medical and scientific determination is final.

Notifications by Parties to the Convention are not a basis for CND decision making about including substances in the treaty schedules. Regarding medical and scientific aspects, these notifications can only serve to inform other Parties, the CND, and WHO for the purposes of their evaluative process.

Following notifications by State Parties, CND can only decide to take provisional control measures, while awaiting the recommendation of the WHO. But in the case of ketamine, since WHO already issued its recommendation, the option of a provisional control measure no longer applies.

How does the continuing pressure on WHO affect its ability to fulfil its mandate under the international substance control conventions?

Following requests from China, the International Narcotics Control Board and others, the World Health Organization’s ECDD reviewed ketamine in 2006, 2012 and 2014, each time concluding that scheduling is not warranted. Ketamine’s medical importance has been well documented, while evidence of its harmful properties is limited. Performing additional reviews in the near future would be inefficient and costly. WHO is also under pressure to evaluate a large number of New Psychoactive Substances (NPS) and to re-evaluate several scheduled substances it had evaluated in the distant past. WHO’s substance evaluation mandate gives it a critical role in safeguarding global health. The ability to fulfil this mandate is dependent on the States Parties and UN bodies abiding by the conventions – in this case, following the WHO’s expert recommendations.

The undersigned organizations support WHO’s work and urge States Parties to the substance control conventions to accept the ECDD recommendations on ketamine and abide by the procedural rules of the 1971 Convention.

⁵ http://www.unodc.org/documents/southeastasiaandpacific/2014/05/gsda/2014_Global_Synthetic_Drugs_Assessment_embargoed_Tokyo_web.pdf

Section III: Further reading and links to evidence based resources

1. United Nations. Convention on Psychotropic Substances. New York: United Nations, 1971.
<http://www.unodc.org/unodc/en/treaties/psychotropics.html>
2. United Nations. Commentary on the Convention on Psychotropic Substances. Vienna: United Nations, 1971.
http://www.unodc.org/documents/treaties/organized_crime/Drug%20Convention/Commentary_on_the_Convention_1971.pdf
3. Expert Committee on Drug Dependence, Thirty-sixth Meeting. Ketamine Update Review Report, Agenda item 6.2. Geneva, 16-20 June 2014. http://www.who.int/medicines/areas/quality_safety/6_2_Update.pdf
4. Untreated surgical disease. <http://worldsurgicalassociation.org/burden-of-surgical-disease/>
5. CND Scheduling procedures:
https://www.unodc.org/unodc/commissions/CND/Mandate_Functions/Mandate-and-Functions_Scheduling.html
6. WHO Essential Medicines list: <http://www.who.int/medicines/publications/essentialmedicines/en/>
7. Executive Summary of 2014 WHO Expert Committee on Drug Dependence Meeting
http://apps.who.int/gb/ebwha/pdf_files/EB136/B136_48-en.pdf
8. ECDD Technical Reports on ketamine:
 - a. 36th meeting: http://www.who.int/medicines/areas/quality_safety/36thecddmeet/en/index5.html
 - b. 35th meeting: http://www.who.int/medicines/areas/quality_safety/35thecddmeet/en/
 - c. 34th meeting: http://www.who.int/medicines/areas/quality_safety/34thecddmeet/en/
9. 2014 World Drug Report UNODC (ketamine misuse is “stabilizing” or “declining”)
https://www.unodc.org/documents/wdr2014/World_Drug_Report_2014_web.pdf
10. World Health Organization. Ensuring balance in national policies on controlled substances: guidance for availability and accessibility of controlled medicines. Geneva 2010.
http://www.who.int/medicines/areas/quality_safety/guide_nocp_sanend/en/