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LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject: 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

COUNCIL DECISION (EU) 2017/...

of ...

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,

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Whereas:

- (1) The United Nations (UN) Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, (the 'Convention on Narcotic Drugs') entered into force on 8 August 1975.
- (2) Pursuant to Article 3 of the Convention on Narcotic Drugs, the Commission on Narcotic Drugs may decide to add substances to the Schedules of that Convention. It can make changes to the Schedules only in accordance with the recommendations of the World Health Organization (WHO), but it can also decide not to make the changes recommended by the WHO.
- (3) The UN Convention on Psychotropic Substances of 1971 (the 'Convention on Psychotropic Substances') entered into force on 16 August 1976.
- (4) Pursuant to Article 2 of the Convention on Psychotropic Substances, 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.

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- (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. Council Framework

 Decision 2004/757/JHA¹ applies to substances listed in the Schedules to the Convention on Narcotic Drugs and the Convention on Psychotropic Substances. Council Decision 2005/387/JHA² does not apply to substances listed in the Schedules to the Convention on Narcotic Drugs or to the Convention on Psychotropic Substances. Thus, any change to the Schedules annexed to those Conventions is directly incorporated into common Union rules.
- (6) The Commission on Narcotic Drugs should, during its sixtieth session on 13 to 17 March 2017 in Vienna, decide 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 that the Member States express the position of the Union on the scheduling of substances under the Convention on Narcotic Drugs and the Convention on Psychotropic Substances.

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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).

² Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances (OJ L 127, 20.5.2005, p. 32).

- (8) The position to be adopted on the Union's behalf at the next session of the Commission on Narcotic Drugs only concerns the scheduling of substances under the Conventions. Matters other than the scheduling of substances are not the object of the present decision and will be dealt by the Member States through coordination in the margins of the session of the Commission on Narcotic Drugs as appropriate. This Decision is without prejudice to the delimitation of competences between the Union and the Member States on other matters in relation to the Conventions.
- (9) The WHO recommended on 2 December 2016 to the Secretary-General of the UN to add two new substances to Schedule I of the Convention on Narcotic Drugs, and eight new substances to Schedule II of the Convention on Psychotropic Substances.
- (10) According to the assessment of the WHO Expert Committee on Drug Dependence (the Expert Committee), U-47700 (3,4-dichloro-N-(2-dimethylamino-cyclohexyl)-N-methylbenzamide) is a compound liable to similar abuse as and with similar ill-effects to those of controlled opioids such as morphine and AH-7921, that are included in Schedule I of the Convention on Narcotic Drugs. 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 that warrants placing the substance under international control. Consequently, the WHO recommends that U-47700 be placed in Schedule I of the Convention on Narcotic Drugs.

- (11) U-47700 is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Decision 2005/387/JHA. U-47700 has been detected in 14 Member States. It has been sold openly on the market. It has been associated with serious adverse events, including deaths, and has been the subject of a public health-related alert issued to the Union Early Warning System.
- (12) Therefore, the Member States should take the position to add U-47700 to Schedule I of the Convention on Narcotic Drugs.
- (13) According to the assessment of the Expert Committee, butyrfentanyl (N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]butanamide) is a compound liable to similar abuse as and with similar ill-effects to those of controlled opioids, such as morphine and fentanyl, that are included in Schedule I of the Convention on Narcotic Drugs. 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 that warrants placing the substance under international control. Thus, the WHO recommends that butyrfentanyl be placed in Schedule I of the Convention on Narcotic Drugs.

- (14) Butyrfentanyl is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Decision 2005/387/JHA. Butyrfentanyl has been detected in six Member States. It has been sold openly on the market. It has been associated with serious adverse events, including the case of at least one death in which it was detected and has been the subject of a public health-related alert issued to the Union Early Warning System.
- (15) Therefore, the Member States should take the position to add butyrfentanyl to Schedule I of the Convention on Narcotic Drugs.
- According to the assessment of the Expert Committee, 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 substantial. 4-MEC has no recorded therapeutic use. The Expert Committee recognises that 4-MEC has similar abuse potential to and similar ill-effects to those of substances in Schedule II of the Convention on Psychotropic Substances. The Expert Committee considers that there is sufficient evidence that 4-MEC is being or is likely to be abused, and therefore constitutes a public health and social problem that warrants placing the substance under international control. Thus, the WHO recommends that 4-MEC be placed in Schedule II under the Convention on Psychotropic Substances.
- 4-MEC is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Decision 2005/387/JHA. 4-MEC has been detected in 19 Member States. It has been sold openly on the market. It has been associated with small number of serious adverse events, including deaths.

- (18) Therefore, the Member States should take the position to add 4-MEC to Schedule II of the Convention on Psychotropic Substances.
- (19) According to the assessment of the Expert Committee, 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 substantial. Ethylone has no recorded therapeutic use. The Expert Committee recognises that ethylone (1-(2H-1,3-benzodioxol-5-yl)-2-(ethylamino)propan-1-one) has similar abuse potential to and similar ill-effects to those of substances in Schedule II of the Convention on Psychotropic Substances. The Expert Committee considers that there is sufficient evidence that ethylone is being or is likely to be abused, and therefore constitutes a public health and social problem that warrants the placing of the substance under international control. Thus, the WHO recommends that ethylone be placed in Schedule II under the Convention on Psychotropic Substances.
- (20) Ethylone is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Decision 2005/387/JHA. Ethylone has been detected in 19 Member States. It has been sold openly on the market. It has been associated with small number of serious adverse events, including deaths.
- (21) Therefore, the Member States should take the position to add ethylone to Schedule II of the Convention on Psychotropic Substances.

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- According to the Expert Committee, the degree of risk to public health and society associated with the abuse of pentedrone or α-Methylaminovalerophenone (2- (methylamino)-1-phenylpentan-1-one), is substantial. Pentedrone has no recorded therapeutic use. The Expert Committee recognises that pentedrone has similar abuse to and similar ill-effects to those of substances in Schedule II of the Convention on Psychotropic Substances. The Expert Committee considers that there is sufficient evidence that pentedrone is being or is likely to be abused, and therefore constitutes a public health and social problem that warrants placing the substance under international control. Thus, the WHO recommends that pentedrone be placed in Schedule II under the Convention on Psychotropic Substances.
- (23) Pentedrone is monitored by the European Monitoring Centre for Drugs and Drug
 Addiction as a new psychoactive substance under the terms of Decision 2005/387/JHA.

 Pentedrone has been detected in 18 Member States. It has been sold openly on the market.

 It has been associated with a small number of serious adverse events, including deaths.
- (24) Therefore, the Member States should take the position to add pentedrone to Schedule II of the Convention on Psychotropic Substances.

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- According to the Expert Committee, the degree of risk to public health and society associated with the abuse of ethylphenidate or EPH (ethyl phenyl(piperidin-2-yl)acetate) is substantial. Ethylphenidate has no recorded therapeutic use. The Expert Committee recognises that ethylphenidate has similar abuse potential to and similar ill-effects to those of substances in Schedule II of the Convention on Psychotropic Substances. The Expert Committee considers that there is sufficient evidence that ethylphenidate is being or is likely to be abused, and therefore constitutes a public health and social problem that warrants placing the substance under international control. Thus, the WHO recommends that ethylphenidate be placed in Schedule II under the Convention on Psychotropic Substances.
- (26) Ethylphenidate is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Decision 2005/387/JHA. Ethylphenidate has been detected in 13 Member 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.
- (27) Therefore, the Member States should take the position to add ethylphenidate to Schedule II of the Convention on Psychotropic Substances.

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- According to the Expert Committee, 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 substantial. MPA has no recorded therapeutic use. The Expert Committee recognises that MPA has similar abuse potential to and similar ill-effects to those of substances in Schedule II of the Convention on Psychotropic Substances. The Expert Committee considers that there is sufficient evidence that MPA is being or is likely to be abused. and therefore constitutes a public health and social problem that warrants placing the substance under international control. Thus the WHO recommends that methiopropamine be placed in Schedule II under the Convention on Psychotropic Substances.
- (29) MPA is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Decision 2005/387/JHA. MPA has been detected in 17 Member States. It has been sold openly on the market. It has been associated with serious adverse events, including deaths.
- (30) Therefore, the Member States should take the position to add methiopropamine to Schedule II of the Convention on Psychotropic Substances.

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- According to the Expert Committee, the degree of risk to public health and society associated with the abuse of MDMB-CHMICA (methyl N-{[1-(cyclohexylmethyl)-1H-indol-3-yl]carbonyl}-3-methyl-L-valinate) is substantial. MDBD-CHMICA has no recorded therapeutic use. The Expert Committee recognises that MDBD-CHMICA has similar abuse to and similar ill-effects to those of substances in Schedule II of the Convention on Psychotropic Substances. The Expert Committee considers that there is sufficient evidence that MDMB-CHMICA is being or is likely to be abused, and therefore constitutes a public health and social problem that warrants placing the substance under international control. Thus, the WHO recommends that MDMB-CHMICA be placed in Schedule II under the Convention on Psychotropic Substances.
- According to the risk assessment report of the European Monitoring Centre for Drugs and Drug Addiction, which was conducted under Article 6(2), (3) and (4) of Decision 2005/387/JHA and submitted on 28 July 2016 to the Commission and to 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 to subject MDMB-CHMICA to Union-wide control measures.

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- (33) Therefore, the Member States should take the position to add MDMB-CHMICA to Schedule II of the Convention on Psychotropic Substances.
- According to the Expert Committee, 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 substantial. It has no recorded therapeutic use. The Expert Committee recognises that 5F-APINACA has similar abuse potential to and similar ill-effects to those of substances in Schedule II of the Convention on Psychotropic Substances. The Expert Committee considers that there is sufficient evidence that 5F-APINACA is being or is likely to be abused, and therefore constitutes a public health and social problem that warrants placing the substance under international control. Thus, the WHO recommends that 5F-APINACA be placed in Schedule II under the Convention on Psychotropic Substances.
- (35) 5F-APINACA is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Decision 2005/387/JHA. 5F-APINACA has been detected in 23 Member States. It has been sold openly on the market. It has been associated with serious adverse events, including deaths.
- (36) Therefore, the Member States should take the position to add 5F-APINACA to Schedule II of the Convention on Psychotropic Substances.

- (37) According to the Expert Committee, 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)methanone is substantial. XLR-11 has no recorded therapeutic use. The Expert Committee recognises that XLR-11 has similar abuse potential to and similar ill-effects to those of substances in Schedule II of the Convention on Psychotropic Substances such as JWH-018 and AM-2201. The Expert Committee considers that there is sufficient evidence that XLR-11 is being or is likely to be abused, and therefore constitutes a public health and social problem that warrants placing the substance under international control. Thus, the WHO recommends that XLR-11 be placed in Schedule II under the Convention on Psychotropic Substances.
- (38) XLR-11 is monitored by the European Monitoring Centre for Drugs and Drug Addiction as a new psychoactive substance under the terms of Decision 2005/387/JHA. XLR-11 has been detected in 17 Member States. It has been sold openly on the market. It has been associated with small number of serious adverse events, including at least one death in which it was detected, and has been the subject of a public health-related alert issued to the Union Early Warning System.
- (39) Therefore, the Member States should take the position to add XLR-11 to Schedule II of the Convention on Psychotropic Substances.

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- (40)Denmark is bound by Framework Decision 2004/757/JHA and Decision 2005/387/JHA and is therefore taking part in the adoption and application of this Decision.
- (41) Ireland is bound by Framework Decision 2004/757/JHA and Decision 2005/387/JHA and is therefore taking part in the adoption and application of this Decision.
- (42) The United Kingdom is not bound by Framework Decision 2004/757/JHA and Decision 2005/387/JHA 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:

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Article 1

The position to be adopted on the Union's behalf by the Member States in the Commission on Narcotic Drugs on 13 to 17 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 that are members of the Commission on 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

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ANNEX

Position to be taken by the Member States which are members of the Commission on Narcotic Drugs acting jointly in the interest of the Union during the sixtieth session of the Commission on Narcotic Drugs on 13 to 17 March 2017 regarding changes in the scope of control of substances:

- (1) U-47700 is to be included in Schedule I of the Single Convention of Narcotic Drugs of 1961 as amended by the 1972 Protocol.
- (2) Butyrfentanyl is to be included in Schedule I of the Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol.
- (3) 4-MEC (4-Methylethcathinone) is to be included in Schedule II of 1971 Convention on Psychotropic Substances.
- (4) Ethylone is to be included in Schedule II of the Convention on Psychotropic Substances of 1971.
- (5) Pentedrone (α-Methylaminovalerophenone) is to be included in Schedule II of the Convention on Psychotropic Substances of 1971.

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- (6) Ethylphenidate (EPH) is to be included in Schedule II of the Convention on Psychotropic Substances of 1971.
- (7) MPA (methiopropamine) is to be included in Schedule II of the Convention on Psychotropic Substances of 1971.
- (8) MDMB-CHMICA is to be included in Schedule II of the Convention on Psychotropic Substances of 1971.
- (9) 5F-APINACA (5F-AKB48) is to be included in Schedule II of the Convention on Psychotropic Substances of 1971.
- (10) XLR-11 is to be included in Schedule II of the Convention on Psychotropic Substances of 1971.

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