



# News release

from the EU drugs agency in Lisbon

COUNCIL IMPLEMENTING DECISION TO CONTROL CYCLOPROPYLFENTANYL AND METHOXYACETYLFENTANYL

## Two new synthetic opioids to be placed under control across the EU

(28.9.2018, LISBON) Today, the European Union has decided to subject two new synthetic opioids to control measures across the 28 Member States. The implementing decision of the Council of the EU <sup>(1)</sup>, based on a proposal from the European Commission, was adopted in the final stage of the three-step legal procedure designed to respond to new psychoactive substances (NPS) that may pose public health and social threats <sup>(2)(3)</sup>. The substances, which have been raising health concerns in Europe, are **cyclopropylfentanyl** and **methoxyacetylfentanyl** <sup>(4)</sup>. Both are chemically related to fentanyl, the controlled drug widely used in medicine in pain management and anaesthesia.

Harmful effects linked to the use of the two substances have been reported by the Member States through the **EU Early Warning System (EWS)**, operated by the **EMCDDA** and **Europol**. Similar to other opioid analgesics, the most serious acute risk arising from their use is likely to be from respiratory depression (which can lead to apnoea, respiratory arrest and death). Naloxone is expected to work as an antidote to poisoning <sup>(5)</sup>.

Today's decision is based on the findings of formal risk assessments of the substances, conducted by the extended **EMCDDA Scientific Committee** in March 2018, with participation of additional experts from the **EU Member States, European Commission, Europol** and the **European Medicines Agency**. The risk assessments explored the health and social risks of the drugs, as well as international trafficking and the involvement of organised crime <sup>(6)</sup>. The decision states that the evidence available provides 'sufficient ground for subjecting cyclopropylfentanyl and methoxyacetylfentanyl to control measures across the Union'. Reasons for the conclusion include: the similarity of the substances to fentanyl and the risks they pose.

Available in the EU since at least June 2017, **cyclopropylfentanyl** has been detected in six EU Member States and Norway. At the time of the risk assessment, 78 deaths with confirmed exposure to the substance had been reported by two EU Member States (Sweden and the UK). **Methoxyacetylfentanyl** has been available on the EU drug market since at least November 2016 and has been detected in 11 EU Member States and Norway. At the time of the risk assessment, 13 deaths with confirmed exposure to the substance had been reported by four EU Member States (Belgium, Czech Republic, Sweden and the UK).

The two substances, sold online in powder form, are also available as ready-to-use nasal sprays. These new dosage forms are both easier to obtain and to consume and have the potential to make use of fentanils more socially acceptable <sup>(7)</sup>. **Cyclopropylfentanyl** has been detected in tablets, among these falsified benzodiazepines (e.g. fake Xanax<sup>®</sup>) and opioid painkillers (e.g. fake OxyContin<sup>®</sup>). This increases the risk of poisoning in unsuspecting users.

A small number of fentanils (e.g. fentanyl, alfentanil, sufentanil and remifentanil) are used legitimately in human and veterinary medicine. But fentanils also have a long history of illicit use as replacements for heroin and other controlled opioids. Over the past few years, there has been a large increase in the availability of fentanils in the United States, Canada and Europe. The **EMCDDA** is currently monitoring

32 fentanils through the EU **EWS** on new psychoactive substances <sup>(8)</sup>; all of these have been detected on the EU drug market since 2012.

Of the nine risk assessments carried out by the **EMCDDA** in 2017, five were related to synthetic opioids (acryloylfentanyl, furanylfentanyl, 4-fluoroisobutyrylfentanyl (4F-iBF), tetrahydrofuranylfentanyl (THF-F) and carfentanyl) <sup>(9)</sup>. All five substances are now controlled internationally under the United Nations 1961 Single Convention on Narcotic Drugs.

Following publication of today's decision on **cyclopropylfentanyl** and **methoxyacetylfentanyl** in the *Official Journal of the European Union*, the EU Member States will have one year to introduce the controls into their national legislation.

## Notes

<sup>(1)</sup> Council implementing decision to be published in the *Official Journal of the European Union*.

<http://data.consilium.europa.eu/doc/document/ST-9420-2018-INIT/en/pdf>

<sup>(2)</sup> Council Decision 2005/387/JHA: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005D0387:EN:HTML>

<sup>(3)</sup> [www.emcdda.europa.eu/activities/action-on-new-drugs](http://www.emcdda.europa.eu/activities/action-on-new-drugs)

<sup>(4)</sup> *N*-Phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]cyclopropanecarboxamide (cyclopropylfentanyl)  
2-Methoxy-*N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]acetamide (methoxyacetylfentanyl)

<sup>(5)</sup> For more on naloxone, see [www.emcdda.europa.eu/publications/insights/take-home-naloxone\\_en](http://www.emcdda.europa.eu/publications/insights/take-home-naloxone_en)

<sup>(6)</sup> See 'Risk assessments' (available in English) at:

[www.emcdda.europa.eu/publications/risk-assessments/cyclopropylfentanyl](http://www.emcdda.europa.eu/publications/risk-assessments/cyclopropylfentanyl)

[www.emcdda.europa.eu/publications/risk-assessments/methoxyacetylfentanyl](http://www.emcdda.europa.eu/publications/risk-assessments/methoxyacetylfentanyl)

<sup>(7)</sup> Fentanils are a family of synthetic opioids, which are chemically related to the controlled drug fentanyl.

Some fentanils are exceptionally potent and small amounts can cause life-threatening poisoning from respiratory depression. These substances pose a serious risk of intoxication to users and are capable of causing explosive outbreaks.

<sup>(8)</sup> *Fentanils and synthetic cannabinoids: driving greater complexity into the drug situation — an update from the EU Early Warning System:*

[www.emcdda.europa.eu/publications/rapid-communications/fentanils-and-synthetic-cannabinoids-ews-update\\_en](http://www.emcdda.europa.eu/publications/rapid-communications/fentanils-and-synthetic-cannabinoids-ews-update_en)

<sup>(9)</sup> [www.emcdda.europa.eu/publications/risk-assessments](http://www.emcdda.europa.eu/publications/risk-assessments)

Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances:

