EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS (AMENDMENT) (ENGLAND, WALES, AND SCOTLAND) REGULATIONS 2017

2017 No. 631

AND

THE MISUSE OF DRUGS (DESIGNATION) (AMENDMENT) (ENGLAND, WALES AND SCOTLAND) ORDER 2017

2017 No. 632

1. Introduction

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

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

2. Purpose of the instrument

2.1 The Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations 2017 ('the 2017 Regulations') add U-47,700, a synthetic opioid, twelve substances closely related to methylphenidate, and sixteen 'designer' benzodiazepines to Schedule 1 to the Misuse of Drugs Regulations 2001 ('The 2001 Regulations').

2.2 The Misuse of Drugs (Designation) (Amendment) (England, Wales and Scotland) Order 2017 ('the 2017 Designation Order') also adds these same substances to Part 1 of Schedule 1 to the Misuse of Drugs (Designation) Order 2015 ('the 2015 Designation Order').

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 The instruments come into force before they can be laid before Parliament and accordingly breach the 21-day rule. It is essential for the instruments to be brought into force on 31st May 2017 as they are entirely consequential on the making of the Misuse of Drugs Act 1971 (Amendment) Order 2017 ('2017 Order') (S.I. 2017/634), which was made by the Privy Council on 3rd May 2017. The 2017 Order comes into force on the 28th day after it was made, i.e. on 31st May 2017. The 2017 Order was made following advice from the Advisory Council on the Misuse of Drugs (ACMD) which recommended that 29 substances be controlled due to their risks to public health and safety. It was therefore essential for the 2017 Order to be made by the Privy Council as soon as possible and imperative for it to be made to come into force in advance of 26th June, as seven of the drugs concerned are currently subject to a temporary class drugs order (TCDO) which expires on that date. If this was not done then the TCDO would lapse leaving these drugs uncontrolled (along with the other 22 substances), meaning it would be legal to possess them. This would give rise to a significant risk to health in light of the substances' potential harms. It is essential for

the 2017 Regulations and the 2017 Designation Order to come into force at the same time as the 2017 Order to ensure that the proper regulatory framework is in place when these drugs become controlled, without which there would be a serious risk of misuse and diversion as well as considerable operational confusion.

3.2 Accordingly, given the current dissolution of Parliament, it is necessary for the instruments to come into force before they can be laid before Parliament. Notification has been provided to the Speaker of the House of Lords, as required by section 4(1) of the Statutory Instruments Act 1946, and notification will also be sent to the Speaker of the House of Commons once the Speaker is elected.

Other matters of interest to the House of Commons

3.3 As these instruments are subject to the negative resolution procedure and have not been prayed against, consideration as to whether there are other matters of interest to the House of Commons does not arise at this stage.

4. Legislative Context

4.1 As required by the Misuse of Drugs Act 1971 ('1971 Act'), these instruments are made following consultation with the Advisory Council on the Misuse of Drugs ('ACMD'). They are consequential on the making of the 2017 Order, which controlled, under the 1971 Act, the synthetic opioid U-47,700 as a Class A drug, twelve methylphenidate related substances as Class B drugs and sixteen 'designer' benzodiazepines as Class C drugs. A number of these methylphenidate related materials were specified under section 2A of the 1971 Act as drugs subject to temporary control by virtue of the Misuse of Drugs Act 1971 (Temporary Class Drug) Order 2016 (S.I. 2016/650) and cease to be subject to such temporary control on the coming into force of the 2017 Order in accordance with section 2A(6)(b) of the 1971 Act.

4.2 The 1971 Act controls drugs that are "dangerous or otherwise harmful". 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. Section 7(3) of the 1971 Act does not apply to any drug designated by order under section 7(4) and these designated drugs are listed in Schedule 1 to the 2015 Designation Order. The ACMD reported that U-47,700, the twelve methylphenidate-related substances and the sixteen 'designer' benzodiazepines had no recognised medicinal use and they are therefore added to Schedule 1 by the 2017 Designation Order.

4.3 The 2001 Regulations regulate legitimate access to drugs controlled under the 1971 Act. Such 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 usefulness, the need for legitimate access, as well as its potential for harm when misused. Scheduling primarily dictates the extent to which it is lawful to import, export, produce, possess, supply, administer the drugs concerned and imposes requirements around prescribing, record-keeping, labelling, destruction, disposal and safe custody. Given that U47-700, the twelve methylphenidate-related substances and the sixteen 'designer' benzodiazepines have no legitimate medical uses, the ACMD recommended adding these substances to Schedule 1 to the 2001 Regulations, thus subjecting them to the strictest level of controls.

5. Extent and Territorial Application

5.1 The extent of these instruments is England, Wales and Scotland.

5.2 The territorial application of these instruments is England, Wales and Scotland.

6. European Convention on Human Rights

6.1 As these instruments are subject to the negative resolution procedure and do not amend primary legislation, no statement is required.

7. Policy background

What is being done and why

7.1 Following consultation with the ACMD a number of substances are being added to Schedule 1 to the 2001 Regulations and Schedule 1 to the 2015 Designation Order.

7.2 The 1971 Act and its associated regulations enable the lawful possession and supply of controlled drugs for medicinal purposes or other special purposes. U-47,700 is a synthetic opioid, originally developed as a research chemical but with no legitimate use. The ACMD reported that they found no evidence that U-47,700 has a recognised medicinal use. As a result, U-47,700 will be added to Schedule 1 to the 2001 Regulations and is designated by the 2017 Designation Order as a drug to which section 7(4) of the 1971 Act applies.

7.3 The ACMD's advice in respect of U-47,700 and the 'designer' benzodiazepines, along with a number of addendums (latest March 2017), can be found here: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/579352/ACMD_TCDO_Report_U47700_and_Etizolam_and_designer_benzodiazepines.pdf

7.4 Similarly the 2017 Regulations add twelve compounds related to the substance methylphenidate (also known as Ritalin) to Schedule 1 to the 2001 Regulations and are designated by the 2017 Designation Order as drugs to which section 7(4) applies. Although Methylphenidate is currently listed as a Schedule 2 substance under the 2001 Regulations, the ACMD reported that the twelve methylphenidate-related substances – Ethylphenidate, Methylnaphthidate ('HDMP-28'), Isopropylphenidate ('IPP' or 'IPPD'), Propylphenidate, 4-Methylmethylphenidate, Ethylnaphthidate, *N*-Benzyl-ethylphenidate, 3,4-Dichloroethylphenidate, 3,4-Dichloromethylphenidate ('3,4-DCMP'), Methylmorphenate, and 4-Fluoromethylphenidate, 4-Fluoroethylphenidate - have no confirmed legitimate medicinal, industrial or commercial uses.

7.5 The ACMD's advice in respect of the methylphenidates is available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/602522/Final_Scheduling_advice_-_23_March_2017.pdf

7.6 Finally, the 2017 Regulations add sixteen 'designer' benzodiazapines to Schedule 1 to the 2001 Regulations and are designated by the 2017 Designation Order as drugs to which section 7(4) applies. These substances - Etizolam, Diclazepam, Flubromazepam, Pyrazolam, Deschloroetizolam, Flubromazolam, Nitrazolam, Nifoxipam, Clonazolam, 4'-Chlorodiazepam, Bromazolam, Meclonazepam, Adinazolam, Metizolam, 3-Hydroxyphenazepam, and Fonazepam have been reported by the ACMD as having no recognised medicinal use in the United Kingdom. However, the Government has asked the ACMD to keep the scheduling of these

'designer' benzodiazepines under close review given that Etizolam has been identified by some countries, including Italy, as having some therapeutic benefits.

Consolidation

7.7 This instrument does not present a suitable opportunity to consider consolidation.

8. Consultation outcome

8.1 The Government has consulted its independent experts, the Advisory Council on the Misuse of Drugs, along with the Medicines and Healthcare Products Regulatory Agency and the Department for Business, Innovation and Skills (now known as the Department for Business Energy and Industrial strategy). The ACMD recommended the Scheduling, under the 2001 Regulations for U-47,700, twelve methylphenidate related substances and sixteen 'designer' benzodiazepines and has confirmed that they should be added to Schedule 1 to the 2015 Designation Order.

9. Guidance

9.1 The control of these drugs and their consequences will be communicated to key stakeholders and the wider public. The Home Office will issue a Circular with legislative guidance primarily for the law enforcement 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 (the Government's national drugs awareness service).

9.2 The changes to the 2001 Regulations will be communicated to healthcare professionals and the wider public by the Home Office and the Department of Health. The Home Office will issue a Circular explaining the changes and will liaise with the Department of Health and the Medicines and Healthcare product Regulatory Agency to issue guidance to interested healthcare institutions and professionals using their usual communication channels.

10. Impact

10.1 There is no impact on legitimate business, charities or voluntary bodies, except for organisations undertaking research using these substances. However, impact on research organisations is expected to be minimal as these organisations are already likely to be handling controlled drugs acting under a Home Office licence, or in accordance with the Misuse of Drugs Regulations 2001, and guidance is already widely available in this area.

10.2 The impact on the public sector is expected to be minimal. Enforcement of offences in relation to the drugs controlled by the 2017 Order will be subsumed into the overall enforcement response to controlled drugs. There may be a benefit to health services and treatment providers where the supply of these substances is restricted.

10.3 Impact Assessments are submitted with these instruments and will be published alongside the Explanatory Memorandum on the legislation.gov.uk website. These assessments were also submitted with the 2017 Order and remain up to date.

11. Regulating small business

11.1 This legislation applies to activities that are undertaken by small business.

11.2 No specific action is proposed to minimise regulatory burdens on small businesses.

11.3 The harm that can result from misuse and diversion of the drugs controlled by the 2017 Order is such that we would expect compliance with the 1971 Act and subordinate legislation made under it, however small the business. However, the impact is minimised for those businesses already likely to be handling controlled drugs, acting in accordance with a Home Office licence or within the 2001 Regulations where guidance is already widely available in this area.

12. Monitoring & review

12.1 The Government will monitor the control measures through the regulatory framework governing medicines and controlled drugs, and also through the oversight of the Accountable Officers and the healthcare regulatory bodies in England and the Devolved Administrations.

13. Contact

13.1 Sara Soleymani at the Home Office. Telephone: 0207 035 3073 or email: Sara.Soleymani@homeoffice.gsi.gov.uk can answer queries about these instruments.