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CONSULTATION ON PROPOSALS TO RESCHEDULE KETAMINE FROM PART 1 OF SCHEDULE 4 TO SCHEDULE 2 TO THE MISUSE OF DRUGS REGULATIONS 2001

SUMMARY OF RESPONSES

CONSULTATION ON PROPOSALS TO RESCHEDULE KETAMINE FROM PART 1 OF SCHEDULE 4 TO SCHEDULE 2 TO THE MISUSE OF DRUGS REGULATIONS 2001

Background

1. In 2012 the Home Secretary commissioned the Advisory Council on the Misuse of Drugs (ACMD) to review the harms from ketamine misuse following increasing evidence of harms and concerns around chronic toxicity from long term misuse. In light of its findings, the ACMD recommended on 10 December 2013 that ketamine should be reclassified as a class B drug under the Misuse of Drugs Act 1971 (the 1971 Act), and listed in Schedule 2 to the Misuse of Drugs Regulations 2001 (the 2001 Regulations), subject to the outcome of a public consultation to assess the impact of Schedule 2 status on healthcare and veterinary practice.
2. The then Minister for Crime Prevention 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, and gave approval for a public consultation to assess the impact of Schedule 2 status on healthcare and veterinary practice to inform a final decision on the ACMD's rescheduling advice.

The Consultation Process

3. In August 2014, the Home Office published a consultation paper seeking views on 4 options, including the Home Office's preferred option (option 2 below) as recommended by the ACMD. The options for rescheduling ketamine were as follows:

OPTION 1: Do nothing

4. This option sought to maintain the current scheduling status of ketamine as a Schedule 4 Part 1 drug. Under this option controls on the availability and use of ketamine in health and veterinary care remain the same. This option was not supported by the Government or the ACMD.

OPTION 2: Reschedule ketamine to Schedule 2 to the 2001 Regulations

5. This option sought to reschedule ketamine to Schedule 2 to the 2001 Regulations with the effect that it will be subject to the requirements below:

- 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 1973¹.

OPTION 3: Reschedule ketamine to Schedule 3 to the 2001 Regulations

6. This option sought to reschedule ketamine to Schedule 3 to the 2001 Regulations. Under this option ketamine will be subject to the requirements listed above for schedule 2 drugs, except those under Regulations 19 (record keeping in a controlled drugs register) and 27 (destruction in the presence of an authorised witness).

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

7. This option sought to reschedule ketamine to Schedule 3 to the 2001 Regulations but with an exemption from the safe custody requirements. Under this option ketamine will be subject to the same requirements as in option 3 above, and additionally exempted from the need for storage in a safe compliant with the Misuse of Drugs (Safe Custody) Regulations 1973.

8. The consultation period closed on 3rd November 2014. This paper provides a summary of the responses received.

SUMMARY /OVERVIEW OF RESPONSES TO INDIVIDUAL PROPOSALS (INCLUDING WHERE APPROPRIATE COMMENTS MADE ON ALTERNATIVE OPTIONS)

9. A total of 70 online, electronic and hard copy responses were received by the closing date of the consultation. The responses to specific options are summarised below;

OPTION 1: Do nothing

10. This option was supported by 9 (**12.86%**) respondents. Some respondents who supported this option were concerned that rescheduling will adversely impact on availability for veterinary and healthcare use, and inevitably patient care. Others were of the view that rescheduling will have no benefits as there is a lack of concrete evidence of diversion from veterinary or healthcare uses. One respondent was of the view that the decision on how to regulate or control availability of ketamine in healthcare should be left to healthcare professionals and not interfered with through legislative measures.

11. The **British Equine Veterinary Association (BEVA)** supported this option and was of the view that “*although most equine practices follow industry guidelines for*

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.

both safe custody and recording as would apply for schedule 2 there remains a concern about the availability of ketamine when treating emergencies in the field. Therefore no added benefit will be gained from re-scheduling as industry guidelines provide the level of production and are enforced by the Royal College of Veterinary Surgeons.” BEVA also highlighted that ketamine is frequently used as an anaesthetic agent in the event of equine emergencies; *“it is therefore the medicine of choice when veterinary surgeons attend to road-side emergencies.”* In its view rescheduling to schedule 2 and the corresponding safe storage requirements *“would result in vets only carrying ketamine in vehicles for specific elective procedures”*, resulting in prolonged delays and suffering in incidents involving horses. BEVA indicated that it would *“support option 2 if similar exemptions for safe custody could be made”*, as applies to another schedule 2 medicine (secobarbital, quinalbarbitone) to ensure general availability in these emergency situations.

12. A respondent also noted that *“the veterinary profession is already keeping Ketamine under schedule 2 conditions with respect to safe custody as an obligation under the RCVS Code to Professional conduct. However, a change to Schedule 2 will create unnecessary additional administration burdens to the significant number of veterinary surgeons working with zoo and wildlife species in this field and make it practically difficult to perform their routine work in zoos and wildlife parks.”* The respondent indicated that they *“could see some merit in moving towards schedule 3 status but with an exemption from additional safe custody requirements”* but as they had seen *“no evidence ketamine abuse is related to the use of veterinary ketamine in zoo and wildlife collections”* they *“consider it is disproportionate to change the scheduling to 2.”*

13. The **British Veterinary Association** indicated that it *“would not be prepared to support the rescheduling of ketamine to full Schedule 2 status, unless there is evidence that this change would reduce the risk of diversion or misuse of ketamine.”*

OPTION 2: Reschedule ketamine to Schedule 2 to the 2001 Regulations

14. This option was supported by the vast majority of respondents (43, **61.43%**) including the **Care Quality Commission (CQC)**, **Association of Ambulance Chief Executives**, **Pharmacy Voice**, the **Royal College of Pathologists**, the **Royal College of Anaesthetists**, the **British Pain Society**, the **Dogs Trust**, the **Guild of Healthcare Pharmacists**, the **Royal Pharmaceutical Society** and the **Royal College of Physicians**.

15. The **CQC** fully supported the ACMD's recommendation to reschedule ketamine to Schedule 2. However, in its view it *“remains unclear as to whether rescheduling will reduce misuse as we do not know to what extent ketamine obtained for recreational purposes is diverted from legitimate healthcare and veterinary sources or obtained elsewhere, including internet suppliers.”*

16. The **British Small Animal Veterinary Association (BSAVA)** *“are prepared to support full Schedule 2 status for ketamine, providing there is evidence that this change would reduce the risk or misuse of ketamine.”*

17. A **veterinary pharmaceutical company** indicated that it had *“no objection to placing ketamine under Schedule 2 in the 2001 Regulations.... However, moving the product to Schedule 3 may still provide better control, whilst minimising the impact.”*

18. **Pharmacy Voice** was of the view that *“in light of the evidence provided by the ACMD and the potential risks of diversion, further legislative action is required.”* It further indicated that *“the potential risk of harm is high if ketamine is diverted from legitimate supply routes”*, adding that *“Controlled Drug Local Intelligence Networks have reported evidence of diversion from health and veterinary settings.”* In its view *“this is sufficient to warrant further controls.”* It noted that *“many hospitals and ambulance trusts recognise the risk and already treat ketamine as if it were in a higher schedule.”* It also noted that *“the Royal College of Veterinary Surgeons Best Practice guidelines state that ketamine should be treated as a Schedule 2 drug.”*

19. Following consultation with various clinical members, the **Royal College of Anaesthetists** reported that *“the vast majority of respondents support option 2”*. It also reported that the view of its members is that *“ketamine has been for many years a bit of an anomaly and that it should be treated like other controlled drugs such as morphine and fentanyl.”*

20. The **Guild of Healthcare Pharmacists** confirmed in their response that the majority of its members *“already treat Ketamine as a Schedule 2 controlled drug. This requirement has arisen to reduce the risk of diversion of ketamine from legitimate use and thereby reduce the misuse.”* In its view *“application of full Schedule 2 requirements is necessary as to do otherwise would cause confusion.”*

21. The **College of Paramedics (COP)** and the **Association of Ambulance Chief Executives (AACE)** both fully supported this option. However, both organisations raised significant concerns around the impact of Schedule 2 status on the use of ketamine under Patient Group Directions (PGD). The **COP** *“agree that this would tighten overall control and reduce the abuse potential related to this drug. Furthermore the additional requirements that this would place on ambulance services and paramedic users are minimal as Ketamine is already strictly controlled within these environments.”* It highlighted that *“an important implication of the reclassification would be that, as with most Schedule 2 drugs, Ketamine will no longer be available for use under a PGD and this will need to be addressed if the appropriate clinical use of this analgesic is to be maintained.”* It therefore advocates *“making the necessary change to the relevant regulation and exemption”*. It suggested two possible options to exempt Ketamine from this restriction in the same way that morphine and diamorphine are exempted for registered nurses and pharmacists.

22. The **AACE** is of the view that *“rescheduling must be accompanied by an amendment of the regulations to permit paramedics and nurses working in ambulance trusts to administer ketamine under a PGD.”* It added that *“regulations also need to be amended to give authority to NHS ambulance trusts to possess and supply controlled drugs to their professional staff as happens with hospitals to improve controlled drugs management and reduce stocks of controlled drugs in the community.”*

OPTION 3: Reschedule ketamine to Schedule 3 to the 2001 Regulations

23. This option was supported by 10 (**14.29%**) respondents who were generally of the view that the additional requirements of recording and safe custody applicable to Schedule 2 drugs will be disproportionate to the risks and harms identified, and that Schedule 2 status will adversely impact the use of ketamine, especially in small animal and mobile veterinary practice.

24. A respondent from the veterinary sector indicated that in their view *“placing ketamine into schedule 3 with full requirements will allow for more stringent control of supply and use of ketamine but without the significant amount of paperwork associated with placing into schedule 2.”* The respondent added that *“placing into schedule 2 may push many veterinary practitioners to stop using ketamine which will have an impact on animal welfare and good analgesia provision.”*

25. The **Royal College of Veterinary Surgeons (RCVS)** is of the view that *“ketamine is a highly important drug in veterinary practice. It is a very effective and widely used general anaesthetic, both in small animal practice and in equine practice, where it regularly has to leave the practice premises for use in the field.”* The RCVS agreed that ketamine should be subject to increased controls. However, it noted that *“reclassification at Schedule 2 would pose significant difficulties for small animal practices, where ketamine is administered in very small doses (e.g. 0.15 ml) leading to natural wastage (approximately 10-15%) which would be difficult to record with sufficient accuracy to comply with Regulation 19.”* Its view is that *“Schedule 3 strikes the best balance between security and practicability.”*

26. A respondent from the research sector indicated that although it *“understands the need to review the scheduling of Ketamine, as a research establishment, it had concerns about moving Ketamine into Schedule 2.”* It noted concerns around difficulties that would be encountered when expired stocks of ketamine had to be destroyed in the presence of an authorised witness, and the police time and administrative effort this would require in order to comply with Regulation 27.

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

27. This option was supported by 5 (**7.14%**) respondents. A respondent who supported this option was of the view that the available evidence shows *“very little medical or veterinary ketamine has been diverted for illegal use.”* In their view this *“shows that the current system for purchase, storage and prescription of medicinal ketamine is robust, effective and safe”* and therefore *“any additional restriction on purchase, storage and prescription, as well as increased requirement for documentation would have negligible impact on illegal ketamine use”* and would simply be *“unnecessarily onerous for healthcare professionals.”*

28. Another respondent was of the view that very little presentations are encountered from ketamine toxicity and *“potentially limiting ketamine’s access and availability will have a negative impact on patient care for a perceived small benefit in pharmacological safety”*, leading to *“additional workload burden for pharmacy and ward staff.”*

GOVERNMENT RESPONSE

29. **The Government acknowledges the responses received. It notes the majority support for ketamine to be listed as a Schedule 2 drug, but also the significant concerns that exist around impact on ketamine’s use under Patient Group Directions following rescheduling, and the need to ensure that rescheduling does not impact on the immediate treatment of sick or injured persons.**

30. The Government also acknowledges the concerns raised around the impact of schedule 2 status on the veterinary sector but notes that it has for some time already been a requirement under the RCVS code of practice for veterinary practitioners to treat ketamine as a Schedule 2 drug due to the associated risk of diversion and misuse and the harms that can result from that misuse. It further notes the specific concerns around the impact on small animal and mobile as well as equine veterinary practice. In response to these concerns, the Government will like to highlight that rescheduling ketamine to Schedule 2 simply puts requirements that are already a good practice requirement on a legislative footing to ensure they are followed consistently across both the health and veterinary sectors. It notes that as some respondents reported, any impact on veterinary practice from Schedule 2 status is expected to be minimal as these requirements are already in place.

31. Additionally, the Government notes that the majority of healthcare institutions already treat ketamine as a Schedule 2 drug, again in light of its misuse potential and resulting harms from misuse. As a result, any impact on the healthcare sector from rescheduling to Schedule 2 is also expected to be minimal. The consultation responses also confirm that health and veterinary practitioners will be able to accommodate ketamine stocks in current safes without the need to expand storage space or invest in new safes.

32. The Government also notes the views of the Association of Ambulance Chief Executives on the need to implement legislative changes to provide authority to NHS Ambulance Trusts to possess and supply controlled drugs to nurses and paramedics employed by the Trust. These changes were the subject of a previous Home Office consultation and were fully supported by the majority of respondents. A statutory instrument implementing the change is currently being prepared with the view to the changes coming into force at the earliest opportunity.

33. The Government has taken on board the responses received and concerns raised, and while it recognises that there may be some minimal impact resulting from Schedule 2 status, it notes that the public protection benefits far outweigh any identified impact. In light of the above, it has decided to pursue option 2 – full Schedule 2 status – as recommended by the ACMD, which in its view will subject ketamine to the most appropriate regime of control but with consequential legislative changes to ensure ketamine remains available for use under Patient Group Directions following rescheduling.