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From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
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Subject:	Proposal for a COUNCIL IMPLEMENTING DECISION on subjecting the new psychoactive substance methyl 1-(2-phenylethyl)-4- [phenyl(propanoyl)amino]piperidine-4-carboxylate (carfentanil) to control measures

Delegations will find attached document COM(2017) 765 final.

Encl.: COM(2017) 765 final



EUROPEAN
COMMISSION

Brussels, 18.12.2017
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Proposal for a

COUNCIL IMPLEMENTING DECISION

on subjecting the new psychoactive substance methyl 1-(2-phenylethyl)-4-[phenyl(propanoyl)amino]piperidine-4-carboxylate (carfentanil) 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 substances¹ provides for a three-step procedure that may lead to the submission of a new psychoactive substance to control measures across the Union.

On 27 July 2017, a joint report 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 was issued. On 15 September 2017, following the request made by the Commission and 13 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 substance methyl 1-(2-phenylethyl)-4-[phenyl(propanoyl)amino]piperidine-4-carboxylate (carfentanil), the involvement of organised crime and the possible consequences of control measures introduced on this substance.

The risks of carfentanil 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 report was submitted to the Commission and to the Council on 14 November 2017. The main results of the risk assessment are the following:

- Carfentanil is a synthetic opioid and is closely related to fentanyl, an internationally controlled substance. Carfentanil is one of the most potent narcotic opioid analgesics.
- Carfentanil was formally notified to the EMCDDA in February 2013. 60 deaths with confirmed exposure to carfentanil have been reported by seven Member States. In at least six deaths carfentanil 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 report, the Commission shall present to the Council either an initiative to subject the new psychoactive substances to control measures across the Union, or 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 report, the Commission considers that there are grounds for subjecting this substance to control measures across the Union. According to the risk assessment report, the acute toxicity of carfentanil is 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 carfentanil 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.

¹ OJ L 127, 20.5.2005, p. 32.

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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 substances², and in particular Article 8(3) thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Parliament³,

Whereas:

- (1) A risk assessment report on the new psychoactive substance methyl 1-(2-phenylethyl)-4-[phenyl(propanoyl)amino]piperidine-4-carboxylate (carfentanil) was 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), and was subsequently submitted to the Commission and to the Council on 14 November 2017.
- (2) Carfentanil is a synthetic opioid and is closely related to fentanyl, a controlled substance widely used in medicine as an adjunct to general anaesthesia during surgery and for pain management. Carfentanil is one of the most potent narcotic opioid analgesics.
- (3) Carfentanil was formally notified to the EMCDDA in February 2013 based on a first detection in December 2012. In the past two years there has been an increase in the availability of the substance as well as seizures by law enforcement. Detections in general are likely to be under-reported since the substance is not routinely screened for. More than 800 seizures were reported by seven Member States, more than a fourth of it in the first half of 2017. Typically, carfentanil was seized as a powder. In some cases it has also been seized as a liquid. 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) 60 deaths with confirmed exposure to carfentanil, occurring between November 2016 and June 2017, have been reported by seven Member States. Many of the deaths involved high-risk drug users, including heroin injectors. Other drugs, including morphine and other fentanils, were also detected in many of the cases. In at least six deaths carfentanil was the cause of death or is likely to have contributed to the death; in many of the remaining cases the investigation into death is ongoing. In addition,

² OJ L 127, 20.5.2005, p. 32.

³ OJ C , , p. .

three acute non-fatal intoxications associated with carfentanil were reported by two Member States. It is likely that naloxone works as an antidote to poisoning caused by carfentanil. 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 carfentanil may pose a risk to law enforcement, emergency personnel, medical and forensic laboratory personnel, as well as to those in custodial settings and postal services.

- (5) There is limited information on the involvement of organised crime or established criminal groups in the manufacture, distribution (trafficking) and supply of carfentanil. In this respect, one Member State reported that almost all trafficking and distribution of fentanils, including carfentanil, are linked with organised crime groups in that Member State. The available data suggest that carfentanil is produced by chemical companies in China/Hong Kong. Data also demonstrate that the capability to manufacture fentanils may also exist within the Union.
- (6) Carfentanil is sold online, both on the surface web and on the darknet, in small and wholesale amounts as a drug in its own right, but also as "research chemical", "pharmaceutical intermediate" and/or "legal" replacement to illicit opioids, typically as a powder. Information from reported seizures and deaths show that carfentanil is being mixed with heroin, fentanyl and other fentanils, sold on the illicit opioid market and injected by opioid users, including heroin injectors. It is highly unlikely that users are aware that they are using carfentanil.
- (7) Carfentanil is authorised as a veterinary medicine in the United States for the immobilisation of large animals. It is possible that the substance may have limited use in veterinary medicine in the Union based on a medicinal product that is prepared extemporaneously in accordance with national legislation. A radiolabelled form of carfentanil is widely used in scientific research. Carfentanil is also used as an analytical reference standard and in scientific research.
- (8) The risk assessment report reveals that many of the questions related to carfentanil 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 substance poses, given also its similarities with fentanyl, provides sufficient ground for subjecting carfentanil to control measures across the Union.
- (9) Carfentanil is 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 substance is currently under assessment by the United Nations system and has been reviewed at the 39th meeting of the WHO Expert Committee on Drug Dependence (ECDD) held from 6 to 10 November 2017 in Geneva. This does not preclude the Union taking a decision to subject the substance to control measures.
- (10) Given that twelve Member States control carfentanil under national drug control legislation and four Member States control carfentanil under other legislation, subjecting this substance 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 its availability and use can pose.
- (11) 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 carfentanil to control measures across the Union.

- (12) Denmark is bound by Decision 2005/387/JHA and is therefore taking part in the adoption and application of this Decision.
- (13) Ireland is bound by Decision 2005/387/JHA and is therefore taking part in the adoption and application of this Decision.
- (14) 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 substance methyl 1-(2-phenylethyl)-4-[phenyl(propanoyl)amino]piperidine-4-carboxylate (carfentanil) 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 substance 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*