Title: IMPACT ASSESSMENT OF NEW DRUG CONTROL IA No:	**Impact Assessment (IA)**
Lead department or agency: HOME OFFICE	**Date:** 05/12/2012
Other departments or agencies: DEPARTMENT OF HEALTH AND ITS AGENCIES DEPARTMENT FOR BUSINESS, INNOVATION AND SKILLS LAW ENFORCEMENT AGENCIES	**Stage:** Final
	Source of intervention: Domestic
	Type of measure: Primary legislation
	Contact for enquiries: Cyrille Marcel (Telephone: 0207 035 0618) (Email: Cyrille.Marcel2@homeoffice.gsi.gov.uk)
Summary: Intervention and Options	**RPC Opinion:** N/A

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**
£NK	£m	£m	No	NA

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

The substances to be controlled – synthetic cannabinoids including compounds which have been controlled since 23 December 2009, methoxetamine (currently a temporary class drug) and other compounds related to ketamine (Class C) and phencyclidine (Class A) by generic definition, as well as *O*-desmethyltramadol – as Class B drugs under the Misuse of Drugs Act 1971 are considered sufficiently harmful, following assessment and advice from the Advisory Council on the Misuse of Drugs (ACMD), to warrant proportionate control measures relating to their possession, supply, production and import/exportation, when unauthorised, with associated criminal sanctions. Government intervention is necessary to help protect the public from the harms of these substances and their misuse.

What are the policy objectives and the intended effects?

To control substances considered as harmful drugs in accordance with the terms of the 1971 Act. The intended effects are to deter misuse by the public and curb availability via suppliers 'self-regulating' following control and enable law enforcement and regulatory authorities to take appropriate action to tackle the unauthorised activities of possession, production, supply and import/exportation relating to these drugs.

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 under the Misuse of Drugs Act 1971 of an extended range of synthetic cannabinoids, methoxetamine and other compounds related to ketamine (Class C) and phencyclidine (Class A) by generic definition, as well as *O*-desmethyltramadol.

Option 2 is the preferred option on the basis of evidence and the ACMD's assessment on the prevalence and harms of these substances and their misuse.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** ongoing					
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: ..... Date: 20-12-12

Summary: Analysis & Evidence

Policy Option 2

Description: Control under the Misuse of Drugs Act 1971 of an extended range of synthetic cannabinoids, methoxetamine and other compounds related to ketamine (Class C) and phencyclidine (Class A) by generic definition and *O*-desmethyltramadol.

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. No legitimate or medicinal use has been identified in the UK beyond potential research, which may be permitted under Home Office licence. Potential costs to the research sector of this option cannot be quantified at this time in the absence of baseline figures. There is no cost if an 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 law enforcement partners, the criminal justice system and regulatory agencies in addition to costs of their activities relating to new psychoactive substances, temporary class drugs and synthetic cannabinoids controlled since 2009, generally. Without baseline figures of prevalence, these cannot be quantified. There are no known additional administrative costs to the research sector in relation to these drugs under the current framework within which legitimate activities are regulated. The new drugs to be controlled have no known legitimate use in 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'

Control measures to curb availability and harms of these substances and their misuse will have benefits across Government and society as a whole. It is expected that controlling families and similar drugs, as well as updating existing generic definitions in the 1971 Act, will bring consistency in law enforcement activities relating to derivatives and analogues of currently controlled drugs, and that members of the public will be protected against the potential harms of these substances and their misuse.

Key assumptions/sensitivities/risks

None.

Discount rate (%)

BUSINESS ASSESSMENT (Option 1)

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 considers the proposal of controlling an extended range of synthetic cannabinoids, methoxetamine and other related compounds - by generic definitions - and *O*-desmethyltramadol as Class B drugs under the Misuse of Drugs Act 1971 (Amendment) Order 2013.

Synthetic cannabinoids

Synthetic cannabinoid receptor agonists ('synthetic cannabinoids') are man-made chemicals that mimic the psychoactive effects of tetrahydrocannabinol (THC), the main active ingredient in cannabis. They are often sprayed on inert herbal mixtures in smoking products such as 'Black Mamba' and 'Annihilation', or in pure form, and act on the body in a similar way to cannabis, although some can be more potent. In 2009, the previous Government accepted the Advisory Council on the Misuse of Drugs' (ACMD) advice in its "ACMD report on the major cannabinoid agonists" to control over 140 synthetic cannabinoids as Class B drugs, by way of generic definitions, on the basis of its assessment of evidence of harms and misuse warranting that they become controlled similarly to cannabis. It is likely that the generic definitions will require further updating as the ACMD continues to monitor the market.

Following this legislative action and, as part of the on-going prioritisation by ACMD and Government of work to tackle new psychoactive substances advertised as 'legal highs' (as set out in the Drug Strategy), the ACMD has continued to monitor synthetic cannabinoids through UK and EU drugs early warning systems. It has identified emerging new synthetic cannabinoids and evidence of their prevalence in the UK and conducted a further assessment of these drugs and their harms to provide extended generic definitions that capture them alongside those synthetic cannabinoids which have been controlled Class B drugs since 2009.

The ACMD has provided advice to Government that the new synthetic cannabinoids include AM-2201 and MAM-2201, which have been identified in samples of 'Black Mamba' and 'Annihilation' 'legal high' products, and are associated with harms similar to cannabis, including an increased heart rate (tachycardia), convulsions, drowsiness, nausea/vomiting, agitation, panic attacks and hallucinations. There is a potential risk of long term harms on the basis of the similarity to cannabis, although the current data are too limited to determine this. The ACMD's advice also highlights evidence indicating that the prevalence of the new synthetic cannabinoids is increasing in the UK. The ACMD's latest report 'Further consideration of the synthetic cannabinoids' was published on 18 October 2012 at http://www.homeoffice.gov.uk/agencies-public-bodies/acmd/.

The Home Office has consulted with the Department for Business Innovation and Skills (BIS) and the Medicines and Healthcare products Regulatory Agency (MHRA), who consulted their contacts in healthcare and the chemical industry to be satisfied that there has been no change in relation to those synthetic cannabinoids controlled since 2009 in relation to legitimate or medicinal use. No legitimate or medicinal use has been identified for the new synthetic cannabinoids which will be captured by the extended generic definitions. The MHRA confirms that there are no marketing authorisations for medicines containing them or as part of their manufacturing process.

It is within this context and on the basis of available evidence that the ACMD recommends control of the new synthetic cannabinoids alongside those controlled as Class B drugs since 2009 under the 1971 Act by way of extended generic definitions. The Government has accepted the ACMD's recommendations to update the existing generic definitions of synthetic cannabinoids so that they capture the new synthetic cannabinoids under the 1971 Act and associated legislation, in consideration of all available evidence and the ACMD's advice.

Methoxetamine and other related compounds

The chemical structure of methoxetamine is similar to that of controlled drugs ketamine (Class C) and phencyclidine (Class A). Methoxetamine has been subject to a temporary class drug order (TCDO) which commenced on 5 April 2012, on Ministers' acceptance of the ACMD's initial advice which was provided under Section 2A of the 1971 Act. A TCDO can last up to 12 months while the ACMD prepares advice on the harms of the temporary class drug for consideration in relation to

permanent control. The ACMD's initial advice reported that the health harms of methoxetamine were sufficient to warrant their temporary control to protect the public and curtail availability while the ACMD provided full advice (its initial advice can be found at http://www.homeoffice.gov.uk/publications/agencies-public-bodies/acmd1/statement-methoxetamine).

In preparing further advice on methoxetamine, the ACMD has reviewed evidence of other compounds which are related to drugs ketamine (Class C) and phencyclidine (Class A) and have similar effects and harms. In its full advice, the ACMD assesses evidence which confirms the physical harms of the methoxetamine and related compounds are broadly similar to those of Class B drugs. These harms include hallucinations, drowsiness, and dissociative effects, as well as hypertension and additional toxicity-related symptoms of agitation and cerebellar features (such as ataxia - unsteadiness on the feet) which are rarely seen in other controlled drugs. The compounds are new psychoactive substances; therefore, there is limited evidence to assess chronic problems in respect of regular or long-term use as seen with ketamine (chronic bladder and other lower urinary tract pathology), although preliminary data from animal studies suggest that methoxetamine is not "bladder friendly" as has been claimed by manufacturers and suppliers of the drug. The ACMD's full advice was published on 18 October at http://www.homeoffice.gov.uk/publications/agencies-public-bodies/acmd1/methoxetamine2012.

The Home Office has consulted with the BIS and MHRA, who consulted their contacts in healthcare and the chemical industry, to be satisfied that there has been no change in relation to the legitimate or medicinal use of methoxetamine since it became a temporary class drug. No legitimate or medicinal use has been identified for methoxetamine and other related compounds captured by the generic definition which the ACMD has provided. It is within this context and on the basis of available evidence of harms that the ACMD recommends Class B control of methoxetamine and other related compounds by generic definition under the 1971 Act. The Government has accepted the ACMD's recommendation, having reviewed all available evidence and the ACMD's full advice on the case for control.

O-Desmethyltramadol

O-Desmethyltramadol is an active metabolite of 'tramadol', its parent drug. While considering evidence on tramadol, the ACMD has reviewed evidence on *O*-desmethyltramadol, which is advertised as a 'legal high' or sold as an active ingredient (sometimes undeclared) in samples of 'legal high' branded products (such as 'Krypton'), despite it having more potent opiate-like effects. In mainland Europe, 'Krypton' has been associated with fatalities in Sweden. Concerned about the harmful properties of *O*-desmethyltramadol and its use as a new psychoactive substance, the ACMD has submitted advice on the drug so that the Government can make a decision on the drug in relation to control under the 1971 Act. The ACMD has considered evidence that the harms of *O*-desmethyltramadol include confusion, dizziness, respiratory depression and seizures, which are commensurate with the harms of controlled Class B drugs.

The Home Office has consulted with the BIS and MHRA, who consulted their contacts in healthcare and the chemical industry and have confirmed that there is no legitimate or medicinal use of *O*-desmethyltramadol in the UK. It is within this context and on the basis of available evidence of harms that the ACMD recommends that the drug be subject to Class B control under the 1971 Act. The Government has accepted the ACMD's recommendation, having reviewed all available evidence and the ACMD's full advice on the case for control.

Description of controls

On indictment, the maximum penalties for offences relating to a Class B drug are - for possession, five years' imprisonment and/or a fine and for supply, production or importation/exportation, fourteen years' imprisonment and/or an unlimited fine. On summary conviction, the maximum penalties for offences relating to a Class B drug are - for possession, three months' imprisonment and/or a fine of £2,500, and for supply, production or importation/exportation, six months' imprisonment and/or a prescribed fine (including, for the latter, one determined by the value of the drugs if greater than the specified amount).

A.2 Groups Affected

The proposal to control new synthetic cannabinoids, methoxetamine and other related compounds as well as *O*-desmethyltramadol may affect groups making legitimate use of any of these

substances, such as organisations which use chemicals for research purposes. This is consistent with activities relating to drugs listed in Schedule 1 of the Misuse of Drugs Regulations 2001, which are subject to Home Office licensing by application from a new producer/supplier (as well as for import/export activities).

The 'legal high' market ('head shops' and internet suppliers) will no longer be able to lawfully market these substances or 'legal high' branded products containing them. There may be minimal costs and resource implications for law enforcement and criminal justice agencies arising from this option, but it is expected that this will be subsumed into the law enforcement and regulatory response to the control of over 140 synthetic cannabinoids since 2009 and the temporary control of methoxetamine as well as alongside other drugs which are controlled under the 1971 Act. However, it is expected that members of the public, especially young people and young adults, will be protected against the potential harms of these substances and their misuse.

B. Rationale

The misuse of drugs imposes a cost on society greatly in excess of the perceived cost to the individual. The licit trade alone does not prevent drugs being diverted into the illicit market. Therefore Government intervention is necessary to protect the public and enable law enforcement activity against the potential harms, diversion and misuse of drugs with reference to available evidence and assessment of their harms by the ACMD:

Further consideration of the synthetic cannabinoids (18 October 2012):
"The ACMD recommends that the substances detailed in Annex A, herein termed synthetic cannabinoids, have potential harms commensurate with those of cannabis and should, therefore, be classified and controlled under the Misuse of Drugs Act (1971) as Class B."

There are risks associated with the misuse of synthetic cannabinoids, with some of them being marketed as 'legal high' products. Data from the Home Office Forensic Early Warning System (FEWS) in July 2012 included results from a test purchasing exercise showing the presence of uncontrolled synthetic cannabinoids, such as AM-2201, RCS-4 and UR-144, in products sold via the internet. In addition, FEWS identified AM-2201 in samples recovered from attendees at music festivals over the 2012 summer period. In Scotland, Strathclyde police seized samples of 'Annihilation' which contained uncontrolled synthetic cannabinoids (AM-2201, MAM-2201 and UR144). The Crime Survey for England and Wales (CSEW) – Drug Misuse Declared 2011/12 – highlighted that 0.1% of 16 to 59 year olds reported using controlled synthetic cannabinoids such as spice and others listed under the 1971 Act in the last year (down from 0.2% in 2010/11). The UK's Drugs Early Warning System collated evidence received from local partnership teams on a significant number of anecdotal user reports, test purchases and forensic testing, indicating a trend towards the increased availability and use of non-controlled synthetic cannabinoids.

Methoxetamine and other related compounds (18 October 2012):
"The ACMD considers, from the available evidence, that the harms of methoxetamine are commensurate with Class B, of the Misuse of Drugs Act (1971); (...) The ACMD also recommend that a number of closely related analogues of ketamine and phencyclidine, some of which have already appeared on sale as "legal high alternatives", be controlled by means of a generic chemical description."

Despite being limited, the evidence base of methoxetamine use indicates some prevalence in the UK while confirming that it is harmful to health. Anecdotal evidence of the prevalence of methoxetamine use is largely confined to LGBT and nightlife populations. A survey conducted across four nights in two South London gay dance clubs in July 2011 highlighting that 6.4% respondents reported lifetime use, 1.9% in the previous month and 1.6% on the night of the survey. Other surveys conducted in Lancashire nightclubs also found low levels of methoxetamine use. Evidence from an online survey of self selected and self reported substance use conducted in November 2011 (Global Drugs Survey) found that, amongst 7,700 respondents in the UK, methoxetamine use was higher than a range of other drugs including DMT; synthetic cannabinoids; Benzofury; MDAI; crack; GBL; BZP; heroin etc. Data from the FEWS festivals work in summer 2012 show that six samples analysed contained methoxetamine and a further

five samples consisted in mixtures of the drug with other controlled/non-controlled NPS. At three of the festivals methoxetamine was identified nine times in tablets. 14 police forces have stated that they made a total of 49 seizures, of which 29 in the South of England (Kent to the South West) for the last 12 months (including pre temporary class drug order), the rest ranging across the Midlands, North England and Wales. Methoxetamine seizures supplied to the Police during 2012 totalled to 249. Before being subject to a TCDO, methoxetamine was available to purchase online. As of August 2012, UK-based sellers were offering methoxetamine for sale at a mark up price on the Silk Road website (an 'anonymous' marketplace accessed using the Tor 'hidden service' browser), indicating a trade outside of normal routes and purchase.

O-desmethyltramadol (25 October 2012):

"The harms associated with the use of O-desmethyltramadol are commensurate with other substances controlled as Class B under the Misuse of Drugs Act 1971. The ACMD therefore recommends that O-desmethyltramadol is controlled under the Misuse of Drugs Act 1971 as a Class B substance".

The ACMD has not indicated evidence of prevalence of the drug in the UK. Its advice refers to evidence shared by European partners including toxicology reports from Germany in relation to the 'legal high' branded product "Krypton" without evidence of use of tramadol or *N*-desmethyltramadol, another major tramadol metabolite, indicating exposure directly to *O*-desmethyltramadol. In late December 2010, authorities in Sweden reported a series of 9 fatalities associated with "Krypton", apparently resulting from opiate-type respiratory depression. The detection of *O*-desmethyltramadol in urine samples in the absence of tramadol or other tramadol metabolites again indicated that the users had been exposed directly to *O*-desmethyltramadol. Due to the harms of the substance, which is more potent than its parent drug, the ACMD decided to provide advice on *O*-desmethyltramadol within the context of the Misuse of Drugs Act 1971.

C. Objectives

The measure to control these substances under the Misuse of Drugs Act 1971 will support the Government's commitment to protect individuals and society from the harmful effects of dangerous or otherwise harmful drugs and their misuse, especially to take swift action to control new psychoactive substances (NPS) where there is evidence that their harms warrant control. This action is in line with the Government's overarching Drug Strategy to take a preventative, enforcement and recovery-based approach to drug-related issues supported by available evidence of harms and prevalence and the expert advice of the ACMD.

The measure is also an essential element in the delivery of the cross-government NPS Action Plan, published on 17 May 2012, which combines legislative measures alongside public health, prevention and international policy approaches to tackle NPS. A successful outcome will be a reduction in the availability and misuse of the extended range of synthetic cannabinoids, methoxetamine and other related compounds as well as *O*-desmethyltramadol, and raised awareness of the harms of these new psychoactive substances.

D. Options

Two options have been considered in respect of these substances:

Option 1 : No change
Option 2 : Control under the Misuse of Drugs Act 1971 of an extended range of synthetic cannabinoids, methoxetamine and other compounds related to ketamine (Class C) and phencyclidine (Class A) by generic definition and *O*-desmethyltramadol.

The Government's preferred option is option 2 and is supported by the ACMD's advice on the basis of evidence and the ACMD's assessment on the prevalence and harms of these substances and their misuse. The use of the 1971 Act in controlling these substances provides the best means to reduce availability and harm to the public.

E. Appraisal (Costs and Benefits)

GENERAL ASSUMPTIONS & DATA

The production, possession, supply and import/export of the new synthetic cannabinoids, other compounds similar to methoxetamine, and *O*-desmethyltramadol, as well as the possession of methoxetamine, are currently not prohibited under the Misuse of Drugs Act 1971. Over 140 synthetic cannabinoids have been controlled since 2009 as Class B drugs. Methoxetamine has been a temporary class drug since 5 April 2012. The temporary class drug order controlling methoxetamine will cease when Class B control comes into effect.

OPTION 2 - Control under the Misuse of Drugs Act 1971 of an extended range of synthetic cannabinoids, methoxetamine and other related compounds by generic definition and *O*-desmethyltramadol.

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 or medicinal use of these drugs in the UK, except for nabilone for which there is no change as it has been controlled since 2009 and its availability in healthcare enabled through the Misuse of Drugs Regulations 2001. Most organisations already dealing with controlled drugs, thus licensed to undertake activities involving controlled drugs of a same schedule under the Regulations, will be able to undertake lawful activities relating to other drugs of the same schedule for the same purposes. The harm potential from diversion and misuse of these drugs are sufficient to warrant their control under the 1971 Act. For those businesses selling these substances in the "legal high" market, the potential harm is such that those trading in this market are expected to comply with the Order or face the risk of prosecution.

Public Sector

Law enforcement and the illicit market (enforcement agencies, CJS, regulators)

Any real and opportunity costs associated with option 2 cannot be predicted in light of nil to limited data on prevalence and use of the new substances to be controlled in the UK, amid some evidence that the market self-regulates. It is expected that any costs arising from this option will be minimal and subsumed into the law enforcement and regulatory response to similarly controlled drugs, mostly in relation to those drugs which were not previously controlled. There is limited law enforcement data on prevalence of use or recorded offences in relation to synthetic cannabinoids controlled since 2009 (3 convictions in 2010/11) or methoxetamine since 5 April 2012 (evidence considered by the ACMD indicates low prevalence), within the context of the broader approach to harmful new psychoactive substances and temporary class drugs generally.

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 as well as new psychoactive substances.

BENEFITS

Business No benefits accrue to businesses from 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 these drugs. 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 cause. Benefits are likely to arise from consistency in the law enforcement and regulatory response to the Class B control of these drugs under the 1971 Act. It is expected that the public will be aware and protected against the potential harm of these drugs and their misuse.

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; and
- Public awareness of, and protection from, the harms associated with the misuse of these drugs.

ONE-IN-ONE-OUT (OIOO)

COSTS (INs)

There may be one-off minimal licensing costs envisaged for voluntary, charity or private sector research organisations or institutions: manufacturers, distributors and wholesalers that produce, supply, import or export these substances 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 £3,133.00 and £4,700.00, and between £326.00 and £1,371.00 for a replacement domestic licence. Licences are valid for a period of 12 months. The fee for an individual import or export licence is currently £24.00 per transaction. Additional licensing costs for a company already licensed to undertake activities relating to Schedule 1-4 drugs would be limited to the cost of additional, sole consignments of new 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 these drugs.

However, organisations dealing with scheduled drugs will already be required to be licensed to undertake activities involving similar controlled drugs under the Misuse of Drugs Regulations 2001. Due to the absence of evidence of legitimate business use and the negligible costs that would be associated with any research use(s), the assumption is made that there are no cost implications to business, including small business. For those businesses selling these substances in the "legal high" market, the potential harm is such that those trading in this market are expected to comply with the Order or face the risk of prosecution.

BENEFITS (OUTs)

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

NET N/A (No costs assumed for businesses).

F. Risks

OPTION 2 - Control under the Misuse of Drugs Act 1971 of an extended range of synthetic cannabinoids, methoxetamine and other compounds related to ketamine (Class C) and phencyclidine (Class A) by generic definition and *O*-desmethyltramadol.

There are risks associated with this option on the basis of evidence and expert advice that the 'legal high' market will want to synthetise and advertise chemical derivatives of some of these or other controlled drugs, or alternative new psychoactive substances imitating their effects, to circumvent current drug control. There are also risks associated with the impact on law enforcement and criminal justice agencies. However, it is accepted that Government intervention is needed to enable law enforcement to protect the public from these drugs under option 2, which may become insufficient over a period of time as the emergence of new related compounds cannot be excluded. This risk is usually mitigated by the ACMD which has a duty to review the situation in relation to both controlled and non-controlled drugs (including new psychoactive substances).

G. Enforcement

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 implementing the legislative and regulatory framework in the UK. Law enforcement by the police will form part of their wider approach to tackling new psychoactive substances and already controlled drugs under the 1971 Act. The UKBF will enforce controls at the border by seizing suspected substances, also as part of their wider border control role. There will be no interference with the regulatory framework and processes implementing control measures in the law enforcement and regulatory agencies as part of their routine activities. Subordinate legislation to the Misuse of Drugs Act 1971 will be amended and an update to the legislation communicated by the Home Office to include substances to be controlled under the 1971 Act.

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 (not quantified) Research organisations and their suppliers if they are not already licensed for undertaking their activities in relation to similar controlled drugs. In relation to law enforcement and the illicit market, on the basis of limited data on prevalence of use or recorded offences in relation to similar drugs already subject to control, it is expected that minimal costs arising from this option will be subsumed into the law enforcement and regulatory response to similar drugs already controlled under the 1971 Act and will be managed within existing resources.	Benefits (not quantified) Benefits are expected to arise from consistency in law enforcement and regulatory response to control these types of drugs which, in most cases, are similar to other substances already controlled under the 1971 Act. It is expected that members of the public will be aware and protected against the potential harm of these drugs and their misuse.

Source:

Option 2 is the preferred approach. The harms associated with the misuse of these drugs 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 costs associated with the misuse of these drugs. Despite the limited amount of data available, there is a good ratio of benefits/costs of option 2 because it consolidates and 'future-proofs' controls of these substances with minimal added costs.

Option 1 bears minimal costs but little/no benefits in light of the prevalence of harmful new psychoactive substances sold as 'legal' alternatives to currently controlled drugs.

I. Implementation

The Government plans to implement these changes via the affirmative resolution procedure of debates in both Houses of Parliament to seek approval of the Misuse of Drugs Act 1971 (Amendment) Order 2013.

J. Monitoring and Evaluation

As part of its statutory duties under the 1971 Act the ACMD keeps the situation relating to drugs under review. Together with the Government, they will continue to monitor synthetic cannabinoids, methoxetamine and other related compounds as well as *O*-desmethyltramadol by gathering data on their prevalence and misuse through UK and EU drugs early warning systems, the health sector and the regulatory framework governing legitimate activities (predominately research) in relation to these drugs. 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 to deliver the Drug Strategy, will continue to monitor the situation in relation to compliance with the regulatory framework.

K. Feedback

No feedback will be sought from suppliers or users as no further legitimate or medicinal use of these drugs have been identified. However, feedback will be sought from law enforcement agencies; the UK Border Force and the Police.

L. Specific Impact Tests

Economic Impacts

Competition Assessment

It is expected that control measures in relation to producers and suppliers of synthetic cannabinoids, methoxetamine and other related compounds as well as *O*-desmethyltramadol will apply equally to firms involved in the domestic trade of similar drugs as well as firms involved in their importation/exportation.

Social Impacts

Health and Well-Being

Control under the 1971 Act reinforces Government measures to raise awareness and to reduce the risk and protect the public from the health and social impact of harmful drugs and their misuse. The legislative approach is supporting Government policies in drug prevention, law enforcement and public health.

Human Rights

Government intervention to protect the public from harmful drugs and the harms associated with their misuse by the introduction of controls to help limit their availability and curb demand constitutes an interference with qualified human rights. However, it is proportionate in circumstances where control is ordered because of the harm, or potential harm, represented by the drugs in question, both to the physical and mental health of the individual users and to society.

Justice

It is expected that many suppliers will 'self-regulate' and that the intervention will curb availability. Therefore, the new legislation should amount to a minimal impact on the criminal justice system as part of its wider activities relating to the implementation of drug control.

Policy Equality Statement

Provided separately.

Home Office

HOME OFFICE

POLICY EQUALITY STATEMENT (PES)

Name of Policy/Guidance/Operational Activity

To control substances considered "dangerous or otherwise harmful" in accordance with the terms of the 1971 Act as a public health and protection measure.
The intended objectives are to deter use and misuse of these substances amongst the general population and to curb their availability through suppliers withdrawing them from sale to comply with control measures as well as enabling law enforcement to take appropriate action to tackle illicit production, supply and import/exportation while the undertaking of activities relating to one or more of the substances to be controlled is enabled under the Misuse of Drugs Regulations 2001.

Summary of the evidence considered in demonstrating due regard to the Public Sector Equality Duty.

The Advisory Council on the Misuse of Drugs' (ACMD) advice to Government on 'novel psychoactive substances or NPS (http://www.homeoffice.gov.uk/publications/agencies-public-bodies/acmd1/acmdnps2011): the ACMD highlights in its considerations evidence that 'Users, particularly young people, who are in possession of what they think are „legal highs" may well be in possession of controlled substances and could face the prospect of being subject to prosecution and a potential criminal record if found in possession of them by the Police.' Its advice also points at the increase in access to and availability of harmful substance through modern technologies which are appealing to young people.

In relation to harms, the ACMD considered that 'The use of NPS can also result in young people and young adults putting themselves in situations where they may be vulnerable or at risk of other harms (e.g. through collapse, intoxication, etc) including accidents and being victims of crime (e.g. sexual or physical assault)'. It also gave due consideration to the impact of legislation in relation to 'Police enforcement and the criminalisation of Young People' outweighed by the need for Government intervention to protect young people from harmful drug use in light of the assessment that they 'have made it clear that the belief that these substances are "legal and therefore safe" is the main driver for trying them.' Government considerations on these issues have resulted in the introduction of legislative provisions to temporarily control a potentially harmful NPS without introducing a simple possession offence in relation to a temporary class drug until a decision is made on whether to control it permanently under the Misuse of Drugs Act 1971. Methoxetamine has been a temporary class drug since 5 April pending full ACMD advice and will continue to be until it becomes a controlled Class B drug.

As part of its advice on NPS, and with reference to such considerations in the 2010 Drug Strategy (http://www.homeoffice.gov.uk/publications/alcohol-drugs/drugs/drug-strategy/), the ACMD has also considered the impact of drug education and considered targeted prevention, treatment and social approaches. On 17 May 2012 the Government published, as an Annex to the first annual review of the Drug Strategy and informed by the ACMD's advice on NPS, a cross-government NPS Action Plan setting out ongoing and future policy objectives ranging from legislative measures to public health and prevention approaches – particularly in relation to harmful NPS use amongst young people – in line with the approaches taken in the drug Strategy. On the drugs to be controlled specifically,

the ACMD included further considerations in its advice to Government on the drugs to be controlled:

- Further advice on synthetic cannabinoids (2012) extending the range of these substances subject to Class B control under the 1971 Act, at http://www.homeoffice.gov.uk/publications/agencies-public-bodies/acmd1/synthetic-cannabinoids-2012: referring to clusters of hospitalisations involving young people linked to their use of branded products associated with harmful new synthetic cannabinoids to be controlled;
- Methoxetamine and related compounds, recommending temporary class drug methoxetamine be subject to Class B control and associated penalties, along with related harmful compounds that are sold as 'legal high' alternatives: http://www.homeoffice.gov.uk/publications/agencies-public-bodies/acmd1/methoxetamine2012 (also, see http://www.homeoffice.gov.uk/publications/agencies-public-bodies/acmd1/statement-methoxetamine): the ACMD highlights anecdotal evidence of the popularity of methoxetamine in – although targeted – LGBT venues, in particular higher prevalence amongst gay male clubbers and young adults; and
- *O*-desmethyltramadol to become a controlled Class B drug, at http://www.homeoffice.gov.uk/publications/agencies-public-bodies/acmd1/ACMD-O-desmethyltramadol: the ACMD has considered evidence that it was being sold as an NPS although a harmful drug with opiate properties, sometimes identified but undeclared as an active ingredient in smoking mixtures like synthetic cannabinoids and linked to casualties in Sweden.

While other protected characteristics were considered but deemed not disproportionately affected, the main policy objective remains public protection, indiscriminately.

Government research and publications - Data collection and statistical bulletins -

- Home Office: Crime Survey for England & Wales and Drug Misuse Declared (England & Wales), at http://www.homeoffice.gov.uk/publications/science-research-statistics/research-statistics/crime-research/drugs-misuse-dec-1112/, looking at prevalence of use amongst age groups and informing ongoing work to target specific higher-risk groups of users.Annual Drug Misuse Declared statistical bulletins have highlighted higher levels of stimulant drug use amongst young adults aged 16 to 24, including NPS now subject to 1971 control such as mephedrone and trends since their control. The data help to inform social interventions i.e. public health (FRANK) targeted at specific user groups.
- National Treatment Agency for Substance Misuse: NTDMS data identifying drug use, harm and treatment trends, including diversity and equality data, as well as stock-take and future challenges to treatment in building recovery, at http://www.nta.nhs.uk/uploads/commentaryfinal[0].pdf and http://www.nta.nhs.uk/uploads/six-yearstudy.pdf. This is further complemented by Schools Drink and Drugs surveys.

SCS sign off	Daniel Greaves	**Name/Title**	Head of Unit

I have read the available evidence and I am satisfied that this demonstrates compliance, where relevant, with Section 149 of the Equality Act and that due regard has been made to the need to: eliminate unlawful discrimination; advance equality of opportunity; and foster good relations.

Directorate/Unit	Crime Directorate Drugs and Alcohol	Lead contact	Cyrille Marcel
Date	6 December 2012	Review Date	N/A