EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS AND MISUSE OF DRUGS (DESIGNATION) (AMENDMENT) (ENGLAND, WALES AND SCOTLAND) REGULATIONS 2019

2019 No. 1362

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 This instrument amends the generic definition of a range of synthetic cannabinoids controlled as Schedule 1 compounds under the Misuse of Drugs Regulations 2001 ('the 2001 Regulations') and designated under the Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015 ('the 2015 Order') to reduce the scope of the definition whilst retaining control over compounds which are known to be, or likely to be, misused and harmful.

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 As the instrument is subject to negative resolution procedure there are no matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business at this stage.

4. Extent and Territorial Application

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

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

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 As required by the Misuse of Drugs Act 1971 ('the 1971 Act'), this instrument is made following consultation with the Advisory Council on the Misuse of Drugs ('the ACMD'). It is consequential on the Misuse of Drugs Act 1971 (Amendment) Order 2019 ('the 2019 Order'), which amends the generic definition of a range of 'third generation' synthetic cannabinoids controlled as Class B drugs under the 1971 Act. This is a group of compounds that mimics the effects of cannabis and which are commonly referred to as 'Spice' and 'Mamba'.

6.2 The 1971 Act controls drugs that are 'dangerous or otherwise harmful' and divides them into classes - A, B and C, with different sentences being issued for offences, dependent on the class of drug involved.

6.3 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 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. 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 around prescribing, record keeping, labelling, destruction, disposal and safe custody.

6.5 By way of example, Schedule 1 drugs are considered to have little or no therapeutic or medicinal value 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. In contrast, Schedule 5 drugs are considered to present little risk of misuse and can be sold over the counter as a pharmacy medicine.

6.6 On the recommendation of the ACMD, a range of 'third generation' synthetic cannabinoids, were permanently controlled as Class B drugs under Part 2 of Schedule 2 to the 1971 Act by the Misuse of Drugs Act 1971 (Amendment) Order 2016 (S.I. 2016/1109) on the 14 December 2016. At the same time, these compounds were added to Schedule 1 to the 2001 Regulations, by the Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations 2016 (S.I. 2016/1125) and Part 1 of Schedule 1 to the 2015 Order, by the Misuse of Drugs (Designation) (Amendment) (England, Wales and Scotland) Order 2016 (S.I. 2016/1124).

6.7 In December 2017, the ACMD recommended an amendment to the generic definition of 'third generation' synthetic cannabinoids under the 1971 Act, 2001 Regulations and 2015 Order to remove from control compounds unintentionally captured while retaining control over those compounds which are known to be, or likely to be, misused and harmful. In accordance with this advice, the 2019 Order amends the generic definition in the 1971 Act. To ensure regulatory alignment, this instrument makes corresponding amendments to the generic definition of third generation synthetic cannabinoids in Schedule 1 to the 2001 Regulations and Part 1 of Schedule 1 of the 2015 Order.

7. Policy background

What is being done and why?

7.1 Following consultation with the ACMD, the generic definition of a range of 'third generation' synthetic cannabinoids permanently controlled as Class B drugs under the 1971 Act has been amended. To ensure regulatory alignment, the corresponding definitions in the 2001 Regulations and the 2015 Order are also being amended.

7.2 The ACMD, first published guidance in 2014 on the 'third generation' of synthetic cannabinoids. This followed the control of the 'first generation' of synthetic cannabinoids in 2009 and the 'second generation' in 2013. The ACMD recommended that synthetic cannabinoids should be captured under a 'generic definition', as Class B drugs under the 1971 Act and also recommended that these compounds were placed under Schedule 1 of the 2001 Regulations. This was due to their associated harms and widespread availability. Whilst noting that there is limited data available on the patterns of acute harm associated with the use of synthetic cannabinoid receptors agonists, a 2012 ACMD report suggests that certain synthetic cannabinoids have psychoactive effects. Anecdotal user reports suggesting that certain synthetic cannabinoids can produce severe adverse effects such as increased heart rate, panic attacks and convulsions were also cited in that report. The 2012 ACMD report also referenced US reports citing effects such as severe agitation, sympathomimetic toxicity, and death associated with certain types of synthetic cannabinoids use. The 2012 report is available at the following link:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/119042/synthetic-cannabinoids-2012.pdf

7.3 The ACMD's 2014 advice in respect of the 'third generation' synthetic cannabinoids, along with a number of addenda, can be found here:

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

7.4 Following the introduction of the definition of 'third-generation' synthetic cannabinoids, concerns were raised by the research community that the definition inadvertently captured compounds used in scientific research which were not intended for control.

7.5 Following discussions between the research community and the ACMD, on 27 December 2017, the ACMD issued advice recommending an amendment to the generic definition of 'third generation' synthetic cannabinoids to reduce the scope. The ACMD recommends replacing the term 'univalent' with a defined member of substituents (alkyl, alkenyl, alkoxy, halide, haloalkyl, cyano, phenyl, benzyl and substituted phenyl and benzyl groups) to reduce the number of compounds unintentionally captured by the generic definition while retaining those compounds that have been found to cause harms. The recommended revised definition continues to exclude the licensed medicines and the Class A drugs previously excluded. The ACMD's advice is available at:

https://www.gov.uk/government/publications/legitimate-use-of-controlled-drugs-research-and-healthcare

7.6 On 18 May 2018, the former Minister of State for Policing and the Fire Service provided his initial response to the ACMD's proposal, suggesting a further meeting between officials, representatives from the research community, the Chief Scientific

Advisers from the Home Office and the Department of Health and Social Care. This is available at:

https://www.gov.uk/government/publications/legitimate-use-of-controlled-drugs-research-and-healthcare

7.7 On 15 January 2019, following consultation with the research community, the Minister sent a further letter accepting the ACMD's recommendation to implement a revised generic definition. This is available at:

https://www.gov.uk/government/publications/legitimate-use-of-controlled-drugs-research-and-healthcare

7.8 The 2019 Order for the amendment of the generic definition to remove compounds from control as Class B drugs under the 1971 Act comes into force on 15 November 2019. This instrument makes corresponding amendments to the generic definition under the 2001 Regulations and the 2015 Order to ensure regulatory alignment. As a result, those compounds which were unintentionally captured, will no longer require a Home Office licence for the conduct of research, as they would no longer be controlled under the 1971 Act.

8. European Union (Withdrawal) Act 2018/Withdrawal of the United Kingdom from the European Union

8.1 This instrument does not relate to withdrawal from the European Union.

9. Consolidation

9.1 The Government intends to consolidate the 2001 Regulations in the future.

10. Consultation outcome

10.1 The ACMD, the independent advisory body set up under the 1971 Act, has recommended amendment of the generic definition for 'third generation' synthetic cannabinoids under the 1971 Act, the 2001 Regulations and the 2015 Order. The Government worked closely with, and consulted representatives from, the research community on the impact of such amendments.

11. Guidance

11.1 The amendment to the generic definition of 'third generation' synthetic cannabinoids 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 setting out the effect of the amendment on the compounds controlled as Class B drugs under the 1971 Act, as Schedule 1 drugs under the 2001 Regulations and designated under the 2015 Order in Autumn 2019.

12. Impact

12.1 The impact on business, charities or voluntary bodies is beneficial. The Order removes a number of compounds from the generic definition which were unintentionally controlled, and consequently permits research on these compounds without the requirement for a Home Office licence. The impact of the change is limited to the pharmaceutical and healthcare research sector.

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

12.3 A full Impact Assessment is submitted with this memorandum and published alongside the Explanatory Memorandum on the legislation.gov.uk website.

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.

13.3 The basis for the final decision on what action to take to assist small businesses is based on the effect of the amendment to the generic definition of 'third generation' synthetic cannabinoids. The instrument removes compounds from the scope of the generic definition, and therefore does not apply any additional regulatory burden on small businesses.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is through the regulatory framework governing controlled drugs, and also through national data collection and surveys on drug misuse. A review provision is not appropriate as the measure is deregulatory in nature and the impact of the measure is expected to be beneficial (i.e. removing compounds from the generic definition of 'third generation' synthetic cannabinoids).

15. Contact

15.1 Emma Nichols at the Home Office, telephone: 07826 241935, email: emma.nichols5@homeoffice.gov.uk, can be contacted with any queries regarding the instrument.

15.2 Gwen Nightingale and Katherine Merrifield, Joint Heads of the Drugs and Alcohol Unit at the Home Office can confirm that this Explanatory Memorandum meets the required standard.

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