Draft Government proposal to Parliament amending the Narcotics Act and section 3 of the Electronic Prescription Act

MAIN CONTENT OF THE PROPOSAL

The proposal includes amendments to the Narcotics Act concerning the control of psychoactive substances prohibited on the consumer market, as well as the provision and receipt of international assistance. Additionally, changes are proposed to the definition of a narcotic medicinal product in the Act on Electronic Prescriptions.

The aim of the proposal, in accordance with the Government Programme of Prime Minister Petteri Orpo's administration, is to implement measures that support the prevention of drug use and the reduction of drug-related deaths among young people. Furthermore, in accordance with the Government Programme, the proposal aims to establish legislation in the social and healthcare sector enabling the provision and receipt of international assistance.

The proposal seeks to prevent the spread of new psychoactive substances, commonly known as designer drugs, and to reduce the public health risks associated with them. It would improve the predictability and effectiveness of regulation in situations where new designer drugs rapidly enter the market and differ only slightly in chemical structure from substances that have already been prohibited. The proposal also aims to prevent circumvention of the prohibitions contained in the Narcotics Act and to stop the marketing of new designer drugs as so-called legal highs. In addition, oversight would be strengthened through changes to record-keeping obligations for the lawful use of substances and through enhanced cooperation among supervisory authorities.

The proposal would also allow the provision and receipt of international assistance involving medicines classified as narcotics in exceptionally urgent crisis situations that threaten human life and health, where there would be insufficient time to obtain the import and export permits normally required under the Narcotics Act. Finally, the definition of a narcotic medicinal product in the Act on Electronic Prescriptions would be clarified to eliminate interpretative ambiguities regarding the regulatory status of certain medicinal substances that are classified as narcotics under national legislation.

The main objective of the proposal is to reduce the supply and demand of new designer drugs and thereby prevent the health, social and societal harms caused by these substances. The objective of the proposal concerning international assistance is to enable the efficient and timely provision and receipt of international assistance. The proposals also aim to clarify the regulatory framework.

The proposed laws are intended to enter into force on 1 June 2027.

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CONTENTS

EXPLANATORY NOTE

1 Background and preparatory work

This proposal is related to the section on social and healthcare service reform (Chapter 2.4) in the Government Programme of Prime Minister Petteri Orpo's administration.

The Government Programme places particular emphasis on preventing drug use among young people and reducing drug-related deaths among youth, and states that any additional measures needed will be assessed separately during the government term. Drug trafficking via the Internet, social media and various instant messaging applications has become more common, and designer drugs are increasingly being ordered to Finland from foreign online shops. As a result of online commerce, designer drugs have become more widely available than before, including in sparsely populated areas and among minors.[1] The current provisions of the Narcotics Act concerning psychoactive substances prohibited from consumer markets were originally created to enable a rapid response to the emergence of designer drugs. However, according to observations by the competent authorities, the legislation needs further improvement, because it is not fully capable of addressing the increasingly rapid and continuous creation of new and more dangerous designer drugs. One shortcoming of the current regulatory framework is that manufacturers and sellers of designer drugs are sometimes able to circumvent legal prohibitions by making minor chemical modifications to the structure of existing prohibited drugs. As a result, these new variants remain legal for a period of time, since each new chemical variation must be prohibited separately. This allows new designer drugs to be temporarily marketed and distributed as so-called "legal highs." The easy availability and apparent legality of these substances lower the threshold for their use, which in turn creates significant public health risks. In particular, efforts should be made to raise the threshold for experimentation with such substances among young people, as drug use started at a young age exposes individuals to both immediate and long-term harms and may lead to substance dependence later in life.[2]

The reasons outlined above have led to a reassessment of the current approach under which new designer drugs are prohibited reactively and individually as psychoactive substances prohibited from consumer markets. At the same time, the supervision of psychoactive substances prohibited from consumer markets has been reviewed comprehensively in cooperation with the competent supervisory authorities. This review has also identified certain areas for improvement relating to record-keeping requirements for the lawful use of such substances and cooperation between authorities.

In addition, the Government Programme aims to establish legislation and operating models within the social and healthcare sector to enable the receipt and provision of international assistance. European countries have intensified their cooperation in preparedness and emergency planning, particularly in the 2020s, in response to changes in the global security environment. Cooperation in areas such as pharmaceutical preparedness has increased following Finland's accession to the NATO defensive alliance. In addition, the European Union has strengthened cooperation through its common civil protection mechanism, *RescEU*, including by establishing new strategic stockpiles of equipment and medicines needed in crisis situations across member states. This increased cooperation has created a need to amend

[1] S. Rönkä – J. Markkula (eds): Drug situation in Finland 2020, Report 13/2020 of the National Institute for Health and Welfare, p. 135.

[2] S. Kailanto – I. Viskari (eds): Finnish model for drug death prevention: Measure proposals and guidelines for practical implementation. Finnish Institute for Health and Welfare 2023, p. 104.

Finnish legislation in areas where it does not already permit the provision and receipt of international assistance. The need for legislative changes concerns the Narcotics Act insofar as, during a crisis situation, it may be necessary to derogate from the normal licensing requirements governing the import and export of medicines classified as narcotics in order to provide or receive international emergency assistance. Section 22 of the Narcotics Act already contains provisions concerning international assistance. However, the current legislation does not take into account arrangements such as emergency assistance provided through RescEU. Exceptions to the ordinary licensing procedure should therefore continue to be provided for in relation to international assistance, so that aid can be delivered and received in a timely and effective manner.

In addition, a number of linguistic issues and matters relating to the interpretation of the law have been identified in the Narcotics Act and in legislation concerning narcotic medicinal products. These could be addressed at the same time as the implementation of the amendments required to achieve the objectives set out in the Government Programme. The current wording of the definition of a narcotic medicinal product in the Act on Electronic Prescriptions may give rise to interpretative inconsistencies when compared with the established practice under which decisions on the level of prescribing control for newly classified narcotic substances are made. Under the current practice, such substances are regulated either as narcotic medicinal products or as psychotropic medicines that primarily affect the central nervous system (CNS medicines).

The principal objectives of the proposal are to prevent the public health risks, particularly to young people, arising from new designer drugs and the resulting social problems. An additional aim is to enable the provision and receipt of international assistance involving medicinal products classified as narcotics in situations where this is not already possible under the current legislation. The proposal also includes amendments intended to clarify the regulatory framework.

The proposal has been prepared as official work by the Ministry of Social Affairs and Health in cooperation with the Finnish Medicines Agency (Fimea). The part of the proposal concerning the classification of new designer drugs as psychoactive substances prohibited from the consumer market has been prepared in cooperation with Fimea, the Customs Laboratory, the Forensic Laboratory of the National Bureau of Investigation and the laboratory of the Finnish Institute for Health and Welfare. The Drug Policy Coordination Group (term of office: 1 January 2024–31 December 2027; project number STM008:00/2024) has monitored the progress of the preparation. The proposal was also discussed by the Ministerial Working Group on a Sustainable Welfare Society on 4 June 2026.

A consultation procedure was organised from 4 June to 30 July 2026. [*Information will be supplemented after being circulated for comments*]

The preparatory documents for the government proposal are available on the Ministry of Social Affairs and Health’s public project portal at stm.fi/hankkeet under reference number STM010:00/2026.

2 Current situation and its assessment

2.1 Control under the Narcotics Act

2.1.1 Legislation

General prohibitions under the Narcotics Act

The control of narcotics in Finland is based on a two-tier system under the Narcotics Act (373/2008), pursuant to which both narcotics and designer drugs (hereinafter also “designer drugs" or "NPS”) are subject to control. The procedures by which a substance is classified as a narcotic are based on international treaties, a common procedure of the European Union (EU), or the national classification of substances. The classification of designer drugs is based on a national procedure. Substances are classified as narcotics or as psychoactive substances prohibited from the consumer market by Government Decree.

Once a substance has been classified as a narcotic, its production, manufacture, import into Finnish territory, export from Finnish territory, transport, transit, distribution, trade, handling, possession and use are prohibited pursuant to section 5(1) of the Narcotics Act (373/2008). Violation of the prohibition is punishable under Chapter 50 of the Criminal Code (39/1889). Derogations from the prohibition may be granted for medical, research, supervisory and industrial purposes.

Once a substance has been classified as a psychoactive substance prohibited from the consumer market, its manufacture, import into Finnish territory, storage, offering for sale and supply are prohibited pursuant to section 5(2) of the Narcotics Act. Violation of the prohibition is punishable under section 5a of Chapter 44 of the Criminal Code. Violation of the prohibition may also constitute the offence of smuggling under section 4 of Chapter 46 of the Criminal Code or handling unlawfully imported goods under section 6 of the same Chapter. Derogations from the prohibition may be granted for research and industrial purposes.

Control of narcotics

International drug policy is based on international treaties under which Finland has undertaken to place substances and preparations agreed between the contracting parties under narcotics control. Under section 3(1)(5) of the Narcotics Act, substances and preparations included in the schedules to the 1961 United Nations (UN) Single Convention on Narcotic Drugs and the 1971 Convention on Psychotropic Substances are classified as narcotics. The schedules to these conventions are updated on the basis of assessments conducted by the World Health Organization (WHO) at meetings of the United Nations Commission on Narcotic Drugs, and the process of classifying a substance as a narcotic drug may take more than one year.

Secondly, the view taken by the European Union has been that it should be possible to bring new synthetic narcotics t under narcotics control more rapidly than through the United Nations decision-making process. Pursuant to section 3(1)(5) of the Narcotics Act, narcotics also include substances for which a decision to subject them to control has been adopted in accordance with Council Framework Decision 2004/757/JHA, as amended by Directive (EU) 2017/2103 of the European Parliament and of the Council amending Council Framework Decision 2004/757/JHA in order to include new psychoactive substances in the definition of ‘drug’ and repealing Council Decision 2005/387/JHA.

Under the Council Decision, Member States report new psychoactive substances detected by them to EU authorities and to other Member States through the Early Warning System (EWS). The Early Warning System facilitates the exchange of information between Member States on all substances reported to the database. The network continuously disseminates information on the potential health effects of new substances, and quantities of such substances seized by enforcement authorities are reported through the network every six months.

The European Union Agency for Law Enforcement Cooperation (Europol) and the European Union Drugs Agency (EUDA) collect information on new substances reported through the EWS using criteria related to the scale of trafficking, organised crime involvement, pharmacological properties and poisonings. Where there is clear evidence relating to any of these criteria, the EUDA prepares an initial report on the substance with the assistance of the Member States. On the basis of this report, the Council, acting through the Member States, may decide to initiate a formal risk assessment. The risk assessment is carried out by the Scientific Committee of the EUDA, which seeks to determine the likelihood and severity of the risks associated with the substance, the prevalence of misuse and any potential legitimate use of the substance. On the basis of the risk assessment of a new psychoactive substance, the Commission may submit an initiative to the Council proposing that the substance be classified as a controlled narcotic drug. If the Council decides to subject a substance to narcotic drug control, Member States must implement the decision in their national legislation by the prescribed six-month deadline.

An EU-wide control procedure is not usually initiated immediately following the first notification of a substance, but only once the substance has become more widespread and has caused harm. Several substances may be brought under control at the same time, but despite this, the different stages of the process often take more than one year to complete.

In addition to the systems based on cooperation within the United Nations and the European Union, Finland has decided to classify new substances as narcotics through national decisions. In Finland, section 3(1)(5) of the Narcotics Act specifically classifies the khat plant, mescaline-containing cacti, Psilocybe mushrooms, and plant powders, grinds and preparations containing dimethyltryptamine (DMT) that are used for intoxicating purposes as narcotics. In addition, an amendment to section 3 of the Narcotics Act that entered into force in 2011 (322/2011) introduced a procedure whereby substances used for intoxicating purposes may be classified as narcotics by Government Decree if they are hazardous to health and have been reported to the aforementioned Early Warning System, or if they are positional isomers of such substances, or medicinal substances whose pharmacological properties are comparable to those of narcotics. Sections 3a and 3b of the Act lay down provisions on the assessment of the properties of substances and on taking into account the possibility that a substance may have industrial uses. The need for national decision-making was justified by the rapid development of new intoxicating substances and the slow pace of international cooperation. In addition, the need to restrict a substance may sometimes be limited to the national level before it becomes a matter of concern throughout the European Union.

Depending on the nature of the offence, a violation of the prohibition concerning narcotics may be punishable by a fine or by imprisonment for a maximum of ten years as a narcotics offence (section 1 of Chapter 50 of the Criminal Code), an aggravated narcotics offence (section 2 of Chapter 50 of the Criminal Code) or a narcotics use offence (section 2a of Chapter 50 of the Criminal Code). Preparatory acts and the promotion of narcotics offences are also criminalised (sections 3, 4 and 4a of Chapter 50 of the Criminal Code).

The substances, preparations and plants prohibited as narcotics under international treaties, the EU procedure and the national procedure are listed in the Government Decree on substances, preparations and plants considered to be narcotics (543/2008).

Control of psychoactive substances prohibited from the consumer market

In 2014, provisions concerning the definition, prohibition and control of psychoactive substances prohibited from the consumer market were added to the Narcotics Act. In addition, an enabling provision was adopted under which more detailed provisions on substances considered to be designer drugs prohibited from the consumer market are laid down by Government Decree (1130/2014). The purpose of the prohibition on designer drugs prohibited from the consumer market was to reduce the supply of new psychoactive substances that are likely to be harmful to health. The prohibition is intended to be used in situations where it is necessary to prohibit the importation and sale of a designer drug rapidly in order to prevent its spread to the Finnish drug market.

Unlike classification as a narcotic, classification as an NPS does not require proof that the substance is harmful to health. Medicinal substances and substances already prohibited as narcotics are excluded from the definition of an NPS. A prerequisite for classifying a substance as an NPS is that it has been reported to the EU Early Warning System and that it may be harmful to health. The potential harmfulness of substances is assessed by the Finnish Medicines Agency (Fimea) in cooperation with Finnish Customs, the Finnish Institute for Health and Welfare and the police, in the same manner as for substances classified nationally as narcotics by Government Decree. In practice, during the last decade, it has been necessary to prohibit new psychoactive substances entering the market because, on the basis of their chemical structure, there have been grounds to assume that their effects are similar to those of substances that had already been prohibited.

Compared with narcotics, the regulation of designer drugs is somewhat less stringent. The importation and storage of NPS for research activities or industrial business purposes are permitted, provided that prior notification is made to Fimea. Unlike narcotics, the possession and use of substances classified as NPS are not punishable. Some substances initially classified as NPS have subsequently been classified as narcotics once further information on their harmfulness and prevalence became available. Not all NPS have been classified as narcotis, for example because they effectively disappeared from the market after being prohibited.

Activities in breach of the prohibition on designer drugs may, depending on the nature of the act, be punishable under the Criminal Code by a fine or a term of imprisonment. The punishable offence may consist of a violation of the prohibition on psychoactive substances prohibited from the consumer market (section 5a of Chapter 44 of the Criminal Code), smuggling (section 4 of Chapter 46 of the Criminal Code), or handling unlawfully imported goods (section 6 of Chapter 46 of the Criminal Code; petty offence under section 6a).

Under section 5a of Chapter 44 of the Criminal Code, any person who, in violation of the Narcotics Act, intentionally or through gross negligence manufactures, imports, stores, offers for sale or supplies a psychoactive substance prohibited from the consumer market shall, unless a more severe penalty is provided elsewhere in the law, be sentenced for violation of the prohibition on a psychoactive substance prohibited from the consumer market to a fine or imprisonment for a maximum term of one year. The provision contains the subsidiary clause “unless a more severe penalty is provided elsewhere in the law”, which directs the authorities

to apply, as a matter of priority, the more severe smuggling provision contained in section 4 of Chapter 46 of the Criminal Code. Under section 4 of Chapter 46 of the Criminal Code, any person who, without the required authorisation or otherwise contrary to provisions or regulations governing importation or exportation, imports or attempts to import into the country, or exports or attempts to export from the country, goods the import or export of which is prohibited or requires an authorisation or inspection by an authority, shall be sentenced for smuggling to a fine or imprisonment for a maximum term of two years. In practice, unlawful imports of designer drugs prohibited from the consumer market are prosecuted primarily as smuggling offences.

Under section 6 of Chapter 46 of the Criminal Code, any person who conceals, acquires, takes possession of or conveys property in respect of which an offence referred to in sections 1–5 of that Chapter or sections 1–3 of Chapter 29 has been committed upon its importation into the country, or who otherwise deals with such property while knowing that it has been imported in that manner, shall be sentenced for handling unlawfully imported goods to a fine or imprisonment for a maximum term of one year and six months. Under this provision, a person may be convicted for concealing, acquiring, taking possession of or conveying a psychoactive substance prohibited from the consumer market that has been smuggled within the meaning of section 4 of Chapter 46 of the Criminal Code.

When determining the penalty, consideration is typically given to the type of narcotic or designer drug from the consumer market, its quantity, concentration, usual single dose, method of use and the manner in which the offence was committed. The key considerations are the harmfulness of the substance concerned and the quantity involved.[3] As evidence, prosecutors generally rely on expert opinions concerning the substance in question or on the assessment forms prepared in connection with Fimea's proposal to classify the substance, which may provide information on the nature of the substance, its typical dosage and its comparability to narcotics that have been in use for a long time.[4] In its case law, the Supreme Court has taken the view that, in the case of new substances, the penalty may be determined by comparing the substance with another substance for which established case law already exists. The substance used for comparison most often belongs to the same so-called chemical family or group.[5]

2.1.2 Need for amendments concerning new designer drugs

New designer drugs may be prohibited in Finland by classifying them nationally, by Government Decree, either as narcotics or as psychoactive substances prohibited from the consumer market. These prohibitions are primarily reactive, meaning that they are imposed only after a particular substance has already been detected on the market and its chemical name and structure have been identified. As long as a particular new substance used solely in the same manner as a narcotic has not yet been individually prohibited by a decree issued under the Narcotics Act, the substance remains lawful from the perspective of the Narcotics Act. The market for designer drugs is dynamic and fast-moving, and market operators seek to circumvent the prohibitions laid down in the Narcotics Act: when one new narcotic is prohibited, minor chemical modifications are made to its structure in order to place on the market a new, similar substance that is not yet covered by the prohibition. In most cases, these synthetic designer drugs, manufactured in illicit laboratories, mimic in their effects and

[3] Helsinki and Rovaniemi Courts of Appeal: Determination of penalties in narcotics, medicinal products and doping offences. Working Group Report 2019, p. 9.
[4] Helsinki and Rovaniemi Courts of Appeal 2019, p. 7.
[5] Helsinki and Rovaniemi Courts of Appeal, 2019, p. 6.

chemical structure a so-called traditional drug, such as cannabis (cannabinoids), the khat plant (cathinones) or various opioids.[6]

New unclassified psychoactive substances are marketed on the open internet as so-called "legal highs". By invoking legality, the risks associated with these substances, both in terms of criminal liability and health harms, may be presented as minimal. Buyers may be attracted by the easy availability, low price and perceived legality of the substances, and the fact that legality creates an impression of safety. Although some online shops selling designer drugs operate on open websites, from the buyer's perspective, normal consumer protection often does not apply. The substances are often marketed using vague descriptions or product names, and the buyer cannot in reality be certain that the substance purchased is what it is claimed to be. There is a risk that the substance is impure or more dangerous than expected.[7]

The proliferation of designer drugs is a significant public health risk.[8] The most important health risks are poisonings caused by these substances, which may result in severe health harm or death. Intravenous use of designer drugs may also increase the risk of infectious diseases and bacterial infections. Because designer drugs circulate rapidly on the market, precise information on their health effects and social harms is initially lacking. This lack of information poses challenges in particular for harm reduction work and for healthcare services treating patients who have experienced adverse effects. New designer drugs enter the market rapidly, and many also disappear quickly following their prohibition. However, some substances remain on the market, in which case more information becomes available on their short- and long-term effects. Such designer drugs have included, for example, alpha-PVP and furanylfentanyl, which are now classified as narcotics .

The increasing prevalence of new designer drugs is illustrated by the fact that in 2024, 1,000 new psychoactive substances were monitored in the European Union Early Warning System, of which 46 substances were reported for the first time.[9] In 2025, 50 new substances were reported. The new substances have mainly included synthetic and semi-synthetic cannabinoids, synthetic cathinones, and synthetic opioids such as nitazenes and so-called orphines. Each year, the Customs Laboratory analyses approximately 10–20 entirely new intoxicating substances arriving in Finland that have not yet been prohibited either as narcotics or as psychoactive substances prohibited from the consumer market. Laboratory analyses have shown that these new substances closely resemble existing prohibited substances in terms of their chemical structure, on the basis of which the new substance can be presumed to be likely harmful to health. According to Finnish Customs, most of the new substances have been synthetic cannabinoids or cathinones. However, Customs or the police cannot seize and destroy such a new substance if it comes into their possession before the substance has been prohibited by Government Decree.

Because the designer drug market operates rapidly and dynamically, developments in market practices require the continuous adaptation of legislative measures, regulatory activities and

[6] EUDA (2025): European Drug Report 2025. New psychoactive substances – the current situation in Europe (hereinafter *EUDA [2025]*).
[7] EMCDDA (2011): Briefing paper: Online sales of new psychoactive substances / "legal highs": Summary of results from the 2011 multilingual snapshots.; EMCDDA – Europol: EU Drug Markets Analysis 2024. Key insights for policy and practice, s. 29.
[8] UNODC Early Warning Advisory on New Psychoactive Substances. https://www.unodc.org/LSS/Page/NPS; EUDA (2025).
[9] EUDA (2025):

preventive substance-abuse work, as well as enhanced cooperation between the relevant actors. Over time, efforts have been made to develop the regulatory framework governing narcotics and designer drugs in order to respond to the challenges posed by rapidly evolving drug markets. Alongside international prohibition procedures, which have been perceived as slow, faster national procedures have been introduced with the aim of responding to the dynamic nature of designer drug markets and to attempts by market operators to circumvent existing prohibitions. Under the current system, the classification of designer drugs prohibited from the consumer market on the basis of the identification of the chemical name of an individual substance has generally been considered effective, but in some cases too slow in its reactive approach, as new designer drugs are being made available increasingly rapidly through the internet, social media and instant messaging services.

Internationally, greater emphasis has been placed in recent years on prevention and preparedness measures relating to new designer drugs, particularly following the spread in Europe of potent synthetic opioids such as fentanyl derivatives, nitazenes and, most recently, orphines. These new opioids have caused deaths even at very low doses, and their demand and supply are significant, for example in Estonia.[10] Several countries have sought to address the threats posed by the rapid development of new designer drugs by amending their legislation so that it becomes considerably more difficult to circumvent prohibitions relating to such substances. In practice, this has been achieved through proactive legislation by defining, on the basis of chemical structure, groups of substances that are prohibited under the law. The prohibition of substances is based on the premise that substances belonging to the same chemical group have similar effects due to their chemical structure. For example, different compounds within the nitazene group have continued, despite only minor structural differences, to produce potent effects by binding to opioid receptors in the central nervous system and have caused respiratory depression as a serious adverse effect. Various forms of group-based prohibitions are in use, for example, in Estonia, Norway, Denmark, Latvia, Lithuania, Poland, Belgium, the Netherlands and Germany. In addition, the European Union is currently considering a proposal by the European Commission under which group-based prohibitions would extend even to variants of substances used in the manufacture of drugs, namely so-called designer precursors.[11]

In the evolving drug situation, the legislative measures recommended by the supervisory authorities and necessary in light of the circumstances should be adopted in order to curb the supply and demand of new designer drugs in Finland and to prevent the health-related and societal harms resulting from the increasing use of such substances. Legislative measures would be employed because research indicates that the status of a substance as legal or illegal affects demand for that substance.[12] Drawing on the models and experiences of several other European countries, the scope of the prohibition on psychoactive substances prohibited from the consumer market in Finland could be expanded to cover, in addition to individual substances, substances belonging to predefined groups of substances. In that case, the manufacture, import into Finnish territory, storage, offering for sale and supply of substances belonging to the substance group would be prohibited under section 5 of the Narcotics Act and punishable under the Criminal Code. On the basis of the legislation of other EU Member

[10] EUDA (2025); information provided by the Estonian National Institute for Health Development.

[11] European Commission, 3 December 2025: Proposal for a Regulation of the European Parliament and of the Council on monitoring and controlling drug precursors and repealing Regulations (EC) No 273/2004 and (EC) No 111/2005.

[12] Ks. esim. A. Ledberg (2015): The interest in eight new psychoactive substances before and after scheduling. Drug and Alcohol Dependence, Volume 152, 2015, s. 73-78.

States applying group-based prohibitions and the most common categories of new substances reported to the EU Early Warning System, an effective prohibition could cover various groups of synthetic cannabinoids, phenethylamines, cathinones, fentanyls, nitazenes, orphines and tryptamines. Introducing a prohibition based on the core structure of these substance groups would enable preventive intervention in harmful activities on the designer drug market. Group-based regulation would bring all substances belonging to a prohibited substance group within the scope of control immediately upon their detection, thereby eliminating the temporal gap that exists under the current legislation.

2.1.3 Other identified needs for amendments concerning the control of designer drugs prohibited from the consumer market

In addition to group-based classification, the legislative preparation has examined other measures aimed at improving the control of designer drugs in order to prevent the spread of designer drugs for illicit use more effectively than at present.

Record-keeping obligations

The supervision of the lawful use of narcotics and psychoactive substances prohibited from the consumer market is supported by the record-keeping obligations laid down in sections 30 and 33a of the Narcotics Act and by the authorities' right to obtain accounting and record-keeping information. The obligation to maintain records concerning the manufacture, export, import and handling of narcotics applies to operators holding an authorisation under the Narcotics Act, as well as to certain operators exempt from the authorisation requirement under section 15(2) and section 22(3) of the Act. However, the record-keeping obligation does not apply to patients who have been prescribed medicinal products classified as narcotics for their personal medication. The record-keeping obligation relating to psychoactive substances prohibited from the consumer market applies to operators importing or storing such substances for use in their own research or production activities. Records relating to narcotics must be retained for at least six years, corresponding to the general retention periods laid down in the Accounting Act (1336/1997). Records relating to psychoactive substances prohibited from the consumer market must be retained for three years. Fimea has the right to obtain and inspect record-keeping information from operators for the performance of its licensing and supervisory duties.

Originally, the different record-retention periods for narcotics and designer drugs were established on the basis that the control regime for designer drugs is less stringent than that applicable to narcotics. However, the differing retention periods have created a degree of administrative burden and have complicated supervision. In Finland, approximately 20 operators have submitted notifications concerning the importation of designer drugs, primarily for research purposes. The vast majority of these operators also hold a valid narcotics licence and are therefore subject to two different record-retention periods. The classification of designer drugs may also change within a relatively short period of time, as such substances may be classified as narcotics at national, EU or UN level, which may create uncertainty as to the applicable retention period for records relating to a particular substance. From a supervisory perspective, it should also be noted that where a potentially large consignment of designer drugs has been imported, the entire consignment may not necessarily have been used within three years, in which case the record-retention obligation would expire. As a result, supervisory authorities might no longer be able to obtain information on what happened to the consignment after the three-year period, even if the substance imported as a designer drug had been classified as a narcotic during that period. Uniform record-keeping and notification

obligations would provide both operators and authorities with improved opportunities to monitor narcotics and designer drugs.

Reference standards

So-called reference standards are used in laboratories carrying out chemical analyses for the reliable identification of narcotics and designer drugs. These typically consist of quantities of a narcotic drug or designer drugs below one milligram or a few milligrams, either in salt form or dissolved in an organic solvent. Laboratories conducting chemical analyses obtain reference standards from suppliers specialising in their distribution or, in special cases, from cooperation partners specialising in drug control, such as the laboratory of the United Nations Office on Drugs and Crime (UNODC) or the European Union Drugs Agency (EUDA). Reference standards may also be obtained from drug consignments seized under section 45 of the Narcotics Act for the prevention and detection of offences, once the substances have been unequivocally identified. A lack of reference standards may sometimes delay the identification of new substances.

The revision of the mandate of the European Union Drugs Agency (EUDA) in 2024 strengthened cooperation between laboratories within the European Union. Laboratories belonging to the EUDA network of forensic and toxicological laboratories are now able, subject to certain conditions, to share reference standards with other laboratories participating in the network. In order to ensure the rapid identification of new designer drugs, it is important that laboratories within the network cooperate to improve the availability of reference standards.

Under the current Narcotics Act, forensic laboratories, the Customs Laboratory and the laboratory of the Finnish Institute for Health and Welfare (THL) may acquire reference standards directly from known foreign suppliers. An entity authorised to handle narcotics may transfer narcotics reference standards to another entity authorised to handle the substance concerned. Consequently, laboratories are, for example, able to share narcotic drug reference standards with one another. However, the current Narcotics Act does not contain a corresponding provision allowing the sharing of reference standards for designer drugs between official laboratories. International cooperation in the identification and assessment of new designer drugs has increased steadily in recent years, and at the same time a practical need has emerged for the sharing of substance reference standards of prohibited psychoactive substance between official laboratories, for example in order to make effective use of the EUDA laboratory network. It would be important that reference standards for designer drugs, in the same way as reference standards for narcotics already are, could be delivered directly to a single national contact-point laboratory in Finland, which could then distribute them onwards to other laboratories.

2.2 International Assistance Activities

In accordance with its programme, the administration of Prime Minister Petteri Orpo seeks to implement legislative amendments introducing into social and health-care legislation the powers and procedures necessary for the provision and receipt of international assistance where such assistance cannot already be provided or received under the current legislative framework in crisis situations. The need for amendments is linked in particular to increased cooperation between EU Member States, including opportunities to share resources and equipment in crisis situations. For example, two strategic stockpiles under the EU Civil Protection Mechanism RescEU have been established in Finland to prepare for threats

involving biological, chemical, radiological and nuclear agents. The latter project, launched in 2024 and focused on the establishment of a strategic stockpile, includes the storage of medical supplies and medicinal products.

Legislation concerning international assistance involving medicinal products is being developed in a separate legislative project prepared by the Ministry of Social Affairs and Health. However, insofar as international assistance involves medicinal products classified as narcotics, the necessary amendments are being introduced as part of this Government proposal.

Medicinal products classified as narcotics and therefore subject, in addition to the Medicines Act, to the Narcotics Act, could be received by Finland or exported from Finland as international assistance. Medicinal products are included in Finland's RescEU strategic stockpile, which is managed by the pharmaceutical wholesale operation of the Finnish Institute for Health and Welfare (THL). The stockpiles include medicinal substances classified as narcotics, some of which are listed under the 1971 United Nations Convention on Psychotropic Substances and others under the 1961 Single Convention on Narcotic Drugs. The export and import of such medicinal products classified as narcotics require an import or export licence from Fimea pursuant to Chapter 2 of the Narcotics Act, as the import and export of narcotics are, as a rule, prohibited under section 5 of the Narcotics Act. Any exceptions to the import and export licensing requirements must be expressly provided for by law. Without a specific statutory exemption, difficulties could arise in situations where medicinal products provided or received as international assistance must be distributed urgently in humanitarian crisis situations. Applications for import and export licences must not delay patients' treatment or jeopardise human health. Finland's RescEU strategic stockpiles are intended for use by Member States and countries participating in the EU Civil Protection Mechanism when the resources of the requesting country are insufficient to respond to a crisis or major emergency. Stored materials must be ready for dispatch to the disaster or crisis area within 12 hours of acceptance of the assistance offer. This creates challenges for the application of the import and export licensing procedures required under the international conventions and the Narcotics Act.

The Narcotics Act already contains provisions on certain exceptions to the ordinary import and export licensing procedures in special situations relating to first aid and crisis management, including exceptions referred to in the United Nations drug control conventions. Under section 22(1) of the Narcotics Act, an import or export licence is not required for medicinal products containing narcotics that are intended for use in first aid and form part of the medical supplies carried on ships, aircraft, ambulances and vehicles used in humanitarian assistance operations engaged in international traffic. Pursuant to section 22(2), such medicinal products must be kept in a sealed first-aid kit stored in a locked medicine cabinet. Responsibility for the medicinal products rests with the master of the vessel and, in the case of an aircraft, ambulance or vehicle used in humanitarian assistance operations, with the person responsible for the medical supplies.

Under section 22(3) of the Narcotics Act, an import or export licence under the Act is likewise not required for medicinal products brought into or taken out of the country by international or domestic military units participating in international cooperation, or by international disaster-relief assistance teams, provided that the medicinal products are intended for the unit's or assistance team's own first-aid use. The medicinal products must be stored in a locked first aid box and any unused medicinal products must be brought back to Finland. The military unit or rescue organisation shall designate the person responsible for the medicinal products and their

export must be reported in advance and import immediately after return to the Finnish Medicines Agency Fimea. In the activities referred to in that subsection, the medicinal products are intended for the use of the mobile unit itself and are not intended to be left in another country.

An amendment to the Narcotics Act adopted in 2022 made it possible to derogate from the import and export licensing requirements laid down in the Act in situations involving a humanitarian assistance organisation holding a pharmaceutical wholesale licence, provided that the operation relates to an exceptional situation or that there is another special reason justifying the derogation. Section 22(4) of the Narcotics Act provides that an organisation engaged in humanitarian aid activities and holding an authorisation referred to in section 32(3) of the Medicines Act is not required to obtain an import or export licence under the Narcotics Act for humanitarian aid activities where the situation concerned is exceptionally serious or there is another specific reason justifying such activities. In this case, the export of the medicinal products must be notified in advance and their import without delay to the Finnish Medicines Agency Fimea. The provisions of section 16 of the Narcotics Act on the requirements for the responsible person and section 17 on the approval of the responsible person shall apply to the import and export of medicinal products in the cases referred to in the subsection. Section 22(4) of the Narcotics Act may be applied, for example, in acute and extremely serious humanitarian crises where the competent authority responsible for import and export licensing procedures in the receiving country may not even be available. A similar situation could also arise where assistance is requested through the EU Civil Protection Mechanism. However, the amendments to section 22 of the Narcotics Act were adopted before the launch of Finland's RescEU stockpiling project, and such situations were therefore not taken into account in that provision.

The provision and receipt of international assistance involving medicinal products should also be possible in exceptionally urgent situations or crisis situations where there is insufficient time to apply for import and export licences under the Narcotics Act, if there is a risk to human life or health. Against this background, the legislative preparation has assessed the need to exempt, in exceptional circumstances, the pharmaceutical wholesale operation of the Finnish Institute for Health and Welfare (THL), which is responsible for pharmaceutical preparedness, from the ordinary import and export licensing requirements where activities are carried out under the RescEU mechanism, under which the export of medicinal products to another country is always preceded by a request for assistance submitted by that country through the mechanism.

Any national derogations from licensing requirements should be consistent with the 1961 United Nations Single Convention on Narcotic Drugs, the 1971 Convention on Psychotropic Substances and the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances. Article 31 of the 1961 Single Convention on Narcotic Drugs lays down the licensing procedures applicable to the import and export of narcotics between States Parties. Article 12 of the 1971 Convention on Psychotropic Substances provides for a corresponding licensing procedure. Pursuant to Article 12, the Parties are required to ensure that the import and export of substances listed in Schedules I and II are subject to a separate authorisation issued on a form approved by the United Nations International Narcotics Control Board (INCB). In addition, Article 12(1)(b) requires that, before authorisation is granted for the dispatch of a substance from the exporting country, an import authorisation must have been issued by the destination country.

As early as the 1990s, the World Health Organization (WHO) and the International Narcotics Control Board (INCB) recognised that, in humanitarian crisis situations, the competent licensing authorities are often unable to perform their licensing functions. For this reason, the International Narcotics Control Board (INCB) adopted Resolution 7 (XXXIX) on the timely provision of controlled drugs for emergency care, and the World Health Organization (WHO) developed model guidelines and a model form encouraging countries to apply simplified licensing procedures in order to ensure the timely delivery of emergency assistance.[13] In 2021, the INCB also issued guidance urging the competent authorities of exporting and receiving States to apply the greatest possible flexibility and discretion in the implementation of the international trade control measures referred to in the above-mentioned articles in emergency situations.[14] The INCB has also sought to provide specific information concerning exceptional crisis situations in which urgently needed medical emergency assistance cannot be delayed because of the absence of, or delays in, licensing procedures. One of the most recent humanitarian emergencies in respect of which such flexibility has been requested is the situation in Israel and Gaza.[15] Subsection 3 concerning the provision of humanitarian assistance, which was added to section 22 of the Narcotics Act in 2022, is intended to apply in situations of this kind. Where a situation requiring medical assistance involving RescEU medicinal products containing narcotics is comparable in nature, simplified licensing procedures could likewise be applied to facilitate the provision or receipt of such assistance.

2.3 Act on Electronic Prescriptions

Some substances classified as narcotics also have medicinal uses. Pharmaceutical preparations containing such substances are subject both to the Medicines Act (395/1987) and the Narcotics Act. Because medicinal products may, in addition to their therapeutic use, have abuse potential as narcotic substances, their prescription to patients is subject to stricter controls than those applied to standard medicines. To distinguish the levels of control, medicinal products containing narcotic substances are defined either as narcotic medicinal products or as centrally acting medicines (so-called CNS medicines).

The level of control is determined by the medicinal use of the products and the severity of the risk of misuse. Control of narcotic medicinal products includes special requirements such as specific prescribing procedures, record-keeping obligations for pharmacies and healthcare units, and security requirements for storage. CNS medicines are typically substances with abuse potential, but where the risk of misuse is considered lower than that of narcotic medicinal products. CNS medicines are subject to lighter but still enhanced control compared to narcotic medicinal products. For CNS medicines, requirements may include limitations on prescription validity, dispensing quantities, and monitoring obligations. The purpose of the regulation is to enable broad medicinal use of these substances while managing the risk of misuse.

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[13] WHO Model Guidelines and Form for the Transport of Internationally Controlled Substances in Emergency Situations, WHO/PSA/96.17, 1996. https://www.incb.org/documents/Narcotic-Drugs/Guidelines/medical_care/Guidelines_emergency_Medical_care_WHO_PSA_OCR.pdf, accessed on 20 May 2026.

[14] UN International Narcotics Control Board (2021): Lessons from countries and humanitarian aid organisations in facilitating the timely supply of controlled substances during emergency situations.

[15] The United Nations International Narcotics Control Board (INCB) (23 October 2023): INCB highlights the need to ensure access to controlled medicines in Israel and Gaza. https://www.incb.org/incb/en/news/news_2023/incb-highlights-the-need-to-ensure-access-to-controlled-medicines-in-israel-and-gaza.html, accessed on 20 May 2026.

Due to the special arrangements relating to the prescription of narcotic medicinal products and CNS medicines, their definitions are laid down separately in section 3, points 8 and 9 of the Act on Electronic Prescriptions and in section 2, points 5 and 9 of the Ministry of Social Affairs and Health Decree on Prescribing Medicines (1088/2010). According to these provisions, a narcotic medicinal product is defined as a medicinal product containing substances listed in Schedules I, II and IV of the 1961 Single Convention on Narcotic Drugs referred to in section 3(1)(1)(a) of the Narcotics Act, as well as substances listed in Schedules I and II of the 1971 Convention on Psychotropic Substances referred to in section 3(1)(1)(b) of the same Act, and substances referred to in section 3(1)(5)(e) of the Narcotics Act.

However, the definition of narcotic medicinal products in the Act on Electronic Prescriptions and in the Ministry of Social Affairs and Health Decree excludes certain substances controlled under the international drug control conventions, such as substances listed in Schedules III and IV of the 1971 Convention on Psychotropic Substances. Medicinal products containing such substances are typically controlled as medicines affecting the central nervous system (CNS medicines) rather than as narcotic medicinal products. The substances referred to last in the definition of a narcotic medicinal product, namely those referred to in section 3(1)(5)(e) of the Narcotics Act, are substances that have been classified as narcotics through a national procedure. Under the current definition, all medicinal products containing substances classified as narcotics at national level would be considered narcotic medicinal products.

The definition of a narcotic medicinal product set out in the Act on Electronic Prescriptions and in Ministry of Social Affairs and Health Decree 1088/2010 is currently inconsistent with the criteria on the basis of which the level of control applicable to medicinal products containing new narcotic substances is determined. The definition treats all medicinal products containing substances classified as narcotics at national level as narcotic medicinal products, even though some medicinal products present a lower risk of misuse and are therefore controlled as CNS medicines. The classification of these medicines as CNS medicines subject to control is justified, inter alia, by the fact that, based on their pharmacological properties, the active substances may be comparable to substances listed in Schedule IV of the 1971 Convention on Psychotropic Substances, which are not covered by the definition of a narcotic medicinal product. In Finland, the inconsistency in the definition of a narcotic medicinal product currently concerns three substances: pregabalin, remimazolam and zuranolone.

Section 23(3) of the Narcotics Act provides for an exception concerning pregabalin, according to which an import or export licence is not required for medicinal products containing a narcotic referred to in section 3(1), point 5(e), where, in view of the substance's extensive medical use, the risk of abuse may be regarded as only minor. According to the provision, for such products the same requirements and restrictions apply to products containing substances listed in List IV on psychotropic substances of the 1971 Convention. From the perspective of the structure of the legislation, however, it is inconsistent that pregabalin may, as a medicinal product referred to in section 3(1)(5)(e) of the Narcotics Act, also fall within the definition of a narcotic medicinal product, even though it is controlled as a CNS medicine pursuant to section 23(3) of the Narcotics Act.

In addition to pregabalin, remimazolam, which was classified as a narcotic in 2021, and zuranolone, which was classified as a narcotic in 2025, are medicinal substances whose pharmacological properties are comparable to those of substances listed in Schedule IV to the 1971 Convention that fall outside the definition of a narcotic medicinal product. However, there has been no need to apply the exception provided for in section 23(3) of the Narcotics Act to those substances, as they have not been widely used for medicinal purposes. In its

classification proposals concerning remimazolam and zuranolone, Fimea has taken a position on their control as CNS medicines, but the current definition of a narcotic medicinal product does not recognise this procedure. In order to remedy the situation, the definition of a narcotic medicinal product in the Act on Electronic Prescriptions should be amended to take into account the fact that not all substances classified as narcotics at national level should be categorically controlled as narcotic medicinal products, as their characteristics are not comparable to the schedules of the conventions referred to in the definition. The same amendment should be made to the Ministry of Social Affairs and Health Decree on Prescribing Medicines.

3 Objectives

The aim of the group-based prohibition of psychoactive substances prohibited from the consumer market is to reduce the supply and demand of new psychoactive substances and thereby prevent the health, social and societal harms caused by such substances. In addition, the purpose of the other proposed amendments relating to the control of psychoactive substances prohibited on the consumer market is to reduce the risk of substances with legitimate uses being diverted to misuse and to improve the conditions for cooperation between supervisory authorities in the identification of new designer drugs.

The objective of the proposal concerning international assistance is to enable the efficient and timely provision and receipt of international crisis assistance relating to medicinal products containing substances classified as narcotics.

The purpose of the proposal concerning narcotic medicinal products is to clarify and harmonise the regulatory framework and the relationship between the regulatory framework and supervisory practice.

4 Proposals and their impacts

4.1 Main proposals

Amendments would be made to the control of psychoactive substances prohibited from the consumer market. The definition of a psychoactive substance prohibited from the consumer market in section 3(3) of the Narcotics Act would be amended so as to recognise the possibility of prohibiting new psychoactive substances on the basis of the group of substances determined by their chemical structure (group-based prohibition). A prohibition based on the core chemical structure of substance groups would make it possible to intervene more effectively and at an earlier stage in harmful activities on the designer drug market by closing the temporal gaps in the current legislation relating to the prohibition of new designer drugs. A group-based prohibition would mean that the manufacture, importation, storage, offering for sale and other supply of substances belonging to such groups would be punishable under the Criminal Code. At the same time, criminal procedural measures would become available to Customs and the police, including the seizure and destruction of substances belonging to such groups in accordance with the Coercive Measures Act (806/2011).

The introduction of a group-based prohibition would be enabled by adding to the definition of designer drugs in the Narcotics Act a reference to substances which, by virtue of their chemical structure, belong to a group of substances that is likely to be hazardous to health. In addition, the location of the definition in section 3 of the Narcotics Act, as well as its wording and placement within the section, would be clarified. Section 3a of the Narcotics Act on the

assessment of the properties of new substances would also be amended to take account of group-based assessment.

The definition of psychoactive substances prohibited from the consumer market already includes an enabling provision under which such substances are further specified in a Government Decree (1130/2014). As a consequence of the amendment to the definition of a designer drug in the Narcotics Act, the Decree would be amended by adding a new Annex 2 defining a number of substance groups, in addition to the existing annex listing individual substances. Each substance group would be defined on the basis of the core chemical structure of the substances concerned, which would be described by means of a structural formula. The structural formula would also specify the variations in the different parts of the core structure covered by the definition of the substance group concerned. The purpose of specifying such variations is to cover different derivatives in a precise and clearly delimited manner. The core structure of an individual substance, and thus its inclusion in a particular substance group, could be objectively demonstrated through laboratory testing. The substance groups are described in greater detail in the separate draft Decree annexed to the Government proposal and in the accompanying explanatory memorandum.

In addition, two minor amendments would be made to the control of designer drugs. The retention period for records relating to the importation and storage of designer drugs under section 33a(1) of the Narcotics Act would be extended from three to six years. In addition, a new subsection 4 would be added to section 23b of the Narcotics Act, enabling the laboratories of the Finnish Institute for Health and Welfare, Customs and the National Bureau of Investigation to provide one another with so-called reference materials of substances classified as designer drugs, i.e. substances and preparations used for the identification of substances.

As regards international assistance, section 22(4) of the Narcotics Act would be amended to confer on the Finnish Institute for Health and Welfare the authority to provide and receive international assistance involving medicinal products containing substances classified as narcotics. As a result, assistance activities for which the Finnish Institute for Health and Welfare is responsible, such as activities carried out within the framework of a rescEU stockpile under the EU Civil Protection Mechanism, would not be subject to the import and export permit requirements laid down in the Narcotics Act. The export of the medicinal products should be notified in advance and their import without delay to the Finnish Medicines Agency Fimea.

As regards narcotic medicinal products, the definition of a narcotic medicinal product in the Act on Electronic Prescriptions would be amended so that medicinal products containing substances classified as narcotics at national level would no longer automatically be considered narcotic medicinal products by virtue of that definition alone. The amended definition would take into account the fact that an active substance classified as a narcotic may, in terms of its pharmacological properties, be comparable to substances listed in Schedule IV to the 1971 Convention on Psychotropic Substances, which are controlled as CNS medicines rather than as narcotic medicinal products. The amendment would clarify and align the definition of a narcotic with established control practice.

4.2 Principal impacts

[The impact assessment will be supplemented during further preparation.]

4.2.1 Economic impact

Impacts on business activities

Extending the scope of the prohibition on psychoactive substances prohibited from the consumer market from individual substances to substance groups would mean that, in the future, the manufacture, import, storage, offering for sale and supply of substances belonging to such groups would be prohibited. The use of these substances for industrial and research purposes would remain subject to a notification requirement. The amendment would affect business activities that are currently considered lawful and involve the marketing of new psychoactive substances for consumer use.

Business activities in the new psychoactive substances market are diverse and include trade in both prohibited substances and substances that have not yet been classified and are therefore legal from the perspective of the Narcotics Act. Some operators offer only substances that are not yet covered by the prohibitions laid down in the Narcotics Act, while others offer both "legal" and prohibited substances. As these substances have few legitimate uses, operators producing them as reference standards for laboratory use are generally the only ones engaged in unquestionably lawful business activities. Other operators knowingly operate in a grey area. Due to the diversity of operators, the international nature of the trade and the dynamic nature of the market, it is difficult to assess the size of the market accurately. New psychoactive substances are typically manufactured outside Europe, for example in China or India, and are then supplied to Europe for further sale and marketing in various products. On the other hand, according to information from the EUDA, laboratories producing new designer drugs, such as synthetic cannabinoids and cathinones, have also increasingly been detected in Europe.[16] No operators manufacturing these substances have been identified in Finland. New designer drugs most commonly arrive in Finland from elsewhere in Europe, such as the Netherlands, for example through consignments ordered from international online stores.[17] In 2024, EU authorities seized a total of 41.4 tonnes of designer drugs. The figure includes both substances previously reported through the EU Early Warning System (350 substances) and newly identified substances detected for the first time (47 substances). According to the Customs Laboratory, in 2025 Finnish Customs analysed 479 samples of substances prohibited from the consumer market and 48 samples of new, unclassified intoxicating substances in connection with suspected customs offences.

The effects of introducing a group-based prohibition would target intoxicating substances that are identified for the first time or have not yet been classified in Finland either as narcotic substances or as designer drugs. On the designer drug market, such substances may be marketed as "legal highs". The operating conditions for the market in such "legal highs" would deteriorate, as the most popular groups of substances would be prohibited and the marketing of substances belonging to those groups to Finland for the purpose of circumventing legislative prohibitions would become more difficult. For example, the activities of foreign online shops targeting Finland could decline as a result of the legislative amendment, as some sellers would likely refuse to supply a substance if they are aware that it

[16] EUDA 2024: EU Drug Market: New Psychoactive substances – in depth analysis.
[17] Customs Laboratory data.

is prohibited in the destination country. [18] Even now, the life cycle of most designer drugs is typically short because new substances are continuously being prohibited. Substances enter the market rapidly and are also withdrawn from the market quickly once they become prohibited.

As the proposal is aimed at weakening the conditions for the trade in so-called legal highs, it would not have a direct impact on the supply of or demand for drugs that are already prohibited. The trade in such drugs already operates unlawfully and largely in concealment. It is possible that, following the entry into force of the proposed legislative amendments, operators engaged in the designer drug trade would seek to identify new substances that do not yet belong to any prohibited substance group in order to take advantage of the possibility of operating legally. However, during the preparation of the proposal, it was assessed that prohibiting the most popular substance groups would reduce the number of operators capable of manufacturing new substances that remain lawful. In addition, it would still be possible in the future to prohibit substances individually and to prohibit new substance groups where sufficient information becomes available regarding their prevalence, typical health risks and chemical structure. Taking these factors into account, group-based classification would likely significantly reduce the annual number of designer drugs that are able to enter the market legally.

Impact on healthcare costs

The purpose of the group-based prohibition is to reduce the entry of new substances onto the market and thereby reduce the health harms associated with their use and the burden on healthcare services. New designer drugs may cause acute poisoning, require intensive care treatment and result in unpredictable long-term health effects. Particularly concerning is the risk of potent synthetic opioids entering the market, as such substances are known to have caused increases in overdoses and overdose deaths in various parts of the world, sometimes described as epidemic waves.[19] A particular challenge in the treatment of overdose cases is that the symptoms caused by new designer drugs are not well understood.[20] Emergency department visits and intensive care episodes in particular may involve high unit costs. However, precise information on the impact of new, unclassified intoxicating substances on healthcare services is not available, as such substances typically cannot be detected through the substance screening tests commonly used in emergency care settings.[21]

Other economic impacts

No economic impacts have been identified in relation to extending the retention period for records concerning the lawful use of designer drugs, introducing into the Narcotics Act an authority for supervisory authorities to transfer designer drugs to one another, or amending the definition of narcotic medicinal products.

[18] A. Ledberg (2015); EMCDDA (2011) p. 5.
[19] EUDA (2025).
[20] U. Tacke – B. den Hollander – K. Simojoki – E. R. Korpi – K. Pihlainen – H. Alho (2011): Designer drugs in Finland. Medical journal Duodecim 2011;127(19):2027-36.
[21] See T. Järvinen and J. Boyd: Overdose patients who have used designer drugs in the Emergency Medical Service of Helsinki, 2009–2012. Medical journal Duodecim 2015;131(18):1659-66. It should be noted, however, that the availability of designer drugs and drug use in general in Finland has increased since 2012.

4.2.2 Impact on the activities of the public authorities

The group-based classification of designer drugs would mean that the ability of authorities such as the police and Finnish Customs to prevent and investigate offences involving designer drugs belonging to new substance groups would improve. These authorities would be able to seize and, where necessary, destroy new designer drugs entering and spreading in Finland, the distribution of which cannot currently be prevented at an early stage under the existing provisions of the Narcotics Act. The laboratory methods currently in use would be suitable for identifying the chemical structure of such substances. Initially, the amendment could require training and guidance on the chemical classification of substances. In addition, the Customs Laboratory, the forensic laboratory of the National Bureau of Investigation, the Finnish Medicines Agency (Fimea) and the laboratory of the Finnish Institute for Health and Welfare could receive a greater number of requests for advice and expert opinions, for example in criminal proceedings. On the other hand, the potentially urgent need for supervisory authorities to classify new substances individually as designer drugs would decrease, although it would remain possible to add individual substances belonging to substance groups to the annex of the decree in order to emphasise their control status. The need for authorities to actively disseminate information on substances detected in Finland and the risks associated with them would remain, in order to increase public awareness of the dangers related to the use of new substances.

For the provision and receipt of international assistance, it is proposed that a simplified licensing procedure in accordance with the guidelines of the International Narcotics Control Board be applied. The amendments concerning the provision and receipt of international assistance would improve the ability of the Finnish Institute for Health and Welfare to carry out its responsibilities relating to international assistance in a timely and efficient manner and within the deadlines required by international obligations. The administrative burden in an urgent crisis situation would be reduced compared with a situation in which such a crisis occurred under the current legislative framework.

Allowing the Finnish Institute for Health and Welfare, the Customs Laboratory and the forensic laboratory of the National Bureau of Investigation to transfer so-called reference standards of designer drugs between one another would facilitate cooperation between the authorities and cooperation within the EUDA laboratory network. This would reduce the administrative burden, as the EUDA would not need to send reference substances separately to each authority.

Extending the retention period for records relating to the import and storage of psychoactive substances prohibited from the consumer market would improve Fimea’s ability to supervise the lawful use of substances suitable for intoxicating use. By extending the record-retention period, both Fimea and operators engaged in lawful activities would have better opportunities to monitor, over the long term, the use of large quantities of substances and to ensure that such substances are not diverted from lawful use to misuse. Harmonised retention periods could facilitate record-keeping by operators handling narcotic substances and designer drugs and support the effective performance of supervisory tasks by the authorities.

The clarification of the definition of a narcotic medicinal product would be a measure clarifying the interpretation of the law. It could reduce the need for guidance provided to competent authorities such as Fimea in potentially unclear practical interpretative situations under the current framework.

4.2.3 Social effects

Effects on human health

In this proposal, the group-based prohibition of designer drugs aims to prevent the spread of new designer drugs and the societal and public health risks arising from their use. The effects are based on reducing both demand and supply. Studies indicate that there is demand for new designer drugs as "legal highs", for example for occasional, recreational and experimental use.[22] Users of designer drugs often seek specific effects and look for substitutes within the same substance group to replace a prohibited substance. Banning an entire substance group may reduce demand for substances within that group, as they can no longer be marketed as "legal". A reduction in demand may decrease use and particularly help prevent health risks associated with highly potent substances, such as overdoses and psychoses.[23] A group-based prohibition also reduces the likelihood that a new designer drug not yet subject to controls under the Narcotics Act would cause fatalities. Deaths caused by new, still unclassified designer drugs occur rarely in Finland, but they are possible. In assessing societal impacts, it is important to note that restricting the drug market is only one part of overall drug policy. Key measures for reducing substance use include effective preventive work, early intervention measures, and the availability of treatment services.

The proposal concerning the receipt and provision of international assistance would have a positive impact on human health in potential crisis situations, as access to critical medicines in healthcare could be ensured without delay. As part of international assistance, narcotic medicinal products may be sent in a limited manner when they are essential, for example for anaesthesia in surgical procedures and for the relief of severe pain. Such medicines may even be life-saving.

Impacts on young people

The effects of the group-based prohibition of designer drugs on the supply and demand of new designer drugs may have preventive effects, particularly on the initiation of drug use among young people. The markets for "legal highs", and especially the trade in synthetic and semi-synthetic cannabinoids, may target young people, as easy availability via the internet or social media, the perceived legality and thus perceived safety of the substances, and product types appealing to young people may create demand among this group.[24] Youth experimentation with drugs may for example involve various synthetic and semi-synthetic cannabinoids derived from cannabis, as cannabis is the most commonly used illicit drug among young people. According to the European Drugs Agency, various semi-synthetic cannabinoids have increased in European markets since 2022 as "legal" substitutes for cannabis and delta-9-THC.[25] Semi-synthetic cannabinoids are sold, among other forms, as e-cigarette products and in edible form (edibles) , in colourful and highly marketed packaging, which may be particularly attractive to young people.

4.2.4 Basic and human rights impacts

Self-determination

[22] EUDA (2024): European Web Survey on Drugs 2024.
[23] EUDA (2025).
[24] EUDA (2025).
[25] EMCDDA (2024): EU Drug Markets Analysis 2024. Key insights for policy and practice, p. 29.

The prohibition of psychoactive substances prohibited from the consumer market primarily targets activities through which a new designer drug is introduced to the Finnish market by manufacturing, offering for sale, importing, storing or otherwise supplying the substance. The prohibition does not apply to possession or use, and the proposed amendments would not entail the criminalisation of these or other new modes of conduct. The amendments therefore have no direct link to a person's personal liberty and self-determination, i.e. the right to decide over oneself and one's own body, for example by using designer drugs.

However, importation may be a preparatory act for personal use. Where the quantity imported corresponds to only a small number of use doses, it may be likely that the substance is intended for personal use rather than distribution. In such cases, importation for personal use could be punishable under the Criminal Code as smuggling or as a breach of the prohibition on designer drugs. Importation for personal use could also be punishable as a less serious offence or subject to a fine if the act, taken as a whole, is deemed minor. Criminal law generally takes a negative view of criminalisation that penalises acts which are harmful only to the perpetrator (the so-called prohibition of paternalism).

On the other hand, crossing a border cannot be considered part of the core of a person's self-determination: it is a preparatory act preceding actual use and is also subject to public control. Moreover, the importation of other goods, such as cars, may be restricted and unlawful importation may be punishable. In addition, a person does not necessarily import psychoactive substances themselves but may obtain them, for example, through street-level dealing. Importation is also a key method by which professional or organised criminal groups smuggle new designer drugs into Finland, meaning that its criminalisation is necessary for the effectiveness of the regulatory framework. Restrictions on importation, including for personal use, can therefore be considered proportionate. The proportionality of the regulation is also addressed later in the section of the proposal concerning its relationship with the Constitution.

A group-based prohibition of designer drugs would be a more anticipatory and general regulatory approach than the current system, as substances within defined groups would no longer need to be listed individually. Determining whether a particular substance belongs to a prohibited group may require more investigation by laypersons without specialist knowledge of chemistry. A layperson may therefore be more likely to be uncertain about the legal status of a substance they have ordered. Avoiding criminal liability may thus require greater diligence than at present, including the need to verify the status of a substance with the competent authority. As a general rule, criminal offences are required to be sufficiently foreseeable.

On the other hand, it should be noted that ordering psychoactive substances for recreational use already requires care under the current framework, as the field is known to be highly regulated and legislation is updated several times a year. Due to the special nature of the field, all actors in the designer drug market can be expected to exercise due diligence in verifying the legality of imports (see European Court of Human Rights case Cantoni v. France, 1996, section 35, and chapter 12.1.4 of the proposal). Even under the current framework, products sold in foreign online stores do not necessarily contain the substance under which they are marketed – a product marketed under the name of a legal substance may in reality contain another substance, for example one that is already prohibited.[26] The exact chemical name of a substance may not be disclosed, or it may be incorrectly stated, in which case verifying its legality against the current list of individual designer drugs may already be difficult or impossible. Mere assertions by a seller or other unofficial party regarding the legality of a

[26] EUDA (2011).

substance in Finland do not, as a rule, exempt the buyer from criminal liability (see Supreme Court of Finland KKO 2015:66). The risks and uncertainty regarding the legality of imports are largely inherent to the operating methods of the designer drug market itself, rather than solely resulting from legislation. In a situation where a layperson knows the exact chemical name of a substance, they are considered able to reasonably determine, if necessary with the assistance of competent authorities, whether the substance belongs to a prohibited substance group listed in a Government Decree or not. In addition, it remains important for competent authorities to continue informing the public about dangerous substances they detect and their illegal status when such substances are identified on the Finnish market. This increases public awareness of prohibited substances and substance groups.

Personal data protection

The proposed amendment to the record-keeping obligation for the import and storage of psychoactive substances prohibited from the consumer market would extend the retention period from three years to six years. Under section 33a of the current Narcotics Act, records must include sufficient information to identify the quantity of the substance and the names and addresses of the seller and buyer.

The record-keeping obligation applies to universities and scientific research institutes using psychoactive substances in research, as well as businesses using such substances in industry. The names and addresses of sellers and buyers appearing in the records are, in practice, those of legal persons and business addresses. However, the records may include, for example, the name of the employee who prepared them or the name of a contact person at the seller or buyer. These constitute personal data relating to natural persons, which are protected under Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation). The legal basis for processing such personal data in the records would be Article 6(1)(c) of the General Data Protection Regulation, i.e. compliance with a legal obligation to which the controller is subject.

The impacts of the proposal on the protection of personal data can be considered limited and relatively minor, as any personal data contained in the records are not sensitive, and the data relate to regulated business activities. The amendment would affect approximately 20 operators that import and store psychoactive substances mainly for research purposes. Most of these operators also handle substances classified as narcotics, for which a six-year record retention period is already in place.

5 Other options for implementation

5.1 Alternatives and their impacts

5.1.1 General

Of the issues proposed, alternative implementation methods have been identified for the group-based prohibition of designer drugs. During the preparatory work, alternatives to extending the scope of the prohibition to substance groups have been assessed. The examination of alternative implementation methods has also been central because a breach of the prohibition is punishable under criminal law, and criminalisation, or in this case its extension, is regarded as a measure of last resort (ultima ratio principle). In its constitutional

practice, the Constitutional Law Committee has required an assessment of whether criminalisation is necessary to achieve an acceptable objective and whether the objective could be achieved by means other than criminalisation that would interfere less with fundamental rights. In legislative practice, it has been considered that the assessment of the ultima ratio principle must also be carried out when extending criminal provisions.[27]

The objective of the proposed regulation is to prevent public health risks arising from the spread of new designer drugs and to reduce both their supply and demand. A key element in achieving this objective is to prevent the importation of substances into Finland and their distribution within Finnish territory. Supervisory authorities should have the ability to remove substances and, where necessary, destroy them. The chosen regulatory approach should correspond to these objectives.

As an alternative to criminalisation, administrative sanctions have been assessed. In addition, the preparation has examined how broad the prohibition on new designer drugs should be in order to be both effective in achieving the regulatory objectives and proportionate.

5.1.2 Administrative sanctions

Instead of extending the scope of the prohibition of designer drugs, and thereby also the scope of criminal liability, to substance groups, the regulatory objectives could be pursued through administrative sanctions. An administrative sanction could, for example, apply only to substances belonging to substance groups, while individual substances would continue to be subject to criminalisation. A group-based prohibition could be incorporated into the definition of designer drugs, or a separate "lighter" category of substances could be created. An administrative sanction as an alternative to criminalisation could be justified in situations where a substance belonging to a group has been imported for personal use and where the person has, for example, made a mistake, been unaware, or been negligent regarding the illegality of a substance that is not explicitly listed in the Decree. From the perspective of fundamental rights impacts, an administrative sanction could be justified on the basis that it would restrict property rights but would not involve a threat of imprisonment (personal liberty) nor require criminal culpability. In order to prevent the spread of dangerous psychoactive substances, an administrative sanction would need to be such that it allows for the permanent removal of the substance from its holder. Whether such permanent seizure can be considered a genuinely administrative sanction or a punitive administrative measure is, however, to some extent unclear. Seizure does not directly correspond to the most typical administrative sanctions, such as prohibiting an activity, recovery of funds, or a safeguard measure aimed at protecting a specific fundamental right. It does not correspond to traditional punitive administrative sanctions either, which more commonly consist of various types of administrative penalty payments. In principle, the seizure of a substance from its holder would, under current arrangements for designer drugs, correspond to a possible confiscation and destruction carried out by the police or Customs, which is a criminal procedural coercive measure. A permanent interference with a person's property rights has punitive characteristics, which is why it has been assessed below within the same legal framework as punitive administrative sanctions in general.

As a rule, when assessing whether to introduce either an administrative sanction or a criminal penalty, the use of administrative sanctions is particularly supported in situations where

[27] S. Melander: Operationalising and concretising the principles of criminalisation and the Constitutional Law Committee's requirements for the acceptability of criminalisation. Publications of the Ministry of Justice, Reports and Guidelines 2024:16, p. 53.

administrative guidance measures or other administrative consequences for infringements cannot be considered sufficient or appropriate, but where the nature of the infringements does not strictly require the use of the criminal justice system. Administrative sanctions are generally considered suitable in situations involving relatively minor or otherwise sector-specific infringements and failures, where breaches of statutory obligations are straightforward to establish. In such situations, the procedure typically does not involve other parties, and imposing the sanction does not require special investigative powers. If the failure or infringement concerns a significant legal interest, is particularly reprehensible, and its investigation requires powers comparable to criminal investigations, then in the absence of criminal provisions it is necessary to assess whether administrative sanctions are sufficient in relation to criminal penalties.[28]

New designer drugs have, throughout the period in which the regulation on designer drugs has been in force, been classified either as such substances or directly as narcotic substances as soon as they have been detected. In practice, these substances, which are produced solely for psychoactive use and for circumventing legislative prohibitions, and which share the same core chemical structure, are in principle equally harmful to health. For this reason, the degree of reprehensibility of their manufacture, importation, offering for sale, storage and supply cannot be considered different depending on whether a substance has been individually classified as prohibited or included as part of a group. Accordingly, an administrative measure or sanction could be considered problematic from the perspective of criminal law equality: it would not correct inconsistencies in the current legislation in situations where, in factually nearly identical cases, one act could be regarded as criminally reprehensible while another would not, depending solely on whether a substance has already been included in a Government Decree list of prohibited substances. Where the general mode of action and effects of substances within a group are known and they are regarded as equally harmful, both types of conduct should be treated as reprehensible.

Reprehensibility should in particular relate to professional activities aimed at distributing substances, and the consequences of unlawful importation should not be mitigated solely on the basis that importation may in some cases be intended for personal use. Nor can a solution in which the importation of small quantities indicating personal use would be subject to administrative sanctions, while large-scale importation for distribution purposes would not, be considered appropriate from the perspective of regulatory effectiveness. Such an approach could, in the absence of criminal penalties, lead to repeated attempts to circumvent the regulation or to an increase in the use of intermediaries. Furthermore, as noted in section 4.2.4, importation is a preparatory act preceding personal use, in which substances are brought onto the Finnish market prior to alleged personal consumption. For the reasons stated above, the manufacture, offering for sale, importation, storage and supply of new designer drugs should be uniformly criminalised, regardless of whether substances are prohibited individually or on the basis of substance groups. This solution is more consistent from a criminal policy perspective and reflects the actual dynamics of the designer drug market. An administrative measure or sanction cannot be considered a sufficient or appropriate regulatory tool compared with criminalisation.

In addition to considerations related to the nature and reprehensibility of the act and the protected legal interest, other factors also do not appear to support administrative sanctions as the primary regulatory tool over criminalisation. The infringement is not straightforward to

[28] Ministry of Justice: Guide for legislative drafting – guidelines on the preparation of national legislation. Chapter 12: General acts and certain general regulatory frameworks. Subchapter 12.10. Principles governing administrative sanctions regulation.

establish (for example, visually), as confirmation of a substance's chemical structure requires laboratory analysis. Such analyses are already carried out in practice by investigative authorities, namely Customs and the police, which does not support the introduction of administrative sanctions. Confiscation of goods would also be substantively equivalent to seizure used in criminal proceedings, and the destruction of substances would resemble forfeiture imposed as a criminal sanction. In practical situations, this could also lead to dual punishable conduct under both administrative and criminal regimes, as importation in violation of the prohibition is already criminalised under Chapter 46, section 6 of the Criminal Code as smuggling, which is also the primary offence classification for the importation of designer drugs. This further underlines that it would be most appropriate to regulate the prohibition of new designer drugs and the consequences of breaching the prohibition in a manner consistent with psychoactive substances prohibited from the consumer market.

5.1.3 Scope of the prohibition

During the preparation, the extent to which the prohibition on new designer drugs should be defined has been assessed in order to ensure that the regulation effectively achieves its objective of preventing the importation of new designer drugs into Finland and their distribution within Finland. The least effective option would be to maintain the status quo, in which cases occur annually in Finland where the confiscation of new designer drugs has not been possible, even though supervisory authorities have taken the substances into their possession. The most effective measure could be considered a prohibition with a scope broader than individual substance groups, which would likely enable the seizure of all psychoactive substances suitable for recreational use. Such a prohibition is referred to below as *the prohibition of generally dangerous substances.* The proposed group-based prohibition of designer drugs falls between these two alternatives, as it would enable more effective seizure of new designer drugs than at present on the basis of substance group classification. On the other hand, it is at least theoretically possible that the designer drug market would seek to produce substances that do not fall within the defined substance groups, and such substances could occasionally emerge.

The prohibition of substances posing a risk to public health and safety would, in practice, mean a ban on new designer drugs that is not based, as in the proposed regulation, on a precisely defined chemical structure. A system not based on chemical structure could be justified by the fact that it is not possible to exhaustively define all possible future chemical structures of psychoactive and harmful substances, as not all substance groups may yet have been invented. Regulation based on general dangerousness would be more general in nature than the proposed substance-group-based classification and could, for example, be based on a substance's harmful and intoxicating effects comparable to those of an already prohibited drug. Under such a system, the manufacture, importation, sale, storage and other supply of a substance could be prohibited if no lawful use other than psychoactive use can be demonstrated. The consequences for breaching the prohibition could be either administrative or criminal.

However, a prohibition of generally dangerous substances can be considered problematic regardless of whether the sanction for breach is a criminal penalty or a seizure defined as an administrative measure or sanction. In both cases, the measure would constitute a restriction of the owner's fundamental rights, and according to the Constitutional Law Committee's established practice, it must therefore be assessed in light of the general conditions for restricting fundamental rights. This would include, among other things, an assessment of

whether a prohibition of generally dangerous substances is sufficiently precise and clearly defined as a regulatory approach.

The prohibition of generally dangerous substances was not considered in the preparation of the proposal to be a sufficiently precise and clearly defined regulatory approach. A party manufacturing, importing, storing, selling or otherwise supplying a substance would find it difficult to foresee whether the act would be subject to a sanction. The nature of the substance and the legality of the act would be determined in ways that are less objectively assessable than under the proposed regulation. As a general rule, a regulatory model in which the assessment is based solely on comparing a substance with another prohibited substance, without objectively verifiable criteria such as chemical structure, may involve a high degree of discretion on the part of the authorities and analogous interpretation by courts. From the perspective of the principle of legality in criminal law, such an approach would be difficult to justify. In addition, regulatory models in which the burden of proof regarding the lawful purpose of a substance is placed on the offender may be problematic in light of the presumption of innocence. The presumption of innocence is enshrined in section 21 of the Constitution as part of the guarantees of a fair trial and good governance. Its core meaning is that the burden of proof in criminal matters always lies with the prosecution, and the accused is not required to prove their innocence in order to avoid punishment. The presumption of innocence must, as a rule, also be observed when imposing sanctions comparable to criminal penalties. For the above reasons, the prohibition of generally dangerous substances cannot be considered a constitutionally justified regulatory approach. From the perspective of regulatory effectiveness and the achievement of objectives, the proposed group-based classification is considered more appropriate. The proposed regulation meets the conditions for restricting fundamental rights (see section 12) while at the same time sufficiently achieving the objectives of the regulation.

5.2 Legislation and other means in place in other countries

[The chapter will be supplemented during further preparation.]

Group-based prohibition of designer drugs

Several countries have introduced prohibitions which, in a manner similar to the proposed group-based prohibition, aim to prevent the spread of new designer drugs within their territory, and are designed to prohibit new substances before they appear on the market. As an umbrella concept, this approach is referred to as a so-called generic classification or prohibition (generic ban / classification). Various forms of generic classification are in use in, inter alia, Denmark, Norway, Germany, Estonia, Austria, Belgium, France, Hungary, Ireland, Latvia, Lithuania, Switzerland, the United Kingdom and the United States. This section examines Denmark, Norway and Germany as Finland's closest comparator countries. The generic classification systems implemented in these countries have also been used in the preparation of the draft regulation defining substance groups. In addition, Sweden is discussed, where a generic classification system has not yet been introduced, but the need for regulation has been assessed in studies over the past ten years.

In Norway, Denmark and Germany, the existing group-based prohibitions for new designer drugs are based on the chemical core structure of the substances and its possible variations. The structure is described in the legislation of each country through chemical structural diagrams and accompanying textual descriptions. The substance groups prohibited in all three countries include various synthetic cannabinoid groups, cathinones, tryptamines and

phenethylamines. There are some differences between the countries in terms of which subgroups of synthetic cannabinoids are prohibited and how their structures are defined. In Norway, fentanyls and nitazenes have also been prohibited since 2017.

In Denmark, group-based classification was introduced under the Act on Euphoriant Substances (lov om eudoriserende stoffer) in 2012. The classification includes ten substance groups, and no additional groups have been added since the entry into force of the Act. The groups include benzoylindoles (synthetic cannabinoids), cathinones, cyclohexylphenols (synthetic cannabinoids), naphthoylindoles, naphthoylpyrroles, naphthylethylindenes, naphthylmethylindoles (synthetic cannabinoids), phenethylamines, phenylacetylindoles (synthetic cannabinoids) and tryptamines.

In Germany, a new Act on Psychoactive Substances (Neue-psychoaktive-Stoffe-Gesetz) was adopted in 2016. The purpose of the Act is to regulate certain substance groups, while individual substances are regulated under the German Narcotics Act. The group-based classification includes seven groups described in the annexes to the Act. Possession or use of substances covered by the Act on Psychoactive Substances is not criminalised, but their supply, offering, sale and marketing are prohibited. The German prohibition covers phenethylamines, various synthetic cannabinoids, benzodiazepines, N-(2-aminocyclohexyl)amides, and certain tryptamine derivatives.

In Norway, a group-based classification for narcotics is applied under the Regulation on Narcotics (Forskrift om narkotika). The Regulation applies to the manufacture, sale, purchase and other transfer and mediation, import, export, transit, delivery, possession and use of narcotics. All substances listed in the Regulation are considered narcotics and are subject to the same level of control. In addition to individual substances, the list of narcotics in the Regulation includes a section on substance groups, which was added in 2013. There are 12 groups: benzoylindoles (synthetic cannabinoids), cathinones, cyclohexylphenols (synthetic cannabinoids), naphthoylindoles (synthetic cannabinoids), naphthylmethylindoles (synthetic cannabinoids), naphthylmethylindenes (synthetic cannabinoids), phenethylamines, phenylacetylindoles (synthetic cannabinoids), tryptamines, fentanyls and nitazenes. The last two groups were added in 2017, following multiple deaths caused by carfentanil and furanylfentanyl, and increasing detections of nitazenes within the EU. As a result of the classification, for example new nitazenes detected in the EU have, at the time of detection, already been prohibited in Norway.[29]

Unlike in Denmark, Germany, Norway and many other countries, Sweden has not yet introduced a group-based classification system. In Sweden, new psychoactive substances may be classified either as narcotics or as substances hazardous to health. Substances are being prohibited individually. In 2016, Sweden carried out a broad assessment of the possibility of transitioning to a group-based definition, but based on the assessment, legislative amendments were not considered timely.[30] The assessment identified, among other things, as advantages of a group-based approach a reduction in supply and demand and more effective drug control. As disadvantages, it was noted that defining chemical structures of substance groups with sufficient precision is difficult, and classification may be unclear and difficult to interpret. In addition, it was considered possible that overly broad regulation could cover substances that do not in fact have psychoactive effects.

[29] Data from the Norwegian Medicines Agency.

[30] Statens offentliga utredningar, SOU 2016:93. Klassificering av nya psykoaktiva substanser.

On the other hand, Swedish legislation includes tools enabling competent authorities to prevent the import of substances in advance, which are not available in Finland. Under the Act on the Destruction of Certain Substances Hazardous to Health and Used for Abuse (Lag [2011:111] om förstörande av vissa hälsofarliga missbrukssubstanser), section 3 provides that if a substance that can be presumed to be classified as a narcotic in the near future, and which in a specific case can be presumed to be intended for intoxicating use or for causing harm or danger to life, a decision on destruction may be issued. The decision is made by a prosecutor. In simple cases, it may also be made by a customs prosecutor. The Swedish legislator appears to have considered that the available enforcement tools are currently sufficient.

6 Feedback

[To be supplemented after the end of the consultation procedure.]

7 Provision-specific rationale

7.1 Act amending the Narcotics Act

Section 3 *Definitions.* The definition of a prohibited psychoactive substance would be amended in subsection 3 of section 3. Its wording and placement within section 3 would be clarified so that the definition is moved to become a new point 9 in section 3(1). The authorisation to issue secondary legislation concerning designer drugs would remain, but it would be moved to subsection 2, where the authorisation concerning the definition of narcotics is also located. The section would thus in future consist of 2 subsections, the first of which would contain 9 points. At the same time, technical amendments would be made to points 7 and 8 of subsection 1 resulting from the addition of the new point 9.

According to the new section 3(1)(9), a 'prohibited psychoactive substance' means a substance used for intoxicating purposes which may be hazardous to health, which is neither a medicinal product nor a narcotic, and: a) for which a notification referred to in section 3(1)(5)(e) has been made, or which is a positional isomer of such a substance; or b) which, on the basis of its chemical structure, belongs to a group of substances which, on the basis of the assessment of properties referred to in section 3a, may be regarded as hazardous to health.

The new definition would largely correspond to the current definition of a prohibited psychoactive substance, but the wording would be rearranged so that a group-based classification system could also be included under point (b). designer drugs would still include substances which may be hazardous to health and for which a notification referred to in section 3(1)(5)(e) has been made to the EU early warning system, or positional isomers of such substances, and which are neither medicinal products nor narcotics. In future, substances would also be considered designer drugs if they may be hazardous to health, are neither medicinal products nor narcotics, and belong, on the basis of their chemical structure, to a group of substances which may be regarded as hazardous to health on the basis of the assessment of properties referred to in section 3a. Such a chemically based substance grouping, i.e. a group-based classification, would mean that new and future psychoactive substances could be classified as designer drugs under section 5 of the narcotics act without a separate regulatory amendment for each substance, on the basis that the substance belongs to a prohibited substance group. The manufacture, import into the territory of Finland, storage, offering for sale and transfer of such substances is prohibited. An exemption from the prohibition may be granted for research and industrial use purposes on a notification basis. The regulation would be preventive in nature, as opposed to the current reactive system.

The group-based classification is based on chemical knowledge of the core structures of the most common new psychoactive substances, as well as on the understanding of the market held by national and international competent authorities responsible for drug control. The market operates largely in such a way that substance-specific prohibitions in legislation are circumvented by manufacturing new designer drugs in which, for example, a single chlorine atom is added to a different position in the structure, so that the modified substance differs from the prohibited substance. Small variations generally preserve the core structure and the chemical group to which they belong. The proposed regulation is intended to better cover such substances, which can be clearly defined in terms of chemical structure as designer drugs, but which in the current system may enter Finland as legal substances before being separately prohibited.

A group-based prohibition would mean that the manufacture, import into Finnish territory, storage, offering for sale and transfer of new substances belonging to the substance groups would be punishable under the Criminal Code. Since the violation of the prohibition on designer drugs is already criminalised under the current system, this would not constitute a new criminalisation as such, but rather an expansion and anticipatory application of an existing prohibition to new substances. These substances would most likely also become prohibited under the current system if they appeared on the market, but under the present system such prohibitions may occur too late in terms of the spread of the substances. Under section 5a of Chapter 44 of the Criminal Code, any person who, in violation of the Narcotics Act, intentionally or through gross negligence manufactures, imports, stores, offers for sale or supplies a psychoactive substance prohibited from the consumer market shall, unless a more severe penalty is provided elsewhere in the law, be sentenced for violation of the prohibition on a psychoactive substance prohibited from the consumer market to a fine or imprisonment for a maximum term of one year. In the first instance, the more severe offence of smuggling under section 4 of chapter 46 of the Criminal Code may be applied: a person who, without the required authorisation or otherwise in breach of provisions or regulations governing import or export, imports or attempts to import into the country, or exports or attempts to export from the country goods whose import or export is prohibited or subject to authorisation or inspection by the authorities, shall be sentenced for smuggling to a fine or imprisonment for a maximum of two years. If smuggling, taking into account the value or quantity of the goods or other circumstances related to the offence, is, when assessed as a whole, minor, the offender shall be sentenced for petty smuggling to a fine (chapter 46, section 5 of the Criminal Code). In some cases, the offence of handling stolen goods related to illegal importation under chapter 46, sections 6 or 6a of the Criminal Code may also be applicable: a person who conceals, acquires, takes possession of, or intermediates property in respect of which an offence referred to in sections 1–5 of this chapter or sections 1–3 of chapter 29 has been committed in connection with importation, or otherwise deals with such property while knowing that it has been imported in this manner, shall be sentenced for handling of illegally imported goods to a fine or imprisonment for a maximum of one year and six months.

In criminal proceedings concerning violations of prohibitions relating to substances belonging to prohibited substance groups, the same tools and practices as in current criminal proceedings would be used. The chemical structure of the substances would be verified through laboratory analysis at either the Customs Laboratory or the Forensic Laboratory of the National Bureau of Investigation, in the same manner as under the current system. The definition of substance groups would be based on a precise chemical structural formula, illustrated by structural diagrams and textual descriptions in Government Decree 1130/2014. By comparing the chemical structure of a new substance with the structure defined in the decree, the legal status of the substance can be determined objectively. Since the structure of the substance and its

possible chemical variations would be predefined in the Government Decree, the regulation would not grant new discretion to investigative authorities, prosecutors, or courts in determining the legal status of a substance. If a new substance is not individually listed in the decree and its structure does not correspond to the structural formula of any defined substance group or its predefined variants, the substance is to be considered legal. No analogical application of any substance group prohibition would be permitted. If such a substance were to be prohibited, it would need to be added individually to the list in the Government Decree. As in the current system, new prohibitions could not be applied retroactively to acts committed while the substance was still legal.

When determining penalties, the nature of the substance, quantity, concentration, typical single dose, method of use and manner of commission would be assessed in line with current practice. The key factor would be how hazardous the substance is. As in current practice, expert statements concerning the substance could be used as evidence, and where necessary, also the assessment of properties conducted by Fimea concerning the substance group. Since there is generally little prior case law on new designer drugs, sentencing could continue to rely on case law concerning long-established narcotics belonging to the same substance group.

The substance groups set out in the draft Government Decree on designer drugs (1130/2014) attached to the proposal are intended to cover the most common substance groups already in use in several other European countries. In the future, it would be possible to define additional substance groups if new groups become widespread, and substances belonging to such new groups, whether existing or emerging, would in principle be regarded as hazardous to health. The definition of new substance groups would require an assessment of properties under section 3a of the Narcotics Act for the substance group concerned. In addition, exceptions to existing group definitions could be introduced by amendment of the decree. Such exceptions could be made, for example, where it is necessary to clarify that a new medicinal substance within a group is not included in the definition, or where a substance has developed widespread legitimate use that justifies its exclusion from the definition. All substances within the groups would, in principle, be highly likely to be hazardous to health based on their structure, but if non-hazardous substances were identified, it would also be possible to include exceptions for such substances within the group-based classification. Since substances within the groups are typically derivatives of existing narcotics, and many designer drugs are later classified as narcotics, certain narcotics may also fall within the chemical structure of the groups. Such substances would be subject exclusively to the prohibition and regulation applicable to narcotics, as narcotics, like medicinal products, are excluded from the definition of designer drugs under the Narcotics Act.

The authorisation to issue Government Decrees that was previously included in connection with the definition of a prohibited psychoactive substance would be moved to subsection 2. As a result, the authorisations concerning the definition of both narcotics and designer drugs would be located in the same subsection. The Government Decree would lay down more detailed provisions on which substances are to be regarded as designer drugs referred to in section 3(1)(9). Substance groups would be defined in greater detail under the authorisation in subsection 2 in the Government Decree on designer drugs. A linguistic amendment would be made to the authorisation provision due to its transfer to another subsection.

Section 3 a. *Assessment of properties of substances and substance groups.* The section provides for the assessment of a substance's properties prior to its classification as a narcotic or prohibited psychoactive substance. The section would be amended to take into account the possibility of carrying out an assessment of properties and issuing a recommendation for

action by Fimea also in relation to a substance group referred to in section 3(1)(9). The title of the section would be supplemented to include reference to substance groups. Other linguistic amendments would be made to the section with the purpose of clarifying it without changing its substantive content.

According to the proposed subsection 1, the psychoactive properties and harmfulness of a substance or substance group shall, where necessary, be assessed by the Finnish Medicines Agency in cooperation with the Finnish Institute for Health and Welfare, the police and Customs.

According to the proposed subsection 2, if the Finnish Medicines Agency considers that the psychoactive properties and harmfulness of a substance or substance group require its classification as a narcotic under section 3(1)(5)(e), or the classification of the substance or substances belonging to the group as designer drugs under section 3(1)(9), the Agency shall submit its assessment to the Ministry of Social Affairs and Health, together with its proposed measures. The proposal shall take into account whether the substance or substances belonging to the group are present in Finland or are likely to appear in Finland.

The reference to substance groups would be added to subsections 1 and 2 in order to enable future assessment of new substance groups and their inclusion in the Government Decree on designer drugs. The reference at the end of subsection 2, "before a decision can be taken on placing the substance under control in accordance with the Council Decision referred to in section 3(1)(5)(c)", would be removed. The reference relates to the EU procedure for classifying new substances as narcotics. The purpose of the reference was originally to justify the introduction of a national system for classifying narcotics, as it is a faster procedure than EU-level classification. At the level of the provision, the reference is unnecessary, as it is more of a rationale than a substantive legal rule. It would also be removed in order to avoid unnecessary interpretative ambiguity. In addition, the reference in subsection 1 to narcotics classified nationally under section 3(1)(5)(e), as well as the reference to the definition of designer drugs, would be moved from subsection 1 to subsection 2 for reasons of linguistic clarity, replacing the reference to the general prohibition under section 5. The linguistic amendment would not result in any change to the substantive application of the provisions; its purpose is to clarify what the assessment-based proposal concerning a substance not yet classified refers to.

Section 22. *Medicinal products necessary for emergency care and crisis management.* The section regulates situations related to first aid and crisis management in which an import and export licence under the Narcotics Act may not be required from operators. Subsection 4 would be amended to take into account the participation of the Finnish Institute for Health and Welfare in the provision or receipt of international medical assistance. Subsection 4 is also proposed to be subject to linguistic amendments to clarify the changes made to it.

Under subsection 4 of the current provision, an organisation engaged in humanitarian aid operations with a licence referred to in section 32, subsection 3 of the Medicines Act shall not need an import and export licence under this Act for humanitarian aid operations if the situation to which the activity relates is exceptionally serious or if there is another special reason for it. Under the new subsection 4, if the situation in question is exceptionally serious or if there is another special reason for it, an import and export licence under this Act would not be required for a humanitarian aid organisation carrying out humanitarian relief activities, nor for the Finnish Institute for Health and Welfare when participating in the provision or receipt of international medical assistance. A further condition for exemption from the import

and export licence requirement is that the operator holds the authorisation referred to in section 32(3) of the Medicines Act. In this case, the export of the medicinal products must be notified in advance and their import without delay to the Finnish Medicines Agency Fimea. The provisions of section 16 on the requirements for the responsible person and section 17 on the approval of the responsible person shall apply to the import and export of medicinal products in the cases referred to in this subsection.

Exemption from the licensing requirement under the Narcotics Act would be subject to the fulfilment of certain conditions, as well as the submission of a notification to Fimea in advance of export and without delay following import. Under the current subsection 4, organizations engaged in humanitarian aid activities are required to hold a wholesale distribution authorization for medicinal products as referred to in section 32(3) of the Medicines Act. Similarly, when carrying out the duties referred to in this subsection, the Finnish Institute for Health and Welfare (THL) would be required to hold a wholesale distribution authorization for medicinal products. No changes are proposed to the current regulation concerning the requirement that humanitarian aid organizations, and in the future also the Finnish Institute for Health and Welfare, comply with the requirements relating to the responsible person under Sections 16 and 17 of the Narcotics Act. The Finnish Institute for Health and Welfare operates a pharmaceutical wholesale business that holds an authorization under section 32(3) of the Medicines Act to engage in wholesale distribution of medicinal products. The implementation of international assistance may involve the import of medicinal products when receiving aid and, where Finland provides assistance to another state, the export of medicinal products, provided that the government of the recipient country has requested emergency assistance from Finland.

The situation referred to in subsection 4, in which international assistance is provided, could arise when medicinal aid containing medicines classified as narcotics is sent from Finland to another country participating in the RescEU cooperation framework. The dispatch of such assistance would have to be preceded by a request for emergency assistance from the government of the recipient country. The EU Emergency Response Coordination Centre (ERCC) coordinates relief operations, and the European Commission decides on the provision of assistance and on which country will respond to the request. The information to be recorded in the assistance request should correspond to the guidance issued by the World Health Organization (WHO) and the International Narcotics Control Board (INCB), namely the Model Guidelines for the International Provision of Controlled Medicines for Emergency Medical Care (WHO/PSA/96.17). The same guidance and the WHO model form are also used for the transport of medicinal products containing narcotics by organizations engaged in the aid activities referred to in this subsection. Accordingly, the recipient country's request for assistance should make it possible to identify at least the medicinal products classified as narcotics covered by the request, as well as the addresses and responsible persons to be listed as recipients on the WHO model form.

Subsection 5 of the section contains an authorisation to issue decrees. Under this provision, more detailed regulations may be issued by Government decree concerning the content of the notifications referred to in subsections 3 and 4. No amendments are proposed to this subsection; however, as a result of the amendments to subsection 4, it would in future also apply to notifications submitted by the Finnish Institute for Health and Welfare.

Section 23b *Psychoactive substances prohibited from the consumer market.* This section lays down provisions concerning situations involving psychoactive substances prohibited from the consumer market where the activity or substance is exempt from the prohibition laid down in

section 5 of the Narcotics Act. A new subsection 4 concerning the transfer of consumer market designer drugs (CPP substances) between authorities would be added to this section, whereby the current subsection 4 would become subsection 5.

Under the new subsection 4, the laboratory of the Finnish Institute for Health and Welfare, the forensic laboratory of the National Bureau of Investigation and the Customs Laboratory would be permitted to transfer to one another a substance or preparation used for the identification of a psychoactive substance prohibited from the consumer market and containing a psychoactive substance prohibited from the consumer market.

The new subsection 4 would concern the transfer of reference materials between official laboratories. The current Narcotics Act does not contain provisions allowing authorities to transfer reference materials to one another, meaning that such transfers are prohibited under section 5 of the Narcotics Act. Each of the laboratories concerned has the authority to obtain reference materials for CPP substances for its own use, both from operators specialising in their supply and, in specific cases, from cooperation partners specialising in drug control, such as the laboratory of the United Nations Office on Drugs and Crime (UNODC) or the European Union Drugs Agency (EUDA). Taking also into account that a corresponding possibility for transfer exists in respect of narcotics, which are subject to stricter regulation, the lack of a possibility for the transfer of CPP substances between authorities may be regarded as an unnecessary administrative burden from the perspective of inter-authority cooperation. Such an administrative burden may arise, for example, in a situation where the EUDA laboratory network distributes reference materials, as a rule, centrally to only one network member in each country for onward distribution. The possibility for mutual transfer would be added to the Act in order to enable effective national and international cooperation and the efficient utilisation of such cooperation, particularly in relation to the latest new psychoactive substances classified as designer drugs, for the identification of which reference materials are required for substance batches entering Finland or circulating within Finland.

Section 31 *Obligation to notify*. Only a linguistic correction would be made to the Finnish-language provision. According to the current subsection 2 of section 31, “in addition, the licence holder must submit to the Finnish Medicines Agency a quarterly notification of substances included in the schedules of the 1961 Single Convention on Narcotic Drugs and in schedules I–III of the 1971 Convention on Psychotropic Substances that have been imported into Finland and exported from Finland.” In the subsection, the word “schedules” would be replaced with “lists” in order to make the wording consistent with the terminology used elsewhere in the Narcotics Act and with the wording of the Act on Electronic Prescriptions proposed below. No amendment would be made to the provision in Swedish.

Section 33a *Obligations relating to the import and storage of psychoactive substances prohibited from the consumer market.* Subsection 1 of the section provides for the obligation to keep records of the import and storage of designer drugs. The obligation to retain records would be extended from three years to six years. The proposal would harmonise the retention period for records concerning designer drugs with the retention period applicable to records concerning narcotics.

According to the proposed subsection 1 of section 33a, any person who imports or stores psychoactive substances prohibited from the consumer market must keep records of the substances imported and of the substances used in their research or production activities and must ensure that the documents contain sufficient information to identify the quantity of the substance and the name and address of the seller and purchaser. The documents must be

retained for at least six years from the end of the calendar year in which the import or storage took place.

7.2 Act amending the Act on Electronic Prescriptions

Section 3. *Definitions.* The definition of medicinal products containing narcotics in section 3, paragraph 9 of the Act would be further specified with regard to medicinal products containing substances referred to in section 3, subsection 1, paragraph 5, subparagraph (e) of the Narcotics Act. Under the new paragraph 9, a medicinal product containing narcotics would mean a medicinal product containing any of the following substances: a) substances included in Schedules I, II and IV of the 1961 Single Convention on Narcotic Drugs referred to in section 3, subsection 1, paragraph 1, subparagraph (a) of the Narcotics Act (373/2008); b) substances included in Schedules I and II of the 1971 Convention on Psychotropic Substances referred to in section 3, subsection 1, paragraph 1, subparagraph (b) of the Narcotics Act; c) substances referred to in section 3, subsection 1, paragraph 5, subparagraph (e) of the Narcotics Act which, due to their pharmacological properties, are equated under section 3, subsection 2 of the Narcotics Act with substances included in the Schedules of the conventions listed in subparagraphs (a) and (b) of this paragraph. The addition in subparagraph (c) to the existing section, stating that medicinal products referred to in section 3, subsection 1, paragraph 5, subparagraph (e) of the Narcotics Act would constitute medicinal products containing narcotics where they are, based on their pharmacological properties, equivalent to substances included in the Schedules of the conventions listed above, would be new compared with the current definition. The subparagraph would refer to section 3, subsection 2 of the Narcotics Act, according to which substances, preparations and plants classified as narcotics are specified in more detail by Government decree.

The amendment would be implemented because the current definition in paragraph 9 classifies all medicinal products containing substances nationally classified as narcotics as medicinal products containing narcotics, regardless of the pharmacological properties of the medicinal product. The definition does not take into account that a medicinal product containing a substance classified as a narcotic may, on the basis of its pharmacological properties, medical use and potential for misuse, be such that it should instead be subject to control as a CNS medicinal product rather than as a medicinal product containing narcotics. Pharmacological properties are already taken into account, as a rule, when a new active substance is classified nationally as a narcotic: under section 3, subsection 1, paragraph 5, subparagraph (e) of the Narcotics Act, classification as a narcotic may be carried out where the active substance is, based on its pharmacological properties, equivalent to a narcotic. In practice, the equivalence is established with a substance prohibited under a Schedule of the 1961 or 1971 Convention, in which case it is also consistent that the new active substance is controlled in the same manner as the substance with which it is equated. Pregabalin, remimazolam and zuranolone are active substances that have been classified as narcotics on the basis that, due to their pharmacological properties, they are equivalent to substances included in Schedule IV of the 1971 Convention on Psychotropic Substances. Substances included in that Schedule are controlled as CNS medicinal products.

By introducing the proposed clarification into the definition in section 3, paragraph 9 concerning the equivalence of nationally classified substances with substances included in the Schedules of the conventions referred to in the section, the definition would be brought into line with long-established practices according to which the level of control of medicinal products containing active substances classified as narcotics is determined. Thus, a medicinal

product containing pregabalin, remimazolam or zuranolone could no longer, on the basis of the definition, be inconsistently interpreted as a medicinal product containing narcotics.

The substances have been defined as narcotics in Government Decree 543/2008. Following the entry into force of the proposed Acts, Annex IV to the Decree could, for example, be supplemented with a statement that active substances classified as narcotics on the basis of section 3, subsection 1, paragraph 5, subparagraph (e) of the Narcotics Act and listed in the Annex are controlled as medicinal products containing narcotics, except where they are, based on their pharmacological properties, equivalent to substances included in Schedule III of the 1961 Convention or Schedule III or IV of the 1971 Convention, or where they have been exempted from the licensing requirement under section 23 of the Narcotics Act. Additional information could be added for remimazolam and pregabalin stating that the substances are equivalent to substances included in Schedule IV of the 1971 Convention. In the current situation, pregabalin is already separately defined in Annex V to the Decree as a substance exempted from the licensing requirement under section 23 of the Narcotics Act.

A corresponding definition is also included in the Ministry of Social Affairs and Health Decree 1088/2010 on the prescribing of medicinal products. Following the approval of the legislative proposal, a corresponding amendment would also be made to paragraph 9 of section 3 of the Decree.

8 Regulation at the level of secondary legislation

As a result of the amendment to the definition of a psychoactive substance prohibited from the consumer market in the Narcotics Act, the Government Decree on psychoactive substances prohibited from the consumer market (1130/2014), issued under the authorisation to issue decrees related to that definition, would also be amended. Section 1 of the Decree would be amended and a new Annex 2 would be added to the Decree, containing descriptions of groups of substances.

According to the proposed section 1 of the Decree, psychoactive substances prohibited from the consumer market would include the substances listed in Annex 1 and substances which, based on their chemical structure, belong to one of the groups of substances listed in Annex 2. Annex 2 to the Decree would define the following groups of substances: phenethylamines, cathinones, fentanyls, nitazenes, orphines, tryptamines, the basic structural framework of synthetic cannabinoids and, as subgroups differing in structure from that basic framework, synthetic cannabinoids consisting of bicyclohexanols, hexahydrodibenzopyranols, gamma-carbolinones and phenylethyl-dihydroisoindolones.

The substance groups and the grounds for their inclusion are described in more detail in the explanatory memorandum concerning the amendment of Decree 1130/2014 attached to the proposal, as well as in a separate draft of the Decree. *[During further preparation, the draft Decree and the explanatory memoranda will be supplemented.]*

In addition, following the entry into force of the Act, paragraph 9 of section 3 of the Ministry of Social Affairs and Health Decree on the prescribing of medicinal products (1088/2010) would be amended correspondingly to reflect the definition of a medicinal product containing narcotics in the Act on Electronic Prescriptions described above.

9 Entry into force

It is proposed that the laws enter into force on 1 June 2027.

10 Implementation and monitoring

With regard to the prohibition of designer drugs by substance group, during further preparation it will be assessed separately whether the implementation of the prohibitions requires amendments, for example, to the information systems of the authorities. By the time the consultation period begins, no specific needs relating to implementation or monitoring have been identified.

11 Relationship to other proposals

The regulation on international assistance proposed in this proposal has links to another legislative project of the Ministry of Social Affairs and Health concerning international assistance involving medicinal products (project reference: STM181:00/2025). The objective of that project is to establish a national procedure for providing and receiving international assistance involving medicinal products in Finland in situations where such international assistance is not subject to any other legislation currently in force. That project concerns the Medicines Act and medicinal products more broadly, whereas the regulation proposed in this proposal concerns only medicinal products classified as narcotics. During the further preparation of the projects, the links between the projects and any possible need to notify Parliament of the order in which the proposals should be considered will be taken into account.

With regard to the definition of a medicinal product containing narcotics in paragraph 9 of section 3 of the Act on Electronic Prescriptions, the further preparation will also take into account, where necessary, that amendments to other paragraphs of section 3 of the Act are planned as part of a Government proposal for legislation concerning the development of pharmacy operations (project reference: STM045:00/2025).

The proposal has no budgetary implications.

12 Relationship to the Constitution and the legislative procedure

12.1 Extension of criminalisation

12.1.1 Starting points for the assessment

Under the proposal, the definition of psychoactive substances prohibited from the consumer market would be extended so that, in addition to individual specifically named substances, the definition would also cover substances which, based on their chemical structure, belong to a specified group of substances. The classification by substance group and the prohibition resulting from it would, similarly to the current prohibition applicable to designer drugs, apply to the manufacture, import, storage, offering for sale and other transfer of the substance, but not to possession or use of the substance. Violation of the prohibition would be punishable under the Criminal Code.

In the practice of the Constitutional Law Committee, the legislature’s discretion in enacting criminal provisions has generally been considered to be relatively broad, although it has been

noted that it is subject to limitations arising both from the Constitution and from international obligations binding on Finland. The limitations imposed by the Constitution arise primarily from fundamental rights (Constitutional Law Committee opinion PeVL 23/1997 vp, pp. 2–3). The proposal concerns an extension of the material scope of application of an existing criminal provision. Therefore, this proposal assesses the extended part of the scope of application, namely classification by substance group, according to the same criteria as a new criminalisation. In this context, it must be assessed whether the extension of criminalisation restricts fundamental rights and whether the criminal provision fulfils the general requirements for restricting fundamental rights, as well as any specific requirements arising from the relevant fundamental rights provision (Constitutional Law Committee opinion PeVL 17/2006 vp, p. 2). The conditions for restrictions include requirements concerning regulation by law, precision and exact delimitation of the law, acceptability of the restriction, proportionality of the restriction, protection of the core content of fundamental rights, adequacy of legal safeguards and compliance with human rights obligations.

The proposed regulation can be identified as having effects on fundamental rights. The proposed regulation would affect professional operators manufacturing and offering for sale new psychoactive substances (freedom of enterprise, section 18 of the Constitution). The criminalisation of new substances would mean that, for example, substances unlawfully imported into Finland could be seized (protection of property, section 15 of the Constitution). Restrictions on the import of substances may, in some situations, also indirectly affect an individual's right to self-determination if a private individual wished to import substances subject to prohibition from abroad solely for their own use (right to personal liberty and protection of private life, sections 7 and 10 of the Constitution).

Due to the requirement that restrictions on fundamental rights must be acceptable, extending the prohibition must be based on a compelling societal need and a justification acceptable from the perspective of the fundamental rights system. According to the Constitutional Law Committee, for example, an obligation to protect a fundamental right may constitute an acceptable basis for criminalisation (Constitutional Law Committee opinions PeVL 48/2017 vp, pp. 7–8, and PeVL 26/2014 vp, pp. 3–4, and the opinions referred to therein). The extension of the criminalisation of violations of the prohibition on designer drugs would be based on the obligation of public authorities under section 19, subsection 3 of the Constitution to promote the health of the population. The regulation would also safeguard the right to life under section 7 of the Constitution, as these substances may even cause death. The extension of criminalisation to certain groups of substances would primarily aim to prevent serious and unpredictable public health harms and deaths that new psychoactive substances may cause. New psychoactive substances belonging to the substance groups proposed to be prohibited are characterised by the fact that, based on their chemical structure, their dosage, interactions and toxicity may involve serious health risks. Under the current situation, some substances may enter the market as legal substances before it has been possible to assess their harmfulness individually in accordance with the requirements of the current legislation. As with individually prohibited designer drugs, the precise degree of harmfulness of substances belonging to substance groups cannot be verified at the time of classification (the wording of the Act: "may be hazardous to health"), as the substances are new and have not yet had time to become widely used – preventing their spread into use is, in fact, the core objective of the prohibition. The substance groups proposed are such that it is important to implement the prohibition proactively, and their emergence together with the resulting harms should not be allowed to occur before action is taken. For example, based on the respiratory depressant mechanism of action of new synthetic opioids, namely fentanyls, nitazenes and orphines, the danger is evident even if there is not yet experience of the use of each individual derivative

substance. Based on data from the EU early warning system, these substances are also most frequently detected in countries close to Finland, namely Estonia, Sweden and Latvia, meaning that their spread to Finland is possible. Classification by substance group would enable proactive intervention in situations where a public health risk is known at the structural level (substance group), even if an individual substance has not yet been separately assessed or classified. The extension of the criminalisation of violations of the prohibition on designer drugs to certain substance groups is considered to have an acceptable and compelling societal justification.

In addition to fulfilling the conditions for restrictions on fundamental rights, it is essential to assess the regulation from the perspective of the principle of legality in criminal law (section 8 of the Constitution). Compliance with the principle of legality in criminal law includes several requirements, at least the requirement that acts punishable as offences are defined by law, the prohibition of retroactive criminal law, the prohibition of the analogous application of criminal law, the requirement that penalties resulting from an offence are defined by law, the prohibition on applying a more severe penalty than that prescribed at the time of the act, and the requirement that criminal law provisions are enacted at the level of an Act of Parliament (Constitutional Law Committee opinion PeVL 309/1993, p. 50). The extension of criminalisation is discussed below from the perspective of the requirements for restricting each fundamental right and the principle of legality in criminal law.

12.1.2 Freedom of enterprise and protection of property

According to section 18, subsection 1 of the Constitution, everyone has the right, as provided by an Act, to earn their livelihood by the employment, occupation or commercial activity of their choice. Regulation based on substance groups would extend the current restriction on freedom of enterprise, which applies to the manufacture, import, storage, offering for sale and other transfer of psychoactive substances. Most of the prohibited forms of conduct concern solely the professional or otherwise profit-oriented distribution of new psychoactive substances. As the purpose of classification by substance group is to prohibit the groups of substances that are most common and popular, the regulation would significantly restrict the possibility of lawfully engaging in business activities involving the consumer sale of new psychoactive substances.

The wording “in accordance with the law” in section 18, subsection 1 of the Constitution refers to the possibility of restricting the right protected by the provision by law, and Finnish legislation does indeed contain numerous restrictions on freedom of enterprise. For example, certain healthcare and social welfare professions may, under the law, only be practised subject to authorisation due to risks relating to health and safety (Government proposal HE 309/1993 vp, p. 67). The grounds on which a fundamental right is restricted must be acceptable within the overall framework of the system of fundamental rights. A basis for restriction may therefore be, for example, the aim of protecting the fulfilment of a fundamental right other than the one being restricted, or achieving another objective that, when assessed on objective grounds, is acceptable from the perspective of the overall system of fundamental rights (see, for example, Constitutional Law Committee opinions PeVL 35/2014 vp, p. 3; PeVL 3/2014 vp, pp. 2–3; PeVL 38/2013 vp, p. 3/II; PeVL 37/2013 vp).

On the grounds set out in the previous section 12.1.1, the significant public health risks associated with the consumer sale of psychoactive substances provide an acceptable basis for extending the restriction on business activities. Such activities typically involve objectionable characteristics that justify reducing the conditions for carrying out the activity by extending

criminalisation. The effects of the proposal would particularly concern activities in which new intoxicating substances are marketed as so-called “legal highs”. By relying on the impression of legality, the risks of criminal liability arising and the health harms caused by the substances may be perceived as minor compared with already prohibited narcotics or designer drugs. Purchasers often do not have ordinary consumer protection, as substances are frequently marketed, for example, using vague descriptions or product names, and consumers in reality have no guarantee that the substance they purchase is what has been marketed. The risk of impure substances or substances that are more dangerous than assumed by the consumer is high. Responsibility may be attempted to be shifted to the consumer through various labelling practices, such as “not for human consumption”, or by describing substances as intended for other purposes, such as research chemicals, herbal incense or bath salts, even though the intoxicating effects of the substance are simultaneously marketed to consumers.

The extension of criminalisation restricting freedom of enterprise is also justified by equality in criminal law as well as by the coherence and effectiveness of the regulation. As the chemical structures and harm profiles of substances belonging to the substance groups are similar, the distribution of new psychoactive substances is, as a rule, an act of equal culpability regardless of whether the classification of the substance is based in legislation on an individual prohibition or a prohibition based on a substance group. From the perspective of equality in criminal law, it may be considered problematic if two persons act in a manner that is equally objectionable in practice, but only one of them commits a punishable act depending on the classification status of the substance. The necessity of criminalisation has also been assessed from this perspective in the previous section 5.1.2 concerning alternative implementation methods, where unequal consequences of acts contrary to the prohibition have not been considered justified (for example, imposing administrative sanctions for violations of a prohibition based on substance groups while criminalising individual substances). On the grounds mentioned above, the introduction of classification based on substance groups may be considered both an acceptable and a necessary means of remedying gaps in the current legislation.

According to the requirement of proportionality related to the acceptability and proportionality requirements included among the general conditions for restricting fundamental rights, a restriction must not go further than is justified, taking into account the importance of the interest underlying the restriction in relation to the legal interest being restricted (see, for example, Constitutional Law Committee opinions PeVL 37/2013 vp, PeVL 14/2013 vp, p. 4/I, PeVL 2/2013 vp, p. 3, PeVL 5/2009 vp, p. 3, and PeVL 8/2006 vp). The assessment of alternative implementation methods (section 5.1.3) has examined the proportionate scope of the prohibition in relation to the legal interests protected by the regulation and the objectives of the regulation. In the proposal for classification based on substance groups, it has been taken into account that the extension of criminalisation concerns only substances belonging to substance groups assessed as dangerous and does not, for example, apply generally to all psychoactive substances or rely on open-ended or discretionary criteria. The proposal would also not unreasonably restrict the use of substances covered by classification based on substance groups in industry or research activities, as even under the current system it is possible to derogate from the prohibition on importing and storing designer drugs. The condition is that the operator uses the substances for lawful industrial or research activities and that a notification concerning the substance and the activity has been submitted to Fimea before import.

Criminalisation means that the prohibited substance may be seized and destroyed. This would constitute a restriction on the right of ownership relating to the substance and on the protection

of property guaranteed by section 10 of the Constitution, according to which everyone's property is protected. The possibility of seizure and destruction is essential for achieving the objectives of the regulation, as it prevents the substances from spreading on the Finnish market. Seizure would be based on the harmfulness of the substances, which in turn is based on a limited and objectively verifiable chemical structure of the substance. The Constitutional Law Committee has emphasised that legal transactions contrary to law or good practice, or unreasonable legal transactions, do not enjoy constitutional protection, and that the Constitution does not protect property acquired through an offence or property directly connected with a person's criminal activity (Constitutional Law Committee opinions PeVL 65/2010 vp, p. 3; PeVL 53/2006 vp, p. 4; PeVL 33/2000 vp, p. 3; PeVL 47/1998 vp, p. 2). The seizure would concern property directly connected with criminal activity, and the restriction affecting such property may be considered acceptable.

On the grounds set out above, the proposed regulation may be considered to fulfil the requirements for restricting fundamental rights relating to freedom of enterprise and protection of property.

12.1.3 Right to personal liberty and protection of private life

The personal liberty guaranteed by section 7 of the Constitution is a general fundamental right in nature, which protects, in addition to a person's physical liberty, their freedom of will and right to self-determination (Government proposal HE 309/1993 vp, p. 46/II). The scope of private life protected under section 10 of the Constitution includes, among other things, an individual's right to determine matters concerning themselves and their body (Government proposal HE 309/1993 vp, p. 53/I; Constitutional Law Committee opinions PeVL 6/2014 vp, p. 2; PeVL 17/2006 vp, p. 3/I; PeVL 15/2001 vp, p. 2/I). In order to guarantee protection of private life, the State has traditionally been required, in addition, to refrain from itself interfering with the private life of citizens (Constitutional Law Committee opinions PeVL 16/2013 vp, p. 2/I; PeVL 6/2014 vp, p. 2). Protection of private life is also provided for in article 8 of the European Convention on Human Rights (ECHR), according to which everyone has the right to respect for their private and family life, home and correspondence. According to the article, public authorities must not interfere with the exercise of this right except where such interference is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, or for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others.

A prohibition based on substance groups and the resulting extension of criminalisation have an indirect connection with the personal liberty protected under section 7 of the Constitution and with the protection of private life protected under section 10 of the Constitution and article 8 of the ECHR. As stated above in section 12.1.2, the prohibited forms of conduct, namely manufacture, offering for sale, import, storage and transfer, mainly concern active and professional market activity or activity carried out for profit-making purposes, where the distribution of new psychoactive substances is aimed at obtaining financial benefit. Mere possession or use of a substance is not punishable. A criminal penalty cannot be imposed for possession of a substance unless the prosecutor is able to demonstrate that the person has acted in violation of the prohibition on designer drugs and, for example, has offered the substance for sale. Otherwise, only in very limited cases where it can be demonstrated that the person knew that the substance in their possession had been smuggled into Finland, it is possible to apply the provision on unlawful handling of imported goods in chapter 46, section 6 of the Criminal Code. The criminalisation does not directly target personal lifestyle choices

falling within the scope of individual self-determination, such as the use of prohibited substances. However, import may take place not only as part of business activities but also by a private individual for their own use, in which case the import may indirectly relate to the exercise of the individual's right to self-determination. Use for personal purposes may, in practice, be indicated, for example, where the quantity of doses obtainable from the imported substance is small.

The proportionality requirement requires an assessment of whether criminalisation is necessary to protect the legal interest underlying it and whether the same objective could be achieved through another means that interferes less with fundamental rights than criminalisation. The severity of the criminal sanction is also connected to the proportionality requirement. The severity of the sanction must be proportionate to the culpability of the act, and the criminal justice system as a whole must fulfil the requirements of proportionality (Constitutional Law Committee opinions PeVL 48/2017 vp, p. 7; PeVL 10/2017 vp, p. 3; PeVL 9/2016 vp, pp. 4–5; PeVL 61/2014 vp, p. 3, and the opinions referred to therein). For this reason, it must be assessed whether extending criminalisation is justified even where an act that may become punishable primarily causes harm to the perpetrator themselves.

A large proportion of new psychoactive substances are manufactured abroad, meaning that they enter the Finnish market mainly through import. The criminalisation of import is an essential part of the effectiveness of criminal regulation targeting new psychoactive substances. If import for personal use were excluded from criminalisation, this would enable circumvention of the regulation: professional activity, for example by organised criminal groups, could be disguised as private import. The use of intermediaries and vulnerable couriers could become more common. In addition, the proportionality of criminalisation is supported by the fact that import cannot be considered part of the core area of the right to self-determination. It concerns a cross-border act that precedes the actual exercise of the right to self-determination, namely the use of the substance. Through import, a specific substance is brought within the scope of the market before it reaches the alleged use. A substance may also end up being used for personal purposes through means other than import (e.g. street-level sales). In addition, import is subject to customs control, and it is characteristic of such control that public authorities may restrict the import of various dangerous substances and objects even where they are intended solely for personal use.

From the perspective of a private individual importing a substance for personal use, the proportionality of the regulation can be ensured by providing that a less serious act, in terms of culpability, may result in a less severe penalty. Under chapter 46, section 4 of the Criminal Code, a person may be sentenced for smuggling to a fine or imprisonment for a maximum of two years. Chapter 46, section 5 of the Criminal Code provides for the possibility of imposing only a fine for minor smuggling. In addition, the threshold for imposing a penalty for violation of the prohibition on designer drugs under chapter 44, section 5a of the Criminal Code is, as a rule, high, as the act requires intent or gross negligence. During consideration of charges, it is also possible, where appropriate, to decide not to bring charges. It should also be taken into account that the dangerousness of the substance in question is relevant when determining the penalty. designer drugs are prohibited on the basis that they may be hazardous to health, whereas narcotics are dangerous because significant harms, such as deaths, have been established. The classification of substances as either designer drugs, narcotics or substances entirely outside the scope of the Narcotics Act is not static, but may change where new findings are made regarding the harmful effects of the substance on the human body. For example, substances belonging to certain groups may later be classified as narcotics if it is established that the substances have caused serious health effects or even deaths. In such a

case, acts involving the substance would become punishable as narcotics offences. It is also possible to exclude individual new substances from the scope of a substance-group prohibition through an explicit exception, for example if findings concerning the use of the substance indicate that its harmfulness is unlikely to be at a level sufficient to justify control of the substance. However, this possibility could be regarded as primarily theoretical. If the classification status of a substance changes, the principle of applying the more lenient law must always be observed in any possible criminal proceedings.

On the grounds set out above, the proposed regulation may be considered to fulfil the requirements for restricting fundamental rights relating to personal liberty and protection of private life.

12.1.4 The principle of legality in criminal law

According to the principle of legality in criminal law laid down in section 8 of the Constitution, no one may be found guilty of an offence or sentenced to a penalty on the basis of an act that was not punishable by law at the time it was committed. A corresponding principle is also laid down in chapter 3, section 1, subsection 1 of the Criminal Code, Article 49 of the Charter of Fundamental Rights of the European Union, Article 7 of the European Convention on Human Rights and Article 15 of the International Covenant on Civil and Political Rights of the United Nations.

Compliance with the principle of legality in criminal law includes several requirements, at least the requirement that acts punishable as offences are defined by law, the prohibition of retroactive criminal law, the prohibition of the analogous application of criminal law, the requirement that penalties resulting from an offence are defined by law, the prohibition on applying a more severe penalty than that prescribed at the time of the act, and the requirement that criminal law provisions are enacted at the level of an Act of Parliament (Constitutional Law Committee opinion PeVL 309/1993, p. 50). This proposal concerns an extension of the material scope of application of an existing criminal provision to a broader range of new substances. It would not result in changes to the current constituent elements of the offence relating to violations of the prohibition on psychoactive substances prohibited from the consumer market, the selected regulatory approach of defining prohibited substances in more detail by Government decree, the chain of references from the Criminal Code to the Narcotics Act and Government Decree 1130/2014, or the legal safeguards. From the perspective of the constitutionality of the proposal, it is essential to assess whether the new regulation is sufficiently precise and clearly defined.

According to the requirement of precision and exact delimitation, the constituent elements of each offence must be expressed in law with sufficient precision so that, on the basis of the wording of the law, it can be foreseen whether an act or omission is punishable (Constitutional Law Committee opinions PeVL 48/2017 vp, p. 9; PeVL 10/2016 vp, pp. 8–9; PeVL 56/2014 vp, p. 2/II, and the opinions referred to therein). As a requirement imposed on the legislature by the principle of legality in criminal law, the scope of regulation must be understandable in advance on the basis of the legal provision, and it must not be left substantially dependent on practical application. The purpose of the principle of legality is to ensure the realisation of legal protection and predictable interpretation of the law in courts. In interpreting the law, a court may not go beyond the wording of the law or supplement or correct the law by relying on analogy (Government proposal HE 44/2002 vp, pp. 29 and 34).

Under the proposed regulation, the constituent elements of the offence would not change, but the definition of the object of the offence or the object subject to the offence would be extended. In addition to listing the chemical names of individual substances, the regulation would introduce a method for defining substances as designer drugs where they belong to a pre-defined substance group. A substance group would be determined on the basis of the core chemical structure of substances and the pre-defined possible variations of that structure. The prohibition based on substance groups would not be substantially dependent on practical application, as determining the chemical structure of a substance and comparing it with the criteria laid down in law would not involve discretion. The chemical structure of a substance can be objectively verified through laboratory examinations and demonstrated by an expert before a court. Verification based on laboratory testing and expert testimony are already used in the current system in criminal proceedings concerning narcotics and designer drugs. The regulation would therefore not enable interpretation by analogy or increase the discretion of competent investigative authorities or courts. The differences between classification based on substance groups and classification methods involving the possibility of analogy and greater discretion (the so-called prohibition of generally hazardous substances) have been examined in more detail above in section 5.1.3 concerning alternative implementation methods of the proposal.

Extending the criminalisation of violations of the prohibition on designer drugs to substances belonging to substance groups would represent a shift from detailed regulation towards more general regulation. The current method of defining each prohibited substance individually may be regarded as highly precise and, as such, as regulation that clearly fulfils the requirements of precision and exact delimitation. On the other hand, the amendment of the current regulation is justified by the fact that a corresponding so-called casuistic, i.e. case-specific, approach to criminal law regulation may be undesirable because such regulation may become outdated rapidly as a result of societal development or may fail to cover forms of conduct that are essential from the perspective of the purpose of the regulation. For example, in connection with the comprehensive reform of the Criminal Code, the Criminal Code was in many respects amended to become more general in nature, when casuistic, i.e. highly case-specific, penal provisions were combined (LaVM 6/1990 vp, p. 4). The Criminal Code also recognises, with regard to instruments of crime, the so-called instrument neutrality principle, meaning that a general concept is preferably used for defining an instrument of crime instead of an exhaustive listing of individual instruments (see, for example, chapter 21, section 6, subsection 1, paragraph 3 of the Criminal Code, where the act involves the use of “a firearm or edged weapon, or another comparable life-threatening instrument”).

The reason for the proposed substance-group-based definition is that the proposed regulation would remedy the shortcomings of the current, more casuistic regulation and would more likely fulfil its purpose with fewer amendments despite changes in the new psychoactive substance market. The current regulation leaves outside its scope objects of the offence or substances subject to the offence that are significant from the perspective of the purpose of the regulation, but which could be covered through regulation based on substance groups. At the same time, the predictability of the regulation could even increase, because the need to amend Government Decree 1130/2014 annually due to the emergence of new substances would decrease. Despite its general nature, the substance-group-based definition would be precise, as it would be based on a clearly defined and objectively verifiable core chemical structure of substances and the possible variations of that structure.

From the perspective of the principle of legality in criminal law, it is essential that regulation made more general in nature retains its predictability. The understanding of what the

requirement of predictability entails has been developed in the practice of the Constitutional Law Committee and the European Court of Human Rights. The Constitutional Law Committee has considered that, based on the wording of a criminal provision, it must be possible to foresee whether a certain activity or omission is punishable (see, for example, Constitutional Law Committee opinions PeVL 68/2010 vp, p. 4; PeVL 29/2001 vp, p. 3; PeVL 22/2001 vp, p. 3). The European Court of Human Rights has considered that, based on the wording of a criminal provision and, where necessary, in light of the courts' interpretative practice concerning the provision, an individual must be able to determine which acts and omissions may result in criminal liability (Kokkinakis v. Greece (1993) and Cantoni v. France (1996)). In other words, predictability is approached from the general perspective of any individual.

On the other hand, criminal law also includes a great deal of so-called specialised regulation (e.g. environmental offences), which is, as a rule, foreseeable to experts in a particular field but not necessarily to every individual. The interpretation of Article 7 of the ECHR by the European Court of Human Rights has also recognised that the foreseeability of regulation depends to a large extent on the regulatory instrument in question and the field of activity it is intended to cover, as well as on the number and status of the persons subject to the regulation (Kononov v. Latvia [GC], 2010, § 235; Cantoni v. France, 1996, § 35). The requirement of foreseeability may be fulfilled even if a person must, to a reasonable extent in the circumstances, seek legal advice. The duty of care and the obligation to obtain information apply particularly to professional activities where professional operators are accustomed to acting in an occupation that generally requires a high level of care (Cantoni v. France, 1996, § 35; Pessino v. France, 2006, § 33; Kononov v. Latvia [GC], 2010, § 23).

Regulation based on the core chemical structure of substance groups would by its nature be more technical than the current regulation. Determining the legality of a specific new substance, for example before importing it, could require more care or chemical understanding than at present. The regulation would include various means of making technically complex regulation easier to understand. The chemical structure of the substances would be illustrated through a simplified structural diagram and verbal explanations thereof, and examples of substances belonging to the substance group could also be provided. Despite this, the regulation could, in practical interpretation situations, be less understandable to individuals than the current regulation. On the other hand, it should also be taken into account that regulation concerning psychoactive substances intended for intoxicating use is, both nationally and internationally, known to be strict and dynamically changing. Therefore, a certain degree of care is, as a rule, required from anyone in determining whether the import of a specific psychoactive substance is prohibited or permitted. The legal and health-related risks and uncertainties of the activity already exist under the current system, even though prohibited substances are listed individually, as the legal status of a specific substance may change rapidly.

The manufacture, import, storage, offering for sale and other transfer covered by the criminalisation are forms of conduct associated with activities in which the distribution of substances is aimed at obtaining financial benefit or carrying out business activities. Based on the status of such operators, it could, in principle, be required under the case law of the European Court of Human Rights that they exercise a higher-than-usual degree of care and determine the legality of their activities. In particular, operators that manufacture new psychoactive substances or introduce them onto the market as the highest-level actors in the sales chain generally possess sufficient chemical expertise for even more technical regulation to be foreseeable and understandable.

The regulation could apply to a private individual if the individual attempted, in violation of the prohibition, to import a new psychoactive substance for personal use (see the preceding section 12.1.3). The interpretation of a more technical chemical definition would not necessarily be understandable to such a person without additional investigation. Whether the legal status of a specific substance would, in practice, be understandable to a layperson would depend on the substance in question and on how familiar the person is with psychoactive substances. The legal status of a substance could, in principle, be clear at least where the chemical names of substances belonging to a substance group resemble each other, meaning that whether a specific new substance belongs to the substance group could be inferred from the names of substances already included in the group. Substances may also be marketed, for example in online stores, under product categories referring to substance-group-based classification. On the other hand, some sellers may not always indicate the relevant substance group, the name of the substance may not correspond to the substances specified in the regulation, or the chemical composition of the substance may not be disclosed at all.

Primarily, in an uncertain situation, a consumer could seek to determine the chemical structure and legal status of the substance from the seller. However, the seller may not necessarily act honestly, as these markets often rely on opaque practices operating on the boundary between illegal and legal activity, where consumers typically do not have full consumer protection applicable to the trade of goods. Substances may be marketed solely under product names without disclosure of the product composition. In particular, foreign online stores may market new psychoactive substances in Finland as legal substances based either on incorrect information or information based on outdated legislation. The importation of substances and their legality already involve risks for consumers under the current system, as the substance may be something other than what has been marketed, or the marketing may be based on incorrect information. Consumer uncertainty and limited possibilities to predict the legality of a particular substance are characteristics of the new psychoactive substance market, not merely consequences of legislation.

In an uncertain situation, a private individual would have the possibility to request guidance from the competent authority, namely Customs or Fimea. These authorities would, in principle, have the ability to provide the importer with reliable guidance based on the information available to the consumer planning the importation. According to the above-mentioned interpretation of the European Court of Human Rights, the requirement of foreseeability may be fulfilled even if a person must, to a reasonable extent in the circumstances, rely on legal advice. A similar interpretation has also been reflected in the Supreme Court decision KKO 2015:66, where a private individual who imported melatonin was charged with a medicinal offence. The defendant invoked the defence of mistake of law under Chapter 4, section 2 of the Criminal Code. In that case, the private individual could reasonably be expected to verify the legality of the importation through official sources. Referring to various newspaper and internet articles suggesting that the importation was legal was not considered sufficient investigation. Ultimately, the legality of the importation should have been verified with the competent authority. Taking into account also the considerations presented regarding the necessity and proportionality of extending the criminalisation of importation in relation to individual self-determination, as well as the necessity of the proposal compared with other regulatory options (Chapters 5.1 and 12.1.3), the possibility that the understandability of the regulation may in individual cases be reduced for individuals must be considered necessary in view of the objectives of the regulation. On the above grounds, a consumer acting in good faith can be considered to have reasonable means available, where necessary, to determine the legal status of a particular substance even if it is not directly apparent from the regulation itself.

The extension of the criminalisation can therefore be assessed as sufficiently fulfilling the requirements of precision and specificity, as well as the requirements arising from the principle of legality in criminal law under section 8 of the Constitution.

12.2 Authorisation to issue decrees

According to section 80 of the Constitution, the President of the Republic, the Government and ministries may issue decrees on the basis of powers provided for in the Constitution or elsewhere by law. However, the principles governing the rights and obligations of private individuals and the other matters that under the Constitution are of a legislative nature must be regulated by Acts. If no separate provision has been made on the authority issuing the regulation, the regulation is issued by the Government.

Regulations may contain more detailed provisions on minor matters relating to individuals' rights and obligations. The authorisation to issue decrees provided for in an Act must be sufficiently precise and clearly defined (HE 1/1998 vp, pp. 131/II and 132/I, and PeVL 15/1996 vp). According to the preparatory works of the Constitution, the Government issues decrees on matters of broad scope and matters of fundamental importance, as well as on other matters where their significance so requires. A Ministry, in turn, issues decrees on matters of lesser social and political significance, where the matter is clearly of a technical nature and concerns implementation (see HE 1/1998 vp, p. 132/II). (See HE 1/1998 vp, p. 132/II).

The proposal would amend the definition of a psychoactive substance prohibited from the consumer market in section 3 of the Narcotics Act, which is linked to an authorisation to issue regulations allowing substances considered psychoactive substances prohibited from the consumer market to be defined in more detail by a Government decree. Under the current system, the decree contains a list of the chemical names of individual substances. The content of the authorisation to issue decrees would not be changed by the proposal. Following the amendment of the definition in the section, the decree would be amended so that, in addition to individual substances, certain substance groups would also be defined, with substances belonging to those groups falling within the scope of the prohibition. The decree would continue to concern detailed and technical regulation, which, based on the Constitutional Law Committee's practice concerning section 80 of the Constitution, is appropriate to maintain at the regulatory level.

12.3 Personal data protection

The proposed amendment to the record-keeping obligation for the import and storage of psychoactive substances prohibited from the consumer market would extend the retention period from three years to six years. Under section 33a of the current Narcotics Act, records must include sufficient information to identify the quantity of the substance and the names and addresses of the seller and buyer. Information from the accounts is primarily information on legal persons, but the information may also concern a natural person who is the contact person of the seller or the buyer or the author of the accounts. In this respect, the records could contain the name of a natural person. Personal data is protected under the EU General Data Protection Regulation and falls within the scope of the protection of private life under section 10 of the Constitution.

The proposal can be considered acceptable and proportionate from the perspective of the protection of a natural person's data and private life. The records would not include sensitive personal data, and the legal basis for the processing of personal data in the records would be

Article 6(1)(c) of the General Data Protection Regulation, i.e. compliance with a legal obligation of the controller. The purpose of extending the retention period is to ensure that authorities have the possibility to carry out effective supervision and trace the movement chains of substances also in situations where misuse or suspicions of criminal activity emerge only after a delay. The retention obligation would correspond to the retention period applicable to records concerning narcotic substances and to the general retention period for accounting records concerning legal persons under the Accounting Act.

Based on the above considerations, the proposals may be dealt with under the ordinary legislative process.

The Government nevertheless considers it desirable that the Constitutional Law Committee should issue an opinion at least on whether the proposed substance-specific classification of psychoactive substances prohibited from the consumer market can be regarded as sufficiently precise and clearly defined, as required by the principle of legality in criminal law.

Based on the foregoing, the following legislative proposal is submitted to Parliament for approval:

1.

Act

amending the Narcotics Act

In accordance with the decision of Parliament

Section 3, section 3a, section 22(4), section 31(2) and section 33a(1) of the Narcotics Act (373/2008), as amended, are amended as follows: section 3 as set out in Acts 934/2018 and 323/2022, section 3a and section 33a(1) in Act 1127/2014, section 22(4) in Act 323/2022 and section 31(2) in Act 775/2009, and

a new subsection 4 is added to section 23b of the Act, as set out in Act 1127/2014, whereby the current subsection 4 becomes subsection 5, as follows:

Section 3

Definitions

For the purposes of this Act:

— —

7) *manufacture of narcotic* refers to all methods, other than production, by which narcotics can be obtained, and the purification and conversion of a narcotic into another narcotic;

8) *Production of a narcotic* means the separation of opium, coca leaves, cannabis or cannabis resin from the plants from which they are obtained; and

9) *a psychoactive substance prohibited from the consumer market* means a substance intended for use for intoxication purposes that may be hazardous to health, which is not a medicinal substance or a narcotic, and:

a) for which a notification referred to in paragraph 5(e) of subsection 1 has been submitted, or which is a positional isomer of such a substance; or

b) which, based on its chemical structure, belongs to a group of substances that may, based on the assessment of properties referred to in section 3a below, be considered hazardous to health.

More detailed provisions on which substances, preparations and plants are considered narcotics referred to in paragraph 5 of subsection 1, and which substances are considered psychoactive substances prohibited from the consumer market referred to in paragraph 9 of subsection 1, shall be issued by Government decrees.

Section 3a

Assessment of properties of substances and substance groups

The psychoactive properties and harmfulness of a substance or substance group shall, where necessary, be assessed by the Finnish Medicines Agency in cooperation with the Finnish Institute for Health and Welfare, the police and Customs.

If the Finnish Medicines Agency considers that the psychoactive properties and harmfulness of a substance or substance group require its classification as a narcotic under section 3(1)(5)(e), or the classification of the substance or substances belonging to the group as designer

drugs under section 3(1)(9), the Agency shall submit its assessment to the Ministry of Social Affairs and Health, together with its proposed measures. The proposal shall take into account whether the substance or substances belonging to the group are present in Finland or are likely to appear in Finland.

Section 22

Medicinal products necessary for emergency and crisis management

— —

If the situation in question is exceptionally serious or if there is another special reason for it, an import and export licence under this Act would not be required for a humanitarian aid organisation carrying out humanitarian relief activities, nor for the Finnish Institute for Health and Welfare when participating in the provision or receipt of international medical assistance. A further condition for exemption from the import and export licence requirement is that the operator holds the authorisation referred to in section 32(3) of the Medicines Act. In this case, the export of the medicinal products must be notified in advance and their import without delay to the Finnish Medicines Agency Fimea. The provisions of section 16 on the requirements for the responsible person and section 17 on the approval of the responsible person shall apply to the import and export of medicinal products in the cases referred to in this subsection.

— —

Section 23b

Psychoactive substances prohibited from the consumer market

— —

The laboratory of the Finnish Institute for Health and Welfare, the forensic laboratory of the National Bureau of Investigation and the Customs Laboratory would be permitted to transfer to one another a substance or preparation used for the identification of a psychoactive substance prohibited from the consumer market and containing a psychoactive substance prohibited from the consumer market.

— —

Section 31

Notification Obligation

— —

In addition, the licence holder must submit to the Finnish Medicines Agency a quarterly notification of substances included in the schedules of the 1961 Single Convention on Narcotic Drugs and in schedules I–III of the 1971 Convention on Psychotropic Substances that have been imported into Finland and exported from Finland.

Section 33a

Obligations relating to the import and storage of psychoactive substances prohibited from the consumer market

Any person who imports or stores psychoactive substances prohibited from the consumer market must keep records of the substances imported and of the substances used in their research or production activities and must ensure that the documents contain sufficient information to identify the quantity of the substance and the name and address of the seller and purchaser. The documents must be retained for at least six years from the end of the calendar year in which the import or storage took place.

— —

This Act shall enter into force on [day] [month] 20...

2.

Act

amending section 3 of the Electronic Prescription Act

In accordance with the decision of Parliament
section 3, paragraph 9 of the Electronic Prescription Act (61/2007), as it is in Act 251/2014, is *amended* as follows:

Section 3

Definitions

For the purposes of this Act:

— —

9) *a medicinal product containing narcotics* means a medicinal product containing any of the following substances:
a) substances included in Schedules I, II and IV of the Single Convention on Narcotic Drugs of 1961 referred to in section 3(1), paragraph 1(a) of the Narcotics Act (373/2008);
b) substances included in Schedules I and II of the Convention on Psychotropic Substances of 1971 referred to in section 3(1), paragraph 1(b) of the Narcotics Act;
c) substances referred to in section 3(1), paragraph 5(e) of the Narcotics Act which, based on their pharmacological properties, are, pursuant to section 3(2) of the Narcotics Act, equated with substances included in the schedules of the conventions referred to in subparagraphs 1 and 2 of this paragraph;

This Act shall enter into force on [day] [month] 20...

Helsinki xx xx 20xx

Prime Minister

First name Last name

..Minister First name Last name

1.

Act

amending the Narcotics Act

In accordance with the decision of Parliament

Section 3, section 3a, section 22(4), section 31(2) and section 33a(1) of the Narcotics Act (373/2008), as amended, are amended as follows: section 3 as set out in Acts 934/2018 and 323/2022, section 3a and section 33a(1) in Act 1127/2014, section 22(4) in Act 323/2022 and section 31(2) in Act 775/2009, and

a new subsection 4 is added to section 23b of the Act, as set out in Act 1127/2014, whereby the current subsection 4 becomes subsection 5, as follows:

Existing Act	*Proposal*
Section 3	Section 3
Definitions	*Definitions*
For the purposes of this Act:	For the purposes of this Act:
— — — — — — — — — — — — — — — —	— — — — — — — — — — — — — — — —
7) *manufacture of narcotics* refers to all methods, other than production, by which narcotics can be obtained, and the purification and conversion of a narcotic into another narcotic; and	7) *manufacture of narcotic* refers to all methods, other than production, by which narcotics can be obtained, and the purification and conversion of a narcotic into another narcotic;
8) *production of a narcotic* means the separation of opium, coca leaves, cannabis or cannabis resin from the plants from which they are obtained.	8) *production of a narcotic* means the separation of opium, coca leaves, cannabis or cannabis resin from the plants from which they are obtained; and
	9) *a psychoactive substance prohibited from the consumer market* means a substance intended for use for intoxication purposes that may be hazardous to health, which is not a medicinal substance or a narcotic, and:
	a) for which a notification referred to in paragraph 5(e) of subsection 1 has been submitted, or which is a positional isomer of such a substance; or
	b) *which, based on its chemical structure, belongs to a group of substances that may, based on the assessment of properties referred to in section 3a below, be considered hazardous to health.*
	More detailed provisions on which

Existing Act

More detailed provisions on which substances, preparations and plants are considered narcotics referred to in paragraph 5 of subsection 1 shall be issued by Government decree.

For the purposes of this Act, a psychoactive substance prohibited from the consumer market means substances used for intoxication purposes that may be hazardous to health and for which a notification has been submitted for the purposes of placing the substance under control in the manner referred to in paragraph 5(e) of subsection 1, or which are positional isomers of such a substance, and which are neither medicinal substances nor narcotics. More detailed provisions on which substances are to be considered psychoactive substances prohibited from the consumer market shall be issued by Government decree.

Section 3a

Assessment of the properties of substances used for intoxication purposes

The Finnish Medicines Agency, in cooperation with the Finnish Institute for Health and Welfare, the police and Customs, shall assess the psychoactive properties and hazardousness of a substance referred to in section 3(1), paragraph 5(e), and subsection 3.

If the Finnish Medicines Agency considers that the psychoactive properties and hazardousness of a substance require the implementation of the prohibitions referred to in section 5, the Agency shall submit its assessment to the Ministry of Social Affairs and Health together with a proposal for measures, based, among other things, on whether the substance occurs in Finland or whether it is likely to occur in Finland, before a decision on placing the substance under control can be made in accordance

Proposal

substances, preparations and plants are considered narcotics referred to in paragraph 5 of subsection 1, and which substances are considered psychoactive substances prohibited from the consumer market referred to in paragraph 9 of subsection 1, shall be issued by Government decrees.

Section 3a

Assessment of properties of substances and substance groups

The psychoactive properties and harmfulness of a substance or substance group shall, where necessary, be assessed by the Finnish Medicines Agency in cooperation with the Finnish Institute for Health and Welfare, the police and Customs.

If the Finnish Medicines Agency considers that the psychoactive properties and harmfulness of a substance or substance group require its classification as a narcotic under section 3(1)(5)(e), or the classification of the substance or substances belonging to the group as designer drugs under section 3(1)(9), the Agency shall submit its assessment to the Ministry of Social Affairs and Health, together with its proposed measures. The proposal shall take into account whether the substance or substances belonging to the group are present in Finland or are likely to appear in Finland.

Existing Act

with the Council decision referred to in section 3(1), paragraph 5(c).

Section 22

Medicinal products necessary for emergency and crisis management

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An organisation engaged in humanitarian aid operations with a licence referred to in section 32, subsection 3 of the Medicines Act shall not need an import and export licence under this Act for humanitarian aid operations if the situation to which the activity relates is exceptionally serious or if there is another special reason for it. In this case, the export of the medicinal products must be notified in advance and their import without delay to the Finnish Medicines Agency Fimea. The provisions of section 16 on the requirements for the responsible person and section 17 on the approval of the responsible person shall apply to the import and export of medicinal products in the cases referred to in this subsection.

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Section 23b

Psychoactive substances prohibited from the consumer market

— — — — — — — — — — — — — — —

Further provisions on the submission of a notification referred to in this section shall be laid down by government decree.

Proposal

Section 22

Medicinal products necessary for emergency and crisis management

— — — — — — — — — — — — — — —

If the situation in question is exceptionally serious or if there is another special reason for it, an import and export licence under this Act would not be required for a humanitarian aid organisation carrying out humanitarian relief activities, nor for the Finnish Institute for Health and Welfare when participating in the provision or receipt of international medical assistance. A further condition for exemption from the import and export licence requirement is that the operator holds the authorisation referred to in section 32(3) of the Medicines Act. In this case, the export of the medicinal products must be notified in advance and their import without delay to the Finnish Medicines Agency Fimea. The provisions of section 16 on the requirements for the responsible person and section 17 on the approval of the responsible person shall apply to the import and export of medicinal products in the cases referred to in this subsection.

— — — — — — — — — — — — — — —

Section 23b

Psychoactive substances prohibited from the consumer market

— — — — — — — — — — — — — — —

The laboratory of the Finnish Institute for Health and Welfare, the forensic laboratory of the National Bureau of Investigation and the Customs Laboratory would be permitted to transfer to one another a substance or preparation used for the identification of a psychoactive substance prohibited from the consumer market and containing a psychoactive substance prohibited from the consumer market.

Further provisions on the submission of a notification referred to in this section shall be laid down by government decree.

Existing Act

Section 31

Notification Obligation

— — — — — — — — — — — — — — —

In addition, the licence holder must submit to the Finnish Medicines Agency a quarterly notification of substances included in the schedules of the 1961 Single Convention on Narcotic Drugs and in schedules I–III of the 1971 Convention on Psychotropic Substances that have been imported into Finland and exported from Finland.

Section 33a

Obligations relating to the import and storage of psychoactive substances prohibited from the consumer market

Any person who imports or stores psychoactive substances prohibited from the consumer market must keep records of the substances imported and of the substances used in their research or production activities and must ensure that the documents contain sufficient information to identify the quantity of the substance and the name and address of the seller and purchaser. The documents must be retained for at least three years from the end of the calendar year in which the import or storage took place.

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Proposal

Section 31

Notification Obligation

— — — — — — — — — — — — — — —

In addition, the licence holder must submit to the Finnish Medicines Agency a quarterly notification of substances included in the schedules of the 1961 Single Convention on Narcotic Drugs and in schedules I–III of the 1971 Convention on Psychotropic Substances that have been imported into Finland and exported from Finland.

Section 33a

Obligations relating to the import and storage of psychoactive substances prohibited from the consumer market

Any person who imports or stores psychoactive substances prohibited from the consumer market must keep records of the substances imported and of the substances used in their research or production activities and must ensure that the documents contain sufficient information to identify the quantity of the substance and the name and address of the seller and purchaser. The documents must be retained for at least six years from the end of the calendar year in which the import or storage took place.

— — — — — — — — — — — — — — —

2.

Act

amending section 3 of the Electronic Prescription Act

In accordance with the decision of Parliament

section 3, paragraph 9 of the Electronic Prescription Act (61/2007), as it is in Act 251/2014, is *amended* as follows:

Existing Act	*Proposal*
Section 3	Section 3
Definitions	*Definitions*
For the purposes of this Act:	For the purposes of this Act:
9) medicinal product containing narcotics is defined as a medicinal product containing substances listed in Schedules I, II and IV of the 1961 Single Convention on Narcotic Drugs referred to in section 3(1)(1)(a) of the Narcotics Act, as well as substances listed in Schedules I and II of the 1971 Convention on Psychotropic Substances referred to in section 3(1)(1)(b) of the same Act, and substances referred to in section 3(1)(5)(e) of the Narcotics Act.	9) a medicinal product containing narcotics means a medicinal product containing any of the following substances: a) substances included in Schedules I, II and IV of the Single Convention on Narcotic Drugs of 1961 referred to in section 3(1), paragraph 1(a) of the Narcotics Act (373/2008); b) substances included in Schedules I and II of the Convention on Psychotropic Substances of 1971 referred to in section 3(1), paragraph 1(b) of the Narcotics Act; c) substances referred to in section 3(1), paragraph 5(e) of the Narcotics Act which, based on their pharmacological properties, are, pursuant to section 3(2) of the Narcotics Act, equated with substances included in the schedules of the conventions referred to in subparagraphs 1 and 2 of this paragraph;

Draft Decree

Government Decree

amending the Government Decree on Psychoactive Substances Prohibited on the Consumer Market

By decision of the Government,
the Annex to Government Decree (1130/2014) on psychoactive substances prohibited from the consumer market, as amended by Decree 1101/2025, is amended, and
a new Annex 2 is *added* to the Decree as follows:

Section 1

Psychoactive substances prohibited from the consumer market are the substances listed in the Annex and substances which, based on their chemical structure, belong to one of the substance groups specified in the Annex.

[Annex 2 to the decree is contained in a separate document attached to the request for comments.]

Annex 1 to the draft Government proposal, 4 June 2026.
STM010:00/2026

Government Decree

amending the Government Decree on Psychoactive Substances Prohibited on the Consumer Market

By decision of the Government,
the Annex to Government Decree (1130/2014) on psychoactive substances prohibited from the consumer market, as amended by Decree 1101/2025, is amended, and
a new Annex 2 is *added* to the Decree as follows:

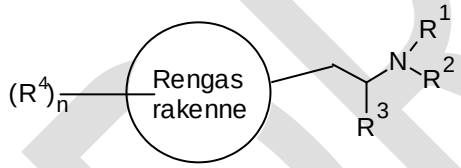
Section 1

Psychoactive substances prohibited from the consumer market would include the substances listed in Annex 1 and substances which, based on their chemical structure, belong to one of the groups of substances listed in Annex 2.

Annex 2

1. Phenethylamines

The general structure of chemical compounds derived from phenethylamines (Figure 1) is:



Rengas rakenne Ring structure

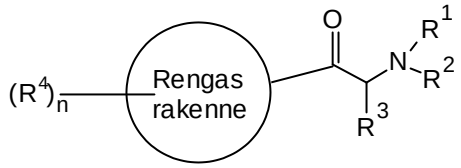
Any compound containing the amine structure shown in Figure 1, where the ring structure in Figure 1 is replaced by a phenyl, naphthyl, tetralinyl, methylenedioxyphenyl, ethylenedioxyphenyl, furanyl, pyrrolyl, thienyl, pyridyl, benzofuranyl, dihydrobenzofuranyl, indanyl, indenyl, tetrahydrobenzodifuranyl, benzodifuranyl, tetrahydrobenzodipyranyl, cyclopentyl, or cyclohexyl group (Figure 2B), and where the structural elements R1–R4 are replaced as follows:

R_1 = H, alkyl (C_nH_{2n+1}) or cycloalkyl, containing no more than 6 carbon atoms, benzyl, mono-, di- or trimethoxybenzyl, halobenzyl, hydroxybenzyl, or their imine analogue, formyl (CHO), hydroxyl (OH);
R_2 = H, methyl, acetyl, formyl;
R_1 and R_2 may also form a ring structure together with the nitrogen atom (for example, a pyrrolidinyl or piperidinyl ring);
R_3 = H, alkyl (C_nH_{2n+1}), aryl;

R_4 = H, alkyl (C_nH_{2n+1}), alkoxy or alkenyl (C_nH_{2n-1}), containing no more than 6 carbon atoms, hydroxyl (OH), nitro (NO_2), halogen, haloalkyl, cyano (CN), allyloxy, aryl, benzyloxy, alkylsulfanyl, haloalkylsulfanyl, carboxyl, alkynyl.

2. Cathinones

The general structure of the chemical compounds derived from cathinones (Figure 2A) is:



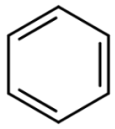
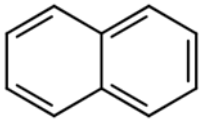
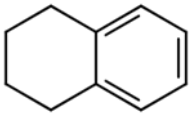
Rengas rakenne Ring structure

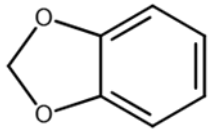
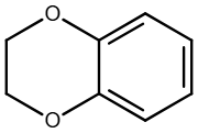
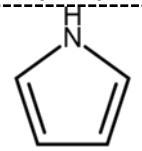
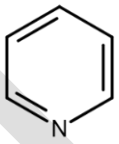
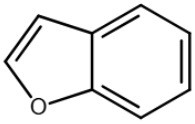
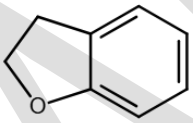
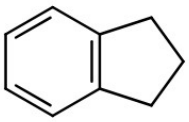
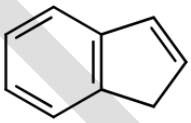
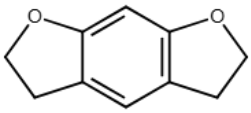
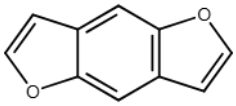
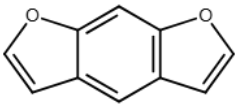
Any compound containing the cathinone structure shown in Figure 1, where the ring structure in Figure 1 is replaced by a phenyl, naphthyl, tetralinyl, methylenedioxyphenyl, ethylenedioxyphenyl, furanyl, pyrrolyl, thienyl, pyridyl, benzofuranyl, dihydrobenzofuranyl, indanyl, indenyl, tetrahydrobenzodifuranyl, benzodifuranyl, tetrahydrobenzodipyranyl, cyclopentyl, or cyclohexyl group (Figure 2B), and where the structural elements R^1–R^4 are replaced as follows:

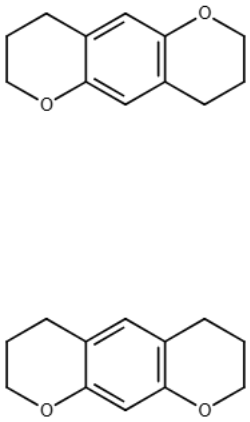
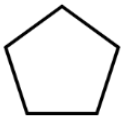
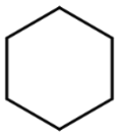
R^1, R^2 = H, alkyl (C_nH_{2n+1}) with a maximum of 7 carbon atoms, aryl (only if R^1=H), and/or arylalkyl. Including derivatives in which the nitrogen atom is attached to a ring structure, for example forming a pyrrolidinyl or piperidinyl ring;
R^3 = alkyl (C_nH_{2n+1}), cycloalkyl, alkenyl or cycloalkenyl with a maximum of 7 carbon atoms, aryl, halogen or haloalkyl;
R^4 = H, alkyl, including when fused into a ring structure, alkoxy (-OR), methylenedioxy (-O-CH_2-O-), halogen or haloalkyl.

Exceptions: Excluding bupropion.

Figure 2B: Structural diagrams of the ring structures found in phenethylamines and cathinones:

Phenyl	Naphthyl	Tetralinyl
		

Methylene dioxyphenyl	Ethylenedioxyphenyl	Furanyl
		
Pyrrolyl	Thienyl	Pyridyl
		
Benzofuranyl	Dihydrobenzofuranyl	Indanyl
		
Indenyl	Tetrahydrobenzodifuranyl	Benzodifuranyl
	 	 

Tetrahydrobenzodipyranyl	Cyclopentyl	Cyclohexyl
		

3. Fentanyl derivates

The general structure of the chemical compound of a fentanyl derivative (Figures 3A and 3B) may be one of the following:

Figure 3A: N-phenyl-1-(2-phenylethyl)piperidine-4-amide structure

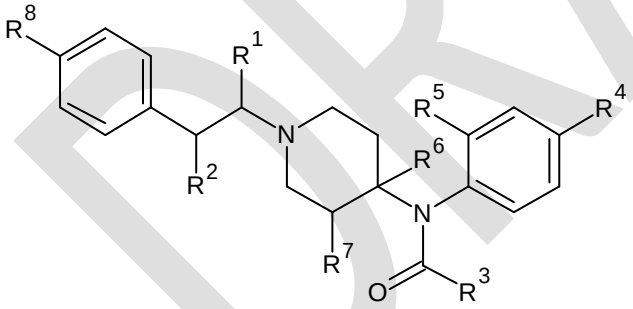
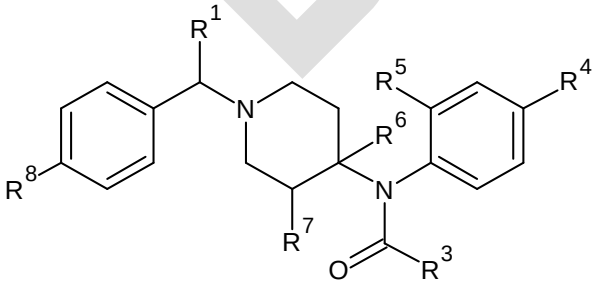


Figure 3B: 1-benzyl-N-phenylpiperidine-4-amide structure



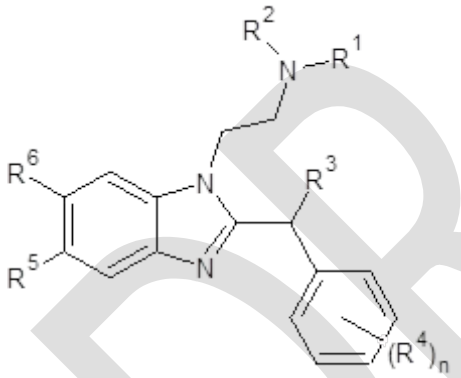
Any compound containing an N-phenyl-1-(2-phenylethyl)piperidine-4-carboxamide structure (Figure 3A) or a 1-benzyl-N-phenylpiperidine-4-carboxamide structure (Figure 3B), where the structural elements R^1–R^8 may be substituted as follows:

The benzene ring in the phenylethyl group in Figure 3A may be replaced by an ethyl-substituted tetrazole or thiophene.

R^1, R^2 = H, methyl (CH_3), ethyl (C_2H_5), hydroxyl (OH), haloalkyl or nitro (NO_2);
R^3 = methyl (CH_3), ethyl (C_2H_5), isopropyl ($CH(CH_3)_2$), methoxymethyl (CH_2–O–CH_3), or another functional group containing no more than 7 carbon atoms;
R^4 = H, halogen, hydroxyl (OH), methoxy (OCH_3);
R^5 = H, halogen, methyl (CH_3), methoxy (OCH_3);
R^6 = H, methyl (CH_3), methoxycarbonyl ($COOCH_3$), methoxymethyl (CH_2–O–CH_3);
R^7 = H, halogen, methyl (CH_3), ethyl (C_2H_5), propyl or isopropyl (C_3H_7);
R^8=H, halogen, methoxy (OCH_3).

4. Nitazenes

The general structure of the chemical compounds of nitazene derivatives (Figure 4) is as follows:



Any compound containing the 2-benzyl-1-aminoethylbenzimidazole structure shown in Figure 4, where the structural elements R^1–R^6 may be substituted as follows:

R^1, R^2 = H, alkyl (C_nH_{2n+1}), or a ring structure in which aliphatic nitrogen forms part of the ring structure, and the alkyl groups and ring structures contain no more than 7 carbon atoms;
R^3 = H, methyl (CH_3), hydroxyl (OH), or carboxamide ($CONH_2$);
R^4 = H, alkyl (C_nH_{2n+1}), alkoxy (O-C_nH_{2n+1}), halogen, hydroxyl (OH), allyloxy (O-CH_2CHCH_2), 2-fluoroethoxy (O-CH_2CH_2F), nitro (NO_2), cyano (CN), acetoxy (-O-CO-CH_3), alkylsulfanyl (S-C_nH_{2n+1}), methylenedioxy (O-CH_2–O), ethyleneoxy (CH_2CH_2O), or 2-ethoxyethoxy (O-CH_2CH_2-O-CH_2CH_3) structures, including one or more substituents containing no more than 7 carbon atoms;
R^5, R^6 = H, nitro (NO_2), alkyl, trifluoromethyl (CF_3), cyano (CN), amino (NH_2), halogen, or acetyl ($COCH_3$).

The benzyl side chain (R^3 = H) may also be replaced by phenylethyl (-CH_2CH_2-C_6H_5), thiophenyl (-S-C_6H_5), or methylthiophene (-CH_2-C_4SH_3). In this case, in the benzene ring of the phenylethyl and thiophenyl groups, R^4 corresponds to Figure 4.

The possible alkoxy and alkyl groups in the structural elements also include branched carbon chains (for example, isopropyl).

5. Orphines

The general structure of the chemical compound of a orphine derivative (Figures 5A and 5B) may be one of the following:

Figure 5A: Orphine structure

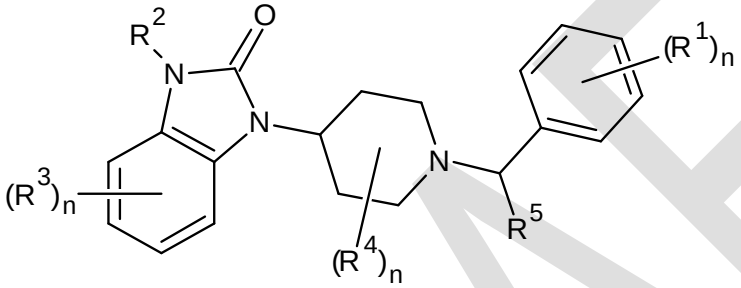
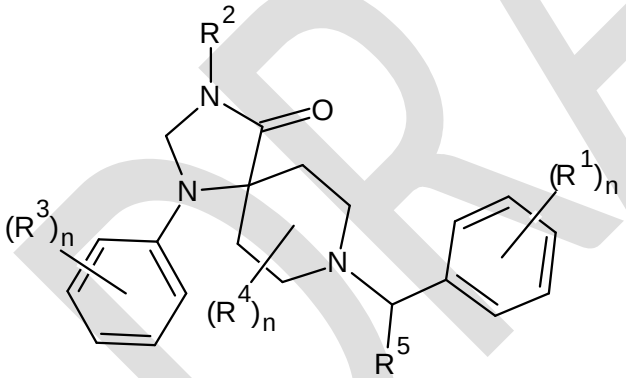


Figure 5B: Triazaspiro structure



Any compound containing the orvin structure shown in Figure 5A (1-(1-benzylpiperidin-4-yl)-1,3-dihydro-2H-1,3-benzimidazol-2-one) or the triazaspiror structure shown in Figure 5B (8-benzyl-1-phenyl-1,3,8-triazaspiro[4.5]decan-4-one), where the structural elements R^1–R^5 may be substituted as follows:

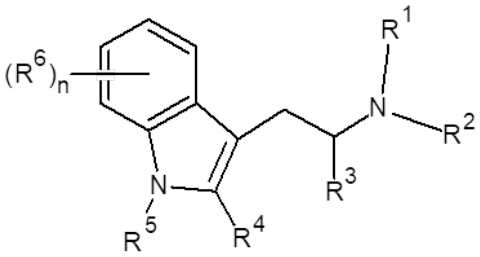
R^1, R^3, R^4 = H, alkyl (C_nH_{2n+1}), alkenyl (C_nH_{2n-1}), alkoxy (O–C_nH_{2n+1}), halogen, hydroxyl (OH), nitro (NO_2), ester/carboxyl or alkyl nitrile group, including one or more substituents containing no more than 7 carbon atoms;

R^2, R^5 = H, alkyl (C_nH_{2n+1}), alkenyl (C_nH_{2n-1}), alkoxy (O–C_nH_{2n+1}), halogen, hydroxyl (OH), nitro (NO_2), ester/carboxyl or alkyl nitrile group containing no more than 7 carbon atoms.

The possible alkoxy and alkyl groups in the structural elements also include branched carbon chains (for example, isopropyl).

6. Tryptamines

The general structure of the chemical compounds of tryptamine derivatives (Figure 6) is as follows:



Any compound containing the indole-3-alkylamine structure shown in Figure 6, where the structural elements R^1–R^6 may be substituted as follows:

R^1, R^2 = H, alkyl (C_nH_{2n+1}), alkenyl (C_nH_{2n-1}), containing no more than 6 carbon atoms;
R^3 = H or alkyl (C_nH_{2n+1}), containing no more than 3 carbon atoms;
R^4 = H or alkyl (C_nH_{2n+1}), containing no more than 2 carbon atoms;
R^5 = H or alkyl (C_nH_{2n+1}), containing no more than 2 carbon atoms;
R^6 = H, hydroxyl (OH), methoxy (OCH_3), acetoxy ($OCOCH_3$), propionyloxy ($OCOCH_2CH_3$) or methylsulfanyl groups, one or more substituents, or a methylenedioxy group connecting two adjacent carbon atoms.

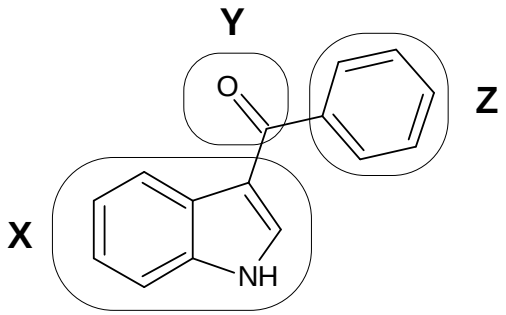
The possible alkyl and alkenyl groups in the structural elements also include branched carbon chains (for example isopropyl).

Exceptions: Excluding tryptamine, serotonin and melatonin.

7. Synthetic Cannabinoids

7.1 Basic structures of synthetic cannabinoids

The basic backbone structure of synthetic cannabinoids divided into substructures X, Y and Z (Figure 7.1A) is as follows:



Any compound containing the basic backbone structure of synthetic cannabinoids shown in Figure 7.1A, where the structure of each substructure X, Y and Z is one of those listed below, and where the possible positions R¹–R⁴ of each substructure may be substituted as follows:

Substructure X:

X = indole, indazole, benzimidazole, indene or pyrrole structure (Figures 7.1B–F), where the possible positions R¹–R⁴ of the structure are substituted as follows:

Figure 7.1B: indole structure	Figure 7.1C: indazole structure	Figure 7.1D: benzimidazole structure

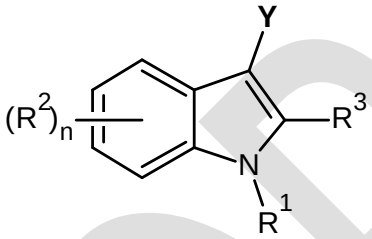
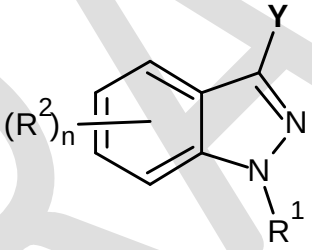
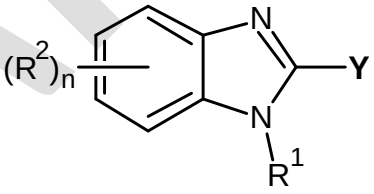
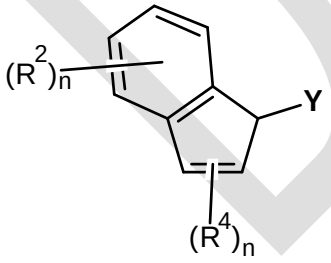
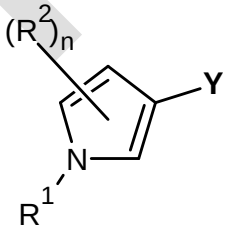

		

Figure 7.1E: indene structure	**Figure 7.1F: pyrrole structure**	
		

R¹ = H, alkyl (C_nH_{2n+1}), cycloalkyl, alkenyl, cycloalkenyl, containing no more than 10 carbon atoms, phenyl, benzyl, cyclohexylmethyl. Any of the above may contain one or more substituents consisting of hydroxyl (OH), carboxyl (COOH), halogen, nitro (NO_2), cyano (CN), tetrahydropyranyl, morpholine, N-methylpyrrolidinyl or N-methylpiperidinyl. All of the above-mentioned ring structures may also be heterocyclic.

R^2, R^3, R^4 = H, alkyl (C_nH_{2n+1}), cycloalkyl, alkenyl, cycloalkenyl, containing no more than 10 carbon atoms, halogen, hydroxyl (OH), methoxy (OCH_3), nitro (NO_2), carboxyl (COOH) or cyano (CN) group. All of the above-mentioned ring structures may also be heterocyclic.

The possible alkyl and alkenyl groups in the structural elements also include branched carbon chains (for example isopropyl).

Substructure Y:
Y = methylene (CH_2), methine (CH), ketone (CO), ester (COO), amide (CONH), acetyl ($COCH_2$), sulfonyl (SO_2).

Substructure Z:
Z = phenyl, naphthalenyl, adamantyl, quinolinyl, tetramethylcyclopropyl, aminodimethyloxobutanyl or dimethylbutanoate structure, and the possible structural elements R^1–R^5 may be substituted as follows:

Figure 7.1G: phenyl structure	Figure 7.1H: naphthalenyl structure	Figure 7.1I: adamantyl structure

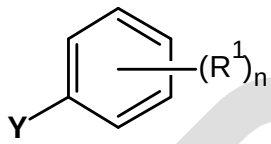
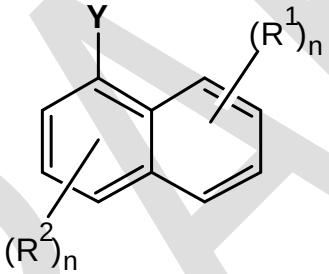
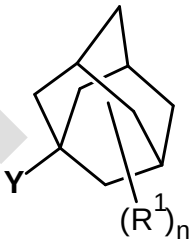

		

Figure 7.1J: quinolinyl structure	Figure 7.1K: tetramethylcyclopropyl structure	Figure 7.1L: aminodimethyloxobutanyl structure

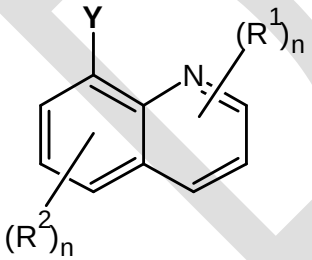
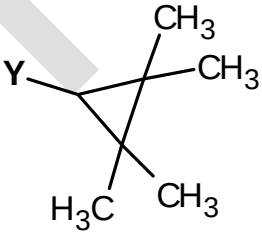
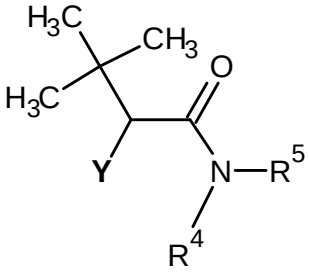
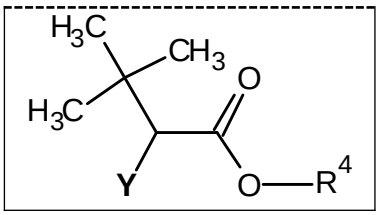

		

Figure 7.1M: dimethylbutanoate structure		



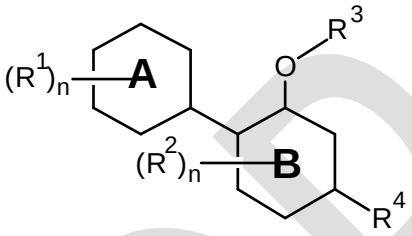
R^1, R^2 = H, halogen, methyl (CH_3), hydroxyl (OH), methoxy (OCH_3), nitro (NO_2) or cyano (CN) group.

R^4, R^5 = H, alkyl (C_nH_{2n+1}), cycloalkyl, alkenyl, cycloalkenyl, phenyl, benzyl, cyclohexylmethyl or any other substituent containing no carbon atoms or containing no more than 10 carbon atoms. All of the above-mentioned ring structures may also be heterocyclic.

In addition, the following groups include compounds belonging to the subgroups of synthetic cannabinoids:

7.2 Bicyclohexanols

The general structure of the chemical compounds of bicyclohexanol derivatives (Figure 7.2) is as follows:



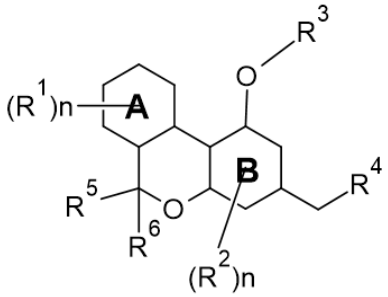
Compounds containing the structure shown in Figure 7.2, where ring A may contain 1, 2 or 3 double bonds and ring B may contain 1, 2 or 3 double bonds or a benzoquinone structure, and where the structural elements R^1–R^4 may be substituted as follows:

R^1, R^2, R^3, R^4 = H or any other substituent containing no carbon atoms or containing no more than 10 carbon atoms.

Exceptions: Excluding cannabidiol and hemp in which cannabinoids potentially belonging to the group occur naturally.

7.3 Hexahydrodibenzopyranols

The general structure of the chemical compounds of hexahydrodibenzopyranol derivatives (Figure 7.3) is as follows:



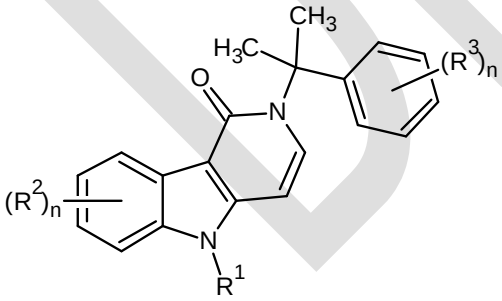
Compounds containing the structure shown in Figure 7.3, where ring A may contain 1, 2 or 3 double bonds and ring B may contain 1, 2 or 3 double bonds or a benzoquinone structure, and where the structural elements R^1–R^6 may be substituted as follows:

R^1, R^2, R^3, R^4, R^5, R^6 = H, or any other substituent. R^2 and R^3 may also form a substituted ring structure. Each R may contain no carbon atoms or contain no more than 10 carbon atoms.

Exceptions: Excluding nabilone and hemp in which cannabinoids potentially belonging to the group occur naturally.

7.4 Gammacarbolinones

The general structure of the chemical compounds of gammacarbolinone derivatives (Figure 7.4) is as follows:

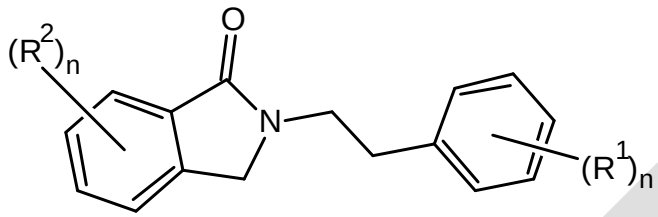


Compounds containing the structure shown in Figure 7.4, where the structural elements R^1–R^3 may be substituted as follows:

R^1, R^2, R^3 = H or any other substituent containing no carbon atoms or containing no more than 10 carbon atoms.

7.5 Phenylethyl-dihydroisoindolones

The general structure of the chemical compounds of phenylethyl-dihydroisoindolone derivatives (Figure 7.5) is as follows:



Compounds containing the structure shown in Figure 7.5, where the structural elements R^1 and R^2 may be substituted as follows:

R^1, R^2 = H or any other substituent containing no carbon atoms or containing no more than 10 carbon atoms.

Psychoactive substances prohibited from the consumer market also include the isomers of substances belonging to the substance groups listed in the Annex, except for those specifically excluded, as well as the salts, ethers and esters of such substances and the salts of the aforementioned isomers, insofar as the existence of such compounds is possible.

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This Decree shall enter into force on [date] [month] 20xx.

Helsinki xx xx 20xx

Minister of ... First name Last name

Title First name Last name

Government Decree amending the Decree on psychoactive substances prohibited from the consumer market

Main content

An amendment is proposed to the Decree issued by the Government on designer drugs. Together with the amendments proposed in the Government proposal to Parliament concerning amendments to the Narcotics Act and section 3 of the Act on Electronic Prescriptions (Government Proposal HE xxxx/2026 vp), the proposal would reform the method by which new psychoactive substances are classified in Finland as psychoactive substances prohibited from the consumer market.

In the Government proposal, the definition in the Narcotics Act (373/2008) of a psychoactive substance prohibited from the consumer market is proposed to be amended so that the definition would identify and enable the classification of new psychoactive substances as NPS on the basis that, due to their chemical structure, they belong to a group of substances that must be considered hazardous to health based on the assessment of properties referred to in section 3a of the Act. The substance groups would be defined in more detail in the Decree on designer drugs.

The proposed Decree is intended to enter into force on 1 June 2027.

1. Background and powers to issue decrees

The proposed amendment to the classification of designer drugs, as set out in the government bill and the Psychoactive Substances Regulation, is linked to the provisions in Prime Minister Petteri Orpo’s Government Programme concerning the prevention of drug use among young people and the reduction of drug-related deaths among young people.

The authorisation to issue decrees concerning psychoactive substances prohibited from the consumer market is laid down in section 3(3) of the Narcotics Act currently in force. In the Government proposal, the provision containing the authorisation to issue decrees is proposed to be moved to section 3(2) of the Narcotics Act; however, the substantive content of the authorisation would remain unchanged. According to the authorisation, more detailed provisions on which substances, preparations and plants are considered narcotics referred to in paragraph 1, point 5, and which substances are considered psychoactive substances prohibited from the consumer market referred to in paragraph 1, point 9, shall be issued by Government decrees.

2. Preparatory work

The amendment to the decree has been prepared together with the Government proposal concerning amendments to the Narcotics Act and section 3 of the Act on Electronic Prescriptions. The preparation has been carried out as official work by the Ministry of Social Affairs and Health in cooperation with the Finnish Medicines Agency (Fimea), the Customs Laboratory, the National Bureau of Investigation Forensic Laboratory, and the laboratory of the Finnish Institute for Health and Welfare. The preparation process is described in more detail in Chapter 1 of the Government proposal.

The draft decree was circulated for comments from 4 June to 30 July 2026 together with the Government proposal. The preparation documents for the draft decree are available on the project page concerning the Government proposal (STM010:00/2026) at the following address: https://stm.fi/hanke?tunnus=STM010:00/2026.

3. Current situation and its assessment

The classification of designer drugs is based on a national procedure. Once a substance has been classified as a psychoactive substance prohibited from the consumer market, its manufacture, import into Finnish territory, storage, offering for sale and supply are prohibited pursuant to section 5(2) of the Narcotics Act. Violation of the prohibition is punishable under section 5a of Chapter 44 of the Criminal Code. Violation of the prohibition may also constitute the offence of smuggling under section 4 of Chapter 46 of the Criminal Code or handling unlawfully imported goods under section 6 of the same Chapter. Derogations from the prohibition may be granted for research and industrial purposes.

As long as a particular new substance has not yet been specifically prohibited under the Narcotics Act, either as a narcotic or as a designer drug, in the relevant Government Decrees, the substance is legal under the Narcotics Act. The designer drug markets operate dynamically and rapidly and seek to circumvent the prohibitions under the Narcotics Act: when one new psychoactive substance is prohibited, a new similar substance is introduced onto the market by making minor chemical modifications to the structure of the substance, which is not yet covered by the prohibition. The proliferation of designer drugs is a significant public health risk. The most important health risks are poisonings caused by these substances, which may result in severe health harm or death.

In 2024, 1,000 new psychoactive substances were monitored in the European Union Early Warning System, of which 46 substances were reported for the first time. The new substances have consisted mainly of synthetic and semi-synthetic cannabinoids, synthetic cathinones, and synthetic opioids such as nitazenes. Each year, the Customs Laboratory analyses approximately 10–20 entirely new intoxicating substances arriving in Finland that have not yet been prohibited by the Narcotics Act either as narcotics or as psychoactive substances prohibited from the consumer market. Laboratory analyses have shown that these new substances closely resemble existing prohibited substances in terms of their chemical structure, on the basis of which the new

substance can be presumed to be likely harmful to health. According to Finnish Customs, most of the new substances have been synthetic cannabinoids or cathinones. However, customs or the police may not seize and dispose of such a new substance if they acquire it before it has been added to the list of prohibited substances by government decree.

Several countries have sought to address the threats posed by the rapid development of new designer drugs by amending their legislation so that it becomes considerably more difficult to circumvent prohibitions relating to such substances. In practice, this has been achieved by defining, on the basis of chemical structure, groups of substances that are prohibited under the law. The prohibition of substances is based on the premise that substances belonging to the same chemical group produce similar effects. Various forms of group-based prohibitions are in use, for example, in Estonia, Norway, Denmark, Latvia, Lithuania, Poland, and Germany.

The government proposal proposes the introduction of a ban on specific groups of substances in Finland. According to the new section 3(1)(9) of the Narcotics, a 'prohibited psychoactive substance' means a substance used for intoxicating purposes which may be hazardous to health, which is neither a medicinal product nor a narcotic, and: a) for which a notification referred to in section 3(1)(5)(e) has been made, or which is a positional isomer of such a substance; or b) which, on the basis of its chemical structure, belongs to a group of substances which, on the basis of the assessment of properties referred to in section 3a, may be regarded as hazardous to health.

4. Objectives and key proposals

The aim of the group-based prohibition of psychoactive substances prohibited from the consumer market is to reduce the supply and demand of new psychoactive substances and thereby prevent the health, social and societal harms caused by such substances.

Section 1 of the Decree on designer drugs would be amended, and descriptions of substance groups would be added to the Annex of the Decree.

According to section 1 of the Decree, consumer-market-designer drugs include the substances listed in Annex 1 as well as substances that, based on their chemical structure, belong to one of the substance groups specified in Annex 2. A new Annex 2 would be added to the Decree, meaning that in addition to the list of individual substances, the Decree would include the following substance groups: phenethylamines, cathinones, fentanyls, nitazenes, orphines, tryptamines, and the core structure of synthetic cannabinoids, including as specific subgroups of synthetic cannabinoids: bicyclohexanols, hexahydrodibenzopyranols, gammacarbolinones and phenylethyl-dihydroisoindolones.

The proposed substance groups have been selected taking into account international developments and legislative solutions adopted in other countries. The selection has emphasised substance groups that have been identified as posing a significant risk to public health and that enable the rapid emergence of new psychoactive substances with modified chemical structures.

On this basis, it is proposed that control measures should particularly cover more traditional groups of psychoactive substances, such as phenethylamines, tryptamines and cathinones.

The above-mentioned groups include a wide range of chemical compounds, including structural modifications of substances that have already appeared on the market. For example, the cathinone group includes various chemically modified variants of α-pyrrolidinovalerophenone (α-PVP), which may arise through relatively small structural changes and which have not yet been detected on the market. The transition to substance-group-based prohibition aims to prevent situations where prohibiting individual substances quickly leads to the emergence of new substances that are technically legal but have equivalent effects.

In addition to the above-mentioned stimulant substance groups and tryptamine groups with hallucinogenic effects, the regulation is proposed to cover synthetic and semi-synthetic cannabinoids as well as synthetic opioids assessed as particularly dangerous. Synthetic cannabinoids form a chemically highly diverse group and occur on the market in numerous structural variations. Although the role of these substances in recreational drug use has not yet become established in Finland in the same way as in some other countries, they are characterised by acting as full agonists at cannabinoid receptors, which significantly increases the risk of severe and unpredictable intoxications. These substances have mainly been used by being mixed with plant material and smoked similarly to cannabis, or as liquids intended for electronic cigarettes. The marketed presentation of synthetic cannabinoid products as a “legal” intoxicant resembling cannabis, as well as their use in forms appealing to young people, such as e-cigarette liquids and edible products (“edibles”), may particularly attract young users.

For synthetic opioids, the starting point would continue to be that they should primarily be classified as narcotics due to their extremely high danger and dependence potential. However, in recent years, new opioid derivatives have appeared on the market at a rapid pace, and some have been offered to consumers before being individually classified. For example, during the current year, almost 40% of new substances notified to the EU Early Warning System have had opioid effects. Opioids act on opioid receptors in the central nervous system and suppress respiration, making new and increasingly potent opioids life-threatening even in small doses. For this reason, the regulation is proposed to be supplemented so that key opioid structures identified as dangerous would be prohibited at group level. These include in particular fentanyl derivatives, nitazene compounds and, as a newly emerging group, so-called orphine-structured opioids.

Substances belonging to the chemical groups listed in the Annex to the Decree would be prohibited as psychoactive substances prohibited from the consumer market. However, under the definition of a designer drug in the Narcotics Act, substances that fit within these substance groups but have been classified as narcotics would not be included in the definition; such substances would be controlled exclusively as narcotics. Medicinal substances would also not fall within the definition.

5. Principal impacts

The effects of the amendments proposed to the Decree have been assessed in the Government proposal together with the effects of the amendments proposed to the Narcotics Act.

6. Entry into force

It is proposed that the Decree enter into force on 1 June 2027. The Decree is intended to enter into force at the same time as the legislative proposals set out in the Government proposal.