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ROADMAPS TO REGULATION

# MDMA

# Roadmaps to Regulation: MDMA

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Roadmaps to Regulation: MDMA

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# Table of contents


| | | |
|---|---|---|
| | Preface, by Prof David Nutt | ii |
| | Executive Summary | 9 |
| | Introduction | 26 |
| | Chapter One: MDMA Past and Present | 32 |
| 1.1 | The History of MDMA: A theraputic and recreational drug | 32 |
| 1.2 | UK MDMA use and consumption practices today | 40 |
| 1.3 | Global MDMA use | 44 |
| | Chapter Two: MDMA-Related Harms Under Prohibition | 46 |
| 2.1 | Inherent harms? 'High-dose' and adulterated MDMA products | 46 |
| 2.2 | Harms associated with use | 53 |
| 2.2.1 | Acute harms and unwanted effects | 53 |
| 2.2.2 | Sub-acute effects and chronic harms | 55 |
| 2.3 | Generations lost: The harm of inaction | 60 |
| 2.4 | Harms associated with production | 63 |
| 2.5 | Harms associated with the product | 64 |
| 2.6 | Harms associated with distribution (supply) | 68 |
| 2.7 | Financial costs of retaining the prohibition status quo | 73 |
| 2.8 | Lost benefits | 74 |
| 2.8.1 | Recreational use | 74 |
| 2.8.2 | Clinical and therapeutic use | 74 |
| 2.9 | Harm reduction under prohibition | 78 |

| | | |
|---|---|---|
| | Chapter Three: Developing a Roadmap to Regulation: MDMA | 84 |
| 3.1 | The goals of policy reform | 84 |
| 3.2 | Proposed model for reform | 85 |
| 3.3 | Phase 1 | 86 |
| 3.3.1 | Rescheduling MDMA | 86 |
| 3.3.2 | Decriminalising possession of MDMA for personal use | 89 |
| 3.4 | Phase 2: Building a strict state-regulated legal market for MDMA | 93 |
| 3.4.1 | Regulating production | 97 |
| 3.4.2 | Regulating distribution (supply) | 99 |
| 3.4.2.1 | MDMA product outlets: Licensed vendors (pharmacy model) | 99 |
| 3.4.3 | User controls and harm reduction | 103 |
| 3.4.3.1 | Pricing and purchase limits | 103 |
| 3.4.3.2 | Marketing controls and information campaigns | 104 |
| 3.4.3.3 | MDMA use in the night-time economy: MDMA-friendly spaces | 106 |
| 3.4.3.4 | On-site MDMA sales in the night-time economy | 110 |
| 3.4.4 | Monitoring and evaluation | 111 |
| | Conclusion | 112 |
| | Testimonials | 116 |
| | Why MDMA should be regulated, by Anne-Marie Cockburn (Martha's mum) | 116 |
| | On the front line of the War on Drugs, by Neil Woods | 119 |
| | MDMA-assisted psychotherapy as a potential treatment for alcoholism, by Dr Ben Sessa | 122 |
| | References | 126 |

# Preface

## Prof David Nutt

I am delighted to be asked to provide a preface to this important policy document as MDMA has been concern of mine since the early 1990s when I was first asked to help advise the UK government on how to mitigate its harms. At the time I had recently returned from the USA and still cherished the belief that UK drugs policy was more evidence-based than that in the USA. Initially the discussions about MDMA were sensible, with our policy recommendations of education, and chill out rooms plus free water in clubs being instigated – and effective.

However a few years later when I accepted to take on the chair of the scientific committee of the ACMD I found that things had deteriorated. When I tried to instigate a sensible discussion about whether the harms of MDMA really warranted Class A, Schedule 1, status I was confronted with statements such as "I would never support a downgrade of MDMA classification" "it would give the wrong message". Still I persevered and instigated a new structured harms assessment process that clearly showed MDMA was more like amfetamine sulphate [Class B] than crack cocaine [Class A] in terms of harms. But the Home Office were resistant and refused to allow the ACMD to do a formal review of MDMA.

Eventually a few years years later, after being admonished by the parliamentary Science and Technology committee, the Home Office allowed us to review MDMA, though at the hearing the Drug Minister made it very clear that they would not downgrade MDMA whatever findings our review came up with.

To help make politicians and the public make sense of this impasse I wrote a thought piece – that was to become my most cited paper with over 7000

downloads. The paper was entitled *Equasy – a harmful addiction with implications for the current debate on drug harms.* In it I compared the harms of ecstasy [MDMA] with those of another addiction I called equasy [equine addiction syndrome]. The latter idea had come to me as a result of seeing a patient who had suffered significant brain damage from falling from a horse and was developed when speaking about comparative harms of different activities at a Beckley Foundation event at the House of Lord's the year before. As most of you will know I concluded that MDMA was less harmful than horse riding especially when the latter involves jumping and eventing.

I hoped that this comparative analysis would help politicians become more reasonable about MDMA but the opposite happened. The Home Secretary at the time was Jacqui Smith who reacted very aggressively, calling me up and shouting down the phone that I had exceeded my position as ACMD Chair by comparing a legal activity with an illegal one. I tried to explain that we had to have some harmful activities with which to compare the harms of drugs in order to decide if a drug was harmful enough to be banned; but she just couldn't [or wouldn't] get it. She showed the same level of intransigence when the ACMD report came out recommending downgrading MDMA to Class B and this suggestion was summarily dismissed. So MDMA stayed as a Class A drug, and the effective ban on research that its Scheduling in the 1980s had resulted in, persisted.

But there is now light at the end of the tunnel. Research on the brain mechanisms of MDMA conducted by our group funded by Channel 4 opened up people's eyes to the science of MDMA and the pioneering work by MAPS demonstrating its utility in treatment-resistant PTSD has helped to change public attitudes. Also the hostile pseudo-scientific claims that MDMA use damaged the brain have been overturned by more recent better controlled scientific analyses. Now I give a lecture on MDMA with the title "A decade of MDMA – from brain damage to brain healing" which emphasises the complete

volte face that has occurred as a result of many research teams around the world. In this report you will discover the most recent one by Ben Sessa and others in our Unit showing how two MDMA treatments given as part of an alcohol treatment programme can help people with PTSD overcome their alcohol dependence. I believe that this is just the start of a major breakthrough in the use of MDMA therapy that will occur if it gets re-scheduled as per this report. Thanks must go to the Beckley Foundation for leading this vital campaign.

Prof David Nutt DM FRCP FRCPsych FMedSci DLaws
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Edmond J. Safra Prof of Neuropsychopharmacology
Imperial College London
November 2019

# Executive Summary

MDMA is well established as a popular psychoactive substance across much of the Western world. Hundreds of thousands of people break the law to access its effects, which include increased energy, euphoria, and enhanced sociability. The categorisation of MDMA as a Class A drug in the UK and Schedule 1 drug internationally – categories reserved for drugs deemed to pose the highest risk to individuals and society – has never meaningfully disrupted its supply, nor its widespread use. MDMA is cheaper and purer than ever before and is available at the click of a mouse via darknet drug markets.

For several years, MDMA-related adverse events and fatalities have been increasing in the UK, with some claiming that taking MDMA today is the riskiest it has ever been. Responses are polarised between those who assert that the risks of MDMA use necessitate mitigation through prohibition and increased law enforcement, and those who perceive prohibition to be exacerbating these risks by exposing users to an unregulated market of pills and powder of unknown strength and quality. Whichever view you take, current policy is not meeting its goal of reducing harms, and greater control of MDMA production, distribution, purchase, and consumption is needed in order to prevent MDMA-related emergencies.

This report examines the acute, sub-acute, and chronic harms related to MDMA use in detail. We examine the production, distribution, purchase, and consumption of the drug; related risks and harms; and the impact prohibition has on these, as well as the potential impact of alternative policies. Crucially, our evidence shows that many harms associated with MDMA use arise from its unregulated status as an illegal drug, and that any risks inherent to MDMA could be more effectively mitigated within a legally regulated market.

Under prohibition, people purchase MDMA pills, crystal, and powder from an illegal market, with little certainty as to what these products contain. Given that illegal drugs are not subject to strict production standards, consumers are exposed to the risks of poisoning or accidental overdose as a result of contamination, adulteration, and unknown strength and purity. Naïve commentators demonise the drug and simply urge young people to 'just say no', whilst failing to account for those who say 'yes'. In the meantime, preventable deaths continue to occur, and otherwise law-abiding people are punished for non-violent offences such as the possession or social supply of MDMA. Governments and the mainstream media persist in perpetuating the myth that the War on Drugs is winnable if it were fought harder, and those calling for drug policy reform – as we do here – are framed as 'radicals' who have little or no regard for the health and wellbeing of citizens.

This characterisation could not be further from the truth. Those calling for careful reform to existing drug policy include the parents of young people whose lives have been lost or ruined by harms related to the prohibition of MDMA. We incorporate their voices in this report alongside those of academics and former police officers, highlighting the 'broad church' of those dedicated to fighting for reform. This includes scientists undertaking ground-breaking research into the therapeutic potential of MDMA, who work within a regulatory regime that makes such research exorbitantly expensive and time-consuming, because of the Schedule 1 status that MDMA holds in the UK.

As we enter the fourth decade of MDMA's widespread use, new thinking is needed on how to better control production and distribution, and on how to reduce the risks associated with its consumption. There is growing evidence to support reorienting drug policy away from an ideologically driven criminal justice-led model to one rooted in pragmatic health and harm reduction principles. This is reflected in the widespread reform of cannabis laws occurring in numerous jurisdictions around the world, and the growth of treatment

programmes for heroin users which include prescription heroin and supervised injecting rooms. These hard-fought policy changes acknowledge the failure of prohibition to meet its goals and produce a 'drug-free world'. They are built on a robust and ever-growing evidence base which demonstrates how permitting or prescribing the use of legally regulated drugs improves health and safety outcomes for people who use drugs and their communities at a reduced cost to the state, whilst also providing wider employment and economic opportunities. This logic can be extended to the use of MDMA and other currently prohibited psychoactive substances.

*Roadmaps to Regulation: MDMA* follows this pragmatic path and pursues policy aims which many of us share, such as improvements in public health promotion, targeted harm reduction, evidence-informed policy and practice, human rights, social justice, participatory democracy, and effective governmental expenditure. For the first time, we outline detailed recommendations for drug policy reform to better control the production, distribution, purchase, and consumption of MDMA products. Reform and the reduction in MDMA-related harms this will bring cannot happen overnight. The changes we outline here, which culminate in a strictly regulated legal market for MDMA, are to be phased in gradually and closely evaluated through independent policy research to ensure health and social outcomes are properly documented, with findings folded back into the ongoing reform process.

## Key findings supporting our recommendations

### Harms associated with MDMA under prohibition

- As with all drugs, certain adverse effects can be caused by or associated with MDMA use. The most serious of these include hyperthermia, hyponatraemia (abnormal water regulation which causes swelling in the brain), serotonin syndrome, and isolated physiological disorders such as cardiac events and liver failure, all of which may result in death. These adverse effects occur through various mechanisms, none of which is as simple as an 'overdose'. Whilst it is widely accepted that risks are increased with higher doses of MDMA, there is no established consensus on the fatal blood concentration level of MDMA, and it is often unclear to what extent the harms are attributable to the toxicity of MDMA alone, or to the circumstances in which it is taken.

- Hyperthermia is the most commonly reported life-threatening medical complication associated with MDMA use. The risk for users is exacerbated by external factors. These include dancing for prolonged periods in overcrowded venues with high ambient temperatures and insufficient ventilation, although risks may not be confined to dance settings. MDMA increases metabolic heat generation and impairs heat dissipation through vasoconstriction, which typically increases body temperature in a manner comparable to moderate exercise. When paired with other heat-generating activities, severe problems can arise for a small but significant number of people.

- Hyponatraemia, another MDMA-related medical complication that has resulted in fatalities, is caused by excessive water intake, often ingested in order to prevent dehydration and overheating following MDMA consumption. MDMA causes the brain to release certain chemicals (e.g., arginine vasopressin) that tell the body to retain water, which is problematic if an excess of water is subsequently consumed.

- Both hyperthermia and hyponatraemia could be prevented with comprehensive harm reduction advice and services. Neither adverse effect has ever occurred in a clinical setting.

- Unlike other recreational legal and illegal drugs such as cannabis and alcohol, occasional use of MDMA is typical. Prolonged daily use – an indicator of problematic use – is atypical and usually only associated with co-occurring mental or physical conditions. Given this, harms associated with chronic use of MDMA may only be relevant for a minority of MDMA users.

- It remains difficult to define conclusively the risks associated with long-term regular use of MDMA, due to multiple confounding factors (e.g., polydrug use, including mixing MDMA with alcohol; purity of MDMA products; and use setting) and the fact that the only available evidence comes from animal experiments, observational studies of human users, and accounts of harm such as clinical case reports. Of these, only the animal experiments have gathered data on the effects of the use of pure MDMA.

- However, proposed neuropsychological risks include neurological and cognitive impairment, psychological and mood problems, and sleep disturbances, which some claim are the result of direct neurotoxicity. The neurotoxicity of MDMA continues to be strongly debated but there is evidence to suggest that heavy use of MDMA may contribute to *temporary* impairments in neuropsychological functions. Liver toxicity has also been reported, although it is impossible to ascertain whether this was driven primarily by MDMA, or was the result of polydrug use or of an adulterated product.

- The number of MDMA-related deaths has been rising in the UK since 2010. This has been mirrored by an increase in 'high-dose' MDMA/'Ecstasy' pills and

powders in circulation, and the presence of high-risk adulterants such as PMA (paramethoxyamphetamine) and PMMA (paramethoxymethamphetamine) in pills sold as MDMA. Recent drug-testing results by the harm reduction organisation The Loop (UK) have identified pills containing as much as 300 mg of MDMA, which is considerably more potent than in previous years. Although the relationship between dose and adverse effects is complicated and cannot be divorced from the user and the user's setting, a significant proportion of MDMA-related medical emergencies and deaths are cases of accidental poisoning through unintentional excessive doses and adulteration with, or substitution of, other substances.

- Assessing the risk profile of MDMA requires distinguishing between MDMA of clinical purity and MDMA produced and sold illegally. It also requires identifying the risks specifically related to the context in which the drug is consumed. Recreational MDMA use has only been studied under conditions of prohibition, and so the evidence can only tell us, at best, how risky MDMA may be in that specific context. Aside from the pre-prohibition era of MDMA use, recreational users have not had access to a pure standardised MDMA product, so we cannot know for certain what harms, at what levels, would be attendant to that scenario. We know that clinical-grade MDMA can be administered with a high degree of safety in a controlled therapeutic setting if sufficient measures are taken to reduce risks: over 1,500 people have participated in studies investigating the effects and therapeutic use of MDMA with no unexpected serious adverse events requiring emergency treatment reported. Although recreational use is distinct from therapeutic use, clinical research helps us to better understand any risks associated with pure MDMA and how these risks can be managed.

## How prohibition exacerbates these risks

- Currently in the unregulated criminal market, MDMA potency and purity is highly variable: pills have been found containing less than 20 mg of MDMA while others contain more than 300 mg of MDMA. MDMA may also contain adulterants that are psychoactive and/or toxic. As users are unaware of the content of their pills, they may be vulnerable to overdosing or other problems caused by product adulteration, particularly if they choose to consume multiple pills. The lack of consistency makes it difficult to establish stable social norms, moderate use, and harm reduction measures, although over the last 30 years of rave and dance culture, specific grassroots risk mitigation measures – such as breaking pills into quarters – have emerged. Ultimately people who take MDMA want to stay safe.

- The variability in MDMA potency and purity is a direct result of global and national prohibitionist policies. Recent developments around *in situ* drug safety testing are an attempt to mitigate the risks of such variability. These risks, such as overdose and/or poisoning, are by no means inevitable or inherent to the drug. If MDMA were clinically produced and legally distributed, users would be assured of the product content and appropriate dosage, and be able to make more informed decisions regarding their MDMA use. In this way the principal risks we associate with MDMA use would be greatly reduced.

- Prohibition makes users less likely to seek medical assistance for fear of 'getting into trouble' with the authorities, especially amongst members of marginalised communities who already receive disproportionate law enforcement attention relative to their involvement in drug markets. Young people may be reluctant to contact emergency services if they, or a friend, experience an adverse reaction to a substance, out of fear of (legal) repercussions in relation to social dealing and/or potential media coverage of their role in the incident.

- Pressures on MDMA users to avoid detection, and on nightclubs, warehouse parties, and festivals to demonstrate zero-tolerance, create conditions that are not conducive to responsible use. Intensive searches and drug (sniffer) dogs may unintentionally encourage users to take all their drugs at once before entering party venues. This has led to several young people experiencing adverse effects as a result of not wanting to be caught with their drugs 'on the door' of nightclubs or events. Avoiding such detection can also lead people to purchase their drugs from unknown dealers inside the venue who, in comparison to dealers known by the user, may offer an even more unpredictable product. The 'zero-tolerance' approach of certain venues or events can lead people to consume MDMA in less regulated private parties or unlicensed venues, where an MDMA-related emergency may take longer to receive medical attention.

- Adolescents and those with pre-existing genetic vulnerabilities, or with specific health diagnoses that may be contraindicated for MDMA use (such as heart conditions or impaired liver function) are not protected by prohibition. There are no age restrictions in a criminal market, no education at point of sale on the risks associated with various products, and no purchase limits to curb heavy use or 'bingeing'.

- The development of online drug sales via darknet markets and social media dealing poses specific kinds of risks and opportunities in addition to the more familiar practice of purchasing drugs from criminal markets. The internet has created an easily accessible supply route for 'tech-savvy' young people who may not otherwise have had access to street or social dealers; this may increase MDMA availability for certain populations. However, for some people, online modes of purchase may be preferable given that they avoid the need to meet dealers in person, and there is some degree of quality control through user ranking/reports on vendors.

- Harm reduction is restricted within a prohibitionist policy regime because the *dominant* focus is on drug prevention and abstinence rather than safer use. Risks such as hyperthermia and hyponatraemia are exacerbated by certain contexts of use and environmental factors. Under prohibition, venues and events are supposed to operate with a 'zero-tolerance' approach to drug taking. For the most part, they are under no obligation to provide basic harm reduction measures, such as *visible* free drinking-water supplies and adequate ventilation and temperature control, let alone measures such as in-house medics and pill checking that could further prevent adverse effects. Indeed, venues and events may be stigmatised for taking a more 'tolerant approach' should an MDMA-related emergency occur.

- The opportunity for education at point of sale, or information campaigns to raise awareness of the risks associated with MDMA use for certain populations and the relative risks of different dosages and contexts of use, is lost within an illegal market. Likewise, the lack of regulations for MDMA producers and distributors means they may remain largely ignorant of the harms to health posed by certain production techniques or the presence of certain contaminants in the products they make and sell.

### Harms introduced by prohibition

- Prohibition has created a lucrative illegal MDMA market that generates wealth for entrenched criminal organisations and criminal entrepreneurs. Those involved in large-scale production, importation, or distribution of MDMA and other illegal drugs are likely to engage in other criminal behaviour as part of their business practice, for example, violence towards consumers and rivals, money laundering, and corruption.

- There is no evidence to suggest that criminalising people who use drugs meaningfully disrupts the supply of controlled drugs or reduces their

availability. However, criminalising (often young) MDMA users can have a devastating impact on their lives, resulting in the loss of education or employment opportunities; negatively impacting housing, personal finance, and social relationships; and, ironically, potentially increasing the likelihood of them developing more problematic drug-using behaviour, especially if they spend time in prison.

- Many people who use MDMA report obtaining their drugs from friends and established contacts. This creates a risk of criminalisation for young people engaging in non-profit 'social supply' amongst peer groups, or small-scale opportunistic dealing. Drug dealing can also attract young people in situations of social vulnerability, which can further perpetuate cycles of harm, trauma, and exclusion if they are prosecuted. The harms of criminalisation are arguably greater than the harms caused by occasional use of MDMA.

- The development of markets for novel psychoactive substances (NPS) intended to mimic the effects of MDMA is directly related to the drug's illegal status. Illegal production results in a market affected by inconsistent quantity and quality of production. If MDMA supplies run scarce due to law enforcement measures or the quality diminishes due to production difficulties, alternatives are sought. A decade ago, NPS as legal replacements for MDMA swiftly emerged, with some MDMA users simply adding them to their polydrug repertoires. NPS such as mephedrone, a stimulant which enjoyed immense if short-lived popularity in the UK, turned out to have a higher risk profile than MDMA, was banned in 2010, and now plagues marginalised stimulant users. NPS are the genie that prohibition let out of the bottle.

## Benefits lost through prohibition

- Before the use of MDMA was prohibited, it was employed by psychotherapists as a valuable and effective tool to augment the psychotherapeutic process, particularly for overcoming fear and anxiety associated with trauma, and in the context of couples' therapy. Due to the regulatory hurdles imposed by the prohibition of MDMA, research into this particular use of MDMA was seriously impeded for almost twenty years. Only recently has it been revived, largely due to the efforts of the Multidisciplinary Association for Psychedelic Studies. Phase 1 and Phase 2 clinical trials of the use of MDMA in the treatment of post-traumatic stress disorder have been completed with positive results, and Phase 3 trials are now underway following the US Food and Drug Administration approval and designation of MDMA as a 'breakthrough therapy' for post-traumatic stress disorder.

- Other research is being conducted to see whether MDMA-assisted psychotherapy can help autistic adults with social anxiety, patients with anxiety relating to a life-threatening illness, and people with alcoholism. Prohibition imposes considerable financial and bureaucratic obstacles to preclinical and clinical research involving prohibited drugs, resulting in trials taking longer and costing more – as much as ten times the equivalent research with unprohibited drugs such as alcohol. A gram of clinically made MDMA can cost researchers in the UK £10,000 as compared to its average street price of £30–£40 per gram.

## Conclusions

Global and UK drug policy is not meeting its stated goals of reducing the demand for MDMA and restricting the supply. The use of MDMA has remained relatively consistent amongst adults over the last thirty years, and the supply has only experienced periods of minor disruption, during which lesser-known NPS entered the market as (often more dangerous) substitutes. Prohibition needlessly exacerbates the risks of medical emergencies and death amongst people who use MDMA. An illegal market leads to the sale of MDMA products of variable potency and purity. Contaminated and adulterated products can cause poisoning, and a lack of awareness regarding purity and dose can lead to accidental overdoses, one of the more common causes of drug-related fatalities. Criminalising users hinders the dissemination of important information and advice about safer forms of use, not to mention the devastating impact a custodial sentence and criminal record can have on a person's life. Finally, in prohibiting MDMA use, governments have failed to capitalise on the therapeutic benefits it could offer users and society. The rescheduling of MDMA would facilitate further medical research and the development of much needed new treatments for a range of health conditions.

## Recommendations for initial reforms

Moving to a strictly regulated commercial market may take time as political, legal, and practical hurdles need to be overcome. Thus, we propose the following interim measures to reduce some of the harms associated with the current system:

- Reschedule MDMA from a Schedule 1 to Schedule 2 drug under the Misuse of Drugs Regulations in the UK, and equivalent legislation internationally. This will reduce the political, bureaucratic, and cost barriers to scientific research associated with the Schedule 1 status and facilitate further research into MDMA's therapeutic uses, as well as allowing us to improve our understanding of its physiological effects.

- Decriminalise the possession of MDMA and all drugs to remove the devastating social and economic effects of being criminalised for drug possession or limited social supply. As well as improving social justice outcomes for users of MDMA (a principal aim of any drug policy), decriminalisation will improve health outcomes by removing barriers to harm reduction and health services, and increasing willingness to access them amongst vulnerable populations who might have previously feared legal repercussions. To reap the full benefits that could be derived from decriminalisation and to help tackle the disproportionality and racial bias of drug policing, it is appropriate that criminal penalties be removed for the possession of *any* drug (and not solely MDMA), as is the case in Portugal.

- Through decriminalisation, enable the comprehensive rolling-out of drug safety checking and other successful harm reduction interventions to occur, which would go some way towards reducing the harms associated with unregulated MDMA products.

## Recommendations for a strict state-regulated legal market for MDMA products for adults:

- Licences would be awarded to selected pharmaceutical manufacturers to produce MDMA certified by Good Manufacturing Practices (GMP). This would ensure product safety and quality and resolve the current issue of adulterants. All MDMA products would be labelled with clear indications for dosage, contraindications, and potential adverse events.

- Licensed MDMA products would be sold in government-licensed MDMA product outlets. These outlets could be pharmacies in the first instance. Pharmacies are uniquely positioned as gatekeepers for controlled drugs. Regulated pharmacy sales would enable the retail of MDMA products to be governed by strict regulatory legislation and a well-defined quality assurance infrastructure.

- Point-of-sale face-to-face discussion is crucial for harm reduction. MDMA product outlet staff (initially pharmacists in our incremental model for policy change) would be specially trained to educate customers on the risks associated with MDMA use. Take-home educational material promoting harm reduction would also be available.

- MDMA products would not be 'on prescription'. Instead, adults who wished to purchase MDMA products would be required to obtain a 'personalised licence' to do so. This licence would only be available to those who had first discussed the risks of MDMA use with a trained pharmacist. Personalised licences would be conditional on adults being able to demonstrate that they understand the risks and how to minimise them. They would be reviewed on an annual basis.

- The development of adult-only MDMA-friendly spaces could provide an environment in which the risks associated with MDMA use could be

further mitigated through well-established harm reduction measures and requirements for on-site medical assistance. These venues would need to incorporate procedures to minimise risks and promote responsible MDMA use, such as ensuring that dancefloors are cool and well ventilated, and that customers exhibiting adverse symptoms quickly receive medical attention. Alcohol-free venues could be trialled as a means of encouraging single-substance use. Alcohol impairs inhibitory control making it easier for people who use drugs to consume drugs faster and in higher quantities than they had intended.

- User controls are essential for supporting the responsible use of MDMA. Controls would aim to minimise the use of MDMA by vulnerable populations, reduce polydrug use (including the mixing of alcohol and MDMA), encourage safer modes and patterns of consumption, and improve user understanding of the potential harms associated with MDMA consumption. User controls would include a strictly enforced age limit, pricing controls, mandated health information on packaging and at point of sale, childproof and tamperproof packaging, a comprehensive ban on marketing and advertising, and a campaign to minimise the social acceptability of driving under the influence of MDMA and to promote alternatives such as designated drivers.

- Sales of MDMA would be permitted to adults over 18 years of age. Prohibitive penalties would be in place to restrict underage sales.

- Information campaigns focusing on MDMA safety and responsible use would be central to the development of a regulated legal market. Such information campaigns would cover all sales outlets and educational establishments (schools, colleges, and universities), and would include information on recognising the symptoms of adverse events in relation to MDMA products and how to manage them.

- Thorough monitoring and evaluation of the impact of legislative change would be undertaken to maintain an evidence-based approach and allow responses 'on the ground' to feed back into policy decision making.

*Roadmaps to Regulation: MDMA* is the first report of its kind to outline a comprehensive model specifically for the regulation of MDMA. Implementing our detailed and pragmatic recommendations would be a progressive move in a policy sphere in which it is risky for those in power to engage in an honest and rational manner. Yet they must. We have squandered decades on prohibitionist policies which have failed to place the health and well-being of citizens at their heart. The time has come to move forward, collectively and carefully. We desperately need a mature approach to MDMA which properly protects vulnerable members of society, whilst allowing those who choose to consume the drug to do so safely. Let us not waste another decade.

# Introduction

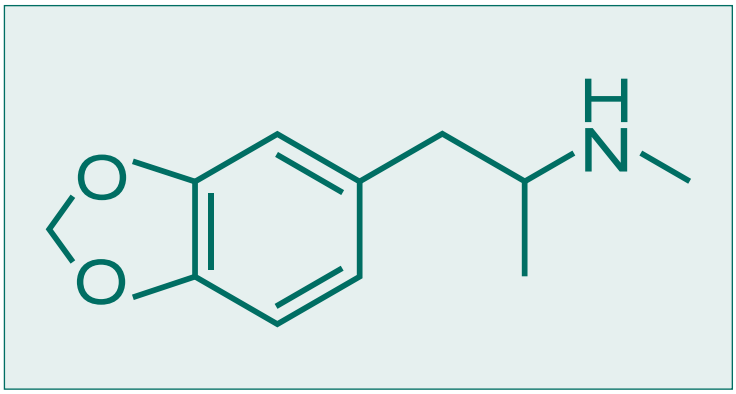



Fig. 1
*Molecular Structure of MDMA*

Source:
The Beckley Foundation

MDMA[a], available in pill, powder, and crystal form, is one of the world's most prevalent prohibited drugs. Typically consumed in a range of leisure spaces, including parties, pubs/bars, nightclubs, and festivals, its desired effects include increased energy, euphoria, sociability, and 'openness'. MDMA is classified as a Class A substance under the UK Misuse of Drugs Act (MDA) 1971, as a Schedule 1 substance under the UK Misuse of Drugs Regulations 2001, and as a Schedule 1 substance in the US under the Controlled Substances Act. The UK/US position on MDMA – as signatories to the UN International Drug Control Conventions – is broadly commensurate with that of the rest of the world. The 1961 Single Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances classified controlled substances in four lists (i.e., Schedules) according to their perceived therapeutic value and potential risk for 'abuse'. MDMA remains a Schedule 1 drug under these UN Conventions, a Schedule reserved for drugs considered to pose the greatest risk to public health, with limited or no therapeutic value. This evaluation of MDMA means it attracts the highest possible penalties for production, supply, and possession offences.

a MDMA is an abbreviation for methylenedioxy-methylamphetamine. Also known as 3,4-methylenedioxymethamphetamine, MDMA is a ring-substituted phenethylamine (compounds based upon the phenethylamine structure), structurally related to amphetamines and mescaline.

Despite long-standing international prohibition, MDMA's availability and popularity remain consistently high. Consumed in more niche party scenes in the US during the 1980s (notably in the gay scene), synonymous with rave and dance music culture from the late 1980s, and enjoying both sustained popularity amongst ageing ravers and a recent resurgence in popularity amongst younger dance music fans, MDMA is evidently here to stay.

Fig. 2

*MDMA Crystals*

Source:
Hypnotoad

The prevalence of MDMA use is captured by general population surveys (GPS), targeted population surveys, and other drug monitoring data sources such as multi-city analysis of wastewater[1,2,3,4]. According to the United Nations Office of Drugs and Crime, 21 million people are estimated to be past-year users of MDMA, with use remaining stable or increasing in Australia and New Zealand, Europe, and North America between 2005 and 2017[5]. In the years preceding 2013, MDMA use had been declining in Western and Central Europe, but more recent data show a stabilisation or an increase in its use in countries throughout the continent, alongside increases in use in Latin America[1,5]. The most recent EU-level figures (2019) suggest that 13.7 million European adults aged 15–64 have used MDMA in their lifetimes (4.1%). Last-year use of MDMA amongst European adults aged 15–64 stood at 2.6 million (0.8%), with 2.1 million (of the 2.6 million) users being young adults aged 15–34 (1.7%)[1]. National prevalence rate estimates of MDMA use among European adults aged 15–64 range from

0.2% in Portugal and Romania to 7.1% in the Netherlands[1]. Countries with the historically highest prevalence of MDMA use in Europe include the Netherlands, the Czech Republic, the UK, Bulgaria, and France[6].

At the global level, millions of people worldwide repeatedly break drug laws on possession and supply to access MDMA's psychopharmacological properties. Despite intense local, national, and international policing efforts, significant disruption of MDMA production and supply has only ever been temporary and localised – with the expanding market more than able to meet the long-term trend in rising global demand. In this context, the economic and human costs of prohibitionist policies towards MDMA are increasingly unjustifiable. By preventing access to legal supplies, prohibition has created a profit incentive for an entirely unregulated global criminal market in illegal drugs – including MDMA – to develop. Those who support prohibition tend to characterise the moving of drug policy reform towards a less punitive regime as 'radical', and as being 'soft-on-drugs', or 'pro-drugs'[7]. However, historically speaking, it is prohibition that is the poorly evidenced and 'radical' policy which has allowed criminal markets to flourish[8]. In direct contrast, a legal regulation model – *not* an absolute or blanket prohibition, *nor* a simplistic free-market legalisation model – would enable state institutions and civil society to exercise far greater *control* over drug markets, including the market for MDMA, via evidence-based regulatory regimes. To this end, all drug policy reform should be built on careful experimentation with innovative policy options routinely evaluated by relevant government bodies, civil society, and independent researchers[9, 10, 11].

In the context of MDMA's enduring popularity, this report's primary aim is to serve as a realistic and comprehensive roadmap out of the impasse of failing prohibition and towards a safer future for people who use MDMA. Whilst others have helpfully produced roadmaps towards dismantling prohibitionist policies and building alternative regimes which focus on illegal substances with some consideration of specific substances[8], this report is unique in its focus on

MDMA[b]. This report is also timely in an era when MDMA use is increasing in the UK and across Europe[1], MDMA is increasingly available for purchase online[1, 6, 12], and preventable MDMA-related deaths have risen considerably over the last six years in the UK[c]. Crucially, an evidence-based alternative model of future possible MDMA regulation which acknowledges the drug's specific qualities, its user groups, and the circumstances of its use, including polydrug use[d], remains under-explored and largely absent from drug policy debate. This is perhaps surprising in light of the enduring press attention given to MDMA-related deaths and recent media coverage of drug safety testing services at music festivals. *Roadmaps to Regulation: MDMA* fills this gap via a review of MDMA research in the UK and beyond, coupled with the policy and scientific expertise of the Beckley Foundation, to produce a much-needed in-depth investigation as to how an alternative model of regulation of MDMA would work in the 'real world'.

This report rests on the following five principles which should underpin all evidence-informed drug policy and practice: promoting public health and reducing harm; safeguarding vulnerable populations, including children and young people; supporting human rights; promoting social justice; and supporting participatory democracy.

*Roadmaps to Regulation: MDMA* has two overarching interlinked objectives:

- To highlight that the harms associated with MDMA use are predominantly related to its prohibition

b For a notable exception, please see Transform Drug Policy Foundation. After the War on Drugs: Blueprint for Regulation. Regulated Drug Markets in Practice: MDMA. Bristol: Transform Drug Policy Foundation; 2009. pp.140–144.

c This issue is covered in more detail in later chapters of this report.

d Polydrug use is the use of more than one type of drug (including alcohol) taken at the same time (simultaneous use), or more than one type of drug being taken within the same period of time, for example, in the last year (concurrent use).

- To propose an alternative regulatory model that would reduce the harms associated with criminalising MDMA use and minimise the risks associated with its use more generally.

*Roadmaps to Regulation: MDMA* is divided into three chapters.

**Chapter One** offers an overview of the history of MDMA, its use as both a therapeutic and recreational (non-medical) drug[e], and a discussion of the current legal and socio-cultural context of MDMA use.

**Chapter Two** explores the harms associated with MDMA and how they are significantly related to its prohibition. The harms associated with MDMA and its prohibition are situated in three main areas: production, distribution (supply), and use. These relate to both the therapeutic and the recreational (non-medical) use of MDMA, and occur at all levels of society. In this chapter we examine two ongoing and well-publicised controversies around MDMA which are commonly marshalled to argue for continued prohibition, namely 'high-strength'[f] and 'adulterated' MDMA products. A careful and considered

e We recognise that making a clear delineation between 'therapeutic' and 'recreational' use may be problematic, because in many cases there are overlaps, and what would commonly be termed 'recreational use' may in fact be accompanied by therapeutic intentions and results. Nevertheless, we have chosen to use the term 'therapeutic use' to refer to MDMA administered in a clinical environment, in conjunction with psychotherapy or another form of therapy, and recreational use to refer to any use not specifically for medical or therapeutic purposes.

f The term 'high-strength' in reference to MDMA pills is problematic in that experiences of 'strength' vary according to user characteristics, e.g., gender, those of lower weight, or those with liver conditions. What may be experienced as 'strong' by one user may not be experienced as such by another. Potency (rather than strength) is a more transparent and meaningful term. High/low-potency MDMA pills, crystal, or powder are relative terms of comparison. Potency conveys that the 'amount' of MDMA is crucial, with a 'high-dose' MDMA pill sitting anywhere between 100 mg and 400 mg. Acknowledging variability between individual users remains crucial.

analysis of both controversies further demonstrates how prohibition is failing to *control* MDMA and instead *exacerbates* harms.

**Chapter Three** details how to implement an incremental move away from this failing prohibitionist model of the past towards an alternative model of legal regulation. It is argued that this can best be achieved via a flexible and evidence-based two-stage process, moving from the rescheduling of MDMA and the decriminalisation of all drugs including MDMA, towards the creation of a government-regulated legal market for MDMA products, supported by investment in proven health and harm reduction interventions.

## Terminology: MDMA or Ecstasy?

MDMA is known by many as 'Ecstasy' (in the UK and US) or 'Molly' in the US. There remains considerable confusion about the terms, so we have used MDMA throughout this report. Whereas MDMA typically (but not exclusively) depicts the abbreviated version of a single chemical compound, 'Ecstasy' often refers to tablets containing MDMA alongside other components. Many government agencies (including the UK's Home Office and the Office of National Statistics) use the (unscientific) term 'Ecstasy' in their statistical reports. We have chosen to use the term MDMA because that is what we would be dealing with in a legally regulated market, and because the term 'Ecstasy' is commonly associated with tablets containing mixed and substances, often a small amount of amphetamines to supply extra energy.

Chapter One

# MDMA, Past and Present

## 1.1 The history of MDMA: A therapeutic and recreational drug

MDMA was first synthesised in 1912 by the Merck pharmaceutical company as an intermediate in the synthesis of another drug[13, 14]. Its unusual effects in humans remained unrecognised for decades. A pivotal moment in MDMA's history came in the mid-1970s when psychopharmacologist Alexander Shulgin was informed by self-experimenting students that MDMA had 'emotional' psychoactive effects worthy of further study. Shulgin, famous for systematically creating and describing numerous psychoactive substances, synthesised and tried the drug himself. Producing the first report on the effects of MDMA in humans, Shulgin and co-author David Nichols noted that the drug produced 'an easily controlled altered state of consciousness with emotional and sensual overtones'[15].

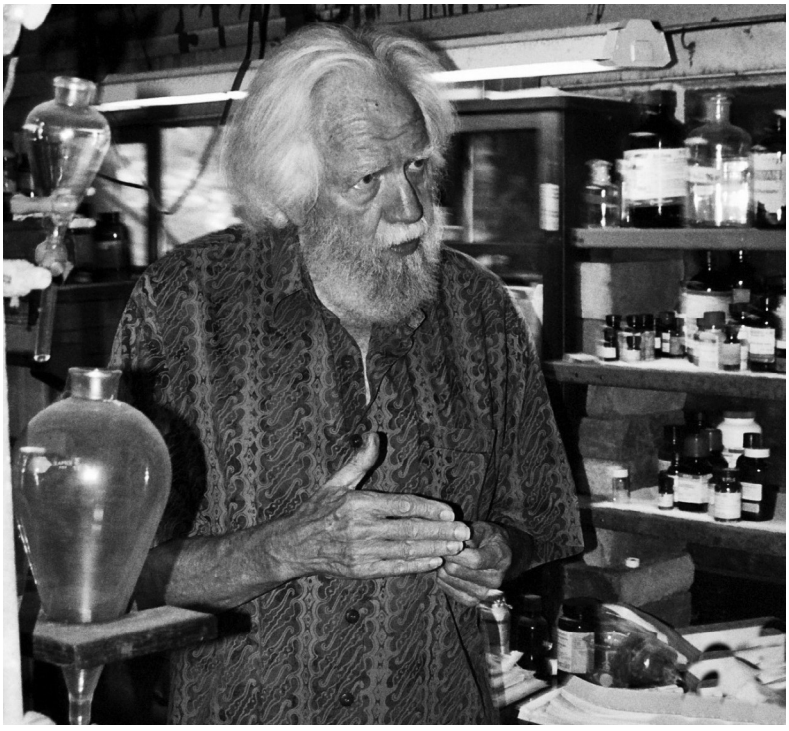


Fig. 3
*Alexander Shulgin*

Source:
Amanda Feilding

Recognising its potential for therapeutic use[a], Shulgin introduced the drug to psychotherapist Leo Zeff, who subsequently achieved success with MDMA-assisted psychotherapy, and was instrumental in spreading word of the drug among therapists[16]. Many of those working with MDMA believed that it enhanced empathy and communication in patient sessions, and helped patients to achieve new and positive insights about their problems. Because of consistently reported experiences of feelings of connectedness and empathy, the term 'empathogen', meaning generating a state of empathy, was coined to describe MDMA and other chemically related compounds. This term was later discarded by several prominent researchers in favour of 'entactogen', meaning 'touching within' to avoid the negative associations with *pathogen* or *pathogenesis*[17]. From the 1970s until 1985, when MDMA was placed into Schedule 1 by the US government, an estimated half million doses were administered in psychotherapeutic settings[18]. During this period there were no associated fatalities, and only eight related emergency room visits reported[19]. No controlled clinical trials on its safety and efficacy were conducted at that time. However, the onset of prohibition was greatly regretted by therapists and patients alike.

MDMA's proposed scheduling in the US was opposed by a group of physicians, researchers, and therapists, who presented evidence of its therapeutic potential at a Drug Enforcement Administration hearing in 1985. The Drug Enforcement Administration's administrative law judge who led the hearings concluded that MDMA should not be placed in Schedule 1 due to its therapeutic utility and low potential for harm and abuse. His decision was overruled and MDMA's therapeutic use was prohibited. Early supporters of therapeutic MDMA protested that drug-war paranoia led to the premature banning of a potentially useful drug with significant benign applications. The restrictive scheduling of MDMA stifled research into its clinical potential, and research

a See Chapters Two and Three for more detail about the potential benefits of the therapeutic use of MDMA, which relates to our call for the rescheduling of MDMA in Phase 1 of the roadmap to regulation.

during the 1990s almost exclusively focused on MDMA's potential harms. However, in 1995 Charles Grob published the first double-blind, placebo-controlled dose-response safety study of MDMA, showing that MDMA could be safely administered within a controlled clinical environment[20]. Despite the bureaucratic hurdles created by the restrictive scheduling of MDMA (as discussed in Chapter Three of this report), research is progressing with positive preliminary results. MDMA-assisted psychotherapy is currently being investigated for use in the treatment of conditions including post-traumatic stress disorder (PTSD)[21, 22], social anxiety in autistic adults[23], and alcoholism[24].

Outside of the clinical context, the drug established a wider appeal beyond the therapeutic uses first identified by Shulgin. Marketed as 'Ecstasy', the non-therapeutic, recreational use of MDMA began to grow during the 1980s. With the explosion of acid house music and rave culture during the 'Second Summer of Love' in 1988/89, MDMA became a popular psychoactive substance in the UK and beyond[25, 26]. Acid house and rave culture in the early 1990s matured into a significant global youth culture with dancing on MDMA at its centre[27, 28], alongside the use of other drugs such as amphetamine ('speed') and LSD ('acid')[29]. The feelings of 'openness', generosity, euphoria, and energy engendered by MDMA[30] have proved popular amongst music-loving party-people. As Reynolds succinctly writes, 'MDMA turned out to have a uniquely synergistic interaction with music, especially up-tempo, repetitive electronic dance music'[28]. However, MDMA was not only used at raves, but also had a much broader appeal, notably within gay party scenes in the US.

In the UK, the control measures taken against acid house parties and raves in the late 1980s and throughout the 1990s were unprecedented, and so may be explained as an indication of their disruptive presence and as a historical continuation of the criminalisation of 'dancing on drugs'[31]. The 1994 Criminal Justice Act criminalised gatherings of more than fifty people (later reduced to ten) listening to 'amplified music' characterised in the legislation as a 'series of

repetitive beats'. Despite widespread 'fight for your right to party' protests by young ravers across the UK, the legislation was passed. However, raves had already moved from abandoned warehouses, urban wasteland sites, and farmers' fields into both ad hoc and purpose-built dance club spaces such as Ministry of Sound in London, which obtained the first UK twenty-four-hour music-and-dance late licence in 1990[32].

Fig. 4
*A festival*

Source: Pixabay

Over the past three decades, global dance cultures linked to MDMA use have been both profoundly *commercialised*[33] and *criminalised* (e.g., police raiding licensed dance events; police sniffer dogs at dance events). Today, dance cultures involve millions of avid fans across the globe dedicated to an eclectic array of dance music sub-genres. In recent years we have seen the enduring appeal of house music, the growth and maturation of European techno and trance music scenes, and the emergence of contemporary electronic dance music ('EDM') in the US. In part related to the enduring appeal of dance music cultures, demand for MDMA has remained a strong feature of the global drugs landscape, with UK researchers highlighting the persistence of MDMA use and related 'poverty of policy' for its users[34].

MDMA has a special place in the hearts of many dance music fans. The 'smiley face' symbol that became an icon of the late 1980s rave scene is redolent

of the intimacy and general bonhomie still experienced at contemporary events whilst under the influence of MDMA. Any policy response to control the use and reduce the harms of MDMA must be based on an understanding of the material and symbolic role the drug has played – and continues to play – in local and global dance music cultures, youth cultures, and youth identities more generally[35, 36]. The UK Criminal Justice Act 1994 is an example of the failure of governments to develop nuanced and effective policy responses to global youth, music, and drug cultures.

If there is one vital lesson to be learned from recounting the history of MDMA, it is that the specific 'setting' in which MDMA is consumed is crucial to the risk profile of the drug and the risks users face[37, 38, 39, 40, 41]. Contemporary dance spaces (mainly indoor, with alcohol readily available) have considerably different risk profiles for people who use MDMA than the rave spaces of the past. As illicit rave culture became rapidly commercialised and criminalised, party-people moved into the hot and sweaty spaces of indoor nightclubs, non-air-conditioned warehouses, and large commercial outdoor festivals. Whilst the move to licensed indoor venues did reduce some of the risks of large unlicensed rave events, which included a lack of adequate security, welfare, and health and safety measures, it was not all good news. Dehydration and overheating emerged as potential risks, linked to a lack of available drinking water and poor venue temperature control in commercial venues (these issues are covered in more detail in Chapters Two and Three).

The acid house parties and illegal raves of the late 1980s and 1990s were often 'dry events', meaning alcohol was not always readily available to purchase. Today, the norm is for alcohol to be available at music venues and events where MDMA use is also prevalent. As rave culture was brought into licensed venues in the early 1990s and growing numbers of young people abandoned alcohol, or at least reduced their use of it in favour of MDMA, the alcohol industry made significant inroads into what had previously looked like a shrinking market.

They did this by lobbying the UK government to curtail raves and by adapting their marketing of alcoholic drinks, describing their effects as similar to the 'psychoactive effect' of illegal drugs. Marketing strategies included co-opting the visual culture of the dance music scene into alcohol branding and marketing, often in conjunction with highly sweetened alcoholic drinks (so-called 'alcopops') and premixed bottled cocktails or shots designed to appeal to youth consumers in night-time party environments[42].

The 2000s saw the emergence of a 'new culture of intoxication'[43] which encouraged binge drinking, a culture which continues today in many UK towns and cities[44]. Alcohol-focused leisure spaces dominate the UK's night-time economy (NTE), with large food and drink chains purchasing buildings in urban centres to offer 'food and booze' to customers. Independent music venues have either been closed or remain under threat of closure as commercial, retail, and residential developers buy up increasingly lucrative land in urban centres. Despite these changes, for many people there remains no satisfactory substitute for the physical and mental effects of MDMA in tailor-made multisensory music-focused environments. The demand for MDMA has been resilient[b, 45], despite the heavy marketing of alcohol in the UK's NTE and a changing UK drug landscape characterised by such developments as the rise in powder cocaine use since 2011/12, and the fall in cannabis use amongst young people over the past two decades[45, c, 46, 47].

Another lesson we can learn from the history of MDMA is how the drug needs to be understood in relation to other drugs such as alcohol (as outlined

b There was a significant increase in last-year use of MDMA among 16–24-year-olds in England and Wales between 2011/12 (3.3%) and 2017/18 (5.1%) (Flatley 2018).

c In England and Wales between 2011/12 and 2017/18, last-year use of powder cocaine increased from 2.1% to 2.6% among 16–59-year-olds, and from 4.1% to 6.0% among 16–24-year-olds (Flatley 2018, p.5). Last-year use of cannabis among 16–24-year-olds peaked in 1998 (28.2%), had more than halved by 2012/13 (13.5%), and now stands at 16.7%.

above) and cocaine when consumed in private, semi-private, and public spaces of recreational drug use[48, 49]. Polydrug use, such as cannabis use before, during, and after MDMA use on a night out, has long been the norm. As previously noted, amphetamines and LSD were also prevalent in the early rave days. In fact, in a study of polydrug use conducted amongst nearly 5,000 participants who regularly attended UK dance music events in 1999, under 4% took MDMA on its own, whereas 77% took it with amphetamines, 75% with cannabis, and 63% with tobacco[50]. MDMA may have fuelled the emergent rave scene, but other (often cheaper and easier to access) legal and illegal drugs have historically played their role too, as they continue to do today. Alcohol use and, more recently, powder cocaine use are prevalent across contemporary NTE spaces, which include dance spaces. The fact that MDMA is frequently but one of a range of drugs (including alcohol) fuelling a night out dancing has crucial policy implications.

Over the past three decades, the availability, purity, and potency of MDMA has been variable. In the UK from 2008 to 2012, access to MDMA of reliably consistent potency and purity decreased. This was likely due to an international crackdown on the sale and distribution of safrole/sassafras oil, a key precursor in the manufacturing of MDMA. Synthetic safrole was internationally prohibited in 1992 due to its role in MDMA production[d], but safrole oil derived from plant sources remained uncontrolled and legally available due to its use in the production of fragrances, cosmetics, and pesticides. In 2006 Cambodian authorities were encouraged to control safrole oil due to its association with MDMA production and issues concerning the sustainability of the *mreah prew phnom* tree (internationally identified as *Cinnamomum parthenoxylon)* from which the oil was being illegally extracted. Large quantities of safrole oil were seized by international law enforcement agencies: in 2008, thirty-three tonnes of the oil were intercepted and burned in a public ceremony in Cambodia. The number of

d In 1992, safrole in its pure chemical form was added to the list of controlled substances under the 1988 United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. See https://www.unodc.org/pdf/convention_1988_en.pdf.

active safrole distilleries in the western Cardamom Mountains decreased from seventy-five to zero between 2006 and 2008[51].

The resulting reduction in the supply of MDMA did not eliminate the appetite or market for psychoactive drugs. Rather, use was partially displaced to newly emergent 'legal highs', since termed 'novel psychoactive substances' (NPS). Dance music clubbers and those attending gay-friendly clubs became early adopters of NPS such as mephedrone[52], although for some attending gay-friendly clubs mephedrone was used alongside rather than instead of MDMA[53]. Mephedrone mimics some of the stimulant effects of MDMA[54] but poses greater acute, sub-acute, and chronic risks, notably a compulsion to re-dose and signs of dependency amongst a third of young users who were recruited to the study through their involvement in dance music scenes[55].

In 2010 the legally available synthetic PMK-glycidate started to be used as a pre-precursor, from which precursors such as PMK and safrole can be synthesised and processed into MDMA[10]. As use of this glycidate spread, reliable access to more consistently high-quality MDMA grew, and by 2012 the market had recovered[e]. In turn, the market for mephedrone contracted considerably, although it did not disappear entirely, especially amongst men who have sex with men in the UK[56]. In March 2019, PMK-glycidate, PMK glycidic acid and Alpha-phenylacetoacetamide (APAA) were added to the list of drugs controlled under the 1988 UN Convention against Traffic in Narcotic Drugs and Psychotropic Substances[57]. It remains to be seen how this ban will affect the MDMA market.

e According to the 2016 report on MDMA by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), PMK-glycidate, a synthetically produced pre-precursor, has been identified as one factor revitalising the global market in MDMA from around 2010/11 onwards. See p.13 of http://www.emcdda.europa.eu/system/files/publications/2473/TD0116348ENN.pdf.

## 1.2 UK MDMA use and consumption practices today

MDMA is the third most popular illegal drug among all UK adults after cannabis and cocaine, and the third most popular among young people aged 16–24 who use drugs[f]. Around 3 million UK adults (aged 16–59) have used MDMA in their lifetimes[45, 46], whilst an estimated 300,000 young people aged 16–24 have taken MDMA in the past year, and over 100,000 in the past month[45, g]. Men are more likely than women to use MDMA[29, 46]. Young people are more likely than adults to take MDMA, and those who frequent UK nightclubs (especially four or more times a month) are also more likely to take MDMA than are their non-clubbing counterparts[45]. Polydrug use is a particularly common and potentially risky trait reported by MDMA users. For example, 57% of UK users reported taking MDMA simultaneously with other illegal drugs[h]. Where MDMA was taken simultaneously, it was most often used with cannabis (64%), powder cocaine (47%), and mephedrone (25%)[45, 47]. Alcohol is also commonly consumed with MDMA, most notably in NTE settings and at music festivals where alcohol consumption is normalised[43].

Despite its popularity and in marked contrast with many other popular legal and illegal drugs such as alcohol and cannabis, occasional use of MDMA is typical, whilst intensive use is very rare. Of those UK adults who had used MDMA in the previous year, 93% said they used it once a month or less, and the proportion of last-year users who took MDMA more than once a month

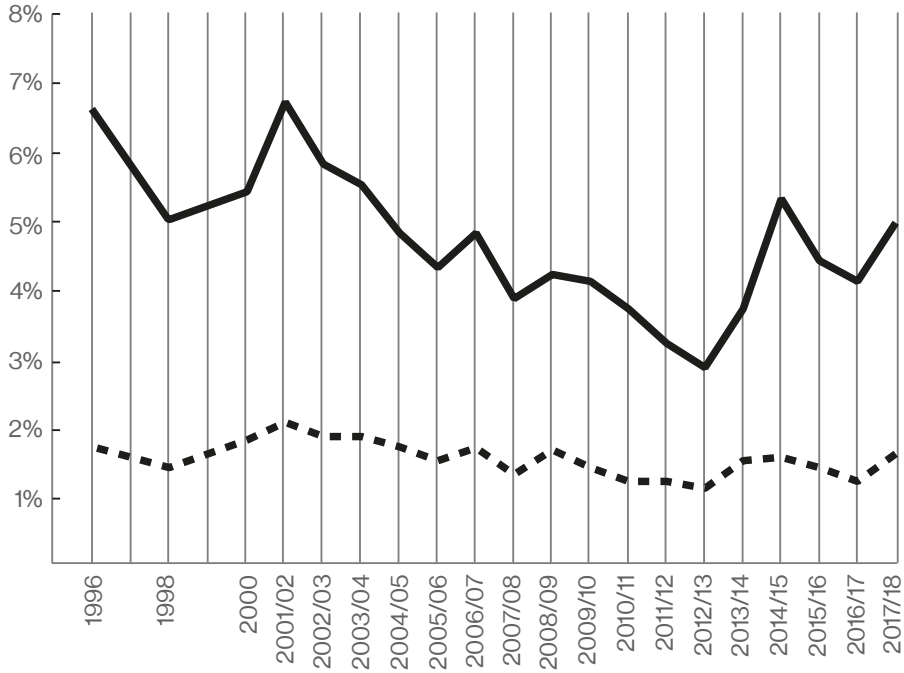
f It is worth noting that the prevalence figures for lifetime, past-year, and past-month use of MDMA (and indeed of other drugs) as captured by national annual GPS are generally recognised to be underestimates given that GPS systematically exclude certain groups of young people, notably students and street homeless people.

g Past-month use of drugs is understood as 'frequent' use across both GPS and targeted population surveys.

h The issue of both polydrug use and polysubstance use by MDMA consumers is dealt with in more detail in Chapter Three where we lay out the two phases of our roadmap to regulation.

Fig. 5

*Proportion of adults using ecstasy in the last year, 16 to 24 [ ——— ] and 16 to 59 [ - - - - ] year olds, 1996 to 2017/18 CSEW*




Source:
Home Office.
Apendix Tables 1.02 & 1.06

has fallen over the last decade[45, 46, 47]. That intensive use is rare is partially related to how MDMA acts on users' bodies, encouraging the release and inhibiting the reuptake of serotonin which brings with it the empathetic, euphoric, and energetic effects the drug is known for. However, continued use of MDMA in any given 'session' offers diminishing returns as the user's brain needs a period of recovery before MDMA can work again. This means that MDMA does not lend itself well (if at all) to daily use, with users typically restricting their use to specific time-bounded sessions unfolding in pre-club, in-club, and post-club spaces, and characteristically at weekends, with at least a week-long break in between to maximise the drug's benefits. However, intensive use across short time spans is apparent during clubbing holidays and festivals[58]. Prolonged daily use of MDMA – an indicator of problematic use – is atypical and most usually associated with co-occurring mental or physical conditions, with only a few cases reported[59, 60]. Very few people seek treatment for problematic use of MDMA. For example, statistics from the most recent Public Health England report reveal that, in every year since 2005, less than 1% of adults seeking treatment for drug problems cited MDMA as

their primary problem drug[61]. Cannabis and alcohol continue to be the most cited primary problem drugs amongst young people in treatment across the UK (92%) as compared to 'Ecstasy' (3%)[62].

For MDMA users, the most common route of administration is oral. Pills, capsules, and MDMA 'bombs' (a dose of crystal/powder wrapped in a cigarette paper) are swallowed. Some users prefer to lick a finger dipped into powder or rub it into their gums. A minority use nasal inhalation ('snorting') as it results in a faster onset of the effects but a shorter high. Injection and other routes of administration are used very rarely[63,64]. With oral administration, it takes twenty to sixty minutes before effects are felt; peak effects are reached between sixty and ninety minutes, whilst the total high lasts for around five hours[65]. Given the 'time lag' between oral ingestion of MDMA and its effects, recent harm reduction advice to consume only quarter or half pills, and/or to 'crush, dab, and wait' when consuming MDMA crystal/powders is particularly important, notably the 'crush' aspect, which can help users avoid consuming a larger dose than they intend to take[66]. Sticking to quarter or half pills (at least when a new 'batch' of MDMA pills is bought) has a long tradition amongst experienced users as part of lay harm reduction advice adopted by 'underground' ravers/dance clubbers[67]. Given the recent proliferation of high-potency pills (discussed below), harm reduction advice around the amount consumed is particularly welcome amongst the many MDMA users concerned about drug safety.

The existing evidence makes it clear that those who engage in the UK's NTE are more likely to use drugs than those who do not. Similar observations about the synergistic relationship between NTEs and drug use have been made by European NTE researchers[68]. UK annual GPS findings reveal that more *frequent* attendance at bars and nightclubs is associated with more *recent* drug use, with 'in the past month' used as a standardised proxy for recent use[i]. MDMA use was

i One example is the Crime Survey for England and Wales, formerly the British Crime Survey, which captures annual self-report data on the use of illegal substances.

found to be significantly higher among those who had visited a pub or bar at least nine times in the last month than among those who had not visited a pub or bar at all in the last month[45]. Unsurprisingly given its stimulant and pro-social effects, as previously noted, MDMA is strongly associated with nightlife and (dance) music settings, such as clubs, festivals, and parties[69, 70]. However, MDMA-related deaths also occur in the home[71], serving as a reminder that non-stereotypical patterns of use must not be overlooked as particularly at-risk users may have atypical styles of use. This also highlights the need to understand MDMA use in private/domestic settings as potentially risky (or safer) spaces involving specific patterns of drug use, such as the use of ketamine and benzodiazepines (e.g., Xanax) to 'come down' from the stimulant effects of MDMA.

## 1.3 Global MDMA use

MDMA use is apparent across all continents[72]. Whilst this report concentrates on the situation in the UK (and to a lesser extent, Europe, the US, Canada, and Australia), MDMA use is widespread around much of the world, albeit with local specificities. In terms of production and distribution, MDMA is embedded in globalised illegal drug supply chains, a point taken up in Chapter Three of this report. Western countries, notably in Europe and the US, Canada, and Australia, have relatively high rates of MDMA use[5]. MDMA use is also growing in non-Western countries with large populations of young people and growing middle classes, including China, Hong Kong, India, and Taiwan. In these countries, use of amphetamine-type substances (including MDMA) has 'grown dramatically'[5].

Dance music cultures, and the concomitant use of MDMA, are a global phenomenon. It is not surprising then that the patterns of criminalisation and demonisation of these cultures seen in the UK have been repeated internationally. Their social and cultural value from the perspective of their participants goes largely unrecognised because of their link to 'criminality' in the form of MDMA and other drug use. This is one aspect of the continuing politicisation of MDMA which has shut down discussion about policy change. In the UK, as elsewhere, MDMA is firmly positioned as an inherently 'dangerous drug' that kills indiscriminately, and so is deserving of its Class A status. This ignores what the scientific evidence and user experiences indicate: that MDMA-related harms, whilst complex, are at least in part related to consumption patterns (e.g., taking too high a dose or mixing it with other drugs) combined with aspects of the illegal MDMA market (e.g., no dose control, adulteration). This means that MDMA use is rendered far more dangerous than it might otherwise be.

The reputation of MDMA as a dangerous drug means that one of the main challenges faced at each stage along the roadmap to regulation is resistance to change from political classes and public commentators who see little popular

appeal in any change in drug policy that might be framed as going 'soft on drugs'. However, this should not deter policy change. Evidence from comparable progressive incremental shifts, such as equality legislation in the UK from the criminalisation of homosexuality to equal marriage, or tobacco control up to the ban on smoking in public, suggests that public opinion can both lead and follow policy change in a virtuous circle. Key objections to reform typically involve citing the risks and harms of MDMA use. We now analyse the evidence on risks and harms relating to MDMA, and show how those associated with MDMA are predominantly related to its prohibition.

Chapter Two

# MDMA-Related Harms Under Prohibition

## 2.1 Inherent harms? 'High-dose' and adulterated MDMA products

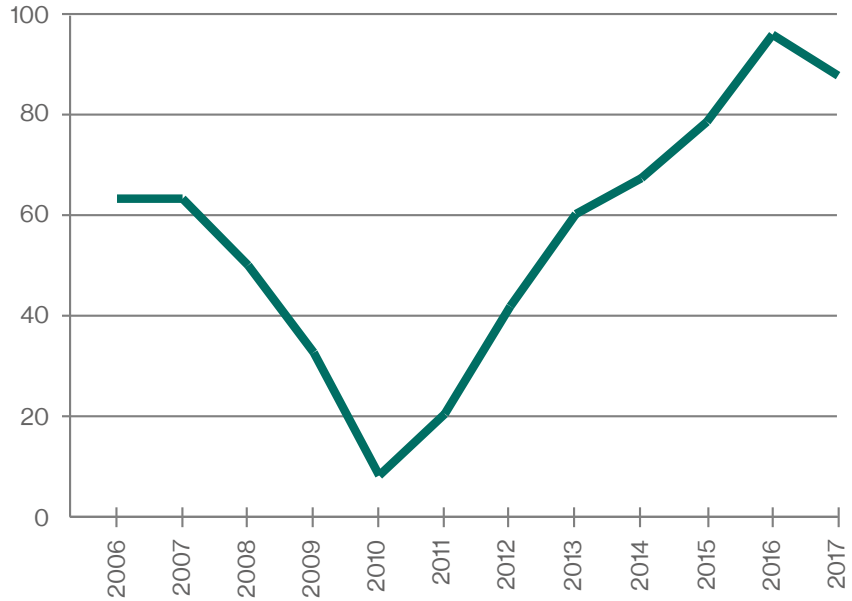
Drugs differ in the degree to which their risks are intrinsic or contingent on circumstance. Optimisation of the political and socio-cultural circumstances in which a drug's use occurs can increase the proportion of users enjoying the drug without harm, but only up to a 'ceiling', representing the intrinsic, ever-present risks of the drug. Tobacco for example has a low 'ceiling': a typical person who initiates smoking even within a well-regulated environment will nonetheless face considerable chronic risks, which include addiction, bodily harm, and smoking-associated diseases. MDMA in contrast has a relatively high 'ceiling' due to its low dependency potential[73] and the fact that no specific syndrome of chronic MDMA harm has been conclusively identified that cannot be reversed with abstinence[74,75]. MDMA's risks are primarily related to acute adverse health effects that have been reported following MDMA consumption. However, there is currently no consensus on the fatal blood concentration level of MDMA, and it is unclear to what extent the harms are attributable to the toxicity of MDMA alone, or to the circumstances in which the drug is taken[76].

The principal concern in relation to MDMA are MDMA-related deaths[a]. In the UK these peaked in frequency in the early 2000s and then fell from 2005 to 2010. Between 2010 and 2016 the number of MDMA-related deaths climbed every year, from nine in 2010 to ninety-seven in 2016, the highest figure ever recorded. Data for the most recent year available (2017) for the UK *in its entirety* (England and Wales, Scotland, and Northern Ireland combined) show a slight fall, with a total of eighty-six MDMA-related deaths[77,78,79]. However, as we go

a It is worth noting that these are called 'Ecstasy-type product'-related deaths in Scotland.

to press in the autumn of 2019, the latest figures for MDMA-related deaths *in England and Wales alone* have been released, showing a staggering increase from fifty-six deaths associated with MDMA use in 2017, to ninety-two deaths in 2018[80]. Of these reported deaths, fifty-five were related to MDMA use without other drugs, while thirty-seven involved poly-drug use[80]. The latest data from Scotland (2018) also reveals an increase in deaths from the consumption of (what the Scottish government calls) 'Ecstasy-type products' – from twenty-seven in 2017 to thirty-five in 2018. However, of the thirty-five deaths, only two were reported as being related solely to 'Ecstasy-type products'[81]. Data from 2018 for Northern Ireland is not yet available.

Figure 6.
*Number of UK MDMA and Ecstasy-related deaths, 2006–17*




Source:
Office of National Statistics / National Records of Scotland / Northern Ireland Statistics and Research Agency

Statistics for the UK as a whole combine deaths associated with MDMA use alone with deaths associated with MDMA use in conjunction with other drugs, making it more difficult to determine the precise cause of death. For England and Wales, and for Scotland, the numbers are recorded separately for both MDMA alone and MDMA with other drugs, but the figure propagated by the media and highlighted in government reports is the one that *includes* the use of MDMA with other psychoactive drugs[82]. This results in an exaggerated

depiction of the rate of MDMA-related deaths and obscures the fact that other drugs were consumed in many of these reported deaths. It is also worth noting that MDMA use in the UK amongst 16–24-year-olds has increased since 2012[45], and that this age group is considered to be more vulnerable to some of the adverse effects of MDMA[b].

Figure 7.
*Ecstasy*

Source:
Tumblr tesk187

The increase in MDMA-related deaths has been mirrored by an increase in 'high-dose' MDMA/'Ecstasy' pills in circulation, and the presence of high-risk adulterants such as PMA (paramethoxyamphetamine) and PMMA (paramethoxymethamphetamine) in pills mis-sold as MDMA, which heighten the likelihood of harm to users. Herein lies the irony. Both the lack of control over dosage (or rather, the lack of user knowledge about purity to inform dosage decisions) and the presence of toxic adulterants, including prohibited NPS[83], are directly attributable to global and national prohibitionist policies. There is no 'inevitability' about these risks of MDMA use. Rather, risks and potential harms

b It is also worth noting that whilst women are considered more vulnerable to the negative effects of MDMA use, it is men who feature most heavily in UK MDMA-related death statistics. This is most likely related to the higher prevalence of MDMA use amongst young men as compared to young women.

are emergent in the intersections of law enforcement policies and practice, and the vagaries of illegal and unregulated drug markets, alongside user practices within varied leisure spaces and times.

Such nuances are lost on those who seek to maintain the prohibitionist status quo[84]. The risks and emergent harms of MDMA have, for example, been uncritically linked to the adulterants PMA and PMMA, mis-sold as MDMA. That these adulterants with high risk profiles are only present because of unregulated production processes within the illegal market for MDMA is ignored by the UK government and most of the British press. The market for PMA and PMMA alone is non-existent, yet they are conflated with MDMA and presented by the UK government as (further) validation of their uncompromising prohibitionist approach, as this statement from a Home Office spokesperson highlights:

> MDMA, PMA and PMMA are all illegal Class A drugs. They destroy lives, cause misery to families and communities, and this government has no intention of decriminalizing them. No drug-taking can be assumed to be safe.[85]

Internationally, media and politicians have voiced concern about MDMA, concern which is largely unrepresentative of the risks policy makers should realistically be weighing up when considering drug policy. Whilst MDMA tabloid stories may be less ubiquitous than they once were, such attention has effectively shaped public opinion to the point where, relative to other drugs, the risks and potential harms of MDMA use appear over-emphasised, exaggerated, and, importantly, are decoupled from the contexts in which most MDMA-related deaths occur.

Presently, MDMA doses contained in single tablets and cumulative doses consumed during a 'session' (drug consumption period) are highly variable.

Maximal ratings of desired effects are reported for tablets containing between 80 and 100 mg of MDMA[86]. However, for more experienced users, 80–100 mg may be considered a suboptimal dose. 'High doses' may produce undesired effects, notably amongst inexperienced, typically young, and/or occasional users. It has been found for example that undesired effects predominate above single doses of 120 mg for inexperienced and irregular users, but not among more experienced and regular users[86]. Gender is also important in relation to vulnerability to potent, high-dose MDMA pills or crystal, as women are more vulnerable to certain adverse effects[87, 88]. Young, female, novice users therefore combine multiple vulnerabilities.

The relationship between dose and potential unwanted effects is complicated and MDMA use cannot be considered in isolation from the user and the users' setting. However, variability in dose and high-dose (also called 'high-strength') products heighten the risks. In the illegal MDMA market, individual tablets and capsules have been found to contain hugely variable doses. A capsule seized from a rave in California in 2010 contained 270 mg of MDMA; twelve people suffered life-threatening reactions to MDMA at this single event, two of whom died[89]. Whilst this event was exceptional, it demonstrates the dangers inherent in the distribution of MDMA as an illegal and hence unregulated product. If these young people had known the dosage contained within their pills and had been sufficiently informed to understand the implication of such dosages, they may have made different consumption choices and such deaths may have been prevented. Serious acute adverse effects and deaths linked to MDMA occur through several mechanisms. None of them are as simple as an 'overdose' and most are preventable through a combination of screening for pre-existing medical conditions[c] and comprehensive harm reduction advice, for example around the risks of water intoxication from excessive water intake when

c Note that this is suggested as one aspect of a legal access regulation model (see Chapter Three) that would include pre-screening for certain pre-existing conditions which render users more vulnerable to MDMA.

trying to prevent dehydration after taking MDMA (hyponatraemia). Risks include serotonin syndrome, liver failure, hyperpyrexia (uncontrolled soaring temperature), or hyponatraemia, when levels of sodium in the blood become abnormally low and abnormal water regulation causes brain swelling[77].

Dehydration and heatstroke remain key concerns for harm reduction initiatives aimed at contemporary MDMA users. Following two drug-related deaths at a festival in the South of England in June 2018, Professor Fiona Measham, founder of the UK-based drug checking and harm reduction organisation The Loop, called for greater responsibility amongst festival organisers with regard to the visible availability of drinking water for festival goers[90], notably during unseasonably hot weather, as people using MDMA can be more vulnerable to overheating[91]. Management of temperature and hydration is an important task for people dancing whilst on MDMA, as both overheating with dehydration[92] and drinking too much water[93] have been linked to MDMA medical emergencies and fatalities. Experienced MDMA users remain mindful of the need for periodic rest, cooling down, moderate water/juice intake, and the avoidance of alcohol intoxication before, during, and after an MDMA 'session'[d].

Figure 8.

*Ecstasy pills handed into The Loop*


Source:
The Loop

As previously noted, MDMA and its relationship with global rave and now post-rave dance music cultures, where (typically young) people attend dance music events such as warehouse parties and festivals, have received sustained

d 'Session' is now used in common parlance to denote a period in which MDMA and other illegal and legal psychoactive substances are consumed, e.g., across the duration of a 'big night out'. See for example [www.vice.com/en_uk/topic/safe-sesh]

and typically sensationalist press reporting[94]. Indeed, inaccurate documenting, press misrepresentations, and public misconceptions about MDMA (and indeed illegal drugs more generally) is a key challenge for any roadmap to regulation[95]. MDMA-related deaths have historically received considerable media coverage, proportionately much more than any other drugs. Forsyth's classic study of drug-related deaths in Scotland in the 1990s found that the press reported on every single death where MDMA was implicated, whereas deaths related to other drugs were less likely to be reported on, with only one in fifty diazepam-related deaths and one in three amphetamine-related deaths covered by the media in the same period[96]. More recent research in the UK has found similar imbalances and inaccuracies in reporting on drug-related issues[97]. US harm reduction organisations have spent time counteracting press coverage of MDMA-related deaths, some of which involves the spreading of misinformation about 'Ecstasy overdoses' which do not capture the reality of why some people who have used MDMA have died[98]. A more open and honest dialogue about MDMA-related deaths is needed, and the troubling relationship between prohibitionist drug policies and MDMA-related deaths properly addressed.

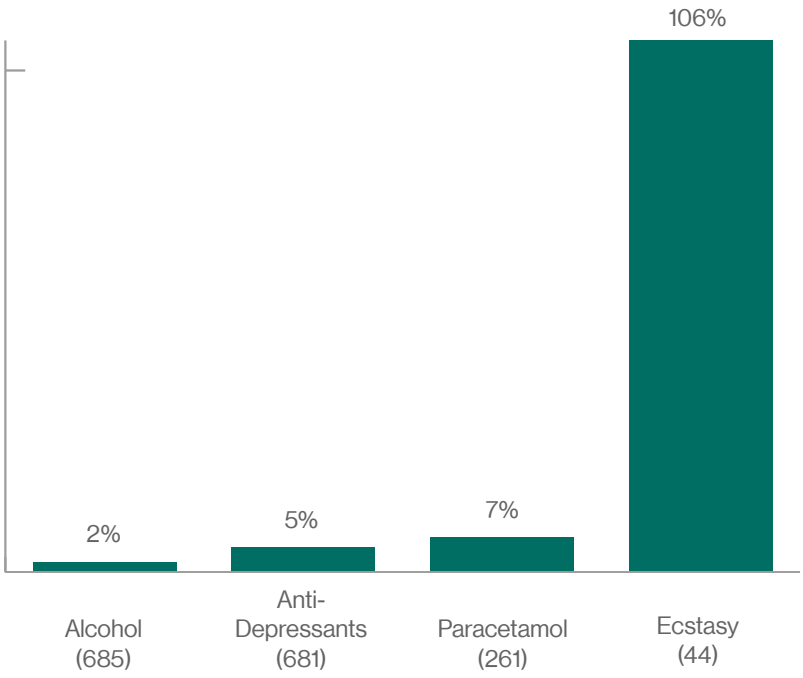



Figure 9.

*Percentage of Drug Deaths Reported in the Media in 2008.*

Source: [informationisbeautiful.net]

## Harms associated with use 2.2

It is worth stressing that it is hard to assess the risks of consuming a particular drug at either the individual or population level outside of its historical and cultural context. Large-scale recreational MDMA use has only been studied under conditions of prohibition, and so the evidence can only tell us, at best, how risky MDMA is in that specific context. Aside from the pre-ban era of MDMA use (which was small scale and not systematically studied), recreational users have not had access to a pure, standardised MDMA product, so we cannot know for certain what harms, at what levels, may be attendant to that scenario. However, as of October 2018, unadulterated MDMA has been administered to 1,570 participants in clinical research settings investigating the effects of MDMA and its potential therapeutic utility[99, 100, 101]. These experiments have demonstrated that single moderate doses of MDMA can be administered safely in a controlled environment, producing consistent and predictable responses with minimal negative side effects. No serious adverse events that required emergency treatment have been recorded[102]. It is important, however, to bear in mind the distinction between the potential harms associated with recreational use and those incurred in the clinical setting, where pure MDMA is administered only a few times in the context of a supportive psychotherapy session[103].

### Acute harms and unwanted effects 2.2.1

Commonly reported undesirable effects of MDMA include characteristic physiological reactions, such as jaw clenching ('gurning'), dry mouth, tachycardia, shivering, feeling cold, sweating, dizziness, nausea, and increased heart rate and blood pressure. More than half of users[104] experience a host of other, rarely serious, physiological and mood symptoms[105, 106, 107, 108]. The exact combination of effects depends on factors such as dose, frequency of use, lifetime MDMA exposure, personal characteristics (e.g., individual differences in drug metabolism, pre-existing cardiovascular problems, personal and family history of mental

illness, etc.), other drugs taken, and the setting. In addition, there are gender differences in responses to MDMA, with women reporting stronger hallucinatory effects, and being more likely than men to experience certain adverse events[109, 110]. MDMA users most frequently present for emergency treatment with symptoms such as dizziness, nausea, or feeling unwell or strange; or arrive having collapsed at a venue[111, 112]. The most common treatments required are monitoring, reassurance, and rehydration.

MDMA can lead to more serious acute physical harms. By simultaneously increasing metabolic heat generation and impairing heat dissipation through vasoconstriction, MDMA typically increases body temperature, an effect that can occasionally develop into severe hyperthermia[113], which can lead to multi-organ failure including acute liver failure[114]. While under laboratory conditions, higher doses of MDMA cause an increase in body temperature comparable to that experienced during exercise. Hyperthermia is a leading cause of MDMA-related deaths[115]. Although deaths from MDMA-induced hyperthermia may happen in other contexts[116], risks to users are exacerbated by external factors associated with indoor raves and nightclubs: the physical activity of dancing, coupled with high ambient temperatures and insufficient ventilation, as well as overcrowding[114].

Another fatal complication related to MDMA consumption is the previously mentioned hyponatraemia, when levels of sodium in the blood become abnormally low and abnormal water regulation causes cellular swelling in the brain. MDMA causes the brain to release hormones (e.g., arginine vasopressin) that cause water retention. This can become problematic when users drink large amounts of water in an effort to stay hydrated. Evidence suggests that women maybe more prone to hyponatraemia than men[117].

MDMA use reliably leads to transient increases in blood pressure and heart rate, with greater elevations witnessed in male users[109]. Although in

most users these changes are akin to those witnessed during exercise and are typically well tolerated[118, 119], such increases may nonetheless increase the risk of several cardiovascular harms, including stroke, myocardial infarction, and subarachnoid haemorrhage[120, 121, 122]. Although such events are well-established complications of hypertension, it is noteworthy that case reports linking such events to MDMA use rarely confirm the presence of MDMA, so the true risk rate remains unknown. No clinical trial of MDMA has so far recorded any such event.

MDMA is also a powerful releaser of serotonin and when used alongside other serotonin-releasing drugs such as the stimulants cocaine and amphetamine, or commonly prescribed selective serotonin reuptake inhibitor antidepressants, it may cause a rapid, synergistic rise of serotonin (5-HT) concentration in the central nervous system. This can lead to the acute and sometimes lethal medical emergency known as serotonin syndrome[123]. Regarding these potential harms, it should be noted that it is difficult to establish to what extent these effects are specifically attributable to MDMA, because factors such as poly-drug use and drug–drug interactions, high dosages, personal vulnerabilities, or the presence of adulterants could also contribute to these effects[77].

## Sub-acute effects and chronic harms 2.2.2

No specific syndrome of chronic MDMA harm has been conclusively identified in recent meta-analyses in moderate users[75]. Chronic high doses could potentially lead to abnormalities in the serotonin system[91, 124], although these changes seem to be reversible with abstinence[125]**.** In the days immediately following MDMA use, many users report experiencing negative after-effects, such as low mood and anxiety, sleep disturbances, or memory problems[126], known colloquially as the 'comedown' or 'mid-week-blues'. However, the role of MDMA in these effects is unclear, as other factors associated with a night out, such as alcohol consumption, sleep deprivation and disturbance of circadian rhythms, and poor nutrition and

hydration, can be major contributors[127, 128]. In contrast, only a small minority of people taking pure, measured doses of lab-grade MDMA in the daytime report experiencing negative physiological and psychological symptoms in the three to five days post-drug[129].

Several cases of sub-acute liver failure, in the absence of any hyperthermia, have been reported in the days following an MDMA 'session', or after months of regular use. The precise cause of liver failure in these instances is poorly understood, although a number of patients who return to MDMA use after recovery experience a renewal of the hepatotoxic effects, suggesting an immunological mechanism[115]. As above, the nature of an unregulated market makes it impossible to ascertain whether the liver toxicity in these cases was driven primarily by MDMA, another psychoactive compound contained in a tablet, some adulterant, or the co-ingestion of MDMA with another substance in the context of polydrug use. Across the completed clinical trials using MDMA, there have been no recorded incidents of liver disease or hepatotoxicity.

It would be unethical to administer MDMA to humans *chronically* in a controlled experiment, to see what damage might occur when other causes (such as adulteration and concurrent use of other drugs) are excluded. This leaves us with only a partial understanding of the risks associated with occasional or regular use over months, years, and lifetimes. The available evidence comes from animal experimentation, observational studies of human users, and accounts of harm, such as case reports. On the basis of these studies, some experts believe that chronic high-dose MDMA use can cause neurological, psychological, and mood problems; sleep problems; and cognitive impairments[76, 108, 130, 131, 132], and claim this is likely the result of direct neurotoxicity[133, 134]. However, such neurotoxic effects have been challenged by others on various grounds[75, 76, 108, 135, 136]. In 2018, it was found that many previous brain-imaging studies on the neurotoxic harms of MDMA use have disproportionally recruited unusually heavy users as participants[137]. Research participants in ten key studies had

consumed on average 720% more MDMA pills than typical users captured by for example the 2015 Global Drug Survey[138]. The implications of this study are that the conclusions of some of the neuroimaging literature on MDMA may significantly overestimate the extent of serotonergic alterations related to more moderate patterns of MDMA use that characterise most consumers. The translatability to humans of studies producing evidence of harm in animals is likewise questionable, as many involve regular and high doses of MDMA that do not reflect typical user behaviour[139].

Meta-analyses, when data are pooled to increase the reliability of findings, tend to support the existence of statistically significant but subclinical deficits in cognitive performance among at least the most regular MDMA users, i.e., they may perform slightly worse than controls on specific tests (e.g., recalling lists of words), but remain within the normal range[108, 140]. However, sources of bias have been identified in these data that still prevent certainty. When samples of MDMA users are compared with non-users and found to show deficits, findings are muddied by the fact that most people who use MDMA also use one or more other drugs. In a study designed explicitly to sample only those people who use MDMA who do not use other drugs, the link to deficits disappeared[141]. After more than 25 years of research, the spectrum of expert opinion shows no signs of narrowing into consensus. For an illustrative example of such discussion read Parrott (2013)[63] and Doblin et al. (2013)[142].

There is some evidence from both animal and human studies to suggest that reduced serotonin levels following maternal MDMA use can adversely affect foetal development. Although rats exposed to MDMA during pregnancy will bear pups of normal weight and without birth defects[143], the pups of mice exposed daily to high levels of MDMA during pregnancy are more likely than controls to display abnormalities[144]. In mice, the lowest amount of maternal MDMA exposure which led to detected offspring abnormalities was 5 mg/kg/day, equivalent to a 60 kg pregnant woman taking 25 mg of MDMA every

day. This pattern of exposure is unlike any reported usage trend in humans, and as such, while the animal literature has identified that MDMA exerts some developmental toxicity, it is insufficient to provide a clear picture of how typical patterns of MDMA use may harm a developing foetus. Self-report surveys investigating drug use in pregnant mothers[145, 146] have found that poorer motor development at four months is predicted by prenatal MDMA exposure, with more heavily exposed infants performing less well than infants with lower, or no exposure. While more research is required to say conclusively, these differences in development may ultimately resolve as infants grow: by twenty-four months, it was only infants with heavy prenatal exposure to MDMA that displayed detectable differences from normal motor development. Mothers of these infants reported taking an average of 1.7 tablets of ecstasy per week during pregnancy, an amount far in excess of most recreational users.

Long-term cardiovascular effects of MDMA use appear to be limited to the heaviest users. In a small study of eight MDMA users with lifetime exposure of between five and 200 doses, echocardiographic readings revealed no abnormalities[147]. A sonographic investigation of the hearts of twenty-nine MDMA users found cardiac abnormalities indicative of potential valvular heart disease only in those people reporting lifetime cumulative doses of 900 tablets, compared to the average 200 lifetime doses among those with no cardiac abnormalities[148].

A crucial driver of chronic drug harm is dependency. The potential for chronic harm from a drug is limited when users can make a free choice to reduce or cease use as soon as they feel that the costs outweigh the benefits. This is the pattern documented for MDMA. MDMA use appears to be largely self-limiting: at first, users may escalate their doses as users of dependency-forming drugs do, increasing the associated risks. However, in contrast to patterns of use for other drugs, when the cost–benefit balance becomes negative, people who use MDMA spontaneously reduce or stop using[149, 150]. Other people 'grow

out of it' and the dance club scene of which it is a part[151]. Although some users report 'cravings' (but not withdrawal symptoms), several lines of evidence suggest that MDMA has relatively low addictive potential, a conclusion supported by the very low rates of identifiable dependent or problematic use (much less than 1% of UK adults presenting for treatment)[152, 61], despite it being the third most commonly used drug in England and Wales[45].

However, the evidence on MDMA's addictive potential is not unequivocal, and a different interpretation is possible. Presentation to treatment statistics may be misleading, as one study suggested that MDMA users are less inclined to seek treatment than are users of other drugs[63]. Animal studies indicating only a mild reinforcing effect of MDMA may be of limited relevance, as they tend not to reflect patterns of use accurately in humans. Whereas rodent self-administration studies involve single-drug use and intravenous administration, human users often engage in polydrug use, and typically ingest or snort MDMA[153]. These differences, as well as 'bingeing' and high-dose use, may affect the potential for dependency in humans[154]. Further investigation is needed to better characterise the risk of dependency in humans, or other harms that are as-yet unrecognised, e.g., the potential link between MDMA and heart-valve problems[149].

Even the gravest assessments of the burden of chronic MDMA harms to society described in the published literature are relatively minor compared to those of drugs such as alcohol and cocaine with which MDMA often shares space in the recreational drug scene. It would however be misguided to assume that because the evidence linking MDMA use to chronic harms is equivocal, such harms do not exist or do not matter. Perhaps the best reason to take chronic MDMA harms seriously is that users themselves generally do. In the major online drug user forums, there seems to be near universal consensus that regular MDMA use can become problematic[155]. Only 1% of adults in England and Wales who took MDMA in the last year think that it is 'ok' to do so frequently, whilst the majority of adult users of MDMA (68%) took the drug once or twice

a year[45]. That figure, along with the fact that most users do not use regularly, supports a view of people who use MDMA as rational agents who balance their perception of risks and rewards, rather than irrational hedonists who are only discouraged from unrestrained consumption by continued prohibition.

## 2.3 Generations lost: The harm of inaction

Another key harm associated with the prohibition of MDMA is the harm of inaction in the face of emergent drug problems and drug-related deaths, when there are well-established policy options available that could have prevented them. The UK's Misuse of Drug Act (MDA) 1971 established the Advisory Council on the Misuse of Drugs (ACMD), an independent, non-departmental public body of experts from a variety of backgrounds. According to the MDA, the ACMD is duty-bound to give recommendations to the government 'on measures (whether or not involving alteration of the law) which in the opinion of the Council ought to be taken for preventing the misuse of such drugs or dealing with social problems connected with their misuse.' In 2008 the ACMD undertook a thorough review of the harms of MDMA and its legal status, including an appraisal of the scientific evidence available at the time[e],and extensive written and oral evidence from experts from a wide range of disciplines. The result of these efforts was a comprehensive report published in February 2009 which is very clear in terms of its findings and recommendations[156]. The recommendations to government are summarised below:

- Continuation of a harm-minimisation approach to the widespread use of MDMA to be ensured
- Access to the Safer Nightlife[157] guidance to be provided for those who work within the NTE
- Young people to receive adequate education on the risks of using MDMA

e The twelve-month ACMD study included a review of 4,000 academic research papers on MDMA.

to support and encourage abstinence

- Parents/carers, teachers, and those working in the criminal justice system to be informed about the risks of MDMA and how these compare with those of other drugs (notably powder cocaine)
- Better data to be captured regarding the form and constituents of seized MDMA
- MDMA to be re-classified as a Class B drug[f]
- Research to be expanded into the effects of MDMA upon brain mechanisms
- Better data to be captured regarding the nature and extent of MDMA use in under-16s
- Further research to be undertaken to quantify the relative risks of, and public attitudes towards, MDMA in comparison to other drugs
- More information to be gathered on the risks and harms resulting from polysubstance and polydrug use
- More research to be carried out focusing on the role of vulnerability factors that make individuals prone to the harms of MDMA[g]
- A national scheme to be developed for the purposes of testing MDMA with a view to providing harm reduction advice and developing monitoring data[h]
- Research into the medicinal uses of MDMA not to be disadvantaged by the legislation and the position of MDMA in Schedule 1 of the Misuse of Drugs Regulations (MDR) 2001

f MDMA remains a Class A substance under the UK's MDA 1971 after the government indicated that it was not prepared to reclassify it despite the ACMD's recommendation.

g For example, around the role of gender and body mass in instances of water intoxication following excessive water intake related to MDMA use.

h This recommendation directly referenced the Dutch Drugs Information and Monitoring System (DIMS), which remains a world leader in multidata harm reduction best practice. Ten years after the publication of the ACMD's review, inroads have been made in relation to on-site drug testing regimes by UK drug charity The Loop. In the event of decriminalisation, such drug testing regimes should be extended.

Each of the recommendations, except for the last, focused on reducing individual and social harms related to (recreational) MDMA use. However, nearly a decade on from the ACMD's review, we have witnessed the pernicious emergence of NPS, a rise in MDMA prevalence (notably amongst young people aged 16–24), and a rise in MDMA-related fatalities, at least in part related to prohibition which increases the market presence of adulterated products and/or unregulated high-dosage products. These developments demand ever greater urgency in moving towards the first phase of our roadmap to regulation. Inaction is no longer an option given the likelihood that retaining the status quo will lead to more MDMA-related deaths.

## Harms associated with production 2.4

Estimating the size of illegal markets is notoriously difficult to do, with indirect measures such as police seizures and prevalence data (from surveys or wastewater analysis) generally acting as a proxy. The most recent EU-level estimate suggests that around 2.1 million European young adults (aged 15–34) used MDMA in the last year (1.7% of this age group), with national estimates ranging from 0.2% in Portugal and Romania to 7.1% in the Netherlands[1]. Countries with the highest prevalence of MDMA use in Europe include the Netherlands, the Czech Republic, the UK, Bulgaria, and France[1]. A recent estimate placed the minimum retail value of the illegal MDMA market in the EU at around €0.7 billion, a modest figure comprising only 3% of the overall illegal drug trade[1]. National data are exceptionally sparse. A 2006 report commissioned and published by the UK Home Office estimated the total value of the MDMA market in England and Wales to be £181.9 million–£353.7 million[158]. The production cost of MDMA is between €0.25 and €0.40 per tablet, but the cost to the European consumer is normally between €6–€10 per pill[1].

While reliable information is hard to come by, experts suggest that MDMA precursors are mostly obtained from China (and to a lesser extent Southeast Asia), with most production operations taking place in the Netherlands, Belgium, and Canada. Overall, the MDMA market is one of increasing sophistication and scale, with a production chain involving multiple locations, countries, and stakeholders[1, 159, 160]. Evidence concerning the production of MDMA in illegal lab settings is patchy at best, but police and journalistic reports from around the globe shed some light on the risks for both producers and users. The available information from seizures suggests that at least some clandestine production takes place in improvised, small-scale underground labs that lack the necessary quality or safety controls and adequate materials[161]. This can introduce adulterants, either intentionally to 'bulk up' the product, or as a by-product of sub-optimal synthesis.

The synthesis of MDMA in such places is also carried out by individuals who may lack advanced knowledge of, or concern for, best practice in practical chemistry, increasing the likelihood of product adulteration and inconsistency, as well as the likelihood of accidents that harm lab workers, such as burns or inhalation of toxic fumes[162, 163]. On the other hand, there is a rise in a more sophisticated industrial-scale operation with innovative production methods and precursors that challenge the global control regime[164]. The producers have reportedly become more flexible and adaptable to changing demands. They have customised equipment and automated production in order to expand the scale of production to meet the increased demand[6]. Some routes of synthesis for MDMA involve sourcing precursor chemicals that are themselves produced in a context of illegality and associated with significant environmental damage. Ecological risks are compounded by the lack of waste disposal standards, often leading to the contamination of streams and soil[165]. This is especially relevant given the recent diversification in the use of precursor chemicals and increase in production. For example, it is estimated that making 1 kg of MDMA results in 6–10 kg of toxic waste. This waste is then disposed of in environmentally damaging ways, such as being poured down the sink or toilet, dumped in a forest or field, loaded in stolen vans or lorries, buried underground, or dumped into the sea[6]. This creates yet another source of harm for members of the general public unconnected to the drugs in question. For example, in August 2015, four children were taken to hospital with chemical burns after cycling through a pool of liquid caustic waste from a synthetic drug production site in Belgium[166].

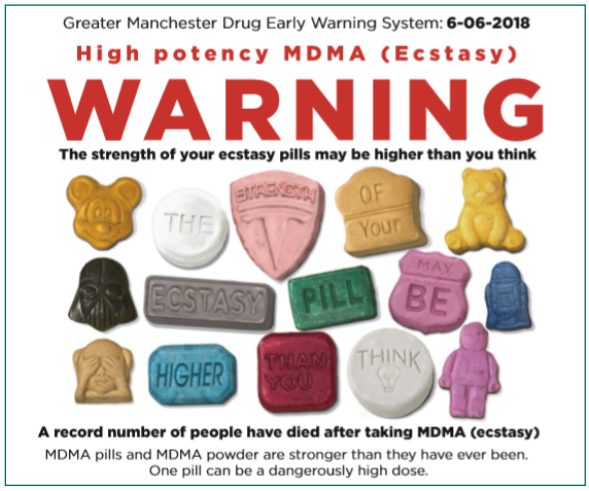
## 2.5 Harms associated with the product

As we have identified previously, the variability in the quality and potency of MDMA heightens the risks of harms. Partly due to their clandestine production at multiple sites in the context of global prohibition of MDMA, the contents of pills and powders sold as 'Ecstasy' vary widely[167]. Studies in 2011 found that the amount of MDMA in pills sold as 'Ecstasy' ranged from 0 mg to upwards

of 240 mg[168, 169], with the most recent tests by drug-testing and harm reduction charity The Loop[170] from the UK festival and nightclub scene identifying pills with MDMA content as high as 350–400 mg[171]. This makes them significantly more potent than in previous years, when the average pill contained about 100 mg of MDMA, and some contained less than 50 mg[172]. In June 2018, the Greater Manchester Drug Early Warning System, in conjunction with the Greater Manchester Police and the popular Parklife Festival in North Manchester, issued a warning on 'High potency MDMA (Ecstasy)'[173]. It is noticeable that issues of high dosage, polysubstance/polydrug use, and overheating are all covered in the warning. Pills sold as 'Ecstasy' contain adulterants, some of which may themselves be psychoactive and/or toxic. As users are unaware of the content of their pills, this is a potential source of risk, notably when used with other substances such as alcohol[64, 174]. The lack of any consistency of product is also a barrier to stable social norms and individual habits of moderate use.

Figure 10.

*High potency MDMA (Ecstasy) Warning*




Source:
[parklife.uk.com]

Periodically, notably between 2006/7 and 2011/12, there have been episodes of particularly low reliability of MDMA on the market, likely in response to supply-reduction enforcement of the MDMA precursor safrole/sassafras oil, as noted earlier. Such fluctuations have several potentially harmful consequences, including adverse effects related to other psychoactive, and potentially toxic,

adulterants, as well as changes in potency. The emergence of pills contaminated with PMA/PMMA is a powerful case which highlights the unintended consequences of prohibition drug law enforcement. The effects of PMA/PMMA have a slower onset than MDMA, potentially misguiding users into a sense that the product is weak and leading them to re-dose. However, PMA and PMMA are far more toxic than MDMA, and a double dose can lead to agitation, seizures, and hyperthermia. Casualties of these drugs intended to take MDMA[175], making this perhaps the starkest example of a potentially deadly risk that is entirely avoidable through the availability of a regulated and hence reliable legal product. Although PMA/PMMA has since largely disappeared, its use as an adulterant, even if only temporary, demonstrates the risks of having criminal entrepreneurs in control of the supply. A similar scenario could easily happen again with another adulterant, and even one rogue batch can cause multiple casualties.


Figure 11.

*Tweet from The Loop warning about extra potent ecstasy pills*

Source: The Loop

Diversification is evident in MDMA product branding. There is a broad variety of novel shapes, colours, and logos, suggesting competition and more active marketing. The Dutch police reported an increase in the number of

new tablet designs, from 50 new designs identified in 2012 to 174 in 2014[176]. 'Ecstasy' pills are often produced and branded for specific events or festivals in an attempt by pill manufacturers to ensure that their pill is recognised by festival-goers as a marketing 'tie-in'. For example, high-dose (> 250 mg) MDMA pills displaying the logo 'ADE' were produced for the Amsterdam Dance Event 2015[177]. However, there is a danger with such branding, whereby if a pill becomes popular, copycat versions appear. This does not guarantee consistency and continuity, but rather adds to the unpredictability for users. In sum, a significant proportion of MDMA-related medical emergencies and deaths are cases of accidental poisoning through unintentional excessive doses[178, 179] and/or adulteration with or substitution of other substances[180]. These clearly identified risks flow directly from the illegal production regimen that current prohibitionist policies promote. Only legal regulation of MDMA products would properly tackle unknown potency, adulteration or use of adulterants, and unregulated branding.

In the last decade, NPS have been developed and marketed as 'legal'[i] substitutes for MDMA products, although experienced drug users report that none have yet achieved the lasting popularity of MDMA. Piperazines, such as mCPP (meta-Chlorophenylpiperazine), BZP (benzylpiperazine), and TFMPP (trifluoromethylphenylpiperazine) have been sold as 'Ecstasy' or 'party pills'. Benzofurans such as 5-APB (5-[2-aminopropyl]benzofuran) have also emerged as a supposed MDMA substitute, given their stimulant and 'empathogenic' properties. Research on the pharmacology of these substances is limited, but nothing suggests they are less risky than MDMA[j]. In contrast to these often cheaper 'unknown white powders', there is currently a relatively stable supply of MDMA products, with prices holding fairly constant since 2010[1]. Under

i Although these 'legal highs' – more appropriately NPS – are now controlled by the Psychoactive Substances Act 2016, there continues to be a significant market for these drugs amongst the most marginalised populations in society such as prison and homeless populations. The NPS market in the UK is now entirely under the control of criminals.

j However, to date no known deaths have been related to BZPs.

prohibition, criminals exploit this market for huge profits. Hence, another crucial aspect of MDMA-related harms relates to the drug's illegitimate distribution (supply) networks.

## 2.6 Harms associated with distribution (supply)

To examine the harms related to the distribution of MDMA, it is worth first making the general point that there are many misperceptions about the nature of the drug supply which make discussion of drug policy reform more difficult[181, 182]. Contrary to the popular perceptions of drug dealers lurking in dark alleyways or around school gates, many people who use MDMA report obtaining their drugs from friends and established contacts. This creates a risk of serious criminalisation, sometimes even imprisonment, for young people engaging in non-profit 'social supply' amongst peer groups or small-scale opportunistic dealing[183]. Such criminalisation can have devastating impacts on the prospects of young people, potentially far more harmful than occasional drug use[184]. If intended to deter use and protect health, the criminalisation of such low-level actors in the drug market is likely to be counterproductive. Not only is there no evidence to suggest that such enforcement meaningfully disrupts supply or reduces availability, but also the negative impact of a criminal record and associated stigma on personal relationships, employment, housing, or personal finance ironically may in fact increase the likelihood of an individual developing more problematic drug-using behaviours. The harms of criminalising young people who use drugs, who engage in 'social supply' to friends, or who are involved in the lower tiers of the drug supply are widely acknowledged. This recognition of the harmful consequences of the status quo has driven calls from health agencies[k] and high-level voices across the UN system, including the World Health Organisation, the UN Office of the High Commissioner for Human Rights, the UN Office on Drugs and Crime,

k These include the Royal Society for Public Health, the Royal College of Physicians, the government's own ACMD, the American Public Health Association, the British Medical Journal, and the UK Faculty of Public Health.

and three consecutive Secretary Generals, for alternatives to the punishment and incarceration of low-level drug offenders to be explored. What is clear is that we need to reform policy and law around MDMA to ensure that young people are not unfairly or disproportionately criminalised[185].

Drug dealing often attracts young people in situations of social vulnerability, which can further perpetuate cycles of exclusion if they are prosecuted[186, 187, 188]. Most recently, there has been growing concern amongst law enforcement agencies and child protection services about the growth of 'county lines' in England and Wales[189, 190]. A 'county line' is where an individual, or more frequently a group, establishes a telephone number (or an address) in an area outside of their normal locality to sell drugs – typically but not exclusively crack cocaine and heroin – directly to users at the street level. This usually involves an organised gang from an urban area expanding their operations by crossing one or more police force boundaries to more rural areas, setting up a secure base, and using drug 'runners' to conduct day-to-day dealing. Urban organised drug gangs are recruiting marginalised children and young people as drug 'runners' for these 'county lines', whilst also establishing 'secure bases' in the homes of vulnerable (often young) people to force their co-operation with actual and threatened physical and sexual violence. Other grooming activities include paying children large sums of money or giving them drugs for their efforts, or 'rewarding' them with additional gang status and responsibility which effectively puts them at greater risk of intergang violence[191].

Whilst there is as yet little evidence of drugs distributed via county lines being sold in the NTE (unsurprising given that county lines focus on lucrative heroin and crack cocaine markets), one source *has* reported the recovery of MDMA from runners[191]. It has been acknowledged by parents, frontline staff, and child protection academics and practitioners that the children and young people in these situations should be treated as victims/survivors, not as criminals[191]. However, in reality, the prohibition system makes this hard

to guarantee when seeking to help and support the young victims/survivors of drug gangs. Conversely, the move to decriminalise simple possession and low-level dealing offences for *all* drugs – including MDMA – which we call for in this report would remove these and other young people entirely from their positioning as 'criminals', providing an opportunity to disrupt the cycle of exclusion that allows organised gangs to prey on them.

The fear of 'getting into trouble' with the authorities is strong amongst members of marginalised communities (especially young people) who already receive disproportionate law enforcement attention relative to their actual involvement in drug markets[192]. In the failed attempt to 'control' drugs through the criminal justice system, drugs are understood through the prism of criminality, rather than that of public health. This is unacceptable given that the goals of drug policy should include the protection of vulnerable populations. Fears around legal consequences are apparent in some young people's reluctance to contact emergency services if they or a friend experiences an adverse reaction to drugs. This means that young people who use drugs are over-policed and under-protected. If young people do experience acute health issues in relation to their MDMA use, they are less likely to seek help as they may fear repercussions in relation to social dealing. They may also worry about potential media coverage of MDMA-related incidents and social supply. This is a justifiable fear, given that nearly every MDMA-related death is covered in the UK press[98]. This further discourages people from seeking medical help if they or their friends become ill or die following the ingestion of unregulated MDMA products. In a recent tragic case in the UK, a young female student who shared MDMA pills with her best friend, who subsequently died whilst out celebrating the end of term at university, was jailed for six months after being charged with possession with intent to supply a Class A drug[193]. Indeed, MDMA media reporting routinely includes articles on the prosecutions of the people – including partners, friends, or acquaintances – who supplied MDMA to someone who later died or experienced a medical emergency. In another widely reported UK case, the

19-year-old boyfriend of Faye Allen, a 17-year-old who passed away the first time she used the drug at the Warehouse Project in Manchester, was jailed for seven months for giving an MDMA pill to Faye which he had purchased from an unknown dealer on the premises[194].

The harms associated with MDMA supply are felt by those caught up in a failing justice system, which often indiscriminately and disproportionately criminalises 'dealing', regardless of motive, intent, or even the extent of activity. The relevant comparison here is that no one is criminalised or imprisoned for buying an alcoholic drink for friends, despite the hugely negative effects of excessive alcohol use in the NTE on young people, local communities, and emergency services. Finally, although few people seek help for problematic MDMA use, MDMA may be but one illegal substance in a person's polydrug repertoire which, in its totality, leads them to experience problems. Willingness to seek help for problematic drug use has been found to be lower amongst those who reside in countries with more punitive prohibition routines, leading some to argue that liberalising national drug policy will increase the propensity of people who take (currently) illegal drugs to utilise health services[195].

As with 'county lines', the prohibition status quo has proven unable to respond adequately in an agile manner to the harms of emergent drug distribution systems. Here, it is crucial to acknowledge the growing role of the internet and, more recently, social media apps in the distribution of MDMA products[196]. There may be harm reduction benefits from the development of online markets, including the avoidance of direct contact with potentially unknown criminal dealers, and user rating systems on the darknet which may help act as a form of quality control[197]. However, online MDMA markets also pose specific kinds of risks in addition to the more common risks associated with purchasing from criminal markets. The internet has created an easily accessible supply route for tech-savvy young people who may not otherwise have access to street or social dealers of MDMA, and may increase MDMA availability for certain vulnerable populations. Of course, there are no age-verification mechanisms

when purchasing MDMA from the darknet. Key areas of continuity and change between MDMA markets of the 1990s and contemporary MDMA markets have been subject to recent scrutiny[198]. Contemporary MDMA markets are increasingly globalised with the emergence of industrialised production processes, intercontinental export, and anonymous and untraceable online drug purchasing through the darknet with cryptocurrencies[199]. The emergence of online markets in one respect reflects the 'success' of conventional supply-side enforcement, which has created risks for both buyers and sellers sufficient to incentivise the move online. However, this more objectively reflects the wider failure of the prohibitionist paradigm; markets are not being eradicated but simply being displaced from face-to-face transactions to a highly flexible online market that is effectively beyond the reach of enforcement. This creates some new risks but also some potential benefits from the user perspective (such as increased anonymity, reduced risk of arrest, avoidance of criminals, and quality control)[200]. These rapid and risky developments in MDMA markets demand novel solutions which challenge the outdated approach of total prohibition. Changes in MDMA distribution models, such as the use of the darknet and social media to obtain MDMA[197], mean that any possible future alternative to prohibition must be prepared to deal with 'real-world' consumer practices.

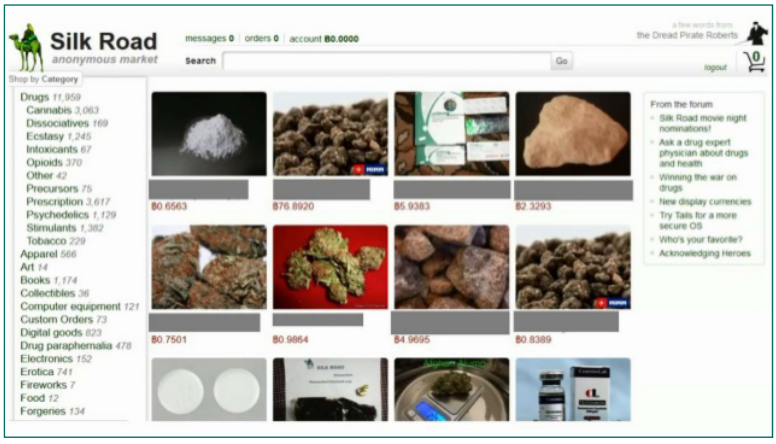



Figure 12.
*Screenshot of the Silk Road, the former online darknet marketplace.*

## Financial costs of retaining the prohibition status quo 2.7

As with any law, there are costs associated with enforcement, such as the cost of policing, courts and judicial procedures, imprisonment, etc. In terms of relative investment of enforcement resources, MDMA is not in the top tier of UK or EU priorities, unlike, for example, cocaine or heroin trafficking. Most law enforcement authorities take a fairly pragmatic approach. Indeed, compared with some other drugs, statistics suggest that MDMA-related offences make up only a small proportion of drug offences[1, 1]. Data detailing the exact costs of enforcement measures for MDMA, in either money or expended time, are unavailable. However, according to recent UK Home Office data, 65% of 'Ecstasy' seizures in 2017/18 involved 10 or fewer doses, whilst only 10% involved over 100 doses[201], demonstrating that significant enforcement time, effort, and funding is being spent on targeting people who use MDMA or on social supply rather than organised crime groups.

Another key cost associated with the prohibition of MDMA is the profits it provides to criminal markets. Prohibition seeks to deter illegal drug production and distribution by heightening the risks of prosecution and imprisonment. However, the low rates of capture and conviction of those operating in illegal drug markets[1] suggest that the theoretical risk of prosecution has a minimal deterrent effect. Instead of deterring criminals, prohibition ensures that their profits remain high as their risks are passed on to consumers in the form of increased costs, combined with simple profiteering within a criminal monopoly

1 Data gathered by the EMCDDA indicate that MDMA was implicated in less than 3% of registered drug offences in the UK. This is 1% higher than the numbers for MDMA-related offences seen throughout the EU. In 2017 (the latest figures available), an estimated 1.5 million drug law offences were reported in the EU. Most of these offences (79%) related to use or possession, totalling around 1.2 million offences, a 27% increase compared with ten years ago. Drug use or possession offences involving cannabis continued to increase. The upward trend in offences for MDMA use or possession continued across the EU in 2017, although they still only account for 2% of use-related offences1.

with no competition from the legal economy. At the same time any opportunities for legitimate economic activity and tax revenue from the market are forgone.

## 2.8 Lost benefits

### 2.8.1 Recreational use

Much research on MDMA use, as with most illegal drugs, has focused on harms, with little attention paid to potential benefits[140], either objective or subjective. The effects experienced when taking MDMA include a well-documented sense of 'openness', euphoria, and closeness to others[130, 202, 203]. These are the highly sought-after effects that help account for the enduring popularity of MDMA. According to a large global web survey of people who use drugs, MDMA has the highest Net Pleasure Index (calculated by subtracting rating scores for negative effects experienced from the scores for positive effects) of all surveyed drugs[204]. Aside from pleasure, MDMA may have social functions that its users find valuable. For example, MDMA use may create a unique environment in which people can express and enjoy closeness in ways that are otherwise outside of their cultural norms. Researchers have long noted the sense of community and belonging experienced by young people in dance music scenes which they may not experience elsewhere[205]. One study has examined ways in which young men on MDMA are able to communicate, play, and experience their friendships in ways that are otherwise not consistent with social norms guiding masculine behaviour[206].

### 2.8.2 Clinical and therapeutic use

Before MDMA acquired its illegal status in the US in 1985, it was used by several dozen psychotherapists who believed it to be a valuable and effective tool to augment the psychotherapeutic process. George Greer, a psychotherapist who administered MDMA during this time, estimated that the combined clinical

experience in the US prior to the ban totalled more than 1,000 sessions[207]. However, the exact size of the medical following MDMA had commanded is impossible to determine and estimates vary considerably[m]. Anecdotal and case reports were published, but no controlled clinical trials were carried out before 1985[208, 209, 210]. Case reports observed that MDMA produced strong positive results for a range of mental health conditions[208, 211]. Available accounts indicate that MDMA-supplemented psychotherapy was thought especially effective in couples' therapy and for overcoming fear and anxiety, for example in the context of PTSD[n]. In 1985, the prohibition of MDMA in the US stopped large-scale studies from putting these uses on a firmer clinical foundation, although there is evidence that the 'underground' use of MDMA for psychotherapy did not entirely cease and that therapeutic use continued in some parts of Europe for some years following this, notably in Switzerland[212, 213].

Due to regulatory obstacles and the preference of conventional funding bodies to support research into the *harms* of controlled drugs more often than into their potential uses, research on MDMA's therapeutic potential stalled for almost twenty years. While still contested by some[214], MDMA is now experiencing a revival of appreciation for its emerging therapeutic properties, especially when administered in a controlled environment, with optimal set and setting using safe clinical research models and methods[215]. Phase 1 and Phase 2 clinical trials have been conducted to test the potential benefits of MDMA-assisted psychotherapy in the treatment of PTSD, with positive results. The latest Multidisciplinary Association for Psychedelic Studies (MAPS)-sponsored study, involving twenty-six individuals (veterans, firefighters, and police officers) with PTSD who were randomly assigned either 30 mg, 75 mg, or 120 mg of MDMA together with psychotherapy, reported that 68% of the participants assigned

m The 2018 MAPS Investigators Brochure refers to 500,000 doses of MDMA having been administered in psychotherapy sessions prior to its scheduling.

n See Neil Wood's testimonial on the relationship between MDMA and PTSD at the end of this report.

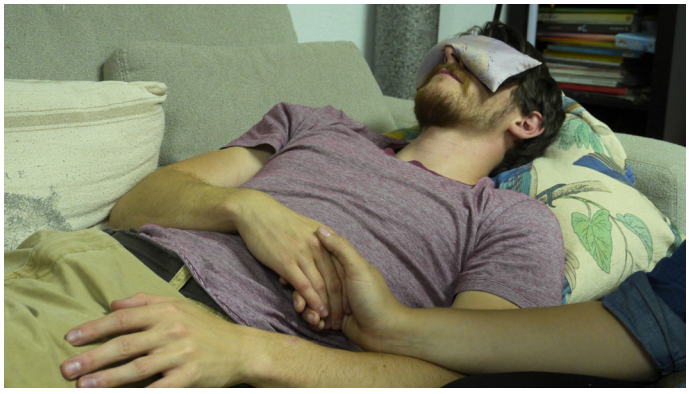
the higher doses no longer qualified for a diagnosis of PTSD one month after their second MDMA-assisted psychotherapy session, while the same was true for only 29% of the group assigned the lower dose. One year later, 67% of all participants no longer qualified for a diagnosis of PTSD, and all of those that retained their diagnosis experienced a reduction in symptoms[216]. Phase 3 trials are now underway following the Food and Drug Administration's approval and designation of MDMA as a 'breakthrough therapy' for PTSD[217].

MDMA is unlikely to be a suitable drug for regular use in the way in which selective serotonin reuptake inhibitors are used to treat clinical depression. However, it is hoped (with increasing evidential support) that lasting benefits can result from a small number of psychotherapy sessions (two to five, typically)[75] in which the drug is administered to the client[218]. So far, MDMA-assisted psychotherapy appears to be remarkably effective in easing or resolving PTSD in individuals who had not been helped by mainstream treatment options[214, 219, 220, 221, 222, 223]. Research is also underway to determine whether MDMA-assisted psychotherapy can help autistic adults with social anxiety[23, 224], patients with anxiety relating to a life-threatening illness, and people with alcoholism. The range of problems for which MDMA could provide therapeutic benefits is yet to be determined, but new insights into its mechanism suggest that appropriate indications for MDMA-assisted psychotherapy could be diverse. The drug may increase the efficacy of psychotherapy by strengthening trust in the therapeutic alliance[225], increasing self-compassion and reducing self-criticism[226], and making it easier to approach and discuss traumatic memories without being overwhelmed[227]. Increases in patients' openness and decreases in neuroticism may help the benefits last[228].

In 2012, the Beckley / Imperial Research Programme carried out the first brain imaging study on individuals under the influence of MDMA, as part of the Channel 4 programme *Drugs Live: The Ecstasy Trial*, which was presented by Jon Snow and was viewed by over 2 million people. This was the first detailed study

to map the neural underpinnings of MDMA's effects, and to explain why it is so valuable for psychotherapy. Following on from insights gained through work with PTSD patients in psychotherapy, this study explored the idea that MDMA makes people's worst memories more bearable. It also offered thoughts on the neurobiological mechanisms that may underlie this characteristic. Favourite memories were experienced as more vivid, emotionally intense and positive after MDMA as compared to placebo, and worst memories were rated as less negative. This manifested in the brain as decreased activity in the amygdala (involved in fear processing), the hippocampus (memory processing), and visual and somatosensory areas[227,229]. Taken together, these results demonstrate the unique value of MDMA in psychotherapy as a tool to facilitate the recall of traumatic memories.

Figure 13.
*A MAPS MDMA therapy session.*



Source:
MAPS

While largely ineffective at tackling the recreational demand for MDMA, the international drug control regime has profoundly undermined the development of MDMA for therapeutic use, confining use to a few underground therapists[212]. In the UK for example, MDMA is listed in Schedule 1 of the Misuse of Drugs Regulations (MDR) 2001, imposing challenging financial and bureaucratic obstacles to preclinical and clinical research[230]. One experienced researcher estimates that research with a Schedule 1 compound takes several years to get approved and can ultimately cost ten times as much as the equivalent research with uncontrolled drugs such as alcohol[231]. Despite these restrictions, a new wave of interest and research into therapeutic uses of MDMA is now underway.

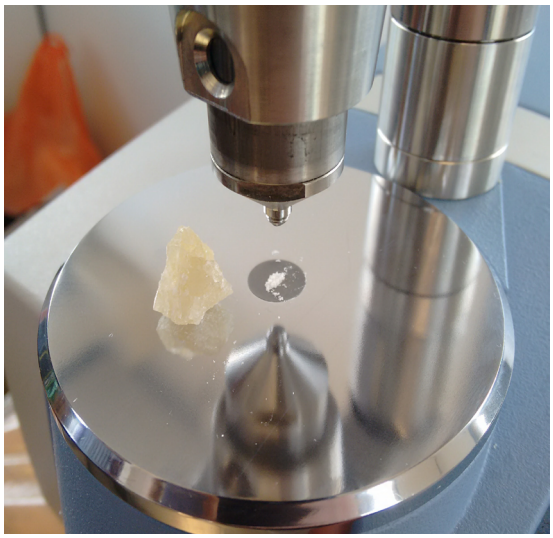
In Chapter Three, in detailing our roadmap to regulation for MDMA, we call for the rescheduling of MDMA to allow scientists and medics to explore its therapeutic potential, notably in the field of mental health, which is of growing concern to many communities and governments.

## 2.9 Harm reduction under prohibition

Having demonstrated how various harms relating to MDMA use are directly related to, or exacerbated by, the current prohibition regime, it is now necessary to consider how people who currently use MDMA mitigate potential harms before, during, and after their 'session'. Whilst there is a long and proud history of harm reduction amongst MDMA users, this is largely ignored by mainstream drug researchers. Much research focuses exclusively on the negative aspects of MDMA use whilst ignoring the more positive aspects reported by users 'on the ground', including lay harm reduction strategies around MDMA use and the efficacy (or otherwise) of harm reduction interventions by concerned parties such as outreach drug services. Such strategies and advice are culturally transmitted among peers, including through the internet on drug user forums, and some are also promoted by interested drug workers and clinicians, organisations, friends, and dealers.

Both lay and expert harm reduction practices and interventions are, in many cases, necessitated by the prohibitionist regime at the same time as being severely curtailed by it. The first difficulty for MDMA users is where and from whom to purchase the drug. Buying from trusted local dealers or friends who rely on reputation and customer loyalty may be a safer option than buying from an unknown, unaccountable dealer at a festival, at a nightclub, or on the street[11]. Some darknet markets provide consumer feedback scores for vendors, which allows for the development of a reputation akin to legitimate sites like eBay. This feature may make darknet purchases less risky than buying from unknown street dealers, although some have questioned the safety of this development in the MDMA market[197].

Figure 14.
*MDMA crystal on The Loop's bruker alpha FTIR testing surface.*



Source:
The Loop

Some users test their purchase using simple qualitative chemical home-testing kits, which indicate the presence of MDMA or some other drugs with a colour change[232]. These kits have the potential to help users avoid some fake or adulterated products, but if their limitations are not recognised (e.g., confirmation of the presence of MDMA does not confirm the absence of a dangerous adulterant, and gives little indication of potency), users may gain a false sense of security[233]. Access to more technologically sophisticated drug testing services is legally constrained in the UK, although the Home Office has recently shown a willingness to step back from its previous objections[234]. The Loop[235] are pioneers in combining on-site drug testing with harm reduction services in the UK, operating with the cooperation of law enforcement, although their testing services are currently only available to a tiny minority of people who use drugs attending specific dance events and festivals, and in a small number of city centre locations. Such services have a longer history of effective, albeit limited deployment in Spain, Austria, Switzerland, and the Netherlands; and are now emerging in Australia, Canada, Latin America, and elsewhere in Europe. The internet provides a way for adulteration warnings and dose information about specific MDMA tablets to be shared (e.g., www.pillreports.net), although the utility of this service is limited by the ease with which pill designs recognised

as high quality can be copied. In the Netherlands, the Drugs Information and Monitoring System (DIMS) has provided consumers with the service of having drugs analysed for free since 1992[236]. In the UK, the Welsh Emerging Drugs and Identification of Novel Substances (WEDINOS)[o] and The Loop perform similar functions.

MDMA dose control still represents a key aspect of harm reduction. Scales with the necessary sensitivity (0.001 g) utilised for single doses of MDMA powder are relatively affordable as an alternative to 'eyeballing' doses. Harm reduction advice, to start with half or a quarter of a pill and wait for the results, has been proposed to minimise the risks of excessive doses and adulteration[237]. However, in the context of high-profile deaths of young people, this remains a highly sensitive and politicised area which suffers from sensationalist press reporting. For example, when suggesting that people who use MDMA should stick to taking pills in halves, Professor Valerie Curran was vilified in the British tabloid press for allegedly 'encouraging' drug use[238]. This has historically been a frequent challenge for more pragmatic drug harm reduction efforts, which still have to negotiate the simplistic 'just say no' and 'zero tolerance' messaging that continues to dominate much political discourse.

Using harm reduction strategies, current users can exert a degree of control over their MDMA experience and risk exposure before, during, and after a given 'session' through careful purchasing, planning of the usage scenario, responsible dosing and self-care, and aftercare. However, some people who use MDMA depend upon word-of-mouth information and peer advice, which may be inaccurate. Targeted harm reduction programmes informed by scientific evidence and 'real-world' practices, and ideally co-developed with young people

o The Welsh Emerging Drugs and Identification of Novel Substances (WEDINOS) project, an initiative receiving support from Public Health Wales, has analysed more than 7,000 samples from across the UK in the last six years. The service currently holds an exemption from the Home Office allowing it to possess controlled drugs – an exemption plausibly maintained because of the service's relative obscurity.

who use MDMA, remain inadequate and under-resourced, not least due to the austerity-driven cuts to public health and education budgets, vital alcohol and drug services, and youth services in the UK.

Just as the pressures of prohibition lead to a needlessly high-risk product, they may also lead to particularly unsafe contexts for use. The pressures on users to avoid detection and on nightclubs and festivals to demonstrate zero tolerance appear to create conditions that are not conducive to responsible use. For example, nightclubs may utilise intensive searches or even sniffer dogs to deter drug use, which may unintentionally encourage users to take all their drugs at once before entering[239]. Australian research on the use of drug detection dogs at outdoor music festivals, a measure introduced in response to a spate of drug-related deaths at such events, points to their failure to deter festival-goers from smuggling drugs into festivals, with a mere 4% of survey respondents indicating that they would change their behaviour if they knew detection dogs were going to be at festival entry points[240]. Australia, the US, Canada, and indeed the UK make extensive use of police sniffer dogs at popular dance events, despite long-standing weak evidence as to their deterrent effect[241] and associated emergencies (including fatalities) resulting from panicked ingestion. Recent responses to drug-related deaths at EDM festivals in Vietnam and Australia have included local leaders talking 'tough on drugs' and banning such events altogether[242, 243].

The evidence from alcohol research shows that when club-goers have an incentive to get intoxicated before arriving (e.g., by on-premise alcohol prices), they drink more in total and are more likely to be involved in risky behaviours[244]. MDMA users may act similarly by starting their consumption before going into the club for fear of being searched, meaning that searches have a harm-exacerbating effect[240]. Users may consume too much, too quickly, inhibiting well-evidenced harm-reducing strategies such as starting with half a pill and waiting for an effect. Additionally, they may then purchase drugs from strangers inside the club who, in comparison to dealers known to the user, are likely to

offer a dangerously unpredictable product. Snatching covert opportunities to consume MDMA is not consistent with careful measurement, or with looking out for one's friends by maintaining awareness of what and how much they are taking. Escalating pressures on users (and banning dance events) may displace MDMA consumption to less regulated private spaces, which are thought to be a risk factor for acute drug harms and deaths[239], or into completely unlicensed events (unlawful 'free parties' and raves) where recent MDMA-related deaths have also occurred[245, 246].

In this chapter we have outlined the harms associated with MDMA production, distribution (supply), and use. We have reviewed the evidence in relation to acute harms from MDMA use, as well as sub-acute and chronic harms, and have demonstrated how the illicit production and distribution (supply) of MDMA entails a range of harms specific to the current policy environment in which they arise. Prohibition needlessly exacerbates the risk of medical emergencies and death amongst people who use MDMA. Criminalising users hinders the dissemination of important information and advice about safer forms of use that significantly reduce potential acute, sub-acute, and (to a lesser extent) chronic harms related to MDMA, not to mention the devastating impact a custodial sentence and criminal record can have on a person's life.

Most MDMA-related harms emerge from the very drug laws which are meant to protect public health, safeguard vulnerable populations, and reduce drug-related harm. Harm reduction initiatives such as drug safety testing services are crucial as they help to mitigate the most negative intended and unintended consequences of prohibitionist policies[247]. Indeed, much drug policy change advocacy rests on evidence from harm reduction research and practice, as is apparent throughout this report. As we move towards the creation of a strictly regulated legal MDMA market, harm reduction will play an increasingly visible role in MDMA user choices.

In a post-prohibition context where users have access to safer legal MDMA products, harm reduction initiatives, such as the supply of free drinking water in nightclubs and at festivals, would continue, whilst others, such as drug safety testing for adulterants, would no longer be needed. For the policy changes we advocate in this roadmap to regulation to work, MDMA users must be 'on board' with measures to reduce potential risks of drug consumption. Fortunately, the appetite for safer drug use practices is already apparent, with 99% of people who used MDMA in England and Wales in 2019 stating that it is not advisable to take the substance frequently[45]. That figure supports a view of users as rational agents who attempt to balance the risks and rewards of drug use in the broader context of their lives, rather than 'out of control hedonists', who, whether purposely or unwittingly, put themselves and society at risk[248]. Club drug users tend to want to have as much fun as possible as safely as possible[249]. Recent successful attempts to engage people who use drugs at music festivals with harm reduction advice following drug safety testing (e.g., The Loop) further supports this view[250]. Overall, we envisage the proposed two-phase drug policy reform process – decriminalisation of possession and low-level dealing followed by legal regulation – as further supporting and empowering people who use drugs to practice harm reduction and responsible use.

Chapter Three

# Developing a Roadmap to Regulation: MDMA

## 3.1 The goals of policy reform

It is important to explore what a fully realised, culturally integrated system of MDMA regulation might look like, whilst also considering the incremental steps needed to make it a reality. Minimising harm during the transition should be the priority, rather than taking the shortest route towards the end goal. The proposed model includes a phased introduction of policy reform, beginning with rescheduling MDMA and decriminalising possession, which would reduce some of the harms associated with current drug policy without requiring significant legislative and administrative restructuring. The second phase of policy reform details the development of a strictly regulated legal MDMA market. The actions in each phase would be carefully monitored and evaluated to ensure that they are fulfilling the specific goals of reform. We need to be very clear about these goals to ensure that the overarching principles of the reform process are not lost. These principles are premised upon the conviction that we can move towards a social and political engagement with drugs driven by public health promotion and harm reduction, evidence-informed policy and practice, human rights, social justice, and participatory democracy. Bearing these principles in mind, the foregoing considerations suggest that the key **goals**, related **actions** for MDMA drug policy reform, and the **phases** of reform they align with are as follows:

### Overarching goals

- Minimise health risks related to MDMA use.
- Minimise social, environmental, and health harms related to MDMA markets (production and distribution).

- Minimise the social and economic costs of MDMA-related policy and its enforcement.
- Harness the therapeutic potential of MDMA.

### Specific goals

- Minimise MDMA use by underage and other vulnerable populations.
- Encourage safer modes and patterns of consumption.
- Ensure the quality and consistency of MDMA products on the market.
- Decrease the income fuelling the criminal market.
- Introduce cost-effective harm reduction methods.
- Ensure optimal opportunities for the scientific study (and application) of MDMA's therapeutic potential.

## Proposed model for reform 3.2

The key actions aligned with each phase are outlined below:

### Phase 1: Actions

- Reschedule MDMA from a Schedule 1 drug to a Schedule 2 drug under the Misuse of Drugs Regulations (MDR) 2001 in the UK. Equivalent rescheduling could take place in other jurisdictions and under UN treaties.
- Decriminalise MDMA possession and low-level supply (as part of broader decriminalisation).
- Roll out drug testing and other relevant harm reduction services.

### Phase 2: Actions

- Build a strictly regulated legal market for MDMA products.
- Establish a new public authority body charged with overseeing, monitoring, and evaluating the implementation of regulation.

- Ensure that public health promotion and harm reduction, evidence-informed policy and practice, human rights, social justice, and participatory democracy inform both Phase 1 and Phase 2.

## 3.3 Phase 1

### 3.3.1 Rescheduling MDMA

The Misuse of Drugs Regulations (MDR) 2001 is the UK legislation that determines who can lawfully produce, supply, and possess controlled drugs, and the conditions under which they are authorised to do so. MDMA is categorised in Schedule 1 in the MDR, and in equivalent positions in other jurisdictions' analogous legislation (e.g., Schedule 1 of the US Controlled Substances Act), as well as in international law (e.g., Schedule 1 of the UN's Convention on Psychotropic Substances).

Schedule 1 drugs are deemed to have minimal or no therapeutic value and are subject to the highest levels of control. MDMA is listed alongside LSD, psilocybin, and cannabis in Schedule 1; whereas heroin, cocaine, and amphetamines, which have established medical uses despite well-known risks associated with non-medical use, are listed in Schedule 2. Although Schedule 1 drugs may be used for the purposes of research in the UK, a Home Office licence is required. Such licences are difficult to obtain, often taking in excess of a year of substantial bureaucracy, costing more than many research budgets can accommodate, and only being available for a limited period (usually one year). Since Schedule 1 drugs for research purposes must be sourced from legitimate organisations, these organisations, their production sites, and their distributors must also meet the onerous licensing requirements imposed by the Home Office. As such, the total costs and bureaucratic demands associated with such research are further increased, and national funding agencies (e.g., the National Institute for Health Research and the

Medical Research Council) have rarely funded clinical trials with Schedule 1 drugs. Placement in Schedule 1 of the MDR is arguably undesirable for any compound given that doing so effectively amounts to a near-prohibition on research. To the extent that policies and practices guided by and based on robust scientific evidence are desirable, restrictions on research should not be so onerous as to exclude scientists working at legitimate institutions from furthering our understanding.

The placement of MDMA in Schedule 1 is also undesirable when considering its position as one of the world's most popular illicit recreational drugs. The more widely taken up any practice is, the more desirable it is to have a fully developed understanding of its health impacts. Moving MDMA into Schedule 2 will reduce the political, bureaucratic, and cost barriers to scientific research associated with a Schedule 1 status. As almost all UK universities can possess and conduct research on Schedule 2 compounds without the need for additional expenses or licences, the wider community of scientists who seek to investigate MDMA's mechanisms of action and effects will be able to do so unimpeded. This will facilitate further research into MDMA's therapeutic uses and non-medical uses, allowing us to improve our understanding of its effects on the body, and deliver insights that can inform the shape and pace of policy reform.

Rescheduling will also facilitate access to MDMA-assisted psychotherapy for specific indications, once clinical trials have demonstrated treatment efficacy. To protect the interests and safety of patients, some of whom may be vulnerable, therapeutic use of MDMA would only be available in the context of MDMA-assisted psychotherapy delivered by qualified and licensed practitioners, following a doctor's referral. This therapy would be provided by mental health professionals who have obtained specialised training in psychedelic-assisted therapy and a licence to administer MDMA for specific indications. In the context of increasing rates of mental health diagnoses in the UK and beyond, promoting the training of MDMA-assisted psychotherapy

practitioners will allow us to capture for society the heretofore lost therapeutic benefits of MDMA.

The UN process for transferring a psychoactive substance from one Schedule to another involves a critical review by the World Health Organisation Expert Committee on Drug Dependence, which is then voted on by the UN International Narcotics Control Board. In practice this is a more fraught process than the domestic one. The mechanics of rescheduling MDMA in the UK from Schedule 1 to the less restrictive Schedule 2 are comparatively straightforward and can be done, for example, by the Home Secretary without recourse to bringing forward primary legislation, but instead via a statutory instrument following consultation with the ACMD. This procedure has recently been witnessed in relation to medicinal cannabis in the UK. If MDMA proves to be a safe and effective treatment for PTSD in the MAPS Phase 3 trials currently running in the US, Canada, and Israel, this will necessitate its rescheduling. However, we suggest that waiting for the completion of these trials will waste several more years, during which important research will be hindered by the needless bureaucracy and prohibitively high costs of securing Schedule 1 research licences.

As it stands, potential concerns around moving MDMA into Schedule 2 remain marginal ones. By itself, rescheduling has no bearing on the matter of recreational use, meaning that those in Parliament who undertake the rescheduling can position themselves as supporting scientific research without risking being perceived as 'soft on drugs'. There is little-to-no risk of diversion to the recreational market: were MDMA to be placed into Schedule 2, it would be subject to the same strict restrictions and controls that are sufficient for significantly more harmful, more dependency-forming drugs such as cocaine and morphine. There are no reports that diversion of cocaine or morphine from clinical or research settings is a significant cause for concern. Moreover, there are no grounds for supposing that there would be such a diversion problem with

MDMA, particularly considering the low reported rates of MDMA dependency, and the fact that current clinical indications for MDMA involve infrequent use in the presence of a therapist, rather than the use of a take-home prescription.

## Decriminalising possession of MDMA for personal use 3.3.2

The first phase of the roadmap to regulation for MDMA must include decriminalising the possession of all illegal drugs. While the term decriminalisation is not formally defined, it is generally understood that under a decriminalisation approach, possession of small amounts of controlled drugs would remain an offence but would be a civil or administrative offence rather than a criminal one. It would be more akin to a speeding offence, no longer involving a criminal record or threat of a custodial sentence. As such it can be seen more usefully as ending the criminalisation of people who use drugs rather than decriminalising the drugs themselves. Following decriminalisation, people caught with a limited amount of MDMA for personal use would have the drugs confiscated and could still be fined or subject to some other sanction or intervention such as a requirement to attend a drug education session (rather like the speed awareness courses for those caught speeding in some countries), or a treatment assessment. Elsewhere, notably in Portugal, there have been changes to penalty regimes which focus more on civil penalties and drug treatment referrals for those understood to be experiencing problems with their drug use[251, 252]. In the UK we are gradually seeing the establishment of local drug offence diversion schemes implemented by local police authorities, creating a de facto system similar to the model in Portugal. Such schemes are a form of harm reduction specific to the pernicious effects of disproportionate police attention and unwarranted involvement in the criminal justice system[253], especially for young black, Asian, and minority ethnic (BAME) people living in urban locales[254]. In the UK, BAME people are subjected to 'stop and search' powers on suspicion of drug possession at almost nine times the rate of white people, despite lower 'find' rates from searches of BAME people, as well as lower self-reported rates of drug use[254].

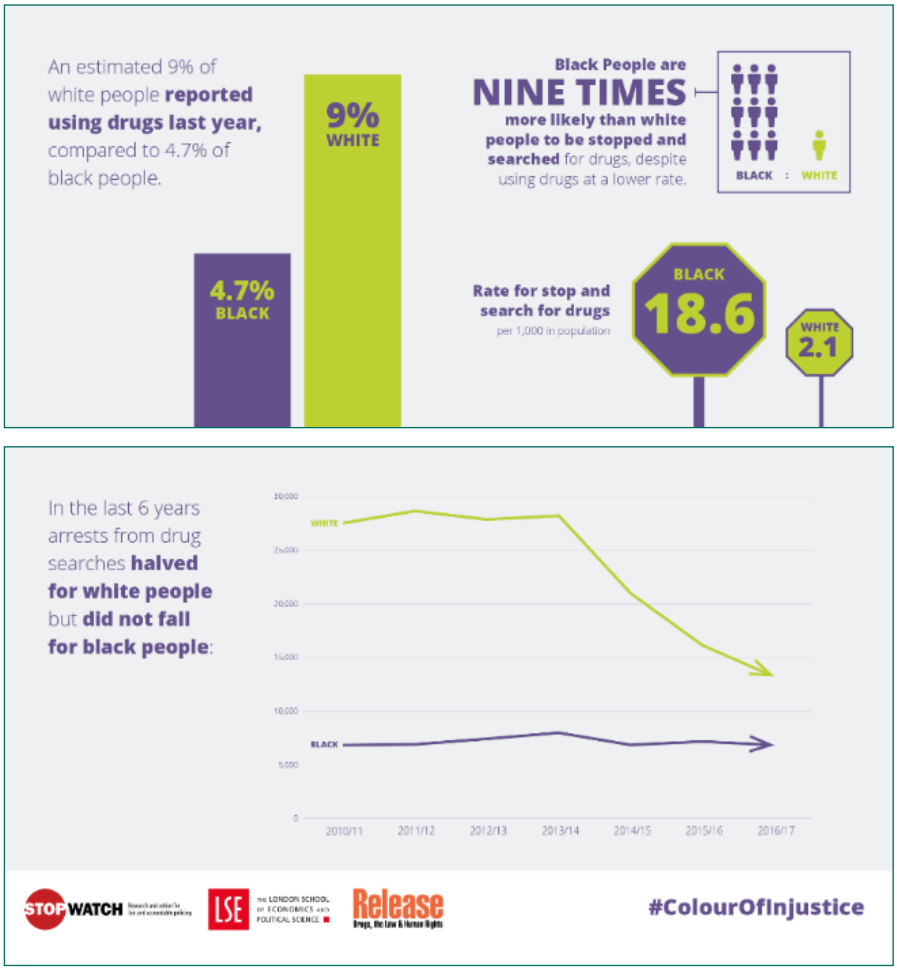



Figure 15.
*The Colour of Injustice.*

Source: [Release.org.uk]

As well as being inherently unjust, disproportionality and racial bias contribute to weakened trust and confidence in the police among ethnic minority communities, compromising operational effectiveness in all aspects of community policing. Whether decriminalisation is de jure in nature, established through amendments to the UK's MDA 1971, or de facto, by police forces making operational decisions to deprioritise or deal differently with minor drug possession offences, decriminalisation would free the criminal justice system from a significant burden. Police resources could be re-diverted to other priorities such as violent crime, and there would be a pronounced reduction in the need for stop-searches, which are justified by suspicion of drug possession in as much

as 82% of cases in some police forces[255]. This point is one reason why we call for decriminalising the possession of all illegal drugs, rather than of MDMA alone; the decriminalisation of MDMA possession alone would not entail the removal of 'suspicion of drug possession' as a basis for stop and search in its entirety and so would not tackle the disproportionality and racial bias of drug policing.

Fears that 'softening' the stance towards drugs such as MDMA would result in a rapid increase in prevalence of use, and therefore harms, are understandable, but are not borne out by existing policy evaluation evidence[256]. Careful consideration of the evidence from Portugal has found that their move from criminal to civil penalties has not led to major increases in drug use prevalence rates[257,258]. There have, however, been reductions in drug-related harms, problematic drug use, and criminal justice overcrowding. The low levels of problematic usage patterns among MDMA users and concomitant low levels of entry into treatment related to its use mean that drug treatment orders are of limited relevance, and that targeted drug education interventions may be more appropriate. In sum, a shift from criminal to civil penalties for MDMA possession and low-level supply offences will ensure that disproportionate consequences for relatively benign infractions of the law do not impact the liberties and lifetime opportunities afforded to users. In the longer term it is reasonable to argue that there should be neither criminal nor civil penalties for people who use drugs, including MDMA users[259]. This aligns with the values, goals, and actions outlined at the beginning of this chapter.

Calls for the decriminalisation of drug possession for personal use can no longer be considered a fringe view. Drug decriminalisation would remove criminal penalties for drug use and possession, and low-level drug sales which correspond to 'social dealing'. The UK government's own ACMD, the British Medical Association, the Royal Society for Public Health, the Royal College of Physicians, and three consecutive UN Secretary Generals alongside multiple UN agencies have all called for the decriminalisation of drug possession. Indeed, in 2018 the

UN Chief Executives Board – representing 31 UN agencies – unanimously endorsed the decriminalisation of drug possession, calling for member states to 'promote alternatives to conviction and punishment in appropriate cases, including the decriminalization of drug possession for personal use'[260]. The UN Chief Executives Board statement also positions drug policy clearly within public health, human rights, and sustainable development agendas, which again aligns with the values, goals, and actions outlined at the beginning of this chapter.

As well as improving social justice outcomes for users of MDMA, decriminalisation will serve to improve health outcomes by removing barriers to harm reduction and health services, and increase willingness to access them amongst vulnerable populations who might have previously feared legal complications. Those on probation, for example, can access treatment support without having to first admit to an offence. Currently, UK drug safety checking services like those offered by The Loop operate in a legal grey area, neither explicitly sanctioned nor prohibited by the government, despite evidence that such services reduce harms to those with whom they interact[261]. It is worth noting that drug safety checking represents a form of de facto localised decriminalisation as it requires police non-enforcement of drug possession laws in order to function. Implementation of such services remains challenging, requiring co-ordination from a variety of stakeholders who are often uneasy, especially considering legislation that suggests that knowingly allowing drug-related activity on one's premises can be an offence[a].

To reap the full benefits that could be derived from decriminalisation, it is appropriate that criminal penalties are removed for possession of any drug, and not solely MDMA. The disproportionate and biased use of stop-searches under

a Under the MDA 1971, if the manager of a premises knowingly permits or suffers the production or supply of drugs or the smoking of cannabis on his premises then s/he is liable to criminal prosecution. The maximum penalty depends on the class of drug involved, e.g., permitting the supply of MDMA on your premises could result in up to 14 years in prison and/or a fine.

Section 23 of the MDA will not decrease if only one drug is decriminalised. Likewise, in the absence of a pragmatic, portable means of reliably distinguishing the identity of chemical compounds, the decriminalisation of one illicit white powder among many will not allow police to reallocate their resources effectively. Drug users intercepted by the police would likely claim that they were in possession of MDMA, and consequently the police would continue to open case files and send suspect samples for testing. The decrease in the stigma associated with problematic drug use and the increased uptake of drug treatment/recovery services, which have been witnessed in Portugal, depend on wholesale decriminalisation. Decriminalising possession of MDMA alone, but not the possession of other drugs (such as heroin), may in fact feed into a narrative which marginalises users of other drugs, making them reluctant to access support. Likewise, the widespread practice of polydrug use calls for the implementation of wholesale decriminalisation so that the harm reduction benefits of drug testing services to be maximised.

Decriminalising people who use drugs, whilst a hugely important and positive step, would not significantly impact the illegal market itself. The production, transit, and supply of drugs remain prohibited under a decriminalisation model and therefore controlled by the same criminal entrepreneurs as before. The comprehensive rolling out of drug safety checking that could more easily occur under national or localised decriminalisation would go some way towards reducing the harms associated with unregulated MDMA products. However, the only way to ensure product reliability and improve safety would be to create a strictly regulated legal market for MDMA.

## 3.4 Phase 2: Building a strict state-regulated legal market for MDMA

A key aim of a state-regulated legal MDMA market for adults is to establish mechanisms to ensure the standardisation of MDMA products and the safety of

the public, semi-public, and private environments in which they are consumed. In this section we outline Phase 2 of *Roadmaps to Regulation: MDMA* in more detail, highlighting how the careful establishment of such a market would meet the goals of drug policy reform, significantly reducing harms and regaining lost benefits for all stakeholders. We recognise that the regulation of MDMA is an emotive and contentious issue involving normative and ethical considerations as well as 'objective' scientific evidence. Accordingly, we suggest that space should be made in any programme of drug policy reform for broader democratic participation in drug policy-making practices[262], and a better understanding of the relationship between (contested) evidence, engagement, and participation (notably of drug users) in the making of drug policies[263, 264, 265]. A participatory process of this kind would ensure that lay public opinions – often excluded from policy-making processes – would be incorporated, and so help address public concerns, hopes and fears[266, 267].

The suggested model for the regulated supply of MDMA is designed to discourage potentially harmful patterns of use, including bingeing, polydrug use[268, 269], use in 'high-risk environments'[39, 40], and use by those under 18 years of age. Regulations around MDMA product accessibility would be vigorously enforced. A regulatory framework enforced by the police, customs officers, environmental health professionals, health and safety officers, and trading standards officers would define what MDMA preparations would be available, who could access them, and when and where they could be purchased. Accessibility for those who meet the purchase criteria (e.g., age, registered user with an available quota) would not be so onerous as to encourage the perpetuation of, or displacement to, illegal markets – although it is acknowledged that there is a balance to be struck between these sometimes conflicting objectives.

Currently, people who use MDMA go to their friends and peers, known or unknown dealers, or the darknet to source MDMA products[199]. As outlined in this report, the illegal MDMA market entails few or no safety checks on either products or their users. Concentrating MDMA product distribution in

specific outlets, licensed for a sole purpose with stringent regulatory systems in place, increases safety and minimises risk. This conclusion and our related recommendations are in keeping with the outcomes of recent attempts to evaluate the relative merits of different drug policy options using multi-criteria decision analysis (MCDA). MCDA is a tool employed in order to distil complex drug policy concerns into 'a set of simpler judgements that lead to consensus about the results'[270]. The MCDA model sets out a series of concerns that drug policy should address, followed by policy options to compare (total prohibition, prohibition with decriminalised use, legal but strictly regulated, and a legal free market), and then assesses how these various policy options address concerns for a given drug, attempting to weight the relative importance of different concerns and allowing for trade-offs where necessary. Policy criteria include the reduction of harm to the user and to others (health), the improvement of education about drugs (social), the supporting of international development and security (political), the protection of children and young people (public), the criminalisation of users (crime), and the generation of tax revenue and reduction of public financial costs (economic)[266].

Following an MCDA model to formulate and appraise drug policy on 27 criteria in relation to alcohol and cannabis, respectively, 17 drug experts and two facilitators arrived at the conclusion that, of the four broad regulatory regimes (total prohibition, decriminalisation, state control, and free market), *a state-regulated legal access market provided the best overall outcomes in terms of minimised harms and maximised benefits*. Nuances in the preferred regulatory regime emerged which reflect the differing harm profiles and associated behaviours relating to alcohol as compared to cannabis, with stricter controls on 'legal access regimes' for alcohol regarded as more important since its consumption produces greater (health) harms to self and others, than cannabis. In a sense it is these drug-specific nuances, as they relate to MDMA, that we deal with in this report.

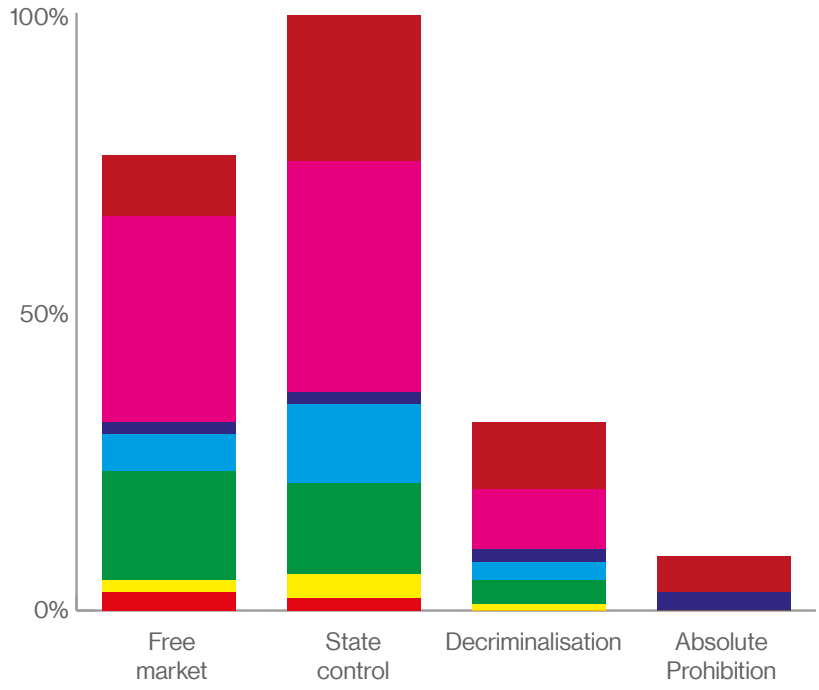



**Figure 16.1**

*Overall preference values across regimes. Displays weighted advantages.*

Cannabis

- Health Impact
- Social Impact
- Political Impact
- Public Impact
- Impact on Crime
- Economic Impact
- Cost

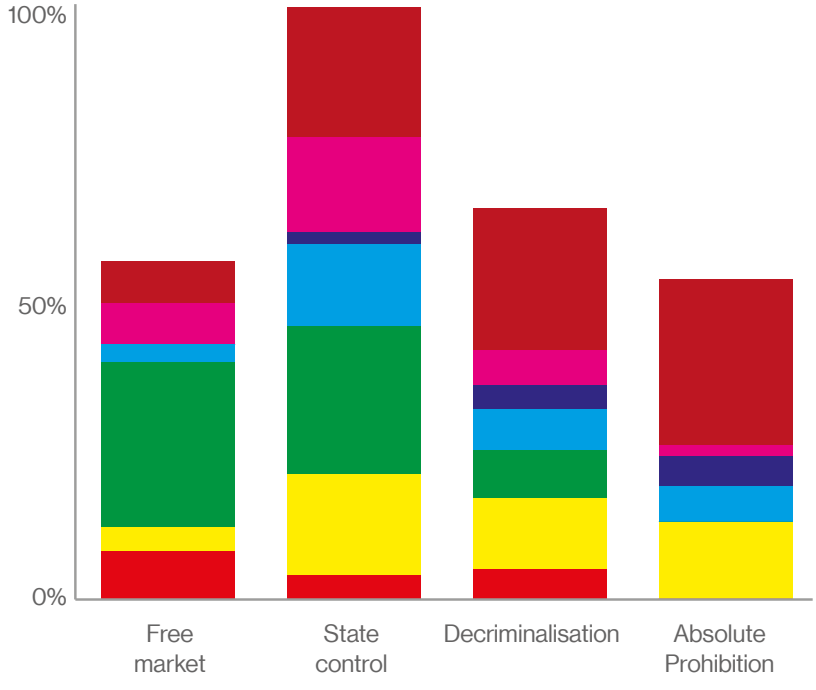



**Figure 16.2**

*Overall preference values across regimes. Displays weighted advantages.*

Alcohol

- Health Impact
- Social Impact
- Political Impact
- Public Impact
- Impact on Crime
- Economic Impact
- Cost

Source: A new approach to formulating and appraising drug policy: A multi-criterion decision analysis applied to alcohol and cannabis regulation.

Source: Science Direct

The MCDA model is but one emergent tool with which to progress towards better drug policy formulation. To reiterate, there would be no 'blind' rush to reform, uninformed by the evidence base, but instead a careful iteration of research–reform–research[8]. To account for unintended consequences, each phase of reform on the roadmap to regulation would be carefully evaluated via the production of high-quality research data, participatory democratic debate amongst key stakeholders (including people who use drugs), and expert judgements as to whether stated goals were being achieved by the actions relating to each phase. If, for example, the suggested model for MDMA product distribution by licensed vendors were to result in unintended harmful consequences for any stakeholder, the reform would be revisited and potentially revised. Models of good governance and democratic participation practices in relation to drug policy could be drawn upon to ensure the minimisation of harm to all involved[271]. With these caveats in mind, we now turn to the specificities of MDMA production, distribution, and use as envisaged in Phase 2.

## Regulating production 3.4.1

A principal harm to users associated with illegal production and supply is the variability of products sold as MDMA. A regulated market with licensed producers operating within enforced standards of product safety and quality and producing MDMA products labelled with clear indications of dosage, potential adverse effects, and contraindications would go a long way towards mitigating these harms. Contracts for licensed producers would be put out to tender by the state, with strict controls and oversight of production and distribution implemented. The state would incur the costs of establishing and running a new regulatory agency to oversee the administration of the legal MDMA market. This agency would be responsible for the granting of production licences to a limited number of chemical manufacturing companies; monitoring and enforcing compliance with health, safety, and trading standards; and tracking the distribution of the product to licensed MDMA outlets. The widespread use

of accurate traceability technology, such as unit-dose packing (with barcodes), would add to overheads shared between producers and distributors (licensed vendors). These are necessary measures to help avert the prospect of legally produced MDMA products being diverted to a parallel illegal market, and are already apparent within well-established markets for high net-worth products (e.g., pharmaceuticals). The implementation of Phase 2 would involve no net cost to the state as costs would be met through licensing fees and taxes on vendors and MDMA products. The state would benefit from tax revenues from legitimate businesses operating where only criminals once did, as well as from a decrease in health care costs associated with adverse events (e.g., through lower admissions to accident and emergency departments). Licit producers would benefit from a legal business opportunity, whilst bearing compliance and administrative costs.

A developing legal market would affect illegal producers, some of whom may turn to other (potentially more damaging) drug markets, such as those in NPS. However, with a forecast reduction in illegal MDMA-related activity, we would witness a decrease in related costs to the police and criminal justice system, especially if decriminalisation were extended to all drugs[b]. With the introduction of environmental controls to the production process, all stakeholders, most notably producer countries and countries where precursors and pre-precursors are made, would benefit from reduced ecological damage. Contextual factors, which would determine the impact of production regulations, include licence costs and requirements, monitoring (e.g., traceability measures), enforcement costs and enforcement spread (e.g., the number of trading standards officers), the level at which taxation is set, and the extent to which licit supply satisfies demand.

b It would be useful to produce a cost–benefit analysis of the creation of a legally regulated market for MDMA akin to the previous Institute of Social and Economic Research and Beckley Foundation report, Licensing and Regulation of the Cannabis Market in England and Wales: Towards a Cost-Benefit Analysis.

## Regulating distribution (supply) 3.4.2

The supply of MDMA under the current prohibitionist framework is in the hands of profit-maximising criminal organisations. In addition to limiting society's ability to control who has access to the product and how much they know about it, this can lead to a situation where MDMA is sold alongside other – often more harmful – drugs, encouraging (uninformed) consumption among adults and young people alike. Moreover, there can be additional adulteration of the substance at the supply stage (notably for MDMA powders). This all points to the need for a properly regulated distribution system (supply) rather than the unregulated 'free-for-all' which currently exists, as detailed throughout this report. Within a strictly regulated legal market, there are many options for applying controls to the accessibility of MDMA, as well as providing opportunities for promoting safer use.

### MDMA product outlets: Licensed vendors (pharmacy model) 3.4.2.1

In order to be able to compete and ultimately supersede long-established illegal MDMA markets, a legal market regulated by the state would have to ensure that MDMA is made available to consumers on terms that are acceptable to all parties concerned. We propose a specialist pharmacist retail model in the first instance as a way of meeting these demands[272]. Pharmacies are a suitable starting point for MDMA product outlets (MPOs) given that, as a model of availability, the pharmacist is uniquely positioned as a gatekeeper for accessibility and specialist drug knowledge[273,274]. Regulated pharmacy sales make it possible for retail to be governed by strict regulatory legislation and a well-defined quality assurance infrastructure[275]. Uruguay was the first country in the world to remove the prohibition on cannabis for nonmedical purposes, and is a working example of the establishment of this pharmacy model[276,277]. With the introduction of this model for MDMA products, the government would be able to tightly control the MDMA produced.

One lesson to be learned from Uruguay's experience is that the state must articulate its commitment to a coherent workable enforcement strategy. A clear commitment to enforcing the rules of an emergent state-regulated market for MDMA products, such as the establishment of a regulatory agency for MPOs, would go some way towards allaying potential public concerns. Finally, drug policy reform in Uruguay is aligned with its public health programmes and human rights obligations, where prohibition is understood to undermine human rights. As a result, the country has been able to respond to criticisms by the International Narcotics Control Board, which is the UN's drug-treaty compliance monitoring body[278]. In reply to condemnation from the International Narcotics Control Board, Uruguay has insisted that legalising the recreational use of cannabis is in line with human rights obligations which take precedence over international obligations on drug control, and that any tension between the two is a matter for international debate, rather than blind acceptance of the status quo. Uruguay's drug policy innovations, including its implementation of the pharmacy model, make it one of the most progressive drug policy regimes in Latin America, a region all too aware of the harms associated with international prohibition.

Establishing the legal distribution of MDMA in specific outlets requires a consideration of the '4 Ps' of marketing: product characteristics, prices charged, place where sold, and promotional activity. Aside from the promise of a safer product (i.e., no adulterants, consistent dosage, clear labelling, harm reduction advice as standard), prices must be competitive if illegal products are to be squeezed out of the market[279]. However, price is but one consideration in drug purchasing decisions, with availability and purity (i.e., non-price variables) also being part of people's considerations. MPOs would be conveniently located, given that they will, at least initially, be in competition with drug-delivery services organised via mobile phones and social media[280]. However, this in no way implies the establishment of a so-called 'supermarket model' of drug distribution[281]. MPOs in the pharmacy model would be tightly regulated so that no direct or indirect promotional activity takes place either in-store or in

other marketing and advertising spaces, such as on social media. In effect this would mean a blanket ban on promotional activity. Local pharmacies are ideally placed to distribute MDMA, and indeed discussion in the Royal Pharmaceutical Society's professional journal indicates its openness to consider this as part of members' roles[282]. In relation to MPOs, availability and ease of access are important non-price factors to consider, but the concerns of other stakeholders, such as local residents, should be addressed, especially given the need to balance potentially conflicting priorities, as multi-criteria decision analysis (MCDA) is able to do[270]. The hours during which customers could purchase MDMA products from pharmacies/MPOs would, for example, be tightly controlled (as the opening hours of NTE venues already are), with more conventional daytime-only opening hours to control trade and to minimise spontaneous impulse purchase, especially if potential customers are already under the influence of drugs such as alcohol.

In Chapters 1 and 2 we detailed how MDMA may be but one of a range of drugs consumed on nights out or at other leisure times/spaces such as festivals or parties in domestic spaces[283], with tobacco, alcohol, cannabis, cocaine, and ketamine identified as key co-consumed drugs. Having strict regulations to reduce the harms of polydrug use must be part of any drug policy reform. As such, those serving in MPOs would be bound by the 'right to refuse purchase' regulation – not serving someone who is judged to be too intoxicated – akin to those enacted in on-licence premises such as pubs, bars, nightclubs, and festivals[c]. Although challenges with 'right to refuse purchase' are acknowledged (not least because of issues around enforcement), it is imperative that any legally regulated market for MDMA ensures the reduction of harm to all stakeholders. Therefore,

c In the UK for example, under the Licensing Act 2003, it is illegal to knowingly sell alcohol, or attempt to sell alcohol, to a person who is drunk. It is also illegal to allow alcohol to be sold to someone who is drunk. It is also an offence for a person knowingly to get, or try to get, alcohol for a drunken person on licensed premises. Breaking the law could result in a fine of up to £1,000. If the convicted person is a personal licence holder, they could lose their licence.

sufficient funds would need to be made available for the enforcement of MPO regulation, and to ensure that any MPO licence stipulations are fully adhered to. There would be a need, for example, for officially mandated compulsory staff training (e.g., of pharmacists in the pharmacy model) concerning MDMA use, risks, and harm reduction. Combining detailed staff knowledge and experience with age restrictions, quantity limits on purchases, non-branded packaging, and labelling requirements providing content and contraindication information would further encourage safer MDMA use. 'Take-away' educational resources would be readily available at these outlets (as well as online) and would include information on MDMA-related risks and harms (including combinations with alcohol and other drugs), how to identify problematic MDMA use, and up-to-date information on harm reduction best practices. The successful techniques pioneered by contemporary on-site drug safety checking services in engaging clients in harm reduction discussions could be translated into future MPOs[284, 285].

It is worth remembering that many young people are tech-savvy 'digital natives' who are used to mobile and web-based marketing, and routinely purchase goods and services online[286]. As discussed earlier, there is a growing body of work on drug purchasing online, using social media sites and drug cryptomarkets on the darknet[12, 196, 197, 199, 200]. Given this, it is likely that a legally regulated market for MDMA may eventually require an online presence, depending on the success, or otherwise, of MPOs. This need not involve a purchasing option, but rather could consist of a 'Find My Nearest MPO' service that also has health and harm reduction information prominently available[d]. Well-respected harm reduction and drug information organisations such as The Loop (UK) have a strong online presence, which could be further enhanced in a legal regulatory model.

d It is worth noting that precluding any online purchases would exclude people living in rural areas who may struggle to get to MPOs. That said, the face-to-face contact enabled by MPOs in town and city centres remains important for ensuring sensible use conversations at point of sale.

## User controls and harm reduction 3.4.3

User controls in MDMA-using contexts would remain crucial in Phase 2 (which is laid out in section 3.4 above). User controls would focus on supporting the responsible use of a legally manufactured product, rather than on the detection of an illegal product, or on mitigating harms produced by consuming an illegal and unregulated product. Drug policy reform must have the protection of citizens at its heart, and user controls would aim to reduce the use of MDMA by underage and vulnerable populations, reduce polydrug use, encourage safer modes and patterns of consumption, and improve user understanding of the potential harms associated with MDMA consumption. The age limit for MDMA product purchase would be 18 years of age. Child-proof and tamper-proof packaging of the kind used for medicines and pharmaceuticals would also be required to reduce the risk of accidental MDMA poisonings[287].

### Pricing and purchase limits 3.4.3.1

Evidence from alcohol control demonstrates that price can be a powerful tool for moderating the consumption of legal drugs[288]. Price is an example of one variable that should come under frequent evidence-based review, to balance optimally the need to discourage excessive purchasing against the imperative not to push consumers towards more harmful alternatives, particularly illegal market MDMA and other available legal and illegal intoxicants. Since typical MDMA use is occasional, whilst alcohol can account for a significant proportion of its users' budget, it may transpire that MDMA consumption patterns will not be so price-sensitive as they are for alcohol. MDMA is a relatively inexpensive drug (as a proportion of disposable income) compared to others, given that typical consumption patterns tend towards the infrequent (e.g., occasional, weekend-only use)[289]. This means that the incentive to purchase from the legal market as opposed to the illegal one will largely depend upon non-price variables such as quality, safety, availability, and support and information offered by MPOs. Due

to the low cost of producing MDMA, it would be possible to collect a reasonable rate of tax on MDMA products whilst still successfully competing with the illegal market and allowing legitimate MDMA product vendors potentially to cover the costs of the regulatory implementation and required staff training.

Limits on the amounts people can purchase at any one time would also reinforce the importance of moderating the frequency of MDMA use and the quantity consumed. In order to access legal MDMA products, the user would have to obtain a 'personalised licence'. An MDMA product personalised licence would only be granted once an adult – on their first visit to an MPO – had demonstrated the capacity for safe use by exhibiting sufficient knowledge and understanding of MDMA pharmacology, the relative safety of different consumption patterns, and the potential harms involved. This capacity would be demonstrated during a discussion with an appropriately trained pharmacist. The stipulations for a personalised licence would include the monitoring of purchase patterns, with challenges made to those attempting to purchase more than a reasonable amount for personal use[290]. If an individual continually purchased (or attempted to purchase) more than the recommended limit, they would be subject to increased scrutiny from pharmacists and risk losing their personalised licence. A 'reasonable amount' for personal use would be determined by pharmacologists and harm reduction experts. As an active dose of MDMA is 80–100 mg, it is likely that this would shape purchase limits alongside personalised harm reduction advice. An individual's level of MDMA experience would, for example, be discussed with the pharmacist, and would be noted on the customer's licence for future reference. The personalised licence for purchase of MDMA products from MPOs administered by pharmacists would be reviewed on an annual basis.

### 3.4.3.2 Marketing controls and information campaigns

Coupled with information on the content and dosage on the packaging, health information would be mandated on packaging and at point of sale to highlight

key risks and discourage use in combination with other drugs or medications. In addition, we propose strict marketing controls, specifically a comprehensive ban on marketing and advertising, including in-store displays, as these have been shown to influence young people's use of legal drugs (e.g. tobacco) and unhealthy food[291]. Packaging requirements add marginally to costs, as will fees for licensing and other quality assurance processes, but these will be borne by the producer/vendor. Information campaigns around MDMA safety and responsible use are central to Phase 2. Such information campaigns would cover all sales outlets and educational establishments (schools, colleges, and universities), and would include a wide range of health messages, including the risks of polydrug use, preventing use during pregnancy, safer dosage information, and information on recognising the symptoms of adverse events in relation to MDMA products and how to manage them. Additional targeted education programmes would address and minimise use by certain groups who are more likely to encounter problems, such as young people (under-18s) and individuals with physiological (e.g., cardiovascular) or psychiatric vulnerabilities.

Well-targeted information campaigns would also be deployed to minimise the social acceptability of driving under the influence of MDMA, and to promote alternatives, such as designated drivers. The success of campaigns to reduce the acceptability of driving after drinking would be a useful model. In a context where alcohol, MDMA, and cannabis were all regulated, a campaign could encourage the generalisation of current norms about the unacceptability of drink driving to all driving whilst impaired. In Canada, laws on impaired driving are being changed to accommodate the country's legalisation of the cultivation, sale, and consumption of recreational cannabis, with tougher penalties for all drug-impaired driving and new roadside tests designed to catch those smoking cannabis and driving (within a given time limit)[292]. However, this call for tougher penalties was politically motivated because drug policy change opponents had raised 'driving under the influence' as one of the many risks of a legal regulation model. The Canadian model also suggests that roadside tests are valid ways to

establish impairment, when in fact they are not (at least not in the same way as alcohol road testing is). The rate of 'false positives' (detection of a drug where there is none) in existing systems is also worrying[293].

Currently, MDMA is one of a group of eight illegal drugs for which a 'zero-tolerance' approach is in force in the UK regarding drug-impaired driving. The law makes it an offence to be in control of a vehicle with *any* detectable trace of these drugs in the body[e], regardless of whether the driver is likely to be impaired in any way. This problematic 'zero tolerance' approach contrasts with the risk-based approach applied to alcohol users, and to the recommendations of scientists commissioned by the government to report on the issue[294]. The alternative risk-based approach, as recommended by the aforementioned expert panel commissioned by the government[294], is for drivers to face prosecution if their blood levels of MDMA are above a threshold that research has shown to be associated with impairment: 300 µg/L or 150 µg/L if the driver has also been drinking alcohol. This risk-based system for defining punishable drug-driving offences works well for alcohol in combination with strong messages discouraging any driving until a person is sober.

### 3.4.3.3 MDMA use in the night-time economy: MDMA-friendly spaces

Night-time leisure spaces are key settings in which MDMA is consumed. As most are formally regulated, they provide an environment in which the risks of acute MDMA-related harm can be managed and reduced. As well as allowing access to a standardised, high-quality, clearly labelled product, Phase 2 should allow for the development of adult-only MDMA-friendly spaces where, free from the hostility of criminalisation, a culture of responsible usage norms would be extended[67,257,295] and medical assistance would be close at hand. The MDMA-friendly spaces we propose here could also be 'dry'. As noted in previous chapters, early patterns of MDMA consumption at illegal parties in the late 1980s and

e Above a threshold deemed to rule out accidental exposure, set at 10 µg/L.

early 1990s involved 'dry raves' where no alcohol was made available to customers on-premises (although this is not to say that alcohol was not consumed by party-goers). Examples of spaces for drug use which already abide by this no-alcohol rule include many cannabis cafés in the Netherlands.

In previous chapters we identified one key feature of contemporary drug use, namely polydrug use, including combining MDMA with alcohol. In Phase 2, considerable effort would be put into minimising this pattern of consumption given its well-documented harms. MDMA makes alcohol users underestimate their drunken impairment (and vice versa), and so puts people at higher risk of road accidents and similar negative incidents[296]. Alcohol impairs inhibitory control and therefore makes it easier for people who use drugs to consume drugs faster or in higher quantities than they may have intended[297], a pattern of drug use which we also see in relation to the combination of powder cocaine or amphetamines and alcohol in the UK's NTEs.

Currently, some licensed venues are hostile to MDMA use, partly because it impacts profitable alcohol sales, and partly due to the ever-present threat of licence revocation if a drug incident or drug dealing occurs on their premises. This said, most licensed premises 'perform' zero tolerance towards all illegal drugs[298] while knowing that without customers who use MDMA and other drugs they would go out of business. At a practical level, it is impossible to prevent all drug use in licensed premises. Even the threat of ejection, the threat of arrest, a visible security and/or police presence, and stringent searches do not deter the many attendees who still smuggle in drugs for their own personal use, or that of their peer group. This clandestine environment is far from conducive to reducing MDMA-related harms. MDMA-friendly spaces would be non-clandestine versions of contemporary NTE venues and events. There are already some MDMA-friendly spaces in existence, even if they are not explicitly labelled as such. These are the licensed venues – typically dance music spaces – where owners, staff, and customers understand that the consumption of MDMA is

occurring and act responsibly on that understanding. In these spaces, MDMA use is neither condoned nor condemned, but rather is acknowledged as a 'fact of life'. Indeed, many harm reduction initiatives – including drug safety testing – are premised on this pragmatic acknowledgment of the reality of the enduring presence of drug use. Only by bringing MDMA use out in the open, instead of it being hidden, can we significantly manage, and reduce, MDMA-related risks. What might this look like in practice?

In the UK there are stipulated technical standards relevant to licensed venues around the regulation of ambient temperatures and the adjustment of those temperatures pertaining to the specificities of the night[299]. The control of ambient temperature and humidity has long been noted as good practice under the 2008 Safer Nightlife guidelines[300], and under specific licensing authorities' jurisdictions, with most recently the City of London stating that temperature levels and humidity control is key to public safety in the NTE[301]. All applications under the UK's Licensing Act 2003 (which came into force in 2005) are accompanied by a 'club operating schedule' whereby applicants must show how they will promote the licensing objectives: the prevention of crime, disorder, and public nuisance; the promotion of public safety; and the protection of children from harm (which focuses on turning away underage customers).

However, the Licensing Act 2003 does not include any specific stipulations around temperature control[302]. Further, technical standards and good practice measures are not consistently adhered to, nor properly enforced across much of the UK. Busier nights in indoor dance venues are often unbearably hot and sweaty. This is not acceptable, given the evidence we have laid out in this report regarding the risks of dehydration and overheating when on MDMA. Looking beyond the UK, the diversity of regulations and the number and range of agencies and/or authorities involved, varies greatly across Europe (sometimes even within different cities/regions of the same country), as do licensing requirements; this makes it difficult to compare legislation and enforcement

measures. However, in a 2012 Club Health survey of nightclub industry representatives across Europe, a majority (78%) stated that they tried to control temperatures at an operational level given its effectiveness at ensuring good health and safety inside their premises[303]. This demonstrates an understanding of the problem of overly hot environments alongside a willingness to consider the introduction of enforced (rather than voluntary) temperature limits, much as noise limiters exist in NTE venues today.

Figure 17
*Nightlife.*

Source: Pixabay

Throughout this report we have highlighted the importance of the use context as it pertains to acute MDMA-related harms. Recommendations for drug policy change rest on these details of contextual harm reduction. This means that by decriminalising and then legally regulating MDMA, new policy possibilities open up, as, in this instance, venues become more responsible for the safety of their MDMA-consuming customers, just as they currently are in relation to alcohol. In contrast to the prohibitionist status quo, under a state-regulated legal market, MDMA-friendly venues and events would be required to take steps to minimise risk and nurture responsible MDMA use. These may include more strictly enforced regulations to ensure that dancefloors and festival tents are cool and well ventilated. The employment of doctors at festivals has been shown to prevent many drug casualties requiring hospitalisation, reducing impacts on local health services[304]. MDMA-friendly spaces would then be

legally bound to ensure that adequately trained in-house medics are available. MDMA-friendly spaces would continue to welcome adult users into regulated spaces where under-18s are strictly excluded, as is currently the case in UK nightclubs. However, the strict exclusion of under-18s from MDMA-friendly spaces may involve the continuation of MDMA use by teenagers in unregulated spaces such as parties in domestic spaces and illegal raves[245 246], the latter of which have grown in number in recent years[305]. Following legal regulation, teenagers may still consume MDMA (although strict age restrictions will apply), but the products they consume will be standardised; education and information will be considerably improved; and perhaps most crucially, if something goes wrong, they will be less fearful of the repercussions around calling for help.

### 3.4.3.4 On-site MDMA sales in the night-time economy

Given the association between dance music cultures and MDMA use, it would seem at first glance that the establishment of a regulated legal market should necessarily incorporate the on-premises purchase of MDMA products at dance music clubs, events, or MDMA-friendly spaces. However, the presence of alcohol, the likely reticence of venue owners to such a scheme, and the need to ensure that harm reduction information is conveyed within an environment conducive to rational, informed choice, does not sit well with such a model of MDMA distribution. Yet the phased nature of reform in this roadmap to regulation does mean that if single-drug use became normalised and polysubstance/polydrug use increasingly de-normalised, the make-up of the UK's NTE may change, creating space for increasingly 'pharmacologically specialised' venues or events[f]. Existing dance music brands and dance music-oriented venues where customers were already predominantly MDMA users may wish to change their business model and move towards the model of MDMA-friendly spaces outlined here, replacing alcohol bars with 'in-house' MPOs.

f This may include the 'pharmacological specialism' of 'no alcohol or drugs' spaces which already exist in cosmopolitan urban centres, for example the many shisha bars and gelato parlours frequented by teetotal young people.

## Monitoring and evaluation 3.4.4

The implementation of Phase 2 must draw on the evidence base around other regulated markets such as tobacco and alcohol to develop assumptions about what the hypothesised impact of an MDMA policy change might be. For MDMA products, even more than is the case for cannabis (currently the most developed emergent regulatory model apart from alcohol, tobacco, and prescription medications), there are significant areas of uncertainty. It would be important to perform detailed impact assessments based on variations in parameters (including levels of price/taxation, and availability) via different outlet models. It would also be important to monitor closely changes in outcomes, and to have a flexible model that could respond to lessons learned during implementation. Monitoring prevalence of use and incidence of specific harms, for example, would be crucial to understanding the impact of any MDMA policy change. MDMA is a popular recreational drug historically linked to specific youth and music cultures in leisure spaces/times. Despite its popularity amongst some people, MDMA does not rival alcohol or cannabis in terms of widespread use. The aim of the proposed regulatory model is to make this relatively popular and comparatively safe drug available to adults within a culture that encourages responsible use and harm reduction. Although difficult to forecast, it is possible that some increase in the number of users will take place if the drug is available legally. Nevertheless, the aim of accompanying controls is to ensure that the use is safer, which will lead to a reduction of drug-related harm and associated health services costs to the state, as well as maximised benefits. While initially the aim would be to control legal access to MDMA products strictly so that the prevalence and frequency of use do not markedly increase, certain trade-offs will be required, since, if access is made too difficult, the illegal market will continue to flourish. If use of legal MDMA is found to cause a net reduction in harms, further cautious easing of restrictions might be considered to realise the benefits of reducing the use of other potentially riskier drugs, such as alcohol. However, at the early stages, a cautious regulatory model is most appropriate.

# Conclusion

Around the early 1980s, governments across the world had a choice. MDMA, an emerging drug with quite unique effects, was growing in popularity. With the benefit of hindsight, we can speculate about how they might have chosen to implement a regulatory structure to manage the burgeoning market for MDMA, and nurture the development of a socially integrated culture of responsible recreational MDMA use. Instead, prohibition of the drug was instituted locally and globally. The result has been a worst-case scenario, a 'lose-lose' situation. Those fighting to eliminate MDMA in order to defend public health, have proved powerless in preventing it from becoming one of the world's most popular recreational drugs. Therapists hoping to explore MDMA as a tool to bring wellbeing to suffering people, have had their ambitions frustrated. People wanting the choice to take a managed personal risk in exchange for a pleasurable experience can only take an unmanaged gamble with pills and powders of sometimes dubious composition, while risking potentially life-changing criminal sanctions for a consenting adult behaviour, less risky than many already legal activities. Public services such as hospitals and courts, and ultimately taxpayers, bear all the financial costs associated with its use, whilst criminals harvest the rewards. The human costs of entirely preventable deaths are impossible to quantify.

In the bitterly ironic terminology of the MDA 1971, MDMA is a 'controlled drug'. In truth, no control exists over its synthesis and formulation into a reliable product, its importation and distribution, or its use. Illegal MDMA is uncontrolled by default, yet there is no reason to believe that it is uncontrollable within the legal sphere. The Beckley Foundation advocates meaningful drug control. What would it mean for MDMA to be a state-controlled, legally available drug? Government control through legal regulation would steer outcomes in the desired direction. Currently, the government's lack of control

means they are failing to manage outbreaks of toxic adulterants such as PMA, or surges in pill/tablet dose. People are dying needlessly in growing numbers as a result. The government claims that MDMA is prohibited because it is dangerous, but this is not so much a falsehood as a non sequitur. The intrinsic dangers of MDMA, relatively moderate as they are, are only compounded by prohibition. This report has set out an alternative framework for a system of MDMA control. Given that such a move has few, if any, precedents, our framework leaves plenty of room for each element to be trialled and adapted in response to evidence and to the public will.

Supporters of the 'tipping point' model of drug reform argue that prohibition has started to crumble, although this claim is contested by those who point to, for example, the increasing militarisation of drug law enforcement. However, incremental change is afoot in some areas. Until recently, many citizens took it on trust that cannabis had to be illegal to prevent a public health catastrophe. Now public opinion is shifting, as the spread of legal cannabis in the US – albeit under a far from optimal, highly commercialised, lightly regulated regime – undermines those myths. A more strictly regulated cannabis market in Uruguay demonstrates that there are multiple pathways available, and Canada is now carving a path somewhere between the US commercial models and the Uruguay state control models, adding more to our understanding of policy options. While cannabis proves that prohibition is not the only way to manage recreational drugs, the very different nature of MDMA's effects, risks, and consumption practices means we cannot uncritically adopt and apply successful elements of cannabis, alcohol, or tobacco regulation without careful consideration of their likely consequences in a new context. MDMA regulation is a unique challenge. When instituted it will be the first modern regulated market for a stimulant of any kind, apart from BZP in New Zealand. However, this is not to suggest that MDMA regulation would be a reckless step into uncharted territory. Unlike alcohol, tobacco, or caffeine, MDMA is not dependence-forming. We already successfully moderate the risks of other substances that are toxic in overdose

such as paracetamol, which demonstrates how relatively simple regulations on packaging and distribution can reduce rates of harm and death.

It is imperative that evidence guides policy choices. This is of course difficult in our local and global political climate, where governments remain reluctant to engage meaningfully with debates around drug reform as a highly complex (and easily sensationalised) policy arena. As with the psychedelics, the power of MDMA to induce extremes of experience and to shock the imagination of others can be perceived as more threatening to established social norms than as a result of any quantifiable harmful consequences of use. Tobacco, as a regulated product, kills one in three of its dedicated users, but generally in a way that fits the established cultural template for what death looks like (ill people in beds). This combined with the absence of obvious intoxication means tobacco does not naturally evoke a comparable degree of social anxiety as MDMA. MDMA-related deaths typically occur suddenly and shockingly, in nightclubs, at festivals, and at parties; these spaces are associated with celebration, not devastation. MDMA-related deaths are nearly always covered in the media, typically in a sensationalist, even ghoulish manner. However, behind the appearance of entrenched division in the drug policy debate, there may be more unity than is recognised, in the form of a common desire to minimise harm and keep people safe. Right now, on a weekly basis, around two people in the UK will die having introduced unregulated MDMA products into their bodies. In response we need to build consensus that taking control of MDMA is the route forward. We have already lost decades of potential MDMA policy reform, so now is *not* the time to tinker. Without a more fundamental change to our approach to MDMA, we risk letting down current and future generations of citizens. Let us not have another wasted decade.

# Why MDMA should be regulated

## Anne-Marie Cockburn (Martha's mum)

Figure 18. *Martha Fernback.* Source: Anne-Marie Cockburn

At 11.20 a.m. on the 20th of July 2013, I got the phone call that no parent wants to receive. A stranger told me that 'my 15-year-old daughter was gravely ill and they were trying to save her life'. Nothing can prepare you for a moment like that and luckily most people will never get to know how this type of loss feels. I've heard it said that losing a child is the ultimate burglary and for the past six years it has felt as though I'm still hoping for my girl to come home. Of course, I know she won't, but it's as though every cell in my body is programmed to being Martha's mum and they've yet to find their new purpose.

So, my reality is that one minute I was a single mum to a beautiful 15-year-old daughter who was three months away from her 16th birthday, and the next

I was childless and alone. A bereaved single mother. Those words choke me as I type them – I don't relate to them because I simply don't want them to be true.

I always worried that something would happen to me and that Martha would be left motherless – but never, ever did it occur to me that she'd go first. Seeing your gorgeous child's photo beneath an horrific headline on the front page of all the newspapers is the most hideous, surreal experience. I just couldn't believe it – the adrenaline and diazepam kept me numb for the first few weeks, and in time I reluctantly came back down to earth and started to search through the wreckage of my old life, in order to find answers to help try to make sense of what had happened. But it doesn't make sense and it never will.

As a parent you do everything you can to help guide your child through life – 'have you got sunscreen on, did you eat your lunch, don't forget your bike helmet' – and as they get a little bit more freedom you hope that everything you've taught them up to that moment will be enough to see them home safely every day. But lurking in every community is a danger that I was so blissfully ignorant of, a danger so widespread that it's become the biggest black market on planet earth, a danger that I naïvely didn't think related to 'a family like mine'. How wrong I was – how clueless and ignorant. I shake my head at my former self and wonder why I had this opinion. Well, I've learned the hard way and I've learned very quickly what I should have known then.

My precious girl's life was wiped away within two hours of swallowing half a gram of white powder that turned out to be 91% pure MDMA – I've been told it was enough for 5–10 people. Martha died from an accidental overdose at exactly 2.17 p.m. on a beautiful sunny Saturday afternoon. Just like that.

My girl truly loved life, but she was curious as many teenagers are. Martha wanted to get high, but she didn't want to die. No responsible parent wants either, but you'd prefer one of those options to the other. That is why I want MDMA

to be legally regulated. Plain and simple. Twelve people die every single day in the UK from a devastating drug-related death. This means twelve more families have to live with the agonising reality that their loved one's death was preventable.

No drug is made safer by leaving it unregulated on the black market. Under the current system, whether you're 5 or 55 you can get easy access to pretty much any substance you want – there is no request for ID, there is no enquiry as to your health, or concern for your wellbeing. The laws are supposed to keep us safe – but the Misuse of Drugs Act 1971 isn't fit for purpose. Drug prohibition has achieved exactly the opposite of what it was set up to do. Therefore, I believe that it is time for our government to be more visionary and to look at new approaches in order to start to truly control and regulate all drugs, including MDMA.

The difference between a poison and a medicine is the dose. Had Martha taken something that was licensed, labelled with a list of ingredients and recommended dosage, she'd still be alive today. My vision is for a legal regulatory model that is for those aged 18+. Under this model even if a younger person inadvertently got their hands on something, at least they could make a more informed decision. I don't want the world to lose another Martha and that is why I tirelessly campaign for legal regulation.

# On the front line of the War on Drugs

Neil Woods

In 2013 Professor David Nutt, former Chair of the UK's Advisory Council for the Misuse of Drugs, publicly declared that the prohibition of certain drugs was the 'worst case of scientific censorship since the Catholic Church banned the works of Galileo'[306]. His point still stands. For decades, scientific research into substances which offer us an improved understanding of the human mind and which have therapeutic potential have been curtailed by global anti-drug laws. However, this scientific censorship is increasingly being questioned, most recently with the Advisory Council for the Misuse of Drugs' recommendation that regulated cannabis-based medicines be made available in the UK, following a public campaign by parents of children whose epilepsy is better managed by such medicines. Whilst it is difficult to get a licence to research drugs such as cannabis and MDMA, and their illegality makes them prohibitively expensive, scientific studies examining their potentially therapeutic properties have been undertaken, including on the therapeutic potential of psilocybin and ketamine to treat severe depression, and more recently, the success of trials of the treatment of post-traumatic stress disorder (PTSD) using MDMA.

The work of the Multidisciplinary Association for Psychedelic Studies (MAPS) based in the US is hugely exciting. As a sufferer of PTSD, I have a personal interest in this. I live with an increasing number of debilitating PTSD symptoms, of which the most persistent and tiring is a profound sense of guilt. I have moments where I exist completely in a memory from over a decade ago, and in so doing I develop breathtaking anxiety. I worry that I will never escape from the memories, all of which concern people I have harmed. As an undercover police officer, I was tasked to catch gangsters. I used and manipulated vulnerable people in order for them to introduce me into the ranks of organised crime. During many years of this shady work I had numerous near-death

experiences. I've had a samurai sword held to my neck and a knife to my groin. I've been stripped at gunpoint and been the target of a deliberate hit-and-run attempt, from which I narrowly escaped. These events have contributed to my current mental state. However, the most dominant memories are of the people I endangered with my Machiavellian manipulations. Anyone introducing a police officer to the gang is likely to suffer, but I made the decision to involve others time and time again, despite being fully cognisant of the dangers they would be exposed to. There is no other form of policing for which the end justifies the means: whereby inflicting harm on somebody is warranted in order to get a desired result. The War on Drugs has brought a military mindset to policing, and with it has come a condition associated with military action.

As a society we now have a better awareness of PTSD. It is widely understood that trauma of all sorts can leave considerable mental scars. We have come a long way from soldiers suffering from 'shell shock' being considered cowards. Complex PTSD is a condition which is not caused by a single event. A car crash survivor may suffer PTSD symptoms from one occasion, but for sufferers like me, things cannot be clearly traced to a specific moment in time. I have colleagues in Law Enforcement Action Partnership (LEAP) UK with similar symptoms to me. We have all done other police work and been at risk during conventional policing, but our symptoms relate specifically to our undercover drugs work. The trials by MAPS have had former soldiers take part, but there is also a police officer who benefited from the experiments. I have discussed the trials with my colleagues in LEAP US and there is a growing understanding amongst law enforcement professionals of the close relationship between the War on Drugs and PTSD. The possibility of a new treatment is welcomed amongst those that acknowledge the problems associated with the condition. I spoke, for example, with retired Detective Justin Boardman, of the West Valley City Police Department, Utah, who told me:

> MDMA therapy shows promise to be a key component in holistic mental health treatment for the police. We don't have enough options, and we're

> often punished for being open about our trauma. Good officers lose their jobs for seeking help. Better departmental policy and access to treatment, including MDMA therapy, could help keep our best officers on the street.

This is a startling thing to hear from a police officer in the US – a nation at the heart of the War on Drugs. Perhaps, as it becomes more widely acknowledged that PTSD is a symptom of that war, the dark irony of this situation will become clear to everyone: the possibility that one of the drugs suppressed by prohibition could be key to relieving the stress and damage caused by it.

The claims of censorship made by Professor David Nutt were met with a variety of reactions in the media and scientific community. At LEAP we are police. We are investigators. We follow evidence. In declaring that we should follow an evidence-based drug policy, we commit to supporting those in the scientific community who share the same goal. This is important, for how can we follow evidence if scientific research is suppressed? The work of MAPS on PTSD in relation to MDMA will, I believe, be one of the most important steps on the road to recovery from prohibition. Not only does it cut through the ideological propaganda relating to the use of the drug, it also offers new understanding of the harms caused by the misinformation which so often stems from the War on Drugs.

# MDMA-assisted psychotherapy as a potential treatment for alcoholism

Dr Ben Sessa

MDMA has been studied successfully in the last 30 years as a treatment for PTSD. The MDMA non-ordinary state of consciousness allows the user to safely address painful emotional memories that would normally be avoided. Often patients with PTSD have had early childhood traumatic experiences. My experience as a child and adolescent psychiatrist working with abused and maltreated children has shown me how unresolved childhood trauma frequently develops into adult disorders, particularly addictions. In recent years, my work with adult patients with addiction has shown the huge difficulty in treating alcoholism because patients often cannot address and resolve their childhood issues. As a result, modern psychiatry's success rate at treating alcoholism is very poor, not much better than in Victorian times: 90% of patients will return to drinking within four years after detox and the best available treatment.

This led our team in Bristol to develop a study exploring MDMA-assisted psychotherapy as a treatment for alcoholism. While classic psychedelic drug-assisted psychotherapy (e.g., with LSD and psilocybin) has a rich history in the treatment of addiction, ours is the world's first study to explore MDMA-assisted therapy for the treatment of any addiction. The rationale is that, since trauma so often underlies addiction and MDMA appears to be effective at treating trauma, MDMA therapy could be useful for treating alcoholism.

We are currently running a small, open-label proof-of-concept feasibility study to prove the safety and tolerability of MDMA-assisted psychotherapy in Bristol. The project is affiliated with Bristol University and Imperial College, London, who are sponsoring the study. Our aim was to treat twenty patients with a diagnosis of alcohol use disorder using an eight-week course of MDMA-

assisted psychotherapy, which entails taking MDMA twice during the course of the eight-week therapy, spaced between non-drug preparation and integration therapy sessions.

Myself and co-therapist Dr Laurie Higbed, an addiction clinical psychologist, are carrying out the psychotherapy sessions. The main outcome measures are the safety and tolerability of this form of drug-assisted psychotherapy for patients with alcohol use disorder. All patients are screened according to strict inclusion and exclusion criteria for eligibility. We monitor physiological observations throughout the MDMA sessions and for seven days after each MDMA session. We see them for eight weeks during the therapeutic course, and then for nine months of follow-up after the therapeutic course to collect outcome data. We assess drinking behaviour and other measures include participants' mental health, physical health, quality of life, sleep, and suicidal status.

So far, we have fifteen patients fully enrolled and we have carried out twenty-six MDMA-assisted psychotherapy sessions. Results are promising, with participants reporting MDMA effects of profound significance. It appears MDMA-assisted psychotherapy helps to unlock rigid, maladaptive, addictive behaviours and support a move towards recovery. There have been no serious adverse events and patients report finding the course to be safe and tolerable, far superior to previous attempts at tackling their lifelong alcoholism. So far, of the thirteen patients who have completed the therapeutic course, only two have returned to their full levels of drinking that they presented with at the start of the course. The project aims to run until December 2019. Thereafter, the Bristol-Imperial MDMA-for-Alcoholism team hope to progress to a placebo-controlled randomised study.

Due to MDMA's status as a Schedule 1 drug, we have encountered enormous financial and regulatory hurdles in setting up this project. The costs of obtaining Schedule 1 licences at multiple sites and overcoming regulatory hurdles associated with obtaining clinical-grade MDMA have impacted our progress. The current

scheduling of MDMA under the Misuse of Drugs Regulations is significantly impairing its clinical research. In total, including manufacturing costs, approval certificates, transport, storage, encapsulation, pharmacy, and dispensing costs, our MDMA is costing the study approximately £9,000 per gram. This prohibitive cost, due primarily to its Schedule 1 status, puts off many would-be researchers and seriously hampers advances in this vital field of medical research, which could have enormous benefits for a large population of patients for whom current traditional clinical treatments are sadly often ineffective.

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