



Home Office

# **A consultation on proposals to reschedule ketamine under the Misuse of Drugs Regulations 2001**

A consultation paper

June 2014

# Contents

1. Introduction	3
2. Background	3
3. Proposal	4
4. Options	4
5. Key questions	5
6. Demographic questions	10
7. General provisions	11

## Introduction

1. This consultation seeks your views on the Advisory Council on the Misuse of Drugs' (ACMD) recommendation to reschedule ketamine to Schedule 2 to the Misuse of Drugs Regulations 2001 (as amended) (the 2001 Regulations) following reclassification under the Misuse of Drugs Act 1971 (the 1971 Act) as a Class B drug on 10 June 2014, more specifically on the record keeping, prescribing and safe custody requirements applicable to Schedule 2 drugs. Ketamine is currently a Schedule 4 Part 1 drug and therefore lightly regulated. These proposals have been prepared in discussion with the ACMD and the Department of Health.

2. Responses should arrive no later than Monday 3<sup>rd</sup> November 2014.

### Objectives:

To seek the views of the public, especially health, social care and veterinary professionals, on the impact of listing ketamine in Schedule 2 to the 2001 Regulations, and the appropriate schedule in which ketamine should be listed.

### Background:

3. Ketamine is a synthetic drug commonly used in medical and veterinary practice as a dissociative anaesthetic and an analgesic (pain reliever). The ACMD first considered ketamine in 2004 and following its advice ketamine was brought under Class C control and listed in Schedule 4 in 2006.

4. The ACMD recently completed a review of the harms associated with ketamine misuse following commissioning by the Home Secretary. The Home Secretary's commission was prompted by increasing evidence, and concerns, around chronic toxicity from long term misuse of ketamine. The ACMD's subsequent review of the evidence confirmed that in addition to the harms identified in 2004, regular ketamine use is now also known to be associated with a range of chronic problems including chronic bladder and other urinary tract pathology, gall bladder, gastrointestinal, central nervous system and kidney damage. The ACMD also reports evidence of acute and chronic toxicity associated with ketamine misuse.

5. The ACMD advised in its report<sup>1</sup> published on 10 December 2013 that ketamine should be reclassified as a class B drug under the 1971 Act, and listed in Schedule 2 to the 2001 Regulations, subject to the outcome of a public consultation to assess the impact of Schedule 2 status on healthcare and veterinary practice. The Minister for Crime Prevention, Norman Baker, accepted the ACMD's advice on reclassification and, following Parliamentary approval, Ketamine was subsequently reclassified as a Class B drug under the 1971 Act on 10 June 2014. The Minister also accepted the ACMD's advice to reschedule ketamine in principle, subject to the outcome of a public consultation. This consultation is being undertaken with a view to gathering evidence on the impact of Schedule 2 status to inform the Minister's final decision on the ACMD's rescheduling advice.

6. In light of the further harms identified in the ACMD report, it is necessary to reschedule ketamine appropriately under the 2001 Regulations to ensure continued access for use in veterinary and healthcare, but with appropriate requirements applied to its availability and use to reduce the risk of diversion and misuse. As a Schedule 2 drug,

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<sup>1</sup> <https://www.gov.uk/government/publications/ketamine-report>

ketamine will be subject to the strictest requirements under the 2001 Regulations namely, record keeping in the controlled drug register, prescription writing, safe custody, requisition, and witnessing of destruction of expired stocks.

### **PROPOSAL:**

7. The proposal – to place ketamine in Schedule 2 to the 2001 Regulations – arises out of the ACMD advice.

### ***Effect of full Schedule 2 status under the 2001 Regulations:***

8. The effect of Schedule 2 status is the application of the requirements under Regulations 14, 15, 16, 19 and 27 of the 2001 Regulations, as set out in paragraph 11 below, and storage in accordance with the Misuse of Drugs (Safe Custody) Regulations 1973.

### **Options:**

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

#### ***Option 1: Do nothing***

10. This option will maintain the current scheduling status of Ketamine as a Schedule 4 Part 1 drug. This option is not supported by the Government or by the ACMD advice.

#### ***Option 2: Reschedule ketamine to Schedule 2***

11. This option will reschedule ketamine to Schedule 2 to the 2001 Regulations with the effect that it will be subject to the requirements below as outlined above in paragraph 8:

- Regulation 14 – which requires a compliant requisition (stock order form with specified information) to be provided to a supplier before stocks of ketamine are supplied to the recipient;
- Regulations 15 and 16 – which require prescriptions for ketamine to be written on specific forms, including use of private prescription pads, with specific information as set out in the 2001 regulations provided, and include a wet signature of the prescriber;
- Regulation 19 – which requires records of stocks held and supplied to be kept in the controlled drug register;
- Regulation 27 – which requires expired stocks to be destroyed in the presence of, and in accordance with the instructions of, an Authorised Witness; and
- Storage in a safe compliant with the Misuse of Drugs (Safe Custody) Regulations 1973.

12. The Home Office view, in light of the ACMD advice and current evidence from veterinary practice, where guidance already requires ketamine to be treated as a Schedule 2 drug, is that this option will provide an effective regime which will reduce the risk of diversion and misuse of ketamine from legitimate sources. However, the Home Office is keen to hear the views of the healthcare and veterinary sectors on the appropriate schedule in which ketamine should be listed.

### **Option 3: Reschedule ketamine to Schedule 3**

13. This option will reschedule ketamine to Schedule 3 to the 2001 Regulations. Under this option ketamine will be subject to:

- Regulation 14 – which requires a compliant requisition to be provided to a supplier before stocks of ketamine are supplied to the recipient;
- Regulations 15 and 16 – which require prescriptions for ketamine to be written on specific forms, including use of private prescription pads, with specific information as set out in the 2001 regulations provide, and include a wet signature of the prescriber; and
- Storage in a safe compliant with the Misuse of Drugs (Safe Custody) Regulations 1973.

**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.

### **Option 4: Reschedule ketamine to Schedule 3, but exempt it from the safe custody requirements.**

14. This option will reschedule ketamine to Schedule 3 to the 2001 Regulations but exempt it from the safe custody requirements. Under this option ketamine will be subject to the same requirements as in option 3 above but without the need for storage in a safe compliant with the Misuse of Drugs (Safe Custody) Regulations 1973.

### **15. Key questions for the proposal on ketamine:**

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

Please tick only one box:

<b>Option 1</b>	Do nothing	<input type="checkbox"/>
<b>Option 2</b>	Full Schedule 2 status under the 2001 Regulations as recommended by the ACMD.	<input type="checkbox"/>
<b>Option 3</b>	Full Schedule 3 status under the 2001 Regulations	<input type="checkbox"/>
<b>Option 4</b>	Schedule 3 status, but <u>with exemption</u> from the safe custody requirements.	<input type="checkbox"/>

Please explain why:

Maximum 100 words

**ii. 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

**iii. 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 the proposal?**

Please tick one box:      Yes ☐      No ☐      Don't know ☐

Please provide details:

Maximum 100 words

**iv. 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 ☐

£100 - £199 ☐

£200 - £299 ☐

£300 - £399 ☐

£400 - £499 ☐

£500 - £1,000 ☐

Above £1,000 ☐

please state amount:

**v. Do you agree that healthcare organisations or businesses will be able to accommodate ketamine in current storage space?**

Please tick one box:      Yes ☐      No ☐      Don't know ☐

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

Maximum 100 words

**vi. 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

**vii. 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 the proposal?**

Please tick one box:      Yes ☐      No ☐      Don't know ☐

Please provide details:

Maximum 100 words

**viii. 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: <input type="text"/>

**ix. Do you agree that healthcare organisations or businesses will be able to accommodate ketamine in current storage space?**

Please tick one box:      Yes ☐      No ☐      Don't know ☐

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

Maximum 100 words

**x. Do you agree with the impact assessment of option 4?**

Please tick one box:      Yes ☐      No ☐      Don't know ☐

If NO, please explain why:

Maximum 100 words

**xi. 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 the proposal?**

Please tick one box:      Yes ☐      No ☐      Don't know ☐

Please provide details:

Maximum 100 words

**xii. 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 ☐

£100 - £199 ☐

£200 - £299 ☐

£300 - £399 ☐

£400 - £499 ☐

£500 - £1,000 ☐

Above £1,000 ☐

Please state amount:

### **Questions on leading time for implementation of rescheduling**

**xii. 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 ☐

**xiii. 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 ☐

**xiv. In your/your organisation's view how much lead time is necessary for implementation if option 4 was adopted?**

Please tick one box:      one month ☐      three months ☐      six months ☐

## Demographic questions

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

Please tick applicable box

**a. Are you responding as a:**

Practitioner (Doctor, Dentist or Vet) ☐

Pharmacist ☐

Other healthcare professional ☐

*(Nurse, midwife, AHP, paramedic etc)*

Other veterinary professional ☐

*(veterinary nurse etc)*

Pharmaceutical wholesaler ☐

Pharmaceutical manufacturer ☐

Professional/Regulatory body ☐

Patient ☐

Other (Please specify below) ☐

**b. Which region are you responding from?**

England ☐

Wales ☐

Scotland ☐

Northern Ireland ☐

## Impact of proposals

17. 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 and veterinary sectors where any direct and/or indirect costs may arise as a result of these proposals.

## Equality

18. It is not anticipated that the rescheduling of ketamine 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

19. 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

20. Implementation of the proposed changes will take place by the end of **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

21. 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](https://www.gov.uk/government/publications?departments%5B%5D=home-office&publication_filter_option=consultations) . You should contact the address given below (in paragraph 22) if you require a copy of this consultation paper in any other format, e.g. braille, large font, audio.

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

Ketamine Consultation  
Drug Legislation Team  
Drugs and Alcohol Unit  
5<sup>th</sup> Floor (NE), Fry Building  
Home Office  
2 Marsham Street  
LONDON SW1P 4DF

or by email to : [Druglegislationconsultations@homeoffice.gsi.gov.uk](mailto:Druglegislationconsultations@homeoffice.gsi.gov.uk)

23. **Comments must be received by Monday 3<sup>rd</sup> November 2014.**

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

### Responses: Confidentiality & Disclaimer

25. 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).

26. 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.

27. 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.

28. 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**

29. 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.*

30. The full Code of Practice on Consultation is available at:  
<http://www.berr.gov.uk/files/file47158.pdf>

### **Consultation Co-ordinator**

31. If you have a complaint or comment about the Home Office's approach to consultation, you should contact the Home Office Consultation Co-ordinator, Barima Asante. Please **DO NOT** send your response to this consultation to Barima Asante. 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.

32. The Co-ordinator can be emailed at: [HO.Consultations@homeoffice.gsi.gov.uk](mailto:HO.Consultations@homeoffice.gsi.gov.uk) or alternatively you can write to him at:

Barima Asante, Consultation Co-ordinator  
Home Office  
Performance and Delivery Unit  
Better Regulation Team  
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London  
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