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2017/0152 (NLE)

Proposal for a

COUNCIL IMPLEMENTING DECISION

on subjecting the new psychoactive substance *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (furanylfentanyl) 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 23 January 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 28 February 2017, following the request made by the Commission and 9 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 furanylfentanyl, the involvement of organised crime and the possible consequences of control measures introduced on this substance.

The risks of furanylfentanyl 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 Chair of the Scientific Committee submitted the risk assessment report to the Commission and to the Council on 24 May 2017. The main results of the risk assessment are the following:

- Furanylfentanyl is a synthetic opioid, closely related to fentanyl which is internationally controlled.
- Furanylfentanyl has been available in the European Union since at least June 2015 and has been detected in 16 Member States. 23 deaths associated with furanylfentanyl have been reported by 5 Member States. In at least 10 deaths furanylfentanyl 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 furanylfentanyl 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 furanylfentanyl to control measures and criminal penalties as provided under their legislation by virtue of their obligations under the 1971 United Nations Convention on Psychotropic Substances.

[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 substances[2], and in particular Article 8(3) thereof,

Having regard to the proposal of the European Commission,

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

Whereas:

(1) A risk assessment report on the new psychoactive substance *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (furanylfentanyl) 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 24 May 2017.

(2) Furanylfentanyl is a synthetic opioid and is structurally similar to fentanyl, a controlled substance widely used in medicine for general anaesthesia during surgery and for pain management. Furanylfentanyl is also structurally related to acetylfentanyl and acryloylfentanyl, which were both the subject of an EMCDDA–Europol Joint Report in December 2015 and December 2016.

(3) Furanylfentanyl has been available in the Union since at least June 2015 and has been detected in 16 Member States. In most cases it was seized in powder form, but also in liquid form and as tablets. The detected quantities are relatively small. However, they should be taken in the context of the potency of the substance.

(4) 23 deaths associated with furanylfentanyl have been reported by five Member States. In at least ten deaths furanylfentanyl was the cause of death or is likely to have contributed to the death. In addition, 11 acute non-fatal intoxications associated with furanylfentanyl were reported by three Member States.

(5) There is no information suggesting the involvement of organised crime in the manufacture, distribution (trafficking) and supply of furanylfentanyl within the Union. The available data suggest that furanylfentanyl is produced by chemical companies based in China.

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

[3] OJ C , , p. .

(6) Furanylfentanyl is sold online in small and wholesale amounts as a "research chemical", typically as a powder and as ready-to-use nasal sprays. Information from seizures suggests that furanylfentanyl may have also been sold on the illicit opioid market.

(7) Furanylfentanyl has no recognised human or veterinary medical use in the Union. There are no indications that furanylfentanyl may be used for any other purpose aside from as an analytical reference standard and in scientific research.

(8) The risk assessment report reveals that many of the questions related to furanylfentanyl 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 furanylfentanyl to control measures across the Union.

(9) Furanylfentanyl 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 not currently under assessment by the United Nations system.

(10) Given that ten Member States control furanylfentanyl under national drug control legislation and three Member State control furanylfentanyl 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 upon the Council implementing powers 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 furanylfentanyl 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, which implements Decision 2005/387/JHA.

(13) 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.

(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, which implements Decision 2005/387/JHA, and is not bound by it or subject to its application,

HAS ADOPTED THIS DECISION:

Article 1

The new psychoactive substance *N*-phenyl-*N*-[1-(2-phenylethyl)piperidin-4-yl]furan-2-carboxamide (furanylfentanyl) 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, complying with their obligations under the 1971 United Nations Convention on Psychotropic Substances.

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