EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS AND MISUSE OF DRUGS (DESIGNATION) (ENGLAND AND WALES AND SCOTLAND) (AMENDMENT) (NO. 2) REGULATIONS 2024

2024 No. 1369

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 Dame Diana Johnson, Minister of State for Policing, Fire and Crime Prevention 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 Sam Batista Morris at the Home Office. Telephone: 07786 445 357 or email: sam.batistamorris@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) (No. 2) Order 2024 "the 2024 Order (No. 2)", which controls six substances and introduces a broader definition for 2-benzyl benzimidazole (nitazenes), a group of synthetic opioids, as Class A drugs, controls 16 substances as Class C drugs under the Misuse of Drugs Act 1971 ("the MDA 1971") and 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.

4.2 This instrument adds 21 substances controlled by the 2024 Order (No. 2), along with 2-benzyl benzimidazole variants (nitazenes) falling under the generic definition, to Schedule 1 to the Misuse of Drugs Regulations 2001 ("the MDR 2001") and Part 1 of Schedule 1 to the Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015 ("the 2015 Order"), owing to their lack of recognised medicinal value in the UK. Consequently, it will only be possible to lawfully import, export, produce, possess, supply and administer these substances under a Home Office licence.

4.3 This instrument also adds one substance, xylazine, a veterinary medicine authorised in the UK, to Part 1 of Schedule 4 to the MDR 2001. This will enable legitimate access to it for veterinary use, subject to requirements in the MDR 2001.

4.4 This instrument also amends the entry for a drug already placed in Schedule 1 to the MDR 2001 and the 2015 Order – methoxyphenidine – to include an additional common name and its full IUPAC name, to aid clarity of the law.

Where does the legislation extend to, and apply?

4.5 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.

4.6 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 explanatory memorandum to the 2024 Order (No. 2), which is published alongside it on www.legislation.gov.uk[1], sets out the full policy background for control, scheduling and designation of these substances including links to the Advisory Council on the Misuse of Drugs ("ACMD") reports with their full advice.

5.2 This instrument complements the 2024 Order (No. 2) by ensuring, in line with ACMD recommendations, that 21 of the 22 specific substances controlled by that Order are placed in Schedule 1 to the MDR 2001 and designated by the 2015 Order, due to their lack of recognised medicinal value in the UK. This means that access to these substances is limited to research or other special purposes under a Home Office licence issued by the Drugs and Firearms Licensing Unit. These 21 substances are as follows:

5.2.1 AP-237;

5.2.2 AP-238;

5.2.3 Azaprocin;

5.2.4 para-methyl-AP-237;

5.2.5 para-nitroazaprocin

5.2.6 Bentazepam;

5.2.7 Bretazenil;

5.2.8 4'-Chloro-deschloroalprazolam

5.2.9 Clobromazolam;

5.2.10 Cloniprazepam;

5.2.11 Desalkylgidazepam;

5.2.12 Deschloroclotizolam;

5.2.13 Difludiazepam;

5.2.14 Flubrotizolam;

5.2.15 Fluclotizolam;

5.2.16 Fluetizolam;

5.2.17 Gidazepam;

[1] https://www.legislation.gov.uk/ukdsi/2024/9780348263046/memorandum/contents

5.2.18 2-Methyl-AP-237;

5.2.19 Methylclonazepam;

5.2.20 Rilmazafone;

5.2.21 Thionordazepam.

5.3 In addition to the above, 2-benzyl benzimidazole variants (nitazenes) falling under the generic definition, also controlled by the 2024 Order (No. 2), are to be placed in Schedule 1 to the MDR 2001 and designated by the 2015 Order due to their lack of recognised medicinal value in the UK.

5.4 The remaining substance controlled under the 2024 Order (No. 2) is xylazine, a non-opioid tranquilizer. In line with ACMD recommendations, this instrument places xylazine in Part 1 of Schedule 4 to the MDR 2001. Xylazine is authorised for use in the UK as a veterinary medicine but has not been approved for use in humans by the Medicines and Healthcare products Regulatory Agency (MHRA). This instrument therefore amends the MDR 2001, in order to enable its use in veterinary care settings, subject to requirements in the MDR 2001 related to record-keeping, preservation of documents, furnishing of information and destruction.

5.5 On 20 March 2024, the Government placed methoxyphenidine, a stimulant, in Schedule 1 to the MDR 2001 and the 2015 Order by virtue of having no recognised medicinal value in the UK[2]. This instrument adds an additional common name (methoxphenidine) and the full IUPAC name to the entry for methoxyphenidine. This does not affect the existing placement or designation of the substance but adds clarity on exactly which drug is referred to in the MDR 2001 and 2015 Order, given there are multiple common names.

5.6 The 2024 Order (No. 2) will control these dangerous substances and ensure that law enforcement have all the tools necessary to address the threat they pose to individuals and wider society, including deaths from drug poisoning. This instrument is set to come into force at the same time as the 2024 Order (No. 2) to ensure that there is no gap in time where a person cannot access these newly controlled substances for legitimate purposes. This is important, as a lack of legitimate access even if only for a short time could result in significant disruption to industry, for instance, in research and veterinary healthcare, and would likely also lead to operational confusion across these sectors.

What was the previous policy, how is this different?

5.7 Prior to the 2024 Order (No. 2), the 22 substances and 2-benzyl benzimidazole variants (nitazenes) falling under the generic definition were likely captured by the Psychoactive Substances Act 2016 (‘the PSA 2016’) by virtue of their ability to produce a psychoactive effect in a person, provided they did not satisfy any of the exemptions. 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. The 2024 Order (No. 2) brings all 22 substances and 2-benzyl benzimidazole variants (nitazenes) falling under the generic definition under the control of the MDA 1971 and they are therefore subject to the increased penalties and additional offence of possession provided by that Act.

[2] https://www.legislation.gov.uk/uksi/2024/248/pdfs/uksiem_20240248_en_001.pdf

5.8 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 (for example healthcare). The Government has laid this instrument alongside the 2024 Order (No. 2) to implement recommendations from the ACMD regarding scheduling of the 22 substances and 2-benzyl benzimidazole variants (nitazenes) falling under the generic definition under the MDR 2001 and, where appropriate, the 2015 Order.

5.9 This instrument will add 21 of the 22 substances controlled by the 2024 Order (No. 2), along with 2-benzyl benzimidazole variants (nitazenes) falling under the generic definition to Schedule 1 to the MDR 2001 and designate them under Schedule 1 of the 2015 Order, owing to their lack of recognised 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, xylazine, will be added to Part 1 of Schedule 4 to the MDR 2001 to enable its use in veterinary medicine. The Government's rationale for classification and scheduling of drugs remains unchanged and relies on expert advice from the ACMD.

6. Legislative and Legal Context

How has the law changed?

6.1 This instrument complements the 2024 Order (No. 2) by scheduling the substances controlled by that Order under the MDR 2001 and, where appropriate, designating them under the 2015 Order, so as to enable the appropriate level of access to them for legitimate purposes.

6.2 The MDR 2001 regulate legitimate access to drugs controlled under the MDA 1971. Controlled drugs are placed in one of five Schedules to the MDR 2001. 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.

6.3 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 these drugs. They are also designated under the 2015 Order. Controlled drugs placed in Part 1 to Schedule 4 to the MDR 2001 are also subject to requirements (albeit less strict than those for controlled drugs placed in Schedules 1 to 3 to the MDR 2001) related to record-keeping, labelling, furnishing of information and destruction.

6.4 Section 7(3) of the MDA 1971 requires the Secretary of State to make regulations to allow drugs controlled under the MDA 1971 to be used for medicinal purposes. However, section 7(3) of the MDA 1971 does not apply to any drug designated by order under section 7(4), and designated drugs are listed in Schedule 1 to the 2015 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; or unlawful for medical practitioners to prescribe, administer, compound or supply that drug except under licence. Designation orders under section 7(4) may be varied or revoked by a further order (pursuant to section 7 (5)).

6.5 Following consultation with the ACMD, this instrument places 21 of the 22 substances controlled by the 2024 Order (No. 2), along with 2-benzyl benzimidazole

variants (nitazenes) falling under the generic definition and also controlled by that Order, in Schedule 1 to the MDR 2001. It also designates these substances under the 2015 Order on the basis that they have no recognised medicinal value in the UK.

6.6 Following the ACMD's recommendation, this instrument also places xylazine in Part 1 of Schedule 4 to the MDR 2001, to allow for legitimate access in veterinary medicine.

6.7 Finally, this instrument adds an additional common name (methoxphenidine) and the full IUPAC name to the MDR 2001 entry for methoxyphenidine. This does not affect the existing placement or designation of the substance but adds clarity on exactly which drug is referred to in the MDR 2001 and 2015 Order, given there are multiple common names.

Why was this approach taken to change the law?

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

7. Consultation

Summary of consultation outcome and methodology

7.1 There is a statutory requirement for consultation with the ACMD ahead of any new controls, scheduling or designation of substances under the MDA 1971, MDR 2001 or 2015 Order. This was carried out with regards to the substances covered in this instrument, including consultation with the MHRA on their legitimate uses, in order to inform the ACMD recommendations on scheduling under the MDR 2001 and, where appropriate, designation under the 2015 Order. Links to the relevant reports containing the ACMD's recommendations can be found in the explanatory memorandum to the 2024 Order (No. 2), which is published alongside it on www.legislation.gov.uk[3].

7.2 The ACMD also recommended consultation with relevant key stakeholders on the introduction of a new generic definition for nitazenes. As such, the Home Office consulted with relevant key stakeholders including academia and the chemical and pharmaceutical industries specifically on the introduction of this new generic definition. This was a targeted consultation to understand whether any substances captured by the definition have legitimate uses that would mean control would result in significant, disproportionate impacts on UK businesses. None of the respondents noted any legitimate uses of substances captured by the generic definition, aside from potential research opportunities for which access may in any case be granted under a Home Office controlled drug licence. There was also no suggestion of wider disproportionate impact on businesses in the UK. No amendments were therefore made to the ACMD's proposed wording for the generic definition. As this was a targeted consultation on a technical subject, the Government's response to it will not be published.

8. Applicable Guidance

8.1 Changes to the law as a result of this instrument and the 2024 Order (No. 2) 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 and the Veterinary Medicines Directorate (VMD). It is part of the remit and responsibility of the ACMD that in making its recommendations

[3] https://www.legislation.gov.uk/ukdsi/2024/9780348263046/memorandum/contents

to Government on scheduling under the MDR 2001 and the 2015 Order, it considers legitimate uses in healthcare through consultation with the MHRA. The Home Office will issue a circular once both instruments come into force, with implementation guidance primarily for the police and the courts. The VMD will issue guidance to the veterinary care sector regarding xylazine.

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, continues 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[4]. There is limited data and evidence on the costs, benefits and risks (including relevant substance prevalence data) associated with this instrument. However, it is expected, according to the data available, to have negligible overall costs to legitimate businesses, while the intended benefits include a reduction in the risk of serious harms associated with drug misuse.

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 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.

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.

[4] https://www.legislation.gov.uk/ukdsi/2024/9780348263046/pdfs/ukdsiod_9780348263046_en_001.pdf

Part Three: Statements and Matters of Particular Interest to Parliament

11. Matters of special interest to Parliament

11.1 This instrument needs to come into force at the same time as the 2024 Order (No. 2) to ensure that there is no gap in time where a person cannot access these newly controlled substances for legitimate purposes. The potential absence of legitimate access and failure of this instrument to come into force at the same time as the 2024 Order (No.2) could result in significant disruption to industry, for instance, in research and veterinary healthcare, with considerable operational confusion also likely. The 2024 Order (No. 2) will come into force on 15 January 2025, 28 days after being made at December's Privy Council meeting. The 2024 Order (No. 2) was made at December's Privy Council meeting to ensure that the necessary controls can commence as soon as possible, which will allow law enforcement to mitigate the effects of these harmful substances, including preventable deaths. Therefore, this instrument is being laid as soon as possible after the 2024 Order (No. 2) was made, on the last sitting day before parliamentary recess to comply with the 21-day rule before coming into force on 15 January 2025. Although most of the 21-day period before this instrument comes into force coincides with parliamentary recess, this is considered the best option to ensure both instruments come into force as soon as possible in the interest of public safety.

12. European Convention on Human Rights

12.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

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").