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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
To:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2014) 716 final
Subject:	Proposal for a COUNCIL DECISION on subjecting 4-methyl-5-(4-methylphenyl)-4,5-dihydrooxazol-2-amine (4,4'-DMAR) and 1-cyclohexyl-4-(1,2-diphenylethyl)piperazine (MT-45) to control measures

Delegations will find attached document COM(2014) 716 final.

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2014/0340 (NLE)

Proposal for a

COUNCIL DECISION

on subjecting 4-methyl-5-(4-methylphenyl)-4,5-dihydrooxazol-2-amine (4,4'-DMAR) and 1-cyclohexyl-4-(1,2-diphenylethyl)piperazine (MT-45) to control measures

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

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

On 20 June 2014, pursuant to Article 6(1) of the Council Decision, the Council requested an assessment of the risks posed by the use, manufacture and trafficking of the new psychoactive substance 4-methyl-5-(4-methylphenyl)-4,5-dihydrooxazol-2-amine (also known as 4,4'-DMAR or 4,4'-dimethylaminorex), the involvement of organised crime and the possible consequences of control measures introduced on this substance.

The risks of 4,4'-DMAR were assessed by the Scientific Committee of the European Monitoring Centre for Drugs and Drug Addiction (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 19 September 2014.

The main findings of the risk assessment are the following:

- The new psychoactive substance 4,4'-DMAR appears to have psychostimulant properties. 4,4'-DMAR is structurally related to two substances listed in the 1971 United Nations Convention on Psychotropic Substances (4-methylaminorex and aminorex).

- 4,4'-DMAR has been available on the drug market in the European Union since at least December 2012 and has been detected in nine Member States.

- Although the information available suggests that this substance has not been widely used, there have been 31 deaths associated with 4,4'-DMAR, registered in three Member States over a period of approximately one year, and one non-fatal intoxication.

On 25 September 2014, pursuant to Article 6(1) of the Council Decision, the Council decided to request the risk assessment of 1-cyclohexyl-4-(1,2-diphenylethyl)piperazine (also known as MT-45).

The risks of MT-45 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 6 October 2014.

The main findings of the risk assessment are the following:

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

- The new psychoactive substance MT-45 is a synthetic opioid, with a unique structure, which had been investigated for its analgesic properties in the 1970s.

- MT-45 has been available on the drug market in the European Union since October 2013 and has been detected in three Member States.

- A total of 28 deaths associated with MT-45 have been reported in one Member State, within a period of nine months, as well as 18 non-fatal intoxications.

Pursuant to Article 8(1) of Council Decision, 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 initiative is not deemed necessary.

Although the scientific evidence concerning the overall risks posed by the two substances is limited at this stage, the Commission considers that there are grounds for subjecting 4,4'-DMAR and MT-45 to control measures across the Union. The main reason is that, according to the information available from the risk assessment reports, the toxicity of these substances is such that it can cause severe harms to the health of individuals. Moreover, the risks are heightened by the fact that these substances have been reported, in some cases, to be consumed unknowingly by certain users together with or instead of other psychoactive substances.

2. OBJECTIVE OF THE PROPOSAL

The objective of this proposal for a Council Decision is to call upon the Member States to subject 4,4'-DMAR and MT-45 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.

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Proposal for a

COUNCIL DECISION

on subjecting 4-methyl-5-(4-methylphenyl)-4,5-dihydrooxazol-2-amine (4,4'-DMAR) and 1-cyclohexyl-4-(1,2-diphenylethyl)piperazine (MT-45) 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 the information exchange, risk-assessment and control of new psychoactive substances[2], and in particular Article 8(3) thereof,

Having regard to the initiative of the European Commission,

Whereas:

(1) A risk assessment report on the new psychoactive substance 4-methyl-5-(4-methylphenyl)-4,5-dihydrooxazol-2-amine (4,4'-DMAR) 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 19 September 2014.

(2) 4,4'-DMAR is a synthetic substituted oxazoline derivative. It is a derivative of aminorex and 4-methylaminorex (4-MAR), two synthetic stimulants controlled under the 1971 United Nations Convention on Psychotropic Substances.

(3) 4,4'-DMAR has been available on the Union's drugs market since at least December 2012 and was notified to the Early Warning System in December 2012. Nine Member States reported detections in seizures, mainly under the form of white or coloured powders and tablets, as well as biological and collected samples.

(4) 4,4'-DMAR emerged on the new psychoactive substances market as a 'research chemical' sold by internet retailers, and it is now available on the street market. 4,4'-DMAR is being sold and consumed as a substance in its own, but it has also been mis-sold on the illicit market as ecstasy and amphetamines.

(5) There have been 31 deaths associated with this substance registered in three Member States, between June 2013 and June 2014. In most cases, 4,4'-DMAR was either the

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

cause of death or is likely to have contributed to death together with other substances. One Member State reported a case of non-fatal intoxication.

(6) There are no studies on the toxicity of 4,4'-DMAR.

(7) There is no prevalence data on the use of 4,4'-DMAR, but the information available suggests that it has not been widely used. Information from death cases also suggests that users unknowingly consumed 4,4'-DMAR when seeking other stimulants.

(8) There is limited involvement of organised crime in the manufacture, distribution, trafficking and supply of 4,4'-DMAR within the Union. The chemical precursors and the synthetic routes used to manufacture 4,4'-DMAR are unknown.

(9) 4,4'-DMAR is not listed for control in the 1961 United Nations Single Convention on Narcotic Drugs or in the 1971 United Nations Convention on Psychotropic Substances; it is currently not under assessment and has not been under assessment by the United Nations' system and no such assessment is planned.

(10) 4,4'-DMAR has no established or acknowledged medical human or veterinary use in the Union. Apart from its use in analytical reference materials, and in scientific research investigating its chemistry, pharmacology and toxicology, there is no indication that it is being used for other purposes.

(11) The risk assessment report reveals that there is limited scientific evidence available on 4,4'-DMAR and points out that further research would be needed to determine the health and social risks that it poses. However, the available evidence and information provides sufficient ground for subjecting 4,4'-DMAR to control measures across the Union. As a result of the risks to health that the consumption of 4,4'-DMAR poses, as documented by its detection in several fatalities, of the fact that users may unknowingly consume it and of the lack of medical value of this substance, 4,4'-DMAR should be subjected to control measures.

(12) Since three Member States control 4,4'-DMAR under national legislation complying with the obligations of the 1971 United Nations Convention on Psychotropic Substances and five Member States use other legislative measures to control it, 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 protect from the risks that its availability and use can pose.

(13) A risk assessment report on the new psychoactive substance 1-cyclohexyl-4-(1,2-diphenylethyl)piperazine (MT-45) was drawn up in compliance with Article 6(2), (3) and (4) of Decision 2005/387/JHA by a special session of the extended Scientific Committee of the EMCDDA, and was subsequently submitted to the Commission and to the Council on 6 October 2014.

(14) MT-45 is an *N,N'*-disubstituted piperazine, having a cyclohexane ring attached to one of the nitrogen atoms of the piperazine ring and a 1,2-diphenylethyl moiety attached to the other nitrogen atom. MT-45 is one of a series of 1-(1,2-diphenylethyl) piperazine analgesics invented in the early 1970s.

(15) MT-45 has been present on the drug market in the Union since October 2013 where it is sold as a 'research chemical', mostly on the Internet. EMCDDA identified 12 sites of

internet suppliers and retailers that offered MT-45 for sale, including some apparently based in the Union.

(16) A total of 28 fatalities occurring between November 2013 and July 2014 were reported by one Member State. In most cases, the presence of MT-45 in biological samples was analytically confirmed. Some 18 non-fatal intoxications were also reported by the same Member State and the clinical features were similar to opioid intoxication, responding in some cases to the opioid receptor antagonist naloxone.

(17) There are several studies in animals indicating that the acute toxicity of MT-45 is several-fold higher than that of morphine.

(18) Available information suggests that MT-45 has not been widely used. The substance appears to be mostly used in the home environment either by users willing to try any new substance or by opioid dependent users with no access to heroin or any other opioid. Users may combine MT-45 with other psychoactive substances. There is no information on the social risks that may be related to MT-45.

(19) There is no evidence of involvement of organised crime in the manufacture, distribution, trafficking and supply. The chemical precursors and the synthetic routes used to manufacture the MT-45 detected in Member States are unknown.

(20) MT-45 is not listed for control in the 1961 United Nations Single Convention on Narcotic Drugs or in the 1971 United Nations Convention on Psychotropic Substances; it is currently not under assessment and has not been under assessment by the United Nations' system, and no such assessment is planned.

(21) MT-45 has no established or acknowledged human or veterinary medical use in the Union. Apart from its use in analytical reference materials, and in scientific research investigating its chemistry, pharmacology and toxicology, there is no indication that it is being used for other purposes.

(22) The risk assessment report reveals that there is limited scientific evidence available on MT-45 and points out that further research would be needed to determine the health and social risks that it poses. However, the available evidence and information provides sufficient ground for subjecting MT-45 to control measures across the Union. As a result of the health risks that it poses, as documented by its detection in several fatalities, and of the lack of medical value of this substance, MT-45 should be subjected to control measures.

(23) Since one Member States controls MT-45 under national legislation complying with the obligations of the United Nations Drug Conventions and seven Member States use other legislative measures to control it, 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 protect from the risks that its availability and use can pose,

HAS ADOPTED THIS DECISION:

Article 1

The following new psychoactive substances shall be subjected to control measures across the Union:

(a) 4-methyl-5-(4-methylphenyl)-4,5-dihydrooxazol-2-amine (4,4'-DMAR);

(b) 1-cyclohexyl-4-(1,2-diphenylethyl)piperazine (MT-45).

Article 2

By *[one year from the date this Decision is published]*, 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 complying with their obligations under the 1971 United Nations Convention on Psychotropic Substances.

Article 3

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

Done at Brussels,

For the Council
The President