Title: IMPACT ASSESSMENT OF NEW DRUG CONTROLS **IA No:** HO **Lead department or agency:** HOME OFFICE **Other departments or agencies:** DEPARTMENT OF HEALTH AND ITS AGENCIES DEPARTMENT FOR BUSINESS AND INNOVATIONS ENFORCEMENT AGENCIES	**Impact Assessment (IA)** **Date:** 21/02/2012 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Primary legislation **Contact for enquiries**: Cyrille Marcel Telephone: 0207 035 0618

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?

The substances to be controlled - chemical derivatives of pipradrol (2-DPMP and related compounds) by generic definition and phenazepam - 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 control measures relating to possession, supply, manufacture and import/exportation activities, 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 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 implementation of control measures as well as enabling law enforcement and regulatory authorities to take appropriate action, i.e. activity to tackle unauthorised production, supply and import/exportation while providing the regulatory framework to enable the undertaking of legitimate activities relating to phenazepam.

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

Option 1 : No change
(also means continuation of importation ban on phenazepam, 2-DPMP and structurally related compounds diphenylprolinol (D2PM) and diphenylmethylpyrrolidine under the Open General Import License (OGIL).
Option 2 : Control under the Misuse of Drugs Act 1971 of 2-DPMP and phenazepam.
Option 3 : Control under the Misuse of Drugs Act 1971 of 2-DPMP and structurally related compounds by generic definition and phenazepam.

Option 3 is the preferred option due to the harm potential of these substances and their 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: 25/02/2012

Summary: Analysis & Evidence

Policy Option 1

Description: No change

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: Control under the Misuse of Drugs Act 1971 of 2-DPMP and phenazepam.

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 data currently available on prevalence and use, including legitimate uses. Potential costs to the pharmaceutical, health and 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 from a Schedule 1 supply/possession to production licence costs £1,371; a whole new licence costs £3,133 to £4,700.00.

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

Potential costs fall to the police, the criminal justice system and other enforcement partners, regulatory and healthcare agencies. 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 2-DPMP under the current framework within which legitimate activities are regulated. Phenazepam 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'

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 these drugs will bring consistency in enforcement activities and that members of the public will be protected against the potential harm of these substances and their misuse.

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

Summary: Analysis & Evidence

Policy Option 3

Description: Control under the Misuse of Drugs Act 1971 of 2-DPMP and structurally related compounds by generic definition and phenazepam.

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 data currently available on prevalence and use, including legitimate uses. Potential costs to the pharmaceutical, health and 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 from a Schedule 1 supply/possession to production licence costs £1,371; a whole new licence costs £3,133 to £4,700.00.

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

Potential costs fall to the police, the criminal justice system and other enforcement partners, regulatory and healthcare agencies. 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 2-DPMP and structurally related compounds under the current framework within which legitimate activities are regulated. Phenazepam has 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 will bring consistency in enforcement activities relating to chemical derivatives of controlled drugs and that members of the public will be protected against the potential harm of these substances and their misuse.

Key assumptions/sensitivities/risks

None.

Discount rate (%)

BUSINESS ASSESSMENT (Option 3)

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 deals with the proposal to control 2-DPMP and structurally related compounds by generic definition and phenazepam under the Misuse of Drugs Act 1971 (Amendment) Order 2012 as follows:

2-DPMP and structurally related compounds
These substances are chemical derivatives of pipradrol, a controlled Class C drug under the 1971 Act listed to Schedule 3 of the Misuse of Drugs Regulations 2001. These are new psychoactive substances identified in white-ish power form and with stimulant effects comparable to amphetamines. In August 2010 the Government asked the Advisory Council on the Misuse of Drugs (ACMD) to keep 2-DPMP under review as a new psychoactive ingredient identified in samples of legal high 'Ivory Wave' branded products. The ACMD produced its initial advice on 29 October 2010 including an assessment of harm based on available evidence at the time. The Government accepted the ACMD's advice and banned the importation of 2-DPMP under the Open General Import License (OGIL), pending full ACMD advice to Government.

On 13 September 2011 the ACMD produced its full advice, having reviewed evidence on prevalence, use and harms of 2-DPMP and related compounds. Harmful effects of these substances include hallucinations, paranoia and severe agitation for prolonged periods. Evidence reviewed by the ACMD included data reported by health agencies on presentations to A&E and Poisons admissions linked to the substances as well as the detection by the Home Office's Forensic Early Warning System of 2-DPMP related compounds such as diphenylprolinol (D2PM) and diphenylmethylpyrrolidine replacing 2-DPMP in 'legal high' products following its importation ban. On 15 November 2011, the Government banned the importation of these two compounds under the OGIL with immediate effect. This decision was supported by the ACMD in further advice provided to Ministers published on the same day.

The ACMD has formulated a generic definition by which to control 2-DPMP and structurally related compounds as Class B drugs under the 1971 Act and also recommended listing to Schedule 1 of the Misuse of Drugs Regulations 2001 as they have no recognised medicinal or industrial uses in the UK. This was confirmed by the Medicines and Healthcare products Regulatory Agency (MHRA) and the Department for Business, Industry and Services. There is one UK-based company that produces and supplies some of these substances for research purposes only. Under Schedule 1 of the Misuse of Drugs Regulations 2001 these activities are authorised under Home Office licence. In light of all available evidence and the ACMD's advice on 2-DPMP and related compounds, the Government accepted the ACMD's recommendation for Class B control on 15 September 2011.

Phenazepam
Phenazepam is a benzodiazepine, a depressant drug being sold as a 'legal high' and counterfeit 'valium' on the internet, in powder and liquid form. It is produced in the Commonwealth of Independent States countries and used in some countries to treat neurological disorders and epilepsy and as a premedication to surgical operation. However, it has no recognised medicinal or other legitimate use in the UK. On 20 July 2011 the ACMD advised Government to take action to reduce the availability of phenazepam in the UK amid evidence of its use as a 'legal high' product and counterfeit medicine in the UK since 2010 but with harms equivalent to those of the family of benzodiazepines which are controlled Class C drugs under the 1971 Act. These harms include amnesia, dependence, drowsiness that can lead to coma and respiratory depression, and are commensurate with those of other benzodiazepines which are listed to Schedule 3 or 4 (1) of the Misuse of Drugs Regulations 2001. The ACMD has recommended listing to Schedule 3 due to the high risk of overdose on phenazepam.

In light of all available evidence and the ACMD's advice on phenazepam, the Government accepted the ACMD's recommendations on 22 July 2011, banning its importation under the OGIL immediately pending Class C control under the 1971 Act.

Description of controls

On indictment, the maximum penalties for offences relating to a Class B drug and a Class C drug are - for possession, five years' and two years' imprisonment and/or a fine, respectively, and for supply, production or importation/exportation in both classes, 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); for possession of a Class C drug, three months' imprisonment and/or a fine of £1,000, and for supply, production or importation/exportation, three months imprisonment and/or a £2,500 fine (including, for the latter, one determined by the value of the drugs if greater than the specified amount).

The Government has banned the importation of 2-DPMP and phenazepam under the Open General Import License (OGIL).

As 2-DPMP (and structurally related compounds) and phenazepam are not controlled to date under the 1971 Act, there is no population or household survey data collection. No border seizure data are currently available to provide an estimate of quantities imported into the UK.

A.2 Groups Affected

The proposal to control 2-DPMP and its structurally related compounds by generic definition and phenazepam may affect groups having legitimate use of any of these substances. In the UK, there is some information to indicate that related compounds to 2-DPMP may be used in research. Information available is found in advertising of production to supply related compounds for research purposes, consistent with activities relating to a number of drugs in Schedule 1 - subject to Home Office licensing by application from a new producer/supplier (as well as for import/export activities). The ACMD has also indicated that there is no legitimate use of phenazepam in the UK.

In terms of the illicit market, the 'legal high' market (head shops and internet suppliers) will no longer be able to market these substances as 'legal high' branded products. 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 already controlled under the 1971 Act. It is expected that members of the public will be protected against the potential harm 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 market alone does not prevent drugs being diverted into the illicit trade. Therefore Government intervention, through its licensing system and regulatory framework, is necessary. This can be examined in relation to the potential harms and misuse of the drugs with reference to available evidence of harm and the Government's independent experts' – the Advisory Council on the Misuse of Drugs - advice:

- 2-DPMP and related compounds: *The harms of desoxypipradrol and related compounds are commensurate with other Class B drugs and recommend that they are controlled under the Misuse of Drugs Act 1971 as Class B substances and listed to Schedule 1 of the Misuse of Drugs Regulations 2001 (as amended).* There are risks associated with the misuse of 2-DPMP and related compounds as stimulants marketed as 'legal high' branded products. Data from the Home Office Forensic Early Warning System since 2010 highlight prevalence of some of these compounds in the UK and associated harms to users presenting to A&E Admissions and Poisons Units. The ACMD also indicated that following the importation ban on 2-DPMP in November 2010 it had been replaced by related compounds D2PM and diphenylmethylpyrrolidine in the UK (with increasing evidence of similar harms to 2-DPMP). However, on 15 November 2011, the Government banned the importation of these two compounds under the OGIL with immediate effect.

- Phenazepam: *In considering its known harms, the ACMD recommends that phenazepam be controlled under the Misuse of Drugs Act 1971 as a Class C substance and scheduled as a schedule 3 substance under the Misuse of Drugs Regulations 2001.* There are risks associated with the use of benzodiazepines, more so in the absence of control measures to reduce the availability of phenazepam over the internet despite its estimated potency being five times that of some other benzodiazepines. Control measures will also send a clear message to users that this drug is potentially harmful.

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, while providing for legitimate activities in relation to their scheduling under the Misuse of Drugs Regulations 2001. 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.

D. Options

Three options have been considered in respect of these substances:

Option 1 : No change (including continuation of ban on importation of phenazepam, 2-DPMP, D2PM and diphenylmethylpyrrolidine under the OGIL).

Option 2 : Control under the 1971 Act of 2-DPMP and phenazepam by definition.

Option 3 : Control under the Misuse of Drugs Act 1971 of 2-DPMP structurally related compounds by generic definition and phenazepam.

The Government's preferred option is option 3 and is supported by the ACMD's advice. The use of the 1971 Act and its Regulations in controlling these substances provides the strongest controls to reduce availability and therefore harm to the public associated with their misuse if this option is adopted. This option adds the benefit of consolidating existing controls and/or enabling legitimate activities in relation to phenazepam.

E. Appraisal (Costs and Benefits)

GENERAL ASSUMPTIONS & DATA

The production, possession and supply of these substances are currently not prohibited under the Misuse of Drugs Act 1971. The Medicines Act 1968 provides the regulatory framework to control the supply and the manufacture of medicines in the UK, and allow licensed medicines onto the UK market. Phenazepam is not licensed to be sold as a medicinal product in the UK. There is also an importation ban on this substance and 2-DPMP and 2 of its related compounds (D2PM and diphenylmethylpyrrolidine).

OPTION 2 – Control under the Misuse of Drugs Act 1971 of 2-DPMP and phenazepam

COSTS

In relation to legitimate use:

The potential costs to the pharmaceutical, health and research sectors of this option cannot be quantified at this time in the absence of baseline figures. Information to hand indicates that volumes and scale of activity in relation to analogue compounds of 2-DPMP is limited to one company advertising their production to supply for the purpose of research (no medicinal or

industrial use) in the UK, which already holds a supply licence for Schedule 1 drugs. There is no known legitimate use of phenazepam in the UK.

In respect of the manufacturers, distributors and wholesalers that produce, supply, import or export these substances, 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 £3,133.00 and £4,700.00, and between £326.00 and £1,371.00 for a replacement domestic licence, 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 1-3 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, 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 these substances is sufficient to warrant such controls.

In relation to law enforcement and the illicit market (enforcement agencies, CJS, regulators)
Any real 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 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
The benefits that could be realised cannot be quantified. However, benefits are likely to arise from consistency in enforcement and regulatory response to control these drugs which may be similar to other substances already banned under the 1971 Act. It is expected that members of the public will be protected against the potential harm of these drugs and their misuse.

NET
There are considerable risks to adopt this option on the basis of evidence and expert advice that the 'legal high' market will quickly adopt chemical derivatives of these substances or new psychoactive substances imitating their effects to circumvent current drug controls. It is likely that Government intervention to enable law enforcement to protect the public from 2-DPMP under option 2 would become insufficient over a relatively short period of time.

ONE-IN-ONE-OUT (OIOO)
N/A
The regulatory framework for controlling drugs is already in place. The control of these new drugs is simply the result of bringing them under the definition of schedule II substances under the 1971 Act, due to the harms they pose, rather than any change in the regulatory framework.

OPTION 3 – Control of all substances under the Misuse of Drugs Act 1971 and its Regulations.

COSTS
In relation to legitimate use:
There is a lack of evidence of prevalence or use of these substances in the UK. Information to hand indicates that volumes and scale of activity in relation to analogue compounds of 2-DPMP is limited to one company's advertising their production to supply for the purpose of research (no medicinal or industrial use) in the UK, which already holds a supply licence for Schedule 1 drugs.

Potential costs to the pharmaceutical, health and research sectors of this option cannot be quantified at this time in the absence of baseline figures.

In respect of the manufacturers, distributors and wholesalers that produce, supply, import or export these substances, 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 £3,133.00 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 1-3 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, 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 these substances is sufficient to warrant such controls.

In relation to law enforcement and the illicit market (enforcement agencies, CJS, regulators)
Any real costs associated with option 3 cannot be predicted in light of nil to very limited data on prevalence and uses of these substances in the UK. However, it is expected that minimal costs arising from this option will be subsumed in to the enforcement and regulatory response to similar drugs already 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
Benefits realised under option 3 are expected to arise from consistency in enforcement and regulatory response to control of compounds which are similar to other substances already banned under the 1971 Act. Consistency in the law may give rise to streamlining of processes and activities relating to the likes of these substances. The added benefit of this option is the adoption of a leaner legislative approach that in that it is 'future-proof', meaning that protection of the public from harm and potential harms by generic definition is more cost effective than by a 'piecemeal' legislative approach of simple definition to control each substance under the 1971 Act.

Due to the small amount of data available on the prevalence and uses of these individual substances, it is not possible to quantify the benefits of the consolidation amongst the health sector, the industry and enforcement partners. However, it is expected that controlling families and similar drugs will bring consistency in activities relating to chemical derivatives of controlled drugs which have otherwise no legitimate or industrial use. It is expected that members of the public will be protected against the potential harm of these substances and their misuse.

NET
It is likely that the regulatory, health and enforcement costs of option 3 would be outweighed in more significant proportion by the benefits of consolidation in existing control measures as well as the contribution of the 1971 Act and its Regulations to reduce the harms and associated costs of use and misuse of harmful substances amongst the general population.

ONE-IN-ONE-OUT (OIOO)
N/A
The regulatory framework for controlling drugs is already in place. The control of these new drugs is simply the result of bringing them under the definition of schedule II substances under the 1971 Act, due to the harms they pose, rather than any change in the regulatory framework.

F. Risks

OPTION 2 – Control under the Misuse of Drugs Act 1971 of 2-DPMP and phenazepam.

There are considerable risks to adopt this option on the basis of evidence and expert advice that the 'legal high' market will quickly adopt chemical derivatives of these substances or new psychoactive substances imitating their effects to circumvent current drug controls. It is likely that Government intervention to enable law enforcement to protect the public from 2-DPMP under option 2 would become insufficient over a relatively short period of time as other structurally related compounds would not be excluded. It is possible that pharmaceutical, health and research sectors may become adversely affected due to 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 lack of data, it may be possible that the legitimate use of these substances has been underestimated.

OPTION 3 – Control under the Misuse of Drugs Act 1971 of 2-DPMP and structurally related compounds by generic definition and phenazepam.

Due to the rapid pace at which the 'legal high' market is progressing, there is a risk that these substances may be replaced by new psychoactive substances imitating similar effects to circumvent any current and new drug controls. It is possible that pharmaceutical, health and research sectors may become adversely affected due to 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 lack of data, it may be possible that the legitimate use of these substances has been underestimated.

G. Enforcement

Enforcement of the proposed legislation will be undertaken by the Police Service, UK Border Agency, Health Regulatory Bodies, the Home Office Drug Licensing Unit, Accountable Officers 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 controlled drugs. The UKBA will enforce import controls by seizing suspected substances at the ports, also as part of their wider import control role. There will be no interference with the regulatory framework and processes implementing control measures in enforcement, health or regulatory agencies as part of their routine activities. The Misuse of Drugs Regulations 2001 will be amended and an update to the legislation communicated by the Home Office to include substances to be controlled under the 1971 Act in line with requirements defined by their scheduling under the Regulations.

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 Manufacturers, distributors and wholesalers that produce, supply, import or export these substances, they 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 drugs already controlled under the 1971 Act and will be managed within existing resources.	Benefits to Benefits are expected to arise from consistency in enforcement and regulatory response to control these drugs which may be similar to other substances already banned under the 1971 Act. It is expected that members of the public will be protected against the potential harm of these drugs and their misuse.
3	£NK	£NK
	Cost to Manufacturers, distributors and wholesalers that produce, supply, import or export these substances, 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). 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 drugs already controlled under the 1971 Act and will be managed within existing resources.	Benefits to Benefits are expected to arise from consistency in enforcement and regulatory response to control of compounds which are similar to other substances already banned under the 1971 Act. The added benefit of this option is the adoption of a leaner legislative approach in that it is 'future-proof', meaning that protection of the public from harm and potential harms by generic definition is more cost effective than by a 'piecemeal' legislative approach of simple definition to control each substance under the 1971 Act. It is expected that controlling families and similar drugs will bring consistency in activities relating to chemical derivatives of controlled drugs which have otherwise no legitimate or industrial use. It is expected that members of the public will be protected against the potential harm of these substances and their misuse.
Source:		

Option 3 is the preferred approach because it is based on Government consideration of evidence and ACMD's expert advice supporting the use of existing control measures which help to protect the public from the prevalence of harmful substances and their misuse. Despite the limited amount of data available, the ratio benefits/costs of option 3 fares better by consolidating and 'future-proofing' controls with minimal added costs than options 1 and 2 which bear minimal costs but little or short-term benefits.

I. Implementation

The Government plans to implement these changes, subject to Parliament's approval, under the Misuse of Drugs Act 1971 (Amendment) Order 2012.

J. Monitoring and Evaluation

The effectiveness of the new regime would be monitored through gathering data on prevalence and illicit drug use, data from the health sector and the regulatory framework governing legitimate activities in relation to controlled substances, and also through the oversight of Accountable Officers and the healthcare regulatory bodies in England and the Devolved Administrations in respect of most medicines. The Home Office, as the regulatory authority on licensing of activities relating to controlled drugs and as lead department working with other Government departments, may further commission research on the prevalence and use of controlled drugs. As part of its statutory duties under the 1971 Act the ACMD keeps the situation relating to drugs under review.

K. Feedback

Feedback will be sought from producers, suppliers, healthcare and medical subscribers.

L. Specific Impact Tests

See Annex 1.

Annex 1. Specific Impact Tests

Statutory Equality Duties

Equality Impact Assessment
See attached EIA form.

To control 2-DPMP and related compounds by generic definition and phenazepam which are considered “dangerous or otherwise harmful” in accordance with the terms of the Misuse of Drugs Act 1971. 2-DPMP and structurally related compounds are new psychoactive substances marketed to imitate the effects of stimulant drugs but not currently subject to control. Phenazepam presents harms from misuse commensurate with their equivalent controlled Class C benzodiazepines but it is not currently subject to control under the 1971 Act. The intended objectives are to deter use of these substances amongst the population, particularly by young people, and curb availability through suppliers 'self-regulating' following implementation of control measures as well as enabling law enforcement and regulatory authorities to take appropriate action, in particular activity to tackle unauthorised production, supply and import/exportation, while providing the regulatory framework required to enable the undertaking of legitimate activities relating to some of these substances.

Economic Impacts

Competition Assessment
It is expected that control measures in relation to producers and suppliers of 2-DPMP and related compounds will apply equally to firms involved in the domestic trade of these substances as well as firms involved in the import/exportation of these substances.

Social Impacts

Health and Well-being
Controls under the 1971 Act and its Regulations reinforce Government measures to protect the public from the health and social impact of harmful substances and their diversion from legitimate use. The legislative approach is supported by Government drug policies in prevention, enforcement and health.

Human Rights
Government intervention to protect the public from harmful substance use and health or harms associated with misuse by the introduction of controls to help limit the availability and regulate activities to legitimate use is 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 some suppliers will ‘self-regulate’. The new legislation would amount to a minimal impact on the criminal justice system as part of its wider activities of implementation of drug controls.