Title: Control of pregabalin and gabapentin, post consultation review **IA No:** HO0321 **RPC Reference No:** N/A **Lead department or agency:** Home Office **Other departments or agencies:** The Department of Health, The Advisory Council on the Misuse of Drugs	**Impact Assessment (IA)** **Date** October 2018 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** Drugs and Alcohol Unit, Home Office

Summary: Intervention and Options

RPC Opinion: Not applicable

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANDCB in 2014 prices)	**One-In, Three-Out**	**Business Impact Target Status**
-£54m	-£0.1m	£0.01m	Not applicable	Not a regulatory provision

What is the problem under consideration? Why is government intervention necessary?

The number of deaths related to pregabalin and gabapentin have increased in recent years (170 deaths registered in England and Wales in 2016, compared to 139 deaths in 2015 and 64 deaths in 2014), and concerns have been raised by a number of organisations relating to their harms. The Advisory Council on the Misuse of Drugs undertook a review of these substances and found significant evidence of potential harms, recommending that they are controlled under the Misuse of Drugs Act 1971 (the 1971 Act) as Class C substances and scheduled under Schedule 3 of the Misuse of Drugs Regulations 2001 (the 2001 Regulations).

Government intervention is necessary to provide a stronger legal framework to restrict their illicit supply.

What are the policy objectives and the intended effects?

The policy objective is to reduce the harms associated with the misuse of pregabalin and gabapentin in the UK. Law enforcement agencies will be given the necessary powers to do so.

The intended effect is to restrict their illicit supply, while maintaining their availability for healthcare purposes.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1: Do nothing. This would leave both drugs subject to the provisions in the Psychoactive Substances Act 2016 when taken for their psychoactive effect. The Government did not consult on this option.

Option 2: Place pregabalin and gabapentin in class C of the 1971 Act and Schedule 3 to the 2001 Regulations (but exclude application of safe custody requirements). This is the **Government's preferred option.**

Will the policy be reviewed? It will not be reviewed. **If applicable, set review date:** N/A

Does implementation go beyond minimum EU requirements?		N/A		
Are any of these organisations in scope?	**Micro** Yes/No	**Small** Yes/No	**Medium** Yes/No	**Large** Yes/No
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** N/A	**Non-traded:** N/A	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister: Victoria Atkins Date: 12th October 2018

Summary: Analysis & Evidence

Policy Option 2

Description: Place pregabalin and gabapentin in class C of the 1971 Act and Schedule 3 to the 2001 Regulations (but exclude application of safe custody requirements).

FULL ECONOMIC ASSESSMENT

Price Base Year 2018	**PV Base Year** 2018	**Time Period Years** 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low: Optional	**High:** Optional	**-54.0**

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low				
High				
Best Estimate	0.3		6.2	**54.0**

Description and scale of key monetised costs by 'main affected groups'

There will be a familiarisation cost to healthcare professionals who prescribe and take prescriptions for the drugs. The cost to pharmacies is estimated to be £97,000 in year 1, and the cost to GPs is estimated to be £172,000 in year 1. There is an additional dispensing cost to the NHS which is estimated at a present value of £53.7 million over the 10 years of the policy.

Other key non-monetised costs by 'main affected groups'

Prescribers will incur the cost of having to complete a form every 30 days and provide a wet signature to issue prescriptions (but the expectation is that electronic prescriptions will in future be available), while wholesalers will incur costs from record keeping requirements. Police forces, law enforcement agencies and the criminal justice system may also incur costs through the more stringent penalties on supply and production, and the imposition of possession penalties, arising from control under the 1973 Act.

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low				
High				
Best Estimate	Not known		Not known	**Not known**

Description and scale of key monetised benefits by 'main affected groups'

It has not been possible to monetise the benefits of this option due to a lack of data.

Other key non-monetised benefits by 'main affected groups'

This option will reduce the risk of diversion of these drugs, reducing the potential for misuse. As a result, there will likely be benefits to health services, law enforcement and the public. There may also be a reduction in the prescribing of these medicines, which could generate significant cost savings for the health service.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5%

Excluding the application of Safe Custody requirements may mean that the risk of diversion is not fully mitigated.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:						**Score for Business Impact Target (qualifying provisions only) £m:**
Costs:	0.01	**Benefits:**	0.00	**Net:**	-0.01	N/A

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 Background

1. Pregabalin and gabapentin are indicated for the management of a number of conditions including of neuropathic pain, epilepsy, as an adjunct therapy for partial seizures, generalised anxiety disorder.

2. However, the chronic harms of pregabalin and gabapentin include physical dependence. Public Health England (PHE) has issued guidance[1] to state that prescribing pregabalin and gabapentin for patients with a known or suspected propensity to misuse may place such people at greater risks from their usage. As a result, the guidance advises prescribers to carry out a proportionate risk benefit assessment prior to prescribing or issuing repeat prescriptions.

3. As shown in the tables below, the number of prescriptions of pregabalin and gabapentin has increased in recent years. Tramadol has been included in the tables for comparison purposes, as it was also recently made subject to control as a Class C drug under Schedule 3 without safe custody requirements.

Table 1 – Items of pregabalin, gabapentin and tramadol dispensed in England, 2012 to 2017[2]

	2012	2013	2014	2015	2016	2017
Pregabalin	2,730,730	3,349,784	4,086,432	4,801,622	5,547,560	6,253,045
Gabapentin	3,531,887	4,212,289	4,978,915	5,722,990	6,466,482	7,086,846
Tramadol Hydrochloride	7,608,409	7,913,030	7,909,333	7,542,483	7,331,639	6,888,354

4. A number of organisations have raised concerns relating to the harms associated with these substances. For example, PHE have written to prescribers to highlight the potential issues related to their misuse, diversion and dependence problems, while the 2014 DrugScope Street Drug Survey[3] reported the significant use of both drugs mainly among the opioid-using and prison populations. In February 2015 Her Majesty's Inspectorate of Prisons reported findings from health staff that a significant number of prisons had high numbers of prisoners being prescribed pregabalin or gabapentin in a way that did not meet best practice guidelines[4]. Initial concerns about the potential misuse of pregabalin were raised in 2014 by the Health and Social Care Board, who noted that the use of pregabalin in Northern Ireland was significantly higher than in the rest of the UK and highlighted growing misuse and abuse[5].

5. The number of deaths related to these substances has also increased in recent years. Office of National Statistics (ONS) data shows that there were 111 deaths in England and Wales in 2016 where pregabalin was mentioned on the death certificate and 59 where gabapentin was mentioned[6]. This compares with 90 deaths from pregabalin and 49 from gabapentin in 2015, and 38 and 26 respectively in 2014. Statistics from the Northern Ireland Statistics and Research

[1] https://www.gov.uk/government/publications/pregabalin-and-gabapentin-advice-for-prescribers-on-the-risk-of-misuse

[2] http://digital.nhs.uk/catalogue/PUB30014 Trend tables, table 10.

[3] http://www.senedd.assembly.wales/documents/s36166/HSC4-04-15%20Paper%203.pdf

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

[5] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/491854/ACMD_Advice_-_Pregabalin_and_gabapentin.pdf See page 1,

[6] https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/deathsrelatedtodrugpoisoninginenglandandwales/2016registrations#deaths-involving-selected-substances

Agency report *"Drug related and Drug Misuse Deaths 2006-2016"* indicate that there were 8 deaths related to pregabalin in 2016. This is an increase from zero in 2006[7].

6. Following these concerns, the Advisory Council for the Misuse of Drugs (ACMD) undertook a review into the potential harms arising from the misuse of pregabalin and gabapentin. The review was published on the 14th January 2016[8], and found evidence of significant potential harms. The report recommended that both drugs be controlled as Class C drugs under the Misuse of Drugs Act 1971 ('the 1971 Act'), and scheduled under Schedule 3 (see Glossary for further information) of the Misuse of Drugs Regulations 2001 ('the 2001 Regulations').

A.2 Groups Affected

- Healthcare providers.
- Pharmacies.
- Pharmaceutical manufacturers and wholesalers.
- Patients.
- Law enforcement agencies: police forces in England and Wales; Police Scotland; National Crime Agency and Border Force.
- Criminal justice agencies: Crown Prosecution Service; courts and HM Prison and Probation Service.

A.3 Consultation

Within Government

7. The Government consulted the Department of Health and Social Care on the consultation document that was published on 13 November.

Public Consultation

8. Following the recommendations of the ACMD, the Government published a consultation which asked for views about categorising the drugs under Schedule 3 of the 2001 Regulations[9], which ran from 13 November 2017 until 22 January 2018. This considered three options and a baseline option.

Option 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).

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),

Option 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.

9. Around 53 per cent of respondents favoured Option 2, compared with 16 per cent who favoured Option 1 and 25 per cent who favoured Option 3. While Option 1 was the recommendation of the ACMD, concerns were raised in relation to the burdens on pharmacies and wards to obtain new controlled drug cabinets for the storage of these substances if they were made subject to the safe

[7] Statistics from the Northern Ireland Statistics and Research Agency report "Drug related and Drug Misuse Deaths 2006-2016 indicate that there were 8 deaths from pregabalin in 2016.

[8] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/491854/ACMD_Advice_-_Pregabalin_and_gabapentin.pdf

[9] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/491854/ACMD_Advice_-_Pregabalin_and_gabapentin.pdf

custody requirements. This included difficulties that could arise from identifying the drugs given that pack sizes vary according to the dosage/strength of the drugs.

B. Rationale

10. In the ACMD's review into pregabalin and gabapentin, they considered that the harms associated with these substances were equivalent to those of other substances controlled under the 1971 Act, and they therefore recommended that they were controlled as Class C substances under the 1971 Act and scheduled under the 2001 Regulations as Schedule 3, so as not to preclude legitimate use on prescription.

11. This would provide a stronger legal framework compared to the Psychoactive Substances Act 2016 (the 2016 Act), which pregabalin and gabapentin are currently subject to. Control under the 1971 Act includes a possession offence, whereas the 2016 Act does not. The offences in the 2016 Act only prohibit the production and distribution of psychoactive substances to be consumed for psychoactive effect, while control under the 1971 Act offers stricter offences of production and distribution than the 2016 Act under any circumstances without a licence. The maximum penalty for committing an offence involving a Class C drug is 14 years imprisonment. This contrasts with the 7-year maximum sentence under the 2016 Act.

12. These more stringent penalties may prove a stronger deterrent to the supply of these drugs, and may therefore more effectively restrict their availability, reduce the risk of diversion and decrease misuse and deaths. The differences between the 2016 Act and the 1971 Act reflect that drugs controlled under the 1971 Act have been subjected to a full harms assessment by the ACMD and that they are being, or are judged by the ACMD likely to be, misused. In addition to this, the misuse of these drugs is judged by the ACMD to have sufficiently harmful effects to constitute a social problem. The 1971 Act is a more appropriate control mechanism than the 2016 Act where this harm assessment has been made.

C. Objectives

13. The policy objective is to prevent the misuse of pregabalin and gabapentin and reduce the harms associated with the drugs by restricting their illicit supply, while ensuring that they remain available for legitimate use in healthcare.

D. Options

14. **Option 1**: Make no changes (do nothing), leaving both pregabalin and gabapentin subject to the provisions in the Psychoactive Substances Act 2016.

15. **Option 2**: Control pregabalin and gabapentin as Class C Drugs under the 1971 Act, and place both in Schedule 3 to the 2001 Regulations, excluding the application of the 1973 (Safe Custody) Regulations.

16. Option 1 would not address the risks and issues that have been identified with the current control of pregabalin and gabapentin. Option 2 would reduce the opportunities for the two drugs being diverted into the illicit market by the record keeping requirements of Schedule 3 of the 2001 Regulations, without imposing the excessive cost to medical suppliers of the drugs that the 1973 Regulations require.

E. Appraisal (Costs and Benefits)

GENERAL ASSUMPTIONS & DATA

For the purpose of estimating costs, the following prescription data for pregabalin and gabapentin Is used:

Table 2 – Items of pregabalin and gabapentin dispensed in England, Wales, Scotland and Northern Ireland, 2016

	Scotland (2015/16)[10]	England (2016)[11]	Wales (2016)[12]	Northern Ireland (2016)[13]	**Total**
Pregabalin	435,498	5,547,560	400,201	294,060	**6,677,319**
Gabapentin	694,293	6,466,482	506,429	165,759	**7,832,963**
Total	**1,129,791**	**12,014,042**	**906,630**	**459,819**	**14,510,282**

- It is assumed that it will take health professionals five minutes to acquaint themselves with the change in legislation. This is based on the fact that healthcare professionals are likely to already deal with many drugs controlled under the 2001 Regulations, and will be familiar with the new processes for pregabalin and gabapentin.
- Non-wage labour costs are assumed to be equivalent to an additional 21 per cent of wage costs14.
- It is assumed that pharmacies already stock other drugs which are controlled under the 2001 Regulations.
- It is assumed that healthcare professionals already write prescriptions for other drugs which are controlled under the 2001 Regulations.
- It is assumed that the extra cost on pharmacies from having to pick up prescriptions is negligible as this service is already provided for other medicines.

OPTION 2 – Place pregabalin and gabapentin in class C of the 1971 Act and Schedule 3 to the 2001 Regulations (but exclude the application of safe custody requirements)

COSTS

Set-up costs

Businesses

17. There may be a familiarisation cost to prescribers, as they acquaint themselves with the changes to the control of pregabalin and gabapentin. These will already be familiar with the requirements of the 2001 Regulations, as they are likely to hold drugs which are already subject to these regulations. New substances are regularly added to the 2001 Regulations (for example tramadol was controlled under Class C of the 1971 Act and made subject to Schedule 3 to the 2001 Regulations (without safe custody requirements) in 2014), so the amount of familiarisation time associated with this change is likely to be minimal.

[10] http://www.isdscotland.org/Health-Topics/Prescribing-and-Medicines/Community-Dispensing/Prescription-Cost-Analysis/
[11] https://digital.nhs.uk/data-and-information/publications/statistical/prescriptions-dispensed-in-the-community/prescriptions-dispensed-in-the-community-statistics-for-england-2006-2016-pas
[12] https://gov.wales/statistics-and-research/prescriptions-dispensed-community/?lang=en
[13] http://www.hscbusiness.hscni.net/services/1806.htm
[14] https://www.ons.gov.uk/file?uri=/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashetable14/2017provisional/table142017provisional.zip table 14.5, code 711

18. It is assumed that it will take health professionals five minutes to acquaint themselves with the new classification of the drugs. The median hourly wage for pharmacists, taken from the Annual Survey for Household Earnings (ASHE) in 2017 was £20.50[15]. To account for non-wage labour costs, this was up-rated by 21 per cent to give a total hourly cost of £24.73[16]. The familiarisation cost per pharmacist was therefore £2.06 (£24.54 x 5/60). There are estimated to be 47,000 pharmacists in the UK. This gives a total familiarisation cost to pharmacists of £97,000 (47,000 x £2.06)[17]. It should be noted that not all pharmacists are involved in the supply of controlled drugs, so this figure may be an overestimate.

19. The majority of GPs are funded by the NHS, but data suggests that around 5% of GPs undertake some private work. However, it is also possible that these GPs also undertake a combination of private and NHS work. Due to the limitations of the data, it is not possible to quantify the number of GPs that may be affected, but the number is likely to be low. As a proportion of all the costs on GPs , the impact on private business is likely to be less than £10,000.

Public health services

20. There may also be a familiarisation cost to NHS healthcare professionals, such as GPs and hospital staff, who issue prescriptions and supply pregabalin and gabapentin. As above it is assumed to take NHS healthcare professionals five minutes to acquaint themselves with the new classification of the drugs. The median hourly wage for healthcare practitioners is estimated to be £33.52, taken from ASHE. This is up-rated by 21 per cent to account for non-wage labour cost, giving a total hourly cost of £40.44. The cost to each GP is therefore estimated to be £3.37 (£40.44 x 5/60). There are estimated to be 51,000 GPs in the UK[18]; the total familiarisation cost to GPs is therefore estimated to be £172,000 (£3.34 x 51,000).

Law enforcement agencies

21. There may be a familiarisation cost to police forces and enforcement agencies, as their staff become acquainted with the new legal status of pregabalin and gabapentin. Substances are regularly brought under the control of the 1971 Act, so the additional familiarisation costs associated with the control of pregabalin and gabapentin are therefore likely to be negligible.

Ongoing costs

Businesses

22. As a result of this legislation, prescriptions will be limited to 30 days treatment and cannot currently be issued by electronic prescription, due to the requirement of a wet signature. The additional time spent processing these prescriptions imposes ongoing costs, as this time could have been spent on other productive activities. However, the NHS provides an additional payment of £0.43 per item to pharmacies for the dispensing of Schedule 3 substances, to compensate for these higher costs, so it is assumed that there are no significant costs for these businesses as a result of this legislation. In Question 8 of the consultation, respondents were asked to provide an estimate of the costs of these changes. Of the respondents who provided estimates, approximately 66 per cent indicated that the additional monthly cost of these changes would be between £0 to £99 per organisation.

23. There may also be an ongoing cost to wholesalers who deliver pregabalin and gabapentin, as the new regulations require them to keep records of their stock of these drugs, which may take extra time. Due to a lack of data on the additional costs of this record keeping, it has not been possible to quantify this cost.

[15] https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashetable14
[16] http://ec.europa.eu/eurostat/statistics-explained/index.php/Hourly_labour_costs
[17] https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashetable14
[18] 'General practise in the UK – background briefing' British Medical Association, April 2017

Public Sector

24. As a result of this legislation, GPs and other public sector healthcare professionals issuing prescriptions for pregabalin or gabapentin will be subject to more stringent requirements. These requirements are as follows:
    a. Repeat dispensing for Schedule 3 controlled drugs is not permitted, which is likely to cause the number of GP appointments and the number of prescriptions for gabapentin and pregabalin to increase.
    b. The Department for Health and Social Care (DHSC) and the Scottish Government recommend that the maximum quantity of a Scheduled 3 controlled drug prescription should not exceed 30 days. This is likely to cause an increase in the number of GP appointments required, especially if the current prescription lengths for pregabalin and gabapentin exceed this limit. Although it should be noted that a GP appointment will not always be required.
    c. There is likely to be a corresponding increase in GP time spent writing prescriptions to meet the 'wet signature' requirements for Schedule 3 controlled drugs. This may be mitigated in the future if the Electronic Prescribing System (EPS) can be used to prescribe controlled drugs electronically instead.

25. The additional time spent processing these prescriptions imposes ongoing costs, as this time could have been spent on other productive activities. Whilst pharmacists are compensated for these additional costs via an additional payment for each item prescribed, this is not the case for GPs. However, the costs to GPs of these requirements could not be quantified due to a lack of data, for example on the number of GP appointments where pregabalin or gabapentin would be prescribed, and how prescribing behaviour may change as a result of these requirements.

26. There may also be additional costs to the NHS from the time required for staff to supervise doses of pregabalin and gabapentin and to witness the supply of controlled drugs, as these activities are required for Schedule 3 substances. These costs have not been quantified as it is not known how many organisations already undertake these activities.

27. There is an additional cost to the National Health Service as Schedule 3 substances attract an additional dispensing payment of £0.43 per item, as previously identified. As shown in Table 2, in 2016 there was a total of 14.5 million pregabalin and gabapentin items prescribed in the United Kingdom, which equates to an additional cost of the National Health Service of £6.2 million per year as a result of these changes (14.5 million items x £0.43 per items). This is a PV cost of £53.7 million over the 10 years of the policy. It is likely that the number of prescriptions issued will fall as a result of these changes, but it is not known with any uncertainty how much they might fall. In the absence of this information it has been assumed that the volume of prescriptions will remain at its current level, which means that this cost is likely to be an overestimate.

Law enforcement agencies

28. There may be some cost to police forces, law enforcement bodies and the criminal justice system as a result of classifying pregabalin and gabapentin under Class C of the 1974 Act, given the more stringent penalties for supply and production, and the introduction of penalties for possession. However, it is assumed that this enforcement activity would be met using existing resources, so the additional costs are assumed to be negligible.

Patients

29. At present, those with a valid prescription for pregabalin or gabapentin can acquire a number of packages at a time, as the prescription is not limited to use within 28 days. In contrast, the dispensing of Schedule 3 drugs is limited to quantities of not more than 30 days' supply. A separate prescription would have to be sought at the end of that 30-day period, if needed, as repeat dispensing is not possible for Schedule 3 drugs.

30. There may therefore be costs for patients prescribed pregabalin and gabapentin for medicinal use arising from having to visit a their doctor and pharmacy at least every 30 days to obtain their

prescription. This is especially true for people who are not exempt from paying prescription charges. They will have to pay for a prescription each time they go to have it dispensed. There may also be costs to patients from having to physically take the prescription to a pharmacy for dispensing rather than using electronic prescriptions. This cost could not be quantified as it is not known how many additional visits to pharmacies would be required by patients.

BENEFITS

31. Including the drugs under Schedule 3 of the 2001 Regulations requires that due consideration is given to whether a person should be given the drugs in question. There are stringent prescription requirements along with audit processes for Schedule 3 control. Specifically, these are that a prescription requires dosage, a wet signature and private prescriptions must be written on specific forms and be sent for audit similar to NHS and HSCNI prescriptions. As a result, more careful consideration must be given to the decision to prescribe or re-prescribe a person either of the drugs. This may reduce diversion and the number of prescriptions to individuals with potential to misuse, producing benefits to both the patient, the health service and wider society.

Businesses

32. The stricter controls on the availability and storage of pregabalin and gabapentin may reduce the diversion of these substances, and therefore create savings for businesses that supply or prescribe them, as the loss of their stock through diversion is reduced. This benefit could not be quantified due to a lack of data on the amount of diversion that might be avoided.

Public Sector

33. If the changes in the regulations reduce diversion and therefore misuse of pregabalin and gabapentin, there may be savings to health services arising from a reduction in the number of people seeking medical assistance after misusing these substances. Qualitative data from responses to the consultation also indicates that there is likely to be a greater awareness of the dangers of the two drugs as a result of controlling them under the 1971 Act, potentially further reducing misuse and associated harms. There may also be savings to the health service from pregabalin and gabapentin being prescribed less frequently.

34. When tramadol became a Schedule 3 controlled drug in 2014, the number of prescriptions fell by 13 per cent, from 7.9 million in 2014 to 6.9 million in 2017, after significant increases in previous years. This indicates that the changes to tramadol had a considerable impact on reducing the amount prescribed, which may have generated savings for the health service. If the number of pregabalin and gabapentin prescriptions also fell by 13 per cent, then this would generate savings of approximately £34 million per year for the NHS in England (based on the current cost to the NHS of £262 million per year[19]). This provides a broad indication of the level of savings that could be realised, but this benefit has not been included in the Net Present Value as it is not possible to estimate with any certainty, as tramadol has significantly different clinical uses to pregabalin and gabapentin.

Personal and Society

35. If the new regulation reduces the availability and therefore misuse of the two drugs, society may experience a benefit through the reduction in the harmful health and social effects resulting from the misuse of drugs, for example a reduction in the number of deaths related to pregabalin and gabapentin. In 2016 there were 170 deaths registered in England and Wales where pregabalin or gabapentin were mentioned on the death certificate[20], an increase compared to 64 deaths registered in 2014 and 139 deaths registered in 2015. The number of deaths related to tramadol fell after it became a Schedule 3 controlled drug, from 240 deaths registered in 2014 to 184 deaths registered in 2016, although it is not possible to identify how much of this fall was due to the change in controls. These benefits therefore cannot be quantified due to a lack of data.

Total costs and benefits, NPV, BNPV and EANDCB

36. The Net Present Value of the policy is -£54 million, the Business Net Present Value is -£0.1 million and the EANDCB is £0.01 million.

F. Risks

37. **OPTION 1 –** The risk of diversion and subsequent misuse of pregabalin and gabapentin would continue, and the potential harms arising from the misuse of the drugs would continue

38. **OPTION 2 –** Excluding the application of Safe Custody requirements may mean that the risk of diversion is not fully mitigated. The requirement of a wet signature and prescriptions every 30 days may add significant costs to organisations prescribing pregabalin and gabapentin. Some responses to the consultation expressed concern that there might be instances in which a person might run low on supplies of either drug and be at risk of, for example a seizure. However, emergency provisions for pharmacists enable them to supply prescription-only medicines to a patient without a prescription in an emergency at the request of a prescriber of a patient.

[19] https://digital.nhs.uk/data-and-information/publications/statistical/prescription-cost-analysis/prescription-cost-analysis-england-2017

[20] https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/deathsrelatedtodrugpoisoninginenglandandwales/2016registrations

G. Enforcement

39. Enforcement of the legislation will be undertaken by police forces, Border Force, the Home Office Drug Licensing unit and other relevant agencies responsible for enforcing the legislative and regulatory framework for controlled drugs in the UK. Police enforcement will form part of their wide approach to tackling new psychoactive substances as well as other drugs controlled under the 1971 Act. Border Force will enforce import controls by seizing suspected substances at the ports, also as part of their wider customs role. There will be no temporary control measures in law enforcement and regulatory agencies as part of their routine activities.

H. Summary and Recommendations

40. Table H.1 outlines the costs and benefits of the proposed changes.

Table H.1 Costs and Benefits

Option	Costs	Benefits
2	£54.0 million (PV over 10 years)	£N/A (PV over 10 years)
	-There will be a one-off cost of £97,000 from pharmacists becoming familiar with the new policy. -There will be a one off cost of £172,000 from GPs becoming familiar with the new policy. - There will be an ongoing dispensing cost of £6.2 million per year to the national health service, a PV of £53.7 million over the 10 years of the policy. -There will be an non-monetised cost to healthcare professionals, public and private, through the increased time taken to issue prescriptions and supply the drugs with increased record keeping. -There will be an non-monetised cost to wholesale retailers through the record keeping requirements arising from the 2001 Regulations. -There may be an non-monetised cost to police forces, law enforcement and the criminal justice system arising from the enforcement of demand penalties, and more stringent ones for production and supply.	- The provision is likely to restrict the number of unnecessary prescriptions of the two drugs and therefore associated health harms. - It is likely to provide a better audit trail which may reduce the opportunities for diversion into the illicit market. - It may also reinforce public awareness of the harms of both drugs by making clear that this substance is of concern, by classifying it according to harm and providing stricter penalties for offences under the Misuse of Drugs Act 1971.

Source: Home Office internal analysis.

I. Implementation

41. The Government plans to implement the control of pregabalin and gabapentin under the 1971 Act via the affirmative resolution procedure. Any change to the 2001 Regulations is undertaken via the negative resolution procedure Order, subject to Parliament's approval. The DOH (NI) plans to implement the changes via negative resolution, subject to the approval of the Northern Ireland Assembly. It is intend that these changes will come into effect before the end of 2018.

J. Monitoring and Evaluation

42. As part of its statutory duties under the 1971 Act, the ACMD keeps the situation relating to the misuse of drugs under review. Together with the Government, they will continue to monitor pregabalin and gabapentin by reviewing data on its prevalence and misuse. The effectiveness of the new regime would be monitored by the Care Quality Commission for England and the healthcare regulatory bodies for Wales and Scotland. The Health Act 2006 also established the role of Accountable Officers with responsibility to establish and ensure appropriate arrangements to comply with misuse of drugs legislation. Accountable officers have a duty to establish local intelligence networks to analyse prescribing practices in their area and ensure that their areas have processes for establishing an incident panel if serious concerns are raised about controlled drugs.

K. Feedback

43. Information gathered from the monitoring and evaluation process will inform future ACMD advice on the classification, designation and scheduling of pregabalin and gabapentin, including any future legitimate uses of these compounds.

Impact Assessment Checklist

The impact assessment checklist provides a comprehensive list of specific impact tests and policy considerations (as of October 2015). Where an element of the checklist is relevant to the policy, the appropriate advice or guidance should be followed. Where an element of the checklist is not applied, consider whether the reasons for this decision should be recorded as part of the Impact Assessment and reference the relevant page number or annex in the checklist below.

The checklist should be used in addition to HM Treasury's Green Book guidance on appraisal and evaluation in central government.

Economic Impact Tests

Does your policy option/proposal consider…?	Yes/No (page)
Business Impact Target The Small Business, Enterprise and Employment Act 2015 (s. 21-23) creates a requirement to assess the economic impacts of qualifying regulatory provisions on the activities of business and civil society organisations. [Better Regulation Framework Manual] or [Check with the Home Office Better Regulation Unit]	Not in scope of BIT

GLOSSARY

UK Law: The Schedules

The 2001 Regulations determine in what circumstances it is lawful to possess, supply, produce, export and import controlled drugs. The authorised scope of activity will depend on the schedule to which the controlled drug is assigned. There are five schedules. Schedule 1 contains those drugs that are considered to have little or no therapeutic value and are subjected to the most restrictive control. Schedule 5 contains drugs that are considered to have therapeutic value and are commonly available as over the counter medicines.

Schedule 1

Drugs belonging to this schedule are thought to have no therapeutic value and therefore cannot be lawfully possessed or prescribed. These include LSD, MDMA (ecstasy) and cannabis. Schedule 1 drugs may be used for the purposes of research but a Home Office licence is required.

Schedule 2 & 3

The drugs in these schedules can be prescribed and therefore legally possessed and supplied by pharmacists and doctors. They can also be possessed lawfully by anyone who has a prescription. It is an offence contrary to the 1971 Act to possess any drug belonging to Schedule 2 or 3 without prescription or lawful authority. Examples of schedule 2 drugs are methadone and diamorphine (heroin). Schedule 3 drugs include subutex and most of the barbiturate family.

The difference between Schedule 2 and Schedule 3 drugs is limited to the application of the 2001 Regulations concerning record keeping and storage requirements in respect of schedule 2 drugs.

Schedule 4 (i) & (ii)

Schedule 4 was divided into two parts by the 2001 Regulations [as amended by the Misuse of Drugs (Amendment No. 2) Regulations 2012.
Schedule 4(i) controls most of the benzodiazepines. Schedule 4(i) drugs can only be lawfully possessed under prescription. Otherwise, possession is an offence under the 1971 Act.
Schedule 4(ii) drugs can be possessed as long as they are clearly for personal use. Drugs in this schedule can also be imported or exported for personal use where a person himself carries out that importation or exportation. The most common example of a schedule 4(ii) drug is steroids.

Schedule 5

Schedule 5 drugs are sold over the counter and can be legally possessed without a prescription.