EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS AND MISUSE OF DRUGS (SAFE CUSTODY) (AMENDMENT) (ENGLAND AND WALES AND SCOTLAND) REGULATIONS 2018

2018 No. 1383

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 These Regulations add pregabalin and gabapentin to Schedule 3 to the Misuse of Drugs Regulations 2001 ('the 2001 Regulations') and to the list of drugs in Schedule 1 to the Misuse of Drugs (Safe Custody) Regulations 1973 ('the 1973 Regulations').

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, 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 the negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

6.1 The 2018 Order controls gabapentin and pregabalin as Class C drugs under the Misuse of Drugs Act ('the 1971 Act') and comes into force on 1 April 2019. Amendments to the 2001 Regulations and the 1973 Regulations are necessary to complement the Misuse of Drugs Act 1971(Amendment) Order 2018 ('the 2018 Order'). As required by the 1971 Act, this instrument is made following consultation with the Advisory Council on the Misuse of Drugs ('ACMD'). The changes have been subject to a public consultation.

6.2 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 Act to be used for medicinal purposes. The Misuse of Drugs

Regulations 2001 ('the 2001 Regulations') regulate the legitimate access to controlled drugs, and the Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) (England and Wales and Scotland) Regulations 2018 ('the 2018 Regulations') add pregabalin and gabapentin to Schedule 3 of those Regulations. The Schedule into which a drug is placed dictates primarily the extent to which it is lawful to import, export, produce, supply, administer and possess that drug, and also imposes requirements about prescription writing, record keeping, labelling and destruction. See paragraph 7.2 for further detail.

6.3 The Misuse of Drugs (Safe Custody) Regulations 1973 ('the 1973 Regulations') provide for the safe custody of controlled drugs, and require such controlled drugs, other than those specified in Schedule 1, generally to be kept either in a locked safe or room or in a locked receptacle. The 2018 Regulations add pregabalin and gabapentin to Schedule 1 to the 1973 Regulations as drugs which are exempted from the safe custody requirements of the 1973 Regulations. See paragraph 7.3 for further detail.

7. Policy background

What is being done and why?

7.1 As the 2018 Order controls gabapentin and pregabalin as Class C drugs under the 1971 Act, these regulations are necessary to ensure their continued availability for legitimate use and to make provision in respect of safe custody.

7.2 Pregabalin and gabapentin are used to treat a variety of conditions, including epilepsy, postherapeutic neuralgia, diabetic peripheral neuropathy and fibromyalgia, and in the management of neuropathic pain. The ACMD recommended that these drugs be scheduled under Schedule 3 to the 2001 Regulations so as not to preclude legitimate use on prescription. Placing gabapentin and pregabalin under Schedule 3 ensures that these drugs will be accessible for medical needs, subject to measures of control. As Schedule 3 drugs, they will be subject to regulations 14 (documentation), 15 (form of prescriptions), 16 (supply on prescription), 19 to 23 (record-keeping and requirements as to registers and other documents), 26 (furnishing of information) and 27 (destruction of the drugs). Measures that they will be subject to include: the writing of prescriptions to specific requirements, including the wet signature of the prescriber, record keeping details about the quantity of the drugs, and the preservation of record keeping registers for two years.

7.3 As Schedule 3 drugs, pregabalin and gabapentin would ordinarily be subject to safe custody requirements. However, due to the large quantities prescribed and dispensed - and to reflect concerns raised, in responses to the consultation document, about the potential costs to store these in controlled drug safes (as explained further in paragraph 10.3 below) - pregabalin and gabapentin are being exempted from these requirements. The drugs are therefore added to the list of drugs in Schedule 1 to the 1973 Regulations. This avoids any impact (such as additional costs to buy and install safes) from storage requirements on hospitals, pharmacies and businesses, etc.

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 due course.

10. Consultation outcome

10.1 The Home Office undertook a public consultation about scheduling proposals following the ACMD advice. The *Consultation on proposals to schedule pregabalin and gabapentin under the Misuse of Drugs Regulations 2001,* ran from 13 November 2017 to 22 January 2018. This consultation proposed three options: Option 1, control as Class C Drugs under the 1971 Act and full Schedule 3 status under the 2001 Regulations, (as recommended by the ACMD), which was supported by 16 per cent of respondents; Option 2, control as Class C Drugs under the 1971 Act (but to exclude the application of the safe custody requirements), which was supported by the majority of respondents, 53 per cent, and which has been adopted by the Government; and Option 3 to place in Part 1 of Schedule 4 to the Misuse of Drugs Regulations 2001 which was supported by 25 per cent of respondents. Five hundred and twenty-nine people or representatives of organisations responded.

10.2 Pharmacies, doctors, pharmaceutical companies, as well as patients, responded to the consultation. Pharmacists made up the largest proportion of responses and the majority of respondents were based in England.

10.3 Sixty-five per cent of respondents did not think that there was space in existing safe storage cabinets for pregabalin and gabapentin (in 2016, there were in excess of 14.5 million prescriptions). Concerns were raised that organisations would have to buy and install new safes to accommodate the two drugs, should the provisions of option 1 apply. Twenty-nine per cent of respondents thought that the costs of Option 1 would result in £1,000 or more to their organisation per month, with over 10 per cent responding that the monthly cost of Option 1 to their organisation would be between £500-£1,000. This compared with approximately 66 per cent who suggested that the additional monthly cost of the changes as a result of Option 2 would be between £0-£99.

10.4 While Option 3 would be the least onerous on patients (who would be able to benefit from repeat prescriptions), pharmacies and GPs, it lacked the safeguards of Option 2. Under Option 3, provisions relating to the very specific prescription requirements, including the wet signature of the prescriber, for example, would not apply. Schedule 4 drugs are subject to fewer administrative controls than substances in Schedule 3 and, consequently, the risk of diversion is higher.

10.5 The summary of responses to the consultation and Government's response is published at: https://www.gov.uk/government/consultations/pregabalin-and-gabapentin-proposal-to-schedule-under-the-misuse-of-drugs-regulations-2001

11. Guidance

11.1 The changes made by this instrument and their consequences of this will be communicated to key stakeholders and the wider public. In preparation for the legislation coming into force in April 2019, the Home Office will liaise with the Department for Health and Social Care and the Medicines and Healthcare products Agency to issue a circular with legislative guidance primarily for the police and the courts. Information about the changes will be made widely available via FRANK (the Government's national drugs awareness service).

12. Impact

12.1 The impact on business, charities or voluntary bodies is expected to be minimal. As a proportion of all costs on GPs, the impact on private business is likely to be less than £10,000.

12.2 The impact on the public sector is expected to be minimal. There is an estimated cost of £97,000 to pharmacies in year one and a cost to GPs £172,000 in year one. There is an additional dispensing cost to the NHS which is estimated at a present value of £53.7m over 10 years of the policy. Enforcement of offences in relation to drugs controlled by the Order will be subsumed into the overall enforcement response to controlled drugs.

12.3 A full Impact Assessment covering the effect of the control and scheduling of pregabalin and gabapentin was published alongside the explanatory memorandum covering the 2018 Order, including cost and harm to the public that would be avoided, and is available on the 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 harm that can follow from the misuse and diversion of pregabalin and gabapentin, which is such that the Government will expect all businesses to comply with the new legislative requirements. Legislative compliance is well established practice among pharmacists, including those in small businesses. The additional impact is minimised for those businesses already likely to be handling controlled drugs, acting under Home Office licence or the 2001 Regulations, and guidance is already widely available in this area. Exemption from the safe custody requirements of the 1973 Regulations will also ensure that additional costs burdens on small business should be limited, for example by not requiring provision of new safes within their premises.

14. Monitoring & review

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

15. Contact

15.1 Sam Hardy at the Home Office Telephone: 0207 035 1784 or email: sam.hardy@homeoffice.gov.uk, can be contacted with any queries regarding the instrument.

15.2 Katherine Merrifield and Gwen Nightingale at the Home Office can confirm that this Explanatory Memorandum meets the required standard.

15.3 Victoria Atkins MP, the Minister for Crime, Safeguarding and Vulnerability, at the Home Office can confirm that this Explanatory Memorandum meets the required standard.