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EMCDDA–Europol 2014 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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About this report

This report presents the key activities performed by the EMCDDA and Europol in 2014, with details on all the relevant activities in support of the implementation of Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances, including new psychoactive substances notified in 2014, Joint Reports produced, risk assessments conducted and public health alerts and advisories issued.

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>

| 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 European Monitoring Centre for Drugs and Drug Addiction (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.'

In compliance with Article 10, the EMCDDA and Europol herewith present the tenth such annual report which covers the period 1 January to 31 December 2014. The report outlines the results of the implementation, describes key issues arising from accumulated experiences and serves as a monitoring tool. The reader is referred to the text of the Council Decision, to facilitate the reading of this report ⁽²⁾. Annex 1 provides the list of new psychoactive substances notified for the first time in 2014. This includes the International Union of Pure and Applied Chemistry (IUPAC) chemical name, the reporting country, and

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

⁽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.

date of notification for each substance. Further information on these substances is available from the EMCDDA and Europol. Annex 2 and 3 provide a detailed analysis of new psychoactive substances in Europe for 2014 from the perspective of the EU Early Warning System. Annex 2 and 3 are also available online and can be downloaded at: www.emcdda.europa.eu/publications/2015/new-psychoactive-substances

1. Overview

The year 2014 was particularly busy for those involved in detecting, monitoring and responding to new psychoactive substances across the European Union (EU). This was due to the continued growth in the number, type and availability of new drugs detected as well as the increase in the number of serious harms that were reported to the EMCDDA (see 'Headline activities in 2014'). In addition, the number of law enforcement investigations and activities concerning new psychoactive substances has also increased. With this increase in substances comes an increase in the amount of information that is collected. The EMCDDA collects a diverse range of information on new psychoactive from 30 countries, international partners, experts and a large amount of information on harms from its monitoring of open source information. Overall, new psychoactive substances continued to be a high policy priority in the EU and in the Member States.

Headline activities in 2014

- **101 new psychoactive substances were formally notified for the first time in 2014.** This compares to 81 in 2013, 74 in 2012, 48 in 2011 and 41 in 2010.
- **The first formal EU law enforcement Joint Investigation Team was established** entirely focussed on an Organised Crime Group responsible for bringing new psychoactive substances from China to a Member State for distribution across the EU.
- **16 public health alerts** were issued by the EMCDDA.
- **6 risk assessments** were conducted by the Scientific Committee of the EMCDDA:
 - | **25I-NBOMe**, a substituted phenethylamine with hallucinogenic effects that was sold as a 'legal' replacement to LSD;
 - | **AH-7921**, a synthetic opioid;
 - | **MDPV**, a synthetic cathinone derivative closely related to pyrovalerone;
 - | **Methoxetamine**, an arylcyclohexylamine that was sold as a 'legal' replacement to ketamine;
 - | **4,4'-DMAR**, a psychostimulant structurally related to the internationally controlled drugs 4-methylaminorex (4-MAR) and aminorex; and,
 - | **MT-45**, a synthetic opioid with analgesic potency similar to morphine.

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

In 2014 the EMCDDA and Europol continued to provide technical expertise and support to the national early warning systems within the Reitox National Focal Points and Europol National Units in order to assist them in their work on new psychoactive substances. Technical expertise and support was also provided to the Member States, the European Parliament, the Council of the European Union, the European Commission, as well as EU agencies.

The analytical data available to the EU Early Warning System Network continued to be expanded during 2014. In addition, data and information was routinely provided on an informal basis by international partners, including Australia, the United States and Japan. This is an important aspect of the exchange of information and emphasises the global nature of the phenomenon.

The EMCDDA also expanded its collection of information related to new psychoactive substances from open source information which was made available to the Member States on the European Database on New Drugs (EDND).

2.1.2. Annual meeting of the EU Early Warning System Network

The 14th Annual meeting of the Reitox Early Warning System Network took place in June 2014. The meeting was organised in conjunction with the second *Spice II Plus – EMCDDA conference*. Topics discussed at the annual EWS meeting included:

- results of implementation of Council Decision 2005/387/JHA, including EMCDDA-Europol Joint Reports and Risk Assessments launched in 2014;
- development of a framework for the toxicovigilance of new psychoactive substances and strengthening the identification and reporting of serious adverse events;
- revision of reporting tools.

2.1.3. Supporting activities

During 2014 the EMCDDA and Europol continued to be prominently involved in organising events and participating in activities that are designed to develop the EU Early Warning System Network and provide support to others working in the field of new psychoactive substances. These events and activities provide a platform to improve collaboration among partners and promote best practice in order to strengthen early warning activities.

- In May, the EMCDDA co-organised the Third International Conference on Novel Psychoactive Substances took place in Rome, Italy.
- Also in May, the EMCDDA participated and delivered training in the Europol – CEPOL training course on dismantling illicit drug laboratories. The course was held in the

International Training Centre for Combating Clandestine Laboratories (ITCCCL) in Legionowo, Poland. The training was attended by 32 law enforcement and forensic experts from 18 Member States, Colombia and a representative from Eurojust.

- In September, the EMCDDA and Europol co-organised the 3rd Law enforcement expert meeting on new psychoactive substances, which was held at Europol. The meeting was focused on the exchange of best practice and experience concerning investigations on new psychoactive substances, including the sale of new psychoactive substances via the so-called Internet 'dark sites'.

The EMCDDA also organised or participated in a number of scientific conferences and meetings with dedicated sessions on new psychoactive substances, reflecting the relevance of this area for traditional illicit drug areas and established key epidemiological indicators. This included meetings covering general population surveys, drug-related deaths and problem drug use.

2.1.4. Europol

Europol has observed that law enforcement agencies across the EU are now becoming more involved with new psychoactive substances investigations. The law enforcement response has included the use of advanced tactics such as the controlled deliveries and cyber-purchase operations. Also, in 2014 the first formal EU Joint Investigation Team was established between two Member States, Europol and Eurojust, entirely focussed on an Organised Crime Group involved in bringing different new psychoactive substances from China to the EU and their distribution across the EU.

Strategically, new psychoactive substances are an EU priority in terms of the Policy Cycle for Organised Crime. The European Multidisciplinary Platform against Criminal Threats (EMPACT) Synthetic Drugs priority includes new psychoactive substances and several operational activities were conducted in the framework of the Operational Action Plan in 2014. The EMPACT Synthetic Drugs Operational Action Plan in 2015 will see even more activities focussed on the issue of new psychoactive substances.

As noted in previous years, China has been reported by Member States as the main source of new psychoactive substances delivered to Europe. Some of the most commonly reported new psychoactive substances were MDPV, pentedrone, 3-MMC, alpha-PVP and 4-fluoroamphetamine. According to Dutch authorities, 4-fluoroamphetamine was one of the most popular and best sold new psychoactive substances in the smart shops in the Netherlands in 2014 and it appears that a market has been established for this new psychoactive substances. To a lesser extent India also plays a role as a source country and it has been noted that mephedrone (4-methylmethcathinone) which was subject to control measures across the EU in 2010, is being imported into to the EU from India. For example, Germany reported a seizure of mephedrone (25 kg), which was shipped from India to Germany via the United Kingdom. Investigations conducted in the Member States and supported by Europol suggest that some Member States are emerging as European hubs for receiving the new psychoactive substances from source countries. New psychoactive substances 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 with other substances such as caffeine, or impregnating chemicals onto herbs or pressing into tablets before packaging takes place. On some occasions this is done by Organised Crime Groups. Although rare, the chemical synthesis of new psychoactive substances has also been reported. Poland, for example, reported illicit laboratories making mephedrone in 2012 and alpha-PVP in 2013. The majority of illicit sites related to new psychoactive

substances production in Europe are linked with processing steps only, i.e. the conversion of bulk materials into retail units. Slovenian authorities reported such a large scale operation where significant quantities of new psychoactive substances were being processed into ‘legal high’ products, including liquid refills containing synthetic cannabinoids for use in electronic cigarettes. Distribution of new psychoactive substances is generally well organised e.g. sale on the Internet, mail service, etc., to other Member States and beyond.

In 2014 only one production site was reported to Europol, which related to the seizure of a tableting site in June 2014 in Hungary. Bulk quantities of pentedrone and alpha-PVP were seized as well as the equipment and chemicals used for processing the substances into tablet form. Europol’s dedicated synthetic drug team supported the Hungarian investigation on the spot. Based on intelligence provided by Member States and a general assessment of new psychoactive substances market in Europe, Europol has assessed that more production facilities are operating in the EU.

Another related issue of concern is the importation of precursors that can be used for the synthesis of new psychoactive substances. At the beginning of 2014, Dutch authorities reported a 15 kg seizure of *N* acetylmeperidone which is a starting material for mephedrone. The consignment, which was falsely declared as another chemical, originated from an import-export company registered in Hong Kong and was destined for a business registered in the Netherlands. Bearing in mind the lack of awareness of precursors for new psychoactive substances by law enforcement and their non-controlled status, Europol has assessed that criminal groups could exploit this gap in future and the synthesis of some new psychoactive substances in Europe may become more common.

Also during 2014, Romania and Latvia reported that new legislation adopted in their countries had changed the distribution of new psychoactive substances from the smart shops to either public or hidden websites hosted abroad (United States, United Kingdom). The distribution is typically made via courier transportation companies and the profits gained via this activity are reported to be substantial.

Many countries are taking concerted law enforcement actions targeting the supply of new psychoactive substances. In August 2014, for example, Europol specialists were in Scotland, United Kingdom to support a national multi-agency operation targeting premises suspected of selling new psychoactive substances. The operation was preceded by a two-week nationwide marketing campaign to raise awareness of the dangers of taking new psychoactive substances.

2.2. Cooperation with the European Medicines Agency and the Pharmacovigilance system

During 2014 the European Medicines Agency (EMA) and the EMCDDA continued to regularly exchange information on new psychoactive substances according to their respective obligations under the Council Decision and EU pharmacovigilance legislation and the working arrangement between the two agencies ⁽³⁾.

⁽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: www.emcdda.europa.eu/attachements.cfm/att_185319_EN_EMA-EMCDDA-2012workingarrangement.pdf

This included formal consultations and exchange of information took place in order to prepare the Joint Reports on 4,4'-DMAR and MT-45 (under the scope of Article 5, see section 3.3), as well as ad hoc reports relating to the misuse and abuse of medicinal products and/or active pharmaceutical ingredients used therein that had been notified as new psychoactive substances.

Diverted or unauthorised imported medicinal products have become a group of new psychoactive substances of increasing importance, which is reflected in the growing number of medicines monitored by the EU Early Warning System. Four of the new substances notified in 2014 are used as active pharmaceutical ingredients in medicines authorised within the European Union: bupropion, orphenadrine, quetiapine and tramadol. At the request of the EMA, the EMCDDA undertook a data collection exercise with the Early Warning System Network to provide the information on quetiapine and bupropion abuse, misuse⁽⁴⁾ and dependency at the national level.

⁽⁴⁾ Note the terms 'misuse' and 'abuse' are used in their regulatory sense. See: www.ema.europa.eu/docs/en_GB/document_library/Other/2013/05/WC500143294.pdf

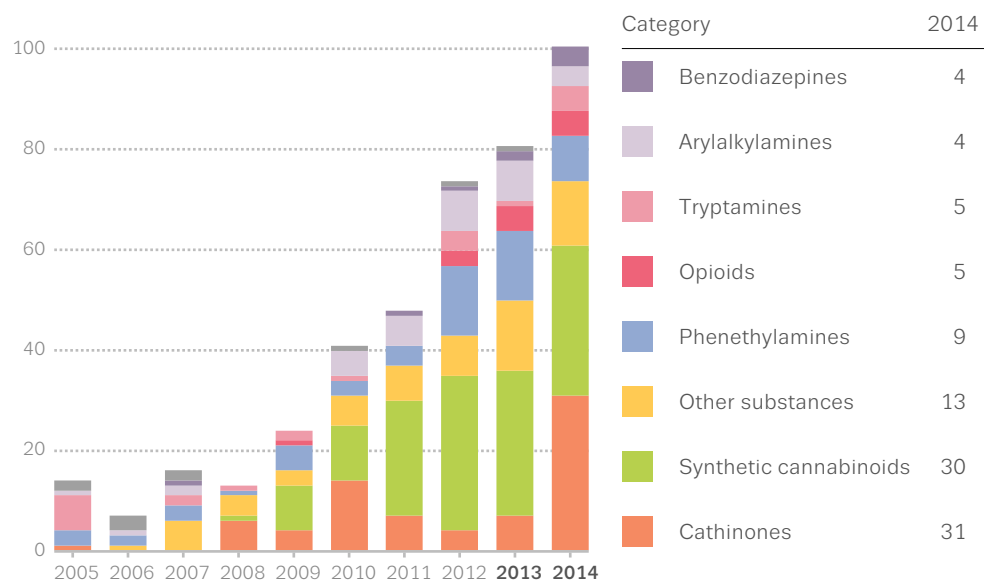
3. Core activities

3.1. Early warning (Article 4)

3.1.1. New psychoactive substances notified in 2014

During 2014 101 new psychoactive substances were notified for the first time within the European Union (Figure 1, Annex 1, Annex 2 and Annex 3). This continues the year on year increase in the number of new substances that have been notified since 2008 and compares to 81 in 2013, 74 in 2012, 48 in 2011 and 41 in 2010.

FIGURE 1
Number of new psychoactive substances notified for the first time to the EU Early Warning System, 2005–14 ⁽⁵⁾



Note: No notifications in 2014 for Aminoindanes, Arylcyclohexylamines, Piperazines, Piperidines and pyrrolidines or Plants and extracts

Of the 101 new psychoactive substances reported during 2014, 31 were cathinones and 30 were synthetic cannabinoids ⁽⁶⁾. This brings the total number of synthetic cannabinoids reported since December 2008 to 134, making them the largest group of substances monitored by the EU Early Warning System; the large number clearly illustrating the continuing attempts by manufacturers to produce new substances in order to circumvent drug control measures. Also reported in 2014 were: 9 phenethylamines, 5 opioids,

⁽⁵⁾ The 2011 annual implementation report listed 49 substances as notified through the EU Early Warning System in 2011; this figure should have been 48. The benzodiazepine phenazepam (7-bromo-5-(2-chlorophenyl)-1,3-dihydro-1,4-benzodiazepin-2-one), was notified by Germany in July 2011 but it had been previously formally notified as ‘fenazepam’ by Finland, on the first half of 2007.

⁽⁶⁾ 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).

5 tryptamines, 4 arylalkylamines, 4 benzodiazepines, and 13 substances that do not conform to the previous groups (Figure 1). Of particular concern to the EMCDDA and Europol in this respect is the number of potent new synthetic opioids — such as 4-fluorobutyrfentanyl (substance 23 in Annex 1), W-18 (substance 62), acetylfentanyl (substance 70) and the fentanyl butanamide analogue (substance 60) — reported this year.

Technical profiles were created on the European Database on New Drugs (EDND) for each of the notified substances. During the course of 2014, 573 reporting forms were submitted by the EU Early Warning System Network which were processed, analysed and added to the EDND. The information from these forms, as well as from other sources, was used to update 392 technical profiles on the EDND. Regular searches of the scientific and medical literature were conducted by the EMCDDA, and additional law enforcement information provided by Europol helped facilitate these profile updates.

Technical expertise and assistance were provided to the Member States on a daily basis. Sixteen public health alerts were issued to the EU Early Warning System Network (section 3.2). Additional data collection and analysis took place on an ad hoc basis, including for the Joint Reports on 4,4'-DMAR and MT-45 (section 3.3).

3.1.2. Revision of reporting tools – 2013 seizure data

The reporting tools for collecting and storing data on new psychoactive substances – as defined in the EWS operating guidelines (7) – were revised in 2014, aiding both data entry into the EDND as well as data analysis. In particular, Joint Report Questionnaires and EWS Progress and Final Reports were collected using a new Excel format. Trends analysis on the seizure data collected through EWS Progress and Final Reports was undertaken for the first time (Annex 2 and Annex 3) (see 'Headline seizure data from 2013').

Headline seizure data from 2013

- 46 730 seizures of new psychoactive substances amounting to more than 3.1 tonnes;
- 21 495 seizures of synthetic cannabinoids amounting to almost 1.6 tonnes;
- 10 657 seizures of synthetic cathinones amounting to more than 1.1 tonnes;
- Seven-fold increase in reported seizures of new psychoactive substances compared to 2008;
- 299 different new psychoactive substances detected across Europe, including many of those seen in previous years.

More information is available in Annex 2 and 3 (*New psychoactive substances in Europe. An update from the EU Early Warning System (March 2015)*), also available at: www.emcdda.europa.eu/publications/2015/new-psychoactive-substances

(7) EMCDDA-Europol Early-warning system on new psychoactive substances — operating guidelines, 2007. Available at: www.emcdda.europa.eu/html.cfm/index52448EN.html

3.2. Public health alerts

Public health alerts are a core activity of the EMCDDA that provide added value to the Member States⁽⁸⁾. Alerts are issued by e-mail within the Early Warning System Network after detection of a signal by the EMCDDA. Usually such signals are related to deaths or other serious harms associated with new psychoactive substances. Information is also exchanged on psychoactive substances that are controlled under the United Nations drug conventions when new forms of use that may pose a risk to public health are detected. Alerts may also provide information on possible public health related measures in accordance with the mandate and procedures of the EMCDDA.

Sixteen public health alerts were issued to the EU Early Warning System Network during 2014. A summary of some of these alerts is provided below.

4,4'-Dimethylaminorex (4,4'-DMAR), 6 February 2014

An alert was issued in February 2014 after the United Kingdom national focal point reported 18 deaths associated with the use of 4,4'-DMAR, a psychostimulant structurally related to the controlled drugs 4-methylaminorex (4-MAR) and aminorex. On 6 February 2015, Europol and EMCDDA published a joint early warning notification focusing on the link between this substance and the fatal cases. Based on these cases and deaths previously reported by Hungary, the Joint Report procedure was launched on 27 February 2014 (see section 3.3). The Joint Report was submitted to the Council, Commission and EMA on 8 May 2014. This led to a request from the Council for a formal risk assessment, which was subsequently conducted on 16 September 2014 by the extended Scientific Committee of the EMCDDA.

MT-45, 25 February 2014

An alert was issued in February 2014 after the Swedish national focal point reported 11 deaths and 2 serious non-fatal intoxications associated with MT-45. After the assessment of available information, a data collection for the preparation of a Joint Report was launched on 16 April 2014 (see section 3.3). The Joint Report was submitted to the Council, Commission and EMA on 25 June 2014. This led to a request from the Council for a formal risk assessment which was conducted by the extended Scientific Committee of the EMCDDA on 16 September 2014.

5F-PB-22, 27 February 2014

An alert was issued in February 2014 after the EMCDDA identified reports of 5 deaths associated with the use of synthetic cannabinoid 5F-PB-22 in the United States. Deaths occurred from July to November 2013. Although at that time the EMCDDA had not received any reports of adverse events associated with 5F-PB-22 in Europe, the alert was issued based on large seizures of 5F-PB-22 and the detection of the substance in 'legal highs' sold within the European Union.

ADB-PINACA, 4 March 2014

An alert was issued in March 2014 after the EMCDDA identified reports of an outbreak of non-fatal intoxications in the United States that were associated with the use of synthetic

⁽⁸⁾ Alerts and advisories issued by the Early Warning System are not legally binding and Member States are not obliged to act upon them.

cannabinoid ADB-PINACA. 263 cases of possible exposure were identified in less than one month in 2013. Although at that time the EMCDDA had not received any reports of adverse events associated with ADB-PINACA in Europe, the alert was issued based on the detection of ADB-PINACA in 'legal highs' sold within the EU.

2-MeO-diphenidine, 8 May 2014

An alert was issued in May 2014 after the United Kingdom national focal point reported a death associated with 2-MeO-diphenidine, a substance which is purported to have similar effects to methoxetamine.

3-MeO-PCP, 10 October 2014

An alert was issued in October 2014 after the Swedish national focal point reported 3 deaths associated with 3-MeO-PCP. 3-MeO-PCP is a derivative of PCP, the dissociative anaesthetic substance controlled under Schedule II of the 1971 UN Convention on Psychotropic Substances.

Diphenidine, 10 October 2014

An alert was issued in October 2014 after the Swedish national focal point reported 9 analytically confirmed non-fatal intoxications associated with the use of diphenidine. A further 9 non-analytically confirmed non-fatal intoxications were noted in the report.

'Spice', 14 October 2014

An alert was issued in October 2014 after the EMCDDA identified media reports of two outbreaks of serious adverse events in the Russian Federation associated with the smoking of a 'legal designer drug' or 'Spice'. The substance involved was identified to be 'MDMB (N) BZ-F' (MDMB-FUBINACA) which has not been detected within the European Union at the time of writing this report (May 2015).

Butyrfentanyl, 17 October 2014

An alert was issued in October 2014 after the Swedish national focal point reported a case of serious non-fatal intoxication associated with the potent opioid butyrfentanyl. The symptoms included respiratory depression, probably also cardiac arrest. Butyrfentanyl is a homologue of the potent opioid analgesic fentanyl.

α-PVT, 21 October 2014

An alert was issued in October 2014 after the Swedish national focal point reported a death associated with α-PVT which occurred in 2014. α-PVT is a derivative of the cathinone α-PVP and is believed to have stimulant-type effects.

4F-α-PVP, 23 October 2014

An alert was issued in October 2014 after the Swedish national focal point reported 2 deaths associated with the 4F-α-PVP. 4F-α-PVP is a synthetic cathinone which is believed to have stimulant-type effects.

Cocaine believed to be white heroin, 28 November 2014

An alert was issued in November 2014 after the Public Health Service in Amsterdam issued an alert regarding 3 deaths and several serious non-fatal intoxications linked to cocaine that had been purchased from the street. At that time it was reported that the substance involved was believed to be white heroin.

MDMB-CHMICA, 12 December and 19 December 2014

Two alerts related to the MDMB-CHMICA were issued in December 2014. The first alert was issued after the Austrian national focal point reported 7 non-fatal intoxications associated with the use of a 'herbal mixture' product called 'Bonzai citrus' and/or 'Bonzai Winter Boost' which was thought to contain MDMB-CHMICA. The second alert was issued after the Swedish national focal point reported 4 deaths and 6 non-fatal intoxications associated with the use of MDMB-CHMICA that occurred between September and November 2014.

PMMA, 22 December 2014

An alert was issued in December 2014 after the Dutch Drugs Information and Monitoring System (DIMS) issued an alert regarding ecstasy tablets containing *para*-methoxy-methamphetamine (PMMA) at high concentration while similar tablets containing MDMA were also reported to be circulating.

3.3. EMCDDA–Europol Joint reports (Article 5)

In February 2014, after a review of the available information on the new psychoactive substance 4,4'-DMAR (see section 3.2), the EMCDDA and Europol launched a formal procedure for the collection of information on this substance ⁽⁹⁾. The Joint Report was submitted to the Council, the Commission and the EMA on 8 May 2014 ⁽¹⁰⁾.

In April 2014, after a review of the available information on MT-45 (see section 3.2), the EMCDDA and Europol launched a formal procedure for the collection of information on this substance. The Joint Report was submitted to the Council, the Commission and the EMA on 25 June 2014 ⁽¹¹⁾.

3.4. Risk assessments (Article 6)

In 2014 the Council of the European Union requested that the Scientific Committee of the EMCDDA undertake six risk assessments on new psychoactive substances that have emerged in Europe over the past few years and that have been linked to serious harms.

On 29 January 2014 the Council requested that formal risk assessments be conducted on four substances: 25I-NBOMe (a substituted phenethylamine with hallucinogenic effects, sold as a 'legal' alternative to LSD (lysergic acid diethylamide)), AH-7921 (a synthetic opioid), MDPV (a synthetic cathinone derivative closely related to pyrovalerone) and

⁽⁹⁾ The Joint Report Questionnaires were collected by using the new structured collection tool (Excel format).

⁽¹⁰⁾ EMCDDA–Europol Joint Report on a new psychoactive substance: 4,4'-DMAR (4-methyl-5-(4-methylphenyl)-4,5-dihydrooxazol-2-amine), July 2014. Available at: www.emcdda.europa.eu/publications/joint-reports/4-4-DMAR

⁽¹¹⁾ EMCDDA–Europol Joint Report on a new psychoactive substance: 1-cyclohexyl-4-(1,2-diphenylethyl)piperazine ('MT-45'), September 2014. Available at: www.emcdda.europa.eu/publications/joint-reports/MT-45

methoxetamine (an arylcyclohexylamine closely related to ketamine, marketed as its 'legal' alternative). In accordance with Article 6 of the Council Decision, the risk assessments were conducted by the extended Scientific Committee of the EMCDDA on 1 and 2 April 2014. A Risk Assessment Report for each substance was submitted to the Council and the Commission on the 22 April 2014 ⁽¹²⁾. The four substances were subsequently subjected to control measures throughout the European Union as of October 2014.

On the basis of the information provided in the Joint Reports (see section 3.3 above), the Council requested that formal risk assessments be conducted on 4,4'-DMAR (on 20 June 2014) and on MT-45 (25 September 2014). In accordance with Article 6 of the Council Decision, a risk assessment for each of the two substances was conducted by the extended Scientific Committee of the EMCDDA on 16 September 2014. A Risk Assessment Report for each substance was submitted to the Council and the Commission on the 19 September 2014 (on 4,4'-DMAR) and on 6 October 2014 (on MT-45).

⁽¹²⁾ Risk assessment publications are available at: www.emcdda.europa.eu/publications/risk-assessments

4. Conclusions

The data presented in this report suggest that the growth of the market in new psychoactive substances will continue to pose a range of challenges for public health and drug policy over the next few years. Particular challenges relate to the speed at which new psychoactive substances appear, their open sale, and, the lack of information on their effects and harms. Critically, strong national and regional early warning systems will continue to play a central role in the early detection of harms and help to ensure timely public health responses within the European Union.

5. References

Risk Assessments

- | Risk Assessment Report of a new psychoactive substance: 1-cyclohexyl-4-(1, 2-diphenylethyl) piperazine (MT-45), November 2014. Available at: www.emcdda.europa.eu/publications/risk-assessment/mt-45
- | Risk Assessment Report of a new psychoactive substance: 4-methyl-5-(4-methylphenyl)-4,5-dihydrooxazol-2-amine (4, 4'-dimethylaminorex, 4,4'-DMAR), November 2014. Available at: www.emcdda.europa.eu/publications/risk-assessment/4,4-DMAR
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Annex 1

New psychoactive substances first notified to the Early Warning System in 2014 under the terms of Council Decision 2005/387/JHA

1. **6-Bromo-MDMA** (1-(6-bromo-1,3-benzodioxol-5-yl)-*N*-methylpropan-2-amine), 7 January 2014, United Kingdom
2. **2-MeO-diphenidine** (1-(1-(2-methoxyphenyl)-2-phenylethyl)piperidine), 14 January 2014, United Kingdom
3. **Tramadol** ((+)-*cis*-2-[(dimethylamino)methyl]-1-(*m*-methoxyphenyl)cyclohexanol: tramadol), 14 January 2014, United Kingdom
4. ***N*-methyl-2C-B** (4-bromo-*N*-methyl-2,5-dimethoxyphenethylamine), 15 January 2014, Finland
5. **Diphenidine** (1-(1,2-diphenylethyl)piperidine), 16 January 2014, Italy, United Kingdom
6. **PB-22 indazole analogue** (quinolin-8-yl 1-pentyl-1*H*-indazole-3-carboxylate), 21 January 2014, Hungary
7. **5F-PB-22 indazole analogue** (quinolin-8-yl 1-(5-fluoropentyl)-1*H*-indazole-3-carboxylate), 21 January 2014, Hungary
8. **4-Methyl-*N*-ethylnorpentedrone** (2-(ethylamino)-1-(4-methylphenyl)pentan-1-one), 28 January 2014, Luxembourg
9. **4F- α -PVP** (1-(4-fluorophenyl)-2-(pyrrolidin-1-yl)pentan-1-one), 5 February 2014, Sweden
10. **2-APB** (1-(1-benzofuran-2-yl)propan-2-amine), 5 February 2014, Sweden
11. **2-MAPB** (2-(*N*-methyl-2-aminopropyl)-1-benzofuran), 5 February 2014, Sweden
12. **3,4-DMeO- α -PVP** (1-(3,4-dimethoxyphenyl)-2-(pyrrolidin-1-yl)pentan-1-one), 7 February 2014, Sweden
13. **4-BEC** (1-(4-bromophenyl)-2-(ethylamino)propan-1-one), 10 February 2014, Poland
14. **FDU-PB-22** (1-naphthyl 1-[(4-fluorophenyl)methyl]indole-3-carboxylate), 12 February 2014, Sweden
15. **JWH-018 indazole analogue** (1-naphthalenyl(1-pentyl-1*H*-indazol-3-yl)-methanone), 21 February 2014, United Kingdom
16. **3,4-dimethylethcathinone / 3,4-DMEC** (1-(3,4-dimethylphenyl)-2-(ethylamino)propan-1-one), 25 February 2014, Hungary
17. **Mepirapim** ((4-methylpiperazin-1-yl)-(1-pentylindol-3-yl)methanone), 25 February 2014, Hungary

18. **Quetiapine** (2-[2-(4-dibenzo[b,f][1,4]thiazepin-11-yl-1-piperazinyl)ethoxy]ethanol), 28 February 2014, Poland
19. **α -Ethylaminopentiophenone** (2-(ethylamino)-1-phenyl-pentan-1-one), 6 March 2014, Austria
20. **Eutylone** (1-(1,3-benzodioxol-5-yl)-2-(ethylamino)butan-1-one), 12 March 2014, Poland
21. **Mesembrine** ((3a*S*,7a*S*)-3a-(3,4-dimethoxyphenyl)-1-methyl-2,3,4,5,7,7a-hexahydroindol-6-one), 12 March 2014, Austria
22. **α -Pyrrolidinohexanophenone / α -PHP** (2-(pyrrolidin-1-yl)-1-(phenyl)hexan-1-one), 12 March 2014, Poland
23. **4-Fluoro butyrfentanyl** (*N*-(4-fluorophenyl)-*N*-[(1-(2-phenylethyl)-4-piperidinyl)]butanamide), 12 March 2014, Poland
24. **Hexedrone** (2-(methylamine)-1-(phenyl)hexan-1-one), 12 March 2014, Poland
25. **4'-Chloro- α -PPP** (1-(4-chlorophenyl)-2-(1-pyrrolidinyl)propan-1-one), 14 March 2014, Poland
26. **2-Methoxyamphetamine** (1-(2-methoxyphenyl)propan-2-amine), 24 March 2014, Sweden
27. **4-Fluoro-*N*-isopropylnorpentadron** (1-(4-fluorophenyl)-2-(1-methylethylamino)pentan-1-one), 24 March 2014, Sweden
28. **3-Methoxymethcathinone / 3-MeOMC** (1-(3-methoxyphenyl)-2-(methylamino)propane-1-one), 24 March 2014, Sweden
29. **Alprazolam triazolobenzophenone derivative** ((2-(3-(aminomethyl)-5-methyl-4*H*-1,2,4-triazol-4-yl)-5-chlorophenyl)(phenyl)methanone), 4 April 2014, Spain
30. **AM-2201 benzimidazole analogue / FUBIMINA** ((1-(5-fluoropentyl)-1*H*-benzo[d]imidazol-2-yl)(naphthalen-1-yl)methanone), 4 April 2014, Latvia and Turkey
31. **4-Bromoamphetamine** (1-(4-bromophenyl)propan-2-amine), 7 April 2014, United Kingdom
32. **AB-CHMINACA** (*N*-[(1*S*)-1-(aminocarbonyl)-2-methylpropyl]-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide), 10 April 2014, Latvia.
33. **5F-AMBICA** (*N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)-1*H*-indole-3-carboxamide), 29 April 2014, Sweden
34. **2-Methylmethcathinone** (1-(2-methylphenyl)-2-(methylamino)propane-1-one), 8 May 2014, Sweden
35. **Orphenadrine** (*N,N*-dimethyl-2-(2-methylbenzhydryloxy)ethylamine), 12 May 2014, Italy

36. **DL-4662** (1-(3,4-dimethoxyphenyl)-2-(ethylamino)pentan-1-one), 26 May 2014, Sweden
37. **1-(4-fluorophenyl)-2-(piperidin-1-yl)pentan-1-one**, 26 May 2014, Sweden
38. **5-MeO-MALT** (*N*-[2-(5-methoxy-1*H*-indol-3-yl)ethyl]-*N*-methyl-prop-2-en-1-amine), 26 May 2014, Sweden
39. **4-Methylpentedrone** (1-(4-methylphenyl)-2-methylamino-pentan-1-one), 3 June 2014, Czech Republic
40. **5F-AMB** (methyl 2-({[1-(5-fluoropentyl)-1*H*-indazol-3-yl]carbonyl}amino)-3-methylbutanoate), 18 June 2014, Hungary
41. **JWH-071** ((1-ethyl-1*H*-indol-3-yl)-1-naphthalenyl-methanone), 19 June 2014, Turkey
42. **NEDPA** (*N*-ethyl-1,2-diphenyl-ethanamine), 19 June 2014, Germany
43. **NPDPA** (*N*-(1,2-diphenylethyl)propan-2-amine), 19 June 2014, Germany
44. **EG-018** (naphthalen-1-yl(9-pentyl-9*H*-carbazol-3-yl)methanone), 20 June 2014, Latvia
45. **Dipentylone** (1-(1,3-benzodioxol-5-yl)-2-(dimethylamino)-pentan-1-one), 20 June 2014, Sweden
46. **4-Fluoropentedrone** (1-(4-fluorophenyl)-2-(methylamino)pentan-1-one), 24 June 2014, France
47. **3-MEC** (2-(ethylamino)-1-(3-methylphenyl)propan-1-one), 9 July 2014, Czech Republic and Sweden
48. **MN-18** (*N*-(naphthalen-1-yl)-1-pentyl-1*H*-indazol-3-carboxamide), 9 July 2014, Sweden
49. **Bupropion** (1-((±)-1-(3-chlorophenyl)-2-[(1,1-dimethylethyl)amino]-1-propanone), 9 July 2014, Slovenia
50. **FUB-AKB48** (*N*-((3*s*,5*s*,7*s*)-adamantan-1-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide, 18 July 2014, Belgium
51. **AB-FUBINACA 2-fluorobenzyl isomer** (*N*-[(1*S*)-1-(aminocarbonyl)-2-methylpropyl]-1-[(2-fluorophenyl)methyl]-1*H*-indazole-3-carboxamide), 4 August 2014, Latvia
52. **Clephedrone** (1-(4-chlorophenyl)-2-(methylamino)propan-1-one), 4 August 2014, Sweden and Belgium
53. **2-EAPB** (1-(1-benzofuran-2-yl)-*N*-ethylpropan-2-amine), 20 August 2014, Sweden
54. **5-MeO-NIPT** (*N*-[2-(5-methoxy-1*H*-indol-3-yl)ethyl]-propan-2-amine), 20 August 2014, Sweden
55. **4-MeO- α -PBP** (1-(4-methoxyphenyl)-2-(pyrrolidin-1-yl)butan-1-one), 20 August 2014, Sweden

56. **Meclonazepam** ((S)-5-(2-chlorophenyl)-3-methyl-7-nitro-1,3-dihydro-2H-1,4-benzodiazepin-2-one), 20 August 2014, Sweden
57. **MET** (*N*-methyl-*N*-ethyltryptamine), 20 August 2014, Norway
58. **NM-2201** (naphthalen-1-yl 1-(5-fluoropentyl)-1*H*-indol-3-carboxylate), 4 September 2014, Sweden
59. **Deschloroetizolam**, 4 September 2014, United Kingdom
60. **Fentanyl butanamide analogue** (*N*-phenyl-*N*-[1-(2-phenylethyl)-4-piperidinyl]-butanamide), 4 September 2014, Poland (Sweden)
61. **5F-SDB-005** (naphthalen-1-yl-1-(5-fluoropentyl)-1*H*-indazole-3-carboxylate), 8 September 2014, Romania
62. **W-18** (4-chloro-*N*-(1-[2-(4-nitrophenyl)ethyl]-piperidin-2-ylidene)benzenesulfonamide), 10 September 2014, Sweden
63. **α-PBT** (2-(pyrrolidin-1-yl)-1-(thiophen-2-yl)butan-1-one), 12 September 2014, Hungary
64. **4F-α-PEP** (1-(4-fluorophenyl)-2-(pyrrolidin-1-yl)heptan-1-one), 12 September 2014, Hungary
65. **ADB-CHMINACA** (*N*-[1-(aminocarbonyl)-2,2-dimethylpropyl]-1-(cyclohexylmethyl)-1*H*-indazole-3-carboxamide), 12 September 2014, Hungary
66. **MDMB-CHMICA** (*N*-[[1-(cyclohexylmethyl)-1*H*-indol-3-yl]carbonyl]-3-methyl-valine, methyl ester), 12 September 2014, Hungary
67. **3F-Phenmetrazine** (2-(3-fluorophenyl)-3-methylmorpholine), 18 September 2014, Hungary
68. **4-Methyl-N,N-dimethylcathinone** (2-dimethylamino-1-(4-methylphenyl)propan-1-one), 18 September 2014, Spain
69. **EFLEA** (*N*-(1-(2,3-dihydrobenzo[*b*][1,4]dioxin-6-yl)propan-2-yl)-*N*-methylhydroxylamine), 18 September 2014, Sweden
70. **Acetylfentanyl/desmethylfentanyl** (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide), 19 September 2014, Poland
71. **3,4-MDPA** (α-methyl-*N*-propyl-1,3-benzodioxole-5-ethanamine), 19 September 2014, Poland
72. **α-POP** (1-phenyl-2-(pyrrolidin-1-yl)octan-1-one), 22 September 2014, Germany
73. **CUMYL-BICA** (1-butyl-*N*-(2-phenylpropan-2-yl)-1*H*-indole-3-carboxamide), 23 September 2014, Slovenia
74. **CUMYL-PINACA** (1-pentyl-*N*-(2-phenylpropan-2-yl)-1*H*-indazole-3-carboxamide), 23 September 2014, Slovenia

75. **ADB-CHMICA** (*N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1*H*-indole-3-carboxamide), 23 September 2014, Slovenia
76. **CUMYL-5FPICA** (1-(5-fluoropentyl)-*N*-(2-phenylpropan-2-yl)-1*H*-indole-3-carboxamide), 23 September 2014, Slovenia
77. **CUMYL-THPINACA** (*N*-(2-phenylpropan-2-yl)-1-((tetrahydro-2*H*-pyran-4-yl)methyl)-1-*H*-indazole-3-carboxamide), 23 September 2014, Slovenia
78. **CUMYL-PICA** (1-pentyl-*N*-(2-phenylpropan-2-yl)-1*H*-indole-3-carboxamide), 23 September 2014, Slovenia
79. **Adrafinil** (2-[(diphenylmethyl)sulfinyl]-*N*-hydroxiacetamide), 26 September 2014, Sweden
80. **4F- α -POP** (1-(4-fluorophenyl)-2-(pyrrolidin-1-yl)octan-1-one), 9 October 2014, Hungary
81. **DALT** (*N*-allyl-*N*-[2-(1*H*-indol-3-yl)ethyl]prop-2-en-1-amine), 13 October 2014, Norway
82. **5-MeO-EIPT** (*N*-ethyl-*N*-[2-(5-methoxy-1*H*-indol-3-yl)ethyl]propan-2-amine), 13 October 2014, Sweden
83. **CUMYL-5FPINACA** (1-(5-fluoropentyl)-*N*-(1-methyl-1-phenylethyl)-1*H*-indazole-3-carboxamide), 13 October 2014, Sweden
84. **3-Chloromethcathinone or 3-CMC** (1-(3-chlorophenyl)-2-(methylamino)propan-1-one), 14 October 2014, Sweden
85. **5-APB NBOMe** (1-(benzofuran-5-yl)-*N*-[(2-methoxyphenyl)methyl]propan-2-amine), 17 October 2014, Germany
86. **4-MMA NBOMe** (*N*-[(2-methoxyphenyl)methyl]-*N*-methyl-1-(*p*-tolyl)propan-2-amine), 17 October 2014, Germany
87. **4-EA NBOMe** (1-(4-ethylphenyl)-*N*-[(2-methoxyphenyl)methyl]propan-2-amine), 17 October 2014, Germany
88. **3,4-DMA NBOMe** (1-(3,4-dimethoxyphenyl)-*N*-[(2-methoxyphenyl)methyl]propan-2-amine), 17 October 2014, Germany
89. **4-Methyl-*N,N*-diethylcathinone** (2-diethylamino-1-(4-methylphenyl)propan-1-one), 20 October 2014, France
90. **Afloqualone** (6-amino-2-(fluoromethyl)-3-(2-methylphenyl)-3*H*-quinazolin-4-one), 20 October 2014, Sweden
91. **Flubromazolam** (8-bromo-6-(2-fluorophenyl)-1-methyl-4*H*-[1,2,4]triazolo-[4,3a][1,4]benzodiazepine), 20 October 2014, Sweden
92. **Modafinidz** (2-[[*bis*(4-fluorophenyl)methyl]sulfinyl]-*N*-methylacetamide (*N*-methyl-4,4-difluoro-modafinil)), 23 October 2014, Luxembourg.

93. **Methylmethaqualone** (3-(2,4-dimethylphenyl)-2-methylquinazolin-4(3H)-one), 28 October 2014, Poland
94. **5F-APP-PINACA** (*N*-(2-amino-1-benzyl-2-oxo-ethyl)-1-(5-fluoropentyl)indazole-3-carboxamide), 6 November 2014, Sweden
95. **APP-FUBINACA** (*N*-(2-amino-1-benzyl-2-oxo-ethyl)-1-[(4-fluorophenyl)methyl]indazole-3-carboxamide), 6 November 2014, Sweden
96. **MDPHP** (1-(1,3-benzodioxol-5-yl)-2-pyrrolidin-1-yl-hexan-1-one), 6 November 2014, Sweden
97. **4-MeO- α -PEP** (1-(4-methoxyphenyl)-2-pyrrolidin-1-yl-heptan-1-one), 19 November 2014, France
98. **5F-APP-PICA** (*N*-(1-amino-1-oxo-3-phenylpropan-2-yl)-1-(5-fluoropentyl)-1*H*-indole-3-carboxamide), 25 November 2014, Sweden
99. **5F-AMB-PICA** (methyl (1-(5-fluoropentyl)-1*H*-indole-3-carbonyl)-L-valinate), 5 December 2014, Hungary.
100. **Flibanserin** (1-(2-(4-[3-(trifluoromethyl)phenyl]piperazine-1-yl)ethyl)-1,3-dihydro-2*H*-benzimidazole-2-one), 05 December 2014, Germany.
101. **AMB-FUBINACA** (methyl-2-(1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide)-3-methylbutanoate), 10 December 2014, Sweden

Annex 2

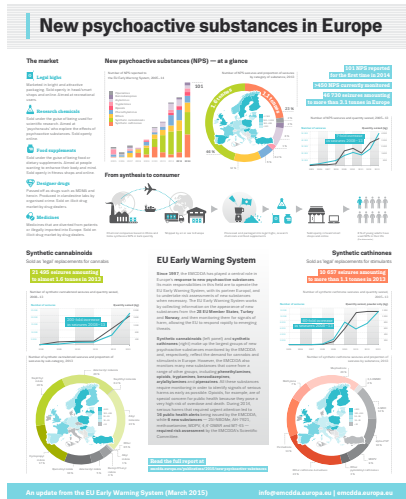
New psychoactive substances in Europe. An update from the EU Early Warning System (March 2015)



Available at: www.emcdda.europa.eu/publications/2015/new-psychoactive-substances

Annex 3

Infographic: New psychoactive substances in Europe. An update from the EU Early Warning System (March 2015)



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Related publications and websites**EMCDDA**

| *European Drug Report 2015: Trends and Developments*, 2015

| *New psychoactive substances in Europe. An update from the EU Early Warning System*, 2015

Full list included in the References section.

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