

**The Royal Pharmaceutical Society is pleased to respond to the consultation on
Pregabalin and gabapentin: proposal to schedule under the Misuse of Drugs
Regulations 2001**

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.
Option 2	Place in Schedule 3 to the 2001 Regulations (but exclude application of safe custody requirements).
Option 3	Place in Part 1 of Schedule 4 to the 2001 Regulations.

Please explain why:

The Royal Pharmaceutical Society (RPS) is supportive of the need to control pregabalin and gabapentin under the 2001 Regulations. The report from the Advisory Council on the Misuse of Drugs shows the sharp increase in prescribing over the last five years. It confirms that the prescribing of this drug is now in need of closer monitoring, as it is subject to abuse and dependence similar to that of tramadol. A similar consultation in 2013 resulted in tramadol being rescheduled under the Misuse of Drugs act 2017

The potential introduction of safe custody requirements that would be needed for option 1, will have a significant impact on the operation of pharmacies and dispensaries in many settings, both private and NHS. Currently, there is no evidence offered that these products are at greater risk of diversion within manufacturing and wholesale processes. We are currently unaware of any increasing problems in community pharmacy thefts that have specifically targeted pregabalin or gabapentin, therefore there is no substantial evidence that changing the pharmacy environment will improve the societal problem of abuse. We would advise that this be monitored and reviewed if increased incidents do occur.

Unless there is evidence of significant diversion from pharmacies we would envisage no added benefit in introducing additional safe storage requirements and would suggest the following issues;

- Within a community pharmacy setting, additional storage requirements within a CD cabinet would be troublesome for pharmacy contractors. These medicines are frequently prescribed and available in a number of different strengths and formulations many of which are of a very large package size.

- Within a hospital environment medicines are stored in a number of settings, including dispensing robots and ward dispensaries. If new storage requirements were to be introduced, it would cause issues at all storage points, especially at ward level where there are usually small CD cabinets. Additionally it may affect the process and increase the time to discharge patients, as take home medicines that contain CDs with safe storage requirement are not supplied in the same manner as other medicines.
- Within care homes the added requirement for safe storage would be burdensome and increase the time taken to administer medicines to patients. This is an area of concern where staff are already under pressure.
- Within secure environments there could be additional costs for storage requirements with no extra benefit as the security of pharmacy stock is already a high priority in these areas and awareness of the abuse potential for both these items is already high.

We believe that there may be benefits from reclassifying both these items through a reduction in prescribing by ensuring it is prescribed appropriately and according to current guidelines. Controlled drugs cannot be added to repeat prescriptions, neither can they currently be sent via electronic prescription systems, where those systems are in use. This will therefore be likely to lead to increased administration costs and time for GP surgeries.

We therefore request an exemption from safe custody requirements and our preferred option is number 2

The impact assessment is available [here](#)

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

No – We do not believe that sufficient evidence has been collected and produced to warrant a change to option 1. We particularly disagree with the statement “Many organisations which need to store pregabalin and gabapentin will be able to accommodate them in existing available storage space without the need to acquire a new safe”. As stated above, these medicines are frequently prescribed and available in a number of different strengths and formulations many of which are of a very large package size.

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?

See Q1

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

N/A

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

No

In many cases this will cause problems and require larger CD cabinets which may be difficult to accommodate in existing premises.

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

These medicines are essential for the control of long-term conditions such as epilepsy and nerve pain which can be caused by conditions such as diabetes. We would hope that sufficient consultation and patient feedback have/will be sought on how this change might affect their care. We would not want to see any unintended negative consequences for patients that rely so heavily on these medicines for maintenance of conditions and their overall health and wellbeing.

Legally pharmacists should not make emergency supply of controlled drugs in schedule 2 or 3, this change could result in many pharmacists having to make very difficult decisions about whether to supply these medicines or not in an emergency. Should options one or two be taken forward we would suggest an exemption to this rule in line with phenobarbital for epilepsy.

We are disappointed that the assessment does not include quantified figures on costs or benefits. We do agree that there would be lower costs to organisations by not applying safe custody requirements, making this a more achievable option. Many hospitals in particular would however apply safe custody measures to all schedule 3 controlled drugs to ensure robustness and consistency when dealing with requisitions etc.

We do welcome the fact that option 2 (as with option 1) would ensure that possession of pregabalin and gabapentin would become a criminal offence under the 1971 Act in cases where they have not been prescribed which would be a positive step in enabling authorities to take action against diversion from legitimate uses and the harms identified in the ACMD advice.

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?

Q8. To help inform the full impact assessment please quantify the additional cash cost per month of option 2 to you or your organisation.

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

N/A

Q9. Do you agree with the impact assessment of option 3?

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?

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

N/A

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** At least

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,