EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS ACT 1971 (AMENDMENT) 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 the Command of His Majesty.

2. Purpose of the instrument

2.1 Following consultation with the Advisory Council on the Misuse of Drugs ("ACMD") this Order amends the Misuse of Drugs Act 1971 ("the 1971 Act") to control 15 substances as Class A drugs, four substances as Class B drugs and one substance as a Class C drug, owing to evidence of harm and of the prevalence of these substances in the UK. All drugs to be controlled are outlined in paragraph 7.

3. Matters of special interest to Parliament

3.1 None.

4. Extent and Territorial Application

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

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

5. European Convention on Human Rights

5.1 The Minister for Crime, Policing and Fire, the Rt. Hon. Chris Philp MP, has made the following statement regarding Human Rights:

"In my view the provisions of The Misuse of Drugs Act 1971 (Amendment) Order 2024 are compatible with the Convention rights."

6. Legislative Context

6.1 The 1971 Act controls drugs that are "dangerous or otherwise harmful". Schedule 2 to the 1971 Act 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. This 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. Controlling these substances under the 1971 Act means they are then subject to the offence for possession and increased criminal penalties for supply, production, import or export.

6.2 All 20 substances are currently likely to be captured under the Psychoactive Substances Act 2016 ("the 2016 Act") by virtue of their ability to produce a psychoactive effect in a person. Whilst the 2016 Act makes it an offence to supply, produce, import, or export these substances knowingly or recklessly for their

psychoactive effect, possession, except with intent to supply or in a custodial institution, is not unlawful. This Order specifies that these substances will now instead be controlled as drugs which are "dangerous or otherwise harmful" under the 1971 Act and as such, they will no longer be captured under the 2016 Act.

6.3 This Order controls 15 substances as Class A drugs, four substances as Class B drugs and one substance as a Class C drug under the 1971 Act. For all but one of the substances – cumyl-PeGaClone – this follows recommendations made by the ACMD. The reports are available on GOV.UK at the following links:

6.3.1 ACMD advice on 2-benzyl benzimidazole and piperidine benzimidazolone opioids published on 18th July 2022, and subsequent addendums published on 19th December 2022 and 6th October 2023.

6.3.2 ACMD advice on the classification and schedule of Remimazolam - GOV.UK (www.gov.uk) published on 2nd December 2022.

6.3.3 ACMD review of the evidence on the use and harms of diphenidine - GOV.UK (www.gov.uk) published on 25th May 2023.

6.3.4 ACMD review of the evidence on the use and harms of Cumyl-PeGaClone - GOV.UK (www.gov.uk) published on 25th May 2023.

6.4 The 1971 Act 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). The ACMD recommended that 19 of these substances are placed in Schedule 1 and one in Schedule 4 (Part 1), to the Misuse of Drugs Regulations 2001 ("the 2001 Regulations"). It is intended that a further statutory instrument will come into force at the same time as this Order. This will amend the 2001 Regulations and, where appropriate, the Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015 ("the 2015 Order") to make such provision as is appropriate for legitimate access to the controlled drugs.

7. Policy background

What is being done and why?

7.1 This Order brings 20 substances under the control of the 1971 Act, following consultation with the ACMD, which is a statutory, independent advisory body established by the 1971 Act. The ACMD makes recommendations to Government on the control of dangerous or otherwise harmful drugs, including the classification and scheduling under the 1971 Act, the 2001 Regulations and where appropriate, the 2015 Order. The ACMD also consider any substances which are, or appear to be, misused and which are capable, or appear to be capable, of having harmful effects.

7.2 Having assessed their harms, the ACMD recommended control of 19 of the 20 substances, except cumyl-PeGaClone, a type of synthetic cannabinoid receptor agonist (SCRA). It instead recommended that a consultation was undertaken with stakeholders on modifications to the generic control for SCRA to capture currently uncontrolled SCRA that have been detected in the United Kingdom (UK) and internationally. The Government agreed to this recommendation but decided to control cumyl-PeGaClone under the 1971 Act in the interim.

7.3 The control of these substances under the 1971 Act will take them outside of the ambit of the 2016 Act and instead place them within the framework of controls of the

1971 Act, as controlled drugs. This will make possession of these substances an offence unless such possession is authorised under the 2001 Regulations or by licence. It will also mean that the penalties and enforcement provisions under the 1971 Act apply.

2-benzyl benzimidazole and piperidine benzimidazolone opioids

7.4 Isotonitazene, metonitazene and brorphine have been listed in Schedule 1 of the United Nations Single Convention on Narcotic Drugs 1961. As a signatory to this Convention, the UK Government requested advice from the ACMD on appropriate control under the 1971 Act and associated Regulations. In addition to review of these substances, the ACMD's report also considered other 2-benzyl benzimidazole (also known as 'nitazenes') and piperidinyl benzimidazolone opioids that have been detected in the UK or elsewhere. The ACMD assessed there to be 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. It reported their involvement 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.

7.5 The ACMD's report and subsequent addendums, as referenced in paragraph 6.3.1, therefore recommend that the following substances are controlled as Class A drugs under the 1971 Act:

7.5.1 brorphine;

7.5.2 butonitazene;

7.5.3 ethyleneoxynitazene;

7.5.4 etodesnitazene (etazene);

7.5.5 flunitazene;

7.5.6 isotonitazene;

7.5.7 metodesnitazene (metazene);

7.5.8 metonitazene;

7.5.9 protonitazene;

7.5.10 *N*-Desethyl etonitazene;

7.5.11 *N*-Desethylisotonitazene;

7.5.12 *N*-Desethyl protonitazene;

7.5.13 *N*-Piperidinyl-etonitazene (etonitazepipne);

7.5.14 *N*-Pyrrolidino-etonitazene (etonitazepyne);

7.5.15 *N*-Pyrrolidino protonitazene.

Remimazolam

7.6 Remimazolam is the active ingredient in a product given medicines authorisation by the Medicines and Healthcare products Regulatory Agency (MHRA) in 2021. The ACMD conducted a review of its harms, and its report as referenced in paragraph 6.3.2 recommends that remimazolam is controlled as a Class C drug under the 1971 Act. As a benzodiazepine, the potential harms of remimazolam would be commensurate with other benzodiazepine drugs already controlled under Class C under the 1971 Act.

Diphenidine, ephenidine and methoxyphenidine

7.7 Diphenidine, a 1,2-diarylethylamine, was added to Schedule 2 of the United Nations Convention on Psychotropic Substances 1971 ("the 1971 Convention") in April 2021, following which the UK Government requested advice from the ACMD on appropriate control under the 1971 Act and associated Regulations.

7.8 The ACMD's report, as referenced in paragraph 6.3.3, noted that diphenidine and methoxyphenidine have been involved in a number of deaths worldwide, including in the UK, as a result of acute drug toxicity. It recommended that diphenidine and related substances, ephenidine and methoxyphenidine, are controlled as Class B drugs under the 1971 Act. This is in line with reports of their dissociative effects as being similar to existing Class B drugs, such as ketamine.

Cumyl-PeGaClone

7.9 Cumyl-PeGaClone, a type of SCRA, was added to Schedule 2 of the 1971 Convention in April 2021, following which the UK Government requested advice from the ACMD on appropriate control under the 1971 Act and associated Regulations. The ACMD report, as referenced in paragraph 6.3.4, noted the use of SCRA can produce important adverse health effects including confusion, anxiety, and psychosis. These effects may cause hospitalisation and in severe cases death may occur.

7.10 Owing to its structure, cumyl-PeGaClone currently falls outside of the generic definition for SCRA in the 1971 Act, and the ACMD's report therefore recommends that the Government consult relevant stakeholders on modification to this definition. The Government has agreed to consult as soon as possible but, to meet our international obligations under the 1971 Convention more quickly, has opted to control cumyl-PeGaClone individually as a Class B drug (in line with other SCRA) under the 1971 Act in the interim.

8. European Union Withdrawal and Future Relationship

8.1 This Order does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act 2018 / implement any future relationship agreement with the European Union within the meaning provided by section 37 of the European Union (Future Relationship) Act 2020.

9. Consolidation

9.1 It is not currently intended that amendments to Schedule 2 to the 1971 Act will be consolidated.

10. Consultation outcome

10.1 The ACMD has been consulted as statutorily required, and recommended control of 19 of the 20 substances named above, which the Government accepted. Links for each report are included in paragraphs 6.3.1- 6.3.4. The exception to this is cumyl-PeGaClone, a SCRA. In their report of 25 May 2023, the ACMD recommended that consultation should be undertaken with stakeholders, including academia and the chemical and pharmaceutical industries on modifications to the current generic control for SCRA. This is to ensure changes to the generic definition for SCRA do not capture a disproportionate number of substances that have legitimate uses, which could then result in increased costs to businesses. The Home Office intends to consult as soon as possible but has opted to control cumyl-PeGaClone in the interim to meet international obligations under the 1971 Convention, under which cumyl-PeGaClone was scheduled in 2021, more quickly.

11. Guidance

11.1 Changes to the law to control these 20 substances under the 1971 Act will be communicated to key stakeholders, including healthcare professionals and the wider public, by the Home Office and the Department of Health and Social Care. The Home Office will issue a circular with legislative guidance, primarily for the police and the courts. The Department of Health and Social Care will issue guidance to the healthcare sector regarding remimazolam.

11.2 The Government will continue to update its messaging on the harms of these substances, including through its FRANK information and advisory service online, which is aimed at young people and adults to inform them of drug related risks and harms.

12. Impact

12.1 There is no, or no significant, impact on business, charities, or voluntary bodies from this Order.

12.2 There is no significant impact on the public sector from this Order. The impact on the public sector, including impact on the police, criminal justice system and prisons, is estimated to be small. This is due to the current low detection of the 20 named substances in society, noting the data limitations set out in the impact assessment. There are potential positive impacts as a result of improved public safety, but these could not be quantified due to insufficient evidence at this stage.

12.3 A full impact assessment will be published alongside the explanatory memorandum on legislation.gov.uk the date the instrument is laid.

13. Regulating small business

13.1 The legislation does not apply to activities that are undertaken by small businesses.

14. Monitoring & review

14.1 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.

14.2 This instrument does not include a statutory review clause.

15. Contact

15.1 Lauren Teer at the Home Office, Telephone: 07587299202 or email lauren.teer@homeoffice.gov.uk can be contacted with any queries regarding the instrument.

15.2 Marcus Starling, Deputy Director for the Drug Misuse Unit at the Home Office can confirm that this explanatory memorandum meets the required standard.

15.3 The Minister for Crime, Policing and Fire, the Rt. Hon. Chris Philp MP at the Home Office can confirm that this explanatory memorandum meets the required standard.