

## *Supplementary Materials for*

# Legal responses to new psychoactive substances in Europe: countries inside the REITOX network, Norway, and Türkiye

**Valeria Aquilina, Francesco Paolo Busardò, Simona Pichini, Giulia Bambagiotti and Silvia Graziano**

*Corresponding author:*

Valeria Aquilina, Dipartimento di Scienze Biomediche e Sanità Pubblica, Università Politecnica delle Marche, Via Tronto 10/a, 60020 Torrette di Ancona, Ancona, Italy. E-mail: v.aquilina@pm.univpm.it.

*Published on*

Ann Ist Super Sanità 2026 Vol. 62, No. 2: 100-114  
DOI 10.4415/ANN\_26\_02\_02

*This PDF file includes:*

**Appendix A.** Country-specific summaries of the main legal instruments in force, the authorities responsible for scheduling decisions, and the modalities through which NPS (new psychoactive substances) are incorporated into national control lists.

## Supplementary Material

### APPENDIX A

The following country-specific summaries outline the main legal instruments in force, the authorities responsible for scheduling decisions, and the modalities through which NPS (new psychoactive substances) are incorporated into national control lists. This analysis provides the foundation for understanding both convergences and divergences in regulatory practice across REITOX (Réseau européen d'information sur les drogues et les toxicomanies) member countries.

#### Austria

Austria employs an individual scheduling system under the Narcotic Substances Act (SMG) of 1998 (*RIS – Suchtmittelgesetz – Bundesrecht Konsolidiert, Fassung Vom 15.06.2025*). Substances are permanently controlled via ministerial regulations, each with a scientifically determined “limit quantity” to distinguish offence severity. Since 2008, procedural simplifications allow new substances to be scheduled within about six months. A simplified risk assessment by an independent expert sets limit quantities within roughly three months, with faster processes possible in urgent cases. Temporary or expedited controls may be imposed within one to three months when serious public health risks arise, often following EU or UN recommendations. The full legislative process for new substances typically takes six to twelve months, including risk assessment, consultations, and drafting.

#### Belgium

The control of new psychoactive substances follows two distinct regulatory pathways. Temporary control measures can be introduced within approximately two to four months under the Royal Decree of 26 September 2017 (*6 septembre 2017. – [Arrêté Royal Réglementant les Substances Stupéfiantes et Psychotropes]*), which allows for rapid intervention based on information from seizures, inspections, and early warning systems at both national and European levels. Permanent scheduling is carried out through the standard legislative procedure established by the Law of 24 February 1921 (*24 février 1921. – [Loi Concernant le Trafic des Substances Vénéneuses, Soporifiques, Stupéfiantes, Psychotropes, Désinfectantes ou Antiseptiques et des Substances Pouvant Servir à la Fabrication Illicite de Substances Stupéfiantes et Psychotropes.]*) on narcotic and psychotropic substances. This process is initiated by the Minister of Health, approved by the Council of Ministers and the Council of State, signed by the King, and published in the Official Journal. It typically takes about one year to complete.

#### Bulgaria

In Bulgaria, the control of new psychoactive substances is governed by the Narcotic Substances and Precursors Control Act (1999, amended 2010), which establishes the National Drug Council and delineates institutional responsibilities. Substances are scheduled through regulatory decree under the Regulation on the Classification of Plants and Substances as Narcotics (Decree n. 293/2011) (*Lex.bg – Zakoni, Pravilnici, Konstitutsiya, Kodeksi, Darzhaven Vestnik, Pravilnici po Prilagane*), organized into three risk-based categories. Each scheduling decision follows a mandatory expert consultation involving relevant ministries and health authorities. The Criminal Code imposes sanctions proportionate to a substance's risk classification. While no formal procedure exists for emergency scheduling, urgent cases are managed within existing administrative frameworks. The legislation does not stipulate fixed timelines for classifying new substances.

#### Croatia

In Croatia, new psychoactive substances are scheduled individually under the Law on Combating Drug Abuse (*Zakon o Suzbijanju Zlouporabe Opojnih Droga*). The process is led by the Minister of Health and usually takes about two months. It begins when the Ministry of the Interior's Forensic Laboratory detects a substance and reports it to the Ministry of Health, which may convene a risk assessment commission. If the substance poses a serious public health risk and lacks medical value, it is added to the controlled list. More commonly, Croatia directly implements UN or EU scheduling decisions through a simplified administrative procedure, usually completed within two weeks to two months. National risk assessments are conducted only in specific cases and do not delay the legal process.

#### Cyprus

Cyprus controls new substances through individual listing under a standard procedure based on the 1977 Narcotic Drugs and Psychotropic Substances Law. The process is initiated by the Pharmaceutical Services and involves multiple governmental steps, taking approximately 6-12 months. Risk assessment is conducted beforehand by public experts, but it is not legally mandated or formally linked to the legal procedure.

#### Czech Republic

The Czech Republic applies a dual regulatory framework for the control of new psychoactive substances (NPS), allowing for both emergency and standard procedures. In urgent cases, substances may be rapidly scheduled within approximately three to six months by government decree, in accordance with Regulation n. 463/2013 Coll. (*463. Order of the Government Regarding the Lists of Dependency Producing Substances*) and amendments to Act n. 167/1998 Coll. This fast-track mechanism enables swift intervention without full parliamentary approval and is informed by data from seizures, inspections, and national or European early warning systems. Permanent scheduling follows the standard legislative procedure under Act n. 167/1998 Coll. on addictive substances. This process is initiated by the Ministry of Health, followed by inter-ministerial consultations, approval by both chambers of Parliament, presidential assent, and publication in the Collection of Laws. It typically takes about one year. Risk assessment is not legally required and is conducted informally on an ad hoc basis, often involving ministry experts and independent scientific advisors.

#### Denmark

New psychoactive substances are controlled under Consolidated Act n. 748/2008 (*Decree n. 1329/2008 [BEK Nr 1329 Af 18/12/2008] Amending the Decree on Narcotics n. 748, July 1st 2008, List B*). The National Board of Health initiates a fast process, usually 2 to 3 days, to add substances, with risk assessments done only if no prior EU or international decision exists. Updates are made through executive orders by the Ministry of Health, with timing varying based on urgency and complexity. This system allows for rapid response to emerging substances.

#### Estonia

The control system allows for the individual listing of substances through a standard procedure based on the Act on Narcotic Drugs and Psychotropic Substances and Precursors thereof (*Act on Narcotic Drugs and Psychotropic Substances and Precursors Thereof-Riigi Teataja*). The process typically begins with a proposal from the State Agency of Medicines, followed by the drafting of a regulation by the Ministry of Social Affairs, a public consultation phase, and final publication in the official gazette. The procedure generally takes at least one month, though timelines may vary depending on urgen-

cy. Control measures are permanent once adopted. Risk assessments are conducted primarily by public administration experts, with occasional input from independent scientists.

### Finland

Finland does not have a national risk assessment procedure for new psychoactive substances. Instead, control measures are implemented following decisions made at the United Nations or European Union level. The classification of controlled substances is outlined in the Government Decree on Substances, Preparations and Plants Considered as Narcotics (Decree 543/2008) (*Government Decree on Substances, Preparations and Plants Considered as Narcotics (543/2008)*).

### France

France uses an individual listing system based on the Code de la santé publique (*Code de La Santé Publique – Légifrance*). The procedure starts with a proposal from the National Narcotic and Psychotropic Substances Board and proceeds through the Director General of the French Agency for the Safety of Health Products, resulting in a Ministerial Decree. The process takes a minimum of 3 months. Risk assessment is legally required and conducted beforehand by specialized centers and a technical committee, under the agency's supervision. It typically lasts around 9 months but can be shortened to 3-4 months in urgent cases.

### Germany

Germany uses an individual listing system under the Narcotics Act (BtMG) (*Decree n. 1329/2008 [BEK Nr 1329 Af 18/12/2008] Amending the Decree on Narcotics n. 748, July 1st 2008, List B*), with both standard and emergency procedures for scheduling substances. The standard procedure involves consultation with an expert commission and government approval, typically taking at least 9 weeks. In urgent cases, an emergency procedure allows the Ministry of Health to act independently, imposing temporary control measures valid for up to one year unless confirmed through the standard process. Internationally controlled substances can be scheduled without further consultation. The expert commission, which meets 2-3 times per year, assesses risks and advises on control measures but is not required in emergency cases.

### Greece

Greece uses an individual listing system through a standard procedure based on Law 3459/2006. Law 3459/2006 – Government Gazette 103/25.5.2006 Code of Laws for Drugs (KNN). The process begins when the Greek Focal Point notifies the Drugs Committee about a new substance. After the Committee's opinion, the Ministries of Health and Justice issue a Joint Ministerial Order, which is published in the Official Gazette. The process takes 1-2 months, and no formal risk assessment procedure is reported.

### Hungary

Temporary control measures can be introduced through a rapid assessment procedure established in 2012 and formalized by Ministerial Decree 55/2014. This allows new substances to be temporarily scheduled for one year, with a possible extension of an additional year, based on information from seizures, expert assessments, and early warning systems at national and European levels. Permanent scheduling is decided following a full risk assessment, which must be completed within three years from the initial temporary control. Based on this assessment, the substance is either permanently scheduled under the psychoactive substances list or classified in schedule D of the Decree, depending on its assessed level of danger.

### Ireland

New psychoactive substances are controlled in Ireland through both individual listing and a generic system under the Misuse of Drugs Act 1977. The procedure involves drafting a memorandum, consulting relevant departments, and issuing a Declaration Order approved by the Cabinet and signed by the Prime Minister. The order is then submitted to Parliament and published. The process typically takes around 6 weeks but may vary depending on circumstances. The Misuse of Drugs Acts and associated regulations are updated periodically to include new substances. The Criminal Justice (Psychoactive Substances) Act 2010 allows for the immediate prohibition of substances with psychoactive effects, even if not yet listed under the Misuse of Drugs Acts. There is no legal requirement for risk assessment, though the EWET sub-committee may conduct informal assessments.

### Italy

Under Presidential Decree n. 309 of 9 October 1990 (*Decreto del Presidente della Repubblica, 9 Ottobre 1990, n. 309 – Normattiva*), Articles 2 and 13 assign the responsibility for updating the national schedules of narcotic and psychotropic substances to the Ministry of Health. This is carried out through a ministerial decree, following consultation with both the Italian National Institute of Health (Istituto Superiore di Sanità, ISS) and the Higher Health Council. The entire procedure generally takes approximately four months to complete.

### Latvia

Controlled substances are listed individually under the 2002 Law on the Procedures for the Coming into Force and Application of the Criminal Law which also sets quantity limits. The law mentions substances with similar pharmacological effects, but the analogue system has not been systematically applied. The relevant ministries (Health, Welfare, Interior) hold the authority to add new substances through a legislative process involving State Secretaries' meetings, inter-ministerial consultations, Cabinet approval, the Saeima, and the President. There is no formal risk assessment procedure, but ad hoc expert evaluations may be requested.

Since 2013, Latvia has a generic control system to rapidly ban groups of related substances. A temporary one-year ban on new NPS can be imposed while conducting a full risk assessment. Amendments to the Criminal Code in 2014 introduced penalties for violating temporary bans, including imprisonment, fines, and community service.

### Lithuania

Lithuania controls new psychoactive substances through an individual listing system under the 1998 Law on the Control of Narcotic and Psychotropic Substances (*VIII-602 Law on the Control of Narcotic Drugs and Psychotropic Substances*). Additions are made by Ministerial Decrees from the Minister of Health, based on proposals from the Drug Control or Police Departments. The State Medicines Control Agency performs a mandatory risk assessment during the process. Once signed, the decree is published and comes into effect within 1 to 7 days. The full procedure usually lasts 1 to 8 months, or 1 to 2 months if expedited by EU/UN recommendations. A temporary ban of up to one year can be applied to new substances pending full assessment, enabling swift responses.

### Luxembourg

Luxembourg controls new psychoactive substances through an individual listing system, using both a standard and a rapid procedure. The standard process is outlined in the Law of 19 February 1973 (*Stupéfiants, 2025*), while the Law of 12 July

1996 permits expedited scheduling. In practice, the rapid procedure is used almost exclusively. The process typically starts when the Ministry of Health, or occasionally the Ministry of Justice, is alerted by relevant authorities or the Inter-ministerial Group on Drugs (IGD). The Ministry's legal department prepares a draft law or decree, with optional consultations involving the Medical Advisory Board, the Chamber of Trade, and the IGD. The draft is reviewed by the Council of Ministers and, in urgent cases, may bypass the Council of State and proceed directly to Parliament. The entire procedure usually takes 1-2 months. Risk assessment is neither mandatory nor formalised; when carried out, it's coordinated by the IGD using information from various government bodies. The rapid procedure ensures swift control when a substance is considered potentially harmful.

### Malta

New psychoactive substances are controlled through two regulatory mechanisms. EU-level measures adopted under Directive (EU) 2017/2103 and Council Decision 2005/387/JHA are transposed into national law within six months. Alongside this, urgent national controls can be introduced by amending the schedules of the Dangerous Drugs Ordinance (cap. 101) (*Legizlazzjoni Malta*) via subsidiary legislation, allowing for faster intervention. Oversight is provided by the Advisory Board on Drugs and Addiction under the Ministry for Social Policy and Children's Rights. The main legal instruments are the Medical and Kindred Professions Ordinance (cap. 31) for psychotropic medicines, and the Dangerous Drugs Ordinance (cap. 101) for narcotics and NPS, complemented by the Drug Dependence (Treatment not Imprisonment) Act 2014.

### Netherlands

The Netherlands employs an individual scheduling system under Article 3a of the Opium Act (*Koninkrijksrelaties*), featuring both a standard and an emergency procedure. The standard route involves an Order in Council subject to a four-week parliamentary review and typically takes 3-6 months. The rapid procedure allows immediate control via a Ministerial Regulation effective within one week, valid up to one year unless replaced by the standard process. Risk assessments are categorized by urgency: fast (24 hours) for acute public health threats, moderate (10 days) for short-term risks, and preventive (several months) for long-term evaluation. These assessments are conducted by the independent Committee for the Risk Assessment of New Drugs, with final scheduling decisions made by government authorities based on their advice.

### Norway

The control of new psychoactive substances is governed by the 1978 Regulation on Narcotics (*Forskrift Om Narkotika (Narkotikaforskriften) – Lovdata*). The Norwegian Medicines Agency (NMA) is responsible for adding substances to the national list of controlled drugs. Substances can be scheduled through either a standard procedure – typically completed within three months – or a rapid procedure for urgent cases, which may bypass full consultation to allow immediate control.

The regulation also includes an analogue provision, enabling substances with similar chemical structure and psychoactive effects to already controlled drugs to be regulated without being explicitly listed.

The NMA bases its decisions on inputs from law enforcement, customs, media sources, and international obligations, particularly UN conventions. A risk assessment is conducted in all cases, whether the substance is listed individually, rapidly, or under the analogue system. Although the process is

not governed by a highly detailed legal framework, it follows a consistent administrative practice.

### Poland

Poland employs an individual scheduling system for controlling new substances through the standard legislative amendment process. The procedure begins with a draft prepared by the National Bureau for Drug Prevention under the Ministry of Health. Following public and administrative consultations, the draft is submitted to the Council of Ministers and subsequently to Parliament, where it is reviewed first by the Sejm and then the Senate. Upon parliamentary approval, the law is signed by the President and published in the National Journal of Laws, typically entering into force within 21 days. The standard procedure takes approximately nine months, while an expedited process can shorten this timeframe by at least three months. Although no formal risk assessment is legally required, such evaluations may be conducted on an ad hoc basis (Polish National Focal Point: [www.Euda.Europa.Eu](http://www.Euda.Europa.Eu)).

### Portugal

Portugal implements an individual scheduling system for controlling new substances through a standard legislative procedure. According to Decree Law 15/93 (*Decree Law n. 15/93 DR*) and Article 161(c) of the Constitution, the Parliament has the authority to add substances to the controlled lists. The initiation of this process can come from either the Institute against Drugs and Drug Addiction (IDT) or INFARMED (National Pharmaceutical and Medicines Institute), depending on whether the trigger originates from European Union or United Nations recommendations.

Although inter-ministerial consultations may occur, they are not mandatory. The legislative proposal is submitted to Parliament by the responsible Ministry, and once approved, it is signed by the President and published in the Official Journal. The regulation generally takes effect within one day of publication. The entire procedure can last from one to twelve months. While there is no formal legal obligation for risk assessment, such evaluations can be performed when deemed necessary.

### Romania

Romania operates an individual scheduling system under Article 1(a) of Law 143/2000 (*Lege (A) 143 26/07/2000 – Portal Legislativ*) on drug control. The process can be initiated by either the Ministry of Health or the Ministry of the Interior, though it is typically started by the latter via the National Anti-Drug Agency. Public consultations involve key bodies such as the Ministry of Health, National Medicines Agency, and College of Physicians, with additional ministries consulted as needed. The Ministry of Justice's opinion is mandatory. The Government adopts the final decision through an Emergency Ordinance, which takes immediate effect upon publication in the Official Journal and is later confirmed into law without delaying enforcement. The process usually lasts about four months. Risk assessments are carried out by public experts during consultations but do not affect the procedure's duration.

### Slovakia

New substances are regulated under Act n. 139/1998 on Narcotic Drugs and Psychotropic Substances. Only Parliament can add substances through law amendments. The process starts with a 10-day Ministry of Health review, followed by a 23-week online consultation with relevant ministries and agencies. After revisions, the draft is signed by the Minister, approved by the government, passed by Parliament, and signed by the President. The law is published and takes effect

within 15 days. The standard procedure usually takes around three months but can be expedited to about one month in urgent cases. A mandatory expert risk assessment guides the substance's classification and can affect the timeline.

### **Slovenia**

The control of new substances in Slovakia is managed through an individual listing system under the framework of the 1999 Illicit Drugs Act and the 2000 Decree on Drug Classification (*Uredba o Razvrstitvi Prepovedanih Drog (PISRS)*). The procedure is initiated by the Minister of Health, who submits a proposal for the regulation of a substance to the Government. Once approved, the amendment is officially published and typically takes effect eight days afterward. The entire process usually spans approximately two months. Although there is no legal requirement for a formal risk assessment, it may be conducted, if necessary, often through informal consultations among experts within the Ministry of Health.

### **Spain**

An adaptive mechanism allows for the rapid inclusion of emerging NPS through Royal Decrees, such as Royal Decree 1675/2012 (BOE-A-2012-15711 Real Decreto 1675/2012, de 14 de diciembre, por el que se regulan las recetas oficiales y los requisitos especiales de prescripción y dispensación de estupefacientes para uso humano y veterinario). This route enables swift scheduling based on scientific evidence, alerts from the European Union Early Warning System, and data from seizures or toxicological reports. The timeframe for implementation varies depending on urgency, but the process is designed to respond efficiently to public health threats. Permanent control is established through a standard procedure based on Royal Decree 1194/2011 (Real Decreto 1194/2011, de 19 de agosto, por el que se establece el procedimiento para que una sustancia sea considerada estupefaciente en el ámbito nacional, 2011). This process is initiated by the Ministry of Health, which issues a Ministerial Order after assessing legal and pharmacological criteria. The Order is published in the Official State Gazette (Boletín Oficial del Estado, BOE) and

typically enters into force within 5 to 15 days. There is no legal requirement for a formal risk assessment, but public administration experts contribute technical data, often aligned with European-level evaluations.

### **Sweden**

Sweden employs an individual listing system to control new psychoactive substances, using either a standard or accelerated procedure, depending on the level of urgency. Substances may be classified as narcotic drugs under the Narcotic Drugs Punishments Act or as "goods dangerous to health" under the Act on the Prohibition of Certain Goods Dangerous to Health (SFS 1999:42). The classification process is initiated by the Public Health Agency or the Medical Products Agency, which conducts a risk assessment and submits a recommendation to the Government. Under the standard procedure, the process typically takes five to six months and includes expert evaluation and inter-agency consultation. In urgent cases, a substance may be scheduled through a fast-track amendment to the ordinance, allowing for control within a significantly shorter time frame. Sweden automatically implements international scheduling decisions from the United Nations; however, European Union classifications require a separate national decision.

### **Türkiye**

Since 2011, Türkiye has applied a generic classification approach that allows for the rapid addition of new psychoactive substances (NPS) to the list of controlled drugs. The country's drug laws are primarily governed by the Turkish Penal Code (Law n. 5237) and the Law on Control of Narcotic Drugs (Law n. 2313), which together establish the framework for combating drug-related offences and protecting public health.

Since 2017, the High Council for the Fight Against Addiction has been responsible for coordinating interministerial efforts on drug and addiction policies. This governance structure supports the updating of legislation and enforcement practices to address emerging threats posed by new psychoactive substances effectively.