



Council of the
European Union

**Brussels, 20 June 2017
(OR. en)**

10506/17

**CORDROGUE 83
ENFOPOL 326
SAN 262**

NOTE

From:	Europol and EMCDDA
To:	Delegations
No. prev. doc.:	10429/16
Subject:	EMCDDA - Europol 2016 Annual Report on the implementation of Council Decision 2005/387/JHA

Delegations will find enclosed the above-mentioned Annual Report, in accordance with Article 10 of Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances.



EMCDDA–Europol 2016 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 notified for the first time in 2016 under the terms of Council Decision 2005/387/JHA.

Annex 2. List of risk communications issued to the EU Early Warning System Network in 2016 under the terms of Council Decision 2005/387/JHA.

Background to this report

As part of the response to new psychoactive substances (NPS) 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 (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 market. 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 (UN) 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* (EU Early Warning System) which is supported by the EU Early Warning System Network (Network).

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).

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

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 twelfth such annual report ⁽²⁾, which covers the period 1 January to 31 December 2016. 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 ⁽³⁾.

Annex 1 provides the list of new psychoactive substances notified for the first time in 2016. 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 list of the risk communications issued to the EU Early Warning System Network in 2016.

⁽²⁾ Implementation reports for 2005-2016 are available at:
[http://www.emcdda.europa.eu/publications-database?f\[0\]=field_series_type%253Aname%3AImplementation%20reports](http://www.emcdda.europa.eu/publications-database?f[0]=field_series_type%253Aname%3AImplementation%20reports).

⁽³⁾ 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

During 2016, 66 new substances were formally notified for the first time in Europe (Section 3.1.1). This brings the total number of substances monitored by the EMCDDA to more than 620 — which is more than twice the total number of substances controlled under the United Nations drug conventions.

While the number of notifications was lower than the previous two years, it was broadly similar to the numbers detected in 2012 and 2013. Importantly, the notifications for 2016 included a large increase in the number of new opioids — with 8 of them being fentanils which are highly potent substances that pose a severe risk of fatal poisoning. This year also saw an increase in reports of serious adverse events associated with the use of new substances, such as opioids and synthetic cannabinoids. These reports played a central role in the decisions both to issue 15 risk communications, including public health-related alerts, to the Network (Section 3.2) and to launch of three Joint Reports (Section 3.3), as well as playing an instrumental role during the risk assessment that was conducted (Section 3.4).

In keeping with trends over the last few years, the total number and quantity of new substances seized in Europe in 2015 continued to increase (Section 3.1.2). In addition, of the some 620 substances monitored, 423 were detected across Europe during 2015, giving some insight into just how complex the market has become.

Headline activities for 2016 are presented in Box 1.

Box 1. Headline early warning and risk assessment activities in 2016

- 66 new psychoactive substances were formally notified for the first time.
- 15 risk communications were issued by the EMCDDA to the Network.
- 692 reporting forms were submitted by the Network to the EMCDDA.
- 3 Joint Reports were launched by the EMCDDA and Europol:
 - MDMB-CHMICA, a synthetic cannabinoid receptor agonist that was associated with 28 deaths.
 - acryloylfentanyl, an opioid closely related to fentanyl that was associated with 42 deaths.
- furanylfentanyl, an opioid closely related to fentanyl that was associated with 23 deaths.
- MDMB-CHMICA was risk assessed — the first synthetic cannabinoid to be risk assessed under the Council Decision.
- 620+ new psychoactive substances are now monitored by the EMCDDA.

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

Similar to previous years, the EMCDDA provided daily support to the 28 Member States, Turkey and Norway, as well as other members of the EU Early Warning System Network during 2016.

This assistance often related to the provision of timely information on the NPS situation in Europe, with a specific emphasis on emerging issues relevant to public health. The EMCDDA transmits essential and urgent technical information as well as risk communications (such as public health alerts) to the Network by email. In addition it also operates and maintains a web-based information system called the European Database on New Drugs (EDND). The system offers round-the-clock access to information on more than 620 new substances based on data reported by the Network, identified by the EMCDDA through its additional monitoring systems, as well as that reported by other partners. Within the EDND, each substance has a profile which includes information on chemistry and analysis, manufacture, pharmacology, toxicology, epidemiology, trafficking and distribution. The EDND remains the most comprehensive source of information on new substances in Europe, and is used on a daily basis by the Network to support national early warning and risk assessment activities (Section 3.1.1).

In addition, the EMCDDA responded to time-sensitive ad hoc technical requests from the Network, including from the national early warning systems and the national focal points. These included queries relating to the development of appropriate chemical nomenclature for new substances, chemical analytical data, as well as in respect to EU legislation on new substances.

2.1.2 Annual meeting of the EU Early Warning System Network

The 16th annual meeting of the Reitox Early Warning System Network took place on 19 and 20 May 2016 in Lisbon in conjunction with the Europol's 5th Law Enforcement Expert Meeting on New Psychoactive Substances.

During the course of the meeting, the national early warning correspondents provided information on recent developments in their national early warning system, including: emerging concerns, national alert systems, research projects, and challenges. The information from these updates were then discussed allowing the participants to strengthen understanding of the NPS situation across Europe. As part of this, data and concerns related to synthetic cannabinoids and new synthetic opioids were also presented and discussed.

2.1.3 Strengthening early warning and response

The rapidly changing nature of the NPS market which is linked to the large number of substances being monitored presents challenges for early warning activities. In response to this development, the EMCDDA has undertaken a rolling programme of work to strengthen early warning and response activities in order to better protect public health. This includes the development of a range of interconnected systems as part of the EU Early Warning System — including a toxicovigilance system, signal management system, open source information monitoring system, and risk communication system — that allows it to better identify, understand, prioritise, and respond to public health threats

The toxicovigilance system allows the EMCDDA to identify, manage, understand, and, through other components of the EU Early Warning System and risk assessment process, react to serious adverse events associated with new substances. Much of the initial work has focused on strengthening the detection, reporting and assessment of serious adverse events reported by the countries which are part of the EU Early Warning System as well as those events identified by the EMCDDA from the scientific and medical literature and other open sources.

It is clear from recent developments that the early identification and response to emerging threats require proactive data collection systems. As a result the EMCDDA is working to improve the ability of the EWS to detect signals of public health relevance from open source information (OSI) by developing and implementing OSI monitoring and analysis systems that can provide new data on areas such as the online drug markets, epidemiology, and reports of serious adverse events.

In 2016, the monitoring of OSI included monitoring for potential serious and urgent events of EU relevance. Relevant information that was identified through this system was cross-referenced with data reported by Network in order to prioritise early warning activities and responses. Internet snapshots to determine the availability of certain substances under intensive monitoring — such as MDMB-CHMICA, acryloylfentanyl and furanylfentanyl — were also conducted.

The increase in data reported to the EMCDDA through the EU Early Warning System and identified from OSI includes an increase in reports of seizures by law enforcement as well as acute poisonings, deaths, and chronic harms by health agencies. As part of the EMCDDA's Signal Management System, these reports are collated, validated, assessed in order to prioritise and support early warning activities, such as public health alerts and Joint Reports, as well as risk assessment activities

Following a recent increase in new opioids detected on the European drug market, the EMCDDA held a technical meeting on the 31 March and 1 April 2016, which examined ways of strengthening early warning and response to these substances. During the meeting recent data on the identification and detection of new opioids including the fentanils on the European drugs market was discussed, along with the clinical aspects of opioid poisoning and its management, and the role of risk communication in reducing the harms.

2.1.4 Links with forensic science and toxicology networks

Cooperation with the Customs Laboratories European Network (CLEN) project group, funded by the EC Customs 2020 programme, and the Institute for Health and Consumer Protection of the European Commission's (EC) Joint Research Centre (JRC) were further strengthened in 2016. The CLEN project group is composed of customs laboratories from the Member States and aims to promote cooperation among them by sharing analytical data, reference samples and expertise on chemicals, including new psychoactive substances. The EMCDDA participated at the sixth meeting of the CLEN project.

In addition the EMCDDA continued to actively cooperate with the European Network of Forensic Science Institutes (ENFSI). This included participation at the ENFSI Drugs Working Group annual meeting which took place in Slovenia in May 2016.

During the year, the EMCDDA also further strengthened its links with other forensic science and toxicology networks. These included The International Association of Forensic Toxicologists (TIAFT) and the United Kingdom and Ireland Association of Forensic Toxicologists (UKIAFT). In order to support early warning and risk assessment activities both within the EU, in third countries, and at international level, the EMCDDA exchanged information with leading forensic and toxicology experts working in the field of new substances.

2.1.5 Supporting activities and cooperation with third countries

During 2016, the EMCDDA provided technical training on NPS in over 20 meetings, conferences, and other events that took place in 14 countries. These events served not only to increase understanding of the phenomenon and the visibility of the EU actions in this area, but also to strengthen and provide technical assistance to the Network.

Headline events in 2016 included:

- the 4th International Conference on Novel Psychoactive Substances which was co-organised by the EMCDDA.
- a webinar on NPS as part of the training programme for law enforcement professionals coordinated by the European Union Agency for Law Enforcement Training CEPOL;
- presentations for EU and national decision makers and policy makers who visited the EMCDDA.

Support was also provided to third countries, and particularly the candidate countries (CC) and potential candidate countries (PCC) to the EU to help support the design and operation of national early warning systems. This included assigning coaches from EU Member States to the interested beneficiary countries in order to help implement capacity development activities with key national stakeholders. Five countries (Bosnia and Herzegovina, the Former Yugoslav Republic of Macedonia, Kosovo* ⁽⁴⁾, Montenegro, and Serbia) attended the 16th Annual Meeting of the Reitox EWS Network, where the status of development of their national early warning system was discussed. This was followed by on-site seminars in Albania, Bosnia and Herzegovina, Serbia, the former Yugoslav Republic of Macedonia, and Kosovo* ⁽⁴⁾.

⁽⁴⁾ This designation is without prejudice to positions on status, and is in line with UNSCR 1244 and the ICJ Opinion on the Kosovo declaration of independence.

2.1.6 Cooperation with international organisations

During 2016, the EMCDDA also continued to be highly active in its cooperation with international organisations. In particular, in order to help support international activities in the response to harms caused by new substances, the EMCDDA provided data and technical expertise to the United Nations Office on Drugs and Crime (UNODC), the International Narcotics Control Board (INCB) and the World Health Organization (WHO Headquarters, Geneva). This cooperation included information exchange activities and support in prioritisation and scheduling discussions.

As part of this work, the EMCDDA and UNODC strengthened their collaboration with respect to data on the identification and seizure of new substances in Europe. This collaboration is based on the recognition of the word-leading role played by the EU Early Warning System and the EMCDDA in the early identification of threats related to new substances. The EMCDDA also participated at the UNODC Expert Consultation on Forensic Toxicology and Drug Control which took place in June.

In addition, the EMCDDA also assisted WHO with data for the prioritisation process and for the preparation of the critical reviews of the twelve psychoactive substances which were reviewed by the 38th meeting of the WHO's Expert Committee on Drug Dependence (ECDD), which took place on 14–18 November 2016. The EMCDDA also participated in the 3rd WHO-UNODC Expert Consultation on New Psychoactive Substances, which took place in May. During the event, the EMCDDA gave detailed presentations on how the EU Early Warning System works, including the signal management system, toxicovigilance system, open source information monitoring system, and risk communication system

2.1.7 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.

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 2016, several operational activities were conducted in the framework of the Operational Action Plan (OAP). For example, in the framework of Large Scale Joint Action Day, the Operation 'CICONIA ALBA' was planned in October 2016. Participating Member States carried out control activities based on intelligence information at the external and internal borders of the EU. Depending on the traffic and local risk criteria, each participating country decided what consignment, parcel or item should be checked. Europol specialists and analysts provided support from its headquarters and also on-the-spot support to the EU Member States. In total, 4.8 kg of amphetamines, 6461 ecstasy/MDMA tablets, 2 kg of synthetic cannabinoids and 213 LSD doses were seized during the Operation 'CICONIA ALBA'.

Trafficking of synthetic drugs and NPS in small postal parcels remains one of the key issues for many European countries.

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 2016 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.

Contributions reported to Europol by the Member States indicated small scale illicit synthesis of NPS with one exception. In July 2016, the Slovak Police in collaboration with the Polish Police seized an industrial scale laboratory in Prievidza, Slovakia, where the production of 3-CMC (3-chloromethcathinone or clophedrone) and *N*-ethylnorpentadone took place (Figure 1).

Figure 1. Pictures of the seizure of an industrial scale laboratory in Prievidza, Slovakia.





Another related issue of concern is the importation of precursors and pre-precursors that can be used for the synthesis of synthetic drugs and NPS.

To address these concerns, a core-group of forensic and law enforcement experts was created in the framework of the EMPACT OAP 2016 to identify and understand applications and practices used by OCG in the production of synthetic drugs and NPS. Trends and developments in this area are continuously monitored by the Member States so that quick responses can be given by issuing Early Warning Notifications and alerts.

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 new substances imported from China (the Netherlands, Spain and the United Kingdom).

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

In 2016, the United Kingdom (Police Scotland), supported by a few Member States and Europol, continued the intelligence enquiry initiated in 2015 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.

There are also increasing concerns on the availability and use of fentanyl, a highly potent synthetic opioid. Fentanyl, which can be produced illicitly or through the diversion of medicines, has been available in the European drug market since the early 1990s and many countries have reported deaths associated with its use.

The risk for overdose is even higher for carfentanil, a fentanyl analogue which is also available within the EU.

Use of these substances in some cities of the United States, where a large number of fatal overdoses associated with fentanils have been reported, has reached epidemic proportions.

The risks posed by the use and even accidental exposure to these substances cannot be underestimated. EU authorities, including Europol and EMCDDA, are monitoring the situation closely and are ready to provide advice and assistance as necessary.

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 2016, as required by the Regulation 1235/2010, the Council Decision 2005/387/JHA, and operationalised through the working arrangement between the two agencies ⁽⁵⁾.

During 2016, the EMA provided a response to three formal information requests made by the EMCDDA in order to prepare Joint Reports on MDMB-CHMICA, acryloylfentanyl and furanylfentanyl (Section 3.3). The EMA also participated in the risk assessment of MDMB-CHMICA as a member of the extended Scientific Committee (Section 3.4).

At the request of the EMA, the two agencies exchanged information on the medicinal products pregabalin, gabapentin, paracetamol and loperamide (see below). The EMCDDA also provided information on the circulation of potential falsified and counterfeit medicines containing new psychoactive substances which, which is a growing concern.

As noted above, following a request from the EMA, the EMCDDA issued a request for information to the Early Warning System Network for information on the misuse and abuse of loperamide to self-treat opioid withdrawal or to cause euphoria. Loperamide is an opioid medicine used to stop acute diarrhoea. The issue was discussed at the EMA's Pharmacovigilance Risk Assessment Committee, which recommended that sections 4.4 ('Special warnings and precautions for use'), 4.9 ('Overdose') and 5.3 ('Preclinical safety data') of the summary product characteristics with regard to serious adverse events and overdoses be updated ⁽⁶⁾.

⁽⁵⁾ 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

⁽⁶⁾ Pharmacovigilance Risk Assessment Committee (PRAC) recommendations on signals, EMA/PRAC/146565/2017, adopted at the 6-9 March 2017 PRAC meeting, 23 March 2017.

A coordination meeting between the EMCDDA and the EMA took place in October 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 and procedures in relation to the collection, processing and use of data collected through EudraVigilance.

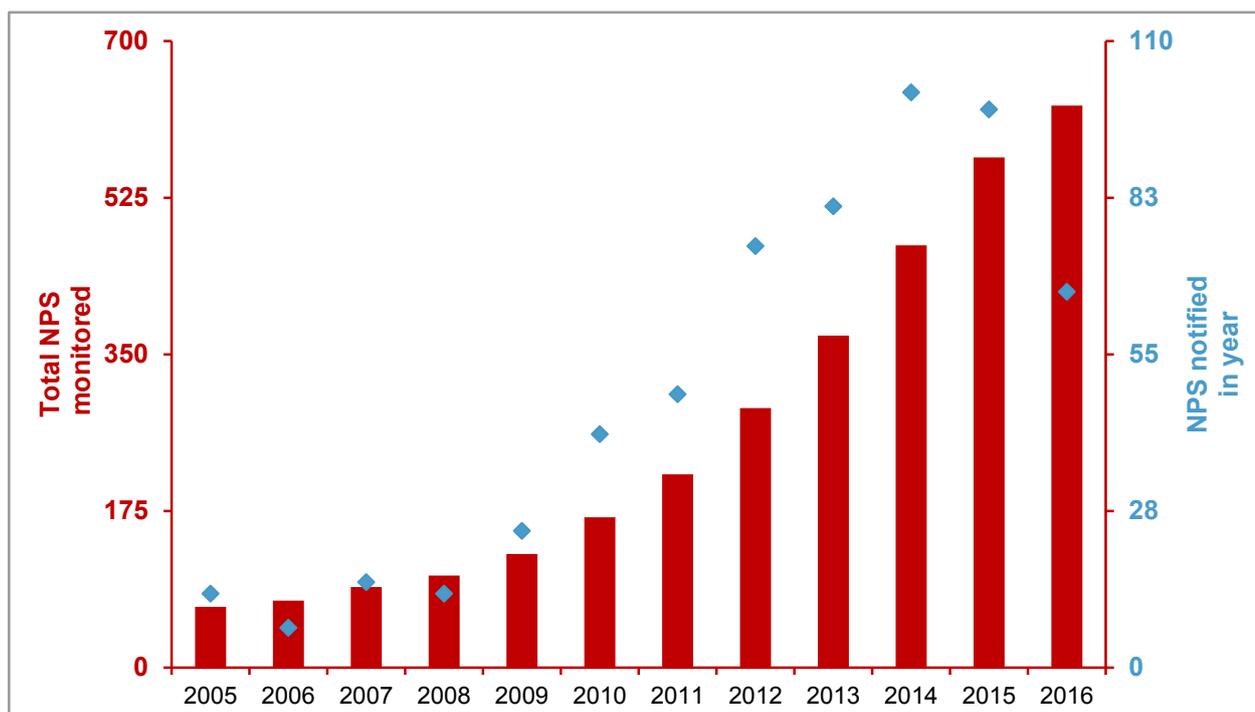
3. Core activities

3.1 Early warning activities (Article 4)

3.1.1. New psychoactive substances detected and formally notified in 2016

Sixty-six new psychoactive substances were formally notified for the first time in Europe during 2016 (Figure 2 and Annex 1 ⁽⁷⁾).

Figure 2. Number of new psychoactive substances formally notified for the first time in Europe (line, left axis) and total number of new psychoactive substances monitored by the EMCDDA, 2005–2016 (bars, right axis)



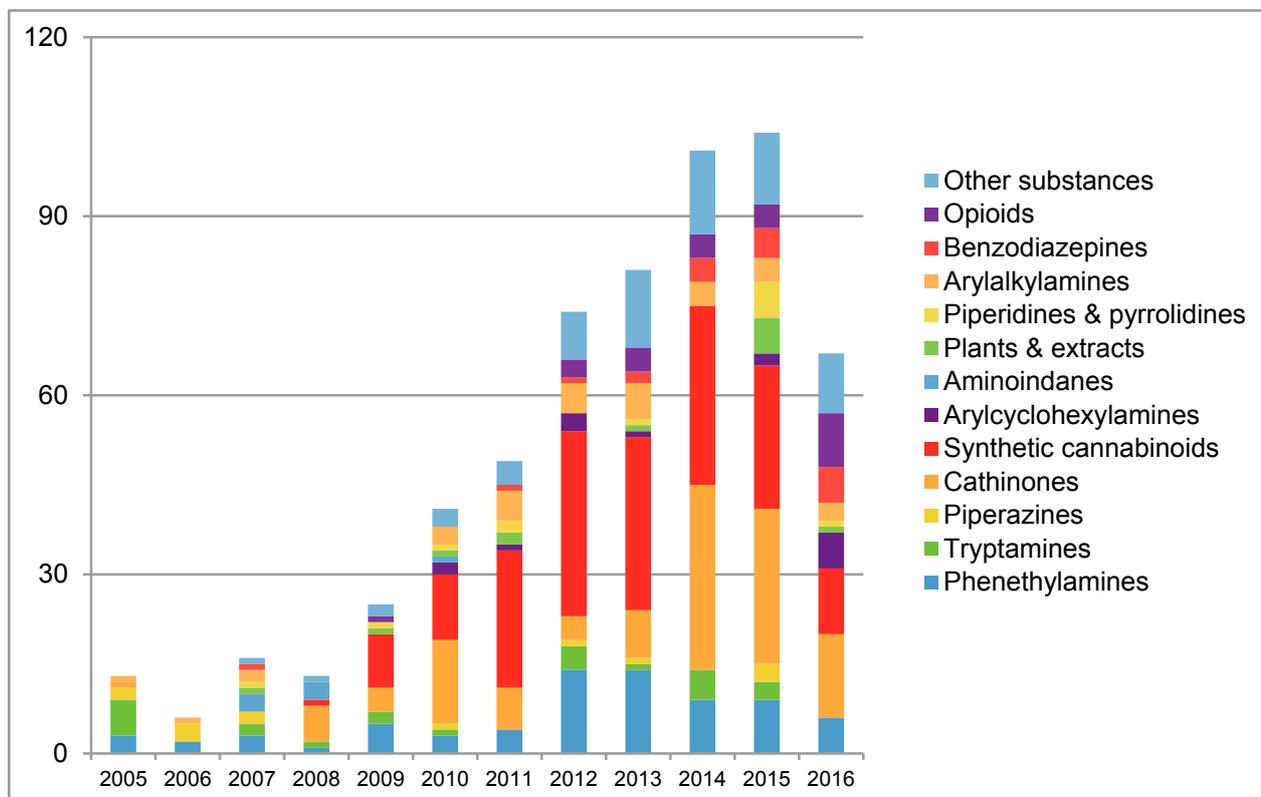
⁽⁷⁾ Following the formal notification of cinazepam, the EMCDDA was alerted to an error in the interpretation of analytical data related to the identification of the substance (Substance 21 in Annex 1). As a result, the formal notification for cinazepam was retracted on 2 May 2016. While such retractions 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.

Of the substances notified in 2016, 14 were cathinones and 11 were synthetic cannabinoids ⁽⁸⁾, which are the two largest categories of new psychoactive substances that the EMCDDA monitors through the EU Early Warning System. Also notified were 9 opioids, 6 phenethylamines, 6 arylcyclohexylamines, 6 benzodiazepines, 3 arylalkylamines, 1 piperidine/pyrrolidine and 10 substances that do not conform to any of the previous groups (Figure 3).

Of note is that the number of synthetic opioids available on the drug market has significantly increased since 2009. These highly potent substances may be sold as heroin and other illicit opioids and pose serious risks to individual- and public health.

⁽⁸⁾ 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).

Figure 3. Number and categories of new psychoactive substances formally notified for the first time in Europe, 2005–2016



For each new substance that is reported by the Network for the first time, the EMCDDA analyses and reviews the information and performs a search to identify other important information that may have been previously published. If confirmed as a new substance, then the EMCDDA issues a formal notification on behalf of the reporting country of the identification of the substance for the first time in Europe. The notification includes the names and identifiers of the substance, chemical and physical properties, analytical methodologies for its identification, pharmacology, toxicology, circumstances of the detection, and any other relevant information. This is transmitted to the Network by email. At this point the EMCDDA begins to formally monitor the substance as a new psychoactive substance as per the legal requirements of the Council Decision.

In 2016, 460 existing substance profiles were reviewed and updated with new information reported by the Network and from information identified by the EMCDDA from its other data sources.

The EMCDDA uses a structured reporting form to collect information on the identification of new substances in the countries that make up the Network. Such reports include the first time a new substance is identified in a country, large or unusual seizures, and trafficking and the involvement of criminal groups. report this to the EMCDDA using a structured reporting form. This year, close to 700 of these forms reporting detections of new psychoactive substances in seizures, collected and/or biological samples were reported, reviewed and analysed by the EMCDDA; of these, 66 led to formal notifications. Importantly, this information is rapidly shared within the Network through email and the EDND, helping to ensure that the Network — such as the national early warning systems — are working with the latest information.

3.1.2. Reporting tools and 2015 seizure data

Formal notifications are an important indicator of the dynamism of the NPS market in Europe. While they show that a large number of new psychoactive substances appear on the drug market each year this metric does not reflect the foothold that each substance gains in the market.

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 every six months to the EMCDDA through Progress Reports and Final Reports. In 2016, 30 Final Reports from the 2015 reporting period and 27 Progress Reports from the 2016 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 2015 reporting period is presented in Box 2.

In 2015, 423 different NPS were detected across Europe including many of those seen in previous years. There was also an increase in both the number of seizures and the amount of new substances seized in Europe. In line with previous years, synthetic cannabinoids and synthetic cathinones were the categories most seized in Europe.

The reporting tool that was developed in 2015 to strengthen reporting of serious adverse events — such as non-fatal and fatal poisonings — associated with new psychoactive substances was increasingly used in 2016. During the year, around 250 serious adverse events were reported to the EMCDDA. These data were reviewed, validated, analysed, and the resulting information used to prioritise and support early warning and risk assessment activities.

In addition, data collected using these and other tools developed by the EMCDDA have led to the launch of three Joint Reports in accordance with Article 5 of Council Decision 2005/387/JHA (Section 3.3).

Work in developing a new information system to replace the European Database on New Drugs (EDND) also made considerable progress during 2016. During 2017, the new system will be piloted with the national early warning systems. Among other features, the system will allow the electronic submission and management of data related to seizures, collected samples, biological samples, and serious adverse events.

Box 2. Headline seizure data for 2015

- 423 different new psychoactive substances were detected across Europe.
- Both the number of seizures and the quantities of NPS seized increased compared to previous years. In 2015, 76,329 seizures of new psychoactive substances were reported, amounting to almost 5 tonnes (4,949 kg). This represents more than 80% increase over the previous year in terms of number of seizures (almost double) and almost 25% increase in terms of total amount of NPS seized.
- Cannabinoids and cathinones continued to be the largest categories of NPS seized in Europe, amounting to 62% of all cases and 88% of the total amounts seized.
- Synthetic cannabinoids: 22,097 seizures, amounting to over 2.5 tonnes of substance seized. This represents a comparable amount of seizures (3% decrease) and a 85% increase (almost double) in terms of total amount of seized compared to the previous year.
- Synthetic cathinones: 25,502 seizures, amounting to over 1.8 tonnes of substance seized. This represents an increase of 205% (more than double) over the previous year in terms of seizure number and 70% increase in terms of total amount seized.

3.2 Public health-related alerts

One of the main functions of the EU 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, particularly in respect to severe and fatal poisonings; sometimes manifesting as deaths and outbreaks of infections associated with the use new substances.

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 2016, some 15 risk communications, including public health-related alerts, were issued to the Network. Most were issued based on information received from the Network and supported by additional information from the EMCDDA's other data sources, including its open source information monitoring system.

The risk communications issued by the EMCDDA during 2016 have addressed a range of public health concerns within the European Union. Briefly, these include: deaths associated with new opioids (such as U-47,700, as well as the fentanils acryloylfentanyl, furanylfentanyl, 4CI-iBF and 4F-iBF); safety measures for handling the opioid carfentanil; non-fatal intoxications and deaths associated with synthetic cannabinoids (MDMB-CHMICA and 5F-MDMB-PINACA); the detection of 'ecstasy' tablets containing high-strength PMMA; intoxications associated with cocaine containing scopolamine; and wound botulism in injecting drug users.

A full list of the risk communications issued in 2016 are provided in Annex 2.

3.3 EMCDDA–Europol Joint reports (Article 5)

As part of the day-to-day early warning activities, the EMCDDA intensively monitors substances that pose serious risks to health. During 2016, three of these substances — MDMB-CHMICA, acryloylfentanyl and furanylfentanyl — met the criteria for the launch of a Joint Report in accordance with Article 5 of Council Decision 2005/387/JHA based on serious harms, including deaths, reported in Europe.

The data collection for the preparation of the Joint Report on the synthetic cannabinoid MDMB-CHMICA was launched on 8 February 2016. Data was collected from members of the Network — the 28 Member States, Turkey, Norway, and the EMA — as well as the World Health Organization. In addition the EMCDDA searched and reviewed open source information. These data were collated, reviewed, validated, and analysed in order to produce a Joint Report within the four-week deadline required by the Council Decision. The report was submitted to the Council, the Commission and the EMA on 14 April 2016 ⁽⁹⁾.

Following the same procedure as for MDMB-CHMICA, data was also collected for Joint Reports on two opioids that are members of the fentanyl family: acryloylfentanyl (launched 7 September 2016; submitted 16 November 2016) ⁽¹⁰⁾ and furanylfentanyl (launched 16 November 2016; submitted 24 January 2017) ⁽¹¹⁾.

3.4 Risk assessments (Article 6)

In accordance with Article 6 of the Council Decision, on 26 May 2016, the Council of the European Union requested that a risk assessment be undertaken by the Scientific Committee of the EMCDDA on MDMB-CHMICA.

The extended Scientific Committee of the EMCDDA met in Lisbon on 22 July 2016 to assess the available information on the substance, including 25 acute intoxications and 28 deaths that had been reported by the Network.

The Risk Assessment Report on MDMB-CHMICA was prepared and submitted to the Council and the Commission on 27 July 2016. The Council Implementing Decision on subjecting MDMB-CHMICA to control measures across the European Union came into force on 4 March 2017 ⁽¹²⁾ ⁽¹³⁾.

⁽⁹⁾ EMCDDA–Europol Joint Report on a new psychoactive substance: methyl 2-[[1-(cyclohexylmethyl)indole-3-carbonyl]amino]-3,3-dimethylbutanoate (MDMB-CHMICA), July 2016. Available at: <http://emcdda.europa.eu/publications/joint-reports/mdmb-chmica>

⁽¹⁰⁾ EMCDDA–Europol Joint Report on a new psychoactive substance: N-(1-phenethylpiperidin-4-yl)-N-phenylacrylamide (acryloylfentanyl), February 2017. Available at: <http://emcdda.europa.eu/publications/joint-reports/acryloylfentanyl>

⁽¹¹⁾ EMCDDA–Europol Joint Report on a new psychoactive substance: N-phenyl-N-[1-(2-phenylethyl)piperidin-4-yl]-furan-2-carboxamide (furanylfentanyl). Available at: www.emcdda.europa.eu/attachements.cfm/att_256124_EN_EMCCDDA-Europol%20Joint%20Report%20furanylfentanyl%20with%20Annexes%20and%20cover.pdf

⁽¹²⁾ Council Implementing Decision (EU) 2017/369 of 27 February 2017 on subjecting methyl 2-[[1-(cyclohexylmethyl)-1H-indole-3-carbonyl]amino]-3,3-dimethylbutanoate (MDMB-CHMICA) to control measures. Official Journal of the European Union L 56/210, 3.3.2017. Available at: <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017D0369>

⁽¹³⁾ MDMB-CHMICA has since been assessed at the 38th Meeting of the World Health Organization's Expert Committee on Drug Dependence (ECDD) held in Geneva, Switzerland during November 2016. The Committee recommended that the substance

4. Conclusions

Over the past decade, and especially the last five years, there has been a large increase in the number, type, and availability of new psychoactive substances in Europe. As a result there have also been large increases in seizures by law enforcement as well as harms — such as severe and fatal poisonings.

As a result, early warning and risk assessment activities both at national- and EU-level in have significantly increased.

In response to this development, the EMCDDA has undertaken a rolling programme of work to strengthen early warning and response activities in order to better protect public health. This includes the development of a range of interconnected systems as part of the EU Early Warning System that allows it to better identify, understand, prioritise, and respond to public health threats, the foundation of which continues to be the chemical identification of new substances in law enforcement seizures and non-fatal and fatal poisonings. In addition, the EMCDDA has also conducted an increasing number of risk assessments on substances causing particular concerns to the European Union.

While the growth of the market at the same pace as over the last decade is not inevitable, the continued availability of new psychoactive substances is driving greater complexity into the drug problem. As the range of substances and products has grown, consumer groups have also broadened out to wider groups of recreational users, people who self-medicate, people wanting to improve how they look or their performance at work, as well as chronic and marginalised drug users. It has also led to growing interactions between the market in new substances and illicit drugs, as increasingly new substances are sold directly on the illicit drug market under their own name and passed off as illicit drugs to unsuspecting users — including feeding the illicit market when established drugs are in short supply.

While the number of new substances identified for the first time in 2016 was lower than the previous two years, the recent large increase in new opioids detected in Europe — especially the 18 fentanils detected between 2012 and 2016 — is a major concern because they pose a severe risk of fatal poisoning.

should be added to Schedule II of the United Nations Convention on Psychotropic Substances, 1971. During the 60th Session of the Commission on Narcotic Drugs in March 2017, a decision was made to place the substance under international control.

This growing complexity highlights the importance of continued investment in strong early warning systems at both national and EU-level as well as a more rapid risk assessment process at EU-level in order to protect the health and security of European citizens. The proposed new legislative framework on new psychoactive substances will play a central role in helping achieve these objectives.

5. Publications

EMCDDA Risk assessments

- Report on the risk assessment of methyl 2-[[1-(cyclohexylmethyl)-1*H*-indole-3-carbonyl]amino]-3,3-dimethylbutanoate (MDMB-CHMICA) in the framework of the Council Decision on new psychoactive substances. 2017. Available at: <http://www.emcdda.europa.eu/publications/risk-assessments/mdmb-chmica>
- Risk assessment report on a new psychoactive substance: *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacrylamide (acryloylfentanyl). 2017. Available at: www.emcdda.europa.eu/attachements.cfm/att_256126_EN_Risk%20assessment%20report%20acryloylfentanyl%20with%20annexes%20and%20cover.pdf
- Risk assessment report on a new psychoactive substance: *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (furanylfentanyl). 2017. Available at: www.emcdda.europa.eu/attachements.cfm/att_256125_EN_Risk%20assessment%20report%20furanylfentanyl%20with%20annexes%20and%20cover.pdf

EMCDDA-Europol Joint Reports

- EMCDDA–Europol Joint Report on a new psychoactive substance: methyl 2-[[1-(cyclohexylmethyl)indole-3-carbonyl]amino]-3,3-dimethylbutanoate (MDMB-CHMICA), July 2016. Available at: <http://emcdda.europa.eu/publications/joint-reports/mdmb-chmica>
- EMCDDA–Europol Joint Report on a new psychoactive substance: *N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacrylamide (acryloylfentanyl), February 2017. Available at: <http://emcdda.europa.eu/publications/joint-reports/acryloylfentanyl>
- EMCDDA–Europol Joint Report on a new psychoactive substance: *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (furanylfentanyl). Available at: www.emcdda.europa.eu/attachements.cfm/att_256124_EN_EMCCDDA-Europol%20Joint%20Report%20furanylfentanyl%20with%20Annexes%20and%20cover.pdf

EMCDDA-Europol implementation reports

- EMCDDA–Europol 2015 Annual Report on the implementation of Council Decision 2005/387/JHA, July 2016. Available at:
<http://www.emcdda.europa.eu/publications/implementation-reports/2015>

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/rapid-communications/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, 2016. 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, 2016. 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>

Annex 1. New psychoactive substances notified for the first time in 2016 under the terms of Council Decision 2005/387/JHA

1. **MDMB-FUBINACA** (methyl 2-[[1-[(4-fluorophenyl) methyl]indazole-3-carbonyl] amino]-3,3-dimethyl-butanoate), Hungary, 11 January 2016.
2. **Viloxazine** (2-[(2-ethoxyphenoxy)methyl]morpholine), Sweden, 14 January 2016.
3. **Fladrafinil** (2-[bis(4-fluorophenyl)methylsulfinyl]-*N*-hydroxyacetamide), Slovenia, 15 January 2016.
4. **Cloniprazepam** (5-(2-chlorophenyl)-1-(cyclopropylmethyl)-7-nitro-1,3-dihydro-2*H*-[1,4]-benzodiazepin-2-one), Sweden, 19 January 2016.
5. **25C-NBOH** (2-[[2-(4-chloro-2,5-dimethoxy-phenyl)ethylamino]methyl]phenol) Germany, 26 January 2016.
6. **Ephylone** (1-(2*H*-1,3-benzodioxol-5-yl)-2-(ethylamino)pentan-1-one), Slovenia, 28 January 2016.
7. **2,4-DMPPP** (1-(2,4-dimethylphenyl)-2-pyrrolidin-1-yl-propan-1-one), Poland, 29 January 2016.
8. **4-CEC** (1-(4-chlorophenyl)-2-(ethylamino)propan-1-one), Sweden, 29 January 2016.
9. **N-ethylhexedrone (NEH)** (2-(ethylamino)-1-phenylhexan-1-one), Hungary (Slovenia and the Netherlands), 16 February 2016.
10. **PDM-35** (3,5-dimethyl-2-phenylmorpholine), Slovenia, 17 February 2016.
11. **3,6-DMPM** (3,6-dimethyl-2-phenyl-morpholine), Sweden (and Slovenia), 22 February 2016.
12. **EG-2201** ((9-(5-fluoropentyl)-9*H*-carbazol-3-yl)(1-naphthalenyl)methanone), Sweden, 22 February 2016.
13. **AKB-57** (1-adamantyl 1-pentylindazole-3-carboxylate), Slovenia, 23 February 2016.
14. **LTI-701** (1-(5-fluoropentyl)-*N*-phenyl-indole-3-carboxamide), Germany, 23 February 2016.
15. **4Br- α -PPP** (1-(4-bromophenyl)-2-pyrrolidin-1-yl-propan-1-one), Poland, 24 February 2016.
16. **25I-NBOH** (2-[[2-(4-iodo-2,5-dimethoxy-phenyl)ethylamino]methyl]phenol), Slovenia, 29 February 2016.
17. **4-CIC** (1-(4-chlorophenyl)-2-(isopropylamino)propan-1-one), Slovenia, 3 March 2016.
18. **CUMYL-4CN-BINACA** (1-(4-cyanobutyl)-*N*-(1-methyl-1-phenyl-ethyl)indazole-3-carboxamide), Hungary, 4 March 2016.
19. **3-CEC** (1-(3-chlorophenyl)-2-(ethylamino)propan-1-one), Sweden, 4 March 2016.

20. **TH-PHP** (2-pyrrolidin-1-yl-1-tetralin-6-yl-hexan-1-one), Finland, 10 March 2016.
21. **Cinazepam** (4-[[7-bromo-5-(2-chlorophenyl)-2-oxo-1,3-dihydro-1,4-benzodiazepin-3-yl]oxy]-4-oxo-butanoic acid) ⁽¹⁴⁾, Norway, 14 March 2016. *A retraction of the formal notification was issued on 2 May 2016.*
22. **Valeryl fentanyl** (*N*-phenyl-*N*-[1-(2-phenylethyl)-4-piperidyl]pentanamide), France, 15 March 2016.
23. **4-Fluoroethylphenidate** (ethyl 2-(4-fluorophenyl)-2-(2-piperidyl)acetate), France, 17 March 2016.
24. **Propylone** (1-(1,3-benzodioxol-5-yl)-2-(propylamino)propan-1-one), Belgium (Sweden), 18 March 2016.
25. **ALD-52** ((8 β)-1-acetyl-*N,N*-diethyl-6-methyl-9,10-didehydroergoline-8-carboxamide), France, 19 April 2016.
26. **Memantine** (3,5-dimethyladamantan-1-amine), Slovenia, 19 April 2016.
27. **3-Hydroxyphenazepam** (7-bromo-5-(2-chlorophenyl)-3-hydroxy-1,3-dihydro-2*H*-1,4-benzodiazepin-2-one), Germany, 2 May 2016.
28. **Benocyclidine** (1-[1-(1-benzothiophen-2-yl)cyclohexyl]piperidine), France, 4 May 2016.
29. **Fonazepam** (5-(2-fluorophenyl)-1,3-dihydro-7-nitro-2*H*-1,4-benzodiazepin-2-one), Sweden, 3 June 2016.
30. **Tiletamine** (2-ethylamino-2-(2-thienyl)cyclohexanone), Spain, 9 June 2016.
31. **25B-NBF** (2-(4-bromo-2,5-dimethoxyphenyl)-*N*-[(2-fluorophenyl)methyl] ethanamine), Sweden, 16 June, 2016.
32. **25B-NBOH** (2-[[2-(4-bromo-2,5-dimethoxy-phenyl)ethylamino]methyl]phenol), Finland, 24 June 2016.
33. **2-MABB** (1-(1-benzofuran-2-yl)-*N*-methylbutan-2-amine), Sweden, 28 June 2016.
34. **4F-NEB** (2-(ethylamino)-1-(4-fluorophenyl)butan-1-one), Sweden, 29 June 2016.
35. **6-IT** (2-(1*H*-indol-6-yl)-1-methyl-ethylamine), Czech Republic, 1 July 2016.
36. **3-Methylphenmetrazine** (3-methyl-2-(3-methylphenyl)morpholine), Slovenia, 4 July 2016.
37. **Acryloyl fentanyl** (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacrylamide), Denmark, 7 July 2016.
38. **G-130** (5,5-dimethyl-2-phenyl-morpholine), Slovenia, 11 July 2016.

⁽¹⁴⁾ Following the formal notification of cinazepam, the EMCDDA was alerted to an error in the interpretation of analytical data related to the identification of the substance. As a result, the formal notification for cinazepam was retracted on 2 May 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.

39. **Methylmorphenate** (2-(morpholin-3-yl)-2-phenylacetate), Slovenia, 11 July 2016.
40. **PRE-084** (2-(morpholin-4-yl)ethyl 1-phenylcyclohexane-1-carboxylate), Slovenia, 14 July 2016.
41. **2-Fluorofentanyl** (*N*-(2-fluorophenyl)-*N*-[1-(2-phenylethyl)-4-piperidinyl]-propanamide), Ireland, 5 August 2016.
42. **Deschloro-*N*-ethyl-ketamine** (2-(ethylamino)-2-phenyl-cyclohexanone), France, 11 August 2016.
43. **ETH-LAD** ((6aR,9R)-*N,N*-diethyl-7-ethyl-4,6,6a,7,8,9-hexahydroindolo-[4,3-fg]quinoline-9-carboxamide), France, 16 August 2016.
44. **4Cl-iBF** (*N*-(4-chlorophenyl)-2-methyl-*N*-[1-(2-phenylethyl)-4-piperidyl] propanamide), Slovenia, 17 August 2016.
45. ***N*-methyl-bk-MMDA-5** (1-(7-methoxybenzo[d][1,3]dioxol-5-yl)-2-(methylamino) propan-1-one), France, 23 August 2016.
46. **4F-iBF** (*N*-(4-fluorophenyl)-2-methyl-*N*-[1-(2-phenylethyl)piperidin-4-yl] propanamide), Slovenia, 26 August 2016.
47. **4-chlorodiazepam** (7-chloro-5-(4-chlorophenyl)-1-methyl-3*H*-1,4-benzodiazepin-2-one), Slovenia, 8 September 2016.
48. **FUB-NPB-22** (quinolin-8-yl-(4-fluorobenzyl)-1*H*-indazole-3-carboxylate), United Kingdom, 9 September 2016.
49. **5F-EDMB-PINACA** (ethyl-2-[1-(5-fluoropentyl)-1*H*-indazole-3-carboxamido]-3,3-dimethylbutanoate), Hungary, 21 September 2016.
50. **5-MAPDI** (1-(2,3-dihydro-1*H*-inden-5-yl)-*N*-methylpropan-2-amine), Slovenia, 27 September 2016.
51. **5F-MDMB-PICA** (methyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethylbutanoate), Germany, 30 September 2016.
52. **AMB-FUBICA** (methyl 2-[[1-[(4-fluorophenyl)methyl]indole-3-carbonyl]amino]-3-methylbutanoate), Slovenia, 3 October 2016.
53. **3-Fluorofentanyl** (*N*-(3-fluorophenyl)-*N*-[1-(2-phenylethyl)-4-piperidyl]propanamide), France, 4 October 2016.
54. **2-Fluorodeschloroketamine** (2-(2-fluorophenyl)-2-methylamino-cyclohexanone), Spain, 6 October 2016.
55. **1-Phenethyl-4-hydroxypiperidine** (1-(2-phenylethyl)piperidin-4-ol), Greece, 7 October 2016.
56. **Flunitrazolam** (6-(2-fluorophenyl)-1-methyl-8-nitro-4*H*-[1,2,4]triazolo[4,3-a][1,4]benzodiazepine), Germany, 7 October 2016.
57. ***N*-methylbenzedrone** (2-[benzyl(methyl)amino]-1-(4-methylphenyl)-1-propanone), France, 17 October 2016.

58. **MDA 19** (*N*-[(*Z*)-(1-hexyl-2-oxoindol-3-ylidene)amino]benzamide), Spain, 19 October 2016.
59. **Bromazolam** (8-bromo-1-methyl-6-phenyl-4*H*-[1,2,4]triazolo[4,3-*a*][1,4]benzodiazepine), Sweden, 21 October 2016.
60. **3-MeO-PCMMo** (4-[[1-(3-methoxyphenyl)cyclohexyl]methyl]morpholine), Slovenia, 10 November 2016.
61. **α -PPP-MeO** (3-methoxy-1-phenyl-2-(pyrrolidin-1-yl)propan-1-one), Germany, 18 November 2016.
62. **α -PHiP** (4-methyl-1-phenyl-2-pyrrolidin-1-yl-pentan-1-one), Slovenia, 9 December 2016.
63. **Methoxyacetylfentanyl** (2-methoxy-*N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]acetamide), Slovenia, 9 December 2016.
64. **U-49,900** (3,4-dichloro-*N*-[2-(diethylamino)cyclohexyl]-*N*-methylbenzamide), Slovenia, 12 December 2016.
65. **Dichloropane (RTI-111)** methyl 3-(3,4-dichlorophenyl)-8-methyl-8-azabicyclo[3.2.1]octane-2-carboxylate, Slovenia, 20 December 2016.
66. **MO-CHMINACA** (1-methoxy-3,3-dimethyl-1-oxobutan-2-yl 1-(cyclohexylmethyl)-1*H*-indazole-3-carboxylate), Sweden, 20 December 2016.
67. **Tetrahydrofuranylfentanyl** (*N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]tetrahydrofuran-2-carboxamide), Sweden, 23 December 2016.

Annex 2. List of risk communications issued to the EU Early Warning System Network in 2016 under the terms of Council Decision 2005/387/JHA

- 1) **MDMB-FUBINACA detected in Europe**, *Alert*, 15 January 2016.
- 2) **Serious adverse events associated with MDMB-CHMICA in Europe**, *Alert*, 8 February 2016.
- 3) **Fatty acid amide hydrolase (FAAH) inhibitors**, *Advisory*, 2 March 2016.
- 4) **U-47,700 in Europe**, *Alert*, 8 June 2016.
- 5) **Ocfentanil sold as heroin in Europe**, *Advisory*, 29 June 2016.
- 6) **5 Deaths and 4 acute intoxications associated with synthetic cannabinoid 5F-MDMB-PINACA (5F-ADB)**, *Alert*, 7 July 2016.
- 7) **2 Cases of wound botulism in men suspected to have injected heroin — Bochum, Germany, 2016**, *Advisory*, 5 August 2016.
- 8) **23 Deaths associated with acryloyl fentanyl in Sweden — April to August 2016**, *Alert*, 26 August 2016.
- 9) **Additional information: 23 deaths associated with acryloyl fentanyl in Sweden — April to August 2016**, *Alert update*, 19 September 2016.
- 10) **DEA Safety Alert regarding carfentanil for law enforcement officers and the public**, *Advisory*, 23 September 2016.
- 11) **Cocaine containing scopolamine associated with 17 intoxications in France — July 2016**, *Advisory*, 30 September 2016.
- 12) **9 Deaths associated with furanylfentanyl in Sweden**, *Alert*, 7 October 2016.
- 13) **Superman ‘ecstasy’ tablets containing PMMA in circulation in Europe**, *Alert*, 21 October 2016.
- 14) **N-ethylhexedrone in Europe**, *Advisory*, 16 November 2016.
- 15) **Deaths associated with 4CI-iBF and 4F-iBF — Sweden, June to October 2016**, *Alert*, 22 December 2016.