



# News release

from the EU drugs agency in Lisbon

## EUROPE GETS STRONGER SYSTEM TO TACKLE NEW PSYCHOACTIVE SUBSTANCES

### New legislation, bringing faster response to new drugs, applies from today

(23.11.2018, LISBON) Europe's ability to rapidly respond to public health and social threats caused by new psychoactive substances (NPS/'new drugs') will be significantly strengthened, thanks to new legislation applying from today <sup>(1)</sup>.

The legislation — applicable across Europe from 23 November 2018 — strengthens the **EU Early Warning System (EU EWS)** and risk assessment procedures on NPS and shortens control processes. The legislation comes in response to the recent growth in the availability of NPS and follows proposals from the **European Commission (EC)**.

The new legislative package consists of:

- a *Regulation* regarding information exchange on, and an early-warning system and risk-assessment procedure for, new psychoactive substances, amending the EMCDDA recast founding regulation <sup>(2)</sup>;
- a *Directive*, which allows NPS to be controlled at EU level as 'drugs' <sup>(3)</sup>.

The legislation retains Europe's current three-step approach to responding to NPS — early warning, risk assessment and control measures — while significantly strengthening existing processes by streamlining and accelerating data-collection and assessment procedures. A new feature in the regulation allows for the potential risks posed by several NPS with a similar chemical structure to be assessed together in a combined risk assessment report. Throughout the new procedure, shorter deadlines are introduced.

The **EMCDDA** will continue to play a leading role in early warning on, and monitoring of, NPS reported by **EU Member States** and will initiate a scientific investigation into any new substance causing concern at EU level. Following the submission by the agency of its initial report, the **EC** will have two weeks to ask the agency to assess the potential risks posed by the substance, to be delivered within six weeks.

Based on the risk assessment report, the **Commission** may propose to control the substance. The **Council of the EU** and the **European Parliament** will then have two months to decide whether they agree. **Member States' authorities** will have six months (instead of 12 under the previous system) to place the substance under control, at national level, once the decision enters into force.

In 2017, 51 NPS were reported for the first time to the **EU EWS** — a rate of around one per week. By the end of 2017, the **EMCDDA** was monitoring over 670 NPS (compared with around 350 in 2013). Health and social harms linked to new synthetic cannabinoids and new synthetic opioids — including acute intoxications and deaths — prompted the **EMCDDA** to conduct an unprecedented nine risk assessments in 2017.

The **EMCDDA** and **Europol** — with the support of the **EU Member States**, the **European Medicines Agency (EMA)** and the **European Commission** — have been working together since 1997 to monitor the appearance of 'new drugs' and the extent of their diffusion in Europe. The first legislative frameworks

(1997 and 2005) <sup>(4)</sup> allowed the partners to develop an advanced early-warning system for monitoring 'new drugs' and a structure for performing scientific risk assessments. Under the new legislation, further EU agencies will also be involved, including the **European Centre for Disease Prevention and Control**, **European Chemicals Agency** and **European Food Safety Authority**.

**Dimitris Avramopoulos, European Commissioner for Migration, Home Affairs and Citizenship**, declared: 'Over the last ten years, the emergence of new psychoactive substances has presented major challenges to public health and safety. These are often highly toxic synthetic substances which become all the more dangerous in easily adapting and changing markets. This is why we need effective legal and operational tools to enable swifter action to ban these substances from the EU, in order to prevent serious health damage, and sometimes even death. The new EU rules will better protect our citizens across the EU from these dangerous drugs — in particular young people.'

**EMCDDA Director Alexis Goosdeel** said: 'The EMCDDA welcomes the new legislation to strengthen Europe's response to new psychoactive substances, which may cause serious health and social risks to users. The rise in the availability of NPS over the past decade, and harms associated with them, require us to boost our early-warning and response capacities. This faster legal mechanism will help us keep pace with the NPS phenomenon and ensure that prompt action is taken to protect public health'.

*For further information on EMCDDA early-warning and risk-assessment activities, see:*  
[www.emcdda.europa.eu/activities/action-on-new-drugs](http://www.emcdda.europa.eu/activities/action-on-new-drugs)

## Notes

<sup>(1)</sup> *Official Journal of the European Union:*

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2017:305:FULL&from=EN>

The legislation came into force on 22 November 2017, to be applicable 12 months after that date.

<sup>(2)</sup> Regulation (EU) 2017/2101 of the European Parliament and of the Council of 15 November 2017 amending Regulation (EC) No 1920/2006 as regards information exchange on, and an early warning system and risk assessment procedure for, new psychoactive substances.

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R2101>

The new legislation amends the EMCDDA recast regulation (Regulation (EC) No 1920/2006 —

<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006R1920>) by adding new provisions

(Articles 5a, 5b, 5c, 5d and Article 2(f)), deleting Article 5(2) 2<sup>nd</sup> sub-paragraph and amending Article 13(2).

<sup>(3)</sup> Directive (EU) 2017/2103 of the European Parliament and of the Council of 15 November 2017 amending Council Framework Decision 2004/757/JHA in order to include new psychoactive substances in the definition of 'drug' and repealing Council Decision 2005/387/JHA (see below).

[https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2017.305.01.0012.01.ENG](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2017.305.01.0012.01.ENG)

<sup>(4)</sup> Joint Action 97/396/JHA of 16 June 1997 adopted by the Council on the basis of Article K.3 of the Treaty on European Union, concerning the information exchange, risk assessment and the control of new synthetic drugs.

<https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:31997F0396>

Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances. <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32005D0387>