Community Pharmacy Scotland

The Home Office Proposals to schedule pregabalin and gabapentin under the Misuse of Drugs Regulations 2001
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Who are Community Pharmacy Scotland (CPS) & what do they do?

Who we are

We are the organisation which represents community pharmacy contractor owners in almost every aspect of their working lives, and are the voice of these vital healthcare professionals as they deliver pharmaceutical care to the people of Scotland.

We are empowered to represent the owners of Scotland's 1256 community pharmacies and negotiate on their behalf with the Scottish Government. This covers all matters of terms of service and contractors' NHS service activity including remuneration and reimbursement for the provision of NHS pharmaceutical services.

What we do

We work with the Scottish Government on the development of new pharmaceutical care services and ensure that the framework exists to allow the owners of Scotland's community pharmacies to deliver these services.

The Scottish community pharmacy contract puts the care of the individual right at its centre and with its focus on pharmaceutical care and improving clinical outcomes, community pharmacy contractors and their employee pharmacists are playing an increasingly important role in maximising therapeutic outcomes and improving medicine safety. Community pharmacy is at the heart of every community and plays an important part in the drive to ensure that the health professions provide the services and care the people of Scotland require and deserve.

Community Pharmacy Scotland

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Introduction

The consultation document is available to view online and our draft response is included below for simplicity.

Q1. In light of the risks of diversion from legitimate uses and the harms identified in the ACMD advice, which option do you support? Please explain Why.

Option 2: Place in Schedule 3 to the 2001 Regulations, but exclude application of the safe custody requirements.

We have selected Option 2, but must make it clear that none of the three options laid out would be the preferred choice for community pharmacy. We would strongly recommend the adoption of option 2, but with the ability to include the two drugs in PGDs and emergency supply arrangements. Although the latter benefits would be conferred by selecting option 3 (Schedule 4(Part 1)), we have chosen option 2 as we recognise that there is a growing problem with online private prescribing of substances liable to abuse by EEA/Swiss-based prescribers which presents a significant risk to the public and only Schedule 3 offers a solution.

CPS accept the facts around the dangers which Gabapentin and Pregabalin pose to public health, and welcome actions taken to restrict illicit use and diversion of these drugs. We also accept that their being subject to the provisions in the Psychoactive Substances Act 2016 is not sufficient to have an effect on the levels of misuse described in the consultation document and ACMD advice note.

However, we firmly believe that the preferred option outlined is excessive, will not provide the desired effect on misuse and will be ultimately impracticable, particularly for community pharmacy teams. We have provided a full discussion on our selection of option 2 (with amendments) below, but would like to draw attention in particular to the section on Safe Custody and why these drugs must be exempted from these requirements.

Fundamentally, the availability of these drugs on the street is via two main routes. Illicit production or importation accounts for a proportion of the volume, but we would suggest that it is post-dispensing diversion that is responsible for the entry of most of this stock onto the black market. This is where a patient has obtained a prescription through legitimate means, has it dispensed but then chooses to sell the drug, pass it on or take it in a different manner than to that instructed. We are not aware of there being any issue, significant or otherwise, of manufacturer, wholesaler or community pharmacy stock being diverted directly or stolen. If it were, we would suggest that this could not occur in great volumes without being picked up by the authorities, nor would it allow for a steady flow of the drugs onto the black market, which seems to be the case. There are already restrictions on these activities to deter illegal trade, and we support the move to a Class C designation for these to strengthen the consequences for criminal activities involving Pregabalin and Gabapentin.

It follows that, although there are many ways in which Pregabalin and Gabapentin can be diverted for illicit purposes, the root cause in the majority of cases is that prescribing management has been inappropriate.

This may be the case for many reasons: the prescriber is not acutely aware of the misuse potential of the drugs; the patient has misled the prescriber as to their symptoms; the patient has a valid diagnosis but chooses to profit from diverting their medication; the patient is vulnerable and another individual has diverted their medication or; the continuing need for the drug has not been assessed according to guidelines, allowing a continued supply where the patient no longer has a need for the medication. This list of possibilities is not exhaustive, but should highlight that few of the proposed options would address the flow of the two drugs onto the black market where they have been obtained on prescription. The introduction of the prescription-writing requirements should go some way to improving the awareness of abuse potential, but it is strong clinical leadership, professional accountability and adherence to existing prescribing and deprescribing guidelines which must be pursued to begin tackling this problem in earnest. Enhanced support for addiction to prescription medications and public awareness campaigns would also be of benefit.

Whilst we will discuss each proposed option and requirement in turn, we must be absolutely clear on our position with regards to the proposed requirement for Safe Custody of these two medications. With the most recent 12 months of Scottish dispensing data available, we have been able to estimate that to keep an average of 3 days' stock of only the most commonly prescribed strength of Gabapentin (300mg) and Pregabalin (150mg), each pharmacy would need 9.5L of CD cabinet space. This is before the other four strengths of Gabapentin and seven strengths of Pregabalin are taken into account.

We must also consider the space needed to store assembled prescriptions which are awaiting collection – most are picked up within two weeks but can remain in storage for up to 28 days, after which they would be returned to stock. The space needed for this would vary considerably between pharmacies, but we have been conservative in estimating that at least double the space calculated for stock would be required – 19L. These two strengths alone would require a new cabinet for most contractors, costing around £160 to obtain and fit at current market prices. This is, of course, an average figure. The pharmacy which dispensed the most Pregabalin 150mg and Gabapentin 300mg would have to find 27L of CD safe space at a cost of around £180 to ensure a 3-day stockholding and space for assembled prescriptions. We estimate that the space required would be multiplied by a factor of 6 to accommodate all strengths in an average pharmacy (at least 114L, £420) when taking into account variations in local prescribing habits and pack size differences between manufacturers. It is clear to see that the costs required to hold all strengths of both of these medications would be excessive and would return little benefit with respect to misuse.

More important than potential costs, there are a significant number of pharmacies in Scotland where there is simply not enough physical space to install even one additional CD safe, and when we consider that a change in regulation would require a number of safes to be installed, very few premises could accommodate this. Effectively, including the Safe Custody of Pregabalin and Gabapentin as a requirement in this reclassification exercise would cause community pharmacy owners and pharmacists to be in breach of the law due to circumstances outwith their control.

This would be an unacceptable situation to place healthcare professionals in, and the unintended consequences of doing so far outweigh any benefits described.

Whilst we recognise that it would be difficult to reliably quantify, the additional staffing time spent storing and retrieving assembled prescriptions for patients must be taken into account. We expect that this would also cause significant disruption to the workflow of a pharmacy, which would have a knock-on effect on patients' experience. The Responsible Pharmacist should have the safe keys in their possession, and if they are unavailable (e.g. providing enhanced services) then the team cannot carry out the most basic of functions in transferring assembled prescriptions to the patient. This can already happen where a CD Schedule 2 is given out, but this is a far rarer occurrence than if all Pregabalin and Gabapentin prescriptions were kept locked up.

When considering which option to pursue, we found it useful to consider the case of Tramadol, reclassified in 2014 to Schedule 3. A review of Tramadol use following reclassification in Scotland was carried out in 2016, which highlighted that prescribing across all settings had dropped by only around 10% on average at the time of publication. The review suggested that the observed reduction was driven by perceived procedural barriers rather than decisions made around clinical risk. This hypothesis was bolstered by the much greater relative reduction in use in hospital settings (over 54%), where strong local prescribing policies had been put in place. The review goes further to state that the safety gains desired in the case of Tramadol were more likely to come from the restrictions on possession, import and export than from any other associated

change in requirements. In light of this review and our own comments, we would urge the DoH to consider whether the proposed reclassification will in fact deliver the desired behavioural changes in prescribers and patients. As an aside, we also note that although these proposals describe the clinical risks of Pregabalin and Gabapentin misuse as similar to that or Tramadol, it was made exempt from safe custody requirements when reclassified. We expect that this was in recognition of the similarly high volume of prescribing of Tramadol, and would ask that the same be applied to the two drugs under consultation.

We also have a concern over the accessibility of medicines for those who legitimately need them. Currently, these two medications can be supplied under the national Unscheduled Care PGD when a patient has run short of their supply. This relieves a great deal of pressure on NHS in- and out-of-hours services, and can prevent prolonged patient journeys and potential gaps in treatment. Each supply is subject to the Pharmacist's professional judgement and the mechanisms employed ensure that repeated use of the PGD will be picked up by the GP practice. There is even a specific section of the PGD which highlights substances liable to misuse, which includes Pregabalin and Gabapentin, so the awareness of the issues around illicit use of these drugs is high relative to other professional groups. If community pharmacies were unable to use this mechanism, it would place additional pressures and workload on our colleagues at NHS24 and local OOH centres, as patients would only be able to obtain supplies by attending these services. This would go against Scottish Government policy to improve access to medicines wherever appropriate in a controlled manner.

For reference, Scottish community pharmacists made emergency supplies of the most common strengths of Pregabalin and Gabapentin on just over 2000 occasions in the period Dec 2016-Nov 2017. These patients would have otherwise had to access our hard-pressed out of hours services, with whom they would not have an established relationship and thus an assessment of whether a supply would be appropriate would not be as informed as is the case in community pharmacy.

Q2. Do you agree with the impact assessment of option 1? If no, please explain why.

No.

We find it unacceptable that an impact assessment has been passed with such little investigation as to the costs and unintended consequences of this option, and welcome the opportunity to provide at least an estimated monetised cost, and expand upon the non-monetised costs and risks. We would argue that the proposed non-monetised benefits have been over-exaggerated and in no way outweigh the costs/risks, be they financial or otherwise. Again, we state our acceptance of the harms which these two drugs can cause, and the need to make a change to their regulation – the evidence for this is irrefutable. We also agree that the prescription-writing requirements of Schedule 3 would encourage there to be due consideration given to whether an individual should be given the drugs at the point of prescribing.

However, we are clear that not only would many pharmacies be unable to house additional CD cabinets to store such volumes of medication (thus being in breach of the law), the estimated cost of doing so would be excessive – at least £420 on average, and £528,000 in total for the community pharmacy network in Scotland. This is representative of less than one tenth of the pharmacies in the UK, but we do not have the prescribing data necessary to provide an estimated cost for the entire nation.

Furthermore, the Impact Assessment cites that "Greater protection against diversion owing to the safe custody requirements", but there is no evidence put forward to support that this would be the case, nor that direct diversion of manufacturer/wholesaler/pharmacy stock is a major issue. We would ask for proof of this, and in the absence of proof would argue that safe custody will have little to no impact on the availability of these drugs on the black market. Particularly as any diversion happening at these points in the supply chain would likely happen before the stock reaches the CD cabinet from an order.

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? Please provide details.

Any wholesaler, hospital premises or other organisation handling these two drugs would also have to find space to hold their stock securely, and often this will be in far greater quantities than in the community pharmacy setting. System suppliers will have to modify their software to ensure the appropriate legislation is complied with. Prescribers will have to change their practice in prescribing, but this would be seen as a positive.

Q4. To help inform the full impact assessment please quantify the additional cash cost per month of this proposal to you or your organisation. Please state amount and any relevant breakdown.

We estimate that there would be an initial cost of around £528,000 for our network, if physical space in premises was available. However, we are certain that this is not the case for most, and Safe Custody requirements will be impossible to implement as desired without pharmacy owners moving premises or instigating major structural changes. The ongoing monetary cost of additional staff resource to support the

procedures associated with Safe Custody is challenging to estimate or evidence but we believe that it would be significant.

Q5. Do you agree that healthcare organisations or businesses will be able to accommodate pregabalin and gabapentin within current compliant safes? If NO, please explain why, including estimated costs to be incurred in acquiring a safe.

No. As discussed in our answer to Question 1, we are absolutely certain that community pharmacies would have to purchase and install additional CD safes. The estimated cost would be excessive and unacceptable - at least £528,000 for the network in Scotland alone, but it is not this cost which presents the most concern. A significant proportion of community pharmacy premises would be unable to accommodate additional safes of the size required to hold 3 days' stock of all strengths of both medications and any assembled prescriptions.

We must stress that there will be a great number of pharmacy premises that cannot accommodate additional compliant safes due to space restrictions and would be put in the position of breaching the law if this requirement were to be included in the reclassification. Moving premises to satisfy a requirement which will have limited impact on illicit drug misuse is unreasonable and thus this change cannot be permitted to happen.

Q6. Do you agree with the impact assessment of option 2? If NO, please explain why.

No. It has not been considered that the inclusion of these two medications in Schedule 3 would preclude them from being supplied against a PGD or via an emergency supply mechanism. Whilst we understand that the aim of this exercise is to restrict availability, it is our view that this would have unintended consequences with respect to access to medicines for those with a legitimate need for prescriptions. If community pharmacists were unable to make appropriate supplies when patients run out, we would expect pressures on NHS24 and OOH centres to increase significantly, given that there is no suitable alternative therapy for neuropathic pain nor any other of Pregabalin or Gabapentin's indications over the counter.

We would also call for the issue of UK and EEA/Swiss-based online prescribing services to be included in the impact assessment. In our experience, we have found that members of the public are able to access these medications readily via these routes, with minimal assessment by a prescriber and no obligation to inform the patient's GP. It is reasonable to expect that this is how a proportion of diverted medication enters the

black market. By including in Schedule 3, this flow of stock could be halted, preventing potential harm.
As discussed in our answer to question 1, none of the options presented are ideal. There is a balance to be struck between allowing access to medication from a pharmacy in an emergency and allowing online prescribing services to supply members of the public with products liable to abuse. This will require an adoption of option 2 with amendments to allow inclusion in emergency supply arrangements and PGDs.

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? Please provide details.

Prescribers would have to change prescribing habits, and system suppliers would need to ensure that their software was compliant. NHS organisations may experience greater patient numbers using their services to access medicines in emergencies if pharmacies can no longer provide this function for these two commonly prescribed drugs.

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 state amount and any relevant breakdown

We do not envisage a significant cash cost for the community pharmacy network should option 2 be implemented.

Q9. Do you agree with the impact assessment of option 3? If NO, please explain why.

No. We would call for the issue of UK and EEA/Swiss-based online prescribing services to be included in the impact assessment. In our experience, we have found that members of the public are able to access these medications readily via these routes, with minimal assessment by a prescriber and no obligation to inform the patient's GP. It is reasonable to expect that this is how a proportion of diverted medication enters the black market. By including in Schedule 4(1), this flow of medication would be allowed to continue – the risks of which outweigh the benefits.
As discussed in our answer to question 1, none of the options presented are ideal. There is a balance to be struck between allowing access to medication from a pharmacy in an emergency and allowing online prescribing services to supply members of the public with products liable to abuse. This will require an adoption of option 2 with amendments to allow inclusion in emergency supply arrangements and PGDs.

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? Please provide details.

No.

Q11. To help inform the full impact assessment please quantify the additional cash cost per month of option 3 to you or your organisation. Please state amount and any relevant breakdown.

We do not envisage a significant cash cost for the community pharmacy network should option 3 be implemented.

Q12. In your (or your organisation's) view how much lead time is necessary for implementation if option 1 was adopted? (1/3/6 months)

We do not think that this option can be implemented.

Q13. In your/ your organisation's view how much lead time is necessary for implementation if option 2 was adopted? (1/3/6 months)

6 months

Q14. In your/your organisation's view how much lead time is necessary for implementation if option 3 was adopted? (1/3/6 months)

1 month