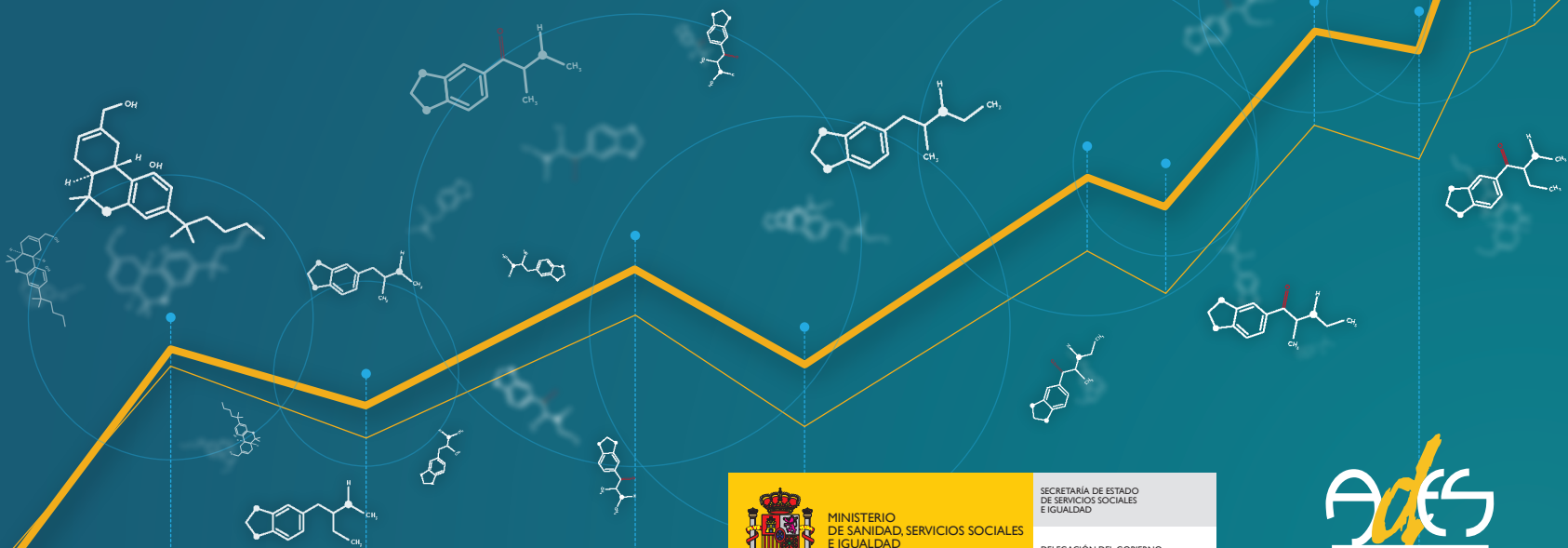


# NEW PSYCHOACTIVE SUBSTANCES.

## A CHALLENGE TO PUBLIC HEALTH

### The Spanish Early Warning System



MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD

SECRETARÍA DE ESTADO DE SERVICIOS SOCIALES E IGUALDAD

DELEGACIÓN DEL GOBIERNO PARA EL PLAN NACIONAL SOBRE DROGAS



Asociación de Técnicos para el Desarrollo de Programas Sociales

**NEW PSYCHOACTIVE  
SUBSTANCES.  
A CHALLENGE TO PUBLIC  
HEALTH**

**The Spanish Early Warning System**

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We would like to thank the Spanish Government Office for the National Drug Plan, and in particular, Mr. Francisco de Asís Babín (Government Delegate), Mr. José Oñorbe (Deputy Director), Ms. Rosario Sendino and Ms. Elena Álvarez, for their collaboration and support.

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# Presentation

The Association of Experts for the Development of Social Programs (Asociación de Técnicos para el Desarrollo de Programas Sociales, or ADES, Spanish acronym), in collaboration with the Spanish Government Office for the National Drug Plan (DGPNSD, Spanish acronym) has developed training and refresher programs on drug addiction over the years, through which the latest and most relevant topics in the field of drug addictions are reviewed

On 6 and 7 November 2013 a Seminar was held, entitled “Training on New Psychoactive Substances”, that provided a forum for debate on the subject with the aim of offering professionals in the sector an updated outlook on the situation in Europe and in Spain specifically, the characteristics of this type of drugs, the circumstances surrounding them, abuse, effects and consequences, as well as coming up with a cross-disciplinary approach and response in conjunction with the Public Administration (General State and Autonomous Regions) and the participation, which is also essential, of NGOs and civil society organization, and the required coordination with the international sphere, especially with the Member States of the European Union through the European Monitoring Centre for Drugs and Drug Addiction.

This manual is the product of the work done at this Seminar and aims to compile information and reflect upon a current, novel topic in the process of being developed, regarding which the last word has not yet been written and in which new technologies are playing a decisive role.

We would like to thank all the professionals who participated in the Seminar and quite particularly those that shared their experiences from their committed daily work:

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- The Spanish Government Office for the National Plan on Drugs, for their constant support, and particularly, the Government Delegate, Mr. Francisco de Asís Babín for his sensitivity regarding this topic.



# Forward

For several years now, the United Nations Office on Drugs and Crime and the European Monitoring Centre for Drugs and Drug Addiction have been sounding the alert on the trafficking and consumption of a series of drugs that are distinct from the traditional illegal ones, given that many of them have characteristics that place them beyond the international drug control conventions, they multiply at unprecedented rates and in relation to which the Internet is playing a key role.

The Spanish Government Office for the National Plan on Drugs, in response to this alert, has been working on the matter since 2010, when it added a specific module about new psychoactive substances or emerging drugs, as they are alternately called, in that year's edition of the National Survey on Drug Use by Secondary School Students ages 14-18 (ESTUDES, Spanish acronym), in order to discern the prevalence of use, perception of risk, availability and degree of knowledge that youths residing in Spain have on them. This module was also used in subsequent editions of the Survey in order to study the evolution of the subject and it has been included in the Household Survey on Alcohol and Drugs in Spain (EDADES, Spanish acronym) as well as completing the study with other age groups.

Likewise, in 2011 the DGPNSD Clinical Commission drew up a report on Emergent Drugs, its report no. 6, with the aim of assessing the status of the issue.

It is worth noting that these projects were forerunners in the study of these substances worldwide.



The 2013-2016 Spanish Action Plan on Drugs, which is part of the implementation of the 2009-2016 National Strategy on Drugs, includes activities aimed at fostering knowledge, providing information and the early warning system on the new psychoactive substances in this country.

In this context, the DGPNSD has an interest in supporting any initiative that enables us to progress in this matter and therefore we are pleased that ADES has decided to create this manual entitled “The New Psychoactive Substances. A Challenge to Public Health. The Spanish Early Warning System”, which will undoubtedly be a significant step toward raising awareness on the subject.

Finally, I would especially like to express my gratitude for the efforts of the actual creator of the document, Dr. Julia González Alonso, a colleague and friend working for many years in Public Health, former Director of the Spanish Observatory on Drugs and Drug Addiction, person responsible for the greatest boost that the “Early Warning System” has ever received, who is now happily retired and yet still continues resolutely collaborating in scientific outreach activities in the field of the epidemiology of addictions whenever asked.

I am certain that the information contained in this manual will be highly useful.

Mr. Francisco de Asís Babín.

Government Delegate for the National Plan on Drugs



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# Introduction

Psychoactive substances, beyond their mere pharmacological value for acting on the central nervous system, have a series of characteristics that define them as notably significant elements within the socio-cultural context in which they are developed.

As Antonio Escobedo<sup>1</sup> rightly states:

“The use of drugs depends on what they have to offer in chemical and biological terms and also on what they represent as pretexts for minorities and majorities. They are specific substances but the guidelines for administration depend highly on how they are thought of in each time and place. Specifically, the conditions of access to consumption are at least as decisive as what is consumed”.

If there is indeed a favorite drug in each time and place, the era of new technologies has substances with specific characteristics, not only from a chemical perspective, but also as regards the market setup, in relation to both the supply and the purchase settings.

It is within this context and from this perspective that we must approach the presence of the new psychoactive substances: drug addiction is an old and well-known phenomenon that has “merely” taken the shape of present times, adopting the peculiarities and circumstances thereof, which endow it with an exceptional pace never seen before in the spread, marketing and renewal thereof.

1:  
“Historia General de las Drogas”  
(Espasa Calpe, S.A. 2008, p. 1184)



# CHAPTER I. General Issues

## Definition

What are we talking about when we use the term “New Psychoactive Substances”? The United Nations describes them as:

“Any substance in pure form or in preparation that is not included in the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances but that may pose a threat to public health”.

The European Monitoring Centre, in turn, takes a similar view of the new psychoactive substances to the United Nations and identifies them in the following terms in Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances:

‘new psychoactive substance’ means a new narcotic drug or a new psychotropic drug in pure form or in a preparation;

‘new narcotic drug’ means a substance in pure form or in a preparation, that has not been scheduled under the 1961 United Nations Single Convention on Narcotic Drugs, and that may pose a threat to public health comparable to the substances listed in Schedule I, II or IV;



‘new psychotropic drug’ means a substance in pure form or in a preparation that has not been scheduled under the 1971 United Nations Convention on Psychotropic Substances, and that may pose a threat to public health comparable to the substances listed in Schedule I, II, III or IV;

But these definitions are not without their shortcomings.

Firstly, because the terms defined include groups of substances that are entirely different, using the same terminology to refer to drugs that are distinct in their chemical structure, effects, legal situation, etc., and this leads to misunderstanding.

These groups and terms include: “Emerging Drugs”, “Legal Highs”, “Research Chemicals”, “Designer Drugs”, “Club Drug” (recreational drugs) or “Pharming parties” (drugs used at certain meetings, parties or private gatherings) (Clinical Commission 2011; Farré 2011; Hill 2011; EMCDDA 2012; EMCDDA 2013; UNODC 2013; Prosser 2011).

Secondly, because the term “new psychoactive drugs” is not synonymous with newly synthesized drugs, given that, while some of them are indeed new, many others have been long known and/or used in medical or veterinary practices. What is truly different now is the new misuse of them, their distribution, spread and purchase over the Internet and social networks and, above all, the pace at which their chemical formulations are modified in order to keep the psychoactive properties while avoiding illegality.

## NEW PSYCHOACTIVE SUBSTANCES A CHALLENGE TO PUBLIC HEALTH



Fig 1. # 6 Report of the Commission  
Clinic DGPNSD

ESP: <http://www.pnsd.msc.es/Categoria2/publica/pdf/InformeDrogasEmergentes.pdf>

ENG: [http://www.pnsd.msc.es/Categoria2/publica/pdf/DROGAS\\_EMERGENTES\\_ingles\\_WEB.pdf](http://www.pnsd.msc.es/Categoria2/publica/pdf/DROGAS_EMERGENTES_ingles_WEB.pdf)

Taking these features into account, Fig. 1. of DGPNSD Clinical Commission Report No. 6, one of the first European studies about this phenomenon, replaces the term new drugs with **Emerging Drugs**, defining them as:

“Substances that appear on the drug market at a specific time and are a novelty in their availability, misuse or synthesis. They may be previously known or newly produced, they may or may not have appeared before, and they are not included in the lists of psychotropic substances or narcotics and therefore they are not illegal (Fig. 1).

Consequently, having made these explanations, in this document the terms ‘new psychoactive substances’ and ‘emerging drugs’ shall be used synonymously and therefore shall be taken to have the same meaning.

## Characteristics of the new psychoactive substances

The European Monitoring Centre on Drugs and Drug Addiction, first, and later, the United Nations (EMCDDA 2011, EMCDDA 2013, UNODC 2013) have described six groups or families of emerging substances:

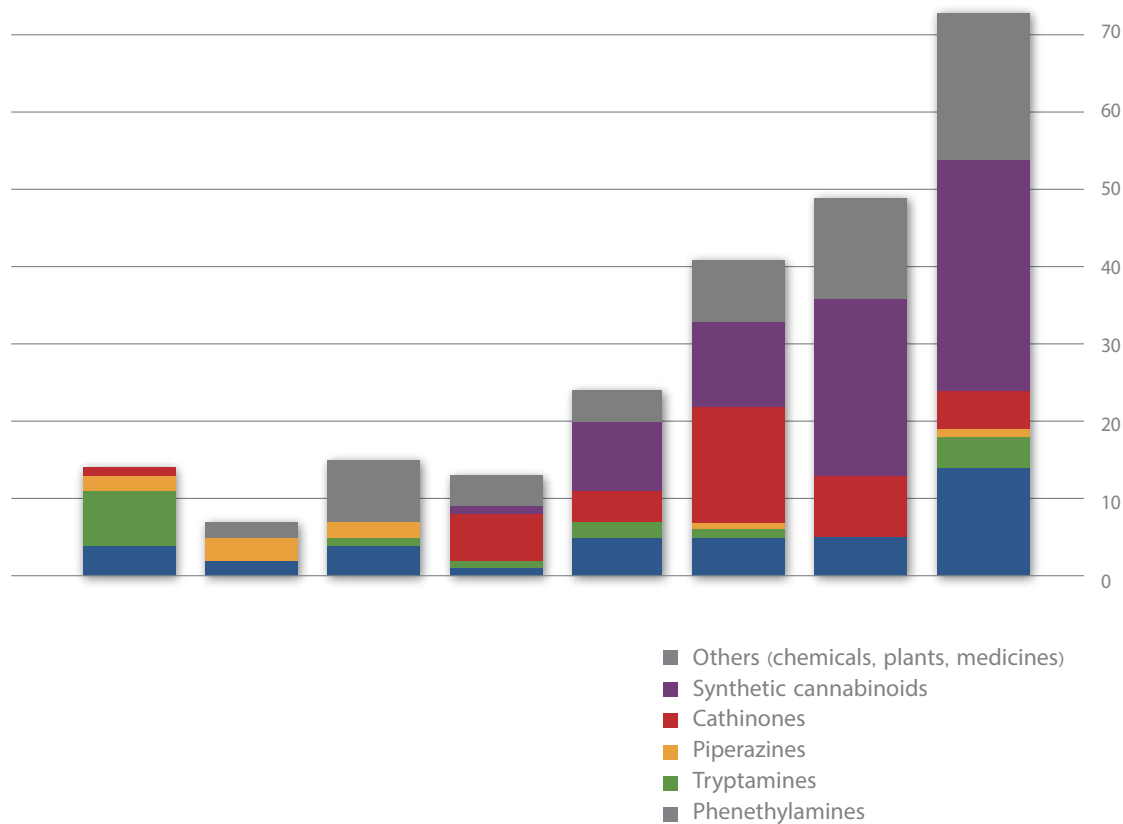
Phenethylamines, tryptamines, piperazines, cathinones, synthetic cannabinoids and a diverse group that covers other types of drugs known as other substances.

The mechanism of action and effects of each one depend on their chemical structure and their intervention in specific areas of the CNS. Phenethylamines, piperazines and cathinones release catecholamines and inhibit the reuptake thereof. Synthetic cannabinoids are CB1 cannabinoid receptor agonists. Tryptamines are agonists or partial agonists of serotonin receptors 5HT2. Certain derivatives of phencyclidine and ketamine are NMDA glutamate receptor antagonists (Farré 2013).

The effects vary depending on the substance and its interaction points, but they are mainly psychostimulant, entactogenic, hallucinogenic and sedative in nature.

The European Monitoring Centre reports on the types of substances that are most commonly detected within EU territory and the relevance of each one overall.

## Trends in the types of drugs detected by the EWS



Source: EWS - EMCDDA | [www.emcdda.europa.eu](http://www.emcdda.europa.eu)

## Classification

### Phenethylamines and amphetamine derivatives

Psychostimulant effects	Amphetamines	Amphetamine (dl-amphetamine)* Dextroamphetamine (d-amphetamine)* Methamphetamine (dl-methamphetamine) Dextromethamphetamine (d-amphetamine) Levomethamphetamine (l-methamphetamine)* Methylphenidate* Ephedrine (Ephedra)* Appetite suppressants (phentermine and other derivatives)*
	Cathinones	Cathinone (khat) Methacathinone (ephedrone) Methylmethcathinone (Mephedrone) Ethylone (see entactogens) Methylone (see entactogens) Butylone (see entactogens)
Entactogenic effects Methylenedioxy-amphetamine		3,4-methylenedioxymethamphetamine (MDMA, “ecstasy”, “Adam”) 3,4-methylenedioxyamphetamine (MDA, “love drug”), 3,4-methylenedioxyethylamphetamine (MDEA or MDE, “Eve”) N-methyl-1-(3,4-methylenedioxyphenyl)-2-butanamine (MBDB) 3,4-methylenedioxymethcathinone (methylone, “explosion”) 3,4-methylenedioxyethylcathinone (ethylone) $\beta$ -keto-N-methylbenzodioxolylpropylamine (bk-MBDB, butylone)
Hallucinogenic effects Methoxyamphetamines		4-Bromo-2,5-dimethoxyamphetamine (DOB) 4-methyl-2,5-dimethoxyamphetamine (DOM, serenity-tranquility-peace or STP)

<p>Hallucinogenic effects Methoxy amphetamines</p>	<p>2,4,5-trimethoxyamphetamine (TMA-2) paramethoxyamphetamine (PMA) 4-bromo-2,5-dimethoxyphenylamphetamine (2CB-MFT) 2,5-dimethoxy-4-bromo-phenethylamine (2-CB, nexus) 2,5-dimethoxy-4-iodo-phenethylamine (2-C-I) 2,5-dimethoxy-4-ethylthiophenethylamine (2C-T-2) 2,5-dimethoxy-4- (n)-propylthiophenethylamine (2C-T-7) 8-bromo-2,3,6,7-benzo-dihydro-difuran-ethylamine(2-CB-Fly) Bromo-benzodifuranyl-isopropylamine (bromo-dragon-fly)</p>
<p>Others</p>	<p>Pyrovalerone Naphyrone (naphthylpyrovalerone, NRG-1) Alpha-pyrrolidinovalerophenone ( -PVP) Methylenedioxyvalerone (MDPV)</p>

## Tryptamines

N,N-dimethyltryptamine (DMT)  
5-methoxy-dimethyltryptamine (5-MeO-DMT)  
Bufotenin (cebilcin, 5-hydroxy-dimethyltryptamine, 5-HO-DMT or 5-OH-DMT) 4-hydroxy-N-methyl-N-isopropyltryptamine (4-HO-MiPT)  
4-acetoxy-N,N-diisopropyltryptamine (4-acetoxy-DiPT, ipracetin)  
O-Acetylpsilocin (4-acetoxy-N,N-dimethyltryptamine, 4-AcO-DMT, 4-acetoxy-DMT) 4-hydroxy-N-methyl-N-ethyltryptamine (4-HO-MET)  
5-methoxy-alpha-methyltryptamine (5-MeO-AMT)  
5-methoxy-diisopropyltryptamine (5-MeO-DiPT, Foxy, Foxy Methoxy) 5-methoxy-methylisopropyltryptamine (5-MeO-MiPT)  
α-Methyltryptamine (AMT)

N,N-diisopropyltryptamine (DiPT)  
 N,N-Dipropyltryptamine (DPT)  
 4-Acetoxy-N,N-diethyltryptamine (4-Acetoxy-DET, ethacetin, ethylacybin, 4-AcO-DET)

## 1-Aryl-piperazine derivatives

Benzylpiperazines	1-benzylpiperazine (BZP) 1-(3,4-methylenedioxybenzyl) piperazine (MDBP)
Phenylpiperazines	1-(3-chlorophenyl)piperazine (mCPP) 1-(3-(trifluoromethylphenyl)piperazine (TFMPP) 1-(4-methoxyphenyl)piperazine (MeOPP)

## Pyrrolidinophenone derivatives

$\alpha$ -pyrrolidinopropiophenone (PPP)  
 4'-Methoxy- $\alpha$ -pyrrolidinopropiophenone (MOPPP)  
 3',4'-Methylenedioxy- $\alpha$ -pyrrolidinopropiophenone (MDPPP)  
 4'-Methyl- $\alpha$ -pyrrolidinopropiophenone (MPPPP)  
 4'-methyl- $\alpha$ -pyrrolidinohexanophenone (MPHP)  
 4-methyl- $\alpha$ -pyrrolidinobutiophenone (MPBP)  
 $\alpha$ -pyrrolidinovalerophenone (PVP)

## Opioid derivatives

Fentanyl analogs	$\alpha$ -methylfentanyl (China White) parafluorofentanyl 3-methylfentanyl
------------------	--

Pethidine analogs	MPPP (contaminated with an impurity called MPTP which can cause permanent symptoms of Parkinson's disease)
Others	Dextromethorphan*

### Arylcyclohexylamines

Phencyclidine derivatives (PCP)	Ketamine*
	3-methoxy-phencyclidine (3-MeO-PCP)
	4-methoxy-phencyclidine (4-MeO-PCP)
	Eticyclidine (PCE, CI-400, N-ethyl-1-phenylcyclohexylamine)
	2-(3-methoxyphenyl)-2-(ethylamino)cyclohexanone (Methoxetamine)
	Rolicyclidine (PCPy; 1-(1-phenylcyclohexyl)pyrrolidine)
	Tenocyclidine (TCP; 1-(1-(2-Thienyl)cyclohexyl)piperidine)
2-(3-methoxyphenyl)-2-(ethylamino)cyclohexane (3-MeO-PCE)	

### Methaqualone derivatives

Methylmethaqualone Mebroqualone Synthetic cannabinoid derivatives
---

### Derivados cannabinoides sintéticos (spice drugs)

AM-694	HU-210	JWH-250
CP 47,497	JWH-018	HC-O-acetate
Cannabicyclohexanol	JWH-073	
CP 55,940	JWH-200	



## GHB and derivatives

Gamma-hydroxybutyrate  
(GHB, liquid ecstasy, gamma-hydroxybutyric acid, hydroxybutyrate, sodium oxybate)\* Gamma-  
butyrolactone (GBL)  
1,4-butanediol (BD)  
Gamma-hydroxyvaleric acid

Source: DGPNSD-MSSSI Clinical Commission. Report No. 6. Emerging Drugs.

\* These substances are sold in some countries although they are subject to diverse types of regulatory restrictions.

The characteristics of each group, their composition, mechanisms of action, formats and consumption methods, routes of administration, pharmacological effects, clinical symptoms, intoxication and therapeutic intervention are contained in DGPNSD Clinical Commission Report No. 6, which we refer to for this purpose.

## Patterns of consumption

Based on the patterns of consumption identified up to now, the new psychoactive drugs can be considered companion drugs, used by people who have already taken other illegal drugs.

There are three patterns followed by consumers of emerging drugs:

1. **Recreational use:** primarily by the youngest age groups, groups of which take them in certain circumstances (special concerts, botellón [outdoor binge

drinking in large groups], dance clubs,...) and associated with the consumption of other drugs (polydrug use), including the almost omnipresent intensive alcohol consumption, and most of the time without knowing which new substances they are taking, much less their effects and the interactions between them. They often lead to acute intoxication and occasionally result in death.

### Polydrug use

According to data from the latest Spanish report to the Reitox network, the prevalence of use of other psychoactive substances among emerging drug users is high. The data attained from the 2012 ESTUDES and 2011 EDADES surveys indicate that it is uncommon to find emerging drug users that take only this type of substances. Along the same lines, confirming these data, the results of the 2012 ESTUDES survey show that 98.4% of all the students that have taken a new psychoactive substance at some time in their lives have also consumed legal substances (alcohol and/or cigarettes) in the last 12 months, and 98% in the last 30 days.

Alcohol is present habitually and in an intensive manner (as binge drinking or alcohol poisoning), and the difference in the prevalence of consumption between users of new drugs and non-users is significant. 81% of all emerging drug users had engaged in binge drinking and 70% had gotten drunk in the last month, whereas among non-users this figure was halved.

In this regard, the EMCDDA notes that is also common among this population group to consume some kind of illegal substance (cannabis, cocaine, ecstasy, amphetamines, hallucinogens, heroin or GHB). Thus, 86% of students that had taken drugs had also consumed some other illegal drug in the last year, while this figure dropped to 24.5% among students that had never taken any emerging drugs.

These differences in the prevalence of polydrug use among users and non-users of emerging drugs are valid for all the substances studied: 68% compared to 14% had smoked cannabis at some time in their lives, 23% had taken cocaine in the last month compared to 0.5%, 21% had taken ecstasy in the last month compared to 0.4% and 20.6% had taken hallucinogens compared to 0.2%.

Polydrug use, a pattern that is currently on the rise, complicates the scenario at every stage, hindering management of the problem (obstructing diagnosis, delaying it most of the time, and hindering treatment and overshadowing the prognosis). Polydrug use associated with new psychoactive substances aggravates the situation extraordinarily due to the lack of knowledge about them and their interactions with other drugs.

2. **Experimental use:** in older young people (25-35 years old on average) that are used to taking other kinds of substances, customary and experienced psychonauts that use them when seeking new experiences. Although acute intoxication is also frequent among this group, the conscious search for and consumption of the substances taken leads to a willingness to tell the health professionals that attend

the user about the experience, thus facilitating treatment, provided that the user is not unconscious, since this group usually consumes alone.

3. **Substitute drug use:** in regular consumers of psychoactive substances taken intravenously who, for numerous reasons, mostly related to a fluctuating market for the substance normally taken (decline in the amount of drugs traded and/or a rise in prices thereof), seek their effects in other available drugs. These people are usually alone when taking the drugs. The lack of awareness that generally exists on how to handle substitute drugs (proper dose, route of administration, purity, onset time, effects) leads to highly severe intoxication symptoms.

Moreover, the situation is further aggravated by intravenous use, which is the preferred route of administration. Numerous outbreaks occurring in Eastern European countries have reported that the frequency of injection and reuse of syringes among these consumers is rising, leading to an increase in the rates of Hepatitis C and HIV among this group.



# CHAPTER II.

## A Challenge to Public Health

In general, consumption of psychoactive substances has always been a challenge to public health, given that the consequences affect not only the individual who takes them but also their entire setting and society as a whole.

In particular, the use of emerging drugs represents a significant public health problem because of several of the features characterizing them and primarily because:

- They are not illegal.
- They are easily synthesized.
- They are not safe for use.
- They are spread over new technology.
- There is a single market in the EU.

Indeed,

“the progress that has enabled organic chemical substances to be synthesized economically and the possibilities for information exchange and marketing offered by the Internet have led the rate of availability of new psychoactive substances to increase at an unprecedented pace which, in conjunction with the possibility of rapidly

spreading throughout a domestic or international territory and the speed at which they appear or are distributed, represent a challenge to the control of the new psychoactive substances”<sup>2</sup>.

## They are not illegal

The legal standing (legal/illegal) of a psychoactive substance is crucial to managing it. In order for a drug to be considered illegal for trade, it must be included in the Conventions drawn up by the UN for this purpose, belonging to families of substances with specific chemical formulations.

Most emerging psychoactive substances do not meet this requirement, as is clearly explained in the definition made by this organization. For this reason, the institutions that are responsible for control and security cannot act in relation to them as they can in relation to illegal drugs.

However, this should by no means lead us to conclude that the drugs not listed in the UN Conventions “are legal” in the case of new psychoactive substances.

According to the Diccionario Ideológico de la Lengua Española [Ideological Dictionary of the Spanish Language], the new substances are not legal because they are not regulated by law or pursuant to the law, yet they are not illegal either, given that they do not violate the law since they are not included in the relevant Conventions.

2:  
Drugs in the spotlight Note by the European  
Monitoring Centre for Drugs and Drug Addiction.  
2011 edition

Therefore, if they are neither in abidance with the law nor unlawful, they are in a situation of denial that could perhaps be defined by the term “alegality” or extralegality.

Thus, it would be more appropriate to refer to new psychoactive drugs as being “not illegal” or “extralegal”.

The precise use of language is always important, not merely in the subject at hand, but also, its repercussions and relevance can sometimes be decisive, and this is particularly the case in the field of drug addiction. Speaking in an inaccurate manner can lead to erroneous interpretations or approaches, and this is generally fostered by the illegal market itself to support its perverse interests. This is especially serious in light of the impact that this can have on younger population groups, which are targeted especially by these messages as potential consumers.

Furthermore, extralegality means that these substances are freely and more cheaply traded than illegal ones, thus making them more affordable, and this is an essential factor for population groups with less purchasing power, the youngest members of society once again being the most vulnerable.

## They are easily synthesized

Anyone, whether professional or self-taught chemists, can prepare this kind of substances. The data provided by the Spanish National Law Enforcement Agencies



and the Regional Police Forces, as well as international entities (Europol and INCB), report that staff lacking in qualifications but properly skilled can synthesize psychoactive substances using incredibly basic instruments.

Information has been published on how to create a laboratory of this kind and there is also detailed information on the Internet (Fig. 2 and 3). The resources needed are minimal, and a laboratory can be set up in a simple bathroom or kitchen (Fig. 4); so little is needed that mobile laboratories have even been confiscated, some inside cars, mobile homes or buses Fig. 5.



Fig. 5  
Source: Servimedia 5 February 2010.

“For the first time in Spain, the National Police Forces have confiscated a “mobile laboratory” of synthetic drugs where 21,000 pills ready for distribution were found. In this operation, nine people were arrested in Valencia and a large enough quantity of substances was seized to have produced another 40,000. The hydraulic press used

to make the tablets never remained more than one month at the same address as a security measure”.

Fig. 4. CLANDESTINE LABORATORY

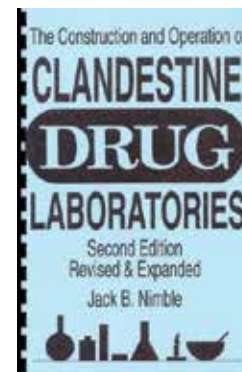


Fig. 2



Fig. 3

**NEW PSYCHOACTIVE SUBSTANCES  
A CHALLENGE TO PUBLIC HEALTH**



International organization exposed. The laboratory was used to prepare hydrochloride liquid, which they intended to export to Europe in asparagus cans.

Source: RPP | RPP / Jesús Verde Huachipa (Peru) December 2011.

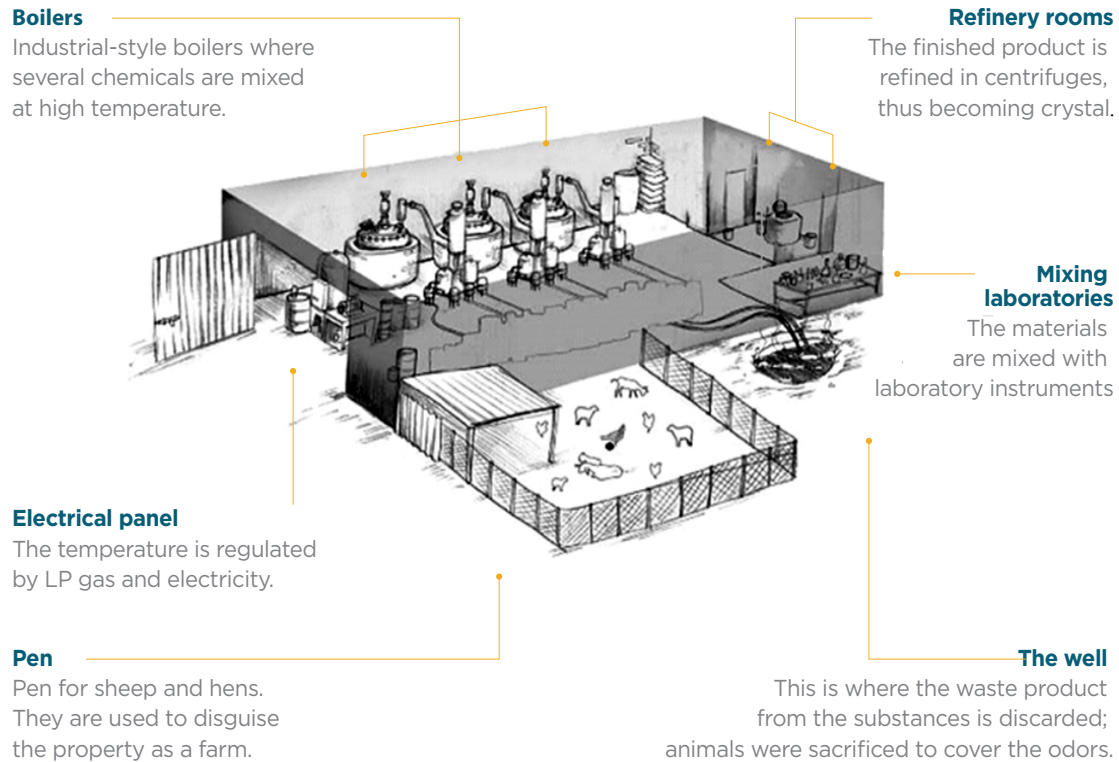
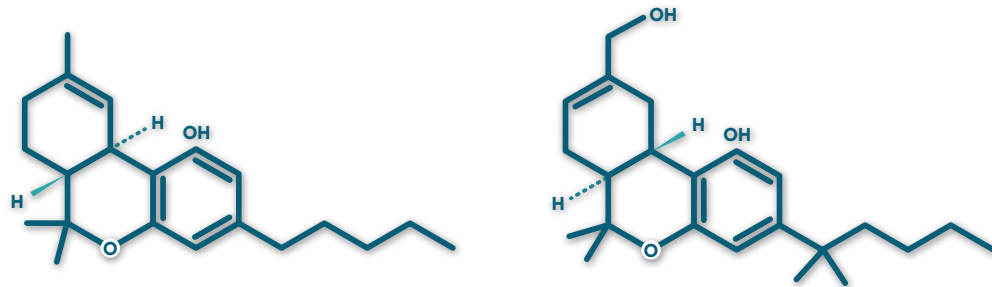


Fig. 6. On a ground reconnaissance mission on the outskirts of the city of Culiacan, Sinaloa-Mexico (October 2011), military personnel located a clandestine laboratory for preparing synthetic drugs hidden amongst the brush, reported by the Secretariat of National Defense (SEDENA).

One of the fundamental goals of these laboratories is the modification of the chemical structure of illegal drugs, thus turning them into “extralegal” ones, since they cease to be included in the UN Convention lists even with the tiniest transformation of a molecule.

For example, simple modifications in the formula for Tetrahydrocannabinol, the active principle of cannabis, turn the latter into a synthetic cannabinoid, placing it out of reach of the control to which cannabis is subjected and making it, from then on, one of the most prevalent emerging substances at this time.

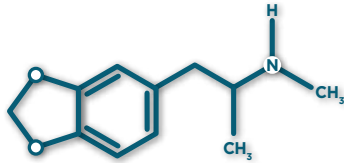


Differences between THC (a traditional cannabinoid) and HU 210 (synthetic cannabinoid).  
Adaptation of the graph from The Challenge of NSP. UNODC. Global Smart Programme 2013.

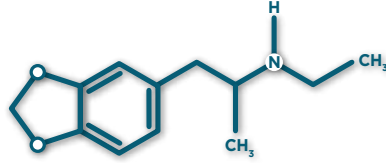
The addition of an oxygen atom with a double bond transforms several illegal amphetamine derivatives in substances with the same effects but which are “not illegal”, in other words, not under control (ecstasy with methylone, MDEA in ethylone and MBDB in butylone).

**CONTROLLED CLASS A**

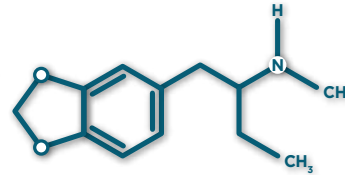
MDMA



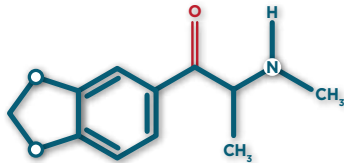
MDEA



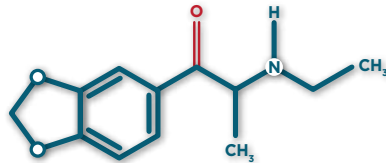
MBDB



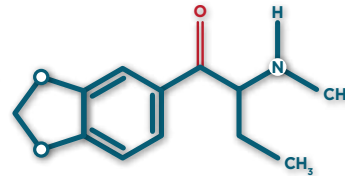
**UNCONTROLLED**



beta keto MDMA - Methylone



beta keto MDEA - Ethylone



beta keto MBDB - 'Butylone'

Source: Dr. John Ramsey

The ease of synthesis and free circulation, given their “alegality”, generally make them cheaper than traditional illegal drugs, thus making them more accessible to all users, though particularly to young ones.

Perceived availability is one variable that informs us about the ease with which people believe they can get these substances.

In response to the question, “What degree of difficulty would you have in obtaining the following psychoactive substances?” in the ESTUDES survey, youths aged 14-18 years old answered that the most accessible ones are anabolic steroids, with one out of every two students that are familiar with the substance considering that they are easy or very easy to

get in 24 hours. The same is true for 52% of those who are familiar with magic mushrooms and 43.6%, as regards methamphetamines. The other substances studied also show figures of more than 30% (Table 1), with piperazines and mephedrone being the most difficult to acquire of the substances assessed.

**Table 1. Trends in perceived availability of psychoactive substances among Secondary School Students ages 14-18.**

**Proportion of students that feel it would be relatively easy or very easy to get each drug, depending on whether or not they had taken the substance at some time in their lives (%). Spain, 2010-2012. ESTUDES.**

	<b>Perceived availability. It is relatively easy or very easy to get</b>					
	<b>All</b>		<b>THEY HAD taken this substance</b>		<b>THEY HAD NOT taken this substance</b>	
	2010	2012	2010	2012	2010	2012
Ketamine	40.2	41.8	83.6	74.4	39.4	41.0
Spice	39.8	42.5	79.1	73.4	39.0	41.4
Piperazines	31.5	34.2	75.6	66.2	31.2	33.8
Mephedrone	30.9	34.2	78.2	66.2	30.5	33.8
Nexus	30.5	34.6	73.4	66.2	30.1	34.1
Methamphetamine	39.8	43.6	80.5	74.7	39.2	43.0
Magic mushrooms	50.3	52.0	84.7	84.2	48.9	50.4
Research chemicals	30.6	34.2	67.0	75.6	30.3	33.8
Legal highs	32.8	35.1	79.3	73.9	32.2	34.7
Sage	-	37.3	-	75.4	-	36.4
Anabolic steroids	-	53.9	-	72.7	-	53.7

Source: Information and Documentation Systems Unit. DGPNSD

The differences between all the students ages 14-18 and those that claim to know the substances are statistically significant ( $p < 0.05$ ), since 30% to 55% of those interviewed did not know the substances and nearly 20% did not answer the question. Likewise, the highest rates of availability are found among consumers.

Perceived availability of these substances among all students is higher in the 2012 survey than the figure seen in the 2010 edition. However, among actual consumers, perceived availability in 2012 is lower than that found in 2010.

We might ask ourselves, 'Where are they getting these substances?' The EDADES survey indicates that it is mainly through friends and acquaintances, dance clubs-bars and dealers, in comparison with data from Europe, which cite friends and acquaintances as the most common sources, followed by music festivals and smart shops, respectively.

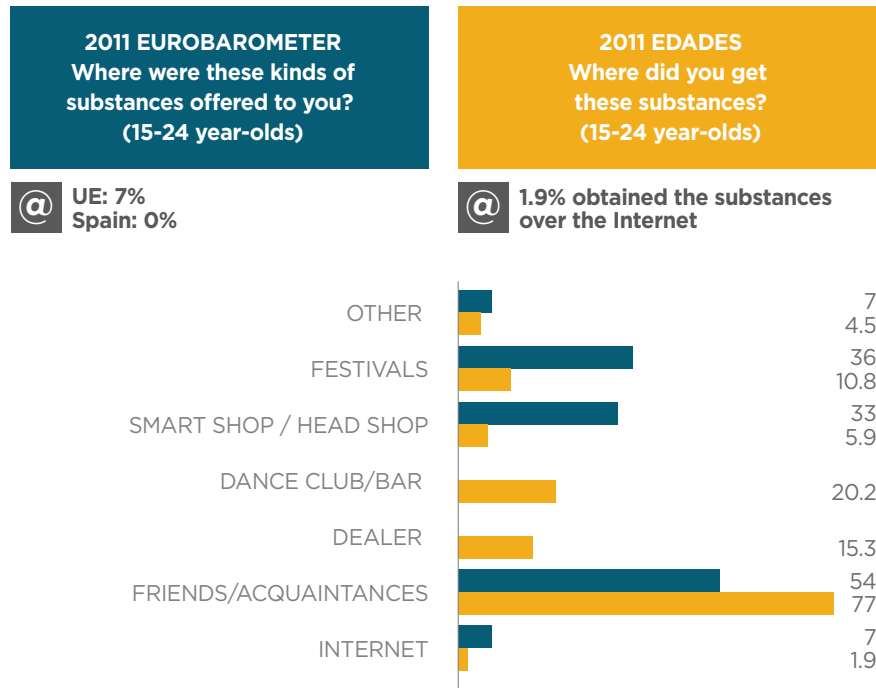
Friends are the main point for getting emerging drugs in both Spain and in Europe. However, it is worth noting, as we will see later, that in the Spanish surveys, friends are not considered desirable sources of information; indeed, they are the least desirable sources.

The fact that bars and dance clubs do not appear as distribution centers in Europe, while in Spain they are one of the main ones, is likely due to the importance that these venues (especially bars) have in Spanish society unlike in Europe, this figure being substituted by the music festivals nearest to dance clubs.

Just 1.9% of the population in the 15-24 year-old age group had acquired them over the Internet, and this percentage is low, considering the 7% found in the Eurobarometer for

Europe as a whole in the same age group. Could it be that dealers in Spain are the ones acquiring them over the Internet and later selling them in a more customary Spanish setting? Or perhaps this might be due to the fact that in general Spanish youths use the Internet less than other Europeans.

**How and where do they get them?**



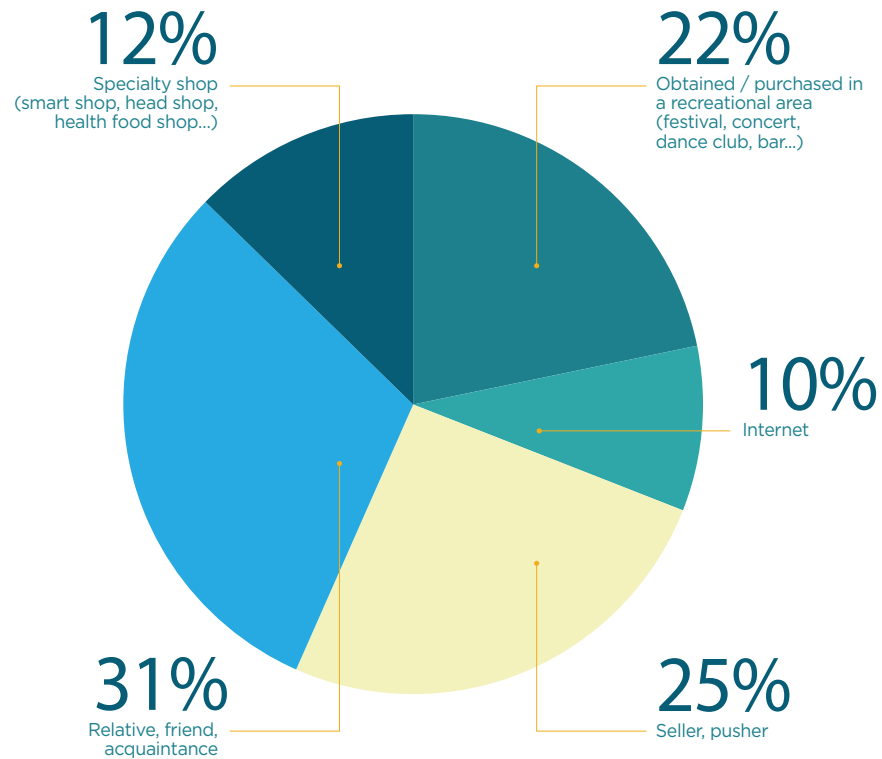
Source: Information and Documentation Systems Unit. DGPNSD-MSSSI



At any rate, these figures can be expected to increase, considering that the availability of the Internet in Spanish households is below that of other Europeans (68% compared to 76%) and that new generations are participating.

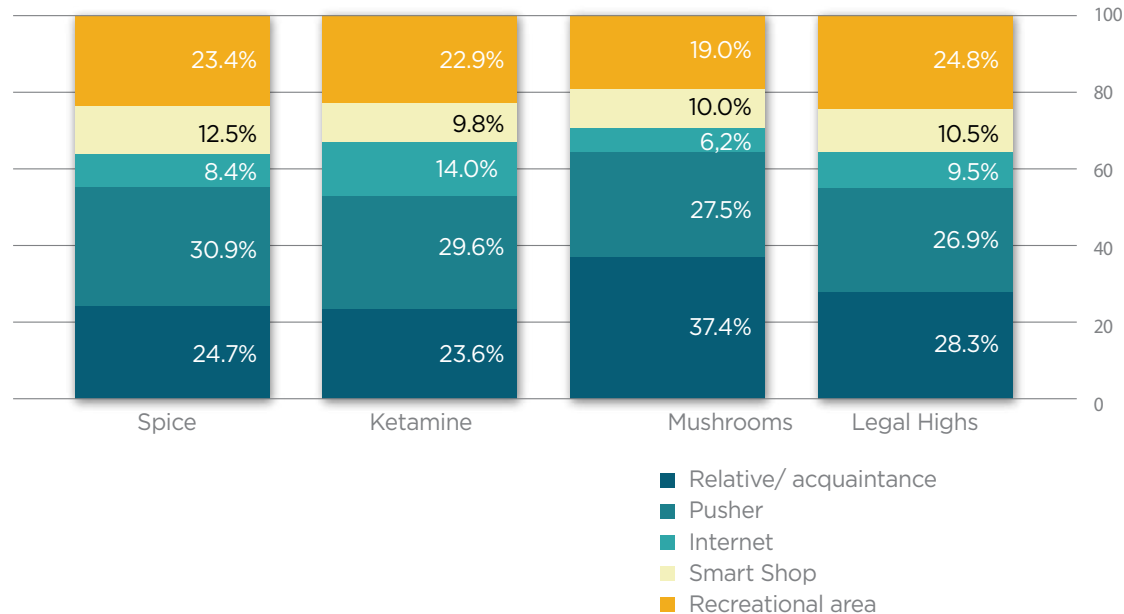
If the assessment is made among adolescents ages 14-18 years old (2012 ESTUDES), we can see that the source used by most of them was a friend or an acquaintance (31%), followed by sellers or pushers (25%), recreational areas (21.8%) and smart shops/head shops (12%), differences being found depending on the substance (Fig. 7).

Fig. 7. Sources for getting emerging drugs among those that have at some point obtained them, among students ages 14-18 years old (percentages). 2012 ESTUDES. Spain.



Source: Survey on Drug Use in Secondary Schools in Spain (ESTUDES 2012). Information and Documentation Systems Unit. DGPNSD-MSSSI

**Fig. 8. Sources for getting the different emerging drug substances among those that have at some point obtained them, among students ages 14-18 years old (percentages). Spain 2012**



Source: Survey on Drug Use in Secondary Schools in Spain (ESTUDES 2012).  
Source: Information and Documentation Systems Unit. DGPNSD-MSSSI.

## They are not safe for use

The conditions in which these types of substances are handled (homemade permanent or mobile laboratories, in the middle of the jungle, equipped with simple tools and in amateur hands) are not the most suitable in terms of hygiene and sanitary conditions to consider that their consumption is free of risk but, given the circumstances, this kind of danger is not the most serious one that potential users are exposed to. The most dangerous issue is that they are handled in clandestine conditions, which forces these drugs to be placed on the market with no kind of control and without their effects on humans having been tested.

The lack of knowledge about and accurate, verified information on key aspects of many of the new psychoactive substances and the absence of a scientific community to study and assess them makes it impossible to establish safety parameters for consumers.

Furthermore, some of the substances that were previously known and used in their time for medical purposes are no longer used in clinical practice because of their negative effects, some of which are serious for users' health and many others of which, while not dangerous, are unpleasant at the least, as is the case of Ketamine.

If we also take into consideration the most common patterns of consumption for this kind of substances (polydrug use or substitute drug use), the safety situation becomes even more serious because the interactions between these drugs and other, more traditional, ones or their performance depending on the personal circumstances of the consumer (age, intravenous drug users, those with other diseases, etc.) are unknown

This overall lack of knowledge is not a problem exclusively for the users, but also for all the professionals related to the management of drug addiction and the field of science in general.

## The new technologies

New technologies in general and the Internet in particular have become essential features that characterize the phenomenon known as the new psychoactive substances.

Earlier in this report, we stated that NPS are merely drugs that are inherent to the present sociological era and the Internet is essential to this time period, playing a leading role in the promotion, distribution, sale and accessibility to many of the substances included within the group of emerging drugs.

There are four basic reasons for which the Internet plays a key role in the new psychoactive substances:

1. It facilitates the knowledge of their existence.
2. It provides information about their performance.
3. It is an instrument of trade.
4. It is a place in which to share experiences with them.

The websites devoted to emerging drugs have features that make them particularly attractive:

- Browsing is very simple, they are easy to access and the designs and slogans are provocative and attractive: bright bath salts, decorative herbs and seeds, incense...with seductive advertising: “for adults only”, “over 18 years of age”...; “only for research purposes”...
- Multiple languages are used so the information can be accessed in any major language.
- They use any currency and the price can be indicated in the currency requested. Easy payment, with numerous methods available, including cards.
- Customer assistance.
- Contact email addresses.
- Shopping cart, just like with any other online purchase.
- Discussion forums.
- Free delivery for purchase over a certain quantity.

But these sites that advertise emerging drugs are commonly and perversely worded with the aim of avoiding any liability, clearly stating that the information supplied is about “indigenous uses and customs”, that the relevant substance “is not fit for human consumption” or is “is only for external use, although some people take them by different means, such as...”;

### New Psychoactive Substances Legal Bath Salts, Air Fresheners, Incense...

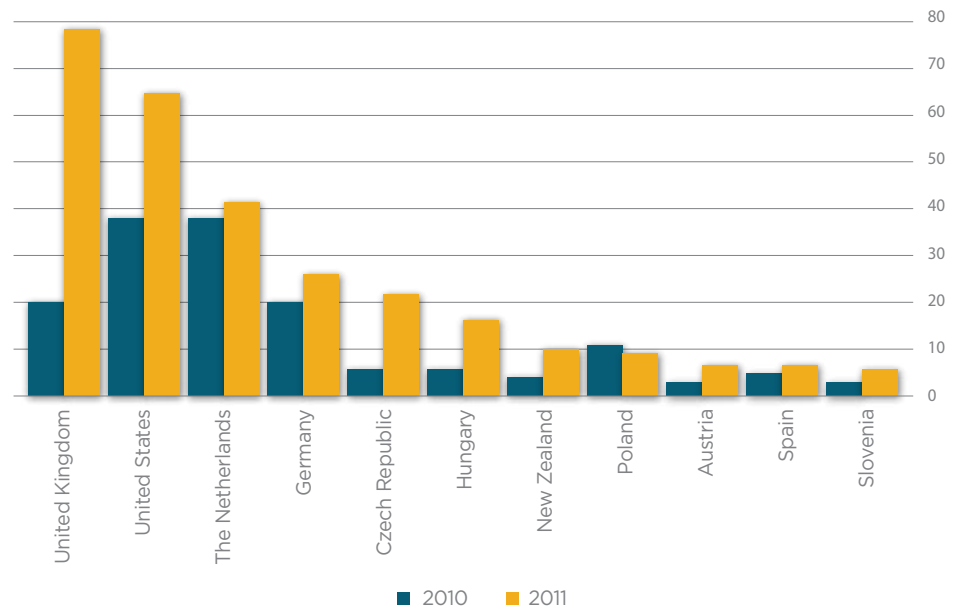


The EMCDDA periodically monitors the availability of NPS by analyzing online shops using the snapshot methodology. In 2010, 170 such shops were identified, in 2011, there were 314 and in 2012, a total of 693. Establishing the country of origin of the online shop is difficult

but based on certain features such as the point of contact, domain country code, currency used and information on deliveries, the United Kingdom is the country in which the largest number is based and English is the most commonly used language.

The number of online shops increases considerably each year, as does the number of substances offered at prices that are lower than on the ordinary market.

Number of online shops detected, according to country of origin. 2010 and 2011. EMCDDA.





Many of these sites are hosted in third-party countries outside the EU, sheltering themselves under the opacity of the Internet in addition to conducting this extralegal trade.

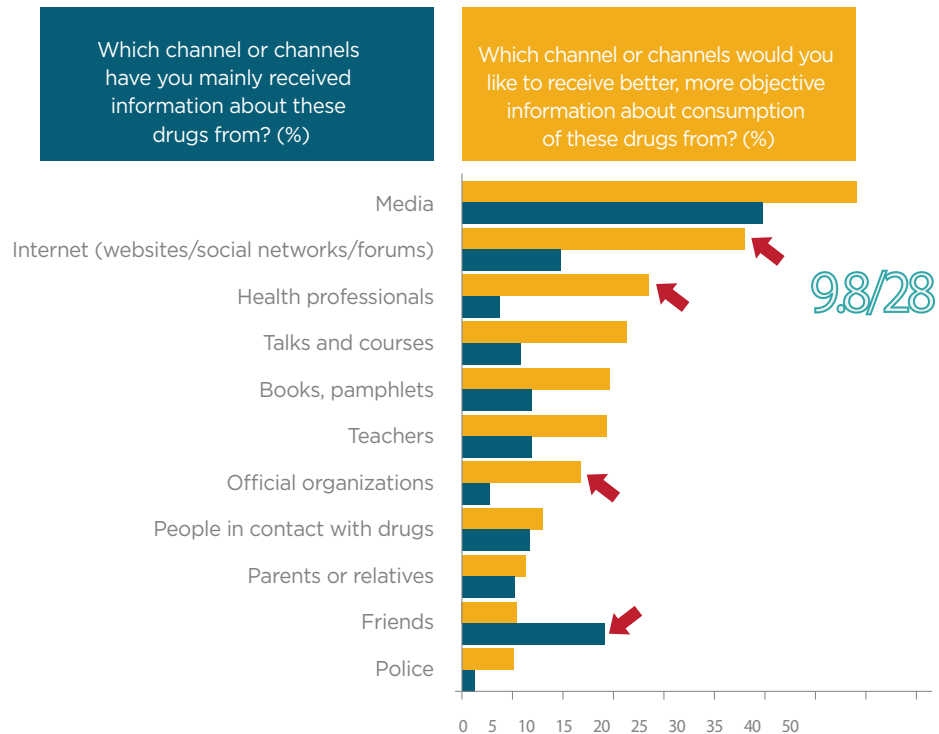
The ESTUDES Survey shows that the main sources through which students ages 14-18 years old receive information are the media, friends and the Internet, in this order, although the channels through which they would most like to receive it are the media, the Internet and health professional, respectively. (Fig. 8).

It is striking that young people have such little regard for the people closest to them - their parents, relatives and friends - and their rejection of the information given by the latter of these as a desirable source is particularly noteworthy. Could it be due to a lack of confidence/uncertainty in their knowledge? In any case, it is worth reflecting upon in relation to a group in which 'peers' come to play a decisive role in individual behavior and the sense of belonging to a group.

In turn, the request for involvement by health professionals made by students is also striking, as is the increasing credibility given to information provided by official organizations.

The survey also spotlights how three times more young people consider the Internet a desirable source of information than the percentage of young people that currently use it (28% compared to 9.8% respectively)

### NPS information channels



Source: Information and Documentation Systems Unit. DGPNSD-MSSSI. ESTUDES 2012

In light of the overall lack of reliable information about NPS, the available information is basically found over the Internet and social networks provided by the market or by

users who express their opinions, and this is sometimes the only source of information available for both users and for professionals.

## The European Union as a single market.

The Treaties of the European Union have turned this region into a borderless territory, a single market, also known as the “internal market”. Within this space, people, goods, services and capital can move freely.

The free movement of goods is one of the foundations of the internal market, established in January 1993 with the elimination of the controls that had been applied up to that time, making the EU a single territory from then on.

Free movement is applied in identical conditions to all the goods that are transported within the EU, including those that come from third countries, except for those that entail risks for consumers, public health or the environment. The prohibition of restrictions on imports and exports between Member States and the mutual recognition principle guarantee compliance with the free movement of goods under the control of the European Commission.

The mutual recognition principle guarantees the free movement of goods and services with no need to harmonize the national laws of the Member States. Thus, the sale of a product legally manufactured in one Member State cannot be prohibited in another Member State, even though the technical or qualitative conditions differ from those of

domestic products. There is one exception: in the case of general interest (protection of health, consumers or the environment) strict conditions apply.

Consequently, once it has been synthesized and authorized by one Member State, a psychoactive substance can move with no restrictions from other States and is available to all citizens. This is particularly meaningful in the case of medicines.

If a substance is synthesized in a third country outside the EU, and one country in the European Union allows it to enter and move throughout its territory, it can be transported with no further requirements to the other Member States. Provided that it does so within the limits clearly expressed in the EU regulations mentioned above.

In the case of NPS, given that they are not illegal and despite their extralegal status, it is perfectly feasible for them to move freely throughout the territory of the EU. If a drug comes from a third country, since it is not “illegal”, seizure at the border of the EU is complex and once it has passed one customs office, free movement is guaranteed.

The lack of information and general ignorance regarding NPS hinders the establishment of measures limiting movement for reasons of general interest. The precautionary principle, which is used regularly in public health, should be considered in relation to this phenomenon, although this is not currently the case.



## CHAPTER III. Monitoring

“Today, the threats to public health on an international level cannot be stopped or prevented through health services and controls at borders. Cooperation and solidarity are the main means of prevention and thus, public health issues in one territory cannot be tackled without including international actions as an essential part of the national public health policy”.

Preface, General Public Health Law 33/2011, of 4 October.

Public health monitoring entails all the activities aimed at gathering, analyzing, interpreting and publishing information about the health conditions of the population and the factors that influence them, in order to lay the groundwork for implementing public health activities (Art. 12.1, Law 33/2011).

The global extent of NPS use is not yet known, but the constant increase in the consumption of these substances and their potential negative effects must be monitored in the different countries.

## 1. On an international level:

### A) United Nations

The United Nations Office on Drugs and Crime, in its World Drug Report 2013, highlights the stability in the use of traditional drugs and the alarming rise in new psychoactive substances.

Countries around the world have reported the appearance of new psychoactive substances/emerging drugs in their territories. UNODC World Drug Report 2013.

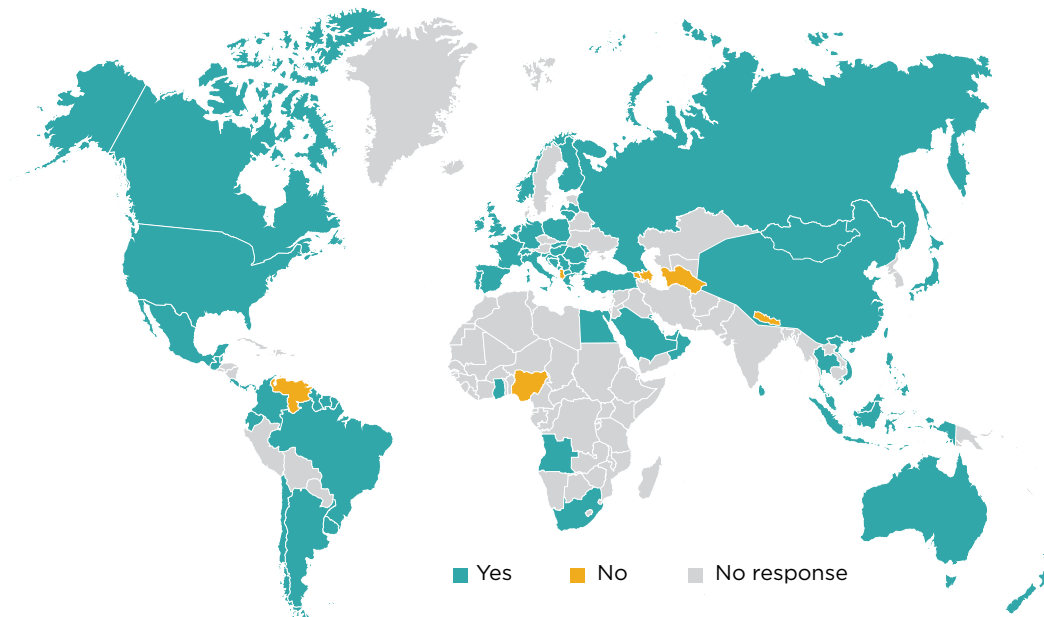
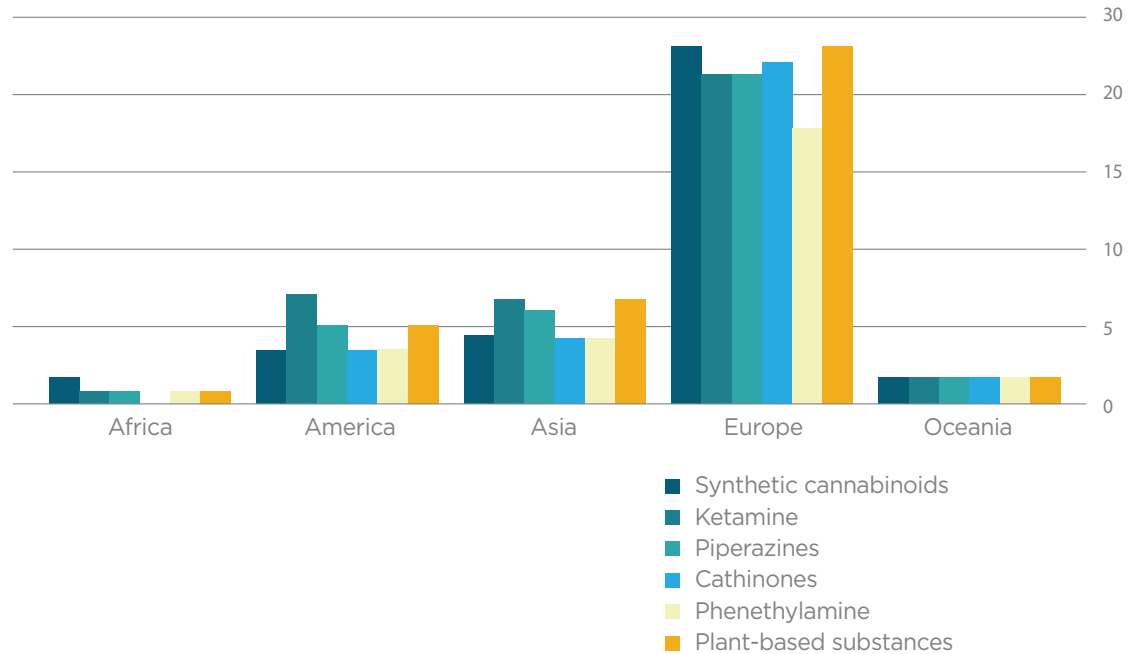


Fig. 9 NPS detected by regions around the world



Source: Adaptation of the graph from the United Nations Office.  
Report: "World Drug Report 2013". "The Change in New Psychoactive Substances" (Vienna, March 2013)

For the first time in history, the number of new psychoactive substances identified (251) exceeds the number of psychoactive substances under control (234).



This World Report warns that:

“... the international drug control system is failing for the first time due to the speed and creativity of the new psychoactive substance phenomenon”.

Indeed, the speed at which NPS appear on the market, the inability to apply relevant enforcement legislation, the slowness in processing their inclusion in the control schedules and the obscurity and opacity afforded by the Internet have caused the current control system to become completely overwhelmed by the phenomenon of new drugs.

In light of this situation, the UNODC concludes that:

“The establishment of an early warning system is needed to inform Member States of emerging substances and to support them in their response to this complex and changing phenomenon.

While the international drug control conventions offer the possibility of scheduling new substances, the sheer rapidity of emerging NPS makes this a very challenging undertaking.

What is needed is an understanding and sharing of methods and lessons learned in regional responses to the situation involving NPS before exploring the setting up of a global response to the problem”.

In general, two basic instruments are used to monitor NPS in diverse regions and countries: population surveys aimed at specific groups, especially young people, which are highly vulnerable targets for psychological and biological reasons and due to the fact that they have the most access to the Internet, and specific warning systems for monitoring these drugs.

Still, the United Nations has admitted that there are considerable limitations to these monitoring systems, primarily arising from the lack of uniform criteria for establishing and implementing them, namely, the design and representation of the sample, the period over which the survey is taken, how the questions are worded, data collection method, substances monitored, differing definitions, different legislation applicable depending on the country, etc. As a result of this diversity, comparisons of data and final conclusions are hindered greatly.

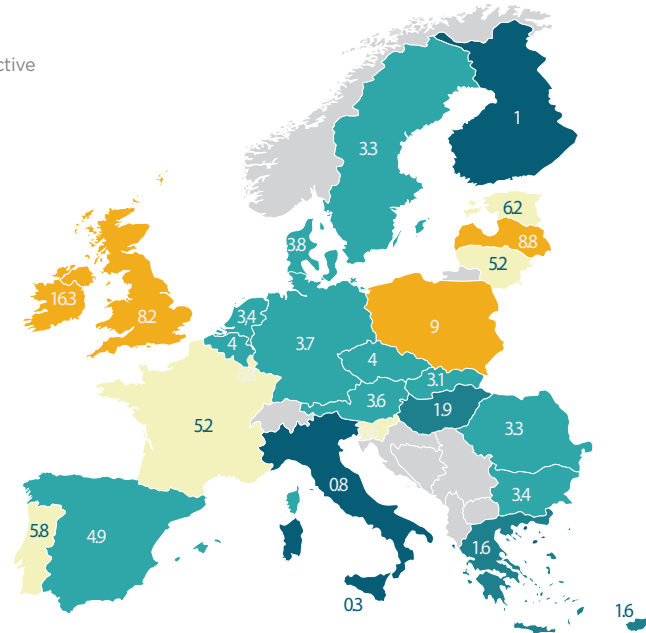
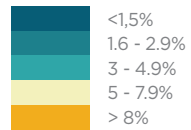
## **B) European Union: EMCDDA/EWS**

The call for a regional response by the UNODC has been met with specific results from the countries composing the EU. On the one hand, a survey system, the Eurobarometer, has been created to gather information about the prevalence of consumption of new psychoactive substances.

**Fig. 10 Prevalence of consumption per European Union countries**  
Percentage of people ages 15 to 24 that have tried "a legal substance that imitates the effects of illegal substances"

**MEAN=5%**

The use of new psychoactive substances is prevalent



Source: Gallup Organization. Report on youth attitudes on drugs.  
Flash Eurobarometer series No. 330 (European Commission)

The 2011 Eurobarometer also indicates that almost three quarters of all NPS users pertain to 5 countries: United Kingdom (23% of the total in the European Union),

followed by Poland (17%), France (14%), Germany (12%) and Spain (8%). The United Kingdom is also the country in which the largest quantity of NPS was found in the European Union (30% of the total in the 2005-2010 period).

On the other, through coordination by and under the leadership of the EMCDDA, in conjunction with EUROPOL, a specific monitoring system for new psychoactive substances has been set up, known as: **EWS/ Early Warning System**.

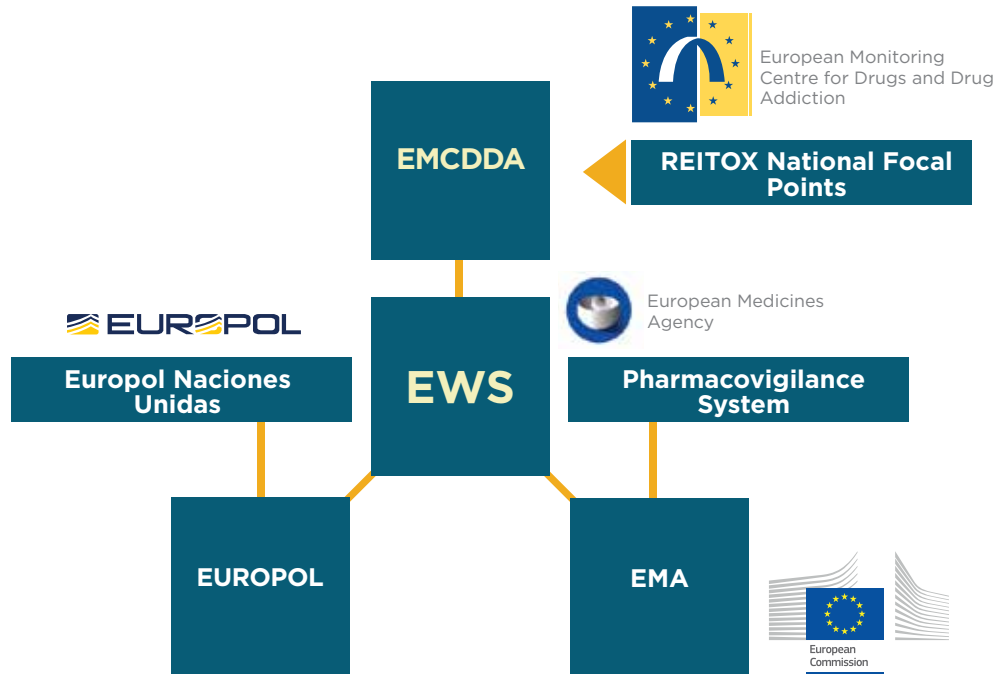
This system was established in late 1997 within the framework of Joint Action 97/396/JHA concerning the information exchange, risk assessment and the control of new synthetic drugs.

Its goal is: To create a rapid exchange system on new synthetic drugs and risk assessment, so that the control measures for psychotropic substances in force in the Member States can also be applied to the new drugs.

### **Features of the EWS.**

The European Monitoring Centre for Drugs and Drug Addiction describes the EWS as a proactive system with defined objectives that spans territorial coverage of a diverse nature, able to integrate numerous sources of information and verify data and that it is useful, safe, comparable and compliant with ethical principles.

## Institutions that participate in the EWS



Source: EWS - [www.emcdda.eu](http://www.emcdda.eu)

The Reitox Network plays an essential role in the European Warning System. It comprises each of the national representatives (focal points) from each Member State of the EU, representatives of the European Monitoring Centre, a representative of the Commission and the focal points of EU candidate countries, plus a national focal point from Norway, which participates with the other countries although it is not a member of the EU.

## The Reitox network: 30 National Focal Points



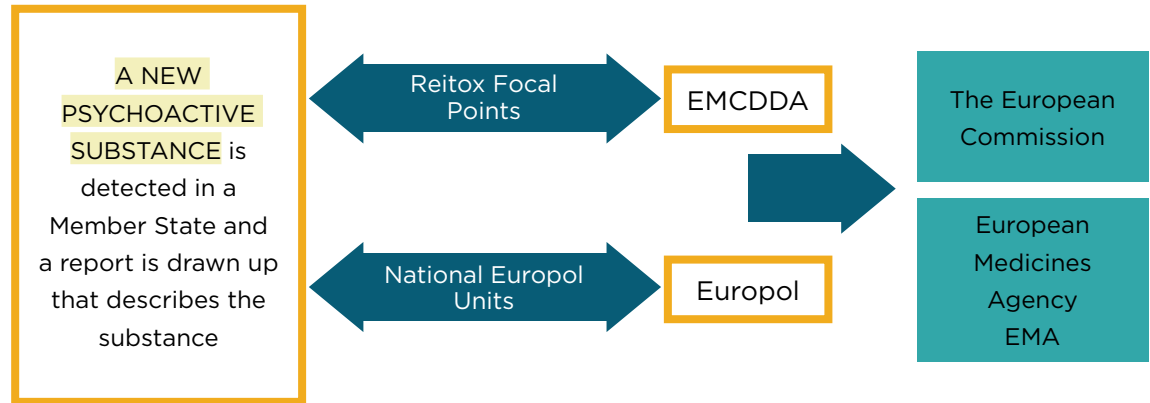
Source: European Monitoring Centre for Drugs and Drug Addiction. EMCDDA

The Joint Action involves any substances that are not listed in Schedules I and II of the 1971 United Nations Convention on Psychotropic Substances, that pose a threat to public health similar to the substances listed in said Schedules and that have limited therapeutic relevance. This refers to end products, not including precursors, which are governed by Council Regulation (EEC) No 3677/90 of 13 December 1990 laying down measures to be taken to discourage the diversion of certain substances to the illicit manufacture of narcotic drugs and psychotropic substances and Council Directive 92/109/EEC of 14 December 1992 on the manufacture and the placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

The speed at which NPS are beginning to be detected requires the EU to seek a new regulatory set-up in order to improve the management of the situation. In 2005, Council of the European Union Decision 2005/387/JHA, of 10 May, on the information exchange, risk assessment and control of new psychoactive substances, was passed, replacing the Joint Action that had been in force up to that time.

The Decision acts as a legal instrument that can be applied to any new drug that has been reported to the EMCDDA and to Europol and establishes the procedure, timeline and deadlines for each stage of activity. The Decision maintains the three operative stages from the Joint Action: information exchange, risk assessment and control measures.

### STEP 1: Information exchange/warning



Source: Spanish Observatory on Drugs and Drug Addiction. DGPNSD-MSSSI.

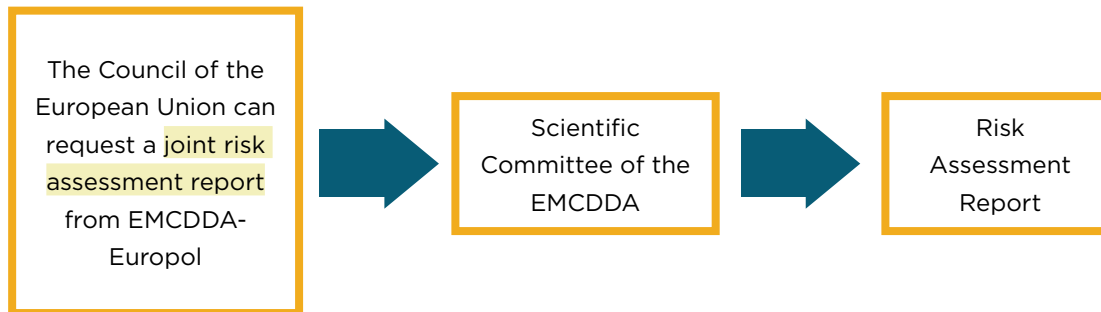
When an NPS is detected for the first time in a Member State, its national Europol unit and/or representative in the Reitox Network furnish information about the production, trade and consumption of the new drug to the Europol Drugs Unit (UDE) or to the European Monitoring Centre (EMCDDA). The UDE and the EMCDDA gather the information received, mutually exchange it and immediately sent it to the relevant national units (Reitox Network), the European Commission and the European Medicines Agency (EMA).



The information is furnished in the protocol officially established by the EMCDDA (ANNEX I). The data sent includes: physical and chemical description and name of the new drug and information on the NPS detected.

If Europol and the EMCDDA consider that the information received is relevant, they prepare a joint report that is sent to the European Council, the Commission and the EMA.

### STEP 2: Risk assessment



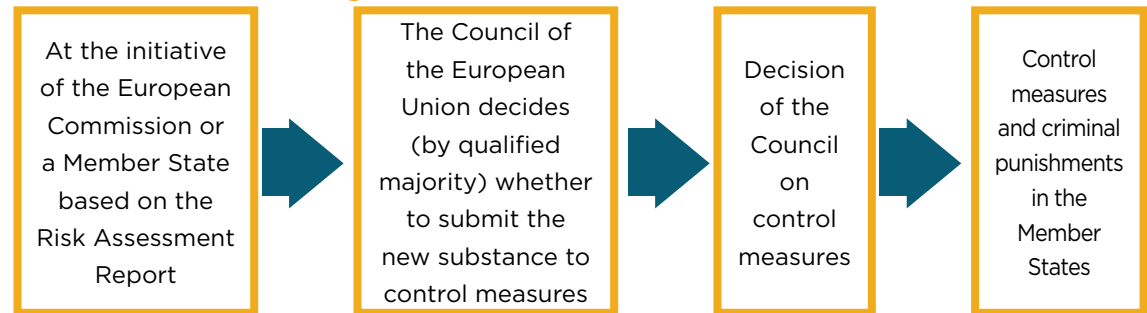
Source: Spanish Observatory on Drugs and Drug Addiction. DGPNSD - MSSSI.

The joint report must contain information about the physical and chemical characteristics of the new substance, the amount seized, synthesis means and methods, involvement of organized crime if any, risks to society and health, user characteristics, whether the substance has been or is in the process of being assessed, possible control measures and chemical precursors, forms and purpose of the established or expected use.

The EMA, in turn, informs Europol and the EMCDDA about whether the new substance is marketed in the EU or any European Community country, or whether it is pending receipt of such authorization or whether it held such authorization at any time but was subsequently suspended.

At the request of a Member State, the Commission or based on the Joint Report, the Council can request that a risk assessment be conducted of the new substance detected.. The European Monitoring Centre will call a special meeting of the Scientific Committee and, if deemed appropriate, extended to include experts appointed by the Member States and representatives of the Commission, the UDE and the EMA will also be invited. When the risk assessment is complete, a report showing the results will be prepared. The risk assessment shall be conducted based on all the information furnished and shall take into consideration all the factors that, pursuant to the 1971 United Nations Convention on Psychotropic Substances, justify that a substance be subject to control.

### STEP 3: Decision-making



Source: Spanish Observatory on Drugs and Drug Addiction. DGPNSD-MSSS

Once the risk assessment report is complete, the Council can decide, by qualified majority or when required by the Commission, whether or not to subject the new substance to control. If it decides not to do so, the reason for this must be supported.

If it decides to do so, the Member States have one year to include the measures on the assessed substance into their respective legal frameworks.

The last two NPS to be subjected to control were Mephedrone and 5-IT. Spain has included them in its regulations immediately pursuant to the Decision. (see ANNEX V).

Any country in the EU can also subject a substance to control unilaterally. In Spain, for example, Ketamine is controlled (ANNEX IV), while the European Council and the UNODC do not have it under control, although they recommend monitoring it.

## EWS. Legal framework in the EU

<b>Joint Action 97/396/JHA</b>	<b>Council Decision 2005/387/JHA</b>
June 1997-May 2005	May 2005-present
<p><b>30 NPS reported</b>  <b>9 Risk assessments:</b>                      MBDB; 4-MTA; GHB; Ketamine; PMMA; TMA-2; 2C-T-2; 2C-T-7; 2C-I</p> <p><b>6 substances subjected to control:</b>                      MTA; PMMA; TMA-2; 2CT-2; 2C-T-7 and 2C-I</p>	<p><b>230 NPS reported</b>  <b>4 Risk assessments:</b>                      BZP; Mephedrone; 4-MA and 5-IT and a joint report on Mcpp</p> <p><b>4 substances subjected to control:</b>                      BZP; Mephedrone; 4-MA and 5-IT</p>

Source: EMCDDA. EWS

While in fairness it must be recognized that Decision 2005/387/JHA has proven to be a useful tool in monitoring NPS, several shortcomings have been detected that hinder their management in the terms needed, mainly caused by the speed at which the NPS are developed. The most common limitations found are:

- Studying the drugs on an individual basis, one by one, rather than by family.
- The prolonged process involved in the risk assessment and decision-making.
- The impossibility of taking provisional measures until the final assessment is made.

For this reason, the 2005 Decision is being reviewed and a new regulatory text that more effectively manages the control of NPS is being studied.

### **European Legal Database on Drugs (ELDD)**

The European Monitoring Centre has a European Legal Drug Database-ELDD that includes permanent updates of the legal classifications of substances, in addition to a comprehensive list of all the controlled substances in the Member States and Norway.

The database contains information about: The M.S. profiles, according to information provided by the national focal points, legal texts in original format, legal reports, publications on the legal status of the drugs, topical reviews, news and any documents considered of interest to the database users.

## European Database on New Drugs (EDND)

This is an online platform for the exchange of information about risk assessment and control of new psychoactive substances based on the Council Decision.

Anyone who participates directly in the implementation of the Decision can access it and it also provides all the existing reports on NPS and entry of warnings in the EWS.

This database is particularly relevant for laboratories that collaborate with the EWS. In a field in which scientific information is scarce, the possibility of having a formal, up to date, integrated tool is highly useful in the identification and verification of the NPS.

## COPOLAD: Cooperation with Latin America

This is a cooperation program between the European Union (EU) and Latin America (LA), aimed at fostering coherence, balance and impact on drug policies through the exchange of experiences, bi-regional coordination and bolstering multi-sector, integrated and coordinated responses.

The second component of COPOLAD is devoted to the consolidation of regional observatories, one of its objectives being to “Analyze the situation existing in different countries as regards systems for gathering information on new drugs or new uses of

drugs (Early Warning Systems), as well as defining possibilities for coordinated action between LA and EU countries within this field”.

SEAT, in conjunction with CICAD and EMCDDA, is leading this activity and acts as a catalyst, contributing its work and experience ([www.copolad.eu](http://www.copolad.eu)).

## 2. On a national level. SEAT: Spanish Early Warning System

The EU encourages the M.S. to work along the same lines, and thus, Article 4 of Decision 2005/387/JHA states:

“Each Member State shall ensure that its Europol National Unit and its representative in the Reitox network provide information on the manufacture, traffic and use, including medical use, of new substances and of preparations containing them”.

Spain, convinced that the phenomenon of addiction inevitably requires an international approach and accepting its international commitments, has placed its general policy on drug addiction within the context of the UNODC and the EU through the 2013-2016 National Strategy currently in force, specified in the 2013-2016 Action Plan, which contains the objectives and tasks to be completed from 2013 to 2016.

Of the 6 focuses of action set out in the Plan, No. 4 (Improvement of basic and applied scientific knowledge), contains nine activities related to research and the

collection, study, analysis and dissemination of information, in three of which the NPS are present:

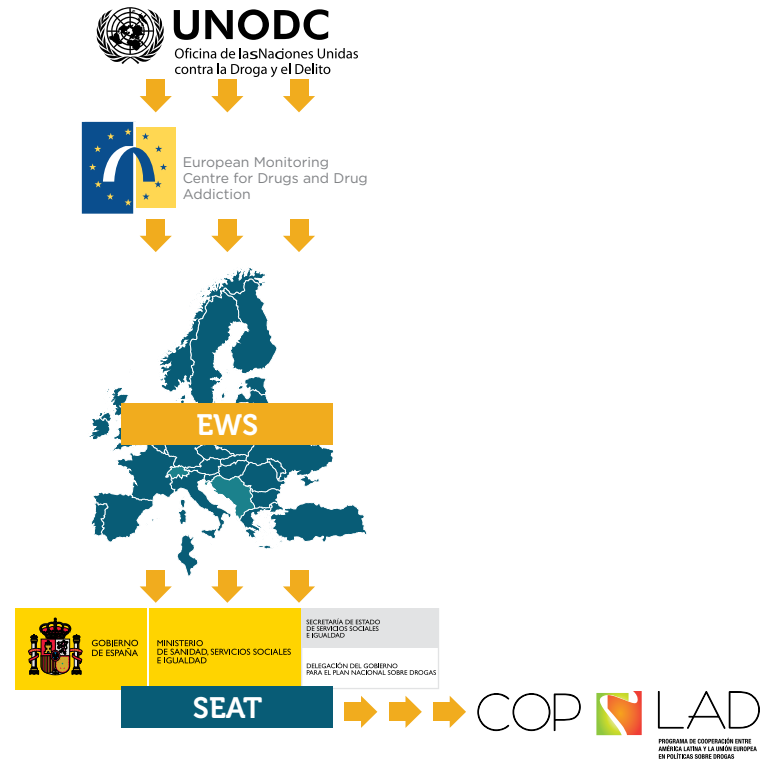
- No. 26. “Fostering research and analysis of data about drug use”.
- No. 27. “Improving the spread of data from the reporting system”.
- No. 28. “Consolidation of the early warning system”.

In all these activities, work is done in accordance with the indications prepared by the UN and the EU, which are the starting point for setting up the study of emerging drugs in this country.

On one hand, in line with the population studies in other countries and in an effort to foster research and data analysis, since 2010 the DGPNSD Spanish System for Drug Addiction Reporting has included a specific module in its main surveys (EDADES and ESTUDES) about the prevalence of use, perception of risk and availability of nine emerging drugs: Magic mushrooms, Ketamine, Spice, Piperazines, Mephedrone, Nexus (2CB), Methamphetamines; Research Chemicals, and Legal Highs ([www.pnsd.msc.es](http://www.pnsd.msc.es)).

And on the other, the **Spanish Early Warning System (Sistema Español de Alerta Temprana or SEAT**, Spanish acronym) has been created, which, like the other Member States, Norway and candidate countries, shares and participates in the EWS, under the proposals of the UNODC.

## Spanish Early Warning System / SEAT



This system is governed by articles 12, 13, 14 and 15 of General Public Health Law 33/2011, which are devoted specifically to monitoring public health, and the key features of interest here are:



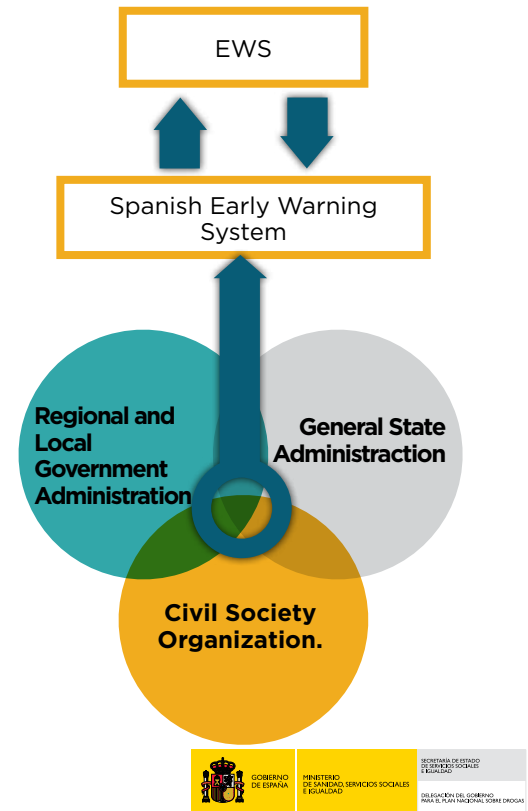
- Public health monitoring shall take into consideration any known public health issues.
- Early warning and rapid response systems are required in the monitoring system in order to detect and assess incidents, risks, syndromes, diseases and other situations that could pose a threat to the health of the people.
- The Autonomous Regions and the Autonomous Cities of Ceuta and Melilla and local government shall ensure, within their scope of competence, that the respective public health monitoring systems comply with regulations in force. Moreover, they must furnish the information set forth under national and international regulations at the intervals and broken down in the manner established in each case.
- The AGE, Autonomous Regions and the Autonomous Cities of Ceuta and Melilla and local government, within their scope of competence, shall be entrusted with the organization and management of the public health monitoring.
- The MSSSI shall be responsible for:
  - Managing the warning system across the Autonomous Regions and those from the EU, WHO and other international organizations.
  - Ensuring the quality of the system.
  - Coordinating and managing information exchanges corresponding to domestic and international monitoring issues.
  - Coordinating any messages in this regard that may be addressed to the public.

## Characteristics

### New Psychoactive Substances. Spanish Early Warning System

#### SEAT

- Cross-disciplinary network that gathers, assesses and disseminates information quickly.
- Commitment to global and international management of the issue.
- Three activity areas: AGE; Local Gov't; CSO.
- Efficient use of resources.
- Virtual network that is triggered in case of warning.
- Two-way information exchange.
- Active monitoring.
- Agile and flexible in adapting to a constantly changing world.



Source: Information and Documentation Systems Unit. DGPNSD - MSSSI.

In Spain there are diverse sources of information coming from other organizations and levels that afford us an understanding of the events occurring in relation to the circulation of NPS in Spain, namely:

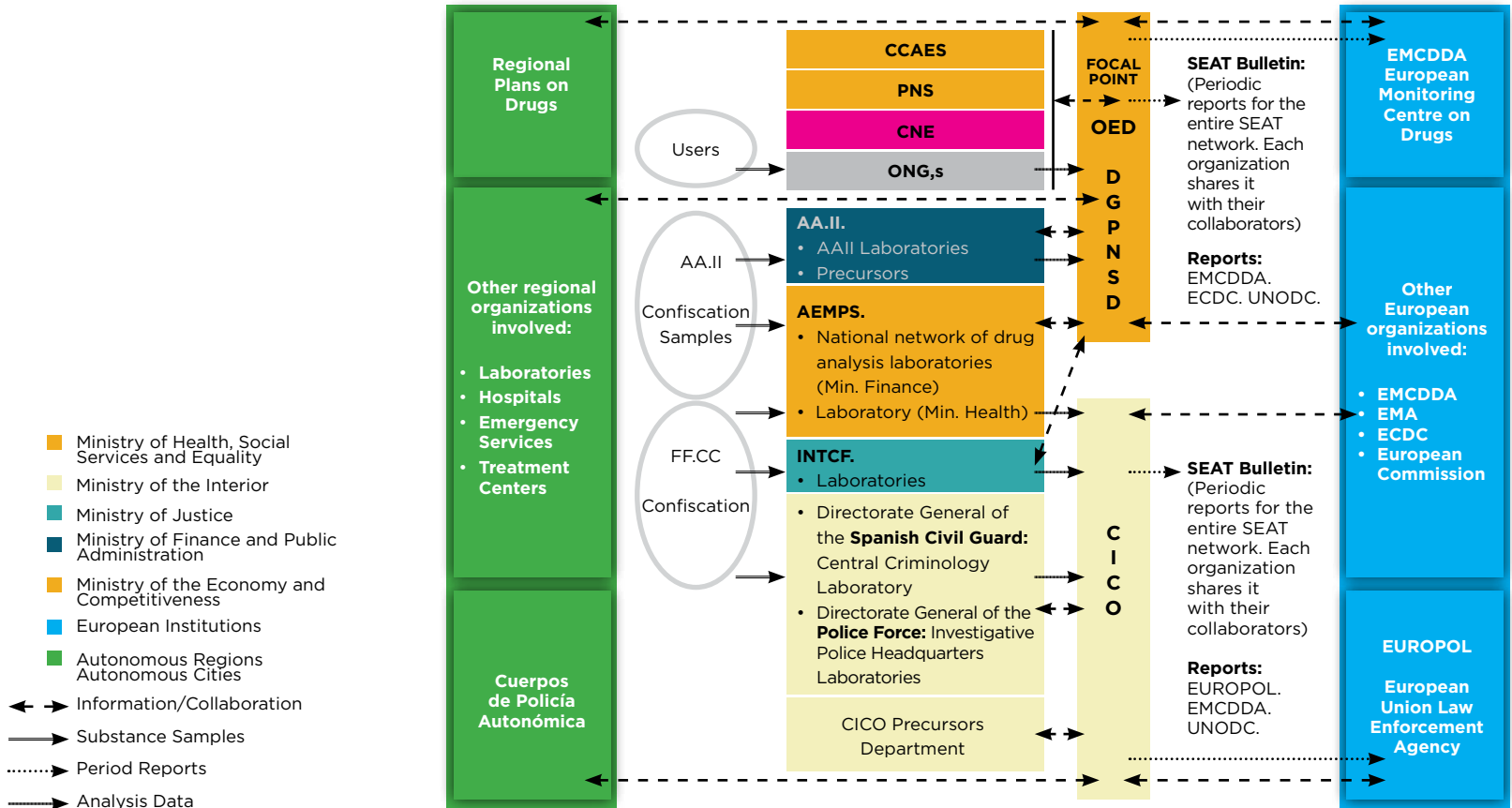
- The System for Analysis, Assessment and Use of Data on Drugs (SENDA), the Drug Investigation Registration System and the Monitoring Center on the Use of New Technology by Trafficking Organizations (CICO)
- The Spanish Pharmacovigilance System (AEMPS)
- The Public Health Warning System (MSSSI)
- Others (Customs Surveillance; NGOs...)

All of these organizations participate in SEAT, creating an integrated and, thus, effective and efficient, system that coordinates previously existing information sources.

As an integrated system was necessary, SEAT was established with the aim of monitoring not only NPS but also any other issues that may arise in relation to drug addiction that could pose a problem for public health.

## Structure

### Structure and operation of the Spanish Early Warning System. SEAT



**OED:** Spanish Observatory on Drugs. **DGPNSD:** Spanish Government Office for the National Plan on Drugs. **CICO:** Organized Crime Intelligence Centre. **AEMPS:** Spanish Agency of Medicines and Medical Devices. **INTCF:** Spanish National Institute of Toxicology and Forensic Sciences. **CCAES:** Center for Coordination of Health Warnings and Emergencies. **CNE:** National Epidemiology Center **PNS:** Spanish National Plan on AIDS. **AAII:** Customs and special taxes. **EMA:** European Medicines Agency. **UNODC:** United Nations Office on Drugs and Crime. **ECDC:** European Centre for Disease Prevention and Control. **FFCC:** Spanish National Law Enforcement Agencies.

Two levels of activity - regional and central - that are permanently connected to the European level.

Four centers of operations: three central ones and one regional.

1. The Information and Documentation Systems Unit of the DGPNSD, the manager and body ultimately responsible for the SEAT, national focal point (Spanish representative) in the EWS and in the Reitox network, liaison with the EMCDDA.
2. The CICO, which is responsible for preparing strategic intelligence in the fight against all kinds of organized crime, liaison with EUROPOL.
3. The AEMPS, which is responsible for coordinating activities related to analyses of the contents of illegally traded narcotic and psychotropic substances and also responsible for making draft proposals of general provisions, technical guidelines, memos and instructions about these substances within their field of competence. Liaison with the European Medicines Agency.
4. The Regional Offices of the National Plan on Drugs, which are the regional authorities and liaisons with the Information and Documentation Systems Unit of the DGPNSD.

Borders are key points in the management of NPS, and we have already seen how the single market entails unique features that affect the circulation of these drugs. Two organizations participate to this end - the Customs Surveillance Service, which answers to the Tax Agency, and whose duties involve investigation, persecution and control of

contraband and cooperation with other EU Member States and third countries in this regard, and the Foreign Health Services under the MSSSI.

These two units receive support, respectively, from the Customs and Special Taxes Laboratory, which conducts analyses and studies of hazardous substances and drug precursors in relation to customs controls, and the Foreign Health Laboratories, all of which collaborate with the SEAT.

The Spanish National Institute of Toxicology and Forensic Sciences, which also participates in the identification of NPS and provides advisory services to the SEAT through a “Framework Agreement for Collaboration between the General Council of the Judiciary, the Public Prosecutor’s Office, the Ministry of Justice and Public Administration, the Ministry of the Interior and the AEMPS, which establishes the protocol to follow in the apprehension, analysis, custody and destruction of toxic drugs, narcotics and psychotropic drugs”.

The Center for Control of Public Health Warnings and Emergencies (CCDES) occupies a strategic position in the coordination between the SEAT and the National Network for Epidemiological Surveillance as well as with the European Centre for Disease Prevention and Control (ECDC).

We must remember that the ultimate goal is to protect the health of the public from a public health standpoint and therefore citizen participation is essential in researching the issue as well as managing it. Here, Non-governmental Organizations, as civil society organizations, play an irreplaceable role. Their proximity to and perceived complicity with the public, especially in a subject that is as ‘delicate’

as this one, would be hard to replace. Three organizations currently participate with the SEAT: Ai-Laket; Spanish Red Cross Youth and Energy Control (Asociación Bienestar y Desarrollo/ABD). Their presence in entertainment venues where young people congregate enable them to gather and identify emerging substances and act as direct counselors.

## Operation

When a certain organization detects a new psychoactive substance or suspected substance, it reports this event to the relevant liaison, which at local/regional level is the Regional Office of the National Plan on Drugs in the region where the drug was found, and the latter, in turn, reports to the Information and Documentation Systems Unit of the DGPNSD. In the event that the organization finding the NPS pertains to the General Administration of the State, it reports the event directly to the Information and Documentation Systems Unit of the DGPNSD.

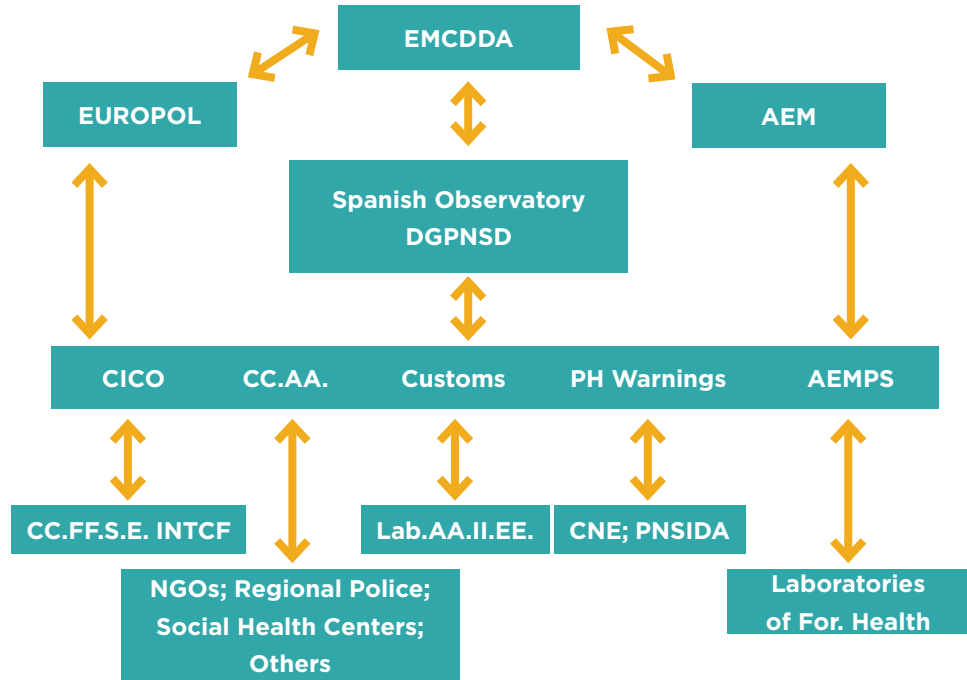
The National Law Enforcement Agencies follow the regulatory procedures and the CICO is responsible for reporting the substance seized to the DGPNSD.

In all cases, the reporting shall be done in line with the protocol established by the European Monitoring Centre (ANNEX I).

The information channel must be strictly observed in order to ensure the effectiveness and feasibility of the system (Fig. 11).

When the Information and Documentation Systems Unit receives a report, it issues a warning to the entire SEAT network and the EWS, which in turn, sends it to the entire EWS network when it is verified that the substance had not been modified previously.

**SEAT. Information channel**




As with any reporting system, feedback is essential. The information sources are notified of the events and how they have been handled, the data reported and the



final outcome of the warning. Furthermore, on a monthly basis the Information and Documentation Systems Unit sends the entire national network a detailed report of all the warnings and notifications that have come out nationally and internationally during the period, in accordance with the protocol established for these purposes (Spanish protocol).

### Information channel. Spanish protocol

Report date:		
Source	Description	Activity

Source: Information and Documentation Systems Unit. DGPNSD-MSSSI





## Conclusions/Recommendations

1. New psychoactive substances/emerging drugs are the current face of the old phenomenon of drugs today, the incorporation of drugs in to the world of social networks, drug addiction within the socio-cultural context of new technologies.
2. Emerging drugs encompass a broad group of psychoactive substances of diverse natures, with differing purposes and effects, some of which are known while others have yet to be discovered, that appear on the market in addition to classic drugs (heroin, cocaine, ecstasy, cannabis, and so on) and constantly being replaced by others.
3. The type of substances included within this phenomenon and their characteristics, spread, dissemination and acquisition lead them to pose a challenge to public health.
4. The extent to which NPS are used by Spanish students and the general public is not alarming in terms of figures at the moment, but it is important to point out that consumption can lead to very serious consequences to health.
5. The lack of information and ignorance about NPS makes monitoring them a key tool for studying and managing them. The SEAT and the specific modules in the EDADES and ESTUDES surveys are ideal components for this monitoring.
6. Further scientific knowledge about these substances is required in order to adequately establish management measures.

7. The extralegal, or 'alegal', status of many of them complicates and even prevents the implementation of certain type of control.
8. The Internet is being used as a first rate tool for spread, information and trade.
9. In this country, there are legal tools for monitoring NPS, but it would be advisable to establish a specific regulatory framework that sets down the rules of the game, identifies its stakeholders and sets forth measures of control and intervention. The use of the precautionary principle as a public health tool and the ability to apply preventive control measures to suspicious substances as soon as conclusive information about them is available should be assessed, in the interest of the general public.
10. Participation and coordination at all levels involved within Spain (Public Administration, Scientific Communities and Civil Society Organizations) is a must. It would be highly positive to include the Public Prosecutor on Anti-drug issues, as an essential figure in criminal proceedings on trafficking of drugs, narcotics and psychotropic substances or money laundering related to such trafficking and the coordinator for activities of different Public Prosecution Offices in relation to this subject, as a part of the SEAT, given that the "non-illegality" of some NPS calls for such coordination.
11. International cooperation is absolutely essential and Spain has an important role to play in this regard.
12. Although work is being done in a coordinated and shared manner within the different International Organizations that are leaders in this subject, specifically

in the EMCDDA, through the Reitox network, to establish a European NPS module that could be included within the surveys conducted by the different EU countries (Spain uses it systematically) we encourage perseverance along this line of work so that joint studies can be established with elements that facilitate data comparisons nationally and internationally.

## Acrónimos

**AEMPS.** Spanish Agency of Medicines and Medical Devices.

**AGE.** General Administration of the State.

**AA.LL.** Local Administration.

**CC.AA.** Autonomous Regions.

**CICAD.** Inter-American Drug Abuse Control Commission.

**CICO.** Organized Crime Intelligence Centre

**COPOLAD.** Cooperation Program between Latin America and the European Union on Drugs Policies.

**DGPNSD.** Spanish Government Office for the National Plan on Drugs.

**EDADES.** Household Survey on Alcohol and Drugs in Spain.

**EDND.** European database on new Drugs.

**EMA.** European Medicines Agency

**EMCDDA/OEDT.** European Monitoring Centre for Drugs and Drug Addiction.  
Observatorio Europeo de la Droga y las Toxicomanías.

**ESTUDES.** Survey on Drug Use in Secondary Schools in Spain.

**EWS.** Early Warning System. European Early Warning System.

**EUROPOL.** European Union Law Enforcement Agency.

**INCB.** International Narcotics Control Board.

**MI.** Ministry of the Interior.

**MSSSI.** Ministry of Health, Social Services and Equality

**UN.** United Nations.

**NPS** New Psychoactive Substances.

**PNSD.** Spanish National Plan on Drugs.

**REITOX.** European Information Network on Drugs and Drug Addiction.

**CSO.** Civil Society Organization

**SEAT.** Spanish Early Warning System.

**CNS.** Central Nervous System.

**EU.** European Union.

**EDU.** Europol Drugs Unit.

**UNODC.** United Nations Office on Drugs and Crime.

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## Related regulations.

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- 1971 Convention on Psychotropic Substances. UN.
- Council of the European Union Decision 2005/387/JHA, of 10 May, on the information exchange, risk assessment and control of new psychoactive substances (literally quoted herein).
- Organic Law 12/1995, of 12 December, on the control of contraband (Spanish National Gazette dated 13 December 1995).
- General Public Health Law 33/2011, of 4 October (Spanish National Gazette dated 4 November 2011).
- Law 17/1967, of 8 April, which updates the regulations in force on narcotics, adapting them to the terms of the 1961 United Nations Convention (Spanish National Gazette dated 11 April, 1967).
- Royal Decree 2829/1977, of 6 October, which regulates the manufacture, distribution, prescription and dispensation of psychotropic substances and preparations (Spanish National Gazette dated 16 November 1977).

- Royal Decree 991/2006, of 8 September, which implements the basic organic structure of the Ministry of the Interior (Spanish National Gazette dated 12 September 2006).
- Royal Decree 1194/2011, which establishes the procedure by which a substance is to be considered a narcotic on the national level (literally quoted herein).
- Ministry Order SAS/2712/2010, under which the substance Ketamine is included in Schedule I of RD 2829/1977 (literally quoted herein).
- Ministry Order SP/201/2011, under which the substance 4-Methylmethcathinone (Mephedrone) is included in Schedule I of RD 2829/1977 (quoted herein in its entirety).
- Ministry Order under which the substance 5-IT is included in Schedule I of RD 2829/1977” (Spanish National Gazette dated 19 May 2014).

**ANNEX**

**ANEXO I: Protocolo Europeo (EMCDDA)**

	<p><b>REPORTING FORM ON NEW PSYCHOACTIVE DRUG</b></p> <p>In accordance with Council Decision 2005/387/JHA of 10 May 2005 on information exchange, risk assessment and control of new psychoactive substances.</p>	 emcdda.europa.eu
<p>This section should be filled in by Europol or EMCDDA</p> <p>Transmitted by Europol <input type="checkbox"/>                      Transmitted by EMCDDA <input type="checkbox"/></p> <p>Ref. n°:    Date of transmission:</p>		
<p>The following sections should be filled by the Europol National Units (ENU) or REITOX National Focal Points (NFP) based on the information available and their respective competences</p>		
<p>1. Member State: Ref. n°: <input type="checkbox"/></p>	<p>Reporting authority: ENU <input type="checkbox"/>                      REITOX</p>	
<p>2. Chemical name: Other name(s): Street name(s):</p>		
<p>3. Source of information (fill one or more as appropriate) Seizure(s) <input type="checkbox"/>                      Specify amount (weight, number of tablets, etc.):</p>		

Seizing authority: Date: <input type="checkbox"/>	Place:
Biological sample(s) <sup>3</sup> <input type="checkbox"/>	Specify type:
Identifying authority: Date: <input type="checkbox"/>	Place:
Collected sample(s) <sup>4</sup>	Specify amount (weight, number of tablets, etc):
Collecting authority:	Anonymous (User of Energy Control Drug Checking service)
Date:	Place:
Other substances present (if more than one case, specify for which one):	
Other ingredients: Unknown substance	
Other ingredients: Diluent (excipient-no active substance)	

<sup>3</sup> Biological (human) samples e.g. body fluids (urine, blood), tissues, hair, etc.

<sup>4</sup> Actively collected by drug monitoring systems for monitoring or research purposes

4. Physical description (in case of seizure/collection)				
Form:	tablet <input type="checkbox"/>	capsule <input type="checkbox"/>	liquid <input type="checkbox"/>	
Other (specify):				
Colour:				
For dosage unit:	weight:	diameter:	shape:	logo/markings:
5. Circumstances:				
production <input type="checkbox"/>	trafficking <input type="checkbox"/>	distribution <input type="checkbox"/>	use <input type="checkbox"/>	
6. Price:				
retail (per dosage unit):	wholesale:			
7. Chemical precursors:				
8. Patterns of use:				
9. Other possible uses <sup>5</sup> :				
10. Effects in man unknown				
Objectively observed:				
Subjective (described by users):				

<sup>5</sup>For example, for medical, industrial, ritual, cosmetic, etc., purposes

<p>11. Context of use</p> <p>User group(s):</p> <p>Setting(s):</p> <p>Availability at consumer level:</p>
<p>12. Indication on possible risks</p> <p>Health (individual):</p> <p>Public health:                      Social:</p>
<p>13. In case of production:</p> <p>large-scale <input type="checkbox"/>    small scale <input type="checkbox"/>    unknown <input type="checkbox"/></p> <p>Has any form of organised crime been detected:    Yes <input type="checkbox"/>                      No <input type="checkbox"/></p>
<p>14. In case of trafficking:</p> <p>large-scale <input type="checkbox"/>    small scale <input type="checkbox"/>    unknown <input type="checkbox"/></p> <p>Has any form of organised crime been detected:    Yes <input type="checkbox"/>                      No <input type="checkbox"/></p>
<p>15. In case of distribution:</p> <p>large-scale <input type="checkbox"/>    small scale <input type="checkbox"/>    unknown <input type="checkbox"/></p> <p>Has any form of organised crime been detected:    Yes <input type="checkbox"/>                      No <input type="checkbox"/></p>



## ANNEX II: Council Decision 2005/387/JHA

### **COUNCIL DECISION 2005/387/JHA**

of 10 May 2005

on the information exchange, risk-assessment and control of new psychoactive substances

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 29, 31(1)(e) and 34 (2)(c) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (1),

Whereas:

- (1) The particular dangers inherent in the development of psychoactive substances require rapid action by the Member States.
- (2) When new psychoactive substances are not brought within the scope of criminal law in all Member States, problems may arise in cooperation between the judicial authorities and law enforcement agencies of Member

States owing to the fact that the offence or offences in question are not punishable under the laws of both the requesting and the requested State.

- (3) The European Union Action Plan on Drugs 2000-2004 provided for the Commission to organize an appropriate assessment of the Joint Action of 16 June 1997 concerning the information exchange, risk assessment and the control of new synthetic drugs (2) (hereinafter ‘the Joint Action’) taking into account the external evaluation commissioned by the European Monitoring Centre on Drugs and Drug Addiction (hereinafter ‘the EMCDDA’) of the early warning system. The assessment showed that the Joint Action had fulfilled its expectations. Nevertheless, the outcome of the assessment made it clear that the Joint Action was in need of reinforcement and reorientation. In particular, its main objective, the clarity of its procedures and definitions, the transparency of its operation, and the relevance of its scope had to be redefined. The Communication from the Commission to the European Parliament and the Council on the mid-term evaluation of the EU Action Plan on Drugs (2000-2004) indicated that changes to the legislation would be introduced in order to enhance action against synthetic drugs. The mechanism as established by the Joint Action should therefore be adapted.
- (4) New psychoactive substances can be harmful to health.
- (5) The new psychoactive substances covered by this Decision may include medicinal products as defined in Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to veterinary medicinal products (3) and in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use (4).

- (6) The information exchange under the early warning system, established under the Joint Action, has proved to be a valuable asset to the Member States.
- (7) Nothing in this Decision should prevent Member States from exchanging information, within the European Information Network on Drugs and Drug Addiction (hereinafter ‘the Reitox network’), on emerging trends in new uses of existing psychoactive substances which may pose a potential risk to public health, as well as information on possible public health related measures, in accordance with the mandate and procedures of the EMCDDA.
- (8) No deterioration of either human or veterinary health care as a result of this Decision will be permitted. Substances of established and acknowledged medical value are therefore excluded from control measures based on this Decision. Suitable regulatory and public health related measures should be taken for substances of established and acknowledged medical value that are being misused.
- (9) In addition to what is provided for under the pharmacovigilance systems as defined in Directive 2001/82/EC and in Directive 2001/83/EC, the exchange of information on abused or misused psychoactive substances needs to be reinforced and appropriate cooperation with the European Medicines Agency (hereinafter ‘EMA’) ensured. The United Nations Commission on Narcotic Drugs (hereinafter ‘CND’) Resolution 46/7 ‘Measures to promote the exchange of information on new patterns of drug use and on psychoactive substances consumed’, provides a useful framework for action by the Member States.
- (10) Introduction of deadlines into every phase of the procedure established by this Decision should guarantee that the instrument can react swiftly and enhances its ability to provide a quick-response mechanism.

- (11) The Scientific Committee of the EMCDDA has a central role in the assessment of the risks associated with a new psychoactive substance, it will for the purpose of this Decision be extended to include experts from the Commission, Europol and the EMEA, and experts from scientific fields not represented, or not sufficiently represented, in the Scientific Committee of the EMCDDA.
- (12) The extended Scientific Committee that assesses the risks associated with new psychoactive substances should remain a concise technical body of experts, capable of assessing effectively all risks associated with a new psychoactive substance. Therefore the extended Scientific Committee should be kept to a manageable size.
- (13) Since the objectives of the proposed action, namely to bring about an exchange of information, a risk-assessment by a scientific committee and an EU-level procedure for bringing notified substances under control, cannot be sufficiently achieved by the Member States and can therefore, by reason of the effects of the envisaged action, be better achieved at European Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality as set out in that Article, this Decision does not go beyond what is necessary in order to achieve those objectives.
- (14) In conformity with Article 34(2)(c) of the Treaty, measures based upon this Decision can be taken by qualified majority as these measures are necessary to implement this Decision.
- (15) This Decision respects fundamental rights and observes the principles recognized by Article 6 of the Treaty and reflected in the Charter of Fundamental Rights of the European Union.

HAS DECIDED AS FOLLOWS:

*Article 1*

**Subject matter**

This Decision establishes a mechanism for a rapid exchange of information on new psychoactive substances. It takes note of information on suspected adverse reactions to be reported under the pharmacovigilance system as established by Title IX of Directive 2001/83/EC.

This Decision also provides for an assessment of the risks associated with these new psychoactive substances in order to permit the measures applicable in the Member States for control of narcotic and psychotropic substances to be applied also to new psychoactive substances.

*Article 2*

**Scope**

This Decision applies to substances not currently listed in any of the schedules to:

- a) the 1961 United Nations Single Convention on Narcotic Drugs, that may pose a comparable threat to public health as the substances listed in Schedule I or II or IV thereof, and the 1971 United Nations.

- b) Convention on Psychotropic Substances, that may pose a comparable threat to public health as the substances listed in Schedule I or II or III or IV thereof.

This Decision relates to end-products, as distinct from precursors in respect of which Council Regulation (EEC) No 3677/90 of 13 December 1990 laying down measures to be taken to discourage the diversion of certain substances to the illicit manufacture of narcotic drugs and psychotropic substances (5), and Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (6) provide for a Community regime.

*Article 3*

**Definitions**

For the purpose of this Decision the following definitions shall apply:

- a) ‘new psychoactive substance’ means a new narcotic drug or a new psychotropic drug in pure form or in a preparation;
- b) ‘new narcotic drug’ means a substance in pure form or in a preparation, that has not been scheduled under the 1961 United Nations Single Convention on Narcotic Drugs, and that may pose a threat to public health comparable to the substances listed in Schedule I, II or IV;
- c) ‘new psychotropic drug’ means a substance in pure form or in a preparation that has not been scheduled under the 1971 United Nations Convention on Psychotropic Substances, and that may pose a threat to public health comparable to the substances listed in Schedule I, II, III or IV;

- d) ‘marketing authorization’ means a permission to place a medicinal product on the market, granted by the competent authority of a Member State, as required by Title III of Directive 2001/83/EC (in the case of medicinal products for human use) or Title III of Directive 2001/82/EC (in the case of veterinary medicinal products) or a marketing authorization granted by the European Commission under Article 3 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (7);
- e) ‘United Nations system’ means the World Health Organization (WHO), the Commission on Narcotic Drugs (CND) and/or the Economic and Social Committee acting in accordance with their respective responsibilities as described in Article 3 of the 1961 United Nations Single Convention on Narcotic Drugs or in Article 2 of the 1971 United Nations Convention on Psychotropic Substances;
- f) ‘preparation’ means a mixture containing a new psychoactive substance;
- g) ‘Reporting Form’ means a structured form for notification of a new psychoactive substance and/or of a preparation containing a new psychoactive substance agreed between the EMCDDA/Europol and their respective networks in the Member States’ Reitox and the Europol National Units.

#### *Article 4*

##### **Exchange of information**

1. Each Member State shall ensure that its Europol National Unit and its representative in the Reitox network provide information on the manufacture, traffic and use, including supplementary information on possible medical use, of new

psychoactive substances and of preparations containing new psychoactive substances, to Europol and the EMCDDA, taking into account the respective mandates of these two bodies.

Europol and the EMCDDA shall collect the information received from Member States through a Reporting Form and communicate this information immediately to each other and to the Europol National Units and the representatives of the Reitox network of the Member States, the Commission, and to the EMEA.

2. Should Europol and the EMCDDA consider that the information provided by a Member State on a new psychoactive substance does not merit the communication of information as described in paragraph 1, they shall inform the notifying Member State immediately thereof. Europol and the EMCDDA shall justify their decision to the Council within six weeks.

#### *Article 5*

#### **Joint Report**

1. Where Europol and the EMCDDA, or the Council, acting by a majority of its members, consider that the information provided by the Member State on a new psychoactive substance merits the collection of further information, this information shall be collated and presented by Europol and the EMCDDA in the form of a Joint Report (hereinafter the 'Joint Report'). The Joint Report shall be submitted to the Council, the EMEA and the Commission.

2. The Joint Report shall contain:

- a) a chemical and physical description, including the name under which the new psychoactive substance is known, including, if available, the scientific name (International Non-proprietary Name);



- b) information on the frequency, circumstances and/or quantities in which a new psychoactive substance is encountered, and information on the means and methods of manufacture of the new psychoactive substance;
- c) information on the involvement of organized crime in the manufacture or trafficking of the new psychoactive substance;
- d) a first indication of the risks associated with the new psychoactive substance, including the health and social risks, and the characteristics of users;
- e) information on whether or not the new substance is currently under assessment, or has been under assessment, by the UN system;
- f) the date of notification on the Reporting Form of the new psychoactive substance to the EMCDDA or to Europol;
- g) information on whether or not the new psychoactive substance is already subject to control measures at national level in a Member State;
- h) as far as possible, information will be made available on:
  - i) the chemical precursors that are known to have been used for the manufacture of the substance,
  - ii) the mode and scope of the established or expected use of the new substance,

- iii) any other use of the new psychoactive substance and the extent of such use, the risks associated with this use of the new psychoactive substance, including the health and social risks.

3. The EMEA shall submit to Europol and the EMCDDA the following information on whether in the European Union or in any Member State:

- a) the new psychoactive substance has obtained a marketing authorization;
- b) the new psychoactive substance is the subject of an application for a marketing authorization;
- c) a marketing authorization that had been granted in respect of the new psychoactive substance has been suspended.

Where this information relates to marketing authorizations granted by Member States, these Member States shall provide the EMEA with this information if so requested by it.

4. Member States shall provide the details referred to under paragraph 2 within six weeks from the date of notification on the Reporting Form as set out in Article 4(1).

5. The Joint Report shall be submitted no more than four weeks after the date of receipt of the information from Member States and the EMEA. The Report shall be submitted by Europol or the EMCDDA, as appropriate, in accordance with Article 5(1) and (2).

*Article 6*

**Risk assessment**

1. The Council, taking into account the advice of Europol and the EMCDDA, and acting by a majority of its members, may request that the risks, including the health and social risks, caused by the use of, the manufacture of, and traffic in, a new psychoactive substance, the involvement of organized crime and possible consequences of control measures, be assessed in accordance with the procedure set out in paragraphs 2 to 4, provided that at least a quarter of its members or the Commission have informed the Council in writing that they are in favor of such an assessment. The Member States or the Commission shall inform the Council thereof as soon as possible, but in any case within four weeks of receipt of the Joint Report. The General Secretariat of the Council shall notify this information to the EMCDDA without delay. The General Secretariat of the Council shall notify this information to the EMCDDA without delay.
2. In order to carry out the assessment, the EMCDDA shall convene a special meeting under the auspices of its Scientific Committee. In addition, for the purpose of this meeting the Scientific Committee may be extended by a further five experts at most, to be designated by the Director of the EMCDDA, acting on the advice of the Chairperson of the Scientific Committee, chosen from a panel of experts proposed by Member States and approved every three years by the Management Board of the EMCDDA. Such experts will be from scientific fields that are not represented, or not sufficiently represented, in the Scientific Committee, but whose contribution is necessary for the balanced and adequate assessment of the possible risks, including health and social risks. Furthermore, the Commission, Europol and the EMEA shall each be invited to send a maximum of two experts.
3. The risk assessment shall be carried out on the basis of information to be provided to the scientific Committee by the Member States, the EMCDDA, Europol, the EMEA, taking into account all factors which, according to the

1961 United Nations Single Convention on Narcotic Drugs or the 1971 United Nations Convention on Psychotropic Substances, would warrant the placing of a substance under international control.

4. On completion of the risk assessment, a report (hereinafter the ‘Risk Assessment Report’) shall be drawn up by the Scientific Committee. The Risk Assessment Report shall consist of an analysis of the scientific and law enforcement information available, and shall reflect all opinions held by the members of the Committee. The Risk Assessment Report shall be submitted to the Commission and Council by the chairperson of the Committee, on its behalf, within a period of twelve weeks from the date of the notification by the General Secretariat of the Council to the EMCDDA referred to in paragraph 1.

The Risk Assessment Report shall include:

- a) the physical and chemical description of the new psychoactive substance and its mechanisms of action, including its medical value;
- b) the health risks associated with the new psychoactive substance;
- c) the social risks associated with the new psychoactive substance;
- d) information on the level of involvement of organized crime and information on seizures and/or detections by the authorities, and the manufacture of the new psychoactive substance;
- e) information on any assessment of the new psychoactive substance in the United Nations system;

- f) where appropriate, a description of the control measures that are applicable to the new psychoactive substance in the Member States;
- g) options for control and the possible consequences of the control measures, and
- h) the chemical precursors that are used for the manufacture of the substance.

*Article 7*

**Circumstances where no risk assessment is carried out**

1. No risk assessment shall be carried out in the absence of a Europol/EMCDDA Joint Report. Nor shall a risk assessment be carried out where the new psychoactive substance concerned is at an advanced stage of assessment within the United Nations system, namely once the WHO expert committee on drug dependence has published its critical review together with a written recommendation, except where there is significant new information that is relevant in the framework of this Decision.
2. Where the new psychoactive substance has been assessed within the United Nations system, but it has been decided not to schedule the new psychoactive substance under the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances, a risk assessment shall be carried out only if there is significant new information that is relevant in the framework of this Decision.
3. No risk assessment shall be carried out on a new psychoactive substance if:

- a) the new psychoactive substance is used to manufacture a medicinal product which has been granted a marketing authorization; or,
- b) the new psychoactive substance is used to manufacture a medicinal product for which an application has been made for a marketing authorization or,
- c) the new psychoactive substance is used to manufacture a medicinal product for which a marketing authorization has been suspended by a competent authority.

Where the new psychoactive substance falls into one of the categories listed under the first subparagraph, the Commission, on the basis of data collected by EMCDDA and Europol, shall assess with the EMEA the need for further action, in close cooperation with the EMCDDA and in accordance with the mandate and procedures of the EMEA.

The Commission shall report to the Council on the outcome.

#### *Article 8*

##### **Procedure for bringing specific new psychoactive substances under control**

1. Within six weeks from the date on which it received the Risk Assessment Report, the Commission shall present to the Council an initiative to have the new psychoactive substance subjected to control measures. If the Commission deems it is not necessary to present an initiative on submitting the new psychoactive substance to control measures, within six weeks from the date on which it received the Risk Assessment Report, the Commission shall present a report to the Council explaining its views.

2. Should the Commission deem it not necessary to present an initiative on submitting the new psychoactive substance to control measures, such an initiative may be presented to the Council by one or more Member States, preferably not later than six weeks from the date on which the Commission presented its report to the Council.

3. The Council shall decide, by qualified majority and acting on an initiative presented pursuant to paragraph 1 or 2, on the basis of Article 34(2) (c) of the Treaty, whether to submit the new psychoactive substance to control measures.

#### *Article 9*

#### **Control measures taken by Member States**

1. If the Council decides to submit a new psychoactive substance to control measures, Member States shall endeavor to take, as soon as possible, but no later than one year from the date of that decision, the necessary measures in accordance with their national law to submit:

- a) the new psychotropic drug to control measures and criminal penalties as provided under their legislation by virtue of their obligations under the 1971 United Nations Convention on Psychotropic Substances;
- b) the new narcotic drug to control measures and criminal penalties as provided under their legislation by virtue of their obligations under the 1961 United Nations Single Convention on Narcotic Drugs.

2. Member States shall report the measures taken to both the Council and the Commission as soon as possible after the relevant decision has been taken. Thereafter this information shall be communicated to the EMCDDA, Europol, the EMEA, and the European Parliament.

3. Nothing in this Decision shall prevent a Member State from maintaining or introducing on its territory any national control measure it deems appropriate once a new psychoactive substance has been identified by a Member State.

#### *Article 10*

##### **Annual report**

The EMCDDA and Europol shall report annually to the European Parliament, the Council and the Commission on the implementation of this Decision. The report will take into account all aspects required for an assessment of the efficacy and achievements of the system created by this Decision. The Report shall, in particular, include experience relating to coordination between the system set out in this Decision and the pharmacovigilance system.

#### *Article 11*

##### **Pharmacovigilance system**

Member States and the EMEA shall ensure an appropriate exchange of information between the mechanism set up by means of this Decision and the pharmacovigilance systems as defined and established under Title VII of Directive 2001/82/EC and Title IX of Directive 2001/83/EC.



*Article 12*

**Repeal**

The Joint Action on New Synthetic Drugs of 16 June 1997 is hereby repealed. Decisions taken by the Council based on Article 5 of that Joint Action shall continue to be legally valid.

*Article 13*

**Publication and taking effect**

This Decision shall take effect on the day following that of its publication in the Official Journal of the European Union.

Done at Brussels, 10 May 2005.

For the Council

The President

KRECKÉ

(1) Opinion delivered on 13 January 2004 (not yet published in the Official Journal).

(2) OJ L 167, 25.6.1997, p. 1.

(3) OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).

(4) OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

(5) OJ L 357, 20.12.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1232/2002 (OJ L 180, 10.7.2002, p. 5).

(6) OJ L 47, 18.2.2004, p. 1.

ANNEX III: Royal Decree 1194/2011

# OFFICIAL STATE GAZETTE

No. 202 Tuesday, 23 August 2011.

## I. GENERAL PROVISIONS.

### MINISTRY OF HEALTH, SOCIAL SERVICES AND EQUALITY.

14074

*Royal Decree 1194/2011, of 19 August, which establishes the procedure by which a substance is to be considered a narcotic on the national level.*

Law 17/1967, of 8 April, which updates Spanish legislation on narcotics, adapting it to the terms set forth in the 1961 United Nations Single Convention, regulates the seizure by the Spanish state, within its own territory, of the cultivation and production, manufacture and extraction, storage, transport and distribution, import, export, and transit of raw materials and narcotic products, in addition to the prescription, dispensation, possession, use and consumption thereof.

Specifically, paragraph 1 of article 2 of said law considers any natural or synthetic substances included in Schedules I and II attached to the 1961 United Nations Single Convention on Narcotic Drugs as narcotics and any others that acquire such consideration on an international level, pursuant to said convention, and on a national level, under the procedure established by law.

The purpose of this royal decree is to establish the procedure by which a natural or synthetic substance that is not included in Schedules I and II attached to the 1961 United Nations Single Convention or that has not acquired such consideration on an international level is to be considered as a narcotic on a national level. Consequently, it also establishes how control measures applicable to narcotics shall be imposed on these substances.

In turn, this royal decree also defines national control measures for the substance Tapentadol prior to its release on the market in Spain, in order to subject it to the control

measures set forth in Law 17/1967, of 8 April, for the substances included in Schedule I attached to the 1961 United Nations Single Convention on Narcotic Drugs. These control measures are essential in correctly managing the risk of misuse, abuse and deviation to the illegal Tapentadol trade.

Tapentadol was classified as a narcotic after the Spanish Agency of Medicines and Medical Devices conducted the relevant assessment process, implemented in accordance with this royal decree, the results of which have been positive.

This royal decree underwent the procedure set forth in Directive 98/34/EC of the European Parliament and of the Council of 22 June, which establishes the reporting procedure in relation to technical rules and regulations and in Royal Decree 1337/1999, of 31 July, which regulates how information is sent in relation to technical rules and regulations regarding information society services, which incorporates this directive into the Spanish regulatory framework.

The Autonomous Regions and the cities of Ceuta and Melilla, as well as the affected sectors, among other parties, were consulted in drafting this royal decree, and the report by the Council of Consumers and Users was attained.

This royal decree was passed in implementation of Narcotics Law 17/1967, of 8 April, and is defined as legislation on pharmaceutical products for the purposes set forth in article 149.1.16 of the Constitution.

In virtue whereof, at the proposal of the Minister of Health, Social Policy and Equality, with prior approval from the Minister of Territorial Policy and Public Administration, in accordance with the Council of State and after deliberation by the Cabinet at their meeting of 19 August, 2011,

I HEREBY DECREE:

Article 1. Subject matter

The subject matter of this royal decree is to establish the procedure by which a substance shall be considered as a narcotic on a national level, in implementation of paragraph 1 of article 2 of Law 17/1967, of 8 April, which updates Spanish legislation on narcotics, adapting it to the terms set forth in the 1961 United Nations Single Convention.

*Article 2. Assessment criteria*

The assessment of substances liable to be considered as narcotics on a national level is the structured process by which verification takes place to determine whether a substance meets all

or some of the following criteria:

- a) Similarities to other known narcotic substances.
- b) Therapeutic use.
- c) Risk of abuse.
- d) Control in other countries and decisions adopted by the competent authorities in the European Union and by the international organizations in which the Kingdom of Spain is a member.
- e) Other accompanying criteria that provide grounds for control of new substances as narcotics in Spain.

*Article 3. Assessment process*

1. The procedure by which a substance shall be considered a narcotic on a national level can be commenced by the powers vested in the Spanish Agency of Medicines and Medical Devices:

- a) When such agency detects such need through the activities in which it engages in accordance with its Bylaws.
- b) At the duly grounded request of another agency, organization or public entity of the General Administration of the State or the Public Prosecutor on Anti-drug issues.

2. When the substance in question is an active substance that is part of an authorized medicine or one in the authorization process, notwithstanding the hearing procedure established for this purpose, the Spanish Agency of Medicines and Medical Devices shall inform the holder or applicant so that the latter can furnish any considerations deemed appropriate before adopting the decision about whether to recognize the substance in question as a narcotic.

In addition, any companies or entities that could be affected by such decision shall be notified of the commencement of the procedure so that they may contribute any declarations, documents or information deemed pertinent within 15 days.

Article 4. *Recognition of classification as a narcotic*

When the assessment stated in article 2 results in a positive conclusion, prior to notification to the competent authorities of the European Union, if required under applicable European regulations, with a report in favor by the Spanish Government Office for the National Plan on Drugs, the Spanish Agency of Medicines and Medical Devices shall prepare and submit to the head of the Ministry of Health, Social Policy and Equality a resolution proposal by which the classification of the substance subject to assessment as a narcotic on a national level is declared, including control measures that should be applied thereto. The final resolution shall be formatted as a Ministry Order and shall be published in the "Spanish National Gazette".

Article 5. *Control measures*

Once the classification of a substance as a narcotic has been determined in accordance with the procedure described herein, the control measures set forth for substances included in either Schedule I or Schedule II attached to the 1961 Single Convention, as appropriate, shall apply on a national level.

Likewise, the relevant control measures shall also be imposed upon medicines containing said substances.

Sole additional provision. *Declaration of the substance Tapentadol as a narcotic on a national level*

1. The substance Tapentadol shall be considered a narcotic on a national level, with the formula: 3-[(1R, 2R)-3-(dimethylamino)-1-ethyl-2-methylpropyl] phenol.

2. The control measures applicable to Tapentadol on a national level shall be those set forth for the substances included in Schedule I attached to the 1961 Single Convention.

3. Consequently, the following measures shall apply to Tapentadol, its salts, esters, ethers and isomers that can be made from it:

a) Upon entry into force of this royal decree, manufacturers or importers shall declare the stocks of this product in their possession to the Spanish Agency of Medicines and Medical Devices.

b) The manufacturing, import or export forecasts of such products shall be submitted to the Spanish Agency of Medicines and Medical Devices for prior authorization.

c) Possession, marketing, distribution, prescription and dispensation of the aforementioned substances and/or preparations shall take place in accordance with the terms of the regulations in force for narcotic substances contained in Schedule I attached to the 1961 Single Convention.

Final provision one. *Competent authority*

This royal decree is passed pursuant to the terms of article 149.1.16 of the Constitution, which grants the State exclusive authority to pass legislation on pharmaceutical products.

Final provision two. *Authorization of regulatory implementation*

The head of the Ministry of Health, Social Policy and Equality is authorized to pass any provisions required for the implementation and fulfillment of the terms set forth herein.

Likewise, the head of the Ministry of Health, Social Policy and Equality is also authorized to amend the sole additional provision herein by means of a Ministry Order.

Final provision three. *Entry into force*

This royal decree shall enter into force on the date following its publication in the "Spanish National Gazette".

Passed in Madrid, 19 August 2011

JUAN CARLOS R

The Minister of Health,  
Social Policy and Equality

LEIRE PAJÍN IRAOLA

ANNEX IV: MO under which Ketamine is included in Schedule I of RD 2829/1977

## OFFICIAL STATE GAZETTE

### I. GENERAL PROVISIONS.

## MINISTRY OF HEALTH AND SOCIAL POLICY

**16025** *Order SAS/2712/2010, of 13 October, under which the substance Ketamine is included in Schedule I of Royal Decree 2829/1977, of 6 October, which regulates the manufacture, distribution, prescription and dispensation of psychotropic substances and preparations.*

*cve: BOE-A-2010-16025*

At its 49th session held in March 2006, the Commission on Narcotic Drugs of the United Nations Economic and Social Council passed resolution 49/6, entitled “Listing of Ketamine as a controlled substance”, which urged Member States to consider the possibility of controlling the use of Ketamine, including this substance in the list of controlled substances pursuant to their national legislations, when the domestic situation so required, taking the extensive misuse and traffic of this substance into account.

In March 2007, the Commission passed Resolution 50/3, entitled “Responding to the threat posed by the abuse and diversion of ketamine”, which encouraged Member States to consider adopting a system of precautionary measures for use by their government agencies to facilitate the timely detection of the diversion of ketamine.

Furthermore, at its 53rd session, held in March 2010, this Commission on Narcotic Drugs passed E/CN.7/2010/L.9, entitled “International cooperation in countering the covert administration of psychoactive substances related to sexual assault and other criminal acts”, by which, among other recommendations, it urges Member States to consider the possibility that national legislation or relevant guidelines may take into account aggravating circumstances in cases where psychoactive substances are covertly administered to commit sexual assault.

In drafting this provision, the affected sectors have been consulted.



For the reasons explained above, and taking into consideration the increase in recent years in data on Ketamine abuse and traffic in Spain, it is incumbent upon me to pass this order, in virtue of the power invested in me under the final provision of Royal Decree 2829/1977, of 6 October, which regulates the manufacture, distribution, prescription and dispensation of psychotropic substances and preparations.

In virtue whereof, I hereby decree:

*Article 1. Inclusion of the substance Ketamine in Schedule IV of Annex I of Royal Decree 2829/1977, of 6 October*

That the substance Ketamine shall henceforth be included in Schedule IV of Annex I of Royal Decree 2829/1977, of 6 October, as well as its stereochemical variants, racemates and salts, whenever the existence of such is possible, and the control measures and criminal penalties set forth for the substances contained in said control schedules shall be applicable.

*Article 2. Actions by entities*

Within three months following the entry into force of this order, the manufacturers, importers, exporters, distributors or dispensers of said substance, as well as its stereochemical variants, racemates and salts, shall adapt their activities to the legal requirements set forth for the psychotropic products in Schedule IV of Annex I of Royal Decree 2829/1977, of 6 October, and in the Order from 14 January 1981.

Sole final provision. *Entry into force*

This Order shall enter into force on the date following its publication in the "Spanish National Gazette".

Madrid, 13 October 2010. The Minister of Health and Social Policy, Trinidad Jiménez  
García-Herrera

ANNEX V: MO under which Mephedrone is included in Schedule I of RD 2829/1977

## OFFICIAL STATE GAZETTE

### I. GENERAL PROVISIONS.

## MINISTRY OF HEALTH, SOCIAL POLICY AND EQUALITY

14074

*16025 Order SPI/201/2011, of 3 February, under which the substance 4-Methylmethcathinone (Mephedrone) is included in Schedule I of Royal Decree 2829/1977, of 6 October, which regulates the manufacture, distribution, prescription and dispensation of psychotropic substances and preparations.*

The European Monitoring Centre on Drugs and Drug Addiction has drawn up a report assessing the risks associated with the use of the psychoactive substance Mephedrone, the street name for 4-Methylmethcathinone.

Based on this report, Mephedrone is considered a new psychotropic substance with physical effects similar to those of other stimulants, especially ecstasy (MDMA), which can be used as an alternative to illegal stimulants, can create addiction and is highly prone to abuse.

In light of its stimulant properties, attractive potential, the health risk posed by the use of Mephedrone, its capacity to create addiction in users, the fact that the European Union currently has no established or recognized medical value or use for it, and the need to act with precaution, the Council of the European Union has adopted Decision 2010/759/EU, of 2 December 2010, which places 4-Methylmethcathinone (Mephedrone) under control measures (Official Journal of the European Union L 322, of 8 December 2010).

Article 1 of this Decision sets forth that Member States shall take the necessary measures to place the substance 4-Methylmethcathinone (Mephedrone) under control measures and criminal penalties pursuant to national legislation in force in this regard, in application of the obligations bestowed upon them in virtue of the 1971 United Nations Convention on

Psychotropic Substances (Spanish National Gazette No 218 dated 10 September 1976).

In drafting this provision, the affected sectors have voiced their opinions.

For the reasons set forth above, pursuant to the power invested in me under the final provision of Royal Decree 2829/1977, of 6 October, which regulates the manufacture, distribution, prescription and dispensation of psychotropic substances and preparations, this provision is passed.

In virtue whereof, I hereby decree:

*Article 1. Inclusion of the substance 4-Methylmethcathinone in Schedule I of Annex I of Royal Decree 2829/1977, of 6 October*

That the substance 4-Methylmethcathinone shall henceforth be included in Schedule I of Annex I of Royal Decree 2829/1977, of 6 October, as well as its stereochemical variants, racemates and salts, and the control measures and criminal penalties set forth for the substances contained in said control schedules shall be applicable.

*Article 2. Actions by entities*

Any entity or individual in possession of this substance or any preparations containing it shall proceed to deposit them at the Narcotic and Psychotropic Drug Unit of the Deputy Directorate General for Medicine Inspection and Control of the Spanish Agency of Medicines and Medical Devices, or at the Pharmacy Services in the Health Departments of the Regional Government Offices or Deputy Offices thereof within 30 calendar days starting from the date on which this order enters into force.

*Final provision one. Regulatory authorization*

This order is passed in virtue of the powers invested under the final provision of Royal Decree 2829/1977 of 6 October.

*Final provision two. Entry into force*

This Order shall enter into force on the date following its publication in the "Spanish National Gazette".

Madrid, 3 February 2011. The Minister of Health, Social Policy and Equality, Leire Pajín Iraola

ANNEX VI: MO under which 5-IT is included in Schedule I of RD 2829/1977

## OFFICIAL STATE GAZETTE

### I. GENERAL PROVISIONS.

#### MINISTRY OF HEALTH, SOCIAL SERVICES AND EQUALITY

**5265** *Order SSI/806/2014, of 8 May, under which the substance 5-(2-Aminopropyl)indole (5-IT) is included in Schedule I of Royal Decree 2829/1977, of 6 October, which regulates medicinal psychotropic substances and preparations, as well as the control and inspection of the manufacture, distribution, prescription and dispensation thereof, and which transfers gamma-hydroxybutyric acid (GHB) from Schedule IV to Schedule II of Annex I of said royal decree.*

Council of the European Union Decision 2013/496/EU, of 7 October 2013, which lists 5-(2-Aminopropyl)indole as a controlled substance, defines 5-(2-Aminopropyl)indole (5-IT) as a new psychotropic substance that must be subject to control measures and criminal penalties set forth in national legislation on this matter, by virtue of their obligations under the 1971 United Nations Convention on Psychotropic Substances (Spanish National Gazette No 218 dated 10 September 1976).

In light of its stimulant properties, hallucinogenic effects, the health risk and the fact that it currently has no known, established or recognized medical use, 5-IT must be placed under control, applying control measures in proportion to the risks posed by the substance.

There are currently no authorized medicines in Spain that contain 5-IT in their composition.

Furthermore, at the 56th session of the United Nations Commission on Narcotic Drugs

Decision 56/1 was passed under a recommendation by the World Health Organization. At the same session, it was agreed to transfer gamma-hydroxybutyric acid (GHB) from Schedule IV to Schedule II of the 1971 United Nations Convention on Psychotropic Substances.

Based on the foregoing, as set forth in paragraph 7 of article 2 of the aforementioned Convention ratified by Spain and in implementation of the power invested in me under the final provision of Royal Decree 2829/1977, of 6 October, which regulates medicinal psychotropic substances and preparations, as well as the control and inspection of the manufacture, distribution, prescription and dispensation thereof, this provision is passed.

In preparing this order, the affected sectors have voiced their opinions. In virtue whereof, I hereby decree:

*Article 1. Inclusion of the substance 5-(2-Aminopropyl)indole in Schedule I of Annex I of Royal Decree 2829/1977, of 6 October.*

That the substance 5-(2-Aminopropyl)indole, also known as 5-IT, shall henceforth be included in Schedule I of Annex I of Royal Decree 2829/1977, of 6 October, which regulates medicinal psychotropic substances and preparations, as well as the control and inspection of the manufacture, distribution, prescription and dispensation thereof, as well as its stereochemical variants, racemates and salts, whenever the existence of such is possible, and the control measures and criminal penalties set forth for the substances contained in said control schedule shall be applicable.

*Article 2. Transfer of the substance gamma-hydroxybutyric acid (GHB) from Schedule IV to Schedule II of Annex I of Royal Decree 2829/1977, of 6 October.*

That the substance gamma-hydroxybutyric acid (GHB), as well as any salts that can be made from it, shall be transferred from Schedule IV to Schedule II of Annex I of Royal Decree 2829/1977, of 6 October.

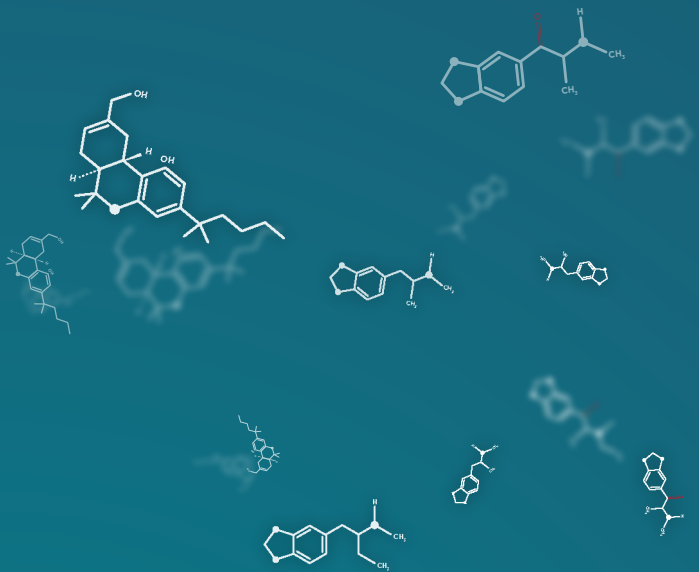
*Sole additional provision. Actions by entities.*

From the time this order enters into force, the manufacturers, importers, exporters, distributors or dispensers of said substance shall adapt their activities to the legal requirements set forth for the psychotropic products in Schedules I and II of Annex I of Royal Decree 2829/1977, of 6 October, and in the Order from 14 January 1981, which implements Royal Decree 2829/1977, of 6 October, which regulates medicinal psychotropic substances and preparations, as well as the control and inspection of the manufacture, distribution, prescription and dispensation thereof.

*Sole final provision. Entry into force.*

This Order shall enter into force on the date following its publication in the "Spanish National Gazette".

Madrid, 8 May 2014. The Minister of Health, Social Services and Equality, Ana Mato Adrover.



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