



European Monitoring Centre
for Drugs and Drug Addiction



EMCDDA–Europol 2015 Annual Report on the implementation of
Council Decision 2005/387/JHA

In accordance with Article 10 of Council Decision 2005/387/JHA on the information
exchange, risk assessment and control of new psychoactive substances

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Annex 1. New psychoactive substances first notified to the Early Warning System in 2015 under the terms of Council Decision 2005/387/JHA

Annex 2. List of Early Warning System alerts issued to the national EWS correspondents in 2015

Background to this report

As part of the response to new psychoactive substances within the European Union (EU), the Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk assessment and control of new psychoactive substances (hereafter the 'Council Decision') established a mechanism for rapid information exchange on substances that may pose public health and social threats, including the involvement of organised crime. This provides a legal basis for the institutions of the EU and the Member States to monitor all new narcotic and psychotropic substances that appear on the European drug scene. Where necessary, the Council Decision also provides for an assessment of the risks associated with these new substances, so that control measures deriving from Member States' obligations to the United Nations drug control conventions ⁽¹⁾ can also be applied to new psychoactive substances.

Under Article 4 of the Council Decision, the EMCDDA and Europol, in close collaboration with their respective expert networks, the Reitox National Focal Points and Europol National Units, are assigned a central role in detecting, notifying and monitoring new psychoactive substances. The information exchange element of the Council Decision has been implemented by the EMCDDA and Europol as the *European Union Early Warning System on New Psychoactive Substances* (hereafter 'EU Early Warning System'). In addition, where necessary, and in cooperation with the European Medicines Agency (EMA), the EMCDDA and Europol may collect, analyse and present information on a new psychoactive substance in the form of a *Joint Report* (Article 5). This report provides evidence to the Council of the European Union and the European Commission on the need to request a *risk assessment* on a new psychoactive substance. Such a risk assessment examines the health and social risks posed by a new substance including: the use of, manufacture of, and, traffic in, a new psychoactive substance; the involvement of organised crime; and, the possible consequences of control measures. In order to conduct the risk assessment, the EMCDDA convenes a special meeting under the auspices of its Scientific Committee, extended with additional experts as necessary (Article 6).

To ensure transparency in the implementation of the Council Decision, Article 10 stipulates that:

'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'.

⁽¹⁾ The 1961 United Nations Single Convention on Narcotic Drugs and the 1971 United Nations Convention on Psychotropic Substances.

In compliance with Article 10, the EMCDDA and Europol herewith present the eleventh such annual report which covers the period 1 January to 31 December 2015. The report outlines the results of the implementation, describes key issues arising from accumulated experiences, and also serves as a monitoring tool. In order to facilitate the reading of the report, the reader is referred to the text of the Council Decision ⁽²⁾.

Annex 1 provides the list of new psychoactive substances notified for the first time in 2015. This includes the International Union of Pure and Applied Chemistry (IUPAC) chemical name, the reporting country, and date of notification for each substance. Further information on these substances is available from the EMCDDA and Europol.

Annex 2 provides a detailed list of all the EWS alerts issued to the national EWS correspondents in 2015.

⁽²⁾ Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances, OJ L 127, 20.5.2005, p. 32.

1. Overview

The year 2015 saw a consistent trend in the number, type and availability of new psychoactive substances detected in Europe. 98 new substances were notified for the first time to the EU EWS in 2015, making the total number of substances routinely monitored by the EWS (more than 560 substances as of December 2015) more than double the total number of substances monitored by both UN conventions. Importantly, these numbers were accompanied by increasing reports of harms associated with the use of NPS. These resulted in 17 public health-related alerts issued, two Joint Reports and a risk assessment.

The total number of NPS seizures and amount of substances seized in Europe in 2014 continued to increase, keeping with the growing trend seen in the last years. In 2014, 365 different NPS were detected across Europe including many of those seen in previous years.

The nature of these challenges along with the pace at which they arise continue to stretch the capacity of the EU and the Reitox Early Warning System networks, who continue to provide rapid response to emerging threats.

Box 1. **Headline activities in 2015**

- 98 new psychoactive substances were formally notified for the first time in 2015;
- **17 public health-related alerts** were issued by the EMCDDA to the EU EWS Network;
- **2 Joint Reports** were prepared by the EMCDDA and Europol:
 - **α-PVP** (1-phenyl-2-(1-pyrrolidinyl)-1-pentanone)

a potent psychostimulant used by 'recreational' drug users, and by those who inject stimulants and opioids;

- **acetylfentanyl** (*N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]acetamide)

a synthetic opioid associated with an outbreak of acute intoxications in 2015;

- **a risk assessment on α-PVP** was conducted by the Scientific Committee of the EMCDDA;
- **more than 560 new psychoactive substances** are now routinely monitored by the EU EWS; Close to **600 reporting forms** were submitted by national early warning correspondents to the EMCDDA;
- More than **30 media requests** were responded to and over **20 technical training events, forums, conferences and meetings on NPS** were attended in 17 different countries.

2. Implementation arrangements and cooperation with the European Union Pharmacovigilance system

2.1 Specific implementation arrangements

2.1.1 Assistance to national early warning systems

The EMCDDA continued to provide assistance, advice and feedback to the 28 Member States, Turkey and Norway, as well as other members of the EU EWS Network on a daily basis.

This assistance was given by providing timely information on the NPS situation in Europe, with a special emphasis on emerging issues relevant to public health, and by maintaining a comprehensive, up-to-date repository of information on close to 600 substances. The information on each of these substances included details on seizures and serious adverse events in individual Member States as well as relevant data on chemistry, chemical analysis, pharmacology, toxicology, and epidemiology extracted from relevant scientific and patent literature and other open information sources (monitored daily).

In addition, the EMCDDA responded to a number of ad hoc requests from the national early warning systems and focal points, many of which were time-sensitive and of a highly technical nature. These included queries on naming of NPS, on analytical data, and details of EU legislation regarding new psychoactive substances among others.

2.1.2 Annual meeting of the EU Early Warning System Network

The 15th annual meeting of the Reitox Early Warning System Network took place on 8 and 9 June 2015 in Lisbon. Prior to the meeting, the correspondents were asked to provide information on: recent developments in their national early warning system; emerging concerns; and national alert systems in place. The emerging themes arising from the responses to the questionnaires were discussed at the meeting, and the discussions were used to gain a shared understanding of the NPS situation at a European level.

The meeting also served to discuss the strengthening of the toxicovigilance component of the EWS. Presentations focusing on substances under intense monitoring (e.g. on fentanyl and other potent opioids) were also delivered.

2.1.3 Detecting signals and responding to harms associated with NPS

The fast-changing nature of the NPS market associated with the sheer number of substances being monitored presents well-known challenges for the early-warning function. The last few years have seen significant efforts to conceptualise and develop a new methodology for detecting and responding to signals of harms associated with NPS.

In 2015, the monitoring of open source information (OSI) was intensified and methodology was strengthened to allow daily monitoring of events that may be linked to serious adverse events and which require urgent responses. Relevant information that was identified through this methodology was cross-referenced with data reported by Member States in order to

prioritise monitoring and responses, which in some cases have resulted in public health-related alerts (see section 3.2). Internet snapshots were conducted for substances/products under intensive monitoring, including α -PVP, acetylfentanyl, MDMB-CHMICA, and a herbal smoking mixture containing synthetic cannabinoid(s) with the brand name 'Mocarz', which was associated with mass intoxications in Poland in July 2015.

The development of the Toxicovigilance System Framework continued to be a key activity, supported by two studies commissioned externally:

- a study focusing on the role of poison control centres for monitoring non-fatal intoxications associated with NPS (concluded);
- a study examining the current body of knowledge and practice with respect to risk communication to drug users and the general population related to serious hazards and risks of an urgent nature that are associated with new psychoactive substances and illicit drugs (in progress);

2.1.4 Links with forensic science and toxicology networks

In 2015, the EMCDDA established cooperation with the Institute for Health and Consumer Protection of the European Commission's Joint Research Centre (JRC) and strengthened the links with the European Commission's Customs Laboratories European Network (CLEN) project group, funded by the EC Customs 2020 programme. The CLEN project group is composed of customs laboratories from the 28 EU Member States and aims to promote cooperation among them by sharing analytical data, reference samples and expertise on chemicals, including NPS. The EMCDDA hosted the second meeting of the CLEN project group, which took place in February.

In addition the agency continued to cooperate actively with the European Network of Forensic Science Institutes (ENFSI).

During the year, the EMCDDA further strengthened its links with other forensic science and toxicology networks. Ongoing exchange took place during the year between the agency's staff and international leading forensic, toxicology and law enforcement experts in the field of NPS.

2.1.5 Supporting activities

In 2015, the EMCDDA provided technical training on NPS in 23 meetings, forums, conferences or events that took place in 17 different countries. These meetings and training events served to increase understanding of the NPS phenomenon and the visibility of the EU actions in this area but also to provide technical assistance and nurture relationships within the Network.

2.1.6 Europol

Europol has observed that law enforcement agencies across the EU are increasingly aware and more involved in investigations concerning NPS, despite many legislative and administrative constraints. Various advanced tactics and techniques, such as controlled

deliveries and cyber-purchase operations have already been used by many Member States to respond to the increasing problem of NPS.

In 2015 the first Joint Investigation Team (JIT) that was set up between two Member States, Europol and Eurojust in 2014, and which focused on an Organised Crime Group (OCG) involved in the importation of different NPS from China to the EU and their further distribution across the EU, was closed with very positive results (including arrests and convictions).

Strategically, NPS are an EU priority in terms of the Policy Cycle for Organised Crime. The Synthetic Drugs priority in the European Multidisciplinary Platform Against Criminal Threats (EMPACT) includes NPS and, in 2015, several operational activities were conducted in the framework of the Operational Action Plan. For example, in the framework of Operation Blue Amber liaison officers from the EU Member States and colleagues from other international partners coordinated the exchange of information and intelligence between national law enforcement authorities from a 24/7 operational coordination centre at Europol's headquarters in The Hague. Europol specialists and analysts provided support from its headquarters and also on the spot in EU Member States. The Operation included two drugs action weeks. Synthetic drugs and NPS trafficking, and the use of small postal parcels to traffic the drugs, are key issues for many European countries. In total, nearly 300 kg of synthetics drugs and NPS were seized within and outside the European Union.

Europol also contributed to two similar operations with global dimensions organised by the World Customs Organization (WCO). Operation CATalyst was completed with successful results, having intercepted and seized 13 408 kg of drugs in 371 cases, of which 1 435 kg were NPS-related. Operation CATalyst helped to expose new global trends of NPS abuse. These findings have been of particular value to country leaders, policy- and law-makers, as well as law enforcement agencies around the world.

The range of the second operation — SKY-NET II — was extended to illicit trafficking and/or diversion of precursors. The results of this operation included 876 seizure cases reported by the participating WCO Members with the interception of 9 293 kg of illicit drugs and precursors. Operation SKY-NET II collected an enormous amount of useful data, which helped Members identify the smuggling trends and the risk areas of postal and express courier channels. It also strengthened the ties between customs, other agencies and stakeholders, and across borders around the world. The Operation provided a good analysis and an overview of the global situation which could assist country leaders, policy-makers and law enforcement agencies in their self-assessment and future steering of enforcement focus.

As noted in previous years, China has been reported by Member States as the main source of NPS delivered to Europe. To a lesser extent, India also plays a role as a source country.

In 2015 Europol observed an increased number of NPS investigations registered as well as a growing number of requests for operational and on-the-spot support. Generally it has been noticed that Member States are showing a greater interest in these types of investigations and that they are focusing on them.

In 2015 no records were provided to Europol by Member States indicating illicit synthesis of NPS with one exception. In October 2015, Dutch authorities seized two illicit synthetic drug

sites in Stevensbeek and Hoornsterzwaag. Illicit laboratories were linked via similar equipment, chemicals and final products seized. The synthesis and crystallisation processes were identified on the two sites. Large-scale manufacture of MDMA and mephedrone was confirmed. In total 160 kg of MDMA and 26 kg of mephedrone crystals were seized.



160 kg of MDMA were seized.



Calculation yield: approx. 1 300 000 MDMA tablets (120 mg concentration, average)



Similar equipment was seized in two locations, which was used for the illicit synthesis of mephedrone. As final product, 26 kg of mephedrone crystals were seized.

These combination sites (where two different products were being manufactured) clearly indicate that OCGs are not just limited to illicit sites where manufacture of traditional synthetic drugs takes place. They use opportunities and market demand to generate more profits.

Another related issue of concern is the importation of precursors that can be used for the synthesis of NPS. Already in previous years notifications on NPS precursors seizures were provided to Europol by Poland and the Netherlands (*N*-acetylmephedrone and 2-bromo-4'-methylpropiofenone as starting material and precursor for mephedrone).

Based on the intelligence gathered, shipment of 2-bromo-4'-methylpropiofenone for illicit mephedrone manufacture is continued and sourced in China. As it was highlighted in previous reports, due to the lack of knowledge about precursors for NPS by law enforcement and to their non-controlled status, criminal groups could exploit this gap in future and the synthesis of some new psychoactive substances in Europe may become more common.

In 2015, a few processing sites of NPS, mainly synthetic cannabinoids (mixing, packaging, labelling), were reported by Poland, Hungary and Germany.

Based on a few indicators such as number of NPS reported for the first time, number of seizures reported in the EU and amount of NPS seized, as well as on intelligence, Europol believes that the number of operating illicit sites producing NPS is much higher than those dismantled and reported to the agency.

With regards to trafficking, the *modi operandi* look similar to previous years. Bulk amounts of NPS are shipped from China to the EU and then further distributed across Europe. For small quantities, either online orders are placed directly with Chinese vendors or via internet smart shops located in some European countries. Orders are then shipped using the postal service and couriers (delivery companies).

Investigations conducted in the Member States, and supported by Europol, identified a few hubs (countries) that are currently used to receive, store and further distribute NPS imported from China (the Netherlands, Spain and the United Kingdom).

NPS are mainly imported in the form of bulk powder or herbal substance. Subsequently, they are further processed for sale to consumers. This can involve mixing them with other substances such as caffeine, or impregnating chemicals into the herbs or pressing them into tablets before packaging takes place.

In 2015 the United Kingdom (Scottish police), supported by a few Member States and Europol, initiated an intelligence enquiry into the use of Damiana herbs and Marshmallow leaves as cutting agents for processing synthetic cannabinoids.

These herbal parts are important ingredients in synthetic cannabinoid products, which are finally sold as 'legal highs'. During the processing of synthetic cannabinoids in Europe, these herbal parts are mixed with active synthetic cannabinoid and laced with acetone. Compared to traditional synthetic drugs, it could be said that these herbal ingredients play a similar role to the cutting agents used for amphetamine, MDMA and methamphetamine.

Therefore it is important to identify the source of these products and track their shipments to the destined EU Member States for further processing. Work in this area will continue and results of this operational analysis will be presented in 2016.

2.2 Cooperation with the European Medicines Agency and the pharmacovigilance system

The cooperation between the EMCDDA and the European Medicines Agency (EMA) was maintained throughout 2015, as required by the Regulation 1235/2010 and the Council Decision 2005/387/JHA (see working arrangement between the two agencies³).

In 2015, the EMA provided a response to two formal consultations issued in order to prepare the EMCDDA–Europol Joint Reports on α -PVP and acetylfentanyl (see Section 3.3) and the EMA nominated an expert to be part of the extended Scientific Committee that assessed the risks of α -PVP (see Section 3.4).

Other communications between the two agencies involved the exchange of information on medicinal products (i.e. modafinil, ketamine and meprylcaine) and on the circulation of falsified medicines which, following on from trends in previous years, are a concern for the EWS. At the request of the EMA, the EMCDDA produced a rapid report on the information available on ketamine in Europe.

In 2014, following its formal notification, the EMCDDA shared with the EMA their concerns related to the misuse of quetiapine in Poland. The signal was raised at the EMA's Pharmacovigilance Risk Assessment Committee, which recommended that a cumulative review of Adverse Drugs Reactions was conducted. As a result, in 2015, section 4.4 of the summary product characteristics with regard to misuse and abuse was updated to the following: 'Cases of misuse and abuse have been reported. Caution may be needed when prescribing quetiapine to patients with a history of alcohol or drug abuse.'

A coordination meeting took place with the EMA in March with respect to cooperation, with a specific focus on strengthening data collection on the misuse and abuse of medicinal products defined as new psychoactive substances under Article 3 of the Council Decision.

3. Core activities

3.1 Early warning (Article 4)

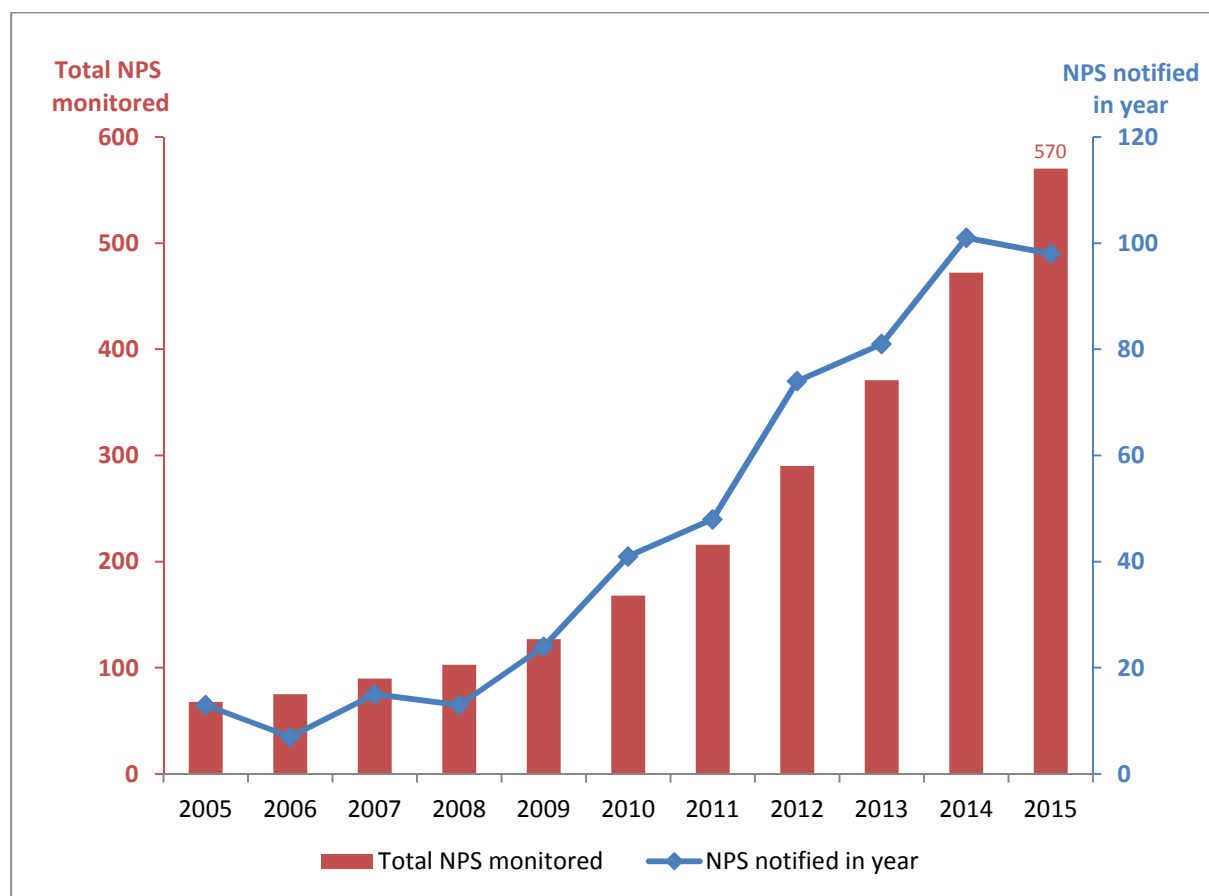
3.1.1. New psychoactive substances notified in 2015

In the year 2015, 98 new psychoactive substances were formally notified for the first time to the Reitox Early Warning System Network (Figure 1, full list in Annex 1) ⁽⁴⁾. This number is in

⁽³⁾ Working arrangement between the European Medicines Agency (EMA) and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), signed on 7 September 2012. Available at: http://www.emcdda.europa.eu/attachements.cfm/att_185319_EN_EMA-EMCDDA-2012workingarrangement.pdf

line with the overall trend for growth in the number of available NPS seen from previous years.

Figure 1. Number of NPS formally notified for the first time each year (line, left axis) and total number of NPS monitored by the EU Early Warning System (bars, right axis) (2005–2015)



Of the notified substances, 26 were cathinones and 24 were synthetic cannabinoids⁽⁵⁾, making these two the largest NPS categories being monitored. Also reported in 2015 were 9 new phenethylamines, 6 piperidines and pyrrolidines, 5 benzodiazepines, 4 arylalkylamines,

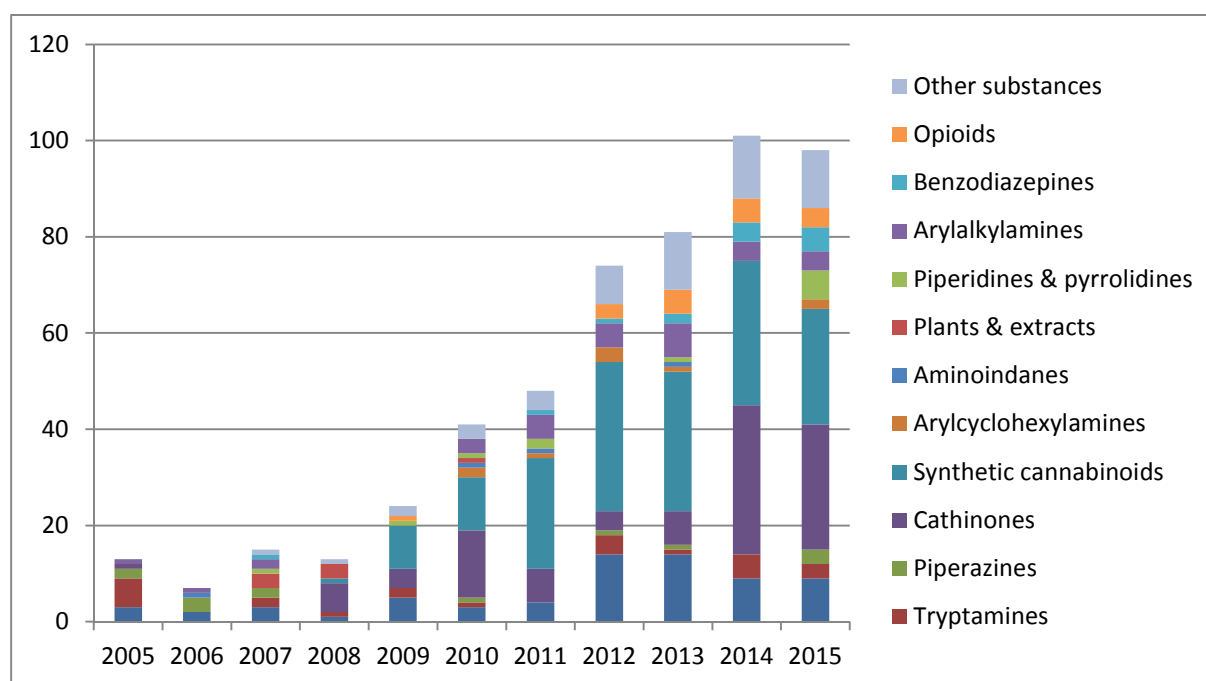
⁽⁴⁾ An error in the interpretation of analytical data related to the identification of 5F-PCN and phenmetrazine was reported to the EMCDDA after the substances had been formally notified (see substances **92** and **94** in Annex 1). As a result, the formal notifications for each of the substances were retracted on 20 April 2016. While such retractions are rare, they are inherent to the very nature of early warning given the analytical challenges faced in this field, including those posed by the continuous appearance of large numbers of new substances and a lack of certified reference materials.

⁽⁵⁾ The term 'synthetic cannabinoids' is used here to include: synthetic cannabinoid receptor agonists (such as JWH-018 which is a CB₁ and CB₂ receptor agonist); allosteric modulators (such as Org 27569) that change the structure of the cannabinoid receptors leading to altered activity when a ligand binds to the receptors; and, substances that act as inhibitors of the fatty-acid amide hydrolase (FAAH), which catalyses the intracellular hydrolysis of the endocannabinoid anandamide (such as URB597).

4 opioids, 3 piperazines, 3 tryptamines, 2 arylcyclohexylamines and 12 new substances that do not conform to any of the previous groups (Figure 2).

The number of synthetic opioids available in the drug market has increased year on year, particularly since 2010. These highly potent substances, which may be sold as heroin, pose serious health concerns and public health risks.

Figure 2. Number of new psychoactive substances notified for the first time to the EU Early Warning System by category (2005–2015)



With each new substance reported to the EWS for the first time, the EMCDDA initiates a process of recording, reviewing, validating and analysing the data provided by the focal point. The validated information is then complemented with the available published data on the substance (including chemistry and pharmacology, for example). Once all the data is collated and reviewed, a notification is sent out to the Network and a substance profile is created in the European Information System and Database on New Drugs (EDND). This profile is kept updated by the EMCDDA as new information becomes available (either from the national focal points, informal networks and daily monitoring of open source information).

In 2015, 101 new profiles were created in the EDND and an additional 328 existing EDND substance profiles were reviewed/updated with new information reported by the EU EWS Network and from information identified from daily searches of open source information. To date, the EDND remains the most comprehensive database of new psychoactive substances in Europe and is accessed daily by experts from various fields.

Other than first detections in Europe, the first detection of a substance in a particular country is also routinely reported to the EMCDDA, in accordance with the Council Decision. This year, close to 600 reporting forms (including detection of new substances, first notifications, reports of serious adverse events and significant updates from Member States) on new psychoactive substances were received, reviewed and analysed by the EMCDDA, 98 of

which resulted in formal notifications. Importantly, the information deriving from this continuous *push-pull* of information is readily and rapidly shared within the Network, ensuring that the national early warning systems are always working with the latest, most relevant information.

3.1.2. Reporting tools and 2014 seizure data

First notifications are an important indicator of the dynamism of the NPS market in Europe, as they show that a large number of new psychoactive substances are made available to the drug market year on year, but it should be noted that the foothold that each substance gains in the market is not reflected from this indicator alone.

One of the several ways that this information can be ascertained is through routine reporting of seizures and biological detections of the substances currently under monitoring. National early warning systems provide this information on a bi-annual basis to the EMCDDA (every 6 months) through Progress Reports (PRs) and Final Reports (FRs) ⁽⁶⁾. In 2015, 30 Final Reports from the 2014 reporting period and 20 Progress Reports from the 2015 reporting period were received, processed, analysed, and published in the EDND. The resulting data and information were then incorporated into monitoring. Headline seizure data for the 2014 reporting period is presented in Box 2.

In 2014, 365 different NPS were detected across Europe — an average of a substance per day — including many of those seen in previous years. There was also an increase in both the number of seizures and the amount of NPS seized in Europe. In line with previous years, synthetic cannabinoids and synthetic cathinones were the largest categories of NPS seized in Europe.

A reporting tool to strengthen the toxicovigilance component of the EWS was developed in 2015 and is being piloted. During the year, more than 30 reports on Serious Adverse Events (SAEs) associated with NPS were received, reviewed, validated, analysed, and the resulting data and information prioritised. The information contained in these reports contains valuable, often unique, information on harms associated with NPS.

The work to develop the new European Database on New Drugs (EDND) made some progress in 2015. A prototype system which focuses on the reporting and review of event-based data was designed and will be further developed in 2016.

⁽⁶⁾ The PRs and FRs were collected by using the new structured collection tool (Excel format).

In addition, data collected using these and other tools developed by the EMCDDA have triggered the launch of two Joint Reports in accordance with Article 5 of Council Decision 2005/387/JHA (see section 3.3 and 3.4).

Box 2. Headline seizure data from 2014

- In 2014, 365 different NPS were detected across Europe.
- Both the number of seizures and the quantities of NPS seized increased with regard to previous years. In 2014, 48,421 seizures of new psychoactive substances were reported, amounting to almost 4 tonnes. This represents a 4% increase over the previous year in terms of number of seizures and 27% increase in terms of total amount of NPS seized.
- In 2014, cannabinoids and cathinones continued to be the largest categories of NPS seized in Europe, amounting to 78% of all cases and 61% of the total amounts seized.
- Synthetic cannabinoids: 29,395 seizures, amounting to almost 1.3 tonnes of substance seized. This represents an increase of 37% over the previous year in terms of seizure number and 14% decrease in terms of total amount of seized.
- Synthetic cathinones: 8,343 seizures, amounting to almost 1.1 tonnes of substance seized. This represents a decrease of 22% over the previous year in terms of seizure number and 5% increase in terms of total amount seized.
- The number of seizures of synthetic opioids has increased more than tenfold in the last 4 years, and more than doubled from 2013.

3.2 Public health-related alerts

One of the core functions of the Early Warning System is to identify signals of serious harms associated with new psychoactive substances and to react to them as necessary. The challenge of fulfilling this important function implies monitoring signals related to a large number of substances of diverse chemical nature and pharmacological action.

The past few years have seen an increase in the reporting of serious adverse events, including mass intoxications, deaths and outbreaks of infections associated with the use NPS. The EMCDDA has responded to this challenge by strengthening the ability of the EU Early Warning System and its Network to identify, monitor, report, understand and respond to such harms.

During 2015, some 17 public health-related alerts (including updates) were produced based on information received, reviewed, validated, analysed from the EU EWS Network and from searches and reviews of OSI. These were then issued to the EU EWS Network. These comprised alerts and updates containing developments and supplementary information. The content of these communications is listed in Annex 2.

It is important to note that some of the alerts were triggered by media reports and open source monitoring ⁽⁷⁾ by the EMCDDA, whilst others originated from spontaneous reporting by the EWS Network. In both cases, the detection of the signal of potential harm was quickly followed up by a period of rapid review of the available data, execution of internet snapshots and intensive periods of queries to our networks, including data requests and analysis of stimulated reporting.

Briefly, in 2015 the public health-related alerts issued by the EMCDDA have addressed public health concerns of diverse nature, such as: deaths associated with the use of potent opioids (deaths associated with ocfentanyl and acetylfentanyl); clusters and outbreaks of intoxications associated with synthetic cannabinoids (alerts on ADB-CHMINACA, ADB-FUBINACA, MDMB-CHMICA and herbal smoking mixtures sold as 'Mocarz'); seizures of 'ecstasy' tablets containing 4-CMA, which has been linked to neurotoxicity; infections among those who inject drugs, including those who inject NPS (alerts on wound botulism and soft tissue infections); and deaths associated with PMMA sold as ecstasy and heroin sold as cocaine.

3.3 EMCDDA–Europol Joint reports (Article 5)

Substances posing serious health concerns were intensively monitored during 2015. Two substances, α -PVP and acetylfentanyl, met the criteria for the launch of a Joint Report in accordance with Article 5 of Council Decision 2005/387/JHA.

The ad hoc data collection for the preparation of a Joint Report on α -PVP was launched on 27 May 2015. Information was collected from the 28 Member States, Turkey, Norway, the EMA and WHO using a Joint Report Questionnaire (JRQ ⁸). In addition an OSI search and review was performed. The data from the JRQs and OSI search and review was collated, reviewed, validated, and analysed and a Joint Report was prepared within a 4-week period. The Report was submitted to the Council, the Commission and the EMA on 3 August 2015 ⁽⁹⁾.

Following the same procedure as for the α -PVP, an ad hoc data collection for the preparation of a Joint Report on the second substance, acetylfentanyl, was launched on 22 September 2015, following health alerts issued concerning acetylfentanyl (see section 3.2) and a review

⁽⁷⁾ Internet monitoring, drug forums, scientific publications, etc.

⁽⁸⁾ The Joint Report Questionnaires were collected by using the new structured collection tool (Excel format).

⁽⁹⁾ EMCDDA–Europol Joint Report on a new psychoactive substance: 1-phenyl-2-(1-pyrrolidinyl)-1-pentanone (α -PVP), September 2015. Available at: <http://www.emcdda.europa.eu/publications/joint-reports/alpha-pvp>

of the existing data available on the substance. The Joint Report on acetylfentanyl was submitted to the institutions on 1 December 2015 ⁽¹⁰⁾.

Both substances have since been assessed at the 37th Meeting of the Expert Committee on Drug Dependence (ECDD) held in Geneva, Switzerland (16 - 20 November 2015). A recommendation was made that the substances be added to the relevant schedules of the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol and the Convention on Psychotropic Substances of 1971 — α -PVP (schedule II, 1971 Convention) and acetylfentanyl (schedules I and IV, 1961 Convention). The Commission on Narcotic Drugs (CND) decided to place them under international control in March 2016 (59th session of the CND).

3.4 Risk assessments (Article 6)

In accordance with Article 6 of the Council Decision, the Council of the European Union requested that in 2015, a risk assessment be undertaken by the Scientific Committee of the EMCDDA regarding α -PVP.

The extended Scientific Committee of the EMCDDA met in Lisbon on 18 November 2015 and reviewed the available information on the substance, including data on 191 acute intoxications and 115 deaths associated with this substance in the countries that participate in the EU EWS.

The Risk Assessment Report on α -PVP was prepared and submitted to the Council and the Commission on 27 November 2015. The Commission's proposal for a Council Decision on subjecting α -PVP to control measures throughout the European Union is dated on 18 December 2015 ⁽¹¹⁾.

4. Conclusions

The new drugs phenomenon shows no signs of slowing down. On the contrary, the number and type of new psychoactive substances reported each year is very high. These numbers, however, fail to convey the enormous amount of work undertaken in real time by the EWS Network at national and EU level and the effort required to manage the networks on a daily basis and provide technical assistance to them.

⁽¹⁰⁾ By the time the Joint Report on acetylfentanyl was submitted, the substance was under assessment by the United Nations system — specifically, a critical review had been published and the drug had been assessed by the WHO ECDD. A recommendation from the assessment had not been published at the time of writing the Joint Report.

⁽¹¹⁾ Proposal for a Council Decision on subjecting the new psychoactive substance 1-phenyl-2-(1-pyrrolidin-1-yl) pentan-1-one (α -pyrrolidinovalerophenone, α -PVP) to control measures. COM/2015/0674 final - 2015/0309 (CNS). Available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015PC0674&rid=1>

In addition, the challenges posed by NPS generate significant public health concerns, hence it remains very high on the EU policy agenda. For the EMCDDA, this translates into an increased amount of work, which is necessary in order to cope with the demanding implementation of the Council Decision 2005/387/JHA, and also in order to respond promptly to the important number of requests for information or technical support coming from its stakeholders and partners, including Member States, EU Institutions, other agencies and international organisations, or third countries.

The nature of these challenges along with the pace at which they arise continue to stretch the capacity of the EU and the Reitox Early Warning System networks, who continue to provide rapid response to emerging threats.

5. Publications

EMCDDA Risk assessments

- Risk Assessment Report of a new psychoactive substance: 1-phenyl-2-(1-pyrrolidinyl)-1-pentanone (α -PVP).

EMCDDA-Europol Joint Reports

- EMCDDA–Europol Joint Report on a new psychoactive substance: 1-phenyl-2-(1-pyrrolidinyl)-1-pentanone (α -PVP), September 2015. Available at: <http://www.emcdda.europa.eu/publications/joint-reports/alpha-pvp>
- EMCDDA–Europol Joint Report on a new psychoactive substance: *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]acetamide (acetylfentanyl).

EMCDDA-Europol implementation reports

- EMCDDA–Europol 2014 Annual Report on the implementation of Council Decision 2005/387/JHA, July 2015. Available at: <http://www.emcdda.europa.eu/publications/implementation-reports/2014>

EMCDDA reports and online resources

- New psychoactive substances in Europe. An update from the EU Early Warning System (March 2015). Available at: <http://www.emcdda.europa.eu/publications/2015/new-psychoactive-substances>
- New psychoactive substances in Europe: Innovative legal responses (June 2015). Available at: <http://www.emcdda.europa.eu/publications/ad-hoc-publication/new-psychoactive-substances-europe-innovative-legal-responses>
- EU Drug Markets Report: in-depth analysis, April 2016. Available at: <http://www.emcdda.europa.eu/publications/eu-drug-markets/2016/in-depth-analysis>
- Early warning system — national profiles, May 2012. Available at: <http://www.emcdda.europa.eu/thematic-papers/ews>
- Risk assessment of new psychoactive substances — operating guidelines, March 2010. Available at: <http://www.emcdda.europa.eu/html.cfm/index100978EN.html>
- Understanding the 'Spice' phenomenon, November 2009. Available at: <http://www.emcdda.europa.eu/publications/thematic-papers/spice>

- Early-warning system on new psychoactive substances — operating guidelines, October 2007. Available at:
<http://www.emcdda.europa.eu/html.cfm/index52448EN.html>

Online resources

- Action on new drugs webpage, <http://www.emcdda.europa.eu/activities/action-on-new-drugs>
- Synthetic cannabinoids in Europe, Perspectives on drugs, 2015. Available at:
<http://www.emcdda.europa.eu/topics/pods/synthetic-cannabinoids>
- Injection of synthetic cathinones, Perspectives on drugs, 2015. Available at:
<http://www.emcdda.europa.eu/topics/pods/synthetic-cathinones-injection>
- Legal approaches to controlling new psychoactive substances, 2015. Available at:
<http://www.emcdda.europa.eu/topics/pods/controlling-new-psychoactive-substances>
- Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances, OJ L 127, 20.5.2005, p. 32. Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005D0387:EN:HTML>