EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS (DESIGNATION) (AMENDMENT) (ENGLAND, WALES AND SCOTLAND) ORDER 2016

2016 No. 1124

AND

THE MISUSE OF DRUGS (AMENDMENT) (ENGLAND, WALES, SCOTLAND) REGULATIONS 2016

2016 No. 1125

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 instruments

2.1 The Misuse of Drugs (Designation) (Amendment) (England, Wales and Scotland) Order 2016 ('the 2016 Designation Order') adds a further range of synthetic cannabinoids to Part 1 of Schedule 1 to the Misuse of Drugs (Designation) Order 2015 ('the 2015 Designation Order').

2.2 The Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations 2016 ('the 2016 Regulations') adds a further range of synthetic cannabinoids to Schedule 1 to the Misuse of Drugs Regulations 2001 ('the 2001 Regulations'). The 2016 Regulations also add the anabolic steroid dienedione to Part 2 of Schedule 4 to the 2001 Regulations.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

Other matters of interest to the House of Commons

3.2 As this instrument is subject to negative resolution procedure and has 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 Act ('the 1971 Act'), these instruments are made following consultation with the Advisory Council on the Misuse of Drugs ('the ACMD'). They are associated with the Misuse of Drugs Act 1971 (Amendment) Order 2016 (the '2016 Order'), which controlled, under the 1971 Act, a further range of 'third generation' synthetic cannabinoids and dienedone as Class B and Class C drugs respectively.

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 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. The ACMD reported that the psychoactive effects and harms of the third generation synthetic cannabinoids controlled by the 2016 Order are similar to cannabis and other synthetic cannabinoids already controlled under the 1971 Act. The ACMD report also concluded that there was no legitimate medicinal use for these compounds and therefore recommended that this further range of synthetic cannabinoids be added to Part 1 of Schedule 1 to the 2015 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. The Schedule primarily dictates the extent to which it is lawful to import, export, produce, possess, supply, administer and imposes requirements around prescribing, record keeping, labelling, destruction, disposal and safe custody. Given that the further range of synthetic cannabinoids has no legitimate medical uses, the ACMD recommended adding them to Schedule 1 to the 2001 Regulations, thus subjecting them to the strictest level of controls. The 2016 Regulations also adds the anabolic steroid known as dienedone to Part 2 Schedule 4 to the 2001 Regulations. Controlled drugs placed in Part 2 of Schedule 4 are exempt from the prohibition on importation and exportation or from the prohibition on possession when in the form of a medicinal product.

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.

5.3 We understand that Northern Ireland will introduce their own legislation to mirror these changes in due course.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does 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 further range of synthetic cannabinoids 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. As reported by the ACMD, the third generation synthetic cannabinoids have no legitimate medicinal uses and affect the CB1 cannabinoid receptors in the brain which can produce psychoactive effects similar to those produced by cannabis. As a result, the third generation synthetic cannabinoids are designated by the 2016 Designation Order as

drugs to which section 7(4) of the 1971 Act applies. This is done through the insertion of a generic definition into Schedule 1 of the 2015 Designation Order, which excludes those synthetic cannabinoids that are already specified in Schedule 1 to the Order, two other compounds which are not required to be designated (clonitazene and etonitazene), and several other compounds that have legitimate medical uses (acemetacin, atorvastatin, bazedoxifene, indometacin, losartan, olmesartan, proglumetacin, telmisartan, viminol and zafirlukast).

7.3 Due to their potential harms, this further range of synthetic cannabinoids is also added to Schedule 1 to the 2001 Regulations. This is done through the insertion of a generic definition, which excludes those synthetic cannabinoids that are already specified in Schedule 1 to the Regulations, two other compounds which are already specified in Schedule 2 to the Regulations, and several other compounds that have legitimate medical uses in either the UK or EU.

7.4 The ACMD's advice in respect of these substances, along with a number of addendums (latest November 2016) which amend the generic definition, can be found here:

https://www.gov.uk/government/publications/third-generation-synthetic-cannabinoids

7.5 Further, in accordance with ACMD advice, dienedione is added to Part 2 of Schedule 4 to the 2001 Regulations. The ACMD has carefully considered the potential physical and social harms of dienedione and advises that these would be commensurate with other anabolic steroids. The ACMD's advice in respect to dienedione is available at:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/491846/ACMD_advice_-_Estra-4_9-diene-317-dione___dienedione_.pdf

Consolidation

7.6 The Government intends to consolidate the 2001 Regulations at the earliest suitable opportunity.

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 know as the Department for Business Energy and Industrial strategy). The ACMD recommended the Scheduling, under the 2001 Regulations, of both the further range of third generation synthetic cannabinoids and dienedione as well as the designation of the former under the 2015 Designation Order.

9. Guidance

9.1 The control of these drugs and its consequences will be communicated to key stakeholders and the wider public. The Home Office will issue a circular with legislative guidance primarily for law enforcement authorities 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 products 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 business, charities or voluntary bodies, except for organisations undertaking research using these compounds. However, impact is minimal as these organisations are already likely to be handling controlled drugs acting under a Home Office licence or in accordance with the 2001 Regulations where 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 drugs controlled under the 2016 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 2016 Order and remain up to date.

11. Regulating small business

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

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 2016 Order is such that the Home Office 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 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 any queries regarding the instrument.