EUROPEAN
COMMISSION

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2018/0118 (NLE)

Proposal for a

COUNCIL IMPLEMENTING DECISION

on subjecting the new psychoactive substances *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]cyclopropanecarboxamide (cyclopropylfentanyl) and 2-methoxy-*N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]acetamide (methoxyacetylfentanyl) to control measures

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

Council Decision 2005/387/JHA on the information exchange, risk-assessment and control of new psychoactive substances[1] provides for a three-step procedure that may lead to the submission of a new psychoactive substance to control measures across the Union.

On 19 December 2017, two joint reports of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and Europol drawn up in accordance with Article 5 of Council Decision 2005/387/JHA were issued. On 29 January 2018, following the request made by the Commission and eight Member States and pursuant to Article 6(1) of the above-mentioned Council Decision, the Council requested an assessment of the risks caused by the use, manufacture and trafficking of the new psychoactive substances *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]cyclopropanecarboxamide (cyclopropylfentanyl) and 2-methoxy-*N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]acetamide (methoxyacetylfentanyl), the involvement of organised crime and the possible consequences of control measures introduced on this substance.

The risks of cyclopropylfentanyl and methoxyacetylfentanyl were assessed by the Scientific Committee of the EMCDDA, acting in compliance with the provisions of Article 6(2), (3) and (4) of the Council Decision. The risk assessment reports were submitted to the Commission and to the Council on 23 March 2018. The main results of the risk assessment are the following:

Cyclopropylfentanyl

- Cyclopropylfentanyl is a synthetic opioid and is structurally related to fentanyl, an internationally controlled substance. Cyclopropylfentanyl is also structurally related to butyrfentanyl, another internationally controlled substance.
- Cyclopropylfentanyl has been available in the European Union since at least June 2017 and has been detected in six Member States. 77 deaths have been reported by two Member States between June and December 2017 where exposure to cyclopropylfentanyl was confirmed. In at least 74 deaths cyclopropylfentanyl was the cause of death or is likely to have contributed to the death.

Methoxyacetylfentanyl

- Methoxyacetylfentanyl is a synthetic opioid and is structurally related to fentanyl, an internationally controlled substance. Methoxyacetylfentanyl is also structurally related to ocfentanil and acetylfentanyl, which are both internationally controlled substances.
- Methoxyacetylfentanyl has been available in the European Union since at least November 2016 and has been detected in eleven Member States between June and December 2017. 13 deaths have been reported by four Member State where exposure to methoxyacetylfentanyl was confirmed. In at least seven deaths methoxyacetylfentanyl was the cause of death or is likely to have contributed to the death.

Pursuant to Article 8(1) of Council Decision 2005/387/JHA, within six weeks from the date of receipt of the risk assessment reports, the Commission shall present to the Council either an initiative to subject the new psychoactive substances to control measures across the Union, or

[1] OJ L 127, 20.5.2005, p. 32.

a report explaining its views on why such an initiative is not deemed necessary. According to the judgment of the Court of Justice of 16 April 2015 in Joined Cases C-317/13 and C-679/13, the European Parliament must be consulted before an act based on Article 8(1) of Council Decision 2005/387/JHA is adopted.

Based on the findings of the risk assessment reports, the Commission considers that there are grounds for subjecting these substances to control measures across the Union. According to the risk assessment reports, the acute toxicity of cyclopropylfentanyl and methoxyacetylfentanyl are such that it can cause severe harms to the health of individuals.

2. OBJECTIVE OF THE PROPOSAL

The objective of this proposal for a Council Implementing Decision is to call upon the Member States to subject cyclopropylfentanyl and methoxyacetylfentanyl to control measures and criminal penalties as provided under their legislation by virtue of their obligations under the 1961 United Nations Single Convention on Narcotic Drugs as amended by the 1972 Protocol.

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THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Decision 2005/387/JHA of 10 May 2005 on information exchange, risk-assessment and control of new psychoactive substances[2], and in particular Article 8(3) thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Parliament[3],

Whereas:

(1) Risk assessment reports on the new psychoactive substances *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]cyclopropanecarboxamide (cyclopropylfentanyl) and 2-methoxy-*N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]acetamide (methoxyacetylfentanyl) were drawn up in compliance with Article 6 of Decision 2005/387/JHA by a special session of the extended Scientific Committee of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) on 21 March 2018, and were subsequently submitted to the Commission and to the Council on 23 March 2018.

(2) Cyclopropylfentanyl and methoxyacetylfentanyl are synthetic opioids and are structurally related to fentanyl, a controlled substance widely used in medicine as an adjunct to general anaesthesia during surgery and for pain management. Cyclopropylfentanyl is also structurally related to butyrfentanyl, another internationally controlled substance. Methoxyacetylfentanyl is also structurally related to ocfentanil[4] and acetylfentanyl, which are both internationally controlled substances.

(3) Cyclopropylfentanyl has been available in the Union since at least June 2017 and has been detected in six Member States who reported 140 seizures in total between June 2017 and January 2018. Detections in general are likely to be under-reported since the substance is not routinely screened for. In most cases, the substance was seized as powder, but it was also seized, to a lesser extent, as liquids and in tablets. The detected quantities are relatively small. However, they should be seen within the context of the high potency that is typical of the fentanils.

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2 OJ L 127, 20.5.2005, p. 32.

3 OJ C …, xx.xx.2018, p. xx.

4 Ocfentanil was scheduled in Schedule I of the United Nations (UN) Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol (the 'Convention on Narcotic Drugs') at the 61st session of the Commission on Narcotic Drugs in March 2018.

(4) 77 deaths have been reported by two Member States where exposure to cyclopropylfentanyl was confirmed. The deaths occurred within a short time period, i.e. between June and December 2017. In most of the cases, other drugs were also detected with cyclopropylfentanyl. In at least 74 deaths cyclopropylfentanyl was the cause of death or is likely to have contributed to the death. No acute intoxications with confirmed exposure to cyclopropylfentanyl were reported. It is likely that naloxone works as an antidote to poisoning caused by cyclopropylfentanyl. Both non-fatal intoxications and deaths are likely to be under-detected and under-reported as they are not routinely screened for. Accidental exposure to cyclopropylfentanyl may pose a risk to family and friends of the user, law enforcement, emergency personnel, medical and forensic laboratory personnel, as well as to those in custodial settings and postal services.

(5) There is no direct evidence showing the involvement of organised crime in the manufacture, distribution (trafficking) and supply of cyclopropylfentanyl within the Union. However, given the fact that it has been detected in a heroin sample and in falsified medicines, the involvement of organised crime cannot be excluded. The available information suggests that cyclopropylfentanyl is produced by chemical companies based in China, but the capability to manufacture fentanils may also exist within the Union.

(6) Cyclopropylfentanyl appears to be sold online in small and wholesale amounts, under the guise of a "research chemical" or as "legal" replacement to illicit opioids, mainly as a powder or as a solution in ready-to-use nasal sprays. In addition, information from seizures shows that cyclopropylfentanyl has also been used to make falsified (fake) tablets of popular benzodiazepine and analgesic medicines. Information from seizures suggests that cyclopropylfentanyl may have also been sold on the illicit opioid market as methoxyacetylfentanyl, as heroin and in mixtures with other opioids such as heroin. Due to this, users may not be aware that they are using a fentanil.

(7) Methoxyacetylfentanyl has been available in the Union since at least November 2016 and has been detected in eleven Member States who reported 44 seizures in total between June and December 2017. Detections in general are likely to be under-reported since the substance is not routinely screened for. In most cases, the substance was seized as powder or liquid, but it was also seized, to a lesser extent, as tablets. The detected quantities are relatively small. However, they should be seen within the context of the high potency that is typical of the fentanils.

(8) 13 deaths have been reported by four Member States where exposure to methoxyacetylfentanyl was confirmed. In all cases, other drugs were also detected with methoxyacetylfentanyl. In at least seven deaths methoxyacetylfentanyl was the cause of death or is likely to have contributed to the death. Two acute intoxications with confirmed exposure to methoxyacetylfentanyl were reported. It is likely that naloxone works as an antidote to poisoning caused by methoxyacetylfentanyl. Both non-fatal intoxications and deaths are likely to be under-detected and under-reported as they are not routinely screened for. Accidental exposure to methoxyacetylfentanyl may pose a risk to family and friends of users, law enforcement, emergency personnel, medical and forensic laboratory personnel, as well as to those in custodial settings and postal services.

(9) There is no information to suggest the involvement of organised crime in the manufacture, distribution (trafficking) and supply of methoxyacetylfentanyl within the Union. The available information suggests that methoxyacetylfentanyl is produced by

chemical companies in China, but the capability to manufacture fentanils may also exist within the Union.

(10) Methoxyacetylfentanyl appears to be sold online in small and wholesale amounts, under the guise of a "research chemical" or as a "legal" replacement to illicit opioids, as powder or as a solution in ready-to-use nasal sprays. Information from seizures suggests that methoxyacetylfentanyl may have also been sold on the illicit opioid market, where it is sold as or is used to make counterfeits of opioid analgesics and benzodiazepine. Due to this, users may not be aware that they are using a fentanil.

(11) Cyclopropylfentanyl and methoxyacetylfentanyl have no recognised human or veterinary medical use in the Union nor, it appears, elsewhere. There are no indications that the substances may be used for any other purpose aside from as an analytical reference standard and in scientific research.

(12) The risk assessment reports reveal that many of the questions related to cyclopropylfentanyl and methoxyacetylfentanyl that are posed by the lack of data on the risks to individual health, risks to public health, and social risks, could be answered through further research. However, the available evidence and information on the health and social risks that the substances pose, given also their similarities with fentanyl, provides sufficient ground for subjecting cyclopropylfentanyl and methoxyacetylfentanyl to control measures across the Union.

(13) Cyclopropylfentanyl and methoxyacetylfentanyl are not listed for control under the 1961 United Nations Single Convention on Narcotic Drugs or under the 1971 United Nations Convention on Psychotropic Substances. The substances are not currently under assessment by the United Nations system.

(14) Given that eight Member States control cyclopropylfentanyl and nine Member States control methoxyacetylfentanyl under national drug control legislation and five Member States control cyclopropylfentanyl and methoxyacetylfentanyl, respectively, under other legislation, subjecting these substances to control measures across the Union would help avoid the emergence of obstacles in cross-border law enforcement and judicial cooperation, and would help protect from the risks that their availability and use can pose.

(15) Decision 2005/387/JHA confers implementing powers upon the Council with a view to giving a quick and expertise-based response at Union level to the emergence of new psychoactive substances detected and reported by the Member States, by subjecting those substances to control measures across the Union. As the conditions and procedure for triggering the exercise of such implementing powers have been met, an implementing decision should be adopted in order to subject cyclopropylfentanyl and methoxyacetylfentanyl to control measures across the Union.

(16) Denmark is bound by Decision 2005/387/JHA and is therefore taking part in the adoption and application of this Decision.

(17) Ireland is bound by Decision 2005/387/JHA and is therefore taking part in the adoption and application of this Decision.

(18) The United Kingdom is not bound by Decision 2005/387/JHA and is therefore not taking part in the adoption and application of this Decision and is not bound by it or subject to its application,

HAS ADOPTED THIS DECISION:

Article 1

The new psychoactive substances *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]cyclopropanecarboxamide (cyclopropylfentanyl) and 2-methoxy-*N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]acetamide (methoxyacetylfentanyl) shall be subjected to control measures across the Union.

Article 2

By *[one year from the date this Decision is published]* at the latest Member States shall take the necessary measures, in accordance with their national law, to subject the new psychoactive substances referred to in Article 1 to control measures and criminal penalties, as provided for under their legislation, in compliance with their obligations under the 1961 United Nations Single Convention on Narcotic Drugs as amended by the 1972 Protocol.

Article 3

This Decision shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

This Decision shall apply in accordance with the Treaties.

Done at Brussels,

For the Council
The President