How to regulate Stimulants
A practical guide
Transform Drug Policy Foundation is a UK-based charity working internationally to promote drug policy reform. We want to create a world where drug policy promotes health, protects the vulnerable, and puts safety first. The legal regulation of drugs is essential to achieving these goals. Because drug policy affects people across society, we work with policy-makers, charities, services and advocates across the health, crime and social policy sectors. We also work directly with families and individuals who wish to change drug policy for the better.

For over two decades, we have argued that in order to end the war on drugs there is a need to develop practical, evidence-based policy alternatives. Our 2009 publication *After the War on Drugs: Blueprint for Regulation* set out, for the first time, what a comprehensive system of legal regulation might look like. Our book *How to Regulate Cannabis: A Practical Guide* has influenced advocates and policymakers across the globe. This new book, generously supported by over 200 donors, aims to move that debate forward into the area of stimulants.
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How to regulate stimulants
The debate on drugs can often be heated and polarising; yet, on one point at least, there is a growing consensus: the ‘war on drugs’ has failed. Global prohibition has not only failed to deter increasing use, it has resulted in more risky behaviours, more dangerous products and more devastating health harms. Far from creating a ‘drug free world’, prohibition has instead created a vast illegal market ruled by violence, corruption and insecurity. The heaviest burden of this policy failure adds to the already difficult conditions of the poorest and most marginalised communities, particularly in impoverished neighbourhoods and rural areas where illegal drug production and trafficking tends to concentrate.

We are already witnessing steady progress in drug policy and law reform in many parts of the world — but there is a great distance yet to travel. Harm reduction, decriminalisation and evidence-based treatment have made great strides in recent decades, but too many of the harms being addressed are caused by prohibition in the first instance.
The Global Commission on Drug Policy to which I belong, has been clear since its formation in 2011 that the status quo is untenable and reform is urgently needed. The world must move away from the failings of this ideologically-driven and criminalisation-led model and reorient decisively towards evidence-based policies rooted in the core values of public health, human rights, economic empowerment, quality education, social justice, and sustainable development.

As a first step, we must end the criminalisation of people who use drugs. Decriminalisation is happening in ever more countries across the world — and was unambiguously endorsed by 30 United Nations entities in their 2019 UN Common Position on Drugs agreed at the Secretary-General’s Chief Executives Board. Yet, while decriminalisation is a critical enabler of any meaningful health and decarceration response, it has little impact on illegal drug markets.

Punitive enforcement of unjust laws is ineffective and antithetical to social justice. We must ground our thinking in the reality that drug use is already widespread in society. Whether we like it or not, drug use is a reality which must be responsibly managed. We cannot wish away drugs — but we can make them and their modes of use safer. That, in turn, requires accepting that legally regulating adult-access markets for currently illegal drugs is the only way in which to mitigate the harms caused by the illegal market. We do not get to choose whether we live in a society with drugs or without them, but we do have a choice over whether and how the market is controlled.

As consensus grows that the ‘war on drugs’ has failed, so does the need for a frank exploration of the alternatives. We all have a responsibility to consider what might replace the status quo, and we need to think about how that applies to all drugs. A meaningful exploration of the regulation of stimulant drugs is a key part of that process.
Legalisation and regulation, particularly of drugs other than cannabis, however, remain challenging for many people. That is understandable. There are legitimate concerns, and difficult but important questions about the practicalities of regulation that need to be answered. That is precisely why we must address them head on, and why I am pleased to welcome this valuable new contribution from Transform Drug Policy Foundation. In this book, Transform outlines a set of clear working principles, and makes pragmatic proposals for the responsible regulation of a group of drugs, stimulants, which have too often been pushed to the margins of the policy debate despite their growing use and the continuing social and health challenges with which they are associated.

I share Transform’s view that there is no single regulatory solution – different approaches will be appropriate for different places, and different drugs depending on their risks. Transform does not claim that regulation is a silver bullet, but only that, if done responsibly, regulation can facilitate the dramatic improvement of the health and wellbeing of people who use drugs and of the wider community.

This book is an important and welcome contribution. It does not contain all the answers: no single publication ever could. It raises, however, many of the most important questions and points to a framework through which solutions may be found. It is essential that we begin a serious discussion on how we regulate stimulants. This book provides a powerful start. It is now up to all of us to take this discussion forward.
Why regulate stimulants?
If we agree that the ‘war on drugs’ has failed, then we need a vision of how to regulate drugs — including stimulants — after the war has ended.
Why regulate stimulants?

THERE HAVE BEEN DRAMATIC DEVELOPMENTS IN DRUG POLICY IN RECENT YEARS. The legal regulation of cannabis has gained momentum, and an increasing number of countries (including major world economies) have moved to allow adult, non-medical use. At the same time, we are seeing more research on the therapeutic uses of psychedelic drugs, leading to calls for change in their legal status. The global consensus on prohibition is starting to fracture.

These developments are welcome, but mark only a partial shift in the larger question of how we should regulate psychoactive substances. It is quite possible, for example, to legalise cannabis and psychedelics while maintaining a blanket prohibition on other substances. Transform, however, has long argued for comprehensive change. Our case for legal regulation is not limited to lower-risk drugs, because we believe that the opportunities for harm reduction offered by regulation apply to all substances, even allowing for (and, indeed, because of) differences in potential harm.

How we might regulate a legal market in stimulant drugs remains one of the most important, but least explored, questions for drug policy reform. By stimulants we primarily mean cocaine, amphetamines and MDMA, which make up the large majority of the illegal stimulants consumed globally. Stimulant use continues to increase, but too often remains at the margins of policy reform discussions. This is perhaps understandable,
given the particular range of challenges that stimulant use presents, but it cannot be a reason for avoiding the question. If we agree that the ‘war on drugs’ has failed, then we need a vision of how to regulate drugs — including stimulants — after the war has ended. This book seeks to look squarely at this difficult problem and set out a possible way forward.

In our 2009 book *Blueprint for Regulation* we explored in depth the challenges and options for regulating different drugs. This book builds on our previous work — providing more detailed model regulatory frameworks. It sets out options for how taking control might work in practice. Which products should be made available? Where, how, and by whom would they be produced? Who would sell, dispense and prescribe them, and where? Who has access to the market? How do we apply the best range of regulatory tools to meet our shared public health and community safety goals?

Such an approach is not about encouraging drug use. We recognise the argument that legalisation may increase some forms of consumption, and will address this in more detail below. However, it is our view that — if properly done — legal regulation provides an alternative that is able to more effectively manage the risks of drugs and drug markets, both for those who use them and for wider society. This book will work systematically through the reasons why we need to regulate stimulants, what regulation means, and how it might be implemented for different substances.

Exploring stimulant policy options creates very particular political challenges. Public support for changing cannabis regulation is linked to the fact that it is perceived as relatively low risk, but also very widely used and culturally embedded in many societies. MDMA, cocaine, and amphetamines sit in a different cultural space. Stimulants are widely perceived as being relatively risky compared to cannabis, and the use of pills and powders can seem more ‘unnatural’ and alien. They are also often perceived as indulgent and hedonistic, or associated with unpredictable behaviour. Particularly in their more concentrated forms, some stimulants have the potential to lead to severe dependency and considerable health harms.
Why regulate stimulants?

Yet stimulants are increasingly widely used, and production is expanding to meet the growing demand. The latest United Nations Office on Drugs and Crime (UNODC) global data suggests (probably conservatively) that in 2018, 27 million people used amphetamines, 21 million people used MDMA, and 19 million people used cocaine. The health risks faced by people who use illegal stimulants are significant, with MDMA and cocaine increasing in potency, ongoing risks from mis-selling, bulking agents and adulterants, and a complete lack of information about either strength or purity to inform safer use. In England and Wales, cocaine-related deaths rose for the seventh consecutive year in 2018, to 637, marking a threefold rise in just over a decade, and a tenfold rise over 20 years. In the US, stimulant-related deaths doubled between 2015 and 2017, reaching record levels.

What are stimulants?

Stimulants are a group of drugs broadly characterised by their effect of increasing activity in the central nervous system. The precise nature of these effects varies but, generally, they increase energy, alertness, and wakefulness. They usually interact with the brain’s monoamine neurotransmitters, which include dopamine, norepinephrine, and serotonin.
These have a role in regulating reward, motivation, body temperature, and pain sensation. The prolonged use of stimulants reduces the body’s natural ability to produce these chemicals, which can lead to both short-term ‘crashes’ following use and longer term patterns of dependent consumption. The term ‘stimulants’ covers a wide range of legal and illegal substances, and includes substances with long-established cultures of use (e.g. coffee, coca or khat) as well as more recently developed compounds. As previously noted, this book deals primarily with the three major illegal stimulants widely used for non-medical purposes today: cocaine, amphetamines and MDMA.

The role of prohibition

The core principle of prohibition is that drug consumption and related harms are reduced (and can, in principle, be eliminated) by imposing strict criminal sanctions for production, supply and possession. As with most other prohibited drugs, however, the production and consumption of stimulants have all risen dramatically over the period in which they have been illegal. This has been driven by an array of complex social and economic factors; nonetheless, the experience of the past 60 years demonstrates that the ‘war on drugs’ has not, and cannot, achieve its stated aims. Worse still, as the UNODC acknowledges, prohibition has generated disastrous ‘unintended consequences’. These range from the horrific violence of Mexico’s drug war and large-scale extra-judicial killing in the Philippines, to the destabilisation of West African transit countries, and street-level crime in urban centres across the globe. Given how entrenched these consequences are, they can no longer really be called ‘unintended’; they are simply the predictable negative consequences of prohibition in the context of growing demand. For a policy that promises, in the United Nations’ own

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4 Other stimulants work in different ways. Ephedrine for example, interacts with the adrenergic receptors, while caffeine has an antagonising effect on adenosine receptors.

Why regulate stimulants?

Psychoactive drugs: a basic taxonomy

language, ‘a drug-free world’, prohibition has been a spectacular, expensive and tragic failure.6

In 2019, the United Nations (UN) System Coordination Task Team, representing all 31 UN agencies, published a report that described punitive drug control policies as ‘ineffective’ and warned that they too often risked ‘violating human rights, undercutting public health and wasting vital public resources’.7 In the same year, the UN Commission on Narcotic Drugs,

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7 UN System Coordination Task Team on the Implementation of the UN System Common Position on drug-related matters (2019). What we have learnt over the last 10 years: a summary of knowledge accrued and produced by the UN system on drug-related matters. p.25. www.unodc.org/documents/commissions/CND/2019/Contributions/UN_Entities/What_we_have_learned_over_the_last_ten_years_-_14_March_2019_-_w_signature.pdf
representing 53 UN member states, produced a high-level ministerial declaration, which stated that under current global drug policies:

The range of drugs and drug markets are expanding and diversifying ... the abuse, illicit cultivation and production and manufacture of narcotic drugs and psychotropic substances, as well as the illicit trafficking in those substances, and in precursors, have reached record levels and that the illicit demand for and the domestic diversion of precursor chemicals are on the rise; that increasing links between drug-trafficking, corruption and other forms of organized crime, including trafficking in persons, trafficking in firearms, cybercrime and money-laundering and, in some cases, terrorism ... are observed.8

The report amounts to a damning indictment of global prohibition by the very institution charged with implementing it.

Despite all this, the UN drug control agencies remain bound to their international treaties. Until recently, this has created a high-level policy environment that routinely ignores the overwhelming evidence that those treaties have failed. The extent of this failure has been chronicled in hundreds of independent assessments by government committees, academic researchers, and non-governmental organisations across the world, over many decades. The evidence for the failure of global drug policy to achieve the ‘drug-free world’ that it promises is, in this respect, uncontestable.9

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8 UN Commission on Narcotic Drugs (2019). Ministerial Declaration on strengthening our actions at the national, regional and international levels to accelerate the implementation of our joint commitments to address and counter the world drugs problem. www.unodc.org/documents/commissions/CND/2019/Ministerial_Declaration.pdf

While Transform has argued for legal regulation for decades, we are not naive to the counter-arguments. We understand the concern that lifting the (flimsy) barrier of illegality risks reducing the costs of drugs; that the entrance of commercial actors into the drug supply chain could encourage the worst aspects of market competition; and that the symbolic message of legalisation could be read as condoning or encouraging use. As the addiction psychiatrist Griffith Edwards once put it:

_The counter-argument [to legal regulation] is ... that, ugly and costly as the present system certainly is, and with much amelioration of its worst excesses readily admitted, there is no workable alternative in sight for at least some of these drugs. Is it really possible to envisage a responsible government letting the full range of currently illicit drugs go up there, prettily branded, on the shelf next to the drinks?_

Of course, no-one is suggesting such an outcome. But there are alternatives to prohibition and it is essential that anyone who accepts current policy has failed considers them. Those alternatives are by no means limited to a commercial free-for-all, or to simply putting illegal drugs ‘on the shelf next to the drinks’ (not least because alcohol is generally poorly regulated). From a public health perspective, the goal of regulation has to be to reduce harm and maximise wellbeing. What we set out here takes this as the fundamental principle on which policy should be developed.

These alternatives need to be explored because a century of prohibition has failed, and offers no solution to the growing problems we face.

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Stimulant markets are here whether we wish them to be or not. Therefore, we must decide who will be in control: governments and regulatory agencies, or organised crime networks and unregulated suppliers?

What is regulation?

All psychoactive substances present both acute and chronic risks to those who use them. Both drug use and drug markets can also create risks to the wider community. In that sense, it is a key responsibility of government to establish and maintain regulatory systems that effectively mitigate those risks. However, government should respect the freedom of individuals to make choices when those decisions do not harm other people. They should also recognise the threat posed to already marginalised communities of policies that entrench social injustice.

Prohibition neither respects personal autonomy, nor the rights and needs of communities. Rather, in the pursuit of eliminating psychoactive substances from society, it has led to human rights abuses and social injustices on an enormous scale.\textsuperscript{11}

Some of the problems created by prohibition can be addressed through decriminalisation; that is, by removing the criminal sanctions placed on people using drugs, or possessing them for personal use, so that they are no longer drawn into criminal justice systems which, in most cases, only make things worse. Ending such criminalisation is an essential element in drug policy reform. However, it only solves part of the problem as it leaves open the question as to where criminal sanctions begin, and what supply activities remain subject to legal action.\textsuperscript{12} Ultimately, if they are not to be


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Definitions

**Prohibition** describes conditions under which the production, transit, supply and possession of specific drugs is illegal, except where there are exemptions for medical or scientific purposes. The global prohibition of ‘controlled drugs’ is based on three United Nations drug conventions (passed in 1961, 1971 and 1988).

**Legalisation** is a process by which the prohibition of a substance is ended, allowing for its production, availability and use to be legally regulated. ‘Legalisation’ is, however, merely the process of legal reform, rather than a policy model in itself. The nature of the regulation model that follows needs to be specified separately.

**Regulation** describes how states legally control the market in a given drug, or activities related to it. This control will usually involve a combination of licensing (i.e. the conditions under which production or retail are permitted), taxation systems (which can shape retail prices), and global controls on aspects such as marketing, packaging requirements or sales to children.

**Decriminalisation** usually means the removal of criminal penalties for the possession of drugs for personal use. More precisely, the ‘decriminalisation of drugs’ means ‘ending the criminalisation of people who use drugs.’ There is considerable variation in how decriminalisation can be implemented, in terms of quantity thresholds (which distinguish between possession for personal use, and possession with intent to supply), how sanctions are enforced and by whom (the police, judges, social workers, or health professionals). Unlike legalisation, decriminalisation is permitted within existing UN drug conventions.

outlawed, then markets in commodities need to be regulated. The question is, how can this be achieved without either replicating the social injustices created by prohibition or opening the door to rampant commercialisation?

The regulation of drug markets can take many forms. In the case of alcohol, for example, regulation operates mainly (but not exclusively) through the licensing of the outlets where alcohol is purchased. This allows local licensing authorities to place controls on hours of sales, the number of outlets in a given area, the layout of premises and so on. Retail licences are issued on the condition that certain requirements are met, and the primary means of ensuring compliance is the threat that the licence will be removed. Tobacco retail is licensed in many countries, but is also subject to the World Health Organization’s (WHO) Framework Convention on Tobacco Control
(FCTC), which is binding in 181 countries. Among other things, the FCTC establishes global requirements on packaging and advertising. As a result, national regulations on tobacco packaging and advertising tend to be far more stringent than is the case for alcohol.

The licensing of retail, and controls on packaging, marketing and information all reflect the fact that alcohol and tobacco are not ‘ordinary commodities’. Rather, they are (or contain) substances that are associated with dependence, long-term health harms and potential negative consequences for people other than the consumer (for example, the effects of passive smoking or the social harms arising from alcohol-related disorder).

In addition to the licensing of open sale, regulation incorporates the licensing of pharmaceutical products for supply as medicines or under supervision. In the UK, for example, the Human Medicines Regulations 2012 allow for the medical prescription of legally produced pharmaceutical drugs that are also widely used non-medically through the illegal market — including, for example, heroin, ketamine, dexamphetamine, methamphetamine, and cocaine.

Viewed in this context, the regulation of adult access to currently illegal drugs is not radical or utopian, but rather an extension of current standard practice, both for licensed recreational drug supply (as in the case of alcohol) and for regulated supply of medicines on prescription. Indeed, from this perspective, prohibition is the ‘radical’ policy response — not regulation. Regulating currently prohibited drugs is a case of applying the regulatory principles and mechanisms that are routinely applied elsewhere.

The question is not if drugs can be regulated, it is deciding which models can achieve the best outcomes for both people who use drugs and wider society. It is also about establishing consensus on what the parameters of

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Why regulate stimulants?

Any regulated market should be. Regulation does not mean the removal of social controls; it means shifting from the attempted eradication of the market through blanket prohibition to controls based on systems of licensing, taxation and so forth.

Getting regulation right is about getting the details correct. However, at the broader level, it is about aiming for a policy framework that is most likely to achieve the intended social outcomes. This can be described as a U-curve of regulatory intensity: at one extreme are the criminal markets created by absolute prohibition, moving through less punitive prohibition models and legally regulated markets, to free markets at the other extreme. The question is, what kind of regulation model will most effectively achieve the goal of reducing drug harms to the minimum?

At either end of this spectrum are effectively unregulated markets, both of which create unacceptably high social and health costs because those in control of the trade – legal or illegal – are motivated almost exclusively by profit. Between these extremes exists a range of regulatory options that can better minimise the harms associated with the use of stimulants or other drugs.
Legalisation and regulation, therefore, does not mean simply ‘liberalising’ markets. Even the most radical advocates of a ‘supermarket model’, accept the need for basic product controls and consumer protections such as ingredients, age-controls and ‘sell by’ dates. However, we are proposing a public health-oriented model of regulation. Such an approach, rooted in the belief that government has a responsibility to minimise harm and promote health, involves using the full range of regulatory tools available to achieve its goals.

The shape and limits of that control will, rightly, be subject to debate: we recognise that for some reformers exchanging the power of arrest and imprisonment with the ‘street-level bureaucracy’ of a licensing regime is problematic. We are also conscious that the social injustices associated with prohibition, which land most heavily on the socially and economically marginalised, will not simply disappear under an alternative regime. Regulation can replicate injustice if not carried out with equity and fairness at the forefront. It is, therefore, imperative that regulation models not only focus on public health but take the promotion of social equity and protection of rights as fundamental principles.

Principles of regulation

Broadly speaking, good drug policy should:

- Respect, protect and promote human rights
- Protect and promote public health
- Promote social equity, improve development opportunities and ensure communities most impacted by prohibition are included in policy development

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Why regulate stimulants?

- Recognise the specific needs, challenges and aspirations of communities most affected by drug issues
- Reduce crime, corruption and violence associated with drug supply
- Protect against excessive corporate influence on policy making
- Limit the incentives for profit-making driven by problematic use
- Protect the young and vulnerable from potential harms
- Incorporate clear outcome indicators, measures of success and evaluation processes

The evidence for the harms caused by prohibition is overwhelming: from vast expenditure on policing, to the violence and corruption that characterise all levels of the supply chain, to the barriers to treatment that the fear of criminal sanctions can create. Nevertheless, it must also be recognised that in an unchecked market the risk of increased use is real, and with that the risk of increased problematic use (though one does not inevitably lead to the other). The UNODC currently estimates that around 10% of illegal drug use can be defined as problematic. This is not dissimilar to working estimates of problematic alcohol use (depending on how this is defined).

As with alcohol, there is a ‘Pareto’ distribution at work here: the heaviest consuming 20% use the majority of all the drugs consumed and account for a disproportionate amount of the harms experienced. While this gives the lie to the claim that illegal drug use is inevitably, or even usually, a source of serious problems, it also points to the need for policy to recognise that

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17 For a longer discussion of these principles, see: Transform Drug Policy Foundation and St George’s House (2020). Challenges for a world where drugs are legally regulated. transformdrugs.org/wp-content/uploads/2020/02/St-Georges-House-Report-WEB.pdf

18 In alcohol research, the assumption that increased use invariably, and uniformly, drives increased harmful use (known as the ‘single distribution model’) has recently been challenged. See, for example, Holmes, J., Ally, A.K., Meier, P.S. et al. (2019). The collectivity of British alcohol consumption trends across different temporal processes: a quantile age-period-cohort analysis. *Addiction*, 114.11. doi.org/10.1111/add.14754

The range and intensity of regulatory tools that should be deployed depend on the risks of a particular product in a given environment. The riskier a drug, the stricter the controls we would reasonably expect to see harmful use — even when concentrated among a small proportion of all people who use stimulants — should be a key focus.

The range and intensity of regulatory tools that should be deployed depend on the risks of a particular product in a given environment. The riskier a drug, the stricter the controls we would reasonably expect to see. We would expect, for example, that coca leaf would be regulated less strictly than cocaine powder. Indeed, policy should work towards progressively discouraging higher-risk products and behaviors, nudging people towards less risky patterns of use and, in the longer term, fostering social norms around less harmful consumption.

Political and social context inevitably shape regulation. Distinct models of cannabis regulation have, for example, emerged in Uruguay, Spain, Canada and different US states. These partly reflect social attitudes to risk, but also political attitudes towards competition and the role of commercial forces in shaping the market.

Regulatory systems should constrain corporate power and influence, but the history of both alcohol and tobacco regulation illustrate how difficult this can be. Starting from scratch, as would be the case for currently illegal drugs, offers an opportunity to learn from those lessons and accept that the interests of health and wellbeing will often necessitate what appear to be more stringent controls than are the case for, say, alcohol, even if the specific risks of the substance are lower.

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As a fundamental principle, drug policy should reflect and address the specific conditions of the country or region to which it applies. There is no one-size-fits-all approach; drug cultures, economic contexts, health provisions, political systems, and market structures are not the same across the globe and drug policy has to reflect this reality. Countries introducing new drug regulation will have to work within constraints specific to their locale. As part of this, they will need to:

- Address, ameliorate and, where necessary, provide reparation for historical injustices that have arisen from drug policy enforcement in that region.

- Negotiate the local legal and policy environment. For example, in the US cannabis remains illegal at the federal level, placing major restrictions on state-level regulators. In Spain, the cannabis social club model has had to comply with the domestic decriminalisation policy and avoid non-compliance with UN treaty obligations.

- Align with existing laws and regulations for other drugs or risky activities, such as those governing poisons, medicines, driving, etc.

- Be realistic economically. If the regulatory requirements are too costly to implement, then the model will be unsustainable.

- Be politically feasible. For example, the need to assuage hostility from political opponents and neighbouring countries has shaped the development of Uruguay’s more restrictive government-controlled regulatory model for cannabis.

Designing drug regulation is complex — especially when replacing over a century of existing practice and entrenched institutions. The options set out in this book do not claim to be definitive or comprehensive. Rather, they are the starting point for a more considered discussion, establishing preferable options based on stated principles and established knowledge.
Five models of regulation

Previously, Transform has set out five basic models for regulating drug supply, all of which are also used for existing products and markets. These are described briefly below, with suggestions as to how they might be applied to stimulants, beginning with the most strictly regulated model first and moving to the least strictly regulated.

1. Medical prescription

For people being treated for (illegal) heroin dependency, the prescription of lower-risk substitutes such as methadone or buprenorphine is widely accepted as a key, evidence-based measure to reduce harm. In cases where people do not respond to opioid substitution therapy (OST), there is strong evidence that the prescription of pharmaceutical heroin (diamorphine) is effective, and heroin prescribing is already allowed in a number of countries. The rationale for, and best practice around, opioid prescribing cannot be transferred directly to stimulants; however, there is a smaller but not insignificant history and evidence base of stimulant prescribing in this context — although mostly limited to amphetamines (see Chapter 7). Prescribing can involve take-home prescriptions or the requirement that consumption takes place under supervision.

2. Specialist pharmacy sale

Pharmacists are trained and licensed to dispense prescriptions, although they generally cannot write them. They can also sell lower-risk medical drugs from behind the counter and are trained to give general health and
safety advice about prescriptions and how to use them. Pharmacists work within a clearly defined legal framework. They are trained, regulated and supported by professional bodies. In some places, pharmacists are already involved in drug management regimes. For example, in the UK, they have been required to supervise the on-site consumption of some methadone prescriptions as a precaution against diversion to the illegal market.

Pharmacies are not usually involved in dispensing or vending drugs for non-medical use. However, a system modelled on pharmacy provision could provide an effective way of managing the availability of some drugs for non-medical use. This is the case in Uruguay where retail cannabis can only be accessed through pharmacies — though some have questioned whether a stringent pharmacy model is appropriate to the risks of cannabis. This approach has also raised questions for pharmacists, some of whom are unhappy moving outside of their established medical dispensing role into non-medical use of drugs, even where there is a clear harm reduction rationale for them doing so.

A specialist, non-medical drug pharmacist model can address some of these concerns. This new professional specialism would be subject to similar training and codes of practice as conventional pharmacists but with additional access control criteria, responsibilities, specialist knowledge and qualifications. Under this strictly controlled retail model, licensed and trained health professionals serve as gatekeepers; they enforce access controls such as restrictions on age, intoxication and amount purchased. Crucially they would also be trained to offer advice on risk, safer use, and access to services where needed.

3. Licensed sale for consumption on the premises (‘on-sales’)

‘On-sales’ allow consumption only in the place where a product is purchased. Pubs and bars, for example, are licensed for the consumption of
1. Licensed sale for consumption on the premises

Licensed sale for consumption on the premises allows for the sale of products on the premises (e.g. in shops and supermarkets). It allows for more control over the consumption of alcohol on the premises. This allows for more control over consumption than is the case for ‘off-sales’ — for example, refusing service to drunk customers, or removing customers who are behaving aggressively. It also allows licensing authorities to influence the environment in which consumption takes place, rather than just how it is sold. They allow a degree of oversight and management of consumption, and create an environment in which potential harms can be better managed.

4. Licensed sale for consumption off the premises (‘off-sales’)

‘Off-sales’ allow for the consumption of products off the premises (e.g. at home) — as in, for example, the sale of alcohol or tobacco in shops and supermarkets. It is the system used for recreational cannabis retail in Canada and most US states that have legalised. Off-sales are not unregulated: they remain licensed and, as such, must be carried out in accordance with licensing conditions. These may be applied on a premises-by-premises basis, but could also be applied product-by-product.

Licensing conditions can include price controls, requirements for responsible vendor training, restrictions on advertising and promotion, age restrictions, [and] requirements for provision of health-and-safety information.

Online sales are another form of ‘off-sales’. However, they present additional challenges. In UK licensing of alcohol, for example, the ‘point of sale’ for licensing purposes is actually the store or warehouse where the stock is picked — not the ‘doorstep’ where the product is delivered. This creates the problem that age-access criteria (i.e. sale to adults only) is determined...
at ‘point of sale’ rather than at delivery. A well-designed licensing regime should, however, be able to address this by determining the ‘point of sale’ as the point of delivery, or mandating a named or adult signatory for a delivery.

5. Unlicensed sale

Drugs of sufficiently low risk, such as coffee or coca tea, require relatively few or no licensing controls. However, they should still be subject to conventional food or beverage regulation concerning ingredients, production practices, labelling, etc. As with food, requirements on labelling and packaging information — as well as warnings — can be established through general legislation operating outside of, or alongside, a licensing system.

Regulation and the motivations for stimulant use

The many reasons why people use stimulants can be divided into three broad categories of use: functional, recreational and dependent. Although these categories are useful for the purposes of this discussion, using behaviours often change over time. These categories, therefore, more accurately describe a spectrum of motivations and behaviours that individuals may move between.

Functional use

Many people use stimulants for their functional benefits: that is, for example, to stave off tiredness, or aid concentration, focus, or performance in a work environment (sometimes described as ‘cognitive enhancement’). Examples include use by long distance drivers, night shift workers, labourers working long hours, business people seeking a competitive advantage, or students with a heavy workload struggling to stay focused.
Historically (and even recently), stimulants have also been deployed for their functional uses by armed forces.24

This category may also overlap with medical uses, whether in relation to formally prescribed medication (e.g. amphetamine use for narcolepsy, or ADHD), informal self-medication, or quasi-medical and lifestyle use (for example, using appetite suppressant properties of amphetamines for weight control).

A legal market in low-level functional stimulants, primarily caffeine-based products, already exists. In many countries, other ‘functional’ stimulants are used. These include both traditional plant-based stimulants including coca, khat, or betel, and pharmaceuticals, such as modafinil and ephedrine (that are mostly scheduled but available on prescription or, in many cases, open sale).

Recreational use

Stimulants are widely used for recreational purposes, motivated by the pleasure of the drug effect itself or the fact it can enhance social activities (by, for example, enabling users to stay awake into the night, enhancing confidence, providing energy for dancing, or enhancing sexual performance). This generally involves higher per-dose consumption than for functional use, but may also be less frequent. As such, it presents a different set of risks and challenges with greater focus on acute harms, not least because the population of people using stimulants recreationally tends to be younger (although there is significant use among older people, especially as the ‘rave’ generation ages).

Among this grouping there is considerable flexibility in behaviours. Stimulants can often be substituted with each other depending on the

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situation, individual predisposition, availability or cost. They are often used in combination with other non-stimulant drugs. Some stimulants tend towards ‘binge’ consumption, others tend to be taken as a single dose. Even though some patterns of use increase risk, and can cause acute harm or death, recreational and occasional stimulant use is not associated with significant health harms for the majority of consumers. Use is generally infrequent and constrained by social norms that emerge among peer groups in their social context. These norms are further tempered by personal controls, based on both experience and (where available) informed understanding of risks.

**Dependent use**

A minority of people who use stimulants do so in a way that may be defined as dependent. Rates of dependence vary, as a proportion of people using any given substance. They are, for example, far higher for cocaine and amphetamines than for MDMA. Issues of dependence are more commonly associated with the higher intensity use of higher potency preparations (such as crack cocaine or methamphetamine) and/or more risky patterns of rapid release consumption — that is, smoking and injection, as opposed to oral use or snorting. Harm reduction and treatment responses to dependent and higher-risk consumption are explored in more detail in Chapter 7.

In any regulated drug market, policy must be designed to reduce or prevent, as far as is possible, the development of high-risk or dependent use. It should also ensure that effective treatment and harm reduction services are available for those who do consume problematically. This would need to be the case in a legal stimulant market, just as it should be the case for alcohol. Prevention involves not only effective education and harm reduction, but also the availability of effective treatment and harm reduction services. Transform is aware of the complexities around definitions of dependence, and the risk of assuming a clear distinction between dependent and non-dependent use. Broadly speaking, we are applying the term as used in the ICD-10 definition of ‘dependence syndrome’ (see here for an overview: [www.who.int/substance_abuse/terminology/definition1/en/]). In alcohol treatment, it is commonplace to distinguish between ‘mild’, ‘moderate’ and ‘severe’ dependence (see, e.g. [www.nice.org.uk/guidance/cg115/chapter/introduction]). This is helpful insofar as it acknowledges that patterns of dependent use, however precisely defined, tend to exist on a spectrum rather than in a binary relationship with ‘moderate’ consumption.
**Caffeine**

Caffeine is the world’s most popular drug, mostly consumed in the form of coffee, tea, soft drinks, and chocolate. It is a functional stimulant that saturates much of contemporary culture. Its near ubiquitous use, legal and largely unregulated status, and cultural normalisation provides useful context for the wider debate on stimulants.

**Examples of energy drinks**

Increasingly popular, and often aggressively marketed on the basis of their stimulant properties.

*Caffeine is relatively low risk, although at higher doses (500–600mg) it can cause insomnia, nervousness, restlessness, irritability, anxiety, upset stomach, rapid heartbeat and muscle tremors. Importantly, however, because of the unpleasant side effects at higher doses its use tends to be self-limiting — meaning people generally stop consuming it before any effects become dangerous.*

Many caffeine users would probably meet some of the diagnostic criteria for dependence — but because of the low risks, the remarkably high prevalence of caffeine dependence receives little attention. Indeed, caffeine is normalised to the extent that it is rarely discussed alongside other stimulant use. It is only relatively recently that some governments have begun to explore or implement increased regulation of certain higher caffeine energy drinks, including mandating health warnings, restricting sales to under 16s, or limiting sales to pharmacies.

**Typical caffeine content**
- **Coffee** 50–200mg
- **Tea** 50mg
- **Cola drinks** 30–60mg (355ml can)
- **Energy drinks** 80–160mg
- **Caffeine pills** 50mg (varies by brand)
Why regulate stimulants?

reduction, but the establishment of universal conditions (through the control of aspects such as availability and price) that make dependent use less likely.

Recognising that the distinction between dependent and other patterns of use is not simple has tangible policy implications. In the case of alcohol for example, regulation throughout much of the twentieth century was grounded in the belief that ‘alcoholism’ was a disease that only afflicted a small number of people, and that ‘alcoholics’ were qualitatively different from all other drinkers. This led to many countries adopting laissez-faire policies towards alcohol control in the belief that the amount the population as a whole drank, the general availability of alcohol, and the amount of marketing carried out by the industry, would have no significant impact on problem use. This view has now been largely discredited.26

Balancing conflicting priorities

Regulating drug markets means balancing conflicting priorities and managing the relative power of different stakeholders.

Commercial imperatives vs public health

A fundamental challenge in drug regulation is managing the often conflicting goals of commerce and public health. We know from the experience of alcohol and tobacco that, especially when large-scale corporate entities are involved, commercial providers will tend to prioritise the maximisation of profit over health promotion. There is a long and well-documented history of alcohol and tobacco industry actors vigorously undermining efforts to restrict or regulate their activities, and seeking to undermine research

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evidence that supports stricter regulation. Any regime of regulated drug markets has to be designed to prevent this from happening, and be robust enough to resist the intense pressure that powerful commercial players are able to exert.

Like legal drugs, such as alcohol, stimulants are not ordinary commodities, and the unique challenges stimulants present justifies a greater level of government intervention than is the case for other consumables. This is particularly so given the novelty of legal stimulant markets at this early stage, and our relative lack of knowledge about how they would function under new conditions. Our view is that, in seeking to strike the right balance between the interests of commerce (that seeks to drive up profits through increasing use) and public health (that seeks to minimise harms through moderating use) the latter should always take priority. Regulation needs to be developed with a clear understanding of how difficult this can be, learning especially from the successes and failures of tobacco, alcohol and emerging cannabis control.

New commercial actors vs impacted communities

The moves towards cannabis legalisation in North America have highlighted the critical importance of promoting social equity in a regulated environment. Some US states, for example, have proactively sought to achieve this through a range of measures including the expungement of previous records for drug offences, ensuring licences are priced so as to reduce barriers to entry in the new market, limiting licences so as to prevent monopolies, and providing training for people from poorer, minority or previously impacted communities. Left unchecked, commodity markets inevitably tend towards the dominance of large commercial operators. In the case of drug markets, where prohibition has led to decades

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of disproportionate criminalisation and economic exclusion, such natural market dynamics cannot be left unconstrained. Rather, the regulatory system has to actively design in social justice, and ensure that impacted communities are part of the policy-development process.

Different conceptions of freedom and autonomy

All regulation implies some degree of restrictions on individual freedom. Unless the goal is a market free-for-all, then the question is not whether we should regulate but where the lines of justifiable intervention should be drawn. This is a key political problem, which cannot be overlooked. The classically liberal position is that the state should not intervene in private behaviours until, and unless, they demonstrably harm other people. The ‘public health’ position is that a degree of further constraint is justified if it protects citizens from health risks, or indeed the uninvited pressures of commercial influence. At the extremes of either side lie either the dereliction of government duty (and the handing over of control to entities driven solely by profit) or the unacceptable intrusion of a paternalistic state (including self-appointed guardians of public health) into aspects of private life where they have no business.

There is, of course, no ‘right’ answer to this question. There are those among drug policy reform communities primarily motivated by the protection of individual rights, others motivated by the prospect of commercial potential, and others whose focus is the promotion of public health. Transform, while recognising the validity of more libertarian arguments, views drug policy through a lens of harm reduction and so, inevitably, emphasises policy solutions in which the trade-off between personal or commercial freedom and public health protection is geared towards the latter.
Regulated *vs* residual illegal markets

Policy is always vulnerable to unintended consequences. In the case of drug policy, regulation restrictive enough to achieve certain harm reduction goals may be too restrictive to provide a viable alternative to illegal markets. Over-burdensome controls may lead to excessively high prices or unacceptably stringent barriers to market access. Whatever good these may be expected to do in theory, if they are simply circumvented then the policy has failed.

On the other hand, if policy is not restrictive enough and an unrestrained commercial market emerges this will severely limit the opportunity to minimise harm. Fortunately, while neither alcohol nor tobacco regulation has ever been perfect, we have decades of experience on which to draw, considering the right balance of controls around products, price, availability and marketing in order to try and manage a regulated market for risky drugs effectively.

Aligning with existing cultures *vs* shaping future behaviours

New regulatory systems have to align with existing cultures of drug consumption. However, those cultures have been profoundly shaped by prohibition and the tendency of suppression to create alternative subcultures involving higher-risk products and behaviours. Pragmatically, legal markets will have to be shaped in ways that attract consumers purchasing from illegal sources, whether for reasons of cost or culture. This is no easy task, and there is a balance to strike between the urgency of implementing reforms and the risk of moving too hastily.

However, this does not mean that policy should simply maintain the status quo. Rather, regulation can progressively shape social norms and encourage moves towards safer behaviours, products, and using environments.
Evidence suggests, for example, that drug consumers are responsive to changes in price — and will consume less of one product as prices go up, potentially moving to another less risky product, should that product’s price fall. While policy is only ever one element in the complex cultural mix that shapes drug-related behaviours, it is the lever over which governments have control and there are plenty of examples from history (e.g. banning smoking in public places) where policy initiatives have had a direct, and transformative, effect on behaviour.

Acknowledging the limits of regulation

The legal regulation of drugs is not a silver bullet. It will not eliminate problematic drug use or dependence and some people will continue to be harmed by their drug use, or as a result of the drug use of others. Furthermore, the social injustices currently exacerbated by drug prohibition — the marginalisation, stigmatisation and mass incarceration of communities, often of colour — will not disappear, though one significant instrument of their enforcement will be greatly reduced.

Regulation as envisaged here would also not entirely eliminate illegal drug markets. As with alcohol, tobacco and a great many other products, there is always a residual illegal market that can, at best, be squeezed but never completely eradicated. Furthermore, a regulatory system is only as good as its enforcement. Yet even a partial reduction in illegal markets and prohibition-related harms still represents a huge net gain for society as a whole.

The regulation of drug markets is also only one aspect of the broader drug policy debate. Drug use, and drug policy, is part of a complex system of intersecting drivers and influences. This system also changes over time. As Babor et al. have rightly noted:

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Unlike technical problems that can be ‘solved’ and then recede into the realm of routine government administration (e.g. how to purify water or build a sturdy bridge), social problems like illicit drugs must be ‘solved’ again and again by each generation. Policy can minimise the damage drugs cause and what sort of problems exist, but it does not allow society to choose to be completely free of drugs or drug problems.  

Nevertheless, complexity is not a reason for inaction. Quite the opposite. Prohibition not only creates and exacerbates a range of health and social harms, but additionally creates both conceptual and practical obstacles to addressing the very real health concerns around problematic drug use. Its replacement with a regulatory system would — by redirecting resources and shifting political and ideological obstacles — enable the adoption of a public health approach that would produce long-term benefits. It would facilitate more rational and evidence-based policy making environments, which can only help in tackling the social conditions that underlie problematic use, and better dealing with wider drug related harms.

The wider political context

Establishing new, legally-regulated markets for currently illegal drugs requires new institutional structures at different tiers of government: international (including global and regional agencies such as the UN and European Union), national and local. Currently, there are tensions emerging between these multi-level structures, highlighting the degree to which they are fraying under the pressure of reform. Because global institutions have tended to show little inclination to lead, drug policy reform has often been driven by local innovation. Uruguay and Canada’s cannabis laws are non-compliant with the UN drug conventions; US state-level cannabis regulation is in conflict with federal law; and an array of local initiatives on

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cannabis regulation, including in Copenhagen, more than 60 municipalities in the Netherlands, and Spain’s Basque country, are challenging national legal frameworks.

### International

The UN plays a fundamental role in setting overarching global drug policy, establishing the barriers within which national drug policies operate. Prohibition is currently underpinned by the UN treaties on drugs, which position the issue squarely as one of crime and enforcement. In the context of global reform, this would have to change. A legal market in stimulants would need to be regulated in ways that not only minimise health harms but also protect the rights and needs of producers, especially in lower-income regions. This would require new international trade agreements as well as greater consideration of drug policy-related human rights standards within key treaty regimes. Responsibility for dealing with drug issues would need to move from the UNODC to the WHO, ideally seeing the development of an international agreement similar to the Framework Convention on Tobacco Control.

The UN’s standards on human rights are consistent with the framework of legal regulation proposed in this book. The same cannot be said for drug prohibition. A recent report by UNAIDS, the WHO and the United Nations Development Programme stated that ‘[N]o drug law, policy, or practice should have the effect of undermining or violating the dignity of any person or group of persons.’\(^\text{30}\) In reality, the drug war has consistently led to flagrant human rights abuses, in clear violation of human dignity.\(^\text{31}\) Legal regulation creates an opportunity for individual and collective rights to be protected in ways currently undermined by the enforcement of prohibition.

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Clearly, comprehensive reform requires either an overhaul of the UN drug control treaties, or a geopolitically viable course of action by which individual states, or groups of like-minded states, can navigate beyond existing treaty obligations. This is a complex issue, dealt with in more detail later in the book.

**National government**

While drug markets are global in reach, national governments must be empowered to determine their own drug policies, within broad parameters established under international trade and human rights law. In a reformed legal landscape, primary responsibility for drug policy should sit with health, rather than home, departments. Although government will retain essential responsibilities of regulatory oversight and enforcement, it is a fundamental principle that drug use (insofar as it poses a risk) is primarily a health issue, and should be treated as such.

Nevertheless, because of its complexity (and as is the case for alcohol) drug policy will always be profoundly cross-departmental. Home departments will still have a key role in enforcing new regulations; treasuries will look to tax generation; there should be a critical role for international development in protecting producers and supporting fair trade; education departments will have a role in prevention and harm reduction, and so forth. For this reason, a co-ordinating body with a cross-departmental brief will be essential in ensuring consistency of approaches across policy domains. Models for this already exist. In Washington State and many Canadian provinces, cannabis policy has been delegated to existing agencies overseeing alcohol regulation. Uruguay, by contrast, established a new Institute for the Regulation and Control of Cannabis.

**Local government**

The street-level implementation and enforcement of regulation invariably falls to local authorities. Licensing generally allows local authorities to
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determine the number, density, and operating practices of outlets in their area, and to tailor those decisions to local need.

It may be that some communities do not wish to see legal sale of stimulants in their areas, even if supply is legalised nationally. This ‘local option’ has been applied historically in ‘dry’ (alcohol-free) counties in the US and Australia, and more recently with cannabis outlets in the US, and cannabis ‘coffee shops’ in different Dutch municipalities. In the US, all states that have legally regulated recreational cannabis allow local authorities flexibility on zoning laws or the option to prohibit retailers entirely.32

The level of regulatory autonomy left to individual communities requires careful balancing. It is critical that local areas have a degree of control over how stimulant regulation manifests in their communities. However, patchwork availability can also make the legal market difficult to access for some communities, and encourage a continuing unregulated illegal market, or informal secondary sales. Online retail and delivery services may offer a partial solution but come with their own set of regulatory challenges.

Can it be done?

The global system of drug prohibition seems so entrenched that it can be hard to imagine an alternative. Despite its conspicuous failures, its social costs, and its role in deepening injustices, prohibition has the advantage of being the existing system. Political change is hard at any time: shifting longstanding global treaties, upheld by institutions as vast and unwieldy as the UN, and reinforced by powerful states whose sway on the global stage is immense is, no doubt, a profound challenge. But, like all change, it is possible — and in order to move towards it, we need to imagine the alternative:

mapping it out, and assessing the different forms it can take. Future historians will, one day, look back and wonder why the drug war lasted as long as it did: this book aims to help move the moment of change forward by proposing specific models for a different system. It is not a matter of if, but when the current system breaks down. This book hopes to set out how the new system should look.

The chapters that follow are designed to take the reader through the pros and cons of different models of regulation, while setting out the version we think holds the best promise. Chapter 2 discusses the rationale for different regulatory approaches, assessing what they can achieve and at what costs, concluding with what we would propose as a ‘standard model’ for stimulant regulation. Later chapters apply this model to specific stimulant types: amphetamines, MDMA and cocaine; addressing how our core principles apply in each case, and what variations there may be. The chapters on harm reduction and sustainable development take two fundamental, cross-cutting themes and lay out how to address them in a new regulatory context.

The discussion that follows is designed to both describe a roadmap for regulation, and stimulate debate on how this might be implemented or improved. We are at an early stage in this area of the drug policy debate, and the proposals set out here are designed to place a marker: describing what we consider the best alternative option while keeping open the space for challenge, and inviting readers to consider how elements may be further developed. Read with that perspective, we believe this book can make an important contribution to achieving the reforms the world so desperately needs.
The practicalities of regulation
Stimulant regulation should be designed, above all, to protect public health, reduce social inequalities and ensure more effective harm reduction.
MOVING FROM PROHIBITION TO REGULATION IS NOT JUST A MATTER OF PRINCIPLE, but of practical details. If we accept that the alternative to criminalisation is not to be a free-for-all, then we have to look closely at what controls are practical, justified and ethical. Because stimulants represent a wide variety of substances, effects and long-term impacts there is no one-size-fits-all model for their regulation. In order to be practical, regulations need to both achieve their goals and be sufficiently amenable to consumers that they will be accepted. In order to be justified, they need to not go beyond what is necessary to reduce harm to a reasonable degree. And in order to be ethical, they must not create unnecessary harms, or exacerbate existing inequalities.

This chapter will set out key principles and questions for regulation. Recognising that the details need to differ in regard to the specific substances, it will discuss broad issues and overarching models of control. It works from the principle that there is no one-size-fits-all approach. On that basis, drug regulation should be developed using a tiered approach, which matches the model of regulation to the risks of use.
Quantifying drug risks

Regulation, as explored in the previous chapter, is essentially a challenge of risk management. Understanding the pharmacological risks of a particular drug, and how they relate to environmental and behavioural risks, is therefore crucial for determining the regulatory and policy response, and for informing risk education for consumers. Contemporary policy and law making has tended to classify drugs within a small number of categories: often, as in the case of the UN drug scheduling system, combining the assessment of non-medical risks with an assessment’s medical usefulness, into a single ranking. These legal classification or scheduling systems have been subject to wide ranging critiques including that they are arbitrary and based on inaccurate, absent or outdated risk analysis; that they omit to include alcohol and tobacco; and that they are primarily tools for establishing a hierarchy of punishments rather than meaningfully shaping a public health response.¹

Beyond these challenges, however, is the more fundamental problem that drug risks are defined along a series of different acute and chronic risk vectors (including, for example, overdose and dependency potential). Different drugs can also have very different secondary risks related to pregnancy, driving impairment, workplace competence, or violence and antisocial behaviour. Rankings for drugs along these different risk vectors will not necessarily align (compare the chronic and overdose risks of heroin and cigarettes for example). Further tiers of complexity are added by the fact that drug risk can be profoundly shaped by the drug preparation, the health of the consumer and other individualised factors (including age, weight, gender, pre-existing health issues), and consumption behaviours (frequency of use, dosage, mode of use, poly-drug use, using environment, etc.). A generalised three- or four-tiered risk ranking system is not a useful policy tool in this context; it may potentially serve as a political totem, but is

¹ Global Commission on Drugs (2019). Classification of Drugs: when science was left behind. www.globalcommissionondrugs.org/reports/classification-psychoactive-substances
largely meaningless in practical terms. More sophisticated efforts to rank drug harms along different risk vectors which are then combined into a single figure index suffer from the same conceptual shortcomings — even before the impacts of the legal policy environment on risks are factored in.²

For the purpose of this book we have, nonetheless, divided up the stimulant drug products into three broad tiers for the purpose of exploring regulatory options. However, rather than focusing only on the more limited conventional pharmacological risk assessments used to inform a hierarchy of punishments, we have based the division of tiers on preparation and related behavioural risk vectors that can more meaningfully inform the practicalities of regulation. This difference in approach is highlighted

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through the classification of cocaine in our risk tier model. While coca leaf, cocaine powder, and crack cocaine are all grouped together under classification systems at the UN level, and in the UK and US, we have instead placed them into three different risk tiers, reflecting the greatly differing actuality of risk between these products. Nevertheless, this three-tiered categorisation inevitably entails a degree of generalisation. It is important to be clear that significant differences in risks still exist between products classified within a given tier, and that the boundaries between tiers may sometimes be blurred.

Policy levers available to government

Regulation cannot, by itself, determine exactly how stimulants will be consumed, by whom, and at what level across the population. However, it represents a fundamental mechanism by which markets and consumption behaviours can be influenced. Broadly speaking, the levers of regulation include controls over: the formulation of products (through controls on preparation or packaging); price (through taxation or pricing controls); availability (through both the licensing of vendors and outlets and controls on consumers such as age access, rationing, or permitted locations for consumption); and marketing. Development issues related to drug production are dealt with in Chapter 6.

This chapter will discuss regulatory challenges and options as they apply to these different areas of control.

Product Controls

The licensed legal production of MDMA, cocaine, and amphetamines for medical and scientific purposes already occurs under existing national, regional, and global legal frameworks that regulate pharmaceutical production more generally. As such, future challenges around legal production
can largely be addressed by expanding production within these existing systems. The more thorny issues, beyond the logistics of scaling up production for potential new markets, are political, legal and bureaucratic.

The quality control of pharmaceutical medicines is managed under regional Good Manufacturing Practice (GMP) regulations to ensure safety of consumers. In a regulated market, all pharmaceutical drugs for non-medical use would need to be produced under the same quality, inspection and testing standards (with any imported drugs meeting GMP standards operating at point of sale).

Any high value product presents some degree of threat from acquisitive crime, including drugs, regardless of whether the products are intended for medical or non-medical markets. Legal alcohol, tobacco and cannabis have all been subject to theft at point of production, in transit or sale. Pharmaceutical stimulant drugs — with a higher value to weight ratio, and a resale market likely to be more accessible than, for example, comparatively niche medical drugs, could prove an attractive target for opportunistic crime.

Security protocols for existing production, transit and sale of high value drugs (for stimulants or indeed any other) are, however, well established. The same security measures will operate just as effectively for high value non-medical drug production as high value medical drug production (especially given that, as noted, in many cases the products are identical, and will also be sold from specialist pharmacies).

Legal issues around international trade in, or transit of, drugs produced for non-medical uses are likely to be more problematic than the comparatively well trodden practical questions around quality control and security. New standards and frameworks will need to be developed at an international level to ensure effective control in these areas, and hurdles posed by the present UN drug control architecture will need to be overcome (for discussion on this, see later in the book).
### Good Manufacturing Practice

‘Good Manufacturing Practice’, or GMP, describes legal minimum standards that pharmaceutical medicines manufacturers must meet to ensure that products are of a consistently high standard and are appropriate for their intended use. GMP standards are established at international level by the World Health Organization (WHO), as well as at regional levels — through organisations like the European Medicines Agency, which harmonises GMP activities across the region.\(^i\) Compliance with GMP may be assessed by reporting and inspection procedures, with non-compliance subject to penalties including licence suspension.\(^ii\)

GMP is set out in regulations and guidance, outlining principles and standards that must be applied throughout the production process, including on: hygiene; materials; equipment used; and training. The primary purpose of GMP is to reduce risks to consumers, for instance those posed by inadequate labelling or product mix-ups — and specifically risks that cannot be eliminated through final product testing.\(^iii\)

As an example, guidelines established in the US by the Food and Drug Administration (FDA) can be summarised by the ‘five ‘p’s’. These describe the key areas that the FDA require manufacturers to meet specified minimum standards, though they are broadly applicable as principles to GMPs more generally (examples given here are not exhaustive):

- **People**: staff must have clear responsibilities and be fully trained and supervised
- **Procedures**: procedures must be recorded and reported on, and cover all key areas
- **Products**: manufacturers must have specifications for each stage of product development
- **Premises and equipment**: must be recorded, validated and allow effective cleaning
- **Processes**: must be clearly documented and reported on, with critical steps identified\(^iv\)

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\(^iv\) Hill, E. (2019). Good practice (GxP) in the pharmaceutical industry. Qualsys. [quality.eqms.co.uk/blog/good-practice-in-the-pharmaceutical-industry](http://quality.eqms.co.uk/blog/good-practice-in-the-pharmaceutical-industry)
The practicalities of regulation

The question of who gets to produce products for the new stimulant market is also paramount, even if we can rest assured that the resultant products will be of comparable quality. The fact that corporations are already licensed to produce pharmaceutical drugs for medical markets means that corporate dynamics are already entrenched, and big players well established.

As has been seen with the transition from medical to non-medical cannabis markets in the US and Canada, favouring existing businesses may make the administration of a new market easier for regulators, but it is not necessarily the best approach to ensure an equitable spread of market space. These are important challenges for authorities to navigate as they seek to develop new licensing procedures (see also Chapter 6 on development issues in drug production).

Preparation controls

The risks associated with a given stimulant are influenced by both the form of drug preparation (whether it is a pill, a powder, a drink, etc.) and the mode of administration (whether it is injected, smoked/inhaled, snorted or taken orally). For any drug, higher dosage means more intense effects and higher risks. However, preparation and mode of administration also impact on risks by changing the speed of onset and duration of drug effects, as well as acute and chronic physical risks associated with smoking, injecting, etc.

The availability of different preparations is directly influenced by regulation, and so – by extension – are the modes of administration. Certain pill formulations, for example, make it difficult to consume the drug other than orally; liquid gel formulations can’t be crushed and snorted; pro-drug

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preparations (which only become psychoactive after metabolisation, such as Lisdexamfetamine) can’t offer the immediate hit of injecting.

Regulation can encourage safer consumption by making stimulant drugs more available (or cheaper) in safer preparations, and less available (or more expensive) in riskier forms. Promoting safer alternatives should not seek to encourage new consumers. Rather, it should seek to change behaviours among existing high-risk users, or steer people who would potentially become high-risk users in the future in a safer direction. For example, better regulation should encourage a shift — at both population and individual levels — away from higher-risk smoking and injecting of stimulants towards safer, slower release oral preparations. The adoption of, or transition towards, safer forms and modes of use is a fundamental harm reduction goal of regulation.

A harm reduction approach should also ensure that people who use stimulant drugs have accurate knowledge of the dose being consumed and the likely effects and risks of consuming in a given form. This would include, for example, how intense the effect is likely to be, how rapidly it will be felt, or how long will it last. Poor understanding of drug effects is a risk factor in itself, as is the unknown and unpredictable potency of drugs, particularly in regard to pharmaceutical preparations. Both are exacerbated by unregulated illegal production and supply. Regulated, clearly labelled products, sold by licensed and trained vendors, cannot prevent high-risk behaviours completely but will make them less likely.

Consumption (whether of drugs or any other commodity) is rarely entirely rational: an array of desires, misperceptions and cognitive biases influence everything we do. However, safer decisions are more likely to be made when consumers have access to information. Therefore, it is a basic responsibility of any regulatory regime to provide as much information as is practicable. Knowledge allows people who use drugs to make more informed decisions about their personal risk behaviours. Indeed, access to accurate knowledge
Summary of risk vector for mode of drug administration

Injection
Injection is the riskiest mode of administration. It immediately exposes the user to the totality of the dose and minimises their ability to control (titrate) dosage, increasing overdose risk. Injecting involves risk of tissue injury, infection, and transmission of blood-borne viruses if injecting equipment is shared. The intensity of experience, with rapid onset of the drug effect, is associated with increased levels of compulsive use and dependency.

Smoking/inhalation
Like injection, inhalation exposes the user to the drug effect almost immediately (although bioavailability is reduced as some of the drug is lost in exhalation). However, it allows a greater degree of control over titration and intoxication, so overdose risk is lower. Not all stimulant drugs can be smoked effectively (base/crack cocaine preparations and methamphetamine can be, but not dexamphetamine, cocaine powder, or MDMA). Inhalation of combusted drugs presents an additional risk of chronic damage to the lungs.

Inhalation risks can be reduced if inhaled in vapour form rather than combustion/smoke, but current vaping devices cannot carry enough of the drug per inhalation (cocaine, amphetamine, or MDMA) to make this a practical option (although it may be developed with potent synthetic stimulants in the future).

Snorting (insufflation)
Powder, or some solution-form stimulants, can be snorted and absorbed through the nasal mucus membranes over a period of minutes. This produces a slower onset of effect than with injecting or smoking. While insufflation generally carries a lower physical risk than injecting or smoking, over a long period there is a moderate risk of chronic damage to nasal membranes.

Oral consumption
Drugs taken orally are absorbed over a longer time period (an hour or more) in the gut. Slower-release orally consumed preparations will generally be lower-risk than rapid release equivalents, as speed of onset and level of exposure at any given time is moderated. However, length of exposure and intoxication is usually prolonged.

Drugs, including coca leaf and cocaine powder, can also be held in the mouth and absorbed through the gums or sublingually.
about health risks and harm reduction is a key element of the fundamental right to the highest attainable standard of health.⁴

In order to support informed decision-making, stimulant drugs should only be available in clearly labelled standardised units. Standardisation of measures would help ensure that consumers know what, and how much, they are taking. It would also, as we are increasingly familiar with in alcohol retail, allow information to be provided that relates directly to those units. Specifics on preparation and dosage for each drug are explored in the relevant chapters.

## Price controls

The consumption of drugs in a legal environment will be shaped by a whole range of environmental variables, of which price is only one.⁵ However, we know from alcohol and tobacco research that pricing is perhaps the most important lever of influence governments hold when it comes to shaping consumption behaviours, and there is an extensive literature on the likely impacts of different approaches.⁶

Under a system of legal regulation, governments are able to influence price using a range of mechanisms:

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⁶ See, e.g.: Wagenaar, A.C., Salois, M.J. and Komro, K.A. (2008). Effects of beverage alcohol price and tax levels on drinking: a meta-analysis of 1003 estimates from 112 studies. *Addiction* 104. www.ncbi.nlm.nih.gov/pubmed/19149811; Gallus, S., Schiaffino, A., La Vecchia, C. et al. (2006). Price and cigarette consumption in Europe, *Tobacco Control* 15. www.ncbi.nlm.nih.gov/pubmed/16565459. There is also an emerging literature on the impacts of cannabis pricing from legalised jurisdictions — but this is both less developed due to the relative novelty of these developments (the first formal non-medical regulation models only commencing in 2014), and the lack of breadth in pricing controls so far explored, mostly limited to more commercialised North American markets.
• **Direct price fixing**: Government specifies fixed prices (which may or may not include tax) at which certain products must be sold.

• **Minimum prices**: Fixed lower pricing limits (which may or may not include tax), allow a degree of market flexibility and competition within defined parameters while preventing excessive competition on price. Minimum unit pricing (MUP), for example, has been used to limit low price competition in the alcohol market.7

• **Fixed per unit (or ‘specific’) tax**: Tax is imposed that charges a set amount per unit of a given drug, for example, per 10 milligrams of cocaine, MDMA or amphetamine. It can be applied at production level, retail level, or both. Generally, a specific tax system is more effective in regulating potency than an ad valorem model (see below) because it establishes a direct relationship between the potency of a product and the duty charged.

• **Ad valorem tax**: Tax is calculated as a fixed percentage of the retail price of the product. In this case, two products of different potencies may be taxed at the same level as long as their retail price is the same.

• **Local tax**: Municipal or other sub-national jurisdiction (county, province, etc.) level tax to cover any localised cost burdens associated with trade. This can help cover specific localised regulatory burdens/costs, or address local concerns, but may incentivise diversion, or geographical displacement of markets. This need not be at a set rate, and flexibility can be given to municipalities.

• **Differential pricing**: any of the above pricing controls can be applied in different ways to different products, or similar products in different locations.

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7 In an example of good regulatory practice, the Scottish Government commissioned NHS Scotland to carry out a comprehensive evaluation of MUP following implementation. Its outputs are published here: [www.healthscotland.scot/health-topics/alcohol/evaluation-of-minimum-unit-pricing-mup/overview-of-evaluation-of-mup/timeline-of-evaluation-of-mup](http://www.healthscotland.scot/health-topics/alcohol/evaluation-of-minimum-unit-pricing-mup/overview-of-evaluation-of-mup/timeline-of-evaluation-of-mup)
Applying pricing controls is not a simple matter. Legally regulated drug markets would operate within the wider context of market and competition law, and the hand of government is consequently constrained. The Scottish Government, for example, faced a sustained legal challenge from the alcohol industry after it sought to introduce a minimum unit price for alcohol. Ultimately, it was only successfully implemented after the UK Supreme Court determined that a less restrictive measure (increased taxes) would not achieve the objective of combating ‘problematic drinking to which the Government’s objectives were always directed’ as successfully.\(^8\)

In developing pricing policies for stimulants, such technical hurdles and, quite possibly, similar challenges from organisations with vested economic interests, would need to be overcome. The scale of this challenge should not be underestimated: regulatory models must be robust enough to withstand the pressure states will inevitably face from business and from the global systems of market regulation under which they operate. However, unlike the examples of alcohol and tobacco, we have the benefit of starting from a legislative ‘blank slate’, thereby allowing regulation to incorporate the lessons learnt from history and build in measures to mitigate against excessive corporate influence. It is vital that these measures are implemented from the outset of any new regulatory system, as recent experiences of cannabis regulation in North America have highlighted that market dynamics are established very early on, and corporate actors can entrench new legal drug markets at great speed.\(^9\)

In reality, political considerations will also distort the design of price interventions. Even where positive public health outcomes are likely, governments tend to avoid measures that put tax revenue at risk — especially if such revenue streams are well established and substantial, as is the case with alcohol and tobacco. The fear of public unpopularity, and the power of

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\(^8\) Scotch Whisky Association and others v The Lord Advocate and another (Scotland) [2017] UKSC 76. www.supremecourt.uk/cases/docs/uksc-2017-0025-judgment.pdf

industry lobbying, remain unavoidable political considerations that do not neatly align with public health goals of reducing or moderating consumption. In the case of stimulants, however, there is likely to be much more political support for effective regulation than is the case for alcohol, which is far more deeply embedded in both culture and the economic fabric.

A state monopoly retail model (discussed later in the chapter) has a number of advantages in addressing these problems. Most obviously, under a state monopoly there is less business incentive to prioritise profit maximisation, meaning that pricing policy can focus on the interests of public health (although history has shown that the priorities of state monopolies with alcohol, tobacco and lotteries can still be distorted by the continuing need to generate revenue). State monopoly retail is also likely to increase total revenue to the state compared to a taxation only model, or a private retail model with fixed or minimum pricing.10

**Price adjustments and changes in demand**

Broadly speaking, for currently illegal drugs, we can assume that the basic laws of supply and demand hold: essentially, as with alcohol and tobacco, as price increases, consumption tends to fall, and as price falls, consumption tends to increase.11 Transferring this basic reality into policy is, however, far from simple. Price changes have very different impacts on different sub-populations of consumers and on different markets for different drugs. Wide variations in price elasticity of demand — that is, the degree to which demand responds to changes in price — have been observed with different groups of people who use drugs, and different patterns of use. Therefore, caution is needed when making generalisations or oversimplifying how price can influence behaviours.

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Furthermore, both patterns and prevalence of drug use demonstrably often rise and fall independently of price. In the US, for example, the price of cocaine powder has dropped by 80% over the last 30 years, but consumption has fallen.\textsuperscript{12} In the UK, by contrast, cocaine has become cheaper (insofar as purity has risen but per gram prices have remained relatively static) and use has risen.\textsuperscript{13} Population levels of consumption are influenced by a range of non-price variables including: fashion and culture; perceived quality and safety; social attitudes; stigma around use; marketing (at least for legal drugs where marketing is permitted); geographical and temporal availability; as well as availability and price of alternative drugs or activities.

The economic burden of drug expenditure relative to total disposable income of the individual consumer is a key factor. If initial prices are sufficiently low, and if use is moderate or occasional, then total spend is likely to be low. In this case, even a fairly dramatic change in price may have only limited impact on demand. This is likely to be the case for MDMA. Given the relatively low per-dose cost (the global average price for a single pill, often enough for two adult doses, is reported at under €10, roughly $12) and the generally infrequent use of MDMA, it is likely that changes in the cost per dose will be less of a factor in influencing demand than for more expensive drugs such as cocaine, especially if more frequently consumed.\textsuperscript{14}

Conversely, where use tends to be more frequent (as is the case with alcohol and tobacco), and/or cost per dose is much higher (as with cocaine for example), the total spend relative to disposable income is higher and price changes can have more significant impacts. Where doubling the price of MDMA pills might only increase the cost of a night’s drug use by

\begin{itemize}
  \item \textsuperscript{14} Prices in this book are generally referred to in US dollars. Unless otherwise stated, where $ used, this refers to the price in US dollars.
\end{itemize}
$10, the doubling in the price of cocaine could mean $50–100 greater outlay. If cocaine was being used on a weekly basis, as opposed to MDMA on a monthly basis, the difference becomes even more pronounced.

Pricing measures are not without their trade-offs. While tax increases and minimum pricing in the alcohol and tobacco market have been shown to be effective at moderating certain consumption behaviours, they are not without their problems. Artificially raising the price of any commodity tends to be regressive insofar as the impacts fall disproportionately on people with lower incomes. This may be considered positive insofar as some high-risk groups (e.g. young people) tend to have lower income. Furthermore, because drug harms impact disproportionately on low-income groups (as in the so-called ‘alcohol harm paradox’), reducing consumption in those social groups can have a greater overall benefit. Nevertheless, such an approach may also be legitimately viewed as unfair or discriminatory towards people on lower incomes more broadly, particularly those who use moderately. Increased price may moderate use in lower-income groups but can also have unintended consequences such as increased crime related to funding purchases, or reduced spending on, for example, a healthy diet. A further general assumption is that people with dependent patterns of drug use are less responsive to price increases than other consumers. In this case, the potential negative effects of price increases can be even more significant.

The availability and costs of substitute drugs, or recreational activities, is also a factor. Increasing the price of one drug may displace consumers towards cheaper alternatives, the outcomes of which may be positive or negative depending on relative risks. Displacement can also take place towards or away from riskier but more cost-effective methods of administration for the same drug, such as smoked or injected use. Under

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prohibition the pattern has tended to be displacement towards riskier drugs or preparations; legal regulation can work to achieve the opposite.

Impact of legal stimulant drug prices on the illegal market

The price of legally supplied stimulant drugs will naturally have an impact on the size of the residual illegal market. Non-price variables are important but a key factor is the relative price difference; in other words, the ability of the illegal trade to undercut legal prices. The nearer the retail price of a given legal drug product is to the cost of bringing it to market, the smaller the profit opportunity that exists for parallel illegal trade. However, the gap between production costs and retail prices can vary enormously between drugs. For some drugs, most obviously cocaine, the gap is disproportionately large compared to more conventional products, and even a substantially cheaper legal product is likely to offer opportunities for undercutting. In the case of tobacco, where taxes are high (e.g. in the UK, where tax makes up over 70% of the retail price) the incentive for illegal sales is significant. Indeed, in 2013 it was estimated that 9% of the UK market in cigarettes, and 38% of rolling tobacco, was smuggled or counterfeit.

The ability to smuggle and counterfeit is also determined by practicalities. Alcohol, simply because it is bulky, and heavier, is harder to smuggle than tobacco. Pill and powder-form pharmaceutical drugs are, by comparison, even easier and more profitable to transport and, therefore, are more amenable to illegal transit and sale.

Illegal producers have a market advantage in not having to incur costs from compliance with regulatory requirements and quality controls. They are also not held accountable for the externalities of their production, such as deforestation in coca-growing regions or the dumping of toxic by-products.

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Canada, which legalised and regulated production, supply and use of non-medical cannabis for adults in October 2018, provides an instructive case study in relation to pricing. Despite making significant inroads into illegal markets, after a year of legal regulation it was clear that uptake to the legal cannabis market remained slower than many hoped, and that comparatively high prices for legal products have been part (though not all) of the reason.\footnote{Statistics Canada (2019). Crowdsourced cannabis prices. www150.statcan.gc.ca/n1/daily-quotidien/200123/dq200123c-eng.htm}

By early 2020, the average price of cannabis on the illegal market was less than the year prior ($5.73 down from $6.44), whereas average prices of cannabis on the legal market were slightly higher ($10.30 up from $9.69), meaning that the gap was wider than it had been shortly after legalisation.\footnote{Slade, H. (2020). Capturing the Market: Cannabis regulation in Canada. Transform Drug Policy Foundation and México Unido Contra la Delincuencia. p.37. transformdrugs.org/product/capturing-the-market/}

Getting the balance right is difficult, and it is clear that excessively high prices will not tempt consumers towards legal sources, and rising price differentials may even push them the other way.

Were legal cannabis to have been significantly cheaper, it is likely that greater inroads would have been made into the illegal market — but there may have been greater coinciding risks from setting prices too low, such as increased overall consumption. In any respect, only through regulation does the state have the ability to adjust those prices, and find a position at which the optimal outcomes can be achieved.
during MDMA production. Nonetheless, they do need to incorporate the risk of seizure and criminal penalties into their costs, and are disadvantaged by the economies of scale and industrial efficiencies more readily available to legal enterprises.

In reality, legal supply cannot displace illegal markets entirely, unless it involves effectively unregulated provision at, or below, cost price. This, clearly, would incur unacceptable public health costs. A parallel illegal market at some scale is, therefore, inevitable — as illustrated by the continuing existence of illegal markets for alcohol and tobacco in most parts of the world. Nonetheless, legal prices need not completely undercut those of the illegal market in order to make effective inroads, as price is often neither the sole nor the primary attraction. Survey data for cannabis has suggested that a majority of consumers value quality over price, while survey data for cocaine has suggested that consumers will pay more for ethically sourced products.\(^\text{18}\)

Packaging controls

Packaging is such a ubiquitous aspect of the consumer experience that it is easy not to notice how much it shapes our decisions. For many years now, debate has raged over the extent to which potentially dangerous products, such as tobacco and alcohol, should be constrained in terms of what the packaging can, or cannot, say or suggest. In the case of tobacco, the argument for large health warnings and for plain packaging has gained considerable ground. At the same time, alcohol labelling remains subject to much debate, but much lighter control.

The core of the argument is twofold. Firstly, whether the packaging of such products should serve to encourage use (beyond, or as a secondary consequence of, the aim to encourage brand switching or loyalty). Secondly,

the extent to which the package should be used as ‘real estate’ for health information. Clearly, it is in the interests of public health for packaging to not encourage use, and to provide as much information as is practical. By contrast, it is in the interests of producers and retailers that packaging entices purchase and does not put potential consumers off with warnings that draw attention to risk.

Potential models for packaging of stimulant products run, theoretically at least, from the kind of glitzy, attractive labels that appear on many alcohol products through to the functional designs of pharmaceutical products or the plain packs now required of tobacco products in some countries. Given the concern that a regulated market should promote public health, our recommendations are oriented to the latter.

**Child-resistant packaging**

Accidental child poisoning is a small but real risk. Designs that reduce such risks are widely mandated for prescription and over-the-counter drugs, e-cigarettes and refills, as well as pesticides and household chemicals. Such packaging should be used by default for all pharmaceutical stimulant preparations, and for all but the lowest risk non-pharmaceutical stimulants (such as coffee or coca tea). Where appropriate, an additional requirement could be made for commercial or domestic storage in sealed or locked cabinets.

**Tamper-evident packaging**

‘Tamper-evident’ packaging contains a seal that makes it obvious if the container has been opened or otherwise tampered with. Such packaging would be essential for any pharmaceutical stimulants, partly because of the scope for illegal adulteration and secondary sales. Examples include blister packs, sealed ampoules, and other forms of sealed containers. This is more important with powder-form drugs than pills, as they are easier to tamper with.
Cocaine packaging design proposal

Child-resistant and tamper-evident lid

Non-branded white packaging

Clear content labelling

Other elements (not visible) include:
- braille content labelling
- use-by dates
- QR code

Vial is unappealing Pantone 448C, as used for tobacco plain packaging, with transparent window on reverse to show content level

Holographic security seal on box lid, with warning logo, acts as tamper-evident, anti-counterfeiting measure

High-visibility health warnings, warning logos and safety advice

Web address for additional health information

Folded paper insert with detailed health information

design: Halo Media
Information on packaging

Over much of the past century, alcohol and tobacco packaging design has largely served to encourage use.19 Reverse-engineering packaging so that it carries clear risk information has proved challenging, with voluntary efforts by the respective industries often woefully inadequate and legislators reluctant to mandate changes fearful of industry pressure and accusations of ‘nanny-state’ interference. This situation has, however, begun to change with tobacco packaging in recent years — firstly with the appearance of prominent health warnings, and more recently with the adoption of plain packaging in a growing number of countries.

We propose that the packaging design and information requirements for pharmaceutical stimulants be closely modelled on established norms for pharmaceutical medical drugs, with plain packaging, devoid of logos or other marketing-led elements. Packaging design should be restricted to product and safety information. This should be clearly mandated by legislation. Information should include:

**Content information**
- Contents: using technical names, but also popular terms for clarification
- Dosage: total contents, and contents per unit (e.g. pill)
- Anti-counterfeiting measures: holograms, etc., as seen with tax stamps on some alcohol/cannabis/tobacco products
- Use-by dates

**Harm reduction information**
- Key effects and side effects
- Potential negative effects
- Likely different effects on different users (with variations according to age, gender, experienced or novice users, or body-mass) by dosage

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General risks
  • Acute health risks
  • Chronic health risks
  • Risks for people with existing medical conditions

Secondary risks
  • Risks in relation to impaired driving, operating machinery and workplace competence
  • Potential risks to those who are pregnant
  • Accidental ingestion by children

Usage
  • Safer methods of consumption
  • Safer products and preparations
  • How to moderate use

Contraindications
  • Risks of consumption with other non-medical drug use or use with prescribed or non-prescribed medications

Packaging should also contain information on where to get further help and advice.

Clearly the volume of health, risk, and harm reduction information listed cannot fit on a single product package label. Solutions to this could involve one or more of the following:

  • Rotating a series of key messages on package labelling (in a similar way to the health messages on cigarette packaging, or cannabis health warnings on cannabis packaging in Canada)\(^20\)

  • Inserts similar to those found in most pharmaceutical products could be used, with a single folded piece of paper with detailed product information inserted into even the smallest containers.

A standardised insert, which would be inexpensive to produce, could be mandated for inclusion with all retail stimulant products for reference whenever needed

- A prominent web link or QR code pointing to an appropriate online resource could be included

Core safety and liability information: ‘keep out of reach of children’, ‘use at your own risk’, etc. should, however, be included on all packaging.

In some scenarios, such as under a purchaser licence model (see below) it may be appropriate to record a named person on the packaging. This could be managed through anonymised digital tagging or bar-codes. It would emphasise that the product is for use by the named individual only, and that they are directly responsible for it. Product tagging could be linked to sanctions, such as loss of purchaser licence, if the product ends up in the hands of a third party.

**Sustainability**

Sustainability in pharmaceutical packaging has tended to be a relatively low priority compared to other design elements, but it is certainly possible to ensure sustainability considerations are more effectively factored in, including by:

- Minimising use of packaging materials generally
- Use of lower environmental impact and/or recycled materials where possible, such as recycled paper/card, recycled PET plastics, moulded fibre plastic alternatives
- Paying attention to end of life disposal — ensuring products are easily recyclable (e.g. paper/card and PET plastics) or biodegradable (e.g. compostable plastics or alternatives) to avoid incineration or landfill
The novelty of this sector offers an opportunity to get sustainable packaging regulations established from the outset. This opportunity was missed in Canada’s emerging legal non-medical cannabis market, lauded by public health advocates for its child-resistant designs, minimal branding and prominent content and health messaging, but criticised for failing to mandate sustainable design leading to wasteful packaging and overuse of plastics.

Vendor and outlet controls (retail licensing)

The licensing of retail outlets, and the requirements established for people working in those premises, plays a fundamental role in influencing how people consume products. Licensing by outlet is the standard process in most countries for regulating alcohol and tobacco, where any such retail controls apply. Licensing is usually administered at a local level in order to be responsive to local needs. It allows licensing authorities to determine the number of outlets in a given area, the shape and layout of outlets, the kind of promotions allowed in any given outlet, the staff training requirements and so forth.

The key licensing requirements that would be applied to stimulant vendors mirror those that are currently applied to pharmacists and retailers of alcohol, tobacco or (legal) cannabis. However, lessons from the successes and shortcomings of these different models should allow a more robust and effective system to be established from the outset.

The main aims of a retail licensing system should be:

- To promote health and wellbeing, and minimise harms to consumers and the wider public
- To protect children, young people and other vulnerable populations from drug-related risks
- To minimise crime, antisocial behaviour and public disorder related to drug use or drug markets
To ensure an equitable allocation of licences, including among those disproportionately impacted by law enforcement of drug prohibition.

The specific measures that must be taken in order to achieve these aims will depend on both the type of outlet and the nature of the products being sold. Lower potency stimulants, including plant-based products such as coffee, coca or ephedra tea, require lower-intensity regulation in accordance with their lower risks. Pharmaceutical pill or powder preparations, by contrast, require far more stringent controls.

**Types of outlet**

Outlets can be licensed for sale only (including online), or for sale and consumption on the premises. Different types of outlets have common and distinct regulatory challenges, which are explored below. Which, or which combination, of these apply will depend on the drug being sold as well as local context.

**Retail only (off-premises licence)**

Off-premises licences can take a number of forms: covering both recreational and medical products. Alcohol is very often sold in shops and supermarkets for consumption elsewhere, as is tobacco. By contrast specialist pharmacies are licensed to sell medicines, almost always for off-site consumption. In regard to stimulants, when we discuss off-premises sales, we are generally referring to a pharmacy sales-type model. We would not envisage a system in which there was something analogous to alcohol off-sales for stimulants, particularly those that present higher risks.

**Retail for consumption on premises (on-licence)**

The close association between stimulant drugs and the night time economy leads to exploration of how such drugs might be sold and consumed in clubs and party venues. From the consumer point of view
We would not envisage a system in which there was something analogous to alcohol off-sales for stimulants, particularly those that present higher risks directly to purchase. However, among the range of experts we spoke to there were significant concerns regarding the practicalities of sales for consumption on the premises, and a clear preference for encouraging purchase in advance from dedicated retail outlets.

Making drugs available for purchase in, for example, nightclubs would be challenging in practice. Planned drug use with purchase in advance will tend to be safer than the more spontaneous drug taking decisions that retail availability in clubs would potentially facilitate. Potential customers may have consumed alcohol or other drugs before they arrive at a club or party venue, making the provision of harm reduction advice difficult, and creating challenges for rules around non-service to people already intoxicated. There is also the challenge of managing the particular risks of stimulant use in conjunction with alcohol. There would be further practical challenges regarding where and how any physical outlet would be situated in a venue, how it might be marketed or promoted, how rationing, sharing or secondary sales might be regulated, and so on.

Some of these challenges could, in theory, be overcome — even if the necessary regulations might seem excessively burdensome and restrictive. For example, membership-only venues would facilitate control over who was purchasing and in what amounts. Alternatively, mobile specialist pharmacist outlets could sell stimulant products at festivals under certain conditions (including restricting hours of sale to daytime). These ideas could potentially be piloted as part of a second regulatory phase. However, in line with the more precautionary approach advocated here, the recommendation would be to limit outlets to retail only...
(physical stores, potentially supported by online/delivery services) in the first instance.

**Online vending (home delivery)**

Some people, for health, disability, geographical or other reasons, may not be able to easily access physical retail outlets. If such outlets were the only option it would exclude such people from accessing the legal market, and possibly incentivise illegal purchase or the diversion of legally obtained drugs into a parallel informal market. This is particularly the case if sales were rationed. In this context it seems inevitable that some form of online market with home deliveries will need to be established to ensure demand can be met in an equitable fashion.

Furthermore, the reality is that online sales already make up a significant proportion of illegal drug markets.\(^\text{21}\) As far as possible, though, regulated online retailing should seek to maintain the key benefits of face-to-face vending outlined above. Key elements could include:

- Identification and purchaser age verification
- Provision of useful and accessible online information, with clear harm reduction guidance
- Delivery to named individual — with signature required

**Outlet location and density**

The concentration of outlets within a given geographical area can be regulated by licensing authorities. Evidence on alcohol outlet density shows that a greater concentration of outlets is often associated with increased alcohol use, misuse and related harms.\(^\text{22}\) The impact of outlet density is

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not the same for different substances: a high density of on-licence alcohol outlets, for example, tends to encourage heavier single-session consumption and increases the risk of conflict among large numbers of drunk individuals in a small area. Restrictions on outlet density would aim to positively influence and moderate patterns of use by helping prevent over-availability, and the excessive ‘normalisation’ of access that can encourage higher use.

At the same time, too low a level of availability will inevitably incentivise illegal markets or secondary sales to meet demand. This challenge has been experienced in the Netherlands, where in municipalities with zero or a low density of cannabis coffee shops, individuals are more likely to turn to the unregulated illegal market for their supply. However, proximity to coffee shops does not seem to be linked to the prevalence or intensity of cannabis use, or to the use of other illegal drugs.23

The usefulness of the comparisons of cannabis and alcohol retailing with potential stimulant retailing are limited. The market for stimulants is much smaller than for alcohol, tobacco or cannabis, in terms of both numbers of consumers and frequency of use and purchase. The number of outlets needed in the first instance will, therefore, be smaller. Furthermore, the convenience of a nearby retail store is less of a priority under the stricter regulation of the specialist pharmacy retail model proposed in this book for the majority of stimulant products. This model is specifically designed to encourage more considered, planned drug use (associated with lower risk), and discourage more spontaneous, impulsive purchase and consumption.

Restrictions could be placed on locating stores near specific areas such as schools or other places where young people gather. In the Netherlands, cannabis ‘coffee shops’ are not permitted within a 250-metre radius of schools (leading to some existing outlets being closed) and local governments have the power to decide whether to accept them in their area.

Similarly, some US states also enforce restrictions on the proximity of cannabis outlets to schools. Washington State, for example, has prohibited cannabis businesses from within a thousand feet of specific areas where children are likely to be, including schools. Such controls may, in reality, serve a more symbolic political purpose rather than a public health necessity, and need to allow flexibility in especially highly-populated areas.

**Appearance and signage**

It is very likely that the well-established link between exposure to alcohol and tobacco marketing and increased use of those drugs applies to stimulants. Marketing includes storefront appearance and signage and should, therefore, be functional rather than promotional — using standardised descriptions without advertising. The Netherlands’ cannabis ‘coffee shops’ are subject to such restrictions, forbidding advertising or making explicit external references to cannabis (though signage with obvious connotations — Rastafari imagery, palm leaves, and even the words ‘coffee shop’ have become the default).

Similarly, Washington State permits only two signs for recreational cannabis outlets, no larger than 1,600 square inches, identifying the outlet’s name, location and nature of the business. Signs may contain images or logos, but these may not contain depictions of plants or products, depict cartoon characters or use any other image that may be appealing to children. Restrictions on the internal appearance of outlets would also apply.

The extensive body of knowledge acquired from tobacco regulation clearly demonstrates that retail environments influence purchase. There is,
for example, evidence that exposure to in-store, point-of-sale displays of tobacco products undermines impulse control among adult smokers and leads to an increased uptake in smoking among children and adolescents. The use of so-called ‘power walls’, vast rows of tobacco products placed directly behind checkout areas, clearly encourages spontaneous purchases. Their development illustrates how, in the absence of effective regulation, commercial interest will exploit opportunities to maximise sales. However, several countries are belatedly moving to regulate in-store tobacco displays, but without actually prohibiting sale. Finland, Iceland, the UK and Australia, among other countries, now require stores to keep tobacco products in opaque cabinets or below the counter.

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The practicalities of regulation

The same principles should apply to stimulants. They should only be sold in dedicated, separate retail spaces, where proper controls apply and can be implemented.

Training requirements

For pharmaceutical products, retailers need to be trained if they are to uphold their statutory duties around licensing conditions, age restrictions, sales to intoxicated customers, etc. They should also be required to provide information and advice to customers on issues such as safer consumption and where to find help or advice.

Training of this sort can be voluntary. In many countries, the alcohol industry has ‘responsible retailer’ codes and provides schemes for staff training. However, to guarantee high-quality training it needs to be a statutory requirement. For specialist pharmacy retail, such training would form part of the specific professional qualifications, but clarity on responsibility for ensuring implementation should also be laid out in operating conditions as they apply to specific outlets.

Purchase controls

Age of purchaser controls

The familiar principle that alcohol and tobacco sales should be age-limited also applies to stimulants. Freedom of choice over drug-taking decisions only reasonably applies to adults. In addition, the short- and long-term health risks associated with drug use are significantly higher for children: the younger the person using drugs, the greater the risks. Age limits are,

therefore, justified on both the principle that stimulant use should not be a matter of free choice for children, and the fact that it is likely to be particularly harmful to them.

Promisingly, age-restrictions for cannabis purchase in the US and Canada have shown high levels of compliance. However, within the goal of ensuring sales to minors are kept to an absolute minimum, sanctions should be proportionate. Some areas that have legalised cannabis have also introduced disproportionately harsh sentencing provision for supply of cannabis to minors. In Canada, for example, and proposed legislation for New Zealand, maximum sentences for supply to children are dramatically higher than the equivalent sanctions for alcohol or tobacco.

Of course, under prohibition drug markets have no age thresholds, and it can be easier for young people to access illegal substances than legally regulated ones. One study found that, in US states where non-medical cannabis has been legally regulated, there was an associated 8% decrease in the likelihood of cannabis use (and 9% of frequent cannabis use) among young people. The authors observed that their findings were ‘consistent with ... the argument that it is more difficult for teenagers to obtain marijuana as drug dealers are replaced by licensed dispensaries that require proof of age’.

Few people would argue that children should have free access to intoxicants. However, there is live debate on where, and how, age thresholds are set. For alcohol, this generally ranges between 16 and 21 depending on context (though in the UK the minimum age for consuming alcohol — as distinct from purchase — is just five). It also varies in places that have legalised non-medical cannabis from 18/19 (Uruguay and most Canadian

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provinces), to 21 (in US states and Quebec). Age thresholds are imperfect and depend on a range of pragmatic choices, ranging from health risk assessment to social norms and political culture.

Inappropriate, or unworkable, age access prohibitions can create unintended consequences, and undermine, rather than augment, social controls and responsible norms. Making the minimum age for cannabis purchase higher than for alcohol can, for instance, preference alcohol for the intervening age period. In the US, the age threshold of 21 for cannabis is consistent with alcohol. In Canada, provinces were allowed to set a higher threshold than the federal minimum age of 18. A number of provinces chose 19 to match their provincial alcohol rules. However, Quebec (where alcohol can be bought at 18) raised it to 21 — potentially encouraging alcohol use and pushing young adults who use cannabis into a criminal space.

While higher age limits may, if followed, delay first use (and thereby reduce longer-term harm) they can also encourage more risky behaviours. In the US, the Amethyst Initiative, supported by 136 chancellors and presidents of US universities and colleges, argues that the alcohol age threshold of 21 has created ‘a culture of dangerous, clandestine “binge-drinking” often conducted off-campus’. Furthermore, ‘by choosing to use fake IDs, students make ethical compromises that erode respect for the law.’

In reality, no matter what restrictions are in place, some young people will access drugs and it is vital that, whatever the legality of their actions, they should be able to access appropriate treatment and harm reduction programmes without fear. The UN Committee on the Rights of the Child has recommended that the implementation of harm reduction strategies

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‘should be employed to minimize the negative health impacts of substance abuse’ specifically in relation to children. Even under a regulated market, these challenges would remain.

Legal age controls can only be part of the solution when reducing drug-related harms to young people. They can limit availability, but not eliminate it. Effective regulation and access controls must also be supported by concerted prevention efforts. These should include evidence-based, targeted drug education that balances the need to encourage healthy lifestyles, including abstinence, while not ignoring the need for risk reduction and, perhaps more importantly, investment in social capital.

**Rationing purchase**

One solution to many of the foregoing challenges is to ration the purchasing of stimulants. At face value, this presents a neat resolution: the complexities of point-of-sale judgements around age, or likelihood of purchased goods being re-sold illegally, can be dealt with by simply requiring that consumers have a licence to purchase, and that their purchases are rationed.

However, the suggestion that purchasers, as well as retailers, should be ‘licensed’ in this way constitutes one of the most challenging problems for stimulant regulation. In most countries, neither tobacco or alcohol consumers require a purchasing licence, so why should such an approach be appropriate to other drugs? The proposition raises difficult questions around both personal freedom and the proper limits of state surveillance. The goal of regulation is to reduce harm, not unnecessarily extend state oversight into the private domain — so the trade-offs between the different implications of rationing need to be explored.

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Alcohol rationing in Greenland

In 1978, Greenland implemented the rationing of alcohol sales, having previously experimented with various forms of alcohol control. Approved by popular vote, the system granted citizens aged over 18 72 tokens per month. One token was worth a 33cl bottle of beer, while a 750cl bottle of spirits required 24 tokens. The system sought to ‘nudge’ consumers towards particular drinks: for instance, the number of tokens required to purchase wine was reduced from six to three, to encourage ‘a more Mediterranean drinking pattern’.

The rationing system had both positive and negative impacts. An immediate problem was the emergence of a secondary market in tokens. A sheet of 72 tokens sold for up to 1,200 krone ($US 150-200 at the time), meaning irregular drinkers were able to profit by selling their tokens on. Trading points were set up (even with visible signage), including outside supermarkets. Prosecution for token trading was ‘rare to non-existent’.

There was also a rise in thefts among some people who drank heavily (who now had to buy alcohol and extra tokens), as well as increased use of lighter fluid and other alcohol substitutes. The negative impacts of the points system struck the poorest hardest. The Greenland Probation agency noted that many vulnerable clients were ending up in ‘social need’, owing to the fact that they had even less disposable income than before. Alcohol smuggling and home brewing also increased. Despite its initial popularity, the rationing system became deeply unpopular and was eventually repealed by a government facing re-election and a deficit in the public purse. Following repeal, the deficit was converted into a surplus, with the huge rise in alcohol sales contributing a $12.9 million windfall.

Despite these problems there were positive outcomes. Between 1978 and 1980 alcohol consumption fell 32% while consumer spending increased on clothing and electronics. There were also reported reductions in child neglect cases, less overall reliance on social welfare and a dramatic drop in violent crimes; between 1978 and 1980, murders more than halved (from 15 to 7), ‘domestic quarrels’ fell 20%; sex crimes fell 19% and assaults fell 27%. Of course, correlation is not the same as causation and these developments may also have been linked to changing relationships with alcohol leading up to rationing.

Following repeal (and in spite of the launch of a drink in moderation marketing campaign) reported consumption rates rose roughly 60% in the following few months. Sex crimes in the capital tripled and domestic incidents doubled by 1983, attempted murders rose from 26 to 34, assault cases rose from 405 to 449 and emergency room admissions tripled within two months. How many of these trends, positive or negative, were directly due to changes in the alcohol system is open to question. Similarly, whether the system could have been amended to work more effectively is unclear: had more tokens been available, the impacts may have been

The primary benefit of purchaser licensing is that it allows more effective enforcement of any limits placed on the amount an individual can buy at any one time. This serves the dual function of helping moderate individual use, as well as limiting the risk of unregulated secondary sales. Rationing controls are often used to limit the purchase of duty-free alcohol and tobacco, although rarely in domestic retail. However, there are some examples of rationing on the general market.

Purchasing limits have, by contrast, been a common feature of cannabis regulation. In the Netherlands, an individual can only buy 5 grams from any ‘coffee shop’ (reduced from an earlier limit of 30 grams) — although there is nothing, bar the inconvenience, to prevent them making multiple purchases from different establishments. In Uruguay, consumers are limited to 40 grams per month, controlled via a licensed purchaser model linked to a centralised registry (although alternative avenues of access exist via home growing provisions and cannabis social clubs). In the US, states with legal non-medical cannabis markets have varied purchase limits for cannabis concentrates — ranging from 3.5 grams in Nevada to 15 grams in Michigan. Purchase limits for herbal cannabis are broadly similar: mostly 1 ounce, except for Maine and Michigan, where it is 2.5. In Maine, this limit expressly applies ‘at any one time, or within one day’, whereas in Michigan, the limit applies to ‘a single transaction’.

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However the term ‘a single transaction’ has caused some difficulty. In Colorado, the owner of one business faced criminal charges for facilitating ‘looping’ (customers buying the maximum amount of cannabis, then simply returning later to purchase more). Some states have been clearer in their regulations: in Oregon the limit applies ‘at any one time or within one day’ while California’s regulations expressly state ‘in a single day’. However, this policy is more difficult to implement effectively without purchaser licensing, or some other reliable means of tracking individual purchases.

In reality, existing cannabis rationing is unlikely to significantly impact on use. The purchase limits are already relatively generous, and people who seek to consume more than the limits may simply make multiple purchases, resort to secondary sales or illegal suppliers, or grow their own. The same is likely to be true for people who use stimulants. Rationing, therefore, may help moderate use to some degree, but for people whose use is heavier or dependent there may be negative unintended consequences — including diversion to more problematic illegal sources.

Rationing is, however, likely to be more useful in preventing large-scale wholesale purchasing for illegal re-sale on secondary markets. It may also facilitate more frequent face-to-face contact with specialist vendors, thereby providing greater opportunities for targeted harm reduction advice. This nonetheless requires careful balancing, as being required to make more frequent purchases may discourage individuals switching from illegal suppliers.

A separate issue to be considered when setting purchase limits is that consumption levels can vary dramatically across people who use stimulants. For instance, the Global Drug Survey suggests that around three quarters of people who use cocaine do so 10 times a year or less — and use between half and one gram per occasion. This suggests that one gram a month would cater for the majority of people. Allowing up to 12 grams a
How to regulate stimulants

year, but up to 2 grams in any month may, to cater for periods of higher use be proposed as reasonable rationing limit. However, while this might meet demand for the majority of people who use cocaine, the majority of the cocaine is consumed by the remaining 20% of heavier users. This ‘Pareto principle’ is observed for most drug consumption – meaning policy cannot simply aim to shape average consumption, but consumption (and, crucially, harm) as it is distributed across the actual population. For the heaviest (and riskiest) consumers of cocaine one gram a month would clearly only cater for a small fraction of their needs.

Purchaser licences and membership-based access schemes

A purchaser licence model has both advantages and drawbacks. On the positive side, it can restrict access to people who meet specific criteria – most obviously age, but also, as in the Uruguayan cannabis model, local or national residency to prevent ‘drug tourism’. Obtaining a purchaser licence could also require attendance at a drug education programme (similar to the requirement to pass a test on the highway code as a condition of getting a driving licence). In this respect, right of access to the legal market would be conditional on an understanding of risks and responsible use. Of course, such requirements would be counterproductive if they simply deter people from switching to the legal market.

A purchaser licence similar to existing pharmaceutical databases (e.g. Pharmanet) would allow for more sophisticated rationing than simple limits to individual purchases. It could allow a maximum purchase level per week, month, or year and prevent multiple purchasing from the same or different outlets. It could also flag higher frequency purchasing to the vendor, who could potentially offer targeted advice. Anonymised data on patterns of purchasing and use among different populations would also be hugely useful for health and social research – helping to shape more effective drug policy interventions and supporting the evolution of regulatory models going forward.
Uruguay adopted a similar model for cannabis, with the aim of limiting access to Uruguayan residents over 18 and restricting individual purchases to 40 grams per month. In order to enforce this, purchasers are required to register with the dedicated regulatory authority. Reassurances have been given that the system will use anonymised registration cards, and anonymity is guaranteed under an existing domestic law put in place to oversee government databases.

Of course, such reassurances will not ease the concerns of everyone, and for such a system to work cast-iron guarantees would need to be provided that data would not, at the time or later, be used in a way that harms the person taking out a licence. This, undoubtedly, is the primary risk of a licensed purchaser system. Again, the problem involves both principles and practicalities. In principle, people may ask why the state should monitor their consumption of some drugs, but not others (or, indeed, any drugs at all). Practically, if concerns around personal data outweigh concerns around illegal purchase, then the approach falls at the first hurdle. Data protection (and the abuse of personal data) is a very real and legitimate problem, and is unlikely to disappear soon. Additionally, what would happen to purchaser data were legislation to change? Records of drug use can, at present, have a negative bearing on employment, family disputes, insurance, travel and so forth. How would that apply were a database of registered consumers to be held by a government that elects to re-criminalise drugs?

A second key question concerns the power vested in licensing authorities. How can social equity be guaranteed in regard to who is considered for a licence, who might such decisions exclude, and what might the consequences of such exclusion be? There is a real risk that already marginalised populations may find themselves excluded either directly or indirectly, or that the system provides a further means of surveillance and intrusion into private matters. Furthermore, if data is collected on purchasing behaviour, there will be justifiable concerns over what social identifiers are included (e.g. on race, gender, sexuality) and how these are used. A purchaser licence
How can social equity be guaranteed in regard to who is considered for a licence, who might such decisions exclude, and what might the consequences of such exclusion be?

A third concern is a more practical issue of cost and bureaucracy. Establishing a purchaser licence system would be expensive, as would its secure maintenance. These are costs that would necessarily be passed on to consumers — or the general taxpayer. This could contribute to the exclusion of people on lower incomes (if costs are factored into any licence fee) or be politically untenable if folded into general taxation. This challenge could be mitigated by ensuring access is sufficiently low threshold (in terms of costs, time, or bureaucratic burden of application), and through proactive outreach and education. However, it seems difficult to envisage how this could support the most marginalised individuals, including the people who are homeless, or migrants and/or people who are displaced with insecure residency status.

A fourth concern is simply whether the state has the right to require a licence for the purchase or use of any psychoactive substance. The principle of driver licensing, for example, rests on the fact that driving a car is, in all cases, a potential risk to other people. This is not the case for drug use. While it may become a risk, this is not inevitable. Therefore, the imposition of a prior restriction — and the subjection of people who use stimulants to prior state surveillance — is problematic.

It is worth noting that any legal access model is likely to be implemented after wider decriminalisation of personal possession and use of drugs. This will impact on how drug use is addressed in law, as well as cultural perceptions and stigma around people who use drugs. So, fears of how inclusion in a drug purchaser licence database might impact on life currently, may be misplaced when transposed into a post-decriminalisation future. Nevertheless, the concerns discussed here are significant, and cannot
be easily dismissed, even if they may be mitigated through careful policy design. Ensuring strict provisions are written into legislation to guarantee that data cannot be accessed or misused by authorities, or anonymised database technology, such as blockchain, may offer further assurances. However, the questions of principle, and the risks to social equity, remain.

An alternative model would be membership-based buyers clubs drawing on elements of the cannabis social clubs in Spain and Uruguay. Clubs such as this enable key elements of a purchaser licence model but without onerous state surveillance. As is the case for alcohol in many parts of the world, the club itself is regulated as a licensed vendor, but in this instance managers would be responsible for overseeing rationing. Membership and purchase data would still need to be collected but could remain private (within the membership club, at least).

Managing an effective rationing system raises difficult questions of how to balance the need to prevent excessive, or oppressive, state intrusion in the private domain with the need to ensure any system of regulation effectively addresses identified risks and vulnerabilities and promotes health and wellbeing. Concerns around a purchaser licence model also have to be balanced against concerns around the impacts of alternative, more open retail models.

There is no perfect solution — and from some perspectives it may be viewed more as a question of choosing the ‘least worst’ option. Given the challenges, it is difficult to see how a full licensed purchaser system could be introduced without considerable additional reassurances and mitigation strategies addressing data protection and social equity. However, these could be addressed through piloting and proof of concept testing within a preliminary move to decriminalisation.

Controls over permitted locations for use

Where sales are licensed for consumption off the premises, the question of how actual consumption should be regulated remains. A common anxiety is that legally regulated drug availability would make consumption far more visible and socially intrusive. In reality, new regulatory regimes would make it possible for drug consumption to be less visible than at present. A range of existing drug consumption controls exist, including:

- Licensed premises for consumption (as is the case for alcohol in pubs and bars)
- Designated outdoor smoking areas
- Laws restricting alcohol use and smoking in specified public and private spaces

The functions of these restrictions differ. Smoking restrictions are usually justified on the basis of the known secondary health impacts of smoke; public alcohol consumption is more often restricted for public order reasons and, to a lesser extent, litter and amenity.

Where they enjoy broad support, such restrictions are generally well observed. Experience suggests that when effectively exercised, such regulation can help foster new social norms, ensuring that less onerous enforcement is needed as time passes.

Before the smoking ban in public places was introduced in the UK in 2007, support for the measure was mixed — with only 51% of the public in support in Spring 2004.37 However, the ban not only led to widespread compliance — recorded at 98.2% in the first 18 months — but has been linked to corresponding reductions in prevalence, and 20% of smokers saying that the ban

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helped them cut down on the amount they smoke.\textsuperscript{38}

Similar restrictions could, justifiably, be applied to other drugs if there is consensus that public consumption is likely to be disruptive, antisocial or a health risk to others. In that respect, bans on public consumption could extend to cover the smoking of any drug. Restrictions on public intoxication and disorder that already exist for drunkenness could, for consistency, equally apply to any form of intoxication, including with stimulants.

On the other hand, it is unrealistic to suppose that consumption of some stimulants can (or necessarily should) be controlled in the way that smoking and drinking currently are. Swallowing a pill, for example, is both impossible to restrict and — in itself — not a risk to public order or amenity. The act of consumption is brief, and the effects may not be felt for some time — making the purpose of consumption controls largely non-applicable.

Snorting is more readily comparable to drinking in public. One justification for public consumption controls (whatever one’s personal view) is that members of the public may simply not wish to witness overt drug consumption in shared spaces. Furthermore, because of the speed of effect, there is a case to be made that public snorting is more likely to be followed by public nuisance than is the case for other types of consumption.

Realistically, however, enforcement of such rules may be difficult in practice, especially if people utilise spoons, bullet-type snorting devices, or nasal sprays. It is also the case that the enforcement of any public consumption or intoxication controls may be disproportionately aimed towards marginalised communities.

As explored later in this book, co-consumption of alcohol and cocaine is a particular risk that regulation should seek to minimise. But this is difficult, if not impossible in most social settings, given the ubiquity of alcohol. It is also very difficult from a venue licensing perspective, given the ubiquity of licensed alcohol retail. Rules disallowing stimulant use in public houses and bars would likely remain conditions of alcohol licences, or indeed cannabis ‘coffee shop’ type venues.

The possibility of alcohol-free venues that are ‘MDMA-friendly’ has been proposed by Moore et al., based, in part, on experiences with MDMA in the sections of the informal rave party scene. But what might work for MDMA seems less likely to be viable for cocaine, when consumption with alcohol is both more commonplace and more actively sought after. There is also a question about the business viability of alcohol-free venues that are tolerant of other drugs. If a venue is tolerating the use of stimulant drugs, but not profiting from their sale (which — under this book’s ‘standard model’ proposals — would be in advance from a specialist pharmacist outlet) and is also not making money from selling alcohol, it would have to rely on entry charges, non-alcoholic drinks, food (which people using stimulants are, in any case, less likely to be interested in), or other forms of retailing or entertainment. There are big questions about the business viability of such a model, certainly for many existing venues.

Smoking or injecting stimulants, while representing only a small fraction of total stimulant use, creates a disproportionately large regulatory challenge. People engaging in higher-risk stimulant smoking or injecting require particular consideration to both protect their own health and wellbeing, and to address the impacts of public use on local communities. It may seem reasonable to implement bans on public smoking or injecting of stimulants, but these are only likely to succeed in reducing real harms if broader harm reduction responses are also established. These include:

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The practicalities of regulation

- Accessible needle and syringe exchange programmes
- Low threshold treatment and harm reduction service provision, including overdose prevention centres (also called safer drug consumption rooms)\(^{40}\)
- Outreach programmes
- Access to social and welfare support, including basic right to housing

Without such policies in place, bans on public consumption, while protecting public amenity, risk exacerbating costs to the homeless, heavily dependent and other high-risk groups who may have little alternative. Public protection and harm reduction are not separate endeavours; they are two sides of the same coin, and need to be treated as such from a policy perspective (see Chapter 7).

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State monopoly retail

The retail of all except the lowest risk (tier 1) drugs would, in most instances, be regulated through licensing. This approach is based on the principle that the state places conditions on the sale of the drug that reflect its particular risks, but beyond that leaves the market open. Licensing is a form of governance at a distance: the market operates according to the same principles as those of any other commodity, but with limitations placed on specific aspects of retail operations by the state — usually devolved to local regulatory authorities. In standard licensing systems, local authorities place conditions on how, when and where retailers can operate.

At the same time, general limitations may be placed on the content of, for instance, advertising materials (as is the case for alcohol and tobacco in

\(^{40}\) See: Transform Drug Policy Foundation (2020). Safer Drug Consumption Rooms or Overdose Prevention Centres (OPCs). transformdrugs.org/overdose-prevention-centres/
many countries); additionally, voluntary codes of practice overseen by commercial actors often cover issues such as vendor training.

Key to these systems is the assumption that, at its foundation, the market remains commercial and private enterprises are free to operate, albeit within constraints set by government. An alternative model, however, is for the state itself to control all, or part, of the market — acting as producer, importer and/or retailer. In this model, retail outlets are not simply placed under regulatory conditions by local authorities: they are owned and managed by state agencies.

Such state monopolies within drug markets are less common, but by no means unknown. For example, they operate for alcohol retailing in most Scandinavian countries and a number of Canadian provinces (on technical distinctions, sometimes referred to as state monopsonies). The justification for state monopolies rests on the principle that psychoactive substances can (in some, though by no means all, cases) lead to dependence, long-term health harms and a range of negative externalities (e.g. alcohol-related violence). Therefore, they do not qualify as the kind of ‘ordinary’ commodities which may be left to a market characterised by usual commercial dynamics — such as aggressive price competition, widespread marketing, and the unregulated development of novel products. ‘State monopoly’ models explicitly acknowledge that the product being regulated is qualitatively different, in regard to both private and public risks, to other commodities. So much so that they should be subject to a significantly more intensive level of regulation.

State monopolies are less often applied to production (not least because alcohol and tobacco are often imported). The key public health risks arising from commercialisation are more significant at the retail, rather than production, end of the market. State production monopolies have existed

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(China’s tobacco industry for example, or Russia’s vodka industry until 1992), but the more common model is for commercial products to be retailed via a state monopoly, as is the case for the Nordic alcohol sales, and non-medical cannabis in Nova Scotia and Quebec.

The notion of states directly acting as the suppliers of stimulant drugs raises many questions. It may be argued that state ownership of any commodity markets is wrong in principle, and that commodity retail should be a matter for private enterprise alone. Others, while not objecting to direct state control of markets *per se*, may be uncomfortable with the idea of state control of non-medical drug markets specifically. This reticence has been witnessed in other contexts, for example in the pushback against state funding of opioid substitution therapy and heroin assisted therapy. The suggestion that the state is somehow facilitating consumption of risky drugs, or, at the more sensationalist extremes, becomes ‘drug dealer in chief’, is one which many may find difficult to accept.

As noted above, however, state monopolies for alcohol are not unusual, and used to be more commonplace in the early 20th century. Many Canadian
provinces have opted for state monopoly retail models for cannabis. In all cases this approach has been justified primarily on public health grounds.

In developing a model for better-regulated tobacco retail, Professor Ron Borland proposed a system under which the state does not own production, but is the sole operator from the point of wholesale purchase. Under this model ‘free enterprise companies would retain the right to manufacture, but a [state] agency would be set up to market tobacco products.’

A state monopoly model could serve as a ‘strategic circuit breaker’ in order to establish new social norms for the legal market

Commercial entities could compete for contracts to produce drug products (in this case tobacco), but within strictly defined parameters regarding potency, preparation, packaging, etc.

Uruguay adopted a model similar to this (including retailing for registered individuals via pharmacies) for its legally regulated cannabis market. Borland proposes that commercial retailers would still be allowed to operate a for-profit system of sales, but their contract would be with the state agency that provided the product, not the private producers. In other words, rather than placing conditions on the retail of commercially supplied products (as is the case for alcohol in many countries), the retailers would enter into supply contracts with the government itself.

There are many variations on the broad concept of a state monopoly, and many challenges. Government reliance on sales income has the potential to distort policy – particularly where revenue streams are significant and established. Without the discipline of market competition, availability may become inadequate to meet key objectives (such as suppression of the illegal market), or lack the flexibility needed to meet changes in demand. Regulated stimulant markets would, however, be a very different

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proposition to alcohol and tobacco markets where such issues have arisen in the past. They would be smaller in scale, but also designed and implemented from scratch within a public health model that seeks to moderate use and minimise harms rather than commercial ones that seek to maximise profits. In this sense, a state monopoly model could serve as a ‘strategic circuit breaker’ in order to establish new social norms for the legal market. 

Overall principles

This chapter has set out some of the overall ideas and principles that inform the regulatory models proposed in the following chapters. In reality, considerable further work would be needed to develop the precise legislation required in any given context. This exploration is not the final word, by any means. However, some core principles have been established:

- That stimulant regulation should be designed above all to protect public health, reduce social inequalities, protect and promote human rights and ensure more effective harm reduction (see further the principles of regulation in Chapter 1).

- That existing licensing models, with adaptation, are amenable to controlled stimulant retail.

- That caution is needed in the early stages of regulation, even if the intention is to ease restrictions later.

- That striking the balance between the demands of personal autonomy and the responsibility of the state to reduce harm requires some difficult, often imperfect, choices – but that these decisions are not so hard as to make the project impossible.

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Decades of drug prohibition make alternative scenarios hard to both imagine and plan. We should not take the challenge of that task lightly. It is not easy to establish a newly regulated infrastructure for a market as challenging as that for stimulants — or to envisage how it might be made practicable. However, the status quo cannot be tolerated any longer so it is vital that these alternatives are not only described, but debated, developed and explored in all seriousness.

**Standard model**

There is not (nor, given local and regional variations, should there be) a one-size-fits-all model for effective drug regulation, and there are a range of models that could — if implemented carefully — meet the key principles of good drug policy established in Chapter 1. However, given where we are in terms of commercial pressures, regulatory practicalities, and the need to establish systems that can garner the widest possible support, it is our view that regulation of risk tier 2 stimulants needs to be different from what has generally been the case for alcohol and tobacco.

Most notably, we conclude that the best option for balancing the needs of access with the need to prevent over-commercialisation is to establish a state monopoly over, at the very least, the retail of tier 2 stimulant products. That is to say: rather than simply licensing private operators to sell stimulants on the open market, the state should directly own and regulate retail outlets. Furthermore, where stimulants are concerned, the main outlet type should be a specialist pharmacy.

The intensity of regulation should always reflect the risks associated with the drug being controlled. These include long- and short-term health risks as well as other societal and behavioural factors. On that basis, while there are strengths and weaknesses associated with all options for regulation, our considered view is that a state retail monopoly is the most practical and
The practicalities of regulation

effective way to regulate tier 2 stimulant markets given the wider economic, political and social context in which regulation would occur.

A state monopoly retail model allows for full and direct control over the key regulatory levers to be exerted by authorities acting for the public good. This provides control over price, availability, and marketing while avoiding the need for a complex and burdensome compliance and enforcement infrastructure to prevent commercial entities exploiting weaknesses in the regulatory structure.

In practical terms, while monopolies over alcohol have been, in almost all cases, imposed on markets previously regulated through licensing, here there would be a regulatory blank slate. Given the alternatives (an uncontrolled illegal market at one extreme, a barely controlled commercial market at the other), we believe a state monopoly is the best option available.

We also conclude that, in most cases, stimulants should be sold through specialist pharmacies. We discuss in more detail how this principle applies to, and varies between, specific drugs in later chapters. However, our overarching model proposes that sales should be for consumption off-premises, in specialist pharmacy-style outlets, with trained staff able to deliver harm reduction advice.

This ‘standard model’ summarises our preferred regulatory model for pharmaceutical preparations of MDMA, cocaine, and amphetamines. Lower potency plant-based stimulant products like coca leaf would be regulated under a less restrictive commercial model, and more risky smoked or injected products would be managed under a non-retail harm reduction model.

It is also important to consider how the development of a legally regulated market for stimulants will impact on international development. These issues are explored in Chapter 7, where we provide further recommendations for ensuring that sustainable development is a core priority of drug policy reform.
# Standard model for regulation

## Overarching market model

- Licensed pharmaceutical companies would produce drug products in accordance with parameters established by a dedicated Drug Regulatory Agency (DRA)
- Companies compete for DRA production contracts
- DRA is the sole purchaser and distributor to physical or online retail outlets. Sale would take place under a state monopoly model, with only government-run specialist pharmacies licensed to sell specific drug products
- All retail revenues/taxes would accrue to the local or national government

## Production controls

- Drug products specified by the DRA would be produced by pharmaceutical companies under licence by the DRA
- Quality control and security issues related to production and transit of drug products would operate under existing or equivalent frameworks for pharmaceutical drugs (which currently already encompass cocaine, amphetamines, and MDMA for medical and scientific uses), extended and appropriately adapted

## Product controls

### Preparation/dosage

- Standardised dosage units for pill or powder formulations (and information on risks/dosage relating to these units)
- Quantity of drug content in milligrams written on individual pills
- Pills are scored to allow easy division into smaller dosage units
- Powder provided in clear vials with dosage calibration lines (approx dosage control via measuring spoon provided)

### Price

- Prices set by DRA — with flexibility for some variation by regional/local/municipal authorities
- Prices initially set at or near those found on the illegal market
- Flexibility to alter prices based on cautious experimentation — only made in small increments at carefully spaced intervals, accompanied by close evaluation/monitoring
- Evaluation of price regulation considering impacts on prevalence and using behaviours (frequency, products consumed/displacement, high-risk use) and relative sizes of parallel legal/illegal markets, and revenues

### Packaging

- Non-branded pharmaceutical-style packaging
- Mandated content information standards, and prominent health warnings
- Child-resistant / tamper-evident design
- Sustainability standards in packaging production and waste
### Vendor and outlet controls

| Outlet type | • Single function physical outlets retailing non-medical drugs only, modelled on medical pharmacy/dispensary, supported by single function online retail outlets for the same non-medical drug products. Retail outlets would operate under a state monopoly
|             | • Option for parallel online retail and delivery |
| Outlet location and density | • Locations of physical outlets determined by local or municipal authorities, operating within parameters established by the DRA (regarding maximum or minimum outlet density), or other restrictions (such as proximity to schools) |
| Outlet appearance and signage | • Minimal, purely functional external appearance and signage |
| Responsibilities and training requirements | • Vendors working within a state monopoly (state employees) required to enforce regulatory restrictions including: age access controls, no sales to intoxicated persons, and purchase limits
• Vendors additionally required to have a professional qualification and training to offer tailored health and harm reduction information and advice to consumers, including referral to relevant drug/support services |

### Purchaser/consumer controls

| Age of purchaser | • Minimum age determined nationally — should be no younger than 18. There may be an imperative to synchronise with age of access to alcohol if higher than 18 in some jurisdictions |
| Rationing sales | • Per purchase availability should be rationed to a reasonable quantity for personal use only (see discussion on rationing and purchaser licences above) |
| Permitted locations for use | • Issues relating to consumption/use in public spaces would be addressed using existing (or appropriately amended) legislation covering public intoxication, or antisocial behaviour
• Consumption could be formally tolerated in certain commercial social spaces — even if drugs were not available for sale, and selling remained prohibited |

### Marketing

| Packaging | • Unbranded pharma-style packaging, with mandated content and prominent health/risk info/warnings |
| Vendors/outlets | • No marketing or promotional activity for retail or online outlets beyond functional availability and price information for adult customers |
3

MDMA
The history of MDMA demonstrates the futility of putting enforcement, targeting either people who use or supply, at the forefront of the policy response to drugs.
What is MDMA?

MDMA is the abbreviation for *MethyleneDioxy-MethylAmphetamine*, a member of a larger group of drugs called the phenethylamines. Its molecular structure is similar to that of its close relative methamphetamine, but the seemingly small variation in the molecular structure causes its amphetamine-like CNS stimulant properties to be complemented by other, very distinctive, psychological effects that set it aside from most other stimulants. MDMA, commonly referred to as ‘ecstasy’, is known for creating a sense of empathy or intimacy, communion and emotional openness that account for its enduring popularity in the dance music party scene, and medical uses in therapeutic settings.

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1 Described by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) as ‘A chemical substance comprising a phenyl group attached to a linear chain of two carbon atoms and terminating in an amino group. The expanded name is 2-phenylethylamine. The phenethylamine family includes a range of substances that may be stimulants, entactogens or hallucinogens.’ EMCDDA (Undated). Drug Profiles: Glossary. www.emcdda.europa.eu/publications/drug-profiles/glossary#Phenethylamine
There are a number of drugs in the phenethylamine group, with similar molecular structures and some similar effects; including MDA (methylenedioxyamphetamine), MDEA (methylenedioxyethylamphetamine) and MBDB (N-methyl-1-(1,3-benzodioxol-5-yl)-2-butanamine). These have some similar effects to MDMA, and have previously been sold on the illegal market as ‘ecstasy’ but have never achieved the same level of popularity and are vastly rarer than MDMA in today’s illegal markets.

**History**

MDMA was first synthesised in 1912 by the Merck pharmaceutical company. However, its distinctive effects in humans remained unrecognised for decades until it was rediscovered by experimental psychopharmacologist Alexander Shulgin. Shulgin re-synthesised the drug and experimented on himself, publishing the first report on the effects of MDMA in humans in 1978, noting how it produced ‘an easily controlled altered state of consciousness with emotional and sensual overtones’.

In the late 1970s and early 1980s, MDMA use was largely confined to the experimental therapeutic arena. During this early phase, an estimated half a million doses were administered in psychotherapeutic settings alone in North America, despite the absence of rigorous clinical trials to establish safety and efficacy. This early phase of research was effectively terminated in 1985 when MDMA was made a Schedule 1 drug in the US. This became a global prohibition issue when MDMA was subsequently included in Schedule 1 of the 1971 UN Convention on Psychotropic Substances in 1986.

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In the early 1980s, MDMA had also begun to establish itself among some more niche US party scenes — including the Deadheads (followers of the Grateful Dead), the Chicago house music scene, and some localised gay scenes, notably in Texas. But it achieved a dramatically higher profile when it became closely associated with the emergent European rave party scene in the late 1980s — establishing a connection with underground and then mainstream electronic dance and club culture that continues to the present day.

**Rave culture**

European rave culture was initially characterised by underground, sometimes spontaneous, and often free dance events. Hosted in ad-hoc venues including warehouses, barns, fields and other semi-derelict and outdoor spaces (often lacking alcohol sales and marketing), MDMA became the drug of choice. Pills were relatively easy to transport and produced effects that suited the all-night party scene.

As it became more mainstream in the late 1990s and early 2000s, the new dance music culture became more commercialised, as entrepreneurs moved
to exploit an increasingly lucrative opportunity. The popularisation of the scene was partly the familiar movement of a subculture into the mainstream, with the predictable commercial exploitation that follows. However, it also occurred despite being accompanied by determined efforts at suppression driven not only by the kind of moral panic that often accompanies the emergence of new drug cultures, but by a commercial targeting of the culture by the alcohol industry. In the UK, for example, while the notorious Criminal Justice and Public Order Act (1994) sought to suppress free raves (see below), alcohol venues — both bars and nightclubs — began to target the new market through both redesigning venues to include dancefloors, DJs, club-style lighting, etc., and through developing new drinks (often referred to as ‘alcopops’) that were marketed using self-consciously ‘clubby’ imagery.5

The rapid penetration of MDMA use into significant segments of the European night-time economy during the 1990s sparked a rash of tabloid media coverage, which, in the UK, was characterised by high-profile reporting of MDMA-related deaths — particularly of young women. While relatively small in number, MDMA-related deaths received hugely disproportionate media coverage compared with deaths related to other drugs — and especially compared to alcohol. As outlined on the right, whereas 9% of heroin and 2% of alcohol poisoning deaths in 2008 were reported, 66% of cocaine-related deaths, and 106% of ecstasy deaths (since some unrelated deaths were misidentified as being due to MDMA) were reported in news media. Related to this, previous research into Scottish newspapers has also found that reporting of drug deaths ‘may be biased towards cases involving certain drugs or types of user’ — particularly deaths of teenagers, and particularly deaths as a result of MDMA.6

This rapid expansion of both MDMA use and reporting of its negative consequences led to a range of policy responses — often pushing in opposite


### UK drug poisoning deaths (2008) vs popular press coverage

<table>
<thead>
<tr>
<th>Drug</th>
<th>Deaths</th>
<th>Press reports</th>
<th>% deaths reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDMA</td>
<td>44</td>
<td>47</td>
<td>106%</td>
</tr>
<tr>
<td>solvents</td>
<td>12</td>
<td>10</td>
<td>83%</td>
</tr>
<tr>
<td>cocaine</td>
<td>235</td>
<td>157</td>
<td>66%</td>
</tr>
<tr>
<td>SSRI (Prozac-like) antidepressants</td>
<td>116</td>
<td>16</td>
<td>13%</td>
</tr>
<tr>
<td>heroin &amp; morphine</td>
<td>897</td>
<td>83</td>
<td>9%</td>
</tr>
<tr>
<td>paracetamol</td>
<td>260</td>
<td>19</td>
<td>7%</td>
</tr>
<tr>
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<td>381</td>
<td>19</td>
<td>5%</td>
</tr>
<tr>
<td>methadone</td>
<td>378</td>
<td>10</td>
<td>2%</td>
</tr>
<tr>
<td>alcohol</td>
<td>685</td>
<td>14</td>
<td>2%</td>
</tr>
</tbody>
</table>

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directions at the same time. On the one hand, pragmatic harm reduction approaches emerged, focusing on creating safer party environments and distributing information encouraging safer behaviours and patterns of use. On the other hand, an array of enforcement crackdowns on the supply of MDMA, and interdiction of its precursors were launched alongside the ramping up of ‘zero tolerance’ security efforts at nightclubs and music festivals to prevent drugs entering or being consumed on site.

Legislative action was also taken to curtail MDMA-driven raves. In the UK, the Criminal Justice and Public Order Act (1994) created police powers to remove ravers, prevent entry to suspected raves and to confiscate sound equipment. The Act sought to justify its measures by applying to gatherings of 100 or more people (since amended in England and Wales to 20) where ‘amplified music is played during the night...[and]...is likely to cause serious
distress to the inhabitants of the locality.’ Not all types of music gatherings were intended to be targeted, so it was notoriously clarified that ‘music’ includes sounds ‘wholly or predominantly characterised by the emission of a succession of repetitive beats’.

The legislation has been interpreted as an attempt to combat a wider ‘threat...to the social order’ by rave parties, seen as infiltrating idyllic countryside locations and at odds with social values, in much the same way that furore about new illegal drugs can often be characterised as a perceived infiltration from an ‘other’ into civilised society. The legislation was a key part of the developments in the UK which saw, simultaneously, ‘the commercialisation and criminalisation of mid-1990s dance space’.

Legislation adopted elsewhere includes the brazenly-named ‘Reducing Americans’ Vulnerability to Ecstasy’ (RAVE) Act in the United States. The Act referred to the ‘tens of thousands of young people...initiated [seemingly without agency] into the drug culture at “rave” parties or events (all-night, alcohol-free dance parties typically featuring loud, pounding dance music)’. The Act went on to state that ‘many rave promoters go to great lengths to try to portray their events as alcohol-free parties that are safe places for young adults to go to dance with friends.’ In establishing substantial fines for anyone allowing spaces to be used for raves, the Act specifically targeted ‘rave promoters’ portrayed as taking advantage of young people by convincing them drug use was safe, then selling them overpriced water and glow sticks.

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In both the UK and US, MDMA and dance culture were conflated into a single enemy – ‘rave’ culture – seen as both undermining traditional values and commandeering the agency of young people. The primary effect of such responses was less to suppress rave culture, than to accelerate the movement of the culture into commercialised club spaces.\(^{11}\) A further effect of the commercialisation of MDMA dance culture was the ‘reascendance of alcohol’. Prior to criminalisation of raves in the UK, there was an ‘anti-alcohol bias’: indeed, it was a period in which alcohol was seen by sections of young people as an older person’s – and, therefore, uncool – drug.\(^{12}\) Hence the swift marketing response, facilitated by the move of dance culture into commercial spaces, in which alcohol companies sought to ‘appeal to a new

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generation of drinkers’ through new products, new spaces and new forms of promotion.13

Despite this, the dance scene grew and diversified, although with alcohol largely reabsorbed as a drug within the culture. As the range of genres and subgenres grew, and despite the successful ‘capture’ of elements of dance culture by the alcohol industry through large-scale sponsorship of events, MDMA remained indelibly associated with the scene. By the 2010s, the industry could be described as having become fully globalised, especially under the EDM (electronic dance music) moniker, with club sizes growing enormously, whole destinations emerging as venues for dance tourism, festivals appearing across the world, and events growing to encompass corporate, stadium scale extravaganzas with correspondingly high price tags. Even if a smaller scale underground scene continued in parallel, a culture inextricably tied to the use, and the visual imagery, of MDMA had become a global phenomenon.

Enforcement responses

Attempts to deter or physically prevent MDMA use in night-life and festival settings have largely failed. Pills and powder drugs are small and easy to conceal, meaning only a relatively small proportion will be intercepted even by the most draconian security measures. This reality must be taken into account by any future regulatory regimes, and provides an important argument for management of night-time economy spaces to incorporate MDMA (and other drug) safety considerations; given the reality of use, the question is not how to stop it, but how to manage it to minimise harms.

If preventing drugs entering nightclubs and music venues has proved difficult, for large-scale outdoor festivals and events it has been effectively impossible. Attempts to enforce ‘zero tolerance’ licensing requirements have, however, often contributed to unintended increased risk, including through:

- Poor provision of safer environments and harm reduction services from event organisers reluctant to publicly acknowledge that drug use is occurring
- Incidents of people concerned about door security (sometimes including sniffer dogs) consuming all their drugs at once before entry
- People seeking to evade entry security by buying from unknown onsite dealers instead of more reliable established sources
- People consuming drugs covertly to avoid detection, making dosage management more difficult

Recent experiences in Australia also point to the extent to which a disproportionate response to the ‘threat’ of MDMA consumption can lead to truly disturbing outcomes. In New South Wales, the practice of enforced strip searches, often of children under 16, heading towards festivals has caused outrage. In this case, we see the prevention of MDMA use apparently
justifying behaviour that, in any other circumstance, could be described as state-sanctioned sexual abuse.\textsuperscript{14}

Enforcement responses targeting MDMA production and supply have proved similarly ineffective, heavy-handed or counterproductive in the face of rising demand.

In the early 2000s a clampdown on the production of safrole oil in China — the key precursor for MDMA manufacture at the time — led to production shifting to Cambodia, where controls were weaker. Seizures increased in Cambodia from 2006 until a series of raids on woodland processing plants and huge seizures in 2008 — totalling more than 30 tonnes of the oil, enough to make hundreds of millions of MDMA pills — dramatically reduced production.\textsuperscript{15} This caused a global MDMA supply shortage that lasted for several years. Despite being hailed a major enforcement success, it had a number of ultimately harmful outcomes — from both enforcement and public health perspectives. The void in the market created by the MDMA shortage was soon exploited by entrepreneurs developing or introducing an array of novel psychoactive substances (NPS) with MDMA-like stimulant effects, but with unknown and potentially more toxic effects — many of which were mis-sold as MDMA.

By 2009, EU seizure data suggested that the majority of MDMA pills in circulation contained little or no MDMA at all. At this time, what Smith et al. describe as the ‘recommodification or rebranding of ecstasy as a higher priced, higher quality product’ in crystal or powder form began to occur, capitalising on ‘disenchantment with cheap, easily available, but poor


quality...ecstasy pills', synonymous with the MDMA drought. Among the NPS that emerged during this period were piperazines (TMFPP, mCPP, and BZP — see BZP case study) which, in 2009, were reportedly ‘present in most ‘ecstasy’ tablets sold in Europe’, as well as mephedrone, which rose rapidly in popularity in 2009 as a substitute for MDMA. Both mephedrone and piperazines were legally available for periods of time in many countries as domestic drug control legislation struggled to keep pace with the growing array of NPS entering the market. Unlike most other substitutes, which have since largely faded into obscurity, the market for mephedrone has survived the 2011-13 re-emergence of MDMA to some degree; its effects are distinct enough from MDMA to help establish its own drug culture niche, notably in the gay party scene.

Another NPS sometimes mis-sold as MDMA during this period was PMA/PMMA – which has some similar stimulant effects to MDMA but is

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MDMA

markedly more toxic and risky. Because it is slower acting (taking two hours for its effects to come on — twice as long as MDMA) people often redosed thinking it was a weak MDMA pill — leading to overdose, emergency events and sometimes death. PMA/PMMA-related deaths in England and Wales inversely track the MDMA drought, only diminishing as MDMA significantly returned to the market again after 2013.

By 2010, however, resilient demand for MDMA and the profit opportunity it offered led to a new production process being developed by illegal market entrepreneurs. This new process used a new precursor, called PMK-methyl-glycidate, that bypassed the need for the internationally prohibited safrole precursors altogether. This innovation, arguably a direct consequence of the earlier safrole oil interdiction ‘success’, meant that a cheap and abundant supply of high quality MDMA became available. This, in turn, led to a drop in price, and a rise in the purity and levels of MDMA content in pills, beginning in 2011-12 and accelerating from 2013.

Use of MDMA has also risen from this point, and has coincided with higher seizure rates: 2.2 million doses of MDMA were seized in the UK in 2018/19, up from 0.43 million in 2012/13. This rising use of MDMA has been seemingly at the expense of many of the NPS that flooded into the market during the MDMA drought.

PMK-methyl-glycidate and its relatives were belatedly prohibited under the 1988 UN Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances in March 2019, although it seems unlikely that this will change its now established role in MDMA production in the short term.

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The present day

While mis-selling of other drugs as MDMA pills has tailed off, what might have been a positive development in some respects (greater certainty for consumers of the substance they are purchasing and a reduction in more risky adulterants and mis-selling) has been countered by the growing risks from high potency MDMA pills and powder. The EMCDDA Trendspotter notes that ‘over half (53%) of all ecstasy tablets tested in 2015 [by the Netherlands Drug Information and Monitoring System (DIMS) that tests over 10,000 pills annually] contained over 140 milligrams of MDMA compared to just 3% in 2009.’

By 2018, an even greater 72% of samples contained over 150 milligrams of MDMA, with an average of 171 milligrams per pill — considerably higher than the average of 50–80 milligrams consistently seen in Europe across the 1990s and 2000s, and a steady rise from 2014. Recent years have also seen the rise of ‘superpills’ — with a range of 270–340 milligrams — up to four times a normal adult dose. Rival producers, flush with low cost raw materials, are competing with each other to market the strongest pills (even if, beyond a certain point, it is unclear whether this is something consumers actually want).


The widening potential range of MDMA content in pills, combined with the emergence of super-high strength pills has been identified as a key driver in the rapid rise in MDMA-related medical emergencies and deaths since 2013.

MDMA has also developed a substantial niche in online darknet markets accessed via dedicated TOR browsers and paid for using cryptocurrencies like Bitcoin. Estimates from darknet market studies in 2015 suggested that MDMA was the third most popular drug (after cannabis and pharmaceuticals) purchased on the darknet, accounting for 25% of drug sales. Of those who reported obtaining MDMA in the 2019 Global Drug Survey, 67% reported having obtained it through the darknet – higher than for any other drug. This is up from 48.7% in 2015, when the percentage was also higher than for any other drug.

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The EMCDDA also reported in 2019 that ‘transactions involving quantities of MDMA tablets indicative of the middle level of the market account for more than double the revenue of sales of retail-level quantities’. This is in stark contrast to other drugs sold on the darknet, like cannabis and cocaine, for which comparative sales are ‘overwhelmingly at the retail level’. User reports suggest that MDMA purchased on the darknet is perceived to be better quality than supply from more conventional face-to-face dealer markets – perhaps in part because of the eBay-style user ratings system for products and vendors acting as an informal system of quality control and increased accountability of sellers. While concerns exist about the ease with which younger potential users might be able to access MDMA (and other drugs) via the darknet (the technical barriers to the market are relatively easily navigated by tech-savvy individuals), there may also be potential for reduced harm through informal quality controls and, for people without access to more established trusted sellers, reduced interaction with unknown dealers.

The pull factors of the darknet in the current illegal market highlight important challenges for a regulated market. Options for future regulated online sales exist but need to account for problems such as the lack of face-to-face interaction with a vendor (and the potential loss of key tailored harm reduction which can be given in person), and meaningful enforcement of age controls.

Lessons learnt

There are several useful lessons from the recent history of MDMA. Perhaps most obviously it demonstrates, yet again, the futility of putting enforcement, targeting either people who use or supply, at the forefront of the policy response to drugs. As so often, enforcement interventions have

failed to prevent rising use, or prevent supply in the longer term, instead only serving to temporarily displace using behaviours and mutate the market in ways that increased health harms.

It is clear that MDMA has considerably more resilient popularity than any other amphetamine-type stimulant or synthetic drug that has entered the market in recent history. Significant numbers of people not only like MDMA’s effects and are willing to take known risks (health and legal) to enjoy them, but they seem to prefer it to most available substitutes.

The displacement from MDMA to other stimulants that took place during 2008–2012 MDMA shortage does, however, demonstrate that people who use stimulant drugs in nightlife and party settings will often be willing to switch between drugs, even to what they may view as inferior options, rather than simply abstain. The demand for stimulants in social environments appears to be resilient more broadly, even in the face of such market shocks. This has implications for the potential of using regulatory interventions to nudge consumption behaviours towards safer products and patterns of use.
How to regulate stimulants

MDMA / Ecstasy
HARM REDUCTION

Consider just ¼ of a pill, or a small dab of powder

Wait at least one hour before taking any more
Many pills in circulation contain a large amount of MDMA—sometimes up to 1x an average adult dose. Pills that look the same, even from the same batch, may have different contents. It may take longer to feel the effects. Always start with a small dose and wait for the effects to hit; this can take 30 minutes or more.

Avoid mixing with other drugs

Mixing with alcohol & other drugs (eg. cocaine & ketamine) increase the risk
Mixing drugs increases their risk to you - be aware of any interactions between drugs including alcohol & prescription medications including antidepressants (eg. SSRIs). Mixing with stimulants like cocaine and MDMA increases the risk to your heart.

Sip water regularly

Aim to drink around ½ pint per hour
MDMA makes it difficult to urinate and makes you feel thirsty. This means it’s easy to drink too much. If you don’t urinate enough this can cause EHYDRATION which is dangerous. If you are sweating a lot you will lose essential electrolytes your brain and body need. Drink slowly and replenish these! Sports drinks are a good choice because they contain electrolytes.

Take frequent breaks to cool down

Pay attention to your body & be mindful of heatstroke
MDMA makes it hard for your body to control temperature. If you are in a hot, crowded environment it can be easy to overheat. Take regular breaks from dancing in a cool area - your body will thank you the next day.

Ask for help if needed

Be aware of the signs of an emergency and know when to get help
Look out for: excessive sweating, disorientation, agitation, people who are hot to the touch or so hot they have stopped sweating. Place yourself, know your limits & look after yourself and those around you.

Oral MDMA Dosages, provided by www.Erowid.org

Light: 40 – 75 mg
Common (small or sensitive people): 60 – 90 mg
Common (most people): 75 – 125 mg
Common (large or less sensitive people): 110 – 150 mg

SOURCE: The Loop
Adaptations in the behaviours of people who use MDMA shows that they are able, willing and indeed eager to minimise their risk exposure where possible. The increasing use of the darknet, and the embrace of harm reduction services such as drug safety checking, are clear indicators of this. Harm reduction is not a principle that policy makers will need to force upon people who use MDMA or other drugs in nightlife and party settings. Given the option, it is clear that people who use MDMA and other drugs...
will embrace harm reduction approaches, and support their development. Given the right information and opportunities, most people who use drugs will make rational risk-management decisions when they do so.

Despite their image as risk-taking hedonists, recreational drug users do seek out and share harm reduction strategies, often alongside ‘pleasure maximisation’ strategies (the latter often requiring considerable knowledge of drug research, policy and practice). For example, many people who use drugs recreationally access internet-based resources to obtain and exchange advice and information about their drugs of choice, with experienced ‘recreational’ drug users frequently offering experiential ‘knowledge’ to young people new to dance club scenes.27

In the Netherlands, possibilities of regulated legal supply of MDMA for non-medical use have been floated, informed by an independent Dutch interdisciplinary expert group (n=18) using dynamic multi-criterion decision analysis. The analysis considers impacts of different policy options across a range of outcomes to develop a new optimised policy model for ecstasy. Hallmarks of the optimal model include regulated production and sales of MDMA, and reduction of MDMA-related organised crime and environmental damage. The model includes precautionary measures related to product control and information provision on safe ecstasy use.28

**Effects**

As well as amphetamine-like stimulant effects and some mild psychedelic effects, MDMA commonly creates a sense of empathy or intimacy, communion and emotional openness in social situations. The combination of these empathic and stimulant effects creates the euphoric or ecstatic

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experience, particularly in intense sensory social or party settings, that led to it becoming known, or at least marketed, as ‘ecstasy’. The particular empathic nature of the experience has led to it also being referred to as an ‘empathogen’, or later (to avoid the inadvertent negative connotations of a ‘pathogen’) the similarly defined term, ‘entactogen’.

When taken orally (as is most commonly the case) effects of MDMA begin between 30 minutes and one hour after consumption and usually peak after around two hours, although this can vary depending on bioavailability of different pills, capsules, wraps or powder/crystal, and whether used on an empty stomach (faster) or not (slower). The main effects last around three hours (from 1–4 hours after ingestion), with some effects felt for 7–8 hours after they are first experienced, potentially longer with higher doses (the blood plasma half life is 6–7 hours).

Tolerance to MDMA develops rapidly making its use naturally more self-limiting than many other stimulants. While people may re-dose over a period of partying after the initial peak has begun to fade, the way that MDMA works (effectively releasing serotonin from storage faster than it can be replenished) means that re-dosing and binge use deliver rapidly diminishing returns. Re-dosing also tends to have a more amphetamine-like
stimulant effect, with less of the sought after MDMA-type euphoric effects. This also holds true over medium-term periods of days, and to a lesser extent even weeks or months (see chronic risks below).

Using behaviours

MDMA is most commonly consumed orally in pill form, although powder/crystal MDMA form has become increasingly popular. As discussed above, the move towards powder crystal began as part of a rebranding away from pills into a higher quality, premium product. This has persisted, however, arguably so has the perception of crystal as more likely to be of a higher quality. Powder/crystal MDMA is usually consumed orally — licked from a fingertip, or swallowed inside a capsule, tissue paper or cigarette rolling paper (capsules of powder are the most common form of MDMA in Australia). Powder/crystal may also be snorted, although this is less common. There are reports of pills being ground and snorted, but as binding agents and fillers make up around 40–70% of pills by weight, this is less appealing and accordingly rare. There are also some reports of MDMA being injected in solution, but this is extremely rare.\(^\text{29}\)

The UNODC has estimated that in 2018, 0.4% of the global population aged 15–64 had used MDMA within the past year. Higher prevalence of use was recorded in Australia and New Zealand (2.2%), North America (0.9%) as well as Western and Central Europe (0.8%).\(^\text{31}\) According to the EMCDDA, around 2.2 million young adults in Europe (aged 15–34) used MDMA in 2018 (1.8% of this age group), with national estimates ranging from 0.2% (Portugal and Romania) to 7.4% (Netherlands). Countries with the highest


The prevalence of MDMA use in Europe among young people include the Netherlands, Czechia, the United Kingdom and Bulgaria. In its analyses of the EU drug markets for the year 2017, the EMCDDA estimated approximately 60 million MDMA tablets were consumed across the EU.

According to the Global Drug Survey, among people who used MDMA within the past 12 months, 13.4% only used MDMA once, with the majority (59.3%) using it 2–10 times in the past year. Both self-report and wastewater analysis shows use is concentrated around weekends. Use is considerably greater in clubs as opposed to bars, especially EDM venues; in 2016, the EMCDDA reported last-year prevalence of MDMA use was 25 times

Therapeutic uses of MDMA

The therapeutic use of MDMA has been the subject of ongoing research, including potential applications for treating depression, anxiety, and post-traumatic stress disorder (PTSD), as well as a tool in psychotherapy (including couples relationship therapy). More recent research has re-visited using MDMA to treat alcohol dependence. Exploring this therapeutic potential has, however, been significantly obstructed since its legal designation in the US at Schedule 1 in 1986, as well as concerns over illegal recreational use. While MDMA research has not been impossible, the bureaucratic hurdles to obtaining research licences have heavily restricted it.

Today, however, there is a resurgent interest in MDMA’s therapeutic possibilities, and a greater openness from regulators to facilitate it. The US-based Multidisciplinary Association for Psychedelic Studies (MAPS) has, following successful phase 2 trials, secured FDA ‘Breakthrough Therapy Designation’ for MDMA-Assisted Psychotherapy for PTSD. Phase 3 trials are expected to be completed in 2021, aiming to make MDMA an FDA-approved prescription medicine by 2022.

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i Sessa, B., Sakal, C., O’Brien, S. and Nutt, D. (2019). First study of safety and tolerability of 3,4-methylenedioxymethamphetamine (MDMA)-assisted psychotherapy in patients with alcohol use disorder: preliminary data on the first four participants. BMJ Case Reports 12:e230109. casereports.bmj.com/content/12/7/e230109

ii MAPS (Undated). MDMA-Assisted Psychotherapy Study Protocols. MAPS. maps.org/research/mdma

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higher (37%) among ‘self-identified ... regular nightclub goers’ aged 15–34 than in the general EU population (1.5%). This is a long-term pattern: in 2004, Measham noted that while ‘the lifetime prevalence rate for use of any illicit drug is 12% among 16– to 29-year-olds in the general population in the 2000 British Crime Survey ... the lifetime prevalence rate among clubbers ranges from 52% to 81%, depending on club location, region, music policy and socio-demographic customer base’.

MDMA is, however, often used in combination with other drugs within social environments, which can significantly increase its risks. It is most commonly, and perhaps also most problematically, used with alcohol – due largely to the ubiquity of alcohol supply in the night-time economy. A study of 8,781 drug-related emergency presentations to emergency services between 2008 and 2014 situated close to party settings in Ibiza found that 46% involved MDMA; alcohol and MDMA is the most common drug combination among all presentations. An EMCDDA/European Drug Emergencies Network (Euro-DEN) study of MDMA-related emergency presentations between 2014 and 2017 found that almost all MDMA presentations (over 95%) involved polydrug use, with co-ingestion with alcohol making up 70% of MDMA presentations where more than one drug was consumed.

MDMA is also used with other stimulants, including cocaine and amphetamines and, in more niche cultures, with ketamine, and LSD.

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Risks

By most measures MDMA is less risky than other commonly-used stimulants. However, it is associated with a number of acute risks (particularly when used in nightlife/social settings) as well as notable, but more difficult to quantify, chronic risks.

Despite a long history of therapeutic use in controlled settings, there have not been sufficient clinical trials in humans to establish the risks and toxicology of MDMA compared to the more extensive medical literature on amphetamines and cocaine. As the EMCDDA notes: ‘much of the clinical evidence [on MDMA risks] is derived from case reports, a small number of prospective observational studies, retrospective audits and analysis of patient records.’

Most MDMA risk analysis, therefore, derives from studies of unregulated, illegal supplies. This data is obviously problematic as people reporting MDMA use will rarely have accurate data on how much they have consumed, or be able to report whether it was adulterated or even another drug mis-sold as MDMA. It is, therefore, difficult to untangle the risks intrinsic to MDMA’s pharmacology and toxicology, from the risks related to using behaviours (e.g. polydrug use in nightlife settings), and risks either created or exacerbated by prohibition (dosage control, adulteration, inadequate harm reduction provision). Drug safety testing services are now shedding more light on the nature of what is being consumed as MDMA and how this has changed over time. The drug safety testing provider, The Loop, has found that around one in five samples of MDMA tested in the UK were, in fact, other substances. Much of what we know about MDMA risk in nightlife settings is, in reality, based on the consumption of a variety of unknown substances.
of unregulated drugs, often taken with alcohol. We can, therefore, only make informed estimates of the level of risk MDMA use may present in a regulated environment.

### Acute risks

As with all drugs, the extent of risk associated with MDMA consumption is determined by the relationship between its basic pharmacology as it interacts with an individual’s particular vulnerabilities, using behaviours, and the using environment. Women appear more vulnerable to certain risk factors than men — though for reasons that are still not entirely clear (body mass, water retention, hormones, behavioural and genetic factors may all come into play). According to the Global Drug Survey, women who used MDMA were more than twice as likely to seek emergency medical treatment following consumption than men — albeit in both cases the figure was low (0.7% of men who had used MDMA in the past 12 months, compared to 1.7% of women).

Sub-acute toxicity can manifest as more common, but generally manageable, unpleasant effects at different points in the experience. These include: agitation or anxiety, nausea (commonly during the initial ‘coming up’ phase), headache, blurred vision, sweating, jaw clenching, teeth grinding, increased heart rate and blood pressure, and insomnia. The Euro-DEN study of hospital presentations involving MDMA recorded agitation and aggression in 33% of presentations and anxiety in 27%.

Higher doses increase the potential for more severe or acute toxicity. Regulation of body temperature and hydration while using MDMA presents

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a series of interrelated acute risks, particularly when it is consumed in nightlife or party settings:

- **Hyperthermia**: MDMA use increases body temperature through increasing metabolic heat generation and reducing heat dissipation by constricting blood vessels. These heating effects are comparable to body temperature increase during exercise and are observed even in laboratory conditions. Overheating symptoms can include confusion, headache, muscle cramps, dizziness and fainting — and, at the extremes, coma and death. The risk of overheating is dramatically increased by dancing in hot weather at summer festivals or in nightclubs with high temperatures, poor ventilation and no cooler ‘chill out’ spaces. This is a significant contributor to MDMA-related emergency episodes and mortality at such events. The Euro-DEN study recorded hyperthermia in 2.4% of MDMA-related hospital presentations.46

- **Hyponatremia** (or water toxicity) can result from consuming too much water (usually in an attempt to avoid dehydration or quench the dry mouth often brought on by stimulants). This can reduce sodium concentrations in the body and lead to swelling in the brain. MDMA is also an antidiuretic (it makes you urinate less) increasing water retention, particularly in women. Symptoms of water toxicity can include headache, nausea, and dizziness, and, at the extreme, coma and death.

- Conversely, **hypernatremia** (or dehydration) can occur from not drinking enough to replace water lost through sweating as body temperature increases, particularly while dancing in hot environments. The presence of both hypernatremia and hyponatremia as corresponding risks highlights the need for accurate and useful harm reduction information to be made available.

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• **Serotonin Syndrome**: MDMA leads to release of the neurotransmitter serotonin, which in extreme circumstances (high doses, or when MDMA is used in combination with other stimulants or medical drugs that affect serotonin release) can lead to agitation and dangerously high blood pressure, as well as contributing to hyperthermia.

• **Cardiovascular issues**: because MDMA raises heart rate and blood pressure it can increase the risk of adverse cardiovascular events, particularly in vulnerable individuals, or when combined with other risk factors. The Euro-DEN study recorded palpitations in 14% of presentations, hypertension in 9% and chest pain in 8.5% of presentations.\(^47\)

### Chronic risks

Understanding chronic risks is particularly difficult for MDMA as there are no longitudinal studies that are not confounded by the fact that use takes place in an unregulated environment. Clearly distinguishing between harms attributable to MDMA, and harms linked to other drugs or behavioural variables, is therefore very challenging.\(^48\) MDMA has also been in widespread use for less time than cocaine and amphetamines, so it is possible that certain longer term chronic harms have yet to emerge, although some 35 years from the first significant wave of use this seems increasingly unlikely. Nevertheless, indications of chronic harms appear to be generally low for moderate users compared to longer-term high intensity users. The degree to which any physiological or psychological damage is reversible with cessation of use remains unclear.

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MDMA’s diminishing effects when used repeatedly in the short term (same session) to medium term (within the next few days, weeks, or months) mean that the compulsive or dependent patterns of use that can develop with other stimulants like amphetamine and cocaine, are rarely observed. The EMCDDA trendspotter report notes that ‘MDMA dependence or tolerance is not common.’ A 2008 report from the UK’s Advisory Council on the Misuse of Drugs, based on an extensive literature review of MDMA risks, noted that ‘MDMA appears not to have a high propensity for dependence or withdrawal reactions.” The EMCDDA further notes that ‘MDMA problems are rarely reported as a reason for entering specialised drug treatment services, with the drug being responsible for less than 1% (around 800 cases) of reported first-time treatment entrants in Europe in 2014.’

There is some evidence that chronic high-dose use can damage the serotonin system, or in other ways negatively affect the brain in the longer term leading to impairment of memory and brain function, and potential impacts on mental health including contributing to depression, anxiety and psychosis. The EMCDDA however notes that ‘the data to support these associations are contradictory.’ The ACMD review concluded that:

*There is presently little evidence of longer-term harms to the brain in terms of either its structure or function. However, there is evidence for some small decline in a variety of domains, including verbal memory, even at low cumulative dose. The magnitude of such deficits appears to be small and their clinical relevance is unclear.*

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### MDMA: key risks and vulnerabilities

<table>
<thead>
<tr>
<th>Risks and vulnerabilities</th>
<th>Indications for harm reduction and regulation</th>
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| Youth — increased acute risks | • Delaying age of initiation as prevention/public health goal  
• Implementing age access controls at a retail level  
• Target evidence-based prevention and harm reduction at vulnerable youth populations |
| Novice users — increased acute risks | • Target novice users with bespoke harm reduction information*  
• Include specifically targeted information on packaging, with links to more detailed information |
| Dosage — optimal dosage for a desired effect will vary between individuals. Higher dosage is associated with elevated risks of acute harms | • Educate users, especially younger and novice users, about dosage effects and risks  
• Make available tailored advice for individuals before and during purchase, and in using environments (incorporating factors including: body mass, gender, pre-existing health conditions, using environment, novice user status, etc.)  
• Ensure people using MDMA know how much they are taking (and bioavailability — speed of onset) through clearly labelled products  
• Limit individual purchase to single use dosage |
| Frequency of use — increased frequency increases risk of chronic harms | • Educate people who use MDMA about effects, tolerance, chronic risks — encourage moderation and leaving sufficient time between uses  
• Possible rationing of sales to single use purchase over fixed time period |
| Overheating — especially in nightlife/festival/party settings | • Use available opportunities (at point of sale, or in consumption environments) to provide basic harm reduction information on managing body temperature  
• Establish regulation and monitoring of nightlife settings and other party environments to ensure adequate ventilation, chill out spaces, free water provision, welfare/medical services, etc.  
• Encourage people to look out for their friends — educate on warning signs and basic care  
• Reduce stigma and barriers to accessing medical services |
| Regulation of hydration — (both dehydration and water toxicity) | • Ensure adequate provision of free water in commercial settings where MDMA is consumed  
• Provide advice on how to regulate hydration |
| Poly-drug use | • Explore alcohol free (or alcohol-light) nightlife/party spaces that are MDMA tolerant  
• Target harm reduction education about specific poly-drug risks |

A widely reported effect is ‘mid-week blues’, or depressed mood in the days following weekend use of MDMA. It is unclear to what extent this is related to neuropharmacological effects of MDMA (such as serotonin depletion), and to what extent it may result from the use of other drugs, lack of sleep, physical exhaustion, poor diet or other factors culturally associated with the consumption of MDMA. Few people administered MDMA in therapeutic settings record such effects.\textsuperscript{54} Conversely, in a recent study, there were even suggestions that participants experienced an ‘afterglow’ where they continued to feel positive for up to a week after each MDMA-psychotherapy session.\textsuperscript{55}

**Proposed regulation model**

Suggesting that MDMA is a relatively low risk drug, even if only in comparison to other stimulants, may be construed as irresponsible in the context of high profile medical emergencies and deaths that often dominate media coverage. Famously, Professor David Nutt was sacked from his role as Chair of the UK Government’s independent expert Advisory Council on the Misuse of Drugs (ACMD) in 2009 for making precisely this suggestion.\textsuperscript{56} It is, of course, important to be clear that ‘relatively low risk’ should not be interpreted as ‘safe’. But in thinking about policy responses it is also important to acknowledge that acute MDMA risks — the key concern when looking at its overall risk profile — are significantly created, and exacerbated, by the legal context in which use takes place. The fact that MDMA is illegal means dosage is often unknown, unpredictable, or of unexpectedly high potency; it encourages mis-selling, adulteration and can lead to


\textsuperscript{55} Sessa, B., Sakal, C., O’Brien, S. and Nutt, D. (2019). First study of safety and tolerability of 3,4-methylenedioxymethamphetamine (MDMA)-assisted psychotherapy in patients with alcohol use disorder: preliminary data on the first four participants. *BMJ Case Reports* 12:e230109. p.3. casereports.bmj.com/content/12/7/e230109

the unintended consumption of drugs that may be far more dangerous; it prevents the use of contents, dosage and harm reduction information on products, at point of sale or in using environments; and it creates a reluctance within the management of venues to promote safer use or facilitate effective harm reduction. At its worst, indeed, it can lead to venue owners that do support safer use being criminalised as a result.57

Even absent of many of the harms created or exacerbated by prohibition, risks remain that regulation must target and mitigate. The nature of MDMA’s effects and tolerance profile, however, mean it is not associated with the patterns of regular functional use or chronic dependent use, more commonly seen with cocaine and amphetamines, particularly in smokable forms or when injected. Nor is there a low dose preparation comparable to coca leaf or ephedra. MDMA’s use is more narrowly limited to less frequent recreational use, with risks correspondingly concentrated on acute harms, particularly associated with certain risk behaviours in social settings. While MDMA’s specific risks point to the critical importance of risk and harm reduction education for users (on packaging, at point of sale and via other channels) and safety management in recreational settings, they also justify strict controls on retail availability.

As such the overarching recommendations for regulating retail availability of MDMA are the same ‘standard model’ proposed for other risk tier 2 products (amphetamine pills and cocaine powder) in Chapter 2. MDMA-specific policy proposals — on preparation, pricing and rationing — are discussed below.

**Preparation controls**

**Form**

MDMA would be available in pill/capsule form only. While a substantial proportion of the illegal MDMA market in some regions is in powder/crystal form, pill form has distinct safety advantages in terms of hygiene, dosage control, reducing risk of adulteration, and moderating the speed of onset. The disadvantages of not making powder form available seem modest, with a quality pill form product able to meet the vast majority of demand.

**Dosage**

Controlling dosage is a key way of moderating risks. Dosages of MDMA consumed in social environments generally range from 80 milligrams to 200 milligrams (sometimes including re-dosing after the initial dose has peaked). Retail supply would be of a dosage intended for a single use by the purchaser (to limit, but necessarily not entirely prevent stockpiling or sharing) and would sensibly aim to limit single session use to less than 150 milligrams. A single purchase could therefore practically consist of a blister pack of 4–5 30 milligram pills in bar-form that could easily be halved into clearly delineated 15 milligram units. This would allow for an appropriate level of dosage calibration for different users (informed by information on insert, packaging, and advice given by the vendor).

An alternative option would be preparation of bespoke user-specific MDMA doses in capsules. The dose would be assessed for each individual consumer on the basis of weight, gender, using experiences and other potential variables and vulnerabilities. Preparation of user-specific doses would be determined in consultation with the specialist vendor, and could be particularly useful for a first time pharmacy purchase, with the consultation providing an opportunity to provide bespoke risk and harm reduction information related to the purchaser’s particular circumstances.
The density and speed of breakdown of pills affect their bioavailability (that is, how rapidly it is absorbed when taken orally). Softer pills will have a quicker effect than more densely pressed pills. Similarly, capsules containing powder can have different time release profiles. The issues here are both about avoiding very rapid release that might increase risks, and about knowing what to expect. Having that information clearly available to consumers, and establishing the consistency between pills (lost in the unregulated production of an illegal market) allows safer behavioural norms to develop.

Price controls

MDMA prices are generally low compared to other stimulants or drugs consumed within the night-time economy and MDMA use is generally relatively infrequent and self-limiting. According to the Global Drugs Survey, the global average price is €10 for a pill — the stronger versions of which may contain enough MDMA for two or even three people. A gram of MDMA powder — enough for anywhere between five and 15 doses — costs, on average, €40, but is now routinely available via the darknet for under €20. It is unsurprising that people who use MDMA rank it highly for ‘value for money’ compared to other drugs.

Previous research has shown that not only do consumers of alcohol, amphetamines, cocaine and MDMA respond to price (i.e. they tend to consume less of a given drug as the price increases), but that they will often switch between these drugs depending on which is perceived to be the best value.

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for money. Given the low per-dose cost (or cost per intoxicated hour — as the unit some academics use to compare drugs), combined with the generally infrequent use of MDMA, it is reasonable to assume that price is likely to be less of a factor in purchasing decisions than for more expensive drugs (e.g. cocaine) or more frequently consumed drugs (e.g. alcohol or tobacco). If so, then non-price variables — most obviously quality control — are liable to take precedence over modest price differentials in privileging regulated supply over any parallel illegal market. The imperative to undercut (or match) prices on the current illegal market may, therefore, be less urgent than with other drugs. What matters most may be convincing potential buyers that a legal product has safety advantages. Nonetheless, given the unanswered questions around how consumers will respond to legal and illegal market price differentials (and other variables) there will be a clear need to proceed cautiously, closely monitor impacts of prices, and price changes, and open the market with a pricing regime that is not too dissimilar to that of the existing local illegal market (see pricing discussion in Chapter 2).

Rationing

We propose that MDMA would be sold on a rationed per-purchase basis in single dosage units (as above), making efforts to prevent multiple purchases by any individual. The precise level to set any purchase limits is a finely balanced question. Increased tolerance is, from anecdotal reports, likely to become an issue if MDMA is used more than four times a year — and start to become a more marked issue if used more than 10–12 times a year. Were an upper rationing threshold set around this level, i.e. a single dose per month, it would capture demand for the majority of users (the Global Drug survey suggesting that around 75% of MDMA users use 10 times or less each year).61

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Enforcing limits of this kind is, however, difficult and would be made easier were a purchaser licensing system to be adopted. This is especially so where intended limits are monthly, rather than daily or even weekly. In this regard, there may be a stronger case for purchaser licences in the case of MDMA than other stimulants. However, for the reasons set out in Chapter 2, such a system comes with risks in regard to data protection, social equity and enforcement. A purchaser licensing system may provide some benefits for mitigating harms: for instance purchase tracking could encourage the vendor to offer targeted information on risks related to periods of higher intensity use. On the other hand, however, were such a system to be widely rejected then there is a strong risk that illegal supply would simply fill the gap.

Again, there is no perfect solution – rather there are trade-offs which need to be chosen between. In the absence of a purchaser licence system, MDMA could still be sold under strict per-purchase limits and in single dosage units (as above). However, greater efforts would need to be made to provide the information and advice needed to prevent consumers from putting themselves at unnecessary risk, and in supporting retailers to prevent multiple purchases. Given use patterns for MDMA (especially the much lower likelihood of heavy episodic consumption), this risk will be lower in any case.
Amphetamines
There are significant variations in the types of amphetamine consumed, consumption behaviours, and motivations for use, between regions. These trends bring important implications for policy and regulatory design.
Amphetamines

What are amphetamines?

Amphetamine

\[
\text{C}_9\text{H}_{13}\text{N}
\]

Methamphetamine

\[
\text{C}_{10}\text{H}_{15}\text{N}
\]

There are a number of related drugs that come under the amphetamine grouping. Amphetamine itself (the name derived from its full chemical name: Alpha-MethylPhenEthylAMINE) is the parent compound for a large number of derivatives, each with a slightly different molecular formation. Amphetamine and methamphetamine — which are the focus of this chapter as they represent the majority of amphetamines consumed — are functionally very similar. Consequently, there is significant overlap in their uses. They are also routinely grouped together in drug surveys and much drug policy analysis.
Amphetamines are psychostimulants, increasing the amount of dopamine, noradrenaline and serotonin in areas of the nervous system such as those involved in reward/pleasure, movement and cognition (among others). The effects of amphetamines are both physical (increased heart rate, blood pressure and respiration) and psychological (increased confidence, energy, alertness, and decreased appetite).

Other amphetamine derivatives include: the beta-keto amphetamines, such as cathine and cathinone (the active drugs in khat); ephedrine and pseudoephedrine (two of the active drugs in ephedra); methcathinone; mephedrone; fenethylline (more commonly known under the brand name captagon); MDMA; and pseudo-amphetamines including methylphenidate (more commonly known under the brand name ritalin). These are sometimes collectively termed ‘amphetamine type stimulants’ (ATS), although some have argued this term is somewhat arbitrary as it excludes the non-synthetic stimulant cocaine, and may lead to overstatement of the extent of amphetamine use.¹

There are two molecular variants of amphetamine: levoamphetamine and dextroamphetamine. Amphetamine technically refers to the racemic free base, which is equal parts levoamphetamine and dextroamphetamine, in their pure amine forms. But ‘amphetamine’ generally refers to any combination, or to either of them alone. Both are central nervous system (CNS) stimulants — although dextroamphetamine is more potent.

¹ Hart et al. note that ‘Cocaine is not an ATS because it is not manufactured synthetically, although it is classified as a stimulant. From a behavioral or neuropharmacological perspective, the grouping of ATS makes little sense. Methylphenidate (Ritalin) and cocaine produce similar effects on human behavior and on monoamine neurotransmitters, which modulate mood and other functions. Yet, only methylphenidate is included as an ATS’: Hart, C., Csete, J. and Habibi, D. (2014). Methamphetamine: Fact vs. Fiction and Lessons from the Crack Hysteria. Open Society Foundations. p.5. www.opensocietyfoundations.org/publications/methamphetamine-dangers-exaggerated
As a legal medicine it is available in pill or capsule form, in various ratios of levoamphetamine and dextroamphetamine, and under a range of brand names (including Adderall, Eveko, and Zenzedi), as well as in liquid or suspension form (ProCentra, Dyanavel XR).

As an illegal drug it is generally sold as a white powder — usually amphetamine sulphate, although occasionally available in an oil or paste form in its base form (more commonly at wholesale market level). This can be snorted, taken orally or dissolved in water and injected, Unlike the hydrochloride salt of methamphetamine, amphetamine sulphate is insufficiently volatile to be smoked.

Methamphetamine found on the illegal market in Europe is usually a mixture of d-methamphetamine and l-methamphetamine (both of which are psychoactive and have stimulant properties) in equal proportions.

Methamphetamine exists in two forms: base (which in its pure form is a clear oil, insoluble in water) and salt (which is a crystalline solid and is soluble in water). Pure base may be converted into methamphetamine hydrochloride, the most prominent form of salt methamphetamine. ‘Ice’ or ‘crystal meth’ is large crystals of methamphetamine hydrochloride, thus named for its appearance. Powder methamphetamine is granulated crystals, which are then commonly mixed with other ingredients — often caffeine.2

As a legal medicine methamphetamine is available in pill form under its generic name as well as brands including Methedrine and Desoxyn.

Aside from methamphetamine’s higher potency, in terms of pharmacological effects, there is little to distinguish amphetamine and methamphetamine. The EMCDDA notes that ‘powder methamphetamine found on the illicit drugs market is similar to powder amphetamine in many ways,

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including purity and appearance, and the two are often indistinguishable, to both users and dealers.\textsuperscript{3}

As Professor Carl Hart has noted:

\begin{quote}
In carefully controlled laboratory studies of human research participants, d-amphetamine and methamphetamine produce nearly identical physiological and behavioral effects...They both increase blood pressure, pulse, euphoria, and desire to take the drug in a dose-dependent manner. Essentially, they are the same drug.\textsuperscript{4}
\end{quote}

The key differences between amphetamine and methamphetamine-related using behaviours, effects and risks are related to their preparation, availability and methods of use. In particular, methamphetamine can be more easily manufactured from over-the-counter medicines. Further, while both amphetamine and methamphetamine can be snorted or ingested orally as powders, or dissolved in water and injected, methamphetamine (unlike amphetamine) is sufficiently volatile to be smoked, most commonly in its crystalline form using a glass pipe.

### History

Amphetamine was first synthesised in 1887 by the Romanian chemist Lazar Edeleanu who named it phenylisopropylamine. For almost 40 years its medical potential was unexplored until experiments by a Los Angeles chemist, Gordon Alles, in 1929. Alles was working for the pharmaceutical company Eli Lilly in search of a drug to improve on ephedrine, a decongestant and bronchodilator that had proved a successful and lucrative treatment for asthma, cold, and allergies. Alles renamed the drug amphetamine.

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patenting amphetamine sulphate and amphetamine hydrochloride in 1932 and striking a deal with another pharmaceutical company Smith, Kline and French (SKF). In 1934 they released the first amphetamine drug to the market in the form of the ‘Benzedrine’ branded inhaler, for congestion.

Methamphetamine followed a similar timeline, being first synthesised in Japan by the organic chemist Nagai Nagayoshi. Nagayoshi first isolated ephedrine from the Ephedra sinica plant in 1885 and went on to devise a method for ephedrine synthesis, later synthesising methamphetamine from ephedrine in 1893.

**World War II**

Both medical and non-medical use of amphetamine-based drugs expanded rapidly in the 1930s and 40s. By the end of 1938 SKF claimed to have shipped over 10 million Benzedrine inhalers.\(^5\) Benzedrine sulphate became available in pill form in 1937, and during World War II Benzedrine pills were

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being used extensively as stimulants by UK and US forces. It is estimated that 150 million pills were used during the conflict.\textsuperscript{6} German forces, meanwhile, were extensively using the Pervitin brand of methamphetamine pills. Pervitin was attractive to German commanders as their famed military tactic, Blitzkrieg, required speed and surprise, but was undermined by distinctly human soldiers who required regular rest and sleep.\textsuperscript{7} Medical historian, Dr Peter Steinkamp, has suggested that ‘Blitzkrieg was guided by methamphetamine. If not to say that Blitzkrieg was founded on methamphetamine.’\textsuperscript{8} The functional use of amphetamines has continued in US forces to this day, notably in the conflicts in Iraq and Afghanistan.\textsuperscript{9}


The use of amphetamines was also widespread across civilian populations in Europe during World War II. This was particularly the case in the United Kingdom and in Sweden, where an estimated 200,000 people, around 3% of the population, were using amphetamines by 1942–3.\textsuperscript{10} It has been conservatively estimated that by the end of 1945 the total production of Benzedrine (and other patent-infringing imitators) averaged about 750 million pills a year.\textsuperscript{11} The spread of non-medical amphetamine into the wider public during the immediate post-war years was significantly linked to the diversion of post-war stockpiles.

The post-war period

In the post-war decades, amphetamines became a popular medical treatment for obesity, symptoms of Parkinson’s disease, mild depression, and narcolepsy. Although, with the exception of narcolepsy, amphetamines are now rarely used for such treatment, use has expanded in recent decades as a key treatment for attention deficit hyperactivity disorder (ADHD) for which the stimulants have a counterintuitive calming effect: reducing impulsiveness, and aiding concentration. Use of amphetamines remains widespread for ADHD, primarily through combination drugs like Adderall containing multiple salts of amphetamine, as well as the pseudo-amphetamine Methylphenidate (sold under the trade name ‘Ritalin’, among others). This is particularly the case in the US, where use expanded significantly in the mid-1990s and early 2000s, accounting for 83.1% of the global volume of ADHD medications by 2003 despite having less than 5% of the world population.\textsuperscript{12} Use of ADHD medication has continued to grow in recent years.\textsuperscript{13}


Non-medical use of amphetamines has fluctuated since 1945, although distinct periods of increased use can be noted in the Global North in the late 1960s, the 1990s and early 2000s, and again in the present day.\textsuperscript{14}

Recreational use of amphetamines has never achieved the glamorous lifestyle cachet of cocaine use, or the communal cultural impact of MDMA, but it has nonetheless penetrated and influenced a wide range of popular culture. Early non-medical use involved cracking open Benzedrine and other inhalers to access the drug inside. John Lennon recounted how ‘The first drugs I ever took, I was still at art school, with the group — we all took it together — was Benzedrine from the inside of an inhaler.’\textsuperscript{15} Writer Jesse Hicks has similarly noted how ‘Until 1959, when the Food and Drug Administration banned them, these inhalers offered a cheap, legal high, inducting Beatnik luminaries like Jack Kerouac and Allen Ginsberg into the habit.’\textsuperscript{16}

Amphetamines have also been widely used for functional purposes. A thriving informal market for amphetamine ‘pep pills’ emerged in the US among long-haul truck drivers during the 1950s and 1960s, linked to long working hours and intense competitive pressures within the industry.\textsuperscript{17} By the late 1960s, the Food and Drug Administration estimated that up to one half of the 8–10 billion amphetamine pills being produced legally in the US were being diverted from medical channels.\textsuperscript{18}

Amphetamine was not immune to the growing hostility towards recreational drug use that accompanied the emergence of the 1960s counter-culture in both the US and Europe, with new narratives about ‘speed freaks’


\textsuperscript{17} Riley, K. (2014). Driving on speed: Long-haul truck drivers and amphetamines in the postwar period. Labor 11.4. labor.dukejournals.org/content/11/4/63.short

\textsuperscript{18} See footnote 14.
Amphetamines

(speed being a popular nickname for amphetamine) entering popular discourse. Combined with growing concerns about amphetamine dependence and other health risks, in 1971, as Nixon prepared to declare his new ‘war on drugs’, amphetamine (and methamphetamine) was made a Schedule-II controlled substance under the UN Convention on Psychotropic Substances. Amphetamines were correspondingly controlled in domestic legislation across much of the world; they were placed in Schedule II in the US under the Controlled Substances Act (defined as having a high potential for abuse and dependence but with accepted medical use), and designated as Class B under the UK’s 1971 Misuse of Drugs Act.

Unsurprisingly, the move to subject amphetamines to international control has not prevented widespread non-medical use. Amphetamines have maintained a strong presence in music and dance scenes, from punk to EDM, and have become embedded in stimulant-using culture of the night time economy and club scene more broadly.
Methamphetamine

Methamphetamine use remained prominent in the US from the 1970s, although has been comparatively uncommon in much of Europe. In the 1980s, methamphetamine use in the US was predominantly limited to white, working class men — often truck drivers or construction workers — and snorted as a powder. At the same time, use started to increase in some states as crystal methamphetamine started to be imported from the Philippines and South-East Asia. By the 1990s, ‘home cooked’ methamphetamine produced from over the counter cold remedies became more widespread, with so-called ‘superlabs’ also emerging in Southern California and Northern Mexico. The growing scale of production resulted in the drug being widely and cheaply available by the 2000s.¹⁹

Methamphetamine has been subject to waves of public concern, echoing and overlapping with those experienced around crack cocaine in the US, in this case often linked to classist narratives portraying methamphetamine as a ‘white trash’ drug.²⁰ Stigmatisation has been honed particularly through campaigns like ‘Faces of Meth’, a project of the Multnomah County Sheriff’s Office in Oregon, where mugshots of individuals before and after methamphetamine use are deployed as a shock-based drug prevention method.²¹ The stigmatising association between methamphetamine, physical deformation, and social revulsion became so ingrained in pop culture that by the 2010s smartphone apps were even developed to recreate ‘before and after’ methamphetamine looks for selfies.²²


These waves of moral panic, and demonisation of people who use methamphetamine, have, in turn, been capitalised upon to justify stringent punishments for supply in the US.\(^\text{23}\)

Methamphetamine was also largely seen as a working class drug in East and South-East Asia. In the 1960s and 70s, it was mainly used as a performance-enhancing drug by truck drivers and factory workers, consumed in tablet form. By the 1990s, methamphetamine use was more diverse, with tablets being used recreationally by young people and students. Crystal methamphetamine, in contrast, was often viewed as a more high-end drug, associated with ‘educated and well-connected high-ranking professionals of status’ due to its comparatively high price.\(^\text{24}\) Methamphetamine use grew increasingly popular in Myanmar, Thailand and parts of China in the 2010s, with increases in drug seizures and arrests matched by observable increases in price. Access to treatment for problematic methamphetamine use has, however, remained ‘insufficient and inadequate’.\(^\text{25}\)

Quantifying the scale of the current methamphetamine market is difficult, particularly in regions with poor surveillance. However, the UNODC reports that the market has expanded rapidly in recent years, with seizures rising more than sevenfold from 25 tonnes in 2008 to 228 tonnes in 2018. The EMCDDA has reported combined seizures of amphetamine and methamphetamine worldwide at an even higher level, topping 300 tonnes in 2017.\(^\text{26}\)


Effects

Individuals will experience the effects of amphetamines differently, depending on a range of variables, including dosage, frequency, and method of use, with more negative effects becoming apparent with more intense use.

The speed of onset varies depending on ingestion: around 15 minutes if snorted; 30–90 minutes if taken orally (a shorter time if used on an empty stomach); and almost immediate if smoked or injected. The duration of effects is dose-dependent, but generally lasts 3–8 hours, although after-effects can last longer. The ‘comedown’ period after amphetamine use can last for a few days. The intensity of experience will also be dose-dependent, but can leave individuals feeling tired, muddled, depressed, irritable, and anxious. Some individuals may also experience insomnia and restlessness, twitching, muscle aches, or a fluctuating temperature. At very high doses the after-effects can be more severe, including vomiting and diarrhoea.

Effects of Amphetamines

- Talkative and sociable
- Euphoria
- Decreased tiredness
- Energetic feeling
- Increased confidence
- Increased alertness
- Increased self-interest
- Overconfidence
- Decreased appetite
- Dry mouth
- Impaired movement
- Repetitive behaviour
- Sweating
- Increased heart rate
- Dilated pupils
- Aggressive and risk-taking behaviour
- Clenched jaw/teeth grinding
- Sneezing, runny nose, nasal congestion and nose bleeding (from snorting)
- Anxiety
- Paranoia
- Headache
- Restlessness
- Insomnia
- Nausea

Adapted from original text, Effects of Amphetamines, Drugs and Me. drugsand.me/en/drugs/amphetamines/
Amphetamines

Using behaviours

According to the UNODC, amphetamines are the third most widely-used illegal drug after cannabis and opioids. They are generally used more than both cocaine and MDMA, although this is not the case everywhere. The UNODC has estimated that, for 2018, 27 million people aged 15–64, or 0.5% of the adult population, used amphetamines in the past year.\(^{27}\)

The highest rates of prevalence, where more reliable data is available, are in North America, with 2.3% of the population having used amphetamines, and Australia and New Zealand, reported at 1.3%.\(^{28}\) In Europe, the EMCDDA reports rates of use at 1% (or 1.3 million) among young adults (15–34) in the past year, with the highest reported rate at 3.9% in the Netherlands. It is estimated that 3.7% of adults (aged 15–64) or 12.4 million people in the EU have tried amphetamines during their lifetimes.\(^{29}\)

Data on use outside of North America and Europe is generally poor, due to limited research capacity, intrinsic challenges researching marginalised populations, and survey barriers created by the fear and stigma of criminality. The UNODC, however, estimates prevalence of 0.5% for Asia, which, while comparable with the global average, would account for nearly half of the global total of amphetamine users, at 12.7 million.\(^{30}\) There are significant variations in the types of amphetamine consumed, consumption behaviours, and motivations for use, between regions.\(^{31}\) These trends bring important implications for policy and regulatory design.

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\(^{28}\) See footnote 27.


Geographical trends

Captagon in the Middle East

There are also thought to be high levels of amphetamine use in the Middle East, particularly of captagon, but survey data are poor and prevalence is mostly inferred from high seizure rates, and a small number of research studies. A 2015 study in Iraq found that people who use drugs reported cannabis ‘very difficult’ to obtain, but reported methamphetamine and captagon ‘very easy’ to obtain.32

High seizure rates of captagon have been repeatedly reported by countries in the Middle East in recent years. More than 15 million captagon tablets were seized in Lebanon in 2015, while the United Arab Emirates seized 45 million tablets in 2017.33 Between 2010 and 2014, Saudi Arabia seized more than 325 million tablets – likely to be captagon, but officially only reported as amphetamine. Recent years have also seen the seizure of captagon tablets transited through European countries, often intended for export to the Middle East; in 2017, French officials seized 350,000 tablets intended for export to Saudi Arabia.34 Owing to large seizure quantities in Saudi Arabia, the UNODC official prevalence estimates of only 0.4% in the country are ‘too low...[and] probably underestimates’.35 It has been separately estimated that captagon is used by 40% of people who use drugs in Saudi Arabia, mainly young men.36 A possible reason for such widespread use is the perception that captagon has functional or medicinal value, and is therefore less stigmatised than other illegal drugs.

35 See footnote 33. p.6.
Vast amounts of amphetamine precursors appear to have been imported into the Middle East in recent years, notably BMK (benzyl methyl ketone, also known as phenylacetone) the primary amphetamine precursor. For example, it is reported that between 2008 and 2011, ‘a total of 98 tonnes of BMK was imported into Jordan, mostly for re-export to Iraq’ — representing ‘more than two thirds of the global trade in BMK during this period’. The EMCDDA suggests this amount of precursor ‘could have produced between 55 and 65 tonnes of amphetamine if it had all been used for the purposes of drug synthesis’. Such figures corroborate high seizure rates of amphetamine–type stimulants in the region in the same timeframe.\(^{37}\)

While there remains an absence of ‘robust qualitative data’ in relation to captagon use, it can be tentatively concluded that production of captagon has shifted to the Middle East, ‘where the main market is.’\(^{38}\) The use of captagon has been reported in conflict settings in much the same way that amphetamine has historically been used by soldiers for alertness (see above).\(^{39}\)
Methamphetamine

Increasing rates of methamphetamine (and particularly crystal methamphetamine) use have been reported in both North America and East and South-East Asia in recent years. In 2020 the UNODC reported that:

More than one third (9.9 million people) of the estimated global number of users of amphetamines are in East and South-East Asia. The increased use of methamphetamine, both in the form of tablets and crystalline methamphetamine, continues to be reported in the subregion.\textsuperscript{40}

The region has seen observable decreases in price with coinciding increases in seizures and arrests. In Thailand, prices for methamphetamine tablets fell from $6-10 in 2008 to $3-5 in 2018, with purity remaining stable. The price of crystal methamphetamine has fallen, with purity remaining very high at around 90%. Almost all countries in the region reported methamphetamine as their primary drug of concern in 2018, compared to only five in 2008.\textsuperscript{41}

Methamphetamine is also widely available in Australia and New Zealand. An online survey conducted in 2017–2018 in New Zealand found that methamphetamine was perceived ‘to be more available than cannabis in all regions of New Zealand’, with 54% of those who had used methamphetamine in the past six months saying that they considered the drug ‘very easy’ to obtain.\textsuperscript{42}

In Australia, the New South Wales Illicit Drug Reporting System survey


found in 2019 that ‘of those who could comment, 94% perceived crystal methamphetamine to be ‘easy’ or ‘very easy to obtain’.  

**Amphetamines in Europe**

Amphetamine use in Western and Central Europe has, in contrast, remained relatively stable since 2000. There are regional variations across Europe, with increased use in Finland but longer term falls in Denmark, Spain and the United Kingdom, possibly linked to more use of cocaine, MDMA, and novel psychoactive substances. Wastewater analysis conducted in 2017 found significant variation in amphetamine load across Europe, with the highest levels reported in cities in the North and East of Europe, and much lower levels in Southern European cities.

The EMCDDA notes that amphetamine sulphate may be ‘neatly viewed as a ‘European drug’ as it remains the most popular synthetic stimulant in Europe while comparatively rare elsewhere in the world compared to methamphetamine. In Europe, methamphetamine consumption has historically been largely restricted to Czechia and Slovakia, although in recent years there have been recorded increases in the north of Europe, including Sweden and Norway.

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Data from European drug testing services found that MDMA, cocaine and amphetamine were the three drugs most frequently submitted for testing, but with significant variation between countries. For example, amphetamines were rarely submitted in Belgium and Portugal, but represented more than 25% of the samples submitted in Italy and Austria. Testing revealed caffeine to be the dominant adulterant, found in almost 60% of amphetamine samples.48

Patterns of using behaviours

Recreational use

Amphetamines have a long history of widespread use in recreational settings, most commonly snorted or taken orally in powder or pill form. They are commonly substituted for other stimulants, including cocaine and MDMA, although the EU Trendspotter survey suggests they are generally perceived as a second choice option, when other drugs are not available or too expensive.49 Wastewater analysis shows that, as with cocaine and MDMA, amphetamine use is concentrated at weekends.50

Amphetamines are also commonly used in conjunction with other drugs: both stimulants and depressant drugs including opioids, benzodiazepines and alcohol. Use with alcohol is a particular issue in social settings as, in a similar fashion to cocaine, it facilitates greater alcohol intake over a longer period. Similarly, alcohol may encourage increased amphetamine use, through reduced inhibitions and a desire to counteract alcohol’s depressant effects.


In some countries, methamphetamine has become commonly associated with the ‘chemsex’ scene; methamphetamine is often used in combination with other drugs (including GHB and mephedrone) to enhance sexual drive, pleasure, and stamina among men who have sex with men. A survey of over a thousand gay and bisexual men in London found one fifth had engaged in chemsex in the past five years and one tenth in the past four weeks.51

Functional use

More than any other stimulants, perhaps with the exception of caffeine, amphetamines have established patterns of functional use. As discussed above, this has been reflected historically through use of pills among truck drivers both in the USA (referred to as ‘pep pills’) and East and South-East Asia (referred to as a ‘diligent drug’), as well as among armed forces. People who use amphetamines in workplace settings often do so to help relieve tiredness, provide energy, promote wakefulness and improve concentration over prolonged periods.52 For these effects, amphetamines have also become popular for use among students, in competitive high pressure office environments, and among people employed as night shift workers, manual and factory workers, labourers and taxi drivers.

Dependent use

As well as higher-risk using behaviours, sustained frequent recreational or functional use can lead to dependence. In 2011, amphetamines were reported as the primary drug in about 5% of all treatment requests in the European Union.53 More recently, the EMCDDA reported that in 2017


Smoked and injected amphetamines can occupy a similar profile to injected heroin or smoked crack cocaine among marginalised and homeless populations with multiple vulnerabilities. Around 30,000 clients entering specialised drug treatment in Europe reported amphetamines as their primary drug. In Germany, Latvia, Poland and Finland, people who primarily used amphetamine accounted for more than 15% of first-time treatment entrants. Treatment admissions have also risen sharply for methamphetamine use elsewhere in the world, including Thailand, where admissions doubled from 87,659 in 2009 to 172,847 in 2017.

Smoked and injected amphetamines can occupy a similar profile to injected heroin or smoked crack cocaine among marginalised and homeless populations with multiple vulnerabilities. The fact that methamphetamine is easily manufactured using online cook-guides and relatively easily obtained products (including ephedrine or pseudoephedrine in over-the-counter cold remedies) has made it particularly available to low-income, marginalised groups. The ease of production, market demographics, and higher risks of use, help explain the differing reputation it has compared toamphetamine sulphate despite their similarities in terms of pharmacological effects. Amphetamine tends to have a relatively low media and cultural profile by comparison to methamphetamine — even in Europe, where its use is much more prevalent.

People with long-term problematic patterns of stimulant and opioid use may often use amphetamines as part of a combination of drugs, either mixed together, or used in sequence. In 2017, the European Syringe Collection and Analysis Project Enterprise (ESCAPE) network found traces of stimulants (cocaine, amphetamines and synthetic cathinones) in a high proportion of the 1,288 discarded syringes tested in six European cities, with half of the


syringes containing two or more drugs; most commonly a mix of stimulant and opioid.\textsuperscript{56} The UNODC also reports on the increasing scale of ‘methamphetamine use in combination with opioids’ in Afghanistan and Iran.\textsuperscript{57} In the US, a 2015 survey of people who inject drugs found that half had injected both methamphetamine and heroin during the past 12 months, considerably more than those who had injected only one of the two drugs. This trend has corresponded with a dramatic rise in reported overdoses among those injecting both heroin and methamphetamine.\textsuperscript{58}

\section*{Risks}

\subsection*{Acute risks}

Sub-acute toxicity can manifest as more common, but generally manageable, unpleasant effects including increased heart rate, agitation, confusion, paranoia, impulsivity and aggression. Such effects are more commonly associated with smoked or injected use — where onset is much more rapid and dosage tends to be greater.

Because amphetamine constricts blood vessels, raises blood pressure, heart rate and body temperature, it presents potentially serious cardiac risks at high doses, with risks increased by the rapid onset associated with smoking or injecting. Chest pains, palpitations, tachycardia and hypertension are the most common complaints among amphetamine users presenting to accident and emergency departments. Deaths from amphetamine-induced strokes or heart attacks are rare but can happen when used...

\begin{itemize}
\item \textsuperscript{56} EMCDDA (2019). Results from the ESCAPE project 2017: Drugs in syringes from six European cities. www.emcdda.europa.eu/system/files/publications/11287/20191061_TD0119176ENN_PDF.pdf
\end{itemize}
### Amphetamines: key risks and vulnerabilities

<table>
<thead>
<tr>
<th>Risks and vulnerabilities</th>
<th>Indications for harm reduction and regulation</th>
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| **Youth** — increased acute risks | • Delaying age of initiation as prevention / public health goal  
• Implementing age access controls at a retail level  
• Target relevant information to vulnerable, novice, youth populations |
| **Dosage** — higher dosage is associated with elevated risks of acute harms | • Educate users, especially novice users, about dosage effects and risks  
• Make tailored advice available to individuals before and during purchase, and in using environments (incorporating factors including: body mass, gender, pre-existing health conditions, using environment, novice user status, etc.)  
• Ensure all people using amphetamines know how much they are taking (and bioavailability — speed of onset of different preparations) through clearly labelled products  
• Prioritise availability of lower potency, slower release oral products |
| **Frequency of use** — increased frequency increases risk of chronic harms | • Educate people who use amphetamines about effects, tolerance, chronic risks — encourage moderation and leaving sufficient time between uses  
• Ration availability to moderate use |
| **Preparation/methods of administration** (influenced by available preparations) — more rapid onset associated with snorting. Smoking (methamphetamine) and injecting increases acute and chronic risks | • Use availability controls to encourage use of safer oral products over powders (subject to snorting/injecting) or crystal |
| **Overheating** — regulation of hydration (both dehydration and water toxicity) | • Use available opportunities (at point of sale, and in using environments) to provide basic harm reduction information on managing body temperature  
• Establish regulation and monitoring of night life settings and other party environments to ensure adequate ventilation, chill out spaces, free water provision, welfare/medical services, etc.  
• Encourage people to look out for their friends, educate on warning signs and basic care  
• Reduce stigma / barriers to accessing medical services  
• Ensure adequate provision of free water  
• Provide advice on how to regulate hydration as part of harm reduction |
| **Poly-drug use** | • Explore alcohol free (or alcohol-light) night life / party spaces  
• Target harm reduction education about specific poly-drug risks |
in high doses, particularly when mixed with other drugs, or when used by people with particular health vulnerabilities. A 2008 study estimated that amphetamine use was responsible for 0.2% of heart attacks in the US state of Texas.\textsuperscript{59}

Taken in high enough doses, amphetamines can induce transient drug-induced psychosis sometimes lasting for days or weeks. Psychotic symptoms can include paranoid thoughts or delusions, and hallucinations. People with pre-existing or family histories of mental health problems are more vulnerable.

In the 2019 Global Drug Survey, methamphetamine was reported as the second most prevalent drug related to individuals seeking emergency medical treatment (behind heroin), while amphetamines more generally were eighth. Survey results also indicate a gendered split: while methamphetamine was also the second most prevalent drug for women seeking treatment, it was fourth for men.\textsuperscript{60}

**Chronic risks**

Amphetamines have a reinforcing effect with similarities to cocaine, and present a relatively high risk of individuals developing dependent or compulsive patterns of use. Crystal methamphetamine is both generally purer and more commonly injected or smoked than other forms of amphetamine, so has a higher dependence potential (although as noted, this is not fundamental to relative pharmacologies beyond its increased potency). Discontinuation of heavy amphetamine use can create withdrawal symptoms, including severe depression, lethargy, and anxiety.


Heavy or longer term amphetamine use can also be associated with a range of mental health conditions including psychosis, depression, suicidal behaviour, anxiety and aggression.\textsuperscript{61} Longer term amphetamine use can contribute to coronary heart disease and stroke risk.

The appetite-suppressant effects of amphetamine can lead to weight loss among regular users and contribute to general health neglect. Poor dental health — sometimes unhelpfully represented in media scare stories as ‘meth mouth’ — is related more to neglect than any specific pharmacological effects of methamphetamine (it is not reported as an issue for people on regular controlled daily amphetamine or methamphetamine prescriptions).

There is evidence from both human and animal studies that prenatal amphetamine use can increase the risk of adverse outcomes in pregnancy including clefting, cardiac anomalies, and fetal growth reduction deficits.\textsuperscript{62}

**Proposed regulation model**

Like cocaine, amphetamine use spans a broad range of products, consumption behaviours and risks (all three risk tiers identified in Chapter 2) — so a similarly broad range of policy responses will be needed. The more extensive functional use of amphetamines in work environments requires specific consideration, alongside its recreational use in social settings, and higher-risk and dependent use, particularly when smoked or injected.

At the lower end of the risk spectrum, ephedra — including ephedrine and pseudoephedrine — is the nearest amphetamine equivalent to coca leaf products. It has long been used as a herbal medicine and mild stimulant


in Asia, most commonly as a tea. Even if sold or marketed as a branded product without a licence, ephedra tea probably has less relevance as a potential harm reduction substitute for pharmaceutical amphetamine than coca leaf products do for cocaine powder. It has significant variability in active content and poses greater concerns about cardiovascular risks related to regular use than other risk tier 1 substances like coca leaf or caffeine beverages.

Pharmaceutical ephedrine was, until relatively recently, widely available without prescription in pill form from pharmacies in many countries. Despite being used as a functional stimulant it never achieved more than a relatively niche market and its use was relatively uncommon as a recreational drug despite being inexpensive and legally available (it has subsequently been subject to much stricter controls due to concerns about its use in manufacture of methamphetamine).

The significant majority of demand for amphetamines is most practically met through variants of lower risk oral pill form products. We propose that such products are most appropriately regulated using the standard model as described in Chapter 2, with locally determined and product specific adaptations explored below.

At the higher risk end of the spectrum, injected amphetamines or smoked methamphetamine present challenges similar to those associated with injected cocaine or smoked crack cocaine. We do not propose a retail model of smokable or injectable amphetamine products, but rather suggest that such use be managed within a comprehensive harm reduction framework, which can include substitute or maintenance prescribing (explored in Chapter 7).
Preparation controls

Form

We propose that, as a starting point, dexamphetamine would be available for retail in pill or capsule form only. While a substantial proportion of the illegal amphetamine market in some regions is in powder form (although much of this is, in fact, taken orally), pills have distinct safety advantages in terms of hygiene, dose control and moderating speed of onset, as well as reducing risk of adulteration. A key goal of regulation would be to meet demand as far as possible while encouraging safer oral use over higher-risk methods like snorting, smoking or injecting.

If dexamphetamine were made available in pill form, it would not be necessary to make methamphetamine also available in pill form, given that the subjective effects are largely indistinguishable when adjusted for relative potency and duration of action. Further, there are already a variety of dexamphetamine preparations available in pill form for widespread medical use, within well-established safety parameters. Other pill options also exist in preparations that are not crushable into a powder, as do pro-drug lisdexamfetamine preparations that are ineffective if injected.

Dosage

A range of dexamphetamine preparations already exist at different doses, generally ranging from 5–20 milligrams (although some higher dosage preparations are also available), and offering different levels of controlled release, providing an effect that can last for four hours at a minimum, and up to 12 hours for some slow-release preparations. The appropriate dose and preparation for a given consumer would depend on what they were seeking from the drug. A shorter-acting preparation with more rapid onset is likely to be more desirable for recreational party use, while a lower-dose, slow-release product might be sought for functional uses. The health and
circumstances of individual consumers will also be important variables. Understanding these issues, and being able to answer questions that arise, is precisely why the specialist pharmacy at the heart of the standard model is so useful — offering the opportunity to educate consumers, inform decision making, encourage less risky behaviours, and reduce harm.

### Price controls

Amphetamines are cheap to produce in large quantities, reflected in their low price on both the legal medical and illegal non-medical markets. Methamphetamine is generally more expensive. Prices vary widely on the illegal market, but can be over $100 per gram, although generally providing much higher purity than dexamphetamine. Methamphetamine pills in South-East Asia, in contrast, can be available for as little as $2 on the illegal market.

The price of legal dexamphetamine for non-medical use would need to reflect current low prices on the illegal market and high availability due to widespread medical use. While a price premium could be assumed for a legally regulated product of known provenance, the further that price were to rise above existing illegal market levels, the greater the incentive for illegal markets to undercut it, or for prescribed supplies to be diverted into secondary markets. The low prices for amphetamines at present suggests that price changes may have relatively smaller impacts on levels of use, particularly for infrequent users.

A more important factor is likely to be price relative to alternatives: most obviously cocaine, for which amphetamine is often seen as a budget substitute. This highlights how pricing of stimulants does not take place in isolation; when setting the price of amphetamines, the price of cocaine will

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need to be considered concurrently. Maintaining a price disparity between cocaine and amphetamine would be helpful in encouraging use of oral amphetamines over snorted cocaine. Such considerations may also have implications for the sequencing of how and when different stimulants are made legally available.

In the short term, and in common with other stimulants, we propose that legal market prices start near to equivalent local illegal market prices and only change in small increments with the purpose of meeting the aims of regulation, subject to careful monitoring. Less potent products could be preferred by making them comparatively less expensive.

**Rationing**

In the first instance, sales of dexamphetamine pills should be restricted to single use quantities per purchase. The specific dosage of a single use would be determined in discussion between the consumer and specialist pharmacy retailer — but might reasonably be 4×10 milligram pills for recreational use to allow for different dosage calibration, or a single slow-release pill for other more functional purposes. If concerns around stockpiling or secondary sales do not materialise, less restrictive rationing thresholds could be explored.

As discussed elsewhere, while a purchaser licence model would assist in the implementation of purchase limits, it comes with numerous trade-offs. A purchaser licence scheme would provide regulators with greater ability to combat diversion of amphetamines for secondary sales, and may also assist in managing sales to people who use amphetamines for functional purposes, who may require larger quantities of purchase (more in line with a medical prescription model, for which daily users may routinely receive 30+ pills). Higher rationing thresholds for such consumers could be made conditional on more regular check-ins with the pharmacist retailer, or an annual health check. However, any benefits of rationing would be severely
undermined if purchaser licences were to deter people using amphetamines from signing up to such a model in the first place, and instead opting to continue purchasing on the illegal market.

CASE STUDY

BZP: The groundbreaking regulation of a legal stimulant

‘BZP’ (Benzylpiperazine) is a synthetic stimulant drug that came to prominence in New Zealand in the early to mid-2000s. It was one of a new wave of novel psychoactive substances (NPS), not yet prohibited by domestic or international laws in many jurisdictions, and arguably the first to achieve any sustained market foothold. It was widely marketed as a ‘legal high’ party drug with similar effects to ecstasy, although its effects are objectively more similar to amphetamines. It was also promoted by producers as a safer legal alternative to methamphetamine, the use of which was rising in New Zealand at the time amid growing public concerns. Often combined with TFMPP (3-Trifluoromethylphenylpiperazine, another related drug in the piperazine family), BZP was sold in pill form under ‘enticing brand names such as “Frenzy”, “Rapture” and “Charge”’.

BZP also had a brief period of popularity among young people in other countries, including the UK, where it was available in ‘head shops’, from online suppliers, and at festival and club ‘legal high’ stalls, most commonly under

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However, its high prevalence of use in New Zealand was a unique phenomenon; between 2002 and 2006, approximately 20 million BZP and TFMPP combined pills were sold. Setting a pattern for many NPS that followed, BZP was initially mis-sold as a ‘dietary supplement’ to avoid potential legal tangles with drugs legislation. As a result, it was widely sold from alcohol retailers, service stations and convenience stores, with little or no restrictions on advertising or age of purchase requirements, beyond limited voluntary controls proposed by product manufacturers.

BZP is self-regulating in its effects, with unpleasant side effects at higher doses, when re-dosing, or when using too frequently, serving to moderate use and prevent patterns of riskier high intensity use developing.

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More serious adverse effects related to BZP use appeared ‘to be limited to a minority of users under particular circumstances, as well as related to a number of other factors’, such as polydrug use, and mis-dosing.69

Regulating BZP

Despite its lower level of risk compared to other stimulants, it was clear that the absence of formal drug regulation for BZP was not sustainable. In 2004, the New Zealand Government’s Expert Advisory Committee on Drugs (EACD) reviewed BZP, concluding that it was low risk; there had been no deaths linked to BZP, and it had low potential for dependency. The Committee noted that:

...the challenge for public health practitioners and regulators is how to respond to these new substances in a way that promotes the public health while protecting individual rights...

When first distributed, this was an approach that allowed users to exit the illicit market with its inherent risks and the often poor quality drugs. Substitution of illicits with Piperazines is occurring, mostly among users who are afraid of the damage to their lives that a conviction would bring and who also wish to normalise the transaction required to purchase their choice of recreational substance. However, being unregulated at this time, they are being promoted within the free market, which has the generation of profit as the driving force....Unlike either novel foods or new medicines, these products are being marketed without adequate scientific safety assessments because there is no need for the distributor to seek regulatory pre-market approval from a regulatory agency.70


Based on this report, the New Zealand Government made the decision to legally regulate BZP, rather than prohibit and risk increased criminalisation of young people and diversion to more risky illegal market stimulants. New Zealand’s existing drugs legislation was amended to establish a new Schedule 4, (informally known as ‘Class D’ as it was appended to the existing three tiered A-B-C classification system modelled on the UK’s Misuse of Drugs Act) under which sale of drugs that pose ‘a less than moderate risk of harm’ could be legally regulated under specified conditions.71 The legislation gave the EACD a statutory responsibility to make recommendations on substances to be included. This meant that, in theory, other NPS could be regulated as Schedule 4 drugs. However, BZP was the only drug to have been included.72

The new legislation established legal requirements in relation to the selling of Schedule 4 drugs, including:

- Age of purchaser controls (no sale to persons under 18)
- Where the drug could be sold (e.g. not near schools)
- In what doses, strengths and quantities it could be sold (based on a risk assessment)
- Restrictions on advertising (e.g. none on TV, radio or newspaper)
- Packaging and labelling requirements
- Product storage requirements, and how much could be stored in each location

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Information to be given to the customer at the point of sale (including information about possible interactions with other drugs and medication)\textsuperscript{73}

Requirements on suppliers, manufacturers and importers included guarantees on dosage, quality and contents of the product, keeping records of checks and demonstrating the capability to recall products if required. Promotion was prohibited and punishable with up to $10,000 in fines. Provisions were also made for individuals (or businesses) to be barred from involvement in the industry if convicted twice of an offence under the Act.\textsuperscript{74}

Emerging challenges

The regulations controlling BZP were well-intentioned and addressed key regulatory concerns, but were inadequate in key areas. No requirements were made for individuals to be trained or licensed before they could sell the product. BZP continued to be widely available in a range of outlets, including alcohol retailers and service stations, ill-equipped to provide important health information about the product. More seriously perhaps, the regulations as they existed were often poorly enforced. Advertising remained commonplace on billboards, fliers, websites and through sponsorships. Many products available were in breach of dosage requirements, with little regulatory response. BZP use remained high during the regulated market period but, despite this, there were some indications of success: one study surveying individuals who had used BZP prior to regulation found that 9% had since stopped because they were too young to purchase it, indicating some success of age controls.\textsuperscript{75}


According to EACD meeting minutes, the ‘absence of a significant administration and enforcement capacity such as exists for pharmaceuticals and for legal drugs, tobacco and alcohol’ were one of its major concerns for the continued viability of the legal regulation model. As a result of increasing practical and political concerns, in 2006, the EACD examined ‘new evidence’ and determined in a letter to the Minister ‘that, based on the available information, BZP posed ‘moderate risk’ and should be reclassified as a Class C1 controlled substance (equivalent to cannabis) – making BZP illegal to sell or possess’. This letter was criticised for referring to non-peer reviewed research and for concerns about the EACD’s decision-making process.

The EACD reiterated its position the following year, after the Associate Health Minister put a bill forward recommending BZP’s reclassification into Class C1. Key discussions during readings of the bill were more in line with historical prohibitionist narratives than those that had informed the EACDs initial pragmatism, including: concerns that BZP might have a ‘gateway effect’; that it was too readily available to young people; and that it was contributing to a wider ‘pill popping culture’ in New Zealand. Engagement with an alternative narrative, exploring the possibilities of better enforcement of existing or improved regulations, was largely absent. In 2008, an amendment was passed to reclassify BZP as a Class C prohibited drug.

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Lessons learned

It has been argued by the New Zealand Police Association that the prohibition of BZP, as enacted by its reclassification, led to an increased street price and reduced availability.\textsuperscript{82} This is corroborated by a study which found the reduction in past year prevalence of BZP use fell from 15.3% to 3.2% between 2006 and 2009 (although this includes the period during which BZP was regulated). 43% of individuals surveyed said they stopped using BZP because the drug was now illegal, and a further 24% because they didn’t know where to buy it anymore.\textsuperscript{83}

However, it is not clear whether reductions in use were primarily down to prohibition of supply or a collapse in demand, as many consumers simply pivoted back to other established illegal stimulant drug markets following BZP’s prohibition. There is evidence that the attraction of BZP was significantly due to its legal status (before and during regulation) relative to alternative illegal stimulants, rather than because its effects were preferred.\textsuperscript{84} Unlike Mephedrone (another NPS stimulant briefly available as a ‘legal high’ in many jurisdictions), BZP use has almost completely disappeared where it has been banned, with almost no residual illegal market demand.

The case of BZP in New Zealand provides an important example of how legal regulation of a stimulant for recreational use can reduce some risks, and does not inevitably lead to disaster — even when inadequately implemented. People may rationally choose a safer regulated drug over a riskier unregulated one, even though the effects are less desirable. However,
it also shows how, to be effective, regulation must be both well designed and adequately enforced. BZP regulation, in contrast, was found wanting. The inability of the regulatory system to evolve in response to its evident weaknesses produced sub-optimal outcomes and allowed negative perceptions to emerge, in turn creating the space for political opponents to agitate for the groundbreaking approach to be abandoned.

What may be seen as a failed experiment in some respects did, however, have a lasting impact on the drug policy debate in New Zealand, leading to the independent Law Commission Inquiry being convened. The Commission’s pragmatic report ‘Controlling and Regulating Drugs: A Review of the Misuse of Drugs Act 1975’ has reshaped the national discourse, and led directly to the Psychoactive Substances Act 2013 — a comprehensive regulatory framework for NPS, passed by cross party consensus, that represents an evolution in regulatory thinking from the shortcomings of the BZP model. While this Act has itself run into political quicksand — currently sitting unused in legislative purgatory — it nonetheless represents a level of engagement with non-medical drug regulation not yet seen elsewhere in the world.

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Cocaine and coca products
A public health approach to cocaine regulation needs to focus squarely on reducing the potential harms associated with its use.
What is cocaine

Cocaine is a synthetic stimulant derived from the leaves of the coca bush – Erythroxylum coca and Erythroxylum novogranatense. Coca leaves have been used as a mild stimulant for millennia among the indigenous peoples of the Andes and Amazonian basin. It forms the basis for a range of derivatives that vary in strength and effects.
Coca leaf and coca leaf-based products

The unprocessed coca leaf can either be chewed (with an alkali such as quinoa ash) or consumed dried in lightly processed forms such as tea. It has a mild stimulant effect (the leaf contains less than 1% cocaine alkaloid), with no known significant risks, and some nutritional and functional benefits, such as countering altitude sickness and increasing endurance for physical labour.

Coca has a long history of non-problematic traditional use among indigenous Andean populations. As well as being consumed in an unprocessed form, coca leaf can be lightly processed into a range of products with a mild stimulant effect similar to chewing of the leaf. Such products include various drinks, sweets and lozenges, flours, and some more novel preparations. There are also a wider range of coca products that do not have stimulant effects.

Cocaine powder

Cocaine hydrochloride is the refined extracted alkaloid of the coca leaf. It is produced both legally, for medical use, and illegally, for non-medical use. Illegal cocaine is invariably cut with adulterants such as lidocaine, caffeine, amphetamines and levamisole, plus bulking agents. Purity therefore varies greatly, from less than 10% to greater than 80%.

Its high melting point means powder cocaine cannot be smoked effectively and is most commonly snorted — with an onset at 2-3 minutes, and bioavailability of around 30%. Less commonly, it can be injected mixed with water — with an onset at around 30 seconds, and bioavailability of 100%. Moderate or occasional use is relatively low-risk, while frequent/heavy or injected use is associated with a range of potentially serious risks, including overdose and dependency.
Crack cocaine

Crack is a form of cocaine alkaloid ‘freed’ from hydrochloride salt. It is, therefore, the ‘base’ or ‘freebase’ of cocaine. Crack is prepared from cocaine hydrochloride powder using a simple procedure that involves heating (‘cooking up’) cocaine with either bicarbonate of soda or ammonia, to create crack ‘rocks’. These rocks can then be smoked (the base form of cocaine is volatile at much lower temperatures), meaning the speed of onset is much faster (8–10 seconds) and the intensity of the effect much greater (but shorter lived) than with snorted cocaine powder. Risks are correspondingly intensified, and crack is more likely to lead to dependent, problematic or risky patterns of use than cocaine powder. Crack can also be prepared for injection if mixed with an acid, turning it back into a water soluble cocaine salt like cocaine hydrochloride.

Paco, basuco, pasta base

Paco, basuco, or pasta base (sometimes also referred to as crack, or Pasta Base de Cocaine — PBC) is a crude intermediate stage product in the processing of coca leaf into cocaine hydrochloride. Pasta base contains freebase cocaine (chemically the same as crack but from an earlier stage in processing) and is smoked (commonly with tobacco or cannabis), but also includes chemicals used in the processing, such as kerosene and other solvents, and adulterants, commonly including caffeine, which are thought to enhance the effects of the cocaine. The high level of impurities and adulterants contribute further to the high risks associated with its use.

Pasta base has generally been associated with urban micro-trafficking rather than large-scale organised crime operations like cocaine powder. Its lower price has also contributed to higher levels of use among some low-income, marginalised urban populations in cocaine production and transit regions of Latin America.
History

The active alkaloid (later named ‘cocaine’) was first isolated in 1855 by Friedrich Gaedcke. From the 1880s, cocaine was promoted as a medicine by the Pfizer and Merck companies, among others. They sent samples to a young Sigmund Freud, who became an early convert and something of an evangelist for cocaine as a ‘magical drug’ for the treatment for depression. In 1884, Freud published Über Coca, describing ‘the most gorgeous excitement’ on first taking it, and an ‘exhilaration and lasting euphoria’ — also noting the suppression of fatigue and hunger.¹ Freud, however, went on to adopt a less positive view as he learnt of some of the potential longer-term side effects.

Freud had also been involved in the development of cocaine as a local anaesthetic (it usefully constricts blood vessels and reduces bleeding) in eye surgery, which continues to this day. In the US, cocaine was included in the original formulation of coca-cola and was enthusiastically included in an array of patent medicines.

Cocaine’s initial success drew from the fact it was a demonstrably effective medical drug in a market swamped by snake oil. However, within just a couple of decades of its widespread production, a combination of factors led to the first cocaine prohibitions in the US. By the turn of the century there were growing calls for controls on cocaine from the medical profession (as well as for the two other key psychoactive plant-based medicines emerging around the same time: opiates and cannabis). These calls were driven, in part, by legitimate professional concerns about unregulated sales linked to increasing reports of cocaine-related dependence and ill health, and sought stronger regulation of promotions, sales, and medical claims, rather than outright prohibition.

Coca Cola

Invented in 1886, Coca-Cola originally contained coca, including a small amount of cocaine (approximately 60 milligrams in a bottle). It was created as an alcohol-free alternative to drinks such as Vin Mariani (a coca-based tonic wine), appropriate in an era when the temperance movement was widespread. The cocaine was removed in 1903, as concerns grew about cocaine misuse, but the coca flavouring continued to be used.

The coca used to make this flavouring today is purchased from South American suppliers in Peru by the Stepan Chemicals Company who have been in the business for over 60 years. They are the only company with a US Federal licence to do so (issued by the Drug Enforcement Agency), processing the imported leaf at a laboratory in Maywood, New Jersey. The de-cocainised product is then shipped to the Coca-Cola company, while the extracted cocaine is sold to Mallinckrodt Inc., a St. Louis pharmaceutical manufacturer that is the only company in the United States licensed to purify the product for medicinal use. The Netherlands is the only other country currently importing coca leaf and producing decocainised coca flavouring and medical cocaine hydrochloride in recent years, albeit at much smaller volumes than the US; the 200 kilograms it imported over 2012 and 2013 for this purpose was dwarfed by the US’s 300,000 kilograms over the same period.

A number of smaller product brands also use coca flavouring, many (unlike Coca-Cola) specifically building their marketing around the coca leaf being an ingredient, despite their drinks having no active coca-derived cocaine content. These include Kdrink (Spain), and for a period of time Red Bull Cola (discontinued in 2011), as well as various spirits and liqueurs, like Agwa and Cocalero.

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ii Separation of the cocaine and flavouring involves a fairly elaborate process in which the leaf is ‘ground up, mixed with sawdust, soaked in bicarbonate of soda, percolated with toluene, steam blasted, mixed with powdered Kola nuts, and then pasteurized’, see: University of Illinois (1999). The Legal Importation of Coca Leaf, Class module 9.3.


However, a new politicised narrative on cocaine was also emerging, driven by xenophobia and racial prejudice. This unabashedly racist narrative was fuelled by sensationalist news coverage linking cocaine use to violent behavior among African Americans. A 1914 New York Times article reported that: ‘Negro cocaine “Fiends” are a new Southern menace: murder and insanity increasing among lower class Blacks because they have taken to “sniffing” since deprived of whisky by Prohibition.’

The physician who authored the piece suggested that: ‘[The ‘fiend’] imagines that he hears people taunting and abusing him, and this often incites homicidal attacks upon innocent and unsuspecting victims.’ These ‘fiends’ were not only claimed to be better marksmen, but also launched the myth of stimulants offering some kind of superhuman immunity to bullets: ‘Bullets fired into vital parts that would drop a sane man in his tracks, fail

to check the “fiend”. In the same year the 1914 Harrison Act effectively outlawed cocaine and opium.

Despite this, non-medical cocaine use rose in the 1920s, only to fall again in the 30s as amphetamines appeared on the market, providing a less expensive and more easily produced alternative stimulant with somewhat similar effects. Cocaine use remained relatively low until the 1960s, the decade that witnessed the emergence of a new youth counterculture across much of the developed world, associated with a rise in illegal drug consumption.

While monitoring of drug use before the 1980s was poor, US National Survey on Drug Use and Health (NSDUH) data suggests that US cocaine consumption rose to a peak around 1985, when it was reportedly being used by up to 3% of the population, before falling to under 1% in 1990 and fluctuating between 0.5 and 1% since then. What the US prevalence data does not reveal, however, is that even as the popularity of powder cocaine began to wane, patterns of individual heavy use continued, and the use of crack cocaine emerged. While these trends affected a smaller population, they led to more serious social and health consequences. A smokeable form of cocaine with more rapid onset and more intense effects, crack cocaine also facilitated the sale of cocaine at smaller unit costs, making it accessible to a larger market. A 1994 study by the RAND corporation noted that:

*The current cocaine epidemic in the United States started in the late 1960s, picked up momentum in the 1970s, and is still going strong in the early 1990s. The number peaked in the early 1980s at around 9 million, and has gradually decreased to a little more than...*
7 million today [1994]. However, that downward trend in the total number of users is misleading because a decline in the number of light users [at least once a year, but less than weekly] has masked an increase in the number of heavy users [once a week or more]. Heavy users consume cocaine at a rate approximately eight times that of light users so the upward trend in consumption by heavy users roughly cancels out the downward trend in light users.\(^6\)

Media reactions to the rapid expansion of crack cocaine in the 1980s and 1990s echoed reactions to cocaine powder earlier in the century: both were, to quote Professor Carl Hart, ‘steeped in a narrative of race and pathology’ from the outset.\(^7\) Just as with the ‘cocaine fiends’ earlier in the century, crack cocaine was widely associated in media and political discourse with violence and addiction among African Americans — while cocaine powder became a symbol of luxury and white affluence.

The crack cocaine debate became littered with ‘a coded theme that crack had the potential to ruin the chastity of white women’.\(^8\) This new threat-based narrative even witnessed the return of myths about invulnerability to bullets. Although the overt racism of the earlier era may have been less prevalent, the ‘urban youth’, ‘troubled’ neighbourhoods, ‘inner cities’ and ‘ghettos’ functioned largely as racially-charged code for African Americans in much of the media reporting.

In 1986, the US Congress passed the Anti-Drug Abuse Act, establishing notorious penalties for crack cocaine 100 times more severe than for cocaine powder, with distribution of 5 grams of crack attracting a minimum five-year federal prison sentence, compared to a 500 gram threshold for

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powder cocaine. Even though the majority of people using crack were white, as of 2010, a staggering 85% of those convicted for crack offences under these penalties were black — helping to fuel the exploding prison population, disproportionately including incarcerated African Americans. This sentencing disparity was partly addressed in 2010, with the Obama administration legislating to reduce the disparity from 100:1 to 18:1. As Professor Carl Hart has observed, ‘One hundred years after the myth of the “Negro cocaine fiend” helped sell the Harrison Act to Congress, its legacy lives on.’

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The racial targeting of drug policy, and the use of drug policy to control minority populations and police political dissent, is well-recognised among historians. In 2016, an article in Harper’s Magazine reported comments allegedly made in an interview by John Erlichman, Richard Nixon’s domestic policy advisor, which revealed much of the political motivation behind American drug policy, and Nixon’s famous declaration of a ‘War on Drugs’ in particular.

The Nixon campaign in 1968, and the Nixon White House after that, had two enemies: the antiwar left and black people. You understand what I’m saying? We knew we couldn’t make it illegal to be either against the war or black, but by getting the public to associate the hippies with marijuana and blacks with heroin. And then criminalizing both heavily, we could disrupt those communities. We could arrest their leaders, raid their homes, break up their meetings, and vilify them night after night on the evening news. Did we know we were lying about the drugs? Of course we did.\(^\text{12}\)

Cocaine was not only outlawed in the US, of course. Concerns arising from increased prevalence and moral panic linked to the stigmatisation of people using cocaine led to the global ban of cocaine — and all other coca-based products. That the prohibition of cocaine was inextricably tied to other forms of social control and the marginalisation of ‘dangerous’ minorities is by no means unique: the same is true for almost all other drugs, and was true for the prohibition of alcohol while it lasted.\(^\text{13}\) However, it serves as a further reminder that our current approach to drugs is rooted in motivations far beyond, indeed entirely unconnected to, harm reduction.

The history of cocaine legislation is interwoven with history of racial prejudice and oppression: serving to demonise, stigmatise and over-police

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people of colour. While prohibition may, from one perspective, seem a rational response to increasing prevalence and harm, the realities of the historical context show that it emerged in no small part as a means to both control minorities within countries, and impose political pressure on producer regions.

Effects

Cocaine powder has characteristics which make it appealing in a range of social settings:

- It is relatively short acting, with the effects dissipating after 45 minutes – 2 hours, and predictable, making the experience relatively easy to manage and control; it doesn’t require a major commitment, as distinct from MDMA or amphetamine where you are potentially committing to an intense 4-7 hour experience

- It provides energy, alertness and confidence in social environments – and can counteract the depressant effects of alcohol
• In more commonly used moderate doses it doesn’t visibly intoxicate – so avoids the potential clenched jaw (‘gurning’) or dilated pupils often experienced with MDMA or amphetamines that can make drug use more overt/visible, and be unattractive to those looking to share photos or video of themselves from nights out on social media.

Crack cocaine, which has the same effects as powder cocaine, only significantly more intense and short-lived, is discussed later in the chapter.

Individuals experience the effects of cocaine differently, depending on a range of personal, environmental and behavioural variables, with more negative effects becoming apparent with more intense use (acute and chronic risks are discussed below).

### Using behaviours

Cocaine is frequently used in social settings for its stimulant effects. Recent estimates from the EMCDDA suggest that around 2.6 million young adults (aged 15–34 years) in the European Union used cocaine in the last year (2.1% of this age group), with national estimates ranging from 0.2% to 4.7%.\(^\text{14}\) Cocaine is now the most frequently seized stimulant in a number of Southern and Western European countries.\(^\text{15}\) The UNODC World Drug Report 2020 estimates, probably conservatively, that there are 19 million people who have used cocaine in the past year.\(^\text{16}\)

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What was once seen as a more exclusive and glamorous drug has, certainly since the 1990s, penetrated a much wider set of demographics and social environments. UK data, for example, highlights that cocaine use in 2000 was twice as prevalent in London as elsewhere in the UK, but rates had equalised a decade later.\(^\text{17}\) By 2019, while London was still consuming more cocaine in quantity than any other city in Europe, it was surpassed by Bristol in terms of cocaine consumed per head.\(^\text{18}\) However, it is not useful to make generalisations about the population who use cocaine. As with all drugs, there are a range of cocaine-using behaviours, motivations for use and — correspondingly — harms related to its use. A detailed global study of cocaine use undertaken by the World Health Organization and UN Interregional Crime and Justice Research Institute (UNICRI) in 1995 noted that:

> It is not possible to describe an ‘average cocaine user’. An enormous variety was found in the types of people who use cocaine, the amount of drug used, the frequency of use, the duration and intensity of use, the reasons for using and any associated problems they experience.\(^\text{19}\)

The report describes a continuum of using behaviours: experimental use; occasional use; situation-specific use; intensive use; and compulsive/dysfunctional use, noting that ‘Experimental and occasional use are by far the most common types of use, and compulsive/dysfunctional is far less common.’\(^\text{20}\)

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\(^\text{20}\) See footnote 19.
The 2018 EMCDDA Trendspotter study notes ‘an increasing acceptability and normalisation of use of powder cocaine across diverse social groups, which are manifested in greater overtness and visibility of use.’ The increasing purity and availability in recent years, at similar or falling prices, appears to have also been a key factor in this trend. Cocaine has become cheaper and more available while seemingly maintaining some of its ‘high class’ cultural status. The same study noted a trend for switching to cocaine from cheaper ‘second class’ stimulants like amphetamines or synthetic cathinones.21

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Social use of cocaine is highlighted by its increased use at weekends. European data from wastewater analysis and emergency hospital admissions suggests that cocaine use is more prevalent at weekends, pointing towards a general pattern of recreational use (and notably contrasting with crack cocaine hospital admission data which are evenly distributed throughout the week).\textsuperscript{22} However cocaine use is also, for most consumers, an occasional occurrence: according to the Global Drug Survey, the typical person using cocaine will have only taken it on 2–10 days in the past year. The survey data highlight that 64.5\% of individuals who reported using cocaine did so ten times a year or less, while only 8.8\% used it on a weekly basis, or more often — using 0.5 grams on average.\textsuperscript{23} However, this does also highlight that more regular patterns of use exist in a minority of consumers.

Cocaine is also routinely shared between friends and acquaintances. In the 2017–2018 European Web Survey on Drugs, the most common source of


cocaine in a number of countries was obtaining it from friends. The 2018 Global Drugs Survey found similar behaviours, with a majority of people using cocaine sharing at least some of it with others:

Estimating the number of occasional cocaine users who will go on to develop regular or dependent patterns of use is, as with all drugs, difficult. The determinants of problematic use are more often to do with personal history or current social conditions than any characteristic of the drug itself. As with other drugs, the large majority of people who use cocaine will not go on to do so in ways that create significant psychological or physiological problems. However, in some cases, occasional use of cocaine can progress towards patterns of use that meet the criteria for cocaine use disorder.

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The EMCDDA reports that, for the large majority of people who use cocaine entering treatment, ‘help is generally sought only after the user has developed severe health and social problems, which appear with more frequent or heavy use.’ It notes that one fifth of those entering treatment for the first time report using cocaine on a daily basis, and the vast majority are men. Alcohol often forms part of using behaviours among individuals entering treatment; the EMCDDA reports that it is the most commonly reported secondary problem substance among individuals seeking treatment for cocaine.26

Risks

As with all drugs, cocaine risks are related to dosage, frequency of use and mode of administration. As examined in Chapter 2, cocaine products cover all three risk tiers utilised in this book: with coca-based products among the lowest risk (tier 1), and crack cocaine among the highest risk (tier 3). The discussion here primarily concerns powder cocaine, which we have assessed as risk tier 2.

Acute risks

As the Global Drug Survey data indicate, most powder cocaine use is relatively moderate and controlled. However, when taken in sufficiently high doses cocaine can cause significant acute toxicity, the effects of which commonly include agitation, anxiety, restlessness, insomnia, paranoia and auditory hallucinations (commonly referred to as cocaine induced psychosis), as well as chest pain, raised heart rate (tachycardia) and raised blood pressure. More severe acute cocaine toxicity can result in hyperthermia (overheating), acute kidney failure, seizures, cardiac arrest (heart attack) and death.

When taken in sufficiently high doses cocaine can cause significant acute toxicity, the effects of which commonly include agitation, anxiety, restlessness, insomnia, paranoia and auditory hallucinations.

European research data on cocaine-related presentations to emergency departments found the most common clinical features were tachycardia (41%), anxiety (32%), chest pain (18%) and palpitations (17%). Tachycardia was higher as a percentage of powder cocaine presentations (43%) than crack cocaine presentations (28%), as was anxiety (32% to 18%). In contrast, issues with respiratory rate and systolic blood pressure were more common for crack cocaine presentations. Sedative drugs were given in roughly a third of all cocaine presentations. Alcohol co-ingestion was recorded in 60% of presentations, with co-use of other drugs also common — with 22% reporting co-ingestion of amphetamines.27

Adulterants and bulking agents used in illegal cocaine can present additional risks.28 A range of substances may be added at different stages in the supply chain so generalisations are difficult, but common adulterants (all white powders with varying risk profiles) include: benzocaine and lidocaine (which produce a cocaine-like numbing effect but without the pleasurable or stimulant effects); caffeine; levamisole (a de-worming medication commonly used as a cutting agent for reasons that remain unclear); boric acid; and glucose.29 The growing cocaine purity experienced across many markets in recent years has resulted in reduced risks stemming from adulterants, though naturally potency-related risks have correspondingly increased. Crack cocaine is manufactured from cocaine so contains the same profile of adulterants although the conversion process can purify it to some degree, leading to lower adulterant content.

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Pasta base/paco is generally less pure and more routinely cut with other substances, commonly including caffeine, as well as containing chemicals from the early stages of cocaine production.

**Chronic risks**

Long-term cocaine use increases mortality risk.\(^{30}\) According to a 2018 Spanish longitudinal study, annual mortality was four times higher among long-term cocaine users and more than ten times higher among those using both cocaine and opioids compared with those in the general population. There are, of course, likely to be other individual or social environmental risk factors linked to both mortality and drug use, and also many users of opioids and cocaine will be using crack cocaine rather than cocaine powder.\(^{31}\) In the same way that cocaine causes numbing of the nose when taken nasally by blocking nerve signals, it also causes the same effects in other parts of the body to a lesser extent. The heart, however, is particularly sensitive to disruption of nerve signalling and this blocking of nerve signals creates a risk of arrhythmia (a problem with the rate or rhythm of the heartbeat) which increases with dose. Combined with cocaine’s ability to shrink blood vessels, reducing oxygen supply, this creates a higher risk of acute heart issues when compared to many other stimulants. Cocaine also poses risks to mental health, including short- to medium-term depressed mood and anxiety (commonly symptoms of withdrawal) and longer-term depressive symptoms.

Regular snorting of cocaine can lead to damage and even perforation of the septum (the cartilage that separates the nostrils). Regular gumming can damage gums and lips. Injection can be associated with tissue injuries, infection and transmission of blood borne viruses where injecting equipment is shared.

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A number of risks have been associated with cocaine use in pregnancy — including low birthweight, premature birth, miscarriage and cognitive deficits in children of mothers using cocaine. This latter risk became the focus of the US ‘crack baby’ panic of the 1980s which was, to quote the US National Institute on Drug Abuse ‘grossly exaggerated’ (and, others have noted, was also grossly racist), as follow-up studies did not find the predicted effects in children. It is difficult to determine the degree to which identified risk associations are the result of cocaine toxicity alone or other environmental or behavioural factors relating to, for example, other substance use, poor antenatal care, or poor diet.

There has been a long running debate over the degree to which cocaine causes physiological symptoms of dependence (developing tolerance, withdrawal symptoms), but cocaine — because of its pleasurability and effect on...
the brain’s reward centers, its rapid onset, and short action — undoubtedly has a strong reinforcing action, potentially leading to psychological dependence and problematic patterns of use. A study from Lopez et al. found that the percentage of people who become dependent after trying cocaine is comparable to alcohol, significantly lower than nicotine, and significantly higher than for cannabis. However, it also found that 7.1% of people who used cocaine developed dependence within the first year, compared to less than 2% of people who used alcohol, nicotine or cannabis.33

As with all drugs, environmental variables — such as histories of childhood adversity, and socio-economic deprivation — are the strongest predictors of the development of dependence. Dependence is never simply a consequence of use; it stems from the complex set of social and psychological factors that interact when an individual is using a substance. Although cocaine undoubtedly brings a higher likelihood of dependent patterns of use becoming established than many other drugs, and needs to be recognised as more ‘risky’ in this respect, such patterns of use always need to be understood in the wider context.

Incidence of dependence developing is more pronounced for crack cocaine, which has a much more rapid onset and will tend to involve higher dosage per use and higher total exposure, but with use also more concentrated in vulnerable populations. Some estimates suggest that dependence is 2–3 times more likely than for powder cocaine.34 By contrast, the risk is negligible for coca leaf-based products. While not dependence in the clinical sense, some people can also come to rely on cocaine in social settings, and feel unwilling or unable to engage in certain social interactions without its effects. However, it is certainly not the case that dependence will follow from a single use of any cocaine product — even crack.


Mixing with alcohol and other drugs

Cocaine is often consumed with other drugs in social settings, most commonly alcohol, creating a set of additional risks and policy challenges. As noted above, the EMCDDA Trendspotter study found that alcohol co-ingestion was recorded in 57% of cocaine-related emergency hospital presentations. These risks are particularly poignant to consider from a regulation perspective, as alcohol is ubiquitous in the nighttime economy and there is no sign that this will change any time soon. Cocaine’s stimulant effects counteract the depressant effects of alcohol, maintaining alertness and sociability as well as allowing — and making more likely — greater alcohol consumption, often over a longer period. Alcohol consumption, in turn, also makes higher cocaine consumption more likely, as alcohol consumers seek it out to reduce sleepiness and inebriation, as inhibitions and personal or social controls are reduced, or to take the edge off the cocaine ‘come down’.

The increased use, and attendant health risks, of both alcohol and cocaine when used together, are complicated further by the fact that a third substance, cocaethylene, is created in the liver when cocaine is metabolised in the presence of alcohol. Cocaethylene has its own psychoactive effects, including euphoria, but with a longer duration of action than cocaine — and users may, even if not knowingly, be seeking the effects of cocaethylene as well as either cocaine or alcohol. Studies suggest that cocaethylene may be substantially more toxic to both the liver and heart than cocaine or alcohol alone. The combined effects of the cocaine and alcohol on the body also allow the user to consume more of both drugs without the

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### Cocaine: Key Risks and Vulnerabilities

<table>
<thead>
<tr>
<th>Risks and vulnerabilities</th>
<th>Indications for harm reduction and regulation</th>
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| **Youth** — increased health risks/vulnerability | • Delaying age of initiation as prevention/public health goal  
• Implementing age access controls at a retail level  
• Target evidence-based prevention and harm reduction resources at vulnerable youth populations |
| **Dosage** — higher dosage is associated with increased acute risks, particularly cardiovascular | • Make available tailored/targeted information (via public health education programmes, before and during purchase, on packaging, and in using environments) on dosage effects and risks  
• Ensure cardiovascular risks are highlighted in risk education resources and campaigns, and via vendors and other face to face drug services  
• Include options for lower potency cocaine powder — with preferential pricing (and potentially more generous rationing thresholds)  
• Include options for lower potency coca oral products in harm reduction information, and at all points of sale for cocaine powder — with lower barriers to access and preferential pricing |
| **Frequency of use** — increased frequency increases risk of dependence and other chronic harms | • Make available tailored/targeted information on risks of high-frequency use, including increased risk of dependence — establishing moderation and periods of abstinence as key harm reduction messages  
• Ration sales to individuals on per purchase, or per time period (potentially under purchaser licence model) to moderate use, and help establish social norms around reasonable safer use limits  
• Use price controls to prevent rapid fall in price that could incentivise more frequent use |
| **Poly-drug use** — increases acute risks | • Make available tailored/targeted information on poly-drug use risks (including increased cardiovascular risk when using cocaine with other stimulants) and related harm reduction  
• Establish regulation and monitoring of nightlife settings and other party environments to ensure provision of harm reduction information, alongside adequate ventilation, chill out spaces, free water provision, welfare/medical services, etc.  
• Encourage people to look out for their friends — share harm reduction information, educate on warning signs and basic care  
• Reduce stigma and barriers to accessing medical services |
| **Use with alcohol** — increases a range of acute, chronic and behavioural risks | • Make available tailored/targeted information on particular risks of consumption with alcohol — including in alcohol retail outlets and bars  
• Explore alcohol free (or alcohol-light) night life/party spaces that are cocaine tolerant |
| **Injected or smoked cocaine (crack)** | • Implement and adequately resource a comprehensive harm reduction approach for higher-risk cocaine use (see Chapter 7) |
‘canary in the coalmine’ (anxiety or sleepiness respectively) causing them to stop. This allows them to accumulate larger amounts of each drug, thereby causing more toxicity overall.

**Proposed regulation model for cocaine powder**

Cocaine is perhaps the most vexing of all drugs when it comes to regulation. The challenge is complicated by the fact that there are such a wide range of coca-based products and preparations — from unprocessed coca leaf through to highly processed cocaine powder and smokable crack. These products vary enormously in their potency, how they are used and their associated risks, occupying all three risk tiers identified in Chapter 2 and therefore requiring a range of different regulatory responses.

The production and supply chain for cocaine is also highly complex. Unlike most other substances discussed in this book, it is based on a plant that is cultivated — often by people working in some of the poorest regions of the world. Therefore, regulation of coca-based products has significant implications for international development, for farmers’ rights, and for the internal politics of producer countries. It is also implicated in security issues, especially the geopolitics of producer regions, in ways that are only comparable to opium production. Coca regulation, therefore, incorporates production and transit in ways that are unique. How products are regulated potentially has implications for a far broader set of communities and (in the case of policies on aerial fumigation, for instance) the environment than the other substances discussed here.

Cocaine also occupies a complex cultural position: stereotypically associated with affluent pleasure-seeking on the one hand, and with some of the most stigmatised forms of drug consumption on the other. None of these, of course, capture the complex realities of how and where coca-based
stimulants are used. Certainly, in parts of the world, cocaine is used by a far wider swathe of the population than any of the stereotypes would suggest. As it becomes cheaper and more widely available, the challenge of effectively regulating cocaine becomes more pressing.

A public health approach to cocaine regulation needs to focus squarely on reducing the potential harms associated with its use. Like alcohol and some of the amphetamines, cocaine presents an entourage of potential harms that cut across behaviour, physical health and psychological wellbeing. Use may, in some cases, lead to aggression and consequent harms to people other than the consumer. It can lead to physical ill-health, both specific conditions and health impacts indirectly linked to heavy use over time. Finally, it can lead to moderate or severe dependence. Patterns of, and motivations for, use vary enormously. Effective regulation needs to consider both the complex nature of how people use cocaine and the different motivations among diverse populations. Any approach needs to consider the risks of taking the drug with the vulnerabilities that underlie high-risk behaviours, and offer a range of concurrent interventions to target and mitigate them. At the same time, public health principles need to inform a regulatory model that balances meeting the needs of people who seek the effects of cocaine, with the imperative to minimise harms related to both cocaine use and the illegal markets that currently supply it.

As a starting point it is important to assert what does not work. Given the high profile health and social problems associated with illegal cocaine use and markets, many will be troubled by the idea of making cocaine legally available for non-medical use in any form. But the argument for cocaine regulation is a pragmatic response to the failure of current policy. Legal regulation should not create a free-for-all; quite the opposite.
As the former presidents of Colombia, and Mexico — who have fought on the front line of the war on drugs — have said, alongside the former President of Switzerland: ‘Ultimately, the choice is simple. We can hand control to governments or to criminal organizations. There is no third way.’

The proposals we detail below build on the more general discussion of drug regulation in the introductory section — applying that thinking to the specific risks and using behaviours associated with cocaine to each of the regulatory challenges. The ‘standard model’ described in Chapter 2 (state monopoly retailing via specialist pharmacy, unbranded products with a complete ban on all marketing, price controls, and rationed sales) is appropriate for cocaine powder retail availability. Further, specific challenges around preparation, pricing, and rationing are explored below. The specific sustainable development issues relating to coca and cocaine production and international markets are explored in Chapter 6.

**Preparation controls**

**Dosage and form**

Pharmaceutical grade cocaine could theoretically approach 100% purity. This is almost unknown in the current illegal market, and would therefore represent a step increase in potency, something known to be associated with increased total exposure and risks. A regulated approach would seek to provide a safer product that helps to moderate use. Regulated cocaine powder would therefore be a pharmaceutical grade product, but reduced from 100% purity with safe, non-toxic cutting agents.

Reducing purity too far would risk making the legal product unappealing, potentially creating space for an illegal market to continue supply of high purity cocaine.

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purity products. Options for making cocaine powder available at different levels of purity might therefore usefully be explored. Tiered cocaine markets have already developed in the illegal markets of many countries, in response to diverse demand, with consumers able to pay more for higher purity if that is what they are seeking. This suggests that there would be a demand for such a tiered purity/price structure in a legal market as well. As a starting point (and subject to careful monitoring and impact evaluation) higher and lower purity options at 35-70% purity could be made available. Pricing controls could be used to make lower potency products relatively more attractive as a way of encouraging moderation.

The option of cocaine being made available in solution as a (medical style) nasal spray that can administer a fixed single dose (of perhaps 20 milligrams) could also be explored. A solution would potentially be less damaging to the nose. Although not seen in the illegal market or among legal medical products, cocaine could also potentially be taken in pill form. Oral bioavailability is not dissimilar to when snorted, but a pill form would have slower onset and pill design could allow for a longer acting, slower release, lower dose product.

**Price controls**

Cocaine prices vary enormously across the globe. As the Global Drug Survey and UNODC data show, prices for a gram of cocaine vary from $4 per gram in Colombia to over $200 in New Zealand and Australia. In Western and Central Europe, and the US, prices are in the $50-100 per gram range. This variation will have a big impact on any potential pricing policy at a local level. As explored in Chapter 2, pricing controls can directly impact consumption rates as they translate into affordability and attraction of a given product.

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relative to other more expensive or cheaper alternatives. Many consumers are willing to pay for cocaine, despite its relative expense.

Recent rising use in Europe appears to be linked, at least in part, to falling prices and rising purity — contributing to an increased perception of better ‘value for money’. In the 2014 Global Drug Survey, cocaine was ranked as the ‘worst value for money’ drug, scoring an average 3.4/10 for value for money. In the 2019 Global Drug Survey, this had risen globally to 4.9/10.\textsuperscript{42} In the US, however, the rapid drop in prevalence of cocaine powder use in the mid-1980s was also concurrent with a fall in price, at the same time as crack cocaine use increased in largely differentiated populations — so clearly other social and cultural variables can be equally or more important in determining use than price alone.\textsuperscript{43}

Legally produced cocaine would certainly be dramatically cheaper in a free market scenario. The fact that a profitable market exists in Colombia where high quality cocaine is available for under $5 a gram demonstrates this, likewise in Brazil where it is available for $15 a gram.\textsuperscript{44} Indeed production costs in a larger scale industrialised market could easily drop to well under $5 a gram. There would, therefore, need to be some form of price controls to avoid a rapid price drop following any move towards legal supply and the likely, but unpredictable, changes in consumption behaviours. The details of how and at what level price controls should function would vary between states — but some key considerations include:

- Price controls would be easier to implement under a state monopoly retail where incentives and opportunities to divert into a parallel market are reduced. The significant profit margins potentially on

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offer would also accrue directly to the state, rather than private enterprise.

- A starting price-point at or near existing market prices (noting again that these vary significantly across the globe) would avoid price shocks and unpredictable changes in behaviour. Haden has proposed initially setting prices at 80% of current illegal market prices, but allowing for the price to slowly be reduced ‘until the illegal market either ceases to function or is substantially reduced to the point where it produces minimal harms’.  

- Starting at 100% of current prices and only then potentially reducing price in small increments would be a cautious default approach. Non-price variables (quality control, avoiding illegal markets, buying from a licensed & trained vendor, ethical production, etc.) would mean that a legal product could command some degree of price premium over an illegal equivalent. The Global Drugs Survey,

for example, found a majority of people who used cocaine would be willing to pay 25% more for ethically sourced cocaine.\textsuperscript{46}

- Using price controls to make lower purity preparations better value for money (in terms of adjusted cost per gram) could be a way of incentivising moderation by making lower risk products more attractive.

### Rationing

The fact that cocaine is often consumed in ‘binges’ (unlike MDMA) makes regulatory systems aimed at moderating use particularly important. But how do we moderate use of a drug that lends itself to immoderate use? Rationing of sales is one way of trying to achieve this. However, it presents the challenge of balancing the aim of reducing availability with the need to move consumers away from illegal sources. The particular risks of heavy episodic use point towards some form of rationing — including the option of a purchaser licence model. The challenges of such a model — in terms of potentially problematic state surveillance, iniquitous access, and undermining broader social equity goals are explored in Chapter 2. The simpler per-purchase volume sales restrictions would prevent larger scale bulk buying, but make it difficult to prevent multiple purchases (on a daily basis, for example). Therefore, the case for pilot models of legal cocaine retailing using a purchaser licence-based rationing would seem to be stronger than for other stimulants explored in this book.

Any rationing system needs clearly established, and viable, purchasing limits. The widespread sharing of cocaine in social settings makes attempts to moderate individual consumption via rationing more difficult, as well as making it difficult to specify a precise amount that may be considered acceptable over a given period of time. Nonetheless, Global Drug Survey

data suggest that 1 gram per month would cater for the majority of people who use cocaine, who use 10 times a year, or less, and on average use half a gram. Any specific amount will seem low to some, or high to others. However, based on the available data we have for casual use, 1 gram per month would provide a reasonable starting point.

As explored in Chapter 2, however, problems with personal limits arise most keenly with the minority of heavier, or more frequent, consumers who will be using the majority of the cocaine. A gram a month would be of little use for someone who, even if only in the short term, wants to use a gram a week, or more. In this case, the only options would be to reduce use or turn to illegal alternatives. We can’t assume everyone would opt for the former. Therefore, flexibility would need to be built into the system. This may include, for example:

- Allowing a degree of flexibility in purchase limits to cater for periods of higher and lower use
- A tiered system that allows higher purchase limits contingent on periodic brief intervention with the specialist pharmacist vendor
- A purchaser licence requirement for larger volumes
- A more generous threshold for lower purity preparations

None of this would detract from the need to provide for people in need of structured support for high-level or dependent consumption. At these higher levels, use is more appropriately managed by treatment specialists within a harm reduction framework (see Chapter 7).

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Proposed regulation models for lower strength cocaine preparations

As explored in Chapter 1, part of a wider stimulant harm reduction strategy involves making lower risk alternative products available — whether safer drugs or safer preparations — and using both regulatory tools, risk education and other available public health tools to lever safer behaviours, more moderate use, and safer methods of administration.

In most of the world — beyond the Andean region — cocaine is only available in its most concentrated forms as powder, crack or pasta base. Yet a range of less processed, less potent, safer coca-leaf based products exist within the traditional coca-using Andean regions. These have never been available in the wider world (at least not in the modern era) due to both international prohibitions, and the economic imperatives of an illegal trade that prioritises the most transportable and profitable preparations. The result is that while higher-risk cocaine powder and crack are easily available in much of the Global North, safer, milder plant-based preparations of the drug are almost completely inaccessible. From a pragmatic harm reduction perspective this is an absurd situation, like having bars that not only don’t serve soft drinks or beers, but in fact only serve spirits and overproof moonshine.

The potential clearly exists for making less potent cocaine products available. Many products already exist and others could be developed further, bringing both harm reduction benefits for people who use cocaine, but also economic development opportunities for traditional coca-growing regions (see Chapter 6). It is, of course, hard to predict how such legal availability would impact on cocaine powder or crack cocaine use over time, and there are many variables that could influence such impacts. But it is perfectly reasonable to assume that such products would meet the needs of at least some existing or potential future cocaine users, but in a safer way. This process of gradually shepherding patterns of use towards safer products and behaviours could be supported by the regulatory
infrastructure, for example, by making milder products relatively less expensive or relatively more available, allowing some degree of marketing or branding for such products, allowing their use in public or in social settings like cafes or bars, or by encouraging substitution with harm reduction education and other public health tools.

Coca leaf

The use of coca leaf in Andean indigenous communities is regionally and culturally specific (it is useful in combating altitude sickness, and provides nutrients not easily available from other local staples). It seems unlikely that there would be a substantial market for traditional Andean style coca leaf chewing in the wider world, even if no legal obstacles to its production and export existed. Other culturally/regionally specific stimulants such as khat and betel nut have similarly not found significant wider markets even when not subject to the global prohibitions that cover coca leaf. Products available for chewing could, nonetheless, be made available for a more niche market space, with other coca leaf products adapted for the broader consumer base.

Coca tea and other coca-based beverages

In the Andean regions, coca tea is used in ways not dissimilar to coffee and conventional tea in much of the rest of the world. There is no reason why it could not be made more widely available elsewhere. Initially, most consumption would probably remain in the Andean region, but it may find a global market share in the speciality tea market. There is no particular reason to think it would replace or seriously encroach on mainstream coffee and tea markets where they are established.

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It is more likely that new coca-based drinks would emerge to compete with the lucrative caffeine-based soft drink market, including cola drinks, and energy drinks like Red Bull. Legitimate concerns have been raised that caffeine energy drinks are appealing to, and being deliberately marketed at, adolescents. Moreover, many of these caffeine drinks have been actively marketed for their stimulant properties, associating them with health, vitality and glamorous lifestyles, for example through branding and sponsorship of celebrities, extreme sports and music events. Regulations should be designed to combat this type of marketing for any coca-based drinks.

While coca tea has a natural limit to its active content, more highly processed beverages could contain larger amounts of coca/cocaine. More potent drinks would have to be subject to additional tiers of regulation, so that active content could be limited, controls placed on labelling, packaging and advertising, and age access restrictions put in place – as has begun to happen with some caffeine energy drinks.
Some European countries have introduced new controls on high-caffeine energy drinks, such as restricting sales to over-16s. Coca beverages over a certain level of potency would need to be more strictly controlled, as cocaine is not self-regulating in the way that caffeine is — with unpleasant effects and tolerance of caffeine kicking in fairly rapidly over a standard active dose. An upper limit of cocaine content per volume of beverage, and per adult serving, would prevent more potent preparations — like some caffeine ‘energy shot’ products — being developed. The sale of any coca energy drinks over a certain potency threshold should require additional regulation including licencing of vendors.

Although coca-based beverages offer a safer, milder, more slowly absorbed cocaine preparation, regulation would need to address the risks of such products being consumed in combination with other drugs — particularly alcohol. This is an issue already experienced in relation to caffeine energy drinks (for instance Jägerbombs, where Jägermeister is mixed with an energy drink and sold at bars). Some pre-mixed combination beverage products have also emerged seeking to capitalise on this caffeine/alcohol

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cocktail trend – and have created sufficient concern to find themselves banned in the US.

**Other coca products**

Since cocaine is absorbed far more efficiently through the gums or sublingually than through the stomach, there is potential for the development of more consumer-friendly oral coca leaf-based products, which would be more appealing as a substitute for cocaine powder than coca leaf chewing or tea for non-traditional markets. There are already numerous variations of such products produced in the Andean region including hard sugar-based sweets, lozenges or oral pouches.

Pouches are comparable to oral tobacco products, like ‘snus’ used in Norway and Sweden (called ‘bandits’ in the USA). A quantity of coca leaf, or coca flour, plus an alkali additive to activate the alkaloid, is contained in a small permeable, tea bag-like pouch, which sits inside the mouth between lip and gum or under the tongue. This releases a lower dose of cocaine over a longer period of time, in a similar way to more traditional coca chewing.

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**The risks of mixed alcohol and stimulant beverages: Four Loko**

‘Four Loko’ was the most notorious of a series of sweet caffeinated alcoholic fizzy drinks that emerged onto US and global markets between 2001 and 2010. Sold in eight fruit flavours, Four Loko had up to 12% alcohol content in a 0.7 litre can, meaning one can contained the equivalent of 4–5 standard bottles of beer, along with 156 milligrams of caffeine (equivalent to two cans of Red Bull). Four Loko marketing targeted young consumers through lifestyle branding and sponsorship of music events.

Around 2009 it began to attract mainstream media coverage when it was associated with high profile incidents of problematic binge drinking and hospitalisations among teenagers and on college campuses. Dubbed ‘liquid cocaine’, ‘crack in a can’ and ‘blackout in a can’ by some media, bans soon followed on campuses, in grocery chains, and then at state level. Four Loko was ultimately pulled from sale in the US by the producers, when the FDA declared that caffeine was an unauthorised food additive raising health concerns (it returned later without the caffeine content).
The onset of the effect is slower than for snorted cocaine, and the effect milder but more consistent and longer lasting — avoiding the highs and lows of repeated redosing with snorted powder. Some existing regional coca products like ‘mambe’ and ‘coca machucada’ already constitute a step in the direction of making chewing more user friendly. Mambe is a traditional form of coca consumption that is now becoming more widespread in Colombia. This is the pulverised coca flour premixed with an alkali ash. Coca machucada is a format used in Bolivia where coca leaf is mixed with flavourings and alkali, then the whole mix is softened with a hammer — making the coca easier to ‘chew’.

Oral coca-based products can also take the form of lozenges, which similarly sit between the lip and gum and are absorbed over a period of up to an hour or more. Both have a distinct coca taste — not to everyone’s liking, but this can be changed to some degree with flavourings. Existing products of this kind are designed for local markets already familiar with coca, rather than people who currently use cocaine powder. However, the potential certainly exists for such products to be developed with non-traditional export markets in mind. It is an open question as to the extent to which they might cater for consumers seeking conventional cocaine effects, and they may play only a small role in displacing cocaine powder use over time. Any answers will be speculative until they are brought to the market.

Such products would only require regulation appropriate to the relatively modest risk they present, probably comparable to nicotine replacement products, with an adults-only, over-the-counter pharmacy sales model. They would sensibly be made available, and be promoted as a lower-risk substitute to cocaine powder.

It should be acknowledged that introducing lower-potency products could create new forms of cocaine consumption where none previously existed, however experience from Peru and Bolivia (where legal coca markets exist but cocaine consumption levels remain relatively low) suggests this
Coca chewing gum, coca lozenges and Coca Mambe

Photos: Steve Rolles, 2019, and (Mambe) Crista Castellanos. bit.ly/33J0kKZ. Shared under a Creative Commons Attribution-Share Alike 4.0 licence (https://creativecommons.org/licenses/by-sa/4.0/deed.en).
is unlikely. From a public health perspective this may not be a significant concern as such products are relatively low-risk, and may merely expand consumer choice between products (such as tea or coffee) that are of comparable low-risk, or others (such as tobacco) that are higher-risk. It is possible, however, that such products could lead to more risky forms of cocaine use for some who would otherwise not have chosen to experiment. It is for this reason that some regulation to mitigate such risks, most obviously age-limits on sales, would be appropriate, even if the likelihood is relatively low.

**Enhanced oral coca products**

Products made from coca are naturally limited in their potency as coca itself contains around 1% cocaine. While coca products provide a mild cocaine effect, there remains a big gap, in terms of intensity, between them and extracted cocaine powder. It would certainly be possible to produce more potent oral products — as snus/pouches or lozenges — that provide a higher dose of cocaine than coca only products, but still providing safer, slower oral administration. These could be purified coca products, or produced to include a ‘booster’ of the extracted alkaloid. Alternatively, they could essentially be pharmaceutical cocaine products in a novel delivery system (somewhat like newer tobacco-free snus, or nicotine replacement lozenges). Moving away from coca content altogether would have implications for the economic development dimension of this discussion *(see Chapter 6)*.

As potency and dosage of enhanced coca products is increased, risks inevitably increase also, even if they remain lower than for cocaine powder. The regulation models for such products would need to reflect this, and the potency threshold at which different levels of control were applied would need to be determined. Such products could only be promoted by the cocaine vendors as a safer alternative to cocaine powder. Rationing could be less strict, and prices lower to incentivise people who use cocaine
to shift to the safer product. While the mildest coca products — like coca tea — could be sold with few restrictions (beyond clear content labelling), stronger products would need to be more strictly controlled.

Proposed regulation model for crack cocaine

What is crack cocaine?

Crack cocaine is cocaine. It is the same drug as cocaine powder simply in a form (in technical terms, the base rather than the salt) that allows a different mode of administration, i.e. by smoking. This means that the effects are the same as cocaine only dramatically more intense and short-lived. Comparing snorted cocaine powder to smoked crack can be conceptualised as the same drug, but with the effects experienced immediately, and all at once; concentrated into between one fifth to one tenth of timescale (over 5–10 minutes compared to 45–120 minutes), so blood plasma levels reach a much higher peak. The effects of injected powder cocaine are of a similar intensity to smoked crack cocaine, although none is lost from exhalation. Crack is also sometimes injected — with effects indistinguishable from injected cocaine powder, as it is converted back into a salt when prepared for injection.

The risks of crack cocaine are greater due to the increased speed and intensity of exposure. There are also additional risks associated with smoking and respiratory damage. Respiratory harms from smoking crack, or pasta base, are increased when it is smoked using improvised pipes made from drink cans or plastic bottles, which can release toxic fumes when heated. The use of short glass crack pipes (without a latex mouthpiece) has also been associated with burns, cuts and infections to lips, and are a potential
transmission route for infectious diseases including herpes, tuberculosis, hepatitis and Covid-19 if shared.

Patterns of crack use vary. The 2018 US National Survey on Drug Use and Health found that while roughly 9 million people over 12 years of age said that they had used crack at some point in their lifetime, only 757,000 had used crack within the past year — meaning over 90% of lifetime users had not. Less than 5% of lifetime users had used crack within the past month. Very similar figures were reported for the year 2017. Occasional recreational crack use in the US has reportedly become more popular in higher income workers in the financial sector in recent years, seemingly at odds with widespread, and highly racialised, media representations depicting crack as uniquely associated with poverty and self-destructive addiction.

Professor Carl Hart has noted that ‘Even at the peak [of] widespread use... only 10–20 percent of crack cocaine users became addicted.’ However, it is also the case that the intensity of the crack experience lends itself to more problematic patterns of compulsive use than cocaine powder. The intensity and detachment associated with crack have certain similarities with heroin: with both the profound experience of pleasure, and the anxiety associated with come-down and withdrawal, driving craving, and repeated use. For crack, alleviation of the come down can often involve other drugs such as alcohol, benzodiazepines, or opioids. However, it is also much more closely associated with heavy episodic use than heroin. The EMCDDA

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How to regulate stimulants

Trendspotter report notes that: ‘unlike in the case of heroin, crack cocaine dependence does not necessarily involve daily use; crack is often used in binges that may last for days until physical or economic exhaustion — although people who use both crack and heroin are much more likely to take crack daily.’\(^5\) In regard to the profile of people who use crack, the EMCDDA notes that:

...users of crack cocaine are often marginalised, either street homeless polydrug users (Ireland), migrants from eastern Europe who switch from amphetamines to crack (France), migrants who belong to ethnic minority groups (France and Denmark) or nationals who are long-term users of crack cocaine and other drugs (Frankfurt).\(^6\)


\(^6\) See footnote 53.
Proposed regulation model

The question ‘but what about crack?’ is never far away when legal regulation of cocaine is discussed. Attempting to regulate crack cocaine, so often associated with high-risk behaviours, personal and social harms, can seem daunting. The answer is to begin by moving beyond the oversimplified solutions that have, over the years, demonstrably failed to produce effective outcomes.

More than four decades of criminal justice enforcement have not eradicated use of crack cocaine. Regardless of how one might feel about it, there is a need to accept that some people want to, and will, use crack despite efforts to persuade them otherwise. Denial, or wishing away the challenge, is counterproductive. Instead we need to consider the available evidence. This will help us understand what kinds of intervention will be most effective at reducing the harms that crack can cause both for people who use it, and for the wider community. This can include a long-term goal of reducing overall levels of crack use, in parallel with a focus on the health and wellbeing of those who continue to use.

To be clear, we do not advocate a model in which crack cocaine would be sold under licence of any kind. But there is no benefit in further criminalising and demonising people who use crack. Instead, we need a concerted public health-led response, combined with appropriate social support. Decriminalising possession of crack for personal use (along with all drugs) and addressing the social conditions that underlie most problematic use of crack is key to reducing high-risk behaviours in the longer term.

Public health responses are more difficult and less well-established for crack than for heroin. While even the most entrenched patterns of heroin use can respond well to regular prescriptions, problematic crack use is often characterised by less easily managed cycles of binging and crashing. Episodic patterns of use tend to lead to sporadic engagement with treatment services which complicates provision of appropriate support.
While people who use illegally supplied heroin can be successfully maintained and stabilised on prescribed preparations of heroin, or accept substitute prescriptions such as methadone, buprenorphine, hydromorphone or even opium, there is no existing medical model for prescribing crack. Some research has explored prescription of substitute stimulants such as amphetamines and Modafinil, or use of less potent cocaine preparations. Heroin prescribing has also been shown to reduce crack use among people who use both crack and heroin: evidence from Heroin Assisted Treatment programmes in Switzerland and the UK shows significant declines in crack use among clients who are able to access prescription heroin regularly. There is some evidence that provision of cannabis is also effective.

The growing concurrent use of crack and heroin is yet another unintended negative consequence of prohibition. In the case of crack cocaine in the UK, the long-established illegal heroin market created a ready made distribution network and receptive market for the new product. This is a market and a culture that regulation would actively and directly help dismantle, bringing short-term benefits as well as helping ensure any future drug ‘epidemic’ would be less likely to take hold. The social benefits of regulation here are particularly acute, as people who use crack are often from already disadvantaged communities, struggling with poverty, poor housing, few work opportunities, and fractured communities.

We need to acknowledge that if powder cocaine is available — via legal retail or prescribed channels — then crack will remain effectively available too.
Making crack from powder cocaine is a simple kitchen procedure, and one that is impossible to prevent. Even if crack is not directly available, determined individuals previously willing to engage with the risks of the illegal market to procure it would clearly not lack the motivation to manufacture it from a legal powder cocaine supply. Therefore, the focus needs to remain on how to reduce harm as far as is possible.

Harm reduction is possible in regard to crack, and interventions are becoming increasingly well established (see Chapter 7). For example, a number of locations in Vancouver distribute crack harm reduction kits, and some experiments have also begun with supervised consumption venues for crack use. These interventions point towards a model in which, although crack might not be available directly, harm reduction provision would be made for those who continued to procure and use it, regardless of whether they do so through illegal or quasi-legal channels.

**A pragmatic three-tiered approach**

There is no simple, or single, answer to the challenge of regulating coca-based products in all their variety. Current drug policy fails entirely to allow for the differences in strength and risk to be reflected in regulation. Our proposal is to recognise these distinctions and construct a system that utilises all the regulatory options available — through licensing, price controls, rationing, and restrictions on marketing — in establishing a tiered approach to achieve the aims of regulation outlined in Chapter 1. Adapting the elements set out in our standard regulation model to products as they vary in potency, allows for the creation of a viable market that neither encourages use nor criminalises it.
Under the tiered model explored in this chapter, lower potency coca products will be more readily available, while the supply of cocaine powder will be strictly controlled and rationed. Crack cocaine, in contrast, will be managed through a dedicated harm reduction response including supervised consumption venues. Of course, no system will eradicate all harms, and every system will have loopholes that can be exploited. Regulation must be proactive, constantly monitoring and evaluating results to ensure that harms are combated and health is prioritised. By bringing the full range of coca-based preparations into an overarching regulatory framework, we can begin this process, and start to undo harms caused by decades of chaotic, uncontrolled supply.
Sustainable development and equitable regulation
Future regulated markets for the non-medical sale of these drugs would not be entirely new. Rather, they would seek to legally regulate large, existing illegal markets.
Assuming that the legal and political challenges can be addressed, the regulated production of stimulants for future legal markets is, on the face of it, not a huge practical challenge. There is no mystery about how to legally produce cocaine, amphetamines and MDMA: they are all already legally produced for medical and scientific uses. Existing frameworks can also serve as guidance when developing regulations for non-medical production.

Future regulated markets for the non-medical sale of these drugs would not be entirely new markets. Rather, they would seek to legally regulate large, existing illegal markets. These markets currently support the livelihoods of millions of people, many of whom, particularly in the case of coca/cocaine markets, live in conditions of extreme economic vulnerability and depend on the illegal drug economy for their survival.

There is a real danger that drug policy reform will lead to economic domination by the same forces of the Global North that have driven global prohibition. This risk has already become clear in the case of cannabis, where multinational companies have begun to exploit production opportunities in traditional growing communities. In the absence of proactive planning, there is a risk that the sustainable development agenda will again be marginalised. The burden of the global drug war has fallen most heavily on economically marginalised populations, particularly in primary production and transit regions, and the benefits of ending prohibition risk being just as unequally distributed. Without active intervention, emerging legal drugs markets will, by default, rapidly fall into the hands of global corporate pharmaceutical and agri-businesses, with those currently dependent on precarious employment in the illegal trade cast adrift.
Illegal drug markets present a development paradox: they actively undermine social and economic development, while simultaneously offering an economic lifeline to some of the most vulnerable. Understanding the dynamics of this paradox is vital to thinking on how it can be navigated as the reform process unfolds.

Illegal drug production and distribution is ruthlessly profit-motivated, yet largely unconstrained by the rules, accountability and institutions that guide legal economies. Flexible and opportunistic criminal organisations are attracted to places where they can operate unhindered. They naturally gravitate towards poorer, vulnerable and geographically marginalised communities, areas of profound structural inequality, fragile states with weaker institutions, and conflict zones. Here, they can avoid threats to their business from the state, minimise production and transit costs, and maximise profits.¹

Where state institutions are already underdeveloped and underfunded, the vulnerability to drug market-related corruption only increases, as organised crime groups seek to secure and expand their control. In a

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parallel and equally destructive dynamic, violence and intimidation can often become the default regulatory tools for illegal drug economies in the absence of legal regulatory infrastructure. When violence and intimidation become normalised in daily life, and corruption becomes endemic within the police, the judiciary and politics, citizens may well lose faith in institutions they see as ineffectual and unaccountable, or worse, complicit in criminal activity. The rule of law is critically undermined and organised crime is further strengthened.

Illegal drug markets can also undermine economic development more broadly. Illegal drug profits and related money laundering and corruption can create unfair competition, and macroeconomic distortions, while drug-related violence and instability can deter investment and tourism. In some regions the resources available to organised crime from drug profits may be equal to, or greater than, those available to the government. At this extreme, the illegal drugs economy becomes an existential threat to the state itself, risking the creation of ‘narco-states’ locked into a spiral of underdevelopment.

‘Global drug control efforts have had a dramatic unintended consequence: a criminal black market of staggering proportions. Organized crime is a threat to security. Criminal organizations have the power to destabilize society and Governments. The illicit drug business is worth billions of dollars a year, part of which is used to corrupt government officials and to poison economies.

Drug cartels are spreading violence in Central America, Mexico and the Caribbean. West Africa is under attack from narco-trafficking. Collusion between insurgents and criminal groups threatens the stability of West Asia, the Andes and parts of Africa, fuelling the trade in smuggled weapons, the plunder of natural resources and piracy.’

**UN Office on Drugs and Crime**

The corruption, violence, and economic destabilisation fuelled by the war on drugs — the ‘unintended consequences’ so clearly identified by the UNODC — are serious obstacles to democratic governance. They also make it difficult, if not impossible, to achieve the United Nations 2030 Sustainable Development Goals for large groups of citizens in the most badly affected regions.

The UN’s Sustainable Development Goals are universal. Thinking about the sustainable development dimension of drugs policy should therefore not be limited by simplistic North versus South, developed versus developing world, or rich consumer country versus poor producer country dichotomies. The war on drugs has exacerbated marginalisation and vulnerability in communities across the world. However, the economic impacts of prohibition (and the risks of continued, albeit different, forms of exploitation and oppression under legal regulation) are especially pronounced in those regions where plant-based drugs are currently grown, and the countries through which products are transported. In the case
of stimulants, that means primarily the coca-growing regions of South America, and the transit countries of Central America. However, it also means anywhere along the supply chain for amphetamines and MDMA.

This chapter explores the development implications of the reform process and considers how development perspectives can, and should, be built into emerging regulation frameworks. Towards the end, it explores how to facilitate social justice more broadly: including at the retail stage, by ensuring new legal markets provide benefits to communities disproportionately impacted by law enforcement under prohibition.

Transitioning to regulated markets

There are very different development and social justice questions relating to each of the stimulant drugs in this book, and for the different people involved in each link of the supply chains: people who grow and produce, people who transport, and people who sell and consume drugs.

At each stage, however, there are common themes of inequality, vulnerability and exploitation. Very few people who work in the illegal drug economy match the stereotypes of moneyed gangsters who dominate news headlines and TV dramas. The reality is that the illegal drugs market is profoundly iniquitous, with a tiny number of wealthy ‘king-pins’ vastly outnumbered by millions of low-earning farmers, couriers and street dealers. These lower tiers of the drug market are disproportionately populated by people who are already socially and economically marginalised. Their migration into the illegal drug economy, while providing a means of short-term economic survival and even enabling a degree of social inclusion, will tend to entrench poverty and marginalisation in the longer run by making them targets of enforcement, subject to criminalisation, incarceration, and violence — as well as exploitation and intimidation from organised crime groups.
MDMA

The illegal market for MDMA is, by value, relatively small in comparison to both amphetamines and cocaine. As discussed in the MDMA chapter, until around 2008, illegal MDMA manufacture did involve a plant-based precursor (safrole oil derived from the sassafras tree in China and Cambodia), but this was modest in scale and economic terms. Illegal MDMA production for the global market has since been replaced with an entirely synthetic chemical process. Relatively few people are engaged in production, which mostly takes place within the European Union, especially the Netherlands, although production has reportedly diversified in recent years to include other countries such as Canada and China.

The nature of MDMA production means that development issues are less acute. Its comparatively small scale dictates that relatively few licensed actors will be required to meet market demand. Nonetheless, any regulatory model for production should be designed with social equity and justice in mind, implementing basic principles outlined in Chapter 1: including the avoidance of excessive corporate capture and ensuring an equitable spread of licences.

Amphetamines

Legal and illegal amphetamine production is now mostly synthetic, using BMK (phenylacetone) as the key precursor, which can itself be relatively easily synthesised, depending on the chemicals available for its manufacture. Methamphetamine can similarly be synthesised from phenylacetone, but also from ephedrine or pseudoephedrine — substances found in many common over-the-counter cold cures (the source of significant

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small-scale methamphetamine production), and in the ephedra plant. Ephedra has a long history of traditional use in China, India and central Asia, where a significant legal market exists for ephedra tea and herbal remedies.

There is also a growing trend in Afghanistan towards cultivation of ephedra for illegal production of methamphetamine, both for domestic consumption and for export into the global market via Iran. While over-the-counter remedies containing ephedrine or pseudo-ephedrine have offered a much easier small-scale precursor option for methamphetamine production, recent trends reported in Afghanistan show some producers switching to a wild variant of the ephedra plant that grows in the mountains, cutting production costs in half and contributing to an expanding regional methamphetamine industry. However, the novelty and relatively small scale of this opportunistic new market suggests that the development implications of transitioning

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**Amphetamine production and armed conflict**

According to the EMCDDA, there is ‘considerable uncertainty about current production’ levels of amphetamine in the Middle East, although the ‘use of captagon is likely to be quite fluid and could change rapidly in the context of the evolving security, political and economic situations’.\(^1\) Armed conflict raises a particular challenge in the development context, precisely due to these rapidly intensifying situations.

There is also a historic trend in the use of amphetamines by combatants. Production (and use) in Syria, in the midst of a violent civil war, highlights an important development challenge. It has been reported that those profiting from drug production and distribution include Lebanon-based armed group Hezbollah, while the UNODC additionally note that captagon remains ‘a potential source of income for terrorist and insurgency groups in the subregion’.\(^2\) The EMCDDA is more cautious, concluding that, ‘while some terrorist groups may exploit the captagon market to finance their activities and some terrorists may at times use captagon or other drugs...the evidence available does not indicate any particular association between captagon and terrorism.’\(^3\)


\(^3\) See footnote i. p.15.

towards some form of legal production would be relatively marginal. This plant-based production is significantly less economically important in scale than illegal opium and cannabis production in Afghanistan, for instance.

Globally, however, the amphetamine and methamphetamine markets are huge, and intimately intertwined in organised crime activity, which has profound impacts on regional security and development. The South-East Asian market has expanded rapidly in the last decade with seizures rising sevenfold for methamphetamine and doubling for amphetamine between 2008 and 2017.\(^7\) Methamphetamine production has also significantly shifted from China, where there has been a concerted enforcement effort,
to more remote and less policed regions in Northern Myanmar.\textsuperscript{8} As the UNODC points out, ‘like any business, transnational criminal enterprises seek out conditions that are good for the bottom line, and in Southeast Asia conditions have been favourable.’ Such conditions include systemic underdevelopment — further exacerbated by illegal drug markets — as well as the ready supply of precursors and well-established chemical industries.\textsuperscript{9}

The majority of precursor trade in recent years has flowed towards the Middle East. Between 2008 and 2011, 98 tonnes of BMK (currently the key amphetamine precursor, and amounting to more than two thirds of global trade) were imported into Jordan, ‘mostly for re-export to Iraq’. The EMCDDA reports that ‘the fate of these imports is unclear’ and that ‘only one precursor seizure’ was officially reported in the Middle East between 2006–2012. As the EMCDDA points out, ‘if even a small percentage of this precursor was diverted’, very large volumes of amphetamine and amphetamine-related substances could have been produced.\textsuperscript{10} The ‘legitimacy’ of these imports has been questioned by the International Narcotics Control Board, with BMK purportedly being imported for developing cleaning products, despite alternatives being available.\textsuperscript{11}

More recently, the ‘dismantling’ of amphetamine synthesis laboratories has been reported in Lebanon and Jordan.\textsuperscript{12} However, only five were dismantled in the Middle East between 2010 and 2018.\textsuperscript{13} Despite these strong suggestions from trends in precursor trade, the exact scale of amphetamine production in the Middle East remains unclear. The EMCDDA speculates that the Syrian civil war has impacted captagon production.
from 2011 onwards, noting that production lines for captagon have shifted from criminal networks in the Balkans in the 1990s and early 2000s to the Middle East in recent years. Captagon was originally a branded medicinal version of the stimulant fenethylline, but it now appears on the illegal market predominantly containing amphetamine (see Chapter 4). The EMCDDA suggests that ‘a combination of weak jurisdiction, increased demand by combatants or affected populations and various factions seeking access to funds through engagement with the drug trade may all have potentially resulted in a greater incentive to increase production of captagon within the region.’

As discussed in Chapter 4, the varying markets and forms of amphetamine in demand around the world present a unique challenge for regulation. In terms of captagon production, this appears to have shifted to the Middle East as that is where the main market is. Regulating existing internal markets within regions is more straightforward. The greater questions for regulation will be in relation to amphetamine produced for consumption elsewhere in the world, and ensuring that the regulation of production in outside ‘consumer’ countries does not remove economic lifelines for those reliant on producing amphetamines for existing illegal markets.

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Cocaine

Pharmaceutical cocaine can already be synthesised entirely from legally obtainable precursors (including atropine, tropinone and carbomethoxytropinone — none of which are currently controlled under the 1988 UN Drug Convention). The process is difficult and currently far less economic than the comparatively simple traditional extraction from the coca plant, discussed in Chapter 5, and is not known to be a source for the illegal market.\footnote{EMCDDA (Undated). Cocaine and crack drug profile. www.emcdda.europa.eu/publications/drug-profiles/cocaine} This situation could, however, potentially change very rapidly with breakthrough technological innovations that could dramatically reshape any future cocaine markets, legal or illegal.

While unpredictable, such a development is not that far fetched. Bioengineers have, for example, recently used yeast genetically modified with opium poppy genes, to produce noscapine, an alkaloid that occurs

\textit{From an early age, children learn to use machetes to prepare the plants ready for sowing in a new coca field. La Playa hamlet, Colombia 2003.} 
\textsc{Photo: }Carlos Villalon, villalon santamaria.com
naturally in opium poppies (used as a non-narcotic cough suppressant), and there have been persistent rumours of attempts by underground scientists to achieve something similar with the cocaine alkaloid.17 This would be an inversion of innovation trends in amphetamine production, discussed above, which are conversely seeing transitions to plant-based production methods in parts of Afghanistan.

In the meantime both the raw coca leaf and pharmaceutical cocaine are subject to strict international controls under the 1961 UN Single Convention on Narcotic Drugs.18 Like heroin (diamorphine), derived from the opium poppy, cocaine is in the strictest Schedule I of the treaty, although not in Schedule IV — which is appended to some Schedule I designations to indicate a drug has no medical uses that outweigh potential for abuse.19 Legal coca cultivation and cocaine production for medical uses do indeed continue to take place under the auspices of the treaty. But given cocaine’s limited medical applications, and limited research thus far on coca itself, production is on a much smaller scale than legal opium production; cultivation was estimated as covering roughly 14,000 hectares in 2017 by the International Narcotics Control Board.20

**CASE STUDY**

**Guinea Bissau**

Growing demand for cocaine in Europe, combined with the increased policing of Caribbean transit routes has displaced supply lines from Latin America to West Africa — an example of ‘the balloon effect’ in action, where

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reduction in illegal drug activity in one region is compensated for by a corresponding rise elsewhere. Guinea Bissau, already experiencing weak governance, endemic poverty and limited policing infrastructure, has been particularly affected — with serious consequences for one of the most underdeveloped countries on Earth.\(^\text{21}\)

In 2006, the entire GDP of Guinea-Bissau was $304 million, the equivalent of six tonnes of cocaine sold in Europe at the wholesale level.\(^\text{22}\) By 2008, an estimated 50 tonnes of cocaine were passing through West Africa each year, with at least 30 tonnes going into Guinea Bissau.\(^\text{23}\) The disparity in wealth between trafficking organisations and authorities has facilitated infiltration and corruption of the little state infrastructure that exists. Investigations show extensive involvement of police, military, government ministers and the presidential family in the cocaine trade, the arrival of which has also triggered a sharp rise in cocaine and crack misuse among the general population.\(^\text{24}\)

Authorities in Guinea Bissau were dramatically under-equipped to deal with the influx of organised crime. In 2019, the President of Guinea Bissau stated that ‘We don’t have aeroplanes, we don’t have boats, we lack the radars that would give us control over our...economic zone,’ to respond to the power of drug traffickers.\(^\text{25}\) Army officials tackling the problem report having only mobile phones as communication devices. However, the official response is also heavily undermined by the sheer scale of corruption, which has in turn been exacerbated by the sudden interest of international organised crime in the country. In 2013, the US’s Drug Enforcement Agency

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got involved, leading to the arrest of a former Guinea Bissau naval chief in 2013, but this also proved ‘ultimately fruitless’.  

The war on drugs has turned Guinea Bissau from a fragile state into a failed narco-state in less than a decade, creating an institutional environment in which nascent development processes are curtailed or put into reverse. Other countries in West Africa are also being impacted or under threat, as are all fragile states with the potential to be used as producer or transit countries. As one distribution line is shut down, another one is forced open — and under-development provides opportunities for drug traffickers to exploit.

In contrast to synthetic MDMA and amphetamine, cocaine is still exclusively produced from the coca leaf (chemical synthesis is possible but not yet economically viable). This creates a series of more acute development challenges. The most recent figures from the UNODC suggest that global illegal cocaine production reached a record high in 2018, with over 240,000 hectares under coca bush cultivation worldwide and an estimated 1,723 tonnes of cocaine manufactured — almost double the equivalent values from 2013.

The UNODC also reported record seizures of cocaine in 2018 at 1,311 tonnes. It can be extrapolated from this that global consumption for 2018 — or at least cocaine available for consumption — was approximately 412 tonnes. However, there are significant question marks over both production and seizure data, which are compiled from a range of methodologically challenging sources, including satellite imagery of thousands of small plots, and the UNODC’s annual report questionnaires from member states.

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These data are not easily adjusted for crop yields, coca paste/cocaine purity, possible double counting, or underreporting, and can therefore only give approximate figures. Assuming 412 tonnes is correct, then, calculating back from the UNODC data for area under cultivation, under a 100% legal framework only 57,000 hectares of coca cultivation would be required to supply current global demand.\(^{29}\) Indeed it would likely be somewhat lower than this as yields per hectare of legal production would presumably increase with commercial efficiencies.

What this usefully illustrates is that the cocaine market, while high in value under prohibition (turning over between $85–165 billion annually at the retail end according to UNODC) — is actually quite small from a farming perspective.\(^{30}\) 57,000 hectares of coca is marginal when compared to the other key global plant-based stimulants: 2.8 million hectares for tea

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\(^{29}\) This calculation is based on the premise that 240,000 hectares were required to produce 1,723 tonnes of cocaine.

cultivation, and 10 million hectares for coffee cultivation.\textsuperscript{31} 57,000 hectares is equal to a square with sides just 14.8 miles in length (or 220 square miles). 412 tonnes of cocaine would fit in just 15 standard shipping containers.

The UNODC estimates that between 280,000 and 370,000 households are involved in coca production.\textsuperscript{32} Coca is, like cannabis and opium, a relatively low-input, high-yield crop. It is grown in remote regions on poor soil at high altitudes, and without the need for sophisticated irrigation or pesticides. It is also much less perishable and easier to transport than most conventional farmed produce, and can be harvested four times a year after as little as 18 months, compared to an annual harvest after three years for coffee. As Julia Buxton notes, ‘Even low levels of cultivation of these high-value-to-weight products provide an economic safety net for the land-, food- and cash-poor, with guaranteed markets, relatively stable prices, [and] cash payment’.\textsuperscript{33}

**CASE STUDY**

**Colombia**

Colombia has been at the epicentre of illegal cocaine production since the 1970s. The vast profits generated fuelled the expansion of the internal armed conflict between the government, guerrilla movements and paramilitary groups and have driven corruption in the police, the judiciary and politics. Despite the 2016 peace settlement, the nexus of drug money, internal conflict and corruption continues.

Many rural farmers in Colombia depend on coca for their economic survival. The UNODC estimates that 106,900 Colombian families are currently involved in the coca industry, with an average annual income per person

www.swansea.ac.uk/media/Drugs-and-Development-The-Great Disconnect.pdf


Sustainable development and equitable regulation

A guerrilla commando of the Revolutionary Armed Forces of Colombia (FARC) deep inside coca-growing territory. La Hacienda, Colombia, 2002.

PHOTO: Carlos Villalon, villalonsantamaria.com

for growing coca leaf and processing it into 'pasta base' of just $960 — less than a third of the minimum wage. The criminalisation of coca production has been used to justify systematic and sustained violence against rural farmers, further marginalising a population already exposed to extreme poverty and social exclusion.

For many years, both US and Colombian governments have deployed five strategies in their efforts to eradicate drug trafficking: extradition, substitution, aerial fumigation, militarisation and eradication. These have had little impact on total coca cultivation, but serious impacts on human health, indigenous cultures and the environment. Aerial crop spraying with glyphosate in Colombia was suspended in 2015 after WHO declared


glyphosate was probably carcinogenic, but the Government announced an intention to restart the programme following the election of Ivan Duque as President in 2018.  

Counter-drug policies aimed at eradicating coca production have transformed Colombia’s internal armed conflict. Since the 1990s, US funding for anti-drug operations has become increasingly militarised and largely indistinguishable from counterinsurgency. Under the US-backed Plan Colombia — a foreign aid package intended to return stability and security to Colombia and eradicate drug trafficking — violence increased and there were widespread human rights violations. Colombia’s armed conflict and related human rights abuses had, by 2019, displaced over 7.5 million people.

In 2016, the Colombian government and the FARC guerrillas signed a peace deal which was designed to end the armed conflict. The National Integrated Program for the Substitution of Illicit Crops (PNIS) was established which pledges to be a ‘Solution to the Illicit Drugs Problem’ and to eliminate the illegal cultivation of coca, cannabis, and opium poppy. Colombia’s coca crop substitution programme, which aims to help farmers voluntarily eradicate their coca crops in exchange for subsidies and government support for switching to legal crops, is an unsatisfactory response to the illegal cocaine trade.

In marginal, peripheral drug producing regions of Colombia, many people who enter into substitution programmes are being threatened or murdered by the cartels. In 2018, homicides in PNIS municipalities increased by 38% with respect to 2017 and the murder of social leaders increased by 165%.

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38 The National Integrated Program for the Substitution of Illicit Crops (Programa Nacional Integral de Sustitución de Cultivos Ilícitos — PNIS), is a crucial part of point four on the peace agreement, which pledges to be a ‘Solution to the Illicit Drugs Problem’ and to eliminate the illegal cultivation of coca, cannabis, and opium poppy.
Rethinking alternative development: an alternative to illegal coca and the war on drugs

The concept of ‘alternative development’ has often dominated international debate on responses to illegal drug crop production. It was initially envisaged as a tool for substituting drug crops with other cash crops to reduce drug supply. It seeks to recognise that illegal drug crop cultivation is often a vital lifeline for many communities by providing an alternative source of income while furthering goals of combating illegal crop cultivation.

Alternative development interventions have tended to be implemented by drug control agencies and security forces guided by eradication targets, with little concern for the actual development needs of impacted communities. They often lack the long-term investment needed to be effective, adopt top down approaches that fail to involve the impacted communities in their design and implementation, and fail to address wider structural inequalities. Like more overtly enforcement-led control efforts, even the most successful localised interventions do not change the fundamental supply and demand dynamics of the global market. While demand remains, the profit opportunity remains also. Localised supply reduction ‘success’ merely displaces production or transit routes — and their accompanying costs and challenges — to other regions. This is the so-called ‘balloon-effect’, so clearly witnessed with Andean coca production, where sequential falls in production in one region were compensated by increases elsewhere. Millions of hectares of coca leaf eradication has had no medium- to long-term impacts on total cocaine production, which has been more than able to meet rising global demand. The resulting cycles of eradication and bringing new areas of land under cultivation have further magnified the environmental damage from aerial spraying and deforestation in some of the world’s most diverse ecosystems.\(^\text{40}\)

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In some of these cases, legacies of inadequate recovery from conflict combined with market liberalisation, few mainstream employment opportunities, low levels of remuneration, weak opportunities for social mobility, and opaque governance—all making the estimated $322 billion per annum international drug trade a rational if not perfect livelihood alternative. AD [alternative development] programs have rarely taken these factors into account, failing to offer opportunities that represent viable and scalable alternatives to people who make survival decisions in difficult circumstances.\textsuperscript{41}

However, the alternative development paradigm cannot be disregarded in its entirety. It does at least represent an acknowledgment of the failings of traditional eradication and interdiction efforts, and, as the Transnational

Institute has noted, represents ‘efforts to find a more humane balance between drug control obligations, supply reduction policy objectives, and the protection of the rights of people dependent on illegal cultivation for basic subsistence.’\textsuperscript{42} At their best, alternative development programmes have attempted to tackle structural factors driving communities to cultivate illegal crops and helped them transition into the legal economy. Some local successes have been achieved, even if there is little impact on wider supply controls.\textsuperscript{43} The more effective alternative development projects have employed long-term, carefully sequenced and adequately financed multi-agency support and avoided criminalising small-scale actors. Rather than demanding the immediate eradication of drug crops as a precondition of participation, they have sought to involve impacted communities in the design of programmes.

The debate around alternative development has evolved to incorporate more sophisticated ideas such as ‘alternative livelihoods’, ‘rural development in a drugs environment,’ or ‘sustainable alternative livelihoods development’. But this welcome new thinking has rarely flowed into practice on the ground. The Transnational Institute has noted that ‘the dominance of repressive realities on the ground and the lack of commitment to alternative development by donors have turned alternative development largely into a “virtual reality”, keeping the myth alive that a humane approach to illegal cultivation exists in practice.’\textsuperscript{44} The alternative development debate has also historically failed to acknowledge drug prohibition as one of the key structural drivers of regional underdevelopment, let alone explore options for regulation as a way forward.

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Regulation promises to deliver the contraction of illegal drug production over time that alternative development, eradication and interdiction have so conspicuously failed to achieve. For example, the emerging legal cannabis markets in the United States are already likely to be affecting the scale of Mexico’s criminal market production. But as this transition continues, the low-level actors in drug crop production will need to establish alternative livelihoods or make the transition to producing drug crops for the nascent legal economy.

In either scenario, the lessons learnt from decades of alternative development: what has worked and what has not, can offer useful guidance. While it is not realistic to propose that all currently illegal coca production can transition into an alternative legal model, the real possibility exists for at least some growers to achieve this. The example of Bolivia’s legal coca market reforms are instructive (see below), as is Turkey’s experience with opium production.

Realism is needed here, however. This will not be an easy process, as it involves some of the poorest, most socially and geographically marginalised populations in the world. The dynamics of any transition will need to be shaped by local conditions and the specific needs of communities in highly differentiated social, cultural, political and economic environments. It will also not be appropriate or possible for all market actors — and will therefore need to be integrated with wider development policies that include those for whom such a transition is not practical.

Furthermore, the transition will unfold over an extended period, and will likely involve a small number of countries at first with more joining over

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time. Even if legally regulated domestic coca-based product markets are established in the short- to medium-term — as in Bolivia — the much larger potential export market for coca and cocaine products will emerge on a longer-term and intrinsically unpredictable time scale; debate on the practicalities of legally regulated cocaine is, after all, only just beginning.  

**CASE STUDY**

**Bolivia**

The use of coca, whether chewed or in tea, is deeply culturally embedded in Bolivia with a history dating back thousands of years. Small-scale subsistence farmers in the Yungas and Chapare regions, supported by a strong indigenous cultural identity and peasant labour unions, grow coca for traditional domestic use, as well as coca diverted into the illegal cocaine market. During the US-financed drug enforcement crackdowns pursued from the mid 1980s to mid 2000s, this coca production was broadly targeted with forced eradication. The coca unions — led by the former Bolivian President Evo Morales — organised national resistance and protests frequently leading to repression, violence and human rights abuses committed by security forces against farmers.  

Ill-considered alternative development efforts were implemented in parallel, with an estimated $300 million being spent between 1982 and 2008 by the United States Agency for International Development (USAID) and a five-year $21 million Agroyungas crop substitution programme of the UN Fund for Drug Abuse Control (UNFDAC) in the late 1980s. Despite some positive infrastructure spending, these efforts largely failed to respond to

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47 See for example the work of México Unido Contra la Delincuencia (MUCD): www.mucd.org.mx


concerns or meet the needs of traditional coca farmers, failing to work with the unions and having coca eradication as a precondition of participation. They only served to displace coca production within Bolivia, or to Colombia or Peru, and fostered discontent between farming communities.

The failures and disruption of these policies was a key platform for former cocalero leader Evo Morales’ rise to the presidency in 2006, at which point Bolivia’s coca policy shifted dramatically. US influence effectively ceased: funding largely ended by 2008, the DEA was expelled in 2009, and USAID in 2013. The Morales administration implemented an Integral Development Plan with Coca, organised under the following guiding principles:

- Human rights are respected
- Coca eradication is no longer a prerequisite for development assistance
- Investment is made first in public works and social services and then in economic/agricultural development under the assumption that if growers have sufficient income, it will be easier for them to reduce their dependence on coca
- Development initiatives are designed to meet unique regional needs, incorporating local knowledge, gender issues, and generational differences
- Institutional, regional, and municipal economic development is promoted
- Coordination with representative local organisations is deemed essential
- Environmental sustainability is encouraged, through initiatives such as increasing organic coca and coffee production, forest species diversification, and reforestation

The new Community Coca Control policy allowed farmers in Chapare and Yungas to register for entitlement of a 1,600-square metre plot of coca destined for legal local coca markets, with internal informal controls exercised through unions. In 2009, the participatory Community Control Support Program (PACS) was established headed by coca growers themselves and supported by $13 million in funding over five years from the European Union — who, unlike the US agencies, have broadly supported the reforms. A series of complementary policies have further supported the community coca control approach, including decriminalisation of traditional coca use with regards to Bolivia’s international treaty obligations; new data systems for registering farmers and traders and monitoring legal and illegal coca production; and attempts to expand the domestic market for coca products such as tea and flower.

Reducing diversion of coca to the illegal cocaine market has remained an important element of the policy (under the ‘Coca Si, Cocaina No.’ slogan), albeit secondary to local development and human rights priorities. In the Bolivian context it has been largely effective, with illegal coca production falling, and 88% of eradicated coca being removed through cooperative reduction with growers.51 The ‘balloon effect’ has inevitably been witnessed, however. Displacement has continued internally with deforestation, coca growing in national parks, and environmental pollution from cocaine processing, albeit at a lower level. Production has also increased in Peru and Colombia.

The new policy has not been without problems — and continues to evolve. Tensions between farmers and the state decreased after implementations, with violence dropping dramatically. Despite the challenges in evaluation, there have been overall positive social and economic impacts for local Chapare and Yungas communities, although benefits have been perceived by many as unevenly distributed, and political tensions between different regions and collectives, and between traditional and newly approved coca farmers have been ongoing.

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Roxana Argandoña, coca grower

‘My name is Roxana Argandoña. I come from the province of Chapare located in the tropics of Bolivia. My family isn’t wealthy and I never completed school because my family couldn’t afford it. For decades my family has made its living from growing coca leaf, it has always played a central role in our day to day lives.

‘Our fight for the coca leaf isn’t new, it dates back many, many years. Previous governments have condemned coca and said it had no place in Bolivia, however on an ancestral level, the coca leaf is and always has been an important part of our culture.

‘Different governments have had different attitudes to the coca leaf during my lifetime. There have been several military efforts to enforce a complete ban on coca production, eradicating by force. Each time it’s happened it’s led to deadly, violent confrontations. I witnessed them first as a young woman and later on as a mother. Extreme violence, murder, the imprisonment of so many young men from our community, and the abuse of women. This was our day to day reality. Without coca, we had no means of subsistence. We were forced to react, to fight back.

‘We spent more time in roadblocks and in marches than at home, yet no one listened. The military would fire gas and bullets at us. Lots of people

52 See: Anyone’s Child. Roxana’s Story. anyoneschild.org/roxana/
died. Life in the Chapare was horrible! We couldn’t even sleep at ease. The military would come into our homes at any time of night, and day. We were constantly being sprayed with gas. We had gas for breakfast, lunch, and dinner. I would never want to relive that or have my children or grandchildren witness what we suffered.

‘Thankfully, we stopped witnessing these atrocities since 2005 when Evo Morales came to power and changed things. We are now allowed to grow a small plot of coca leaf per family. We can finally live and sleep in peace. We can walk around freely and grow coca leaf and hold meetings without fear of violence or repercussion.

‘Banks are now for the first time offering loans with low interest to farmers and producers like me. This has enabled us and many families to have money to build our own houses, and get a car. In the past, women from my village would go to the city to give birth. Three of my children were born in Cochabamba because hospitals in the tropics were ill-equipped. I was scared of delivering my babies there. One of my sons died here because of the lack of medical aid. He was stillborn. After that, I didn’t want to deliver my children here. However, now that the municipality has experienced a lot of growth, more hospitals are being built and the conditions are improving.

‘My youngest was born in Villa Tunari. Education has improved tremendously as well. Before we didn’t have proper schools. The roofs in the classrooms were made out of mud or straws. Now we have schools. In the past, younger people from the Chapare suffered discrimination, especially at universities. Society didn’t want or expect our children to go to university, but we are seeing changes now. Now both men and women are aware of their rights. Our children are attending university and receiving degrees. Producing coca leaf doesn’t lead to violence or instability or to any of the horrors that I’ve observed in my life. It’s government bans and the military approaches used to fight us that has caused me the greatest horror.’
In a legally regulated production regime, coca and other drug crops will become a more conventional commodity market within the wider sustainable development discourse. Even if freed from the negative consequences of prohibition (the parallel threats from both organised crime groups and drug law enforcers), making the transition to legal production could still thrust ill-prepared economic actors into an unforgiving global capitalist economy. Small-scale farmers will not realistically be able to compete with large-scale corporate agri-businesses. Some forms of protectionism may be needed to guarantee livelihoods, but this is also a natural opportunity
for well-established fair trade principles and structures to be applied.\textsuperscript{53} A broader understanding of ‘fair trade’ involves guaranteed minimum prices for producers to provide economic sustainability, and a premium paid by the consumer that is then invested in community development projects, education, and training. This is alongside a goal of ensuring wider realisation of development goals including: the protection of workers rights; empowerment of women; protection of children; and responsible environmental stewardship.

A new sustainable development-focused policy approach could pragmatically target key vulnerable communities and regions, whether traditional indigenous coca growers, or more recent economically marginalised market entrants, to encourage a transition as the legal market for coca-based products expands. In many cases, there will be a need for additional resources and technical assistance to ensure stability of livelihoods, and to cushion and support any transition process.

Certain drug crops, including coca leaf, could be subject to protection along the lines of the Geographical Indications of the World Intellectual Property Organization (WIPO) or the European Union’s Protected Designation of Origin (PDO).\textsuperscript{54} While such protection could benefit the kind of locally produced coca-based products explored elsewhere in this book, it would be meaningless for pharmaceutical powder cocaine — which is stripped of any regional distinction. Legal powder cocaine derived from Andean coca would be no different from legal cocaine produced anywhere else.

It is also the case that other countries or regions opting to legalise and regulate coca-based products, potentially including cocaine, could grow coca and produce their own cocaine as they wished. Indeed new


countries could enter the coca production market to service global demand, and compete with any regulated Andean supply. It is a common misunderstanding that coca can only be grown in high altitude Andean locations. In reality, developments in agricultural technology mean it could relatively easily be grown near key consumption hubs in, for example, North America or Europe. Protecting the livelihoods of traditional coca

Key elements of legal coca production that support sustainable development goals

- Key responsibility for drugs and development issues — including those relating to regulation — moving from enforcement agencies to local, regional, and international development agencies; government; and local communities. At the UN, for example, this would involve lead responsibility moving from UNODC to UNDP (United Nations Development Programme)

- Ending ‘drug free’ and eradication targets and establishing development-centered metrics for evaluating drug policy outcomes

- The meaningful participation of impacted communities in all policy development, implementation and evaluation

- Ensuring that design of new legal market models prioritises the interests of small-scale economically vulnerable farmers and market actors, and communities most negatively impacted by the war on drugs

- Exploring the options for transitioning illegal market participants into legal production — learning from, and building on experiences in Bolivia — through licensed growers, farmers unions and co-operatives

- Developing international markets for coca products (beginning with lower potency plant-based products) based on fairer trade and social justice principles that ensure the achievement of inclusive economic growth; protection of workers’ rights and sustainable incomes; empowerment of women; protection of children; and responsible environmental stewardship

- Supporting alternative sustainable livelihoods for those currently engaged in the illegal coca production unable to transition into the new legal market, and integrating coca-related development programmes within wider development

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growers in this context will require more substantive agreements between Andean producer countries and their key markets in the Global North. It is here that — just as the alternative development paradigm can be adapted to thinking about future legal regulation — so the ‘shared responsibility’ narrative, pervasive in high level and UN drug policy forums for some decades, should also be rethought for a post-prohibition world.

### Moving from ‘shared responsibility’ for eradication to ‘shared responsibility’ for equitable regulation

The principle of ‘shared responsibility’ has had a historically high profile in international drug policy. It seeks to balance supply reduction in primary producer regions with demand reduction in primary consumer regions in developed economies. Nonetheless, it has never been able to realise even its more reasonable ambitions in the context of a fundamentally iniquitous drug war. Moving towards regulation of plant-based drugs on a global scale, or at least based on bilateral or interregional trading agreements, offers a more realistic prospect for addressing the challenges faced by producer, transit and consumer regions — even while acknowledging these distinctions are becoming increasingly blurred.

In *After the War on Drugs: Blueprint for Regulation*, we argued that affected communities could be supported through a post-drug war ‘Marshall Plan’. The equity provisions being developed in some US states that have recently legalised cannabis are a provisional example of such thinking becoming a reality, though many are still in their infancy and there are large hurdles to overcome (see below). Such an approach could also be more broadly applied in global drugs and development discourse. A substantial amount

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How to regulate stimulants

of development aid is currently conditional on counterproductive, repressive drug control objectives, such as Plan Colombia. This is a situation that urgently needs to evolve as we shift away from prohibition.

As part of this realignment of resources, support could instead be directed to formerly illegal drug-producing and transit economies. This would help support alternative livelihoods, and foster good governance and institution building. Funding could come from the ‘peace dividend’ that would arrive with the end of the war on drugs — redirecting domestic enforcement spending, and enforcement-conditional aid — and could be further supported by new tax income from legal markets.

There is a shared responsibility for all to ensure that these emerging markets function in an equitable fashion that supports sustainable development for all, and undertakes a responsibility to support those who have been most harmed by the failure of the war on drugs. Civil society organisations, governments and intergovernmental agencies already working in alternative development, as well as the wider development field whose work is inevitably engaged by drug issues, need to begin discussing and planning how their expertise can be more widely used in such contexts.

The wider context of social justice

Beyond growers of drug crops, a much broader and more diverse group of low-level actors work in the production, transit and retail-selling sectors of the illegal drug economy. As with growers, it is vital that no affected individuals or communities are forgotten in the transition to legal regulation. For low-level dealers or drug couriers of pharmaceutical stimulants there are relatively fewer of the same clear pathways into a post-prohibition market that exist for coca growers, as well as fewer obviously transferable skills. This, however, does not mean that there are no opportunities for social equity programmes. Rather, this dictates that policies should seek to focus resources (including financial resources obtained from tax revenue,
and from money saved in lieu of enforcement spending) on investing in social capital for impacted individuals and communities, as opposed to simply creating opportunities for specific transitioning into newly regulated markets.

Some of the more forward-thinking US cannabis reforms point towards possibilities in this area. Many US states, for example, allow for the expungement of convictions (or sealing of records) for drug offences that, post-reform, would no longer be crimes. In California and Illinois, this process is automatic, while in other states there is some requirement for the individual to petition the relevant Court for their criminal records to be sealed, or expunged. A similar expungement programme for stimulant drug offences will be a vital part of reducing the lifelong stigma and disadvantage that criminal convictions can burden already vulnerable individuals with, as well as their families, dependents and communities. This will need to go beyond mere possession offences to include a range of low-level production, transit and supply offences.

Cannabis regulation in the US has also featured varying efforts to redirect benefits from new legal markets towards those disproportionately impacted by law enforcement under prohibition. In the states where cannabis is legal, it is retailed under a commercial model; social equity programmes have therefore focused on facilitating market access for qualifying equity applicants, primarily through the running of cannabis retail stores. While such schemes are not directly transferable to stimulant markets, the central thinking behind them — ensuring that the benefits of emerging legal markets are proactively directed towards those most negatively impacted by prohibition — is certainly transferable. The equity

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transformdrugs.org/product/altered-states-cannabis-regulation-in-the-us/
programmes used in some US states also demonstrate that the concept of building a social justice agenda into legislation guiding emerging legal markets is a politically practical proposition – at least at the local scale. Early experiences emphasise the importance of building in this agenda from the outset, before market dynamics are established and entrenched.

For a range of cultural and political reasons, winning support for stimulant regulation is going to be more challenging than for cannabis, and the same issues will apply to any attendant social equity programmes. There is the additional challenge that schemes which may be able to command popular political support at the local level may struggle to muster the same support when transposed into the international trade and development arena, given the modest public appetite for international development spending more generally. It may be the case that this is something that has to be supported at a government and institutional level – making leadership from UN development, health and human rights agencies all the more critical at this point.
Stimulant harm reduction
There is an urgent need for a substantially increased focus on harm reduction research and resources on issues related to stimulants.
THERE IS NO UNIVERSALLY ACCEPTED DEFINITION OF ‘HARM REDUCTION’, ALTHOUGH the key principle is the reduction of harms associated with drug use. Harm Reduction International (HRI) define the term as follows:

Harm reduction refers to policies, programmes and practices that aim to minimise negative health, social and legal impacts associated with drug use, drug policies and drug laws. Harm reduction is grounded in justice and human rights — it focuses on positive change and on working with people without judgement, coercion, discrimination, or requiring that they stop using drugs as a precondition of support.¹

Since its emergence in the 1980s, the concept has been widely incorporated into drug policies around the world, with harm reduction now advocated as best practice by the UN. In 2018, HRI reported that 85 countries include explicit supportive reference to harm reduction in national policy documents.²

As alluded to in this definition, the concept of harm reduction often usefully includes consideration of the structural drivers of harm. This includes economic and social factors, but significantly may also include harms experienced through policy and law, such as the impacts of criminalisation of drug use and corresponding law enforcement. ‘Harms’ can also go beyond health harms experienced through drug use to include ‘social or economic

harm such as acquisitive crime, corruption, over-incarceration, violence, stigmatisation, marginalisation or harassment’. UN policy documents also highlight this wider context, more recently referring to ‘supportive laws and policies’ as one of the ‘critical enablers’ of an effective harm reduction policy response. Notably, the 2019 UN Common Position on Drugs strongly advocates for the decriminalisation of people who use drugs. UN positions, however, whilst acknowledging the harms of prohibition, do not yet support legally regulated drug availability beyond medical prescribing in a treatment context.

Stimulant harm reduction includes interventions aimed at lower risk use in social settings (see for example, Chapter 3 on MDMA), as well as distinct interventions targeting higher-risk use, specifically including smoking and injecting – which are the focus of this chapter. As discussed in earlier chapters, this book does not propose a retail model for stimulants classed as risk tier 3, including: smokable or injected amphetamine; injected cocaine or smoked crack cocaine/pasta base/basuco; and other high-risk smoked or injected stimulants. Instead, we propose a non-retail harm reduction model, which would be rooted in the principles and examples outlined in this chapter. This reflects the reality that, even with efforts to encourage lower risk patterns of stimulant use (including by making lower-risk products available through a strictly regulated market), many people will still choose to smoke or inject stimulant drugs. As discussed in the section on crack cocaine, these people should not be criminalised. Instead there should be a concerted public health-led response, combined with appropriate social support. Addressing the social conditions that underlie most problematic stimulant use is key to reducing high-risk behaviours in the longer term, but the immediate response must be one rooted in harm reduction, to best protect the right to health of people who use stimulants.

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Within the wider harm reduction field, stimulants have generally been an under-explored and underserved issue. The historic focus of harm reduction efforts has been on opioid injecting, particularly in the context of the HIV response. This focus on people who inject drugs has tended to marginalise issues concerning smoking and snorting of drugs more commonly associated with stimulants. Given the sharply rising levels of high-risk stimulant use and associated harms in recent years this is an untenable situation. There is an urgent need for a substantially increased focus on harm reduction research and resources on issues related to stimulants. This call notably comes at a moment when harm reduction funding more generally is moving in the wrong direction, under threat from a combination of factors including austerity, donor retreat, and shifting political priorities.  

Harm reduction responses for opioids (and other depressants) and stimulants are, of course, not independent. They overlap, both in conceptual and practical terms, and significantly because many people who use drugs, consume both. Higher-risk polydrug use has become increasingly common, meaning new approaches to stimulant harm reduction will require new approaches to opioid harm reduction as well.

There are structural challenges undermining development of stimulant harm reduction. Innovation has historically been driven by smaller-scale localised crisis responses, rather than top down leadership from governments, in the first instance. For stimulants in particular, progress may therefore be held back by developments being small-scale, standalone,


taking place in often hostile political environments, lacking sustainable funding and being inadequately evaluated. Nonetheless, there are positive signs that the issue is being taken more seriously, albeit belatedly, by governments and international agencies. International research bodies and non-governmental organisations have also contributed to a growing body of work, demonstrating leadership and accelerating understanding and knowledge on efficacy and best practice around the world.\(^7\)

In 2018, the Netherlands based organisation Mainline published ‘Speed limits: Harm reduction for people who use stimulants’, authored by Rafaela Rigoni, Joost Breeksema and Sara Woods. The report is a groundbreaking global literature review of harm reduction activities for people who use stimulants, documenting and analysing examples of good practice in stimulant harm reduction from around the world. We are grateful to Mainline for allowing us to reproduce an edited summary of these key harm reduction interventions outlined in the report below.

### Good practice examples

Adapted text from the Mainline report, ‘Speed limits: Harm reduction for people who use stimulants’.\(^8\)

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\(^8\) The text used below is an edited and adapted version of text from the executive summary of ‘Speed limits: Harm reduction for people who use stimulants’, incorporating some additional text from the main report, and some new, additional references. Please reference, quote or credit the original report (cited as follows) rather than the adapted text used here: Rigoni, R., Breeksema, J. and Woods, S. (2019). Speed Limits: Harm Reduction for People Who Use Stimulants. Mainline. mainline-eng.blogbird.nl/uploads/mainline-eng/2018_Mainline_%E2%80%93_Harm_Reduction_for_People_Who_Use_Stimulants_%E2%80%93_Full_Report.pdf
Safer smoking kits

For people who smoke stimulant drugs, safer smoking kits have been found to prevent injuries to the mouth and lungs caused by the use of self-made pipes. While most evidence refers to safer smoking kits for crack, some studies also evaluate kits for methamphetamine. In the kits, filters help reduce damage to the throat and lungs, while pipes and (rubber) mouthpieces may reduce cuts and burns to the lips, as well as reduce damage to the lungs and toxicity. By reducing mouth injuries and sharing of pipes, safer smoking kits can also reduce the risk of transmission for diseases including HIV, Hep C, and Covid 19.9

The content of safer smoking kits for crack varies in the different countries where they are distributed, but a complete kit typically contains: a pipe (usually a heat-resistant glass stem or, alternatively, a wooden pipe); a rubber or silicone mouthpiece; screens/gauzes (made of steel or brass); substances used to protect the lips (lip balm or petroleum jelly); information about safer drug use (including prevention of sharing equipment and safe disposal); and safer sex information and materials (condoms and lubricant).

A number of studies found that the distribution of safer smoking kits increases safer smoking techniques and practices, and significantly decreases injection practices.10 One important factor to assure the effectiveness of the intervention is that kits must be adapted to people’s preferences and needs, as this increases the acceptance of safer smoking equipment and prevents people who use stimulants from continuing to use self-made pipes. In some cases, when communities of people who use

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stimulants resist switching to more sterile instruments, an alternative may be teaching methods that can reduce the harm of using self-made pipes. Kits distributed in health settings can be an opportunity to give advice on safer use and direct people to other services. Kit distribution may also be a useful way of engaging some hard-to-reach populations who are not already in contact with service providers.

One of the countries where the distribution of safer smoking kits has been widely implemented and studied is Canada. Canadian best practice guidelines encourage needle and syringe programmes (NSPs) and other harm reduction programmes to distribute safer smoking equipment, educate clients on safer smoking practices, and to provide options for safe disposal of used equipment.\(^\text{11}\) Many needle and syringe programmes in Canada also offer safer crack smoking kits and education.\(^\text{12}\)

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Chemsex

The term chemsex is generally used to define the intentional combination of sex with the use of certain psychoactive drugs, among men who have sex with men (MSM). Chemsex usually occurs in private settings, such as someone’s home, or during multiple-day sex parties (Pakianathan et al. 2016). In the USA and Australia, chemsex is better known as party and play.

In these settings, the drugs, or chems — as they are sometimes called in this scene — frequently include the stimulants methamphetamine and mephedrone (4-MMC), as well as GHB/GBL and a variety of other substances. These are often used in combination, to facilitate, enhance and prolong sexual sessions lasting several hours, or sometimes even days, with multiple sexual partners.

Drug use leads to lower use of condoms, and increased numbers of sexual partners. Many authors identify the need to reduce both drugs use and sexual risk behaviours in these environments.

New approaches include provision of chemsex services within MSM-friendly sexual health clinics or services, instead of referring men to existing drug services, targeting of dedicated harm reduction information, safer sex and safer drug use packs.

Prevention of sexual risks

Sexual health risks and stimulant use are strongly connected. Examples of this include:

- Being under the influence of a drug can lead to disinhibition and consequently to unintended sexual activities that may have negative consequences (e.g. mental distress, sexually transmitted diseases [STDs], pregnancy)

- Engaging in sex work to fund drug use

- Using substances to enhance sexual performance and pleasure (chemsex)

- Using substances as a coping strategy for dealing with the emotional distress arising from a sexual health problem, such as an HIV diagnosis
Sexual health and drugs services are rarely co-located making it harder to address both issues at the same time. Because of the strong interrelation, the EMCDDA states that integration of services for drug use and sexual health is needed. In any case, expertise should be shared, and services encouraged to work together more closely. Also, a better understanding of risk behaviours and treatment needs is necessary.\textsuperscript{13}

To a certain extent, prevention of sexual risks is no different for people who use stimulants than for other drug using populations. Prevention of sexual risks should include free access to condoms and lubricant, information about sexually transmitted infections (STI) and HIV, low-threshold access to HIV and STI testing and treatment, contraception and pregnancy testing and counselling, talking about sexual risks, and developing plans to improve self-control over risky behaviours.

Some sexual risks, as well as the responding harm reduction and prevention measures, apply more specifically to people who use stimulants. Stimulants tend to dry mucous membranes and decrease sensitivity, increasing the chances of longer and more intense sex. Therefore, individuals should use plenty of lubricant. This is especially true for people who make use of stimulants to facilitate and improve sexual activity, such as males who use stimulants as part of the chemsex scene.

Addressing sexual and physical violence, transactional and commercial sex, and abusive relationships are also important.

**Female-focused interventions**

Compared to men, women face different risks and contexts of drug use. Women experience more stigma, are at a greater risk of exposure to violence, are more under the influence of their partners in their drug use.

patterns and sexual behaviours, are more defined by their parental role, and are more likely to engage in sex work, thus increasing the risk of exposure to blood-borne infections.\textsuperscript{14}

Despite these gender differences, studies and strategies specifically aimed at women who use drugs are still underdeveloped, even more so where stimulant use is concerned.

Specific strategies for females fall in three categories: access to care, pregnancy and parenting, and sexual and reproductive health and rights. The EMCDDA best practice portal provides guiding principles on how to respond to these needs, irrespective of the drug of choice.\textsuperscript{15}

Providing specific services for all women who use drugs is recommended. Guiding principles include having specific services for women which are non-judgmental, supportive, physically and emotionally safe, and promote healthy connections to family members and significant others. For pregnant and parenting women these should include obstetric, gynaecological and STI care, mental health, personal welfare, and childcare and family support.

For those engaged in sex work, evening opening hours and mobile outreach help increase access to services. Other recommendations include removing legislation that makes drug use alone the rationale for extracting children from their parents’ custody or that seeks to punish women for using drugs during pregnancy.\textsuperscript{16}

\begin{itemize}
\item \textsuperscript{15} EMCDDA (2018). Best Practice Portal. www.emcdda.europa.eu/best-practice_en
\end{itemize}
Interventions also need to include partners of female users. For pregnant women who use stimulants, some guidelines mention improving nutrition, decreasing tobacco smoking, decreasing alcohol and other drug use, promoting dental health and encouraging physical activity, encouraging early and continuing prenatal care, and reducing any enforced actions in services, such as requiring abstinence to receive care.

**Drug consumption rooms**

Drug consumption rooms (DCRs, also variously known as overdose prevention sites/centers and supervised injection/drug consumption facilities) are professionally supervised healthcare facilities where individuals can use drugs in safer and more hygienic conditions. The three primary goals of DCRs are to reduce morbidity and mortality by providing a safe environment.

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17 Transform Drug Policy Foundation (2020). Safer Drug Consumption Rooms or Overdose Prevention Centres (OPCs). transformdrugs.org/overdose-prevention-centres/
and training people who use drugs in safer use, to reduce public drug use and improve public amenity in open drug scene areas, and to promote access to social, health and drug treatment facilities.  

Although DCRs have mostly targeted people who inject drugs, they increasingly also focus on people who smoke or snort their drugs. In a 2017 inventory among 43 DCRs, 41 facilities offered spaces for safe injection, 31 also offered spaces for smoking, with 22 DCRs also facilitating spaces for sniffing. 34 of these DCRs allowed for at least two different means of drug administration (inject, snort or smoke), either in separate spaces or in the same room. In this same inventory, stimulants — including amphetamines, crack cocaine, cocaine, and cathinones — seemed to be the substances most commonly used, irrespective of route of administration. Almost just as common is the use of heroin, followed by a combination of opiates and stimulants (speedballing). DCRs that provide spaces for both injection and inhalation, are likely to facilitate a transition from injection to less risky forms such as smoking.

Many of the benefits of supervised injection facilities also apply to facilities for smokers: they provide a safe, non-rushed environment; users have

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19 See footnote 18.

access to sterile equipment; ideally have access to other health and social services (including psychosocial support, medical services, addiction treatment, etc.). DCRs have strong potential to reach hard-to-reach people who use drugs. The DCR can connect them to health and social services, such as healthcare, drug treatment, referrals to legal services, housing programmes, helping address the harms associated with the broader risk environment.

Self-regulation

Self-regulation approaches focus on empowering people who use drugs in developing skills and competencies to gain more control over their drug use. Self-regulation can be trained, and a high degree of self-regulation is associated with reduced levels of use and related problems.

Some of the methods that people who use drugs can apply to help control their use include: setting rules for their use (e.g. amount or frequency of use); the set (or mindset, e.g. only using when feeling well); the setting (e.g. using only with friends, not when at work).

Various strategies are being employed by people who use drugs themselves, even if they are not necessarily convinced of the risks, such as: always carrying their own drug use paraphernalia; refusing to share; assessing risks visually (e.g. does someone have visible wounds); or asking people if

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they have HIV or HCV. Dissemination of these basic self-regulation mechanisms is ideally done with the close involvement of peers.

Several studies indicate that mindfulness-based interventions can enhance self-regulation and reduce cocaine and methamphetamine use. These interventions are characterised by systematically paying attention to the present moment with a non-judgmental and accepting attitude. This can help people who use stimulants to cope with distressing events or emotions by changing unhelpful thought patterns, reducing the use of stimulants as a means of escaping from unwanted emotions, and more generally increasing self-control.

Mindfulness based interventions are also effective in treating stress, anxiety, and depression — all aspects of mental health that are associated with problematic (stimulant) drug use and relapse.

**Housing first**

The problematic use of stimulants has been associated with poverty, unemployment, incarceration, homelessness and unstable housing. Strategies and interventions that help with these issues therefore have the capacity to address several of the harms of problematic stimulant use. Homelessness specifically can be addressed through Housing First interventions.


Housing First seeks to move people into permanent housing as quickly as possible. Permanent and stable housing is emphasised as a primary strategy for the care of homeless people, people with mental health problems, and people who use drugs. This is in contrast to treatment first, which demands people go through a series of stages, such as becoming abstinent, before they are ready for housing.

The eight principles of housing first are:

- Housing as a basic human right
- Respect, warmth, and compassion for all clients
- A commitment to working with clients for as long as they need
- Scattered-site housing in independent apartments
- Separation of housing and services
- Consumer choice and self-determination
- A recovery orientation
- Harm reduction

An adequate supply of stable housing can be considered a harm reduction intervention in itself. Additionally, housing first interventions are related to decreases in drug use, higher quality of life, higher levels of autonomy, reduced stress and an increase in personal safety. For people who use stimulants, a stable housing situation provides the basis for stability, daily routines, privacy, and less stigmatisation, and leads to healthier eating and sleeping habits.

A Canadian study found that 74% of the participants of housing first programmes said their drug use had decreased since they moved into housing; 33% had quit using drugs completely, and 41% had decreased

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their use. In Brazil, Braços Abertos, a programme offering housing to people who use drugs helped 65% of participants to decrease their crack consumption. In a housing first programme in Brazil, Atitude, 38% of participants said they quit crack use after participating in the programme. Finally, studies have shown that having a stable house can encourage people to choose less harmful routes of drug administration. In a study among young people injecting methamphetamine in Canada, housing was found to be an important factor in facilitating cessation of injection. Similarly, studies in the US and India found a stable housing situation to be associated with decreased drug injection.

Substitution

Substitution is defined as the conscious choice to replace use of one drug with another, based on ‘perceived safety, level of addiction potential, effectiveness in relieving symptoms, access and level of acceptance’. Substitution is replacing one’s stimulant of choice with a substance that has comparable effects, typically with a longer duration, milder and fewer side effects.

Over the years, researchers and people who use stimulants alike, have looked for substances that can support maintenance therapy, reduce stimulant use or reduce the adverse effects associated with its use, similar to the role of methadone and buprenorphine for people who use heroin. Much like substitution for opioids, the effective implementation of substitution programmes for stimulants may be challenged by diverse legal frameworks, which at times allow for the substituting of substances and at other times not.

Various plant-based substitutes have been tentatively explored, but results from a few small-scale trials remain inconclusive and further research is needed. There have been some experiments using coca as a milder alternative for people who use cocaine, or crack. This substitution practice has been documented in Peru, Bolivia, and Brazil, but still has inconclusive results.36

Some evidence exists for the use of cannabis in diminishing anxiety, aggression and paranoia in people who use freebase cocaine (crack or pasta base). Cannabis can also reduce craving (including when smoked with cocaine), stimulate appetite and promote sleep, and alleviate discomfort during withdrawal periods. A 2018 study in Brazil followed 62 people who use freebase cocaine over the course of four weeks, looking at the role of cannabis on craving for crack cocaine. The authors found

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that the use of cannabis was strongly correlated with decreases in anxiety and also found that greater use of cannabis was related to lower craving experiences.\(^{37}\) In 2017, a longitudinal survey was conducted among people who use drugs in Vancouver, Canada, demonstrating the effectiveness of intentional cannabis use in reducing the frequency of crack cocaine consumption.\(^ {38}\) Some studies have also demonstrated the effects of cannabis substitution for other stimulants. However, cannabis can have negative side effects for some users, and notably remains illegal for non-medical use and very restricted for medical use in most jurisdictions.

Evidence for the use of pharmaceutical substitutes is inconclusive. The idea behind (supervised) agonist therapy is to replace the illicit drug with a pharmacologically similar drug that has comparable effects but can be used more safely. Ideally, the agonist has a longer effect, less impairment/intoxication, and a lower addictive potential.\(^ {39}\) This approach can be applied both to treatment modalities aiming at complete abstinence, as well as for harm reduction purposes, allowing people who use stimulants to gain more control over their use, reducing use-related harms, and improving quality of life. This approach has proven effective for users of opioids and tobacco.\(^ {40}\)

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A 2016 Cochrane meta-review on the evidence of substitution treatment for cocaine dependence using other stimulant drugs (e.g. (lis) dexamphetamine, methylphenidate, modafinil, methamphetamine, and amphetamine) demonstrated very little impact on treatment retention when compared to placebo, and some evidence that people who use cocaine stayed abstinent longer when compared to placebo. Dexamphetamine was considered to be a potentially promising agonist for cocaine dependence treatment, especially for poly-users of heroin and cocaine.\(^{41}\)

No evidence was found for the clinical use of direct dopamine receptor agonists (DA-agonists) that don’t have any psychostimulant properties (such as amantadine, bromocriptine, L-dopa, and pramipexole) for people who use cocaine.\(^{42}\) Indirect dopamine- agonists that do have cocaine-like effects (e.g. bupropion, dexamphetamine), on the other hand, did seem to have some promise as a substitute substance for cocaine dependence.\(^{43}\)

Another meta-review looked at the available literature for both amphetamine and cocaine treatment, comparing dopamine releasers (DRAs, e.g. amphetamine, methamphetamine) with dopamine reuptake inhibitors (DRIs, e.g. methylphenidate and bupropion). The review showed that DRIs are more effective than DRAs in treating amphetamine use, whereas DRAs seem more effective in reducing use of cocaine. Specifically, methylphenidate significantly reduced amphetamine but not cocaine use, whereas (dex-) amphetamines did significantly reduce cocaine use. Interestingly, there was no evidence for the effectiveness of using dexamphetamine to reduce amphetamine use.\(^{44}\)

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43 See footnote 41.

Some evidence suggests that dexamphetamine may be effective for people who use (crack) cocaine, and that methylphenidate (Ritalin) and bupropion may work for people who use amphetamine.

Finally, there is some evidence from two recent trials that modafinil may be effective as a substitute for cocaine, although earlier trials sometimes failed to show positive impact. The same inconsistent results are reported from studies looking at the use of methylphenidate for cocaine use. It seems likely that the effectiveness of most agonist agents for the treatment of stimulant dependence seem to be dependent on the particular stimulant they intend to replace, as well as on dosing, and the specific subpopulation of people who use stimulants (whether they’re single or poly-drug users, for example).

Outreach and peer-based interventions

Outreach work helps to reach those people who use drugs who do not come to harm reduction services themselves. It is an entry point to services and into the community. This increases people’s access to care and can encourage bonding between people who use stimulants and other service providers.

Evidence shows that peer education — in a supportive non-stigmatising and non-incriminating environment — is the most effective way to share new knowledge and skills among people who use drugs. Peers are trusted more easily, because they share norms, experiences, language and background. This makes it easier to convey honest harm reduction education.

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Peer-based outreach projects stimulate social inclusion, encourage knowledge sharing among people who use stimulants, and strengthen prevention strategies. For example, they may increase the acceptance of projects such as safer crack-smoking kit distribution. Furthermore, peers are good at identifying new trends and responding to them quickly and effectively. Peer outreach work with people who use stimulants has been demonstrated to reduce the frequency of stimulant use and sexual risk behaviour, as well as risks of contracting an infectious disease such as HIV, HCV, and TB.

Outreach work can also support people who use stimulants to avoid starting injecting or encourage people who inject to transit to non-injection routes of administration. This can be done through informing people about the risks of injecting or about safer methods to use. In one study, people who injected methamphetamine frequently mentioned that having harm reduction information was helpful in moving away from injecting to smoking the drug. Peer outreach also increases acceptance of safer smoking kits distribution.


The World Health Organization advocates for providing culturally sensitive and clear messages to people who use stimulants when doing street-based work. These outreach messages should be both evidence-based and relevant for their context. Important and effective messages are: decrease quantity and frequency of stimulant use; drink water; improve diet; get adequate rest; employ strategies to help control drug intake; monitor one’s own behaviours; and do not use drugs alone. Other counselling messages include avoiding mixing stimulants with other legal or illegal drugs, avoiding injection, and using condoms.\textsuperscript{54}


Drop-in Centres

Drop-in centres (DICs) are an important low-threshold harm reduction service that is offered throughout the world. They function as places where people who use stimulants and other drugs can meet others, find a listening ear, access a range of information and, for some, attain a degree of distance from potentially problematic home or street environments.

In practice, this means that DICs offer an informal social setting, responding to some basic needs (e.g. food, shelter from the cold, shower and clean clothes) and offer some additional services. These services can be as basic as offering an opportunity for social contact in a safe environment, or offering (psychosocial) support to improve well-being or work on life changes. Drop-in centres can provide vulnerable people — be they people who use drugs, sex workers or homeless people — with a safe and supportive environment, while stimulating them to make use of wider community resources or make changes in their lives.\(^{55}\)

DICs should be located near the communities of people who use drugs and involve members of the community in running the programme, offering services, and decision-making processes relating to service provision. A 2015 review on the impact of drop-in centres found them to contribute to a general improvement of overall wellbeing and health as well as ‘a range of benefits including reduced drug use, and reduced exchange of sex for drugs, as well as improvements in social participation/engagement, mental health, days housed (although no improvements securing permanent housing were found) and access to sexual and reproductive health services’.\(^{56}\)

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Drugs safety testing

Drugs safety testing, or drug checking, is a harm reduction measure developed for people who use drugs in night-life and festival settings, but has subsequently been adopted in a wider variety of contexts.

Safety testing comprises a variety of technologies used to check and monitor dosage, contents, and presence of potentially hazardous adulterants in the samples provided by people who use drugs. This information can be used to issue tailored health warnings, and to address specific groups of users. Drug checking services can run up against legal obstacles, even if decriminalisation policies have been implemented, as possession can remain a sanctionable civil or administrative offence — impacting both the service users in possession of drugs, and the service providers handling the samples. This may require either informal tolerance policies operating at a local level or more formalised legal exemptions being implemented at national/government level.\(^\text{57}\)

Drug checking is a useful way to get in contact with and educate hard-to-reach young people who use drugs. Drug checking can also incentivise people to not consume a particular sample, e.g. if it is found to contain an unwanted substance or a harmful adulterant. Different levels of technological sophistication are available that have varying levels of accuracy and reliability, and range from simply demonstrating the absence or presence of a specific substance to fully quantifying every substance present in a sample.

Drug checking can be done by stationary laboratories (either dedicated facilities or as part of an existing drug service), or mobile labs at festivals or parties. While checking, it allows the service to provide drug counselling and harm reduction advice to people who use stimulants and other drugs who would not come to services otherwise, providing messages that can

\(^{57}\) For an example of a drug safety testing organisation, see: The Loop. wearetheloop.org/about-the-loop
Drug checking services have also been established in some supervised drug consumption facilities — allowing service users to test their drugs — and receive targeted harm reduction information before consuming them (or opting not to).

**Online interventions**

An online drug treatment intervention has been defined as an internet-based programme that offers a specially developed, structured drug treatment intervention. It is thus different from more general websites providing information and education on substances. However, online interventions do not just deal with drug treatment. In a broader sense, online interventions have been defined as: ‘a professional offer in selective

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prevention that is delivered via internet, includes interactive elements and provides individual feedback to young PWUD [people who use drugs]. These online services can ‘be fully automated and self-guided or include contact with a professional’. They are generally cost-effective and can be accessed at any moment, requiring only internet access, reducing obstacles for treatment access.

There is strong evidence that online treatment interventions are effective for a variety of mental health issues like anxiety and depression, as well as for self-help interventions based on cognitive behavioural therapy (CBT) that aim to control and/or reduce alcohol use.

Evidence of the effectiveness of online treatment interventions specifically for people who use stimulants is scarce. Several online interventions have been piloted for people who use cocaine and ATS, although few have been evaluated thoroughly. The available evidence shows that online interventions, especially when combined with other therapeutic interventions such as a community reinforcement approach, contingency management or CBT, may help people stay in treatment, stay abstinent, and/or reduce drug use.

**Therapeutic interventions**

Therapeutic interventions are predominantly used in treatment settings aimed at abstinence but can also be powerful tools in a harm reduction environment. These interventions can assist people in dealing with acute mental health issues and other problems associated with stimulant drug use, they can support people in developing self-regulation strategies, and people may benefit from therapeutic interventions in a drug treatment setting.

Comorbidity is relatively common among people who use stimulants and there are strong associations between substance use and mental health

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disorders, such as attention deficit hyperactivity disorder (ADHD), anxiety, depressive disorders, PTSD and eating disorders.60

The use of stimulants may precipitate or exacerbate various mental health problems, such as anxiety, eating problems, depression, paranoia, sleep disruption and psychotic episodes. For more severe symptoms, crisis interventions by mental health professionals are recommended by the WHO.61 Non-mental health professionals working with people who use stimulants in a harm reduction setting can apply several simple techniques to aid people who use stimulants suffering from paranoid thoughts, anxiety, hallucinations or withdrawal. Interventions such as CBT, contingency management, motivational interviewing, family therapy, CRA and brief interventions have proven to be effective in the treatment of cocaine and methamphetamine use. They can help people identify drug-related problems and commit to change, increase treatment adherence, reduce drug-related harms, help create a support network and manage drug use.

60 Comorbidity is the presence of one or more additional diseases or disorders co-occurring with a primary disease or disorder. In this case, when mental health illnesses and problematic substance use occur together.

Navigating the UN drug control system
Drug policy should be re-imagined at a UN level as a health issue, rather than a criminal justice issue.
As discussed in Chapter 1, the United Nations (UN) plays a fundamental role in setting overarching global drug policy, establishing the barriers within which national drug policies operate. The UN has, over many years, developed detailed standards of human rights, which are consistent with the framework of legal regulation proposed in this book, but at odds with the effects of drug prohibition. Legal regulation creates an opportunity for the further articulation of existing human rights standards in line with this new approach to drug policy, including:

- The right to privacy (concerning levels of interference with personal drug use)
- The right to freedom of thought, conscience and religion (concerning religious or spiritual use of drugs)
- The right to health (concerning access to, and research into, drugs for medical use, as well as access to health information and harm reduction for non-medical use)

Drug policy should be re-imagined at a UN level as a health issue, rather than a criminal justice issue. This would necessitate redirecting responsibility for drug-related issues from the UN Office on Drugs and Crime (the UNODC, essentially a law-enforcement agency) to the World Health Organization (WHO). Ideally, this would additionally involve the development of an international agreement similar to the WHO Framework Convention on Tobacco Control which, among other things, establishes global requirements on packaging and advertising.
The reshaping of this international architecture is likely to have global implications in ending the criminalisation of personal drug use. Such reforms would not, however, necessitate that national governments legally regulate stimulants or other drugs. The decisions of whether, and how, to legally regulate stimulants would remain in the hands of individual governments, as discussed in Chapter 1.

The strength of the UN treaty system is based on the consensus of support from member states and the legitimacy of its goals. For the drug control treaties this consensus has fractured, and their legitimacy is weakening owing to their negative consequences. More and more states are viewing the core punitive elements of the drug treaties as not merely inflexible, but outdated, counterproductive and in urgent need of reform. If this growing dissent is not accommodated through a meaningful formal process to explore reform options, the drug treaty system risks becoming even more ineffectual and redundant, as more reform-minded member states unilaterally opt to distance themselves from it.\footnote{Global Commission on Drugs (2014). Taking control: Pathways to drug policies that work. p.18. www.globalcommissionondrugs.org/reports/taking-control-pathways-to-drug-policies-that-work}

The drug control system’s negative consequences were a key reason why the UN General Assembly convened a Special Session (UNGASS) on the global drug problem in 2016. Many key issues, such as human rights, harm reduction and decriminalisation, were tackled at this meeting. However, the limits of the latitude permitted by the treaties regarding regulation
were also very clear, restricting the scope of the formal agenda and the debate that followed. This meant that while questions about regulation, and reformation of the UN drug control institutions were raised, the much-needed substantial discussions were marginalised. Since then, the treaty tensions surrounding the moves by some countries toward legal regulation have become the ‘elephant in the room’ in key high-level drug policy forums.

The UNGASS debates clearly demonstrated the fracturing of the consensus behind a punitive drug control paradigm, and the wider shift of emphasis in drug policy thinking towards health, human rights and development-based approaches. It is increasingly clear that as the momentum for reform continues to build, high-level forums are no longer able to ignore the regulation question. Honest reflection by member states and UN agencies on the longer-term implications of this global shift is inevitable. Therefore, it is now a question of when, not if, the UN and other international agencies seriously consider the legal reforms required to bring the international drug control system’s original goal of securing ‘the health and welfare’ of humankind closer to reality.

The practical problem, however, is how to bring this about in the context of a system as complex, and divided, as the United Nations. How can the UN

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3 See footnote 2.
How to regulate stimulants

...maintain and enhance critical elements of the system while implementing change? How, as the senior management of UNODC asked in 2008, can the system be made ‘fit for purpose’?*

Realistically, given the strong views on this question and the glacial pace of institutional reforms within the UN drug control system, it is important to consider what reforms are possible in any given time frame, at which stages, as well as specifically; what steps can be taken in the short-to-medium term to help realise this longer-term reform vision. Any such reorganisation or restructuring within the system should support the principle of UN ‘system-wide coherence’ – reflecting the inter-sectoral nature of drug policy, and the centrality of input from the UN health, human rights, and development agencies that emerged as such a positive contribution to the UNGASS. The development of a UN Common Position on Drugs in 2019

by the UN Chief Executives Board (representing the heads of all 31 UN agencies) reflecting these priorities is a notable positive outcome of the UNGASS. The statement includes a clear call for the ‘decriminalization of drug possession for personal use’ and ‘changes in laws, policies and practices that threaten the health and human rights of people’. However, despite this progress on decriminalisation the statement does not engage with or specifically acknowledge the debate and real world reforms relating to legalisation and regulation, or the treaty tensions these are creating (despite such questions featuring in preparatory discussions).  

In moving towards a larger scale modernisation of the international drug control framework, a set of interrelated principles can help guide the necessary decisions. First, decisions should be guided by promotion of the health and welfare of humankind, and the wider goals and values outlined in the UN Charter. Second, serious efforts would have to be made to engage in, and facilitate, dialogue between member states, UN agencies and other key stakeholders. Third, coordinated, collective action by like-minded states would be the most positive and constructive basis on which to approach reform. Finally, any reform should be rigorously monitored and evaluated against explicitly stated objectives.

Below, the potential of five options for how reform can be achieved are explored:

1. A new framework Single Convention

One solution is to work progressively towards a new UN Single Convention on drugs designed to meet the needs and aspirations of all member states.

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This would ultimately replace the three existing Conventions. In some respects this process would mirror the original 1961 Single Convention on Narcotic Drugs, which consolidated a series of multilateral drug control treaties dating back to 1912.

A new unified treaty would make it possible for member states to regulate domestic markets. It could also establish the rules and parameters for this, such as minimum standards, monitoring and reporting requirements, and international trade and border controls. In this way, a new unified drug treaty could — as proposed by the Global Commission in 2014 — ‘extend the ambitions of the [1961] treaty to regulate medical and scientific uses of drugs...to embrace the regulation of drugs for non-medical uses, in pursuit of the same set of UN goals’.

A new treaty could also seek to remedy shortcomings in the existing framework. It should, for example, include a structured periodic review mechanism (conspicuously absent from the current framework) and an improved scheduling procedure that strikes a better balance between ensuring availability of controlled substances for legitimate uses and preventing problematic use. Such a treaty could incorporate elements of the 1988 UN Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, which addresses organized crime and corruption, into the other relevant treaty frameworks with which the 1988 drug treaty is already closely aligned.

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11 More modern treaties, including the 2000 Transnational Organized Crime Convention (UNTOC), the 2003 Convention against Corruption (UNCAC), and the 2003 WHO Framework 53 Convention on Tobacco Control (FCTC) have an inbuilt Conference of the Parties (COP) mechanism that requires them to undergo periodic reviews, facilitating modernization in the face of changed circumstances. The three drugs treaties, however, with roots predating the UN and its contemporary system norms, have no such COP mechanism. See also: Global Commission on Drug Policy (2019). Classification of Psychoactive Substances: When Science Was Left Behind. www.globalcommissionondrugs.org/wp-content/uploads/2019/06/2019Report_EN_web.pdf

Coca leaf and the UN drug conventions

In 1950 an ECOSOC-mandated study published as the Report of the Commission of Enquiry on the Coca Leaf, recommends to suppress ‘the harmful habit of chewing coca’ within a few years.ii

In 1952 the WHO Expert Committee on Drugs Liable to Produce Addiction concluded that ‘coca chewing comes so close to the characteristics of addiction ... that it must be defined and treated as an addiction’ and advised this to the Commission on Narcotic Drugs.iii

Coca, together with cannabis and opium, became one of the main control targets of the 1961 Single Convention on Narcotic Drugs, including special restrictions on cultivation, proscribing the phasing out of traditional use within 25 years and listing the coca leaf as ‘a substance liable for abuse’ in Schedule 1.iv

The 1988 Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances forced states to criminalize coca, under article 3, paragraph 2: ‘Subject to its constitutional principles and the basic concepts of its legal system, each Party shall adopt such measures as may be necessary to establish as a criminal offence under its domestic law, when committed intentionally, the possession, purchase or cultivation of narcotic drugs or psychotropic substances for personal consumption contrary to the provisions of the 1961 Convention, the 1961 Convention as amended or the 1971 Convention’, but it also makes an exemption for traditional use; Article 14 states: ‘Each Party shall take appropriate measures to prevent illicit cultivation of and to eradicate plants containing narcotic or psychotropic substances, such as opium poppy, coca bush and cannabis plants, cultivated illicitly in its territory’, but then continues to say that the ‘measures adopted shall respect fundamental human rights and shall take due account of traditional licit uses, where there is historic evidence of such use’.v One official reservation was made, only by Bolivia, upon signing and confirmed upon ratification of this Convention to preserve the right to use coca leaf for traditional purposes.vi

The INCB annual report for 1994 stressed that: ‘The conflict between the provisions of the 1961 Convention and the views and legislation of countries where the use of the coca leaf is legal should be solved. There is a need to undertake a scientific review to assess the coca-chewing habit and the drinking of coca tea’.vii A supplement to the 1994 report dedicated one section to ‘Coca leaf: a need to clarify ambiguities’, calling for ‘a need to examine the situation regarding State parties to the 1961 Convention that have made reservations under article 49 of that Convention. A true assessment of the habit of coca leaf chewing is urgently called for’.viii

In 1995 the WHO finished ‘the largest global study on cocaine use’, including one part on the use of coca leaf, concluding that ‘the use of coca leaves appears to have no negative health effects and has positive therapeutic, sacred and social functions for indigenous Andean populations’, apparently one of the reasons the study was obstructed in a peer review process, and never published.ix
In September 2007 the UN adopted the Universal Declaration on the Rights of Indigenous Peoples, reflecting a global commitment to respect cultural traditions and medicinal practices of all indigenous populations. This recognition reflects a clear contradiction in international law regarding the legal status of traditional use of coca.\textsuperscript{x}

In March 2009, the government of Bolivia proposed to amend the 1961 Single Convention, by removing two sub paragraphs of article 49 that ban coca leaf chewing. A US-led coalition presented objections within the 12-month period established by the procedure, and blocked the amendment.\textsuperscript{xi}

In July 2011 Bolivia denounced the 1961 Single Convention, which came into effect in January 2012. Bolivia re-acceded the treaty on the 10th of January 2013 with a new reservation that came into force when two thirds of all parties to the Convention did not express objections.

\begin{itemize}
  \item \textsuperscript{i} Taken from: Transnational Institute (2012). Fact Sheet: Coca leaf and the UN Drugs Conventions. www.tni.org/en/publication/fact-sheet-coca-leaf-and-the-un-drugs-conventions
  \item \textsuperscript{vi} United Nations Treaty Collection (as of 2020). United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, Declarations and Reservations. treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=VI-19&chapter=6&lang=en#EndDec
  \item \textsuperscript{x} UN Declaration on the Rights of Indigenous Peoples. www.un.org/esa/socdev/unpfii/documents/DRIPS_en.pdf
\end{itemize}

2. Amending the existing drug control conventions

In theory, the existing conventions could be amended to introduce sufficient flexibility for member states to experiment with alternative regulation. There are notable precedents for this. The 1961 Single Convention was amended with the 1972 Protocol, after a multilateral conference was convened. The US government argued that it was ‘time
for the international community to build on the foundation of the Single Convention, since a decade has given a better perspective of its strengths and weaknesses.\textsuperscript{13}

The latitude under the 1961 Convention with regard to 'alternatives to incarceration' (which, effectively, creates the opportunity for decriminalisation) only exists due to a treaty amendment agreed in the 1972 Protocol. However, such amendments require a consensus among state parties. Given the polarised nature of views on regulation at the United Nations, achieving such a consensus to allow for regulated markets seems highly unlikely.

The treaties also contain mechanisms for the modification of the scheduling of a particular drug (following the recommendation of WHO or a state party) requiring only a majority vote, rather than consensus.\textsuperscript{14} Such modification could, in theory, remove specific drugs from the treaty framework altogether, and in doing so facilitate legal regulation for member states who wish to explore it. However, current political realities mean this option also appears out of reach. In the absence of any realistic short-term prospect of achieving reform via amendment or modification, reform-minded member states face a narrower menu of options.

3. Withdrawal (potentially re-joining with reservation)

Perhaps the simplest option for an individual member state would be to withdraw from the treaties, at which point questions of non-compliance would no longer apply. However, such a radical step would not only incur diplomatic and reputational costs; it would also jeopardise the important parallel role of the treaties in regulating the scientific and medical use


\textsuperscript{14} The 1961 convention requires a simple majority vote, whereas the 1971 convention requires a two thirds majority vote.
Families from the Anyone’s Child campaign calling for legal regulation at the UN General Assembly Special Session on Drugs in 2016

Photo: Steve Rolles
of drugs. This, unlike blanket prohibition on non-medical drug regulation, still commands a strong consensus among member states. A related possibility is to withdraw from the relevant treaties, and then re-join (technically known as re-acceding or re-accession) with a reservation on the specific articles preventing regulation of a given drug. This was the strategy adopted by Bolivia regarding the treaty prohibition on traditional use of the coca leaf, having initially failed to achieve a consensus for amendment. While Bolivia was successful in its strategy, there are questions about how widely this approach could be applied to other drugs (coca is one of a small number of drugs, alongside cannabis and opium, specifically mentioned by name in the main treaty text).

4. Respectful non-compliance

Given the potentially severe implications of outright withdrawal, and limitations of the withdrawal-reaccession option, another option is to remain a party to the treaties but proceed with domestic reforms. This would inevitably mean non-compliance with the relevant treaty articles. How a member state could manage the implications of such a move raises further difficult questions.

Of the countries that have already moved to regulate cannabis, Canada is the first to make a clear formal acknowledgement that it is ‘in contravention of certain obligations related to cannabis under the UN drug conventions’. An acknowledgement of legal realities such as Canada’s appears preferable to denial, avoidance, or somehow attempting to hide behind questionable legal arguments concerning ‘flexible interpretation’ of the treaties. Periods of partial non-compliance are commonplace ahead of actual

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A practical guide
treaty reform. However, in order to take this approach, the reasoning behind the decision needs to be made clear. Uruguay, for example, clearly framed its cannabis regulation model in terms of promoting the health and welfare of humankind and the core values of the UN Charter.

Potential tensions can also be minimised if it is clear that the regulatory norms of existing treaties are adhered to. For example, demonstrating that comprehensive monitoring and reporting to the treaty bodies will continue, and paying attention to border issues and the concerns of neighbouring states. On this basis, a temporary period of what some analysts have described as ‘principled’ or ‘respectful’ non-compliance, in parallel with ongoing dialogue and efforts to resolve the tensions with treaty obligations, appears to be a viable short-term option for unilateral action.

5. Inter se modification of the conventions?

A legally grounded and coordinated approach to reform would have obvious benefits compared with a potentially chaotic scenario of a growing number of different unilateral defections, reservations and questionable re-interpretations. One such reform option, which is not constrained by the requirement for consensus among all member states, is inter se treaty modification. This is an established mechanism within the 1969 Vienna Convention on the Law of Treaties for a group of member states to modify

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18 In 2015, Uruguay co-sponsored a UN Human Rights Council resolution calling upon the UN High Commissioner for Human Rights (UNHCR) to prepare a report ‘on the impact of the world drug problem on the enjoyment of human rights.’ Uruguay’s contribution to UNHCR’s preparations laid out the country’s stance regarding the primacy of human rights: ‘We reaffirm the importance of ensuring the human rights system, underscoring that human rights are universal, intrinsic, interdependent and inalienable, and that is the obligation of States to guarantee their priority over other international agreements, emphasizing the international drug control conventions.’ See: Junta Nacional de Drogas (2015). Impact of the World Drug Problem in the exercise of Human Rights: Uruguayan contribution to the implementation of the resolution ‘Contribution of the Human Rights Council to the Special Session of the UN Assembly the World Drug Problem 2016’. www.wola.org/sites/default/files/Drug%20Policy/AportoedR0UJaluUNGASS2016enDDHHENG.pdf

a treaty ‘amongst themselves’. Article 41 allows for such modification provided that it is not prohibited by the treaty and does not affect the enjoyment by other parties of their rights under the treaty; and ‘does not relate to a provision, derogation from which is incompatible with the effective execution of the object and purpose of the treaty as a whole’. \(^{20}\)

The drafters of the 1969 Convention considered the option of *inter se* modification as a core principle for international law. As the International Law Commission discussed in 1964, ‘the importance of the subject needed no emphasis; it involved reconciling the need to safeguard the stability of treaties with the requirements of peaceful change.’ \(^{21}\) *Inter se* may, therefore, offer an ‘elegant’ and legally viable pathway forward, and one that provides a useful safety valve for collective action to adjust a treaty regime arguably frozen in time.

In the longer term the lessons and shifting dynamics that result from both unilateral and collective action can serve to prepare the ground for a more flexible post-drug war consensus, and a modernised drug control system to support it.


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If we are serious about reducing harms we need a grown up conversation about what moving beyond prohibition could mean in practice. How to regulate Stimulants is an important step in that direction.

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If we are serious about reducing harms we need a grown up conversation about what moving beyond prohibition could mean in practice. How to regulate Stimulants is an important step in that direction.

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I lost my two sons on the same night after they took MDMA of unknown purity and strength. It’s time to accept drug use happens and find ways to make it safer. I hope this book helps make those reforms a reality.

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