Advocacy note

October 2018

Contribution to the 41st WHO Expert Committee on Drug Dependence: IDPC recommendations on cannabis and tramadol

Introduction

The Expert Committee on Drug Dependence (ECDD) of the World Health Organization (WHO) will hold its 41st Meeting in Geneva on 12th to 16th November 2018. The ECDD is the body mandated by the Single Convention on Narcotic Drugs of 1961 and the UN Convention on Psychotropic Drugs of 1971 to conduct scientific reviews of substances with a view to understanding their public health risks and therapeutic uses, and to recommend their assignment to the appropriate schedule within the international drug control conventions.[1]

In the context of the proliferation of new psychoactive substances, the principle of scientific review is of special significance. Many governments are presently subject to anxieties that can drive the process of scheduling – not on an evidential basis, but a political and ideological one. This gives an added importance to the Expert Committee, that of ensuring its recommendations are made on the basis of scientific evidence, as per its mandate and despite political pressures.[2] The significance of this role is underscored by the UNGASS Outcome Document of 2016, which devotes an entire chapter to the issue of access to controlled medicines.[3] Among a broad collection of substances subject to critical review at the 41st ECDD meeting,[4] an especially important medicine is included: tramadol, which is currently not under international control.[5] Certain countries have called for tramadol to be placed under international control, in particular, Egypt, which submitted a conference room paper on the issue to the 60th Session of the Commission on Narcotic Drugs.[6]

In the meantime, discussions around the scheduling of cannabis at national and global levels have accelerated over the past few years, while more and more countries are adopting medicinal cannabis schemes. For the first time in the history of the current international drug control regime, a critical review of cannabis and its derivatives is also planned for the 41st ECDD meeting.

This IDPC advocacy note will provide recommendations on both tramadol and cannabis, with the hope that it will inform the discussions of the Expert Committee for its meeting in November.

The critical review of Tramadol

Characteristics and uses of tramadol

Tramadol is a centrally acting analgesic with an opioid effect when administered orally; it is calculated to have approximately one tenth the analgesic potency of morphine, though when used at high doses, it can produce a euphoria similar to that of oxycodone.[7] Side effects including itching, nausea and constipation have been reported, while serious side-effects can comprise seizures, serotonin syndrome, decreased alertness and dependence. Despite this, tramadol is widely conceived to carry low potential for dependence when compared to morphine, and withdrawal symptoms are comparatively mild.[8] Fatal over-

dose is rare and is usually the result of combination with other drugs.

Tramadol is used to relieve moderate to moderately severe pain in both acute and chronic instances. Its use is authorised in over 100 countries, where it is generally available as a prescription medicine.[9] While not listed on the WHO Model List of Essential Medicines, several national jurisdictions include it in their own listings and it is widely regarded by medical practitioners as an important component in the therapeutic toolkit. Its efficacy has been shown in post-operative pain, dental pain, pain due to trauma, abdominal pain, labour pain, as well as cancer pain, pain due to osteoarthritis, chronic low back pain, neuropathic pain, and fibromyalgia. It has also been employed in the treatment of opioid dependence. As discussed below, tramadol is often the only analgesic available for those suffering moderate to moderately severe pain, particularly in the developing world.

Previous ECDD reviews of tramadol

The ECDD has reviewed tramadol six times previously: in 1992, 2000, 2002, 2006, 2014 and 2017. In 2017, the ECDD conducted a pre-review of the substance.

The reviews of tramadol have grown in severity of reported risk since the first pre-review in 1992, which concluded that, 'On the basis of its low abuse liability, tramadol was not recommended by the Committee for critical review'.[10] In the next review, in 2000, the Expert Committee shifted its position, recommending a critical review. The ensuing critical review of 2002 concluded that there was insufficient data to recommended that tramadol be placed under international control, but did recommend that the substance be kept under surveillance.[11] The pre-review of 2014 found, once again, that on the basis of evidence related to 'dependence, abuse and risks to public health, the Committee recommended that a critical review of tramadol is not warranted at this time'.[12] The pre-review of the 39th Expert Committee meeting in 2017 recommended that the process moved to critical review,[13] which will be undertaken at the 41st ECDD in November 2018.

Illicit use of tramadol

The main producers of illicit tramadol appear to be India and China. There is growing evidence of the illicit use of the substance in North and West Africa, including Egypt, Gaza, Jordan, Lebanon, Libya, Mauritius, Saudi Arabia, Cote d'Ivoire, Nigeria, Benin, Ghana and Togo.[14] In much of West Africa, the substance is bought illicitly, but is actually for medical purposes, as many of the developing countries where the drug is used currently lack legal availability sufficient to meet medical demand through established healthcare systems.[15]

Recommendations on the question of international control

The issue of the non-medical and self-medication consumption of tramadol is a complex one which will not be resolved resolved by scheduling tramadol under the international drug control conventions. International control has been shown to reduce availability and access to medicines in developing countries[16] and therefore, even if scheduling were to reduce the public health problem associated with non-medical use, it is liable to generate concurrent public health costs in the form of untreated pain in developing countries – especially in those where tramadol is one of few, or the only, pain medication available. International control should not substitute one set of difficulties with another.

Moreover, the latest research from West Africa indicates that much of the non-medically used tramadol is impure, sometimes significantly so. Conversely, tramadol pills are also often produced with contents well in excess of standard clinical dosages – creating a different set of risks.[17] The problem associated with this substance is therefore likely to be centred on illicit manufacture rather than diversion – to be specific, on counterfeit and substandard medicinal products. These problems are unlikely to be positively impacted by the international drug control conventions, and may, in fact, be exacerbated.

What is needed is a more incisive international convention to address the problem of medicrime, the present medicrime convention being weak in its legal regulations.[18] In the absence of such an international instrument, however, IDPC respect-

fully advises the ECDD to recommend to CND that international control of the substance is presently unnecessary, and would be counter-productive in its effects on public health. We also advise the ECDD to recommend the expansion of healthcare services for problematic tramadol use in contexts where it does occur.

The critical review of cannabis

IDPC welcomes the long-overdue critical review of the cannabis plant and resin, extracts and tinctures of cannabis, Delta-9-THC and isomers of THC by the ECDD.[19] We also welcome the decision, by the ECDD, not to recommend the international scheduling of CBD.[20]

Assessing the harms of consumption and of drug policy

Historically, cannabis was last reviewed in 1935 under the League of Nations-administered system of the interwar period. The 1935 review was strongly biased by racial and cultural stereotypes and prejudices, and was scientifically questionable. In the more than 80 years since that 'review', the science and the standards for conducting a rigorous critical review have evolved significantly – and a scientific review of the latest evidence of the substance by the Expert Committee is therefore timely. It is, however, essential to acknowledge the legal and policy environment in which cannabis consumption and cannabis markets exist. The harms of a drug – to users and to the wider society – do not exist in isolation. The legal and policy environment, which may be significantly determined by the scheduling of a drug, can itself profoundly impact on the harms to the user and to the wider community. This is a concept that the WHO describes very clearly in its work on alcohol, and nicotine – but has been less prominent in its work on drugs controlled under the 1961 and 1971 conventions, which has tended to focus more narrowly on physical health harms.

Illustrating this distinction between drug use and drug policy harm, cannabis has long been the most widely used illegal drug in the world, and cannabis is also one of the substances most targeted by drug law enforcement efforts. In the United States, for instance, of the 8.2 million cannabis arrests between 2001 and 2010, 88% were for simple cannabis possession.[21] Punitive legal frameworks that criminalise people who use cannabis have caused enormous harm and suffering, especially for already disadvantaged populations and communities, in particular young people, ethnic minorities and the poor. These harms can no longer be ignored. Cannabis supplied via an unregulated illegal market is also intrinsically riskier – being of unknown potency, having an unknown ratio of THC to CBD, and also having no quality control in terms of adulterants, pesticides, or fungal contamination.

Considering evolutions in cannabis policy reform worldwide

In recognition of the harms being generated, or exacerbated, by the punitive approach to cannabis, policies around the world are currently undergoing rapid changes. This has included an accelerating growth in reforms to provide lawful access to cannabis for medical purposes. Today, 48 countries have adopted some form of medical cannabis access, reflecting increasing evidence of the benefits of cannabis-based medicines to treat a range of illnesses such as multiple sclerosis, epilepsy, or mitigating the side effects of chemotherapy.[22]

26 countries have also removed criminal sanctions for cannabis use or possession for personal use. These decisions have acknowledged that the evidence for a deterrent effect from criminalisation was weak, but the evidence of harm from mass criminalisation on the health and well-being of users was significant.[23] It is worth noting that ending the criminalisation of all people who use drugs is advocated across the UN system, including the WHO.[24]

Furthermore, since 2012, subnational and national jurisdictions have begun to legally regulate cannabis markets for non-medical or recreational use. So far, these have been established in nine US states,[25] as well as in Uruguay[26] and – since 17th October 2018 – Canada.[27]

Recommendations on the question of international control

Currently, cannabis is placed in Schedule I

(highly addictive and liable to abuse) and Schedule IV (that is, certain substances included in Schedule I that are rarely used in medical practice) of the 1961 Single Convention on Narcotic Drugs. Confusingly, its main psychoactive compound, delta-9-THC or dronabinol, is also placed in Schedule II of the 1971 Convention, and several of its isomers even in Schedule I. This level of classification impedes scientific research on the active components of the plant because of the administrative difficulties, security imperatives and high financial costs scientists are faced with to access these components for their research – hence severely limiting the amount of scientific literature on cannabis.[28]

The assigning of cannabis to Schedules I and IV of the 1961 Single Convention was not based on a WHO scientific assessment, and its inclusion in schedule IV is inappropriate at the present time, given the widespread medical use of the substance and its derivatives.[29] The imprecisions in the definitions of cannabis-related substances placed under international control, and the classification of its flowering tops, resin and extracts as 'narcotic drugs' but its active compounds as 'psychotropic substances', represent inconsistencies that both the ECDD and the INCB have pointed out before. We hope this 41st ECDD meeting, apart from discussing the critical review and pre-review reports, will also take time to reflect on the anomalies in the history of international cannabis control, and will recommend improvements with regards to the current definitions and division over the 1961 and 1971 conventions.

The 41st ECDD meeting is a key opportunity to address the confusion around cannabis, by conducting an objective review of the plant and its derivatives – far from political and ideological interference. By conducting such a review, the ECDD can also help to dismantle some of the myths associated with cannabis by collating all available scientific evidence on the effects – both positive and negative – of the plant and its derivatives. Crucially, the Committee should not ignore the profound impact of the legal and policy environment on cannabis-related harms and benefits to both users and the wider community – and should apply the same scientific rigor to considering policy impacts, as it does to pharmacological health risks.

Endnotes

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About this advocacy note

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About IDPC

The International Drug Policy Consortium is a global network of non-government organisations that specialise in issues related to illegal drug production and use. The Consortium aims to promote objective and open debate on the effectiveness, direction and content of drug policies at national and international level, and supports evidence-based policies that are effective in reducing drug-related harm. It produces briefing papers, disseminates the reports of its member organisations, and offers expert advice to policy makers and officials around the world.

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