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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 sixty-eighth 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) 2025/…

of …

on the position to be adopted on behalf of the European Union in the sixty-eighth 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 (the 'Convention on Narcotic Drugs')[1], entered into force on 8 August 1975.

(2) Pursuant to Article 3 of the Convention on Narcotic Drugs, the Commission on Narcotic Drugs (CND) may decide to add substances to the Schedules to that Convention. When the World Health Organization (WHO) notifies the CND to add substances to the Schedules, the CND can make changes in the Schedules only in accordance with that notification of the WHO, but it can also decide not to make the changes so notified.

(3) The UN Convention on Psychotropic Substances of 1971 (the 'Convention on Psychotropic Substances')[2] entered into force on 16 August 1976.

(4) Pursuant to Article 2 of the Convention on Psychotropic Substances, the CND may decide to add substances to the Schedules to that Convention or to remove them. It has broad discretionary powers to take into account the recommendations of the WHO, as well as economic, social, legal, administrative and other factors, but the CND is not empowered to act arbitrarily.

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1 United Nations Treaty Series, vol. 978, No. 14152.
2 United Nations Treaty Series, vol. 1019, No. 14956.

(5) Changes to the Schedules of the Convention on Narcotic Drugs and the Convention on Psychotropic Substances have direct repercussions on the scope of application of Union law in the area of drug control. Council Framework Decision 2004/757/JHA[3] applies to substances listed in the Schedules to those Conventions. Thus, any change to the Schedules to those Conventions is directly incorporated into common Union rules.

(6) The CND is to decide, during its 68th session planned for 10 to 14 March 2025 in Vienna, on the addition of six new substances to the Schedules to the Convention on Narcotic Drugs and to the Convention on Psychotropic Substances.

(7) The Union is neither a party to the Convention on Narcotic Drugs nor to the Convention on Psychotropic Substances. It has an observer status with no voting rights in the Commission on Narcotic Drugs, of which 13 Member States[4] are members with the right to vote in March 2025. It is necessary for the Council to authorise those Member States to express the position of the Union on the scheduling of substances under those Conventions, since decisions on the addition of new substances to the Schedules fall under the competence of the Union.

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[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, ELI: http://data.europa.eu/eli/dec_framw/2004/757/oj).

[4] Belgium, Spain, France, Italy, Lithuania, Hungary, Malta, Netherlands, Austria, Poland, Portugal, Slovenia and Finland.

(8) The WHO has recommended the addition of four new substances to Schedule I to the Convention on Narcotic Drugs, one new substance to Schedule II to the Convention on Psychotropic Substances, and one new substance to Schedule IV to the Convention on Psychotropic Substances.

(9) All substances reviewed by the WHO Expert Committee on Drug Dependence (ECDD) and recommended for scheduling by the WHO are monitored by the European Union Drugs Agency (EUDA) as new psychoactive substances under Regulation (EU) 2023/1322 of the European Parliament and of the Council[5].

(10) According to the assessment by the ECDD, protonitazepyne (IUPAC name: 5-nitro-2-[(4-propoxyphenyl)methyl]-1-(2-pyrrolidin-1-ylethyl)benzimidazole) is a synthetic opioid in the nitazene analogue family. Protonitazepyne has not previously been formally reviewed by the WHO. Protonitazepyne has no known therapeutic uses or marketing authorisations. There is sufficient evidence that protonitazepyne is being, or is likely to be, abused and can constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that protonitazepyne be listed in Schedule I to the Convention on Narcotic Drugs.

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[5] Regulation (EU) 2023/1322 of the European Parliament and of the Council of 27 June 2023 on the European Union Drugs Agency (EUDA) and repealing Regulation (EC) No 1920/2006 (OJ L 166, 30.6.2023, p. 6, ELI: http://data.europa.eu/eli/reg/2023/1322/oj).

(11) Protonitazepyne has been detected in six Member States and is controlled in at least two Member States. Protonitazepyne is under intensive monitoring by the EUDA. Seventy-four acute poisonings with suspected exposure to protonitazepyne were reported by one Member State.

(12) Therefore, the position of the Union should be to support adding protonitazepyne to Schedule I to the Convention on Narcotic Drugs.

(13) According to the assessment by the ECDD, metonitazepyne (IUPAC name: 2-[(4-methoxyphenyl)methyl]-5-nitro-1-(2-pyrrolidin-1-ylethyl)-1*H*-benzoimidazole) is a synthetic opioid of the nitazene analogue family. Metonitazepyne has not previously been formally reviewed by the WHO. Metonitazepyne has no known therapeutic uses or marketing authorisations. There is sufficient evidence that metonitazepyne is being, or is likely to be, abused and can constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that metonitazepyne be listed in Schedule I to the Convention on Narcotic Drugs.

(14) Metonitazepyne has been detected in four Member States and is controlled in at least two Member States. Metonitazepyne is under intensive monitoring by the EUDA.

(15) Therefore, the position of the Union should be to support adding metonitazepyne to Schedule I to the Convention on Narcotic Drugs.

(16) According to the assessment by the ECDD, etonitazepipne (IUPAC name: 2-[(4-Ethoxyphenyl)methyl]-5-nitro-1-(2-piperidin-1-ylethyl)-1*H*-benzoimidazole) is one of several synthetic 2-benzylbenzimidazole opioids, collectively known as 'nitazenes'. Etonitazepipne has not previously been formally reviewed by the WHO. Etonitazepipne has no known therapeutic uses or marketing authorisations. There is sufficient evidence that etonitazepipne is being, or is likely to be, abused and can constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that etonitazepipne be listed in Schedule I to the Convention on Narcotic Drugs.

(17) Etonitazepipne has been detected in five Member States and is controlled in at least six Member States. Etonitazepipne is under monitoring by the EUDA. Two deaths and one acute poisoning with confirmed exposure to etonitazepipne have been reported by three Member States.

(18) Therefore, the position of the Union should be to support adding etonitazepipne to Schedule I to the Convention on Narcotic Drugs.

(19) According to the assessment by the ECDD, *N*-desethyl isotonitazene (IUPAC name: *N*-ethyl-2-[2-[(4-isopropoxyphenyl)methyl]-5-nitro-benzimidazol-1-yl]ethanamine) is a benzimidazole-derived synthetic opioid with a chemical structure and pharmacological similarities to drugs under Schedule I to the 1961 United Nations Conventions, such as isotonitazene, and is a metabolite of isotonitazene. *N*-desethyl isotonitazene has not previously been formally reviewed by the WHO. *N*-desethyl isotonitazene has no known therapeutic uses or marketing authorisations. There is sufficient evidence that *N*-desethyl isotonitazene is being, or is likely to be, abused and can constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that *N*-desethyl isotonitazene be listed in Schedule I to the Convention on Narcotic Drugs.

(20) *N*-desethyl isotonitazene has been detected in two Member States and is controlled in at least two Member States. *N*-desethyl isotonitazene is under intensive monitoring by the EUDA. Two deaths with confirmed exposure to *N*-desethyl isotonitazene have been reported by one Member State.

(21) Therefore, the position of the Union should be to support adding *N*-desethyl isotonitazene to Schedule I to the Convention on Narcotic Drugs.

(22) According to the assessment by the ECDD, hexahydrocannabinol (HHC) (IUPAC name: 6a,7,8,9,10,10a-hexahydro-6,6,9-trimethyl-3-pentyl-6*H*-dibenzo[*b,d*]pyran-1-ol) is a semi-synthetic cannabinoid that is most commonly synthesized from cannabidiol as a precursor. Hexahydrocannabinol has not previously been formally reviewed by the WHO. Hexahydrocannabinol has no known therapeutic uses or marketing authorisations. There is sufficient evidence that hexahydrocannabinol is being, or is likely to be, abused and can constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that hexahydrocannabinol be listed in Schedule II to the Convention on Psychotropic Substances.

(23) Hexahydrocannabinol has been detected in twenty-five Member States and is controlled in at least twenty Member States. Hexahydrocannabinol is under intensive monitoring by the EUDA. Four cases of acute poisoing with confirmed exposure to hexahydrocannabinol have been reported by two Member States. Seven cases of acute poisoning with probable exposure to hexahydrocannabinol have been reported by two Member States. Six cases of acute poisoning with suspected exposure to hexahydrocannabinol have been reported by three Member States.

(24) Therefore, the position of the Union should be to support adding hexahydrocannabinol to Schedule II to the Convention on Psychotropic Substances.

(25) According to the assessment by the ECDD, carisoprodol (IUPAC name: (2RS)-2-[(carbamoyloxy)methyl]-2-methylpentyl (1-methylethyl)carbamate) is a centrally acting muscle relaxant used in the short term as an adjunct to symptomatic treatment of acute musculoskeletal disorders associated with painful muscle spasm. The potential for misuse of carisoprodol can be related to both its sedative effects and its capacity to enhance the effects of other substances. Thus, the sedative effects of carisoprodol can be potentiated when it is combined with benzodiazepines, opioids or alcohol. Prolonged or excessive use of carisoprodol can lead to dependence. Carisoprodol can be diverted from legitimate medical channels and enter the illicit market to be sold without proper medical supervision, increasing potential abuse and adverse consequences. Carisoprodol was pre-reviewed in 2001 at the 32nd ECDD meeting. The Committee did not recommend critical review of carisoprodol at that time. Carisoprodol was further presented, discussed and pre-reviewed in 2023 at the 46th ECDD meeting, where proceeding to critical review was recommended. Carisoprodol is a prescription medication and appears to be a licensed drug in several countries and territories. However, it is no longer used medically in Europe since the European Medicines Agency Committee for Medicinal Products for Human Use suspended all marketing authorisations for carisoprodol throughout Europe. Carisoprodol has no known industrial use. There is sufficient evidence that carisoprodol is being, or is likely to be, abused and can constitute a public health and social problem warranting the placing of the substance under international control. Thus, the WHO recommends that carisoprodol be listed in Schedule IV to the Convention on Psychotropic Substances.

(26) Carisoprodol has been detected in two Member States. Carisoprodol is under monitoring by the EUDA. Two deaths with confirmed exposure to carisoprodol have been reported by one Member State.

(27) Therefore, the position of the Union should be to support adding carisoprodol to Schedule IV to the Convention on Psychotropic Substances.

(28) It is appropriate to establish the position to be taken on the Union's behalf in the CND, as the decisions on listing the aforementioned six substances will be capable of decisively influencing the content of Union law, namely the scope of Framework Decision 2004/757/JHA.

(29) The Union's position is to be expressed by the Member States that are members of the CND, acting jointly.

(30) Denmark is bound by Framework Decision 2004/757/JHA, and is therefore taking part in the adoption and application of this Decision.

(31) Ireland is bound by Framework Decision 2004/757/JHA, and is therefore taking part in the adoption and application of this Decision,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf in the 68th session of the Commission on Narcotic Drugs, from 10 to 14 March 2025, when that body is called upon to adopt decisions on the addition of substances to the schedules to the United Nations Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, and to 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 on Narcotic Drugs, acting jointly in the interest of the Union.

Article 3

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

Done at …, …

For the Council
The President

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 68th session of the Commission on Narcotic Drugs planned to take place from 10 to 14 March 2025 regarding changes in the scope of control of substances:

(1) N-pyrrolidino protonitazene (protonitazepyne) is to be included in Schedule I to the Convention on Narcotic Drugs (IUPAC name: 5-nitro-2-[(4-propoxyphenyl)methyl]-1-(2-pyrrolidin-1-ylethyl)benzimidazole).

(2) N-pyrrolidino metonitazene (metonitazepyne) is to be included in Schedule I to the Convention on Narcotic Drugs (IUPAC name: 2-[(4-methoxyphenyl)methyl]-5-nitro-1-(2-pyrrolidin-1-ylethyl)-1H-benzoimidazole).

(3) Etonitazepipne (N-Piperidinyl etonitazene) is to be included in Schedule I to the Convention on Narcotic Drugs (IUPAC name: 2-[(4-Ethoxyphenyl)methyl]-5-nitro-1-(2-piperidin-1-ylethyl)-1H-benzoimidazole).

(4) N-desethyl-isotonitazene is to be included in Schedule I to the Convention on Narcotic Drugs (IUPAC name: N-ethyl-2-[2-[(4-isopropoxyphenyl)methyl]-5-nitro-benzimidazol-1-yl]ethanamine).

(5) Hexahydrocannabinol is to be included in Schedule II to the Convention on Psychotropic Substances (IUPAC name: 6a,7,8,9,10,10a-hexahydro-6,6,9-trimethyl-3-pentyl-6H-dibenzo[b,d]pyran-1-ol).

(6) Carisoprodol is to be included in Schedule IV to the Convention on Psychotropic Substances (IUPAC name: (2RS)-2-[(carbamoyloxy)methyl]-2-methylpentyl (1-methylethyl)carbamate).