EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS AND MISUSE OF DRUGS (DESIGNATION) (AMENDMENT) (ENGLAND, WALES AND SCOTLAND) REGULATIONS 2021

2021 No. 897

1. Introduction

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

2. Purpose of the instrument

2.1 Following an assessment of their harms, the Advisory Council on the Misuse of Drugs ('ACMD') has recommended the control of three benzodiazepines, flualprazolam, flunitrazolam, norfludiazepam, as Class C drugs under the Misuse of Drugs Act 1971 ('the 1971 Act'). This instrument places these three benzodiazepines, under Schedule 1 to the Misuse of Drugs Regulations 2001 ('the 2001 Regulations') and amends Schedule 1 to the Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015 ('the 2015 Order') which specifies controlled drugs to which section 7(4) of the 1971 Act applies. This instrument complements measures in the Misuse of Drugs Act 1971 (Amendment) Order 2021 as outlined in paragraphs 6.3 and 6.6 below.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 N/A.

4. Extent and Territorial Application

4.1 The territorial extent of this instrument is England, Wales and Scotland.

4.2 The territorial application of this instrument is England, Wales and Scotland.

5. European Convention on Human Rights

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

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. 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.

6.2 The Misuse of Drugs Act 1971 (Amendment) Order 2021 controls the benzodiazepines flualprazolam, flunitrazolam and norfludiazepam as Class C drugs under the 1971 Act following recommendations made by the ACMD.

6.3 This instrument complements the Misuse of Drugs Act 1971 (Amendment) Order 2021. 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) does not apply to any drug which is 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. Designation Orders under section 7(4) may be varied or revoked by a further order (pursuant to section 7(5)).

6.4 The 2001 Regulations provide access to controlled drugs for legitimate medicinal purposes (and exceptionally for industrial purposes) under the 1971 Act. Drugs are placed into 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 usefulness, the need for legitimate access as well as its potential for harm when used. The Schedule primarily dictates the extent to which it is lawful to import, export, produce, possess, supply and administer. It imposes requirements in relation to prescribing, record keeping, labelling, destruction, disposal and safe custody.

6.5 Schedule 1 drugs are considered to have no known medicinal use in the UK and are subject to the greatest restrictions, requiring a Home Office licence for access to such drugs and they are also designated under the 2015 Order.

6.6 Following the recommendation of the ACMD, this instrument will complement the provisions in the Misuse of Drugs Act 1971 (Amendment) Order 2021 by placing flualprazolam, flunitrazolam and norfludiazepam under Schedule 1 to the 2001 Regulations and will designate these substances under the 2015 Order as they have no known legitimate medicinal use in the UK.

7. Policy background

What is being done and why?

7.1 The ACMD was set up under the 1971 Act as an independent body which makes recommendation to the government on the control of dangerous or otherwise harmful drugs, including the classification and scheduling under the 1971 Act and the 2001 Regulations. 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 The ACMD report published on 29 April 2020 states that adverse effects of benzodiazepines include drowsiness, psychomotor impairment, unsteadiness and incoordination, memory loss and confusion. Higher doses may cause loss of consciousness and respiratory depression, especially if used in combination with alcohol or other sedatives. Owing to the greater prevalence of flualprazolam, flunitrazolam and norfludiazepam than the other ten benzodiazepines listed in the report, the ACMD has recommended that those three compounds should be controlled

as Class C drugs the 1971 Act and scheduled under Schedule 1 to the 2001 Regulations[1].

7.3 The ACMD provided addendum advice, dated 16 November 2020 recommending that these three benzodiazepines should also be designated under section 7(4) of the 1971 Act as drugs which have no know legitimate medicinal use in the UK and further to include them in Part 1 of Schedule 1 to the 2015 Order[2]. This instrument places these substances under Schedule 1 to the 2001 Regulations which will mean that only those with a licence granted by the Home Office will be able to legally possess these. The instrument also designates them as drugs to which section 7(4) of the 1971 Act applies as they have no known legitimate medicinal use in the UK.

7.4 Benzodiazepines can be misused in a variety of ways, often in the context of polydrug use. They may be used with other sedatives to increase their effects, or they may be used to 'come down' after stimulant use.

7.5 The April 2020 ACMD report confirmed that in relation to flualprazolam, as of March 2020, there had been 12 flualprazolam-associated deaths in the UK recorded by regional statistical agencies. Norfludiazepam has been identified in the UK twice, both in 2017: once from a police seizure and once by drug identification provider TICTAC. In relation to flunitrazolam, the report states that it is likely that its potency is greater than that of the already highly potent flunitrazepam (Rohypnol) which is controlled as a Class C drug under the 1971 Act. A small number of seizures have been made at the UK border between 2014 and October 2019.

8. European Union Withdrawal and Future Relationship

8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act 2018.

9. Consolidation

9.1 This Statutory Instrument does not consolidate the 2001 Regulations; the Government will review whether to consolidate these in the future.

10. Consultation outcome

10.1 The ACMD has recommended the control of the three benzodiazepines as Class C substances under the 1971 Act, and that they be listed in Schedule 1 of the 2001 Regulations and added under Part 1 to Schedule 1 to the 2015 Order, following a review of their harms.

11. Guidance

11.1 The effect of the control of these three benzodiazepines under the 1971 Act, their inclusion in Schedule 1 to the 2001 Regulations and the 2015 Order will be communicated to key stakeholders and the wider public. The Home Office will issue a Circular with legislative guidance primarily for the police and the courts. The Government will continue to update its messaging on the harms of these substances, including through its FRANK information and advisory service online.

[1] A review of the evidence of use and harms of novel benzodiazepines (publishing.service.gov.uk)
[2] Addendum to ACMD's report on novel benzodiazepines - GOV.UK (www.gov.uk)

12. Impact

12.1 There is no, or no significant, impact on business, charities or voluntary bodies. Any impact on companies or research organisations having lawful reason for possessing these three substances is expected to be minimal. These organisations are already likely to be handling controlled drugs acting under a Home Office licence, or in accordance with the 2001 Regulations. Guidance is already available in this area.

12.2 There is no, or no significant, impact on the public sector.

12.3 An Impact Assessment has not been prepared for this instrument given the limited expected impact of the changes. However, we have prepared and published an Economic Note covering the effect of the control, scheduling and designation of flualprazolam, flunitrazolam and norfludiazepam.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 No specific action is proposed to minimise regulatory burdens on small businesses, as the ACMD report confirms, having consulted the Medicines and Healthcare products Regulatory Agency, the three benzodiazepines subject to this instrument have been identified as having no known legitimate medicinal use in the UK. As a result, no significant impact or costs on legitimate businesses are expected.

13.3 Theoretically, businesses could incur further costs as they would need to purchase a licence to possess the substances for a permitted purpose, such as research. However, any businesses conducting research on benzodiazepines are highly likely to already have a Home Office controlled drugs licence. Equally, the recommendation to schedule these three benzodiazepines under Schedule 1 to the 2001 Regulations is consistent with the ACMD's advice about the scheduling of 16 designer benzodiazepines – including etizolam - under Schedule 1 to the 2001 Regulations in 2017. The additional cost to businesses affected by this measure is therefore expected to be minimal. Domestic licences are issued under the 2001 Regulations. Between 2,250-2500 domestic licences are issued per year, with 135 licences for drugs scheduled under Schedule 1 to the 2001 Regulations issued between 3 March 2020 to 2 March 2021. Licences are annually renewable and are specific to site and organisations.

14. Monitoring & review

14.1 The Government will continue to monitor the control measures through the regulatory framework governing controlled drugs, this will include national data collection and surveys on drug misuse.

15. Contact

15.1 Sam Hardy at the Home Office Telephone: 020 7 035 1784 or email: sam.hardy@homeoffice.gov.uk can be contacted with any queries regarding the instrument.

15.2 Marcus Starling, Deputy Director for Drug Misuse and Firearms Unit, at the Home Office, can confirm that this Explanatory Memorandum meets the required standard.

15.3 The Minister for Crime and Policing, Kit Malthouse MP at the Home Office can confirm that this Explanatory Memorandum meets the required standard.