Response to the Home Office consultation on proposals to schedule pregabalin and gabapentin under the Misuse of Drugs Regulations 2001

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Introduction

The Pharmaceutical Services Negotiating Committee (PSNC) is grateful for the opportunity to comment on the Home Office consultation on proposals to schedule pregabalin and gabapentin under the Misuse of Drugs Regulations 2001.

The consultation considers three options (in addition to the 'do nothing' option) which are:

1. *Control pregabalin and gabapentin as Class C Drugs under the 1971 Act and place both in Schedule 3 to the 2001 Regulations, applying the provisions of the Misuse of Drugs (Safe Custody) Regulations 1973 (the 1973 Regulations).*
2. *Control pregabalin and gabapentin as Class C Drugs under the 1971 Act and place both in Schedule 3 to the 2001 Regulations (but exclude the application of safe custody requirements),*
3. *Control pregabalin and gabapentin as Class C Drugs under the 1971 Act and place both in Part 1 of Schedule 4 to the 2001 Regulations.*

Option 1 is the Government's preferred option and would mean both drugs are subject to the full requirements of schedule 3 including very specific prescription requirements such as the total quantity in words and figures on the prescription and a 'wet' signature of the prescriber; and storage of the drugs in a controlled drugs cabinet complying with the detailed requirements of the safe custody regulations. Option 1 is not feasible for community pharmacy within a reasonable cost burden.

Option 2 is feasible to implement, but only if – this is a pre-requisite that must be met in advance of implementation – it is possible to prescribe/generate and dispense prescriptions for schedule 3 pregabalin and gabapentin using the NHS electronic prescription service.

Comments and Observations

Option 1 - the impact assessment for the consultation states two key assumptions:

> *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 compliant with the 1973 [Regulations]. However, some organisations such as community pharmacies may struggle to store the two*

drugs in their existing safes and may need to acquire additional safes if the safe custody provisions apply. We would particularly welcome information on this in the public consultation. (Page 11)

Electronic prescribing (where completed currently with these substances) will be replaced by arrangements such as pharmacy pick up of prescriptions from practices. We do not anticipate any extra cost on pharmacies picking up prescriptions as this service is already provided for other medicines. Prescriptions for pregabalin and gabapentin will form part of the bundle of prescriptions picked up. Patients do not pay for this service, and we do not envisage that to change, as the service is offered by pharmacies free of charge to generate business. (Page 11)

These assumptions do not give an accurate account of the impact of the proposals on community pharmacy.

The application of the safe custody regulations to pregabalin and gabapentin would be a significant and costly issue for community pharmacy. As the information in the impact assessment indicates there are significant numbers of prescriptions for these drugs, particularly pregabalin; they are also prescribed and dispensed in large quantities, for example, four boxes of 56 pregabalin at one time; and there are many different packaging sizes and strengths of the drugs held in stock by each pharmacy. Storage of these drugs in the pharmacy while awaiting delivery will also be affected.

The volume of the containers for these drugs, particularly pregabalin is significant – see the photograph at the end of this part of the text and estimates below – and it is highly unlikely that existing controlled drugs cabinets would have sufficient room for these two drugs. This would necessitate the purchase of one of more additional controlled cabinets by community pharmacies.

One pharmacy chain has calculated/estimated as follows:

…The impact assessment grossly underestimates the number of these products that pharmacies have in stock and the physical volume that they occupy. In a brief survey of 69 of our 524 pharmacies in Britain we found the following:

- *The average pharmacy held 37 packets of pregabalin in stock in varying strengths and brands*
- *The average size of a packet of pregabalin (across all strengths and brands) is 529cm^3. This means that the approximate average physical volume of stock in the average pharmacy is 19,573cm^3 or almost 20 litres.*
- *The average pharmacy held 23 packets of gabapentin in stock in varying strengths and brands.*

- *The average size of a packet of gabapentin (across all strengths and brands) is 642cm3. This means that the approximate average physical volume of stock in the average pharmacy is 14,766cm3 or almost 15 litres.*
- *Only 6 pharmacies from the 69 surveyed would be able to fit their current stock in the CD cabinet alongside their other CD medication even when the CD cabinet was tidied and organised. Each of ..[these 63].. pharmacies would therefore require an additional CD cabinet ….*

On this basis, over 90% of the approximately 11,700 NHS pharmacy contractors may require an additional controlled drugs cabinet at a cost of approximately £300 to £800, with the additional cost of installation by somebody with knowledge of the specific requirements of the the Misuse of Drugs (Safe Custody) Regulations 1973. Given that the installation is of a specialist nature; is usually undertaken outside normal working hours to avoid disruption to the pharmacy business; and there needs to be some form of security or guard present while the work is undertaken, it is estimated to be approximately £2,000 for each community pharmacy. In addition, pharmacies may not have space or be easily able to accommodate an additional controlled drugs cabinet which would necessitate further costs to comply with the proposals.

There are also likely to be additional costs in the supply chain for the storage of controlled drugs by wholesalers etc. which are usually passed on to the pharmacy; as well as additional costs for pharmacy deliveries of these drugs to patients and the dispensing of these drugs into compliance aids.

There is also additional work/cost for pharmacy when dealing with any controlled drug, for example, due to additional recording requirements.

The additional cost burden of many millions of pounds does not appear to be justified given that the primary aim of the proposal is to address misuse of drugs which have been prescribed legitimately. Given the likely costs associated with Option 1, it cannot be said that 'overall the costs associated with this option are expected to be negligible.'

The cost burden would also be at a time when community pharmacy funding is being cut, the Government claw back of margin earned by community pharmacy is taking place and there is volatility in that market for medicines, all of which is affecting pharmacy income/costs; any additional cost burden at the current time would be more significant than usual.

There is also likely to be significant impact on other stakeholders. The drugs are dispensed to patients in care homes that are subject to the safe custody regulations, often in compliance aids which have considerable volume.

Option 1 and Option 2 - Implementation would require existing electronic prescriptions to be transferred to hard copy / paper prescriptions and new prescriptions to be handwritten or hard copy.

The additional workload of hard copy prescriptions would be borne by patients, GP practices and pharmacies, particularly the transfer of prescriptions from electronic to paper. Nominated pharmacies for electronic prescribing can be a distance from the prescriber and patients could be significantly inconvenienced by the need to return to the GP practice for a hard copy prescription. Emergency supplies of these medicines would no longer be permissible. In addition, for patients on more than one medicine, there is an increased likelihood of prescribed medicines split between electronic prescriptions and hard copy prescriptions. This creates its own risks and practical problems for patients and additional workload for GP practices and pharmacies; there are also patient safety issues associated where patients are unable to obtain their medicines in a timely manner.

When Tramadol became a Schedule 3 controlled drug this caused significant problems - transferring the drug to and managing the resulting split prescriptions, as well as the storage of the drug in the controlled drugs cabinet. Such problems would be even greater with the current proposals because first, there is increased use of the electronic prescription service and second, there is longer duration of treatment (more drugs are prescribed on each prescription).

Option 2 should be implemented only when the electronic prescription service is able to manage schedule 2 and 3 prescriptions.

The ongoing work to enable the electronic prescribing of prescriptions for schedule 2 and 3 controlled drugs is currently moving to a pilot phase. Full implementation may be sometime in 2018, however, there are technical issues to be overcome to ensure that the quantity of a controlled drug can appear in both words and figures on the electronic script. It is arguable that this long-standing requirement of the regulations is no longer necessary because patients do not have access to the electronic script (which passes direct from the GP practice to the pharmacy via the NHS electronic 'spine') and the writing on electronic prescriptions is always clear; but this is a separate issue.

Until the electronic prescribing service can accommodate prescriptions for schedule 2 and 3 controlled drugs – until medical doctors are able to prescribe such drugs using electronic prescriptions and pharmacies can dispense

against such electronic prescriptions - the cost, workload and disruption issues associated with Option 2 are such that the option is not feasible within a reasonable cost burden.

Option 3 - if pregabalin and gabapentin are classified as Class C, schedule 4 controlled drugs - prescriptions for both can remain electronic and the current electronic prescription pathways have security features to ensure the GP's signature authorises the prescription. This option is feasible within a reasonable cost burden.

Consultation Questions

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

Subject to one pre-requisite or condition, PSNC supports reclassification set out in option 2: Control pregabalin and gabapentin as Class C Drugs under the 1971 Act and place both in Schedule 3 to the 2001 Regulations (but exclude the application of safe custody requirements).

The pre-requisite or condition is that the electronic prescription service is fully enabled for schedule 3 (and 2) controlled drugs to ensure that all current prescriptions (and new prescriptions) for the drugs are electronic and patients do not have split prescriptions.

Do you agree with the impact assessment of option 1?

No. The impact assessment does not address the cost issues for community pharmacy and acknowledges this. It is not known why this was not explored with community pharmacy prior to the drafting of the consultation documentation. See above for more information.

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?

Yes. The application of the safe custody regulations to pregabalin and gabapentin would be a significant and costly issue for community pharmacy. As the information in the impact assessment indicates there are significant numbers of prescriptions for these drugs, particularly pregabalin; they are also prescribed and dispensed in large quantities, for example, four boxes of 56 pregabalin at one time; and there are many different packaging sizes and strengths of the drugs held in stock by each pharmacy. Storage of these drugs in the pharmacy while awaiting delivery will also be affected.

The volume of the containers for these drugs, particularly pregabalin is significant – see the photograph at the end of this part of the text and estimates below – and it is highly unlikely that existing controlled drugs cabinets would have sufficient room for these two drugs. This would necessitate the purchase of one of more additional controlled cabinets by community pharmacies.

There is also likely to be a significant impact on care homes as well as wholesale dealers of medicines.

To help inform the full impact assessment please quantify the additional cash cost per month of option 1 to you or your organisation.

The cost estimate for an additional controlled drugs cabinet for many pharmacies in England is outlined above, but there would be even greater cost to community pharmacy if structural changes are required to existing premises to make space for additional cabinets or if relocation of the pharmacy is required. See also the answer to the next question.

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

No. One pharmacy chain has calculated/estimated as follows:

…The impact assessment grossly underestimates the number of these products that pharmacies have in stock and the physical volume that they occupy. In a brief survey of 69 of our 524 pharmacies in Britain we found the following:

- *The average pharmacy held 37 packets of pregabalin in stock in varying strengths and brands*
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- *Only 6 pharmacies from the 69 surveyed would be able to fit their current stock in the CD cabinet alongside their other CD medication even when the CD cabinet was tidied and organised. Each of ..[these 63].. pharmacies would therefore require an additional CD cabinet ….*

On this basis, over 90% of the approximately 11,700 NHS pharmacy contractors may require an additional controlled drugs cabinet at a cost of approximately £300 to £800, with the additional cost of installation by somebody with knowledge of the specific requirements of the the Misuse of Drugs (Safe Custody) Regulations 1973. Given that the installation is of a specialist nature; is usually undertaken outside normal working hours to avoid disruption to the pharmacy business; and there needs to be some form of security or guard present while the work is undertaken, it is estimated to be approximately £2,000 for each community pharmacy. In addition, pharmacies may not have space or be easily able to accommodate an additional controlled drugs cabinet which would necessitate further costs to comply with the proposals.

There are also likely to be additional costs in the supply chain for the storage of controlled drugs by wholesalers etc. which are usually passed on to the pharmacy; as well as additional costs for pharmacy deliveries of these drugs to patients and the dispensing of these drugs into compliance aids.

There is also additional work/cost for pharmacy when dealing with any controlled drug, for example, due to additional recording requirements.

The additional cost burden of many millions of pounds does not appear to be justified given that the primary aim of the proposal is to address misuse of drugs which have been prescribed legitimately. Given the likely costs associated with Option 1, it cannot be said that 'overall the costs associated with this option are expected to be negligible.'

The cost burden would also be at a time when community pharmacy funding is being cut, the Government claw back of margin earned by community pharmacy is taking place and there is volatility in that market for medicines, all of which is affecting pharmacy income/costs; any additional cost burden at the current time would be more significant than usual.

There is also likely to be significant impact on other stakeholders. The drugs are dispensed to patients in care homes that are subject to the safe custody regulations, often in compliance aids which have considerable volume.

Do you agree with the impact assessment of option 2?

No. The impact assessment does not assess the considerable impact of moving these drugs from electronic prescriptions and managing them on hard copy prescriptions; or the issues associated with split prescriptions; or the increased scale of the issues with these drugs compared to Tramadol, which was previously transferred to schedule 3. See also earlier comments and the answer to the next question.

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?

Yes. Implementation of Option 2 would require existing electronic prescriptions to be transferred to hard copy / paper prescriptions and new prescriptions to be handwritten or hard copy.

The additional workload of hard copy prescriptions would be borne by patients, GP practices and pharmacies, particularly the transfer of prescriptions from electronic to paper. Nominated pharmacies for electronic prescribing can be a distance from the prescriber and patients could be significantly inconvenienced by the need to return to the GP practice for a hard copy prescription. Emergency supplies of these medicines would no longer be

permissible. In addition, for patients on more than one medicine, there is an increased likelihood of prescribed medicines split between electronic prescriptions and hard copy prescriptions. This creates its own risks and practical problems for patients and additional workload for GP practices and pharmacies; there are also patient safety issues associated where patients are unable to obtain their medicines in a timely manner.

When Tramadol became a Schedule 3 controlled drug this caused significant problems - transferring the drug to and managing the resulting split prescriptions, as well as the storage of the drug in the controlled drugs cabinet. Such problems would be even greater with the current proposals because first, there is increased use of the electronic prescription service and second, there is longer duration of treatment (more drugs are prescribed on each prescription).

Option 2 should be implemented only when the electronic prescription service is able to manage schedule 2 and 3 prescriptions.

The ongoing work to enable the electronic prescribing of prescriptions for schedule 2 and 3 controlled drugs is currently moving to a pilot phase. Full implementation may be sometime in 2018, however, there are technical issues to be overcome to ensure that the quantity of a controlled drug can appear in both words and figures on the electronic script. It is arguable that this long-standing requirement of the regulations is no longer necessary because patients do not have access to the electronic script (which passes direct from the GP practice to the pharmacy via the NHS electronic 'spine') and the writing on electronic prescriptions is always clear; but this is a separate issue.

Until the electronic prescribing service can accommodate prescriptions for schedule 2 and 3 controlled drugs – until medical doctors are able to prescribe such drugs using electronic prescriptions and pharmacies can dispense against such electronic prescriptions - the cost, workload and disruption issues associated with Option 2 are such that the option is not feasible within a reasonable cost burden.

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

No additional figures are available.

Do you agree with the impact assessment of option 3?

No comment.

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?

Option 3 - if pregabalin and gabapentin are classified as Class C, schedule 4 controlled drugs - prescriptions for both can remain electronic and the current electronic prescription pathways have security features to ensure the GP's signature authorises the prescription.

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

This option is feasible within a reasonable cost burden.

In your (or your organisation's) view how much lead time is necessary for implementation.

At least six months is required for any implementation.

Conclusion

Option 2 is feasible to implement, but only if – this is a pre-requisite that must be met in advance of implementation – it is possible to prescribe/generate and dispense prescriptions for schedule 3 pregabalin and gabapentin using the NHS electronic prescription service.