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