

## ***Information Note-COM (2019) 631 Final***

### **1. Proposal**

*This Proposal concerns the decision establishing the position to be taken on the Union's behalf in the 63<sup>rd</sup> session of the Commission on Narcotic Drugs (CND) on the scheduling of substances under the UN Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, and the UN Convention on Psychotropic Substances of 1971*

### **2. Date of Commission document**

*17/12/2019*

### **3. Number of Commission document**

*COM (2019) 631*

### **4. Number of Council document:**

*15126/19*

### **5. Dealt with in Brussels by**

*Horizontal Working Party on Drugs (HDG)*

### **6. Department with primary responsibility**

*Department of Health*

### **7. Other Departments involved**

*None*

### **8. Background to, Short summary and aim of the proposal**

*The aim of the proposal is to allow for an EU position to be adopted at the 63<sup>rd</sup> session of the Commission on Narcotic Drugs (CND) meeting due to take place in Vienna from 2 to 6 March 2020 on the scheduling of substances under the UN Conventions.*

*CND regularly amends the list of substances that are annexed to the United Nations (UN) Single Convention on Narcotic Drugs of 1961 (the 1961 Convention) and to the UN Convention on Psychoactive Substances of 1971 (the 1971 Convention) on the basis of recommendations from the World Health Organisation (WHO).*

*While all EU Member States are signatories of the Conventions, the EU itself is not.*

*The World Health Organisation (WHO) recommended on 15 November 2019 to the Secretary General of the UN to add 12 of the 13 substances which were critically reviewed by the WHO Expert Committee on Drug Dependence to the schedules of the Conventions. The CND will adopt decisions on the scheduling of these 12 substances under the Conventions on Narcotic Drugs and the Convention on Psychotropic substances at its March meeting.*

*Changes to the schedules of both Conventions impact on the scope of application of EU law in the area of drug control for all Member States. The Drugs Framework Decision 2004/757/JHA of 25 October 2004 lays down minimum rules relating to the constituent*

*elements of the criminal offences of illicit trafficking in drugs and applies to substances listed in both schedules. The EU has an interest therefore in agreeing a common position regarding additions to the schedules and in this instance is seeking to include all the substances in the schedules.*

*None of the 13 substances, which have been reviewed by the Expert Committee on Drug Dependence, is subject to control measures across the Union yet.*

*The practice in 2015 and in 2016 was that Member States on their own initiative coordinated their positions within the Horizontal working Party on Drugs (HDG) and also in the margins of CND meetings. In 2017 the EU Commission submitted a Proposal COM (2017) 072 to coordinate an EU position and that this position would be expressed by Member States that are currently full members of the CND. Council Legal Services confirmed at the time that as the CND's decision on scheduling the substances will have legal effects under the EU Drugs Framework Decision, the EU has exclusive competence for the conclusion of an international agreement. The proposal was adopted and the EU spoke with one voice at the 2017 March CND meeting. It is now proposed to adopt the same approach in 2020 and agree a common position for the meeting to be expressed by the Member States that are members of the CND.*

#### **9. Legal basis of the proposal**

*Article 83(1) in conjunction with Article 218 (9) of the Treaty on the Functioning of the European Union (TFEU).*

#### **10. Voting Method**

*Qualified Majority Voting (QMV)*

#### **11. Role of the EP**

*None*

#### **12. Category of proposal**

*Establishment of a coordinated EU position as provided under Article 218 (9) TFEU.*

#### **13. Implications for Ireland & Ireland's Initial View'**

*The EU Commission is seeking to coordinate a position in advance of the CND meeting from 2 to 6 March 2020 and is requiring those Member States that are full members of the CND to express the EU position at CND. In view of the confirmation from Council Legal Services that decisions on scheduling substances by the CND fall within the exclusive external competence of the Union, Ireland supports the Commission's proposal.*

*Ireland participates in Drugs Framework Decision 2004/757/JHA so as a substance is added to the UN Schedules, at national level that substance is brought under the scope of the Misuse of Drugs Legislation. In addition there is nothing in EU legislation to prevent a member state from introducing national control measures if required.*

*With regard to the 12 substances on the WHO list, 6 (Crotonylfentanyl, Valeryl fentanyl, DOC, 4-CMC, N-ethylhexedrone and Alpha-PHP) are already controlled under Irish legislation. The remaining 6 substances, AB-FUBINACA, 5F-AMB-PINACA, 5F-MDMB-PICA, 4-F-MDMB-BINACA, Flualprazolam and Etizolam will be added to the schedules of the Misuse of Drugs Legislation.*

#### Crotonylfentanyl

*This substance is controlled by SI 173/2017 under Schedule 1, paragraph 1(f) by it being structurally derived from fentanyl and by replacement of the N-propionyl group by another acyl group (in this case an N-crotonyl group).*

#### Valeryl fentanyl

*This substance is controlled by SI 173/2017 under Schedule 1, paragraph 1(f) by it being structurally derived from fentanyl and by replacement of the N-propionyl group by another acyl group (in this case an N-valeryl group). A valeryl group is also known as an n-pentanoyl group.*

#### DOC

*DOC is already controlled under SI 173/2017 under Schedule 1, paragraph 1(I) (page 37) as it is structurally derived from alpha-methylphenethylamine and is substituted by alkoxy groups (2 x methoxy groups) and a halo substituent (a chloro substituent).*

#### 4-CMC

*4-CMC is controlled under SI 173/2017 under Schedule 1, paragraph 1(b) (page 35) as the substance is structurally derived from 2-amino-1-phenyl-1-propanone and is further modified by substitution in the phenyl ring with a halo substituent (a chloro substituent in this case) (subparagraph (i)) and is substituted at the nitrogen atom with one alkyl group (in this case, a methyl group) (subparagraph (iii)).*

#### N-ethylhexedrone

*N-ethylhexedrone is controlled under SI 173/2017 under Schedule 1, paragraph 1(b) (page 35) as the substance is structurally derived from 2-amino-1-phenyl-1-propanone and is further modified by substitution at the 3-position of the propanone side-chain with an alkyl substituent (in this case, an ethyl group) (subparagraph (iii)).*

#### Alpha-PHP

*Alpha-PHP is controlled under SI 173/2017 under Schedule 1, paragraph 1(b) (page 35) as the substance is structurally derived from 2-amino-1-phenyl-1-propanone and is further modified by substitution at the 3-position of the propanone side-chain with an alkyl substituent (in this case, a pyrrolidine ring) (subparagraph (iii)).*

### **14. Impact on the public**

*The addition of new identified substances to the schedules will help protect public health in Ireland by ensuring that criminal law provisions apply to substances which have been identified as posing serious risks to public health. While some of the substances are controlled nationally the extension of controls at EU and international level will improve cross border law enforcement and cooperation.*

### **15. Have any consultations with Stakeholders taken place or are there any plans to do so?**

*Yes. Health Products Regulatory Authority (HPRA)*

### **16. Are there any subsidiarity issues for Ireland?**

*No*



**17. Anticipated negotiating period**

*N/A*

**18. Proposed implementation date**

*Immediate*

**19. Consequences for national legislation**

*N/A*

**20. Method of Transposition into Irish law**

*N/A*

**21. Anticipated Transposition date**

*N/A*

**22. Consequences for the EU budget in Euros annually**

*None*

**23. Contact name, telephone number and e-mail address of official in Department with primary responsibility**

*Conor Brennan*

*Assistant Principal Officer*

*Controlled Drugs and Pharmacy Legislation Unit*

*Tel 01 6354415*

*Email: [Conor\\_Brennan@Health.Gov.ie](mailto:Conor_Brennan@Health.Gov.ie)*

**Date 13<sup>th</sup> January 2020**



EUROPEAN  
COMMISSION

Brussels, 13.12.2019  
COM(2019) 631 final

2019/0278 (NLE)

Proposal for a

### **COUNCIL DECISION**

**on the position to be taken, on behalf of the European Union, in the sixty-third 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**

## **EXPLANATORY MEMORANDUM**

### **1. SUBJECT MATTER OF THE PROPOSAL**

This proposal concerns the decision establishing the position to be taken on the Union's behalf in the 63<sup>rd</sup> session of the Commission on Narcotic Drugs on the scheduling of substances under the UN Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, and the UN Convention on Psychotropic Substances of 1971. The 63<sup>rd</sup> session of the Commission on Narcotic Drugs is scheduled to take place from 2 to 6 March 2020.

### **2. CONTEXT OF THE PROPOSAL**

#### **2.1. The UN Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, and the UN Convention on Psychotropic Substances of 1971**

The United Nations (UN) Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, (the 'Convention on Narcotic Drugs')<sup>1</sup> aims to combat drug abuse by coordinated international action. There are two forms of intervention and control that work together. First, it seeks to limit the possession, use, trade in, distribution, import, export, manufacture and production of drugs exclusively to medical and scientific purposes. Second, it combats drug trafficking through international cooperation to deter and discourage drug traffickers.

The UN Convention on Psychotropic Substances of 1971 (the 'Convention on Psychotropic Substances')<sup>2</sup> establishes an international control system for psychotropic substances. It responded to the diversification and expansion of the spectrum of drugs of abuse and introduced controls over a number of synthetic drugs according to their abuse potential on the one hand and their therapeutic value on the other.

All EU Member States are parties to the Conventions, whereas the Union is not.

#### **2.2. The Commission on Narcotic Drugs**

The Commission on Narcotic Drugs (CND) is a commission of the UN Economic and Social Council (ECOSOC) and its functions and powers are *inter alia* set out in the two Conventions. It is made up of 53 UN Member States elected by ECOSOC. 13 Member States will be members of the CND with the right to vote in March 2020<sup>3</sup>. The Union has an observer status in the CND.

#### **2.3. The envisaged act of the Commission on Narcotic Drugs**

The CND regularly amends the list of substances that are annexed to the Conventions on the basis of recommendations of the World Health Organisation (WHO) which is advised by its Expert Committee on Drug Dependence.

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<sup>1</sup> United Nations Treaty Series, vol. 978, No. 14152.

<sup>2</sup> United Nations Treaty Series, vol. 1019, No. 14956.

<sup>3</sup> As of 1 January 2020, the following 13 Member States will be members of the CND with the right to vote: Austria, Belgium, Croatia, Czech Republic, France, Germany, Hungary, Italy, Netherlands, Poland, Spain, Sweden and the United Kingdom.



The WHO recommended on 15 November 2019 to the Secretary General of the UN<sup>4</sup> to add 12 of the substances which were critically reviewed by the WHO Expert Committee on Drug Dependence to the schedules of the Conventions.

The CND, in its 63<sup>rd</sup> session, tentatively taking place in Vienna from 2 to 6 March 2020, is called upon to adopt decisions on the scheduling of these substances under the Conventions.

### 3. POSITION TO BE TAKEN ON THE UNION'S BEHALF

Changes to the schedules of the Conventions have direct repercussions for the scope of application of Union law in the area of drug control for all Member States. Article 1(1) of 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<sup>5</sup> (the 'Framework Decision') states that, for the purposes of the Framework Decision, "drug" means a substance covered by either the Convention on Narcotic Drugs or the Convention on Psychotropic Substances and any of the substances listed in the Annex to the Framework Decision. The Framework Decision therefore applies to substances listed in the Schedules to the Convention on Narcotic Drugs and the Convention on Psychotropic Substances. Thus any change to the schedules annexed to these Conventions directly affects common EU rules and alters their scope, in accordance with Article 3(2) of the Treaty on the Functioning of the European Union (TFEU). This is irrespective of whether the substance in question was already placed under control across the Union.<sup>6</sup>

None of the 13 substances, which have been reviewed by the Expert Committee on Drug Dependence, is subject to control measures across the Union yet.

The Commission proposal for a Union position suggests supporting the WHO recommendations as these are in line with the current state of play of scientific knowledge. As regards the new psychoactive substances, the addition of these substances to the Schedules of the Conventions is supported also by information available from the European Database on New Drugs of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA).

It is necessary that the Council establishes the Union's position for the meeting of the CND when it is called to decide on the scheduling of substances. Such position, due to the limitations intrinsic to the observer status of the Union, should be expressed by the Member States that will be members of the CND in March 2020, acting jointly in the interest of the Union within the CND. The Union, is not a party to these Conventions but has exclusive competence in this area.

To this end, the Commission is proposing a Union position to be expressed by the Member States that will be members of the CND in March 2020, on behalf of the European Union, in the 63<sup>rd</sup> session of the CND on the scheduling of substances under the Convention on

<sup>4</sup> [https://www.who.int/medicines/access/controlled-substances/UNSG\\_letter\\_42ECDD\\_recommendations\\_15Nov19.pdf?ua=1](https://www.who.int/medicines/access/controlled-substances/UNSG_letter_42ECDD_recommendations_15Nov19.pdf?ua=1).

<sup>5</sup> OJ L 335, 11.11.2004, p. 8, as amended by Directive (EU) 2017/2103 of the European Parliament and of the Council of 15 November 2017 amending Council Framework Decision 2004/757/JHA in order to include new psychoactive substances in the definition of 'drug' and repealing Council Decision 2005/387/JHA, OJ L 305, 21.11.2017, p. 12.

<sup>6</sup> See the Annex to the Framework Decision as amended through Commission Delegated Directive (EU) 2019/369 of 13 December 2018 amending the Annex of Council Framework Decision 2004/757/JHA as regards the inclusion of new psychoactive substances in the definition of 'drug', OJ L 66, 7.3.2019, p. 3.



Narcotic Drugs and the Convention on Psychotropic Substances. This is the fourth time that the Commission presents such a proposal for a Union position.<sup>7</sup> The Council adopted the Union positions<sup>8</sup> and this allowed the EU to speak with one voice at the previous CND meetings regarding the international scheduling, since the Member States participating in the CND voted in favour of the scheduling in line with the adopted Union position.

#### **4. LEGAL BASIS**

##### **4.1. Procedural legal basis**

Article 218(9) of the Treaty on the Functioning of the European Union (TFEU) provides for decisions establishing *'the positions to be adopted on the Union's behalf in a body set up by an agreement, when that body is called upon to adopt acts having legal effects, with the exception of acts supplementing or amending the institutional framework of the agreement.'*

Article 218(9) TFEU applies regardless of whether the Union is a member of the body or a party to the agreement<sup>9</sup>. The concept of *'acts having legal effects'* includes acts that have legal effects by virtue of the rules of international law governing the body in question. It also includes instruments that do not have a binding effect under international law, but that are *'capable of decisively influencing the content of the legislation adopted by the EU legislature'*<sup>10</sup>.

The CND is "a body set up by an agreement" within the meaning of this Article, given that it is a body established by ECOSOC – an organ of the United Nations – and that it has been given specific tasks under the Convention on Narcotic Drugs and the Convention on Psychotropic Substances.

The CND's scheduling-decisions are "acts having legal effects" within the meaning of Article 218(9) TFEU. According to the Convention on Narcotic Drugs and the Convention on Psychotropic Substances, decisions of the CND automatically become binding, unless a party has submitted the decision for review to ECOSOC within the applicable time-limit<sup>11</sup>. The decisions of ECOSOC on the matter are final. The CND's scheduling decisions also have legal effects in the EU legal order by virtue of Union law, given the fact that they are capable of decisively influencing the content of EU legislation, namely Council Framework Decision 2004/757/JHA. Changes to the schedules of the Conventions have direct repercussions for the scope of application of this EU legal instrument.

The envisaged act does not supplement or amend the institutional framework of the Agreement.

Therefore, the procedural legal basis for the proposed decision is Article 218(9) TFEU.

##### **4.2. Substantive legal basis**

The substantive legal basis for a decision under Article 218(9) TFEU depends primarily on the objective and content of the envisaged act in respect of which a position is taken on the Union's behalf.

<sup>7</sup> COM(2017) 72 final; COM(2018) 31 final; COM(2018) 862 final.

<sup>8</sup> Adopted by the Council on 7 March 2017, on 27 February 2018, and on 5 March 2019, respectively.

<sup>9</sup> Judgment of the Court of Justice of 7 October 2014, Germany v Council, C-399/12, ECLI:EU:C:2014:2258, paragraph 64.

<sup>10</sup> Judgment of the Court of Justice of 7 October 2014, Germany v Council, C-399/12, ECLI:EU:C:2014:2258, paragraphs 61 to 64.

<sup>11</sup> Article 3(7) of the Convention on Narcotic Drugs; Article 2(7) of the Convention on Psychotropic Substances.



The main objective and content of the envisaged act relate to illicit drug trafficking.

Therefore, the substantive legal basis of the proposed decision is Article 83(1) TFEU, which identifies illicit drug trafficking as one of the crimes with a particular cross-border dimension and empowers the European Parliament and the Council to establish minimum rules concerning the definition of offences and sanctions in the area of illicit drug trafficking.

#### **4.3. Variable geometry**

In accordance with Article 10(4) of Protocol (No 36) on transitional provisions annexed to the Treaties, the United Kingdom notified that it does not accept the full powers of the Commission and the Court of Justice with regard to acts in the field of police and judicial cooperation in criminal matters adopted before the entry into force of the Lisbon Treaty. As a consequence, Council Framework Decision 2004/757 JHA has ceased to apply to the United Kingdom as from 1 December 2014<sup>12</sup>.

Since the CND's scheduling decisions do not affect common rules in the area of illicit drug trafficking by which the United Kingdom is bound, the United Kingdom does not take part in the adoption of a Council Decision establishing the position to be adopted on the Union's behalf when such scheduling decisions are adopted.<sup>13</sup>

Denmark is bound by Council Framework Decision 2004/757/JHA as applicable until 21 November 2018 which states in its Article 1 that "drugs" shall mean any of the substances covered by either the Convention on Narcotic Drugs or the Convention on Psychotropic Substances.

Since the CND's scheduling decisions affect common rules in the area of illicit drug trafficking by which Denmark is bound, Denmark takes part in the adoption of a Council Decision establishing the position to be adopted on the Union's behalf when such scheduling decisions are adopted.

#### **4.4. Conclusion**

The legal basis for this proposal is Article 83(1) in conjunction with Article 218(9) TFEU.

### **5. BUDGETARY IMPLICATIONS**

No budgetary implications.

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<sup>12</sup> See point 29 of the List of Union acts adopted before the entry into force of the Lisbon Treaty in the field of police cooperation and judicial cooperation in criminal matters which cease to apply to the United Kingdom as from 1 December 2014 pursuant to Article 10(4), second sentence, of Protocol (No 36) on transitional provisions (OJ C 430 of 1.12.2014, p. 17).

<sup>13</sup> This proposal concerns establishing the position to be adopted on the Union's behalf at a meeting that will take place after the United Kingdom withdrawal from the Union, unless the United Kingdom requests a fourth extension of the period under Article 50 of the Treaty, to which the European Council (Article 50) agrees by unanimity. However, at the moment when the Commission adopts its proposal, the United Kingdom is a Member State. Therefore, e.g. references in recitals of the proposal on a number of Member States where given substances were detected cover also the United Kingdom.

Proposal for a

## **COUNCIL DECISION**

**on the position to be taken, on behalf of the European Union, in the sixty-third 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 1961, as amended by the 1972 Protocol<sup>1</sup>, ('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 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 ('the Convention on Psychotropic Substances')<sup>2</sup> 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.
- (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/JHA<sup>3</sup> applies to substances listed in the Schedules to these Conventions. Thus any change to the Schedules annexed to the Conventions directly affects common Union rules and alters their scope, in accordance with Article 3(2) of the Treaty on the Functioning of the European Union (TFEU).

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<sup>1</sup> United Nations Treaty Series, vol. 978, No. 14152.

<sup>2</sup> United Nations Treaty Series, vol. 1019, No. 14956.

<sup>3</sup> 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).



- (6) The Commission on Narcotic Drugs, during its sixty-third session tentatively scheduled for 2 to 6 March 2020 in Vienna, is to adopt decisions on the adding of 12 new substances to the Schedules of the UN 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 thirteen Member States are to be members with the right to vote in March 2020<sup>4</sup>. 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 Convention on Narcotic Drugs and the Convention on Psychotropic Substances 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 to add two new substances to Schedule I of the Convention on Narcotic Drugs, one new substance to Schedule I, seven new substances to Schedule II and two new substances to Schedule IV of the Convention on Psychotropic Substances<sup>5</sup>.
- (9) All substances reviewed by the WHO Expert Committee on Drug Dependence ('the Expert Committee') and recommended for scheduling by the WHO are monitored by the European Monitoring Centre for Drugs and Drug Addiction ('EMCDDA') as a new psychoactive substance under the terms of Regulation (EC) No 1920/2006 of the European Parliament and of the Council<sup>6</sup>. None of the substances has been subject to an initial report nor to a risk assessment at Union level.
- (10) According to the assessment of the Expert Committee, crotonylfentanyl (chemical name: *N*-phenyl-*N*-[1-(2-phenylethyl)-4-piperidinyl]-2-butenamide) 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. Crotonylfentanyl has no therapeutic uses nor has it received a marketing authorisation as medicinal product. There is sufficient evidence that crotonylfentanyl 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 crotonylfentanyl be placed in Schedule I of the Convention on Narcotic Drugs.
- (11) Crotonylfentanyl has been identified only in autumn 2019 for the first time in the EU (in the Netherlands). No deaths or acute intoxications have been associated with the substance yet.
- (12) The Member States should take the position to add crotonylfentanyl to Schedule I of the Convention on Narcotic Drugs.
- (13) According to the assessment of the Expert Committee, valeryl fentanyl (also referred to as fentanyl pentanamide analogue; chemical name: *N*-phenyl-*N*-[1-(2-phenylethyl)-4-piperidyl]pentanamide) is a synthetic opioid. Valeryl fentanyl has no therapeutic uses nor has it received a marketing authorisation as medicinal product. There is sufficient evidence that valeryl fentanyl is being or is likely to be abused and may constitute a public health and social problem warranting the placing of the substance under

<sup>4</sup> As of 1 January 2020, the following 13 Member States will be members of the CND with the right to vote: Austria, Belgium, Croatia, Czech Republic, France, Germany, Hungary, Italy, Netherlands, Poland, Spain, Sweden and the United Kingdom.

<sup>5</sup> [https://www.who.int/medicines/access/controlled-substances/UNSG\\_letter\\_42ECDD\\_recommendations\\_15Nov19.pdf?ua=1](https://www.who.int/medicines/access/controlled-substances/UNSG_letter_42ECDD_recommendations_15Nov19.pdf?ua=1).

<sup>6</sup> Regulation (EC) No 1920/2006 of the European Parliament and of the Council of 12 December 2006 on the European Monitoring Centre for Drugs and Drug Addiction (OJ L 376, 27.12.2006, p. 1).



international control. Thus, the WHO recommends that valeryl-fentanyl be placed in Schedule I of the Convention on Narcotic Drugs.

- (14) Valeryl-fentanyl has been detected in four Member States and is controlled in at least four Member States. No deaths or acute intoxications have been associated with the substance yet.
- (15) Therefore, the Member States should take the position to add valeryl-fentanyl to Schedule I of the Convention on Narcotic Drugs.
- (16) According to the assessment of the Expert Committee, DOC (also referred to as 2,5-Dimethoxy-4-chloroamphetamine; chemical name: 1-(4-chloro-2,5-dimethoxyphenyl)propan-2-amine) is a phenethylamine. DOC has no therapeutic uses nor has it received a marketing authorisation as medicinal product. There is sufficient evidence that DOC 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 DOC be placed in Schedule I of the Convention on Psychotropic Substances.
- (17) DOC has been detected in 27 Member States and is controlled in at least twelve Member States. It has been associated with at least one death and four acute intoxications.
- (18) Therefore, the Member States should take the position to add DOC to Schedule I of the Convention on Psychotropic Substances.
- (19) According to the assessment of the Expert Committee, AB-FUBINACA (also referred to as FUB-AMB; chemical name: *N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide) is a synthetic cannabinoid. AB-FUBINACA has no therapeutic uses nor has it received a marketing authorisation as medicinal product. There is sufficient evidence that AB-FUBINACA 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 AB-FUBINACA be placed in Schedule II of the Convention on Psychotropic Substances.
- (20) AB-FUBINACA has been detected in 24 Member States and is controlled in at least 13 Member States. It has been associated with at least 20 deaths and 19 acute intoxications.
- (21) Therefore, the Member States should take the position to add AB-FUBINACA to Schedule II of the Convention on Psychotropic Substances.
- (22) According to the assessment of the Expert Committee, 5F-AMB-PINACA (also referred to as 5F-AMB, 5F-MMB-PINACA, 5-fluoro AMB, 5-fluoro AMP or 5F-AMP; chemical name: Methyl 2-([1-(5-fluoropentyl)-1*H*-indazol-3-yl]carbonyl)amino-3-methylbutanoate) is a synthetic cannabinoid. 5F-AMB-PINACA has no therapeutic uses nor has it received a marketing authorisation as medicinal product. There is sufficient evidence that 5F-AMB-PINACA 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 5F-AMB-PINACA be placed in Schedule II of the Convention on Psychotropic Substances.



- (23) 5F-AMB-PINACA has been detected in 17 Member States and is controlled in at least eight Member States. It has been associated with at least two deaths and three acute intoxications.
- (24) Therefore, the Member States should take the position to add 5F-AMB-PINACA to Schedule II of the Convention on Psychotropic Substances.
- (25) According to the assessment of the Expert Committee, 5F-MDMB-PICA (also referred to as 5F-MDMB-2201 or MDMB-2201; chemical name: methyl 2-[[1-(5-fluoropentyl)indole-3-carbonyl]amino]-3,3-dimethyl-butanoate) is a synthetic cannabinoid. 5F-MDMB-PICA has no therapeutic uses nor has it received a marketing authorisation as medicinal product. There is sufficient evidence that 5F-MDMB-PICA 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 5F-MDMB-PICA be placed in Schedule II of the Convention on Psychotropic Substances.
- (26) 5F-MDMB-PICA has been detected in 22 Member States and is controlled in at least three Member States. It has been associated with at least eight deaths and one acute intoxication.
- (27) Therefore, the Member States should take the position to add 5F-MDMB-PICA to Schedule II of the Convention on Psychotropic Substances.
- (28) According to the assessment of the Expert Committee, 4-F-MDMB-BINACA (also referred to as 4F-ADB, 4F-MDMB-BINACA or 4F-MDMB-BUTINACA; chemical name: methyl 2-(1-(4-fluorobutyl)-1*H*-indazole-3-carboxamido)-3,3-dimethylbutanoate) is a synthetic cannabinoid. 4-F-MDMB-BINACA has no therapeutic uses nor has it received a marketing authorisation as medicinal product. There is sufficient evidence that 4-F-MDMB-BINACA 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 4-F-MDMB-BINACA be placed in Schedule II of the Convention on Psychotropic Substances.
- (29) 4-F-MDMB-BINACA has been detected in 14 Member States and is controlled in at least one Member State. It has been associated with at least one acute intoxication. 4-F-MDMB-BINACA was the subject of a EU Early Warning System Briefing in April 2019.
- (30) Therefore, the Member States should take the position to add 4-F-MDMB-BINACA to Schedule II of the Convention on Psychotropic Substances.
- (31) According to the assessment of the Expert Committee, 4-CMC (also referred to as 4-chloromethcathinone or clephedrone; chemical name: 1-(4-chlorophenyl)-2-(methylamino)propan-1-one) is a synthetic cathinone, which is structurally related to mephedrone<sup>7</sup>, which is scheduled under the Convention on Psychotropic Substances. 4-CMC has no therapeutic uses nor has it received a marketing authorisation as medicinal product. There is sufficient evidence that 4-CMC 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 4-CMC be placed in Schedule II of the Convention on Psychotropic Substances.

<sup>7</sup> Mephedrone is controlled on EU-level based on Council Decision 2010/759/EU of 2 December 2010 on submitting 4-methylmethcathinone (mephedrone) to control measures, OJ L 322, 8.12.2010, p.44, included as no 5 in the Annex to Council Framework Decision 2004/757/JHA.

- (32) 4-CMC has been detected in 24 Member States and is controlled in at least eight Member States. It has been associated with at least four deaths and three acute intoxications.
- (33) Therefore, the Member States should take the position to add 4-CMC to Schedule II of the Convention on Psychotropic Substances.
- (34) According to the assessment of the Expert Committee, *N*-ethylhexedrone (also referred to as NEH, Hexen, Ethyl-Hex, Ethyl-hexedrone or HEX-EN; chemical name: 2-(ethylamino)-1-phenylhexan-1-one) is a synthetic cathinone. *N*-ethylhexedrone has no therapeutic uses nor has it received a marketing authorisation as medicinal product. There is sufficient evidence that *N*-ethylhexedrone 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 *N*-ethylhexedrone be placed in Schedule II of the Convention on Psychotropic Substances.
- (35) *N*-ethylhexedrone has been detected in 23 Member States and is controlled in at least six Member States. It has been associated with at least 31 deaths and nine acute intoxications.
- (36) Therefore, the Member States should take the position to add *N*-ethylhexedrone to Schedule II of the Convention on Psychotropic Substances.
- (37) According to the assessment of the Expert Committee, alpha-PHP (also referred to as PV-7,  $\alpha$ -PHP,  $\alpha$ -pyrrolidinohexanophenone; chemical name: 1-phenyl-2-(pyrrolidin-1-yl)hexan-1-one) is a synthetic cathinone. It is a higher homologue of alpha-PVP,<sup>8</sup> which is scheduled under the Convention on Psychotropic Substances. Alpha-PHP has no therapeutic uses nor has it received a marketing authorisation as medicinal product. There is sufficient evidence that alpha-PHP 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 alpha-PHP be placed in Schedule II of the Convention on Psychotropic Substances.
- (38) Alpha-PHP has been detected in 21 Member States and is controlled in at least seven Member States. It has been associated with at least 27 deaths and two acute intoxications.
- (39) Therefore, the Member States should take the position to add alpha-PHP to Schedule II of the Convention on Psychotropic Substances.
- (40) According to the assessment of the Expert Committee, flualprazolam (also referred to as Ro 11-5073/000; chemical name: 8-chloro-6-(2-fluorophenyl)-1-methyl-4*H*-[1,2,4]triazolo[4,3-*a*][1,4]benzodiazepine) is a benzodiazepine. Flualprazolam has no therapeutic uses nor has it received a marketing authorisation as medicinal product. There is sufficient evidence that flualprazolam 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 flualprazolam be placed in Schedule IV of the Convention on Psychotropic Substances.

<sup>8</sup> Alpha-PVP is controlled on EU-level based on Council Decision (EU) 2016/1070 of 27 June 2016 on subjecting 1-phenyl-2-(pyrrolidin-1-yl)pentan-1-one ( $\alpha$ -pyrrolidinoverophenone,  $\alpha$ -PVP) to control measures, OJ L178, 2.7.2016, p. 18, included as no 10 in the Annex to Council Framework Decision 2004/757/JHA.



- (41) Flualprazolam has been detected in eight Member States and is controlled in at least two Member State. It has been associated with at least 26 deaths. Flualprazolam was the subject of an Union Early Warning System Advisory in March 2019.
- (42) Therefore, the Member States should take the position to add flualprazolam to Schedule IV of the Convention on Psychotropic Substances.
- (43) According to the assessment of the Expert Committee, etizolam (also referred to as Y-7131 or Depas; chemical name: 4-(2-chlorophenyl)-2-ethyl-9-methyl-6*H*-thieno[3,2-*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine) is a benzodiazepine-type substance. Etizolam has been reviewed by the Expert Committee on three occasions, most recently in 2017. There is sufficient evidence that etizolam 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 etizolam be placed in Schedule IV of the Convention on Psychotropic Substances.
- (44) Etizolam has been detected in 21 Member States and is controlled in at least seven Member States. It has been associated with 43 deaths<sup>9</sup>. While etizolam is an authorised medicine<sup>10</sup> in several countries (Japan, Italy, India), it is thought that most of the substance that is sold on the drug market in Europe is not from diverted medicines but purchased as a powder in bulk quantities from chemical companies based outside of Europe. It is then imported into the Union using express mail and cargo services and then typically pressed into tablets and sold either as etizolam or passed off as fake diazepam and alprazolam. Etizolam is often sold as 'street valium'. The number of Union spontaneous cases reported to EudraVigilance (EV) for etizolam that can be identified through the Standardised MedDRA Query 'Drug abuse, dependence and withdrawal' is small.<sup>11</sup> In 2017, etizolam was the most commonly seized benzodiazepine reported to the Union Early Warning System both by number of cases and by amount. Etizolam was the subject of an Union Early Warning System Briefing in March 2019.
- (45) Therefore, the Member States should take the position to add etizolam to Schedule IV of the Convention on Psychotropic Substances.
- (46) It is appropriate to establish the position to be taken on the Union's behalf in the Commission on Narcotic Drugs, as the decisions on the different scheduling decisions as regards the 12 substances will be capable of decisively influencing the content of Union law, namely Framework Decision 2004/757/JHA.
- (47) The Union's position is to be expressed by the Member States that are members of the Commission on Narcotic Drugs, acting jointly.
- (48) Denmark is bound by Framework Decision 2004/757/JHA as applicable until 21 November 2018 and is therefore taking part in the adoption and application of this Decision.
- (49) Ireland is bound by Framework Decision 2004/757/JHA and is therefore taking part in the adoption and application of this Decision.

<sup>9</sup> Detections of etizolam in deaths and non-fatal intoxications appear to be under-reported to the EMCDDA. According to data from the National Records of Scotland, etizolam has been detected in several hundred deaths in Scotland, United Kingdom, in the past few years, in the context of poly-drug use among high risk opioid users.

<sup>10</sup> The scheduling of medicines may have the consequence of affecting the medical use of these medicines as a medicinal product in its authorised indications, despite its recognised use in clinical practice.

<sup>11</sup> MedDRA version 22.1, EV up to 7 October 2019.

- (50) The United Kingdom is not bound by Framework Decision 2004/757 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:

*Article 1*

The position to be adopted on the Union's behalf in the sixty-third session of the Commission on Narcotic Drugs from 2 to 6 March 2020, 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, is set out in the Annex to this Decision.

*Article 2*

The position referred to in Article 1 shall be expressed by the Member States that are members of the Commission of Narcotic Drugs, acting jointly.

*Article 3*

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

Done at Brussels,

*For the Council  
The President*





EUROPEAN  
COMMISSION

Brussels, 13.12.2019  
COM(2019) 631 final

ANNEX 1

**ANNEX**

**to the**

**Proposal for a Council Decision**

**on the position to be taken, on behalf of the European Union, in the sixty-third 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**

## 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 sixty-third session of the Commission on Narcotic Drugs tentatively scheduled from 2 to 6 March 2020 regarding changes in the scope of control of substances:

- (1) Crotonylfentanyl is to be included in Schedule I of the Convention on Narcotic Drugs;
- (2) Valeryl fentanyl is to be included in Schedule I of the Convention on Narcotic Drugs;
- (3) DOC is to be included in Schedule I of the Convention on Psychotropic Substances;
- (4) AB-FUBINACA is to be included in Schedule II of the Convention on Psychotropic Substances;
- (5) 5F-AMB-PINACA (5F-AMB, 5F-MMB-PINACA) is to be included in Schedule II of the Convention on Psychotropic Substances;
- (6) 5F-MDMB-PICA (5F-MDMB-2201) is to be included in Schedule II of the Convention on Psychotropic Substances;
- (7) 4-F-MDMB-BINACA is to be included in Schedule II of the Convention on Psychotropic Substances;
- (8) 4-CMC (4-chloromethcathinone; clephedrone) is to be included in Schedule II of the Convention on Psychotropic Substances;
- (9) *N*-ethylhexedrone is to be included in Schedule II of the Convention on Psychotropic Substances;
- (10) Alpha-PHP is to be included in Schedule II of the Convention on Psychotropic Substances;
- (11) Flualprazolam is to be included in Schedule IV of the Convention on Psychotropic Substances;
- (12) Etizolam is to be included in Schedule IV of the Convention on Psychotropic Substances.