

Extended Fact Sheet on ketamine scheduling

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To be read in combination with the Fact Sheet on the Proposal to Discuss International Scheduling of Ketamine at the 58th CND (available at the IDHDP web site idhdp.com: <http://bit.ly/1ETsgr5>)

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. Placing ketamine in *any* schedule of the Convention on Psychotropic Substances will leave these populations with no alternative anaesthesia for essential surgery, and will further deepen the already acute global crisis of surgery.

The Commission on Narcotic Drugs, 58th Session, has been asked to review a proposal to place ketamine in Schedule I of the 1971 Convention. This has been addressed already in the Fact Sheet mentioned above, which has received 57 endorsements by 27 February 2015. However, since the Fact Sheet was published, national representatives raised other questions and endorsing organizations provided additional data. This Extended Fact addresses those questions and provides additional data.

Regulatory Aspects of Ketamine Scheduling

International law

All states are obliged to realizing the Right to the Highest Attainable Standard of Health, as described in article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), to which many countries are signatories. Others acquired this obligation through adhering to the Constitution of the World Health Organization and/or to other human rights conventions. The Commission on Economic, Social and Cultural Rights (CECSR) in its authoritative General Comment 14 (GC14) stipulates the Right to Health.

GC14 obliges parties to the convention to make essential medicines available to their populations (paragraph 12(a)). States are under the obligation to respect the Right to Health by, inter alia, refraining from denying or limiting equal access for all persons (paragraph 34). State parties are responsible for promoting the realization of the Right to Health in other countries. In relation to the conclusion of other international agreements, States parties should take steps to ensure that these instruments do not adversely impact upon the right to health. Similarly, parties have an obligation to ensure that their actions as members of international organizations take due account of the Right to Health (paragraph 39).

Alternative to applying the substance control legislation

Not placing ketamine in any of the schedules of national substance control legislation does not mean that it will be completely unregulated. Normally, countries have pharmaceutical legislation that identify substances like ketamine as prescription-only medicines, e.g. because it is an injectable or

because it is an anaesthetic. States should enforce the pharmaceutical legislation they already have on the books to prevent availability of ketamine for non-medical/non-veterinary use.

Procedural Aspects of ketamine scheduling

The preparations by the CND Secretariat and the recent CND Intersessional Meetings regarding a decision on scheduling ketamine are problematic from the procedural perspective. The decision to put the Chinese proposal to a vote contravenes the scheduling procedures set out in the 1971 Convention. This Convention requires that the World Health Organization (WHO) explicitly recommended that a substance be placed in a schedule before CND can act. The official Commentary to the Convention (Number 22 on page 71) reads that if WHO communicates that "a substance does not have the dangerous properties [..required for scheduling and..] expressly or impliedly recommends [...] that the substance should not be controlled, the Commission would not be authorized to place it under control. Doing so would be incompatible with the provision that the WHO assessment should be 'determinative as to medical and scientific matters', and also with the basic assumptions of the authors of the Vienna Convention which is intended to deal only with problems arising from the abuse of the substances which have dangerous qualities as defined [above]". Since WHO has clearly concluded that the dangerous qualities of ketamine do not warrant its scheduling, the provisions and guidance of the 1971 Convention prohibit the CND from even considering a decision to schedule ketamine, let alone taking a vote in favor of such scheduling. Thus, the mere placement of the topic on the agenda as an item to be voted on is a violation of the Convention.

This question has been addressed by a Legal Opinion of the Office of Legal Affairs (OLA) of the United Nations. In its Legal Opinion, the OLA concluded the opposite. However, in its analysis which led to this opinion (annexed to the Legal Opinion), it did not comprehensively include the Commentary for consideration, took selectively only one paragraph, and omitted and/or overlooked the most compelling argument from the Commentary. For this reason the OLA conclusion is erroneous.

Moreover, the Preamble of the Psychotropic Substances Convention, expresses concern about the "health and welfare of mankind". Through the Preamble, the Parties to the convention express their intention "to prevent and combat abuse of such substances and the illicit traffic to which it gives rise", while "recognizing that the use of psychotropic substances for medical and scientific purposes is indispensable and that their availability for such purposes should not be unduly restricted." However, the OLA failed to mention and consider this dual enabling principle of the Convention.

Consequences of listing ketamine in Schedule III or Schedule IV

A possible compromise of placing ketamine in a schedule with lighter restrictions than Schedule I is not a solution to disagreement on scheduling between CND Member States. Despite the fact that the restrictions for Schedule IV substances theoretically allow ready access to the medicines made from these substances, Article 23 of the Psychotropic Substances Conventions allows countries to apply stricter rules than those the convention demands, and many countries automatically do so.

There are few national scheduling systems which do have eight schedules altogether like the 1961 and 1971 Conventions have. Usually, countries aggregate their lists; some jurisdictions have only two schedules. Obviously in such cases, the nuances of control intended by international scheduling are lost, and it is easy for the practical outcome in country settings to be more restrictive than is appropriate for substances.

Case in Point: Phenobarbital

In practice, many countries restrict access to phenobarbital. Phenobarbital is an anti-epileptic medicine already in Schedule IV of the 1971 Convention and a first choice option for the treatment of epilepsy, particularly in resource-poor settings, in view of its efficacy and cost profile. Phenobarbital is the only medicine listed in national Essential Medicines Lists in many of the low income countries (LICs). Yet, approximately 80% of people with epilepsy do not receive appropriate treatment in LICs. If the Commission votes to place ketamine in Schedule IV of the drug control conventions, the same thing will happen with ketamine in these countries when they apply their set of rules for Schedule IV substances to it. If placed in Schedule III, it may be expected that this will affect ketamine availability even more.

Uses of ketamine

Ketamine is widely used for anaesthesia around the world and allows surgical procedures to take place in remote places where power supply is unreliable and when no oxygen flasks and/or equipment for lung ventilation and/or patient monitoring equipment are available. In these cases, anaesthesia with inhalants is impossible.

Furthermore, it is also the anaesthetic of choice for emergencies and in disaster relief, both in developing and industrialized countries, and it is often used off-label as an analgesic. Experimentally there is evidence that it is effective as an anti-depressant.

Moreover, being it the main stay of veterinary medicine and wild-life conservation, restricted availability of ketamine will have economic consequences for agricultural production, even in industrialized countries. Since veterinarians can administer ketamine by dart-gun injection, it contributes to professional safety when an dangerous animal needs to be approached. Without ketamine there would be huge difficulties in managing many field programmes in conservation medicine e.g. blood sampling and radio-tracking collar attachment.