

Title: Impact Assessment of the control of tramadol and the reclassification of ketamine IA No: HO Lead department or agency: HOME OFFICE Other departments or agencies: DEPARTMENT OF HEALTH, DEPARTMENT FOR BUSINESS INNOVATIONS AND SKILLS AND LAW ENFORCEMENT AGENCIES	Impact Assessment (IA)	
	Date: 07/02/2014	
	Stage: Final	
	Source of intervention: Domestic	
	Type of measure: Primary legislation	
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Summary: Intervention and Options	RPC Opinion: Not in scope	

Cost of Preferred (or more likely) Option			
Total Net Present Value	Business Net Present Value	Net cost to business per year (EANCB on 2009 prices)	In scope of One-In, Two-Out? Measure qualifies as
N/A	N/A	N/A	No N/A

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

The substances to be controlled and reclassified - tramadol and ketamine - under the Misuse of Drugs Act 1971 are considered sufficiently harmful when misused, following assessment and advice from the Advisory Council on the Misuse of Drugs, to warrant control measures relating to possession, supply, manufacture and import/exportation with associated criminal sanction.

Government intervention is necessary to help protect the public from the potential harms of these substances whilst ensuring their availability for use in healthcare.

What are the policy objectives and the intended effects?

The policy objective is to protect the public from the harms posed by these drugs.

The intended effect is to deter diversion and therefore restrict the misuse of these substances.

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

Option 1 : No change

Option 2 : Control tramadol as a Class C and a Schedule 3 drug, and reclassify ketamine as a Class B drug under the Misuse of Drugs Act 1971, and the Misuse of Drugs Regulations 2001 respectively.

Option 2 is the preferred option. It provides an appropriate level of control with corresponding criminal sanctions for unlawful possession production, supply etc, whilst at the same time enabling access to these drugs for use in healthcare under an effective framework that prevents diversion and misuse.

Will the policy be reviewed? It will/will not be reviewed. If applicable, set review date: Month/Year					
Does implementation go beyond minimum EU requirements?				Yes / No / N/A	
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.		Micro No	< 20 No	Small No	Medium No
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)				Traded:	Non-traded:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible Minister: _____ Norman Baker _____ Date: 26 February 2014

Summary: Analysis & Evidence

Policy Option 2

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	High: N/A	Best Estimate: N/A

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A	N/A	N/A
High	N/A	N/A	N/A
Best Estimate	N/A	N/A	N/A

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

There are no monetised costs associated with this policy.

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

This measure is expected to impose some limited costs on practitioners who will have to sign tramadol prescriptions and on law enforcement agencies from enforcing these measures. These costs have not been monetised due to a lack of available data.

BENEFITS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	N/A	N/A	N/A
High	N/A	N/A	N/A
Best Estimate	N/A	N/A	N/A

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

There are no monetised benefits associated with this policy.

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

Stricter control of these drugs is expected to reduce the risk of crime and health harms faced the public sector and individuals. We are not able to monetise these benefits.

Key assumptions/sensitivities/risks

Discount rate (%) 3.5%

There is a risk that the control of these substances will lead to new, uncontrolled substances appearing on the market. This risk is mitigated by the ACMD's continual review of the situation regarding both controlled and non-controlled drugs.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: N/A	Benefits: N/A	Net: N/A	No	N/A

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 Background

A.1a – Tramadol (from ACMD report¹)

1. Tramadol is a synthetic analogue (differing from the natural compound in both form and function) of the phenanthrene alkaloid codeine. It is an opioid used in medicine for treating moderate to severe pain. It has wide ranging applications, including the treatment of fibromyalgia (chronic widespread pain), cancer pain and moderate to severe musculoskeletal pain.
2. The Advisory Council on the Misuse of Drugs (ACMD), the Government's statutory advisory body on drug issues, reviewed² the harms associated with the non-medical use of tramadol, prompted by an increasing number of reports within the NHS of tramadol's misuse and harms. The ACMD's subsequent review of the evidence confirmed an increase in Defined Daily Doses (England)³, from approximately 5.9 million in September 2005 to 11.1 million in September 2012, and an increase in deaths where tramadol is mentioned as a contributory factor (that is, deaths where tramadol was implicated in the death, was mentioned as the sole agent implicated in the death, or where tramadol was implicated but was not prescribed or the route of supply was 'not known').
3. On 26th February 2013 the ACMD published its advice on tramadol following conclusion of its considerations. The ACMD advises that tramadol should be controlled as a class C substance under the 1971 Act, and listed in Schedule 3 to the 2001 Regulations, which it considers would provide the correct controls to prevent diversion and misuse, including stricter requirements for prescribing, supplying and storing the drug.
4. The ACMD report noted "*that in the absence of evidence from clinical practice, the ACMD is unclear whether the prescription requirements associated with Schedule 3 could present further burden for prescribers.*" The ACMD therefore recommended that the Home Office should consult with health and social care practitioners on the impact of Schedule 3 (Regulation 15) requirements to ensure any change is proportionate to the harms and risk of diversion outlined in their report⁴.
5. The consultation on the appropriate schedule in which to place tramadol concluded in October 2013. A summary of the consultation response is to be published alongside the legislative instrument and impact assessment.

A.1b – Ketamine (from ACMD report⁵)

6. Ketamine is a synthetic drug commonly used in medical and veterinary practice. It is used as a dissociative anaesthetic and a pain reliever. The ACMD first considered ketamine in 2004 and following its advice ketamine was brought under Class C control in 2006.
7. The ACMD reviewed its advice on ketamine following commissioning by the Home Secretary in 2012 informed by increasing concerns around evidence of chronic toxicity and irreversible bladder damage⁶.

¹ ACMD, 2013, <https://www.gov.uk/government/publications/acmd-advice-on-tramadol>

² ACMD, 2013, <https://www.gov.uk/government/publications/acmd-advice-on-tramadol>

³ The Defined Daily Doses (DDD) is a measure of prescribing volume maintained by the World Health Organisation (WHO) based upon international prescribing behaviour. It represents the assumed average maintenance dose per day for a drug used for its main indication in adults. The DDD is not a recommended dose but an analytical unit to compare prescribing activity.

⁴ <https://www.gov.uk/government/publications/acmd-advice-on-tramadol>

⁵ <https://www.gov.uk/government/publications/ketamine-report>

⁶ <https://www.gov.uk/government/publications/ketamine-report>

8. The ACMD reported that the evidence of harms from the misuse of ketamine has developed over the years. These are reported as increased heart rate and cardiac output, high blood pressure – with potentially dangerous effects for people with diseases of the cardiovascular system including those with coronary artery disease, irregularities of heart rhythm, and in individuals at risk of stroke – and hallucinations and experiences of alternate realities similar to those found in schizophrenia associated with long term ketamine misuse.
9. In addition to the harms identified in 2004, regular ketamine use is now also known to be associated with a range of chronic problems including chronic bladder and other urinary tract pathology, gall bladder, gastrointestinal, central nervous system and kidney damage.
10. The ACMD reports that there is less data available on social harms associated with ketamine use than with drugs such as heroin or cocaine. However, it identifies the social harms from ketamine misuse as negative impact on families, social skills and participation in social activities. Large doses of ketamine are also known to induce dissociation – intense detachment that can be unpleasant and frightening and can put the user in a position of vulnerability to robbery, assault or rape. The number of deaths where ketamine is mentioned as present has also seen a rise in the past two years (11 in 2011 and 12 in 2012) following a drop from 15 in 2009 to 6 in 2010.
11. The ACMD therefore recommended that ketamine should be reclassified as a Class B drug, and subject to a public consultation to assess impact on healthcare, a Schedule 2 drug under the 2001 Regulations. As ketamine is already controlled and scheduled, the Government accepted the advice in principle. The advice on reclassification is being implemented immediately with the intention to reschedule ketamine appropriately at a later date following a public consultation to be held in the summer.

A.2 Groups Affected

12. Groups affected are healthcare professionals, patients, pharmaceutical manufacturers and wholesalers, and the health sector.

A.3 Consultation

Within Government

13. The ACMD and the Department of Health have been consulted.

Public Consultation

14. Proposals to schedule tramadol under the 2001 Regulations were the subject of a Home Office consultation last year (2013). A separate consultation on scheduling proposals for ketamine is due in the summer.

B. Rationale

15. The misuse of drugs imposes a high cost on society in terms of crime and health services. Consumption also imposes health costs on the users themselves. The market does not take into account the costs that misuse of these drugs imposes on society. Government intervention is therefore necessary to prevent the listed compounds from being diverted from legitimate use and to protect the public from their harmful effects.

C. Objectives

16. The objective is to protect individuals and society from the harmful effects of dangerous or otherwise harmful drugs in support of the overarching aim of UK drugs laws. Tramadol and ketamine present a risk of dependence and misuse.

17. Successful outcomes would be a reduction in the risk of diversion and therefore misuse of these drugs with a consequential reduction in the risk of harms from misuse to the public.

D. Options

Option 1 - to make no changes (do nothing).

18. This option is not acceptable to Government nor was it supported by ACMD advice. The UK Government would not be acting to protect the public from the potential harms associated with the diversion and misuse of these substances if this option is adopted.

Option 2 - to control tramadol as a Class C drug and a Schedule 3 drug, and reclassify ketamine as Class B drug, under the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001 respectively.

19. This option is proposed to Parliament as the Government's preferred option and is supported by the ACMD's advice. Controlling these drugs in the manner proposed will ensure that the UK Government will be acting to support its overarching aim on drugs - to protect the public from the potential harms associated with these drugs. This proposal will also ensure the safe provision of medicines to patients through the regulatory and governance framework on controlled drugs.

E. Appraisal (Costs and Benefits)

GENERAL ASSUMPTIONS & DATA

Assumptions

1. The vast majority of prescribers (NHS and private) will use computer generated prescriptions.
2. While controlled drugs require different prescription pads to those required for ordinary medicines, these will simply replace existing prescription pads and will not impose new costs.
3. Electronic prescribing will be replaced by arrangements such as pharmacy pick up of prescriptions from practices. This is not expected to impose any further costs as this service is currently offered free of charge by pharmacies for other medicines.
4. The economic and social costs of drug supply in the UK are estimated at £10.7 billion⁷. However, the calculation of these costs is constrained by the scarcity of available data.

OPTION 2 – control tramadol as a Class C drug and a Schedule 3 drug, and reclassify ketamine as Class B drug

COSTS

Business

20. Manufacturers require licences to produce, possess and supply Schedule 3 drugs. However, the manufacturers of these drugs will already be in possession of the requisite Home Office licence for the other drugs within these schedules⁸. This measure therefore imposes no new licensing costs.
21. As a Schedule 3 drug all prescriptions for tramadol have to comply with regulation 15 of the Misuse of Drugs Regulations 2001, which sets out the information to be provided on such prescriptions. With the exception of a wet signature, all other requirements on a prescription for tramadol can be computer generated. The impact from prescribing is therefore limited to the time used to sign the prescription by the prescriber. As there is no information readily available on the number of tramadol prescriptions in the UK, we are not able to monetise this cost.

⁷ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/246390/horr73.pdf

⁸ Our records confirm that all manufacturers of these drugs already possess Home Office licences.

Public Sector (enforcement agencies, CJS, regulators)

22. The law enforcement response to this measure would involve using intelligence to tackle supply and trade and disrupting criminal activities relating to these drugs. Since these activities are currently used to tackle other controlled drugs, most costs arising from option 2 will be subsumed into current law enforcement and regulatory activities. The law enforcement response will be managed within existing resources, informed by policy and operational prioritisation. The police and other law enforcement agencies will prioritise resources towards tackling crime, including drug related crime, with a focus on those offences which cause the most harm. As such, operational activity may focus on Class A and B drugs as well as new psychoactive substances. There may be some additional costs associated with enforcing this measure but we are unable to quantify this due to a lack of available data.
23. Some costs are expected to be faced by the public sector in relation to prescribing and storing tramadol and ketamine, as outlined under costs to business. However, we are not able to quantify these costs due to a lack of available data.

Individuals and society

24. No private costs will be incurred by people who currently use ketamine as the drug will continue to be available under medical prescription as a Schedule 4 Part 1 drug. Private costs will be incurred by people who can no longer legitimately purchase tramadol on the internet. We are unable to monetise these costs.

BENEFITS

Business

25. No benefits are expected to accrue to businesses from this policy.

Public Sector (health services, enforcement agencies, CJS, regulators)

26. Benefits accruing to the public sector arise from savings to be made through a reduction in the number of people seeking medical assistance due to the misuse of these substances. These savings cannot be quantified due to the novelty of the substances in relation to long-term/chronic use and the novelty of the challenges that they pose to healthcare and treatment services in light of the harms that they can cause.

Personal and society

27. Private benefits arise from the protection against potential harms from the misuse of tramadol and ketamine. Society will be protected against possible social harms (including crime and health service costs) resulting from people who misuse tramadol and ketamine.

ONE-IN-TWO-OUT (OITO)

28. This proposal does not create new regulation- rather, it adding new drugs to an existing regulatory framework. This policy is therefore not in scope of one-in-two-out.

F. Risks

OPTION 2 – to control tramadol as a Class C drug and a Schedule 3 drug, and reclassify ketamine as Class B drug.

29. There is a risk that the control of these substances will lead to new, uncontrolled substances appearing on the market. This risk is mitigated by the ACMD's continual review of the situation regarding both controlled and non-controlled drugs.

G. Enforcement

30. Enforcement of the proposed legislation will be undertaken by Police Forces, the UK Border Force, the Home Office Drug Licensing Unit and other relevant Agencies responsible for enforcing the legislative and regulatory framework in the UK. Police enforcement will form part of their wider approach to tackling new psychoactive substances as well as existing drug controlled under the 1971 Act. UK Border Force will enforce import controls by seizing suspected substances at the ports, also as part of their wider import control role.

H. Summary and Recommendations

The table below outlines the costs and benefits of the proposed changes.

Option	Costs	Benefits
2	This policy is expected to impose some limited costs on practitioners who will have to sign tramadol prescriptions and on law enforcement agencies from enforcing these measures. These costs have not been monetised due to a lack of available data.	Stricter control of these drugs is expected to reduce the risk of crime and health harms faced by the public sector and individuals. We are not able to monetise these benefits due to a lack of available data.

31. The harms associated with the use and misuse of tramadol and ketamine requires government to act through effective legislation to prevent their diversion and misuse, in order to protect the public, whilst enabling legitimate access for use in healthcare. There are benefits to be derived from implementing the proposal through a reduction in the harms and medical needs associated with misuse of these drugs.
32. Option 2 provides an effective framework for drugs that are considered dangerous or otherwise harmful when misused.

I. Implementation

33. The Government plans to implement these changes via an Affirmative Order and a negative instrument in May 2014 subject to Parliamentary approval.

J. Monitoring and Evaluation

34. 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 within their area and ensure their areas have processes for establishing an incident panel if serious concerns are raised about controlled drugs.

K. Feedback

35. This will be fed back into future ACMD considerations to inform advice for instance on rescheduling or reclassification etc to address any further risks identified.