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Decree of 25 October 2021, amending lists I and II, belonging to the Opium Act, in connection with the placement on list II of 3-MMC, as well as placement on lists I and II of some other means

We Willem-Alexander, by the grace of God, King of the Netherlands, Prince of Orange-Nassau, etc. etc. etc.

On the recommendation of Our Minister of Health, Welfare and Sport of 19 July 2021, reference 3229300-1010134-WJZ;

Having regard to Commission Delegated Directive (EU) 2020/1687 of 2 September 2020 amending the Annex to Council Framework Decision 2004/757/JHA as regards the inclusion of the new psychoactive substance N,N-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1 H-benzimidazole-1-ethanamine (isotonitasene) in the definition of «drug» (PbEU 2020, L 379),

Commission Delegated Directive (EU) 2021/802 of 12 March 2021 amending the Annex to Framework Decision 2004/757/JHA as regards the inclusion of the new psychoactive substances methyl 3,3-dimethyl-2-{[1-(pent-4-ene-1-yl)-1H-indazol-3-carbonyl]amino}butanoate (MDMB-4en-PINACA) and methyl 2-{[1-(4-fluorobutyl)-1H-indole-3-carbonyl]amino}-3,3-dimethylbutanoate (4F-MDMB-BICA) in the definition of «drug» (PbEU 2021, L 178) and Article 3a, first and second paragraphs, of the Opium Act;

Heard the Advisory Division of the Council of State (opinion of 1 September 2021, No.W13.21.0229/III);

Having regard to the further report of the State Secretary for Health, Welfare and Sport of 18 October 2021, reference 3253374-1010134-WJZ;

Have found and understood:

ARTICLE I

A

List I, belonging to the Opium Act, is amended as follows:

1. The following shall be inserted after the text relating to the means 4,4'-DMAR:

(a) in the column «International Non-proprietary Name (INN)»: –;

(b) in the column «other names»: 4-CMC (clefedrone, 4-chloromethathione);

c. in the column «further description»: 1-(4-chlorophenyl)-2-(methylamino)propane-1-one.

2. The following shall be inserted after the text relating to the means 4-FA:

(a) in the column «International Non-proprietary Name (INN)»: –; –;

(b) in the column «other names»: 4F-MDMB-BICA, 4F-MDMB-BUTICA;

c. in the column «further description»: methyl 2-{[1-(4-fluorobutyl)-1 H-indol-3-carbonyl]amino}-3,3-dimethylbutanoate.

3. The following shall be inserted after the text inserted with the above part:

(a) in the column «International Non-proprietary Name (INN)»: –;

(b) in the column «other names»: 4F-MDMB-BINACA;

c. in the column «further description»: methyl 2-{[1-(4-fluorobutyl)-1 H-indazol-3-carbonyl]amino}-3,3-dimethylbutanoate.

4. The following shall be inserted after the text relating to the means 4-MEC:

(a) in the column «International Non-proprietary Name (INN)»: –;

b. in the column «other names»: 5F-AMB-PINACA (5F-AMB, 5F-MMB-PINACA);

c. in the column «further description»: methyl 2-{[1-(5-fluorpentyl)-1 H-indazol-3-carbonyl]amino}-3-methylbutanoate

5. The following shall be inserted after the text relating to the product 5F-APINACA:

(a) in the column «International Non-proprietary Name (INN)»: –;

(b) in the column «other names»: 5F-MDMB-PICA (5F-MDMB-2201);

c. in the column «further description»: methyl 2-{[1-(5-fluorpentyl)-1 H-indol-3-carbonyl]amino}-3,3-dimethylbutanoate.

6. The following shall be inserted after the text relating to the plea AB-CHMINACA:

(a) in the column «International Non-proprietary Name (INN)»: –;

(b) in the column «other names»: AB-FUBINACA;

c. in the column «further description»: *N*-[1-amino-3-methyl-1-oxobutane-2-yl]-1-[(4-fluorophenyl)methyl]-1 H-indazol-3-carboxamide.

7. The following shall be inserted after the text relating to alpha-methylthiofentanyl:

(a) in the column «International Non-proprietary Name (INN)»: –;

b. in the column «other names»: alpha-PHP;

c. in the column «further description»: 1-phenyl-2-(pyrrolidin-1-yl)hexane-1-one.

8. The following shall be inserted after the text relating to the means of concentrate of spherical cover:

(a) in the column «International Non-proprietary Name (INN)»: –;

(b) in the column «other names»: crotonylfentanyl;

c. in the column «further description»: (2E)-*N*-phenyl-*N*-[1-(2-phenylethyl)piperidine-4-yl]but-2-eenamide.

9. The following is inserted after the entext relating to CUMYL-4CN-BINACA:

(a) in the column «International Non-proprietary Name (INN)»: –;

(b) in the column «other names»: CUMYL-PEGACLONE;

c. in the column «further description»: 5-pentyl-2-(2-phenylpropane-2-yl)-2,5-dihydro-1H-pyrido[4,3- b]indole-1 on.

10. The following is inserted after the text relating to *N*,*N*diethyltryptamine:

(a) in the column «International Non-proprietary Name (INN)»: –;

(b) in the column «other names»: diphenidine;

c. in the column «further description»: 1-(1,2-diphenyllethyl)piperidine.

11. The following shall be inserted after the text relating to dmhp:

(a) in the column «International Non-proprietary Name (INN)»: –;

(b) in the column «other names»: DOC (4-chloro-2,5-dimethoxyamphetamine);

c. in the column «further description»: 1-(4-chloro-2,5-dimethoxyphenyl)propane-2-amine.

12. The following shall be inserted after the text relating to the product N-ethyl-3,4-methylenedioxyamphetamine:

(a) in the column «International Non-proprietary Name (INN)»: –;

(b) in the column «other names»: N-ethylhexedron;

c. in the column «further description»: 2-(ethylamino)-1-phenylhexane-1-one.

13. The following shall be inserted after the text relating to the product isomethadone:

(a) in the column «International Non-proprietary Name (INN)»: –;

(b) in the column «other names»: isotitasone;

c. in the column «further description»: *N*,*N*-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1 H-benzimidazole-1-ethaneamine.

14. The following shall be inserted after the text relating to the product lysergide:

(a) in the column «International Non-proprietary Name (INN)»: –;

(b) in the column «other names»: MDMB-4en-PINACA;

c. in the column «further description»: methyl 3,3-dimethyl-2-{[1-(pent-4-ene-1-yl)-1 H-indazol-3-carbonyl]amino}butanoate.

15. After «mefedron» in the column «other names», «(4-MMC, 4-methylmethathinone)' is added.

16. The following is inserted after the text relating to the product 2-methoxy-4,5-methylenedioxyamphetamine:

(a) in the column «International Non-proprietary Name (INN)»: –;

(b) in the column «other names»: 3-methoxyfencyclidine;

c. in the column «further description»: 1-(1-(3-methoxyphenyl)cyclohexyl)piperidine.

17. The following shall be inserted after the text relating to the means UR-144:

(a) in the column «International Non-proprietary Name (INN)»: –;

(b) in the column «other names»: valerylfentanyl;

c. in the column «further description»: *N*-phenyl-*N*-[1-(2-phenylethyl)piperidine-4-yl]pentaanamide.

B

List II, belonging to the Opium Act, is amended as follows:

1. The following shall be inserted before the text relating to the allobarbital

(a) in the column «International Non-proprietary Name (INN)»: –;

(b) in the column «other names»: 3-MMC (3-methylmethathinone);

c. in the column «further description»: 2-(methylamino)-1-(3-methylphenyl)propane-1-one.

2. The following shall be inserted after the text relating to clonazepam:

a. in the column «International Non-proprietary Name (INN)»: ––;

(b) in the column «other names»: clonazolam;

3. The following shall be inserted after the text relating to diazepam:

(a) in the column «International Non-proprietary Name (INN)»: –;

(b) in the column «other names»: diclazepam;

4. The following shall be inserted after the text relating to ethylamphetamine:

a. in the column «International Non-proprietary Name (INN)»: etizolam;

(b) in the column «other names»: -.

5. The following shall be inserted after the text relating to the drug phentermine:

(a) in the column «International Non-proprietary Name (INN)»: –;

(b) in the column «other names»: flualprazolam;

6. The following shall be inserted after the text inserted with the above part:

(a) in the column «International Non-proprietary Name (INN)»: –;

(b) in the column «other names»: flubromazolam;

ARTICLE II

This Decision shall enter into force on the day following the date of issue of the Official Gazette in which it is published.

Charges and orders that this decision with the accompanying explanatory note will be placed in the Official Gazette.

The Hague, 25 October 2021

Willem-Alexander

The State Secretary for Health, Welfare and Sport,

P. Blokhuis

Issued the twenty-seventh October 2021

The Minister of Justice and Security,

F.B.J. Grapperhaus

EXPLANATORY NOTE

The present decree provides for the placing of various substances on list I belonging to the Opium Act (hereinafter: list I) and list II belonging to the Opium Act (hereinafter: list II). Specifically, it concerns the placement of the agents 4CMC, 4F-MDMB-BINACA, 4F-MDMB-BICA, MDMB-4en-PINACA, 5F-AMB-PINACA, 5F-MDMB-PICA, AB-FUBINACA, *alpha-PHP*,CUMYL-PEGACLONE, crotonylfentanyl, diphenidine, DOC, isotonitazeene, N-ethylhexedron, 3-methoxyfencyclidine and valerylfentanyl on list I and the placement of the agents 3-MMC, clonazolam, diclazepam, etizolam, flualprazolam and flubromazolam on list II. In addition, additional names are added to the product mefedron on list I, this is not a substantive change.

Placing the aforementioned substances on list I and list II respectively means that articles 2 and 3 of the Opium Act prohibit the placing, cultivation, preparation, processing, sale, delivery, supply, transport, presence or manufacture of the substances within or outside the territory of the Netherlands.

3-methylmethathinone or 3-MMC is a new psychoactive substance (NPS) that belongs to the

3-MMC

synthetic cathinones and has been found on the drug market for several years. In 2020, signals were received about a noticeable increase in the use of this drug and concerns about the health effects of this use. The number of reports of mild to severe incidents due to 3-MMC use has increased, as has the demand for information about the drug. User experiences indicate addiction potential of 3-MMC. The easy availability, low price and legal status may lower the threshold for use. In connection with the possible health risk as a result of the use of 3-MMC, the State Secretary for Health, Welfare and Sport has requested the Coordination Point Assessment Monitoring new drugs (CAM) to carry out a multidisciplinary risk assessment into the harmfulness of 3-MMC as a matter of urgency.

This risk assessment was completed in May 2021 and contains the recommendation to place 3-MMC on list II of the Opium Act. The CAM considers placement on list II justified in view of the increasing popularity of this drug, especially among (young) young people, signals that indicate addiction potential of this drug and an increase in the number of health incidents related to 3-MMC use. The CAM concluded that, on the basis of the information available at that time, it cannot be established that this substance poses an unacceptable risk, as with hard drugs such as cocaine and heroin placed on List I of the Opium Act. By placing 3-MMC on list II of the Opium Act, the easy availability due to the legal status is prevented and the user group is warned of the negative effects of using this substance. The recommendation of the CAM has been followed and has led to this decision adding 3-MMC to list II to the Opium Act.

The Single Convention and the Psychotropic Substances Convention

Pursuant to Article 3a, first paragraph, of the Opium Act, resources are added to List I or List II by general administrative order if those substances are brought into effect of the Single Convention on Narcotic Drugs concluded in New York on 30 March 1961(Trb. 1962, 30,hereinafter referred to as the Single Convention) or the Convention on Psychotropic Substances concluded in Vienna on 21 February 1971(Trb. 1989, 129, hereinafter referred to as the Psychotropic Substances Convention). On 4 March 2020, the United Nations Commission on Narcotic Drugs (hereinafter referred to as the CND) decided, on the basis of Article 3(3) (iii) of the Single Convention, that crotonylfentanyl and valerylfentanyl are to be added to the Single Convention and, moreover, that on the basis of Article 2, fifth paragraph, of the Psychotropic Substances Convention, the means DOC, AB-FUBINACA, 5F-AMB-PINACA, 5F-MDMB-PICA, 4F-MDMB-BINACA, 4-CMC, N-ethylhexedron, alpha-PHP are added to list II of the Psychotropic Substances Convention. [1] Furthermore, on 14 April 2021, on the basis of Article 3(3)(iii) of the Single Convention, the CND decided that isotonitas be added to the Single Convention and, on the basis of Article 2(2) of the Psychotropic Substances Convention, decided that the substances 4F-MDMB-BICA, MDMB-4en-PINACA, CUMYL-PEGACLONE, 3-methoxyfencyclidine and diphenidine are to be added to List II of the Psychotropic Substances Convention.

Pursuant to Article 4 and Article 2,7 of the aforementioned Conventions respectively, States are then obliged to subject these resources to control measures. These products are added to List I by this Decision because they are very similar in structure and effect to hard drugs already on that list.

The CND has also decided that clonazolam, diclazepam, etizolam, flualprazolam and flubromazolam are added to list IV of the Psychotropic Substances Convention,[2] these substances are added to list II by this Decision.

Framework Decision 2004/757/JHA

In addition to the above-mentioned treaty obligations, on the basis of Article 3a, first paragraph, of the Opium Act, resources are also added to list I or list II by general administrative order to implement an obligation under Council Framework Decision 2004/757/JHA[3] (hereinafter: Framework Decision 2004/757/JHA). This Decision placed the substance isotonitasene on List I. This implements Delegated Directive (EU) 2020/1687. [4] Delegated Directive (EU) 2020/1687 brings isotitazes under the definition of «drug» in Framework Decision 2004/757/JHA. Delegated Directive (EU) 2021/802[5] also aligns the means 4F-MDMB-BICA and MDMB-4en-PINACA under the definition of «drug» in Framework Decision 2004/757/JHA.

Before Delegated Directive (EU) 2020/1687 entered into force, several Member States had already brought isotonitas under their drug laws and linked measures to them, while others had not yet done so. Also, 4F-MDMB-BICA and MDMB-4en-PINACA have already been brought under their drug laws by several Member States. Including these substances in the definition of «drug» in Framework Decision 2004/757/JHA helps to avoid obstacles to cross-border law enforcement and judicial cooperation, and protects against the risks that their availability and use may entail. Delegated Directives (EU) 2020/1687 and 2021/802 require Member States, together with Framework Decision 2004/757/JHA, to take the necessary measures to prohibit the production, manufacture, extraction, preparation, offering for sale, distribution, sale, delivery, whatever the conditions, trade, transit, transport, input or export of istonitase, 4F-MDMB-BICA and MDMB-4en-PINACA in accordance with their national legislation. This Decision fulfils those obligations. The addition of isotonitzane and MDMB-4en-PINACA to List I also gives substance to the above-mentioned decisions of 14 April 2021 of the CND to add isotonitas to the Single Convention and to add MDMB-4en-PINACA to the Psychotropic Substances Convention. [6.]

European legal aspects

The addition, on national grounds, of plea 3-MMC to List II could be regarded as quantitative restrictions on imports or measures having equivalent effect within the meaning of Article 34 of the Treaty on European Union ('TFEU'). This concerns, in particular, the prohibition on, inter alia, the import, export and sale of the 3-MMC product. Article 36 of the TFEU allows Member States

to introduce a quantitative restriction on imports or measures having equivalent effect if a number of conditions are met which have been further developed in the case-law of the Court of Justice of the European Union (hereinafter: CJEU)[7.]

- the measure must comply with overriding reasons in the public interest;
- the measure must be appropriate for ensuring the attainment of the objective pursued;
- the measure shall not go beyond what is necessary to achieve that objective;
- the measure must be known and predictable;
- the measure must be applied without discrimination.

In the government's view, the measures contained here, if they would constitute an obstacle to trade at all, are justified with a view to protecting public health. Article 36 TFEU explicitly mentions the protection of public health as a justification. The case law of the CJEU shows that Member States have considerable policy freedom in the field of public health and determining the level of protection. [8th]

Research has shown that the drug 3-MMC poses health risks. This conclusion is based on the increased number of health incidents due to the use of 3-MMC and signals that indicate an addiction potential of this drug. At the same time, there is an identifiable increase in the use of 3-MMC by groups of (vulnerable) young people in particular, which is partly caused by the easy availability of the drug. That is why the government chooses to prohibit the trade in the drug 3-MMC, by adding it to list II. The aim of these rules is to ensure that fewer people have access to the means 3-MMC. The rules are therefore justified in the interest of public health. For that reason, the Government considers that a total ban on trade in the 3-MMC is an appropriate measure to achieve that objective. The proposed measure does not go beyond what is necessary in order to achieve the stated objective. It is important here that less far-reaching measures such as warnings on the packaging or restrictions on sales will not be sufficient to protect public health. A complete ban is the only effective measure because no safe use is possible. The proposed measure is therefore proportionate. The requirements of knowability and predictability are met by publication of this decision in the Official Gazette. The requirements will be applied without discrimination regardless of the nationality of the seller or the origin of the product.

Notification

Because the placing on list II of the means 3-MMC is not based on an international agreement, this draft decision was notified to the European Commission on 6 September 2021 pursuant to Article 5, first paragraph, of Directive (EU) 2015/1535[9.] In view of the health risks and the increasing popularity of 3-MMC, it is important that action can be taken as soon as possible

against the easy availability of 3-MMC and to warn the user group of the negative health effects of this medicine. Therefore, in view of urgent reasons in the context of public health, the urgency procedure referred to in Article 6, seventh paragraph, of Directive (EU) 2015/1535 has been invoked. On 27 September 2021, the European Commission accepted the appeal for urgent reasons.

Curtain

In accordance with Article 3a, fourth paragraph, of the Opium Act, a draft of this general administrative measure was sent to both chambers of the States General on 16 June 2021 (Parliamentary Documents I/II 2020/21, 35 863, no. 1). This has not led to any substantive comments.

This decision does not affect administrative burdens or substantive compliance costs for citizens and businesses.

Article by article

Article I(A)

Through this section, 4-CMC, 4F-MDMB-BINACA, 4F-MDMB-BICA, MDMB-4en-PINACA, 5F-AMB-PINACA, 5F-MDMB-PICA, AB-FUBINACA, alpha-PHP, CUMYL-PEGACLONE, crotonylfentanyl, diphenidine, DOC, isotonitazeene, N-ethylhexedron, 3-methoxyfencyclidine and valerylfentanyl are placed on list I of the Opium Act. In addition, additional names of the product mefedron are added, this is not a substantive change.

Article I(B)

By means of this section, 3-MMC, clonazolam, diclazepam, etizolam, flualprazolam and flubromazolam are placed on list II of the Opium Act.

Article II

This article regulates the date of entry into force. Because of the above-mentioned, rapid implementation date and the major risks associated with these new psychoactive substances, the so-called fixed change moments are deviated from. This general administrative order enters into force on the day after publication in the Official Gazette.

Transposition tables

Determination of Delegated Directive (EU) 2020/1687	Provision in implementation scheme or existing scheme	Description of policy space	Explanation of the choice(s) in the implementation of the policy space
Article 1	List I of the Opium Act	Chosen for listing I	It is a strong-acting opioid that is related to etonitase that is also on list I
Article 2	By its very nature, no implementation is necessary	No	–
Article 3	By its very nature, no implementation is necessary	No	–
Article 4	By its very nature, no implementation is necessary	No	–

Determination of Delegated Directive (EU) 2021/802	Provision in implementation scheme or existing scheme	Description of policy space	Explanation of the choice(s) in the implementation of the policy space
Article 1	List I of the Opium Act	Chosen for listing I	These are high-risk substances similar to those already on List I
Article 2	By its very nature, no implementation is necessary	No	–
Article 3	By its very nature, no implementation is necessary	No	–
Article 4	By its very nature, no implementation is necessary	No	–

International decision	Part of this decision
Decision 63/2	Article I(A)(8)
Decision 63/3	Article I(A)(17)
Decision 63/4	Article I(A)(11)
Decision 63/5	Article I(A)(6)
Decision 63/6	Article I(A)(4)

International decision	Part of this decision
Decision 63/7	Article I(A)(5)
Decision 63/8	Article I(A)(3)
Decision 63/9	Article I(A)(1)
Decision 63/10	Article I(A)(12)
Decision 63/11	Article I(A)(7)
Decision 63/12	Article I(B)(5)
Decision 63/13	Article I(B)(4)
Decision 64/1	Article I(A)(13)
Decision 64/2	Article I(A)(9)
Decision 64/3	Article I(A)(14)
Decision 64/4	Article I(A)(16)
Decision 64/5	Article I(A)(10)
Decision 64/6	Article I(B)(2)
Decision 64/7	Article I(B)(3)
Decision 64/8	Article I(B)(6)

The State Secretary for Health, Welfare and Sport,

P. Blokhuis

1

These are decisions 63/2, 63/3, 63/4, 63/5, 63/6, 63/7, 63/8, 63/9, 63/10 and 63/11 of the CND, which can be consulted via: https://www.unodc.org/unodc/en/commissions/CND/Resolutions_Decisions/resolutions-and-decisions-2020-2029.html.

2

These are decisions 63/12 and 63/13 of the CND, which can be consulted via: https://www.unodc.org/unodc/en/commissions/CND/Resolutions_Decisions/resolutions-and-decisions-2020-2029.html#a2020 and decisions 64/6, 64/7 and 64/8 of the CND, consultable via:

https://www.unodc.org/unodc/en/commissions/CND/Resolutions_Decisions/resolutions-and-decisions-2020-2029.html#a2021

3

Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum rules on the constituent elements of criminal offences and penalties in the field of illicit drug trafficking (OjEU 2004, L 335).

4

Commission Delegated Directive (EU) 2020/1687 of 2 September 2020 amending the Annex to Council Framework Decision 2004/757/JHA as regards the inclusion of the new psychoactive substance N,N-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1 H-benzimidazole-1-ethanamine (isotonitazeene) in the definition of «drug» (OjEU 2020, L 379).

5

Commission Delegated Directive (EU) 2021/802 of 12 March 2021 amending the Annex to Framework Decision 2004/757/JHA as regards the inclusion of the new psychoactive substances methyl 3,3-dimethyl-2-{[1-(pent-4-ene-1-yl)-1H-indazol-3-carbonyl]amino}butanoate (MDMB-4en-PINACA) and methyl 2-{[1-(4-fluorobutyl)-1H-indole-3-carbonyl]amino}-3,3-dimethylbutanoate (4F-MDMB-BICA) in the definition of «drug» (PbEU 2021, L 178).

6

These are decisions 64/1 and 64/3 of the CND, which can be consulted via: https://www.unodc.org/unodc/en/commissions/CND/Resolutions_Decisions/resolutions-and-decisions-2020-2029.html#a2021

7

CJEU 30 November 1995, ECLI:EU:C:1995:411 (Gebhard); CJEU 4 July 2000, ECLI:EU:C:2000:357 (Haim); CJEU 1 February 2001, ECLI:EU:C:2001:67 (Mac Quen and Others).

8

CJEU 13 July 2004, ECLI:EU:C:2004:141 (Commission t. France), recital 33.

9

Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJEU 2015, L 241).

The Official Gazette, Staatscourant and Tractatenblad will be published as PDF files as of 1 July 2009. The pdf files of these journals offered here constitute formal announcements within the meaning of the Constitution. For publications made before this date, only the sheets published in paper form have formal status; the electronic versions thereof offered here are offered as a service.