Council of the European Union

Brussels, 15 June 2015
(OR. en)

9668/1/15
REV 1

Interinstitutional File:
2014/0340 (NLE)

CORDROGUE 42

NOTE

From:	Presidency
To:	Delegations
No. Cion doc.:	16240/14
Subject:	Draft Council implementing 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

In its judgement of 16 April 2015 in Cases C-317/13 and C-679/13 the Court of Justice of the European Union, ruled that the Council should consult the European Parliament before adopting a decision to ban new psychoactive substances following the procedure foreseen in Council Decision 2005/387/JHA. The initial Commission proposal has been revised taking into account the new procedure established by the Court and submitted for the endorsement at the HDG through a silence procedure.

The amendments proposed during the silence procedure are in **bold** for the new text compared to doc. 9668/15 CORDROGUE 42.

Proposal for a

COUNCIL IMPLEMENTING DECISION

of …

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[1], 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[2],

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 accordance 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.

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

[2] Opinion of XX XX 2015 (OJ / not yet published in the Official Journal).

(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 drugs market in the Union since at least December 2012 and was notified to the Early Warning System in December 2012. Nine Member States have reported detections as a result of seizures of the substance, mainly in 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 on 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 4,4'-DMAR registered in three Member States, between June 2013 and June 2014. In most cases, 4,4'-DMAR was either the cause of death or, together with other substances, is likely to have contributed to death. One Member State has 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. However, the information available suggests that it has not been widely used. Information obtained from cases involving death 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 under the 1961 United Nations Single Convention on Narcotic Drugs or under the 1971 United Nations Convention on Psychotropic Substances. It is not currently 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 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.

(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 evidence and information currently available 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) Given that 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 against 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 accordance 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 drugs market in the Union since October 2013, where it is sold as a 'research chemical', mostly on the internet. The EMCDDA has identified 12 sites of internet suppliers and retailers that have 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 have been reported by one Member State. In most cases, the presence of MT-45 in biological samples was analytically confirmed. Some 18 non-fatal intoxications have also been reported by the same Member State, the clinical features of which 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) Currently 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 a 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 of MT-45 in the Union. 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 under the 1961 United Nations Single Convention on Narcotic Drugs or under the 1971 United Nations Convention on Psychotropic Substances. It is not currently 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 evidence and information currently available provides sufficient grounds 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) Given that one Member State controls MT-45 under national legislation complying with the obligations under the 1961 United Nations Single Convention on Narcotic Drugs and under the 1971 United Nations Convention on Psychotropic Substances 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 against the risks that its availability and use can pose.

(24) Decision 2005/387/JHA confers upon the Council implementing powers with a view to giving a quick and expertise-based response at the 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 put 4,4'-DMAR and MT-45 under control across the Union.

(25) 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.

(26) 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.

(27) The United Kingdom is not bound by Decision 2005/387/JHA and is therefore not taking part in the adoption 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 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 **and/or under the 1961 United Nations Single Convention on Narcotic Drugs**.

Article 3

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

Done at …,

For the Council

The President