EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS ACT 1971 (AMENDMENT) ORDER 2018

2018 No. *

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 Gabapentin and pregabalin are drugs used to treat epilepsy but misuse of these drugs has been associated with avoidable deaths. The Advisory Council on the Misuse of Drugs has recommended additional safeguards. The Order in Council (the "Order") brings gabapentin and pregabalin under permanent control as a Class C drugs under Part of 3 Schedule 2 to 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 Laws)

3.2 The territorial application of this instrument includes Scotland and Northern Ireland

3.3 The powers under which this instrument is made cover the entire United Kingdom (section 40 (2) of the 1971 Act) and the territorial application of this instrument is not limited either by the Act or by the instrument.

4. Extent and Territorial Application

4.1 The extent of this instrument is the United Kingdom.

4.2 The territorial application of this instrument is the United Kingdom.

5. European Convention on Human Rights

5.1 The Minister for Crime, Safeguarding and Vulnerability, Victoria Atkins MP, has made the following statement regarding Human Rights:

"In my view the provisions of the Misuse of Drugs Act 1971 (Amendment) Order 2018 are compatible with the Convention rights."

6. Legislative Context

6.1 The Misuse of Drugs Act 1971 ("the 1971 Act") controls drugs that are "dangerous or otherwise harmful". Schedule 2 to the 1971 Act specifies these drugs and groups them in three categories – Part 1 lists drugs known as Class A drugs, Part 2 lists Class B drugs and Part 3 lists Class C drugs. The three-tier system of classification (A, B and C) provides a framework within which criminal penalties are set with reference to the harm a drug has, or is capable of having when misused, and the type of illegal activity undertaken in regard to that drug.

6.2 The classification of gabapentin and pregabalin is predicated on an assessment of their respective harms, and in accordance with recommendations made by the Advisory Council on the Misuse of Drugs ('ACMD'). The ACMD reported that the drugs present a risk of addiction and a potential for illegal diversion and medicinal misuse. It recommends that both drugs are controlled as Class C drugs under the 1971 Act. As appropriate, controls on these substances are extended to their simple derivatives (salts, stereoisomeric forms) and their esters.

A further statutory instrument will come into force at the same time as the Order. This will add gabapentin and pregabalin to the appropriate Schedules to the Misuse of Drugs Regulations 2001 and make provision in relation to the Misuse of Drugs (Safe Custody) Regulations 1973.

7. Policy background

What is being done and why?

7.1 The Government is controlling gabapentin and pregabalin permanently as Class C drugs under the 1971 Act, due to their potential harms. The ACMD reported that while both gabapentin and pregabalin have medicinal uses as anticonvulsant drugs, with a well-defined role in managing a number of disabling, long-term conditions, the harms associated with these compounds are commensurate with those of other substances controlled under the 1971 Act, and the potential for abuse is similar to other Class C substances such as tramadol.

7.2 The ACMD presented findings to support its recommendation for control. The ACMD identified a number of harms, noting that, when the drugs were used in combination with other depressants, that they could cause drowsiness, sedation, respiratory failure, and death. Pregabalin causes a 'high' or elevated mood in users; the side effects may include chest pain; wheezing, and vision changes. Some users have reported that the effects from gabapentin can be similar to taking a stimulant drug, such as an amphetamine. Both substances have been linked to drug related deaths.

7.3 The ACMD has recommended that both substances should be controlled as Class C drugs, under the 1971 Act, and scheduled under the 2001 Regulations as Schedule 3 so not to preclude legitimate use on prescription. The ACMD's advice can be found here:

https://www.gov.uk/government/publications/advice-on-the-anticonvulsant-drugs-pregabalin-and-gabapentin

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 Consolidation is not relevant to this Order.

10. Consultation outcome

10.1 The ACMD, the independent advisory body set up under the 1971 Act, has recommended control of the two drugs concerned, following review of their harms.

11. Guidance

11.1 The control of pregabalin and gabapentin 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 police 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.

11.2 A Home Office circular will be published following engagement with interested parties about the effect of the legislation in preparation for it coming into force in April.

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 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 harm that can follow from the misuse and diversion of gabapentin and pregabalin. Compliance with the 1971 Act is well established practice among pharmacists, including those in small businesses. And the additional impact is minimised as these businesses are already likely to be handling controlled drugs, acting under Home Office licence or the Misuse of Drugs Regulations 2001. And guidance is already widely available in this area. Exemption from the 1973 Regulation requirements will also ensure that small business should not incur additional cost, e.g., for providing new safes within their premises.

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 in England and the Devolved Administrations.

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.