Council of the European Union

Brussels, 11 June 2018
(OR. en)

9420/18

Interinstitutional File:
2018/0118 (NLE)

CORDROGUE 52
SAN 165
ENFOPOL 285

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject:	Draft 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

DRAFT

COUNCIL IMPLEMENTING DECISION (EU) 2018/…

of …

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

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[1], 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[2],

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

[2] Opinion of … (not yet published in the Official Journal).

Whereas:

(1) In accordance with Article 6 of Decision 2005/387/JHA, 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 by a special session of the extended Scientific Committee of the European Monitoring Centre for Drugs and Drug Addiction on 21 March 2018, and were 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[1] and acetylfentanyl, which are both internationally controlled substances.

[1] The 61st session of the Commission on Narcotic Drugs in March 2018 decided to schedule Ocfentanil in Schedule I of the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol .

(3) Cyclopropylfentanyl has been available in the Union since at least June 2017. It has been detected in six Member States, which reported 140 seizures in total between June 2017 and January 2018. In general, detections are likely to be under-reported since cyclopropylfentanyl is not routinely screened for. In most cases, cyclopropylfentanyl was seized as powder, but it has also been seized, to a lesser extent, as a liquid and 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.

(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 the case of at least 74 of those 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 caused by cyclopropylfentanyl are likely to be under-detected and under-reported, as cyclopropylfentanyl is 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 fake 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 a 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 fake tablets of popular benzodiazepine and analgesic medicines. Information from seizures suggests that cyclopropylfentanyl can 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. It has been detected in 11 Member States, which reported 44 seizures in total between June and December 2017. In general, detections are likely to be under-reported since methoxyacetylfentanylis not routinely screened for. In most cases, methoxyacetylfentanyl was seized as powder or as a liquid, but it has also been 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 the case of at least seven of those deaths, methoxyacetylfentanyl was the cause of death or was likely to have contributed to the death. Two cases of acute intoxication 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 caused by methoxyacetylfentanyl are likely to be under-detected and under-reported, as methoxyacetylfentanyl is 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 fake 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 they 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 cyclopropylfentanyl and methoxyacetylfentanyl pose, given also their similarities with fentanyl, provide sufficient grounds 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. They 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 that five Member States control cyclopropylfentanyl and methoxyacetylfentanyl under other legislation, subjecting cyclopropylfentanyl and methoxyacetylfentanyl 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 poses.

(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, which implements Decision 2005/387/JHA.

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

(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 of publication of this Decision], Member States shall take the necessary measures, in accordance with their national law, to subject cyclopropylfentanyl and methoxyacetylfentanyl 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 or under the 1971 United Nations Convention on Psychotropic Substances.

Article 3

This Decision shall enter into force on the date 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