WHO

Medical Usage of Drugs

INTRODUCTION TO THE COMMITTEE

WHO works worldwide to promote health, keep the world safe, and serve the vulnerable. Our goal is to ensure that a billion more people have universal health coverage, to protect a billion more people from health emergencies, and provide a further billion people with better health and well-being.

For universal health coverage, we:

- focus on primary health care to improve access to quality essential services
- work towards sustainable financing and financial protection
- improve access to essential medicines and health products
- train the health workforce and advise on labour policies
- support people's participation in national health policies
- improve monitoring, data and information.

For health emergencies, we:

- prepare for emergencies by identifying, mitigating and managing risks
- prevent emergencies and support development of tools necessary during outbreaks
- detect and respond to acute health emergencies
- support delivery of essential health services in fragile settings.

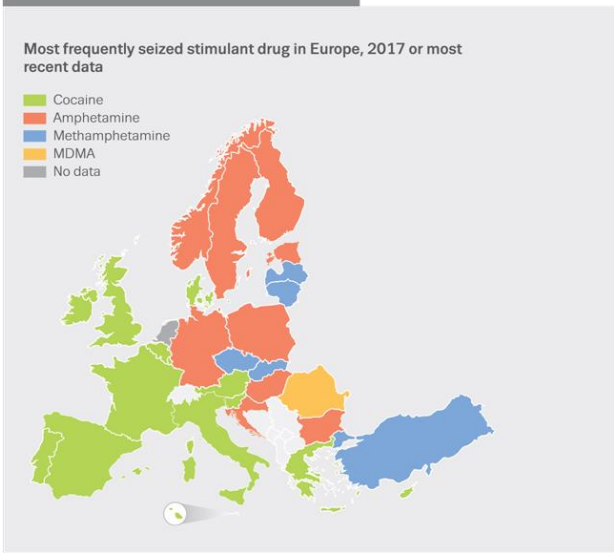
For health and well-being, we:

- address social determinants
- promote intersectoral approaches for health
- prioritize health in all policies and healthy settings.

Through our work, we address:

- human capital across the life-course
- noncommunicable diseases prevention
- mental health promotion
- climate change in small island developing states
- antimicrobial resistance
- elimination and eradication of high-impact communicable diseases.

FIGURE 1.5



Many drugs are made “illegal” in an attempt to reduce their availability and so their harms. This control occurs at both national and international levels—in the latter case, in the United Nations conventions that make a whole range of drugs from cannabis to heroin “illegal.” Many people are aware of the challenges to this system of control in terms of human rights abuses by those who seek to implement a prohibitionist approach to drug control, as well as the failure of, and massive collateral damage from, the “War on Drugs” that is currently being waged to stop drug use. Less well known are the perverse restrictions that these laws have had on pharmacology and therapeutics research. Here I will show how they have led to censoring of life science and medical research, with disastrous consequences that have lasted for more than 50 years and counting.

Recently additional controls have started to be developed, provoked by the fear of so-called “legal highs.” These are drugs that mimic the actions of controlled drugs but are of different chemical structures, so they fall outside the UN conventions or local laws. So, for example, the Republic of Ireland has now banned the sale of any chemical that might be used recreationally, a move that if enforced could stop all pharmaceutical research and development in the country. In the United States, city and state governments often move to outlaw novel drugs before the federal government believes it has sufficient evidence to make that determination. Some have been extreme in their lack of understanding of pharmacology. For example, a bill in Maryland would have outlawed any compound with any binding to any cannabinoid receptor, with no mention of thresholds for binding affinity, whether the ligand had agonist or antagonist efficacy, or whether actions at other receptor sites might moderate overall abuse potential.

This demonstrates a very extreme version of prohibition, in which molecular entities that have yet to exist are deemed Schedule 1, as if we had absolute ability to perfectly predict the activity of a novel chemical structure.

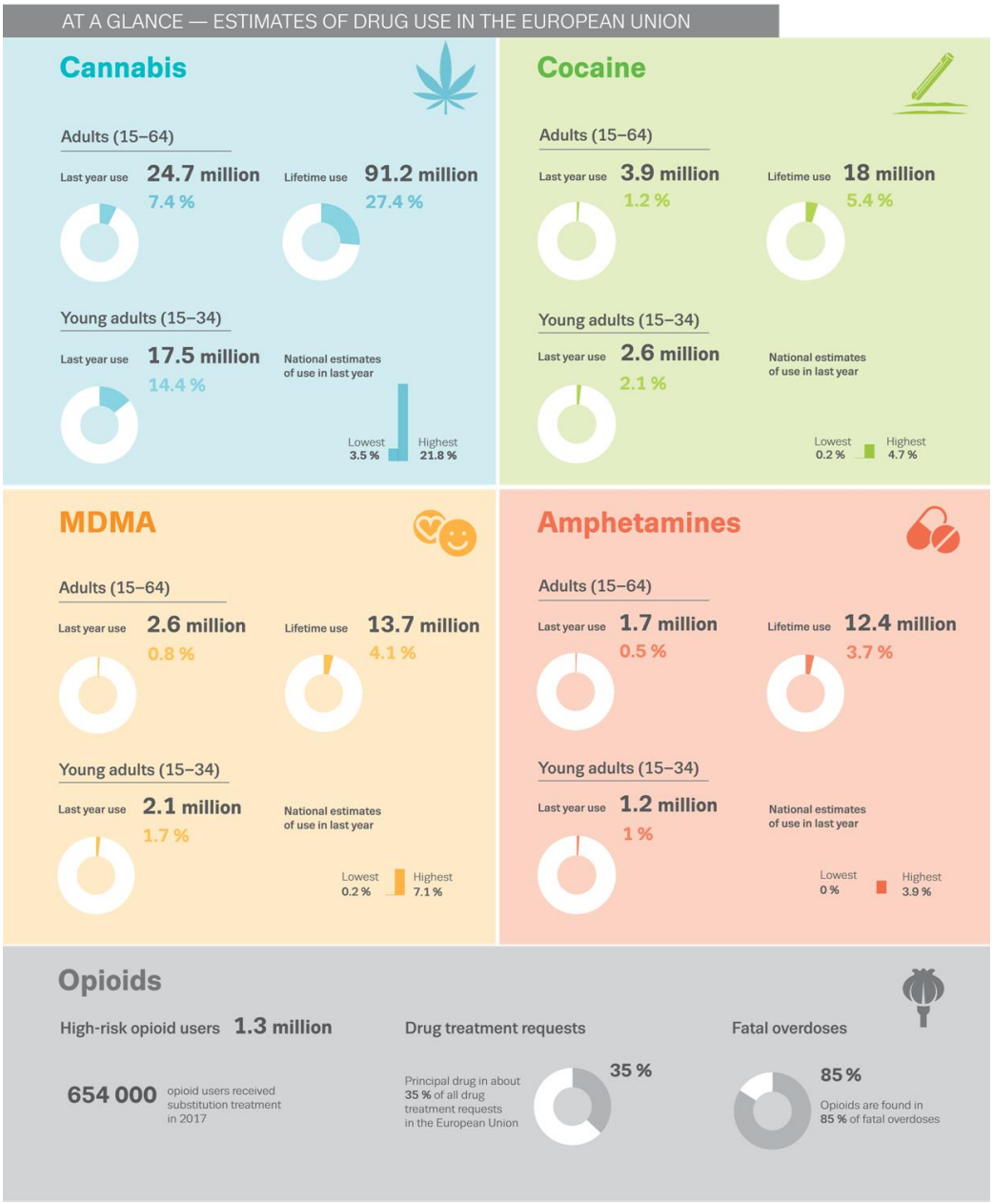


Table 1

The current status of drugs in the UN Conventions and UK and US drugs legislation.

Drug	**UN Conventions**	**UK Misuse of Drugs Act**	**US Controlled Substances Act**
Amphetamine/ methamphetamine	Schedule II	Schedule 2	Schedule II
Cannabis	Schedules I and IV	Schedule 1 In Sativex = 4	Schedule II
Cocaine	Schedule I	Schedule 2	Schedule II
DMT	Schedule I	Schedule 1	Schedule I
Heroin	Schedule I	Schedule 2	Schedule I
Ketamine	Not listed	Schedule 2	Schedule III
LSD	Schedule I	Schedule 1	Schedule I
MDMA	Schedule I	Schedule 1	Schedule I
Psilocybin	Schedule I	Schedule 1	Schedule I
D9THC (dronabinol)	Schedule II	Schedule 2	Schedule III

Drug Control Laws

Most national laws controlling "illegal" drugs are based on the UN Single Convention on Narcotic Drugs (1961) and the Convention on Psychotropic Substances (1971) that define a range of substances that are supposedly sufficiently harmful to be removed from the usual sales regulations They are made "illegal," which means that punishments are implemented for sale and, in most cases, possession. Some of these can be very severe; e.g., some countries have the death penalty for personal possession of heroin and other opioids.

The UN and US Schedules use roman numerals, whereas the UK uses Arabic numbers. DMT = dimethyltryptamine. MDMA = methylenedioxymethylamphetamine (ecstasy). LSD = lysergic acid. THC = tetrahydrocannabinol.

However, many "illegal" drugs have medicinal uses: for example, opioids for pain, amphetamines for narcolepsy and attention deficit hyperactivity disorder (ADHD), and even cocaine for local blood control and anesthesia in ear nose and throat (ENT) surgery. In most Western countries there is an attempt to make the medical use of these exempt from the legal controls that try to limit recreational use. So, in the United Kingdom and US, drugs such as morphine and amphetamine are exempted from the most severe controls that apply to non-medical drugs, such as crack cocaine and crystal meth. In practice this means that they are available from pharmacies and most universities can hold them for research purposes.

The problem for researchers comes from two sources: (1) the banning of certain medicines and (2) current regulations limiting the study of the medical potential of drugs, e.g. LSD, psilocybin, and MDMA, that are subject to the most stringent level of control.

The Banning of Certain Medicines

Many traditional medicines have been defined out of the pharmacopeia by international and national conventions. These include plant sources of DMT such as ayahausca and ibogaine, but the most obvious one is cannabis. Cannabis has been used medically for over 4,000 years, yet since the 1961 UN Single Convention on Narcotic Drugs, it has been defined as not having such value. As a result, cannabis is put into Schedule 1. Drugs located in Schedule 1 are subject to the most stringent level of control in most countries in the world (for a fuller description of these schedules and laws justifying them). This status means that researchers (both preclinical and clinical) require a special license to hold the drug. In the UK only four (out of many hundred) hospitals have such a license, though all can hold heroin, a much more harmful and sought-after drug by anyone's estimate, because heroin is in Schedule 2. These restrictions have meant that research on the medical uses of cannabis has hardly occurred in the past 50 years, despite substantial increase in knowledge of the many pharmacologically active components of the cannabis plant, many of which have medical potential. Moreover, what little research has taken place—such as the development of the cannabis oral spray Sativex—has been delayed by the question of what license it would be given (now in the UK, it is Schedule 4 despite being identical in pharmaceutical content to plant cannabis, which is still held in Schedule.

Similar controls apply in the US, where therapeutic studies on cannabis products have been hampered by intense regulations: in the US only three people hold Drug Enforcement Agency licences to research cannabis clinically. As a result, in many US states the population defied Federal laws and voted for the legalization of medical cannabis (with Colorado and Washington State making recreational use legal as well. In the UK sub-national democracy for health issues does not exist, so it is estimated that over 30,000 people use medical cannabis illegally, and many get arrested for doing so, particularly as, since 2005, self-medication with cannabis has been specifically excluded as a defense in UK law (despite the fact that it can still be pleaded as a defense for the use of any other "illegal" drug for self-medication)

How the Law Stops Innovation of New Medicine

Table 2 shows that many popular "illegal" drugs have plausible medical uses. Some of these come from studies that were conducted when they were legal. For instance, LSD was tested in six clinical trials for alcoholism before it was banned in the 1960s. A recent meta-analysis of these studies found an effect-size equal to that of any current treatment for this addiction. So why has the therapeutic potential of LSD not been developed for the past 50 years? The answer is that, because of its Schedule 1 status, research is almost impossible. Most hospitals are banned from holding it, as are many university research institutions. Getting a Schedule 1 license in the UK takes about a year and costs around £5,000, with £3,000 for the license and £2,000 for the other requirements such as extra security for the drug cabinets, police checks, etc.

What Is the Possible Solution?

This is remarkably simple; all that needs to happen is for each national government to redefine UN Schedule 1 drugs as Schedule 2 in their country. The governments would still be complying with the UN conventions (i.e., the drugs would still be "illegal"), but the drugs could be held by research establishments and hospitals alongside drugs currently in Schedule 2, e.g., opioids and stimulants. There would be no increased risk of diversion, but a significant easing of the regulatory burden for research. A more rational European approach to GMP production of research compounds for Phase I and II clinical trials would also make clinical research much easier without any significant risk to participants.

As we work towards lifting the ban on pharmacological innovation and research with current Schedule 1 drugs, it will be important to encourage and support the efforts of scientists to oppose harmful new legislation, such as blanket bans on chemical or pharmacological series. In the US, researchers have intervened in these political processes when city-based or state-based proposed legislation has threatened current or upcoming medical research projects.

Table 2

Demonstrated and potential medical uses of "illegal" drugs.

Drug	**Indications** *(Potential ones in italics)*
Cannabis	Pain, spasticity PTSD Cancer ADHD
LSD	Addiction Terminal anxiety
MDMA	PTSD ***Parkinson disease*** Brain trauma
Mephedrone	***Cocaine misuse***
Psilocybin	Cluster headaches OCD ***Depression*** Cancer-related depression Tobacco addiction Alcoholism

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