EXPLANATORY MEMORANDUM

The Misuse of Drugs (Designation) (Amendment No. 2) Order (NI) 2024

S.R. 2024 No. 223

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department of Health to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.

1.2 The Statutory Rule is made under section 7(4) and (5) of the Misuse of Drugs Act 1971 (the 1971 Act) as adapted by section 7(9) of that Act and now vested in it and after consultation with the Advisory Council on the Misuse of Drugs in accordance with section 7(7) of that Act.

1.3 This Order is subject to negative resolution before the Northern Ireland Assembly.

2. Purpose of the Regulations

2.1 The purpose this Statutory Rule is to add twenty-one substances (including four acyl piperazine opioids, two chemically bridged acyl piperazine derivatives, 15 benzodiazepines and related compounds) and that of a broader range of 2-benzyl benzimidazole variants (nitazenes), to Part 1 of Schedule 1 to the Misuse of Drugs (Designation) Order (Northern Ireland) 2001 ("the 2001 Order") for the purposes of designating them as controlled substances which have no known legitimate medicinal use in Northern Ireland.

2.2 The Statutory Rule also adds an additional common name and the full International Union of Pure and Applied Chemistry ("IUPAC") name to the entry for methoxyphenidine, which is already included in Schedule 1 to the 2001 Order.

2.3 This will ensure that it will be unlawful to produce, possess or supply these designated drugs except under licence for research or other special purposes, with similar restrictions imposed on practitioners and pharmacists.

3. Background and Legislative Context

3.1 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.

3.2 The Advisory Council on the Misuse of Drugs (ACMD) makes recommendations to Government on the control of dangerous or otherwise harmful drugs, including classification and scheduling under the 1971 Act and its subordinate Misuse of Drugs Regulations and Orders. The control of these substances is predicated on an assessment of their respective harms, and in accordance with recommendations made by the ACMD.

3.3 The UK Government recently introduced an amending Order entitled the Misuse of Drugs Act 1971 (Amendment) (No. 2) Order 2024 to amend the 1971 Act to:

- bring four acyl piperazine opioids and two chemically bridged acyl piperazine derivatives under control as Class A drugs under the 1971 Act;
- bring a range of 2-benzyl benzimidazole variants under control as Class A drugs under the 1971 Act by use of a generic definition, excluding those which are already controlled under the 1971 Act as Class A drugs;
- add an additional common name and the full International Union of Pure and Applied Chemistry name to the entry for methoxyphenidine, which is already controlled as a Class B drug under the 1971 Act; and
- bring fifteen novel benzodiazepines and related compounds, and xylazine under control as Class C drugs under the 1971 Act.

3.4 Section 7(3) of the 1971 Act requires regulations to allow drugs controlled under that Act to be used for medicinal purposes. Section 7(3), however, does not apply to any drug which is designated by order under section 7(4) of that Act.

3.5 Controlled drugs are designated where the Department of Health is of the opinion that it is in the public interest for production, supply and possession of that drug to be either wholly unlawful or unlawful except for research or other special purposes, or for medicinal use of the drug to be unlawful except under licence. Schedule 1 to the Order specifies the list of controlled drugs to which section 7(4) of the 1971 Act applies.

4. Consultation

4.1 Following consultation with the ACMD, the affirmative Order, the Misuse of Drugs Act 1971 (Amendment) (No. 2) Order 2024, was made in UK Parliament on 18th December 2024 and will come into operation on 15th January 2025. The explanatory memorandum to the Misuse of Drugs Act 1971 (Amendment) (No. 2) Order 2024, which is published alongside it on www.legislation.gov.uk[1], sets out the full policy background including links to the ACMD reports with its full advice.

4.2 This amending Order complements the 2024 Order and further implements the recommendations made by the ACMD by adding 21 of these substances to Part 1 of Schedule 1 to the 2001 Order to designate them as controlled substances which have no known legitimate medicinal use in Northern Ireland. Those substances being:

- AP-237;
- AP-238;
- Azaprocin;
- Bentazepam;
- Bretazenil;
- Clobromazolam;

[1] Explanatory Memorandum to the Misuse of Drugs Act 1971 (Amendment No. 2) Order 2024

- Cloniprazepam;
- Desalkylgidazepam;
- Deschloroclotizolam;
- Difludiazepam;
- Flubrotizolam;
- Fluclotizolam;
- Fluetizolam;
- Gidazepam;
- Methylclonazepam;
- para-methyl-AP-237;
- para-nitroazaprocin
- Rilmazafone;
- Thionordazepam;
- 2-methyl-AP-237;
- 4'-Chloro-deschloroalprazolam

4.3 In addition to the above, nitazenes falling under the generic definition contained in the Misuse of Drugs Act 1971 (Amendment) (No. 2) Order 2024 are also now designated by this Order by virtue of this definition now also being added to Part 1 of Schedule 1 to the 2001 Order.

4.4 This amending Order also adds an additional common name (methoxphenidine) and the full IUPAC name to the entry for methoxyphenidine, which is already included in Part 1 of Schedule 1 to the 2001 Order. This does not affect the existing placement or designation of the substance in the 2001 Order; but adds clarity on exactly which drug is referred to given there are multiple common names.

4.5 The ACMD reports on these substances are available on GOV.UK at the following links:

- https://www.gov.uk/government/publications/acmd-advice-on-acyl-piperazine-opioids-including-2-methyl-ap-237/acmd-advice-on-acyl-piperazine-opioids-including-2-methyl-ap-237-accessible;
- https://www.gov.uk/government/publications/uncontrolled-novel-benzodiazepines-2024-update/cover-letter-from-acmd-recently-encountered-uncontrolled-novel-benzodiazepines-and-related-compounds-2024-update-accessible-version;
- 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; and

- https://www.gov.uk/government/publications/use-and-harms-of-xylazine-medetomidine-and-detomidine.

5. Equality impact

5.1 The Department of Health has concluded that the proposed amendments will not have a significant impact on equality of opportunity for any group referred to in section 75 of the Northern Ireland Act 1998 and a full Equality Impact Assessment has not been considered necessary.

6. Regulatory impact

6.1 It is not anticipated that these Regulations will have any adverse impact on business, charities, social economy or voluntary bodies.

7. Financial implications

7.1 None anticipated.

8. Section 24 of the Northern Ireland Act 1998

8.1 The Department of Health has considered section 24 of the Northern Ireland Act 1998 and is satisfied that these Regulations are not incompatible with any of the Convention rights; are not incompatible with Community law; do not discriminate against a person or class of person on the grounds of religious belief or political opinion; and do not modify an enactment in breach of section 7 of the Northern Ireland Act 1998.

9. EU implications

9.1 There are no anticipated EU implications as a result of these amendments.

10. Parity or Replicatory Measure

10.1 The provisions included in this Statutory Rule seek to replicate similar amendments to the Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015 which are being taken forward by the Home Office and will ensure that the legislative arrangements in Northern Ireland will be in line with GB.

11. Additional information

11.1 Not applicable