EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS (AMENDMENT) (ENGLAND, WALES AND SCOTLAND) REGULATIONS 2020

2020 No. 559

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 places Epidyolex, a cannabis-based medicine, in Schedule 5 to the Misuse of Drugs Regulations 2001 ('the 2001 Regulations'), with the result that it is excepted from the prohibition on importation, exportation and possession in the Misuse of Drugs Act 1971 ('the 1971 Act').

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 Law

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, 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 As required by the 1971 Act, this instrument is made following consultation with the Advisory Council on the Misuse of Drugs ('the ACMD'). 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.

6.2 The 2001 Regulations provide access to controlled drugs for legitimate medicinal or exceptionally for industrial purposes. Drugs which are controlled under the 1971 Act are listed in one of five Schedules to the 2001 Regulations, based on an assessment of their medicinal or therapeutic usefulness, the need for legitimate access and their potential harms when misused. The Schedule into which a drug is placed 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. Schedule 1 controlled drugs are subject to the greatest restrictions and Schedule 5 to the lowest.

6.3 On 1st November 2018, cannabis-based products for medicinal use in humans ('CBPMs') were placed in Schedule 2 to the 2001 Regulations and removed from Part 1 of the Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015, meaning that CBPMs could be prescribed for medicinal use in the UK. Epidyolex satisfies the definition of a CBPM, and on 19 September 2019, the European Commission issued a marketing authorisation in relation to it. Following this authorisation, the ACMD reviewed the appropriate Schedule into which Epidyolex should be placed, distinct from CBPMs generally, and recommended that it be placed in Schedule 5 to the 2001 Regulations. This instrument therefore makes the necessary amendments to the 2001 Regulations to place Epidyolex in Schedule 5 to the 2001 Regulations.

7. Policy background

What is being done and why?

7.1 Epidyolex is a cannabis-based medicine licensed for the treatment of rare forms of epilepsy. It mostly consists of the active ingredient cannabidiol ('CBD') and a small amount of delta-9-tetrahydrocannabinol ('THC'), which is controlled as a Class B drug under the 1971 Act.

7.2 Prior to receiving a marketing authorisation from the European Commission, Epidyolex was considered an unlicensed CBPM (i.e. without marketing authorisation granted in accordance with the medicines legislation applicable in the UK). This meant that only clinicians on the General Medical Council's specialist register, or doctors acting under their direction, were able to prescribe this medicine.

7.3 On 19 September 2019, the European Commission issued a marketing authorisation for Epidyolex which meant that it became a licensed CBPM in the UK. This meant that it could be prescribed in line with all other Schedule 2 controlled drugs by any practitioner, such as a General Practitioner, with the authority to do so under the 2001 Regulations. In December 2019, the National Institute for Health and Care Excellence ('NICE') also recommended Epidyolex for use, in combination with clobazam, for treating seizures associated with Lennox–Gastaut syndrome and Dravet syndrome in people aged 2 years and older.

7.4 As a result of the marketing authorisation issued by the European Commission, the ACMD considered the appropriate Schedule into which Epidyolex, as a licensed cannabis-based medicine, should be placed. The ACMD concluded that Epidyolex should be placed in Schedule 5 to the 2001 Regulations because THC is present only as an impurity and as it has a low risk of abuse potential, low risk of dependency and low risk of diversion. The ACMD's advice is available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/861607/ACMD_advice_Epidyolex.pdf

7.5 The Government considered the ACMD's recommendation and, on 22 April 2020, The Minister of State for Crime and Policing wrote to the ACMD accepting the recommendation to place Epidyolex in Schedule 5 to the 2001 Regulations. This is available at:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/882901/Epidyolex_scheduling_and_definition_under_the_Misuse_of_Drugs_Regulations_2001.pdf.

7.6 This instrument gives effect to the ACMD's recommendation by placing Epidyolex in Schedule 5 and consequently excepting it from the prohibition on importation, exportation and possession.

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

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

9. Consolidation

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

10. Consultation outcome

10.1 The Home Office has consulted the ACMD, the Department of Health and Social Care, the Medicines and Healthcare products Regulatory Agency and GW Pharmaceuticals, who manufacture Epidyolex, extensively on the proposed scheduling decision and definition for Epidyolex. In addition, the Home Office has consulted and sighted the relevant clinical and regulatory bodies on the proposed scheduling decision for Epidyolex. Those consulted include the Care Quality Commission, British Paediatric Neurology Association, Association of British Neurologists, Royal College of General Practitioners, British Medical Association, Royal Pharmaceutical Society, and the Pharmaceutical Services Negotiating Committee. Northern Ireland has also been consulted on the scheduling decision. Those consulted agreed with the decision to place Epidyolex in Schedule 5 to the 2001 Regulations.

11. Guidance

11.1 This legislative change and its consequences will be communicated to key stakeholders and the wider public through a Home Office circular with legislative guidance. NHS England will also issue guidance to the healthcare sector.

12. Impact

12.1 There is no, or no significant, impact on business, charities or voluntary bodies.

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 that any loss in revenue would be negligible. Some smaller individual pharmacies may experience a decline in their revenue because of the ability to increase the quantity of

Epidyolex supplied through one prescription once it is placed in Schedule 5, which in turn will reduce the frequency of dispensing. The reason for this is that the fees paid to pharmacies each year for dispensing prescriptions includes the total number of prescription items they dispense, plus an additional fee for dispensing Schedule 2 drugs. However, as discussed in the Small and Micro Business Assessment contained in the Impact Assessment, since Epidyolex prescriptions represent a small proportion of the total prescriptions dispensed by pharmacies, the loss in revenue affecting their businesses will be negligible.

14. Monitoring & review

14.1 The approach to monitoring of this legislation is through the regulatory framework governing medicines and controlled drugs, and also through the oversight of the healthcare regulatory bodies.

14.2 This instrument does not contain a review provision as the measure is deregulatory in nature and the impact of the measure is expected to be beneficial.

15. Contact

15.1 Emma Nichols at the Home Office, Telephone: 07826 035 1535 or 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 and Policing, at the Home Office can confirm that this Explanatory Memorandum meets the required standard.