EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS ACT 1971 (AMENDMENT) (NO. 2) ORDER 2024

2024 No. XXXX

1. Introduction

1.1 This explanatory memorandum has been prepared by the Home Office and is laid before Parliament by Command of His Majesty.

2. Declaration

2.1 Dame Diana Johnson, Minister of State for Crime, Policing and Fire in the Home Office confirms that this Explanatory Memorandum meets the required standard.

2.2 Marcus Starling, Deputy Director of the Drug Misuse Unit at the Home Office confirms that this Explanatory Memorandum meets the required standard.

3. Contact

3.1 Sara Anderson at the Home Office, Telephone: 07586980709 or email: Sara.Anderson@homeoffice.gov.uk, can be contacted with any queries regarding the instrument.

Part One: Explanation, and context, of the Instrument

4. Overview of the Instrument

What does the legislation do?

4.1 This Order controls 22 dangerous or otherwise harmful substances and introduces a broader definition for 2-benzyl benzimidazole (nitazenes), a group of synthetic opioids, under the Misuse of Drugs Act 1971 ("the MDA 1971"), owing to their potential to cause harm when misused. Further information on these substances is set out in paragraphs 5.3-5.20.

4.2 Most substances are already likely to be captured by the Psychoactive Substances Act 2016 ("the PSA 2016") by virtue of their capability to produce a psychoactive effect in a person who consumes it. This means it is already an offence to supply, produce, possess with intent to supply, possess in a custodial institution, import or export these substances knowingly or recklessly for their psychoactive effect.

4.3 Control under the MDA 1971 will make possession of these substances a criminal offence and attract increased criminal penalties for a range of unlawful activities including the supply, production, import or export of any of these substances.

4.4 This Order also amends the entry for an existing Class B drug – methoxyphenidine – to include an additional common name and its full International Union of Pure and Applied Chemistry (IUPAC) name to aid clarity of the law.

Where does the legislation extend to, and apply?

4.5 The extent of this Order (that is, the jurisdiction(s) which the instrument forms part of the law of) is England and Wales, Scotland and Northern Ireland.

4.6 The territorial application of this instrument (that is, where the instrument produces a practical effect) is England and Wales, Scotland and Northern Ireland.

5. Policy Context

What is being done and why?

5.1 Following several recommendations made by the Advisory Council on the Misuse of Drugs (ACMD) which the previous Government accepted, this Order controls 22 substances (six acyl piperazine opioids, 15 benzodiazepines and related compounds, and xylazine) and introduces a definition which captures a range of nitazenes under the MDA 1971.

5.2 The ACMD is a statutory, independent advisory body established by the MDA 1971, which makes recommendations to the Government on the control of 'dangerous or otherwise harmful' drugs. This includes classification and scheduling under the MDA 1971, the Misuse of Drugs Regulations 2001 ("the MDR 2001") and, where appropriate, the Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015 ("the 2015 Order").

Acyl piperazine opioids

5.3 2-methyl-AP-237, a type of synthetic acyl piperazine opioid, was added to Schedule 1 of the United Nations Single Convention on Narcotic Drugs 1961 ("the 1961 Convention") in March 2023. As a signatory, the UK is obliged to ensure appropriate domestic control of this substance. Therefore, in June 2023, the previous Government commissioned the ACMD to advise on classification and scheduling under the MDA 1971 and associated Regulations. The ACMD report and recommendations were published on 27 March 2024[1] and the previous Government accepted these recommendations on 14 May 2024[2].

5.4 The ACMD advised that acyl piperazine opioids are expected to have similar adverse effects to those of heroin, fentanyls and nitazenes. The most serious acute health risk is likely to be respiratory depression, which in overdose could lead to respiratory arrest and death. 2-methyl-AP-237 has been detected in seizures in the US and Europe but not yet in the UK. Its potential harms are, however, deemed to be significant and the ACMD therefore recommended control of four acyl piperazine opioids and two chemically bridged acyl piperazine derivatives as Class A drugs under the MDA 1971.

5.5 This Order controls the following six substances as Class A drugs under the MDA 1971:

5.5.1 AP-237;

5.5.2 AP-238;

5.5.3 Azaprocin;

5.5.4 para-methyl-AP-237;

5.5.5 para-nitroazaprocin;

5.5.6 2-Methyl-AP-237.

[1] https://www.gov.uk/government/publications/acmd-advice-on-acyl-piperazine-opioids-including-2-methyl-ap-237

[2] https://www.gov.uk/government/publications/government-response-to-acmd-report-on-acyl-piperazine-opioids

Introduction of a generic definition for 2-benzyl benzimidazole variants (nitazenes)

5.6 Nitazenes are synthetic opioids which have serious associated acute health risks, such as respiratory depression, which in overdose can lead to death. Due to their high potency, the risk of unpredictable and severe opioid toxicity is increased. The ACMD reported the involvement of nitazenes in a number of drug-related deaths and near-fatal overdoses in the UK and elsewhere and deemed that their availability presents a significant potential threat to public health.

5.7 In its report of 18 July 2022[3] and addenda of 19 December 2022[4] and 6 October 2023[5] the ACMD recommended that the Government control a number of individual synthetic opioids and consult key stakeholders, including academia and the chemical and pharmaceutical industries, on the introduction of a generic control for nitazenes. The previous Government accepted these recommendations. The ACMD went on to provide a third and fourth addendum (of 15 December 2023[6] and 5 April 2024[7]) to that report, which updated the proposed wording for the generic definition based on evidence of the emergence of new nitazenes that were not previously captured by it, which the previous Government also accepted.

5.8 As a result, on 20 March 2024, 15 synthetic opioids, 14 of which were nitazenes, were controlled as Class A drugs under the MDA 1971[8].

5.9 The previous Government conducted a targeted consultation on the introduction of a generic control for nitazenes with key stakeholders, as recommended by the ACMD. No legitimate uses of chemicals captured by the proposed generic definition were identified and there was broad agreement that the introduction of this generic control would not have a disproportionate impact on businesses in the UK.

5.10 This Order introduces the recommended generic control for nitazenes, meaning that substances which are captured by the generic definition will be controlled as Class A drugs under the MDA 1971. The introduction of a generic control for nitazenes is intended to reduce the likelihood that criminals can circumvent existing controls by making minor alterations to the chemical structure of nitazenes that are already controlled as Class A drugs under the MDA 1971.

Novel benzodiazepines and related compounds

5.11 Benzodiazepines are sedative and anxiolytic (anxiety-reducing) compounds, many of which are licensed medicines in the UK. They are associated with health harms including drowsiness, psychomotor impairment, unsteadiness and incoordination, memory loss and confusion. Higher doses may cause loss of consciousness and

[3] https://www.gov.uk/government/publications/acmd-advice-on-2-benzyl-benzimidazole-and-piperidine-benzimidazolone-opioids/acmd-advice-on-2-benzyl-benzimidazole-and-piperidine-benzimidazolone-opioids-accessible-version

[4] https://www.gov.uk/government/publications/acmd-advice-on-2-benzyl-benzimidazole-and-piperidine-benzimidazolone-opioids/addendum-to-acmds-report-on-the-use-and-harms-of-2-benzyl-benzimidazole-nitazene-and-piperidine-benzimidazolone-brorphine-like-opioids-acces

[5] https://www.gov.uk/government/publications/acmd-advice-on-2-benzyl-benzimidazole-and-piperidine-benzimidazolone-opioids/addendum-to-acmds-report-on-the-use-and-harms-of-2-benzyl-benzimidazole-nitazene-and-piperidine-benzimidazolone-brorphine-like-opioids-6-oct

[6] https://www.gov.uk/government/publications/acmd-advice-on-2-benzyl-benzimidazole-and-piperidine-benzimidazolone-opioids/addendum-to-acmds-report-on-the-use-and-harms-of-2-benzyl-benzimidazole-nitazenes-and-piperidine-benzimidazolone-brorphine-like-opioids-15-d

[7] https://www.gov.uk/government/publications/acmd-advice-on-2-benzyl-benzimidazole-and-piperidine-benzimidazolone-opioids/fourth-addendum-to-acmd-report-on-the-use-and-harms-of-2-benzyl-benzimidazole-nitazene-and-piperidine-benzimidazolone-brorphine-like-opioids

[8] https://www.legislation.gov.uk/uksi/2024/190/contents/made

respiratory depression, especially if used in combination with alcohol or other sedatives.

5.12 Due to the detection of 18 new benzodiazepines and related compounds in Europe and the UK since the ACMD's last report in 2020[9], the ACMD provided advice on recently encountered novel benzodiazepines on 28 March 2024[10]. None of the substances considered in the ACMD report are licensed as medicines in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA).

5.13 The ACMD recommended control of 15 novel benzodiazepines and related compounds as Class C drugs under the MDA 1971, which the previous Government accepted on 14 May 2024[11].

5.14 This Order controls the following 15 substances, as Class C drugs under the MDA 1971:

5.14.1 Bentazepam;

5.14.2 Bretazenil;

5.14.3 4'-Chloro-deschloroalprazolam;

5.14.4 Clobromazolam;

5.14.5 Cloniprazepam;

5.14.6 Desalkylgidazepam;

5.14.7 Deschloroclotizolam;

5.14.8 Difludiazepam;

5.14.9 Flubrotizolam;

5.14.10 Fluclotizolam;

5.14.11 Fluetizolam;

5.14.12 Gidazepam;

5.14.13 Methylclonazepam;

5.14.14 Rilmazafone;

5.14.15 Thionordazepam.

Xylazine

5.15 Xylazine is a non-opioid tranquiliser that has sedative, analgesic and muscle relaxant properties. In the US, it is increasingly being added to opioids, such as heroin or fentanyl by organised criminal groups, to produce a mixture which is known as 'tranq' or 'tranq dope'. Xylazine can dangerously lower an individual's level of consciousness and heart rate and its use with opioids is known to increase the severity and duration of their sedative effect. Injection of drugs containing xylazine has also been reported to cause significant skin ulcers.

5.16 The first death in the UK involving xylazine (May 2022) was reported by the National Programme on Substance Abuse Deaths in December 2022. In June 2023, the previous Government requested advice from the ACMD on the harms of xylazine,

[9] https://www.gov.uk/government/publications/novel-benzodiazepines-prevalence-and-harms-in-the-uk
[10] https://www.gov.uk/government/publications/uncontrolled-novel-benzodiazepines-2024-update
[11] https://www.gov.uk/government/publications/government-response-to-the-acmds-report-on-novel-benzodiazepines

including appropriate classification and scheduling under the MDA 1971 and associated Regulations. The ACMD report was published on 16 February 2024[12].

5.17 The ACMD considered the toxicity of xylazine to be similar to that of benzodiazepines when used with opioids and therefore recommended it is controlled as a Class C drug under the MDA 1971. The previous Government accepted these recommendations on 21 March 2024[13].

5.18 This Order controls xylazine as a Class C drug under the MDA 1971.

5.19 Xylazine is authorised for use in the UK as a veterinary medicine but has not been approved for use in humans by the MHRA. In line with ACMD recommendations, the Government therefore intends to make provisions to enable legitimate use in veterinary care by amending the MDR 2001 via a corresponding statutory instrument, which would come into force at the same time as this Order.

Methoxyphenidine

5.20 On 20 March 2024, the previous Government controlled methoxyphenidine, a stimulant, as a Class B drug under the MDA 1971[14]. This Order adds an additional common name (methoxphenidine) and the full IUPAC name to the entry for methoxyphenidine. This does not affect the existing control of the substance but adds clarity on exactly which drug is controlled given that there are multiple common names.

What was the previous policy, how is this different?

5.21 Prior to this Order, 21 of the 22 substances and any substances captured by the generic definition for nitazenes (which are not already controlled as Class A drugs under the MDA 1971), were already likely to be captured by the PSA 2016 by virtue of their capability to produce a psychoactive effect in a person who consumes it. The PSA 2016 makes it an offence to supply, produce, import, or export these substances knowingly or recklessly for their psychoactive effect. However, possession, except with intent to supply or in a custodial institution, is not unlawful under the PSA 2016. Control under the MDA 1971 means that those substances are now subject to the increased penalties and additional offence of possession under that Act and the offences and penalties under the PSA 2016 will no longer apply.

5.22 All offences relating to substances captured by the PSA 2016 carry a maximum penalty of up to seven years in prison, a fine, or both, whereas supply of a Class A drug under the MDA 1971 carries a maximum penalty of up to life imprisonment, an unlimited fine, or both. Supply of a Class C drug under the MDA 1971 carries a maximum penalty of up to 14 years in prison, an unlimited fine, or both. The offence of possession will now also apply to the substances controlled by this Order – for a Class A drug, the maximum penalty is up to seven years in prison, an unlimited fine, or both, and for a Class C drug, the maximum penalty is up to two years in prison, an unlimited fine or both.

5.23 The remaining substance, AP-237 is not approved as a medicine in the UK but is known to be used as a medicine in other jurisdictions and may therefore have been exempt from the PSA 2016. Controlling it under the MDA 1971 ensures that,

[12] https://www.gov.uk/government/publications/use-and-harms-of-xylazine-medetomidine-and-detomidine
[13] https://www.gov.uk/government/publications/response-to-the-acmds-report-on-xylazine-and-related-compounds
[14] https://www.legislation.gov.uk/uksi/2024/190/made

similarly to the other substances controlled by this Order, all relevant drug offences under the MDA 1971 now apply.

6. Legislative and Legal Context

How has the law changed?

6.1 The MDA 1971 controls drugs that are "dangerous or otherwise harmful". Schedule 2 to the MDA 1971 specifies these drugs and groups them in three categories – Part 1 lists drugs known as Class A drugs, Part 2 lists Class B drugs and Part 3 lists Class C drugs. The three-tier system of classification (A, B and C) provides a framework within which criminal penalties are set with reference to the harm that a drug has, or is capable of having when misused, and the type of illegal activity undertaken with regards to that drug. Control under the MDA 1971 brings these substances outside the ambit of the PSA 2016, under which all but one were previously captured.

6.2 The MDA 1971 allows the Secretary of State, by regulations and orders, to establish a framework for the legal use of controlled drugs in appropriate circumstances (e.g. healthcare). It is intended that a further statutory instrument will come into force at the same time as this Order. This will amend the MDR 2001 and, where appropriate, the 2015 Order to make such provision as is appropriate for legitimate access to the controlled drugs.

Why was this approach taken to change the law?

6.3 This is the only possible approach to make the necessary changes.

7. Consultation

Summary of consultation outcome and methodology

7.1 The ACMD has been consulted as statutorily required. In addition to recommendations on classification under the MDA 1971, the ACMD also make recommendations on appropriate scheduling under the MDR 2001 and, where appropriate, the 2015 Order. Amendments to the MDR 2001 and the 2015 Order are intended to be implemented by a corresponding statutory instrument, which would come into force at the same time. Links to the relevant reports containing recommendations by the ACMD can be found in the footnotes throughout this document.

7.2 Additionally, in line with the recommendation from the ACMD, since that advice was published, the Home Office has consulted relevant key stakeholders including academia and the chemical and pharmaceutical industries on the introduction of a generic definition for nitazenes. This was a targeted consultation to understand whether any substances captured by the generic definition have legitimate uses which would mean that control would result in significant and disproportionate impacts on UK businesses. The respondents to this consultation did not note any legitimate uses of substances captured by the generic definition for nitazenes, aside from potential research opportunities for which access can be granted under a Home Office controlled drug licence, nor did they note any disproportionate impact on businesses in the UK. Therefore, no amendments were made to the ACMD's proposed wording for the generic definition. As this was a targeted consultation on a technical subject, the previous Government's response to the consultation will not be published.

8. Applicable Guidance

8.1 Changes to the law as a result of this Order will be communicated to key stakeholders, including healthcare professionals (particularly those in veterinary medicine in relation to the control of xylazine), and the wider public by the Home Office, the Department of Health and Social Care (DHSC) and the Veterinary Medicines Directorate (VMD). The Home Office will issue a circular with legislative guidance primarily for the police and the courts once these measures come into force.

8.2 The Government will continue to update its messaging on the harms of these substances, including through its FRANK information and advisory service, which is aimed at young people and adults to inform them of drug-related risks and harms. The National Poisons Information Service (NPIS), which is commissioned by the UK Health Security Agency, continue to keep TOXBASE updated; TOXBASE provides health professionals with advice on the features and management of poisoning.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 An economic note of the effect that this Order will have on the costs of business, the voluntary sector and community bodies is available with the Explanatory Memorandum alongside this instrument on www.legislation.gov.uk.

Impact on businesses, charities and voluntary bodies

9.2 There is no, or no significant, impact on businesses, charities or voluntary bodies from this instrument.

9.3 The legislation does not impact small or micro businesses.

9.4 There is no, or no significant, impact on the public sector. This is due to the current low detection of the 22 named substances and those controlled under the generic definition in the UK noting the data limitations set out in the economic note. There are potential positive impacts owing to improved public safety, but these could not be quantified due to insufficient evidence at this stage.

10. Monitoring and review

What is the approach to monitoring and reviewing this legislation?

10.1 The Government will continue to monitor the control measures through the regulatory framework governing controlled drugs. It will also maintain oversight through the healthcare regulatory bodies in England and through engagement with the Devolved Administrations. This will include national data collection and surveys on crime and drug misuse.

10.2 This instrument does not include a statutory review clause.

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 None.

12. European Convention on Human Rights

12.1 The Minister of State for Crime, Policing and Fire has made the following statement regarding Human Rights:

"In my view the provisions of The Misuse of Drugs Act 1971 (Amendment) (No.2) Order 2024 are compatible with the Convention rights."

13. The Relevant European Union Acts

13.1 This instrument is not made under the European Union (Withdrawal) Act 2018, the European Union (Future Relationship) Act 2020 or the Retained EU Law (Revocation and Reform) Act 2023 ("relevant European Union Acts").