European Monitoring Centre
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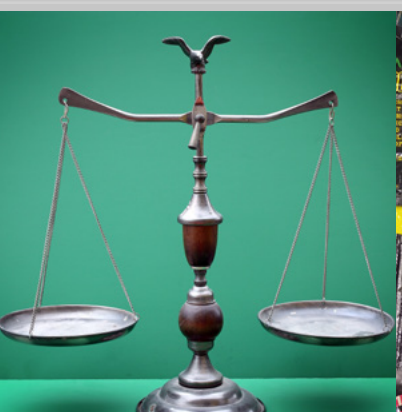
New psychoactive substances in Europe

Legislation and prosecution — current challenges and solutions





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Summary

With nearly 300 new psychoactive substances (NPS) reported to the EU's early warning system in the 2013-2015 period, the evolution of the European market for NPS has accelerated to a speed that the public authorities' established response — drug control laws — has struggled to match. Varying legal responses have been introduced in different countries, whether: by using existing laws that focused on consumer or health protection or medicinal products; by modifying drug laws to introduce group definitions of substances under control; or by developing innovative new legislation. Use of medicinal product laws — which are based on an EU directive — was challenged in the Court of Justice of the European Union (CJEU), which ruled in 2014 that substances are not medicinal products if they do not have beneficial effects on human health. As a result, Eurojust and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) were called upon to consider challenges for judicial cooperation and explore creative solutions to address the problems related to the prosecution of non-controlled NPS.

The first part of this joint report is aimed at policymakers. It lists four challenges in NPS control, and then describes the different legislative solutions used in many of the Member States. Focusing on the innovative new laws that are designed to address the issue, the report gives the reader a breakdown of their key elements: the criteria used to define NPS; the systems for listing them; and the penalties for non-compliance.

The second part of the report is aimed at legal practitioners. It outlines the NPS judgment of the CJEU and its practical effects on transnational prosecution of NPS cases, and describes the responses of some of the Member States most affected by the ruling.

Combining the top-level monitoring activities of the EMCDDA with the operational experience of Eurojust in transnational prosecutions, this joint report aims to provide succinct but useful information to the key actors in this area.

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Introduction

In recent years the evolution of the European market for new psychoactive substances (NPS) has accelerated to a speed that the public authorities' established response — drug control laws — has struggled to match. Internationally, United Nations conventions control drugs in order to protect public health, based on identified risks as assessed by the World Health Organization. Countries signing the conventions are required to establish criminal penalties to deter and punish unauthorised trade in controlled substances. As it is a general principle that criminal law must be certain, the substances subject to such penalties must be clearly specified, which means listing them individually, or in some cases in tightly defined groups according to their chemical structure. On this basis, when a new psychoactive substance is identified, its risk to health should be assessed and then it could be included in the list of those controlled under the criminal law. However, with about 560 NPS being monitored by the EMCDDA in 2015 — more than double the number of substances controlled under the United Nations international drug control conventions — these established approaches struggle to keep pace (EMCDDA and Europol, 2016).

Member States have responded in a variety of ways to this challenge to drug control systems. Several Member States had started to rely on the (EU-harmonised) definition of a medicinal product to rapidly control NPS. However, the judgment of the Court of Justice of the European Union (CJEU) of 10 July 2014 (known as the NPS judgment) on the prosecution of NPS found that they were excluded from the scope of medicinal products (CJEU, 2014). Consequently, the prosecution of NPS cases based on medicine laws has become more difficult. Additionally, on a transnational level, if the supply of a substance is not a criminal offence in the concerned countries (double criminality), judicial cooperation becomes very difficult.

Against this background, in September 2014, the outcome report of Eurojust's Strategic Meeting on Drug Trafficking (Eurojust, 2014), held in The Hague on 29-30 September, called for a focus on:

> *'Exploring "creative" solutions to address the problems related to the prosecution of "legal" NPS/pre-precursors, such as the use of administrative laws (e.g. withdrawing permits for shops), consumer legislation, and food safety legislation.'*

This Eurojust and European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) report therefore presents a joint analysis of the variety of approaches to NPS control adopted across the EU and the judicial cooperation challenges related to NPS.

Part I of the report provides a broad overview of the different approaches to NPS control adopted across the EU and will be of particular interest to those involved in developing legislation and policy in the area.

Part II, which will be of key interest to legal practitioners, focuses on the NPS judgment and the effect of this judgment on prosecutions and the current legal framework in Member States most likely affected by this ruling, in order to identify and share possible solutions to overcome potential obstacles created by the judgment.

PART I

Legal responses to new psychoactive substances around Europe

Until about 10 years ago, psychoactive substances not listed for control within the conventions tended to emerge on the illicit drug market. They were limited to a handful of substances each year, which were typically passed off as controlled drugs such as MDMA (methylenedioxymethamphetamine), amphetamine or heroin.

However, over the last decade, entrepreneurs have started selling substances not listed for control on the open market, reasoning that whatever is not expressly prohibited must be allowed for open sale. The combination of globalisation and innovation in communications technologies means that substances have been developed, produced and marketed internationally at great speed, and sold openly in specialised shops in towns and cities, as well as via the internet. From this, four distinct policy challenges have arisen.

1. Some substances are so new to the field that, at least initially, there is very limited evidence of public health risks — the risks being one of the primary justifications for punitive control measures.

2. The process of updating the law can take time; some countries require criminal laws to be agreed by parliament, which may take more than a year. However, the speed with which new drugs appear means that as soon as one new psychoactive substance is identified by the authorities and controlled a replacement is often already on the shelves.

3. Entrepreneurs have used the lists in the drug laws simply as exclusions from their potentially vast product range, yet very broad definitions that might control many substances can be so vague that a prosecutor has difficulty proving that distribution was a crime.

4. Adding substances to the list obliges law enforcement to test for those substances, but technical and financial resources for the new tests are not always increased accordingly.

Governments in Europe have responded in different ways to the challenges posed by the market in new psychoactive substances (NPS). Among these measures designed to reduce the availability and use of NPS, three broad, sometimes overlapping, groups of legal responses can be identified ([1]).

In the first group, existing laws that focused on consumer or health protection or medicines have been used. In the second group, drug laws have been modified, most commonly by introducing group definitions of substances under control. In the third group, innovative new laws have been developed to address these substances, in a few cases even defining a psychoactive substance by its effect rather than its chemical structure.

Consumer safety and medicines laws

A number of European Member States have successfully used consumer safety laws, which, as they are based on harmonised EU definitions, should already be operational (and available for use) in all Member States. In practice, different types of consumer safety laws have been enforced, some targeting psychoactive products in general (as happened in Poland in 2010, resulting in mass closures of the specialist sales outlets), others directed towards individual substances. In Italy, for example, regulations requiring that goods or food on sale be clearly and accurately labelled in relation to their expected use have been invoked to confiscate products containing synthetic cannabinoids that were not labelled in the national language. A similar approach was used in the United Kingdom to stop the sale of mephedrone labelled as bath salts and plant food. Having first used consumer safety laws, Poland subsequently modified its legal definition of a 'substitute drug' (a substance used instead of a drug or for the same purposes) and updated the health protection law so that it could be used when there was suspicion that a substitute drug posed a health threat.

As the harmonised EU definition of a medicinal product appeared not to require such a product to have beneficial effects on human health, there has been room for countries to use this legislation to respond to NPS. When a national medicines agency classifies a new psychoactive substance as a medicinal product, it can then demand a licence for any importation, marketing or distribution. In this way at least seven Member States ([2]) have used medicines laws to control supply of one or more new drugs at national level since 2007. However, in July 2014 the CJEU ruled that this was not a correct interpretation of the harmonised EU definition, and so this method is now limited; see Part II for a full discussion of this NPS judgment.

(1) The EMCDDA receives regular and ad hoc reports and information on drug control laws from its national legal correspondents and Reitox networks. These sources were used to compile the information presented here on the different approaches to NPS control across the EU.

(2) Germany, Spain, France, the Netherlands, Austria, Finland and the United Kingdom.

Modification of drug laws

Another response to the threat of new substances has been for Member States to manage them under existing drug legislation, through either modification or extension of these laws. In order to accelerate legal processes some countries have introduced temporary control regimes, allowing time for investigation of the need for permanent control. For example, temporary control procedures were enacted in Latvia and Slovakia in 2013, implemented respectively by the Centre for Disease Prevention and Control and the Minister for Health. In 2011 the United Kingdom enacted a procedure allowing temporary class drug orders, under which named substances could be quickly controlled under drug laws for up to 1 year. A similar system was enacted in Hungary in 2012, revising the risk assessment process and allowing the addition of non-therapeutic drugs to the list of controlled substances on the basis that they can pose as serious a threat to public health as substances already listed in the drug schedules. In the Czech Republic controlled drugs had been listed in a parliamentary law; their transfer to a new government decree in 2014 should reduce the time required to add new substances in future. At the end of 2014, Finland extended its Narcotics Act to cover also 'psychoactive substances banned from the consumer market', listed in a new government decree following the above risk assessment, with unauthorised supply punishable by up to a year in prison as an offence endangering health and safety.

Several Member States have chosen to extend the coverage of existing drug laws by listing tightly defined 'generic' groups of substances, rather than individual drugs as had been done previously. Germany is in the process of adopting a group definitions approach and in 2014 Belgium established the legal basis to implement it. However, the Netherlands rejected it in 2012 because of the complexity of targeting some substances while not restricting others that may have valid uses.

Innovative legal responses

A third group of responses are the innovative new laws that have been developed specifically to address these substances. Three main aspects of the innovative legal responses can be identified: the criteria used to define the substance or the motivation for use; the listing mechanisms that reduce the time needed to control new substances; and the levels of punishment established. These are summarised below and a country-by-country summary of the key elements of the law is provided in the Annex to this report. These country summaries include: the wording used to legally define a new psychoactive substance; whether any criteria of harmfulness is included; the mechanisms used to assess and control a new psychoactive substance; whether a control measure is temporary or permanent; the agency responsible for enforcement; and the penalties possible.

Criteria of psychoactivity, motive and harm

The definition of a substance as requiring control usually consists of two of the three following elements: a substance should be psychoactive; there should be a motive of abuse or intoxication; and there should be some possible harm or threat to health (see Table 1).

TABLE 1

Elements considered in innovative legal responses to new psychoactive substances

	Defining psychoactive effects	Motive (abuse or intoxication)	Harm or threat to health
Ireland	+		Dependence
Latvia (*)			
Hungary	+		+
Austria	+	+	+
Poland	+	+	+
Portugal	+		+
Romania	+		Dependence
Slovakia		+	+
Finland		+	+
Sweden (*)			
United Kingdom (2011)		+	+
United Kingdom (2016)	+	+	

NB:

(*) In the legal responses of Latvia and Sweden there is no mention of the three elements in their laws, as the decision on qualification as a new psychoactive substance is taken by a separate entity (see the country summaries in the Annex for more information).

'+' indicates that the element is included in the definition.

The Irish and Romanian laws set their definition of psychoactivity to a certain threshold, with the Irish requiring 'significant' mental disturbance or change (as in Portugal) and the Romanian requiring effects comparable to other substances controlled as drugs (as in Hungary and Portugal). Both also establish the capacity or likelihood of causing dependence as a criterion.

Listing of new psychoactive substances

In an analysis conducted in 2009, the EMCDDA considered the implications of the level of administrative decision required to list a substance as a drug, with a ministerial decree being approved much quicker than a change in a parliamentary law, but with a correspondingly lower level of scrutiny (Hughes and Blidaru, 2009). In the laws considered here ministerial approval is required in Hungary, Austria, Poland (for NPS), Portugal and Slovakia; approval of the government is required in Finland, and of the parliament in the United Kingdom (as the substance will be temporarily controlled as a drug); and in Latvia and Sweden the decision will be taken by government agencies in the health sector (Table 2). The trade-off between the speed and supervision of control is important. In Finland the law was only passed when the proposal was changed so that the decision to control would be taken by the government rather than the Ministry of Social Affairs and Health, as it was felt that such a fast decision should be accorded due oversight. Four Member States have a system in which no list of NPS is established, but any substance meeting the criteria will be considered to qualify (Ireland, Poland, Romania, United Kingdom) ([3]).

Penalties for offences

The offences defined in the innovative laws relate mainly to the supply of NPS (manufacture, import, sale or distribution), but some of the laws emphasise advertising the substances as a specific offence. The penalties for these offences range from simple confiscation and destruction of the product in Sweden, to a maximum of 14 years in prison in the United Kingdom. The high penalty available in the United Kingdom is due to the substance being temporarily considered as a controlled drug and thus attracting the same penalty as other drug supply offences. The most severe penalties available for the different legal measures are listed in Table 3. In Portugal and Slovakia, only a monetary fine is provided for, as the offence is considered administrative rather than criminal; this is also the case for manufacture or distribution in Poland. Non-criminal penalties may be chosen for reasons of proportionality against an uncertain harm, though such an approach may complicate judicial cooperation in transnational cases, when dual criminality may be required. Longer prison sentences are possible in Austria and Latvia in the case of serious health consequences, while Poland and Romania attach the most severe penalties to acts of advertising rather than distribution itself. Only two countries have established penalties for possession of NPS for personal use, with Hungary criminalising possession of preparations that contain more than 10 grams of a new psychoactive substance, and Latvia establishing possession for personal use as an administrative offence punishable by a warning or fine, with possible criminal liability if a further offence occurs within a year.

For a more detailed breakdown of the key parts of these laws, see Annex.

TABLE 2

Bodies deciding on inclusion of new psychoactive substances in list

Ministry	Government or higher	Other	No list
Hungary: Human Capacities	Finland: Government	Latvia: Centre for Disease Prevention and Control	Ireland
Austria: Health	United Kingdom (2011): Home Office, approved by parliament	Sweden: Medical Products Agency, National Institute of Public Health	Poland ('substances with similar effects')
Poland: Health (NPS)			Romania
Portugal: Health			United Kingdom (2016)
Slovakia: Health			

([3]) This approach was also attempted in the Portuguese autonomous region of Madeira in 2012, but it was struck down by the Portuguese constitutional court for vagueness.

TABLE 3

Most severe penalties in legislation for supply of a new psychoactive substance

	Imprisonment (years)		Fine in EUR (if no imprisonment)	Confiscation (if no fine)
	Normal	Aggravated		
Ireland	1	5		
Latvia	2	5		
Hungary	3 or 5	5 or 8		
Austria	2	10		
Poland	1 (advertising)	—	250 000 (manufacture or distribution)	
Portugal	—	—	45 000	
Romania	2 or 3	5		
Slovakia	—	—	332 000	
Finland	1	—		
Sweden	—	—	—	Yes
UK (2011)	0.5	14		
UK (2016)	1	7		

NB: These are not the only laws that may be applicable to an offence, and in practice penalties will vary with the particular charge chosen in the case.

PART II

The NPS judgment and its impact on prosecutions

Eurojust surveyed Member States/national desks on their NPS legislation and prosecution practices in 2014. The results indicated that Germany, Spain, France, the Netherlands and Finland were the Member States most likely to face challenges as a consequence of the NPS judgment (Eurojust, 2015). Therefore, Eurojust conducted a second survey after the NPS judgment in 2015, focused on these Member States, asking about the challenges they face and their specific responses to them.

To begin with, an overview of the NPS judgment is provided to demonstrate the complexity and extent of the matter at issue. This is followed by consideration of the impact of the judgment on those countries that had been using medicines legislation to control NPS and how they are addressing these issues.

The CJEU judgment on the definition of 'medicinal product'

The case

The NPS judgment arose from a German court's decision whereby the German authorities brought charges against the defendants for a breach of the German Medicines Act, because at the time the German Act on Narcotic Drugs did not cover synthetic cannabinoids. Both defendants were convicted of the sale of unsafe medicinal products. On appeal, the Federal Court was required to decide whether the sale of mixtures containing synthetic cannabinoids (used as a marijuana substitute) could induce criminal law proceedings on the grounds of unlawful sale of unsafe medicinal products. The Federal Court concluded that it would depend on whether synthetic cannabinoids could be regarded as medicinal products under Article 1(2)(b) of Directive 2001/83/EC relating to medicinal products for human use (European Parliament and Council, 2001). In other words, if the substance did not qualify as a medicinal product, no criminal sanctions could be triggered under the German Medicines Act.

Against this backdrop the Federal Court requested a preliminary ruling on the subject from the CJEU. The latter ruled that synthetic cannabinoids are not medicinal products since they do not have any beneficial effects — either immediately or in the long term — on human health. Rather, they are consumed solely to induce a state of intoxication and, as such, are detrimental to human health.

The reasoning of the judgment

The CJEU based its decision primarily on Article 1(2)(a) and (b) of Directive 2001/83/EC, according to which medicinal products are:

'(a) *Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or*

(b) *Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.'*

The main reasoning of the CJEU may be summarised as follows.

- The wording 'modifying physiological functions' does not expressly clarify whether the alteration must be positive or negative. However, the intent of the legislator clearly was — in the view of the CJEU — to include substances having a beneficial effect on human beings.
- The aforementioned intention becomes clearer since the terminology 'modifying' is employed in connection with the wording 'restoring [and] correcting physiological functions', which implies beneficial effects.
- The term 'modifying' must therefore be interpreted as meaning an alteration accompanied by beneficial effects to human health.

The effect of the NPS judgment — the challenge for prosecution

The decision of the CJEU might give way to legal gaps with the potential of undermining NPS prosecutions in Member States that resort to medicine law as the legal basis for sanctioning the possession, production and/or trade of NPS. This potential challenge was discussed during Eurojust's Strategic Meeting on Drug Trafficking (29 and 30 September 2014), where it was pointed out that prosecution was not possible in several Member States (Eurojust, 2014). Not being able to prosecute can pose serious difficulties to the fight against drug trafficking and related cross-border judicial cooperation, as evidenced in some of the cases in which Eurojust has been involved (see case illustrations on the next page).

Germany, Spain, France, the Netherlands and Finland concluded that the NPS judgment created a legal gap in their respective domestic systems since medicine laws may no longer be used to ground prosecutions in NPS cases. However, the extent and nature of the problem varied. More specifically, the following points were made.

- Spain noted that while the qualification of illicit substances is grounded on a closed list that does not include NPS, prosecution may still be possible under Article 359 of the Spanish Criminal Code, a provision that criminalises the production, manufacturing or marketing of substances that might have an adverse effect on human health. This notwithstanding, the penalties for this crime type are relatively low, since it was not conceived of as covering NPS offences.

- France explained that, to a significant extent, NPS fall outside the scope of the list of narcotics and psychotropic substances despite the 2012 legislative reform that introduced the generic approach to the regulation of NPS (Ministry of Social Affairs and Health, 2012); that is, criminalisation refers to a group or family of products rather than a specific substance. In addition, the NPS judgment hindered control actions, especially by customs.

- Finland identified that, after the NPS judgment, if there were evidence that a specific NPS could have beneficial effects on human health, prosecution could be based on medicine law. Accordingly, the Finnish Medicines Agency (MFA) issued a statement whereby it acknowledged that some NPS could have such an effect. The MFA statement is applicable to only a limited number of NPS. An additional challenge was that some domestic courts interpreted the NPS judgment in a manner that led to charges being dismissed despite evidence of beneficial effects on human health.

  Specifically, the Supreme Court was requested to give its decision on how the NPS judgment should be interpreted in Finland. There were at least three different possible interpretations: (i) that all charges based on the old medicine law will be dropped; (ii) that the prosecutor has to prove that some NPS also have medicinal effects in addition to the intoxicating effects, in which case charges could be brought and an accused could be convicted; (iii) that the NPS judgment has no direct effect on ongoing national proceedings, but it would only show the necessity of changing the conflicting national legislation accordingly. If there is a conflict between EU law and national legislation, it does not mean per se that national legislation would not be applicable (YLE, 2015).

  The Supreme Court decided that the EU law has priority over the national law. If the conflict cannot be avoided by interpreting the national law according to the EU law, the national law should not be applied. Substances that have no beneficial effect on human health and only alter the functions of the body cannot be considered as medicines. Therefore, such cases cannot be prosecuted using the medicine law. The substances have to be assessed on a case-by-case basis using the criteria of being beneficial or not beneficial for human health.

Case illustration I: Mephedrone (4-methylmethcathinone) and subproducts

In 2013, following several seizures of parcels coming from a Dutch company and directed to Italy, the Italian authorities uncovered trafficking of NPS. Among the intercepted substances ([1]) was mephedrone (4-methylmethcathinone), which is listed in Table I of the Italian Law against Psychotropic Substances (Decree 309/90) as being among the most dangerous drugs (e.g. heroin, cocaine).

At the beginning of 2014 the case was referred to Eurojust to facilitate the execution of letters rogatory to gather evidence in the case through judicial measures, including search and seizure.

Initially the Dutch authorities agreed on the execution of these measures, considering that mephedrone is listed in Table I of Dutch drug laws. A parallel investigation was also launched against the main suspect, who was expected to be arrested in the Netherlands at the beginning of 2015.

However, the technical analysis of the substances seized in Italy appeared to show that the substance sent from the Dutch company was not mephedrone but a derivative subproduct, thus falling outside the legal basis provided in the Netherlands to authorise judicial measures. More specifically the Dutch prosecutor explained that, following the decision of the CJEU in July 2014, the laws on medical products could no longer be used to authorise judicial measures against the trafficking and production of NPS. The prosecutor explored other legislative acts to be applied in this case, but concluded that none was viable, thus the judicial request from Italy could not be executed due to the lack of double criminality and the parallel investigation started in the Netherlands had to be closed.

This case illustrates the severe impact that the CJEU decision may have on cross-border cooperation on NPS in the EU and the difficulties presented by the technical analyses of the substances.

([1]) Other seized substances were: methylone, 4FA, 4-MEC, pentedrone, 6APB, MDPV, alpha-PVT, 3-MMC, MMC, isopentedrone, methyltryptamine.

Case illustration II: 3,4-Methylenedioxypyrovalerone (MDPV) and α-Pyrrolidinovalerophenone (alpha-PVP)

In 2014 trafficking of NPS, for example MDPV and alpha-PVP from China via Spain to Finland, was investigated by the Finnish and Spanish national authorities. The substances in question were classified in both Member States, but on different legal bases: as narcotics in Finland and harmful substances for health in Spain. Therefore, the trafficking of MDPV and alpha-PVP was a narcotics offence in Finland, but not in Spain, where the applicable regulation was Article 359 of the Spanish Criminal Code. One problem was that 1 kilogram of alpha-PVP was analysed in Spain and found to be pyrovalerone, which is a narcotics substance in both countries. However, it was analysed again in Finland and found to be alpha-PVP.

In June 2014 the case was referred to Eurojust, and the first coordination meeting was held in July 2014, just a day before the CJEU judgment was given, to agree on a way forward in judicial cooperation. It was decided that Spain would open a parallel investigation, allowing a joint investigation team (JIT) to be established at a later stage. Eurojust and Europol would support the JIT. After the CJEU judgment was given, it became evident that without a JIT it would be difficult to proceed in this case.

Another coordination meeting at Eurojust was needed to find solutions to overcome the legal obstacles. As some of the substances destined for Finland were confiscated in Spain, and therefore the possession of the substances took place in Spain, there was discussion of double criminality in court proceedings in Finland. In particular there was discussion of whether Finland has jurisdiction to investigate the charges of the possession that has happened in Spain, if there was no evidence that the substance was to be smuggled from Spain to Finland. Also, a court decision of the application of Article 359 of the Spanish Criminal Code was needed since in Spain the harmful substances are not listed.

This case illustrates how international judicial cooperation tools, for example JITs, Eurojust coordination meetings and the spontaneous exchange of information via Eurojust channels, can be crucial in overcoming judicial obstacles and legal gaps, such as those created by the NPS judgment. In addition, direct contacts in this case were essential, not only during the pre-trial investigation, but especially during court proceedings, when information on Spanish law and legal practice, for example, was needed urgently.

Responses to the NPS judgment

Germany, the Netherlands and Finland declared that legislative initiatives have been adopted or are being planned in response to the judgment, though their nature varies.

- In Germany, a draft law was adopted by the government in May 2016 and the federal parliament in September. It is expected to enter into force by the end of 2016. Under this draft law, NPS are defined as any substance or preparation belonging to the specified generic (group) definitions for synthetic cannabinoids and compounds derived from 2-phenylethylamine. However, substances already listed in the Narcotics Act or Medicines Act are excluded. The Ministry of Health can amend these definitions in future based on expert advice. The law prohibits producing, trading, importing, offering and possessing NPS, and empowers the police to confiscate and eventually destroy such substances using their general powers to protect life and health. Customs authorities may confiscate substances that they have good reason to believe are relevant NPS. For supply-related offences the law sets out various penalties, up to 10 years in prison for aggravated cases. Trade for recognised commercial, industrial or scientific uses is excluded.

- The Netherlands is planning legislative action with a view to reconciling legal certainty and clarity with the need to avoid being one step behind when the chemical composition of substances changes slightly. Accordingly, a number of studies have been planned, notably: (i) the Dutch Healthcare Inspectorate (IGZ) and the Netherlands Forensic Institute are to examine the possibility of determining groups of substances that can be listed in the Dutch Opium Act; (ii) lawyers are to assess the feasibility of resorting to special investigative methods and powers under the Commodities Act; (iii) additional risk assessment studies taking into account health risks in Europe rather than the Netherlands only; and (iv) opportunities for temporary listings.

- Finland replied that, following the NPS judgment, new legislation came into force on 20 December 2014. Thereby, NPS are covered under the Finnish Narcotics Act and listed in the government regulation on the consumer market of psychoactive substances. It is important to note that for a specific NPS to be forbidden in Finland it must be listed in the aforementioned regulation. In addition, the Finnish Criminal Code was amended so as to provide for a general provision of subsidiary application, which criminalises the manufacture, import, storage, holding for sale and disposal of a prohibited psychoactive substance (Chapter 44, Section 5a). This provision will apply only where the act is not more severely punished by another criminal provision. Therefore, the provision has a limited range of application since most NPS offences relate to the importing thereof, and consequently are prosecuted as smuggling, which provides for a higher criminal sanction (Chapter 46, Section 4). Finland stated that the legislative reform bestowed greater clarity upon the government regulation on the consumer market of psychoactive substances. Currently, all substances that are enumerated in the annexes to the medicine list can be considered medicine without hesitation. Furthermore, all NPS are in a single list.

Other countries reacted in other ways. Specifically, the following points were noted.

- Spanish prosecutors endeavour to resort to provisions of a more general nature (e.g. offences against public health) to avoid impunity.

- France established a specialised working group within MILDECA ([4]), in the context of the governmental working plan on the fight against drugs and abusive behaviour 2013-2017. The working group was composed of representatives of the Ministries of the Interior, Justice, Economy and Health, with the mandate of examining the legal instruments and/or tools that may be used to capture NPS that are potentially dangerous to human health. France noted that NPS are submitted for regular assessment and classified as narcotics. To illustrate this, on 19 May 2015 seven families of synthetic cannabinoids were defined as such as per the decree of the Minister for Health. Furthermore, prosecutors endeavour to balance the existing legal gap by indicting, to the extent possible, for criminal association (*association de malfaiteurs*). In addition, if the traffickers or distributors present NPS as having the same characteristics and producing the same effects as illicit drugs, it is possible to resort to the crime of incitement to the use or trafficking of drugs (*provocation à l'usage ou au trafic de produits stupéfiants*) under the Code of Public Health, Article L.3421-4. This latter crime is particularly relevant in respect of online commercialisation.

([4]) *Mission interministérielle de lutte contre les drogues et les conduites addictives* (Interministerial Mission for the Fight against Drugs and Addictive Behaviour).

Conclusion

This brief report provides an overview on how different European Member States are developing responses to a rapidly evolving market for NPS that challenges public health, drug policy and the cross-border prosecution of drug crimes. Member States are forced to act by the speed at which NPS appear and their open sale begins, balancing the precautionary principle of rapid control against the credibility and enforceability of the criminal law, which is not always backed by evidence of harm to public health. One response to regulating supply, the classification of NPS as medicines, has been curtailed by the CJEU in 2014. Yet Member States are also using legislation aimed at consumer safety or drug control, and even developing innovative legislation specifically to address NPS. On a transnational level, the prosecution of cases can depend on the supply of a substance being a criminal offence in both countries. Lessons may be learned from observing the evolution of legislation in different Member States and seeing how some responses may subsequently be adapted. Continuous monitoring of the situation is necessary to ensure an effective public health response tailored to the needs and context of the particular country.

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Learn more about the legal responses to new psychoactive substances:
http://www.emcdda.europa.eu/topics/pods/controlling-new-psychoactive-substances

Learn more about the work of the EU early warning system:
http://www.emcdda.europa.eu/ews

Learn more about judicial cooperation in drug trafficking cases (involving precursors and NPS):
http://www.eurojust.europa.eu/doclibrary/Eurojust-framework/Pages/casework.aspx

Annex

Innovative laws: key elements

This annex provides a country-by-country summary of the key elements of the innovative laws, which include: the definition of a new psychoactive substance, noting any criteria of psychoactivity, abuse or harmfulness; mechanisms used to assess and control a new psychoactive substance; whether a control measure is temporary or permanent; the agency responsible for enforcement; and the penalties possible. The countries concerned are: Ireland, Latvia, Hungary, Austria, Poland, Portugal, Romania (two laws), Slovakia, Finland, Sweden and the United Kingdom (two laws).

The following information is provided in summary form for the purpose of contrasting the general approach being used in different EU Member States. The reader should note that much of this information is based on translations of original legal texts that have not been certified.

Ireland

Law: Psychoactive Substances Act 2010

Definition: 'Psychoactive substance' means a substance, product, preparation, plant, fungus or natural organism that has, when consumed by a person, the capacity to: (a) produce stimulation or depression of the central nervous system of the person, resulting in hallucinations or a significant disturbance in, or significant change to, motor function, thinking, behaviour, perception, awareness or mood; or (b) cause a state of dependence, including physical or psychological addiction (Section 1).

Named exclusions: Medicinal products, animal remedies, intoxicating liquor, tobacco products, food, controlled drugs, other substances specified by the ministry (Section 2).

Duration of control: Permanent.

Listed by: No list

Offences and penalties: Selling, importing or exporting a psychoactive substance knowing or being reckless as to whether that substance is being acquired or supplied for human consumption (Section 3). Publishing or displaying an advert to sell substances or to promote the consumption of substances for psychoactive effects with information about how or where to obtain them (Section 5). On summary conviction, a fine not exceeding EUR 5 000 or imprisonment for a term not exceeding 12 months, or both; conviction on indictment, a fine or up to 5 years' imprisonment, or both (Section 20).

Enforcement: Law enforcement

Latvia

Law: Law on procedures for the legal trade of narcotic and psychotropic substances and medicinal products (amended 2013), Criminal Code (amended 2014) and Administrative Violations Code (amended 2014).

Definition: Substances that are not included in the lists of controlled drugs and for which the information has been obtained from the early warning system or from reports received from any of five named (forensic) authorities (Law on Procedures (amended 2013), Article 4, part 2).

Duration of control: Temporary, 1 year.

Listed by: Centre for Disease Prevention and Control.

Offences and penalties: Unauthorised manufacture, acquisition, possession, transportation and transfer with the purpose of the distribution of new psychoactive substances or products, up to 2 years' imprisonment, or up to 5 years if the offence has caused grave consequences (Criminal Code, Section 2481). Unauthorised acquisition, storage, transport or transfer of new psychoactive substances or products containing new psychoactive substances, without the intent to sell them, warning or fine of up to EUR 280. Crime if repeated within 1 year.

Enforcement: Law enforcement.

Hungary

Law: Government Decree 66/2012, Decree 55/2014, Act XCV on Medicinal Products 2005 (amended 2015) and Criminal Code (amended 2014).

Definition: A substance that appears on the market (or is formally notified to the EU early warning system) will undergo a formalised rapid assessment that must reach two conclusions. Firstly, the substance can affect the central nervous system, so it can change the mental state, behaviour or perception and therefore pose as serious a threat to public health as the substances listed in the 1971 UN convention; and secondly, the substance has no therapeutic use (amended Act XCV, Section 15B). May include compound groups.

Duration of control: Temporary, 1 year, renewable. Within 1 year of being placed on the 'Schedule of NPS', the drug must be risk-assessed, resulting in full drug control or transfer to the 'Schedule of substances removed from the Schedule of NPS'. Absence of relevant information can extend the risk-assessment procedure by 1 year (or until information becomes available with a risk assessment every 2 years). Compound groups will remain as long as any substance in the group fulfils the requirements (amended Act XCV 2005, Section 15C).

Listed by: Ministry of Human Capacities decree (Decree 55/2014 includes schedule of new psychoactive substances) and government decree (Decree 66/2012 includes a schedule of substances removed from the schedule of new psychoactive substances).

Offences and penalties: Import, export, transport, manufacture, up to 3 years' imprisonment (if aggravating circumstances, 1 to 5 years). Supplying, placing on the market, offering or dealing, 1 to 5 years' imprisonment (up to 1 year if a small amount, 2 to 8 years with aggravating circumstances). Possession for personal use of more than a small amount (preparation contains more than 10 grams of new psychoactive substances), up to 3 years (Criminal Code Sections 184, 184/A-D). Possession of a small amount is a misdemeanour that falls within the competence of the police.

Enforcement: Law enforcement.

Austria

Law: Psychoactive Substances Act 2012.

Definition: Substances not subject to the UN conventions of 1961 and 1971 are listed if they have the potential for 'psychoactive effects' (stimulating or depressing the central

nervous system, resulting in effects such as hallucinations or disturbances in motor functions, perception, behaviour, mood) (Section 1(2)), are likely to be used by certain sections of society and a threat to consumer health cannot be excluded (Section 3). May include compound groups.

Named exclusions: Substances placed on the market in accordance with drug, pharmacy or medicine import regulations, as well as substances subject to the Narcotic Drugs Act (Section 2).

Duration of control: Permanent.

Listed by: Ministry of Health regulation (Section 3).

Offences and penalties: Unauthorised production, import, export or supply is a crime if the supplier aims to benefit and intends that the product be used for its psychoactive effects. Punishable by up to 2 years' imprisonment, or 1 to 10 years if supply results in many serious injuries or a death (Section 4). Seizure of any amount of a substance is possible even when there is no suspicion of supply (Section 5). Customs may also confiscate imported/exported goods (Section 7).

Enforcement: Law enforcement.

Poland

Law: Act amending the Act on Counteracting Drug Addiction and the Act on State Sanitary Inspection, 2010; further amended 2015.

Definition: 'New psychoactive substance' (NPS) is defined in the 2015 amendment to the Act on Counteracting Drug Addiction (ACDA) as a substance of natural or synthetic origin in any physical state with effects on the central nervous system that is published in the regulation of the Minister for Health. 'Substitute drug' is redefined by the amending laws as a product containing at least one new psychoactive substance or another substance of similar effects on the central nervous system, which might be used instead of, or for the same purposes as, a controlled drug, whose manufacture and introduction to trade is not governed by separate laws (both definitions in ACDA Article 4). The law makes no specific reference to whether the substitute drug should first be considered as harmful; NPS are classed as such following risk assessment by a multidisciplinary team. Before the 2010 amendment, under the Act on State Sanitary Inspection (SSI), the inspectors were empowered to act against any 'failure to meet hygiene and health requirements'. They now have the specific right to withdraw from trade a 'substitute drug' for up to 18 months in order to assess its safety, if there is a justified suspicion that it might pose a threat to life or health. If the substance is judged to be potentially harmful, costs are borne by the supplier; if not, costs are paid by the state (amended Act on SSI, Article 27c). From 2015 the customs office may impound the consignment of imported product if there is reasonable suspicion that it might be a substitute drug or new psychoactive substance, for up to 18 months (amended ACDA, Article 44d).

Named exclusions: Substitute drugs are not governed by regulations on the general safety of products (amended ACDA, Article 4).

Duration of control: Substitute drugs, temporary, up to 18 months (amended Act on SSI, Article 27c). NPS, permanent.

Listed by: NPS listed by Ministry of Health from 2015; no list of substances 'of similar effects'.

Offences and penalties: The penalty for manufacturing NPS or substitute drugs, or introducing them into circulation, is a fine by the state sanitary inspector of between PLN 20 000 and 1 000 000 (about EUR 5 000-250 000) (amended ACDA, Article 52a). The penalty for advertising the psychoactive effects of a substance is up to 1 year's imprisonment (amended ACDA, Article 68).

Enforcement: State sanitary inspector; customs.

Portugal

Law: Decree-law 54/2013.

Definition: Psychoactive substances that pose a public health risk comparable to that posed by controlled drugs, from their effects on the central nervous system, with the ability to induce significant alterations in the level of motor function, as well as mental functions, namely reasoning, critical judgment and behaviour, often with states of delirium, hallucinations or extreme euphoria, with the ability to cause dependence and, in certain cases, produce long-term or permanent damage to the health of consumers (Article 2). Any substance that is suspected of posing a grave risk to human health (Article 7).

Named exclusions: Permission may be given for supply when intended for industrial or pharmaceutical purposes (Article 4).

Duration of control: Permanent.

Listed by: Ministry of Health (Article 3).

Offences and penalties: Production, import, export, advertising, possession and distribution of these substances or their derivatives (Article 4), closure of the premises involved (Article 6), as well as administrative fines of up to EUR 45 000. Users are referred to a commission for the dissuasion of drug addiction (Article 10).

Enforcement: Portuguese Economy and Food Safety Authority.

Romania

Law: Joint Ministerial Order establishing mixed teams to control new psychoactive substances (2011).

Definition: The order set up multidisciplinary teams of representatives from ministries (e.g. health, interior, agriculture) and health and consumer protection agencies, to target environments where 'harmful unregulated psychoactive substances' were being distributed or consumed. The group is tasked to enforce all existing laws in their respective fields to stem the distribution of these substances.

Duration of control: Permanent.

Listed by: No list.

Offences and penalties: All relevant existing offences and penalties.

Enforcement: Mixed teams.

Romania

Law: Law 194/2011 laying down rules to counter operations with products likely to generate psychoactive effects, other than provided by current laws.

Definition: Any product ('substitute', Article 2a) likely to provoke psychoactive effects similar to those caused by substances controlled under drug laws (Article 1). These effects are defined as stimulation or inhibition of the central nervous system provoking 'changes in functions and mental processes and behaviour', or 'causing dependency' (Article 2e). The law makes no specific reference to 'harmful' substances. It establishes a system of pre-authorisation via the National Health Veterinary and Food Safety Authority evaluation commission. It takes about 5 months for a decision to be made (Articles 3-12).

Duration of control: Permanent.

Listed by: No list.

Offences and penalties (from February 2014): Distribution without a permit (particularly if consumption was likely) — 3 months' to 2 years' imprisonment when the psychoactive effects are unknown but likely, and 6 months' to 3 years' imprisonment when the psychoactive effects are known (Article 16). Advertising the psychoactive effects — 1 month's to 1 year's imprisonment (Article 19). Distribution of products likely to have psychoactive effects without a permit and claiming that they are lawful — 1 to 5 years' imprisonment (Article 17). No penalty for the possession of these substances for the purpose of use. Failure to ban access to website within 12 hours — fine of EUR 12 000-23 000 (Article 15.1).

Enforcement: Ministry of Health, National Authority for Consumer Protection, National Health Veterinary and Food Safety Authority, Ministry of Internal Affairs, Ministry for Information Society.

Slovakia

Law: Law 40/2013, amending Act No 139/1998 Coll.; Ministry of Health Decree 298/2013.

Definition: Substances for which there is reasonable suspicion of the existence of persistent or sporadic and deliberate abuse, which is accompanied by harmful physical or mental reactions (Article 16a(1) of amended Act 139/1998).

Duration of control: Temporary. After 3 years a substance is either deleted from the list or is moved to the list of controlled substances following the normal legislative procedure (Article 16a).

Listed by: Ministry of Health (Article 16a(4)).

Offences and penalties: Administrative breach of consumer law — selling, promoting or putting the life or health of consumers in danger (Act No 128/2002 Coll. on the state control of internal market in consumer protection matters, and Act No 250/2007 Coll. on consumer protection), maximum fine EUR 332 000.

Enforcement: Slovak Trade Inspection Authority.

Finland

Law: Narcotics Act (amended 2014), Criminal Code (amended 2014), government decree 2014.

Definition: 'Psychoactive substances banned from the consumer market' means those substances used for intoxicating purposes that might be a danger to health and that have been decided to be made subject to control in accordance with the decision of the Council of the European Union or are positional isomers of such a substance and are neither medicines nor narcotic drugs (Section 3). Evaluation by the Finnish Medicines Agency together with the National Institute for Welfare and Health, police and customs (Section 3a).

Named exclusions: Medicines and narcotic drugs (Section 3). There are provisions for exemptions when the substances may also have industrial or research uses (Section 3b, Section 23b).

Duration of control: Permanent.

Listed by: Government decree.

Offences and penalties: Production, import, storage, keeping for sale or transfer is punishable by a fine or up to 1 year's imprisonment (Criminal Code, Chapter 44 (Offences endangering health and safety), Section 5a).

Enforcement: Law enforcement.

Sweden

Law: Act of destruction of certain substances of abuse hazardous to health (2011:111).

Definition: The substances covered by the act are goods or substances that: (1) the government has decided to list as narcotics or as goods injurious to health; (2) are included in an international convention to which Sweden is party but where listing has not entered into effect; or (3) can be presumed to be injurious to health (Article 2).

Duration of control: Permanent.

Listed by: Medical Products Agency and Swedish National Institute of Public Health.

Offences and penalties: The only 'penalty' is confiscation of property. All matters are handled according to the Administrative Act (1986:223) and are not viewed as criminal offences. Certain protocols must be used and the decision can be appealed to court.

Enforcement: Law enforcement.

United Kingdom

Law: Police Reform and Social Responsibility Act 2011, amending Misuse of Drugs Act 1971.

Definition: 'Temporary class drug orders' (TCDOs) may be drawn up where a substance is misused or likely to be misused, and where that misuse is having, or is capable of having, harmful effects (amended Misuse of Drugs Act (MDA), Section 2A(4). To proceed with such an order, the home secretary must consult the Advisory Council on the Misuse of Drugs

(ACMD). However, there is also an 'urgency procedure', to consult only the ACMD chair, if the likelihood of misuse poses an urgent or significant threat to public safety or health (amended MDA, Section 2B).

Duration of control: Temporary, 1 year (amended MDA, Section 2A(6)).

Listed by: Home Secretary with approval of Parliament (amended MDA, Section 2A).

Offences and penalties: TCDOs apply only to supply-related offences under the MDA (amended MDA, Section 2B), and carry the same penalties as drug supply offences, i.e. 14 years' imprisonment and an unlimited fine on indictment, or 6 months' imprisonment and a fine of GBP 5 000 (about EUR 6 900) on summary conviction. Simple possession of a temporary class drug is not an offence. However, law enforcement officers with suspicion may search an individual and seize and dispose of anything they believe is a temporary class drug (amended MDA, Section 23A) to prevent possible harm to the individual.

Enforcement: Law enforcement.

United Kingdom

Law: Psychoactive Substances Act 2016.

Definition: A psychoactive substance is any substance that is capable of producing a psychoactive effect in a person who consumes it. This means that, by stimulating or depressing the person's central nervous system, it affects the person's mental functioning or emotional state (Section 2).

Named exclusions: Controlled drugs, medicinal products, alcohol, nicotine and tobacco products, caffeine and food. Other substances may be added by the secretary of state (Section 3, Schedule 1).

Duration of control: Permanent.

Listed by: No list.

Offences and penalties: Producing, supplying or possessing with intent to supply, importing or exporting a psychoactive substance with intention, knowledge, or recklessness that the substance will be consumed for its psychoactive effects. Supply offences are aggravated by proximity to school, using a minor as a courier, or being carried out in a custodial institution. Maximum penalties are 7 years' imprisonment on indictment or 1 year on summary conviction. Possession of a psychoactive substance (not for supply) in a custodial institution is punishable by up to 2 years' imprisonment on indictment or 1 year on summary conviction (Sections 4-10).

Enforcement: Law enforcement.

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The EMCDDA's publications are a prime source of information for a wide range of audiences including: policymakers and their advisors; professionals and researchers working in the drugs field; and, more broadly, the media and the general public. Based in Lisbon, the EMCDDA is one of the decentralised agencies of the European Union.

About Eurojust

Eurojust (the European Union's judicial cooperation unit) supports and strengthens judicial coordination and cooperation between national authorities in the fight against serious cross-border crime affecting the European Union. Drug trafficking is one of the crime types most frequently referred to Eurojust for the purposes of facilitating the judicial coordination and cooperation of Member States. Eurojust supports the EU Member States by coordinating investigations and prosecutions, helping to resolve conflicts of jurisdiction and facilitating the drafting and execution of EU legal instruments, such as European Arrest Warrants, confiscation and freezing orders and joint investigation teams.

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