25 November 2014

Dear Mr Secretary-General,

With reference to Article 2, paragraphs 1, 4 and 6 of the Convention on Psychotropic Substances (1971) and Article 3, paragraphs 1, 3 and 5 of the Single Convention on Narcotic Drugs (1961), as amended by the 1972 Protocol, and following the 36th meeting of the Expert Committee on Drug Dependence in June 2014, I am pleased to submit recommendations of the World Health Organization.

The recommendations are that:

- AH-7921, be placed in Schedule I of the Single Convention on Narcotic Drugs (1961), that

- Gamma-butyrolactone (GBL); 1,4-butanediol; 25B-NBOMe (2C-B-NBOMe); 25C-NBOMe (2C-C-NBOMe) and 25I-NBOMe (2C-I-NBOMe), be placed in Schedule I of the Convention on Psychotropic Substances (1971) and that:

- N-benzylpiperazine (BZP); JWH-018; AM-2201; 3,4-methylenedioxypyrovalerone (MDPV); Methylone (beta-keto-MDMA); Mephedrone, be placed in Schedule II of the Convention on Psychotropic Substances (1971).

The recommendations and the assessments and findings on which they are based are set out in detail in the Report of the 36th Expert Committee on Drug Dependence, which is the Committee that advises me on these issues. An extract of the Committee’s Report is attached in Annex 1 to this letter.

ENCL: (1)

cc: The Secretary, Commission on Narcotic Drugs, Vienna
A notification has been made by the United Kingdom of Great Britain and Northern Ireland, pursuant to article 2, paragraphs 1 and 3 of the Convention on Psychotropic Substances, 1971 concerning a proposed recommendation for international control of mephedrone. The Expert Committee critically reviewed this substance and considered that the degree of risk to public health and society associated with the abuse liability of mephedrone is substantial and therefore considered that the evidence of its abuse warranted its placement under international control, in Schedule II of the Convention on Psychotropic Substances (1971).

Following a notification under Article 2, paragraph 1 of the Convention on Psychotropic Substances (1971) by the Government of the People’s Republic of China concerning proposed recommendation for international control of ketamine, the Expert Committee critically reviewed this substance, following its previous critical reviews of ketamine at its 35th and 34th meeting and the pre-review undertaken at its 33rd meeting. The information provided by China with its notification to the Secretary-General was brought to the Expert Committee’s attention. The Expert Committee’s assessment was that ketamine “is widely used as an anaesthetic in human and veterinary medicine, and is included in the WHO Model List of Essential Medicines and the WHO Model List of Essential Medicines for Children as well as in many national lists of essential medicines”. The Expert Committee found that it was presented with “compelling evidence […] about the prominent place of ketamine as an anaesthetic in developing countries and crisis situations”. While the Expert Committee “acknowledged the concerns raised by some countries and UN organizations”, it stated that “ketamine abuse currently does not appear to pose a sufficient public-health risk of global scale to warrant scheduling” and recommended “that ketamine not be placed under international control at this time”. “Countries with serious abuse problems may decide to introduce or maintain control measures, but should ensure ready access to ketamine for surgery and anaesthesia for human and veterinary care”.

During its meeting, the Expert Committee also discussed the importance of having reliable and sufficient data that could inform the review process in particular for New Psychoactive Substances (NPS), acknowledging the fact that more and more NPS will likely be reviewed in the future, for which data will not always be readily available. UNODC and WHO will hold an international experts consultation in December 2014 to identify selection criteria for prioritisation of NPS to be reviewed by the Committee as well as relevant indicators, methods and tools for data collection on NPS.

I am very pleased with the ongoing collaboration between WHO, UNODC and INCB for improving access to controlled medicines while preventing misuse and trafficking and for preparing the Special Session of the United Nations General Assembly on the World Drug Problem in 2016.

Yours sincerely,

Dr Margaret Chan
Director-General
Annex 1

Extract from the Report of the 36th Expert Committee on Drug Dependence

Substances recommended to be scheduled in Schedule I of the Single Convention on Narcotic Drugs (1961), as amended by the 1972 Protocol:

AH-7921

AH-7921 is an N-substituted cyclohexylmethylbenzamide and is chemically 3,4-dichloro-N-{{1-(dimethylamino)cyclohexyl}methyl} benzamide.

AH-7921 had not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO’s attention that AH-7921 is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party. Preliminary data collected from literature and different countries indicated that this substance may cause substantial harm and that it has no medical use.

AH-7921 is an opioid with “morphine-like” effects. The Committee considered that the degree of risk to public health and society associated with the abuse liability and accompanying evidence warranted its placement under international control. The Committee recommended that AH-7921 be placed in Schedule I of the Single Convention on Narcotic Drugs (1961), as amended by the 1972 Protocol.

Substances recommended to be scheduled in Schedule I of the Convention on Psychotropic Substances (1971):

Gamma-butyrolactone (GBL)

Gamma-butyrolactone (GBL) is chemically oxolan-2-one. GBL can be synthesised from gamma-hydroxybutyric acid (GHB) or tetrahydrofuran.

During the discussion of GHB at the 34th Meeting of the WHO Expert Committee on Drug Dependence (ECDD), the Committee “noted information relating to the abuse of GBL itself (convertible to GHB in the body) and suggested this substance for pre-review”. Based on the evidence presented in the pre-review of GBL during its 35th Meeting, given its close association with GHB, and the recommendation made by the Committee to reschedule GHB from Schedule IV to Schedule II of the Convention on Psychotropic Substances (1971), the Committee recommended that a critical review of GBL be undertaken.

The Committee considered that the degree of risk to public health and society associated with the abuse liability of GBL is especially serious. Whilst the Committee recognized widespread and important industrial use, it has no defined therapeutic usefulness. The Committee considered that the evidence of its abuse warranted its placement under international control within Schedule I of the Convention on Psychotropic Substances (1971).
1,4-butanediol

1,4-butanediol (butane-1,4-diol, 1,4-BDO or 1,4-BD) is one of four stable isomers of butanediol.

During the discussion of gamma-hydroxybutyric acid (GHB) at its 34th Meeting, the Committee "noted information relating to the abuse of 1,4-BD itself (convertible to GHB in the body) and suggested this substance for pre-review". Based on the evidence presented in the pre-review of GBL during its 35th Meeting, given its close association with GHB, and the recommendation made by the Committee to reschedule GHB from Schedule IV to Schedule II of the Convention on Psychotropic Substances (1971), the Committee recommended that a critical review of 1,4-BD be undertaken.

1,4-butanediol produces its effects in the body through the in vivo formation of the scheduled substance GHB. The Committee considered that the degree of risk to public health and society associated with the abuse liability of 1,4-butanediol is especially serious. Whilst the Committee recognized widespread and important industrial use, it has no defined therapeutic usefulness. The Committee considered that the evidence of its abuse warranted its placement under international control within Schedule I of the Convention on Psychotropic Substances (1971).

25B-NBOMe

25B-NBOMe (2C-B-NBOMe) is chemically 2-(4-bromo-2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl)methyl]ethanamine.

25B-NBOMe had not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO's attention that 25B-NBOMe is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party. Preliminary data collected from literature and different countries indicated that this substance may cause substantial harm and that it has no medical use.

The Committee noted the challenges associated with the evidence base concerning the substance. The Committee considered that the degree of risk to public health and society associated with the abuse liability of 25B-NBOMe is especially serious. Whilst the Committee noted its use in medical research, it has no recorded therapeutic use.

The Committee considered that the evidence of its abuse warranted its placement under international control and recommended that 25B-NBOMe be placed in Schedule I of the Convention on Psychotropic Substances (1971).

25C-NBOMe

25C-NBOMe (2C-C-NBOMe) is chemically 2-(4-chloro-2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl)methyl]ethanamine.
25C-NBOMe had not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO’s attention that 25C-NBOMe is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party. Preliminary data collected from literature and different countries indicated that this substance may cause substantial harm and that it has no medical use.

The Committee noted the challenges associated with the evidence base concerning the substance. The Committee considered that the degree of risk to public health and society associated with the abuse liability of 25C-NBOMe is especially serious. Whilst the Committee noted its use in medical research, it has no recorded therapeutic use. The Committee considered that the evidence of its abuse warranted its placement under international control and recommended that 25C-NBOMe be placed in Schedule I of the Convention on Psychotropic Substances (1971).

25I-NBOMe

25I-NBOMe (2C-I-NBOMe) is chemically 2-(4-iodo-2,5-dimethoxyphenyl)-N-[(2-methoxyphenyl)methyl]ethanamine.

25I-NBOMe had not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO’s attention that 25I-NBOMe is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party. Preliminary data collected from literature and different countries indicated that this substance may cause substantial harm and that it has no medical use.

The Committee noted the challenges associated with the evidence base concerning the substance. The Committee considered that the degree of risk to public health and society associated with the abuse liability of 25I-NBOMe is especially serious. Whilst the Committee noted its use in medical research, it has no recorded therapeutic use. The Committee considered that the evidence of its abuse warranted its placement under international control and recommended that 25I-NBOMe be placed in Schedule I of the Convention on Psychotropic Substances (1971).

Substances recommended to be scheduled in Schedule II of the Convention on Psychotropic Substances (1971):

N-benzylpiperazine (BZP)

N-benzylpiperazine (BZP) is an aryl-substituted piperazine and is chemically 1-benzyl-1,4-diazacyclohexane.

BZP was pre-reviewed at the 35th ECDD meeting and based on the reported psychostimulant effects, evidence of abuse and adverse effects, the Expert Committee concluded that a critical review was warranted.
BZP has been shown to have effects similar to amphetamine. The Committee considered that the degree of risk to public health and society associated with the abuse liability of BZP is substantial. Its therapeutic usefulness has been assessed to be little, as it is not currently licensed for use. The Committee considered that the evidence of its abuse warranted its placement under international control. The Committee recommended that BZP be placed in Schedule II of the Convention on Psychotropic Substances (1971).

**JWH-018**

JWH-018 is chemically naphthalen-1-yl(1-pentyl-1H-indol-3-yl)methanone.

JWH-018 had not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO’s attention that JWH 018 is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party. Preliminary data collected from literature and different countries indicated that this substance may cause substantial harm and that it has no medical use.

The Committee noted the challenges associated with the evidence base concerning the substance. The Committee noted analytically confirmed cases of non-fatal and fatal intoxications involving JWH 018. The Committee therefore considered that the degree of risk to public health associated with the abuse liability of JWH 018 is substantial. Its therapeutic usefulness has been assessed to be none. As per the Guidance on the WHO review of psychoactive substances for international control, higher regard was made to the substantial public health risk as opposed to the lack of therapeutic usefulness [p.18, paragraph 56, penultimate sentence]. The Committee recommended that JWH 018 be placed under international control in Schedule II of the Convention on Psychotropic Substances (1971).

**AM-2201**

AM-2201 is chemically [1-(5-fluoropentyl)-1H-indol-3-yl]-naphthalen-1-ylmethanone.

AM-2201 had not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO’s attention that AM 2201 is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party. Preliminary data collected from literature and different countries indicated that this substance may cause substantial harm and that it has no medical use.

The Committee noted the challenges associated with the evidence base concerning the substance. The Committee noted analytically confirmed cases of non-fatal and fatal intoxications involving AM 2201. The Committee therefore considered that the degree of risk to public health associated with the abuse liability of AM 2201 is substantial. Its therapeutic usefulness has been assessed to be none. As per the Guidance on the WHO review of psychoactive substances for international control, higher regard was made to the substantial public health risk as opposed to the lack of therapeutic usefulness.
[p.18, paragraph 56, penultimate sentence]. The Committee recommended that AM 2201 be placed under international control in Schedule II of the Convention on Psychotropic Substances (1971).

3,4-methylenedioxyprovalerone (MDPV)

3,4-methylenedioxyprovalerone (MDPV) is chemically \((R,S)-1-(1,3\text{-benzodioxol-5-yl})-2-(pyrrolidin-1-yl)\)pentan-1-one.

MDPV had not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO’s attention that MDPV is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party. Preliminary data collected from literature and different countries indicated that this substance may cause substantial harm and that it has no medical use.

The Committee considered that the degree of risk to public health and society associated with the abuse liability of MDPV is substantial. Its therapeutic usefulness has been assessed to be none. The Committee considered that the evidence of its abuse warranted its placement under international control. As per the Guidance on the WHO review of psychoactive substances for international control, higher regard was made to the substantial public health risk as opposed to the lack of therapeutic usefulness [p.18 para 56, penultimate sentence]. The Committee recommended that MDPV be placed in Schedule II of the Convention on Psychotropic Substances (1971).

Methylene (bk-MDMA)

Methylene (beta-keto-MDMA) is chemically \((R,S)-1-(1,3\text{-benzodioxol-5-yl})-2-(methylamino)\)propan-1-one.

Methylene had not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO’s attention that methylene is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party. Preliminary data collected from literature and different countries indicated that this substance may cause substantial harm and that it has no medical use.

The Committee considered that the degree of risk to public health and society associated with the abuse liability of methylene is substantial. Its therapeutic usefulness has been assessed to be none. The Committee considered that the evidence of its abuse warranted its placement under international control. As per the Guidance on the WHO review of psychoactive substances for international control, higher regard was made to the substantial public health risk as opposed to the lack of therapeutic usefulness [p.18, paragraph 56, penultimate sentence]. The Committee recommended that methylene be placed in Schedule II of the Convention on Psychotropic Substances (1971).
Mephedrone

Mephedrone (4-methylmethcathinone, 4-MMC) is chemically (R,S)-2-(methylamino)-1-(4-methylphenyl)propan-1-one.

Mephedrone had not been previously pre-reviewed or critically reviewed. A direct critical review was proposed based on information brought to WHO’s attention that mephedrone is clandestinely manufactured, of especially serious risk to public health and society, and of no recognized therapeutic use by any party. Preliminary data collected from literature and different countries indicated that this substance may cause substantial harm. A critical review was further undertaken by the Committee given that the Government of the United Kingdom of Great Britain and Northern Ireland had made a notification concerning a proposed recommendation for international control of mephedrone (4-methylmethcathinone), under article 2, paragraphs 1 and 3 of the Convention on Psychotropic Substances, 1971.

The Committee considered that the degree of risk to public health and society associated with the abuse liability of mephedrone is substantial. Its therapeutic usefulness has been assessed to be none. The Committee considered that the evidence of its abuse warranted its placement under international control. As per the Guidance on the WHO review of psychoactive substances for international control, higher regard was made to the substantial public health risk as opposed to the lack of therapeutic usefulness [p.18, paragraph 56, penultimate sentence].

The Committee recommended that mephedrone be placed in Schedule II of the Convention on Psychotropic Substances (1971).