EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS AND MISUSE OF DRUGS (DESIGNATION) (ENGLAND AND WALES AND SCOTLAND) (AMENDMENT AND REVOCATION) REGULATIONS 2024

2024 No. 248

1. Introduction

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

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Declaration

2.1 Chris Philp, Minister for Crime, Policing and Fire at 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 Lauren Teer at the Home Office Telephone: 07587299202 or email: lauren.teer@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 instrument complements the Misuse of Drugs Act 1971 (Amendment) Order 2024 ("the 2024 Order"), which controls 15 substances as Class A drugs, four substances as Class B drugs and one substance as a Class C drug under the Misuse of Drugs Act 1971 ("the 1971 Act").

4.2 This instrument adds 19 substances controlled by the 2024 Order to Schedule 1 to the Misuse of Drugs Regulations 2001 ("the 2001 Regulations") (S.I. 2001/3998) and Schedule 1 to the Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015 ("the 2015 Order") (S.I. 2015/704), owing to their lack of known medicinal value in the UK. Consequently, it will only be possible for an authority to lawfully import, export, produce, possess, supply and administer these substances under a Home Office licence.

4.3 This instrument moves two existing Class A drugs under the 1971 Act (clonitazene and etonitazene) from Schedule 2 to Schedule 1 to the 2001 Regulations and designates them by placing them in Schedule 1 to the 2015 Order, as they have no known medicinal value in the UK. The effects will be as set out in paragraph 4.2.

4.4 This instrument adds one substance, remimazolam, to Part 1 of Schedule 4 to the 2001 Regulations, to enable access in healthcare settings, subject to requirements in the 2001 Regulations.

4.5 This instrument also revokes and replaces the Misuse of Drugs and Misuse of Drugs (Designation) (England and Wales and Scotland) (Amendment) Regulations 2024 (S.I. 2024/239) ("the initial 2024 Regulations"), which were made in error before the 2024 Order was made.

Where does the legislation extend to, and apply?

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

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

5. Policy Context

What is being done and why?

5.1 The Advisory Council on the Misuse of Drugs ("the ACMD") are 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 and the 2001 Regulations, and where appropriate, the 2015 Order.

5.2 The explanatory memorandum to the 2024 Order, which is published alongside it on www.legislation.gov.uk[1], sets out the full policy background including links to the ACMD reports with their full advice. In summary, all 20 substances in the 2024 Order were sufficiently 'dangerous or otherwise harmful' to warrant control under the 1971 Act. Based on advice from the ACMD, the 2024 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.

5.3 This instrument complements the 2024 Order by ensuring that all 20 substances are scheduled under the 2001 Regulations and, where appropriate, designated by the 2015 Order. This is based primarily on whether access is required for medicinal purposes or whether this should be limited to research or other special purposes under a Home Office licence issued by the Drugs and Firearms Licensing Unit.

5.4 Following consultation with the ACMD, 19 of the 20 substances controlled by the 2024 Order are to be placed in Schedule 1 to the 2001 Regulations and designated by the 2015 Order by virtue of having no known medicinal value in the UK. The substances are as follows:

5.4.1 brorphine;

5.4.2 butonitazene;

5.4.3 cumyl-PeGaClone;

5.4.4 diphenidine;

[1] The Misuse of Drugs Act 1971 (Amendment) Order 2024 - Draft Explanatory Memorandum (legislation.gov.uk)

5.4.5 ephenidine;

5.4.6 ethyleneoxynitazene;

5.4.7 etodesnitazene (etazene);

5.4.8 flunitazene;

5.4.9 isotonitazene;

5.4.10 methoxyphenidine;

5.4.11 metodesnitazene (metazene);

5.4.12 metonitazene;

5.4.13 protonitazene;

5.4.14 *N*-Desethyl etonitazene;

5.4.15 *N*-Desethylisotonitazene;

5.4.16 *N*-Desethyl protonitazene;

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

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

5.4.19 *N*-Pyrrolidino protonitazene.

5.5 The remaining substance controlled under the 2024 Order is remimazolam. This instrument places remimazolam, a benzodiazepine, in Part 1 of Schedule 4 to the 2001 Regulations. This is because of its known medicinal value in the UK as the active ingredient in a medicine given marketing authorisation (a medicines licence) from the Medicines and Healthcare products Regulatory Agency (MHRA). Placing remimazolam in this Schedule to the 2001 Regulations will enable its use in healthcare settings, subject to requirements in the 2001 Regulations related to record-keeping, preservation of documents, furnishing of information and destruction.

Clonitazene and etonitazene

5.6 In their report of 15 December 2022[2], the ACMD provided additional advice on two synthetic opioids, clonitazene and etonitazene, which are already controlled as Class A drugs under the 1971 Act.

5.7 When clonitazene and etonitazene were controlled under the 1971 Act, they were also added to Schedule 2 to the 2001 Regulations. In their 2022 report, the ACMD consulted the MHRA about legitimate medicinal use of clonitazene and etonitazene, alongside the other synthetic opioids being considered for control under the 1971 Act. Following the MHRA's confirmation that neither drug has been marketed in the UK as a medicine, imported for legitimate purposes or been involved in a clinical trial where the applicant has applied to the MHRA, the ACMD recommended they be

[2] ACMD advice on 2-benzyl benzimidazole and piperidine benzimidazolone opioids (accessible version) - GOV.UK (www.gov.uk)

moved to Schedule 1 to the 2001 Regulations, owing to their lack of known medicinal value. The Government accepted the ACMD recommendations, and this instrument therefore moves clonitazene and etonitazene from Schedule 2 to Schedule 1 to the 2001 Regulations and designates them under the 2015 Order.

What was the previous policy, how is this different?

5.8 Prior to this instrument, the 20 substances controlled by the 2024 Order were likely only captured by the Psychoactive Substances Act 2016 ('the PSA') by virtue of their ability to produce a psychoactive effect in a person. The PSA 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. The 2024 Order brings all 20 substances under the control of the 1971 Act and they are therefore subject to the increased penalties and additional offence of possession provided by that Act.

5.9 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 Government has laid this instrument alongside the 2024 Order to implement recommendations from the ACMD regarding scheduling of the 20 substances under the 2001 Regulations and, where appropriate the 2015 Order.

5.10 Of the 20 substances controlled by the 2024 Order, this instrument will add 19 substances to Schedule 1 to the 2001 Regulations and designate them under Schedule 1 of the 2015 Order, owing to their lack of known medicinal value in the UK. This means they can only be accessed under a Home Office licence for research or other special purposes. The remaining substance, remimazolam, will be added to Part 1 of Schedule 4 to the 2001 Regulations to enable its use in healthcare as a medicine. The Government's rationale for classification and scheduling of drugs remains unchanged and relies on expert advice from the ACMD.

5.11 Prior to this instrument, clonitazene and etonitazene were listed as Schedule 2 drugs under the 2001 Regulations. This meant that access was possible in some circumstances without the need for a Home Office licence. The ACMD consulted the MHRA on any known legitimate medical uses for clonitazene and etonitazene and identified no medicinal value of either drug in the UK. As such, they recommended they should be moved from Schedule 2 to Schedule 1 to the 2001 Regulations and be designated by the 2015 Order where their import, export, production, possession, supply and administration are only authorised under a Home Office licence. This instrument implements those recommendations.

6. Legislative and Legal Context

How has the law changed?

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. 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. The 2024 Order controls 15 substances as Class A drugs, four substances as Class B drugs, and one substance as a Class C drug. It therefore brings them outside of the remit of the PSA, under which they were previously likely captured.

6.2 This instrument complements the 2024 Order by scheduling the substances controlled by that Order under the 2001 Regulations to enable the appropriate level of access to those drugs for legitimate purposes, and, where appropriate, designates them under the 2015 Order.

6.3 The 2001 Regulations regulate legitimate access to drugs controlled under the 1971 Act. Controlled drugs are placed in one of five Schedules to the 2001 Regulations. The Schedule into which a drug is placed is based on an assessment of its medicinal or therapeutic value in the UK, the need for legitimate access and the potential for harm when misused. The Schedule in which a controlled drug is placed primarily dictates the extent to which it is lawful to import, export, produce, possess, supply and administer the controlled drug, and imposes requirements around prescribing, record-keeping, labelling, destruction, disposal and safe custody.

6.4 Schedule 1 drugs are considered to have no known medicinal value in the UK and are subject to the greatest restrictions, requiring a Home Office licence for access to such drugs. They are also designated under the 2015 Order. Controlled drugs placed in Part 1 to Schedule 4 to the 2001 Regulations are also subject to requirements (albeit less strict than those for controlled drugs placed in Schedules 1 to 3 to the 2001 Regulations) related to record-keeping, labelling, furnishing of information and destruction.

6.5 Section 7(3) of the 1971 Act requires the Secretary of State to make regulations to allow drugs controlled under the 1971 Act to be used for medicinal purposes. However, section 7(3) of the 1971 Act does not apply to any drug designated by order under section 7(4), and designated drugs are listed in Schedule 1 to the 2015 Designation Order. Controlled drugs are designated where the Secretary of State is of the opinion that it is in the public interest for the production, supply and possession of that drug to be either wholly unlawful or unlawful except for research or other special purposes under licence. Designation orders under section 7(4) may be varied or revoked by a further order (pursuant to section 7(5)).

6.6 Following consultation with the ACMD, this instrument places 19 of the 20 substances controlled by the 2024 Order, as well as clonitazene and etonitazene (two substances already controlled as Class A drugs under the 1971 Act), in Schedule 1 to the 2001 Regulations. It also designates these substances under the 2015 Order on the basis that they have no medicinal value in the UK.

6.7 Following the ACMD's recommendation, this instrument places remimazolam in Part 1 of Schedule 4 to the 2001 Regulations, to allow for legitimate access in healthcare. This is because it is has legitimate medical value as the active ingredient in a medicine given marketing authorisation (a medicines licence) by the MHRA.

6.8 This instrument also revokes the initial 2024 Regulations in order to re-make their substance at a slightly later point in time. The initial 2024 Regulations were made on 20th February 2024 and, if not revoked by this instrument, would have come into force on 20th March 2024. Regulations 2 and 3 of this instrument reflect, and replace, the substance of the amendments made by the initial 2024 Regulations and come into force at the same time as the 2024 Order (i.e. on the 20th March 2024).

Why was this approach taken to change the law?

6.9 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, which included consultation with the MHRA on legitimate uses of all substances covered in this instrument to inform the ACMD recommendations on scheduling under the 2001 Regulations and, where appropriate, the 2015 Order. Links to the relevant reports containing recommendations by the ACMD can be found in the explanatory memorandum of the 2024 Order[3] for the 20 substances controlled by that Order and paragraph 5.6 of this explanatory memorandum for the ACMD report on the rescheduling of clonitazene and etonitazene. The ACMD was also consulted on the designation of the 21 substances being placed in Schedule 1 to the 2015 Order, the results of which were recommendations to make the changes being implemented in this order.

8. Applicable Guidance

8.1 Changes to the law as a result of this instrument and the 2024 Order 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. It is part of the remit and responsibility of the ACMD that in making its recommendations to Government on scheduling under the 2001 Regulations and the 2015 Order, it considers legitimate uses in healthcare through consultation with the MHRA. The Home Office will issue a circular as both instruments come into force, 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.

8.2 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.

Part Two: Impact and the Better Regulation Framework

9. Impact Assessment

9.1 A full impact assessment and an economic note of the effect that this instrument will have on the costs of business and the voluntary sector and community bodies are available with the Explanatory Memorandum alongside this instrument on www.legislation.gov.uk. In summary, there is no, or no significant, impact on business, charities, or voluntary bodies from the 2024 Order or this instrument. The impact of the rescheduling clonitazene and etonitazene on legitimate businesses is assumed to be small to none, and no impact on the criminal justice system is expected to arise given both substances will remain in Class A.

9.2 The impact assessment[4] was drafted and published alongside the 2024 Order on 27 November 2023, which covers the control, scheduling and, where appropriate, designation of the substances. The economic note was drafted in addition to that impact assessment to cover the specific impacts of the rescheduling of clonitazene and etonitazene, which is implemented by this instrument.

[3] The Misuse of Drugs Act 1971 (Amendment) Order 2024 - Draft Explanatory Memorandum (legislation.gov.uk)
[4] The Misuse of Drugs Act 1971 (Amendment) Order 2024 - Impact Assessment (legislation.gov.uk)

Impact on businesses, charities and voluntary bodies

9.3 There is no, or no significant, impact on business, charities or voluntary bodies from this instrument.

9.4 The legislation does not impact small or micro businesses.

9.5 There is no, or no significant, impact on the public sector. This is due to the current low detection of the 22 named substances in society, noting the data limitations set out in the impact assessment and economic note. 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.

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 This instrument is being made in breach of the 21-day rule. Following the making of the initial 2024 Regulations (S.I. 2024/239), the Department became aware that those Regulations were made prior to the 2024 Order being made. The Department notes the twenty-second report of session 2012-2013 of the Joint Committee on Statutory Instruments[5], in which the JCSI reported similar instruments on the ground that there appeared to be a doubt as to whether they were *intra vires.*

11.2 In view of this, the Department decided to revoke the initial 2024 Regulations and replace them with this instrument. The coming into force provisions of this instrument have the effect that the initial 2024 Regulations will be revoked before they come into force. The remaining provisions of this instrument (namely, the provisions which replicate the amendments made by the initial 2024 Regulations) come into force at the same time as the 2024 Order (i.e. 20th March 2024).

11.3 The Department sincerely regrets the breach of the 21-day rule. It is necessary to ensure that the revocation of the initial 2024 Regulations takes place before those Regulations come into force and the replacement provisions in this instrument come into force at the same time as the 2024 Order. The procedure for the free issue of this instrument has been applied.

[5] Twenty-second Report of Session 2012-13 - Joint Committee on Statutory Instruments (parliament.uk).

12. European Convention on Human Rights

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

"In my view the provisions of The Misuse of Drugs and Misuse of Drugs (Designation) (England and Wales and Scotland) (Amendment and Revocation) Regulations 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").