European Monitoring Centre
for Drugs and Drug Addiction

News release

from the EU drugs agency in Lisbon

AMENDMENT TO EMCDDA FOUNDING REGULATION

New legislation published today to bring faster response to new drugs

(21.11.2017, LISBON) Europe's ability to rapidly respond to public health and security threats caused by new psychoactive substances (NPS) will be significantly strengthened, thanks to new legislation published today by the European Union ([1]).

The legislation includes a stronger **EU Early Warning System (EWS)** and a faster risk-assessment process. The developments are in response to the recent growth in the market in NPS and follow a proposal from the **European Commission** (EC) comprising:

- a *Regulation* regarding information exchange on, and an early-warning system and risk-assessment procedure for, new psychoactive substances (amending the EMCDDA founding regulation)([2]); and
- a *Directive* including new psychoactive substances in the definition of 'drug' ([3]).

The new legislation retains the 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. Throughout the new procedure, shorter deadlines are introduced.

The **EMCDDA** will continue to play a leading role in monitoring NPS reported by **EU Member States** and will initiate an in-depth scientific investigation into any new substance causing concern. Following the submission by the agency of its initial report, the **European Commission** will have two weeks to request it 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 whether or not to control the substance through a formal decision. The **Council of the EU** and the **European Parliament** will then have two months to agree or not. **National authorities** will have six months (instead of 12) to place the substance under control on their territory once the decision enters into force.

In 2016, 66 NPS were detected for the first time via the **EU Early Warning System (EWS)** — a rate of over one per week. The **EWS** currently monitors over 620 new psychoactive substances compared with around 350 in 2013. This total included 24 new fentanils, highly potent opioids detected on Europe's drug market in the past few years. Exposure to very small amounts of fentanils can cause life-threatening poisoning, reflected in the substantial increase in the number of reported fatalities involving their use.
Over the last year, for example, more than 60 deaths in Europe involved carfentanil ([4]).

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 on the European drug scene. The first legislative frameworks (1997 and 2005)([5]) have allowed the partners to develop an advanced early-warning system for monitoring new drugs and a structure for performing scientific risk assessments.

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Commenting today, **EMCDDA Director Alexis Goosdeel said:** 'The EMCDDA welcomes this new legislation to strengthen the EU's response to new psychoactive substances. The unprecedented rise in the availability of new drugs in recent years clearly requires us to strengthen our early-warning and response capacity. This faster legal mechanism will help us keep pace with the NPS phenomenon and ensure that prompt action is taken to protect public health'.

Notes

([1]) *Official Journal of the European Union*; http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2017:305:FULL&from=EN The legislation will come into force tomorrow and will become applicable 12 months after that date.
([2]) http://eur-lex.europa.eu/legal-content/EN/ HIS/?uri=consil:ST_9566_2017_INIT
([3]) http://eur-lex.europa.eu/legal-content/EN/ HIS/?uri=CONSIL:ST_9567_2017_INIT
([4]) For more, see www.emcdda.europa.eu/publications/joint-reports/carfentanil_en
([5]) Joint action on new synthetic drugs (16 June 1997); Council Decision (2005/387/JHA)(10 May 2005).