



Home Office

Summary of responses to the consultation on proposals to schedule tramadol, and remove the prescription writing exemption for temazepam, under the Misuse of Drugs Regulations 2001

Prepared by Home Office

Background

1. On 13 February 2013 the Advisory Council on the Misuse of Drugs (ACMD) recommended that tramadol should be controlled as a Class C drug under the Misuse of Drugs Act 1971 (the 1971 Act), and a Schedule 3 drug under the Misuse of Drugs Regulations 2001 (the 2001 Regulations), subject to a public consultation to assess the impact of Schedule 3 status on healthcare professionals.
2. The then Minister for Crime Prevention accepted the ACMD advice to control as a Class C and gave approval for a public consultation on the appropriate schedule in which tramadol should be listed.
3. In light of the ACMD recommendation, and subsequent changes in the prescription requirements for Schedules 2 and 3 drugs, the Home Office also considered the need to review the current exemptions applicable to temazepam prescriptions. A proposal to remove the current exemptions applicable to temazepam prescriptions to bring it in line with other Schedule 3 drugs was therefore included in the consultation.

The Consultation Process

4. In September 2013, the Home Office published a consultation paper seeking views on 5 options, including the Home Office's preferred option (option 2 below). The options for scheduling tramadol and removing the current exemptions for temazepam under the 2001 Regulations were as follows:

OPTION 1: Do nothing

5. Under this option tramadol will be controlled as a Class C 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. Temazepam will continue to remain a Schedule 3 drug under the 2001 Regulations with current prescribing exemptions maintained. This option is not the Government's preferred option, and was not supported by current evidence, or by the ACMD.

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.

6. This was 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 (prescription writing) of the 2001 Regulations. Under this option, tramadol will also be subject to the safe custody provisions¹. This option will also remove the current exemptions for temazepam prescriptions meaning that the full requirements under Regulation 15 will also apply to the prescribing of temazepam.

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.

¹ 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.

7. This option is similar to option 2 above with the 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 both tramadol and temazepam prescribing under this option following legislative change.

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

8. Under this option tramadol will be placed 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.

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

9. 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 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. There will be no changes to the current exemptions applicable to temazepam prescriptions under this option.

10. The consultation period closed on 11th October 2013. This paper provides a summary of the responses received.

Summary/overview of responses to the specific proposals

11. A total of 287 responses were received by the closing date of the consultation. The responses to specific proposals are summarised below;

Proposal 1: To schedule tramadol under the Misuse of Drugs Regulations 2001

12. Two thirds (**66%**) of all respondents to the consultation supported the scheduling of tramadol under the 2001 Regulations. However, there were differing views on which schedule was appropriate given the evidence of misuse and harms. Of those who supported scheduling under the 2001 Regulations, three-quarters opted for Schedule 3 status with or without exemptions.

13. Significant concerns were raised by respondents around application of the safe custody requirements to tramadol. Respondents were of the view that given the large number of prescriptions for tramadol, the various formulations, types and strengths, application of the safe custody requirements will significantly burden both manufacturers, wholesalers and pharmacies, who will be forced to expand storage facilities to accommodate current stocks of tramadol at huge costs. As a result, about two-thirds (**63%**) of all respondents who opted for Schedule 3 status also opted for exemption from the safe custody requirements if tramadol were to be placed in Schedule 3. The remainder (**about 37%**) of respondents opted for Schedule 3 status, but with exemptions from both safe custody and prescription writing. A negligible minority opted for full Schedule 3 status.

14. The proposal to place tramadol in Schedule 3, but with exemptions from the safe custody requirements, was supported by the **Royal College of Physicians**, the **British Pain Society**, the **Faculty of Pain Medicine**, the **UK Clinical Pharmacy Association**, the developers of

tramadol (**Grunenthal**), **NAPP Pharmaceuticals**, who manufacture tramadol, and the **British Association of Pharmaceutical Wholesalers** amongst others.

15. The **Royal Pharmaceutical Society** was of the view that *“the introduction of safe custody provisions will have a significant impact on the operation of community and hospital pharmacies and are not warranted for patient safety reasons.”* It therefore preferred listing tramadol in Schedule 4 to the 2001 Regulations, *“with a review of this arrangement in 12 -24 months time.”* However, the **Care Quality Commission** was of the view that full Schedule 3 status with both safe custody and prescriptions writing requirements applicable *“provides the greatest level of control and monitoring for tramadol to help reduce harms for patients and the public.”*

16. The **Secure Environment Pharmacists’ Group**, **HM Inspector of prisons**, and a **Medical Director** of NHS England expressed concerns around the implications of Schedule 3 status for secure environments such as prisons, youth offender institutions and police custody suites. Their view was that Schedule 4 status would be more appropriate as Schedule 3 status would require administration under supervision and record keeping similar to Schedule 2 medicines, creating a significant time consuming and costly operational burden for this sector.

17. Further, it was the view of **HM Inspector of prisons** that *“Schedule 3 status could potentially have a negative impact on prisoner well-being by reducing access to purposeful activity, due to extended drug administration times.”* A **Medical Director** of NHS England also noted that *“there is a risk that less appropriate medication that is easier to manage, may be prescribed which could result in severe adverse outcomes for some prisoners.”* The general view was that *“safeguards are already in operation in prisons and other secure sites to combat diversion and abuse, supported by national guidance.”*

Other responses

18. A number of respondents from the pharmacy profession/community pharmacies supported the scheduling of tramadol but were of the view that tramadol should be listed in Part 2 of Schedule 4 to the 2001 Regulations and treated similar to anabolic steroids. In their view this will control its prescribing whilst allowing exports to the EU against a valid prescription. They highlighted that a large number of EU patients rely on safe and professionally controlled supply of tramadol from UK pharmacies, and would be adversely affected by Schedule 3 status as this would require an export permit for each prescription exported to the EU.

Government response

19. The Government acknowledges the comments received. It notes that while there is support for tramadol to be listed as a Schedule 3 drug, significant concerns exist around application of the safe custody requirements. Its assessment is that whilst Schedule 3 status will provide an appropriate level of protection from the risk of diversion and misuse, on balance the impact from application of the safe custody requirements will be disproportionate. The costs likely to be incurred by both the public and private sectors would likely be significant and difficult to justify. The Government has taken on board the concerns raised in the consultation and has therefore decided to pursue option 2a whereby tramadol is placed in Schedule 3 to the 2001 Regulations but with exemption from the safe custody requirements.

20. The Government also recognises the time and cost concerns raised by a minority of respondents around the impact of Schedule 3 status on the secure environment sector, but notes that supervised consumption of drugs that are likely to be misused is

not a legal requirement resulting from scheduling, but good practice set out in guidance that applies to all drugs that are likely to be misused within the secure environment.

Proposal 1: To remove the current exemptions applicable to temazepam prescriptions

21. The majority of respondents (**63%**) who supported Schedule 3 status, with exemptions from the safe custody requirements for tramadol, also supported the proposal to remove the current exemptions for temazepam prescriptions. It was the general view of respondents that with prescriptions for temazepam being at low levels, and with the majority of temazepam prescriptions now being electronically generated, removing the current exemptions will not unduly burden prescribers. Again specific concerns were expressed for the secure environment sector, prescribing within the community, and in some secondary care settings where electronic prescriptions are yet to be adopted, although this was not of similar magnitude to those expressed in relation to application of safe custody requirements to tramadol.

22. A number of respondents expressed the view that having exemptions for drugs such as temazepam within a schedule causes confusion for healthcare practitioners. In their view having standardised requirements for all drugs listed within a schedule provides more clarity and consistency.

23. Some respondents also highlighted that temazepam is already being treated as a full Schedule 3 drug in some hospitals which supports the view that the current exemptions are no longer necessary. The **Care Quality Commission** and the **Royal College of Physicians** support the removal of prescription writing exemptions for temazepam for the reasons highlighted above.

24. The **Royal Pharmaceutical Society** was of the view that “*the reintroduction of prescription writing requirement will have a negative effect for no significant gain or benefit to patient safety.*” It further highlighted that whilst the use of computer generated prescriptions may be the norm for primary care, “*it is not yet the case in secondary care and for GP prescribing outside of their surgery or out of hours, both situations where temazepam is often prescribed. Additionally computer generated scripts are not the norm in many mental health trust in England, where temazepam prescribing is justifiably high.*” It therefore concluded “*that within the secondary care setting, reintroducing the prescription writing requirements for temazepam will have an impact*”, although it was unable to gauge the degree of impact at this time.

Government response

25. The Government acknowledges the comments and views received. It notes the majority support for the removal of the existing exemption for temazepam prescriptions. It also notes the concerns, expressed by a minority of respondents, around the impact on secondary care, out of hours GP prescribing and mental health trusts etc, where computer generated prescriptions have not been adopted. However, the Government has considered the responses in the light of ongoing concerns around the misuse of temazepam, the fact that the vast majority of temazepam prescriptions are computer generated, evidence that prescribing of temazepam is currently at very low levels, and also in light of efforts to introduce electronic prescribing for Schedules 2 and 3 controlled drugs in the near future. The Government assesses that on the available evidence, the existing exemption for temazepam prescriptions are no longer warranted and should therefore be removed as in option 2a. This will enable continued monitoring of temazepam prescriptions, especially in the public sector, and ensure that temazepam is treated in the same way as other Schedule 3 drugs.