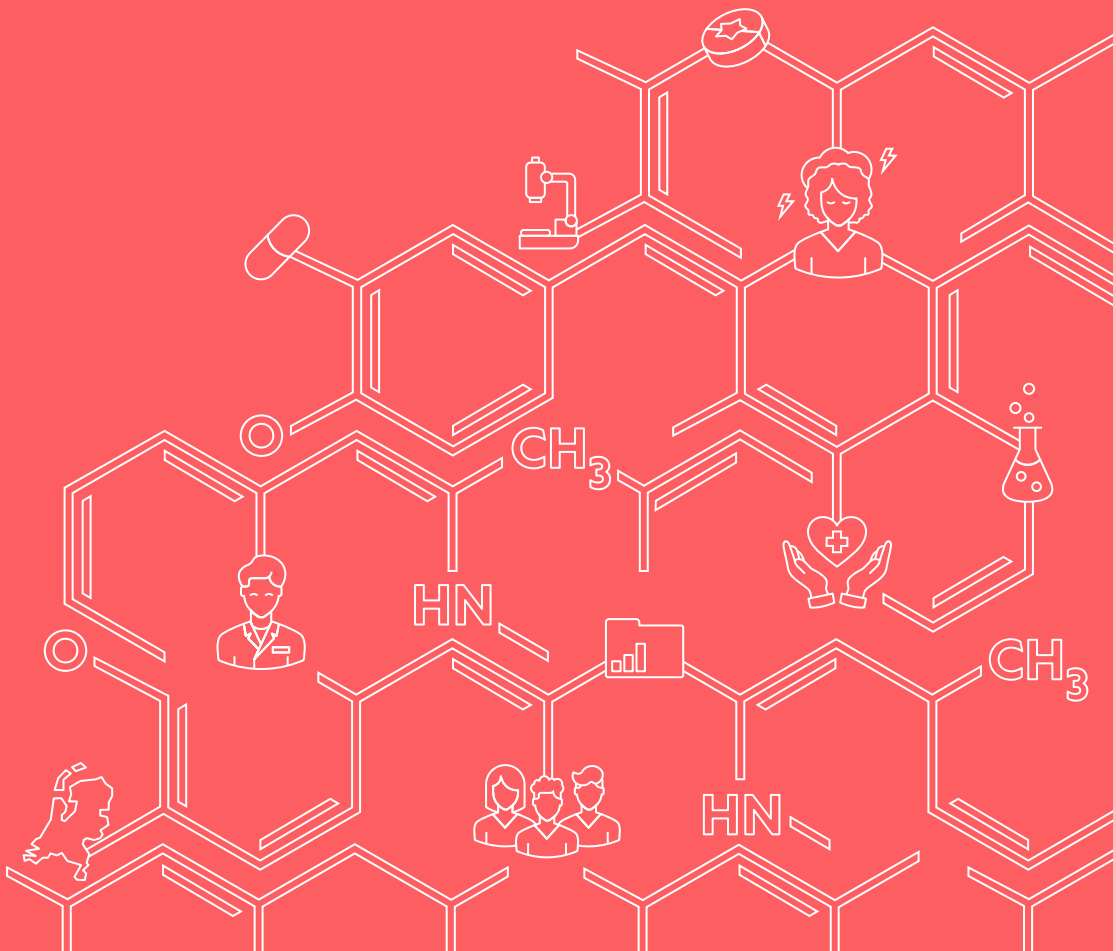
Report of the
State Commission on MDMA ///

MDMA ///
Beyond Ecstasy



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This is a digital publication of the State Commission on MDMA.

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State Commission on MDMA ///

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Summary

Chapter 1: A short history of MDMA
Chapter 1 provides a brief historical overview of MDMA. The substance was discovered in 1912 during the search for a coagulant and rediscovered 65 years later as a medication to support the effects of psychotherapy. It was not until the early 1980s that MDMA was first identified in dance venues. It was prohibited in the Netherlands in 1988. In tablet form – better known as ecstasy – MDMA is still quite popular as a party drug. Since the 2010s, new scientific studies have been conducted that also include a focus on the potential of MDMA-assisted therapy for the treatment of mental health issues.

Chapter 2: Use and effects
Chapter 2 describes the mode of action and effects of MDMA and the recreational use of ecstasy. Given that MDMA is hardly addictive, it is totally different from substances such as alcohol or cocaine. MDMA intensifies the sense of social communion among users, enhances their ability to cope with intense stimuli and increases their stamina. In the Netherlands, over half a million people use MDMA incidentally on a yearly basis – more than ever before. The number of users is also high compared with the numbers in other countries.

Compared with various other substances, ecstasy involves relatively low risks to users. Studies have shown that the use of MDMA does not result in reduced cognitive capacity in the short term. Studies into long-term effects have proven to be difficult to conduct, because many frequent MDMA users also use other substances. However, the average ecstasy tablet currently available in the Netherlands contains a lot of MDMA, making the substance more harmful than necessary. The harmfulness of ecstasy strongly depends on the setting and on user characteristics. For example, the risk of ecstasy is high when taken in hot spaces by users engaging in prolonged dancing or other substance use as well. This can result in hyperthermia and, occasionally, in organ failure and death. Such rare complications have thus far not been studied sufficiently. In addition, there are no figures about the exact number of ecstasy-induced deaths in the Netherlands, because autopsies are extremely rare in this country and the Dutch mortality register does not sufficiently distinguish between the various types of drugs-related deaths.

Chapter 3: Dutch MDMA policy: practice and challenges
Chapter 3 analyses Dutch policy on MDMA. That policy serves two objectives: to promote public health on the one hand, and to enforce compliance with the Dutch Opium Act and fight organised crime on the other. In the Netherlands, public health always takes precedence over enforcement, and for good reason. This ensures that priority is given to preventing further harm to individuals and society at large. This approach fits in with the broader effort to reduce the stigmatisation of substance use, so that users and those close to them need not feel shame or fear when asking for help.

From a public health perspective, Dutch policy has been successful in a variety of ways. Despite the large numbers of ecstasy users, the volume per user is relatively low. This is why the number of ecstasy-related deaths is probably lower in the Netherlands than in neighbouring countries. Dutch users generally seem fairly capable of mitigating the risks of use, thanks in part to good information, effective monitoring of the ecstasy market and high-quality care and facilities at parties and festivals. An effective prevention policy distinguishes between target groups and is based on scientific insights. Any policy that fails to meet these criteria is potentially counterproductive.

The other part of MDMA policy focuses on the ban on the possession and production of, and trade in, ecstasy. The possession of a single ecstasy tablet is tolerated, unless there are indications that the tablet is intended for sale. Fighting the symptoms of drugs production and trade, such as violence and illegal dumping of waste, is putting an increasing strain on police capacities. Criminal networks produce mainly for the global market, and there is not enough capacity to tackle them effectively. As a result, the measures targeting the use of ecstasy on the one hand and those aimed at reducing illegal production on the other belong to two entirely different policy domains in the Netherlands.

Dutch drug policy is based on an integrated government vision document from 1995 that was most recently reviewed in 2009. Back in 1995, the main drugs-related problems were heroin and public nuisance on the streets; today, the main problems are cocaine, designer drugs and large-scale organised crime. There clearly is an urgent need for an updated vision for national drug policy, reviewed by relevant knowledge institutions.

There is also a need for an overarching policy. Organised crime finds new recruits among young people, mainly from disadvantaged neighbourhoods – the 'new blood'. Young people are particularly vulnerable to recruitment by criminals. That is why it is important to ensure structural and long-term investment in youth work, education and disadvantaged neighbourhoods.

Chapter 4: The debate on MDMA regulation

Chapter 4 considers the current political debate on the regulation of drugs. The State Commission notes that many of the views exchanged in this debate are based on spurious arguments. While the participants agree on many problems, many solutions that are being proposed are inadequate. The State Commission calls on the participants to conduct the debate on the basis of facts and scientific insights.

Compared with other prohibited substances in Schedule I of the Opium Act, the health effects of ecstasy are not very serious and appear to legitimise a transfer of ecstasy from Schedule I to Schedule II. Separate from the debate on the health effects, however, the State Commission finds that the discussion on MDMA is to a certain extent being hijacked by the criminological dimension. Until certainty is provided that organised crime is pushed back and until regulation options have been elaborated in a proper way, it would be ill-advised at this time to remove MDMA from the Opium Act or transfer it to Schedule II. Schedule I to the Opium Act is the sole legal framework currently available to the police and the judicial authorities for fighting drugs-related crime. That is why, under the current circumstances, the State Commission's advice is to maintain the inclusion of MDMA in Schedule I to the Opium Act.

Chapter 5: MDMA-assisted therapy

Chapter 5 describes the use of MDMA in health care through MDMA-assisted therapy. Usually referred to by its English abbreviation, MDMA-AT has so far been studied principally for the treatment of (serious) post-traumatic stress disorder (PTSD). While various effective treatment options are available to fight PTSD, they do not always work and they do not work for everybody. PTSD causes intense suffering among patients, as well as significant pressure on the health care system and on people in the patients' immediate environment. Recent clinical studies suggest that MDMA-AT is safe and extremely effective for PTSD patients, especially where existing treatments produce little or no effect. Owing to these positive results, MDMA-AT has been submitted to the US registration authority for approval and is expected to be registered as a medicine for the treatment of PTSD by the end of 2024. However, this does not mean that it will also become available on the European or the Dutch market. There is a serious need for a legal scope for action that would see MDMA approved for the treatment of serious PTSD in the Netherlands.

Chapter 6: Rights and obligations concerning MDMA-AT

Chapter 6 presents an analysis of the legal context and legislation pertaining to MDMA-AT. It focuses on human rights, the United Nations drug treaties, European legislation and Dutch legislation. Even though MDMA is registered nationally and internationally as a prohibited substance, there is no legislation that prevents its registration for use as a medicine. Furthermore, under certain conditions PTSD patients could invoke specific fundamental and human rights to claim access to therapies that have been proven to be effective, which might in the near future include MDMA-AT.

Chapter 7: Will MDMA-AT be provided in the Netherlands?
Chapter 7 answers the question whether MDMA-AT can be made available in the Netherlands. The United States and Australia have already made concrete steps towards offering MDMA-AT. Within the European Union, however, there is no reason to expect formal registration of MDMA-AT with the medicines authorities any time soon, since no company or organisation has so far submitted a request for such registration for Europe or the Netherlands.

In view of the convincing scientific evidence regarding the safety and efficacy of MDMA-AT and the considerable suffering among PTSD patients, the State Commission recommends that the implementation of MDMA-AT for the treatment of PTSD be facilitated as soon as possible. In the absence of formal registration as a medicine, this can probably only be achieved by making MDMA-AT available to patients specially selected for this purpose through a multi-year, large-scale naturalist study within the frameworks of scientific research. That study may also provide insight into aspects such as the feasibility and cost-effectiveness of MDMA-AT in the Netherlands.

Chapter 8: Therapeutic use of MDMA outside the treatment room
Chapter 8 shows that views on MDMA-AT have already started to take on a life of their own in the Netherlands, outside of the legal framework. The State Commission observes that this growing interest in MDMA-AT is generating undesirable developments, such as the use of ecstasy for therapeutic purposes without proper supervision, and a growing number of commercial providers of therapies inspired by regular MDMA-AT, many of them incompetent. The State Commission recommends that the government develop policies targeting providers of psychedelic-assisted therapies. The provision of such therapies must be contained, and the potential target group must be informed about the safety risks involved. Policies targeting MDMA-AT and providers of MDMA sessions outside the regular health care system will become increasingly relevant in the years ahead, as other psychedelic drugs are also being studied for use in a range of therapies or for mental health issues. That is why the State Commission advises the government to adopt its recommendations.

MDMA /// Beyond Ecstasy

ec·sta·sy /ɛkstəsi (pl. ecstasies)
1 an overwhelming feeling of great happiness or joyful

The title *MDMA: Beyond Ecstasy* can be interpreted in various ways. First of all, it refers to the effect of MDMA on the user: a temporary buzz. A buzz which, in 2022, a record 550,000 people in the Netherlands experienced at least once. In most cases it all ends well – but in some cases it does not, given the serious health incidents involving MDMA, including several deaths each year. Despite the health concerns, approximately 10 per cent of people in the Netherlands have had an experience with MDMA. Moreover, there are no indications that the use of MDMA is decreasing.

The title also refers to the impact of MDMA on society. MDMA production in the Netherlands has reached an almost industrial scale. This country is a major exporter of synthetic drugs such as ecstasy. The consequences are felt in all layers of Dutch society. From the dumping of waste and the recruitment of young people by drug gangs to cash flows surfacing in the regular economy: Dutch society is paying a high price for the production of these tablets.

Recent years have also seen increasing interest in a completely different aspect of MDMA. There is a growing body of scientific evidence for the potential therapeutic effect of MDMA, which combined with therapy can help people suffering from PTSD. This particular use of MDMA confronts mental health care providers and government bodies with a number of difficult questions and complex issues. In anticipation of official approval, some therapists and coaches have already begun experimenting with this substance, which is creating all sorts of risks.

All these aspects come together within a single substance, which calls for a balanced approach. Given that this issue attracts attention from many different quarters in society, this is easier said than done. In addition, there is an increasingly polarised debate on the desired course of Dutch MDMA policy, in which moderate voices are rarely heard.

The government asked the State Commission on MDMA to provide advice on both aspects of this substance: the status of recreational ecstasy use within a public health context, and the pros and cons of using MDMA as a therapeutic drug. The State Commission chose to examine and discuss both aspects extensively. In the process, the concept of public health was given a broad, socially oriented interpretation.

In this report, the State Commission maps out the historical, legal, policy-related, public health science and therapeutic aspects of MDMA. How was this substance created? How is it currently regulated? What are the physical effects and the risks of using it? What are the societal dimensions? How effective is treatment with MDMA in medical settings, and if effective, what is needed to make it available for medical use?

The members of the independent State Commission represent a variety of scientific disciplines. This has enabled us to study the matter from a broad range of perspectives. The end result is a report that presents neutral and factual recommendations on MDMA and its use in both recreational and medical-therapeutic settings.

In presenting its findings in this report, the State Commission was able to rely on the writing skills of two extremely competent secretaries: Philippus Zandstra and Ward de Kock. In addition, we had the pleasure of benefiting from conversations with a considerable number of experts representing a range of civil-society organisations. The State Commission would additionally like to thank its student assistants, reviewers and all other individuals who assisted us in our work.
In conclusion: the State Commission argues that MDMA is a substance that offers opportunities and raises questions at the same time. These questions require careful and extensive consideration. As a result, answering those questions and solving the associated problems so as to make steps forward costs more time in many cases than we would like to have available. Nevertheless, the State Commission hopes that this report and its recommendations will prove to have a lasting influence both on Dutch ecstasy policy and the use of MDMA in medical settings in the Netherlands.

Brigit Toebes
Chair of the State Commission on MDMA

Beyond Ecstasy
Introduction

Background and urgency

For nearly 40 years, MDMA has been used as a party drug in the Netherlands. Today, more than one in 10 people have used this prohibited substance at least once. Quite separate from this recreational use, MDMA also has a medical use, like ketamine or cannabis. This medical use of MDMA has been the subject of research for nearly half a century.

In sum, MDMA is definitely not a novelty in Dutch society; it has been present here for decades. Why, then, should we have a State Commission on MDMA at this specific point in time?

The State Commission was established in response to several developments. MDMA use is still increasing. In addition, we are seeing changes in the locations where MDMA is used for recreational purposes. Originally taken during illegal parties ('raves'), MDMA moved on to clubs and is currently common at large-scale events. In the background, a growing and increasingly violent criminal industry is producing MDMA tablets for the domestic and world markets. Previously operating clandestinely, criminal gangs have taken root in broad daylight over the past decades with increasing success.

In recent years, the use of MDMA and the criminal activity associated with its production have been at the centre of a heated debate. Some are calling for measures to bring the production of MDMA under legal control. Others focus on users and their alleged ignorance of the criminality generated by ecstasy production.
At the same time, we are witnessing developments in the medical domain. The growing awareness of the importance of mental health has created more space for studies on the use of MDMA for the treatment of several medical conditions. These studies have been so successful that the medical authorities in Australia, Canada, the United States and Switzerland have since integrated MDMA-assisted therapies into their mental health care services, or are researching to do so.

In the Netherlands, few steps have so far been made to arrive at a long-term, evidence-based drug policy in response to these developments. Current Dutch drug policy dates from 1995 and has not been reviewed since 2009. It is safe to say that this policy, with its dual purpose of protecting public health and preventing damage to society, dates from a different era. It urgently needs a thorough review in light of the developments outlined above. It is not the State Commission on MDMA's mandate to review the entire drug policy. In this report, however, the State Commission does offer an analysis of the current situation and issues a number of recommendations to bring about several lasting improvements.

The State Commission's mandate

In December 2021, several political parties in the House of Representatives (VVD, CDA, D66 and ChristenUnie) signed a coalition agreement entitled *Omzien naar elkaar, vooruitkijken naar de toekomst* (Looking out for each other, looking ahead to the future). In it, they announced the establishment of a State Commission on MDMA.[1] The State Commission was officially inaugurated by royal decree on 24 March 2023. Its mandate reads as follows:

'A State Commission will be established to investigate the status of MDMA ('ecstasy') in the context of public health and to issue recommendations on the advantages and disadvantages of medicinal use, including a multidisciplinary analysis of health risks, prevention and the European context and relevant treaties.' [2]

Within this mandate, the State Commission identified two sub-mandates. First, the coalition partners asked the State Commission to investigate the status of MDMA in the context of public health. This sub-mandate covers the first part of this report. The State Commission held conversations with a range of stakeholders, including policymakers, prevention and enforcement organisations, health care professionals and scientists. The State Commission used the outcomes of those conversations to identify a series of issues that form the basis of the first part of the report. This concerns various different aspects that have an influence on public health, including the criminality engendered by the production of MDMA tablets (ecstasy). The State Commission is not proposing any straightforward solution for all the problems that have been identified: there is no holy grail, such as a ban on substance use or legalisation of MDMA. Instead, the State Commission is calling for a debate on the future of Dutch drug policy that is grounded in scientific insights. The State Commission also provides tools for organising such a debate and argues that moderate views should be given more space.

Second, it is part of the State Commission's mandate to issue an advisory opinion for the government on the advantages and disadvantages of the medicinal use of MDMA. The reason for this is the growing body of scientific research into the treatment of post-traumatic stress disorder (PTSD) using MDMA-assisted therapy. This is the subject of the second part of this report.

1 VVD, D66, CDA and ChristenUnie, *Omzien naar elkaar, vooruitkijken naar de toekomst: Coalitieakkoord 2021-2025* (15 December 2021), 22.

2 Ministry of Health, Welfare and Sport, 'Decree establishing a State Commission on MDMA', *Government Gazette* 11158 (24 March 2023).

Note that the State Commission prefers to use the terms 'MDMA-assisted therapy' (MDMA-AT) and 'therapeutic use of MDMA', rather than 'medicinal use of MDMA'. This is because the term 'medicinal' wrongly suggests that people take MDMA as a medication, like a daily antidepressant, whereas MDMA-assisted therapy is in fact different from such types of treatment in that it is a proven element of a supervised and therapeutic treatment administered at a health care institution.

Similarities and differences

What the two sub-mandates have in common is that they both concern the substance MDMA and the Opium Act that governs it. Both sub-mandates also call for an interdisciplinary analysis of the health risks and possible prevention strategies. In addition, they call for an analysis of the Opium Act and the relevant international and European conventions.

In all other respects, however, the two sub-mandates are fundamentally different from each other. The target group for recreational use of MDMA is completely different from the patient population for its therapeutic use. The settings are also worlds apart: recreational use often involves settings like events, whereas the therapeutic use of MDMA takes place in controlled environments, such as a treatment room. Recreational users obtain their MDMA on an unregulated and illegal market, whereas patients receive it in the form of a high-quality and pharmaceutically produced substance. Key aspects of policy targeting recreational use are prevention and law enforcement, whereas policy regarding therapeutic use is much more concerned with the position of MDMA in mental health care. Aside from the Opium Act, moreover, the two sub-mandates are governed by totally different branches of legislation, resulting in very different policy issues.

This is why the State Commission on MDMA has structured its advisory opinion on the basis of the two sub-mandates formulated above. Part I is about recreational use, Part II is about therapeutic use. These two parts are preceded by Chapter 1, which provides context by presenting a historical overview on the rise of MDMA in the Netherlands. Part I is subdivided into three chapters. In the first of these chapters, the State Commission describes how MDMA works and what harm it may cause. This also covers prevalence and usage patterns in the Netherlands. In the next chapter, the focus is on Dutch policy targeting MDMA supply and use, and on harm reduction measures. Chapter 4 deals with the debate on the regulation of MDMA, which has recently gained in intensity. In this chapter, the State Commission takes a stance in the debate.

Part II starts with Chapter 5, which provides an overview of the latest scientific insights into the use of MDMA in the medical domain. Chapter 6 discusses the legal aspects of MDMA-assisted therapy, while Chapter 7 deals with the challenges associated with the implementation of this type of therapy in the Netherlands. Finally, Chapter 8 covers the problems that could arise from delays in the introduction of MDMA-assisted therapy.

For clarity's sake, note that the State Commission uses the abbreviation MDMA to refer to the active ingredient and its properties. The State Commission uses the name ecstasy to refer to the tablets that are illegally sold by dealers. In other words, MDMA concerns the pure substance (usually in a known dosage), while ecstasy concerns illegally produced tablets, which may also contain other substances and in which the concentration of the active ingredient is not clearly known upon purchase.

Method

In the *Decree establishing a State Commission on MDMA,* the Minister of Health, Welfare and Sport and the Minister of the Interior and Kingdom Relations stipulated that the State Commission was not to conduct any new research of its own into MDMA, given the short time frame available.[3] In preparation for this report, the State Commission held conversations with various relevant authorities, government bodies and experts, endeavouring to cover the issue from as many different perspectives as possible. The conversations also served as the basis for an extensive literature study.[4] For statistical data, the State Commission consulted publications of the Trimbos Institute, including the National Drugs Monitor (NDM)[5], the 2023 edition of *Het Grote Uitgaansonderzoek* (The Comprehensive Nightlife Survey) and earlier iterations of those studies.[6]

3 Ministry of Health, Welfare and Sport, 'Decree establishing a State Commission on MDMA', *Government Gazette* 11158 (24 March 2023).

4 Ministry of Health, Welfare and Sport, 'Decree establishing a State Commission on MDMA', *Government Gazette* 11158 (24 March 2023).

5 National Drugs Monitor, 'Home' (Utrecht: Trimbos Institute).

6 R.J.J. van Beek, K. Monshouwer, F. Schutten, W. den Hollander, R. Andree and M. van Laar, *Het Grote Uitgaansonderzoek 2023: Uitgaanspatronen, middelengebruik, gezondheid en intentie tot stoppen of minderen onder uitgaande jongeren en jongvolwassen* (Utrecht: Trimbos Institute).

1
A short history of MDMA

A short history of MDMA

1912 The company Merck synthesizes MDMA for the development of a blood coagulant. However, the formula for the substance ends up in the archive.

1938 Chemist Albert Hoffman first synthesizes LSD for the Swiss drug manufacturer Sandoz.

1943 Hoffman accidentally discovers the hallucinogenic qualities of LSD.

1947 Sandoz makes LSD available to researchers. Especially psychiatrists seem to be interested in the substance.

1961 The Dutch psychiatrist Jan Bastiaans treats camp survivors with LSD.

1966 LSD is banned in the Netherlands due to concerns about a possible stunt by anarchists during the wedding of Princess Beatrix and Claus von Amsberg.

1967 The United States bans LSD; the research into the therapeutic potential comes to an international standstill.

1969 Filmmaker Louis van Gasteren releases the documentary 'Now do you get it why I'm crying?', which shows how Bastiaans guides a patient during an LSD-assisted session.

1975 Chemist Alexander Shulgin learns about the psychotropic effects of MDMA. He synthesizes the substance and starts experimenting with it.

1977 Shulgin introduces MDMA to Leo Zeff, a psychotherapist who then points out to colleagues the possibilities of MDMA for therapeutic purposes.

1981 MDMA is given the street name 'ecstasy' for the first time. The substance is increasingly being used for recreational purposes.

1984 The DEA announces it will ban MDMA. Therapists and scientists object.

1985 The WHO MDMA puts MDMA on Schedule I of the Convention on Psychotropic Substances; at the same time, its Expert Committee recommends that Member States should research this 'interesting substance'.

After a series of legal procedures, MDMA becomes officially prohibited in the US.

1986 Founding of the Multidisciplinary Association for Psychedelic Studies (MAPS), an American organization dedicated to the therapeutic use of substances such as MDMA.

1988 In the summer house breaks through in the Netherlands, and with it MDMA. The Dutch authorities ban the substance in October. The NGO Adviesburo Drugs conducts on site testing for tablets.

1994 After two ecstasy-related deaths, MDMA gets on the political agenda.

1995 Publication of *Stadhuis en House*, which provides municipalities with instructions on how to deal with the new nightlife culture and drugs.

A diplomatic row breaks out with France over the Dutch drug policy.

1996 Establishment of the Unit Synthetische Drugs (USD) to tackle ecstasy gangs and keep foreign criticism on Dutch drug policy at bay.

2004 After a number of major successes, the USD merges with the National Police.

2007 At a number of parties, undercover police officers arrest visitors being caught with a small amount of drugs.

2009 Dutch producers can no longer obtain raw materials, causing a temporary ecstasy drought.

2018 Publication of the report *Waarin in een klein land groot kan zijn* in which researchers estimate the size of the Dutch synthetic drugs industry at around 18.6 billion euros per year.

Researchers present the results of a clinical study into the use of MDMA in treatment of PTSD in The Lancet.

2019 Renowned science journalist Michael Pollan publishes with *How to change your mind* an international bestseller on psychedelics.

2024 Australia makes it possible to treat PTSD with MDMA assisted therapy; the American medicines authority FDA assesses the substance for the treatment of PTSD.

The history of MDMA can be traced back to the beginning of the last century. Two German pharmaceutical companies, Bayer and Merck, were fighting for dominance on the market for blood coagulants. When Bayer managed to patent a synthetic formula, Merck felt it had no option but to develop an alternative that could be produced outside of its competitor's patents. During that search, a chemist called Anton Köllisch, employed by Merck, synthesised MDMA as a compound that could result in a new blood coagulant.[1] That substance was patented in 1912. However, since no concrete uses were found for MDMA, it ended up in the company archive.[2] Today, we know more about the psychotropic effects of MDMA, but those effects were completely unknown at the time.[3]

Psychotropic agents
A psychotropic agent is an agent that alters the user's mental processes after ingestion. These are processes that potentially govern a person's behaviour, perception, consciousness, mood or emotion. Some psychotropic agents, such as LSD and psilocybin, are also hallucinogenic. The effects of MDMA are described in detail in Chapter 2.

The 'discovery' of MDMA as a psychotropic agent is associated with the development, in 1938, of another substance. In that year, a chemist called Albert Hoffman, working for Swiss pharmaceutical company Sandoz, synthesised lysergic acid diethylamide – a substance better known today as LSD – for the first time. When Hoffman accidentally ingested a small quantity in 1943, he discovered its strong hallucinogenic effect. Sandoz then launched a search for a concrete use for LSD, sending it to researchers in various countries to see for what purposes it might be used.

There was considerable interest, in particular, among psychiatrists. As LSD enabled users to relive certain experiences, including traumatic ones, treating physicians recognised its potential for the treatment of trauma-related disorders. The initial focus on LSD was to expand by the end of the 1950s and the early 1960s, when other psychedelic substances caught the attention of researchers, including mescaline (derived from cacti) and psilocybin (from truffles and mushrooms).[4]

LSD-assisted therapy in the Netherlands

There was considerable interest in therapies based on psychedelic substances, also in the Netherlands. In 1961, Dutch psychiatrist and professor Jan Bastiaans initiated LSD-assisted psychotherapy for concentration camp survivors. Many seriously traumatised patients were positive about their experiences with professor Bastiaans. They suffered from what was known in psychiatry at the time as post-concentration camp syndrome or KZ syndrome (derived from the German word for concentration camp, *Konzentrationslager*). Patients with this syndrome were typically in a constant state of anxiety and more or less unable to enter into relationships. Later, post-concentration camp syndrome was moved to the more general family of post-traumatic stress disorders (PTSD).[5]

1 One common misconception is that MDMA was developed as an appetite suppressant.
2 Torsten Passie, *The History of MDMA* (2023), 10.
3 Roland Freudenmann et al., 'The origin of MDMA (ecstasy) revisited: the true story reconstructed from the original documents', *Addiction* (2006).
4 Bram Enning, *De oorlog van Bastiaans* (2009), 73.
5 Leo van Bergen, *Dutch newspapers on war victims and their LSD-treatment by Jan Bastiaans: from*

Documentary filmmaker Louis van Gasteren filmed Bastiaans and a patient during an LSD-assisted session as part of his documentary entitled *Now do you get it why I'm crying?* (1969). This documentary led to increased attention in the Netherlands for traumatic experiences and the fate of holocaust survivors. At the same time, however, there were serious doubts about the efficacy and safety of this type of therapy. There was no solid scientific basis, as most of the data came from small-scale studies that did not involve control groups.[6]

Towards the recreational use of LSD

Developments outside psychiatrists' treatment rooms reversed the reputation of LSD as a medicine, which had been positive until then. For example, in the United States a media hype emerged in the 1960s about the recreational use of LSD among students.[7] Within the hippie movement, researcher and activist Timoty Leary urged his followers to turn their backs on American society by using LSD: 'Turn on, tune in and drop out'. The debate began to be dominated by excesses – 'bad trips' with sometimes fatal consequences – that overshadowed the therapeutic uses of LSD. Several American states banned LSD, and this was followed by a federal ban in 1967.[8] One unintended consequence of this development was that all official research into LSD came to a halt.

In the Netherlands, LSD had been subject to the Opium Act since 1966. Again, this had little to do with its use in therapy. In 1966, so-called Provos (adherents of an anarchic protest movement in the Netherlands) announced their intention to disturb public order during the wedding ceremony of Princess Beatrix and Prince Claus. The plan was to feed sugar cubes containing LSD to the horses that were to take the pair in the gilded coach through the streets of Amsterdam. When reports about this appeared in *De Telegraaf* newspaper, LSD was banned with immediate effect.[9]

The search for an alternative to LSD

The ban on LSD triggered a search for an alternative among scientists and treating physicians. It was not long before they turned their attention to MDA (3,4-methylenedioxyamphetamine). Therapists had been working with MDA since the 1960s and, after the ban on LSD, it seemed a practical alternative. However, the interest in MDA soon faded after it was found to cause medical complications, which sometimes even proved fatal.[10]

During the search for an alternative to LSD and MDA, a chemist called Alexander Shulgin rediscovered MDMA (3,4-methylenedioxymethamphetamine). In his laboratory in Lafayette, a small town in California, Shulgin studied psychoactive substances and tested them on volunteers, often including himself. Initially he conducted this research on behalf of chemical giant Dow Chemical, but that company terminated the agreement in 1966. Shulgin continued as an independent researcher and was granted an exemption that enabled him to work with substan-

KZ-syndrome to PTSD (2023).

6 Bram Enning, *De oorlog van Bastiaans* (2009), 86.

7 Martin Lee et al., *Acid Dreams* (1988), 150.

8 Martin Lee et al., *Acid Dreams* (1988), 149.

9 Philippus Zandstra et al., *XTC: een biografie* (2020), 19–20.

10 Torsten Passie, 'The early use of MDMA ('Ecstasy') in psychotherapy (1977–1985)', *Drug Science, Policy and Law* (2018).

ces in Schedule I to the American opium law, in cooperation with the U.S. Drug Enforcement Administration (DEA).[11]

Shulgin may have created MDMA before, in 1965, but without using it himself. He heard about the psychotropic effects of the substance in 1975, and then began to experiment with it. This is also what led Shulgin to give his friend Leo Zeff a dose of MDMA, two years later. Almost immediately after using it, Zeff, a retired psychotherapist, was wildly enthusiastic about its therapeutic potential. He decided to pick up his work as a therapist again and introduced MDMA to fellow therapists.[12]

This shows that MDMA was continuing a development that had been initiated by LSD. The therapeutic use of MDMA largely remained a secret in those years, as treating physicians feared that the LSD scenario might repeat itself. This explains the dearth of scientific studies from that period on the therapeutic efficacy of MDMA.

From MDMA to ecstasy

All this secrecy did not prevent the substance from becoming quite popular among a small group of recreational users in the early 1980s. The name ecstasy first appeared in American underground magazine Wet in 1981, in an article in which several editors described the effects of MDMA and their own experiences after having used it.[13]

On 27 July 1984, the DEA announced its intention to ban the substance, in response to signals from several US states that the use of MDMA was increasing.[14] The proposed ban provoked criticism from researchers and therapists alike, who had worked with the substance for years and felt it was harmless and in fact showed promising results in therapeutic sessions. The DEA claimed that MDMA was not being used for therapeutic purposes, but the therapists argued that it most certainly was.

For this reason, the process of incorporating MDMA into legislation took rather longer than expected. It was not until after a series of lawsuits that MDMA actually became subject to the US Controlled Substances Act, on 1 July 1985. Pursuant to that Act, MDMA was included in Schedule I in the US, which – according to the people who compiled it – includes 'substances or chemicals' that have 'no currently accepted medical use' and are associated with 'a high potential for abuse'.[15]

11 Udo Benzenhöfer et al., 'Rediscovering MDMA (ecstasy): the role of the American chemist Alexander T. Shulgin', *Addiction* (2010).

12 Udo Benzenhöfer et al., 'Rediscovering MDMA (ecstasy): the role of the American chemist Alexander T. Shulgin', *Addiction* (2010).

13 Torsten Passie, *The History of MDMA* (2023), 88.

14 Torsten Passie, *The History of MDMA* (2023), 116.

15 DEA, 'Drug Scheduling', *dea.gov* (2018).

In the month in which the DEA initiated proceedings to get MDMA banned in the United States, the agency also submitted a request to the Expert Committee on Drug Dependence (ECDD) of the World Health Organization (WHO) asking for an international ban. The DEA submitted this request by invoking the *Convention on Psychotropic Substances* (refer to Chapter 3).

In April 1985, the ECDD ruled that MDMA should indeed be included in Schedule I to the Convention. It regarded MDMA as a substance that posed serious risks to public health, while its therapeutic value had not yet been recognised at the time. What was unusual about this is that the ECDD failed to achieve consensus and needed to hold a vote on the issue. The ECDD chair would have preferred to postpone publication of the recommendation on MDMA pending further data on its therapeutic uses.[16] In the definitive report, the ECDD concluded that MDMA should be included in Schedule I to the *Convention on Psychotropic Substances*, but also recommended that countries facilitate research into 'this interesting substance'.[17] Notwithstanding his recommendation, however, all research into the therapeutic uses of MDMA came to a complete standstill.

MDMA in the Netherlands

By the time the ECDD published its recommendations on MDMA, the Netherlands had not yet become a party to the *Convention on Psychotropic Substances*. During that period – the mid-1980s – the Dutch government chose to not to sign the Convention. According to the then Chief Inspector of Medicines, there were too many substances within the scope of the Convention whose risk of abuse was practically unknown.[18] In addition, the Dutch system of schedules, which had included a Schedule I for soft drugs and a Schedule II for hard drugs since 1976, was difficult to reconcile with the four schedules to the *Convention on Psychotropic Substances*.[19]

In 1985, therefore, MDMA was not yet covered by the Opium Act. Dutch drug policy primarily targeted cannabis, cocaine and the heroin epidemic, which was causing considerable nuisance in inner-city areas. While there are no figures on the number of MDMA users in that period, there is some evidence to suggest it was being used in some circles.

This included self-reported therapeutic use, especially among therapists with ties to the then quite popular Rajneesh movement.[20] In that context, MDMA was used in group sessions with some 10 participants and one or more supervisors. During the sessions, participants mainly discussed relational problems. Prior to the session they were handed a 'guide' that included texts about the effects of the substance and tips on how to prepare effectively for the session.[21]

16 Torsten Passie, *The History of MDMA* (2023), 120.

17 WHO Expert Committee on Drug Dependence, *Twenty-Second Report* (1988), 25.

18 Correspondence of the Chief Medicines Inspectorate (1988).

19 Correspondence of the Chief Medicines Inspectorate (1988).

20 Philippus Zandstra et al., *XTC: een biografie* (2020), 18.

21 Philippus Zandstra et al., *XTC: een biografie* (2020), 20.

1988 to 2010: The party drug

In the Dutch media, the term 'ecstasy' first appeared in 1986. It appeared, for instance, in 'trip reports' in which the authors related their experiences or in descriptive articles on ecstasy as the latest nightlife trend.[22] However, these reports remained incidental. Unlike cannabis or cocaine, MDMA was not yet being used on a large scale in that period.

This changed when the house scene emerged. Initially, this music genre was mainly found in specific clubs on Ibiza. The island attracted a huge variety of people, including the first DJs, hippies and tourists – and fans from the Netherlands. Ecstasy soon became extremely popular in these circles.
In the Netherlands, house had its breakthrough in the late summer of 1988. Initially, the regular nightlife venues had no interest at all in house, with the exception of one or two clubs. This was to change, however, when the first raves were organised: parties in squatted or abandoned sites outside of the regular discos. So, in addition to introducing a new musical genre, house launched an entirely new nightlife concept with participants dancing and contacting each other through the night.

Ecstasy fitted within that concept very well. On the one hand it produces a great deal of energy in users, enabling them to keep dancing for nights on end, while on the other it generates a sense of openness and empathy that resonated with the hippie-like nature of the early house movement. These raves responded to a growing need to say goodbye to a bleak decade of unemployment and nuclear threat. Indeed, there was talk of a 'second summer of love', a repeat of 1967, when hippie culture was at its peak. Ecstasy appeared to be the perfect substance to accompany this. Talking about the drug in 1988, two TV presenters hit the nail on its head: 'ecstasy is aspirin for the 1980s and vitamin for the 1990s'.[23]

The 1980s: the Netherlands joins the ban on MDMA

At the time of the breakthrough of house in 1988, MDMA was not yet subject to the Opium Act. While warnings about the alleged health damage did reach the press, case histories and hard data about its supposed negative effects were not yet available. For that reason, the Dutch government saw no cause to take action. For example, the Chief Medicines Inspectorate was 'not aware of any abuses' associated with the substance until August 1988.[24]

Even so, MDMA was included in Schedule I to the Opium Act shortly after the 'breakthrough'. The National Criminal Intelligence Division (CRI) had received intelligence about a large shipment of PMK that was on its way from Germany to the Netherlands. PMK is what is known as a precursor: a chemical compound required for the production of MDMA, with hardly any other uses.

What made the shipment even more suspicious was the fact that its customers were found to have a background in the production of amphetamine, or speed. However, as long as MDMA remained outside of the scope of the Opium Act, this group could continue to import PMK into the Netherlands without any legal

22 'XTC: te mooi om waar te zijn', *Nieuwe Revu* (1988), 8-11.

23 TV show *Jonge Helden* (1988).

24 Correspondence of the Chief Medicines Inspectorate (1988).

obstruction. This resulted in a designation order to include MDMA in Schedule I to the Opium Act in accelerated proceedings, together with four other substances, in October 1988.[25]

MDMA was to be included in that schedule of the Opium Act anyway that year. At the end of 1988, the Netherlands acceded to the Convention on Psychotropic Substances. As a result, the substances covered by that Convention would have to be incorporated into the Opium Act. So even if the CRI had not received that intelligence, MDMA would have been banned anyway a few months later in 1988.[26]

The 1990s: ban, contamination, distribution

Despite the ban, the role of ecstasy in the Dutch drugs scene continued to increase. Once again, this was driven mainly by forces in youth culture. Initially regarded as a mere hype, house was to change the music scene for good in the years after its breakthrough. Nightlife culture was transformed accordingly, causing the popularity of ecstasy to increase even further.

Illegal producers met the demand for MDMA, trying to get as much money out of the trade as possible. The tablets were often found to contain other, potentially harmful substances instead of MDMA. This contamination resulted in dangerous situations because users – especially in the early stages of the house rage – were hardly informed about what they should do in case things went wrong. To make things worse, the organisers of (illegal) parties often did not know either. At many events, there was a lack of free drinking water, chill-out spaces, first-aid staff and proper ventilation.[27]

The first reports on fatal incidents involving ecstasy appeared in 1990, sparking a fierce debate on the harmfulness of MDMA. Was the substance in itself fatal, or should the focus shift to the context in which it was used? The lack of knowledge about the precise mode of action of MDMA and its harmfulness made it all the more difficult to assess the risks involved.

Government bodies took very little interest in MDMA at the time. Adviesburo Drugs, an independent organisation based in Amsterdam, was already testing visitors' tablets at parties in 1988 and spreading information about the risks. As soon as the organisation found a dangerous tablet, it issued a red alert, which it disseminated through targeted actions using flyers and adverts in relevant media. In this way, it warned users about specific tablets, adding detailed descriptions. In some cases, it also held the producer to account in a stern talking-to. Adviesburo Drugs also tested drugs on weekdays. As the house hype continued, more and more test sites were set up, at local municipal public health services and addiction care centres.

25 'Designation order on substances to be covered by the Opium Act with immediate effect', *Government Gazette* (1988).

26 Philippus Zandstra et al., *XTC: een biografie* (2020), 68–70.

27 Philippus Zandstra et al., *XTC: een biografie* (2020), 136–137.

Increasing concerns about recreational use

Despite this development, concerns about the use of the drug at parties continued to increase. The gabber movement was a particular source of concern. This subgenre emerged in 1992 and was characterised by the extremely rapid beat of hardcore tracks played during gabber parties. To keep up with the beat, partygoers used large quantities of substances. At the same time, the number of parties continued to increase while municipal authorities had very little knowledge about this new nightlife culture and the associated substance use. And while house culture used to be typically associated with locations outside the regular nightlife venues, the new gabber cult was increasingly emerging in traditional discos and bars.

It was against this background that ecstasy first appeared on the national political agenda in 1994 – during a week in which two deaths occurred in which MDMA was involved. The government received over a hundred parliamentary questions about ecstasy and requests to explain its policy.

In 1995, the new government led by Prime Minister Kok issued a guideline entitled *Stadhuis en House*, advising municipal authorities on which aspects to check and monitor when large parties were organised within their territory. For example, requirements were introduced governing access to water, proper ventilation and the availability of chill-out rooms.[28] This focus on the setting within which ecstasy was used was intended to help reduce the number of health-related incidents. However, as the problems with contaminated tablets persisted, drugs testing remained critically important.

The concerns about the health of users were accompanied by increasing concerns about the origin of the tablets. During the late 1980s, most tablets were imported from the United States and Germany, but in the early 1990s Dutch producers emerged who were keen to cash in on the growing demand for ecstasy. Thanks to international transit routes (through Rotterdam and Schiphol Airport), the proximity of chemical industries for raw materials and a dense network of financial sector services, the Netherlands offered the ideal business climate for producers. In addition, the Dutch underworld had already gained experience with the production and distribution of synthetic substances: long before the birth of ecstasy, the Netherlands was home to drugs rings that produced amphetamine (speed).

In the first half of the 1990s, the fight against synthetic drugs was not on the agenda of the Dutch police. This was due in part to a lack of experience with the phenomenon of ecstasy labs, but also to the focus on robber gangs, violence by hooligans and the cultivation of cannabis. One complicating factor was the IRT (Interregional Crime Squad) scandal in the early 1990s, which involved the police allowing monitored drug shipments to cross the border in an attempt to tackle specific gangs of criminals. In 1993, this method and the use of informers with a criminal background sparked a huge controversy that eventually resulted in a parliamentary inquiry. During the prolonged aftermath of the IRT scandal, the investigation capacity of the police was seriously affected, as a result of which the ecstasy gangs – which had been receiving little attention anyway – could solidify their position further.

28 Chief Department for Alcohol, Drugs and Tobacco Policy, *Stadhuis en House: Handreikingen voor gemeentelijk beleid inzake grootschalige manifestaties en uitgaansdrugs* (1995).

Ideological criticism of the Netherlands

The Dutch government came under international pressure to scale up its efforts to tackle the drugs rings. Many countries were annoyed by the distinction made by the Dutch authorities between hard drugs and soft drugs. In addition, they felt that the Netherlands was not doing enough to fight the export and production of drugs. For example, in 1995 France threatened to withdraw from the Schengen Agreement and reinstate border controls because Dutch heroin allegedly ended up in Nice through Belgium – an incorrect claim, as the port of transit for heroin at the time was in fact Marseille.[29] According to the Dutch government, therefore, much of the criticism was ideological in nature and particularly targeted the distinction between hard drugs and soft drugs:

'Recent reports by authoritative drugs experts abroad endorse the distinction made by the Dutch legislator between soft drugs and hard drugs. It goes without saying that criticism arising from views on health risks for which the scientific literature no longer offers any support cannot serve as a ground for adapting Dutch policy.' [30]

Even so, a police analysis published at the time showed that the fight against synthetic drugs-related crime had for many years been low on the list of priorities of the Dutch government. By combining information, the then South Netherlands Core Team managed to identify a number of groups that were producing ecstasy on a large scale.[31] Combined with international criticism, this prompted Minister of Justice Sorgdrager to establish the Synthetic Drugs Unit (USD) in 1996. The USD was made up of multiple authorities, including the police, the Customs Administration and the Tax Administration. The unit was a success and proved capable of dismantling labs and tackling drugs rings at a rapid pace, which also helped to improve the image of the Netherlands abroad.

The 2000s: stabilisation, zero tolerance, shortages

In the first decade of the century, ecstasy use in the Netherlands was levelling off. With the house hype having subsided, ecstasy appeared to have lost some of its appeal among young people. The genre had become part of regular nightlife. At the same time, the use of cocaine was increasing due to falling prices on the world market.

In this period, the number of dismantled labs also decreased, thanks to the efforts of the USD, which had managed to eliminate most gangs and was scaled down partly for that reason. In 2004, the USD was disbanded, in preparation for the even larger reorganisation of police departments into the National Police. These changes also arose from the shift in investigation priorities towards other types of crime.

At the local level, the zero-tolerance principle was a source of considerable controversy. The police and the Public Prosecution Service had for many years worked on the basis of the principle that possession of a small quantity of drugs did not warrant prosecution, so as to prevent overburdening the justice chain.

29 Philippus Zandstra et al., *XTC: een biografie* (2020), 162.

30 House of Representatives, *session year 1994-1995* (1995), 9.

31 Philippus Zandstra et al., *XTC: een biografie* (2020), 166.

However, it was decided around 2007 that even possession of small quantities of drugs should no longer be tolerated, especially during festivals in and around Amsterdam. Undercover police officers arrested users who were found to carry small quantities of drugs. In a section of the festival site cleared for this purpose, the Public Prosecution Service offered those visitors a proposal for an out-of-court settlement.

The use of such 'justice lanes' at events attracted a great deal of criticism, especially because persons who had accepted the out-of-court settlement proposal were no longer able to obtain a certificate of good conduct (VOG) and, as a result, found their access to certain professions barred. In addition, they had no access to a lawyer for on-site assistance. Hence, questions were raised about the proportionality and lawfulness of this measure.

By the end of the decade, the supply of ecstasy came under pressure due to shortages of the chemicals required for its production. More and more countries, and China in particular, tightened their supervision of the production and export of precursor PMK, which caused problems for the ecstasy gangs in the Netherlands. On Queen's Day in 2009, some cities actually experienced what was referred to as an ecstasy drought.[32] The shortage stimulated the introduction of another substance, mephedrone (4-MMC), as an alternative for MDMA.

The 2010s: subversive crime, investigation, festivals

The shortages in 2009 proved to be temporary, because the clandestine industry changed dramatically at the start of the new decade. New production methods enabled criminal groups in the Netherlands to produce precursors themselves, instead of having to import them, resulting in an increase in ecstasy-related crime. The number of cases of illegal dumping in the natural environment also increased, due to the intense clandestine activity involving chemicals. It was during this period that the term 'subversive crime' gained currency, which can be defined as follows:

'Disruption of social structures and foundations and erosion of the rule of law caused by the interconnectedness of clandestine and legitimate operations due to or associated with organised crime'.[33]

In a report entitled *Waar een klein land groot in kan zijn* (2018), which translates into English as 'hidden greatness of a small country', researchers of the Police Academy of the Netherlands presented a detailed picture of working methods in the Dutch clandestine industry. Old-fashioned, 'vertically oriented' gangs no longer exist. They have been replaced by loosely organised partnerships whose key players are more difficult to trace. According to the researchers, the Netherlands is an ideal location for the production of synthetic drugs due to the low chance of producers being caught. The reorganisation of police authorities to form the National Police has not been helpful in this regard.[34] According to an estimate by the researchers, the Dutch synthetic drugs industry is worth €18.6 billion per year, and 80 per cent of all tablets are exported. In a rectification, the Police Academy

32 Hans van der Beek, 'Help, de XTC is op!', *Dagblad van het Noorden* (2009).

33 Emile Kolthoff, 'Ondermijning van het platteland', *Cahiers Politiestudies* (2021).

34 Pieter Tops et al., *Waar een klein land groot in kan zijn* (2018).

of the Netherlands subsequently gave an export percentage of 99 per cent. This means that Dutch users 'only' consume approximately 1 per cent of all the ecstasy produced by criminals in this country.[35]

The report triggered an intensive debate, and its impact was huge. The Ministry of Justice and Security provided the necessary funds to intensify the fight against drugs. Not long after that, the debate about the role of users re-emerged, as some people claimed it were the users who helped the drugs market survive.
During this period, more and more festival-goers began to use MDMA. Along with the growth in the number of festivals (a record number of 1,344 in 2016 alone)[36], some of those festivals offered a night-time programme as well as a day programme. This allowed ecstasy to break through outside of the electronic music scene as well.

This trend came to a halt when the COVID-19 pandemic broke out. During the lockdowns in 2020 and 2021, both nightlife venues and the entire festival sector – key settings for the recreational use of MDMA – closed down. As soon as the COVID-19 restrictions were eased, the number of parties increased again – and so did the use of MDMA (chapter 2 presents a detailed analysis of consumption figures).

The psychedelic renaissance

A notable development – and one that is crucial for this report – is the renewed interest that emerged in the 2010s in the therapeutic potential of MDMA. Researchers were particularly interested in the use of MDMA for the treatment of PTSD, combined with psychotherapy.

The studies into MDMA were consistent with a growing interest, in broader society, in substances with psychoactive effects. This also generated more and more interest in microdosing, a practice in which users take very small quantities of psilocybin or LSD to stimulate their creative faculties. Likewise, therapeutic home use of such drugs attracted increasing interest, as reflected in the countless publications about psychedelics in newspapers and TV series. For example, award-winning science journalist Michael Pollan wrote an international bestseller, *How To Change Your Mind*, on how substances such as LSD, DMT and psilocybin were changing his life. A four-part documentary adaptation of the book appeared on US platform Netflix in 2022.

MDMA-based treatments of PTSD became available in Australia in January 2024, although the number of qualified treating physicians was small at first. The U.S. Food and Drug Administration (FDA) is expected to issue an assessment on the use of MDMA for the treatment of PTSD in the United States in late 2024. MDMA could acquire the status of medicine and be formally admitted for medicinal use for the first time in history.

35 Police Academy of the Netherlands, 'Meer xtc-export, dan hogere omzet', *politieacademie.nl* (2018).

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Part I: Recreational use of MDMA

Introduction

As described in the preceding chapter, scientific knowledge about MDMA has grown considerably over the years. During that period, the position of MDMA in society has also changed. The following chapters deal with both of these aspects in detail. In this context, the State Commission wishes to emphasise the importance of an up-to-date policy, i.e. a policy that evolves to reflect developments in society. There has been no such policy over the past 30 years. The last time a Dutch government drew up an integrated policy document on drugs was in 1995. That document was based on the policy issues and consumption patterns prevailing at the time. The next three chapters focus on the various tasks associated with the context today.

Reader's guide

Chapter 2 explains how MDMA works, including a description of its psychotropic effects, its addiction profile and its harmfulness. The State Commission provides an analysis of actual or potential harmful effects, the complications and deaths arising from such effects and the registration thereof. In addition, the State Commission presents an overview of use figures, reasons for use, users' estimates of safety, and the dangers of using illegally produced ecstasy tablets. Comparisons with other drugs and other countries have been included where this helps to clarify the status of MDMA in Dutch public health care.

Chapter 3 provides an analysis of MDMA within the framework of the Opium Act and of Dutch drug policy, while also presenting the outlines of possible policy strategies. In this connection, the State Commission presents a number of findings concerning the absence of an up-to-date, overarching policy vision for drugs and the serious consequences thereof. This chapter also focuses on the definition of frameworks for a drug policy based on scientific evidence. The State Commission also considers the dangers of a policy that fails to learn from past experiences and that ignores the findings of scientific research.

This chapter further discusses a number of criminological aspects of drug policy. That discussion centres around the investigation and prosecution priorities for the police and the justice system, the tendency towards fighting symptoms rather than causes, and the organisation and recruitment practices of organised crime.

Chapter 4 is about the current debate on MDMA. There is increasing concern, voiced at conferences and in the media, whether the existing MDMA policy can still be justified. The State Commission observes that this debate is becoming increasingly polarised. This chapter deals with a number of common arguments from both sides in the debate and subjects them to a factual accuracy test. Finally, the State Commission itself also takes a stance in this debate.

2 Use and effects

Introduction

Since the breakthrough of MDMA as a party drug, there have been warnings about the risks of using it. In the early years, little was known about its long-term and short-term effects. Today, in 2024, researchers are still trying to fill the gaps in our knowledge about the harmfulness of MDMA for users.

In this chapter, the State Commission describes the mode of action of MDMA in more detail. As explained below, users' responses to MDMA vary from case to case. This may be due to individual user characteristics, but also to differences in dosage and context of use and in type of use (on its own or in combination with other substances).

The second half of this chapter describes the risks associated with the use of this substance. This part also considers factors that may mitigate or increase those harmful effects, such as the dosage and purity of MDMA. Finally, this chapter deals with the knowledge gaps, as a number of aspects are still uncertain.

2
Use and effects

Findings

The State Commission finds as follows:

/// **Within the range of nightlife drugs, MDMA occupies a special position.** Unlike alcohol, tobacco and drugs like cocaine and speed, MDMA cannot be used on a daily basis to achieve the desired effect. As a result, it hardly has any addiction potential.

/// **In 2022, 550,000 people in the Netherlands used MDMA at least once.** This equals 3.9 per cent of the adult Dutch population. This represents an increase relative to previous years, following a period of stabilisation. This increase can be explained in part by the COVID-19 pandemic having come to an end, and the subsequent revival of nightlife. However, there had already been another increase in 2019.

/// **The main reasons for using ecstasy are the sense of social communion and the intense sensual experience that it evokes, the desire to experience elevated levels of energy and stamina, curiosity and sometimes also peer pressure and self-exploration.**

/// **The number of MDMA users in the Netherlands is high compared with other countries. Dutch people are also much more open about using MDMA, which means the consumption statistics are more reliable than in countries where MDMA use is prohibited or stigmatised.** The actual differences between the Netherlands and other European countries could therefore be slightly smaller than suggested by the current statistics.

/// **While the average concentration of MDMA in ecstasy tablets is high, it has decreased sharply (from 172 milligrams MDMA base in 2019 to 136 milligrams MDMA base in 2022).** Given that only a fraction of tablets are found to be contaminated, the composition of ecstasy tablets raises no public health concerns at present. However, since the production of this substance is illegal, in theory this situation can potentially change and deteriorate at any moment.

/// **The harmfulness of MDMA is the subject of a large number of scientific publications.** Nevertheless, various rare complications associated with MDMA have not yet been studied sufficiently.

/// **There is also uncertainty about the exact number of fatal incidents.** Since there is no legal obligation to keep exact records of fatal incidents, deaths related to MDMA use – like those associated with other toxic substances – are likely to be underreported.

/// **The number of MDMA-related incidents has returned to its pre-pandemic level.** These incidents regularly involve a combination of MDMA and other substances, although this does not apply to the majority of cases. The number of MDMA-related incidents is increasing, and those affected are relatively young (median=23 years) compared with other drugs.

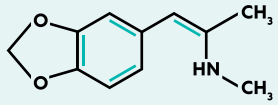
/// **Some research has been conducted into the long-term effects of the use of MDMA on the memory.** The latest studies have shown that recent MDMA use does not reduce users' cognitive capacities. A serious disadvantage of studies of this type is that the respondents tend to be highly educated young individuals who use other substances as well as MDMA. The effects on an older person's brain and the effects of MDMA mono-use remain unclear. The scientists interviewed by the State Commission do not seem to be very concerned about this, however, given the minor nature of the effects observed.

/// **Young people in nightlife settings have been gradually assessing ecstasy use as less risky.** This may lead to a more risky use of ecstasy, for example in combinations with other drugs or in high dosages.

/// **Both the desired and the negative effects of MDMA strongly depend on the individual user and the context of use.** Most users in nightlife settings believe that the harmfulness of one or two ecstasy tablets per year is low. There is a small group of young people who are considering using ecstasy, but do not appear to be properly informed about the risks and the measures to reduce harmful effects.

Effects of MDMA

/// Within the range of nightlife drugs, MDMA occupies a special position. Unlike alcohol, tobacco and drugs like cocaine and speed, MDMA cannot be used on a daily basis to achieve the desired effect. As a result, it hardly has any addiction potential.



3,4-Methylenedioxymethamphetamine

=

MDMA or Ecstasy

Ecstasy and XTC are different names for one and the same drug, whose active ingredient is *3,4-methylene dioxymethamphetamine* (MDMA). Pure MDMA is available in crystalline form and as a powder. When the active ingredient is mixed with a binding agent and pressed into a tablet, the drug is often called ecstasy. These tablets are the most common form in which MDMA is available. MDMA and ecstasy are therefore different names for the same drug.

MDMA promotes the secretion of serotonin in the brain while also blocking the reuptake of this substance. Serotonin plays an important role in communication between nerve cells within the nervous system. It has functions in regulating body temperature and in the ability to experience various different emotions.[1]

In addition, MDMA blocks the reuptake of noradrenaline and dopamine. Noradrenaline plays a key role in dealing with stress. Dopamine plays a role in our experience of reward in motivated behaviour. As long as MDMA remains active in the body, there is no reuptake of serotonin, noradrenaline and dopamine in the nerve cells, which means they keep sending signals to each other.[2]

Furthermore, MDMA stimulates the secretion of oxytocin. This substance plays a role in creating social bonds, in recognising emotions in others and in the desire for social contact. Popularly known as the 'love drug', oxytocin plays an essential role in child-parent bonding, in establishing and maintaining friendships, and in romantic feelings and sexuality.[3]

1 Thierry Favrod-Coune et al., 'The Health Effect of Psychostimulants: A Literature Review', *Pharmaceuticals* (2010).

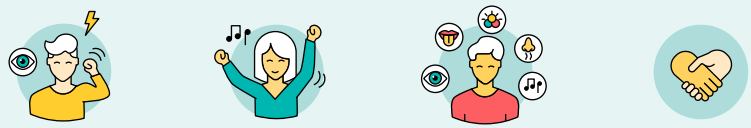
2 Thierry Favrod-Coune et al., 'The Health Effect of Psychostimulants: A Literature Review', *Pharmaceuticals* (2010).

3 Cihan Atila et al., 'Oxytocin in response to MDMA provocation test in patients with arginine vasopressin deficiency (central diabetes insipidus): a single-centre, case-control study with nested, randomised, double-blind, placebo-controlled crossover trial', *The Lancet Diabetes & Endocrinology* (2023).

Finally, MDMA promotes the secretion of the antidiuretic hormone, which regulates urine production and urine concentration by retaining water. This is why users cannot urinate.[4]

The effects of MDMA start 20 to 60 minutes after oral intake and are strongest 90 minutes after intake. The effects last some three to six hours in all, unless the user takes an additional dose of MDMA and the serotonin supply is not depleted.
The effects of MDMA are twofold. On the one hand, users experience higher levels or energy and alertness and an urge to move or dance. On the other hand, MDMA alters the user's consciousness, also known as its entactogenic effect. This effect typically provides more intense experiences of music, smells and colours as well as a strong sense of communion with others and elimination of social inhibitions. Entactogenic altered consciousness specifically concerns the way in which the substance influences the user's emotional and social interaction. MDMA does not induce hallucinogenic alteration of consciousness with changes in visual perception. As such, MDMA is an 'atypical' psychedelic, like for example ketamine.[5]

Figure 14
Effects of MDMA

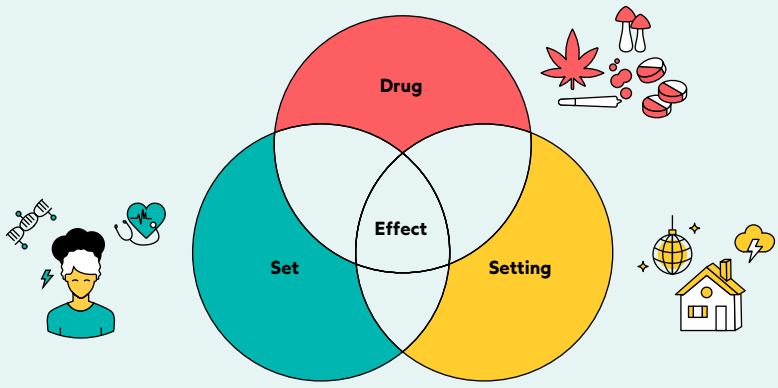


In addition to these intended effects, MDMA has various physical and mental side effects. For example, it causes pulse, blood pressure and body temperature to rise, potentially resulting in hyperthermia and sometimes in serious or even fatal incidents. Under the influence of MDMA, the body produces no extra serotonin, but depletes its existing supply. In the days after use, the resulting serotonin deficiency can induce feelings of dejection, also known as the 'Tuesday dip'. Users may also experience memory and concentration issues during the week after use. MDMA is not addictive. It does not, or only minimally, lead to abuse, dependency or use-related disorders. If a person takes MDMA shortly after their previous use – i.e. before the serotonin supply has been replenished – the entactogenic effect will not occur. This is because the body needs time to restore the supply of serotonin. The only effect, in that case, is the noradrenergic, stimulating effect, which increases energy and alertness, but does not induce the euphoric and communal experience associated with MDMA. It can take several weeks for the serotonin supply to reach its former level.

4 John Henry et al., 'Low-dose MDMA (ecstasy) induces vasopressin secretion', *The Lancet* (1998).
5 National Drugs Monitor, '18.1 Over psychedelica', *Nationale Drug Monitor* (2024).

The precise effects of MDMA depend on a number of factors. Not all MDMA users experience the same effects. Terms typically used in this context are drug, set and setting.

Figure 15
Effects depend on drug, set and setting [6]



Drug, set and setting

Drug refers to the substance itself and the quantity of MDMA that a user takes per session.

Set is about the individual who uses the substance and his or her characteristics. Relevant factors in this connection include the user's expectations, their physical and mental condition, their diet and any latent conditions. Concomitant use of alcohol and other drugs, known as polydrug use, also influences the effects.

Setting is about the location and social context within which the use takes place. In the case of recreational use, the setting may vary from quiet domestic environments to busy nightlife venues where MDMA users spend the time dancing in an extremely hot environment. In the case of clinical MDMA use, the setting is a quiet treatment room in the presence of two therapists (refer to Chapter 5).

All these variables can strongly influence the way in which users experience intended and undesirable effects.[6,7,8,9]

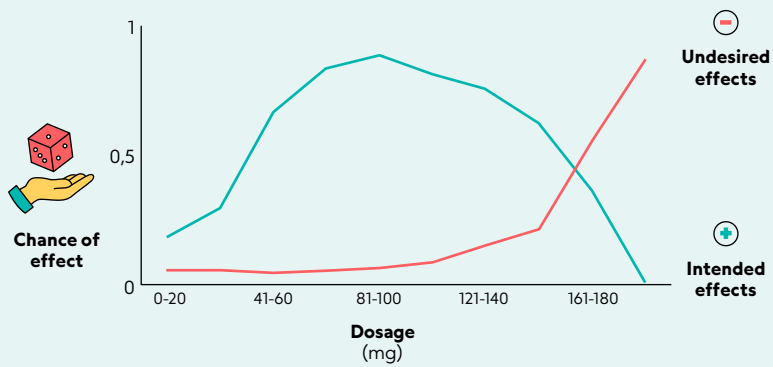
6 Jan van Amsterdam et al., 'Hard Boiled: Alcohol Use as a Risk Factor for MDMA-Induced Hyperthermia: a Systematic Review', *Neurotoxicity Research* (2021).
7 Esther Papaseit et al., 'MDMA interactions with pharmaceuticals and drugs of abuse', *Expert Opinion on Drug Metabolism & Toxicology* (2020).
8 Marion Istvan et al., 'First results of the French OCTOPUS survey among festival attendees: a latent class analysis', *Harm Reduction Journal* (2023), 43.
9 Li-Tzy Wu et al., 'The variety of ecstasy/MDMA users', *The American Journal on Addictions* (2010).

Dosage

/// While the average concentration of MDMA in ecstasy tablets is high, it has decreased sharply since 2019. Since the early 2010s, the MDMA sold on the illegal market has been almost 100 per cent pure. At present, therefore, the composition of ecstasy tablets raises no public health concerns. However, since the production of this substance is illegal, this situation can potentially change and deteriorate at any moment.

One important variable governing the experience of intended and undesirable effects of MDMA is the dosage. A study from 2012 identified a correlation between subjective intended and undesirable effects on the one hand and the quantity of MDMA used. This concerned effects reported by the users themselves.[10] The researchers asked about intended effects such as 'liking things' (general), feeling euphoric, relaxed or excited, and the social effects.

Figure 16
Relationship between dosage and intended/undesirable effects [11]



They also asked about undesirable effects such as nausea, dizziness, headaches, hallucinations, allergic reactions, hyperthermia, abdominal cramps, palpitations and irritability. The study showed that the chance of these undesirable effects increases in proportion to the quantity of MDMA used. An MDMA dose of 80 to 100 milligrams produces the greatest chance of a desired effect and the smallest chance of an undesirable effect. When the dose exceeds 120 milligrams per tablet, the chance of positive effects decreases sharply, while the chance of negative effects increases. With a dose of around 160 milligrams, the chances of a positive or negative effect are balanced; beyond that, the chance of undesirable effects is greater. In sum, an unduly high dose is associated with an increased chance of undesirable effects.[11]

10 Tibor Brunt et al., 'Linking the pharmacological content of ecstasy tablets to the subjective experiences of drug users', *Psychopharmacology* (2011).

11 Tibor Brunt et al., 'Linking the pharmacological content of ecstasy tablets to the subjective experiences of drug users', *Psychopharmacology* (2011).

This concerns self-reported effects, but an analysis of the Drug Incidents Monitor (MDI), which includes data from ambulance services, A&E departments in hospitals and police surgeons, confirms the picture. The MDI also shows that the higher the quantity of MDMA used, the more serious the incidents.[12] The second part of this chapter provides further explanations on the nature and frequency of these incidents.

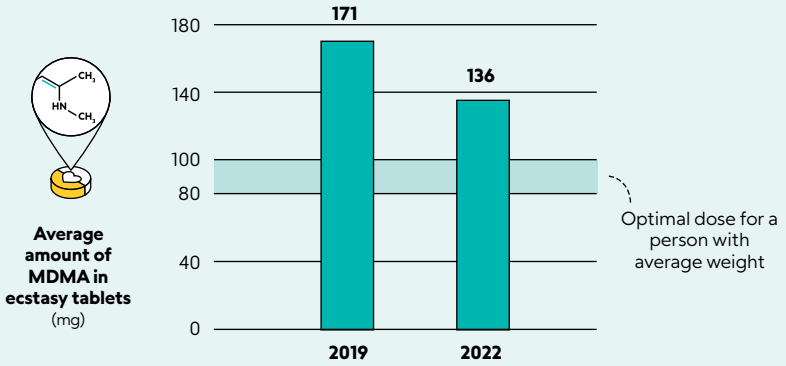
Supply

The tablets offered on the Dutch illegal market are extremely pure: in 2022, 94.4 per cent of all samples presented at test sites as ecstasy actually contained MDMA. Tablets contained 136 milligrams of MDMA each, on average. One striking finding is that the average MDMA content per tablet increased until 2019, to an average of 172 milligrams of MDMA – far in excess of what users consider to be the optimum dose, namely 100 to 120 milligrams. Despite a recent decline, therefore, ecstasy tablets in the Netherlands still contain too much MDMA.[13]

Stronger tablets result in more health incidents. This has caused users to adjust their behaviour to the higher doses; on average, they only take one or two tablets per session.[14] According to Antenne (a long-term qualitative study among partygoers in Amsterdam), users are more likely to take one tablet than two per evening. Additionally, users report that instead of swallowing a tablet in one go, they break it and take the pieces in the course of the evening (a quarter first, then half a tablet and finally the other quarter).[15]

So far, there has been no convincing explanation for the high MDMA content in tablets up to 2019, nor for the decrease of MDMA content in more recent years.

Figure 17
Ecstasy tablets contain too much MDMA



12 Lotte Wijers et al., *Kenmerken en klinische gegevens van patiënten met ernstige ecstasyintoxicaties* (2016), 14-16.

13 National Drugs Monitor, '6.8 Aanbod en markt', *Nationale Drug Monitor* (2024).

14 National Drugs Monitor, '6.2.3 Gebruikspatronen', *Nationale Drug Monitor* (2024).

15 Ton Nabben et al., *Antenne 2019* (2020), 57-58.

4-FA

The high MDMA doses in ecstasy tablets caused users to look for alternatives. One such alternative, known as 4-FA, appeared around 2017. In contrast with MDMA, this substance was not illegal, and in popular media and forums it was referred to as 'ecstasy-light'. This name suggested that the substance was a safe alternative to the high-dose ecstasy tablets. However, this was misleading, because it was soon discovered that 4-FA could cause brain haemorrhages.[16] As a result, it was made subject to the Opium Act. Due to this ban, combined with preventive measures and specific warnings against the risks, the substance rapidly fell out of favour and was replaced by the 'old' MDMA.

This was not the first time that a substance whose effects resemble those of MDMA gained ground in response to supply-side problems. In 2009, for instance, a severe shortage of raw materials for ecstasy triggered the short-lived rise of mephedrone (4-MMC). As soon as the supply of raw materials for ecstasy was sufficient once again to meet the demand, demand for mephedrone fell accordingly. In 1992, widespread contamination of ecstasy tablets fuelled the rise of MDEA, also known as Eva. MDEA was not covered by the Opium Act and soon became very popular as a 'reliable' alternative. In 1993, following persistent reports in the press, the substance was included in Schedule I to the Opium Act.

Use of MDMA in the Netherlands

/// In 2022, 550,000 people in the Netherlands – 3.9 per cent of the adult Dutch population – used MDMA at least once. This represents an increase relative to previous years, following a period of stabilisation. This increase can be explained in part by the COVID-19 pandemic having come to an end, and the subsequent revival of nightlife. However, there had already been another increase in 2019.

Unlike many other countries, the Netherlands has a fairly good idea of which legal or illegal substances are being used. Population screening programmes and drugs monitors usually distinguish between three categories of use: lifetime use, past-month use and past-year use. The category of lifetime users includes both regular users of MDMA and people who have so far used it only once in their lives. In 2022, approximately 1.42 million people in the Netherlands had used MDMA at least once in their lives. This equals around 10.1 per cent of the population over the age of 18, compared with a share of lifetime users of 7 per cent in 2015.[17]

Note that this figure only provides an indication of the experience of people in the Netherlands with MDMA. It does not say anything about trends in the use of MDMA. For trend data, researchers prefer to study past-year use. In 2022, 550,000 people in the Netherlands – around 3.9 per cent of the Dutch population over the age of 18 – used MDMA at least once.[18] This represents a considerable increase compared with earlier years. Since 2015, consumption figures appeared to have stabilised, despite the peak in 2019. The decrease in 2020 and 2021 must be

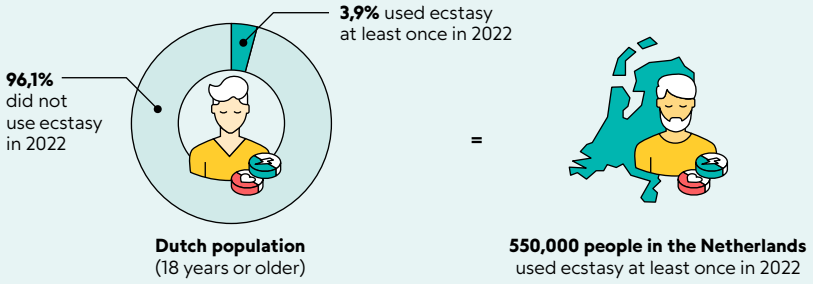
16 New Drugs Risk Assessment Committee, *Risicobeoordeling 4-fluoramfetamine (4-FA)* (2016).

17 National Drugs Monitor, '6.2 Gebruik: algemene bevolking', *Nationale Drug Monitor* (2023).

18 National Drugs Monitor, '6.2 Gebruik: algemene bevolking', *Nationale Drug Monitor* (2023).

attributed to the COVID-19 pandemic, which broke out in March 2020. Nightlife was closed due to the lockdowns, and since MDMA is mainly used during events, MDMA use figures fell accordingly.[19] This seems to be confirmed by the rise in consumption figures in 2022, which is known in nightlife circles as knaldrang (urge to go all-out): after two years of restrictions, many people in the Netherlands decided to catch up on the party time they had lost. It remains to be seen whether this increase heralded a peak in use or whether figures have stabilised at that level.

Figure 18
The Netherlands has a relatively large number of ecstasy users



Over one third of the 550,000 people who used ecstasy in 2022 did not use it more than once in that year. More than half (56.7 per cent) used it several times, but less frequently than every month, while 7.6 per cent of users took MDMA at least once every month.

In addition, the use per session (for example, at a club or festival) appears to be low. As mentioned above, MDMA use averaged one or two tablets per session. Over a third of users took less than one tablet per session. Just under one third took one tablet, while 4.6 per cent took more than two tablets per session.[20]

Methods of studying drug use in the Netherlands

Quantitative data on drug use are mainly gathered through population screening programmes and surveys, such as the Lifestyle Monitor, the Global Drug Survey and the Comprehensive Nightlife Survey. Another method used to measure trends in use is wastewater analysis. All of these methods have advantages and disadvantages. Surveys provide no guarantee that all target groups are represented in their data sets, resulting in a potential bias in the conclusions extrapolated to the population as a whole.

Wastewater analysis has been on the rise in recent years. This measurement method does not exclude any group and also generates more material for comparison, both at the national and international level. However, this analysis is unable to guarantee that any MDMA found in wastewater actually results from use by individuals; after all, the results may be influenced by

19 Ruben van Beek et al., *Het Grote Uitgaansonderzoek 2023* (2024), 67.

20 National Drugs Monitor, '6.2.3 Gebruikspatronen', *Nationale Drug Monitor* (2024).

the dumping of drug waste.[21] The SCORE study, conducted in 2024, involved analysis of wastewater from Rotterdam, Amsterdam, Leeuwarden, Utrecht and Eindhoven as part of a comparison of 88 European cities. The results for Eindhoven were excluded, however, as they may have been influenced by such a dumping incident.[22] Also note that wastewater analysis is a snapshot in time, as in many cases only one measurement is taken in one period of the year (March in the case of the SCORE study). A period with many events can be expected to provide a different picture than one without any events.

The Lifestyle Monitor (LSM) serves as the basis for a great deal of research into drug use in the Netherlands. It also provides the data for the figures on MDMA in the National Drugs Monitor (NDM). Developed by Statistics Netherlands and others, the LSM has several strengths. The choice for a target-group-oriented approach based on the population register is intended to ensure sufficient response per target group. In addition, the LSM uses a single questionnaire to ask respondents about all lifestyle factors. This makes it possible to identify various connections and link them to other Statistics Netherlands population screening programmes. All the same, as the LSM is a questionnaire survey, ensuring representativeness remains a challenge. Certain target groups are less likely to respond, such as people in low-income groups or with a migration background. In addition, some target groups are not included in the LSM sample, and some characteristics cannot be used as selection criteria, such as health issues.[23]

MDMA users are found predominantly in nightlife venues, and specifically among party and festival attendees.[24] The Comprehensive Nightlife Survey of 2023 shows that 53.8 per cent of respondents had used MDMA within the preceding 12 months.[25] As such, MDMA was the most commonly used drug, disregarding alcohol and tobacco. Its use had increased compared with the 44 per cent found in the previous edition of the survey, in 2020.[26] Incidentally, the questionnaires in that edition focused on MDMA use prior to the lockdowns during the COVID-19 epidemic.[27] The 2016 edition gave an MDMA use rate of 46 per cent.[28]

Since MDMA is mainly used in the nightlife scene, we may assume that most users can be found in the lower age categories. When we break down past-year use by age category, this assumption is confirmed: MDMA use is highest in the 20–24-year-old and 25–29-year-old categories. In contrast, there is a sharp drop in the 30–39-year-old category, which continues into the 40–49-year-old category. It appears, therefore, that MDMA is particularly popular among people in a specific life phase (students or first-time employees without children). The Antenne study confirms this picture. The conversations with former users of MDMA suggest that, at a certain point in time, they began to outgrow their appetite for it: 'The

21 Laura Smit-Rigter, 'Meer drugs in stedelijk rioolwater, maar wat zegt dat?', *Trimbos.nl* (2020).
22 EMCDDA, 'Wastewater analysis and drugs – a European multi-city study' (20 March 2024).
23 Ellen de Hollander et al., 'De Leefstijlmonitor', *Tijdschrift voor gezondheidswetenschappen* (2022).
24 Ruben van Beek et al., *Het Grote Uitgaansonderzoek 2023* (2024), 67.
25 Ruben van Beek et al., *Het Grote Uitgaansonderzoek 2023* (2024), 61.
26 Karin Monshouwer et al., *Het Grote Uitgaansonderzoek 2020* (2021), 49.
27 Karin Monshouwer et al., *Het Grote Uitgaansonderzoek 2020* (2021), 6.
28 Karin Monshouwer et al., *Het Grote Uitgaansonderzoek 2016* (2016), 47.

substance becomes predictable, its side effects become more serious or the impact of the intoxication begins to cause trouble in a person's life.'[29]

As mentioned above, MDMA use has increased since nightlife reopened after the COVID-19 pandemic. However, this change in behaviour cannot be explained by the pandemic alone. Players in the events sector have pointed out that due to high prices of beer and high admission fees, visitors have increasingly been looking for alternative substances. At festivals, a single ecstasy tablet costs almost as much as drink but, unlike a single alcoholic drink, its effect lasts hours. This is what makes tablets particularly attractive for young visitors, who tend to have less money to spend.[30]

Another recent phenomenon is the use of drugs in public. Since the end of the lockdowns during the COVID-19 pandemic, young people in particular have become less discreet in their use of drugs. More people can be found sniffing or swallowing drugs openly on the dance floor, whereas previously they tended to do so in secluded spots. Before the COVID-19 pandemic, experienced partygoers used to pass on norms of drug use to the younger generations. It may be the case that the lockdowns disrupted this process for two years. Some clubs have raised the minimum age due to the excessive and public use of drugs among young people, in an attempt to keep the 'COVID-19 generation' out.[31]

Why do people use MDMA?

/// The main reasons for using ecstasy are the sense of social communion and the intense sensual experience that it evokes, the desire to experience elevated levels of energy and stamina, curiosity and sometimes also peer pressure and self-exploration.

The motives for the recreational use of MDMA have been described in several national and international studies.[32] The outcomes are consistent: young adults say they expect to have cheerful, happy feelings, have a great time with friends and be less bothered by social inhibitions. They also report a more intense experience of music, higher levels of energy and a feeling that everybody is on the same wavelength. They experience a heightened sense of social communion, higher levels of energy and stamina, and more intense sensual perceptions, but also curiosity and, sometimes, peer pressure and self-exploration.

Several studies have found that ecstasy is mainly used in the social context of festivals and parties.[33,34] It is also found, to a lesser extent, at private house parties and in clubs. ecstasy is hardly ever used in the streets, in illicit drinking dens or in bars.[35]

29 Ton Nabben et al., *Antenne 2019* (2020), 55.

30 Conversation with the Dutch Association of Music Venues and Festivals and the Dutch Association of Event Management Companies.

31 Tahrim Ramdjan, 'Een pil op de bank, een snuif aan de bar', *Het Parool* (2022).

32 Martha de Jonge et al., 'What Do Young Adults Expect from the Recreational Use of Ecstasy?', *European Addiction Research* (2023).

33 Martha de Jonge, *Persona's in Middelengebruik: Eindrapportage* (2021).

34 Ruben van Beek et al., *Het Grote Uitgaansonderzoek 2023* (2024), 86.

35 Ruben van Beek et al., *Het Grote Uitgaansonderzoek 2023* (2024), 86.

MDMA is a social drug, as reflected in the extremely sharp decline in use figures during the COVID-19 lockdowns. Apparently MDMA lost its appeal to potential users, if only for a short period of time, if they had no opportunity to use it in the company of others.

Research into MDMA-assisted therapy for PTSD patients is a new development. Publications in this field receive considerable media attention and potentially also affect recreational users. In 2023, the target group of the Comprehensive Nightlife Survey was asked about this aspect for the first time. Approximately 6.7 per cent of respondents who use MDMA do so, among other things, in an attempt to relieve psychological or emotional problems (albeit only temporarily). A very large majority of this group are aware of the studies.[36]

Since this was the first time questions on this type of use were included, no conclusions about trends can be drawn at this stage. Also note that the therapeutic use of MDMA predates its recreational use: MDMA was already used by inquisitive therapists before the breakthrough of house. It is impossible to say, therefore, whether those 6.7 per cent of users are a new group or represent a continued tradition of MDMA use that already existed.

The influence of reports about the therapeutic use of these substances on recreational use is unknown at this time. In a study into ketamine use among partygoers, no effect was found on recreational use or on people's perception of the risks associated with ketamine since the introduction of its therapeutic use. However, since this concerned a different substance (ketamine), the question is whether these results can also be deemed to apply to MDMA.[37]

Use in an international perspective

/// The number of MDMA users in the Netherlands is high compared with other countries. Dutch people are also much more open about using MDMA, which means the consumption statistics are more reliable than in countries where MDMA use is prohibited or stigmatised. The actual differences between the Netherlands and other European countries could therefore be slightly smaller than suggested by the current statistics.

The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)[38], which is based in Lisbon, gathers all data about drug use in the European Union plus Turkey and Norway, enabling an international comparison. In comparisons published by the EMCDDA, the Netherlands tops the list of past-year use, at 3.7 per cent in the 15–65-year-old category. With 2.7 per cent past-year use, the Republic of Ireland comes second on the list, followed by Austria (1.5 per cent) and Finland (1.4 per cent). The lowest use figures were found in Turkey and Portugal (0.1 per cent).[39]

36 Ruben van Beek et al., *Het Grote Uitgaansonderzoek 2023* (2024), 122.

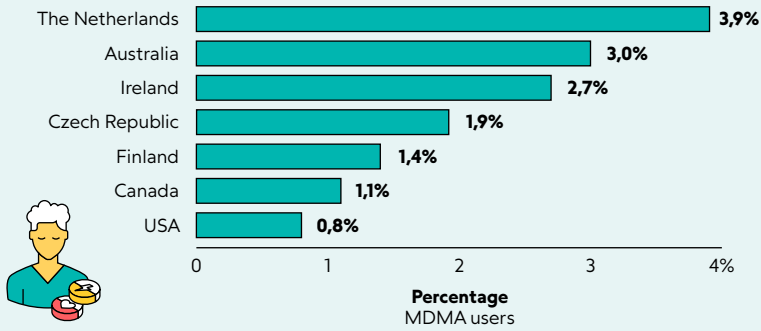
37 Meryem Grabski et al., 'Is approving esketamine as an antidepressant for treatment resistant depression associated with recreational use and risk perception of ketamine?', *International Journal of Drug Policy* (2022).

38 This Centre is also commonly known in the Netherlands by its English name. Effective 2 July 2024, the EMCDDA will be renamed the European Union Drugs Agency (EUDA).

39 EMCDDA, *European Drug Report 2023* (2023).

The Netherlands is also the country with the highest MDMA use compared with countries outside of Europe. In Australia, the past-year use rate is 3 per cent (among users aged 14 and over),[40] in Canada 1.1 per cent (among users aged 15 and over) and in the United States 0.8 per cent (among users aged 18 and over).[41]

Figure 19
Compared to other countries, many Dutch people use ecstasy occasionally



These differences and the relatively high rate of MDMA use in the Netherlands compared with other countries can be explained in part by the measurement methods used. In the Netherlands, there has been extensive research into drug use for many years, while other countries have hardly seen any such research. Moreover, the data supplied to the EMCDDA are not always recent: while the latest data from the Netherlands concern 2021, the most recent data supplied by Turkey go back to 2016. In addition, countries use different categories in some cases. For example, while the Dutch National Drugs Monitor distinguishes between adult and underage users, the EMCDDA uses two age categories: all adults (15–64) and young adults (15–34).

An additional problem is that attitudes towards drugs sometimes differ enormously between countries. The data used for this comparison were derived from questionnaires. The extent to which respondents can be relied upon to be honest about their drug use may vary from country to country, depending on the prevailing attitudes regarding drugs and drug use. For example, the use of drugs is a punishable offence in many countries, but not in the Netherlands. In countries with a policy that aims to remove the stigma from the use of drugs, the answers to such questions may be more honest (and the resulting figures may be more reliable) than in countries where the use of drugs is largely taboo. It is not clear, therefore, to what extent the prevalence figures in other countries are realistic, or whether the removal of stigma from Dutch users is causing reported differences between countries to appear larger than they really are.

Wastewater analysis may help to improve our understanding of this issue. In an analysis performed in 2023, the largest concentrations of MDMA were found in cities in Belgium, France, Germany, the Netherlands and Spain.[42]

40 Australian Institute of Health and Welfare, 'Illicit drug use', *AIHW.gov.au* (2024).

41 National Drugs Monitor, '6.5 Gebruik: internationale vergelijking', *Nationale Drug Monitor* (2024).

42 EMCDDA, 'Wastewater analysis and drugs: a European multi-city study', *emcdda.europa.eu* (2024).

Underage users of MDMA

Underage users are a group that merits special attention. The available data for secondary education were derived from the so-called Peilstationsonderzoek and the study entitled Health Behaviour in School-aged Children (HBSC). In the latter study, past-year use was not measured.
In 2021, lifetime use in the 12–16-year-old group was 1.9 per cent. It varied from 0.9 per cent among 12-year-olds and 1.5 per cent among 14-year-olds to 5.7 per cent among 16-year-olds. No major fluctuations were found compared with previous years. Since 2003, use in the 12–16 age group has averaged around 2 per cent. There are no significant differences in use between different levels of education.[43]

Harmfulness of MDMA

/// The harmfulness of MDMA is the subject of a large number of scientific publications. Nevertheless, various rare complications associated with MDMA have not yet been studied sufficiently.

Since the breakthrough of MDMA in 1988, a great deal of information has been collected about its mode of operation and the consequences of use. Most of that information by far was obtained through self-reporting following recreational use or from first-aid stations and hospitals. As explained in the box 'Drug, set and setting', the risks and effects of the use of drugs are associated with the dosage of the substance used, the user and the circumstances of the use. In the case of a health incident, by no means all those circumstances are registered, which means that it is not always possible to compare the data like-for-like. For example, instead of providing one standard type of ecstasy tablet, the market offers a huge variety of tablets made by different illegal producers.

Also note that the circumstances of use may limit the possibilities for a useful comparison. Use settings range from outdoor festivals to poorly ventilated clubs or domestic settings. This results in differences in ambient temperature, for instance, and in opportunities for people to chill out, the availability of water, ice or food and the presence of friends or experienced professionals wo are ale to detect and alleviate problematic situations at an early stage.

Finally, effective comparison may be impeded by the physical or mental state of the users. The combined use of ecstasy and alcohol or other drugs may increase the risk of complaints or health-related incidents. In people who do not feel at ease with themselves or have mental health issues prior to use, MDMA can increase the risk of a panic attack or mental complaints. ecstasy users may also have underlying conditions, such as a heart disease, of which they were not aware. Finally, there is a small group of ecstasy users in whom, for no apparent reason, the effects of MDMA trigger a highly adverse response, sometimes with very serious consequences. In most cases, those rare complications have not yet been studied sufficiently. These factors have an influence on the user's physical or mental state, but are difficult to identify, because to all intents and purposes the patient is incompetent and not in the best position to tell his or her story.

43 Maartje Boer et al., *HBSC 2021: Gezondheid en welzijn van jongeren in Nederland* (2022).

Generally speaking, the use of ecstasy can lead to incidents which, in by far the majority of cases, are mild and do not require hospitalisation. Many of those incidents can be dealt with on site at the first-aid station of the event. The report *Ranking van Drugs* (2009), in which various drugs are compared for their harmful effects, shows that tobacco and alcohol have much higher harmfulness scores than ecstasy. This should also be attributed to the fact that far more people use alcohol and tobacco, which means that the overall damage for society is also many times larger. It remains difficult, therefore, to give a reliable estimate of the harmfulness of ecstasy.

The complications associated with MDMA use can be divided into physical and mental complications. Examples of mild physical complaints include nausea, rapid pulse or breathing or pain in the chest. Potential serious complications include hyperthermia, water poisoning, tetanus, liver failure, cerebral haemorrhage, heart attack and pneumomediastinum (air in the space between the lungs). All of these complications are potentially fatal.

Mild mental complications that occur immediately after use are usually associated with anxiety. Some patients develop signs of depression during the days after use. One very rare complication is a condition of persistent visual disruption after MDMA use, which is typically associated with hallucinogenic psychedelics, such as LSD. Some people develop prolonged mental complaints after using ecstasy, such as a depression or anxiety disorder. This may be accompanied by a sense of alienation from the self (depersonalisation). The appendix lists the complications described above.

Incidents

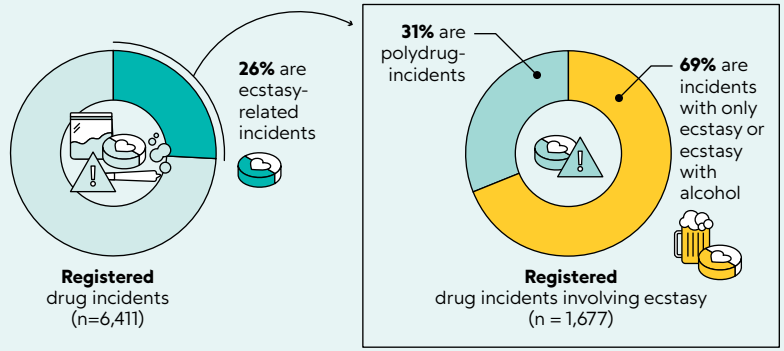
/// The number of MDMA-related incidents has returned to its level before the lockdowns during the COVID-19 pandemic. These incidents regularly involve a combination of MDMA and other substances, although this does not apply to the majority of cases. The number of MDMA-related incidents is increasing, and those affected are relatively young (median=23 years) compared with other drugs.

Another key aspect of the health effects of MDMA are acute incidents such as those that occur at parties and events. The Trimbos Institute uses the MDI to register drug intoxication data from various hospitals, ambulance services, first-aid stations at events and forensic medical examiners. As such, the MDI gives an indication of developments in and the number and seriousness of drugs-related health incidents in the Netherlands. However, it does not provide an overall picture of all incidents in the Netherlands. The monitor works on a random sample basis, and the sample does not cover all A&E departments.

In 2022, the MDI registered 1,677 health incidents that were related to the use of MDMA. This is approximately 26 per cent of all 6,411 registered drugs-related incidents in that year. This means incident numbers have returned to their pre-lockdown level. In March 2021, only 583 incidents were registered.

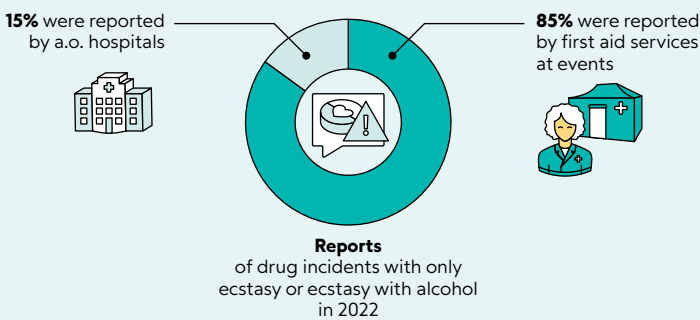
The State Commission emphasises that the distinction between MDMA-related incidents on the one hand and polydrug incidents involving MDMA on the other is important. A situation in which a user has only taken MDMA is known as mono-use. In polydrug incidents, users have also taken substances like ketamine, cocaine or GHB in addition to MDMA. Of the 1,677 incidents in 2022 mentioned above, 1,161 (69 per cent) involved the use of only MDMA or of MDMA plus alcohol.[44]

Figure 20
Drug-related incidents in 2022



The share of serious health incidents rose from 2 per cent in 2019 to 15 per cent in 2021, and then fell to 11 per cent in 2022. According to the Trimbos Institute, this might point to an increase in high-risk ecstasy use, particularly among young and often inexperienced first-time users after a year of COVID-19 restrictions. The users treated at first-aid stations at parties and festivals are also remarkably young. In 2022 the median age of these people for all drugs was 28, but for ecstasy users it was 23, up from 22 in 2021.[45]

Figure 21
Locations where health incidents with ecstasy were reported in 2022



44 Laura Smit-Rigter et al., *Jaarrapportage Meldpunt Nieuwe Drugs 2022* (2023).

45 Laura Smit-Rigter et al., *Jaarrapportage Meldpunt Nieuwe Drugs 2022* (2023).

In the Netherlands, depending on the size of an event and local authority requirements, event venues have a first-aid service. In many cases, this service is provided by private companies that employ health professionals and are hired by the event organiser. MDMA-related incidents are usually reported, and treated on site, by these services. This prevents patients from having to be sent to the emergency department of a hospital and, as such, reduces the burden on the collective health care system. In 2022, the majority of ecstasy-related mono-intoxication incidents (85 per cent) were reported by these first-aid services. The remaining 15 per cent were registered by hospitals, ambulance services and forensic medical examiners.[46]

First aid during the Amsterdam Dance Event

A study conducted during the 2016 edition of the Amsterdam Dance Event showed that of the estimated 375,000 visitors, 459 reported to a first-aid service with complaints; such services were available at just over half of all parties. During that period, Ambulance Amsterdam saw 113 patients reporting complaints after drug use; the Amsterdam A&E departments saw 81 patients. These figures represented a 225 per cent increase for Ambulance Amsterdam and a 236 per cent increase for the A&E departments in the number of drugs-related complaints relative to other weeks in 2016. Of the 81 A&E patients, 34 had only used MDMA; the others had used multiple drugs at the same time.[47]

Another source that provides insight into problems after use is the National Poisons Information Centre (NVIC), which professionals such as GPs or A&E staff can consult for advice about intoxications. Between 2018 and 2022, the NVIC was consulted 833 times about MDMA intoxications among patients aged 13 and over. This figure has shown a clear upward trend in recent years. Many of the incidents involved polydrug use: 54 per cent of the patients concerned had combined MDMA with alcohol or other drugs. One patient for whom the NVIC had been contacted died in this period. This was a case of mono-intoxication with MDMA, as confirmed by a laboratory analysis.[48]

So, what do these data tell us about the risk of an incident? In the Netherlands, the chance of serious complications following MDMA use is estimated at one for every 900 tablets used (0.11 per cent). It is difficult to compare this with the risk of other substances. For cocaine, the chance of serious complications is one for every 1,600 doses used (0.06 per cent) and for GHB the chance is one for every 95 doses (1.05 per cent).[49] These figures make it seem as though MDMA is much more dangerous than cocaine, but in practice this is not the case. After all, we should also consider the number of doses a user takes on a single day, how often they have such days and whether they ask for medical assistance. All these factors can make a huge difference.

46 Lonja Schürmann et al., 'Monitor drugsincidenten: Factsheet 2021' (2021).

47 Femke Gresnigt et al., 'Recreational Drug Use During the Amsterdam Dance Event', *Substance Use: Research and Treatment* (2022), 16.

48 Johanna Nugteren-van Lonkhuyzen, 'Vergiftigingen met MDMA gemeld bij het Nationaal Vergiftigingen Informatie Centrum (2018-2022)' (undated).

49 Jan van Amsterdam et al., 'Fatal and non-fatal health incidents related to recreational ecstasy use', *Journal of Psychopharmacology* (2020).

As described above, if MDMA is used on a daily basis it will not produce the effects that the user is after. Most users take one to two tablets and leave it at that for the rest of the evening. By contrast, first-time cocaine users sometimes do multiple lines on one evening, and experienced users may even do six or seven per evening.[50] In addition, cocaine can be used on a daily basis without reducing its effect, which means that users are likely to increase the number of lines per year rapidly compared with the number of tablets taken by experienced ecstasy users per year.

Fatalities

/// There is also uncertainty about the exact number of fatal incidents. Since there is no legal obligation to keep exact records of fatal incidents, deaths related to MDMA use – like those associated with other toxic substances – are likely to be underreported.

The use of MDMA can potentially trigger a fatal incident. It is difficult to say how often this happens in the Netherlands per year. This is because there is no reporting duty in the Netherlands for intoxications or for deaths associated with intoxications. As a result, there are no reliable, absolute data on the number of deaths caused by the use of MDMA (or other drugs). Moreover, in the case of fatal overdoses, registered data on other factors that may have played a role in the death are often lacking.

For example, environmental factors can play a role, such as a very high ambient temperature in an indoor event venue. The person concerned may have drunk too much water, resulting in sodium deficiency in the blood (hyponatremia). A death may also be the result of the use of multiple substances at the same time.

Besides factors that increase the risk of a fatal incident, cases are known to have occurred where there were no risk factors and where no clear cause was identified. In these cases, the dose used, water intake or multiple substance use probably did not play a role. The true cause of death in these cases usually remains unclear, although we do know that this can also happen to experienced users of MDMA.

In other words, while the chance of a person dying from an overdose of MDMA is extremely small, it can by no means be excluded. And even if users took every possible safety precaution, they still would not be able to eliminate the risk of death.

Due to the absence of adequate mortality registration, this aspect of the use of ecstasy remains controversial. The lack of conclusive mortality figures prevents a clear and comprehensive analysis of the health effects of MDMA. Based on the available data, there appear to be five to ten fatal incidents in the Netherlands per year. Between 1999 and the end of 2015, in total 77 MDMA-related deaths were reported, i.e. an average of four or five each year.[51] In 2022 – the most recent year for which data are available – seven people died of ecstasy; in five of these cases,

50 Jellinek, 'Hoe gebruikt men cocaïne?', *jellinek.nl* (2015).

51 Annabel Vreeker et al., *MDMA-gerelateerde sterfgevallen onderzocht door het Nederlands Forensisch Instituut* (2017).

ecstasy was the only substance that had been used.[52] This is probably an underestimate; the real number may prove to be higher once our insight into the mortality figures increases.

By contrast, the United Kingdom does have compulsory registration of ecstasy-related deaths, as well as reasonable estimates on the total number of users. An analysis conducted in 2020 aimed to provide an estimate of the chance of a fatal incident involving the use of ecstasy. The analysis showed that one in every 2,000 to 10,000 users had died as a result of an ecstasy-related incident. This meant that the chance of a fatal incident among ecstasy users was sightly higher than among amphetamine users (one in every 20,000 users), the same or slightly lower than among cocaine users (one in every 2,000 users) and much lower than among heroine users (one in every 290 users). The chance of a person dying as a result of using an ecstasy tablet was calculated to be one in every 20,000 to 33,000 tablets. The margin depends, among other things, on whether other drugs are used at the same time.[53]

However, figures from the Netherlands and from the United Kingdom cannot easily be compared. For example, in Scotland the number of sessions and the number of tablets per session was much higher than in the Netherlands and even higher than in England. In addition, various other factors potentially have a significant influence on comparisons between the Netherlands and the United Kingdom, such as the concentration and quality of the ecstasy tablets, the applicable harm reduction policy, overall public health and nightlife and drinking culture. Moreover, the figures for the United Kingdom appear improbable when extrapolated to the Dutch situation. Assuming there were 550,000 Dutch users in 2022, at least 55 of them would have died in that year alone. That figure is much higher than the number of deaths actually registered in the Netherlands. According to Statistics Netherlands, between 2013 and 2022 the number of deaths due to the use of psychostimulants (including MDMA, as well as speed, for instance) varied from four to 28 cases per year.[54]

Cognitive effects

/// **Some research has been conducted into the long-term effects of the use of MDMA on the memory. The latest studies have shown that recent MDMA use does not reduce users' cognitive capacities. A serious disadvantage of studies of this type is that the respondents tend to be highly educated young individuals who use other substances as well as MDMA. The effects on an older person's brain and the effects of MDMA mono-use remain unclear. Scientists do not seem to be very concerned about this, however, given the minor nature of the effects observed.**

Despite the many studies that have been conducted, no definitive conclusion has been drawn yet as regards the causal link between cognitive problems and the use of ecstasy, and the seriousness of those problems. For example, MDMA does appear to have a minor adverse effect on the functioning of the brain; people who

52 Laura Smit-Rigter et al., *Jaarrapportage Meldpunt Nieuwe Drugs 2022* (2023).

53 Jan van Amsterdam et al., 'Fatal and non-fatal health incidents related to recreational ecstasy use', *Journal of Psychopharmacology* (2020).

54 National Drugs Monitor, '6.7.2. Sterfte', *Nationale Drug Monitor* (2024).

have used MDMA seem to have more difficulty performing the same cognitive tasks than others. One year after use, however, these neurological effects can no longer be detected, so the harm – if any – does not seem to be permanent.[55] One important problem, however, is that most studies into these effects are conducted among a specific group of respondents, namely healthy and highly educated young people who also use other drugs besides MDMA. It is difficult to establish a direct link between these minor effects and MDMA use for this group, because the effects may also have been caused by some other substance or combination of substances.

It may also be that a brain with high neuroplasticity – as is the case in this group of users – is able to adapt quickly and compensate for any neurotoxic damage that has been done. In such a case, the effects of MDMA (and other drugs) become less conspicuous. The effects of drug use on cognition might be more noticeable among respondents in older age categories, but specific data for these groups are often lacking.

In the longer term, the therapeutic use of MDMA may provide an answer to the question about causality. This population only uses MDMA and does so in a controlled setting, which may provide new insights.

Another aspect that researchers brought to the attention of the State Commission was that the lack of clarity about long-term effects might be attributed to what is known as funding bias. Particularly in the US, studies that specifically focused on the negative effects of MDMA were more likely to attract funding. While it is true that negative effects were found, the researchers often failed to show how small they were. Neither did they point out that the impact of those effects on cognitive functions was likely to be temporary.

Based on the existing evidence, the State Commission has found no clear indications that MDMA causes permanent cognitive damage. The experts consulted by the State Commission were not convinced of the seriousness of potential cognitive damage.

Risk of addiction

Given that the mode of operation of MDMA prevents frequent use, its addiction risk is minimal. If a person were to use MDMA for several days in a row, they would not experience the same effects after the first tablet. This is because the serotonin supply is usually depleted after that first tablet, and to be able to produce serotonin the body actually needs a period without use. That is why MDMA is one of the least addictive drugs available on the market, after LSD and mushrooms.[56] Even so, a very small number of cases have emerged of people seeking help primarily for addiction to MDMA.

The National Alcohol and Drug Information System (LADIS) collects data from addiction care services. The most recent data indicate that in 2021, fewer than 1 per cent of all people who sought addiction care services were primarily addicted

55 Catharine Montgomery et al., 'Neurological and cognitive alterations induced by MDMA in humans', *Experimental Neurology* (2021).

56 Jan van Amsterdam et al., *Ranking van drugs* (2009), 83.

to MDMA. In absolute figures, this is a group of 130 cases out of a total of 54,865 people who sought help. Clearly, addiction to MDMA compared with other recreational drugs is very rare.[57]

How do users view these risks?

/// Young people in nightlife settings have been gradually assessing ecstasy use as less risky. This may lead to a more risky use of ecstasy, for example in combinations with other drugs or in high dosages.

The use of MDMA comes with certain risks. Even so, this does not prevent many people from using it – in 2022 alone, there were 550,000 users, mostly in the 18–25-year-old category.

It this context, it is useful to also consider various perspectives on the harmfulness of MDMA. The Comprehensive Nightlife Survey, which collects data among people in nightlife settings in the 16–35-year-old category, shows that over the past few years respondents' estimates of the risks of MDMA have become lower and lower. For example, in 2023 only 68 per cent of all respondents in the survey believed regular use of MDMA is harmful, compared with 73 per cent in 2019. According to 9 per cent, the use of one or two tablets per year is harmful, compared with 15 per cent in 2019.[58,59]

/// Both the desired and the negative effects of MDMA strongly depend on the individual user and the context of use. Most users in nightlife settings believe that the harmfulness of one or two ecstasy tablets per year is low. There is a small group of young people who are considering using ecstasy, but do not appear to be properly informed about the risks and the measures to reduce harmful effects.

Studies among the most frequent users (age category 18–25) but not limited to nightlife provide a more detailed picture of how they assess the risks of ecstasy.[60] There are two distinct groups: young people who have experience with MDMA and young people who do not have such experience.

Young people who neither use MDMA nor have any intention of doing so tend to have predominantly negative expectations and assess the harmfulness and risks as being very high. Young people who have experience with MDMA themselves and who also have friends with such experience do see risks associated with the use of MDMA. However, they feel those risks are outweighed by the desired effects.

Within the group of inexperienced young people, there are some who are interested in using MDMA, are curious and may have a desire to self-explore Some experience social or peer pressure. While these young people do come into contact with users, they are not always very well informed about the harmfulness and potential risks of ecstasy. Some of them are inclined to underestimate the risks

57 LADIS, *Tussenrapportage Kerncijfers Verslavingszorg 2016-2021* (2023).

58 Karin Monshouwer et al., *Het Grote Uitgaansonderzoek 2020* (2021).

59 Ruben van Beek et al., *Het Grote Uitgaansonderzoek 2023* (2024).

60 Martha de Jonge et al., 'What Do Young Adults Expect from the Recreational Use of Ecstasy?', *European Addict Research* (2023).

and harmfulness of MDMA and are not up to date with any existing measures to mitigate those risks either. This group merits special attention from a drug prevention perspective.[61]

Conclusion

The use of ecstasy in the Netherlands has been increasing slowly but steadily for years. Today, more than 10 per cent of the population have experience with MDMA, the active substance in ecstasy. The past few years have seen several changes, however. The COVID-19 pandemic and the subsequent lockdowns resulted in the closure of nightlife and the festival sector, which was reflected in decreasing ecstasy use figures in those years. This shows how strongly the use of ecstasy is connected to nightlife.

After the COVID-19 restrictions were lifted, the use of ecstasy soon returned to pre-pandemic levels, and in 2022 no fewer than 550,000 people said they had used ecstasy. This trend was accompanied by an increase in the number of incidents, particularly among young users, a quarter of whom experienced moderate or serious intoxication. One notable finding in this regard is that young people have been gradually assessing MDMA as less harmful.

MDMA has a special position in the drugs spectrum when it comes to harmfulness. For example, it is hardly addictive. Moreover, its harmfulness strongly depends on dosage, type of user and use context. Note, however, that this is not the whole story. Serious complications do occur and deaths have been known to occur even with low doses, although these cases have not been clearly explained so far. There is no statutory requirement in the Netherlands to keep records on ecstasy-related mortality and drugs-related mortality in general. This means that the number of deaths is most likely to be an underestimate.

In addition, our knowledge of the long-term effects of MDMA on the memory is incomplete. Many studies into these effects are 'contaminated', because many respondents also use other drugs besides MDMA. It has appeared to be very difficult to find a research population that only uses MDMA. While the available data do not suggest that MDMA causes serious harm to cognition, more research is required among a varied research population.

Recommendations

1 **Continue the existing prevalence monitoring of the use of drugs, and of behaviours and attitudes with respect to the use of drugs. Where possible, extend the monitoring effort to include other target groups as well.**
At the national level, the prevalence of drug use is monitored among the general population, students, young people in nightlife settings and secondary school students. In addition, data are collected among drug users on a wide range of topics, including attitude, social standards, motives, interest in reducing or quitting substance use, risk assessment, availability and measures to reduce harmful effects. According to the State Commission, this monitoring effort must be continued to support and further improve drugs and drug

61 Martha de Jonge et al., 'What Do Young Adults Expect from the Recreational Use of Ecstasy?', *European Addict Research* (2023).

prevention policies. It should also be possible to expand the monitoring effort (temporarily or permanently) in order to include new target groups and new types of drugs and behaviours.

2 **Introduce a compulsory system for the forensic investigation, registration and annual reporting of the role of MDMA and other substances in fatal incidents.** Continue the monitoring of drugs-related incidents. Despite the extensive knowledge about the harmfulness of MDMA use, there is uncertainty about the number of fatal incidents. Since there is no legal obligation to register mortality figures, it is very likely that incidents and deaths caused by MDMA are persistently underreported. This recommendation also applies to other substances. For this reason, the State Commission recommends that:

   a forensic toxicological research be made compulsory and should include registration of the context of the death;
   b an institution designated for that purpose report on drugs-related mortality in the Netherlands, periodically and also on an ad hoc basis if required;
   c the insights gained through these reports be incorporated in drug prevention policies.

In 2021, the Trimbos Institute, in its report entitled *Drugsgerelateerde sterfte in beeld* (Drugs-related mortality in the picture), already noted the lack of adequately informative registration of drugs-related mortality.[62]

3 **Ensure that the providers of care during drugs-related incidents have sufficient knowledge.** The State Commission has received indications from the field that MDMA-related care could have been better if the treating physician concerned had had more toxicological expertise. It is important that every physician caring for intoxicated patients has sufficient knowledge in this field. Toxicology does not currently form part of the basic medical curriculum.

4 **Continue pre-hospital care during events.** A&E doctors say that pre-hospital care at events is extremely helpful to relieve the workload in hospitals. Pre-hospital care is particularly effective when the need for it can be reliably estimated in advance. That is why it is important for municipal authorities to be up to date on the guidance for municipalities on this issue.[63]

5 **Ensure clear communication about MDMA-assisted therapy to the group of recreational ecstasy users.** Some of the people who use ecstasy for recreational purposes also use it as self-therapy. In the communication about MDMA-assisted therapy (refer to Chapters 5–8), it is important to negate any suggestion that taking MDMA helps to alleviate psychological problems. The use of ecstasy for mental health issues without proper guidance may exacerbate the existing complaints.

62 Eefje Vercoulen, Manon Ceelen, Tina Dorn, Marcel Buster, Esther Croes and Margriet van Laar, *Drugsgerelateerde sterfte in beeld: Onderzoek naar de praktijk van de detectie en registratie van drugsgerelateerde sterfte en ontwikkeling van een blauwdruk voor een speciaal register* (Utrecht: Trimbos Institute 2021).

63 J. de Greeff, F.X. Goossens, A.M.L. Sannen, C. Harreveld, H. Kooke and N.E. van Hasselt, *Alcohol, drugs en tabak op evenementen: Leidraad voor gemeenten 3.0* (Utrecht: Trimbos Institute 2019).

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Appendix 1: Overview of complications following MDMA use

Below is a description of the most common complications associated with the use of MDMA. Based on the current level of scientific knowledge, there is no or only partial evidence for a causal relationship between these complaints and the use of ecstasy.

The use of MDMA in combination with other substances may pose an increased risk of other health problems, such as serotonin syndrome. Caused by a surplus of serotonin, this syndrome may develop when MDMA is combined with other substances that increase serotonin levels, such as antidepressants, stimulating drugs or opioid-type painkillers.[64]

Physical complications

Hyperthermia

Hyperthermia following MDMA use can have serious consequences and may even be fatal. MDMA increases the level of serotonin. Serotonin is a semiochemical in the nervous system and is involved in temperature regulation, for example. The use of MDMA causes the body temperature to rise. This effect probably depends on the dose. In addition, MDMA is often used at parties or festivals where users engage in physical activity (such as dancing) in a hot environment. The combination of these factors may result in hyperthermia. The higher the temperature, the greater the risk of serious complications, possibly resulting in organ failure and even death.[65]

Water poisoning

MDMA also inhibits the discharge of water, because the MDMA-induced increase of a certain hormone (antidiuretic hormone) means that users urinate less. When such a user then drinks a lot of water, the electrolytes in the blood are diluted to such an extent that the level of sodium may become dangerously low. This effect occurs even after taking the recreational dose. Water poisoning is mainly seen among young women (89 per cent of cases). The condition can result in confusion, reduced consciousness, epileptic seizures and swelling of the brain, and may be fatal.[66] A Dutch study into MDMA-intoxicated patients admitted to intensive care showed that 20 per cent of these people were admitted due to water poisoning.[67]

64 Tigran Makunts et al., 'Reported Cases of Serotonin Syndrome in MDMA Users in FAERS Database', *Frontiers in Psychiatry* (2022).

65 Jessica Mead et al., 'Mephedrone and MDMA', *Brain Research* (2020).

66 Ana Carolina Faria et al., 'Drinking to death', *Drug and Alcohol Dependence* (2020).

67 M. Zuidema et al., 'Acute complications and treatment in critically ill MDMA-intoxicated patients' (2023).

Lockjaw

The study of intensive care patients mentioned above showed that 31 per cent of MDMA-intoxicated patients had been admitted because of the risk of upper airway obstruction caused by lockjaw. Lockjaw is potentially dangerous if the patient has difficulty keeping their airways unobstructed, for example in the case of reduced consciousness, because they cannot open their mouth.[68]

Complications for the unborn child

The use of MDMA during pregnancy also has effects on the unborn child. One study showed that children who had been exposed to MDMA before birth (n=28) experienced less effective mental and motor development after one year than children who had not been exposed to MDMA (n=68).[69] The developmental delay in fine and gross motor skills persisted after 24 months.[70] MDMA can also cause acute and long-term mental complications.

Mental health issues

Depression and anxiety disorders

Depression and anxiety disorders are common among moderate and heavy users. Theoretically, this might well be attributable to depletion of serotonin supplies, since serotonin has an effect on a person's mood and emotions.[71] Several studies found an elevated risk of depression among MDMA users.[72] In another study, however, MDMA use was found to reduce the risk of serious depression.[73] Research has also shown that people with depression and anxiety disorders are more likely to start using ecstasy. The exact relationship between ecstasy use and feelings of depression and anxiety is not clear at the moment.[74] Ecstasy use also raises the cortisol level (the stress hormone) which, if prolonged, can lead to psychological problems. It has not been studied whether this also applies to ecstasy users. The use of ecstasy is also related to acute and probably also to persistent sleep problems.

Cognitive functions

The use of MDMA can also cause mental complaints in the longer term. Animal studies have shown that ecstasy can damage nerves in the brain. It is less clear whether this also applies to human beings, but neuroimaging studies do show changes in the brain of heavy ecstasy users. Several higher cognitive functions (such as memory and performing complex tasks) also appear to be affected in the long term in ecstasy users.[75] Although the quality of the research is moderate, even low ecstasy use appears to affect the memory, but the clinical relevance of

68 M. Zuidema et al., 'Acute complications and treatment in critically ill MDMA-intoxicated patients' (2023).

69 Lynn Singer et al., 'One-year outcomes of prenatal exposure to MDMA and other recreational drugs', *Pediatrics* (2012).

70 Lynn Singer et al., 'Motor delays in MDMA (ecstasy) exposed infants persist to 2 years', *Neurotoxicol Teratology* (2016), 22–28.

71 Esther Croes et al., *Langdurige klachten na ecstasygebruik* (2017).

72 Jessica Mead et al., 'Mephedrone and MDMA', *Brain Research* (2020).

73 Grant M. Jones et al., 'Lifetime use of MDMA/ecstasy and psilocybin is associated with reduced odds of major depressive episodes', *Journal of Psychopharmacology* (2022), 57–65.

74 Esther Croes et al., *Langdurige klachten na ecstasygebruik* (2017).

75 Esther Croes et al., *Langdurige klachten na ecstasygebruik* (2017).

this remains unclear. Neither do we know whether the memory recovers once the MDMA use stops.[76]

Hallucinogen persisting perception disorder

Another psychological condition that has been described in connection with MDMA use is hallucinogen persisting perception disorder (HPPD), a condition that makes users see halos, flashes of colour, oddly moving objects or 'snow' (like the static on a TV screen when no signal is received), while they know that what they see does not exist in reality. It is not known how frequent this phenomenon is among users. People may experience HPPD symptoms without being bothered by them. The most common HPPD symptoms (93/116) were snowy vision, floaters (annoying specks inside the vitreous of the eye), a tingling sensation in the head, the sense of a 'dry brain', dizzy spells, after-images, light flashes or a persistent annoying sound.[77]

Depersonalisation and derealisation

There also appears to be a connection between the use of ecstasy and long-term symptoms of depersonalisation and derealisation (a sense of alienation from the self and the world, depersonalisation syndrome), but high-quality studies into this have so far been lacking. Moreover, depersonalisation and derealisation also occur in the general population without prior drug use. A retrospective study among 126 patients (50 per cent ≤ 24 years of age and 75 per cent male) with subjective HPPD and depersonalisation issues found that 50 per cent of those individuals had had complaints for at least a year. The total number of ecstasy tablets they had used in their lives ranged from one to 1000, and there was also considerable variation in numbers of tablets per session, without dosage statistics. Many cases involved combined drug use, especially combinations with alcohol, cannabis and other stimulants.[78]

Most patients with depersonalisation symptoms (81/119) had mixed complaints of depersonalisation and derealisation, and considerable overlap with HPPD. Feelings of anxiety and panic were described for 88 patients with depersonalisation symptoms (75 per cent), which is far more than among the general population, and feelings of depression for nearly half of 108 patients with depersonalisation symptoms. More than 50 per cent (out of 104 patients) reported concentration issues and fatigue, just under 50 per cent mentioned memory issues and nearly 40 per cent reported sleep problems. A prior history of mental health issues, mainly AD(H)D, mood disorders or addiction was reported by 44 of 97 patients with depersonalisation symptoms. Based on this study, there is no evidence for a causal relationship between these complaints and the use of ecstasy. However, researchers suspect that these patients have a special propensity or vulnerability to developing chronic, adverse effects of ecstasy use.[79]

76 Esther Croes et al., *Langdurige klachten na ecstasygebruik* (2017).

77 Esther Croes et al., *Langdurige klachten na ecstasygebruik* (2017).

78 Esther Croes et al., *Langdurige klachten na ecstasygebruik* (2017).

79 Esther Croes et al., *Langdurige klachten na ecstasygebruik* (2017).

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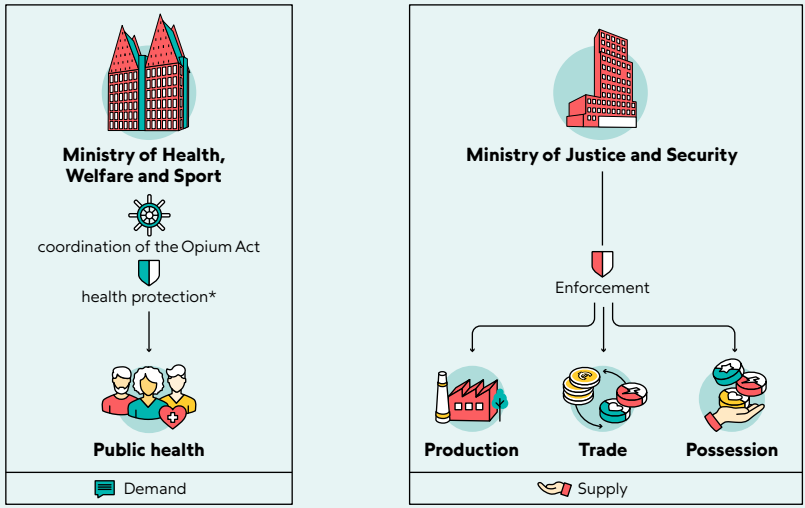
3 Dutch MDMA policy: practice and challenges

To be able to formulate advice on the status of MDMA for public health, we need more than just an analysis of the health effects of MDMA. After all, government policy also has a direct and indirect influence on the extent to which the substance is harmful to public health.

How government policy is made and what objectives it prioritises differs from country to country. In Dutch drug policy, public health is the number one priority.[1] In the Netherlands, the prevention of drug use and of the associated harm to users and their environment always has priority over criminal prosecution. In legal terms, this means that the use of drugs is not a punishable offence in this country. Internationally, this principle meets with appreciation, but also with incomprehension. After all, some countries have opted for a zero-tolerance policy.

Figure 22
The relationship between responsibilities and drug policy in the Netherlands



*takes precedence over enforcement

Dutch drug policy also focuses on the fight against illegal trade and production. Ecstasy production is a huge challenge for the Netherlands, as hundreds of millions of ecstasy tablets are produced here illegally, mainly for foreign markets. Despite the substantial investment in the fight against organised drugs-related crime in recent years, illegal ecstasy is still widely available and the price per tablet remains low.

The health objectives (focusing on users) and the crime objectives (focusing on producers) constitute two different tasks. By consequence, these two tasks have been assigned to two separate, cooperating Ministries: Health, Welfare and Sport (VWS) on the one hand, and Justice and Security (JenV) on the other, with the former being responsible for coordinating the approach.[2] Over the past few years, however, the segregation of these two tasks appears to have become less evident. Given the size of the crime-fighting task, politicians are tempted to also incorporate crime-related objectives in policy aimed at *users* – to the detriment of public health and the work of organisations responsible for promoting it, such as the Ministry of Health, Welfare and Sport and specialised addiction care centres.

1 Margriet van Laar et al., *Evaluatie van het Nederlandse drugsbeleid* (2009), 35, 50.
2 Ministry of Health, Welfare and Sport, 'Uitgangspunten huidig drugsbeleid' (2015).

At first sight, the argument that users should be made responsible for production seems reasonable: after all, there can be no supply without demand. The crucial question, however, is to what extent Dutch users have any real influence on a criminal sector that mainly produces for the world market.

The fight against the production and sale of drugs has an impact on public health. Reduced supply can lead to reduced use (as was demonstrated by alcohol policy[3]), but effective measures against production lead to lower-quality drugs and more contamination on the market, with the risk of a corresponding rise in health incidents. This explains why the various objectives of drug policy cannot be dealt with in isolation. Successes in one domain may have unintended consequences for the other domain.

In this chapter, the State Commission presents current Dutch policies regarding MDMA. The State Commission points out that many of the policies mentioned have a general scope and also apply to other substances.

Prevention, harm reduction and crime

This chapter covers three themes. The health-related objectives are explained in the sections on prevention and harm reduction. The drug policy objective concerning crime-fighting is covered in the sections on drugs-related crime. This third theme, drugs-related crime, may seem rather out of place in this report, since the State Commission's mandate is limited to the status of MDMA within the context of public health. Nevertheless, certain aspects of MDMA production also interface with public health. Those aspects are mentioned in the final section of this chapter.

The structure of this chapter is based on the Harm Minimisation Model, whose principles can be used to structure and explain the principles of Dutch drug policy. Drug policy is divided into three elements, which are:

1. curbing the 'demand' for drugs by means of an effective prevention policy;
2. adopting harm reduction policies to reduce the damage to society and public health caused by drug use;
3. reducing the 'supply' of drugs by investigating and prosecuting producers and dealers.[4]

All these elements are also part of the EU Drugs Strategy for 2021–2025.[5] Objectives 1 and 2 above mainly have to do with health and come under the policy domain of the Ministry of Health, Welfare and Sport. Objective 3 concerns public order and safety, which is the policy domain of the Ministry of Justice and Security. The structure of this part of the report reflects the elements of the model. We will first discuss the Opium Act, which serves as the basis for the existing policy. Objectives 1 and 2, which concern public health, are discussed in Chapter 3a. This is followed by an analysis of the key challenges. Objective 3, fighting the production of and trade in drugs, is dealt with in Chapter 3b.

3 Robyn Burton et al., 'A rapid evidence review of the effectiveness and cost-effectiveness of alcohol control policies: an English perspective', *The Lancet* (2017).

4 Anneke van Wamel et al., *Modelplan lokaal drugspreventiebeleid* (2023).

5 Secretariat-General of the Council of the European Union, *EU Drugs Strategy* 2021-2025 (2021).

3a
Health

Findings

The State Commission finds as follows:

/// **As regards drug use, Dutch drug policy focuses on protecting (public) health rather than on curbing the use or possession of drugs.**

/// **The criminalisation of drug use and users is at the expense of public health.** The stigmatisation arising from prosecuting users or making them responsible generates feelings of shame among users and a tendency to avoid seeking help in the event of incidents or problems.

/// **Since 1995, no explicit government vision for drug policy has been published in the Netherlands.** It is not clear to what extent that old vision still applies and what the integrated vision and interdepartmental objectives are that existing drug policy is being tested against.

/// **To be able to carry out targeted and effective preventive activities, information about the target group, use context and behavioural determinants is essential.** In the current situation, this information is gathered at the national level using various monitoring programmes and summarised annually in the National Drugs Monitor.

/// **Drug prevention policies that are not based on scientific evidence may be counterproductive and increase the risk of harm to health and society.** In addition, such policies can undermine the authority of the government.

/// **Use figures in the Netherlands are high.** Even so, Dutch prevention policies do appear to achieve successes: the use per person and the amount of ecstasy used per session are relatively low, as is the number of ecstasy-related deaths reported thus far (compared with the figures for the United Kingdom or Germany, for example).

/// **Drugs information services remain necessary, but should target specific groups and focus on specific risks and the associated preventative measures.** General public campaigns are not advisable, because they can have both a normalising and a stigmatising effect.

/// **It is possible to study the effects of drug prevention policies, provided a number of conditions are met.** For example, it is important to define specific targets and target groups for prevention policy, and to ensure that sufficient funds are available for implementation and effect studies.

/// **The DIMS network ensures that the ecstasy market in the Netherlands is monitored effectively.** This makes it possible to issue targeted warnings against drugs that are proven to be particularly risky. It also provides a moment of contact with users to inform then about harm-reducing measures.

/// **Due to the changing social context of drug policy, parties in the safety domain regularly launch drug prevention initiatives.** Such initiatives do not always utilise the scientific insights and quality standards in drug prevention that are known among behavioural scientists and prevention professionals, and they can have harmful effects.

/// **The debates about the 'normalisation' of drug use create confusion about the actual prevalence of ecstasy use: in reality, only a fraction of the Dutch population use ecstasy.** At the same time, drug use is quite common within certain groups of the population. These discussions complicate the support for groups with significant high-risk use. Furthermore, the discourse on normalisation can encourage use by mistakenly giving the impression that drug use is already widely accepted.

/// **There is a lack of a nationwide, scientifically substantiated vision for drug prevention.** As a result, the range of interventions in the Netherlands consists of a mixture of effective, ineffective and potentially even harmful interventions. Providers range from addiction care centres to commercial marketing agencies.

/// **It is uncertain whether municipalities have sufficient financial resources available for prevention.** Effective prevention requires a long-term commitment and, hence, a structural investment.

/// **Foreign visitors to events in the Netherlands form a target group of significant concern.** They use MDMA in a more risky manner, probably because they have not been informed effectively at home. This leads to incidents that could have been prevented and places an additional burden on the Dutch health care system.

The legal frameworks

MDMA and the law

On 23 January 1912, twelve countries signed the first *International Opium Convention* in The Hague. This marked the beginning of the development of an international drug control regime. The central objective was to suppress the production of and trade in existing substances such as opium and morphine, as well as new substances such as cocaine and heroin. The convention highlighted the dangers of the recreational use of opium and the non-medical trade in opium and other drugs. Initially, the convention remained unenforced, until negotiators included it in the peace talks in Versailles in 1919, after the First World War. This resulted in the ratification of the Opium Convention and the establishment of the League of Nations, which was tasked with overseeing its enforcement.[6]

After the Second World War, the international drug control regime was transferred from the League of Nations to the United Nations. Various amendments were incorporated into existing conventions, and the resulting fragmentation provoked a desire to work towards a single convention. To achieve this, the *Single Convention on Narcotic Drugs* (Single Convention, SCND) was adopted in 1961.[7]

The international drug control regime currently consists of three conventions: the *Single Convention*, which came into force in 1964; the *Convention on Psychotropic Substances* of 1971; and the *United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances* of 1988 (Illicit Traffic Convention).[8,9] The Netherlands is a party to all these conventions and must therefore meet the associated obligations. These conventions serve as the basis for the Opium Act.[10]

The convention system

The *Single Convention* (1961) and the *Convention on Psychotropic Substances* (1971) each list more than a hundred substances. Each does so with its own four schedules. Inclusion of a substance in a schedule depends on its therapeutic value and potential harm if abused. These schedules are regularly amended, meaning that new substances are added or substances are moved from one schedule to another.[11]

The schedule system provides for various levels of supervision and control. The World Health Organization (WHO) advises on any changes to the schedules to these two conventions.[12,13] The International Narcotics Control Board (INCB) is responsible for the administrative control system of the

6 Kathryn Meyer et al., *Webs of Smoke* (1998), 40.
7 For a detailed analysis, refer to Martin Jelsma et al., 'Drugs and crime' (2019).
8 This convention has mainly tightened criminal measures to criminalise non-medical abuse and is therefore less relevant for this advisory opinion.
9 Two more recent UN conventions that focus more on crime are not addressed in this report: the *UN Convention against Transnational Organized Crime* (UNTOC 2003) and the *UN Convention against Corruption* (UNCAC 2003).
10 Henk Garretsen et al., *Drugs in lijsten* (2011).
11 Henk Garretsen et al., *Drugs in lijsten* (2011).
12 UN Office on Drugs and Crime, 'United Nations Commission on Narcotic Drugs' (undated).
13 Henk Garretsen et al., *Drugs in lijsten* (2011), 20.

1961 and 1971 Conventions and makes recommendations for changes to the schedules to the *Illicit Traffic Convention* (1988) regarding substances commonly used in the illegal production of controlled drugs.

The decision-making process regarding changes to the schedules is then entrusted to the Commission on Narcotic Drugs (CND), a political body established by the United Nations Economic and Social Council in which 53 State Parties to the drug treaties are represented.[14] Decisions based on WHO or INCB recommendations are made by the CND with a simple majority for changes to the schedules to the 1961 Convention, but require a two-thirds majority for changes to the schedules to the 1971 and 1988 Conventions.

Besides the UN drug treaties, the human rights conventions include provisions that are relevant to drug policy. A human rights approach should include an emphasis on prevention, harm reduction measures and protection of the rights of drug users.[15] Within this discourse, there is a huge emphasis on decriminalisation.[16] In that sense, there is a certain tension with the UN drug treaties, which have a greater emphasis on repression.

More recently, it seems that the two international frameworks are converging. In April 2016, the drug problems issue featured prominently on the agenda of the United Nations General Assembly. In an outcome document, heads of state made a commitment to align drug policies more closely with human rights.[17] Two years later, the UN reaffirmed this approach in a series of principles.[18]

The framework of the European Union closely aligns with the Single Convention (1961) and the Illicit Traffic Convention (1988). The European Union itself is a party to the latter convention, insofar as it pertains to matters within the Union's competence.

At the European Union level, public health is a significant theme, although drugs legislation is actually scarce. The *Treaty on the Functioning of the European Union* (TFEU) stipulates that a high level of human health shall be ensured in the implementation of all Union policies and actions. However, primary responsibility for protecting public health lies with the Member States (Article 168). Therefore, the European Union legislation complements Member State legislation, also in efforts to reduce drugs-related health damage (Article 168).

In addition, Article 83(1) provides the European Parliament and the European Council with the power to establish minimum rules by directive concerning

14 Henk Garretsen et al., *Drugs in lijsten* (2011), 20–21

15 UN Development Programme, *International Guidelines on Human Rights and Drug Policy* (2019).

16 For example, refer to the statement by the UN High Commissioner for Human Rights: Michelle Bachelet, 'Aligning Drug Policies with Human Rights' (2022).

17 United Nations, *Outcome Document of the 2016 United Nations General Assembly Special Session on the World Drug Problem* (2016).

18 United Nations, *United Nations system common position supporting the implementation of the international drug control policy through effective inter-agency collaboration* (2018).

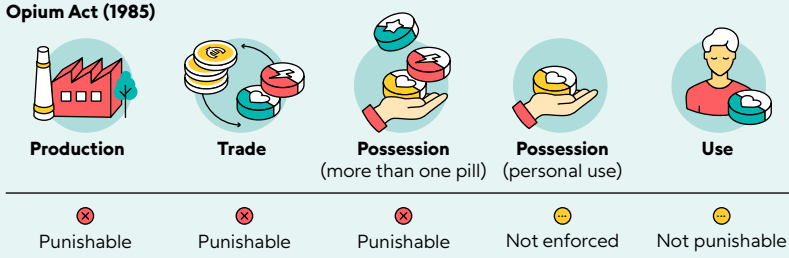
the definition of criminal offences and sanctions in connection with forms of serious crime with a cross-border dimension, including illicit drug trafficking. Under the *Treaty of Lisbon*, based on Article 83(1) TFEU, only one such directive related to drugs has been adopted, aimed at amending the definition of drugs in a Framework Decision on illicit drug trafficking.[19]

The EU's control mechanism is aligned with the UN drug treaties mentioned above.[20] This is because the EMCDDA assesses the potential risks associated with the trade in and use of new substances and reports on those risks accordingly. Based on these assessments, the Council of the European Union decides by majority whether a substance should or should not be placed under control.[21] EU Member States are required to implement those decisions in accordance with their national legislation.[22] Unlike the UN and the domestic level, the EU does not schedule drugs on a set of lists.[23]

The Opium Act

/// As regards drug use, Dutch drug policy focuses on protecting (public) health rather than on curbing the use or possession of drugs.

Figure 23
The purpose of the Opium Act is to protect public health and public order



The original purpose of the Opium Act was to protect public health. According to the Explanatory Memorandum, the Opium Act has been aimed at both public health and public order since its amendment in 1976.[24] The measures in the Opium Act are designed to prevent harm to the health of users and to society. To achieve this, the Act includes provisions on preventing the production, trade and use of substances covered by it as prohibited.

19 Council of the European Union, *Framework Decision 2004/757/JHA of the Council* (2004).
20 The Council of the European Union adopted Joint Action 97/396/JHA on 16 June 1997, on the basis of Article K.3 of the Treaty on European Union, concerning the information exchange, risk assessment and the control of new synthetic drugs (OJEU L 167, 25 June 1997), as amended by Decision 2005/387/JHA of 10 May 2005 of the Council of the European Union (OJEU L 127, 20 May 2005). Refer to Henk Garretsen et al., *Drugs in lijsten* (2011), 21.
21 Henk Garretsen et al., *Drugs in lijsten* (2011), 21.
22 Henk Garretsen et al., *Drugs in lijsten* (2011), 21.
23 Henk Garretsen et al., *Drugs in lijsten* (2011), 21.
24 House of Representatives, *Parliamentary Papers II* 13407.3 (1974-1975).

The international conventions influence how substances are classified under domestic law. For example, Section 3a of the current Opium Act specifies that changes to the schedules to the Single Convention or the Convention on Psychotropic Substances also require corresponding changes to the schedules to the Opium Act. The same applies to decisions made by the Council of the European Union.[25] Additionally, the Minister of Health, Welfare and Sport has the authority to classify substances under the Opium Act at their discretion, even if these substances are not yet included in the convention system. Pursuant to Section 3a(2), this applies to substances included in Schedules I or II 'if it is shown that these substances affect human consciousness and can cause harm to health and society when used by humans'.[26]

In all cases, this process is carried out through an Order in Council (AMvB), unless a substance needs to be prohibited 'with immediate effect'. In such cases, the substance can be designated by ministerial decree. However, simultaneously, a draft Order in Council with the same content must be submitted to the Council of Ministers.[27]

In 1988, when MDMA was prohibited, the Netherlands had not yet joined the Convention on Psychotropic Substances, but it was to do so later that year. Prior to joining the convention, there were indications that local gangs were interested in producing MDMA, necessitating swift action by the Minister. MDMA was included in the Opium Act 'with immediate effect' by ministerial decree on 22 November 1988.[28] An Order in Council followed on 6 September 1989.

Two schedules

MDMA is included in Schedule I to the Opium Act. The distinction between Schedule I and Schedule II was motivated by a legislative amendment in 1976. Cannabis and hemp were included in Schedule II for so-called soft drugs, which are less risky than hard drugs. Schedule I contains hard drugs, such as heroin and cocaine, which are 'more harmful to health than soft drugs'.[29] The 1976 government used this dual-schedule system in an attempt to separate the drugs markets. A person who wanted to buy cannabis could do so through special outlets ('coffeeshops') where only that particular product was sold. As a result, cannabis users were spared the necessity of turning to street dealers who offered far more dangerous and addictive drugs alongside cannabis, such as heroin.

The dual-schedule system also allowed for the differentiation of penalties. The rationale behind this was to mitigate stigma against users. By applying different penalties to Schedule II, possession of small quantities was categorised as an offence rather than a crime, as in the case of Schedule I substances.
The two UN drug treaties, whose signatories include the Netherlands, each feature four schedules with distinct classifications. In 2011, the Dutch government sought

25 Henk Garretsen et al., *Drugs in lijsten* (2011), 25.

26 Opium Act, Section 3a(2) (2024).

27 Henk Garretsen et al., *Drugs in lijsten* (2011), 25.

28 'Designation order on substances to be covered by the Opium Act with immediate effect', *Government Gazette* (1988).

29 Ministry of Justice and Security et al., 'Wat maakt verschil tussen harddrugs en softdrugs', *Rijksoverheid.nl* (undated).

advice from the Garretsen Committee on this matter, which concluded that there was no conflict at that time between international conventions and national legislation.[30] This means that the way in which the Netherlands classifies and regulates drugs, while potentially differing from practices in some other countries, remains consistent with its international obligations.

Tolerance policy

MDMA is included in Schedule I to the Opium Act, which means that the mere possession of the substance is considered a crime. However, in practice, a distinction is made between possession for personal use and possession for trade (known as intent to deal). According to the 2015 *Designation order concerning the Opium Act*, which governs the investigation and prosecution of offences under the Opium Act, the primary focus in cases involving small quantities for personal use should be on providing assistance to the user. Specifically, this concerns quantities no larger than one ecstasy tablet. If the police find such a small quantity with a user, it is confiscated, but the person is not detained and no criminal record is issued. If multiple tablets are found, this will in principle qualify as intent to deal, and prosecution may follow.[31]

The Public Prosecution Service's *Guideline for prosecution under the Opium Act* from 2019 adopts the same principle as the *Designation order concerning the Opium Act*, namely that possessing a small amount for personal use (i.e. one tablet) results only in the confiscation ('withdrawal from circulation') of that tablet without further consequences. For larger quantities, penalties escalate quickly, and although quantities slightly larger than those required for personal use do not automatically result in an intent to deal, they will always be subject to punishment. Based on the facts and circumstances of the case, it may be evident that a slightly larger quantity is still intended for personal use only, without indicating an intent to deal. The *Guideline* uses tables to outline penalties. Possession of tablets for personal use, for instance, results in a fine of €375 for possession of two tablets, while a community service order of 80 hours is issued in the case of intent to deal. In cases of repeated offences, the punishment for possession of two tablets for personal use can rise to one month of unconditional imprisonment, and intent to deal to ten weeks of unconditional imprisonment.[32]

In conclusion, this means that possession of a small amount of drugs for personal use, up to one tablet, is tolerated in the Netherlands. This is a crucial aspect of Dutch drug policy and will be further explained later in this chapter.

Dutch drug policy over the years

Until the 1960s, **cannabis** posed no significant problem to Dutch society. However, as the use of cannabis rapidly increased and the police continued to arrest users, the judicial system faced the threat of congestion in 1970, at the Holland Pop Festival in Kralingen, police officers were instructed for the first time *not* to enforce the law. This eventually led to a legislative amendment

30 Henk Garretsen et al., *Drugs in lijsten* (2011), 16.

31 *Designation order concerning the Opium Act* (2015).

32 Board of Procurators General, *Guideline for prosecution under the Opium Act: Hard-Drug Offences* (2019).

in 1976, introducing a distinction between hard drugs on the one hand and soft drugs, such as cannabis, on the other. The sale of cannabis in coffeeshops (where no other drugs could be sold) also prevented users from coming into contact with street dealers offering heroin.

Heroin emerged in the early 1970s and was to cause severe trouble in Dutch inner cities for two decades. The need to obtain heroin often led to (property) crime and public order problems that undermined the livability of entire neighbourhoods. Initially, users were compelled to undergo detoxification, but soon after reintegration into society, many reverted to their old, destructive patterns. This made the authorities decide to adopt a harm reduction strategy: until a person voluntarily chose to quit, the harm to both the individual and the community had to be minimised as much as possible. Successful measures such as needle exchange programmes, free dental care, methadone treatment and, later, the provision of heroin helped to control the harm to users and society: at the peak of the crisis in the 1980s, there were around 30,000 users; today there are 14,000 at most.[33] Addiction care services monitor some 6,700 users of heroin or other narcotic substances.[34] Today, users cause little or no nuisance.

The emergence of **MDMA** on the recreational market in the 1980s triggered a new development. As demand for ecstasy increased, so did the numbers of poor-quality tablets on the market. After a series of incidents in 1994, a testing service was introduced where users could have their tablets analysed. If a dangerous tablet was identified (for example, due to its composition or high concentration), a targeted information campaign (red alert) was launched to warn users. Today, there are 32 testing sites spread across the Netherlands. Red alerts are still issued today, albeit sporadically.

Advice

A substance that is included in schedules to the international conventions is automatically covered by the Opium Act in the Netherlands, even if it is not used in the country. This is based on international risk assessments by the UN or the EMCDDA.

It can also happen that a substance appears specifically in the Netherlands (such as 4-FA), or that an existing substance suddenly finds a new use (such as nitrous oxide). In such cases, the Minister of Health, Welfare, and Sport can seek advice from the Coordination Point Assessment and Monitoring new drugs (CAM). Since 1999, the CAM's Risk Assessment Committee has issued risk assessments of new drugs. Those assessments are based on four criteria:

1. The health risks for individual users
2. The risks to public health
3. The risks to public order
4. The risk of involvement of (organised) crime [35]

33 Guus Cruts et al., *Aantal en kenmerken van problematische opiatengebruikers in Nederland* (2013).

34 LADIS, *Tussenrapportage Kerncijfers verslavingszorg 2016-2021* (2023).

35 Peter Keizers et al., *Basisnotitie Coördinatiepunt Assessment en Monitoring nieuwe drugs* (2018).

After weighing these risks, the CAM can propose a range of measures to the Minister, including inclusion of the substance in the schedules to the Opium Act. This is an advisory opinion, not a mandatory measure. For example, in 2013, the Minister decided to make the mildly stimulating substance khat subject to the Opium Act against the advice of the CAM.[36]

Many substances, including MDMA, were made subject to the Opium Act before the establishment of the CAM. In 2021, the House of Representatives passed a motion urging the government to investigate whether the inclusion of various relevant substances in the schedules to the Opium Act was justified in the light of objective scientific research.[37]

Reassessment of MDMA

In response to this motion, the CAM created a working group to perform a quick scan (overall assessment) into he risks of cannabis, cocaine, GHB, LSD, oxycodone, 3-MMC and MDMA. In this process, available information about these substances and the expertise of the working group members were used. The CAM concluded that it was appropriate for MDMA to be brought within the scope of the Opium Act. Furthermore, the working group stated:

'For MDMA, it could be considered to carry out a more detailed analysis of the substance-specific data of MDMA as part of a comprehensive risk assessment. We need to improve our understanding of how the risks of MDMA use compare to those of other drugs.[38]

The State Commission is of the opinion that further research by the CAM into the inclusion of MDMA in one of the two schedules to the Opium Act is desirable, also considering the societal debate on this issue (also refer to Chapter 5). According to the State Commission, this advisory process can add substantial value to the political and societal debate if the CAM is transparent in its risk assessment report about how its advice came about and how the arguments were weighed.

Public health

/// The criminalisation of drug use and users is at the expense of public health. The stigmatisation arising from prosecuting users or making them responsible generates feelings of shame among users and a tendency to avoid seeking help in the event of incidents or problems.

In the Netherlands, the use of drugs is considered in the first instance to pose a threat to individual users and to public health. Criminal prosecution should be considered a last resort.[39] In practice, this means that the Ministry of Health, Welfare and Sport coordinates its policies with those of the Ministry of Justice

36 House of Representatives, 'Verslag schriftelijk overleg inzake het Ontwerpbesluit houdende wijziging van lijst II, behorende bij de Opiumwet', *session year 2011-2012* (2012).

37 House of Representatives, 'Motie van het lid Van Nispen over onderzoek naar de wetenschappelijke rechtvaardiging van de huidige omgang met typen drugs', *session year 2020-2021* (2021).

38 M.W. van Laar et al., 'Totaalrapportage Motie van Nispen' (1 May 2024).

39 Margriet van Laar et al., *Evaluatie van het Nederlandse drugsbeleid* (2009), 383.

and Security and the Ministry of Foreign Affairs. By the same token, the Ministry of Health, Welfare and Sport also has final responsibility for the Opium Act, which covers all prohibited substances – including MDMA.

The production, trade and possession of hard drugs are prohibited in the Netherlands, as in any other country. However, one aspect in which the Dutch approach differs from that in many other countries is its emphasis on public health and, consequently, on the position of the user in policy. In the Netherlands, using drugs is not punishable, as the Opium Act does not prohibit their use. The aim of this policy is to remove the stigma.

Stigma is a strong social disapproval of personal characteristics or beliefs that deviate from social norms. It can lead to exclusion and discrimination. When someone who uses drugs encounters an incident or problem, it is crucial that they receive help as quickly as possible. Stigma can hinder this, as those who fear being handed over to the police may delay seeking help, leading to a further deterioration of their health. Openness creates possibilities for rapid action.[40,41]

All the same, one key principle of the Dutch approach is that drug use is *not* part of a normal and healthy lifestyle. The current drug prevention policy focuses on preventing use – and if drugs are nevertheless used, the policy aims to minimise the social, societal and health problems arising from this use as much as possible.[42]

1995 Policy Document on Drugs

/// Since 1995, no explicit government vision for drug policy has been published in the Netherlands. It is not clear to what extent that old vision still applies and what the integrated vision and interdepartmental objectives are that existing drug policy is being tested against.

The last time a Dutch government incorporated drug policy in an integrated vision was in a Policy Document drawn up by the first Labour/Liberal government. According to that Policy Document from 1995, the central task of Dutch drug policy was 'mitigating the adverse effects of drug use on public health and managing the use of high-risk drugs as a health and social issue'.

The term 'social issue' in this context did not primarily refer to (organised) drugs-related crime. In the 1990s, drugs-related nuisance in particular was a major concern, causing degradation of public spaces, public insecurity and the presence of problematic users in the streets. Thanks to effective policies focused on care and targeted enforcement, this is now a thing of the past. International scepticism towards this policy has since transformed into international recognition and sometimes even admiration and interested study.[43] As described in more detail below, this policy primarily focused on harm reduction, placing the needs of users

40 Lisa Maher et al., 'Collateral damage and the criminalisation of drug use', *The Lancet HIV* (2017).

41 David Dixon et al., 'Anh Hai: Policing, Culture and Social Exclusion in a Street Heroin Market', *Policing and Society* (2010).

42 State Secretary for Health, Welfare and Sport, 'Voortgang aanpak drugspreventie' (2023).

43 John-Peter Kools et al., 'Hedendaagse drugssistuatie vraagt om hedendaags beleid', *trimbos.nl* (2024).

centre stage. Incidentally, the policy did also feature repression targeting users, for example by relocating addicted homeless individuals from a shopping centre to a tunnel, but did not present this as part of the ultimate solution.[44]

When the 1995 Policy Document was drafted, the situation regarding MDMA was hardly comparable to the current situation. There was a lack of knowledge about the harmful effects of MDMA, and the market was flooded with toxic and dangerous tablets. Additionally, municipalities were each trying to cope, in their own specific ways, with a new nightlife culture that extended beyond clubs and discos, particularly manifesting at parties and raves, illegal or otherwise.

The most recent evaluation, in 2009

The most recent evaluation of Dutch drug policy took place in 2009. That evaluation revealed a lack of clear criteria to measure whether and, if so, how the policy had been successful. Several factors contribute to the complexity of the situation. The 1995 Policy Document on Drugs lacked a clear primary focus. Was it about risk management and control, about prevention of drug use, or both?

Judging by the first criterion (risk management), the government was 'reasonably' successful in achieving its objective. Regarding the second criterion (prevention of drug use), according to the policy document, the policy had been 'less successful'. The researchers wondered whether this was problematic, considering that drug use is a transient phenomenon for the individuals concerned, peaking between ages 20 and 30 and declining sharply thereafter. However, this age group is particularly vulnerable because the brain is still developing at this age.

Regarding drugs in general, the researchers noted that Dutch policy had not been able to prevent an increase in drug use from the late 1980s to the mid-1990s, including among young people. Nevertheless, drug use in the Netherlands was lower than in some other countries, with the exception of ecstasy. In terms of individual risks, the researchers noted that the policy had been partly successful. Regarding party drugs, while it was true that there had been acute health incidents, 'but as far as known, those incidents rarely lead to serious complications'.

The evaluation further raised the question of the extent to which policy had influenced drug use and indeed whether it could be influenced at all. The evaluation indicated that prevention activities 'at most have modest effects on drug use itself'. Additionally, the evaluation suggested that while supply-side interventions did impact drug prices and purity, 'drug use shows no significant changes'. This concerned the short-term effects; any long-term effects were not yet known at the time.[45]

44 Jasper Bongers, 'Menselijkheid in Hoog Catharijne', in *Cohesie en polarisatie in de stad* (The Hague 2022), 31–32.

45 Margriet van Laar et al., *Evaluatie van het Nederlandse drugsbeleid* (2009).

Clearly, the findings of the 1995 Policy Document on Drugs are still having an effect today. The Ministry of Health, Welfare and Sport uses a 'staircase' model to shape Dutch drug policy, as described in an appendix to a Letter to Parliament from 2015 and from discussions with Ministry officials, and that model still places a strong emphasis on prevention of use. The 'staircase' features the following steps:

1. Prevention of use;
2. If drugs are used nevertheless, prevention of health damage (acute incidents, addiction etc);
3. Deployment of an early detection policy and brief interventions to prevent users from becoming addicted;
4. Effective treatment of people whose drug use and addiction has got them into trouble;
5. Reducing damage to health (harm reduction).[46]

The Ministry of Health, Welfare and Sport itself explained its approach as follows: 'Prevention is better than treatment, treatment is better than harm reduction and harm reduction is better than doing nothing.'[47] In the case of MDMA, steps 1, 2 and 5 are particularly relevant. In the remainder of this section, the focus will therefore be on these elements. Steps 3 and 4 mainly concern addiction (substance use disorder), which occurs only sporadically in the case of MDMA (and when it does occur, it often involves combinations with other substances).

Prevention policy

Step 1: Prevention of use

Prevention is fundamental to the drug policy of the Ministry of Health, Welfare and Sport. To prevent health damage from drug use, the Ministry employs evidence-based prevention policies aimed at preventing use, problematic use, dependence, and social and health problems resulting from use. Additionally, another component of prevention policy is support for reducing and quitting drug use.

Effective preventive interventions require a well-founded selection of target groups and determinants of use to focus on. This knowledge stems from national and local level monitoring and from scientific insights into risk and protective factors. In the Netherlands, information on types of drugs, user groups, patterns of use, contexts of use and behavioural determinants that lead to use or reduction/cessation is monitored at the national level by the Trimbos Institute. The National Drugs Monitor (NDM) gathers data from the Lifestyle Monitor, the Comprehensive Nightlife Survey and the Monitor of Mental Health and Substance Abuse among Students in Higher Education, among other sources. Knowledge derived from national monitoring programmes, in turn, provides the basis for deploying or developing preventive interventions targeted at specific groups.

/// **To be able to carry out targeted and effective preventive activities, information about the target group, use context and behavioural determinants is essential. In the current situation, this information is gathered at the national level using various monitoring programmes and summarised in the National Drugs Monitor.**

46 Ministry of Health, Welfare and Sport, 'Uitgangspunten huidig drugsbeleid' (2015).

47 Ministry of Health, Welfare and Sport, 'Uitgangspunten huidig drugsbeleid' (2015).

Four levels of prevention

This part of the report includes various references to preventive techniques. These techniques can be deployed as universal, selective, or indicated measures. It is important to keep these different categories in mind while reading this report:

1. Universal prevention targets the general population without taking specific risk factors into account.
2. Selective prevention is intended for groups known to be at increased risk of problematic drug use, such as young people in certain neighbourhoods or schools.
3. Indicated prevention targets individuals at increased risk of developing problematic drug use, for example due to specific circumstances during upbringing, mental health issues or trauma, or previous experience with drug use.[48]

Finally, we should consider the term 'harm reduction'. Harm reduction aims to minimise the social and health problems that may result from substance use, without directly discouraging substance use itself. There is a distinction between 'traditional' harm reduction and harm reduction aimed at recreational users.

Traditional harm reduction interventions include providing foil, smoking pipes, clean injection needles or methadone distribution, which help reduce the additional harm from drug use, such as infectious diseases. They are used in the case of serious use patterns, often involving opiates and/or cocaine. These interventions contribute to longer life expectancy among users and reduce societal disruption. Moreover, the costs of interventions of this type are low.[49]

Harm reduction for recreational users of ecstasy mainly involves drug testing services and providing free water and chill-out spaces during festivals to reduce the risks associated with the use of this drug.

Drug prevention is implemented in various settings, each characterised by specific target groups. The most important of these settings are: 1) family/home situations; 2) schools; 3) work environments; 4) community settings; 5) the physical environment; 6) social and other media. Local and regional parties, such as prevention departments of addiction care centres and municipal health services, have an important role in this context. Drug prevention is most effective when implemented from within multiple settings aimed at specific target groups as part of an integrated strategy.

Below, the State Commission provides insights into drug prevention within several settings. This overview is not exhaustive, but outlines key approaches to drug prevention.

48 VZinfo.nl, 'Wat is preventie?' (undated).

49 Marcel Dijkgraaf et al., 'Cost utility analysis of co-prescribed heroin compared with methadone maintenance treatment in heroin addicts in two randomised trials', *BMJ* (2005).

Figure 24
An integrated prevention approach is the most effective

Prevention through users' parents
One effective strategy to delay the initial use of MDMA among young people involves engaging their (social) environment, such as the school environment or parents. Instead of directly targeting young people themselves, efforts focus on educating parents about the risks associated with MDMA use, and on recognising signs of use and fostering dialogue. The goal of this type of prevention is to encourage parents and caregivers to discuss substance use with their children, with a view to delaying or preventing actual use, for example of MDMA.

These interventions are delivered through parent information sessions (such as those taking place in schools), websites and social media channels for parents, podcasts and training sessions offered by prevention departments of regional addiction care centres.

Prevention through education
One important advantage of school-based prevention is its ability to reach many children simultaneously. Effective school-based interventions consist of multiple components, including educational programmes for students, parent evenings, expertise sessions for teachers and clear school policies regarding risky behaviour and healthy behaviour. Additionally, school-based interventions can positively influence the physical environment and the atmosphere at schools, with potentially beneficial impacts on behaviour and use reduction.

Many schools have successfully implemented universal prevention strategies focusing on protective factors and risk factors that influence the likelihood of drug use (and other risky behaviours). It is known, for instance, that issues with emotional regulation and perception, lack of health education and limited after-school activities increase the likelihood of problematic drug use. This is why many schools opt for universal prevention efforts focused on developing social-emotional skills. This approach helps reduce the likelihood of engaging in risky behaviours such as drug use. In the Netherlands, *Helder op School* (Clear-minded at school) is one of the most widely used school-based intervention programmes to prevent the use of tobacco, alcohol and drugs. The Guidelines on addiction prevention in education specify existing preventive interventions per age group and school type, as well as those that should preferably be avoided.

Prevention in centres for residential and juvenile justice care

Another key target group for prevention programmes are young people in centres for residential and juvenile care. We know that young people in residential youth care (homes or institutions) are more likely to be confronted with risk factors that increase the chance of drug use. A study into substance use among vulnerable youth also shows that they have more frequent experiences with MDMA compared to their peers.[50] Prevention in this setting often concerns policy development and support for professionals in identifying and managing drug use among young people in care settings.

Prevention through campaigns

Nationwide prevention campaigns have a broad reach and are used to set standards or support policy measures. Such campaigns are particularly effective when the message is relevant to the majority of recipients. Examples include the BOB and NIX18 campaigns, both of which are aimed to set a social standard and support a zero-tolerance alcohol policy for drivers and minors. These campaigns also target the social environment of their ultimate target audience. The themes of alcohol use in traffic and by minors are suitable for nationwide attention because nearly 80 per cent of the adult Dutch population consumed alcohol in the past year.[51]

As regards ecstasy, however, more than 90 per cent of the adult population has never come into contact with this substance and is not interested in it either. This means that a universal campaign aimed at reducing MDMA use will primarily reach people who have no experience with or interest in using MDMA. Scientific insights into behavioural change suggest that such a campaign is unlikely to lead to reduced MDMA use.[52] However, a targeted campaign with a clear course of action focusing on specific groups, such as parents of young people who go out or visit festivals and the like, may be effective.

A nationwide campaign aimed at preventing drug use can actually have harmful effects, for example in the form of stigmatisation, reduced access to care and polarisation and could potentially even provoke a sense of insecurity.[53] In this context, the State Commission is concerned by the fact that the House of Representatives approved a motion on 13 February 2024 to roll out a nationwide campaign 'confronting drug users with the consequences of drug use for society'.

/// Policies that are not based on scientific evidence may be counterproductive and increase the risk of harm to health and society. In addition, such policies can undermine the authority of the government.

50 Marjan Möhle et al., *Preventie en gebruik van alcohol, tabak, cannabis en andere middelen in de residentiële jeugdzorg* (2021).

51 National Drugs Monitor, '11.2 Gebruik: volwassenen', *Nationale Drug Monitor* (2024)

52 Martha de Jonge et al., 'Drugsvoorlichting in de klas: een slecht idee', *Tijdschrift Verslaving & Herstel* (2023).

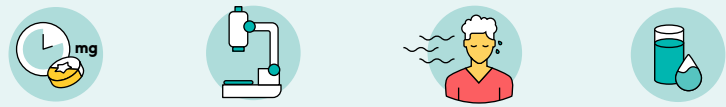
53 Edwin Kruisbergen et al., 'Voorkomen is beter dan genezen..., toch? Over goed bedoelde maar potentieel schadelijke vormen van preventie van ondermijning', *Tijdschrift voor Veiligheid* (2023).

Step 2: If drugs are used nevertheless, prevent health damage (acute incidents, addiction etc)

/// Use figures in the Netherlands are high. Even so, Dutch prevention policies also achieve successes: the use per person and the amount of ecstasy used per session are relatively low, as is the number of ecstasy-related deaths reported thus far (compared with the figures for the United Kingdom or Germany, for example).

One important component of drug prevention policy is the provision of information on the risks associated with the use of drugs. Prevention departments of regional addiction care centres and the Trimbos Institute have an official government-related role to provide users of MDMA and the people in their social environment with information about the risks. This type of prevention targets MDMA users and people who are seriously considering to start using MDMA again. Examples of information that can help to reduce the harmful effects of MDMA include tips about dosage and the importance of cooling off and drinking water.[54,55]

Figure 25
Examples of harm reduction information on ecstasy use



This information will prevent part of the potential health incidents related to MDMA use. This type of prevention is selective, as it specifically targets people who use drugs or intend to do so. The aim is to provide these people with all the information they need to make an informed decision about whether or not to use MDMA and to prevent health incidents related to drug use. Although a relatively large number of Dutch people use ecstasy, Dutch users seem to use it in a less risky manner compared to, for example, users in the United Kingdom and Germany.[56,57] This may be due to the Dutch prevention policy.

One frequent misconception is that providing information about the risks of drugs will also reduce their use. This is not the case. International scientific literature shows that providing information about drugs and their risks to young people

54 Drugs en Uitgaan, 'Beperk de risico's van XTC', *drugsenuitgaan.nl* (undated).

55 Unity, 'MDMA/XTC', *unity.nl* (undated).

56 Ruben van Beek et al., 'Polydrug Use Typologies of Regular Ecstasy Users Visiting Electronic Dance Music Events: A Latent Class Analysis', *European Addiction Research* (2023).

57 Tessa-Virginia Hannemann et al., 'Consumption Patterns of Nightlife Attendees in Munich', *Substance Use & Misuse* (2017).

who have no experience with drugs and are not interested in them either, does not lead to reduced drug use. On the contrary, such interventions can actually kindle their interest and increase the chance of first-time drug use.[58,59]

D.A.R.E. – Setting the wrong example

A programme called D.A.R.E., which stands for Drug Abuse Resistance Education, was launched in the United States in 1983. The core idea was that police officers gave lessons in primary and secondary schools about the risks of drugs (including alcohol) and gang criminality The programme consisted of 17 sessions during which children also received merchandise, such as T-shirts and other clothing with the D.A.R.E. logo. The aim was to make schoolchildren more resilient to peer pressure to use drugs or join a youth gang. By the mid-1990s, the programme had been rolled out in about three-quarters of all American schools.

The programme was not without controversy. Officers brought along sports cars that had been confiscated from dealers to show that a career in crime did not pay off. However, by doing so they actually promoted the glamorous side of being a dealer. Additionally, the lessons were targeted at a population of children who mostly knew nothing about drugs but were now made aware of their existence. This led to increased interest and, in some cases, to drug use.[60] Given the high costs of the programme (estimated at 750 million dollars), the U.S. Government Accountability Office (GAO) decided to conduct a large-scale evaluation in 2003, examining the effects five and ten years after the last intervention. The evaluation revealed that children at schools where D.A.R.E. programme was taught were not significantly less likely to use illegal drugs than the control group. Any positive behavioural changes that the programme did achieve had disappeared after a year.[61] Other studies confirmed that the programme was ineffective.[62, 63]

More and more parties from the safety chain are being engaged to contribute to drug education as part of drug prevention programmes. Examples include community police officers teaching school children, or projects set up by the Regional Information and Expertise Centres (RIECs). Crime prevention and drug education are often addressed within a single project or meeting.

58 Martha de Jonge et al., 'Drugsvoorlichting in de klas: een slecht idee', *Tijdschrift Verslaving & Herstel* (2023).

59 UN Office on Drugs and Crime, *International Standards on Drug Use Prevention* (2019).

60 Dennis Rosenbaum et al., *Assessing the Effects of School-Based Drug Education: A Six-Year Multi-Level Analysis of Project D.A.R.E.* (1998).

61 Marjorie Kanof, 'Youth Illicit Drug Use Prevention: DARE Long-Term Evaluations and Federal Efforts to Identify Effective Programs' (2003).

62 Susan Ennett et al., 'Long-term evaluation of drug abuse resistance education', *Addictive Behaviors* (1994).

63 Richard Clayton et al., 'The Effectiveness of Drug Abuse Resistance Education (Project DARE): 5-Year Follow-Up Results', *Preventive Medicine* (1996).

/// Drugs information services remain necessary, but should target specific groups and focus on specific risks and the associated preventative measures. General public campaigns are not advisable, because they can have both a normalising and a stigmatising effect.

Addiction prevention

There is a range of services that precede 'addiction care' and that are relatively unknown among drug users. Prevention departments of regional addiction care centres offer accessible services for people who are concerned about their substance use or have questions about it. These departments offer advisory consultations and online self-tests, which help individuals gain better insight into their use and how to reduce it. The Trimbos Institute also offers the Drugs Information Line, with the same goal: to provide information and advice. If necessary, they will refer callers to more specialised care or an addiction clinic.

Does prevention actually work?

Any attempt to answer this question will encounter a significant problem: we only know what has happened, not what has been prevented. The data from the Trimbos Institute show the prevalence of use and the number of incidents, but there is no control group of persons who experienced a different policy to compare the data with. For example, we do not know who refused an ecstasy tablet, whether this meant that an incident had been prevented and whether this was thanks to prevention efforts.

The most recent evaluation of Dutch drug policy, held in 2009, raised the question of the extent to which policy had influenced drug use and indeed whether it could be influenced at all. The evaluation indicated that while prevention activities do help to control the risks, they 'at most have modest effects on drug use itself'.[64] Since 2009, drug prevention policy in the Netherlands has been professionalised, with a focus on implementing evidence-based interventions whenever possible. However, it remains difficult to assess the overall effectiveness of the policy. It makes more sense to investigate the effects of a specific intervention or measure on a specific behaviour within a specific target group. Additionally, most funding for prevention appears to go towards developing new interventions, with little to no funding allocated for implementation or effectiveness studies of existing policy measures or effective interventions.

/// It is possible to study the effects of drug prevention policies, provided a number of conditions are met. For example, it is important to define specific targets and target groups for prevention policy, and to ensure that sufficient funds are available for implementation and effect studies.

64 Margriet van Laar et al., *Evaluatie van het Nederlandse drugsbeleid* (2009), 386.

Step 5: Harm reduction

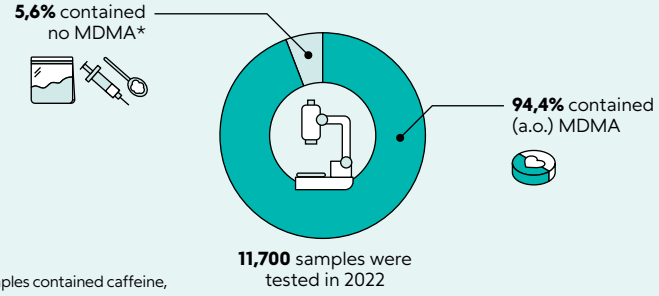
Harm reduction aims to minimise the social and health problems that may result from substance use, without directly discouraging substance use itself. The main focus is on minimising harm when a person decides to use drugs regardless. MDMA users do not typically encounter traditional types of harm reduction, such as user rooms or syringe exchange systems. Other types of measures to reduce harmful effects are more relevant for this group. The main target group for these interventions is young adults aged 20 to 30 who go out frequently, as MDMA use is highest within this age group. The most visible interventions are those that focus on preventing health problems resulting from use.

Drugs Information and Monitoring System (DIMS)

One important instrument in this context is the Drugs Information and Monitoring System (DIMS). This is a nationwide network of testing sites that aims to gather knowledge of the illegal drugs market. In the Netherlands, there are 32 testing sites where people can have their ecstasy tablets (and other drugs) tested anonymously.

In 2022, these testing sites analysed almost 18,000 samples, 65 per cent of which had been sold as ecstasy. Of those tablets, 94.4 per cent were actually found to contain MDMA. The remaining 5.6 per cent of the tablets tested (also) contained other substances, such as amphetamine or caffeine. Some samples contained substances such as 2C-B, 4-MMC, 3-CMC or 4-CMC instead of MDMA.[65]

Figure 26
Knowledge of the illegal ecstasy market through the Drugs Information and Monitoring System (DIMS)



In addition to providing better insight into the illicit drugs market and contributing to user knowledge about the risks of drug use, the DIMS enables the rapid identification of particularly dangerous drugs. When such drugs are detected, this may trigger a red alert, followed by a campaign to warn users against the drug. For example, in 2015, a red alert was issued for a very strong tablet bearing the Amsterdam Dance Event logo, which contained 300 milligrams of MDMA. A year later, a red alert was issued for a tablet with the Superman logo containing a high

65 Nadia Hutten et al., *DIMS Jaarbericht 2022* (2023).

dose of PMMA. This is a substance that takes longer for users to feel its effects, creating a risk that they consume more of the drug as a result, which could lead to an overdose.

/// The DIMS network ensures that the ecstasy market in the Netherlands is monitored effectively. This makes it possible to issue targeted warnings against drugs that are proven to be particularly risky. It also provides a moment of contact with users to inform then about harm-reducing measures.

How does testing work?
When an ecstasy tablet is tested, a staff member scrapes a small amount from the tablet and then applies a drop of Marquis reagent. If the scraped material turns dark blue, this indicates the presence of MDMA. If it turns orange, it indicates the presence of speed; green indicates 2C-B and purple indicates heroin. During testing, there is a talk about the risks of use, and information is collected about the context of use, as well as the place and price of purchase. While a blue colour confirms the presence of MDMA in a tablet, it does not indicate the quantity. This is why the shape and size of the tablet, and the logo printed on it, are also checked. Using these characteristics, staff members consult the DIMS archive to determine if the tablet has been identified elsewhere and, if so, what its composition was. If the tablet proves to be unknown (because it is a new batch from a producer), the owner may offer it for further analysis. The details of the tablet are then stored in the DIMS archive. The person who submitted it can phone the lab for the test result on Thursday, i.e. before the weekend.

Harm reduction at festivals and events
An important component of harm reduction efforts is the involvement of organisations behind events and clubs. Most festivals pursue a zero-tolerance policy and have agreements with the authority granting their license (usually the municipality) that drug use will not be tolerated. The practical implementation of such policies varies from one festival or event to another. Examples of measures taken include the use of drop-boxes or drug lockers, pat-down searches, drug-sniffing dogs or age verification checks.[66]

A pragmatic approach means that, besides a zero-tolerance policy, priority is given to measures to reduce harm, since many festival-goers will take drugs anyway. Most municipalities, as the licensing authorities, also impose this as a requirement on the organisers. This means that event organisers are a crucial component in the effort to minimise harm from drug use. Several measures to reduce harm can be taken at the festival site. Examples include access to qualified first-aid staff, free drinking water and chill-out spaces.[67] These measures were already included in the 1995 guideline *Stadhuis en House*, which provided municipalities with guidelines on how to manage the house culture, which was relatively new at the time. Some festivals and recreational events also use Unity, an initiative involving experienced users from the target group providing information about drugs.

66 J. de Greeff et al., *Alcohol, drugs en tabak op evenementen: Leidraad voor gemeenten 3.0* (2019).
67 J. de Greeff et al., *Alcohol, drugs en tabak op evenementen: Leidraad voor gemeenten* (2019).

What makes these sessions particularly accessible is that the instructors and the audience are from the same target group. Several party and festival organisers promote harm reduction measures through the Celebrate Safe initiative, in cooperation with Unity.

The measures taken by event organisers in cooperation with first-aiders lead to a significant reduction in the burden on regular hospital care (also refer to Chapter 2; most intoxications are reported at events). A person experiencing mild or moderate intoxication can be assisted on site at the festival grounds and need not be transported by ambulance to a hospital. Based in part on the national Field Standard for Event Care (VNEZ), the GHOR (Regional Medical Assistance Organisation) advises municipalities on the capacity and quality of medical assistance required.[68]

Harm reduction in practice

For ecstasy, the harm reduction measures listed below are promoted in leaflets, online, by Unity and at testing sites to mitigate side effects and risks. All these tools are used to communicate the following message: *The use of MDMA comes with certain risks. Would you prefer to avoid taking any risk? Then don't take MDMA.*

- Have your ecstasy **tested** so that you know what you are taking.
- **Dose:** A recreational dose ranges from 1 to 1.5 mg of MDMA per kilogramme of body weight per evening/night, no more than once every two to three months.
- Make sure to **cool down and rest** by occasionally leaving the dance floor and chilling out in the designated area. This reduces the risk of hyperthermia (overheating).
- Don't combine your ecstasy with alcohol or other drugs.
- **Drink** water regularly but not excessively, even if you're feeling thirsty. One glass per hour is enough.
- Allow your body to **recover** by eating healthily and well, and getting plenty of rest.

Policy challenges: reducing demand, and harm reduction

Public health versus drugs-related crime

Dutch drug policy has been under a magnifying glass for several years. Due to the status of the Netherlands as a production and export hub for MDMA and amphetamines, as well as a transit country for cocaine from South America, the focus on the criminal aspects of drugs is increasing. It is not the policy itself that has changed, but the societal context in which that policy is implemented. Entities in the safety domain that focus on crime prevention are increasingly branching into drug prevention or education.

Despite the scientific consensus on the effectiveness (or lack thereof) of large-scale public campaigns, recent years have actually seen increasing calls for such campaigns. The key focus of those campaigns is not the prevention of potential health damage among users but rather the role of those users in perpetuating a

68 Marieke Cottaar et al., *Veldnorm Evenementenzorg* (2019).

criminal system that increasingly infiltrates legitimate sectors and circles. This trend began in 2018 when the then chief of police Erik Akerboom spoke of 'cocaine yogis' (translated in the press as 'yoga snorters'). He meant users who lead responsible and healthy lives during the week but indulge in MDMA (or cocaine) on weekends.[69] This sparked a debate on the primacy of prevention, prompting organisations and institutions seemingly unrelated to addiction care to launch campaigns aimed at curbing use through a moral appeal to users.

/// Due to the changing social context of drug policy, parties in the safety domain regularly launch drug prevention initiatives. Such initiatives do not always utilise the scientific insights and quality standards in drug prevention that are known among behavioural scientists and prevention professionals in the health domain.

In 2022, the police launched a game called xtcwatjijnietziet.nl. According to the press release, 'Users do not reflect on the damage caused by what they consider to be an "innocent" little tablet.' Through the game, the police aimed to encourage the target audience 'to discuss ecstasy with friends, parents and teachers'.[70] The campaign targeted children from grade 8 onwards, who were made aware of the violent world behind ecstasy through the characters Molly and Pipa. After attracting criticism from prevention experts concerning the non-targeted approach and far too young target group, the game was taken offline. The police explained this move by referring to 'new research insights'.[71] However, those insights had been known to addiction care centres, municipal health services and the Trimbos Institute for a long time.

In 2023, the municipality of Rotterdam, in cooperation with an advertising agency, launched a poster campaign in bus shelters with slogans such as 'There's blood on your tablet' and 'Your line, his execution'. One problem with campaigns like this is that they are not sufficiently targeted. Most users will not feel called on to respond to the campaign. Moreover, there is no clear course of action for people who do wish to respond.[72] Despite warnings from the addiction services sector, the municipality decided to go ahead with the campaign. It appeared that the very understandable desire to 'do something' about drugs-related crime had overruled the need for science-based policy.[73]

At the national level, the Rotterdam approach was widely applauded. During a debate on the new legislation regarding new psychoactive substances (NPS), the House of Representatives adopted a motion to launch a campaign at the national level based on the Rotterdam model. The Minister of Justice and Security had a hard time explaining why such campaigns are ineffective, and there was a great deal of misunderstanding among representatives about this.[74]
In all such situations, the State Commission advocates a scientific evaluation

69 Ton den Boon, 'yogasnuiver', *Lexiton Taalbank* (2018).
70 Police, 'Game om jeugd bewust te maken van XTC-wereld', *politie.nl* (2022).
71 Peter Huting, 'Games over drugs die kinderen uit criminaliteit moeten houden: nuttig of weggegooid geld?', *EenVandaag* (2023).
72 Kim Witte et al., 'A meta-analysis of fear appeals', *Health Education and Behavior* (2000).
73 Martha de Jonge et al., 'Drugsvoorlichting in de klas: een slecht idee', *Tijdschrift Verslaving & Herstel* (2023).
74 House of Representatives, *27th plenary session* (2023).

of new preventive initiatives and a careful consideration of costs, benefits and potential negative consequences. Such evaluations are preferably conducted by independent centres of expertise, such as the Trimbos Institute and the National Institute for Public Health and the Environment (RIVM).

Normalisation of drug use

Within the context of the moral appeal to users, there is a discussion surrounding the alleged normalisation of drug use. Various civil-society organisations have reported that drugs are considered a 'normal' phenomenon by some groups of young people. Especially in the media, there are frequent reports suggesting that drugs such as MDMA are simply 'part of the scene'.

In many of those reports it is unclear what is meant by normalisation. Sometimes the term is used to refer to drugs being used openly, for example in pubs or at house parties; in other cases, it refers to the openness with which people talk about (their own) drug use. Some authors imply that normalisation means 'increasing numbers' of young adults have experiences with drug use.

/// **The debates about the 'normalisation' of drug use create confusion about the actual prevalence of ecstasy use: in reality, only a fraction of the Dutch population use ecstasy. These discussions complicate the support for groups with significant high-risk use. Furthermore, the discourse on normalisation can encourage use by mistakenly giving the impression that drug use is already widely accepted.**

Scientifically, normalisation pertains to several different dimensions: the availability and accessibility of drugs, the prevalence of use (lifetime use and past-year use), social norms surrounding drug use and the societal acceptance of drug use. As explained in a recent blog of the Trimbos Institute, these dimensions of normalisation are not found in society at large.[75] Most people have never used ecstasy and have no idea where to obtain it. And most people will not consider it normal to find somebody in their neighbourhood using drugs.

Among young people, the use of ecstasy is higher, but in that group, too, social acceptance of ecstasy use is seen mainly among young people who use it themselves. Research data from the regional SKIP project on normalisation in East Brabant, for instance, show that people who do not use drugs themselves tend to have a negative stance towards substance use and do not consider it normal.[76] Similarly, data from The Comprehensive Nightlife Survey showed a direct relationship between having friends who accept ecstasy use and one's own experience with ecstasy. Since acceptance of ecstasy use seems to occur primarily within certain groups and contexts, it is a relative notion.

Paradoxically, the debate about 'normalisation' can actually result in increased drug use. If media reports suggest that drugs have already been normalised, the threshold for a non-user to start using will be lower. After all, the implication is that according to the societal norm surrounding drugs, drug use is 'normal'.[77] According to the State Commission, the term 'normalisation' is confusing, is

75 Desirée Spronk, 'Wees voorzichtig met zeggen dat drugsgebruik normaal is', *Trimbos.nl* (2023).

76 SKIP regional project, *Determinanten en normalisering van drugsgebruik* (undated).

77 Desirée Spronk, 'Wees voorzichtig met zeggen dat drugsgebruik normaal is', *Trimbos.nl* (2023).

often used erroneously and may actually result in an *increase* in the number of users.[78] The State Commission advises prevention staff and government bodies to use the term 'normalisation' and the associated explanatory models with care. 'Social acceptance' could be a useful alternative, as this term does not so much imply standardisation of drug use and allows for more nuance and context in the discussion about drugs and related policies.

Need for a national drug prevention strategy

/// There is a lack of a nationwide, scientifically substantiated vision for drug prevention. As a result, the range of interventions in the Netherlands consists of a mixture of effective, ineffective and even harmful interventions. Providers range from addiction care centres to commercial marketing agencies. The range of prevention tools available is fragmented and not always consistent.

Another issue brought to the attention of the State Commission by care providers is the varying quality of prevention services. At the European and international levels, efforts are underway to establish quality standards for drug prevention. These standards form the basis for a scientifically supported drug prevention policy. In the Netherlands, cooperative addiction care centres are addressing this through the basic addiction prevention package: a coherent set of – where possible – proven interventions. Efforts are also under way to implement these quality standards through the rollout of a national basic training programme in substance abuse prevention as a standard qualification for prevention workers. Schools and municipalities are supported in implementing effective prevention policies through resources such as a Model Plan for Local Drug Policy and Guidelines on addiction prevention in education.[79,80]

In response, Municipal Health Services and addiction care centres are increasingly opting for standardised approaches and scientifically validated interventions. However, the municipalities are responsible for implementation, through the Public Health Act. This is because substance use varies from one municipality to another. For example, GHB may be a concern in one place, while amphetamine (speed) may be the issue elsewhere. Consequently, municipalities are best placed to determine their needs in terms of drug prevention.

However, a problem arises in that existing knowledge about substance use and prevention does not always reach the local level. The choice, ultimately, is not always for scientifically validated interventions or comprehensive approaches, as other parties outside of the Municipal Health Services and addiction care are sometimes given a say in prevention policies. This can lead to a maze of providers and interventions with varying degrees of scientific basis or proven effectiveness. Nationally, there is a lack of frameworks, guidance or a vision for evidence-based and effective prevention.

78 Lisa Williams, 'Muddy waters?: Reassessing the dimensions of the normalisation thesis in twenty-first century Britain', *Drugs: Education, Prevention and Policy* (2016).

79 Anneke van Wamel et al., *Modelplan lokaal drugspreventiebeleid* (2023).

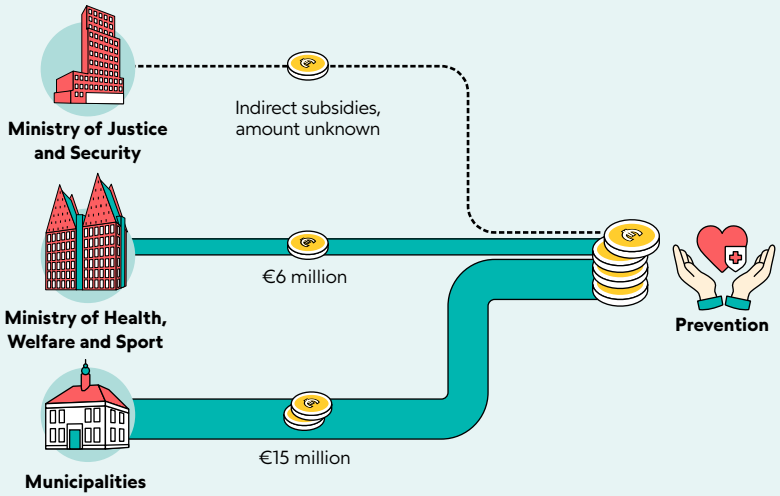
80 Simone Onrust et al., *Richtlijnen verslavingspreventie binnen het onderwijs* (2021).

/// It is uncertain whether municipalities have sufficient financial resources available for prevention. Effective prevention requires a long-term commitment and, hence, a structural investment.

Prevention funding

Another important aspect is prevention funding. Drug prevention often remains a low priority that tends to be handled on a project-by-project basis. Typically, the focus is on developing new interventions, with relatively few financial resources available for implementing measures and interventions or studying their effectiveness – despite the fact that prevention is a cost-effective measure. In 2022, for instance, the Ministry of Health, Welfare and Sport allocated €6.6 million to drug prevention measures out of a total budget of €35 billion.[81] The Ministry of Justice and Security also contributes financially to specific projects, such as the National Drugs Monitor.[82]

Figure 27
The financing of prevention is mostly a municipal matter



Since prevention falls under the Public Health Act and is managed by municipalities, they also allocate funds for prevention activities. These funds come from the Municipal Fund (*Gemeentefonds*), and the amount varies from one municipality to another, often influenced by local coalition priorities. The financial capacities of municipalities depend on their size; some larger municipalities can afford to allocate resources equivalent to one full-time position for substance abuse prevention, whereas smaller, less affluent municipalities may lack such capabilities. Many municipalities prefer to cooperate with addiction care centres, where much of the expertise in this area is concentrated. According to estimates from the Substance Use Expertise industry association (VKN), the 342 municipalities in

81 Minister of Finance, 'XVI Volksgezondheid, Welzijn en Sport' (2024).

82 State Secretary for Health, Welfare and Sport, 'Voortgang aanpak drugspreventie' (2023).

the Netherlands collectively spend €15 million on prevention activities, including alcohol abuse prevention efforts.[83]

So, while one municipality has the capacity to invest in a long-term strategy to fight substance use, others can do so only incidentally, at best. Prevention policies in particular require a long-term policy commitment.

In a context where demand for health care continues to grow while supply is diminishing, investing in the prevention of health damage is a cost-effective measure. The question remains whether the current financial resources are effectively utilised for prevention. That is why the State Commission welcomes the initiative of the National Rapporteur on Addictions (NRV) to develop guidelines for addiction prevention in the upcoming period[84], especially if this guideline can serve as a tool to strengthen public health and reduce the social and economic burdens of addiction.

/// Foreign visitors to events in the Netherlands form a target group of significant concern. They use MDMA in a more risky manner, probably because they have not been informed effectively at home. This leads to incidents that could have been prevented and places an additional burden on the Dutch health care system.

Parties in the field and the event sector share these concerns about tourists. Events in the Netherlands are highly international, featuring artists from abroad and attracting significant numbers of international visitors. A study conducted during the 2016 edition of the Amsterdam Dance Event revealed that 51 per cent of A&E admissions concerned foreign visitors.[85]

This group is not very well informed about the risks of MDMA and other substances, or about safe doses to minimise harm. Information from Dutch addiction care centres hardly reaches them. Additionally, foreign visitors often hesitate to visit first-aid services. Not everyone is familiar with Dutch drug policy, where drug use is not a criminal offence, unlike the more repressive policies in the countries where many of these people come from. Some people fear that when they seek help from first aid or security personnel, they will be handed over to the police. As a result, foreign visitors may delay seeking medical assistance, leading to increased health damage. A mild intoxication that could have been quickly resolved with on-site first-aid assistance might escalate into an ambulance trip to a hospital – or worse.

83 State Secretary for Health, Welfare and Sport, 'Voortgang aanpak drugspreventie' (2023).

84 National Rapporteur on Addictions, *Gokken met Gezondheid: Advies over online kansspelen* (2024).

85 Femke Gresnigt et al., 'Recreational Drug Use During the Amsterdam Dance Event', *Substance Use: Research and Treatment* (2022).

3b
Crime

Findings

The State Commission finds as follows:

/// **The Minister of Health, Welfare and Sport shares his responsibility for drug policy with the Minister of Justice and Security.** The focus of the judicial domain is on enforcing the Opium Act, which prohibits the possession and production of, and the trade in drugs. In practice, enforcement is restricted almost entirely to production, trade and possession of quantities indicating an intent to sell.

/// **The current enforcement strategy involves investigating and prosecuting production and trade, while tolerating possession in small quantities for personal use.** This strategy aligns with Dutch cultural norms and is reasonably effective. However, law enforcement authorities are increasingly engaged in fighting symptoms of drug production and trade, such as visible violence and dumping of drug waste. This reduces the capacity required to address the root causes of these issues, namely production itself.

/// **Drug production and trade are intertwined with criminal networks, whose development is linked to parallel socio-economic factors, such as living conditions in disadvantaged neighbourhoods.**

/// **Young people are particularly vulnerable to recruitment by criminal networks, often starting at a young age and influenced by socio-economic status, among other factors.** The judicial authorities primarily focus their attention on drug offences committed by these young people, rather than on the criminal exploitation[86] they may be victims of.

/// **Legalising or regulating MDMA appears unlikely to affect ecstasy production significantly.** Only domestic trade (estimated at 10 per cent, at most, of total production and trade in the Netherlands) might decrease, although even that is uncertain. Currently, illegal products are typically pure, reliable and inexpensive. Legal supply would need to compete effectively with these illegal products, which will persist as long as the Netherlands remains a production and export hub.

86 Criminal exploitation, classified as human trafficking, is criminalised under Section 273f of the Dutch Criminal Code.

Tackling the supply side

Since the most recent Policy Document on Drugs (1995), the supply side has seen many changes. Organised drugs-related crime has become a multibillion-dollar industry. Alongside this explosive growth, the financial interests of criminal organisations have also expanded. The lengths to which organised crime is willing to go to defend these interests have surpassed many people's expectations, although awareness has definitely increased following the murders of Derk Wiersum and Peter R. de Vries. A study by the Police Academy of the Netherlands in 2018 revealed that the turnover from ecstasy produced in the Netherlands was approximately €10.7 billion.[87] However, according to subsequent research by *Denkwerk* (2022), the turnover from ecstasy is 'only' €0.5–0.7 billion, while the Dutch turnover from cocaine, to take an example, is many times greater.[88]

In short, the actual value of the ecstasy industry in the Netherlands remains speculative. Due to its illegal nature, it is impossible to obtain a clear picture of the size of this industry and the turnover it generates. Whatever the case, the supply of ecstasy is abundant, as is evident from its street price. Typically, when supply decreases, prices rise; however, in the case of ecstasy, the price in the Netherlands has been stable at around €4 to €5 per tablet for years. This indicates that there have been no significant shifts in availability.

Dutch ecstasy production is sufficient to supply the entire domestic market. However, the primary focus of this industry is on the international market: an estimated 90 to 99 per cent of synthetic drugs produced in the Netherlands are exported.[89,90] This means that the issue of drugs-related crime cannot be resolved solely through regulation or legalisation of these drugs within the Netherlands, or by calling Dutch users to account over their drug consumption.

Hence, the Netherlands finds itself in a unique and challenging position: despite having a relatively large number of users, this country is only a very small market for local producers. At the same time, the Netherlands is the largest producer of ecstasy. According to the EMCDDA, the production of ecstasy in Europe is concentrated in the Netherlands and Belgium.[91]

This is why any strategy to tackle supply will present huge challenges for the government, the Public Prosecution Service, the police and, ultimately, the judicial authorities. Before discussing this issue in further detail, the State Commission will briefly touch upon some aspects of the production of and trade in ecstasy in the Netherlands. These aspects reflect the complex nature of drugs-related crime, affecting society in a variety of ways.

87 Police Academy of the Netherlands, 'Meer xtc-export, dan hogere omzet', *politieacademie.nl* (2018).

88 Barbara Baarsma et al., *Drugs de baas: Hoe Nederland zijn drugsprobleem onder controle kan krijgen* (2022), 20.

89 Police Academy of the Netherlands, 'Meer xtc-export, dan hogere omzet', *politieacademie.nl* (2018).

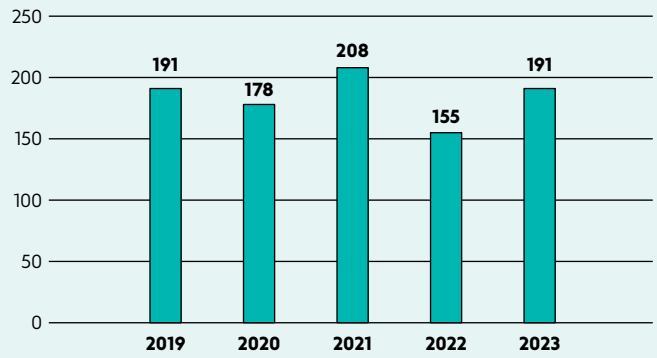
90 Gjalt-Jorn Peters, 'Nederland gebruikt veel minder XTC pillen dan geschat', *Gjalt-Jorn Peters' website* (2018).

91 EMCDDA, *European Drug Report 2023* (2023), 68.

Harm to the user's social environment

As described in Chapter 2, the use of MDMA entails certain risks to the user's health. In addition, drug use can also cause social damage, i.e. harm to the user's (social) environment. This includes, for example, relatives of people who are addicted to drugs or who qualify as problematic users, as well as damage to the environment due to the behaviour of people who are under the influence of drugs. Concrete examples of harm to the social environment include unacceptable behaviour in nightlife settings, driving under the influence, aggression or vandalism and disruption of public order. Several studies show that due to the nature of its effects, such damage related to ecstasy is relatively small compared to other drugs.[92]

Figure 28
Number of detected drug waste sites



Damage to the natural environment

A completely different category of societal damage is the dumping of drug waste by drug producers into the environment. The production of synthetic drugs generates significant amounts of chemical waste, which criminals dump illegally in various ways, especially in rural areas and surface waters.[93]

Between 2001 and 2010, the number of detected synthetic drug waste dumps in the Netherlands declined.[94] However, this was followed by a sharp increase in the number of drug waste dumps registered by the police. In 2010, there were 35 registered dumps nationally, but the figure had doubled by 2012 and reached 172 by 2014. After a slight decrease to 161 dumps in 2015, the numbers rose once again

92 For example, refer to Jan van Amsterdam et al., 'Ranking the harm of alcohol, tobacco and illicit drugs for the individual and the population', *European Addiction Research* (2010).

93 Yvette Schoenmakers et al., 'Drugsafval in Brabant', *Justitiële verkenningen* (2017).

94 R. Neve, M. van Ooyen-Houben, J. Snippe and B. Bieleman, *Samenspannen tegen XTC. Eindevaluatie van de XTC-nota*, Groningen/The Hague: Intraval/WODC 2007, p. 79; KLPD, *Synthetische drugs en precursoren: criminaliteitsbeeldanalyse*, Woerden: National Police Services Agency - National Criminal Investigation Department 2012, p. 83.

to 177 in 2016.[95] In 2023, the most recent year for which data are available, the police recorded 191 dumps.[96] Note that these more recent figures are not broken down by specific drug type; they encompass all dumps related to drug production, including MDMA, speed, methamphetamine, and the processing of heroin and cocaine.

Criminologists Yvette Schoenmakers and Shanna Mehlbaum emphasise that these figures are probably a significant underestimate. After all, not all discovered dumps are reported to the police, and the police do not always handle and record such reports in a consistent manner.[97] Landowners and local authorities incur substantial financial damage in their efforts to dispose of encountered waste streams safely. Moreover, illegal dumping poses direct health risks to the public, especially when these chemicals end up in – for example – surface waters. People and animals can also suffer injuries from direct contact with these chemicals.

The effects of production and trade on the quality of living

Another form of social and societal harm associated with the production of and trade in chemical drugs, including MDMA, concerns the quality of living in residential areas. Outside built-up areas, but also and particularly in certain residential neighbourhoods, when drugs-related crime becomes a defining factor a culture emerges in which people become afraid and tend to look away. Residents' physical safety is also compromised; for instance, consider the large number of attacks with explosives related to gangland killings and intimidation.

Physical damage resulting from the production of synthetic drugs

Incompetent handling in laboratories for synthetic drug production regularly results in accidents, sometimes with fatal consequences. For example, in January of this year, three residents of Rotterdam died in an explosion that probably originated in a drug laboratory in the building where they lived.[98] The production of ecstasy requires the combination of several chemicals into a mixture than can explode if handled incompetently. Additionally, people can fall ill – fatally ill, in extreme cases – due to the release of chemicals resulting from incompetent handling in a laboratory.[99] The danger for residents living near such an illegal laboratory is therefore significant.

95 Y. Schoenmakers, S. Mehlbaum, M. Everartz and C. Poelarents, *Elke dump is een plaats delict. Dumping en lozing van synthetisch drugsafval: verschijningsvormen en politieaanpak*, Apeldoorn: Politie & Wetenschap 2016, p. 45; J. van Den Besselaar and M.van Grootel, *ERISSP meldingen. Synthetische drugs, precursoren, nieuwe psychoactieve stoffen 2014, 2015 en 2016. Meldingen omtrent productielocaties, opslaglocaties en dumplocaties*, Central Police Unit/National Investigation Service 2017.

96 Police, 'Nationaal overzicht drugslocaties 2023', *politie.nl* (1 May 2024), 7–8.

97 Y. Schoenmakers, S. Mehlbaum, M. Everartz and C. Poelarents, *Elke dump is een plaats delict. Dumping en lozing van synthetisch drugsafval: verschijningsvormen en politieaanpak*, Apeldoorn: Politie & Wetenschap 2016, p. 53–58.

98 For reports about this issue, refer to (for example) 'Zo gevaarlijk is een drugslab in een woonwijk: "Grootschalige controle nodig"', *NOS* (2024).

99 For reports about this issue, refer to (for example) Sebastiaan Quekel et al., 'Twee mannen dood bij drugslab in Kaatsheuvel: woningen ontruimd vanwege explosiegevaar', *Brabants Dagblad* (2017).

Criminal exploitation within production and trade

A final form of social harm in this non-exhaustive list is the criminal exploitation of young people recruited for work in the production of and trade in of drugs. In a study among secondary school and vocational education students in the province of Zeeland, it was found that over 4 per cent of students had experienced criminal exploitation, and nearly 11 per cent had been asked to do something that qualified as criminal exploitation.[100]

Subversion by drugs-related crime

Finally, the State Commission points to the subversive effects of drugs-related crime, which have now significantly escalated due to the corruption of legal systems and structures in our society. Subversion literally means 'to undermine the power and authority of an established system or institution'. In the context of organised crime, the State Commission uses the following definition of subversive crime:

Disruption of social structures and foundations and erosion of the rule of law caused by the interconnectedness of clandestine and legitimate operations due to or associated with organised crime.[101]

In other words, subversion is not synonymous with organised crime, but one of its consequences. The underworld and the legitimate world are becoming increasingly intertwined, in a process that erodes the foundations of society. Legitimate businesses – wittingly or otherwise – act as facilitators of criminal activities and organisations.[102] Banks provide accounts and loans, real estate agents arrange housing, courier companies transport drugs throughout the Netherlands, and accountants, lawyers and civil-law notaries provide the necessary legal and regulatory cover. Meanwhile, the government issues permits, fails to enforce regulations or prioritises the economy over crime-fighting efforts. One key characteristic of organised crime is the willingness of the criminals to use violence and to compromise the government and other legitimate structures of our society.[103] The first manifestations of 'subversive crime' in the literature appeared in the mid-1990s. The focus at the time, rather than on 'subversive crime', was on the subversive effects of crime (usually organised crime). In English-language literature, this is often referred to simply as 'corruption', with authors focusing principally on the effects on economic transactions. In a detailed study, the Italian economist Paolo Pinotti was the first to show the precise economic consequences of organised crime.[104] The activities of the mafia in the two Italian regions that were studied showed a 16 per cent loss of gross national product compared to two control regions where the mafia was less active.

Likewise, American policy researchers John McDowell and Gary Novis take the economic perspective as the starting point for their discussion of the consequen-

100 Ayten Üstüner-Tüfekci et al., *Criminele uitbuiting onder scholieren en studenten in Zeeland* (2022).

101 Emile Kolthoff, 'Ondermijning van het platteland', *Cahiers Politiestudies* (2021).

102 Emile Kolthoff et al., 'Ondermijnende aspecten van georganiseerde criminaliteit en de rol van de bovenwereld', *Tijdschrift voor Criminologie* (2016).

103 Maarten van Traa et al., *Inzake opsporing* (1996).

104 Paolo Pinotti, 'The economic consequences of organized crime: Evidence from Southern Italy', *The Economic Journal* (2015), 3.

ces of money laundering as the final link in the chain of organised crime.[105] They argue that the legal financial and banking system is almost always involved in money laundering, and this alone puts established systems at risk of compromising their integrity. However, McDowell and Novis claim that the legitimate private sector (particularly small and medium-sized enterprises) is also affected by the activities of criminal organisations seeking to launder their illicit gains. The perpetrators often use front stores for their activities, which in turn impacts the quality of life in local neighbourhoods.

In this way, subversive crime is increasingly – and ever more openly – associated with or actually declared more or less synonymous with organised crime. The main focus in the international literature remains on cross-border crime. For example, the United Nations Office on Drugs and Crime emphasises that transnational organised crime – such as human trafficking, drug trafficking, cybercrime and money laundering – subverts the economic, social, cultural, political and democratic development of societies worldwide.[106]

In the Netherlands, the concept of 'subversive crime' first appeared in the mid-1990s – in particular during the parliamentary inquiry (led by the Van Traa Commission) into investigation methods. This was held in response to the so-called IRT affair, where the police had infiltrated the criminal circuit and became involved in the controlled delivery of drugs.[107] In 2008, the parliamentary working group Joldersma published a report entitled *Intertwinement of the legitimate world and the underworld*.[108] Although the report is based solely on the results of criminal investigations (and thus by definition misses part of the reality), it still provides important insights and clues. While the Van Traa Commission concluded, in 1996, that legitimate sectors in the Netherlands were not under the control of organised crime and saw no reason to question the privileges of professional groups such as civil-law notaries and lawyers (including client confidentiality and the right to professional secrecy), more than a decade later the Joldersma Commission took a step further. They stated that according to data from follow-up research and the Organised Crime Monitors, more and more people from the legitimate world were becoming involved in criminal activities. A 2017 study showed that many disciplinary investigations against law enforcement officers for ties with organised crime concerned drugs-related crime.[109]

Tackling organised crime in practice

In tackling drugs-related crime, the police and the Public Prosecution Service focus their efforts on organised crime in general, which, in the Netherlands, is mainly (though not exclusively) related to drugs. The investigative authorities involved primarily include the specialised detective units within the ten regional divisions of the National Police and the National Investigation and Intervention

105 J. McDowell et al., 'Consequences of Money Laundering and Financial Crime', *Economic Perspectives* (2001), 6-8.

106 UN Office on Drugs and Crime, 'Transnational organized crime: the globalized illegal economy', *unodc.org* (undated).

107 Maarten van Traa et al., *Inzake opsporing* (1996).

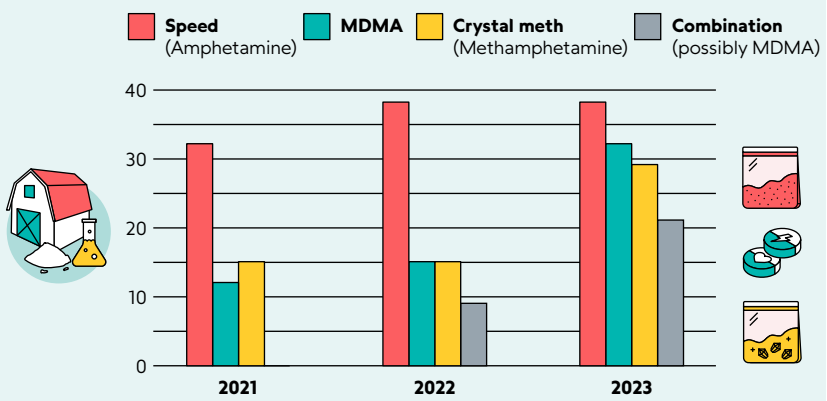
108 C. Joldersma et al., *Verwevenheid van de bovenwereld met de onderwereld: Rapport van de parlementaire werkgroep verwevenheid onderwereld/bovenwereld* (2008), 8.

109 Hans Nelen et al., *Schaduwen over de rechtshandhaving* (2017).

Unit. Additionally, organisations such as Customs and several national inspectorates play a crucial role in the investigation of drug offences. Furthermore, the ten Regional Information and Expertise Centres (RIECs) and the National Information and Expertise Centre (LIEC) focus on cooperation in combating organised crime. They connect the information, expertise and capacity of various government agencies. Additionally, the RIECs and the LIEC stimulate and support public-private partnerships in addressing subversive crime. After collecting and processing information, the RIECs can present so-called signal files to the local triumvirate (the institutionalised structure for consultation between the mayor, chief public prosecutor and chief of police). The triumvirate then select the most suitable approach, which may include both criminal-law and administrative interventions.

The policy decisions made in the mid-1990s prioritising general policing tasks (and emphasising visible police presence on the streets) have come at the expense of various specialised units within the police force. In a parallel development, we are now seeing more and more experts within the police force reaching retirement age. This has resulted in investigation capacity issues, impacting the drug dossier in particular. It is anticipated that the low point in capacity will be reached in 2026.

Figuur 29
Number of dismantled labs by synthetic drug type



Currently, the main priority in investigating drugs-related crime is the production of and trade in synthetic drugs. Investigations into synthetic drugs do not distinguish between types of drugs in advance. The number of labs has increased in recent years, and the assumption is that the number of operational laboratories far exceeds those that have been shut down. In 2023, a total of 32 MDMA labs were shut down, compared with 12 in 2021. Over the same period, the total number of production sites for synthetic drugs – including, for example, crystal meth – rose from 93 to 125. This also includes the relatively new phenomenon of combined production sites, where multiple synthetic drugs are manufactured. For example, MDMA, amphetamine and methamphetamine can be produced at one and the same location because they require partly the same raw materials and hardware.[110]

110 Police, 'Nationaal overzicht drugslocaties 2023', *politie.nl* (1 May 2024), 5–6.

Within the investigative authorities, we are witnessing increasing investment in intelligence technology. The authorities are becoming more and more successful in intercepting encrypted messages and further developing forensic investigation and technology. For instance, by hacking the encrypted messaging service EncroChat the authorities discovered that many criminals are keen on transitioning to methamphetamine, where profit margins are much higher. Due to the extensive experience in the Netherlands with synthetic drugs such as MDMA and previously amphetamine, this transition is relatively easy, since the logistical infrastructure and expertise are already in place.[111]

A two-year pilot project named 'Syndru', which was conducted by the East Netherlands Unit and the National Unit of the National Police and was recently completed, has revealed that targeted forensic trace evidence investigation in drug labs can uncover much more than just the identities of the 'cooks'. In cooperation with the Public Prosecution Service, the Netherlands Forensic Institute and a private forensic institute, Eurofins TMFI, the police investigated a total of 18 production sites in the eastern part of the Netherlands between 2021 and 2023. During this investigation, it was found that forensic investigation methods can help to identify not only the people manufacturing synthetic drugs in the labs, but also other suspects within the criminal network such as lab builders, hardware suppliers and even individuals acting on behalf of clients. Cooperation between forensic investigation, intelligence services and criminal investigation proved to add value and merits further development.[112]

The State Commission considers the further development of such initiatives to be promising and believes that making investigation tactics 'smarter' is an important trend whose future impact may well exceed that of mere efforts to expand capacity.

Challenges – Tackling the supply side

/// **The Minister of Health, Welfare and Sport shares responsibility for drug policy with the Minister of Justice and Security. The judicial sector focuses on reducing supply through enforcement of the Opium Act, which prohibits the possession and production of and the trade in drugs.**

The coordinating responsibility of the Ministry of Health, Welfare and Sport for the Opium Act seems to be at odds with the increasing role of the Ministry of Justice and Security in enforcing the Opium Act. While the Ministry of Health, Welfare and Sport is responsible for reducing drug demand through prevention, the Ministry of Justice and Security's role is to curb supply by tackling production and trade.

The State Commission observes that while this division of responsibilities is clear to policy staff members at the respective Ministries, it has not been laid down in a single, overarching drug policy. Moreover, the role of Justice and Security has significantly expanded in recent years in response to rising drugs-related crime, sometimes overshadowing the coordinating role of the Ministry of Health, Welfare

111 Pieter Vermaas, 'Het elan tegen synthetische drugs is terug', *Opportuun* (2021).

112 East-Netherlands Police Unit et al., *Proeftuin Syndru* (2024).

and Sport, particularly in financial terms. This can lead to ambiguities regarding the division of responsibilities. It is necessary, therefore, for the government to reflect on relationships, responsibilities and cost-effectiveness within the existing Opium Act framework.

/// **The current enforcement approach is focused on investigation and prosecution of the production of and trade in drugs, while the possession of small quantities intended for personal use is tolerated. This approach is quite consistent with convictions and practices in Dutch society and is generally successful. However, the police and the judiciary are increasingly confronted with the side effects of drug production and trafficking, such as the rise in organised crime, public violence and the dumping of chemical waste. These issues place significant pressure on the available capacity, leaving fewer resources for directly addressing drug production itself.**

Enforcement of the current Opium Act is impeded by capacity limits caused by staffing shortages. Particularly, the police's involvement in combating severe drugs-related violence and the (entirely justified) protection of judges, lawyers and public prosecutors against this violence come at the expense of all other files.[113] Moreover, the State Commission wishes to point out to the government that the claim on capacity resulting from the fight against drugs-related violence is also hampering efforts to combat the root cause of that violence, namely drug production.

Staff shortages are also affecting courts, resulting in delays in the processing of cases. The number of court cases being cancelled due to staff shortages is expected to continue to increase in the coming years, as reported by the Dutch Association for the Judiciary to *NRC* newspaper in 2023.[114] This mainly concerns cases where 'no victims' were involved, according to the Public Prosecution Service. Many drugs-related cases also fall into this category, particularly those involving possession or cultivation.[115]

This staff shortage is not easily resolved, as it is also a demographic issue.[116] Even with the planned measures to train more judges, their numbers are expected to decline in the coming years due to aging.[117] These shortages – including at courts in North Brabant, a province known for its drugs-related crime issues – engender choices made out of necessity.[118] For instance, violations of the Opium Act involving possession of a relatively small quantity of MDMA do not take priority over more serious drugs-related cases.

113 Christel van der Meer, 'Belangrijk politieonderzoek blijft liggen door personeelstekort, ook minder inzet bij voetbalduels', *Omroep Brabant* (2019).

114 Bram Endewijk et al., 'De rechter ligt er wakker van: het lukt niet meer om op tijd én goed te vonnissen', *NRC* (2023).

115 Loes Bomers, 'Openbaar Ministerie kan door personeelstekort sommige strafbare feiten niet meer vervolgen: "We moeten scherper kiezen"', *EenVandaag* (2023).

116 The Minister for Legal Protection, 'Rechtertekort en opleidingscapaciteit rechterlijke ambtenaren' (2023).

117 Bram Endewijk et al., 'De rechter ligt er wakker van: het lukt niet meer om op tijd én goed te vonnissen', *NRC* (2023).

118 Editorial board of advocatie.nl, 'LinkedIn-oproep: rechters gezocht!', *advocatie.nl* (2023).

/// **MDMA production is intertwined with criminal networks. The development of this criminal network is closely associated with parallel socio-economic developments. Young people are particularly vulnerable, especially to criminal exploitation.**

Organised drugs-related crime in the Netherlands results from the profitability of drug production, particularly through export. The fact that some individuals (often in poorer socio-economic conditions) consider or are tempted to engage in this type of crime to improve their circumstances is a source of social and societal harm.

In studies on drugs-related crime, researchers cite the influence of (social) networks as the most common reason why people become involved in crime.[119] The more members of a young person's network (within family or household circles, for example) are involved in crime, the greater the likelihood of that young person getting involved in criminal activities themselves.[120] Organised crime gangs also recruit young people at schools and at the community level. Researchers at the Open University estimate that tens of thousands of children in the Netherlands come into contact with the drug industry. To many boys in disadvantaged neighbourhoods, drugs-related crime offers 'a way out'.[121] Years of budget cuts in youth and community work have contributed to this situation.

To create a sustainable policy against drugs-related crime, policymakers need to take a step back. In the longer term, an approach that consists of merely addressing incidents will not work. The State Commission notes that in combating the social issues associated with drugs-related crime, policymakers must also look beyond the domains of the Ministries of Health, Welfare and Sport and Justice and Security. The government should invest in disadvantaged neighbourhoods, youth work, employment opportunities for underprivileged youth and education. It is now widely recognised that investigation alone will not suffice in the fight against drugs, and that there is a significant role for local authorities and societal institutions to focus mainly on prevention policies. This calls for a long-term vision that extends beyond the average term of Dutch administrators and government officials and explicitly considers the social vulnerability of large groups – especially young people – within the population.[122]

Drugs-related crime is too big for the Ministries of Health, Welfare and Sport and Justice and Security to handle on their own – and this also applies to the social issues arising from drug use. In 2011, the Garretsen Committee presented examples of social and societal damage caused by drugs, also explicitly including school drop-out rates, absenteeism from work, road accidents and damage to the international reputation of the Netherlands. These examples still apply today.[123]

119 Statistics Netherlands, 'Onderscheidende kenmerken van jonge drugsverdachten', *cbs.nl* (2023). Based on Francesco Calderoni et al., "Recruitment into organised criminal groups: A systematic review", *Trends & issues in crime and criminal justice* (2020).

120 Statistics Netherlands, 'Onderscheidende kenmerken van jonge drugsverdachten', *cbs.nl* (2023). Based on Brenda Bos et al., "Persoonsnetwerken en criminaliteit van Nederlandse jongeren", *Tijdschrift voor Criminologie* (2022).

121 Emile Kolthoff et al., '"Georganiseerde misdaad aanpakken begint in de wijk"', *ou.nl* (2023).

122 N. Vettenburg et al., 'Maatschappelijke kwetsbaarheid: een theorie over systematische delinquentie door jongeren', in P. Goris et al. (eds.), *Van kattenkwaad en erger* (2002).

123 Henk Garretsen et al., *Drugs in lijsten* (2011), 29.

Conclusion

In this chapter, the State Commission considered current Dutch policies regarding MDMA. Remarkably, no new Policy Document on Drugs has been written since 1995. MDMA was still a relatively new drug at the time, and not much was known about it. Efforts to investigate ecstasy producers hardly existed.

Since then, knowledge about the harmful effects of ecstasy use has expanded enormously. An extensive system of testing sites has been created to monitor the drugs market, and users feel safe enough to ask for information. At the same time, as pointed out in the previous chapter, there are concerns about perceptions of harmfulness among young people, who increasingly perceive the risk as lower. There is a lack of a nationwide, scientifically substantiated vision for drug prevention. The range of prevention services available in the Netherlands is too fragmented, too incidental and also poorly funded. In a time when the harmful effects of ecstasy – particularly when combined with other substances or under specific conditions – are increasingly underestimated, this creates a worrying situation.

Since 1995, the crime associated with the production of and trade in MDMA has also become much more complex. The networks behind MDMA production are characterised by an enormous adaptive capacity, with criminals skilfully utilising the legitimate world for their ow purposes. Tackling this type of crime cannot be the responsibility of the police and the Public Prosecution Service alone, but requires a much broader front in which local authorities, social institutions and stakeholders all play a significant role.

In recent years, the persistence of drugs-related crime and its many ramifications have led to a new focus on users, who are wrongly accused of maintaining a criminal system by consuming drugs. This viewpoint has generated new initiatives to reduce demand and thereby undermine the business model of criminals. These initiatives tend to be inspired mainly by a desire ‘to do something’, and because they often lack a scientific basis may actually be counterproductive.
It is essential, therefore, that a new vision for drug prevention should be evidence-based. Scientists already know which strategies are effective and which are not, but so far little use has been made of these insights. From that scientific basis, it remains crucial that in any new vision, public health takes precedence. In addition, clear objectives must be formulated to enable progress to be mapped out. In fact this point was already made in the most recent drug policy evaluation, which dates back to 2009.

Recommendations

1 **Continue the Dutch approach to drug policy by retaining the primary focus on promoting individual public health. Never criminalise the users of drugs.**
According to the State Commission, criminalising drug use will not help to reduce drug use, but may instead result in stigmatisation and reduced access to support and care services. An approach aimed at combating drug production and trafficking yields the best outcomes for public health and society alike.

To minimise the harm caused by MDMA to individual users, the State Commission makes the following harm reduction recommendations:

a **Provide information on drugs targeting specific groups.**
Information about the harmful effects and risks of ecstasy use remains necessary, but must be targeted towards specific groups. People who intend to use ecstasy should be informed about the specific risks and the corresponding preventive measures. General public campaigns are not advisable, as they tend to either stigmatise users or normalise use.

b **Maintain funding for the Drug Information and Monitoring System (DIMS) to preserve the ability for users to anonymously test ecstasy tablets for dosage and the presence of harmful adulterants.**
In addition to providing better insight into the market for illicit drugs and contributing to users' knowledge about the risks of drug use, the DIMS enables the rapid identification of particularly dangerous drugs.

c **Ensure effective harm reduction measures at events, such as chill-out spaces and sufficient water.**
Certain harm reduction measures, such as chill-out spaces and sufficient access to drinking water, can prevent users from needing pre-hospital care at events. It is important, therefore, that event organisers are well informed about the field standards for event care[124] and that local authorities are well aware of the guidelines for municipalities.[125]

d **Develop policy for foreign tourists and visitors of events.**
There is considerable concern about foreign tourists and event visitors in the Netherlands. Dutch prevention services do not reach these groups, which are also more likely to use ecstasy in riskier ways, probably because they have not been very well informed about the risks at home. Incidents in this group place an extra burden on the Dutch health care system.

2 **Develop a new, integrated and long-term vision for Dutch drug policy.**
The State Commission emphasises the need for a new, integrated and long-term vision of Dutch drug policy. That vision should also reflect supplementary national strategies and explicitly identify the responsibilities within the Opium Act framework. That vision, the strategies and the responsibilities should be included in an up-to-date Policy Document on Drugs. Incorporate scientific insights on effective prevention in the development of the vision, strategies

124 Marieke Cottaar et al., *Veldnorm Evenementenzorg* (2019).

125 J. de Greeff et al., *Alcohol, drugs en tabak op evenementen: Leidraad voor gemeenten* (2019).

and policy document. Ensure that the vision, strategies and policy document themselves are reviewed by independent centres of expertise, such as RIVM and the Trimbos Institute.

a **Adhere to the central principle established in 1976.**
The Policy Document on Drugs from 1995, *Continuity and Change*, provides a suitable starting point for the new document. The central principle of the existing drug policy, as defined by the House of Representatives in the fundamental amendment of the Opium Act in 1976, must be maintained: preventing harm and promoting (public) health. Additionally, efforts to mitigate nuisance and combat drugs-related crime must also feature prominently in the policy.

b **Develop a vision for cooperation between the Ministries, lower-level public authorities and relevant government and non-government organisations involved, clearly defining their respective responsibilities in drug policy.**
In practice, responsibility for curbing demand for drugs rests with the Ministry of Health, Welfare and Sport, while the Ministry of Justice and Security is responsible for reducing drug supply. To this end, the two Ministries work with each other and with a majority of the other Ministries. However, the responsibilities and agreements regarding this cooperation have not been formalised. According to the State Commission, formalising the relationships between the Ministries involved in drug policy is a precondition for developing an effective, integrated and long-term drug strategy.

In this context, ensure that the Minister of Health, Welfare and Sport retains overall responsibility for the Opium Act as a piece of legislation and as a system.

c **From within the Ministry of Heath, Welfare and Sport, develop an evidence-based vision on drug prevention and incorporate it into a National Drug Prevention Strategy.**
There is a lack of a nationwide, scientifically substantiated vision for drug prevention. As a result, the range of interventions in the Netherlands consists of a mixture of effective, ineffective and potentially harmful interventions. Providers range from addiction care centres to commercial marketing agencies.

The State Commission envisages a role for the Ministry of Health, Welfare and Sport in developing a drug prevention vision and establishing quality standards for drug prevention. Existing international quality standards can be used for this purpose. The State Commission welcomes the initiative of the National Rapporteur on Addictions to integrate prevention activities and develop a comprehensive addiction prevention guideline in the period ahead.[126]

d **Provide sufficient funding to ensure that the prevention policy can be implemented and evaluated effectively.**

126 National Rapporteur on Addictions, *Annual Report for 2023* (2024), 12.

Given their statutory responsibility, municipalities are crucial partners in prevention policy. This is why it is important to ensure financial continuity in the implementation of prevention policy.

e **Integrate into the new policy a vision for communication about, and scientific research into, the clinical use of psychedelics.**
The State Commission discusses the advantages and disadvantages of MDMA-assisted therapy in Chapters 5, 6, and 7. Considering the potential positive effects of certain drugs under controlled conditions, the State Commission recommends that this aspect be included in policy considerations so as to limit health damage from intended therapeutic use outside clinical settings.

3 **Identify and name the considerations in ministerial decision-making when weighing up the advice of the CAM when deciding to include substances in the schedules to the Opium Act.**
The State Commission supports the conclusion of the CAM that there is a need for a thorough reassessment of MDMA to ensure its appropriate classification under the Opium Act.

4 **Ensure sufficient enforcement tools to support the fight against the production of and trade in ecstasy in case of a change in the status of MDMA under the Opium Act.**
If, at any point in time, MDMA were no longer classified under the Opium Act, a crucial pillar of enforcement policy would be removed. Enforcement (also pursuant to Section 140 of the Dutch Criminal Code, on participation in a criminal organisation) would then need to be justified under the Economic Offences Act, environmental legislation (for example, Section 173a of the Dutch Criminal Code) or under the Medicines Act if MDMA-AT were to become an authorised therapy. However, all these alternatives involve significantly lighter maximum sentences. Additionally, the responsibility for enforcement would primarily fall on the inspectorates, which currently lack sufficient capacity.

5 **Invest in preventing the recruitment of young people ('new blood') into drugs-related crime by allocating more funding towards information and awareness campaigns in education and community youth facilities (among youth workers, youth centres, coaches etc.). Ensure a special focus on the vulnerability of young people.**
It is estimated that tens of thousands of young people in the Netherlands have been exposed to drugs-related crime. Years of budget cuts to youth facilities and community services have made young people even more vulnerable than they already were. It is crucial, therefore, to invest in deprived neighbourhoods, youth work, job opportunities for disadvantaged youth and education to prevent young people from becoming victims of organised drugs-related crime.

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4
The debate on MDMA regulation

Introduction

Over the past few years, there have been frequent pleas – in the media, at several conferences and in a range of other locations – both in favour of and against the regulation of various types of drugs.[1] The State Commission considers that practically all participants in this debate on the reform of our drugs system share certain objectives: to improve public health and to provide more effective tools to fight crime associated with the production of and trade in drugs.

1 Femke Halsema, 'As the mayor of Amsterdam, I can see the Netherlands risks becoming a narco-state', *The Guardian* (2024); Amsterdam Events Bureau, 'Conference Dealing with Drugs: Cities and the quest for regulation' (undated). The conference was held at the Beurs van Berlage on 26 January 2024; LEAP Nederland, '30 januari Symposium: Hoe verder met het drugsbeleid?', *Leap-Europe.org* (2023); John van den Heuvel, 'Nieuwe politiebaas wil drugs legaliseren: wat uit te leggen aan FBI en DEA', *De Telegraaf* (2024); Anton Slotboom, 'Rotterdamse burgemeester Aboutaleb: "Miljoenen extra nodig voor aanpak drugscriminaliteit"', *Trouw* (2024); John-Peter Kools et al., 'Hedendaagse drugssistuatie vraagt om hedendaags beleid', *trimbos.nl* (2024).

4
The debate on MDMA regulation

Findings

The State Commission finds as follows:

/// **The political debate on drug policy reform has become polarised.** This has made it difficult to engage in a genuine discussion and prevents people from considering moderate voices.

/// **The health effects of MDMA appear to justify its transfer from Schedule I to Schedule II.** However, organised crime and the societal harm arising from illicit production and trade practices make it undesirable to remove MDMA from its current schedule at this point in time.

Even so, the debate has become polarised. Two main schools of thought have emerged, making it increasingly difficult to take up a moderate position. One of the causes of this polarisation is the tendency among the parties involved to use distorted, caricatured representations of each other's viewpoints. Those who advocate regulation as the basis for a new drug policy are often accused of aiming to 'legalise' drugs altogether, while those who prioritise significant reduction in drug use are accused of waging a 'war on drugs'. Unfortunately, the current discourse is stuck in this polarised deadlock. As such, if fails to offer solutions to the complex issues faced on a daily basis by police officers, prevention workers, policymakers, youth welfare workers and event organisers.

In this chapter, the State Commission considers this debate and the various arguments and assumptions put forth by participants. In this way, the State Commission primarily hopes to be able to provide a factual foundation for the debate on the future of MDMA policy.

Polarisation?

/// The political debate on drug policy reform has become polarised. This has made it difficult to engage in a genuine discussion and prevents people from considering moderate voices.

In the debate on drug policy reform, two distinct groups can be identified, which seem to have taken opposing positions. These positions are exemplified in two recent municipal projects. Amsterdam recently announced its conference on drug regulation. accompanied by a call to combat organised crime by exploring options for international drugs regulation.[2] A month earlier, Rotterdam launched a public campaign aimed at alerting drug users to their role in perpetuating a criminal system. The city faces alarming levels of drugs-related violence, including two hundred explosions in 2023 alone.[3]

The two groups have a very different take on this policy challenge. One group fears that the other is paving the way for easy and accessible drug consumption, while the other group is concerned that preparations are being made for an all-out war on drugs. The State Commission agrees that both scenarios should be avoided. The Prohibition era in the United States, from 1920 to 1933, and the American war on drugs, which started in 1971, have shown that attempts to eradicate drug use through punitive measures always have adverse effects or other disastrous consequences for society. Blaming drug users for organised drugs-related crime was part of the reasoning that preceded the war on drugs, but currently, there are no attempts in the Netherlands to actually criminalise drug use.

At the same time, fully legalising the drugs market can lead to undesirable societal outcomes. It is important to remember, however, that nobody in the political debate is seriously calling for legalisation. After all, this could potentially lead to the commercialisation of the drugs market and an increase in the use of substances with serious health risks. Those advocating regulation instead propose various

2 Femke Halsema, 'As the mayor of Amsterdam, I can see the Netherlands risks becoming a narco-state', *The Guardian* (2024).

3 Jeroen den Blijker, 'Aboutaleb bepleit mediastilte in strijd tegen drugsgeweld', *Trouw* (2024).

models for the production and sale of drugs that involve conditional supply. These groups anticipate that such measures could displace criminals from their market and make drug use safer.

Regulation, legalisation, decriminalisation

Several key terms in the debate on drug policy are used in a confusing manner.

Regulation concerns the conditions under which a substance may be legally provided. This includes rules regarding the type of sales outlets, age limits, dosage restrictions and whether advertising for the substance is permitted. Tobacco and alcohol are examples of substances governed by a wide variety of regulations globally.

Legalisation, on the other hand, refers to the process of ending the prohibition regime that governs a particular substance. Regulation aims to enable a substance to become available under certain conditions, but legalisation has no such aim. Legalisation is necessary to produce a product legally and make it available under (strict) regulation.

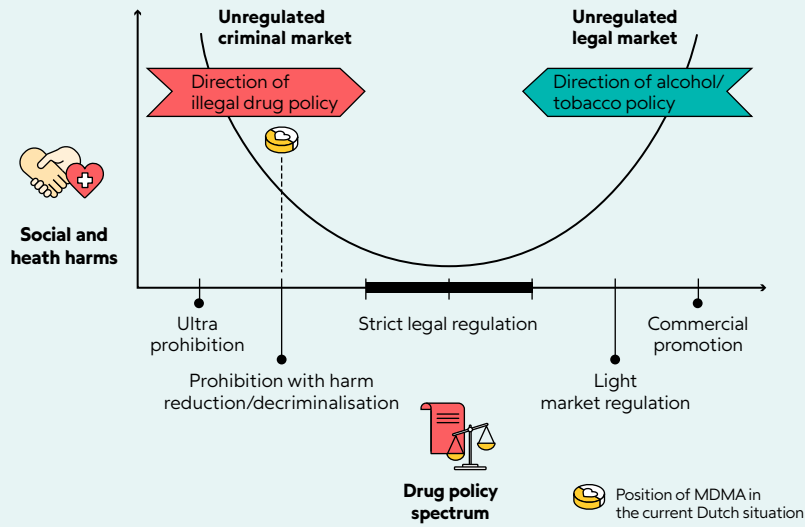
Another term frequently heard in this debate is **decriminalisation.** Decriminalisation is not about legalisation or regulation of a substance, but about the position of users: following decriminalisation, the use and/or possession of drugs are no longer punishable offences. In the Netherlands, use and possession have, to a certain extent, been decriminalised, as drug use is not punishable and individuals in possession of very small quantities of drugs (for personal use) are not prosecuted. Unlike legalisation, decriminalisation is permissible under international conventions.[4]

Regulating a substance currently classified under the Opium Act depends on the specific aspects of the case. Each regulated substance has its own set of rules. For instance, in 2020 the British think tank Transform Drug Policy published a report entitled *How to regulate stimulants*, which includes the graph below. The horizontal axis shows policy options ranging from a total ban to full legalisation, including advertising. The vertical axis represents the social and health damage caused by a substance. Both full legalisation and a total ban will cause that damage to increase. This is because in both these situations, there are no longer any rules that could help to limit the damage.

The graph on the right shows the data for tobacco and alcohol, which are both legally available on the market. The policy for tobacco is increasingly shifting towards a strictly regulated model. The government imposes high excise duties on the sale of tobacco and has prohibited advertising. There are mandatory health warnings on the packaging, and the number of sales outlets is restricted further and further. The sale of tobacco products to those under 18 is prohibited.
For substances like cannabis, several countries are transitioning from prohibition to a regulated market. This includes the Dutch cannabis experiment, which imposes requirements on the production, packaging and sale of a substance included in Schedule II to the Opium Act.

4 Steve Rolles et al., *How to regulate Stimulants: A practical guide* (2020).

Figure 30
A spectrum of policy options [5]



In the case of ecstasy, the current prohibition has led to the emergence of an unregulated criminal market. Simultaneously, there is a policy of decriminalisation and harm reduction aimed at mitigating the harm associated with its use.

As regards regulation, various different scenarios are conceivable. According to British policy analyst Steve Rolles, roughly five regulation categories can be distinguished:

Available on prescription: The user obtains a dose under strict conditions from a dispensing point and may have to use the substance on site (often under supervision). This is how heroin is dispensed in the Netherlands. This type of regulation does not apply to recreational use, but does involve the regulated provision of drugs.

Pharmacy model: No prescription is required, but the sale is subject to strict conditions and takes place through specialised pharmacists who are knowledgeable about the side effects of the substance. They can provide information about the substance and monitor the amounts sold to each customer.

Licensed sale for on-site consumption: The substance is sold under a licence for immediate on-site consumption (like the sale of alcohol in pubs). In this model, sellers can cease sales if a user has consumed too much or intervene if something goes wrong. At the same time, the environment in which the substance is used is subject to specific conditions to minimise harm.

5 Marks, J. "The paradox of prohibition", *Mersey Drugs Journal 1* (1987).

Licensed sale for consumption elsewhere: This can be compared to the sale of cannabis in Dutch coffeeshops and in Canada, where licensed establishments are allowed to sell cannabis. Conditions may be imposed, for example as regards age, price and quantity. The substance is normally consumed elsewhere.

Open sales: All outlets are free to offer the substance. For example, this is how caffeine, a stimulant, is offered for sale in supermarkets. No restrictions are imposed on how much of the substance may be sold and to whom. The substance itself is subject to control, though.[6]

6 Steve Rolles et al., *How to regulate Stimulants: A practical guide* (2020).

Arguments from the public debate

The State Commission is aware of the many complexities in the debate surrounding the risks of MDMA and, as such, its legal status. To help the debate move forward, the State Commission will now consider a range of arguments that regularly occur in the public discourse. The State Commission will affirm some arguments, refute others, provide nuance or determine that further research is necessary. Note that not every case allowed for a simple conclusion.

"The legalisation of MDMA and the creation of a legal market will make MDMA more accessible, leading to increased use."

This assumption is based on scientific research into alcohol and cannabis policies. Research into alcohol use has shown that an increase in availability leads to increased consumption. The more easily a product is available, the more it will be sold or used.[7]

Studies into the effects of legalisation of cannabis in some areas of the United States and Canada have shown a slight rise in prevalence rates in those areas following legalisation, with some age groups showing a higher increase than others.[8,9]

In this context, the possible effects of commercialisation, such as advertising and the potential effects of normalisation, come into play. If MDMA were sold in attractive stores or available in pharmacies, this might suggest that it is a safe product suitable for a healthy or normal lifestyle.

However, when considering this argument it is important to bear in mind that legalisation can take many forms. Strict regulation combined with high-quality information will prevent commercialisation and misconceptions about the safety of the substance.

Note, moreover, that in the case of MDMA it is not clear to what extent the market is saturated. Illegal supply of tablets is considerable at the moment, and the tablets are inexpensive. In principle, every person who wishes to buy MDMA may already have found their way to a seller. However, it can be argued against this reasoning that it is not known how many users have direct access to a dealer, or if they can only obtain MDMA through, for example, a friend at the location where they use it. Research into the share of users that have direct access to ecstasy and the share of those who can only obtain it indirectly may provide more insight into the actual accessibility of the illegal market.

7 Robyn Burton et al., 'A rapid evidence review of the effectiveness and cost-effectiveness of alcohol control policies: an English perspective', *The Lancet* (2017).

8 Dafna Rubin-Kahana et al., 'The impact of cannabis legalization for recreational purposes on youth', *Frontiers in psychiatry* (2022).

9 Michelle Rotermann, 'What has changed since cannabis was legalized?', *StatCan.gc.ca* (2020).

"The current policy of tolerance regarding the possession of a "user's quantity" suggests that MDMA is not particularly harmful. Penalising possession and use will cause demand to fall."

The assumption here is that penalising users will have a deterrent effect. A comparison with other countries, such as the United States, shows that a strict war on drugs hardly reduces usage. In 2023, the United Nations High Commissioner for Human Rights stated that despite decades of punitive measures, drug production and consumption had not decreased. At the same time, this war on drugs was responsible for a deterioration of public health and oppression of certain groups. This policy also led to overcrowded prisons.[10]

In the Netherlands, there is no such a widespread war on drugs. When, in the early 2000s, some municipalities began stricter enforcement against the open use of MDMA at parties and festivals, those measures were widely criticised for being disproportional. There is no evidence that this zero-tolerance policy reduced the demand for or the use of ecstasy.[11]

The lack of evidence for the effectiveness of zero-tolerance interventions is in itself sufficient reason not to promote this policy. Additionally, zero tolerance can actually cause significant harm. Criminalising possession of quantities for personal use can lead to the stigmatisation of users. While stigma is most dangerous with substances carrying addiction risks, it is crucial that MDMA users, too, do not feel inhibited to discuss problematic use or seek medical help when necessary.

"By keeping MDMA in Schedule I, the government issues a warning about MDMA."

As soon as a new substance enters the market, attention is often drawn to the symbolic value of Schedule I. The hope is that inclusion of a substance in Schedule I will reduce its use.

4-FA, 3-MMC and nitrous oxide were classified under the Opium Act in 2017, 2021 and 2024, respectively. All these three substances are harmful to human health. The use of 4-FA and nitrous oxide did indeed decrease after they were banned. However, the use of 3-MMC actually increased rather than decreased, and the increase continued after it was made subject to the Opium Act.[12]

Users therefore do not always directly link inclusion of a substance under the Opium Act with its harmfulness. If inclusion under the Opium Act is relevant at all for users, apparently it is only one of the variables determining their decision whether or not to use a substance.

10 UN Human Rights Council, *Human rights challenges in addressing and countering all aspects of the world drug problem* (2023), 19–20.

11 Ton Nabben, *High Amsterdam: Ritme, roes en regels in het uitgaansleven* (2010), 300–310.

12 Ruben van Beek et al., *Het Grote Uitgaansonderzoek 2023* (2024), 71.

Another important factor is the extent to which users are aware of the harmfulness of a substance. The bans on the three substances mentioned above were accompanied by a great deal of media attention regarding their health effects. The harmfulness of nitrous oxide as perceived by users increased significantly after reports of paralysis and other health effects appeared in the media.[13] 4-FA declined in popularity after it was shown to involve a risk of brain haemorrhages; many users subsequently turned (or returned) to ecstasy.[14] In addition to the expected risks of cardiovascular problems, 3-MMC carries significant risks related to sleep, anxiety, depression and dependency.[15] Nevertheless, its current use is higher than ever. Possibly, the information about the health risks of this substance remains insufficient or, for many users, the positive effects they experience still outweigh those risks.

"Legal production of MDMA prevents contaminated ecstasy tablets and tablets with very high or unclear dosages."

The availability of legally and pharmaceutically produced MDMA tablets prevents health incidents. The fact is, however, that the levels of contamination in illegal supply are currently very low, although many ecstasy tablets are overdosed. In theory, this situation can change quickly if certain developments occur within the criminal world, such as a sudden shortage of raw materials leading to the use of harmful substitutes. This means that legal production is much more effective in guaranteeing consistent good quality and dosage, resulting in fewer health incidents.

Nevertheless, pure tablets containing only MDMA in a 'normal' dosage can still cause (serious) health problems. Scientists still do not fully understand why MDMA proves fatal for some users, as explained earlier in Chapter 2. Even with fewer incidents due to better and responsible dosing, incidents can never be completely ruled out.

"The legal sale of MDMA by the state, through a state monopoly, provides more opportunities to control its distribution."

Currently, the entire ecstasy market is controlled by dealers who do not ask customers for their age. Regulated MDMA supply could require providers to enforce an age limit. Additionally, in a legal market a certain (potentially higher) minimum price could be enforced, making it more difficult, especially for young people, to purchase the substance.

However, for such a legal market to be effective, the illegal supply will have to be displaced. As long as the illegal market continues to exist – and the huge export volumes make it very likely that it will – users will continue to find ways of

13 Desirée Spronk, 'Lachgas', *trimbos.nl* (undated).

14 'Bij drug 4-FA werkt een slecht imago beter dan een verbod', *NOS* (2017).

15 '3-MMC: Risico's', *DrugsInfo* (undated).

buying cheap ecstasy from drugs dealers. A legal supply of MDMA will also have to compete with the convenience of dealers delivering their products directly to users' homes.

"Legal sales of MDMA provide more opportunities for conveying a prevention or harm reduction message during the sales transaction."

When people have to purchase their ecstasy from a staff member at a sales counter, there are possibilities for a talk about prevention. This talk may also cover the decision to use ecstasy. The staff member can share knowledge about harm reduction measures, and information for users can also be printed on legal MDMA packaging or leaflets. Under the current policy, such information can be provided when users have their tablets tested at a testing site, but many users will not do so.

"By moving MDMA from Schedule I to Schedule II, the government is more consistent in how it applies the Opium Act, which dictates that substances in Schedule I are more harmful than those in Schedule II."

In 2009, the National Institute for Public Health and the Environment (RIVM) conducted a comparative study into the harmfulness of drugs, including alcohol and tobacco. The researchers concluded that alcohol and tobacco, among others, are more harmful than MDMA, and that ecstasy is less harmful than cannabis.[16] This appears to create a divergence between scientific and legal reality; after all, the Opium Act classifies hard drugs as more harmful than soft drugs and includes both.

While such research can be helpful to increase the scientific validity of legislation, it remains important to note that substance bans are always determined by the context. This is mainly because, to some extent, such a ranking compares apples to oranges.[17] The damage to society and health caused by tobacco, for example, is fundamentally different from that caused by MDMA, making them virtually incomparable for policy purposes.

16 Jan van Amsterdam et al., *Ranking van drugs: Een vergelijking van de schadelijkheid van drugs* (2009), 9, 20.

17 Due to the diverse societal and health impacts of different drugs, there is not just one way to weigh them against each other. Additionally, evolving insights and societal developments regarding these substances must be taken into account. This is illustrated by a German comparative study from 2020, in which the researchers arrived at a different ranking than RIVM's ranking from 2009. The German study concluded that ecstasy was more or less equally harmful as cannabis. Refer to Udo Bonnet et al., 'Ranking the Harm of Psychoactive Drugs Including Prescription Analgesics to Users and Others–A Perspective of German Addiction Medicine Experts', *Frontiers in Psychiatry* (2020).

"The legalisation of MDMA and the creation of a legal market will reduce or eliminate the ability of criminal organisations to sell MDMA."

Proponents of this economic argument argue that by eliminating the Dutch sales market, illegal production will largely or completely disappear. After all, in a legal market customers who previously purchased ecstasy from dealers can be expected to switch to legal suppliers, directly impacting the revenue model of dealers and producers.

However, regarding MDMA in the Netherlands, it is more likely that such (hypothetical) legalisation will result in two parallel markets, with some consumers deliberately choosing the illicit one. Their reasons for doing so could include higher prices in the legal market, an age limit requirement or the convenience of immediate on-site delivery. Experience with cannabis in Canada shows that even several years after legalisation, there are still users who buy from the illegal market.

Furthermore, more than 90 per cent of Dutch production is intended for export. So even if demand for illegal MDMA were to decrease in the Netherlands, demand from abroad would persist, maintaining illegal production and trade, as well as the associated (organised) crime and environmental damage.

"Removing MDMA from the Opium Act would make it harder to prosecute and punish criminal organisations."

If MDMA is no longer classified under the Opium Act, its production or trade would no longer be a criminal offence under this Act. This means the possibility to apply Section 11b of the Opium Act or Section 140 of the Dutch Criminal Code in the prosecution of producers of and traders in ecstasy would be lost.[18]

The above statement is therefore correct. While it would still be possible to prosecute criminals for environmental offences and other criminal activities, an important ground for investigation and prosecution would be lost. To prosecute criminal MDMA producers without recourse to the Opium Act, alternative legislation would need to be identified and drafted to enable effective prosecution of production and trade.

One alternative may be found in the Medicines Act, provided MDMA is registered as part of a medical treatment. In the following chapters, the State Commission will discuss this therapeutic use of MDMA in further detail. If MDMA-assisted therapy becomes a standard medical treatment, MDMA will fall under the Medicines Act and illegal production and trade will be punishable under that Act.[19] However, the Medicines Act imposes much lighter penalties compared with the Opium Act. Additionally, under the Medicines Act, the investigation of crimes is assigned to inspectorates.

18 Section 11b of the *Opium Act* (2024).

19 Chapter 11 of the *Medicines Act* (2024).

Another consequence of such a move is that it could make the Netherlands even more attractive for international gangs. This will certainly be the case if the Netherlands is the only country to make this move and no other countries join this initiative.

"Moving MDMA to Schedule II means that less investigation capacity will be available to tackle and prosecute criminal organisations."

Illegal activities involving substances in Schedule II to the Opium Act carry lighter penalties than for substances in Schedule I, so if MDMA is moved to Schedule II, the penalties for trafficking and production will be reduced. Due to the lower maximum penalties for production and trafficking of substances in Schedule II, the provisional detention and consequently arrest of persons not caught in the act is not possible, unless the suspect is acting in the course of a profession or business. In addition, acts in preparation for the production and trafficking of MDMA would no longer qualify as criminal offences. Preparatory acts are criminalised under Section 10a of the Opium Act and constitute an independent offence. These acts can range from providing premises to selling specific goods that can facilitate drugs-related crimes.

These circumstances will result in reduced prioritisation of the investigation and prosecution of MDMA production and trafficking by the police and Public Prosecution Service. At the highest level, this policy is established in a guideline from the Public Prosecution Service. The general principle in the most recent guideline is 'the distinction made in the Opium Act between substances in Schedule I (hard drugs) and other substances (soft drugs)'.[20]

However, the most recent guideline dates from 2015. The explanatory notes to the policy regarding substances in Schedule II only discuss cannabis and mushrooms (psilocin, psilocybin and muscimol). Furthermore, the guideline states that 'if the violation of the Opium Act additionally involved organised crime, Section 11b of the Opium Act or Section 140 of the Dutch Criminal Code must be applied whenever possible'.[21] However, this only applies to substances in Schedule I to the Opium Act.

In practice, the investigative authorities and public prosecutors will deploy their capacity where this is likely to generate the most gains. Transfer of MDMA to Schedule II will reduce its priority.

"If MDMA is moved to Schedule II, recreational users may potentially face less stigmatisation. The use of MDMA in mental health treatment may also raise fewer concerns."

20 Article 2.1 of the *Designation order concerning the Opium Act* (2015).

21 Article 2.3 of the *Designation order concerning the Opium Act* (2015).

As described, removing the stigma from drug use is beneficial for public health. However, it is uncertain whether moving MDMA to Schedule II is conducive to this goal. Many people in the Netherlands are unfamiliar with the distinction between the two schedules, so a reclassification will probably yield little impact. At the same time, the term 'soft drugs' may carry less stigma than 'hard drugs'. However, there has not been enough research into the perceived symbolic value of the distinction between the two schedules to draw conclusions.

For patients considering MDMA-assisted therapy (refer to Chapter 5), the distinction could potentially be significant. The use of hard drugs in medical therapies can lead patients to reject the treatment method or experience self-stigmatisation. Effective information from the physician can make a significant difference; however, the established reputation of a substance can persist as long as it remains classified as a hard drug.

"The legal production of MDMA prevents drug waste."

The production of MDMA generates drug waste, and the illegal dumping of this chemical waste from MDMA labs is a major problem, especially in regions with high synthetic drug production. The waste is often dumped in the countryside, causing severe ecological damage and health risks to local residents. Decontamination of these dumpsites is extremely costly and complex, and the environmental damage can be long-lasting. Due to the illegal nature of production, there are no avenues to process this waste legally.

While legal production also generates waste, it can be processed in a professional manner. At legal production facilities, the costs of waste disposal can be significant but are often seen as an essential part of responsible business operations and regulatory compliance. The expectation is that the high costs involved (investments in the infrastructure required for waste management, operational costs and costs incurred to ensure compliance with environmental rules and standards) will be reflected in the price of legal MDMA. The big advantage, however, is that the waste does not end up in the natural environment. It must again be noted that even in a legal market, illegal export will continue to exist, and with it, the waste from illegal production. So, the above statement only holds if effective measures are in place to curb criminal production of MDMA.

"International conventions are never set in stone, and this also applies to the international ban on MDMA"

The ban on MDMA is enshrined in the international convention system. Pursuant to the 1971 Convention on Psychotropic Substances, MDMA falls under the strictest regime, which requires countries that are parties to that convention to include MDMA in their own opium legislation. Since this convention does not impose any sanctions if a country acts differently, it should in principle be possible for the Netherlands to pursue a divergent course.

In practice, however, things are more complicated. A country's decisions in one area (removing MDMA from the Opium Act) can have huge consequences for other policy areas that are relevant to the Netherlands. Consider the rights of minorities and legal equality, issues which have attracted strong Dutch advocacy internationally. By unilaterally deciding not to comply with the 1971 convention, the Netherlands would lose considerable credibility. This could negatively impact the legitimacy of other conventions that are important to this country.

/// **The health effects of MDMA appear to justify its transfer from Schedule I to Schedule II. However, organised crime and the societal harm arising from illicit production and trade practices make it undesirable to remove MDMA from its current schedule at this point in time.**

The State Commission's considerations

In the previous sections, the State Commission endeavoured to set frameworks concerning regulation, repression and intermediate approaches. The State Commission itself also engaged in discussions about this, both among its own members and with experts in the fields of public health, individual health, investigation and prosecution.

In view of the health hazards described in Chapter 2, it is not self-evident that MDMA should be in Schedule I to the Opium Act. Compared with other substances in that schedule, MDMA is far less harmful or addictive. The safety risks attributed to ecstasy 40 years ago, when it was a new substance, have largely been negated. As described, however, there is a very small risk of death following a dose of MDMA. Current knowledge about the causes of this is insufficient. There are reasons to classify this mortality risk as acceptable (and classify MDMA as a soft drug) but also to classify it as unacceptable (and classify MDMA as a hard drug); arguments can be found for both viewpoints. In either case, its inclusion in the Opium Act is defensible.

The State Commission is of the opinion that MDMA should continue to be governed by the Opium Act. In this regard, the State Commission argues that the individual and health risks, as well as the nuisance caused by users, are limited enough to justify inclusion of MDMA in Schedule II. The risks of MDMA are comparable or even smaller than many other risks in society that we consider acceptable, such as participation in road traffic, horse-riding, mountaineering and drinking alcohol. In this context, MDMA would be considered a substance with an *acceptable* health risk. The effects of this move will have different effects in different fields.

Users

For the existing group of users, inclusion of MDMA in Schedule II will not change anything. After all, using MDMA is not prohibited even today, and possession of very small quantities for personal use is tolerated. People who intend to use MDMA already know where to find the DIMS testing sites, and at events they feel safe consulting first-aid services without fear of prosecution.

For some people who currently do not use MDMA, reclassifying it from an unacceptable to an acceptable risk could be the final push to consider using MDMA once, or more frequently. However, MDMA use in the Netherlands is already high, making a significant increase unlikely. Including MDMA in Schedule II might affect the frequency of use: the current population of users might start taking MDMA more often because the risk is deemed acceptable. It should be reiterated in this context that the estimated harmfulness of MDMA has decreased in recent years.

Crime

Inclusion of MDMA in Schedule II would have consequences – mainly undesirable ones – as regards crime. In such a scenario, sentences for production and trade will become less severe, potentially making the clandestine MDMA industry even more attractive for criminals. Lower sentences will come on top of the attractive existing infrastructure for MDMA production that has been available in the Netherlands for years. In this context, inclusion in Schedule II not only makes the production and trafficking of MDMA even more attractive for Dutch criminals, but may also encourage foreign criminals to continue or develop activities in this country – again thanks to the existing infrastructure. It can be argued, however, that the penalties arising from the Opium Act – regardless of the schedule in which MDMA is included – are only one part of the overall charges against a dismantled drugs ring. Nevertheless, inclusion in Schedule II can affect the applicability of articles of law related to 'participation in a criminal organisation'. It may also have consequences for investigation. The police and the Public Prosecution Service have their own considerations in prioritising investigations. The severity of sentences is an important factor in these considerations. If sentences become less severe, it is possible that fewer resources will be allocated to investigating and combating the illegal MDMA industry. Given the significant societal impact of this type of crime, this outcome is unlikely. However, law enforcement could be hindered by legal obstacles such as the decriminalisation of preparatory acts and the inability to apply pre-trial detention in certain cases. Moreover, the reduced sentences may attract more criminal activity, thereby potentially increasing the demands on the police, even as their investigation capacity is already strained.

Conclusion

The State Commission calls for a debate on drug policy reform based on scientific insights into the actual effects of these reforms. This debate should result in a comprehensive vision for the future that addresses the complex issues faced by all legitimate stakeholders. Until organised crime is halted and this debate has been conducted, therefore, the State Commission believes it would be unwise to remove MDMA from the Opium Act or transfer it to Schedule II.

Recommendations

1 **Make sure that the societal and political debate on the future of drug policy is based on scientific insights.**
The State Commission has observed that spurious arguments are being used in the debate on the future of drug policy. A great deal of the existing knowledge on the effectiveness of drug policy interventions is rarely used, if at all, in the current polarised debate. The State Commission calls for all stakeholders to create space for evidence-based 'moderate positions' in this debate.

2 **Under the current circumstances, maintain the inclusion of MDMA in Schedule I to the Opium Act.**
Compared with other prohibited substances, the health effects of ecstasy are not serious and, as such, appear to legitimise a transfer of ecstasy from Schedule I to Schedule II. Separate from the debate on the health effects, however, the State Commission finds that the discussion on MDMA is to a certain extent being hijacked by criminals. Until certainty is provided that organised crime is pushed back and until all regulation options have been exhausted, it would be ill-advised at this time to remove MDMA from the Opium Act or transfer it to Schedule II.

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Part II: The therapeutic possibilities of MDMA

Introduction

A new era

Chapter 1 detailed the social developments in the 1960s that contributed to the end of clinical investigations into psychedelics-assisted therapy. A new era began at the start of the 21st century with the resurgence of scientific research into the therapeutic potential of psychedelics. This renewed interest is due to a number of developments. The State Commission will discuss the three most important among them.

Lack of effective innovation

First of all, biological psychiatry has been in a state of crisis since the end of the 20th century. For decades now, mental health conditions have increasingly been treated with medication, including antidepressants, relaxants, opioid painkillers and other psychoactive substances.[1] However, the number of patients has not decreased. In fact, this group of patients only appears to grow in size. Contrary to expectations, biological psychiatry has not contributed to a decrease in the number of mental health disorders, even though it has been supported by innovative medical technologies.

In the meantime, institutional psychiatry, dominated by psychiatric hospitals, was being replaced by an ambulatory approach. Medicines were supposed to make it easier for patients to reintegrate more easily into society. However, this approach was only partly successful and often did little more than suppress symptoms. Of note in this development is the place taken up by trauma-related conditions.

Since 1980, well-known disorders that had long been associated with war, exposure to death threats and serious injury have received specific attention. The action mechanism of biological psychiatry only partially held up when treating these disorders, in particular post-traumatic stress disorder (PTSD). Even though certain trauma-related complaints could be diminished by the daily intake of antidepressants, this did not suffice for truly processing the trauma.[2]

By now, we have reached a situation where biological psychiatry has, for decades, been unable to produce effective new treatments and some pharmaceuticals have actively withdrawn from researching new medication for mental health disorders.

Mental health care receives appropriate attention

Second, there is increasing social awareness of the individual and collective burden of disease of mental health disorders. For a long time, it was common to deny or even ridicule this burden. People with mental health problems or conditions are still victims of stigmatisation, more than people who suffer from physical diseases.[3] However, more attention has been paid recently to unstigmatisation and the proper acknowledgment and treatment of mental health conditions, such as depression, anxiety disorders and addictions. As a consequence, the Dutch government submitted the memorandum 'Good mental health for all' to the House of Representatives in 2022.[4] The topic has been put on the agenda at the European level as well. In 2023, the European Commission published a strategy to improve mental health in Europe.[5] These developments have contributed to renewed attention to new treatments, social awareness, as well as new forms of prevention.

1 Petra Gaffke et al., '1,2 miljoen Nederlanders slikken antidepressiva, dat zijn meer mensen dan ooit: "Medisch model wordt te snel toegepast"', *EenVandaag* (2023).
2 Anne Harrington, 'Mental Health's Stalled (Biological) Revolution: Its Origins, Aftermath & Future Opportunities', *Daedalus* (2023).
3 Wulf Rössler, 'The stigma of mental disorders: A millennia-long history of social exclusion and prejudices', *EMBO reports* (2016).
4 Maarten van Ooijen et al., 'Aanbieding aanpak "Mentale gezondheid: van ons allemaal"' (2022).
5 Directorate-General for Health and Food Safety, *A comprehensive approach to mental health* (2023), 1.

Even though the State Commission focuses on MDMA-assisted therapy in this report, it does underscore that prevention is always better than cure. This is a challenge for society as well. The Trimbos Institute, for example, has noted the different developments contributing to the rise of mental health problems, including the increased individualisation of society, the flexibilisation of the labour market, a one-sided focus on self-reliance, loneliness and decreasing social cohesion.[6] In addition, the European Commission has pointed to the consequences of the COVID-19 pandemic, the impact of the war in Europe (Ukraine) and other places in the world, the energy crisis, inflation, climate change, loss of biodiversity and environmental pollution.[7] The State Commission acknowledges that the present state of affairs calls for a comprehensive approach to promoting our mental health and effectively treating mental health conditions.

Promoting our mental health and reducing mental health disorders has significant advantages, both for reasons of solidarity and for the good of the economy. In the Netherlands, 25 per cent of collective expenses are related to health care, with mental health care forming an increasingly large segment thereof. Between 2003 and 2018, mental health care expenses grew from €5 billion to €8 billion.[8]

The effective prevention of mental health disorders may free up funding and staff for the provision of treatments that truly contribute to healing mental health patients. Various initiatives – including MDMA-assisted therapy – have been started up that can be deemed revolutionary. It is of major importance in this connection that sufficient funding and staff are made available for such treatments – provided they are demonstrably effective and safe – to allow health care services to continue to provide them.

Stigma surrounding psychedelics is decreasing

Third, certain developments, as described in the previous part of this report, play a role. Policy makers in various countries and cities are starting to question the usefulness, effectiveness and excesses of the international War on Drugs. For example, they wonder if the dangers related to the use of psychedelics like MDMA and psilocybin have not been overestimated and whether any (or all) psychedelics should be listed on a list of banned substances. Within psychiatric practice, these social developments have at any rate led to stagnation in the accumulation of knowledge and clinical and scientific research into the effectiveness and safety of psychedelics.[9]

6 Laura Shields-Zeeman et al., *Samen werken aan een mentaal gezonde samenleving: Bouwstenen voor mentale gezondheidsbevordering en preventie* (Utrecht: Trimbos Institute 2021), 5.

7 Directorate-General for Health and Food Safety, *A comprehensive approach to mental health* (2023), 1.

8 'Troonrede biedt aanknopingspunten voor Preventieakkoord GGZ', *Trimbos Institute* (2018).

9 David Nutt et al., 'Effects of Schedule I drug laws on neuroscience research and treatment innovation', *Nature Reviews Neuroscience* (2013).

Given this context, and partly in response to various well-programmed research initiatives[10], scientific interest in the therapeutic possibilities of psychedelics was renewed early this century.[11] Within the scientific community, the stigma surrounding research into the therapeutic use of psychedelics has decreased. Clinical studies of ever better methodological design and ever-increasing scope are once again being set up and conducted. The results of these new studies have been revolutionary to the point that the FDA has given them the status of breakthrough therapy.

As applies to all innovations, critical responses are heard as well[12], for example concerning the blinding used during studies and the long-term effects of treatment, and research proposals continue to be improved.[13] One consequence thereof, and of the three developments discussed above, is that treating physicians and patients express their support of research into and development of treatment methods that had been taboo for a long time more openly and with greater acceptance.

The following chapters will discuss these new developments.

10 Partly under the guidance of psychopharmacologist Roland Griffith at the Johns Hopkins Institute in Baltimore.

11 Michael Pollan, *How to Change Your Mind* (London 2018), 29.

12 L. Jacob Flameling et al., 'Expectancy Effects Cannot Be Neglected in MDMA-Assisted Therapy Research', *ACS Chemical Neuroscience* (2023).

13 Michiel van Elk et al., 'History repeating: guidelines to address common problems in psychedelic science', *Therapeutic Advances in Psychopharmacology* (2023).

Reader's guide

Chapter 5 discusses the definition and symptoms of PTSD, the existing treatments and their effectiveness. This is followed up on by a description of MDMA-assisted therapy and an overview of studies into the effectiveness and safety of this new treatment. The State Commission also raises a few points of attention requiring additional research. The State Commission's opinion is that MDMA-AT forms a promising, effective treatment that meets a need by treating physicians and patients to use MDMA in a specific setting and with assisted therapy (MDMA-AT).

Chapter 6 is a legal analysis of the rights and obligations with respect to MDMA-AT. It focuses on human rights, the United Nations drug treaties, European legislation and Dutch legislation.

Chapter 7 answers the question whether and how MDMA-AT can be made available in the Netherlands. The State Commission has identified various challenges in this connection, including the lack of an obvious financial incentive for the pharmaceutical industry to have this treatment registered at the European or national level. The State Commission describes various 'alternative routes' and discusses the advantages and disadvantages of these alternatives. Looking for solutions that appear to be effective elsewhere, we also consider the implementation of MDMA-AT in Australia and the United States, as well as the long experience with its use in Switzerland.

Chapter 8 shows that MDMA-AT has already started to take on a life of its own in the Netherlands, outside of the legal framework. Interest in and demand for MDMA-AT outside of the regular health care institutions appears to be increasing. The State Commission finds that this is leading to multiple undesirable developments, specifically: 1) patients and interested persons are, by way of experiment, using illegally produced and traded ecstasy to provide a therapeutic effect; 2) health care professionals and patients who are both convinced of the effectiveness and safety of MDMA-AT are finding each other and agree on illegal treatment appointments; and 3) commercial providers of MDMA-AT-inspired therapies treat patients without being competent to do so. In this chapter, the State Commission finds that no effective regulation on these developments exists and that patients with bad experiences have no way to raise a complaint.

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5 MDMA-assisted therapy

Introduction

In the past few years, MDMA has reached the headlines because of – among other things – its recreative use and the illegal production of and trade in the substance. It has also received attention as a possible new therapeutic remedy for certain mental health complaints. This particularly concerns the growing evidence of the effectiveness of MDMA-assisted therapy[1] to treat patients suffering from long-term PTSD complaints.

1 Commonly abbreviated as MDMA-AT.

5 MDMA-assisted therapy

Findings

The State Commission finds as follows:

/// **A number of proven treatments for PTSD exist, including pharmacotherapy, cognitive behavioural therapy (CBT) and Eye Movement Desensitisation and Reprocessing (EMDR).** Not all patients are sufficiently helped by these treatments. For certain patients with a chronic or therapy-resistant form of PTSD, existing treatment methods are insufficient.

/// **PTSD patients experience a great deal of suffering.** The care burden on those close to them is significant as well, as are the health care expenses and the burden on health care staff capacity.

/// **MDMA-AT is a proven and effective intervention for the treatment of PTSD.** This treatment may provide relief for patients who respond insufficiently to CBT and EMDR, either with or without additional pharmacotherapy.

/// **The specific treatment, of which the effectiveness has been studied, consists of two to three MDMA-assisted therapy sessions, followed by therapeutic integration sessions.** All sessions involve two treating physicians and one patient.

/// **Sufficient evidence exists to find that MDMA-assisted therapy for PTSD offered in a clinical, controlled setting is not only effective, but also relatively safe.**

/// **No scientific evidence exists that the (repeated) administration of MDMA only, without psychotherapy, forms an effective intervention for the treatment of PTSD.** No research has been conducted into MDMA as a purely medical intervention, as no indications exist that this is effective.

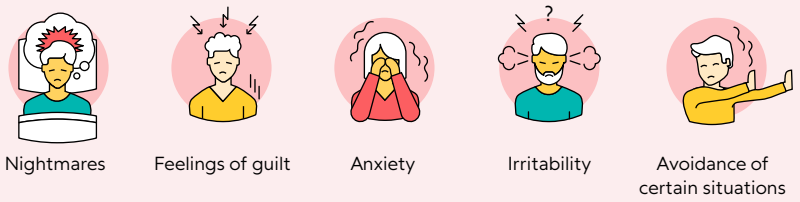
/// **For the purposes of its recommendations, the State Commission has only considered the treatment of PTSD with MDMA-AT, i.e. treatment with MDMA in combination with psychotherapy.** Too little is known about the possible use of MDMA-AT for other psychiatric or neurological conditions to make any definite conclusions on such use at this point in time. The State Commission is aware of the fact that, in due course, MDMA-AT could be used more widely in treatment settings, i.e. also for conditions other than PTSD.

/// **The use of MDMA-AT for the treatment of serious and usually long-term PTSD within clinical studies always took place within the existing legal framework.** MDMA of pharmaceutical quality was used and the therapy was given by certified therapists in treatment environments specifically equipped for this purpose.

/// **The State Commission believes MDMA-assisted therapy to be a promising form of treatment, one that is effective and meets the need of people suffering from long-term or therapy-resistant PTSD**.

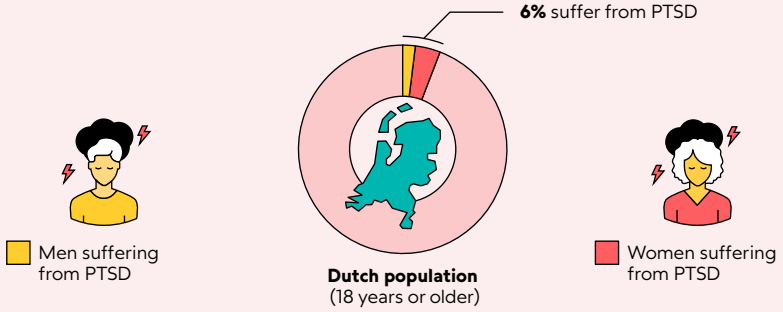
/// A number of proven treatments for PTSD exist, including pharmacotherapy, cognitive behavioural therapy (CBT) and Eye Movement Desensitisation and Reprocessing (EMDR). Not all patients are sufficiently helped by these treatments. For certain patients with a chronic or therapy-resistant form of PTSD, existing treatment methods are insufficient.

Figure 1
Characteristic symptoms of post-traumatic stress disorder (PTSD)



Nightmare, anxiety, feelings of guilt, irritability and avoidance: these are just a few of the symptoms of a post-traumatic stress disorder. An estimated 400,000 residents of the Netherlands have their quality of life diminished because of this condition, which may be the result of living through a potentially traumatising event that may involve having been confronted with death, serious injury or physical, emotional or sexual abuse during early childhood or after.[2] Women suffer from PTSD twice as often as men do, also because women are more often victims of sexual violence. PTSD is also more common than average among certain professions, including health care professionals, police officers, defence personnel, fire brigade staff and train drivers and conductors.[3]

Figure 2
Women are more likely to experience post-traumatic stress disorder



2 National Health Care Institute, *Verbetersignalement: Posttraumatische stress-stoornis* (2020), 4-10.
3 VZinfo.nl, 'Posttraumatische stressstoornis' and subpages (RIVM).

The symptoms may consist of re-living the trauma as flashbacks and in nightmares; sleeping problems; avoiding conversations, places and people; excessive vigilance; the inability to experience positive emotions; anxiety; and – sometimes – feelings of guilt and shame. These symptoms may also result in irritability, depression and physical complaints, but also in addiction and – sometimes – in self-destructive behaviour. Not only the people suffering from post-traumatic stress have their quality of life impacted: it also affects the lives of those close to them. Moreover, it puts a burden on society.[4]

Figure 3
Causes of post-traumatic stress disorder (PTSD)

War/conflict | Disasters | (Sexual) violence

Of the estimated 400,000 persons suffering from post-traumatic stress, some 90,000 receive mental health care each year. PTSD is also a factor for an estimated 18 to 23 per cent of the people looking for mental health care. A study by the National Health Care Institute has found that about 39 per cent of people suffering from PTSD receive trauma-related treatment, which is the preferred form of intervention. In 2020, the National Health Care Institute drew up an improvement plan for the treatment of PTSD, urging for the provision of more trauma-oriented psychological treatment to people suffering from the condition.[5]

Figure 4
PTSD is more prevalent among those in uniformed professions

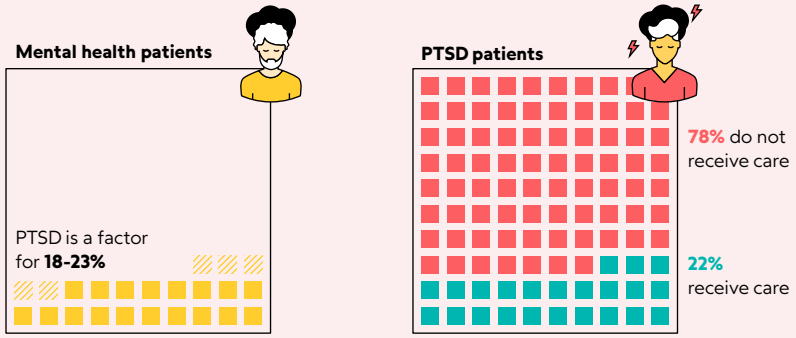
They face a **higher risk of exposure** to potential trauma
and are more likely to respond **less effectively to therapy**

4 National Health Care Institute, *Verbetersignalement: Posttraumatische stress-stoornis* (2020), 4-10.
5 National Health Care Institute, *Verbetersignalement: Posttraumatische stress-stoornis* (2020), 4.

Available PTSD treatments

In its report, the National Health Care Institute advised trauma-oriented psychotherapy for treating PTSD. At present, patients are mainly given trauma-oriented cognitive behavioural therapy (TO-CBT), such as exposure therapy, or Eye Movement Desensitisation and Reprocessing (EMDR). Other interventions focused on exposure are used as well. Some of the persons treated experience fewer symptoms and health complaints afterwards. They experience an increasing quality of life and of social and work-related functioning.

Figure 5
There are many PTSD patients, but only a fraction receive treatment for PTSD



Sixty-one per cent of the 90,000 PTSD sufferers in mental health care do not receive trauma-oriented treatment. This may be because of a lack of available slots, but also because the patient deems the treatment to be too intensive and causing too much anxiety. These patients continue experiencing symptoms and do not process their trauma properly. Instead of a trauma-oriented treatment, the majority of this group is given a combination of supportive treatment (such as conversations focused on regulating stress and emotions) and pharmacotherapy, usually by way of benzodiazepines and/or certain antidepressants.[6]

Benzodiazepines are potentially addictive substances that are often prescribed for sleeping and anxiety problems and, thus, for PTSD as well. Antidepressants are also prescribed in PTSD cases. This is always done to treat the symptoms; it does not constitute medicinal treatment of the PTSD itself. Two substances for treating PTSD are registered.[7] A recent study has shown that these often result in chronic use and are no more efficient than psychotherapy.[8] In its report, the National Health Care Institute called on physicians to prescribe benzodiazepines less often.[9] Medication is to be prescribed only for specific symptoms in case of crises, extreme anxiety, problems sleeping or disorganising vigilance.

6 National Health Care Institute, *Verbetersignalement: Posttraumatische stress-stoornis* (2020), 14, 55.

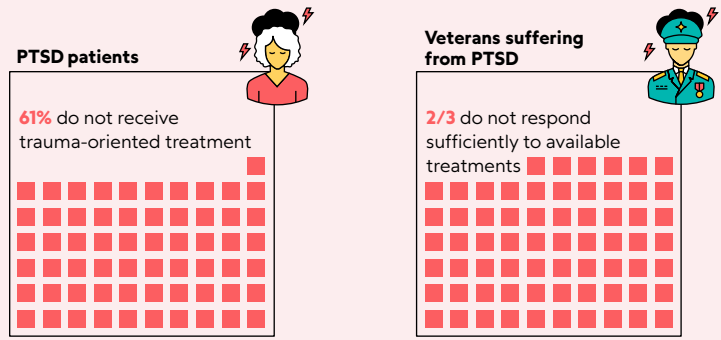
7 These are the selective serotonin reuptake inhibitors sertraline and paroxetine.

8 Ghazi Al Jowf et al., 'To Predict, Prevent, and Manage Post-Traumatic Stress Disorder (PTSD): A Review of Pathophysiology, Treatment, and Biomarkers', *International Journal of Molecular Sciences (2023),* 5238.

9 National Health Care Institute, *Verbetersignalement: Posttraumatische stress-stoornis* (2020), 4.

The National Health Care Institute has designated exposure therapy as the preferred treatment of PTSD. This type of therapy, which involves exposing patients to trauma-related memories in a systematic and controlled fashion, has proven to reduce PTSD symptoms effectively. By confronting their traumatic experiences in a safe, therapeutic environment, patients can learn to reduce their fears and to give new meaning to their experiences. This approach has been consistently supported by clinical research and is recommended as the treatment of first choice in the guidelines for treating PTSD.[10]

Figure 6
A large portion of PTSD patients hit roadblocks in regular care



Even though existing trauma-oriented therapy is effective for one segment of patients, another segment does not respond to it sufficiently well. They continue struggling with symptoms of PTSD. This applies in particular to certain specific audiences, primarily the uniformed professions. The effectiveness of available treatments has been studied among veterans treated for PTSD. Only a third of them was found to lose their PTSD diagnosis using the available treatments.[11]

/// PTSD patients experience a great deal of suffering. The care burden on those close to them is significant as well, as are the health care expenses and the burden on health care staff capacity.

This means that the existing treatments will not be effective for some tens of thousands of patients among the entire Dutch population suffering from PTSD. These patients will have tried multiple therapies, but failed to profit from them – a state that is named being 'therapy resistant'. Incidentally, this does not mean they cannot be helped by any therapy whatsoever. These patients continue to experience a great deal of suffering – which is often complicated by associated problems, such as depression, anxiety disorders or substance abuse – and run an increased risk of suicidal behaviour or desiring to end their life in another fashion.[12]

10 National Health Care Institute, *Verbetersignalement: Posttraumatische stress-stoornis* (2020), 9-11.

11 Maria Steenkamp et al., 'Psychotherapy for Military-Related PTSD: A Review of Randomized Clinical Trials', *Journal of the American Medical Association* (2015), 489-500.

12 Rahat Akbar et al., 'Posttraumatic stress disorder and risk of suicidal behavior: A systematic review and meta-analysis', *Suicide and Life-Threatening Behavior* (2022), 163-185.

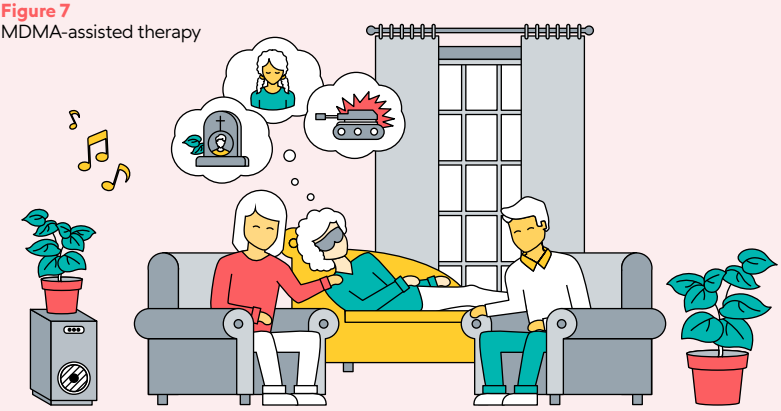
The State Commission finds that this therapy-resistant group of patients requires help – not just in the interest of improving their quality of life, and that of those close to them, but also in order to decrease the overall social and economic burden caused by PTSD. In this regard, the State Commission also wishes to note that PTSD can be prevented in some cases if victims are able to seek help in time after having experienced a traumatic event.

The State Commission calls on the government to allow for more research into variations of existing treatment methods and into innovative new treatment methods, in particular MDMA-AT, which has by now been proven to be effective. Exploring these and other new interventions may lead to more effective treatment and align more closely with personalised care, by which the patient and the treating physician decide together which treatment links up to the individual needs and circumstances of the patient.

The effect of MDMA in MDMA-AT

/// **MDMA-AT is a proven and effective intervention for the treatment of PTSD. This treatment may provide relief for patients who respond insufficiently to CBT and EMDR, either with or without additional pharmacotherapy.**

Figure 7
MDMA-assisted therapy



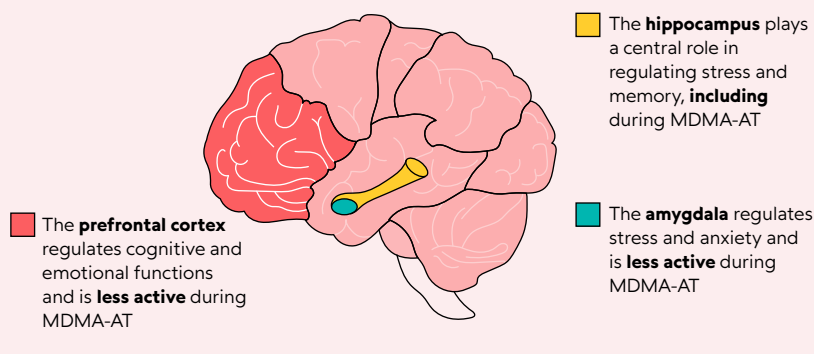
One crucial difference with the regular pharmacotherapeutic treatment of psychiatric disorders, including PTSD, is that MDMA is only used as a catalyst in psychotherapy sessions. Benzodiazepines and antidepressants are used to reduce depression and anxiety in the patient's daily life. No evidence exists that the use of MDMA in itself leads to reduced PTSD complaints, but it contributes to patients being more receptive to trauma processing, and thus to the therapy, as they experience less fear.

MDMA-AT involves the patient taking MDMA under the supervision of medical professionals. These therapists stay with the patient for the entire time the substance is active (depending on the dosage, this can be from four to six or from six to eight hours). In a common protocol, such MDMA-assisted therapeutic sessions take place two or three times. This means that, in contrast to existing medication taken for PTSD – such as antidepressants or benzodiazepines – the patient will not take pills daily or over a longer period of time. The MDMA

catalyses the therapy process and allows for the processing of traumas by those persons who have difficulty doing so otherwise.

As the National Health Care Institute noted as recently as 2020, exposure therapy still forms the most effective treatment for people with PTSD.[13] However, for some patients, mentally returning to the traumatic event in the context of exposure therapy is so emotionally taxing that they do not experience improvement from regular psychotherapy.[14] The use of MDMA during a therapeutic session helps patients reduce their anxiety and open themselves up in a more relaxed state. This allows for kickstarting the effective processing of traumatic memories and discussing it after the MDMA session.[15,16] Brain activity measurements have established that people who have taken MDMA have a less reactive amygdala – that part of the brain that plays a key role in processing and regulating stress, anxiety and other negative emotional stimuli. It would appear that the use of MDMA in this fashion allows patients mentally to relive a traumatic experience without becoming emotionally overwhelmed. The patient and the psychotherapist may then make use of this experience when processing the traumatic event and search for the new meaning best befitting it.[17]

Figure 8
MDMA expands the 'window of tolerance' (the extent to which people can process intense emotions in a healthy manner)



13 National Health Care Institute, *Verbetersignalement: Posttraumatische stress-stoornis* (2020), 9-11.

14 Catrin Lewis et al., 'Dropout from psychological therapies for post-traumatic stress disorder (PTSD) in adults: systematic review and meta-analysis', *European Journal of Psychotraumatology* (2020).

15 Friederike Holze et al., 'Distinct acute effects of LSD, MDMA, and D-amphetamine in healthy subjects', *Neuropsychopharmacology* (2019), 462–471.

16 Cédric Hysek et al., 'MDMA enhances emotional empathy and prosocial behavior', *Social Cognitive and Affective Neuroscience* (2013), 1645–1652.

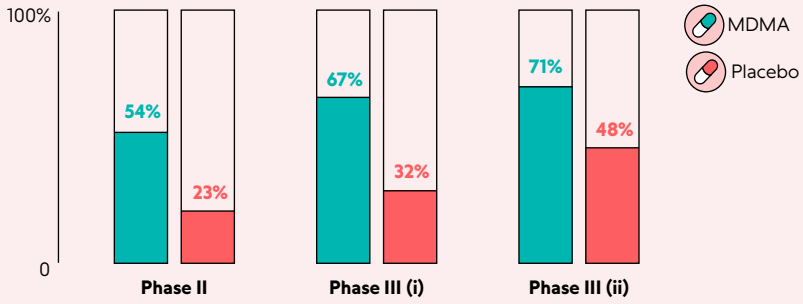
17 Jennifer Mitchell et al., 'MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study', *Nature Medicine* (2021), 1025–1033.

Studies into MDMA-AT

The Multidisciplinary Association for Psychedelic Studies (MAPS), an American NGO, plays a leading role in international research into the use of MDMA for treating PTSD. Ever since the 1980s, MAPS has been actively promoting studies into psychedelics in the context of various mental health conditions. Funding, from the Pentagon and by way of sizeable donations, allowed MAPS to set up small-scale studies into the effectiveness and safety of the use of MDMA for treating veterans suffering from serious PTSD. The organisation then set up six phase II trials (total n=103), which were published in bundled format in the medical journal *The Lancet*. The publication showed that 54 per cent of the participants who were administered MDMA no longer met the criteria for PTSD, as opposed to 23 per cent from the group who received an active placebo and supporting psychotherapy – a very significant effect.[18]

/// The use of MDMA-AT for the treatment of serious and usually long-term PTSD within clinical studies always took place within the existing legal framework. MDMA of pharmaceutical quality was used and the therapy was given by certified therapists in treatment environments specifically equipped for this purpose.

Figure 9
The results of MAPS research on MDMA-AT are positive



The MDMA used in the studies into MDMA-AT was produced by specially licensed medicine manufacturers. The MDMA capsules used met Good Manufacturing Practices (GMP), the medical standard of the World Health Organization. The studies took place in treatment settings set up for MDMA-AT. Refer to Chapter 6 for the legal frameworks concerning MDMA-AT.

/// No scientific evidence exists that the (repeated) administration of MDMA only, without psychotherapy, forms an effective intervention for the treatment of PTSD. No research has been conducted into MDMA as a purely medical intervention, as no indications exist that this is effective.

18 Michael Mithoefer et al., 'MDMA-assisted psychotherapy for treatment of PTSD: Study design and rationale for phase 3 trials based on pooled analysis of six phase 2 randomized controlled trials', Psychopharmacology (2019), 2735–2745.

The studies into MDMA-AT always investigated the combination of MDMA and psychotherapy to treat PTSD. This means that no research has been conducted into MDMA as a purely medicinal intervention. As a result, no scientific evidence exists for ascribing any independent therapeutic effect to the substance MDMA.

Clinical trials in four phases

Four trial phases are distinguished when developing a treatment, such as a pharmacological treatment with a medicine. Researchers adhere to the following phases for each study into a new treatment:

Phase I

The first trial phase focuses on whether the medicine or other treatment type is safe. This phase usually takes no longer than one year. As a rule, a small number of healthy volunteers participate, but patients for whom other treatments were not effective may also be involved in the study. The researchers study the tolerance and safety of the medicine or treatment. One important aspect of phase I trials is determining the maximum dosage before toxicity becomes unacceptable. One way to investigate such harmful effect is by increasing the dosage in increments until a predetermined level of toxicity is reached.[19]

Phase II

The focus during the second trial phase is on the effectiveness of the treatment for a small number of patients who suffer from the relevant condition. If the treatment appears to be ineffective, the trial stops at this phase. In certain cases, this phase is composed of IIa and IIb trials. The IIa phase focuses on the dosage that appears to be most effective and the IIb phase focuses on both the intended and the side effects. This phase commonly lasts a few years. Ideally, between 100 and 300 carefully selected patients participate in a phase II trial.[20,21]

Phase III

During trial phase III, the findings of the phases I and II are confirmed in a three to four-year study among multiple hundreds or even a few thousand patients, who are monitored for a long time. This method also provides for the measurement of long-term effects. During this phase, the researchers compare the effects with those of existing treatments and/or of a placebo. The results of a phase III trial form the basis for the submission of a registration dossier with a medicines authority.[22]

Phase IV

Trial phase IV starts following the registration of the treatment studied. From that moment onwards, physicians are allowed to prescribe the medicine or treatment. However, when they do so, they are required to monitor their patients and to report new side effects to the medicines authority.[23,24]

19 Lawrence Friedman et al., *Fundamentals of Clinical Trials* (2015), 5-7.
20 CCMO, 'Fase I, II, III en IV', *ccmo.nl* (undated).
21 Lawrence Friedman et al., *Fundamentals of Clinical Trials* (2015), 7-9.
22 CCMO, 'Fase I, II, III en IV', *ccmo.nl* (undated).
23 CCMO, 'Fase I, II, III en IV', *ccmo.nl* (undated).
24 Lawrence Friedman et al., *Fundamentals of Clinical Trials* (2015), 9-10.

The results of these studies provided cause for the U.S. Food and Drug Administration (FDA) to award the therapy the status of breakthrough therapy in 2017. Being awarded this status means that researchers are able to complete the registration procedure in an accelerated fashion, in cooperation with the medicines authority.[25] The FDA acknowledged that MDMA-AT provided substantial advantages compared to existing PTSD treatments, such as treatment with antidepressants.[26]

Two phase III trials were set up after the breakthrough therapy status was awarded. This is a common sequence for clinical studies in medication. During phase III trials, the effectiveness and safety of a new treatment are evaluated against existing standard treatments. These trials usually involve a great many participants. They are essential for having new medicines approved by the regulatory body, such as the FDA in the United States or the European Medicines Agency (EMA) (refer to box on page 159).

In 2021, the results of the first phase III trial were published in the leading journal *Nature Medicine*. In order to measure the seriousness of the complaints, the Clinician Administered PTSD Scale for DSM-5 (CAPS-5), the default method for diagnosing PTSD, was used. With the CAPS-5, the existence and seriousness of PTSD is established on the basis of the patient's answers to 30 questions. Should the patient exceed a certain threshold (commonly 35) for certain symptom categories (distinguished in the CAPS-5 interview), a PTSD diagnosis may be made.[27] Over the course of the first phase III trial, the CAPS-5 score of the group receiving MDMA-AT decreased by 24.4 points, as compared to a 13.9-point decrease in the group receiving a placebo. With an 'effect size' of d=0.91, the effect was once again significant. Following treatment with MDMA-AT, 67 per cent of participants scored below the PTSD threshold, as opposed to 32 per cent in the placebo group.[28]

Applying for a registration procedure with the FDA requires the completion of two phase III trials. The second phase III trial, published in 2023, confirmed the results of the first trial. This trial showed that 71 per cent of participants in the MDMA-AT group no longer met the PTSD criteria, as opposed to 48 per cent of participants in the placebo group. This trial also included participants from various ethnic backgrounds, without any significant differences in the established effect being found between the various ethnic groups.[29]

Recently, the long-term results of the first phase III trial were presented as well. They show that the positive effects of the intervention were long-term in nature

25 MAPS, 'FDA Grants Breakthrough Therapy Designation for MDMA-Assisted Therapy for PTSD, Agrees on Special Protocol Assessment for Phase 3 Trials', *maps.org* (2017).

26 Allison Feduccia et al., 'Breakthrough for trauma treatment: Safety and efficacy of MDMA-assisted psychotherapy compared to paroxetine and sertraline', *Frontiers in Psychiatry* (2019), 1–9.

27 Arq Psychotrauma Expert Groep, 'Clinician-administered PTSD scale for DSM-5 (CAPS-5)', *psychotraumadiagnostics.org* (2018), 1–22.

28 Jennifer Mitchell et al., 'MDMA-assisted therapy for severe PTSD: a randomized, double-blind, placebo-controlled phase 3 study', *Nature Medicine* (2021), 1025–1033.

29 Jennifer Mitchell et al., 'MDMA-assisted therapy for moderate to severe PTSD: a randomized, placebo-controlled phase 3 trial', *Nature Medicine* (2023), 2473–2480.

and that no relapse or increased tendency to repeated MDMA use were identified.[30] In late 2023, MAPS submitted the results of this and of previous trials to the FDA to apply for the registration of MDMA-AT as a treatment for PTSD. Expectations are that approval will be granted in late 2024 or early 2025.[31]

The course of the treatment

/// The specific treatment, of which the effectiveness has been studied, consists of two to three MDMA-assisted therapy sessions, followed by therapeutic integration sessions. All sessions involve two treating physicians and one patient.

The MDMA-AT treatments have been clinically researched in studies funded by the MAPS NGO. These studies followed a uniform protocol. Summarily put, the entire MDMA treatment can be split into three phases.

1 **Preparation phase:** The patient and the therapists discuss the objectives and how to realise them using MDMA-AT. The patient and the therapists also work on building up their bond of trust and explore their mutual expectations and the support available at home. As a rule, this takes up three 90-minute sessions. It is also during this phase that the psychiatric and medical background and the patient's medication use are recorded.[32]

2 **MDMA-assisted sessions:** Two or three MDMA-assisted sessions are held, with one-month intervals. The patient is provided with a capsule containing 80 to 120 milligrams of MDMA at the start of the session. A supplementary tablet containing 40 to 60 milligrams may be offered. Due to the length MDMA is active, this session lasts six to eight hours. The effect of MDMA allows patients to focus on an internal process. MDMA opens up avenues to connect with moments and events that were too painful, shocking or confusing at the time the patient was exposed to the trauma. This allows for exploring and sharing various emotional experiences. The role played by the treating physicians differs from that during trauma-oriented therapy. They adopt a non-directive attitude, which means that the patient determines the pace and direction, and the treating physicians follow the process. These sessions are also characterised by the use of instrumental (non-verbal) music and patients may wear an eye mask to make contact with the intensified experience without external visual stimuli. Regular verbal contact is made in order to follow the patient. Typical for MDMA-assisted sessions is that the patient is better able to explore the emotional burden of traumatic memories under the influence of MDMA than they would be in regular psychotherapeutic sessions, when the emotions are unreachable because of the pressure exerted by anxiety or any form of resistance.

3 **Integration:** As a rule, each MDMA-assisted session is followed up on by three

30 Jennifer Mitchell, 'Primary Findings From a Long-Term Observational Follow-Up Study on MDMA-Assisted Therapy for Treatment of PTSD: MPLONG', *Neuropsychopharmacology* (2023), 1–62.

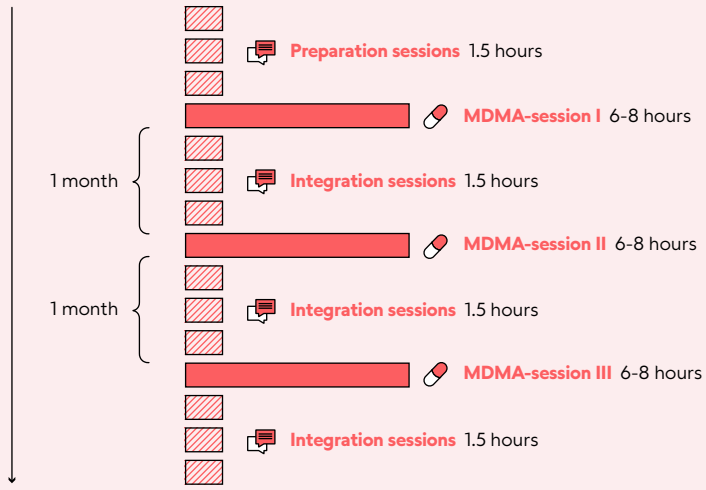
31 MAPS, 'MAPS Celebrates Submission of New Drug Application to FDA for MDMA-Assisted Therapy for PTSD', *maps.org* (2023).

32 William Richards et al., 'Psychedelic Psychotherapy: Insights From 25 Years of Research', *Journal of Humanistic Psychology* (2016), 323–337.

to four therapeutic sessions, the first of which takes place on the morning immediately following the MDMA session. During these therapeutic sessions, the patient discusses how the impressions they received during the MDMA-assisted sessions can be translated into daily life. In addition, the patient and the treating physicians explore how, for example, the persons close to the patient are involved in the process. They may also join the conversation. This phase is mainly about searching for meaning in what was experienced during the MDMA-assisted session and the meaning of the access to elements of the traumatic past that could not be examined before. An exploration takes place of how these experiences may lead to insight – or, in more classical terms, to 'processing' or 'cognitive restructuring'.[33, 34, 35]

In principle, the MDMA-assisted sessions are separated by a month. The complete treatment therefore takes about four months. As a rule, then, the patient is administered MDMA under supervision three times during this period.

Figure 10
The course of the MDMA-AT treatment



33 Giorgio Mauro et al., 'Psychedelica en psychedelica-ondersteunde psychotherapie', *Tijdschrift voor Psychotherapie* (2023).

34 Michael Mithoefer, *A manual for MDMA-assisted psychotherapy in the treatment of posttraumatic stress disorder* (2017).

35 Macha Godes et al., 'Perceived key change phenomena of MDMA-assisted psychotherapy for the treatment of severe PTSD: an interpretative phenomenological analysis of clinical integration sessions', *Frontiers in Psychiatry* (2023).

/// Sufficient evidence exists to find that MDMA-assisted therapy for PTSD offered in a clinical, controlled setting is not only effective, but also relatively safe.

Safety

The safety of MDMA-AT is a subject of current research.[36] The current clinical studies show the following results:

1. MDMA-AT appears to have a safe profile when used in a clinical setting, under the supervision of trained treating physicians. The sessions take place in a controlled, therapeutic environment. A thorough screening is performed beforehand, meticulous monitoring takes place during the session and aftercare is provided.
2. Some side effects reported when using MDMA in therapeutic settings include fatigue, headache, insomnia and emotional dysregulation shortly after the session. Serious side effects, such as may result from recreative MDMA use (including overheating, lack of natrium and excessive muscle wasting), have not yet been reported following the use of MDMA under professional supervision.
3. The screening beforehand is important, as certain risks are associated with MDMA – in particular for persons suffering from specific medical conditions, like heart problems.
4. The research into the safety and effectiveness of MDMA-AT is still in full swing. Large-scale clinical trials and long-term studies are required to obtain a more complete picture of its safety and effectiveness.

Side effects

The side effects of MDMA-AT can be divided into three time periods following the consumption of MDMA and on the basis of the observed side effects.[37,38]

First 24 hours following consumption: Patients may suffer from fatigue, insomnia and panic attacks. Physical side effects in this phase include headaches, teeth grinding and dizziness.

24 to 72 hours after consumption: Symptoms like headaches, insomnia and heart palpitations may occur, as may psychological effects like fatigue and anxiety. These side effects at times resemble the 'Tuesday dip' experienced by recreative users[39], but may also be related to the coping process following a therapeutic MDMA session.[40] No side effects like permanent visual distortions ((Hallucinogen Persisting Perception Disorder, HPPD) have been identified during the MDMA-AT studies. These side effects do occur, albeit rarely, among

36 National Library of Medicine, 'Search Results', *clinicaltrials.gov* (undated).

37 Joost Breeksema et al., 'Adverse events in clinical treatments with serotonergic psychedelics and MDMA: A mixed-methods systematic review', *Journal of Psychopharmacology* (2022), 1100–1117.

38 Christiaan Hucke, 'Tolerability and Safety of MDMA-Assisted Psychotherapy: A Systematic Review. Insights for Public Health and Treatment Decisions' (2023).

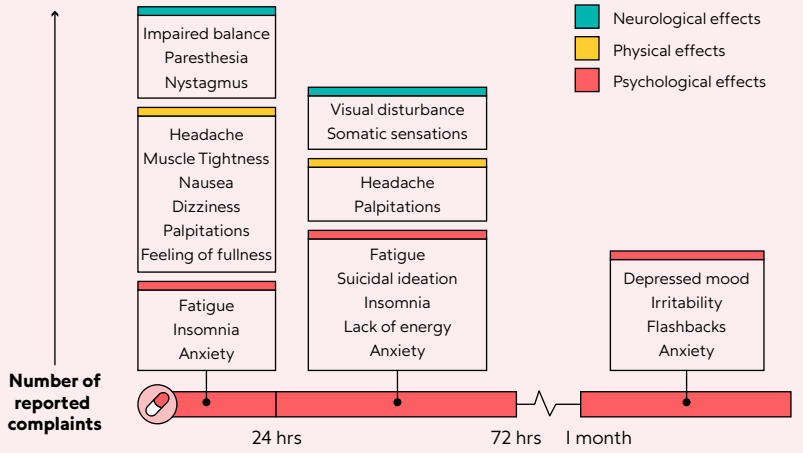
39 Ben Sessa et al., 'Debunking the myth of "Blue Mondays": No evidence of affect drop after taking clinical MDMA', *Journal of Psychopharmacology* (2021), 360–367.

40 Jacob Flameling et al., 'Not too quick on 'Debunking the myth of "Blue Mondays"'', *Journal of Psychopharmacology* (2022), 1001–1004.

recreative psychedelics users.[41] Two of the 90 participants in the phase III trials reported suicidal thoughts and one participant was hospitalised in this connection. Both participants were in the control group, who had taken a placebo instead of MDMA.[42]

72 hours to one month after consumption: No physical side effects are experienced any longer, but psychological side effects like anxiety, irritation, depressed mood and flashbacks may occur and may be related to the initial complaints the patient had when starting the programme. This emphasises the importance of screening (refer to Figure 10).[43]

Figure 11
Adverse effects of MDMA-AT: complaints and phases



Source Chris van Hucke (2023)

These side effects occur despite the clinical setting and the use of pharmaceutically produced MDMA. Even though serious side effects are rare, care must still be taken.

One review into the negative side effects observed in clinical MDMA studies reported that these side effects are often not defined consistently or clearly. This renders any comparison between studies more difficult. Uniform registration methods are crucial to obtaining a better insight into these side effects and how to prevent them.

41 Christiaan Hucke, 'Tolerability and Safety of MDMA-Assisted Psychotherapy: A Systematic Review. Insights for Public Health and Treatment Decisions' (2023), 9, 16.

42 Joost Breeksema et al., 'Adverse events in clinical treatments with serotonergic psychedelics and MDMA: A mixed-methods systematic review', *Journal of Psychopharmacology* (2022), 1100–1117.

43 Joost Breeksema et al., 'Adverse events in clinical treatments with serotonergic psychedelics and MDMA: A mixed-methods systematic review', *Journal of Psychopharmacology* (2022), 1100–1117.

Contraindications and warnings

A contraindication is an indication or circumstance that militates against prescribing a certain treatment or medicine. The safety and effectiveness of MDMA-AT are still being studied, meaning that new information may still lead to adjustments to currently used contraindications. The contraindications of MDMA include factors that make the use of MDMA dangerous to or unsuitable for certain individuals. They are the following:

1 **Heart conditions:** Persons suffering from existing heart conditions, including uncontrolled hypertension, heart failure or an earlier myocardial infarction, run an increased risk because of the stimulating effects of MDMA, which may increase heart rate and blood pressure.

2 **Neurological conditions:** Persons suffering from epilepsy and other neurological conditions may run an increased risk of side effects from MDMA use.

3 **Pregnancy and breastfeeding:** The use of MDMA during pregnancy or when breastfeeding is discouraged due to the associated risks for the baby.

4 **Interactions with medication:** MDMA may interact dangerously with certain medication, such as MAOIs, certain antidepressants (including SSRIs and SNRIs) and other psychoactive or stimulating substances.

5 **Liver or kidney problems:** Persons with clinically significant liver or kidney problems may run an increased risk due to how MDMA is metabolised and excreted, possibly resulting in an overdose. This is a theoretical risk that exists for all medicines.

6 **Serious psychological instability:** Persons who currently are seriously psychologically instable or display a high rate of suicidality are possibly not suitable MDMA therapy candidates.

Finally, care must be exercised in connection with persons suffering from psychiatric disorders, like bipolar disorder, schizophrenia or other psychotic disorders, as MDMA may exacerbate the symptoms of those conditions. While this is not a contraindication, it is a point of concern.

Depression and anxiety disorder do not, in themselves, constitute a contraindication in the studies into MDMA-AT to treat PTSD.[44]

44 Michael Mithoefer et al., 'MDMA-assisted psychotherapy for treatment of PTSD: Study design and rationale for phase 3 trials based on pooled analysis of six phase 2 randomized controlled trials', *Psychopharmacology* (2019), 2735–2745.

Treatment capacity

Therapists who perform MDMA-AT sessions must be specifically trained to work with patients under the influence of this psychedelic substance within a therapeutic context. This training includes learning about the effects of MDMA, but also learning skills to counsel patients during the often intense processes and the associated intense emotions that the use of MDMA may cause. It is therefore important that the availability of MDMA-AT is limited to those institutions and professionals in possession of the right training and qualifications to offer this specialised form of therapy safely and effectively. This requires significant investments in the training and infrastructure required in order to reach satisfactory treatment capacity and, therefore, to make this treatment form sufficiently accessible.

Effectiveness of MDMA-AT

The number of registered studies into the clinical effectiveness of MDMA-AT for PTSD has increased significantly in recent times. Since 2001, about 33 of such clinical studies have been or are still being conducted. This is a relatively sizeable amount for a non-registered treatment. The research into MDMA-AT to treat PTSD in the United States initially focused mainly on veterans and other uniformed professionals.[45] That is to say, it concentrated on those professions where PTSD most often results in therapy resistance and suicide.[46] As became apparent from the various clinical trials, MDMA-AT proved highly effective for many people who could not be helped using traditional, proven effective treatment methods. The approach not only reduces symptoms effectively, but may in certain cases even result in the PTSD diagnosis no longer applying, which effectively means that these patients have recovered.

In this report, the State Commission only assesses the use of MDMA-AT to treat the diagnosis of PTSD, as far fewer studies have been conducted in the context of other conditions. The State Commission is, however, aware that MDMA may, in time, be used more broadly for treatment. The effectiveness of this is yet to be assessed. Nevertheless, the present advice considers a future in which MDMA-AT might be used more widely.

45 Aaron Wolfgang et al., 'Psychedelic-Assisted Therapy in Military and Veterans Health care Systems: Clinical, Legal, and Implementation Considerations', *Current Psychiatry Reports* (2023), 514.

46 Rahat Akbar et al., 'Posttraumatic stress disorder and risk of suicidal behavior: A systematic review and meta-analysis', *Suicide and Life-Threatening Behavior* (2022), 163–185.

MDMA-AT to treat other conditions

/// For the purposes of its recommendations, the State Commission has only considered the treatment of PTSD with MDMA-AT, i.e. treatment with MDMA in combination with psychotherapy.
Too little is known about the possible use of MDMA-AT for other psychiatric or neurological conditions to make any definite conclusions on such use at this point in time. The State Commission is aware of the fact that, in due course, MDMA-AT could be used more widely in treatment settings, i.e. also for conditions other than PTSD.

In contrast to its use to treat PTSD, research into its use for other diagnoses has barely started up. The unique entactogenic effect of MDMA, which boosts feelings of emotional openness, empathy and connection, could potentially be used to treat conditions like autism[47,48], social anxiety[49], alcohol addiction[50] and eating disorders.[51] It may also be used to address the fear associated with the approaching end of one's life. In addition to studies into the effects on veterans and other uniformed professions (police, health care professionals), future studies may also focus on other audiences, such as refugees and adolescents, and on various indications, such as prolonged grief disorder, as well as less well-known indications, such as moral trauma.[52] The transdiagnostic limits of MDMA-AT have not been fully established yet, as the research in the context of diagnoses other than PTSD is often limited to one or only a few studies.

47 Alicia Danforth, 'Embracing Neurodiversity in Psychedelic Science: A Mixed-Methods Inquiry into the MDMA Experiences of Autistic Adults', *Journal of Psychoactive Drugs* (2019), 146-154.

48 Alicia Danforth et al., 'Reduction in social anxiety after MDMA-assisted psychotherapy with autistic adults: A randomized, double-blind, placebo-controlled pilot study', *Psychopharmacology* (2018), 3137–3148.

49 Jason Luoma et al., 'Potential processes of change in MDMA-Assisted therapy for social anxiety disorder: Enhanced memory reconsolidation, self-transcendence, and therapeutic relationships', *Human Psychopharmacology: Clinical and Experimental* (2021).

50 Ben Sessa et al., 'First study of safety and tolerability of 3,4-methylenedioxymethamphetamine-assisted psychotherapy in patients with alcohol use disorder', *Journal of Psychopharmacology* (2021), 375–383.

51 Timothy Brewerton et al., 'MDMA-assisted therapy significantly reduces eating disorder symptoms in a randomized placebo-controlled trial of adults with severe PTSD', *Journal of Psychiatric Research* (2022), 128–135.

52 Also known as moral injury: an injury to the moral compass of, for example, veterans and police officers after they have become witnesses to or co-perpetrators of violations of their own moral expectations and beliefs. Moral injury may express itself in anger, shame, feelings of guilt and moral disorientation. Refer to Tine Molendijk, 'Warnings against romanticising moral injury', *The British Journal of Psychiatry* (2021), 1–3.

Studies into the use of MDMA-AT to treat PTSD have already considered the alcohol and drug abuse of participants, as such use is more prevalent among PTSD patients. A small-scale study into MDMA-AT to treat PTSD featuring 14 participants reported a positive change in alcohol abuse levels, but more research is required to prove the effectiveness of MDMA-AT to counter substance abuse.[53] Finally, MDMA-AT could possibly be used to treat existential anxiety, in particular among terminally ill patients. MDMA might help such patients to resign themselves to their mortality, reduce their fear for their life ending and improve their quality of life in their final days. As is the case for the study into alcoholism, the scientific evidence for its use in palliative care is so far limited.[54,55]

Conclusion

/// The State Commission believes MDMA-assisted therapy to be a promising form of treatment, one that is effective and meets the need of people suffering from long-term or therapy-resistant PTSD.

The scientific basis for the therapeutic use of MDMA has grown rapidly in the past few years. In the opinion of the State Commission, there now appears to be sufficient evidence for its effectiveness as regards the primary indication: the treatment of PTSD. In addition to a significant decrease in symptoms, patients are often no longer diagnosed as suffering from PTSD. Furthermore, the studies show that this treatment is safe when provided in a clinical setting. However, uncertainties about conditions that may emerge following the PTSD treatment still exist. In view of the limited options available to treat severe PTSD, the State Commission considers MDMA-AT to be a fruitful addition to the mental health care system.

Recommendations

Basing itself on the currently available knowledge, the State Commission has arrived at a number of recommendations. These are bundled with the recommendations from Chapter 7 on pages 186–204.

53 Ben Sessa et al., 'First study of safety and tolerability of 3,4-methylenedioxymethamphetamine-assisted psychotherapy in patients with alcohol use disorder', *Journal of Psychopharmacology* (2021), 375–383.

54 Philip Wolfson, 'MDMA-assisted psychotherapy for treatment of anxiety and other psychological distress related to life-threatening illnesses: A randomized pilot study', *Scientific Reports* (2020), 20442.

55 Xuepeng Jing et al., 'Psychedelic medicines for end-of-life care: Pipeline clinical trial review 2022', *Palliative & Supportive Care* (2023), 1–8.

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6 Rights and obligations concerning MDMA-AT

Introduction

A range of international treaties and Dutch laws are important in the context of using a psychotropic substance as a medicine. The international treaties include the United Nations drug control conventions (treaties) as well as the human rights treaties of the United Nations. No legislation specifically relating to MDMA-AT exists at the European level: the European Union has aligned itself with the United Nations treaties.

On the following pages, the State Commission will analyse the legal frameworks touching upon the legal use of MDMA-assisted therapy.

6 Rights and obligations concerning MDMA-AT

Findings

The State Commission finds as follows:

/// **The World Health Organization (WHO) renders advice to the Commission on Narcotic Drugs on the possible move of a substance from one list to another.** In order to create additional legal room for manoeuvre, the Netherlands may apply to the WHO to assess and, if necessary, reconsider the current inclusion of MDMA in Schedule I to the Convention on Psychotropic Substances of 1971.

/// **The United Nations allow the use of MDMA for very limited medical purposes under the Convention on Psychotropic Substances of 1971 (hereinafter: the Convention).** Based on the Commentary on the Convention and existing practice, sufficient scope exists to prescribe MDMA for the purposes of MDMA-AT.

/// **Human rights are set forth in treaties concluded by the United Nations and the Council of Europe.** While their focus differs from those of the drug treaties, they do not necessarily contradict them where MDMA-AT is concerned.

/// **Human rights give patients entitlements to proven effective psychiatric treatment, provided that the Netherlands has sufficient financial (and other) resources to make such treatment available.** The affordability of the treatment therefore plays a part.

/// **European legislation does not impose legal limitations on the medical use of MDMA.**

/// **Were MDMA to be registered as a medicine, both the Dutch Medicines Act and the Dutch Opium Act would apply.** This means that the Opium Act would not cease to have effect if MDMA were to be designated a medicine. An exemption under the Opium Act therefore continues to be a requirement.

/// **In addition to the Opium Act, the Opium Act Decree is relevant.** To allow for the therapeutic use of MDMA, it must be listed in Schedule 1 to the Opium Act Decree.

International treaties

Objective of the UN drug treaties

/// The WHO renders advice to the Commission on Narcotic Drugs on the possible move of a substance from one list to another. In order to create additional legal room for manoeuvre, the Netherlands may apply to the WHO to assess and, if necessary, reconsider the current inclusion of MDMA in Schedule I to the Convention on Psychotropic Substances of 1971.

The United Nations drug treaties were discussed in Chapter 3. As was explained in that Chapter, the essence of the UN drug treaties is that they are to prevent social and health problems. At the same time, they endorse the medical and scientific use of substances. This becomes apparent from the preamble to the Convention of 1971, which reads:

> ***'Noting with concern the public health and social problems resulting from the abuse of certain psychotropic substances,'***[1]

but also:

> ***'Recognizing that the use of psychotropic substances for medical and scientific purposes is indispensable and that their availability for such purposes should not be unduly restricted.'***[2]

By consequence, the objective of the two drug treaties is to establish control measures to guarantee the availability of narcotics and psychotropic substances for medical and scientific purposes and at the same time to prevent them from ending up in illegal channels. The treaties therefore aim to create a balance between facilitating medical and scientific use on the one hand and preventing illegal trade and other forms of abuse on the other. The legal experts Piet Hein van Kempen and Masha Federova refer to a 'double fundamental objective' in this connection.[3]

Both treaties allow for the production, distribution or possession of the relevant substances for medical and scientific use. However, neither of the two treaties defines such medical and scientific use, providing State Parties with room for interpretation.[4]

MDMA is included in Schedule I to the *Convention on Psychotropic Substances* of 1971. This means that it is subject to strict checks and has been criminalised in most countries. Article 7(a) of the Convention requires Parties to '[p]rohibit all use except for scientific and *very limited medical purposes* [...].'[5]

1 Preamble of the *Convention on Psychotropic Substances* (1971).
2 Idem. The preamble of the *Single Convention on Narcotic Drugs* (New York, 1961) contains similar phrases.
3 Piet Hein van Kempen et al., *Internationaal recht en cannabis* (2014), 15. Having reference to United Nations, *Commentary on the Single Convention on Narcotic Drugs*, 1961 (1973), 110. Also refer to Centre for International Law, 'Drugsbestrijding', *centruminternationaalrecht.nl*.
4 United Nations, *Commentary on the Single Convention on Narcotic Drugs*, 1961 (1973), 111.
5 Article 7(a) of the *Convention on Psychotropic Substances* (1971). Italics by the authors.

/// The United Nations allow the use of MDMA for very limited medical purposes under the Convention on Psychotropic Substances of 1971. The Commentary on the Convention and existing practice provide sufficient scope for prescribing the substance for the purposes of MDMA-AT.

The question that arises is how wide an interpretation may be given to the phrase 'very limited medical purposes' in the Convention. In principle, the text of the Convention leaves very little room for medical use; only use for medical-scientific purposes is permitted. In practice, this provision is not applied as a strict condition, but as a recommendation; or so it appears from the conversations the State Commission has had with experts.[6]

This approach is in line with the Commentary on the Convention (hereinafter: the Commentary), which can be deemed the UN guideline for the implementation of the Convention. The Commentary provides that the ultimate decision on the use for medical purposes is left to the State Parties.[7] According to the Commentary, the drafters of the Convention cannot have intended a total ban or undue restrictions being placed on medical use. The Commentary also indicates that it is difficult to predict whether a substance may be of use for treating diseases in the future. In such circumstances, the Commentary notes, it can be useful to allow such use. This is to be done under the strict control provisions of Schedule I, without moving the substance to another schedule.[8]

Strict conditions for medical use

The Commentary therefore acknowledges that State Parties will have different approaches where the therapeutic use of a drug is concerned.[9] The Commentary does, however, suggest that only a limited number of medical experts be allowed to use such substances for therapeutic purposes.[10] Whenever appropriate substances listed in other schedules are available, these must be used.[11] Another condition is that this policy may not undermine the drug policy of other countries.[12]
In addition to this restriction of medical use, the Convention also lays down a number of strict control measures to prevent non-medical use and illegal trade. Article 6, for example, requires that special records are kept. Articles 7b–7f impose requirements relating to production, trade and distribution and to the maintenance of a medical file. They also impose import and export restrictions. Article 8 prescribes a licensing system and Article 9 stipulates that the substances may only be made available by way of medical prescription.[13]

6 Including a conversation with Martin Jelsma of the Transnational Institute (11 October 2023).
7 United Nations, *Commentary on the Convention on Psychotropic Substances* (1971), 138-140.
8 United Nations, *Commentary on the Convention on Psychotropic Substances* (1971), 138 § 3.
9 Idem, 139 § 6.
10 Idem, 139 § 4.
11 Idem, 139 § 5.
12 Idem, 139 § 6.
13 Article 6-9 of the *Convention on Psychotropic Substances* (1971).

These administrative obligations do not, in principle, obstruct the medical use potential of MDMA. One condition is that all government bodies involved see eye to eye, so that these requirements can be properly met. Any reluctance or inadequate cooperation by one of the Ministries involved or by investigative officials may render it difficult to obtain the required licenses or authorisation to conduct a research project or medical experiment, or to be able to obtain the substance necessary for conducting it. Researchers are often faced with such difficulties in many countries, in particular where substances listed in Schedule I to the Convention on Psychotropic Substances are concerned.[14] Moving MDMA from Schedule I to the 1971 Convention to another schedule might reduce this problem. Inclusion in another schedule would lead to a gradually less strict legal regime, but all State Parties to the Convention would still be required to limit the export, import, issue and stockpiling of, trade in, use of and possession of the substances in Schedules II, III and IV to medical and scientific purposes.[15] To promote the medical use of MDMA-AT, the World Health Organization may consider reviewing its qualification under the Convention.

Human rights provisions

/// Human rights entitle patients to proven effective psychiatric treatment, provided the Netherlands has sufficient financial (and other) resources to make such treatment available. The affordability of the treatment therefore plays a part.

It is apparent from the foregoing that the UN drug treaties do not, in principle, raise major barriers where allowing the use of MDMA as a medicine in a therapeutic context is concerned. At the same time, the question arises of how MDMA-AT must be considered from the human rights perspective. In essence, the question is whether and, if so, how the human rights treaties are complementary to the UN drug treaties.[16] This gives rise to questions like: Which rights are at stake? How do they regulate, facilitate or restrict the medical use of MDMA? How does this align with the UN drug treaties?

Human rights are embedded in treaties concluded by the United Nations and the Council of Europe. The *Charter of Fundamental Rights of the European Union*, too, contains an authoritative catalogue of human rights that is relevant to both the EU itself and to the Member States. Many national constitutions, including the Dutch Constitution, also contain a catalogue of fundamental rights.[17]

The human rights relevant in this context are the right to health, the right to life, the freedom from inhuman treatment, the right to privacy and family life and the right to physical and mental integrity.[18] Table 1 provides an overview of the relevant human rights provisions.

14 Conversation with Martin Jelsma of the Transnational Institute (11 October 2023).

15 Article 5 of the *Convention on Psychotropic Substances* (1971).

16 Piet Hein van Kempen et al., *Internationaal recht en cannabis II* (2016).

17 Chapter 1 of the *Constitution* (2023).

18 Piet Hein van Kempen et al., *Internationaal recht en cannabis II* (2016), 3.

Table 1
Relevant human rights in the context of medical MDMA use

Standard	Provision
Right to health	12 ICESCR (1966)[19] 12 CEDAW (1979)[20] 24 CRC (1989)[21] 25 CRPD (2006)[22] 11 ESC (1996)[23] 35 CFREU (2000)[24] 22-1 Dutch Constitution[25]
Right to enjoy the benefits of scientific progress and its applications	15-1-b ICESCR
Right to life	6 ICCPR (1966)[26] 2 ECRM (1950)[27]
Prohibition of torture andinhuman and degrading treatment	7 ICCPR 3 ECRM 4 CFREU
Right to private and family life	8 ECRM 7 CFREU 10 Dutch Constitution
Right to physical and mental integrity	3 CFREU 11 Dutch Constitution

Right to therapeutic use if proven effective

/// Human rights are embedded in treaties concluded by the United Nations and the Council of Europe. While their focus differs from those of the drug treaties, they do not contradict them.

Is access to MDMA-AT a right? Article 12 of the *International Covenant on Economic, Social and Cultural Rights* (ICESCR, 1966) lays down the right to health. The Covenant requires State Parties to guarantee the 'highest attainable standard of physical and mental health' for their residents. This treaty therefore explicitly emphasises mental health, which includes psychiatric care. On the basis of this standard, the government is required to provide these types of care. It may, however, take account of the available financial and other resources in this connection.[28] A cost-benefit analysis may therefore be performed.

19 United Nations, *International Covenant on Economic, Social and Cultural Rights* (1966).
20 United Nations, *Convention on the Elimination of All Forms of Discrimination against Women* (1979).
21 United Nations, *Convention on the Rights of the Child* (1989).
22 United Nations, *Convention on the Rights of Persons with Disabilities* (2006).
23 Council of Europe, *European Social Charter (Revised)* (1996).
24 European Parliament, *Charter of Fundamental Rights of the European Union* (2000).
25 Chapter 1 of the *Constitution* (2023).
26 United Nations, *International Covenant on Civil and Political Rights* (1966).
27 Council of Europe, *European Convention on Human Rights* (1950).
28 Article 2(1) of the *International Covenant on Economic, Social and Cultural Rights* (1966).

An authoritative explanation (a so-called 'General Comment') on the right to health as laid down in Article 12 of the ICESCR states that providing access to essential medicines is a 'core obligation' under the right to health.[29] A core obligation is an obligation of the government of a mandatory nature. In view of the dynamic nature of the obligations under the ICESCR, certain obligations are, therefore, mandatory in nature.[30] State Parties must advance pressing reasons for failing to meet such obligations.[31] According to this Comment, essential medicines are those substances covered by the *WHO Action Programme on Essential Drugs*. Having MDMA included on this list would therefore strengthen entitlement to it within psychedelics-assisted therapy.

Nevertheless, medical use of MDMA may also be guaranteed under the right to health even without it being covered under this WHO programme. This would be the case if it has become established that this treatment is proven to be effective. The studies into MDMA-AT and the fact that FDA is anticipating the registration of MDMA-AT point to such proven effectiveness. The entitlement is reinforced by Article 15(1)(b) of the ICESCR: the right to enjoy the benefits of scientific progress and its applications.

General Comment 14 also states that the required care must be available, accessible, acceptable and of good quality. Accessibility relates to equal access (non-discrimination), physical accessibility, affordability and the accessibility of information on this care.[32] These conditions may play a role in providing greater shape to the access to the therapeutic use of MDMA.

In addition to Article 12 of the ICESCR, the *Convention on the Rights of Persons with Disabilities* (CRPD) is relevant. This Convention protects the rights of persons suffering from physical and mental (psychosocial) disabilities.[33] The WHO classifies PTSD as a mental health disorder.[34] PTSD is therefore within the scope of the CRPD. Its Article 25, for example, guarantees the right to health of persons with a physical and mental disability. It also formulates the right to access to care, including the care they require because of their disability. Such care must minimise and prevent further disabilities.[35]

Other relevant human rights in this context are the right to life, the prohibition of torture and inhuman and degrading treatment, and the right to privacy and family life. The authoritative European Court of Human Rights (ECtHR) increasingly considers these standards to be applicable in a medical context, as well as in the

29 UN Committee on Economic, Social and Cultural Rights, *CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)* (2000) § 43(d).

30 Also refer to Piet Hein van Kempen et al., *Internationaal recht en cannabis II* (2016), 53.

31 UN Committee on Economic, Social and Cultural Rights, *CESCR General Comment No. 3 (1990) on the Nature of States Parties' Obligations (Art. 2, Para. 1, of the Covenant)* (1990) § 10.

32 UN Committee on Economic, Social and Cultural Rights, *CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)* (2000) § 12.

33 For an evaluation of the terminology used, refer to Natalie Abrokwa, *The right to mental health: A human rights approach* (2023) 17-20. The term 'psychosocial disability' is used in addition to 'mental disability'.

34 WHO, 'Mental disorders', *who.int* (2022).

35 Article 25(b) of the *Convention on the Rights of Persons with Disabilities* (2006).

context of a score of health-related themes, including euthanasia, abortion and environmental hygiene. Without delving into the matter in great detail, the State Commission suggests that the right to privacy and family life might entitle a patient to MDMA-AT, should this contribute to their family life and well-being.[36]

No clash between treaties

So how do the aforementioned human rights relate to the UN drug treaties where MDMA-AT is concerned? As noted above, human rights aim among other things to protect mental health. Access to MDMA-AT may be a part thereof. In the above, the State Commission found that the UN drug treaties in principle allow for the use of MDMA-AT. In addition, these drug treaties must, according to experts, be implemented with due regard for human rights.[37] The State Commission therefore finds that, where MDMA-AT is concerned, the UN drug treaties and the human rights treaties do not clash.[38]

Right to prevention

The right to health in Article 12 of the ICESCR and in Section 22(1) of the Dutch Constitution explicitly concerns *public health*. This very evidently includes the prevention aspect, in this case: preventing damage due to the use of MDMA. Section 22(1) of the Dutch Constitution requires the governments to implement measures to promote public health. The right to health thus also expresses the duality arising from the UN drug treaties: on the one hand, guaranteeing medical use and, on the other, preventing negative consequences.
The State Commission finds that, while the various treaties and rights have a different focus, they do not contradict each other.

/// European regulations do not impose explicit legal limitations on the medical use of MDMA.

For the sake of completeness, the State Commission briefly addresses the relevant EU framework with respect to MDMA-AT. No explicit EU regulations imposing limitations or conditions on MDMA-AT exist (as yet). The EU framework is in line with the UN drug treaties. An EU institution focusing on drug use does exist: the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) in Lisbon. However, the EMCDDA has not (yet) taken any position on MDMA-AT. This institution might play a role in making policies in Europe on this theme.[39]

36 For an extensive analysis of the health-related case law of the European Court of Human Rights, refer to Aart Hendriks, 'The Council of Europe', in Brigit Toebes et al., *Health and human rights: Global and European perspectives* (2022), 119-161.

37 Piet Hein van Kempen et al., *Internationaal recht en cannabis II* (2016), 269.

38 For a similar discussion of the cultivation of and trade in cannabis, refer to Piet Hein van Kempen et al., *Internationaal recht en cannabis II* (2016), 269-300.

39 For a very limited reference to medical use made by the EMCDDA, refer to "MDMA ('Ecstasy') drug profile", *EMCDDA* (undated).

/// Were MDMA to be considered a medicine, both the Dutch Medicines Act and the Dutch Opium Act would apply. This means that the Opium Act would not cease to have effect if MDMA were to be designated a medicine. An exemption under the Opium Act therefore continues to be a requirement.

The Opium Act provides that it is prohibited to take MDMA into or out of the territory of the Netherlands; to prepare, process, sell, supply, provide or transport MDMA; to have MDMA available; and to produce MDMA.[40] Prescribing MDMA is also prohibited, unless an exception is made.[41]

In addition to the Opium Act, an Opium Act Decree exists. This Decree lists substances to which the prescription ban does not apply. Cocaine, for example, is included in Schedule I to the Opium Act, as MDMA is, but it is also included in Annex 1 to the Opium Act Decree. This allows for a physician to prescribe cocaine and for it to be used in a medical setting.

At the moment, prescribing MDMA to human subjects is already allowed in the context of medical and scientific research on humans.[42] Such research may only take place in specific institutions, like hospitals, addiction care facilities, custodial institutions and universities.[43] The prohibition on preparing, processing, selling, supplying, providing or transporting the designated substance, or to having it available, does not apply to pharmacists and dispensing physicians either, provided the activities are performed for medical and/or scientific purposes and within the normal course of their profession.[44]

MDMA and the Medicines Act

In the future, MDMA might be designated a medicine in Europe and in the Netherlands. If so, it would fall under the scope of the Medicines Act. This Act regulates the safe use of medicines and contains provisions on – among other things –the production of, trade in, prescription of and provision of medicines. MDMA must be registered in order to have it designated as a medicine. In the Netherlands, the Medicines Evaluation Board (MEB) and the European Medicines Agency (EMA) have the competence to register new medicines.[45]

As soon as MDMA has been registered as a medicine, the provisions of the Medicines Act will apply. All activities related to medicines may only be carried out by a person or body licensed to do so or having the competence to do so in any other fashion. The law distinguishes various licenses and authorisations. Marketing authorisation is granted by the MEB or the EMA. Pursuant to Section 40 of the Medicines Act, it is '... prohibited to have a medicine for which no marketing authorisation has been granted in stock, to offer it for sale, to sell it, to supply it, to make it available, to import it or to export it.' The same applies to manufacturers

40 Section 2 of the *Opium Act* (2024).
41 Section 4(1) of the *Opium Act* (2024).
42 Article 2 of the *Opium Act Decree* (2023).
43 Article 2(2) in conjunction with Article 16 of the *Opium Act Decree* (2023).
44 Section 5(1) of the *Opium Act* (2024).
45 Refer to Chapter 7 for the process of registering a new medicine.

Table 2
There are sufficient possibilities to prescribe MDMA within the framework of MDMA-AT.

Convention on Psychotropic Substances of 1971	
Article 7 (a)	requires, in respect of substances in Schedule I, parties to "prohibit all use except for scientific and very limited medical purposes by duly authorized persons."
Articles 7 (b-f)	impose requirements regarding the manufacture, trade, and distribution, the preservation of medical records, and impose restrictions on import and export.
Article 6	requires the maintenance of a special administration.
Article 8	prescribes a licensing system.
Article 9	requires that the substances be supplied or dispensed by medical prescription only.

and wholesalers: without a manufacturing or wholesale license, they are banned from producing, importing, stockpiling, supplying or exporting medicines, from offering them for sale or from operating a wholesale business.[46] Both manufacturing and wholesale licenses are issued by Farmatec, a division of the Ministry of Health, Welfare and Sport.

Section 45 of the Medicines Act contains an exhaustive list of the grounds for the MEB or the EMA to refuse marketing authorisation. In principle, the assessment authority will issue the authorisation if:

- the assessment of benefits and risks has a positive result;
- the medicine has the alleged therapeutic effect;
- the medicine is of the stated qualitative and quantitative composition;
- and the data or documents provided to corroborate the application are in agreement with the provisions of this Act.

Relation between the Medicines Act and the Opium Act

Should MDMA be designated as a medicine to be used in MDMA-AT, both the Opium Act and the Medicines Act would apply. This is because MDMA would continue to be a substance listed under the Opium Act. The question next arises what the relation between these two pieces of legislation would be in that case. The Opium Act is a so-called *lex specialis* vis-à-vis the Medicines Act.[47] This means that the system of the Opium Act will continue to apply, as will the additional provisions of the Medicines Act. The prohibition to prepare, trade in or possess MDMA laid down in Section 2 of the Opium Act will continue to remain in force. The party that carries out any activity with MDMA must therefore possess a manufacturing or wholesale license under Section 18 of the Medicines Act. In addition, all traders, intermediary traders and manufacturers must apply for an exemption under Sections 6 and 8 of the Opium Act in order to trade in or produce the substance. This exemption must be granted by the Minister, who will only do so if this is in the interest of public health. The exemption requirement does *not* apply to the

46 Section 18 of the *Medicines Act* (2024).

47 H.J.J. Leenen et al., *Health law handbook* (2020), 527.

users of a medicine or medical aid listed in one of the schedules of the Opium Act, such as physicians and pharmacists.[48] Traders and manufacturers must possess both a license under the Medicines Act and an exemption under the Opium Act.

/// In addition to the Opium Act, an Opium Act Decree exists. To allow for the medical use of MDMA, it must be listed in Schedule 1 to the Opium Act Decree.

As soon as MDMA is designated as a medicine when used for MDMA-AT, it will also be listed in Annex 1 to the Opium Act Decree. This will make it possible to prescribe MDMA. However, such a prescription will need to meet certain conditions. The prescription must, for example, be drawn up in indelible letters and be signed, stating the date of signing.[49] The prescription must list the name and initials, address, town and telephone number of the prescriber, the name of the prescribed substance listed under the Opium Act and its quantity.[50]

Conclusions

This chapter dealt with the legal framework relevant to making MDMA-AT available. The 1971 UN Convention on Psychotropic Substances formed a starting point, as MDMA is included in Schedule I to this Convention. The Netherlands followed the system of this UN Convention in 1988 by listing MDMA in Schedule I to the Opium Act. Elsewhere in this report, the State Commission recommends *not* to move MDMA to Schedule II to the Opium Act unilaterally, also because this will not solve the problem of the substantial illegal MDMA production in the Netherlands and its export abroad.

A possible move to another schedule to the UN Convention may, however, be considered in the international context. The Netherlands could, for this purpose, ask the WHO to reassess its inclusion of MDMA in Schedule I to the 1971 UN Convention. This would promote the taking of steps in the international context and the Netherlands could play a guiding role in this connection.

Previously in this report, human rights have been referred to as a framework that is relevant to recreative use: human rights promote prevention, the limitation of damage and decriminalisation of use. In the context of MDMA-AT, the human right to mental health is relevant, as it may entitle a patient to MDMA-AT, provided it is affordable and proven to be effective. The State Commission deems a comprehensive human rights approach encompassing both recreative and medical use to be desirable. International literature provides a sound basis for doing so.

Once MDMA has been registered as a medicine, the Medicines Act will come into play, in addition to the Opium Act. The next chapter deals with the requirements for registering MDMA as a medicine.

48 Section 5(2) of the *Opium Act* (2024) in conjunction with Article 16(a) of the *Opium Act Decree* (2023).

49 Article 3 of the *Opium Act Decree* (2023).

50 C.P.M. Cleiren et al., *Criminal law text and commentary* (2022), commentary on Section 4 of the Opium Act, note 7.

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7
Will MDMA-AT be provided in the Netherlands?

Introduction

As was discussed in the previous chapter, MDMA-assisted therapy (MDMA-AT) appears to be effective and safe as a treatment of people suffering from PTSD. The use of this form of therapy for other indications is also being studied. In the United States, the U.S. Food and Drug Administration (FDA), the national medicines authority, will likely allow MDMA-AT on the market before the end of 2024. The State Commission sees a need to ensure that MDMA-AT is made available for Dutch patients suffering from long-term or therapy-resistant PTSD as soon as possible, while taking due account of the potential risks.

This chapter will discuss the various ways to make MDMA-AT available in the Netherlands for treating PTSD. The most obvious route, registering MDMA-AT with the European Medicines Agency, turns out to be more complicated than was originally believed. While sound scientific evidence exists for the effectiveness and safety of MDMA-AT, there are certain other obstacles that impede registration. The State Commission will also discuss alternative options of making MDMA-AT available.

7 Will MDMA-AT be provided in the Netherlands?

Findings

The State Commission finds as follows:

/// **The United States and Australia have already made concrete steps towards offering MDMA-AT as a treatment for patients suffering from PTSD.** Nevertheless, there is as yet no prospect of registration of MDMA or MDMA-AT for this purpose in the Netherlands or the European Union.

/// **Registration in Europe and the Netherlands will require a legal entity in possession of the scientific data to submit a registration dossier with the European or Dutch medicines authority.** As the European Medicines Agency (EMA) might demand additional European research, this will not be financially attractive to the American pharmaceutical company driving the research.

/// **It may also be possible for a new party to compile a new dossier with new, European studies for the purpose of registering MDMA-AT with the EMA.** However, it is incredibly difficult to make such a project profitable, given the high research costs. Academic institutions, for example, do not appear to have the financial resources to do so.

/// **It is unlikely for a registration dossier to be submitted to the EMA or the Dutch Medicines Evaluation Board (MEB) for the purpose of obtaining marketing authorisation in the foreseeable future.** As a result, MDMA-AT cannot be prescribed widely through the regular channels for the time being.

/// **While alternative routes exist for making MDMA-AT available in the Netherlands, these are limited and can only be used on a very limited scale. This restricts the accessibility and scalability of the treatment.**

a These alternatives are: compassionate use; supply through a doctor's certificate; and naturalist research.

b The following are not alternatives: off-label use (the use of a registered substance for a treatment other than the one it was registered for); and setting up a government institution along the lines of the Office of Medicinal Cannabis (as international treaties do not allow for this).

/// **No legislation exists that prevents implementation of MDMA-AT in the Netherlands, despite MDMA being listed in Schedule I to the Opium Act.**

/// **Should MDMA-AT be registered, the next challenge will be the availability of qualified and experienced treating physicians.** No accredited training courses have been set up yet and the required competences that treating physicians must possess have not yet been determined.

/// **Every new type of therapy comes with its own points for attention. MDMA-AT is no different.** The required staffing level is one of those points. During MDMA-AT studies, there were always two therapists present during the MDMA sessions. The consequences for effectiveness or security of varying this number have not been studied. Once further research has been conducted into the exact staffing level required, this may influence the as-yet insufficient insight into cost-effectiveness.

Role played by the medicines authorities

MDMA-AT is not registered for any medical indication in the Netherlands. Based on the developments in the United States, it is likely that, should MDMA-AT be registered in Europe or the Netherlands, this will be for the treatment of PTSD. However, the State Commission anticipates that this will take years.

Formally, there are no legal barriers to registering MDMA-AT as a medicine or treatment in the Netherlands. Its inclusion in Schedule I to the Opium Act does not, for instance, have any consequences for its development and registration as a medicine (refer to Chapter 6). The Dutch government considers the developments concerning MDMA (and other psychedelics) as the development of a regular medicine.[1] This means that MDMA, just like other medicines, will be assessed on the same merits, in this case by the Medicines Evaluation Board (MEB).

The EMA is following the dossier on psychedelics with a great deal of interest. In early 2023, EMA representatives and a number of European health organisations jointly published a comment in *The Lancet*, indicating that the development of psychedelics must be considered a regular registration process. According to this group, the fact that this process concerns substances listed under opium legislation does not have to stand in the way of research into the therapeutic benefits of psychedelics.[2]

Australia did not wait for registration

In early 2023, the Australian registration authority, the Therapeutic Goods Administration (TGA), announced that MDMA (in the context of MDMA-AT) would be included in another schedule to the Poisons Standard, starting from July that year. The Poisons Standard is the Australian equivalent of the Dutch Opium Act and classifies all drugs, medicines and chemicals in a total of nine schedules.

Until July 2023, MDMA was included in Schedule 9, just like all other banned drugs. The change that entered into effect in July concerned a 'rescheduling' to Schedule 8, making it a controlled substance that is available only for treating PTSD. This was not, therefore, a complete rescheduling: MDMA will continue to be a Schedule 9 substance in all other respects. A limited rescheduling of psilocybin became effective at the same time as that of MDMA: the substance is included in Schedule 9, but the regime of Schedule 8 applies to it as well in the context of treating therapy-resistant depression.[3]

This decision was the result of the tensions between the various tiers of government in federalist Australia. In the old situation, physicians were allowed to prescribe MDMA to certain patients if they so wished. To do so, they had to ask the TGA for permission. Whereas the TGA would grant approval at the federal level, the States were dead against any use of MDMA, as the substance was illegal.[4]

1 Minister of Health, Welfare and Sport, *Kamervragen* (2022).
2 Florence Butlen-Ducuing et al., 'The therapeutic potential of psychedelics: the European regulatory perspective', *The Lancet* (2023), 714-716.
3 Therapeutic Goods Administration, 'Change to classification of psilocybin and MDMA to enable prescribing by authorised psychiatrists', *tga.gov.au* (2023)
4 Conversation with Peter Hunt, co-founder of Mind Medicine Australia.

In order to remove this discrepancy and to allow for the medical use of MDMA, the charitable interest group MIND Medicine Australia (MMA) set up an intensive lobby in order to move the substance to another Schedule. In June 2022, the TGA still held that MDMA and psilocybin could in no case be moved to another Schedule, as the scientific basis was too limited at the time.[5] In response, MMA mobilised patients and interested parties and had them object against the decision, resulting in some 3,500 letters to the TGA. These mainly contained individual views, not new scientific insights.[6] The TGA changed its position in February 2023.

This move by the registration authority proved controversial. The only scientists researching the effects of psilocybin in Australia believed that the scientific basis for prescribing these substances was too weak, or so they argued in a critical article in the *Australian & New Zealand Journal of Psychiatry*.[7] Even though the authors noted that the initials results were promising, they argued that too little was known about the possible side effects. Many felt that social pressure had been the sole reason for rescheduling the substances after all.[8] Questions also still remained as to what type of psychotherapy was most effective in combination with these substances and, therefore, as to what skills the treating physicians should possess. The scientists wrote:

> *'The psychotherapy component is considered absolutely critical to the success of this intervention. The TGA provided no comment on the psychotherapy, likely because there is no consensus on what the therapy should look like. Research is certainly in its infancy in this regard, with many questions remaining as to the psychotherapeutic component.'* [9]

The TGA defended its decision by acknowledging that the scientific basis was limited, but that the benefits of the treatment nevertheless outweighed the risks.[10] In June 2023, the TGA announced that only authorised persons would be allowed to prescribe MDMA. A medical ethics committee was to determine who these persons are.[11] In addition, the Australian college of psychiatrists

5 Steve Kisely et al., *An Evaluation of the Therapeutic Value, Benefits and Risks of Methylenedioxymethamphetamine (MDMA) and Psilocybin for the Treatment of Mental, Behavioural or Developmental Disorders: A Report to the Therapeutic Goods Administration* (2021).

6 Steve Kisely, 'The down-scheduling of MDMA and psilocybin(e): Too fast and too soon', *Australian & New Zealand Journal of Psychiatry* (2023), 933–934.

7 Susan Rossell et al., 'Why didn't the TGA consult with Australian researchers and clinicians with experience in psilocybin-assisted psychotherapy for treatment-resistant major depressive disorder?', *Australian & New Zealand Journal of Psychiatry* (2023), 935–936.

8 Annika Blau et al., '"Serious concerns" over TGA's decision making on landmark psilocybin, MDMA ruling', *ABC News* (2023).

9 Susan Rossell et al., 'Why didn't the TGA consult with Australian researchers and clinicians with experience in psilocybin-assisted psychotherapy for treatment-resistant major depressive disorder?', *Australian & New Zealand Journal of Psychiatry* (2023), 935–936.

10 Melissa Davey, 'Australian decision to allow psychedelic drug prescriptions criticised by mental health experts', *The Guardian* (2023).

11 Therapeutic Goods Administration, 'Update on MDMA and psilocybin access and safeguards from 1 July 2023', *tga.gov.au* (2023).

issued a first guideline on the provision of MDMA-AT.[12] Treating physicians are required to provide data to MMA in order to monitor the effectiveness and other matters.

Of note in the Australian case is that the registration of MDMA-AT as a medicine, as will soon happen in the US, was not awaited. MMA imports MDMA from Canada that has been produced in accordance with pharmaceutical quality standards and then distributes it to the authorised prescribers. The cost of MDMA for three treatments is AUD 400 to AUD 500 (€250 to €300). MMA is currently offering training courses to therapists who wish to start working with psychedelics for a price of AUD 9,000 (€5,400). The first treating physicians started in January 2024.[13] While the costs of the medication are borne by MMA, it is as yet unclear who will pay for the psychotherapy.

In the United States, the FDA will in all likelihood register MDMA-AT for the treatment of PTSD in late 2024 or early 2025. The United Kingdom may follow the United States' example. Ever since Brexit, the British medicines authority has been adopting the assessments of reliable foreign medicines authorities like the FDA under a mutual recognition agreement (MRA).[14] The European Union does have its own, functional medicines authority, meaning that it is unlikely to adopt an assessment made by the FDA.

The EMA or MEB can only grant marketing authorisation when they themselves have arrived at a positive assessment of the balance between the effectiveness and the risks of MDMA-AT as a treatment for PTSD. Following this, the Minister of Health, Welfare and Sport must ask the National Health Care Institute to issue an advisory opinion on the question as to whether MDMA-AT meets the 'state of scientific knowledge and of practice' and whether MDMA-AT, in terms of both costs and cost-effectiveness, may be eligible for reimbursement through the Dutch basic health insurance package. Having the treatment included in the basic package means that it is considered part of the necessary medical care every patient in the Netherlands is entitled to.[15] At present, other PTSD treatments, like CGT and EMDR, are included in the basic package.[16]

12 The Royal Australian and New Zealand College of Psychiatrists, 'Therapeutic use of MDMA for PTSD and psilocybin for treatment resistant depression', *ranzcp.org* (2023).

13 Conversation with Peter Hunt, co-founder of Mind Medicine Australia.

14 Matthew Limb, 'UK to give "near automatic sign off" for treatments approved by "trusted" regulators', *BMJ* (2023), 380.

15 MEB, 'Procedures handelsvergunning', *cbg-meb.nl* (undated).

16 Zorgwijzer (health insurance comparison tool), 'EMDR therapie' (2024).

Registration in the Netherlands may take a long time

/// The United States and Australia have already made concrete steps towards offering MDMA-AT as a treatment for PTSD. Nevertheless, there is no prospect of registration of MDMA or MDMA-AT for this purpose in the Netherlands or the European Union.

The fact that a substance is covered by the Opium Act does not preclude it from being developed as a medicine. Nevertheless, this does not mean that registration of MDMA-AT to treat PTSD will soon be effected in Europe or the Netherlands. In order to register a medicine, a legal entity must submit a registration dossier with the EMA or the MEB. The party best able to do so is Lykos Therapeutics, the owner of the study submitted to the American authorities.
However, Lykos Therapeutics has indicated it will limit its activities to the United States for now. Registration in Europe will most likely involve additional costs and the profit margins do not outweigh them.

/// Registration in Europe and the Netherlands will require a legal entity in possession of the scientific data to submit a registration dossier with the European or Dutch medicines authority. As the EMA might demand additional European research, this will not be financially attractive to the American pharmaceutical company driving the

The EMA and the MEB retain the right to ask the party submitting the dossier for additional evidence. This can be necessary, for example, when it is unclear whether the data in the existing dossier also apply to patients in Europe or the Netherlands and the health care system in force here.

There are no indications that the American submitter of the MDMA-AT dossier will also apply for registration in the European Union or the Netherlands in the short or medium term. Nor does this party appear likely to sell the registration dossier to a third party, so it may apply for registration and marketing authorisation in Europe.

/// In order to register MDMA-AT with the EMA, a new party could also compile a new dossier containing new, European studies, but it is very difficult to make such an endeavour profitable given the high research costs. Academic institutions, for example, do not appear to have the financial resources to do so.

If the American party continues to show no interest in the European market, the only other way to arrive at European registration is for a new party to initiate research for the purpose of registration. It will most likely not be possible to make use of the research results of the American submitter, as Lykos has stipulated it must be granted data exclusivity for a number of years.

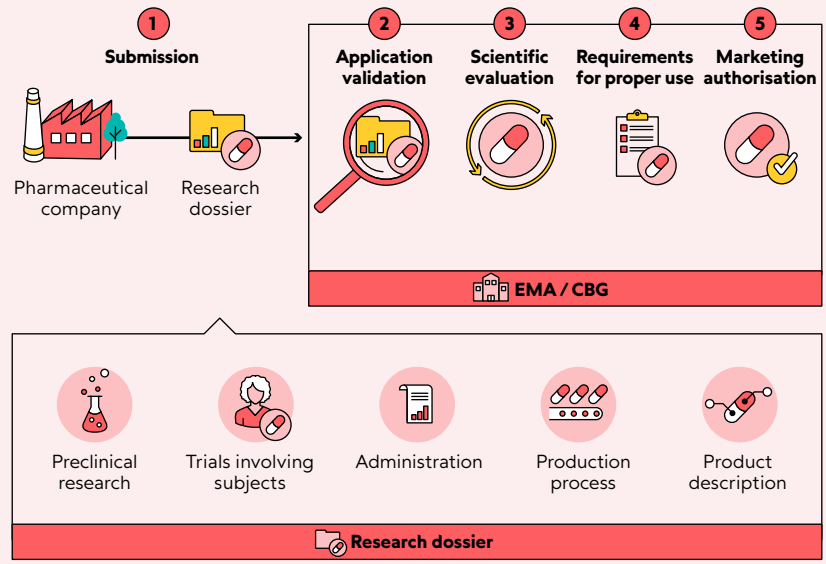
/// It is unlikely for a registration dossier to be submitted to the EMA or the Dutch Medicines Evaluation Board (MEB) for the purpose of obtaining marketing authorisation in the foreseeable future. As a result, MDMA-AT cannot be prescribed widely through the regular channels for the time being.

When possessing data exclusivity, a party retains the exclusive right to the results of its own research for a specific period of time. In the United States, such exclusivity lasts six years; in Europe, eight. This means that other parties may not make use of those research data to register and market a substance for an indication without the explicit permission of the original manufacturer. They must obtain such data from their own research.

Once the period of exclusivity has lapsed, other parties are allowed to market generic versions of the medicine.[17] This therefore discourages other parties from initiating their own research for the purpose of registration. For the manufacturer, patience is in this case the cheaper option.

Nor is it attractive to a party to conduct its own research, because it is difficult to recoup the costs incurred using MDMA-AT: the patent for the substance MDMA has long since expired.[18] Under normal conditions, a manufacturer may demand a monopoly for a medicine for a number of years using a patent, allowing it to recoup its development costs. As the MDMA patent has expired, but significant research costs must still be incurred before a party is able to have it registered, marketing the substance is an unattractive proposition to pharmaceutical companies. Moreover, the psychotherapeutic component of MDMA-AT cannot be patented individually.[19]

Figure 12
The drug registration process in the EU



17 EMA, 'Data exclusivity / Generics / Biosimilars: Regulatory and procedural guidance' (2008; 2012).

18 Robert Schoevers, Joost Breeksema and Rutger Boesjes, *Signalement Therapeutische toepassingen van psychedelica* (2023), 31.

19 Robert Schoevers, Joost Breeksema and Rutger Boesjes, *Signalement Therapeutische toepassingen van psychedelica* (2023), 31.

The United States register substances with data exclusivity

The United States are the trailblazers in researching the therapeutic use of MDMA. Shortly after the substance was banned in 1986, a number of therapists and researchers established the *Multidisciplinary Association for Psychedelic Studies* (MAPS).[20] This non-governmental organisation (NGO) aimed to enable research into treatment using MDMA, despite the ban. The studies into the use of MDMA-AT for long-term PTSD discussed in Chapter 5 were all, without exception, funded by MAPS.

In 2014, MAPS founded a Public Benefit Corporation (MPBC), currently named Lykos Therapeutics. A Public Benefit Corporation is an American for-profit corporate entity that also aims to realise other, more social goals. This company is to offer MDMA to treating physicians once MDMA-AT to treat PTSD has been registered. The company will also provide MDMA-AT training courses, albeit only for the period following registration: ultimately, this is to be taken over by the industry.

Lykos Therapeutics has obtained data exclusivity from the FDA. For a period of six years, no other parties are allowed to use the (crucial) data collected by Lykos Therapeutics. As a consequences, access to these data is virtually impossible, except if another company is conducting its own research and is granted separate permission by MAPS.[21] This is not the case, however, meaning that Lykos Therapeutics will be the only provider of MDMA-AT to treat PTSD in the United States in the near future.

The registration of MDMA-AT to treat PTSD has consequences for American law. At present, MDMA is included in Schedule I to the American opium law, meaning that, in legal terms, the substance has no medical benefit. This will change once MDMA has been registered as a medicine by the FDA. The Drug Enforcement Administration (DEA) will therefore have to include the substance in another schedule, though it is not sure at this time which schedule this will be.

Lack of treating physicians

/// **Should MDMA-AT be registered, the next challenge will be the availability of qualified and experienced treating physicians. No accredited training courses have been set up yet and the required competences that treating physicians must possess have not yet been determined.**

Should registration be effected in the Netherlands in a few years, the availability of the treatment will soon become a problem. In particular at the start of the potential implementation of MDMA-AT, there will only be a few trained and accredited treating physicians for MDMA-AT who are able to offer this complex treatment. In addition, the treating physicians will – in view of the intensity of

20 Torsten Passie, 'The early use of MDMA (Ecstasy) in psychotherapy (1977–1985)', *Drug Science, Policy and Law* (2018).

21 U.S. Food and Drug Administration, 'Frequently Asked Questions on Patents and Exclusivity', *fda.gov* (2020).

the treatment – most likely not be able to treat more than one to three patients per week. This means that, even if there is a great deal of demand for MDMA-AT immediately after its registration, the treatment offer will be very limited and MDMA-AT treatment options will be lacking.

Nor is it sure at this time who will and will not be allowed to provide this new treatment form. In all likelihood, a psychiatrist will ultimately be responsible for the treatment and will prescribe the MDMA, but which specialists will and may be present during the sessions itself is still a topic of discussion. Within the mental health care system, the ultimately responsible psychiatrist is not by definition the person who administers the treatment. In theory, this might be a psychologist or a specialist nurse.

In 2023, an international research group conducted a survey among 75 experts, asking for their opinions on the regulation of MDMA-AT. These experts were conducting clinical MDMA-AT trials in Europe. The group of experts were impressed by the clinical effects of MDMA-AT. They did emphasise two issues: the importance of specialised training for therapists, and the importance of active regulations and international cooperation in order to realise the effective integration of MDMA-AT into the European mental health care system. In so doing, the expert group also underlined the importance of ethical questions and equal access to the treatment.[22]

Working with a psychedelic requires a specific set of skills. Training programmes on the therapeutic use of MDMA are already being offered abroad. Some of these programmes are commercial training courses that, in addition to MDMA, also cover other psychotropic substances, like psilocybin and ketamine. Dutch psychologists and psychiatrists treating clients with PTSD can already study these foreign programmes. They are awarded accreditation points – which they are required to collect a specific amount of every five years by their professional associations – for doing so. However, this does not automatically mean that these treating physicians are then allowed to treat patients using the knowledge on psychedelics-assisted psychotherapy they gained. The Dutch organisations for professionals in the mental health care industry – the Dutch Association for Psychiatry, the Dutch Association of Psychotherapy, the Dutch Association of Psychologists and the Netherlands Association of Nurses and Carers – will have to decide which training courses can be qualified as being of sufficient quality.

Cost-effectiveness

/// **Every new type of therapy comes with its own points for attention. MDMA-AT is no different. The required staffing level is one of those points. During MDMA-AT studies, there were always two therapists present during the MDMA sessions. The consequences for effectiveness or security of varying this number have not been studied. Once further research has been conducted into the exact staffing level required, this may influence the as-yet insufficient insight into cost-effectiveness.**

22 Jerome Herpers et al., 'Expert Opinions on Implementation of MDMA-Assisted Therapy in Europe: Critical Appraisal towards Training, Clinical Practice, and Regulation', *European Journal of Psychotraumatology* (2024).

We do not know enough about the cost-effectiveness of MDMA-AT in the Netherlands yet. MDMA-AT treatment consists of two or three MDMA-assisted sessions, each of which is followed up on by an integration session. Two therapists are present at each session. A single MDMA-AT treatment may therefore cost up to 100 man hours. This means that staffing forms the main cost item for this treatment, as the substance itself is not necessarily expensive. Given the current shortage of staff in the mental health care sector, the question arises as to whether this treatment form does not overly reduce capacity available for other indications. At the same time, the target audience of MDMA-AT is comprised of therapy-resistant patients suffering from PTSD. This means that these patients have had previous treatment and require a lot of care. The costs associated with these patients will be, and will remain, very high for as long as no permanent treatment is available for them.

Patients suffering from therapy-resistant PTSD require a lot of care. MDMA-AT may, in the long term and because of the permanent effect of the interventions, provide a cost-effective and capacity-saving solution, thereby in fact improving health care accessibility. However, too little research has been conducted so far into the cost-effectiveness of MDMA-AT within the context of the Dutch mental health care system. As regards the cost-effectiveness of MDMA-AT in general, the available literature is mainly based on the American health care system, which is very different from the Dutch system.[23]

Only one study has been conducted into the cost-effectiveness of MDMA-AT in the Netherlands. It was conducted by pharmaceutical economist Inge Buiter, who at the time was in training. This cost-effectiveness analysis considered both the costs of treatment and the impact on the quality-adjusted life years (QALYs) of patients. Assessed over the span of multiple years, MDMA-AT was found to be cost-effective in comparison to many interventions currently in use, in particular because of the long-term effect of the intervention.[24]

However, the cost-effectiveness of MDMA-AT is no higher than of EMDR when EMDR works for the patient. The cost-effectiveness of MDMA-AT may still improve, should it become apparent from studies that cheaper variations to the protocol used in the MAPS studies are at least equally effective. The search for the most cost-effective treatment protocol therefore forms a sound reason for studying multiple variations to the MAPS protocol. For example, it is still an open question whether two treating physicians are required during the two or three MDMA-assisted sessions of eight hours. One conceivable alternative is to have two sessions with one MDMA-AT therapist and a supporting co-therapist, such as a qualified psychologist or nurse specialist. Another option would be to conduct the integration sessions in a group, as has already been done with studies into psilocybin-assisted therapy for cancer patients suffering from depression.[25] It may be worthwhile to investigate whether such

23 Elliot Marseille et al., 'Updated cost-effectiveness of MDMA-assisted therapy for the treatment of posttraumatic stress disorder in the United States: Findings from a phase 3 trial', *PLoS ONE* (2022).

24 Inge Buiter, 'Beyond Traditional Therapies: Evaluating the Economic and Therapeutic Value of 3,4-Methylenedioxymethamphetamine-assisted psychotherapy for Post-Traumatic Stress Disorder' (2023).

25 Benjamin Lewis et al., 'HOPE: A Pilot Study of Psilocybin Enhanced Group Psychotherapy in Patients With Cancer', *Journal of Pain and Symptom Management* (2023) 258-269.

variations are equally effective and safe, while costing less and placing less of a burden on the workforce. The relevant professional associations are to draw up guidelines on who is competent and qualified to treat patients using MDMA-AT and during which parts of the treatment they can participate in what capacity.

More research into which medical professionals could perform MDMA-AT must be conducted. Other variables should be explored, too. Even though the effectiveness of MDMA-AT using the MAPS protocol has been proven, very few variations to this treatment protocol, such as group sessions or the use of MDMA in combination with an exposure-focused intervention like CBT or EMDR, have been studied. Without further research, it is impossible to state whether the treatment would even be effective when, for example, another MDMA dosage is provided, the number of sessions is changed, or a group session is held instead of an individual session.

Alternatives to registration

/// While alternative routes exist for making MDMA-AT available in the Netherlands, these are limited and can only be used on a very limited scale. This restricts the accessibility and scalability of the treatment.

As was shown in Chapter 5 and will also become evident in Chapter 8, patients suffering from severe and therapy-resistant PTSD have an interest in new treatment options. MDMA-AT may provide a solution. However, patients enquiring after it with treating physicians will continue to be disappointed for the foreseeable future. Chapter 8 will show that this has led to frustration among both a segment of patients and among some of the treating physicians. While awaiting registration, however, legal alternatives allowing for treatment in some cases using a substance not registered in Europe or the Netherlands do exist.

Switzerland has made allowance for MDMA-AT since 2014

The Swiss Federal Bureau for Public Health (BAG) regulates the use of non-approved narcotics. Physicians who possess a professional license, mainly psychiatrists and psychotherapists, may apply for exemptions to use MDMA, LSD and psilocybin. These applications are assessed on the basis of the applicant's psychotherapeutic practice, their network within professional associations and their involvement with peer review and supervision.
The exemptions are issued for one specific patient and one specific substance, for the term of one year, with the possibility of an extension. In order to be eligible, a patient must meet strict criteria: among other things, they must suffer from an incurable disease, find relief through the narcotic, have exhausted existing therapies and be capable of living a more independent lifestyle. This therapy does not constitute a treatment of first choice. Instead, it is intended for patients who have tried various other treatments without lasting success.

The exemption holder will decide on the dosage, session frequency, setting, form and intensity of the accompanying psychotherapy. Elements of the treatment may be delegated to trained non-medical colleagues, like psychotherapists.

Since 2014, over 1,000 exemptions allowing for the use of MDMA, LSD and psilocybin in therapeutic settings have been issued to about 60 physicians. The treatments, estimated to amount to some 2,000 to 3,000, are carefully supervised and monitored. A professor of Pharmacology at the University of Basel supplies the substances to be used and verifies their quality.

The training offered to therapists in the field is still being developed, with specialised training courses for a limited number of trainees being offered by the Schweizerische Ärztegesellschaft für Psycholytische Therapie. This specialised treatment is qualified as a treatment for complex disorders. According to the president of the Ärztegesellschaft, it does not appear to impact recreative drug use in Switzerland.[26]

Compassionate use

/// The alternative routes are: compassionate use; supply through a doctor's certificate; and naturalist research.

There exists a way to prescribe unregistered substances legally. Within Europe, this way is referred to as 'compassionate use'. This regulatory mechanism allows a prescriber to provide patients with access to experimental treatments, such as MDMA-AT for PTSD. The EMA imposes the condition that the medicine is already being used in clinical trials, which applies to MDMA-AT. The EMA also allows for compassionate use in case of properly studied medicines that have been submitted for registration, which does not hold true for MDMA-AT.[27]

Compassionate use takes place outside of clinical trials and is restricted to cases where standard treatments are not effective. It was designed to as yet provide aid to patients in urgent medical situations and, at the same time, to collect valuable data on the safety and effectiveness of new treatments.

The MEB also allows for compassionate use in cases of extreme hardship. This means that a substance that has already been submitted to the MEB for its approval, but has not yet been assessed, can be prescribed. One example is the esketamine nasal spray produced by the Janssen corporation. This substance was approved for compassionate use in 2019. The National Ketamine Nasal Spray Consortium, composed of twelve health care providers, used esketamine nasal spray in this way. The Consortium collected and shared data for the benefit of the registration of the substance.[28] It also allowed therapists to gain experience with using the substance. By now, the nasal spray has been approved by the MEB and the institutions involved offer it for treatment.

Supply through a doctor's certificate

Another alternative for making MDMA-AT available prior to its registration, is the supply of MDMA through a doctor's certificate. This method involves a physician

26 Information from correspondence between the State Commission and the Swiss psychiatrist Peter Gasser, president of the Schweizerische Ärztegesellschaft für Psycholytische Therapie.

27 EMA, 'Compassionate use', *ema.europe.eu* (undated).

28 Jaco Bobas et al., *Ketamine in de Nederlandse geestelijke gezondheidszorg: Implementatie, risico's, vraagstukken* (2022), 21.

deciding to supply the substance without marketing authorisation, i.e. without the substance having been registered as a medicine. This avenue primarily exists to treat conditions or cases for which no approved substances are available in the Netherlands. In these cases, the physician completes a statement allowing the pharmacy to request permission for the production and supply of the substance by that pharmacy from the Health and Youth Care Inspectorate. Should the Inspectorate agree, the physician may prescribe the substance for that specific patient.[29]

Even though this avenue allows for helping people with PTSD in the period of time between registration in the United States and possible registration in the Netherlands, the administrative burden is immense.

Naturalist research

The final possible alternative to registration is making MDMA-AT available through large-scale naturalist research in the Netherlands. This type of research is called 'naturalist', as it does not concern a medical experiment and all patients are monitored for some years following the treatment in order to study the effectiveness of MDMA-AT treatment. Scientific literature uses the term 'real-world data collection', as this type of research allows for providing a personalised type of therapy, as would be the case in the normal course of events.

MDMA may be used for this research objective, provided an exemption from the application of the Opium Act has been applied for with, and awarded by, the Minister of Health, Welfare and Sport. It is irrelevant in this connection whether the substance is included in Schedule I or Schedule II.[30]

Such naturalist research involves treating eligible patients suffering from PTSD with MDMA-AT. This is done on the condition that they participate in long-term follow-up research into the long-term effectiveness and safety, and into their personal experiences with this form of treatment.

The role played by the pharmaceutical industry

One condition for providing MDMA-AT is the pharmaceutical production of MDMA according to European medicines standards. For pharmaceuticals, the development of a profitable MDMA product is a condition for producing the substance. As has previously been indicated, this can be very difficult for a substance like MDMA, the patent on which has expired.

However, it is not impossible to develop a (very) profitable type of general substance. The patent on anaesthetic ketamine, which is clinically used to alleviate pain and anaesthesia but is also used as a recreative drug, has also expired. In 2000, interest in the use of the substance as an antidepressant to be used in cases of therapy-resistant depression, arose. One pharmaceutical company has been offering the strong variant esketamine by way of a patented nasal spray since 2019. Within the European Union, only this nasal spray may be used when prescribing esketamine in cases of therapy-resistant depression.[31]

29 Health and Youth Care Inspectorate, 'Leveren op artsenverklaring', *igj.nl* (undated).

30 *Beleidsregels opiumwetontheffingen,* Sections 1 and 2 (consulted on 31 January 2024).

31 Jaco Bobas et al., *Ketamine in de Nederlandse geestelijke gezondheidszorg: Implementatie, risico's, vraagstukken* (2022), 25.

One dose of generic esketamine costs €20. However, the nasal spray is ten times as expensive in the Netherlands.[32,33] The difference may even rise to a factor of 100 in other countries.[34] The pharmaceutical company has stated that the price has been determined on the basis of the value of the increased quality of life resulting from the substance. The research, production and trading costs did not, therefore, play a part.[35] In practice, this means that the pharmaceutical company has looked for the highest possible price within the boundaries of common cost-benefit analysis methods. As the quality of life, but also the productiveness of the patient and those close to them, is severely reduced by therapy-resistant depression, depression is an expensive condition. According to this calculation method, the price of an effective medicine is therefore a proper one if it is just a little less than the costs associated with depression.

If there is a demand for pharmaceutical MDMA and a manufacturer is able to offer it in a patentable and profitable manner, this condition will have been met for MDMA-AT. However, the State Commission also wishes to point out that the hunt for profit may take on extreme forms that are contrary to societal standards and various human rights provisions.

Social and legal developments holding companies to account for their social responsibility are on the rise. In 2021, for example, the The Hague District Court ordered Royal Dutch Shell to reduce its CO_2 emissions, as Shell's share in the responsibility for global warming is – among other things – contrary to various human rights, including the right to life.[36] The State Commission in the framework of the human rights detailed in Chapter 6 points to the social responsibility of the pharmaceutical industry to ensure that medicines are accessible and affordable.

Stipulating too high a price impinges on the right of patients to access to proven effective forms of care. Should an overly high price result in the government being unwilling to making MDMA-AT available in the basic health insurance package, patients (including vulnerable ones) would be denied care they could have benefited from. This is at odds with, for example, the right to the highest attainable standard of mental health.

32 Eric Sagonowsky, 'Cost watchdogs scold J&J for "overpricing" its new ketamine-like antidepressant', *Fierce Pharma* (2019).

33 National Health Care Institute, 'Kostenoverzicht esketamine (nasaal)', *Farmacotherapeutisch Kompas* (2024).

34 The George Institute, 'Why low-cost ketamine is still inaccessible to many with severe depression', *USNW Newsroom* (2023).

35 William Borden, 'A Complex Patent & Pricing Picture: Regulating Psychedelics More of a Journey Than a Trip', *Pharmaceutical Executive* (2022).

36 The Hague District Court, 'Klimaatzaak tegen Royal Dutch Shell', *de Rechtspraak* (2021).

/// The following are not alternatives: off-label use (the use of a registered substance for a treatment other than the one it was registered for); and setting up a government institution along the lines of the Office of Medicinal Cannabis (as international treaties do not allow for this).

Finally, there are two dead ends. These are off-label use and the setting up of a government institution along the lines of the Office of Medicinal Cannabis. The State Commission will address these two avenues, as they are often brought up during discussions on making MDMA-AT available.

Off-label use is the use of a registered medicine to treat an indication it has not been registered for. Physicians may prescribe an off-label treatment for patients who appear not to benefit from on-label treatment. It is up to the physicians themselves to estimate if off-label use is worth trying, but they must adhere to established procedures and standards when doing so.[37] However, as MDMA is not registered with the Dutch or European medicines authority for any use at all, the substance cannot be prescribed for off-label use, either.

Another option was inspired by the Office of Medicinal Cannabis. This State enterprise supervises the cultivation of cannabis and supplies cannabis when a physician prescribes it to a patient. However, cannabis is not registered as a medicine with either the MEB or the EMA. Physicians themselves estimate whether a patient might benefit from medicinal cannabis. If such a system could be set up for MDMA, for the purpose of MDMA-AT, registration would not be required. Such a system is not legally possible, however.

The 1961 *Single Convention on Narcotic Drugs* provides that a State is entitled to set up one or more State enterprises that allow for cultivating specific drugs. The cultivators are, however, required to hand over their entire harvest to the State enterprise. The State enterprise has the exclusive right to the import of, export of, wholesale trade in and stockpiling of the drugs. This treaty was drawn up before the rise of MDMA and other psychotropic substances. The 1961 Convention therefore only refers to the processing of the opium poppy, the cannabis plant and the coca bush.[38] Following the rise of new drugs, the United Nations adopted an additional treaty in 1971, the *Convention on Psychotropic Substances*. This covers various synthetic drugs, including MDMA. However, the 1971 Convention does not contain a provision on the possibility of setting up a State enterprise.[39] Setting up a State enterprise for therapeutically applied MDMA is therefore not possible.

Weighing up the alternatives

The three legal alternatives available for MDMA-AT all of allowing treating physicians to prescribe MDMA-AT sooner. Patients suffering from serious PTSD who may stand to benefit from MDMA-AT will not have to wait for it to be finally registered when these alternatives are used. Furthermore, it would allow for a

37 Marjolein Weda et al., *Off-labelgebruik van geneesmiddelen: Verkenning van de complexiteit en problematiek* (2017), 15, 21.

38 *Single Convention on Narcotic Drugs,* Articles 1, 29 and 30 (1961).

39 *Convention on Psychotropic Substances* (1971).

continuation of the research into MDMA-AT within the Dutch health care context, ensuring that we will come to know more about the long-term effectiveness and safety of MDMA-AT and having treating physicians already gaining experience with this new treatment form.

Yet, at the same time, there are certain downsides. It will be deployed on a small scale only, in particular in the cases of compassionate use and supply through a doctor's certificate. In addition, the administrative burden will be high, likely impacting the cost-effectiveness. Finally, compassionate use and supply through a doctor's certificate will always mean obtaining individual exemptions, meaning that its use cannot be based on coordinated research objectives.

A large-scale naturalist study has an edge over the other two alternatives. It would allow for the coordinated study of additional questions on MDMA-AT, such as the long-term effectiveness, the cost-effectiveness in the Netherlands and the practicability in the Netherlands. After all, there are additional research questions that can only be answered by way of long-term research and by studies conducted in the Netherlands.[40]

Conclusion

The current legislation at the international, European and Dutch levels does not impede the registration of MDMA as a medicine. Economic operators may submit a registration dossier with the competent authorities. However, due to the problematic revenue model, such parties are currently lacking. While academic parties are interested, they appear to lack the required finances to set up studies. At the same time, this new treatment is very likely to be approved in the United States soon, while MDMA-AT is already allowed in Australia. In addition to having to overcome financial and legal hurdles, the Netherlands also struggles with the lack of qualified therapists able to work with MDMA, meaning there will be very little capacity following registration.

Recommendations

The State Commission has formulated recommendations for various parties. The list starts with its recommendations to the government. These are followed by the recommendations to the relevant professional associations and the treating physicians.

Recommendations to the government

1 **In view of the convincing scientific evidence, the State Commission recommends that medical use of MDMA to treat PTSD be developed in the Netherlands as soon as possible and that its implementation be facilitated. In this context, it also recommends monitoring the developments with respect to registration and licensing in the United States.**
Scientific resarch has shown that MDMA-AT is an effective and safe treatment method. This treatment method is very likely to become available in the short term as a regular treatment for PTSD in the United States. The State Commission deems it desirable that this treatment method becomes available in the Netherlands as soon as possible.

40 Robert Schoevers et al., *Signalement Therapeutische toepassingen van psychedelica* (2023).

2 **In order to prevent the risky or harmful use of MDMA-AT by the health care sector, the government must lay down clear frameworks and preconditions.** MDMA-AT is different from other pharmacological treatments. MDMA serves as a catalyst for effective trauma processing within the context of integrative therapy. Within this treatment, the therapy is considered to be just as important as the substance. In order to have this therapy be as effective and safe as possible, the State Commission advises the government to guarantee the following preconditions:

   a **Organise a national assessment body to distribute access to MDMA-AT.** For the time being, the demand for MDMA-AT will be significantly higher than the supply on offer. Centres for the treatment of PTSD should therefore prepare to distribute the limited treatment capacity over the patients. A national assessment body may play an important guiding role in this connection.

   b **Exclusively offer MDMA-AT through designated and equipped knowledge and expertise centres for the treatment of PTSD.** These centres must have qualified therapists possessing specific clinical skills at their disposal. In addition, they must possess the proper facilities and support networks to guarantee safe and effective treatment.

   c **Call on professional associations of psychiatrists, psychologists and nurses to develop and accredit specific MDMA-AT training courses.** Treating physicians must have completed such a training course before being allowed to work with MDMA. This includes determining the proper professional background (psychologists, psychiatrists, specialised nurses) and the required skills and knowledge. The State Commission believes that professional associations have a major role to play in compiling training programmes.

   d **For the time being, MDMA-AT should only be used to treat long-term or therapy-resistant PTSD.** Other treatments with proven effectiveness are currently preferable, as more experience has been gained with them and more treatment capacity is available for them. Therefore, MDMA-AT should be reserved for patients suffering from long-term or therapy-resistant PTSD for now.

   e **Adopt a uniform and centrally organised system for registering the effects and side effects of MDMA-AT.** This will improve insight into the aforementioned items and increase the options available to prevent side effects and any complications.

3 **Set up naturalist research to make MDMA-AT available as soon as possible.** Upon consideration of all options, naturalist research into MDMA-AT provides the sole realistic option to use this treatment as soon as possible – prior to registration with the EMA/MEB – to help a group of people for which no other effective treatment exists. In addition, such research will provide answers to questions concerning:

a the long-term effectiveness of MDMA-AT;
b the risks and side effects of mono use of MDMA in the short and long term;
c the cost-effectiveness of MDMA-AT;
d the practicability and implementation of MDMA-AT;
e the effect of variations of the existing treatment protocol and, possibly, of a greater range of indications MDMA-AT can be used for.

In addition to obtaining funds from the Ministry of Health, Welfare and Sport, funding may also be requested from health care insurers, invoking health care innovation.

4 **Explore whether existing psychedelic substances require a different registration approach than 'normal' medication does. New legal frameworks may have to be set up for unregistered substances with a known medical use that are already available on the illegal market.** The State Commission has noted a certain rigidity among the responsible bodies when it comes to taking a solution-oriented approach to this type of new medication. In contrast to what is the case for the usual registration of new medicines, MDMA and other psychedelics are already widely available on the illegal market. This factor should be taken into consideration when drafting policy.

Recommendations to the professional associations

5 **The professional associations must draw up guidelines for the treatment of PTSD using MDMA-AT.** The working method used during the MAPS studies must be adhered to as much as possible. MDMA-assisted treatment comprised of MDMA sessions supervised by two accredited therapists and closely matched integrative therapy will always be preferable to treatment lacking these elements.

6 **Develop special training courses for providing MDMA-AT.** Using MDMA to treat PTSD (and at a later stage possibly other indications, as well) requires the treating physicians to possess a high level of knowledge. This does not only concern knowledge about the indication (PTSD), but also knowledge about MDMA and about how to use it in a professional manner. Sound education is therefore a necessity.

Recommendations to treating physicians and/or treatment organisations

7 **Raise realistic expectations in your communication with patients.** MDMA-AT is not a regular type of pharmacotherapy. Not only do patients enter an altered state of consciousness requiring specific attention, but there is also a need for intensive preparation and integration sessions, which require tremendous effort from the patient and intensive supervision by skilled treating physicians. In addition, it must be made clear that many patients will benefit from MDMA-AT, but not all. The Ministry of Health, Welfare and Sport must draw up a communication plan with the professional associations in this regard.

8 **Use MDMA of pharmaceutical quality in order to guarantee the correct dosage and purity of the MDMA.** For the aforementioned large-scale naturalist research, use must be made of MDMA of pharmaceutical quality, produced under Good Manufacturing Practice and used as study medication.

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8
Therapeutic use of MDMA outside the treatment room

Introduction

In the previous chapter, we outlined the possible use of MDMA-AT in the Netherlands. It is likely that MDMA-AT will soon be registered for the treatment of PTSD in the United States. This will not be the case in the Netherlands – and the rest of the European Union – for a long time to come. The State Commission has identified this as a problem and will address the implications thereof in greater detail in this chapter.

8 Therapeutic use of MDMA outside the treatment room

Findings

The State Commission finds as follows:

/// **The research into the therapeutic use of MDMA does not take place in a vacuum.** More psychedelics are being studied in the context of a wide range of conditions. These developments are already impacting society, even though the treatments are still at the research stage.

/// **The State Commission has received signals from both official professional organisations and patient's associations that patients are interested in MDMA-AT.** This interest it not limited to patients suffering from PTSD, but has also been expressed by patients with other, or less severe, mental health conditions.

/// **An increasing number of patients expects to benefit from the therapeutic use of MDMA.** Some of them already appear to be using high-risk alternatives to MDMA-AT, which have not been proven to be effective. The State Commission finds that the associated risks are significant.

/// **Some people are looking for a therapeutic use of MDMA by self-medicating with ecstasy.** Self-administration as a motive for 'recreative use' is relatively uncommon, but appears to be increasing in popularity. This is likely the consequence of positive media publications on the possibilities offered by MDMA-AT. This group indicates that ecstasy is also being taken in order to cope better with negative feelings and emotions.

/// **Certain BIG-registered therapists choose to use MDMA in treatments provided outside of the regular, supervised system.** They are doing this due to the urgency of the treatment needs, moral pressure, the state of scientific knowledge and the long time it takes until official registration is effected.

/// **There is a network of commercial, usually unqualified providers of MDMA-like sessions inspired by the studies into MDMA-AT.** This group employs recent scientific insights, both to embed them into the product on offer and to legitimise its practices and advertise its product. This network operates outside of the official medical and therapeutic system.

/// **The product currently offered by many providers consists of at least one MDMA session or a session with a structural MDMA analogue.** Without a doubt, some of these providers neglect the crucial integration sessions and aftercare.

/// **There is no effective monitoring of the current providers of MDMA therapies, nor are patients with bad experiences able to receive aid or report the matter.** Enforcement and punishment only take place when things go wrong. No central reporting centre to lodge complaints with exists within this network.

Interest raised

The studies into the use of MDMA for treating PTSD have received extensive coverage by the press. On the one hand, these publications marvel about how a substance known as a party drug may help heal from trauma. On the other hand, mental well-being has received increasing attention over the past few years. At the same time, there is an ever-increasing range of popular scientific literature about the therapeutic use of MDMA and other psychedelics.[1]

The interest in this type of therapy thus appears to be significant. However, no supply currently exists – barring the international exceptions discussed in Chapter 7. Nevertheless, there are signs that a circle of providers has come into being as a consequence of the developments surrounding MDMA-AT. In June 2023, *The New York Times* wrote that 'MDMA treatments are becoming more mainstream', even before registration by the FDA.[2] It discussed both medical professionals and amateurs, all of whom have offered clandestine services in the past few decades. Their clients include people without a medical file who believe they are suffering from a trauma, as well as people who wish to practice self-development. In addition, they include patients suffering from PTSD who, after years of treatment within the regular health care system, fail to make steps processing their trauma.[3]

The Netherlands is increasingly noting similar developments. Here, too, certain psychiatrists and entrepreneurs are closely following the studies into MDMA-assisted therapy. They want to use these insights to help people or simply see them as a way to make money. As was discussed in Chapter 5, the Netherlands is home to some tens of thousands of people suffering from PTSD who do not benefit, or benefit to an insufficient degree, from treatment within the regular health care system. Only a limited segment of them is currently interested in MDMA-AT, partly because it remains not very widely known. It is expected that familiarity with MDMA-AT will increase following the registration of this treatment in the United States (and previously in Australia).

Increasing familiarity will increase the demand for the treatment. It is very likely that some of the interested persons do not want to await registration in Europe. Specifically with respect to MDMA, the State Commission has identified a group of PTSD patients who want to take matters into their own hands. Their numbers are swollen by people suffering from other more or less serious complaints. This last group includes people with indications with respect to which MDMA-AT has not proven to be effective. Finally, there are people who, inspired by the successes with MDMA-AT, will try to improve their mental health or practice self-development using psychedelics.

The expected benefits of MDMA-AT (and other therapies involving psychedelics) are high among treating physicians and patients in the Netherlands as well, partly because of the discussions in the media.[4]

1 In 2022, Netflix broadcast the documentary series *How To Change Your Mind*. This series was based on the eponymous 2018 book by journalist Michael Pollan.

2 Dana Smith, 'What Does Good Psychedelic Therapy Look Like?', *The New York Times* (3 June 2023).

3 William Brennan et al., 'A Qualitative Exploration of Relational Ethical Challenges and Practices in Psychedelic Healing', *Journal of Humanistic Psychology* (2021).

4 Michiel van Elk, 'Beperkingen bij geestverruimers', *De Groene Amsterdammer* (2023).

/// The research into the therapeutic use of MDMA does not take place in a vacuum. More psychedelics are being studied in the context of a wide range of conditions. These developments are already impacting society, even though the treatments are still at the research stage.

In Chapter 5, we noted that there appears to be sufficient evidence that MDMA-AT is effective when using the protocols studied. These scientific findings should not be misinterpreted, however. For instance, the effectiveness of any therapeutic use of MDMA other the clinical use studied – i.e., two to three MDMA sessions in combination with therapy prior to, during and after the MDMA sessions by trained therapists – has not been proven.

In addition, there are also expectations about the therapeutic value of other psychedelics. Ketamine, LSD, psilocybin, 5-MeO-DMT and ibogaine are currently the subject of scientific studies. Most studies are still exploratory in nature, except in the case of psilocybin. A phase III trial is being conducted into the effectiveness of psychotherapy with the assistance of this substance to treat therapy-resistant depression.[5] In addition, two phase II trials into psilocybin-assisted psychotherapy to treat PTSD and anorexia nervosa are being conducted.[6] More recently, LSD also made headlines: the FDA awarded this substance breakthrough therapy status when used to treat anxiety disorders, as it had done for MDMA.[7]

In 2021, a group of scientists affiliated with various Dutch universities and mental health care parties prepared a manifesto on the progress made with psychedelics-assisted psychotherapy. They wrote:

'Of special note is the fact that psychedelics appear to be effective in treating various conditions. This not only provides prospects to chronically suffering people, but also to people suffering from multiple disorders and, usually, complex problems.' [8]

Accordingly, there is a great deal of interest into these substances among academic institutions and professional scientific associations. Researchers are studying how these substances contribute to new therapeutic approaches, focusing on their ability to improve neuroplasticity and offering psychological insights. This renewed focus marks a significant shift in the recognition given to the potentially curative characteristics of psychedelics by the medical community and its integration into mental health care.

5 Compass Pathways, 'Compass Pathways initiates UK component of global phase 3 study of psilocybin treatment in treatment-resistant depression, and launches new research center', *compasspathways.com* (2023).

6 Compass Pathways, 'Study results of psilocybin treatment in bipolar II depression published in JAMA Psychiatry', *compasspathways.com* (2023).

7 Mind Medicine Inc., 'Mindmed receives FDA Breakthrough Therapy Designation and announces positive 12-week durability data from phase 2b study of MM120 for generalized anxiety disorder', *mindmed.co* (2024).

8 Therapeutic Psychedelics Use Working Group, 'Manifest Therapeutisch gebruik van psychedelica', *umcg.nl* (undated).

Whether this is part of a wider psychopharmacological renaissance is unclear at this time, as most treatments are still in the research stage. These developments already have an impact on both treating physicians and patients, however.

Concerns about this interest

/// The State Commission has received signals from both official professional organisations and patient's associations that patients are interested in MDMA-AT. This interest it not limited to patients suffering from PTSD, but has also been expressed by patients with other, or less severe, mental health conditions.

The State Commission has received signals from psychiatrists about patients who cannot make any improvements within the Dutch health care system and are already asking their treating physicians if their situation could not be improved with MDMA. Some patients ask if they could participate in a clinical study into MDMA-AT. Care institutions with special expertise into treating PTSD have often received these questions when treating patients from the uniformed professions. The total number of patients concerned is not yet known.[9]

The State Commission therefore expects that certain patients will approach providers outside of the regular mental health care system that offer a product inspired by MDMA-AT. The aforementioned professionals share these concerns and scientists are issuing warnings about the commercialisation of MDMA-assisted treatment and similar treatments using psychedelics. They write:

'One real risk is that persons suffering from psychiatric complaints will themselves start experimenting with psychedelics, without supervision or supporting psychotherapy. This is a practice that may lead to dangerous situation and cause serious harm. We also find that the offer by commercial providers of psychedelic therapy outside of the regular health care system is increasing and that investors and start-ups are focusing on using (or patenting) new psychedelics. Interests other than those of the patient may easily take precedence in this regard. We must ensure that patients do not become victims of overly rapid or ill-considered implementation and use.' [10]

Even if the registration of MDMA-AT in the United States were suddenly halted and even if MDMA-AT will never be provided through regular channels in the Netherlands, the developments in the field of therapy using MDMA are by now widely known. There will always be a group of people wanting to be eligible for this type of treatment. Some of these people will have a treatment demand, either following diagnosis or otherwise. A demand for a treatment not legally offered may arise among them. The consequence would be that people will start looking for alternatives outside of regulated care.

Another problem is formed by the (overly) high and often misplaced expectations by potential recipients of this new treatment. There is a belief that taking a pill twice will permanently remove all complaints and that everyone will benefit from

9 Conversation with the Psychedelic Platform of the Dutch Association for Psychiatry.

10 Therapeutic Psychedelics Use Working Group, 'Manifest Therapeutisch gebruik van psychedelica', *umcg.nl* (undated).

this treatment. Nothing could be further from the truth. While the treatment does include two to three sessions involving the administration of MDMA under supervision, patients will, in the following integration session, have to work hard to give a place to the insights and experiences they gained from the MDMA sessions. This is a form of therapy requiring a treating physician who has completed a relevant course. This aspect is often overlooked in the public discourse, even though it is crucial to the success of this therapy. The pill makes it easier to enter the process, but it is the process of therapeutically processing the trauma that ultimately helps the patient.

It is important that people who may benefit from MDMA-AT are properly informed about how the therapy works. Such an information campaign may prevent patients from approaching providers who offer MDMA-AT-inspired alternatives that have not been proven to be effective.

Three illegal and semi-legal alternatives to MDMA-AT

/// An increasing number of patients expects to benefit from the therapeutic use of MDMA. Some of them already appear to be using high-risk alternatives to MDMA-AT, which have not been proven to be effective. The State Commission finds that the associated risks are significant.

The next three paragraphs discuss how the therapeutic use of MDMA is starting to have a life of its own in the Netherlands. Roughly put, three developments are visible: self-medication, registered therapists conducting experiments, and the 'grey economy'. The State Commission pays particular attention to this last development. This concerns a sector in which providers of 'trip sessions' operate who are relatively open about their practices.

All these uses involve illegal MDMA or related substances, also referred to as 'structural MDMA analogues': substances that have a similar effect to MDMA, but are not illegal. The new legislation on new psychoactive substances, which is likely to enter into force on 1 July 2024, allows for banning such MDMA-like substances.[11] It may be that, following the entry into force of this new Act, providers using these substances will become less open about their way or working.

As was discussed in Chapter 5, the effectiveness and safety of MDMA-AT for treating PTSD have been thoroughly studied. This part of the report concerns a wider group of therapeutic users, however. Two categories are distinguished in this context.

User group 1
People experiencing psychological complaints

User group 2
People pursuing personal growth

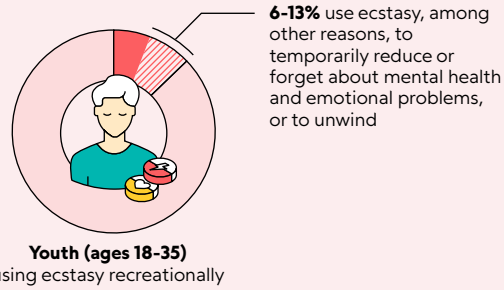
11 This Act was adopted by the House of Representatives on 16 January 2024 and is, at the time of writing, yet to be debated by the Senate.

One the one hand, it concerns the group of persons with mental health issues, like PTSD, depression or one or more other psychiatric conditions. This is a group that feel forced to look for help outside the regular mental health care system. They have exhausted their options within the mental health care system and pinned their – sometimes last – hopes on MDMA treatment. The grey economy has providers who offer MDMA sessions for people suffering from these sorts of complaints, or even for treating autism or dyslexia. And there definitely appears to be a market for these types of MDMA or MDMA-like treatments.

On the other hand, there is a group of people who use MDMA in a therapeutic fashion to foster personal growth, for self-research or for spiritual reasons.[12] Not all of these persons end up with a commercial party for their supervision. A 2020 survey shows that people from this group seek supervision from, for example, a friend or life partner.[13] Last year, *de Volkskrant* wrote how two friends went on bicycle rides while under the influence of MDMA in order to, as they put it, 'improve their mental health'.[14] Cases are also known of couples wishing to discuss their relationship while having taken a dose of MDMA.[15]

The State Commission will primarily focus on the first category, as the risks are largest for that group.

Figure 13
Motivations for ecstasy use



12 Frederiek Schutten et al., 'Psychedelica-therapie: Over psychedelica en de therapeutische toepassingen van psychedelica bij psychische aandoeningen' (2023), 7.
13 Frederiek Schutten et al., 'Psychedelica-therapie: Over psychedelica en de therapeutische toepassingen van psychedelica bij psychische aandoeningen' (2023), 7.
14 Machteld van Gelder, 'Doorgaan met MDMA als zelfmedicatie?', *De Volkskrant* (2023).
15 Daan Borrel, 'Stellen zoeken verbinding met mdma bij kaarslicht', *NRC* (31 July 2017).

I. Self-medication

/// Some people are looking for a therapeutic use of MDMA by self-medicating with ecstasy. Self-medication as a motive for 'recreative use' is as yet relatively uncommon, but increasing in popularity. This is likely the consequence of positive media publications on the possibilities offered by MDMA-AT. This group indicates that ecstasy is also being taken in order to cope better with negative feelings and emotions.

Users
People experiencing mental health complaints or pursuing personal growth

Substance
Ecstasy

Location
At home or at social venues

Taking MDMA without therapeutic treatment is wholly different from taking MDMA within the framework of the MDMA-AT studied. Nevertheless, some people take MDMA in response to hearing such scientific news. This group assumes that taking MDMA two or three times will have a therapeutic effect. These people administer XTC to themselves, possibly in the presence of loved ones, and prepare their 'trip' as they wish. In so doing, they overestimate themselves and underestimate the impact of such use.

It is not certain that these people are aware of the risks associated with the use of MDMA with a view to therapeutic gains. An MDMA experience can stir up a great deal, including renewed contact with traumatic memories. Without supervision, this may result in disappointment, confusion, frustration or even an increase in complaints from the previous level. It may also result in people trying out other substances, which have no effect either.

It is difficult to get an overview of this group, though it is being given greater attention. Various studies by the Trimbos Institute show that a small segment (between 6 and 13 per cent) of youths (aged 18–35) using MDMA in a recreative fashion also takes it in order to reduce mental health or emotional problems.[16,17] The most recent study also showed that over 80 per cent of them had experienced a positive effect, which sometimes was temporary but could also be longer lasting.[18] At the same time, a minority of 19 per cent indicated they did not experience any positive effects or even had their complaints worsen. If and to what extent these respondents were suffering from mental health conditions is not known. It is therefore difficult to draw solid conclusions from these experiences. However, the negative experiences emphasise that self-medicating with MDMA without professional supervision can be risky.

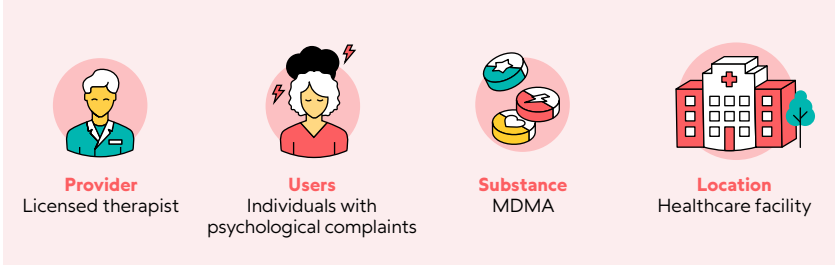
16 Ruben van Beek, *Het Grote Uitgaansonderzoek 2023* (2024), 119-123.

17 Martha de Jonge, *Persona's in middelengebruik* (2021).

18 Ruben van Beek, *Het Grote Uitgaansonderzoek 2023* (2024), 124-126.

II. Registered therapists acting ahead of regulation

/// Certain BIG-registered therapists choose to use MDMA in treatments provided outside of the regular, supervised system. They are doing this due to the urgency of the treatment needs, moral pressure, the state of scientific knowledge and the long time it takes until official registration is effected.



In addition to people who perform therapeutic experiments with MDMA themselves, certain registered therapists choose to use MDMA in treatments outside of the regular mental health care system. These treating physicians are driven by the urgency of the treatment need of their patients, by moral pressure, by their own interpretation of the scientific research into MDMA-AT and by a lack of confidence that MDMA-AT will soon be registered in the Netherlands. Enquiries among several psychiatrists have informed us that various patients suffering from PSTD have applied for euthanasia as the options to treat their PTSD were exhausted. No exact numbers are known. The moral pressure of being aware of an intervention that could be life-saving may lead to some treating physicians becoming willing to conduct a therapeutic experiment, as they do not wish to fail their patient or wish to prevent them from looking for aid in alternative circles.

The State Commission is worried about the fact that some therapists elect to use MDMA-AT in their treatment practices outside of the established, regulated frameworks, as significant risks and challenges are associated with doing so. First of all, there is the qualification and training problem. It cannot be verified whether these therapists have had sufficient specialised training, which is essential for the safe and effective use of MDMA-AT. It may be, however, that they have had such training. Accredited psychedelics therapist training courses are available in a number of countries, including the United States, Australia and Switzerland. Not having had proper training may result in suboptimal or even harmful treatment.

A second point of concern relates to the legality and ethics of using illegal ecstasy outside of an approved medical or therapeutic context. Not only are these practices illegal, they also put both the therapist and the patient at legal risk. The practice also raises ethical questions about the responsibility and safety of the patient.

Third, quality control and supervision are lacking in unregulated environments. Without standardised protocols and quality controls, the consistency and reliability of the treatment cannot be guaranteed. This may seriously undermine effectiveness.

III. The grey economy: commercial parties

/// There is a network of commercial, usually unqualified providers of MDMA-like sessions inspired by the studies into MDMA-AT. This group employs recent scientific insights, both to embed them into the product on offer and to legitimise its practices and advertise its product. This network operates outside of the official medical and therapeutic system.

Provider
Commercial entity

Users
People experiencing mental health complaints or pursuing personal growth

Substance
MDMA analogue, ecstasy, or truffles

Location
Business premises or on retreats

The provision of psychedelics treatment to people with a psychiatric indication by the grey economy is a worrying development. The quality of the treatment provided – which is often presented and experienced as medical care – is not supervised. Because of the illegal nature of MDMA, therapy with this substance is monitored far less than the legal 'truffle retreats'. The State Commission believes there to be fewer providers of MDMA sessions than of such truffle retreats.

Psilocybin retreats

An extensive network of retreats offering ceremonies involving truffles has developed in the Netherlands. In contrast to mushrooms containing psilocybin, truffles containing psilocybin are not covered by the Opium Act, because they grow underground (*sic)*. As a result, a good overview can be obtained of these providers, as they are approachable and advertise their offerings on their websites.

A characteristic of these retreats is that the participants remain on a specific site for a number of days. Other activities, like singing and dancing, often take place as well, and the truffle ceremonies are usually conducted within a group. They are usually held in a remote location surrounded by nature. In a publication in *De Groene Amsterdammer* of 23 March 2023, scientist Michiel van Elk noted that the Netherlands has at least 50 centres offering legal truffle ceremonies.[19] The primary aim for participating is personal growth, not the treatment of PTSD or other mental health conditions. As far as is known, incidents are rare.[20] Some providers have even adopted guidelines to screen participants and thereby prevent a negative experience.[21] Knowledge of psilocybin is shared through the platform guildofguides.org, meaning that some self-regulation exists.

19 Michiel van Elk, 'Beperkingen bij geestverruimers', *De Groene Amsterdammer* (2023).

20 Conversation with scientist Michiel van Elk (Leiden University).

21 Conversation with philosopher Joost Breeksema (University of Groningen; Director of Open Foundation).

Table 3 displays a few examples of providers of MDMA sessions offering their services through their websites. These sessions are explicitly targeted at neuro-divergent people (like people with autism or dyslexia) or people suffering from a psychiatric condition or an addiction. Most counsellors are not BIG-registered, accredited or properly trained. The parties listed in the figure never go so far as to proclaim they heal people. Nor do they establish a formal diagnosis, as they are usually not competent to do so.

Such parties are mainly individual providers free-riding on the positive attention given to MDMA-AT in scientific literature. The websites of these providers repeatedly refer to, for example, the studies conducted by MAPS (into MDMA-AT), Compass Pathways (into psilocybin-AT) or other parties who made or make research possible. In so doing, they make selective use of the evidence: while they pay a great deal of attention to the role played by MDMA, hardly any attention is given to the therapy and aspects like transfer, disappointment, resistance and possible re-traumatisation. Nor is hardly any attention given to the possible side effects and risks.

In contrast to the truffle sessions – which involve a legal substance – the providers of MDMA sessions indicate they do not use MDMA during the treatment they offer; instead, they offer treatment using a structural MDMA analogue. These are MDMA-like substances that are chemically just different enough from MDMA to be legal. These providers do not explicitly note which substance they do use, as they might not know, exactly. The fear of them having to close their practice because the substance will be prohibited in the future may also play a part.[22] This is because, on 16 January 2024, the House of Representatives adopted an amendment to the Opium Act banning MDMA analogues starting 1 July 2024. The consequences thereof for the grey economy cannot yet be predicted. While some providers may close shop, it may also be that they become even less visible and even more difficult to monitor.

Uncertainty about the exact substances on offer

The exact MDMA-like substances used in the grey economy and their associated dosages are unknown. This therefore also applies to the clients, who are unable to verify the substances used by such providers. What exact analogue is used? What are the side effects of this substance? Where does the substance come from? How much does a pill contain?

Moreover, it cannot be determined with certainty whether the provider actually does use legal analogues. In practice, it is much simpler to use the cheap and well-known substance, ecstasy. This is easy to obtain for both the provider of the therapy and the client. The new NPS Act will almost certainly affect the way the grey economy offers its MDMA-like therapy, but this does not have to mean a change of practice.

Nor are the clients able to verify what type of provider they are dealing with. Some providers do not list their family name on their websites. These appear to be the providers with the least amount of experience in offering this therapy. Providers who do state their full name often have a professional background in a specific

22 Conversation with pharmacist Wim Best (Health and Youth Care Inspectorate).

therapy format, such as hypnotherapy or osteopathy. This means that, while these providers are therapists, the fact that this title is not protected means that this does not constitute any guarantee that they are able to provide reliable MDMA-assisted therapy.

/// The product currently offered by many providers consists of at least one MDMA session or a session with a structural MDMA analogue. Without a doubt, some of these providers neglect the crucial integration sessions and aftercare.

These providers often refer to the scientific literature on MDMA-AT. In so doing, they create the impression that they offer the same treatment, implicitly promising the same results. However, most providers deviate significantly from the protocol studied, as becomes evident from the indications they offer treatment for, their own qualifications and the fact that they also offer group sessions.

MDMA-AT assumes that the extensive integration sessions held after the treatment with MDMA are crucial. It is uncertain whether an unqualified therapist is willing and able to enter into such a long and intense treatment relationship with a client. In addition, other, underlying conditions like anxiety, anger, shame, and sadness may come up when treating trauma. Moreover, physical reactions like tension, trembling and a raised pulse may occur. These reactions are often related to the trauma and can be intense in nature, requiring a careful and sensitive approach to address them within the therapeutic setting. If the supervision is lacking, a client may leave a treatment in a worse state than when entering it.

Table 3
Anonymised examples[23]

	Provider A
Treatment offered	Provider A offers exposure therapy under the influence of MDMA to people suffering from traumas. Provider A not only focuses on trauma, but also offers MDMA sessions to people with autism, a negative self-image or social anxiety.
Substance	Even though provider A advertises with the use of MDMA, they preferably use legal psychedelic truffles. Upon request, an undefined substance that 'imitates MDMA' can be used.
Promises	Provider A promises his clients various changes in personality, including increased empathy and emotional intelligence. The provider does warn about side effects, such a wobbly eyes, difficulty urinating, tightness of the chest and strokes. However, provider A emphasises that these risks are outweighed by the potential benefits.
Treating physicians	The treating physicians working for provider A prefer to keep their family names secret. This is a diverse team, encompassing a chemist, a coach and other professionals. One treating physician is present at each session.
Location	Provider A visits the client at home. An alternative is for the client to rent an AirBnB, hotel room or holiday home.
Price	All treatments offered by provider A cost between €500 and €900. A session with MDMA will cost the client €700.

23 These providers have been anonymised, as the State Commission does not wish to give individual providers a platform. The examples are provided for illustration purposes only. In order to render the providers less recognisable, their details have been shifted between them and amounts have been rounded.

Provider B	Provider C
Provider B has something to offer to everyone: from individuals to groups of friends, to treat PTSD and to foster spiritual growth. This package is composed of three MDMA sessions and two intervening integration sessions. Yoga, massages and nutrition advice are included.	Provider C does not target specific audiences. The provider and the client establish in consultation if an MDMA session will be helpful. The sessions are provided to individuals or couples. Following the session, a six-hour period is available for integration by email, telephone or video calls.
Provider B uses MDMA and psychedelic truffles. It is not clear whether this is a structural MDMA analogue or ecstasy.	Provider C uses the (currently) legal structural MDMA analogue 5-MAPB.
According to provider B, clients suffering from PTSD can expect great improvement. The provider calls MDMA a wondrous substance that has magical effects. Provider B asserts that clients are incapable of processing their traumas because they lie to themselves about their painful memories. According to this provider, MDMA is a truth serum used by the CIA that also enables the processing of traumas.	Provider C primarily promises peace of mind. The MDMA session is said to calm down emotional life and dissolve thresholds. In addition, provider C promises that unhealthy and undesirable behavioural patterns will attenuate. All told, the provider promises a general increase in the quality of life.
The treating physicians of provider A list their family and personal names. They are persons with a background in mental health care and alternative medicine. Two treating physicians are present at each session.	Provider C works alone. He is a psychologist providing his personal and family name.
Provider B uses business premises for the individual sessions. Group sessions take place in public, for instance in the woods.	It is not known where provider C offers his services.
The treatments offered by provider A cost between €700 and €800.	Provider C offers flexibles packages. The default package includes an intake, an MDMA session and six hours of integration. The total price is €1,800

Finally, it must be noted that it is highly likely that a major share of the MDMA therapy on offer is not advertised, but marketed to clients through word of mouth.

Monitoring of the grey economy

/// There is no effective monitoring of the current providers of MDMA therapies, nor are patients with bad experiences able to receive aid or report the matter. Enforcement and punishment only take place when things go wrong. No central reporting centre to lodge complaints with exists within this network.

There is no organisation that monitors whether the grey economy complies with the law. Enforcement only takes place once someone reports serious malpractice to the Health and Youth Care Inspectorate. This concerns malpractice in which the police needs to become involved.[24] No central reporting centre to lodge complaints with exists within the grey economy.

If required, the Health and Youth Care Inspectorate can reprimand these providers. The sole enforcement instrument available to the Inspectorate is Section 3b of the Opium Act:

1. Every publication seemingly aimed at promoting the sale, supply or provision of a substance as referred to in Section 2 or Section 3 is prohibited.
2. The prohibition laid down in the first subsection does not apply to publication in the context of providing medical or scientific information.[25]

The substances this Section refers to are the substances listed in Schedule I and II to the Opium Act, which therefore includes MDMA. The said section of the law prohibits providers from explicitly advertising an offer of MDMA. As noted before, it is not certain how this affects actual practice.

Sexually transgressive behaviour

The final aspect the State Commission wishes to address, is the risk of persons who have taken MDMA or a structural MDMA analogue entering into an altered state of consciousness. Questions remain as to how professional an attitude provider in the grey economy are able to adopt towards a patient in a state of heightened emotional susceptibility and whether this increases the likelihood of mental, physical or sexual abuse by a therapist lacking clear professional boundaries. The lack of proper supervision is a problem with respect to the practices of treating physicians operating outside of the regular system.

Transgressive behaviour also occurs within the regulated mental health care system and the matter is, therefore, considered a serious problem. In 2022, the Health and Youth Care Inspectorate received 50 reports of sexually transgressive behaviour within the mental health care system, rendering it the most vulnerable health care sector for such abuses, together with the care sector for disabled persons.[26] This is one of the reasons why, in the scientific trials, every MDMA session was always supervised by two treating physicians and why all sessions were recorded on video. This condition is also laid down in the protocol.

24 Conversation with pharmacist Wim Best (Health and Youth Care Inspectorate).

25 Opium Act, Section 3a (consulted on 30 January 2024).

26 Health and Youth Care Inspectorate, 'Cijfers meldingen seksueel grensoverschrijdend gedrag', *igj.nl* (most recently updated with the figures for 2022).

Nevertheless, this is no guarantee for preventing such abuses: sexually transgressive behaviour took place during a clinical study into MDMA-AT in Canada. The websites of providers in the grey economy show that multiple providers do not adhere to this 'four-eyes principle'. The risk of transgressive behaviour will therefore be higher than within the regular health care system. For this reason as well, the State Commission recommends that a centre be set up for receiving reports of bad experiences in the grey psychedelic treatment sector.

Abuse during MDMA-AT

As part of the international phase II trial by MAPS into MDMA-AT conducted in Vancouver, one patient suffering from PTSD as a victim of sexual violence had herself treated for her traumas by a married couple in 2015. The therapeutic team in this case consisted of a female psychiatrist and her husband, who purported to be a psychologist but was afterwards found not to possess the required qualifications.

During the session, the patient was pushed onto a bed against her will by the male therapist, while the female therapist tried to blindfold her using a towel. At another moment, both therapists were hugging the woman, the man pressing his crotch against the patient. After the therapy ended, the patient continued to meet with the male therapist, who allegedly abused her. The patient made her story public in a 2018 podcast.[27] The supervising team and the sponsor, MAPS, labelled the behaviour by the male therapist disturbing and unethical and ended their cooperation with the couple for this reason.[28] In addition, the police felt it had reason to prosecute them in 2019. However, the Canadian public prosecution service thought otherwise.[29] The presence of an unqualified psychologist in addition to a trained psychiatrist was found not to be an exception. This was a cost-saving measure in order to keep the therapy affordable for patients.[30] Because the man was not a psychologist, no professional association could call him to order, nor was the patient able to file a complaint with anybody. As a result, she felt forced to go public with the story.[31]

The victim affirmed in the scientific journal *JAMA Psychiatry* that, in addition to conducting more research into the side effects, more attention should also be provided to the relationship between the treating physician and the treated person.[32]

27 New York Magazine, 'New York Magazine's Investigative Series Podcast, Cover Story: Power Trip Is Out With Part Two', *nymag.com* (2022).

28 MAPS, 'Statement: Public Announcement of Ethical Violation by Former MAPS-Sponsored Investigators', *maps.org* (2022).

29 Bethany Lindsay, 'Footage of therapists spooning and pinning down patient in B.C. trial for MDMA therapy prompts review', *CBC News* (2022).

30 Grace Brown, 'The Therapy Part of Psychedelic Therapy Is a Mess', *WIRED* (2023).

31 Bethany Lindsay, 'Footage of therapists spooning and pinning down patient in B.C. trial for MDMA therapy prompts review', *CBC News* (2022).

32 Sarah McNamee et al.,'Studying Harms Is Key to Improving Psychedelic-Assisted Therapy—Participants Call for Changes to Research Landscape', *JAMA Psychiatry* (2023), 411–412.

Conclusion

The State Commission is worried about the life of its own the reports about MDMA-AT have taken. The patient population has become very interested in MDMA-AT. Given the media attention its registration in the United States will provoke, it is likely that this interest will only continue to grow. In view of the recent scientific developments, this interest is understandable.

However, for as long as no or only insufficient legal treatment options exist, dangerous alternatives will increasingly pop up to meet their needs. The more attention is paid to this treatment, the more people will seek out illegal and semi-legal alternatives. The ease with which MDMA can be obtained on the illegal markets heavily contributes to this development. The State Commission considers this to be undesirable and calls on the government to steer these developments in the right direction while it still is able to.

The amendment of the Opium Act that will enter into force on 1 July 2024 – provided the Senate agrees – provides some tools for tackling treatment providers. At the same time, there is the risk that this group – which can currently still be found online – will go underground as soon as this amendment enters into force, increasing the likelihood of accidents.

Recommendations

In Chapter 7, the State Commission already made its most important recommendation, also with respect to the problems outlined in this chapter: offer patients a professional and accredited MDMA-AT treatment option. At the same time, the available capacity for this treatment will be insufficient to meet the demand in the years to come. The government needs to take this factor into account as well. As a consequence, the demand for (illegal) alternatives will continue to exist for the time to come, though it may be limited.

1 In addition to promoting a professional and accredited MDMA-AT treatment option, the government is to create policy regarding the grey economy.

The demand for therapeutic uses of MDMA (and other psychedelics) outside of the regular health care system will continue to exist and may even increase. This requires setting up prudent policies. The State Commission recommends that the government focus its policies on the following aspects:

a Restrict the irregular (high-risk) supply.
b Inform the potential audience about the dangers associated with treatment within the grey and underground sectors while doing so.

In so doing, indicate the minimum demands consumers should make on treating physicians in the grey economy and on clandestine providers in order to limit the risks as much as possible. For example, develop a checklist that would help potential consumers to identify a less risky and more reliable provider.

c Also inform the audience about the risks associated with purchasing MDMA and like substances on the illegal markets.

Pharmaceutically produced MDMA and the product of illegal labs (ecstasy) are very different, for example as regards certainty about the dosage, purity and the setting in which it is purchased. Warnings should also be issued about MDMA analogues, as a lot less is known about these substances than about MDMA. The State Commission definitely finds that addiction centres and the Trimbos Institute have a role to play in this connection.

d Set up a national reporting and support centre for people who have had negative experiences with MDMA-AT in the grey or underground sector or facilitate expertise centres to collect such information.

A national reporting and support centre for people who have had a negative experience with psychedelics in the grey or underground sector could help these people process that experience. It may also lead to more insight into the scope of this phenomenon. This reporting and support centre should refer people to the regular assistance and care centres. At present, neither the size of the group that has turned to the grey or underground sectors nor their positive and/or negative experiences are known.

The reporting and support centre may also be tasked with imposing sanctions on providers that have been complained about. In addition, the reporting and support centre could form a starting point for an accessible regular health care programme for persons who have made a report of negative experiences in the grey economy, so as to prevent their complaints from worsening.

2 Pay special attention (as government and professional associations) to illegally operating professionals in the grey economy.

Professional associations must make it clear to their members what is professionally, legally and ethically acceptable.

It is up to the professional associations to draw up guidelines on how to deal with BIG-registered therapists who assist patients suffering from PTSD and have already offered sessions involving MDMA, even though they are not (yet) accredited to do so.

3 Act proactively and develop policy frameworks with respect to other indications and other substances in good time.

This advisory opinion almost exclusively pertains to the use of MDMA to treat PTSD. However, a wave of studies is being conducted into treatment for other indications and into other substances in the psychedelic spectrum. These studies are already under way, but their results can still be anticipated on. It is essential that the government acts proactively and in a timely fashion to develop policy frameworks that not only respond to the current state of research and treatment, but are also prepared for future developments.

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Afterword

The aim of the State Commission on MDMA during its one-year existence was to provide a balanced view on MDMA. The government's instruction was '*... to investigate the status of XTC (MDMA) in the context of public health and to issue recommendations on the advantages and disadvantages of medicinal use, including a multidisciplinary analysis of health risks, prevention and the European context and relevant treaties.*' [1]

This task proved to be bigger than was originally believed. The State Commission was established in 2023 and was to publish its report in January 2024. However, more time was needed to do justice to the complexity of the subject – as is highlighted by the long list of experts, literature and studies consulted.
The State Commission has effectively written two advisory opinions. The first is about MDMA as the drug better known as ecstasy, which has been part of this country's nightlife culture for 40 years. The second advisory opinion is about the new use of MDMA as a supporting medicine when treating patients suffering from a post-traumatic stress disorder. One substance, with two completely different uses, raising completely different questions.

One important dilemma the State Commission was confronted with concerned the fact that the use of MDMA is not, in itself, all that risky compared to other illegal drugs or legal substances like alcohol or tobacco. At the same time, however, the production of and trade in MDMA causes major damage to persons, the living environment and society as a whole. The problem becomes even more complex due to the international role played by Dutch ecstasy criminals.

The State Commission concludes that there is an urgent need to reassess and update the Dutch drug policy on the basis of scientific insights, not emotions. The Dutch approach to ecstasy users is rather unique around the globe and is based on prevention and the limitation of damage. For years now, the results

1 Minister of Health, Welfare and Sport, 'Instelling Staatscommissie MDMA' (2023).

have been positive, at a relatively low cost. The Netherlands spends relatively little on prevention as part of its drug-related policy and there are opportunities available in this connection, in particular if the Netherlands were to properly invest in drug prevention by making more financial means available on a regular basis.

In addition, MDMA offers thus far unused opportunities for people suffering from a post-traumatic stress disorder. Despite the scientific evidence, making this treatment available in the Netherlands and the rest of the European Union will require a major effort. In this context, it should not be forgotten that, in addition to MDMA, other psychedelics – like psilocybin, LSD and ketamine – have received interest from scientists in connection with the provision of treatment for many mental health and neurological conditions. All these substances are already available, be it legally or illegally, and there is a lot of media attention for such new treatment forms. Alternative providers are already active, but their level of professionalism is questionable. The developments around MDMA provide the government and its partners with lessons to anticipate on such developments in the future.

Because of the wide-ranging composition of the State Commission, comprised as it is of experts in the field of psychiatry, medicine, prevention, law and criminal investigations, all questions and dilemmas could be properly addressed. In the end, this has resulted in an outcome individually endorsed by all members of the Commission and based on both scientific insights and pragmatism.

The dilemmas and inconsistencies and, thus, the need for nuanced assessment and alternatives are reflected in the various conclusions and recommendations. At times, firm and clear conclusions could be drawn, resulting in strong recommendations (as was the case for counterproductive prevention messages), but more often, the Commission had to make complex assessments and offer a provisional conclusion that ultimately still had to lead to a clear recommendation (such as keeping MDMA in Schedule II). At yet other times, the State Commission only presents important fact-based considerations in this report, without making a specific recommendation.

It is now up to politicians, policymakers and professionals to benefit from this report and to use its conclusions and recommendations to move beyond ecstasy.

The Hague, May 2024

List of persons and organisations consulted

The advisory opinion of the State Commission on MDMA has been made possible with the cooperation of a great many persons and organisations. These contact moments helped the State Commission to formulate an informed and independent advisory opinion. Between April 2023 and April 2024, the State Commission consulted with the following persons.

Persons consulted
Name / Position / Organisation

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Willem Woelders
Head of Operations, Central Unit
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Researcher
University of Amsterdam

Organisations consulted
Organisation / Representative(s)

Medicines Evaluation Board
Agency employee

Coordination Point Assessment and Monitoring new drugs
National Institute for Public Health and the Environment employee

MIND Platform
Focus group of persons having (or having experience with) PTSD

Ministry of Justice and Security
Group of officials from the Directorate-General for Subversive Crime and the Department for Security and Management

Ministry of Health, Welfare and Sport
Group of officials from the Nutrition, Health Protection and Prevention, Curative Care, and Pharmaceuticals and Medical Technology Departments

Psychedelic Platform of the Dutch Association for Psychiatry
Group of psychiatrists

PsychedelicsEUROPE
Representatives

Trimbos Institute
Group of employees relevant to the topic

Dutch Health Care Institute
Mental health care, social domain and pharmaceutics-economics advisers

Other contributions

The following (then) students gave a presentation to the State Commission about their research:
Inge Buiter, **Jill van Dorp**, **Chris Hucke**, **Willemijn Krugers-Dagneaux** and **Marloes Niessen**.

The following (then) students took minutes of the meetings of the State Commission:
Jet Dorhout, **Willemijn Krugers-Dagneaux** and **Jorrit Westerhof**.

The following persons proofread parts of this report for factual inaccuracies:
Martin Jelsma, **Kim Kuypers**, **Margriet van Laar**, **Laura Smit-Rigter** and **Metten Somers**.

Ministerie van Volksgezondheid,
Welzijn en Sport

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Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum 17 maart 2023
Betreft Instelling Staatscommissie MDMA

Geachte voorzitter,

In het Coalitieakkoord is afgesproken dat er een Staatscommissie MDMA komt. In deze brief informeer ik u over de voortgang rondom deze Staatscommissie.

Ik kan u meedelen dat met prof. mr. dr. Brigit Toebes een voorzitter is geworven. Daarnaast nemen de volgende leden zitting in de Staatscommissie:
Prof. dr. W. (Wim) van den Brink
Prof. dr. E.W. (Emile) Kolthoff
Prof. dr. H.G.J.M. (Eric) Vermetten
Drs. M. (Martha) de Jonge
Drs. F.M.J. (Femke) Gresnigt

De Staatscommissie wordt gevraagd de status van XTC (MDMA) in het kader van de volksgezondheid te onderzoeken en advies uit te brengen over de voor- en nadelen van medicinaal gebruik, met inbegrip van een analyse vanuit verschillende disciplines van risico's voor de gezondheid, preventie en de Europese context en relevante verdragen.

De Staatscommissie streeft ernaar om het advies voor 31 januari 2024 aan de regering aan te bieden. Het kabinet zal op basis van het advies een standpunt innemen. Het voornemen is om dat voor de zomer van 2024 met uw Kamer te delen.

Hoogachtend,

de minister van Volksgezondheid,
Welzijn en Sport,

Ernst Kuipers

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