Home Office

A consultation on proposals to schedule pregabalin and gabapentin under the Misuse of Drugs Regulations 2001.

Government response to the consultation

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Government response

Introduction

1. Following advice from the Advisory Council on the Misuse of Drugs (ACMD) about the harms associated with pregabalin and gabapentin, the Government published a consultation entitled: A consultation on proposals to schedule pregabalin and gabapentin under the Misuse of Drugs Regulations 2001 ('the 2001 Regulations') ('consultation document'). The consultation was prepared in discussion with the Department of Health and Social Care and the Department of Health (Northern Ireland) and ran from 13 November 2017 to 22 January 2018. It contained proposals to control the two drugs under Class C of the Misuse of Drugs Act 1971 ('the 1971 Act') and a choice of three scheduling options which are specified in paragraphs 5 to 9 below. The references in this document to the 2001 Regulations and the Misuse of Drugs (Safe Custody) Regulations 1973 ('the 1973 Regulations') should also be read as the Misuse of Drugs Regulations (Northern Ireland) 2002 and the Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973.

Background

2. In January 2016, the ACMD recommended that pregabalin and gabapentin should be controlled under Class C of the 1971 Act and placed under Schedule 3 to the 2001 Regulations, applying the provisions of the 1973 Regulations. The then Minister for Vulnerability, Safeguarding and Countering Extremism, Sarah Newton, replied to the ACMD's recommendation on 6 December 2016 to state that she accepted the recommendations of the ACMD subject to a public consultation to assess the effect on the healthcare sector, if both gabapentin and pregabalin were to be listed in Schedule 3 to the 2001 Regulations[1].

3. As set out in the consultation document, the ACMD had stated that both pregabalin and gabapentin presented a risk of addiction, potential illegal diversion and medicinal misuse. The ACMD reported that the harms of the substances were equivalent to those of other drugs controlled under the 1971 Act, including tramadol, which was controlled as a Class C drug in 2014.

4. The dangers of the two drugs are outlined in paragraphs 5 to 8 of the consultation document. As pregabalin and gabapentin have legitimate use on prescription, it is

[1] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/578067/Minister_Newton_to_Les_Iversen_-_Pregabalin_and_Gabapentin.pdf

necessary to schedule the drugs under the 2001 Regulations so not to preclude their legitimate use on prescription.

Summary of responses

5. The consultation document sought views on the three options:

Option 1: Place pregabalin and gabapentin under schedule 3 to the Misuse of Drugs Regulations 2001 applying the provisions of the Misuse of Drugs (Safe Custody) Regulations 1973.

6. This option was recommended by the ACMD and would place pregabalin and gabapentin in Schedule 3 and require that all prescriptions for pregabalin and gabapentin comply with the requirements set out in Regulation 15 (prescription writing) of the 2001 Regulations. Under option 1, pregabalin and gabapentin would also be subject to:

- Regulation 14[2] – which requires a compliant requisition to be provided to a supplier before stocks of pregabalin and gabapentin were supplied to the recipient;
- Regulations 15 and 16 – which require prescriptions for pregabalin and gabapentin to be written to very specific requirements, including wet signature of the prescriber; and
- Storage in a safe compliant with the Misuse of Drugs (Safe Custody) Regulations.

The two drugs would also be subject to the following provisions:

- Regulation 18 - which requires the marking of bottles or containers;
- Regulation 22 – record keeping with details about the quantity of the drug;
- Regulation 23 – the preservation of record keeping registers for two years;
- Regulation 24 – keeping of invoices or similar documents by the producer and wholesaler of the drugs (this does not apply to schedule 4 drugs);
- Regulation 26 – furnish information as required about drugs; and
- Regulation 27 – the destruction of drugs in front of an authorised person.

[2] This Regulation is not in operation in Northern Ireland

7. **Option 2**: Control pregabalin and gabapentin as Class C substances under the 1971 Act and place both in Schedule 3 to the 2001 Regulations (but exclude the application of safe custody requirements).

   Under this option, though controlled, the drugs would be exempted from the provisions of the 1973 Regulations. However, the requirements of the 2001 Regulations summarised in paragraph 6 would still apply.

8. **Option 3**: Place pregabalin and gabapentin in Part 1 of Schedule 4 to the 2001 Regulations.

   Under this option, the prescription requirements under Regulation 15 and 16 would not apply to its prescribing. Both pregabalin and gabapentin would still be subject to Regulations 22, 23, 26, and 27 of the 2001 Regulations, but not the provisions of the 1973 Regulations. The requirement to complete a mandatory requisition form would not apply. For more detail about the effects of the options, please see paragraphs 13 to 16 of the consultation document.

9. Responses to the questions were submitted either via an online survey or by sending written responses by email or post. All who had an interest in the consultation were invited to comment on the three options. The consultation consisted of 14 questions all of which provided for quantitative responses (indicated by a tick in the box closest to the respondent's view) and qualitative responses (by the provision of a written text box). These sought views on: which of the three options respondents preferred; whether they agreed with the preliminary impact assessments for all three options; the impact on healthcare professionals, institutions or industry as a result of the changes; costs to the respondent or the organisation he or she represented; and in relation to option 1, whether there was room in existing safes (compliant with the 1973 Regulations) for the storage of pregabalin and gabapentin. The consultation document also sought demographic information about the respondents including their professional interest from one of eleven options (including whether they were a patient or a pharmacist, for example) and the region from which they were replying.

10. The Home Office received a total of 529 submitted responses to the consultation. Of these, 483 were made online and the remaining 46 were either sent by email or received by post. Response totals are based on the numbers of responses and percentages for online responses and the combined number of email and written responses, separately.

11. Of the online responses, in total, 339 indicated that they were based in England, seven in Wales, 21 Scotland, and five in Northern Ireland. 111 respondents did not complete this section. Of the email and written responses, 30 indicated that they were based in England, one in Wales, one in Scotland, four in Northern Ireland, four from all four constituent countries of the UK and six provided no response. Professional interests were represented in the following numbers for online responses: 30 Practitioners (doctor, dentist or vet), 233 pharmacists, 10 pharmacy technicians, 13

other healthcare professionals (including nurses, midwives, AHPs, paramedics, etc), two pharmaceutical wholesalers, two pharmaceutical manufacturers two[3], 16 professional/regulatory bodies, nine patients, 60 others (drug treatment providers, Local Pharmaceutical Committee, pharmacy associations, etc). 108 online respondents did not complete this section. Of the email and written responses, the responses were: three practitioners (doctor, dentist or vet), five pharmacists, zero pharmacy technicians, one 'other healthcare professionals' (including nurses, midwives, AHPs, paramedics, etc), nine professional/regulatory bodies, five patients, 21 others (drug treatment providers, Local Pharmaceutical Committee, pharmacy associations, etc)[4]. Two responses were unclear.

12. Substantive comments are summarised in the analysis below. This includes comments on the impact assessments for each of the options.

Responses to specific questions

Question 1: 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 the application of safe custody requirements)

Option 3 Place in Part 1 of Schedule 4 to the 2001 Regulations.

13. Sixteen per cent of respondents (79) to the online survey indicated a preference for option 1 compared with 13 per cent (6) of email and written responses. The majority favoured option 2 with 54 per cent (260) of the 483 online respondents indicating a preference for option 2 and 46 per cent (21) of the 46 email and written responses. This gave a combined total of 53 percent. Twenty-five per cent (121) of online responses indicated a preference for option 3 compared with 26 per cent (12) of email and written responses. Although one respondent, who replied as part of the cohort of email and written responses, indicated that they were happy with both options 2 and 3. Five per cent of online responses (23) skipped the question, while seven per cent (3) of written and email responses did not respond to any of the options and 13 per cent (5) of written and email responses were unclear as to which option they favoured.

[3] The two entries for pharmaceutical wholesalers and the 2 entries for pharmaceutical manufacturers have been recorded as 'other' in the table headed 'respondent type' in Annex A. Accordingly, there are 64 responses for 'others' in the 'respondent type' table.

[4] This includes pharmaceutical wholesalers and pharmaceutical manufacturers.

14. Option 1 was supported by the **Faculty for Pain Medicines at the Royal College of Anaesthetists** as providing the best protection for patient and the general public. **The South Eastern Health and Social Care Health Trust** stated that this option would make diversion the more difficult and that the costs of the option would be trivial in relation to the lives that could be saved.

15. Among those who indicated a preference for option 2 included the **National Pharmacy Association**, the **Royal Pharmaceutical Society**, and **a pharmaceutical company**. The **Royal Pharmaceutical Society** added that the safe custody requirements of option 1 would have a significant impact on the operation of pharmacies and dispensaries in many settings, both private and NHS. The **National Pharmacy Association** thought that the biggest group of concern was among 'opiod-users and prison populations'. It thought that community pharmacies were relatively safe and questioned the necessity for safe storage, as well as the cost for the two substances.

16. Option 3 was supported by the **Company Chemists' Association.** The CCA did not think that there was enough evidence to suggest diversion of pregabalin and gabapentin from community pharmacies. They felt that consideration should be given to ensuring that those with a history of substance misuse were not prescribed either substance. They felt that option 3 would be the least onerous on practising pharmacy teams and the entire medicines supply chain. **A major manufacturer** of pregabalin and gabapentin stated in its reply that it did not believe that there was strong enough evidence that any of the options would benefit patients or help prevent diversion. It also outlined its concerns about the effects of controlling the drugs under the 1971 Act and scheduling them under the 2001 Regulations. **One major pharmacy chain** also did not support any of the options but suggested that the Home Office worked with health departments and the NHS to address concerns about inappropriate prescribing of the two drugs.

17. **The major manufacturer of pregabalin and gabapentin referred to above** also expressed its broad concern that any consideration of scheduling the two substances under the 2001 Regulations "should take into account the extensive clinical use [and] the nature and size of the underlying patient population that will also be affected, the scope of unintended harms…and the limited treatment selection of alternative treatment options for neuropathic pain…".

Question 2: Do you agree with the impact assessment of option 1?

18. Thirty-six per cent (175) of those who responded to the online consultation and 13 per cent (6) of those who replied by email and written responses agreed with the impact assessment of option 1. This compared with 44 per cent (211) of those who responded online and 52 per cent (24) of email and written responses who did not agree with the assessment. Thirteen per cent (65) of online responses stated, 'don't know', while none of the responses submitted by email or in writing responded

accordingly. Seven per cent (32) of online responses did not provide an answer while 35 per cent (16) of email and written responses were unclear or no answer was provided. Among the responses were concerns that the Impact Assessment did not quantify the 'significant costs' to pharmacies that would arise as a result of option 1 and that it did not fully consider the lack of storage space in many pharmacies.

Question 3: Are you aware of any other impact on healthcare professionals, institutions or industry?

19. Fifty-three per cent of online (256) and 59 per cent (27) of email or written responses stated that they were aware of other effects on these bodies. One response, from a physio therapist, suggested that once the substances were controlled under the 1971 Act, only a physiotherapist supplementary prescriber would be able to prescribe the substances using a written Clinical Management Plan. Twenty-six per cent (124) of those who responded online stated that they were not aware of any other impact, compared with four per cent (2) of email and written respondents. Fourteen per cent (68) of online responses stated 'don't know'. Seven per cent (35) of online responses provided no answer, while 37 per cent (17) of email or written replies were unclear. Some respondents raised concerns about financial costs associated with obtaining new control drug cabinets for community pharmacies and hospital wards.

Question 4: To help inform the full impact assessment, please quantify the additional cash cost per month of this proposal to you and your organisation.

20. 20 per cent (95) of online respondents to the consultation and seven percent (3) of respondents who replied by email or in writing stated that this would be between £0-£99. Eight per cent of online respondents (37), thought that it would be between £100-£199; and five per cent of online responses (26) thought that it would be between £200-£299. There were no written or email responses for either of these ranges. Five per cent (25) of online responses indicated a cost of £300-£399, while two per cent (1) of written and email responses suggested that range. Four per cent (17) of online responses indicated a cost between £400-£499, compared with two per cent (1) of email and written responses. Eleven per cent (54) of online responses and two per cent (1) of email and written responses indicated a range between £500-£1000. The biggest group in both cases indicated a cost per month of over £1000. This was 29 per cent (140) of online respondents and 26 per cent (12) of those responding by email or in writing. Eighteen per cent (89) of online respondents provided no answer. A much higher percentage of responses by those who provided written or email responses, 61 per cent (28), were either unclear or did not provide an answer. Again, where respondents provided written comments on this section, these tended to stress that the main cost would be buying and installing a controlled drug safe.

21. Where specific comments and cost estimates were made, these varied. For example, the **Pharmaceutical Services Negotiating Committee** estimated on the basis of a sample it conducted of its pharmacies that 90 per cent of the 11,700 NHS pharmacy

contractors might require an additional drugs safe costing in the range of £300-£800. The response added that in addition to this would be installation costs which could increase the total cost to up to £2,000 per pharmacy. It added that there would be other costs resulting from safe custody requirements for wholesalers which were often passed onto pharmacies. One pharmaceutical company, estimated the combined costs from option 1 to each of its sites to be between £500-1000 per site per month.

Question 5: Do you agree that healthcare organisations or businesses will be able to accommodate pregabalin and gabapentin in current compliant safes?

22. The majority of responses, both online and by email or in writing did not think that organisations would be able to accommodate the drugs in existing safes. Respectively these were 66 per cent (318) and 54 per cent (25). Only 15 per cent (71) of online respondents thought that the existing safes were sufficient, and only four per cent (2) of written and email responses agreed. Twelve per cent (60) of online respondents stated 'don't know' while seven per cent (34) of online respondents did not answer the question. Forty-one percent (19) of written and email respondents did not answer or provided an unclear answer. None of the email or written replies stated 'don't know'.

23. The **British Medical Association** felt that existing compliant safes or medicine cupboards would be inadequate for the volume of medications needed in some GP dispensing practices, for example rural premises. The **Company Chemists' Association** stated that as pregabalin and gabapentin came in a range of strengths and formulations which resulted in different package sizes, and given the frequency of prescribing, that the CD cabinets in community pharmacies would not be capable of holding the quantities needed.

Question 6: Do you agree with the impact assessment of option 2?

24. Forty-seven (227) per cent of online respondents and 20 per cent per (9) of written or email responses agreed with the Impact Assessment (IA). Twenty-one per cent (102) of online respondents and 33 per cent (15) of email and written responses did not agree with it. Twelve per cent (56) of online respondents indicated 'don't know' while no responses by email or in writing replied to that effect. Twenty per cent (98) of online responses provided no answer to the question compared with 48 per cent (22) of written and email responses who either provided no answer or whose response was unclear. A few of the comments from all forms of responses expressed the view that they did not think that the IA fully appreciated the effect on GPs and prescribers.

25. **A major manufacturer of the two substances** in its response, thought that even without safe custody requirements that there would be significant additional costs throughout the dispensing supply chain and thought that the measure would affect 1.25 million packs of pregabalin and gabapentin per month which would create a burden to wholesalers and pharmacies. **Community Pharmacy NI** stated in its response that it thought that there would be an increase in community pharmacy

workload as a result of the new controls associated with the supply of Schedule 3 drugs. The **Welsh Pharmaceutical Committee**, preferring option 3, thought that the prescription requirements under Option 2 would mean that electronic prescribing would not be possible.

Question 7: 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?

26. per cent (135) of online responses stated that they were aware of other things that would have an effect on healthcare professionals, institutions or industry, compared with 39 per cent (18) of email and written responses. Among these included a view from the **Pharmaceutical Services Negotiating Committee** that option 2 would require existing electronic prescriptions to be transferred to hard copy and paper prescriptions and new prescriptions to be handwritten or made in hard copy. The **Company Chemists' Association** thought that CD prescribing requirements could result in delayed or omitted doses for patients where there were prescription errors. Thirty-five per cent (168) of online responses and nine per cent (5) of email and written responses responded that they were not aware of any other impact. Fifteen per cent of online responses (73) stated that they 'didn't know' compared with two per cent (1) of email and written responses. Twenty-two per cent of online responses (107) did not provide a response while 50 per cent (22) of email and written responses either did not respond or their response was unclear.

Question 8: 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?

27. Thirty-four per cent (164) of on-line respondents and four percent (2) of written and email responses estimated that it would cost between £0-£99 a month. The overall percentage of those who responded with estimated costs that ranged between £100-£1000 was low. Five per cent (26) of online respondents thought that the costs would be between £100-£199. There were no responses from those responding by email or in writing indicating any costs in the regions of £200-£299 and £300-£399. For online responses, four per cent (20) thought there would be a cost between £200-£299, and three per cent (14) between £300-399. One per cent (6) of online responses thought that there would be costs of between £400-£499 a month, compared with four per cent (2) of online responses. Just over two per cent (11) of online responses thought that there would be costs between £500-£1000 a month as a result of option 2, with no email or written replies indicating costs between those amounts. Seventeen per cent (80) of online responses thought that there would be a cost of over £1000 a month. This compared with 13 per cent (6) of email and written responses. A significant percentage, 33 per cent (162) of online responses did not answer the question while

78 per cent (36) of email or written responses either provided no reply or their response was unclear.

28. A number of online responses which indicated that costs would be over £1000 per month, stated that it was difficult for them to estimate the costs. **Community Pharmacy NI** stated that the cost would be significantly less than option 1 and that the main cost associated with the additional workload would relate to increased governance requirements. A number of responses stated that much depended on the size and staff number of the organisation, particularly for community pharmacies.

Question 9: Do you agree with the impact assessment of option 3?

29. Forty-three per cent of online respondents (207) and 26 per cent of email and written responses (12) indicated that they agreed with the impact assessment of option 3. This compared with 19 per cent (93) of online responses and 22 per cent (10) of email or written responses who did not agree. Fifteen per cent (71) of online responses indicated 'don't know', compared with two per cent (1) of email and written responses. Twenty-three per cent (112) of online respondents did not answer the question while 50 per cent (23) of email and written responses either did not provide an answer or were unclear.

30. There was a variety of reasons given by those who indicated that they disagreed with the impact assessment. These included views from some that the substances should not be controlled at all to comments expressing concern that scheduling under Part 1 of Schedule 4 was not stringent enough. One online respondent stated that "at least with option 3, there is less burden on community pharmacies and GPs than there would be with option 1 and 2". **The Cheshire and Wirral Local Pharmaceutical Committee** stated that while option 2 was its preferred choice, option 3 would have the least impact on community pharmacies. The **BMA** reflected the views of those that expressed concern about the viability of option 3 stating that, "[we] do not believe that this option would effectively tackle the harms of pregabalin and gabapentin [and] agree with the assessment that option 3 would produce limited benefits compared to the other options".

Question 10: Are you aware of any other impact on healthcare professionals, institutions or industry, including those resulting from application of drug controlled licensing requirements, or costs associated with prescription forms, as a result of option 3?

31. Ten per cent (49) of online responses stated that they were aware of other impacts. Many of these comments were short and either did not provide additional detail or referred to comments made earlier in their reply without specifically responding to the question. Of those who commented, a number expressed support for option 3 stating that they thought it would result in the least change from the existing position. Equally, there were comments expressing concern that the option would not provide sufficient safeguards to prevent diversion. This compared with 20 per cent (9) of written and

email responses. per cent (230) of online responses stated that they were not aware of any other effect compared with 15 per cent (7) of online and written responses. Eighteen per cent (87) of online responses answered, 'don't know' [if there was any other effect] compared with four per cent (2) of online and written responses. Twenty-four percent (117) of online respondents did not provide an answer, while 61 per cent (28) of email and written responses provided either no answer or were unclear in their response.

Question 11: to help inform the impact assessment, please quantify the additional cash cost per month of option 3 to you and your organisation. Please provide details of cost per month.

32. Forty-five45 per cent (217) of online respondents indicated a cost of £0-£99 compared with nine per cent (4) of email and written responses. Four percent (19) of online responses suggested a cost of £100-£199; one per cent (5) of online responses suggested £200-299; and half a per cent (2) stated £300-399. There were no returns for those three cost brackets for email or written responses. One per cent (5) of online responses stated a cost of £400-£499. This compared with two per cent (1) of email and written responses. Just under one per cent (4) of online respondents stated a cost between £500-£1000, while no email or written responses returned that cost. Ten per cent (50) of online responses indicated a cost above £1000 a month. This compared with seven per cent (3) of email and written responses. A relatively high percentage, 37 per cent (181), of online responses provided no answer and a very high proportion of email and written responses either provided no answer or an unclear answer, 83 per cent (38).

Question 12: In your and your organisation's view, how much lead time is necessary for implementation if option 1 is adopted?

33. Seven per cent (34) of online responses, but no email or written responses, indicated that they thought a one month lead-in time would be sufficient. Twelve per cent (59) of online responses thought that a 3 three months lead-in time would be necessary. This compared with seven per cent, (3) of email and written responses. Fifty-two per cent (252) of online responses thought that it would take six months. This compared with 43 per cent (20) of email and written responses. The consultation document did not provide a 'don't know' option, so none of the respondents to the online survey stated 'don't know', but of the email and written responses two per cent (1) stated 'don't know' in additional text. Twenty-nine per cent (138) of online responses did not answer the question while 50 per cent (22) of email and written responses were unclear or did not provide an answer.

Question 13: In your and your organisation's view, how much lead time is necessary for implementation if option 2 is adopted?

34. Twenty-two per cent of online responses (106) stated that they thought one month's lead-in time would be needed, compared with only two per cent (1) of email and written responses. Thirty per cent on online responses (146) thought three months would be necessary, compared with 21 per cent (10) of email and written responses. Eighteen per cent of online responses (87) thought that six months would be needed compared with 30 per cent (14) of email and written responses. No responses to the online survey, nor those made via email or written responses, stated 'don't know', but 30 per cent of online responses (144) did not provide an answer. This compared with 46 per cent (21) of email and written responses whose response was either unclear or for which no response was provided.

Question 14: In your and your organisation's view, how much lead time is necessary for implementation if option 3 is adopted?

35. Forty-three per cent (209) of online respondents and 17 per cent of email and written responses (8) thought it would take one month. This compared with 19 per cent (91) of online respondents who thought that it would take three months, with 24 per cent (11) of email and written responses agreeing. Six per cent (30) of online responses thought this option would take six months to implement with nine per cent (4) of email and written responses agreeing. Thirty-two per cent (153) of online responses provided no response with 50 per cent of email and written responses providing either no answer or one that was not clear.

Conclusion

36. The Government is grateful for the views of those who responded to the consultation. 53 per cent of respondents indicated a preference for option 2, control under Schedule 3 to the 2001 Regulations but without the requirements to store the substances in controlled drugs cabinets. The Government has acknowledged the concerns about costs that many respondents raised in relation to option 1. It notes that while option 1 would provide the highest level of protection to prevent diversion and misuse, that the effect of the application of safe custody requirements would be disproportionate and result in considerable costs owing to the need to buy and install new controlled drug cabinets in many organisations.

37. While those who are legitimately prescribed the drugs will have a slight burden of having to renew their prescription via their GP or prescriber once their prescribed dose is used up (roughly, every 30 days), the Government is satisfied that option 2 will provide sufficient safeguards to prevent diversion without imposing a disproportionate burden on those most affected by the changes including prescribers and pharmacists. This will ensure that there are specific prescription writing requirements that have to be met, such as dose, form and strength. These measures, together with record keeping requirements that also apply, will help to reduce illicit diversion.

38. The Chief Inspector of Prisons highlighted in a recent report that the diversion of prescription drugs, including gabapentin and pregabalin were taking place in high security and vulnerable prisoner populations. Applying the provisions of option 2 will ensure that there are record keeping provisions and protocols in relation to both pregabalin and gabapentin. The measure will also help to ensure that there are penalties for those who supply the two substances illicitly once controlled[5].

39. In relation to option 3, while 25 per cent of respondents were in favour of the option, the Government is mindful of the concerns raised about the lack adequate safeguards in Part 1 of Schedule 4 to the 2001 Regulations to prevent the diversion of both substances.

40. In response to concerns that were raised about the electronic prescription service not applying to controlled drugs, while there would be a requirement for patients to return to their GPs for further prescriptions, and for additional work by pharmacy staff and GPs (given that repeat prescriptions are not possible for schedule 3 drugs), we believe that this is a proportionate requirement to prevent stockpiling of the drugs and thus the possibility of diversion. There remain plans to introduce a pilot to expand the application of the EPS to schedule 2 and 3 drugs[6].

41. On balance, the Government is of the view that option 2 - to schedule the drugs under Schedule 3 to the 2001 Regulations but without the safe custody requirements - provides appropriate and necessary safeguards while ensuring that there are not unduly onerous storage requirements for pharmacists, wholesalers and others. Of those who responded to question 8 with estimates about the additional cost per month of option 2 to their organisation, approximately 66[7] per cent indicated that the additional monthly cost of these changes would be between £0-99 per organisation, indicating that the ongoing costs to pharmacies and GPs are unlikely to be substantial.

42. While there might be a degree of initial familiarisation needed as a result of the new changes, these measures would be the same as those brought about when tramadol was brought under control under Class C of the 1971 Act and scheduled under Schedule 3 to the 2001 Regulations but not made subject to the safe custody requirements of the 1973 Regulations. The majority of pharmacies and wholesalers would be familiar with schedule 3 requirements so we would not anticipate an extended period of confusion or uncertainty during this period.

43. For these reasons, the Government deems option 2 to be the most suitable measure to apply to pregabalin and gabapentin.

[5] HMI Prisons response to ACMD request for update on intelligence on the misuse of pregabalin in prisons in England and Wales, February 2015

[6] The Electronic Prescription Service is not available in Northern Ireland

[7] The 66 percentexcludes respondents who indicated that the costs would be over £1000 per month but did not provide an estimate.

Consultation principles

The principles that government departments and other public bodies should adopt for engaging stakeholders when developing policy and legislation are set out in the consultation principles.

https://www.gov.uk/government/publications/consultation-principles-guidance

Annex A – Analysis of responses to the online consultation

1. The consultation document asked three questions about the proposal.

2. Percentages for the questions below are based on the total number of people who clearly answered the questions and have been rounded to the nearest whole number. Responses to unanswered questions have been included the percentage totals.

3. This section relates to both the online survey and the email and written replies .

4. For further information about the analysis of the data, please see Annex C.

Question 1: In light of the risks of diversion from legitimate uses and the harms identified in the ACMD advice, which option do you support?

Response options	Online Response %	Online Response Total	Email/written response %	Email/written response total
Option 1	16%	79	13%	6
Option 2	54%	260	46%	21
Option 3	25%	121	26%	12[8]
None of the Options	0%	0	7%	3
Unclear	5%	23	13%	5
Total response		483		46

[8] One respondent indicated a preference for both options 2 and 3. The total number of respondents was 46 with 47 responses.

Question 2: Do you agree with the impact assessment of option 1?

Response options	Online Response %	Online Response Total	Email/written response %	Email/written response total
Yes	36%	175	13%	6
No	44%	211	52%	24
Don't Know	13%	65	0%	0
No response/ Unclear	7%	32	35%	16
Total response		483		46

Question 3: Are you aware of any other impact on healthcare professionals, institutions or industry?

Response options	Online Response %	Online Response Total	Email/written response %	Email/written response total
Yes	53%	256	59%	27
No	26%	124	4%	2
Don't Know	14%	68	0%	0
No response/ Unclear	7%	35	37%	17
Total response		483		46

Question 4: To help inform the full impact assessment, please quantify the additional cash cost per month of this proposal to you and your organisation.

Response options	Online Response %	Online Response Total	Email/written response %	Email/written response total
£0 - £99	20%	95	7%	3
£100 - £199	8%	37	0%	0
£200 – £299	5%	26	0%	0
£300 - £399	5%	25	2%	1
£400 - £499	4%	17	2%	1
£500 - £1000	11%	54	2%	1
Above £1000	29%	140	26%	12
No response/ Unclear	18%	89	61%	28
Total Response		483		46

Question 5: Do you agree that healthcare organisations or businesses will be able to accommodate pregabalin and gabapentin in current compliant safes?

Response options	Online Response %	Online Response Total	Email/written response %	Email/written response total
Yes	15%	71	4%	2
No	66%	318	54%	25
Don’t Know	12%	60	0%	0
No response/ Unclear	7%	34	41%	19

Total response		483		46

Question 6: Do you agree with the impact assessment of option 2?

Response options	Online Response %	Online Response Total	Email/written response %	Email/written response total
Yes	47%	227	20%	9
No	21%	102	33%	15
Don't Know	12%	56	0%	0
No response/ Unclear	20%	98	48%	22
Total response		483		46

Question 7: 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?

Response options	Online Response %	Online Response Total	Email/written response %	Email/written response total
Yes	28%	135	39%	18
No	35%	168	9%	5
Don't Know	15%	73	2%	1
No response/ Unclear	22%	107	50%	22
Total response		483		46

Question 8: 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?

Response options	Online Response %	Online Response Total	Email/written response %	Email/written response total
£0 - £99	34%	164	4%	2
£100 - £199	5%	26	0%	0
£200 – £299	4%	20	0%	0
£300 - £399	3%	14	0%	0
£400 - £499	1%	6	4%	2
£500 - £1000	2%	11	0%	0
Above £1000	17%	80	13%	6
Unclear	33%	162	78%	36
Total Response		483		46

Question 9: Do you agree with the impact assessment of option 3?

Response options	Online Response %	Online Response Total	Email/written response %	Email/written response total
Yes	43%	207	26%	12
No	19%	93	22%	10
Don't Know	15%	71	2%	1
No response/ Unclear	23%	112	50%	23

Total response		483		46

Question 10: Are you aware of any other impact on healthcare professionals, institutions or industry, including those resulting from application of drug controlled licensing requirements, or costs associated with prescription forms, as a result of option 3?

Response options	Online Response %	Online Response Total	Email/written response %	Email/written response total
Yes	10%	49	20%	9
No	48%	230	17%	8
Don't Know	18%	87	4%	2
No response/ Unclear	24%	117	59%	27
Total response		483		46

Question 11: To help inform the impact assessment, please quantify the additional cash cost per month of option 3 to you and your organisation. Please provide details of cost per month.

Response options	Online Response %	Online Response Total	Email/written response %	Email/written response total
£0 - £99	45%	217	9%	4
£100 - £199	4%	19	0%	0
£200 – £299	1%	5	0%	0
£300 - £399	0.5%	2	0%	0
£400 - £499	1%	5	2%	1

£500 - £1000	1%	4	0%	0
Above £1000	10 %	50	7%	3
No response/ Unclear	37%	181	83%	38
Total Response		483		46

Question 12: In your and your organisation's view, how much lead time is necessary for implementation if option 1 is adopted?

Response options	Online Response %	Online Response Total	Email/written response %	Email/written response total
1 month	7%	34	0%	0
3 months	12%	59	7%	3
6 months	52%	252	43%	20
Don't Know	0%	0	2%	1
No response/ Unclear	29%	138	50%	22
Total response		483		46

Question 13: In your and your organisation's view, how much lead time is necessary for implementation if option 2 is adopted?

Response options	Online Response %	Online Response Total	Email/written response %	Email/written response total
1 month	22%	106	2%	1
3 months	30%	146	21%	10
6 months	18%	87	30%	14
Don't Know	0%	0	0%	0

No response/ Unclear	30%	144	46%	21
Total response		483		46

Question 14: In your and your organisation's view, how much lead time is necessary for implementation if option 3 is adopted?

Response options	Online Response %	Online Response Total	Email/written response %	Email/written response total
1 month	43%	209	17%	8
3 months	19%	91	24%	11
6 months	6%	30	9%	4
Don't Know	0%	0	0%	0
No response/ Unclear	32%	153	50%	23
Total response		483		46

Demographic responses

Respondent type:

Response options	Online Response %	Online Response Total	Email/written response %	Email/written response total
Practitioner (Doctor, Dentist or Vet)	6%	30	7%	3
Pharmacist	48%	233	11%	5
Pharmacy technician	2%	10	0%	0
Other healthcare professional (Nurse, midwife, AHP, paramedic etc)	2%	13	2%	1
Professional/ Regulatory body	3%	16	20%	9
Patient	2%	9	11%	5
Other	13%	64[9]	46%	21
Unclear/no response	22%	108	4%	2
Total Responses		483		46

[9] This includes results for ‘pharmaceutical wholesaler’ and ‘pharmaceutical manufacturer’.

Responses by region:

Response options	Online Response %	Online Response Total	Email/written response %	Email/written response total
England	70%	339	65%	30
Wales	1%	7	2%	1
Scotland	4%	21	2%	1
Northern Ireland	1%	5	9%	4
UK wide	0%	0	9%	4
Unclear/No response	23%	111	15%	6
Total Responses		483		46

Annex B – The consultation process

1. A total of 530 consultation responses were received. This included 484 responses to the online survey and 46 replies by email and post. Two identical responses to the online survey were submitted, presumably in error by the same organisation. For the purposes of analysis we have therefore adjusted the figures accordingly to state that 529 responses were received, consisting of 483 online responses and 46 replies by email or post. All online, email and postal responses referring to the consultation proposal and received during the consultation period were considered.

2. Data from responses to the online survey were recorded and analysed. In cases where a respondent left an answer to one of the questions blank, these responses have been categorised as unanswered. The analysis in Annex A relates to online and written responses. Only online data has been analysed in relation to demographic questions relating to the capacity in which a person or organisation has responded and the region from which they have responded.

3. Percentages have been rounded up to the nearest whole number and therefore totals may not always add up to 100 per cent. Unanswered questions have been excluded from the percentage totals.

4. We have summarised in this document some of the main themes from the online, email and written responses.

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