



Home Office

A consultation on the scheduling of tramadol, and a review of exemptions for temazepam prescriptions, under the Misuse of Drugs Regulations 2001

A consultation paper

July 2013

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Introduction

1. This consultation seeks your views on the Advisory Council on the Misuse of Drugs' (ACMD) recommendation to place tramadol in Schedule 3 to the Misuse of Drugs Regulations 2001 (as amended) (the 2001 Regulations) following control under the Misuse of Drugs Act 1971 (the 1971 Act) as a Class C drug, more specifically on the prescribing and safe custody requirements applicable to Schedule 3 drugs. Tramadol is currently a prescription only medicine. The consultation also seeks your views on the continued application of current exemptions for prescriptions for the Schedule 3 drug temazepam. These proposals have been prepared in discussion with the ACMD and the Department of Health.

This consultation is not seeking views on whether tramadol should be controlled under the Misuse of Drugs Act 1971.

2. Responses should arrive no later than 11 October 2013.

Objectives:

To seek the views of the public, especially health and social care professionals, on:

1. the impact of placing tramadol in Schedule 3 to the 2001 Regulations; and
2. the current exemptions applicable to prescriptions for temazepam under the 2001 Regulations.

Background:

Tramadol

3. Tramadol is a synthetic analogue of the phenanthrene alkaloid codeine and is an analgesic of significant medical use for treating moderate to severe pain. It has wide ranging applications, including the treatment of fibromyalgia (chronic widespread pain), cancer pain and moderate to severe musculoskeletal pain.

4. The ACMD recently completed a review of the harms associated with the non-medicinal use of tramadol. The ACMD's review was prompted by an increasing number of reports within the NHS of tramadol's misuse and harms. The ACMD's subsequent review of the evidence confirmed an increase in Daily Defined Doses (England)¹, from approximately 5.9 million in September 2005 to 11.1 million in September 2012, and an increase in deaths where tramadol is mentioned.

5. On 26 February the ACMD published its advice on tramadol. The ACMD advises that tramadol should be controlled as a class C substance under the 1971 Act, and listed in Schedule 3 to the 2001 Regulations, which it considers would provide the correct controls to prevent diversion and misuse.

6. As a Class C controlled drug, the possession, supply, and production etc of tramadol will become unlawful under the 1971 Act unless these take place under a Home Office licence or

¹ The Defined Daily Doses (DDD) is a measure of prescribing volume maintained by the World Health Organisation (WHO) based upon international prescribing behaviour. It represents the assumed average maintenance dose per day for a drug used for its main indication in adults. The DDD is not a recommended dose but an analytical unit to compare prescribing activity.

permitted through regulations. It is therefore necessary to schedule tramadol appropriately under the 2001 Regulations to ensure continued access for use in healthcare, but with appropriate requirements to its prescribing and storage etc. to prevent diversion and misuse.

7. The ACMD report noted “*that in the absence of evidence from clinical practice, the ACMD is unclear whether the prescription requirements associated with Schedule 3 could present further burden for prescribers.*” The ACMD therefore recommended that the Home Office should consult with health and social care practitioners on the impact of Schedule 3 (Regulation 15) requirements to ensure any change is proportionate to the harms and risk of diversion outlined in their report. The ACMD report is available at <https://www.gov.uk/government/publications/acmd-advice-on-tramadol>. The Minister for Crime Prevention, Jeremy Browne MP, accepted the ACMD advice to control tramadol in principle subject to a public consultation on the impact of Schedule 3 status. This consultation is being undertaken with a view to gathering evidence on impact of Schedule 3 status to inform the Minister’s final decision on the ACMD advice.

8. The Home Office view is that placing tramadol in Schedule 3 would be consistent with the scheduling of other opioids, such as codeine, for treating moderate to severe pain.

Temazepam

9. Temazepam is an intermediate-acting psychoactive drug of the benzodiazepine class which is used for its sedative and anxiety-relieving effects. Like many other drugs in the benzodiazepine family, it is also widely misused.

10. In 1996 temazepam was rescheduled from Schedule 4 to Schedule 3 under the 2001 Regulations. At the time temazepam was rescheduled, the requirements applicable to prescriptions for Schedule 3 drugs under Regulation 15 had to be hand written. In order to limit the impact on prescribers from rescheduling, all prescriptions for temazepam were exempted from these requirements. However, private prescriptions for temazepam are still required to be written on a prescription form issued by the relevant NHS England’s local lead CDAO, Scottish Health Board lead CDAO or Local Health Boards in Wales for the purposes of private prescribing, and submitted for auditing.

11. Subsequent changes in 2003 to the requirements under Regulation 15 mean that with the exception of a wet signature, all other information on a prescription for temazepam can now be computer generated. In light of the shift to computer generated prescriptions and the current ACMD advice on tramadol, the Home Office wishes to explore whether the exemption applicable to temazepam prescription is still necessary. The Home Office’s assessment is that the exemption is no longer necessary. However, we will like to hear the views of health and social care professionals on the need to maintain or remove the current exemption.

PROPOSAL:

12. The proposal – to place tramadol in Schedule 3 to the 2001 Regulations (and remove current exemptions for temazepam prescriptions) – arises out of the ACMD advice.

Effect of full Schedule 3 status under the 2001 Regulations:

13. The effect of Schedule 3 status is the application of the requirements under Regulation 15 of the 2001 Regulations, including the use of a specific form for private prescribing, the provision of specific information outlined in Regulation 15 on a prescription, and a wet signature. Full Schedule 3 status also means application of provisions under the Misuse of Drugs (Safe

Custody) Regulations 1973. However, with the exception of a wet signature all other requirements under Regulation 15 can be computer generated.

Options:

14. The Home Office has identified four options for this consultation;

Option 1: Do nothing

15. This option will mean tramadol will remain unscheduled, following control, and no changes to temazepam's current status. Under this option tramadol will become a Class C controlled drug under the 1971 Act but will not be scheduled under the 2001 Regulations. The effect of a lack of scheduling is that tramadol will not be available for use in healthcare.

16. Temazepam will continue to remain a Schedule 3 drug under the 2001 Regulations but with current prescribing exemptions maintained under this option. This option is not the Government's preferred option, and is not supported by current evidence on harms or by the ACMD advice.

Option 2: Place tramadol in Schedule 3 to the 2001 Regulations, apply provisions under the Misuse of Drugs (Safe Custody) Regulations 1973 and remove current exemptions for temazepam prescriptions.

17. This is the Government's preferred option. This option will place tramadol in Schedule 3 and require all prescriptions for tramadol to comply with the requirements set out in Regulation 15 of the 2001 Regulations (summarised below). Under this option, tramadol will be subject to the safe custody provisions². This option will also remove the current exemptions for temazepam prescriptions and will mean that the full requirements under Regulation 15 will also apply to the prescribing of temazepam following legislative change. The Home Office view, supported by the ACMD advice, is that this option will provide an appropriate level of control to prevent diversion and misuse of tramadol.

18. In the light of the subsequent changes enabling the use of computer generated prescriptions for Schedule 3 drugs, the Home Office is also of the view that this option will provide an appropriate level of control for temazepam without introducing excessive burdens on prescribers.

19. The requirements currently applicable to prescriptions for Schedule 3 drugs under Regulation 15 are:

- a. the prescription must be written, dated and signed;*
- b. if a private prescription;*
 - be written on a specific form for private prescribing*
 - specify the prescriber identification number of the prescriber*
 - specify the address of the prescriber*
- c. if issued by a dentist or veterinary practitioner;*
 - include a declaration to that effect*

² The Misuse of Drugs (safe custody) Regulations 1973 specify the requirements for the storage of drugs including setting out the minimum standards for safes, buildings etc. The provisions under the safe custody regulations apply to retail pharmacies and care homes but are accepted as the minimum standard for storage in other environments.

- specify the name and address of the person to whom it is issued or to whom the drugs should be delivered

d. specify the dose to be taken

e. if to be supplied on instalments contain a direction specifying the instalment amounts.

Option 2a: Place tramadol in Schedule 3 to the 2001 Regulations (but exclude application of safe custody requirements) and remove the current exemptions for temazepam prescriptions.

20. This option is similar to option 2 above with the only difference that tramadol will be exempted from provisions under the Misuse of Drugs (Safe Custody) Regulations 1973. All the requirements listed at paragraph 15 above will apply to tramadol and temazepam under this option.

Option 3: Place tramadol in Schedule 3 to the 2001 Regulations, but with prescribing and safe custody exemptions.

21. This option will place tramadol in Schedule 3 but with exemptions (similar to that currently applicable to temazepam prescriptions) applicable to its prescribing and storage. There will be no change to the exemptions applicable to temazepam prescriptions under this option, and the only requirements under Regulation 15 that will be applicable to the prescribing of tramadol under this option will be;

a. if a private prescription;

- be written on a prescription form for private prescribing*
- specify the prescriber number*
- specify the address of the prescriber*

Note: The move to extend electronic prescribing to drugs in Schedules 2 and 3 in the future, when implemented, will make the reasons for applying prescribing exemptions for specific drugs based on impact on prescribers weaker.

Option 4: Place Tramadol in Part 1 of Schedule 4 to the 2001 Regulations (No changes to temazepam exemptions)

22. This option will place tramadol in Part 1 of Schedule 4 to the 2001 Regulations with the effect that the prescription writing requirements under Regulation 15 (specified at option 1 above) will not apply to its prescribing. Tramadol will also not be subject to provisions under the Misuse of Drugs (Safe Custody) Regulations 1973 under this option, nor will there be the ability to audit private prescriptions for tramadol. There will be no changes to the current exemptions applicable to temazepam prescriptions under this option.

Key questions for the proposal on tramadol and temazepam:

a. In light of the risks of diversion and harms from misuse identified in the ACMD advice which option do you support?

Please tick only one box:

Option 1	Do nothing	<input type="checkbox"/>
Option 2	Full Schedule 3 status for tramadol under the 2001 Regulations (including application of safe custody requirements) and removal of exemptions for temazepam prescriptions.	<input type="checkbox"/>
Option 2a	Schedule 3 status for tramadol under the 2001 Regulations (but exclude application of safe custody requirements) and removal of exemptions for temazepam prescriptions.	<input type="checkbox"/>
Option 3	Schedule 3 status for tramadol under the 2001 Regulations, but with exemptions from prescribing requirements, similar to temazepam, and safe custody provisions (No changes for temazepam).	<input type="checkbox"/>
Option 4	Schedule 4 Part 1 status for tramadol (No changes for temazepam).	<input type="checkbox"/>

Please explain why:

Maximum 100 words

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

Please tick one box: Yes No Don't know

If NO, please explain why:

Maximum 100 words

c. Are you aware of any other impact on healthcare professionals, institutions or industry as a result of the proposal, for example additional costs from specific forms used for private prescribing?

Please tick one box: Yes No Don't know

Please provide details:

Maximum 100 words

d. To help inform the full impact assessment please quantify either the:

- **additional cash cost per month of this proposal to you or your organisation, or**
- **the savings 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: <input type="text"/>

Please provide details of savings **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: <input type="text"/>

e. Do you agree that healthcare organisations or businesses will be able to accommodate tramadol in current storage space?

Please tick one box: Yes No Don't know

If NO, please explain why:

Maximum 100 words

f. Do you agree with the impact assessment of option 3?

Please tick one box: Yes No Don't know

If NO, please explain why:

Maximum 100 words

g. Are you aware of any other impact on healthcare professionals, institutions or industry as a result of the proposal?

Please tick one box: Yes No Don't know

Please provide details:

Maximum 100 words

j. Are you aware of any other impact on healthcare professionals, institutions or industry as a result of the proposal?

Please tick one box: Yes No Don't know

Please provide details:

Maximum 100 words

k. To help inform the full impact assessment please quantify either the:

- **additional cash cost per month of this proposal to you or your organisation, or**
- **the savings 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: <input type="text"/>

Please provide details of savings **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: <input type="text"/>

Demographic questions

23. To assist in analysing the responses the Home Office will be grateful if you could answer the following demographic questions;

Please tick applicable box

i. Are you responding as a:

- | | |
|---------------------------------------|--------------------------|
| Doctor | <input type="checkbox"/> |
| Pharmacist | <input type="checkbox"/> |
| Dentist | <input type="checkbox"/> |
| Veterinary practitioner | <input type="checkbox"/> |
| Paramedic | <input type="checkbox"/> |
| Nurse/Midwife | <input type="checkbox"/> |
| Pain management specialist/consultant | <input type="checkbox"/> |
| Independent prescriber | <input type="checkbox"/> |
| Supplementary prescriber | <input type="checkbox"/> |
| Pharmaceutical wholesaler | <input type="checkbox"/> |
| Pharmaceutical manufacturer | <input type="checkbox"/> |
| Allied Health Professional | <input type="checkbox"/> |
| Professional/Regulatory body | <input type="checkbox"/> |
| Patient | <input type="checkbox"/> |
| Other (Please specify below) | <input type="checkbox"/> |

ii. Are you a;

- | | |
|----------------------|--------------------------|
| Private practitioner | <input type="checkbox"/> |
| NHS practitioner | <input type="checkbox"/> |
| Both NHS & Private | <input type="checkbox"/> |

iii. Which region are you responding from?

- | | |
|----------|--------------------------|
| England | <input type="checkbox"/> |
| Wales | <input type="checkbox"/> |
| Scotland | <input type="checkbox"/> |

Impact of proposals

24. A consultation stage impact assessment has been prepared in line with the proposals outlined above (see accompanying Annex). The impact from these proposals has been assessed to be negligible. The Government is however interested to hear from the healthcare sector and healthcare professionals where any direct and/or indirect costs may arise as a result of these proposals.

Equality

25. It is not anticipated that placing tramadol in Schedule 3 to the 2001 Regulations or removing the exemptions for temazepam prescriptions will have any impact on equality issues in relation to age, disability, gender, race or sexual orientation. However, the Government invites comments and views on any equality-related issues that may be associated with the proposed legislative changes.

GENERAL PROVISIONS

Application of any legislative changes to England, Wales, Scotland and Northern Ireland

26. The proposed changes to the Misuse of Drugs Regulations 2001 would have effect in England, Wales and Scotland. Northern Ireland has its own misuse of drugs regulations.

Responding to this consultation

27. Implementation of the proposed changes will take place in **2014** subject to any comments received in response to this document, views of Ministers and the timescale for the parliamentary process. We would welcome any comments on the proposed measures and on the consultation stage Impact Assessments in the Annex accompanying this document.

Circulation of Proposals and Consultation Responses

28. A copy of this documents and attachments is also available at https://www.gov.uk/government/publications?departments%5B%5D=home-office&publication_filter_option=consultations . You should contact the address given below (in paragraph 17) if you require a copy of this consultation paper in any other format, e.g. braille, large font, audio.

29. The Government would welcome your views on the proposals contained in this document. Please send written comments to:

MDR Consultation
Drug Legislation Team
Drugs and Alcohol Unit
4th Floor, Fry
Home Office
2 Marsham Street
LONDON SW1P 4DF

or by email to : Druglegislationconsultations@homeoffice.gsi.gov.uk

30. **Comments must be received by 11 October 2013.**

31. A summary of responses will be published before or alongside any further action.

Responses: Confidentiality & Disclaimer

32. The information you send us may be passed to colleagues within the Home Office, the Government or related agencies. Information provided in response to this consultation, including personal information, may be subject to publication or disclosure 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).

33. If you want other 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.

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

35. The Department 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.

Government Code of Practice on Consultation

36. The Consultation follows the Government's Code of Practice on Consultation the criteria for which are set out below:

Criterion 1 – When to consult – Formal consultation should take place at a stage when there is scope to influence the policy outcome.

Criterion 2 – Duration of consultation exercises – Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.

Criterion 3 – Clarity of scope and impact – Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.

Criterion 4 – Accessibility of consultation exercises – Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.

Criterion 5 – The burden of consultation – Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees' buy-in to the process is to be obtained.

Criterion 6 – Responsiveness of consultation exercises – Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.

Criterion 7 – Capacity to consult – Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

37. The full Code of Practice on Consultation is available at:

<http://www.berr.gov.uk/files/file47158.pdf>

Consultation Co-ordinator

38. If you have a complaint or comment about the Home Office's approach to consultation, you should contact the Home Office Consultation Co-ordinator, Adam Mcardle. Please **DO NOT** send your response to this consultation to Adam Mcardle. The Co-ordinator works to promote best practice standards set by the Government's Code of Practice, advises policy teams on how to conduct consultations and investigates complaints made against the Home Office. He does not process your response to this consultation.

39. The Co-ordinator can be emailed at: Adam.Mcardle2@homeoffice.gsi.gov.uk or alternatively you can write to him at:

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