

Council of the European Union

> Brussels, 21 February 2017 (OR. en)

6504/17

Interinstitutional File: 2017/0026 (NLE)

> CORDROGUE 23 SAN 69 RELEX 152

NOTE

From:	Presidency
То:	Delegations
No. prev. doc.:	5912/17
Subject:	Draft Council decision on the position to be adopted, on behalf of the European Union, in the sixtieth session of the Commission on Narcotic Drugs on the scheduling of substances under the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol and the Convention on Psychotropic Substances of 1971

Delegations will find attached the revised text of the above-mentioned proposal, including the amendments proposed by the Council Legal Service.

Changes compared to doc. 5912/17 CORDROGUE 11 SAN 52 RELEX 93 are in **bold-underline** for new text and strike through for deleted text.

2017/0026 (NLE)

draft

COUNCIL DECISION

on the position to be adopted, on behalf of the European Union, in the sixtieth session of the Commission on Narcotic Drugs on the scheduling of substances under the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol and the Convention on Psychotropic Substances of 1971

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 83(1), in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The United Nations (UN) Single Convention on Narcotic Drugs of 1961¹ as amended by the 1972 Protocol,² entered into force on 8 August 1975.
- (2) Pursuant to Article 3 of the UN Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol, the Commission on Narcotic Drugs may decide to add substances to the Schedules of that Convention. It can make changes in the Schedules only in accordance with the recommendations of the World Health Organisation (WHO), but it can also decide not to make the changes recommended by the WHO.
- (3) The UN Convention on Psychotropic Substances of 1971 entered into force on 16 August 1976.
- (4) Pursuant to Article 2 of the UN Convention on Psychotropic Substances of 1971, the Commission on Narcotic Drugs may decide to add substances to the Schedules of that Convention or to remove them, on the basis of the recommendations of the WHO. It has broad discretionary powers to take into account economic, social, legal, administrative and other factors, but may not act arbitrarily.

¹ United Nations Treaty Series, vol. 978, No. 14152.

² United Nations Treaty Series, vol. 1019, No. 14956.

- (5) Changes to the Schedules of both Conventions have direct repercussions on the scope of application of Union law in the area of drug control for all <u>participating</u> Member States. Council Framework Decision 2004/757/JHA ³ applies to substances listed in the Schedules to the UN Single Convention on Narcotic Drugs of 1961 and the UN Convention on Psychotropic Substances of 1971. <u>Council Decision 2005/387/JHA does not apply to substances listed in the Schedules to the UN Convention on Psychotropic Substances of 1971</u>. <u>Thus any change to the Schedules annexed to those Conventions directly affects common Union rules and alters their scope, in accordance with the meaning of Article 3(2) of the Treaty on the Functioning of the European Union.</u>
- (6) The Commission on Narcotic Drugs should, during its sixtieth session of 13 to 17 March 2017 in Vienna, take decisions on the addition of ten new substances to the Schedules of the Conventions.
- (7) The Union is not a party to the relevant UN conventions. It has an observer status in the Commission on Narcotic Drugs where currently 12 Member States are members with the right to vote. It is therefore necessary for the Council to authorise the Member States to express the position of the Union on the scheduling of substances under the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol and the Convention on Psychotropic Substances of 1971 since the decisions on the addition of new substances to the Schedules of the Conventions fall under the exclusive competence of the Union.
- (8) The WHO recommended on 2 December 2016 to Secretary-General of the UN to add two new substances to Schedule I of the UN Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, and eight new substances to Schedule II of the UN Convention on Psychotropic Substances of 1971.
- (9) U-47700 (3,4-dichloro-N-(2-dimethylamino-cyclohexyl)-N-methyl-benzamide) is, according to the assessment of the WHO Expert Committee on Drug Dependence, a compound liable to similar abuse and with similar ill-effects to controlled opioids such as morphine and AH-7921, that are included in Schedule I of the UN Single Convention on Narcotic Drugs of 1961. It has no recorded therapeutic use, and its use has resulted in fatalities. There is sufficient evidence that it is being or is likely to be abused, and may become a public health and social problem warranting the placing of the substance under international control. Consequently, the WHO recommends that U-47700 be placed in Schedule I of the UN Single Convention on Narcotic Drugs of 1961.
- (10) U-47700 is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Council Decision 2005/387/JHA⁴. U-47700 has been detected in fourteen Union Member States. It is being sold openly on the market. It has been associated with serious adverse events, including deaths and has been a subject of a public health-related alert issued to the Union Early Warning System.

³ Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking (OJ L 335, 11.11.2004, p. 8).

⁴ Council Decision 2005/387/JHA on the information exchange, risk-assessment and control of new psychoactive substances (OJ L 127, 20.5.2005, p. 32).

- (11) Therefore, the Member States of the Union should take the position to add U-47700 to Schedule I of the UN Single Convention on Narcotic Drugs of 1961.
- (12) Butyrfentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-**p**iperidinyl]butanamide) is, according to the assessment of the WHO Expert Committee on Drug Dependence, a compound liable to similar abuse and with similar ill-effects to controlled opioids such as morphine and fentanyl that are included in Schedule I of the UN Single Convention on Narcotic Drugs of 1961. It can also be converted into fentanyl . It has no recorded therapeutic use and its use has resulted in fatalities. There is sufficient evidence that it is being or is likely to be abused and may constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that butyrfentanyl be placed in Schedule I of the UN Single Convention on Narcotic Drugs of 1961.
- (13) Butyrfentanyl is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Council Decision 2005/387/JHA. Butyrfentanyl has been detected in six Union Member States. It has been sold openly on the market. It has been associated with serious adverse events, including detection in at least one death and has been the subject of a public health-related alert issued to the Union Early Warning System.
- (14) Therefore, the Member States of the Union should take the position to add butyrfentanyl to Schedule I<u>I</u> of the UN Single Convention on Narcotic Drugs of 1961.
- (15) The degree of risk to public health and society associated with the abuse of 4-Methylethcathinone or 4-MEC (2-(ethylamino)-1-(4-methylphenyl) propan-1-one) is, according to the assessment of the WHO Expert Committee on Drug Dependence, substantial. Therapeutic usefulness has not been recorded. It recognized that it has similar abuse potential and similar ill-effects as substances in Schedule II of the UN Convention on Psychotropic Substances of 1971. The Committee considered that there is sufficient evidence that 4-MEC is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that 4-MEC be placed in Schedule II under the UN Convention on Psychotropic Substances of 1971.
- (16) 4-MEC is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Council Decision 2005/387/JHA. 4-MEC has been detected in nineteen Union Member States. It has been sold openly on the market. It has been associated with small number of serious adverse events, including deaths.
- (17) Therefore, the Member States of the Union should take the position to add 4-MEC to Schedule I<u>I</u> of the UN Convention on Psychotropic Substances of 1971.

- (18) The degree of risk to public health and society associated with the abuse of ethylone (1-(2H-1,3-benzodioxol-5-yl)-2-(ethylamino)propan-1-one) is, according to the assessment of the WHO Expert Committee on Drug Dependence, substantial. Therapeutic usefulness has not been recorded. The WHO Expert Committee on Drug Dependence recognized that ethylone (1-(2H-1,3-benzodioxol-5-yl)-2-(ethylamino)propan-1-one) has similar abuse potential and similar ill-effects as substances in Schedule II of the UN Convention on Psychotropic Substances of 1971. The Committee considered that there is sufficient evidence that ethylone is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that ethylone be placed in Schedule II under the UN Convention on Psychotropic Substances 1971.
- (19) Ethylone is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Council Decision 2005/387/JHA on the information exchange, risk-assessment and control of new psychoactive substances. Ethylone has been detected in 19 EU Member States. It has been sold openly on the market. It has been associated with small number of serious adverse events, including deaths.
- (20) Therefore, the Member States of the Union should take the position to add ethylone to Schedule I<u>I</u> of the UN Convention on Psychotropic Substances of 1971.
- (21) The degree of risk to public health and society associated with the abuse of pentedrone or α -Methylaminovalerophenone (2-(methylamino)-1-phenylpentan-1-one), according to the WHO Expert Committee on Drug Dependence, is substantial. Therapeutic usefulness has not been recorded. It recognized that it has similar abuse and similar ill-effects as substances in Schedule II of the United Nations 1971 Convention on Psychotropic Substances. The Committee considered that there is sufficient evidence that pentedrone is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that pentedrone be placed in Schedule II under the United Nations 1971 Convention on Psychotropic Substances.
- (22) Pentedrone is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Council Decision 2005/387/JHA. Pentedrone has been detected in eighteen Union Member States. It has been sold openly on the market. It has been associated with a small number of serious adverse events, including deaths.
- (23) Therefore, the Member States of the Union should take the position to add pentedrone to Schedule I<u>I</u> of the UN Convention on Psychotropic Substances of 1971.
- (24) The degree of risk to public health and society associated with the abuse of ethylphenidate or EPH (ethyl phenyl(piperidin-2-yl)acetate) is, according to the WHO Expert Committee on Drug Dependence, substantial. Therapeutic usefulness has not been recorded. It recognized that it has similar abuse potential and similar ill-effects as substances in Schedule II of the UN Convention on Psychotropic Substances of 1971. The Committee considered that there is sufficient evidence that ethylphenidate is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that ethylphenidate be placed in Schedule II under the United Nations Convention on Psychotropic Substances of 1971.

- (25) Ethylphenidate is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Council Decision 2005/387/JHA. Ethylphenidate has been detected in thirteen UnionMember States. It has been sold openly on the market. It has been associated with serious adverse events, including soft tissue infections and deaths. Soft tissue infections related to injection have been the subject of a public health-related alert issued to the Union Early Warning System.
- (26) Therefore, the Member States of the Union should take the position to add ethylphenidate to Schedule I<u>I</u> of the UN Convention on Psychotropic Substances of 1971.
- (27) The degree of risk to public health and society associated with the abuse of MPA or methiopropamine (N-methyl-1-(thiophen-2-yl)propan-2-amine) is, according to the WHO Expert Committee on Drug Dependence (ECDD), substantial. Therapeutic usefulness has not been recorded. It recognized that it has similar abuse potential and similar ill-effects as substances in Schedule II of the United Nations 1971 Convention on Psychotropic Substances. The Committee considered that there is sufficient evidence that methiopropamine is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus the WHO recommends that methiopropamine be placed in Schedule II under the UN Convention on Psychotropic Substances of 1971.
- (28) MPA is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Council Decision 2005/387/JHA. MPA has been detected in seventeen Union Member States. It has been sold openly on the market. It has been associated with serious adverse events, including deaths.
- (29) Therefore, the Member States of the Union should take the position to add methiopropamine to Schedule I<u>I</u> of the UN Convention on Psychotropic Substances of 1971.
- (30) The degree of risk to public health and society associated with the abuse of MDMB-CHMICA (<u>methyl</u> N-{[1-(cyclohexylmethyl)-1H-indol-3-yl]carbonyl}-3-methyl-L-valinate) is, according to the WHO Expert Committee on Drug Dependence, substantial. Therapeutic usefulness has not been recorded. It recognized that it has similar abuse and similar ill-effects as substances in Schedule II of the UN Convention on Psychotropic Substances of 1971. The Committee considered that there is sufficient evidence that MDMB-CHMICA is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that MDMB-CHMICA be placed in Schedule II under the UN Convention on Psychotropic Substances of 1971.

- (31) According the risk assessment report of the European Monitoring Centre for Drugs and Drug Addiction conducted compliance with the provisions of Article 6(2), (3) and (4) of Council Decision Council Decision 2005/387/JHA ⁵ and submitted on 28 July 2016 to Commission and the Council, the high potency of MDMB-CHMICA and the highly variable amounts of the compound in "legal high" products constitute a high risk of acute toxicity. Eight Member States have reported a total of 28 deaths and 25 acute intoxications associated with MDMB-CHMICA. The Commission therefore adopted on 31 August 2016 a proposal in order to subject MDMB-CHMICA to Union-wide control measures.⁶
- (32) Therefore, the Member States of the Union should take the position to add MDMB-CHMICA to Schedule I<u>I</u> of the UN Convention on Psychotropic Substances of 1971.
- (33) The degree of risk to public health and society associated with the abuse of 5F-APINACA or 5F-AKB-48 (N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide) is according to the WHO Expert Committee on Drug Dependence considered substantial. Therapeutic usefulness has not been recorded. It recognized that it has similar abuse potential and similar ill-effects as substances in Schedule II of the UN Convention on Psychotropic Substances of 1971. The Committee considered that there is sufficient evidence that 5F-APINACA is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that 5F-APINACA be placed in Schedule II under the UN Convention on Psychotropic Substances of 1971.
- (34) 5F-APINACA is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Council Decision 2005/387/JHA. 5F-APINACA has been detected in twenty three Union Member States. It has been sold openly on the market. It has been associated with serious adverse events, including deaths.
- (35) Therefore, the Member States of the Union should take the position to add 5F-APINACA to Schedule I<u>I</u> of the UN Convention on Psychotropic Substances of 1971.
- (36) The degree of risk to public health and society associated with the abuse of XLR-11 [1-(5-fluoropentyl)-1H-indol-3-yl](2,2,3,3-tetramethylcyclopropyl)<u>methanone</u> is according to the WHO Expert Committee on Drug Dependence substantial. Therapeutic usefulness has not been recorded. It recognized that it has similar abuse potential and similar ill-effects as substances in Schedule II of the UN Convention on Psychotropic Substances of 1971 such as JWH-018 and AM-2201. The Committee considered that there is sufficient evidence that XLR-11 is being or is likely to be abused so as to constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that XLR-11 be placed in Schedule II under the UN Convention on Psychotropic Substances of 1971.

⁵ OJ L 127, 20.5.2005, p. 32.

⁶ Proposal for a Council Decision on subjecting the new psychoactive substance methyl 2-[[1-(cyclohexylmethyl)-1*H*-indole-3-carbonyl]amino]-3,3-dimethylbutanoate (MDMB-CHMICA) to control measures (COM(2016)548 final).

- (37) XLR-11 is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Council Decision 2005/387/JHA. XLR-11 has been detected in seventeen Union Member States. It has been sold openly on the market. It has been associated with small number of serious adverse events, including detections in at least one death and has been the subject of a public health-related alert issued to the Union Early Warning System.
- (38) Therefore, the Member States of the Union should take the position to add XLR-11 to Schedule I<u>I</u> of the UN Convention on Psychotropic Substances of 1971.
- (38a) Denmark is bound by Framework Decision 2004/757 JHA and Council Decision 2005/387/JHA and is therefore taking part in the adoption and application of this Decision.
- (38b) Ireland is bound by Framework Decision 2004/757 JHA and Council Decision 2005/387/JHA and is therefore taking part in the adoption and application of this Decision.
- (39) The United Kingdom is not bound by In accordance with Article 10(4) of the Protocol No 36 on transitional measures, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, Framework Decision 2004/757 JHA and Council Decision 2005/387/JHA have ceased to apply to the United Kingdom as from 1 December 2014. The United Kingdom and is therefore not taking part in the adoption of this Decision, and is not bound by it or subject to its application.

HAS ADOPTED THIS DECISION:

Article 1

The position to be adopted on the Union's behalf by the Member States in the Commission on Narcotic Drugs in March 2017 when that body is called upon to adopt decisions on the addition of substances to the Schedules of the United Nations Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol and the United Nations Convention on Psychotropic Substances of 1971 at its sixtieth session shall be in accordance with the Annex to this Decision.

The position shall be expressed by the Member States which are members of the Commission of Narcotic Drugs, acting jointly in the interest of the Union.

Article 2

This Decision is addressed to the Member States in accordance with the Treaties.

Done at Brussels,

For the Council The President