Title: IMPACT ASSESSMENT OF SUBJECTING METHOXETAMINE TO TEMPORARY CONTROL **IA No:** HO **Lead department or agency:** HOME OFFICE **Other departments or agencies:** DEPARTMENT OF HEALTH, DEPARTMENT FOR BUSINESS INNOVATIONS AND SKILLS AND ENFORCEMENT AGENCIES	**Impact Assessment (IA)** **Date:** 29/03/12 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Primary legislation **Contact for enquiries**: Joseph Ponan (Telephone: 0207 035 6069) (Joseph.Ponan@Homeoffice.gsi.gov.uk

Summary: Intervention and Options

RPC Opinion: RPC Opinion Status

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, One-Out?**	**Measure qualifies as**
£m	£m	£m	No	NA

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

Methoxetamine, an analogue of Class C ketamine, has been assessed by the Advisory Council on the Misuse of Drugs (ACMD) as a sufficiently harmful drug to warrant control as a temporary class drug under Section 2A of the Misuse of Drugs Act 1971. Government intervention is necessary to take early action on methoxetamine, in order to prevent it from gaining a foothold in the UK drugs market and to protect the public from its immediate harms, while the ACMD undertakes a full assessment of the substance for consideration for its permanent control under the 1971 Act.

What are the policy objectives and the intended effects?

The policy objective is to take early action by legislating quickly, through the use of the power to invoke a temporary class drug order on methoxetamine for up to 12 months. The intended effect is to deter misuse, curb availability via suppliers 'self-regulating' following control and enable law enforcement agencies to take appropriate action to tackle unauthorised production, supply and import/exportation.

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

Option 1 : Do nothing
Option 2 : Make a temporary class drug order under the Misuse of Drugs Act 1971 on methoxetamine and its simple derivatives.

Option 2 is the preferred option due to the harms associated with methoxetamine misuse.

Will the policy be reviewed? It will 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** Yes	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
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: Lord Henley Date: 29th March 2012

Summary: Analysis & Evidence

Policy Option 1

Description: No temporary class drug order invoked.

FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:**

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

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

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

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				**NK**

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

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

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

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs:	**Benefits:**	**Net:**	Yes/No	IN/OUT/Zero net cost

Summary: Analysis & Evidence

Policy Option 2

Description: Make a temporary class drug order under the Misuse of Drugs Act 1971 on methoxetamine and its simple derivatives.

FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low:	**High:**	**Best Estimate:** NK

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

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

It is not possible to monetise the costs of this option from existing data as there are very few robust data currently available on prevalence and use. Potential costs to the research sector of this option cannot be quantified at this time in the absence of baseline figures. No cost if existing licence is suitable (i.e. for activities with same schedule drugs); an upgrade to a Schedule 1 licence for supply and production costs £1,371; a whole new licence costs £3, 655 to £4,700.

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

Potential costs fall to the police, the criminal justice system and other enforcement partners. However, without baseline figures of prevalence, these cannot be quantified at this time. There are no known additional administrative costs to the research sector in relation to methoxetamine under the current framework within which legitimate activities are regulated. Methoxetamine has no known legitimate use in the UK.

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

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

It is not possible to monetise the benefits of this option in light of current data availability.

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

Invoking temporary control measures aims to curb the availability and harms of methoxetamine and its misuse at an early point, limiting associated costs on enforcement and treatment, and will therefore have potential benefits across Government and society as a whole. Listing methoxetamine as a temporary class drug will enable enforcement activities for the duration of that temporary class drug order. The public will be protected against the potential harm of methoxetamine and its misuse for up to 12 months', while the ACMD undertakes a full assessment for consideration for its permanent control under the 1971 Act.

Key assumptions/sensitivities/risks

None.

Discount rate (%)

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			**In scope of OIOO?**	**Measure qualifies as**
Costs:	**Benefits:**	**Net:** 0	No	NA

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 Background

This Impact Assessment assesses the proposal to make a temporary class drug order on methoxetamine and its simple derivatives (salts, esters, ethers, stereoisomeric forms and preparations) under the Misuse of Drugs Act 1971 (Temporary Class Drug) Order 2012.

Methoxetamine is an analogue of ketamine, a controlled Class C under the 1971 Act. On 5 March 2012, the Government referred methoxetamine to the ACMD for initial advice pursuant to Section 2A of the 1971 Act (provisions to make a temporary class drug order) following the identification of methoxetamine through seizures and by the Home Office Forensic Early Warning System. The available evidence indicated that methoxetamine is growing in popularity and availability through internet websites where it is sold and advertised as a safe and legal alternative to Class C ketamine.

On 23 March 2012, the ACMD responded to the Government's referral, providing its initial advice on the harms and misuse of methoxetamine, pursuant to Section 2B of the 1971 Act (provisions on temporary class drug orders – role of the Advisory Council). It reported that the chemical structure of methoxetamine bears a close resemblance to that of both ketamine and phencyclidine (PCP), which are controlled drugs under the 1971 Act. The available information in case reports and, drawing from the analytically confirmed acute methoxetamine toxicity cases presenting to UK hospitals in the last six months, the current evidence suggests that the pattern of adverse effects reported following acute use is similar to that seen with acute ketamine toxicity – which includes – hallucinations, catatonia and dissociative effects. However, methoxetamine appears to present significant additional toxicity; which effects include – agitation, cardiovascular effects including tachycardia (a fast heart rate) and hypertension (a high blood pressure) and cerebellar features such as ataxia (unsteadiness on the feet). The ACMD highlights that cerebellar features are rarely seen with other recreational drugs and are not seen with acute ketamine toxicity.

Following consultation with the Department for Business Innovation and Skills (BIS) and the Medicines and Healthcare products Regulatory Agency (MHRA), methoxetamine has been identified as having no legitimate industrial or medicinal use, though there may be some limited use for research purposes. The MHRA also confirms that there are no marketing authorisations for medicines containing methoxetamine.

In light of the evidence, the ACMD recommends that methoxetamine should be subject to a temporary class drug order. The ACMD's assessment details that methoxetamine is a substance that is being misused and that its misuse is having harmful effects. The ACMD also recommends that methoxetamine be treated as a Schedule 1 drug under the Misuse of Drugs Regulations 2001 (as amended), having identified that methoxetamine has no legitimate or recognised medicinal uses.

In line with the agreed working protocol, the ACMD will continue to gather all available evidence while the temporary class drug order is in force, and will aim to provide a full independent expert assessment to recommend whether methoxetamine should be subject to permanent controls under the Misuse of Drugs Act 1971. The ACMD are due to undertake a review of the harms and classification of ketamine and its analogues. It is therefore likely that advice on methoxetamine will be included in this review which is due in March 2013.

Description of controls

Under the Misuse of Drugs Act 1971, on indictment, the maximum penalties for offences relating to drugs listed under the temporary class drug order are - for supply, production, import/export, up to 14 years' and/or an unlimited fine. On summary conviction, the maximum penalties for offences relating to supply, production or importation/exportation are six months' imprisonment and/or a

prescribed fine (including, for the latter offences, one determined by the value of the drugs if greater than the prescribed amount).

There is no offence or penalty for simple possession of a temporary class drug order. However, under Section 23A of the 1971 Act, law enforcement officers have been given the following powers to:

- search and detain a person (vehicle or vessel) where there are reasonable grounds to suspect that the person is in possession of a temporary class drug;
- seize, detain and dispose of a suspected temporary class drug; and
- arrest or charge a person who commits the offence of intentionally obstructing an enforcement officer in the exercise of their powers in respect of temporary class drugs.

A.2 Groups Affected

Groups affected by the policy are purveyors of methoxetamine, drug misusers and potentially organisations which use chemicals for legitimate research.

The 'legal high' market (head shops and internet suppliers) will no longer be able to lawfully market methoxetamine as a 'legal high'. There may be minimal costs and resource implications for enforcement and criminal justice agencies arising from this option but it is expected that this will be subsumed into the enforcement and regulatory response to similar drugs permanently controlled under the 1971 Act.

A.3 Consultation

Within Government

The Home Office has consulted with the Department of Health, the MHRA and BIS in deciding its preferred options.

Public Consultation

The Government has considered the recommendations of the Advisory Council on the Misuse of Drugs.

B. Rationale

New Psychoactive Substances, so called "legal highs", imposes a cost on society in the form of health costs due to the harmful effects misuse can have. Government intervention is necessary to prevent methoxetamine from taking a foothold in the UK and from the harmful effects of the drug. *It is the view of the ACMD that methoxetamine is a drug that is being misused and that the misuse is having harmful effects. The ACMD therefore advise that methoxetamine be subject to a temporary class drug order. The Council have found no evidence that methoxetamine has a recognised medicinal use and therefore advise that methoxetamine be treated as a Schedule 1 drug in applying the provisions of the Misuse of Drugs Regulations 2001 (as amended).*

Data from the Home Office Forensic Early Warning System (FEWS) indicated the prevalence of methoxetamine in the UK as well as its growing availability and popularity. Along with the evidence of FEWS, the ACMD highlighted the prevalence of methoxetamine through a number of sources which included results from the Global Drugs Survey which reported that out of 7,700 UK respondents, 4.2% used methoxetamine in the last year and 2.4% used it within the last month. The survey indicated there were higher levels of methoxetamine use than a range of currently controlled/non controlled drugs. The ACMD also identifies the use of methoxetamine in 5 out of 150 clients at the London Club Drug Clinic while other treatment providers across the UK have reported its awareness and use. Further, it indicates at least nine cases of analytically confirmed acute methoxetamine cases presenting to UK hospitals in the last 6 months. From these cases, methoxetamine appears to present significant additional toxicity, in addition to those of its close chemical analogue ketamine (which presents hallucinations, catatonia and dissociative effects). These effects include – agitation, cardiovascular effects including tachycardia (a fast heart rate)

and hypertension (a high blood pressure) and cerebellar features such as ataxia (unsteadiness on the feet). The European Monitoring Centre for Drugs and Drugs Addiction (EMCDDA) also reports the presence of methoxetamine in many European countries and the sale of the substance by online retailers to EU customers, while FRANK reports a higher number of visits to the website on methoxetamine as well as a number of calls. The data from the National Poisons Information Service database (TOXBASE) also suggests increasing presentations to hospitals relating to the use of methoxetamine. Other sources are listed in the ACMD's statement of evidence on methoxetamine available in their report at http://www.homeoffice.gov.uk/publications/agencies-public-bodies/acmd1/statement-methoxetamine.

C. Objectives

The policy objective is to make a temporary class drug order on methoxetamine under the Misuse of Drugs Act 1971 to support the Government's commitment to reduce the risk of harm from new psychoactive substances, while providing sufficient time for the ACMD to provide a full independent expert assessment, to inform whether its harms and effects warrant permanent control under the 1971 Act. Legitimate activities, limited to research, will be enabled under the Misuse of Drugs Regulations 2001 for those who are existing Schedule 1 licence holders or for those companies/establishments being granted a new licence. This action is also in line with the Government's overarching Drug Strategy to take a preventative, enforcement and recovery-based approach to drug-related issues supported by the available evidence and expert advice of the ACMD.

A successful outcome will be a reduction in the availability and misuse of methoxetamine in the UK.

D. Options

Two options have been considered in respect of these substances:

Option 1 : Do nothing
Option 2 : Make a temporary class drug order under the Misuse of Drugs Act 1971 on methoxetamine and its simple derivatives.

The Government's preferred option is option 2 and is supported by the ACMD's initial advice. The use of the 1971 Act and its Regulations to temporarily control these substances provides the best means to reduce availability and therefore harm to the public.

E. Appraisal (Costs and Benefits)

GENERAL ASSUMPTIONS & DATA
None.

OPTION 2 - Make a temporary class drug order under the Misuse of Drugs Act 1971 on methoxetamine and its simple derivatives.

COSTS

Business

The potential costs to the research sector of this option cannot be quantified at this time in the absence of baseline figures. There is no known legitimate use of methoxetamine in the UK except limited research uses.

In respect of the manufacturers, distributors and wholesalers that produce, supply, import or export methoxetamine, they will need a 'domestic licence' issued by the Home Office Drug Licensing and Compliance Unit and an import or export licence (for each consignment). Licences are currently issued for a fee and can be easily applied for online. The fee for an initial application for a domestic licence currently ranges between £3, 655 to £4,700, and between £326 and £1,371 for a

replacement domestic licence, valid for a period of 12 months. The fee for an individual import or export licence is currently £24 per transaction. Most business conducting research already possess schedule 1 licences. Additional licensing costs for a company already licensed to undertake activities relating to Schedule 1 drugs would be limited to the cost of additional, sole consignments of new temporary controlled substances under licence. The licence fees are necessary to maintain the regulatory framework needed to protect the public from the potential harms posed by the misuse and diversion of Schedule 1 drugs which will include methoxetamine under temporary controls. However, most organisations already dealing with scheduled drugs, thus licensed to undertake activities of drugs of the same schedule, will only incur licence upgrade (i.e. lower) costs. The harm potential from diversion and misuse of methoxetamine is sufficient to warrant controls under a temporary class drug order.

Public Sector

In relation to law enforcement and the illicit market (enforcement agencies, CJS, regulators)

Any costs associated with option 2 cannot be predicted in light of nil to very limited data on prevalence and use of these substances in the UK. However, it is expected that minimal costs arising from this option will be subsumed into the enforcement and regulatory response to similar drugs already fully controlled under the 1971 Act. The 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.

BENEFITS

Business

No benefits accrue to businesses form this policy

Public Sector

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 methoxetamine. These savings cannot be quantified. Benefits are also likely to arise from consistency in the enforcement and regulatory response following the temporary control of methoxetamine under the 1971 Act. It is expected that the public will protected against the potential harm of methoxetamine and its misuse for up to 12 months', while the ACMD undertakes a full assessment of the substance for consideration for its permanent control under the 1971 Act.

Net Effect

- Overall it is considered likely that the benefits from the proposals will outweigh the costs. However, it has not been possible to quantify these benefits and costs. The main benefits to arise from the proposals are:

    - A reduction in the number of people seeking medical help and therefore a reduction in costs to the public purse

    - Public protection from the harms associated with the misuse of methoxetamine

ONE-IN-ONE-OUT (OIOO)

COSTS (INs)

There may be one-off minimal licensing costs envisaged for private sector research organisations or institutions. However, most private business conducting research will already possess schedule 1 licences which will cover their possession and use of methoxetamine. No costs are envisaged to the third sector or to micro business**.**

Due to the absence of evidence of legitimate business use and the negligible costs that would be associated with any such use, the assumption is made that there are no costs to business.

BENEFITS (OUTs)

No benefits accrue to the third or private sector from this proposal.

NET

N/A (No costs assumed for businesses).

F. Risks

OPTION 2 – Make a temporary class drug order under the Misuse of Drugs Act 1971 on methoxetamine and its simple derivatives.

There are risks associated with this option on the basis of evidence and expert advice that the 'legal high' market will quickly adopt chemical derivatives of methoxetamine or alternative new psychoactive substances imitating its effects to circumvent current drug controls. It is likely that Government intervention to enable law enforcement to protect the public from methoxetamine under option 2 would become insufficient over a relatively short period of time as other chemically related analogues would not be excluded. There is also a limited possibility that pharmaceutical, health and research sectors may become adversely affected due to the potential costs of updating or applying for a domestic license although this cannot be quantified at this time in the absence of baseline figures. In addition, given the initial advice from the ACMD and limited data held, it may be possible that the legitimate use of methoxetamine has been underestimated.

G. Enforcement

Enforcement of the proposed legislation will be undertaken by Police Forces, the UK Border Agency, 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. The UKBA 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.

Table H.1 Costs and Benefits

Option	Costs	Benefits
2	£NK	£NK
	Cost to (not quantified) Manufacturers, distributors and wholesalers that produce, supply, import or export methoxetamine will need a 'domestic licence' issued by the Home Office Drug Licensing and Compliance Unit and import or export licences (for each consignment). In relation to law enforcement and the illicit market it is expected that minimal costs arising from this option will be subsumed into the enforcement and regulatory response to similar	Benefits to (not quantified) Benefits are expected to arise from consistency in enforcement and regulatory response to temporarily control methoxetamine which is an analogue to Class C controlled ketamine under the 1971 Act. It is expected that members of the public will be protected against the potential harm of methoxetamine and its misuse for up to 12 months', while the ACMD undertakes a full assessment of the substance for consideration for its permanent control under

	drugs subject to full controls under the 1971 Act and will be managed within existing resources.	the 1971 Act.
Source:		

Option 2 is the preferred option. The harms associated with the use/misuse of this drug require Government to act through effective legislation to protect the public. There are benefits to be derived from implementing the proposal through a reduction in medical needs associated with misuse of these drugs.

I. Implementation

The Government plans to implement these changes via the made affirmative resolution, subject to Parliament's approval, under the Misuse of Drugs Act 1971 (Temporary Class Drug) Order 2012.

J. Monitoring and Evaluation

The Government will continue to monitor methoxetamine by gathering data on the prevalence and illicit use (whilst under temporary control) through its early warning systems, from the health sector and the regulatory framework governing legitimate activities (predominately research) in relation to methoxetamine. The Home Office, as the regulatory authority on licensing of activities relating to all controlled drugs and as lead department working with other Government departments, will continue to monitor the situation. As part of its statutory duties under the 1971 Act the ACMD keeps the situation relating to drugs under review.

K. Feedback

No feedback will be sought from suppliers or users as a result of the lack of medical and industrial uses of methoxetamine. However, feedback will be sought form law enforcement agencies; the UK Border Agency and the Police. The ACMD will undertake a full assessment of the substance for consideration for its permanent control under the 1971 Act.

L. Specific Impact Tests

See Annex 1.

Annex 1. Specific Impact Tests

Economic Impacts

Competition Assessment

It is expected that temporary control measures in relation to producers and suppliers of methoxetamine will apply equally to firms involved in the domestic trade of this substance as well as firms involved in importation/exportation.

Environmental

Social Impacts

Health and Well-being

Temporary controls under the 1971 Act and its Regulations reinforce Government measures to reduce the risk and, protect the public, from the health and social impact of harmful new psychoactive substances. The legislative approach is supported by Government drug policies in prevention, enforcement and health.