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A consultation on proposals to schedule pregabalin and gabapentin under the Misuse of Drugs Regulations 2001

Government consultation

This consultation begins on 13/11/2017

This consultation ends on 22/01/2018

About this consultation

- To:** This is a public consultation. Any member of the public can respond.
- Duration:** From 13/11/17 to 22/01/18
- Enquiries (including requests for the paper in an alternative format) to:** Sam Hardy
5th Floor, Fry Building, 2 Marsham Street, London, SW1 4DF
Tel: 0207 035 1784
Email: DrugsLegislationTeam@homeoffice.gsi.gov.uk
- How to respond:** Please send your response by 22/01/18 to:
Drugs Legislation Team
5th Floor, Fry Building, 2 Marsham Street, London, SW1 4DF
Email: DrugsLegislationTeam@homeoffice.gsi.gov.uk
- Additional ways to respond:** Responses can be made via the on-line questionnaire at:
<http://www.homeofficesurveys.homeoffice.gov.uk/s/4WEQO/>
- Response paper:** The results of the consultation and the Government's response will be published on GOV.UK in early 2018.

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Executive summary

This consultation seeks views on options whether, and how, to schedule pregabalin and gabapentin under the Misuse of Drugs Regulations 2001 following the recommendation by the Advisory Council on the Misuse of Drugs (ACMD) that these two drugs should be controlled as Class C drugs under the Misuse of Drugs Act 1971 ('the 1971 Act') and placed in Schedule 3 to the Misuse of Drugs Regulations 2001. The consultation is aimed at members of the public, healthcare professionals, institutions, all sectors within the supply chain including the pharmaceutical industry, wholesalers and community pharmacies in the UK. Comments from all those with an interest in the consultation are welcome.

The baseline position is to 'do nothing' (i.e., do not control pregabalin and gabapentin under the 1971 Act (and therefore not seek to schedule the drugs under the 2001 Regulations). This would leave the illicit supply subject to provisions in the Psychoactive Substances Act 2016. The 'do nothing' option is included only as a means to assess baseline against which the options in the impact assessment have been measured. The Government is not inviting views on whether the illicit supply of pregabalin and gabapentin should be subject to the provisions in the Psychoactive Substances Act 2016.

There are three options:

- 1) Control pregabalin and gabapentin as Class C Drugs under the 1971 Act and place both in Schedule 3 to the 2001 Regulations, applying the provisions of the Misuse of Drugs (Safe Custody) Regulations 1973 (the 1973 Regulations).
- 2) Control pregabalin and gabapentin as Class C Drugs under the 1971 Act and place both in Schedule 3 to the 2001 Regulations (but exclude the application of safe custody requirements),
- 3) Control pregabalin and gabapentin as Class C Drugs under the 1971 Act and place both in Part 1 of Schedule 4 to the 2001 Regulations.

Option 1 is the recommended option of the ACMD.

Please refer to the document *Control of pregabalin and gabapentin, pre consultation assessment (impact assessment)*, for a more detailed exploration of the options when responding to the questions.

Responses are due by 22/01/18.

Introduction

1. This consultation seeks your views on the Advisory Council on the Misuse of Drugs' (ACMD) recommendation to place pregabalin and gabapentin in Schedule 3 to the Misuse of Drugs Regulations 2001 (as amended) ('the 2001 Regulations').

This will be alongside the classification of these substances as Class C drugs under the Misuse of Drugs Act 1971 ('the 1971 Act').

Currently, neither pregabalin nor gabapentin is controlled under the 1971 Act or scheduled under the 2001 Regulations.

These proposals have been prepared in discussion with the Department of Health, and the Department of Health Northern Ireland.

This is a UK-wide consultation and reference to the Misuse of Drugs Regulations 2001 and to the Misuse of Drugs (Safe Custody) Regulations 1973 should also be read as the Misuse of Drugs Regulations (Northern Ireland) 2002 and the Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973 respectively.

2. Responses should arrive no later than 22/01/18.

Objectives

3. To seek the views of the public, especially, healthcare professionals, institutions, and all sectors within the supply chain including the pharmaceutical industry, wholesalers and community pharmacies on the effect of placing both gabapentin and pregabalin in Schedule 3 to the 2001 Regulations.

Background

4. In January 2016, the Advisory Council on the Misuse of Drugs (ACMD) recommended that gabapentin and pregabalin should be controlled as Class C drugs under the 1971 Act and placed in Schedule 3 of the 2001 Regulations.

5. The ACMD noted that both pregabalin and gabapentin present a risk of addiction, potential illegal diversion and medicinal misuse. The ACMD reported that the harms of these substances are equivalent to those of other drugs controlled under the 1971 Act, including tramadol, which was controlled as a Class C drug in 2014.

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6. The ACMD reported that when both pregabalin and gabapentin are used in combination with other Central Nervous System (CNS) depressants, they can cause drowsiness, sedation, respiratory failure and death. Pregabalin may have a higher abuse potential than gabapentin. Pregabalin can bring about an elevated mood in users, but side effects may include chest pain, wheezing, vision changes and, less commonly, hallucinations. Gabapentin can produce feelings of relaxation, calmness and euphoria. Some users have reported that the 'high' from snorting gabapentin can be similar to taking a CNS stimulant.

7. The Minister for Crime, Safeguarding and Vulnerability, Sarah Newton, accepted the ACMD's advice, subject to parliamentary approval, to control gabapentin and pregabalin as Class C drugs under the 1971 Act. The Minister also accepted in principle the ACMD's advice to schedule both gabapentin and pregabalin under Schedule 3 subject to the outcome of a public consultation.

8. In light of the further harms identified in the ACMD report, it is necessary to schedule pregabalin and gabapentin under the 2001 Regulations so not to preclude legitimate use on prescription. This consultation is being undertaken with a view to gathering evidence on the effect of classifying the two substances under Schedule 3 to the 2001 Regulations to inform the relevant Minister's final decision on the ACMD's scheduling advice.

9. An Impact Assessment indicates that groups such as the NHS and most people currently prescribed pregabalin and gabapentin are not likely to be particularly affected. The proposals are unlikely to lead to additional costs or savings for businesses, charities or the voluntary sector, or on the public sector, although there might be an impact on community pharmacies if option 1 is chosen. The Impact Assessment is available at <https://www.gov.uk/government/consultations/pregabalin-and-gabapentin-proposal-to-schedule-under-the-misuse-of-drugs-regulations-2001>

Comments on the Impact Assessment are very welcome.

The proposals

10. The proposal – to place pregabalin and gabapentin in Schedule 3 to the 2001 Regulations – arises out of the ACMD advice:

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/491854/ACMD_Advice_-_Pregabalin_and_gabapentin.pdf

11. The effect of Schedule 3 status is the application of the requirements under Regulations 14, 15, 16, 18, 22, 23, 24, 26 and 27 of the 2001 Regulations, as set out in paragraph 13 below, and storage in accordance with the 1973 Regulations.

Baseline position

12. If the government were to 'do nothing', pregabalin and gabapentin would not be controlled under the 1971 Act nor the 2001 Regulations. The illicit supply would be supply to the provisions in the Psychoactive Substances Act. As explained in the Executive Summary, this option is not a viable option – it is the baseline position against which the options have been measured and was not supported by current evidence, or by the ACMD.

Options

Option 1: Place pregabalin and gabapentin in Schedule 3 to the 2001 Regulations, apply provisions under the Misuse of Drugs (Safe Custody) Regulations 1973

13 This option is recommended by the ACMD. This would place pregabalin and gabapentin in Schedule 3 and require that all prescriptions for pregabalin and gabapentin comply with the requirements set out in Regulation 15 (prescription writing) of the 2001 Regulations. Under this option both pregabalin and gabapentin will be subject to:

- Regulation 14¹ – which requires a compliant requisition to be provided to a supplier before stocks of pregabalin and gabapentin are supplied to the recipient;
- Regulations 15 and 16 – which require prescriptions for pregabalin and gabapentin to be written to very specific requirements, include the wet signature of the prescriber; and
- Storage in a safe compliant with the Misuse of Drugs (Safe Custody) Regulations 1973 ('The 1973 Regulations').

¹ This Regulation is not in operation in Northern Ireland

They would also be subject to the following Regulations:

- Regulation 18 - which requires the marking of bottles or containers;
- Regulation 22 – record keeping with details about the quantity of the drug;
- Regulation 23 – the preservation of record keeping registers for two years;
- Regulation 24 – keeping of invoices of similar documents by the producer and wholesaler of the drugs (this does not apply to schedule 4 drugs);
- Regulation 26 – furnish information as required about the drugs; and
- Regulation 27 – the destruction of drugs in front of an authorised person.

As an example, temazepam which is used to treat insomnia, anxiety and breathlessness is subject to these requirements.

Note: *Regulation 27 – which requires expired stocks to be destroyed in the presence of, and in accordance with the instructions of, an Authorised Witness only applies to a producer of a Schedule 3 controlled drug.*

14. In light of the ACMD advice, this option will provide an effective regime which would most likely reduce the risk of diversion and misuse of pregabalin and gabapentin into the illegal/ illicit market from legitimate sources and is the measure most likely to restrict the availability of the two drugs and therefore to protect against the health harms. However, we are keen to hear the views of patients, healthcare professionals, institutions, and all sectors within the supply chain including the pharmaceutical industry, wholesalers and community pharmacies on the appropriateness of placing pregabalin and gabapentin in Schedule 3. We are particularly interested in the implications that this option might have on businesses, particularly community pharmacies and whether they would be limited as to the amount of stock that they could carry.

Option 2: Place pregabalin and gabapentin in Schedule 3 to the 2001 Regulations, (but exclude application of the safe custody requirements)

15. This option is similar to option 1 above with the difference that pregabalin and gabapentin will be exempted from provisions under the 1973 Regulations. This option would not require controlled drugs to be stored in safes, although all the requirements of the 2001 Regulations, summarised in paragraph 13 above would apply to both substances. The provision is likely to help restrict the availability of the two drugs. While not as stringent as the measures in option 1 – given that this option would exclude the safe custody requirements, it would impose a number of auditing requirements, including the mandatory requisition form, to prevent diversion.

Option 3: Place pregabalin and gabapentin in Part 1 of Schedule 4 to the 2001 Regulations

16. This option will place gabapentin and pregabalin in Part 1 of Schedule 4 to the 2001 Regulations with the effect that the prescription requirements under Regulation 15 and 16 will not apply to its prescribing, (although they would still be subject to Regulations 22, 23, 26 and 27). Under this option, gabapentin and pregabalin would not be subject to provisions under the 1973 Regulations. This option would provide similar benefits to option 2 but does not provide the same safeguards against diversion into the illicit drugs market as the other two options.

Questionnaire

Please see www.gov.uk for an online questionnaire, which can be completed and returned online.

We would welcome responses to the following questions set out in this consultation paper.

Q1. In light of the risks of diversion from legitimate uses and the harms identified in the ACMD advice, which option do you support?

Option 1	Full Schedule 3 status under the 2001 Regulations as recommended by the ACMD.	<input type="checkbox"/>
Option 2	Place in Schedule 3 to the 2001 Regulations (but exclude application of safe custody requirements).	<input type="checkbox"/>
Option 3	Place in Part 1 of Schedule 4 to the 2001 Regulations.	<input type="checkbox"/>

Please explain why:

Q2. Do you agree with the impact assessment of option 1?

Please tick one box: Yes No Don't know

If NO, please explain why:

Q3. Are you aware of any other impact on healthcare professionals, institutions or industry, including those resulting from application of controlled drug licensing requirements, or costs associated with prescription forms, as a result of option 1?

Please tick one box: Yes No Don't know

Please provide details:

Q4. To help inform the full impact assessment please quantify the additional cash cost per month of this proposal to you or your organisation.

Please provide details of cost **per month**:

- | | | |
|---------------|--------------------------|-------------------------------------------------|
| £0 - £99 | <input type="checkbox"/> | |
| £100 - £199 | <input type="checkbox"/> | |
| £200 - £299 | <input type="checkbox"/> | |
| £300 - £399 | <input type="checkbox"/> | |
| £400 - £499 | <input type="checkbox"/> | |
| £500 - £1,000 | <input type="checkbox"/> | |
| Above £1,000 | <input type="checkbox"/> | please state amount and any relevant breakdown: |

Q5. Do you agree that healthcare organisations or businesses will be able to accommodate pregabalin and gabapentin within current compliant safes?

Please tick one box: Yes No Don't know

If NO, please explain why, **including estimated costs to be incurred in acquiring a safe:**

Q6. Do you agree with the impact assessment of option 2?

Please tick one box: Yes No Don't know

If NO, please explain why:

Q7. Are you aware of any other impact on healthcare professionals, institutions or industry, including those resulting from application of controlled drug licensing requirements, or costs associated with prescription forms, as a result of option 2?

Please tick one box: Yes No Don't know

Please provide details:

Q10. Are you aware of any other impact on healthcare professionals, institutions or industry, including those resulting from application of controlled drug licensing requirements, or costs associated with prescription forms, as a result of option 3?

Please tick one box: Yes No Don't know

Maximum 100 words

Please provide details:

Q11. To help inform the full impact assessment please quantify the additional cash cost per month of option 3 to you or your organisation.

Please provide details of cost **per month**:

£0 - £99

£100 - £199

£200 - £299

£300 - £399

£400 - £499

£500 - £1,000

Above £1,000

Please state amount and any relevant breakdown:

Maximum 100 words

Questions on lead - in time for implementation for the scheduling of pregabalin and gabapentin.

Q12. In your (or your organisation's) view how much lead time is necessary for implementation if option 1 was adopted?

Please tick one box: one month three months six months

Q13. In your/ your organisation's view how much lead time is necessary for implementation if option 2 was adopted?

Please tick one box: one month three months six months

Q14. In your/your organisation's view how much lead time is necessary for implementation if option 3 was adopted?

Please tick one box: one month three months six months

Further details, if needed:

About you

Please use this section to tell us about yourself

Please note that you are under no obligation to provide this information should you not wish to do so. If you are happy to provide personal information please note that:

- any personal information will be stored on a secure system.
- it will not be shared with third parties.
- your personal information will be kept on record for no more than six months and be used for purposes of this consultation only; and
- you may be contacted by a Home Office official for your feedback on this consultation and to discuss your answers in more detail.

Full name	
Job title or capacity in which you are responding to this consultation exercise (for example, member of the public)	
Date	
Company name/organisation (if applicable)	
Address	
Postcode	
If you would like us to acknowledge receipt of your response, please tick this box	<input type="checkbox"/> (please tick box)
Address to which the acknowledgement should be sent, if different from above	

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If you are a representative of a group, please tell us the name of the group and give a summary of the people or organisations that you represent.

Contact details and how to respond

Please send your response by 22/01/18 to:

Drugs Legislation Team
5th Floor, Fry Building, 2 Marsham Street, London, SW1P 4DF

Tel: 0207 035 1784

Email: DrugLegislationTeam@homeoffice.gsi.gov.uk

Complaints or comments

If you have any complaints or comments about the consultation process you should contact the Home Office at the above address.

Extra copies

This consultation is available online at
[:https://www.gov.uk/government/consultations/pregabalin-and-gabapentin-proposal-to-schedule-under-the-misuse-of-drugs-regulations-2001](https://www.gov.uk/government/consultations/pregabalin-and-gabapentin-proposal-to-schedule-under-the-misuse-of-drugs-regulations-2001)

Alternative format versions of this publication can be requested from the Drugs Legislation Team. Email: DrugLegislationTeam@homeoffice.gsi.gov.uk

Publication of response

A paper summarising the responses to this consultation will be published in early 2018. The response paper will be available online at www.gov.uk.

Representative groups

Representative groups are asked to give a summary of the people and organisations they represent when they respond.

Confidentiality

Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality

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disclaimer generated by your IT system will not, of itself, be regarded as binding on the Home Office.

The Home Office will process your personal data in accordance with the DPA and in the majority of circumstances, this will mean that your personal data will not be disclosed to third parties.

Impact Assessment

As stated in paragraph 9, the impact assessment for the proposals in this consultation can be found at the following link: <https://www.gov.uk/government/consultations/pregabalin-and-gabapentin-proposal-to-schedule-under-the-misuse-of-drugs-regulations-2001>

Consultation principles

The principles that government departments and other public bodies should adopt for engaging stakeholders when developing policy and legislation are set out in the consultation principles.

<https://www.gov.uk/government/publications/consultation-principles-guidance>



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