EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS ACT 1971 (AMENDMENT) ORDER 2011

2011 No. 744

1. This explanatory memorandum has been prepared by the Home Office and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 The Order in Council classifies the following drugs for control under Schedule 2 to the Misuse of Drugs Act 1971:

(i) tapentadol; and
(ii) amineptine

2.2 The Order in Council makes clarifying amendments to paragraph 1(a) of Part 2 of Schedule 2 to the Misuse of Drugs Act 1971 in respect of "4-methylmethcathinone" (also known as mephedrone).

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Legislative Context

4.1 The Misuse of Drugs Act 1971 (the 1971 Act) controls drugs that are "dangerous or otherwise harmful". Schedule 2 to the 1971 Act specifies these drugs and groups them in three categories – Part 1 lists drugs known as Class A drugs, Part 2 lists Class B drugs and Part 3 lists Class C drugs. The three-tier system of classification (A, B and C) provides a framework within which criminal penalties are set with reference to the harm a drug has or is capable of having when misused and the type of illegal activity undertaken in regard to that drug.

4.2 Section 2 of the 1971 Act enables amendments to be made to the list of drugs controlled under the Act by means of an Order in Council. Recommendations to make such Orders are not made unless a draft of such an order has been approved by resolution of both Houses of Parliament and section 2(5) also provides that the Secretary of State shall not lay a draft order except after consultation with the Advisory Council on the Misuse of Drugs (ACMD).

4.3 The classification of each of the drugs listed in paragraph 2.1 above is predicated on an assessment of their respective harms and in accordance with recommendations made by the ACMD, pursuant to the statutory duty to consult under section 2(5) of the 1971 Act.

4.4 Tapentadol is a recently developed centrally-acting analgesic (painkiller), with effects similar to opioids like morphine, likely to be marketed in the UK in the near future. The ACMD has concluded that tapentadol presents a risk of misuse, diversion from legitimate sources, addiction and potential medicinal misuse. Amineptine is a powerful and fast acting antidepressant, misuse of which has been reported mainly in Asia and Europe. In 2003, the Commission on Narcotic Drugs, on the recommendation of the World Health Organisation, decided to include amineptine in Schedule II of the Convention on Psychotropic Substances of 1971. The UK is a signatory to the 1971 UN Convention. The ACMD recommends that tapentadol and amineptine are controlled under the Misuse of Drugs Act 1971 in Class A and Class C respectively and Schedule 2 to the Misuse of Drugs Regulations 2001 (as amended) (the 2001 Regulations).

4.5 When 4-methylmethcathinone (mephedrone) was controlled in April 2010, the policy intention was to make it clear to the public that the substance was controlled by specifying this on the face of the 2010 Order. This amendment further clarifies the legislation on mephedrone and means mephedrone will now be captured by the generic definition in paragraph 1(aa) of Part 2 of Schedule 2 to the 1971 Act which controls related cathinone derivatives. The control of mephedrone – as a Class B drug under the 1971 Act – is not affected by this clarification.

5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

6.1 The Minister for Crime Prevention, James Brokenshire, has made the following statement regarding Human Rights:

> In my view the provisions of the Misuse of Drugs Act 1971 (Amendment) Order 2011 are compatible with the Convention rights.

7. Policy background

- ***What is being done and why***

7.1 The effects and risks associated with tapentadol are similar to those of other μ-opioid analgesics, including hydromorphone and morphine (both controlled as Class A drugs under the Misuse of Drugs Act 1971). Tapentadol presents a risk of addiction, and potential medicinal misuse. The risks associated with an overdose of tapentadol are constriction of the pupils, vomiting, loss of consciousness, seizures, difficulty in breathing and a risk of serious complications likely to lead to death. Tapentadol's control as a Class A drug under the 1971 Act, as recommended by the ACMD, not only acts as a precautionary measure but also brings the drug in line with similar μ-opioid analgesics, including hydromorphone and morphine. The ACMD's advice in

respect of tapentadol can be found at http://www.homeoffice.gov.uk/publications/drugs/acmd1/acmd-letter-tapentadol.

7.2 Amineptine was included in Schedule II of the Convention on Psychotropic Substances of 1971, by the Commission on Narcotic Drugs, on the recommendation of the World Health Organisation. The UK is a signatory to the 1971 Convention. The ACMD, the statutory body which advises Government on drug issues, has considered amineptine in the light of its potential harms and advises control as a Class C drug under the 1971 Act. The ACMD's advice in respect of amineptine can be found at; http://www.homeoffice.gov.uk/publications/drugs/acmd1/acmd-letter-amineptine.

7.3 It is intended to make a further related statutory instrument amending the Misuse of Drugs Regulations 2001 (as amended), to insert tapentadol and amineptine in Schedule 2 to the 2001 Regulations, with the effect that the requirements of Regulations 14, 15, 16, 18, 19, 20, 21, 23, 26, and 27 would apply to these drugs.

7.4 When mephedrone was controlled in April 2010, the policy intention was to make it clear to the public that the substance was controlled by specifying this on the face of the 2010 Order. The Order controlling mephedrone specifically carved out mephedrone from the generic definition used to control other related cathinone derivatives to highlight its control. This amendment further clarifies the legislation on mephedrone, subsuming mephedrone within the generic definition created by paragraph 1(aa) of Part 2 of Schedule 2 to the 1971 Act which controls related cathinone derivatives. The control of mephedrone – as a Class B drug under the 1971 Act – is not affected by this clarification.

- ***Consolidation***

7.5 None.

8. Consultation outcome

8.1 Consultation is not necessary or beneficial in the control of tapentadol and amineptine. Tapentadol is currently not licensed by the Medicines and Healthcare products Regulatory Agency and no evidence on UK prescribing either by the National Health Service or privately is available. Amineptine is also currently off-patent and not licensed for use in the UK.

9. Guidance

9.1 The law changes and their consequences will be communicated to key stakeholders and the wider public. The Home Office will issue a Circular with legislative guidance primarily for the police and the courts.

10. Impact

10.1 The impact on business, charities or voluntary bodies principally relates to potential additional administrative costs for the pharmaceutical industry in respect of the drugs proposed for control which have legitimate uses, although this is likely to be small.

10.2 The potential impact on the public sector relates to certain healthcare sectors. There are potential additional administrative costs to certain sectors of healthcare in respect of the availability and use of these drugs, although these are likely to be small.

10.3 An Impact Assessment and Equality Impact Assessment are attached to this memorandum.

11. Regulating small business

11.1 The legislation applies to small business.

11.2 The harm from misuse and diversion of these drugs is such that the pharmaceutical industry and certain sectors of healthcare will be expected to comply with the 1971 Act (as amended) and subordinate legislation made under it, however small the business. However, the potential impact is minimal as these businesses are already likely to be handling controlled drugs, acting under Home Office licence or the 2001 Regulations (as amended), and guidance is already widely available in this area.

12. Monitoring & review

12.1 The Government will monitor the control measures through the regulatory framework governing medicines and controlled drugs, and also through the oversight of the healthcare regulatory bodies in England and the Devolved Administrations.

13. Contact

Des Niimoi at the Home Office, tel: 020 7035 3533 or e-mail: Desmond.Niimoi@homeoffice.gsi.gov.uk, can answer any queries regarding the instrument.

Title:	Impact Assessment (IA)
Impact Assessment of Controlling of Tapentadol and Amineptine under the Misuse of Drugs Act 1971	**IA No:** HO0023
Lead department or agency: HOME OFFICE	**Date:** 08/10/2010
Other departments or agencies:	**Stage:** Final
	Source intervention: Domestic
	Type of measure: Primary legislation
	Contact for enquiries: Des Niiimoi(X 3533)

Summary: Intervention and Options

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

The substances to be controlled – tapentadol and amineptine under the Misuse of Drugs Act 1971 are considered sufficiently harmful when misused, following assessment and advice from the Advisory Council on the Misuse of Drugs, to warrant control measures relating to possession, supply, manufacture and import/exportation with associated criminal sanction. Government intervention is necessary to help protect the public from the potential harms of these substances.

What are the policy objectives and the intended effects?

To control substances considered potentially "dangerous or otherwise harmful" in accordance with the terms of the Misuse of Drugs Act 1971. The intended effects are to deter misuse and restrict diversion and therefore misuse of these substances.

What policy options have been considered? Please justify preferred option (further details in Evidence Base)

Option 1 : No change

Option 2 : Control under the Misuse of Drugs Act 1971 (the 1971 Act) for each of the substances with alternative options regarding the level of control under the 1971 Act as described below under options.

Option 2 is the preferred option.

When will the policy be reviewed to establish its impact and the extent to which the policy objectives have been achieved?	It will be reviewed 10/2015
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	Yes

Ministerial Sign-off For final proposal stage Impact Assessments:

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) the benefits justify the costs.

Signed by the responsible Minister: James Brokenshire ..... Date: 11 January 2011 .....

Summary: Analysis and Evidence

Policy Option 1

Description:

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	negligible		negligible	**negligible**

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

Potential costs fall to the pharmaceutical industry and the Health sector in the case of tapentadol. However, without baseline figures of prevalence and use, these cannot be quantified at this time. There are no known potential additional administrative costs to the healthcare sector in respect of amineptine. Both drugs are currently not licensed in the UK

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

None

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	Unknown		Unknown	**Unknown**

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

It is not possible to monetise the benefits due to lack of available data.

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

Control measures bringing about the curtailment of availability of these substances will have benefits across government and society as a whole.

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

None

Impact on admin burden (AB) (£m):			Impact on policy cost savings (£m):	In scope
New AB:	**AB savings:**	**Net:**	**Policy cost savings:**	Yes/No

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			United Kingdom		
From what date will the policy be implemented?			30/11/2010		
Which organisation(s) will enforce the policy?			UK Border Agency, Police Service, Her Majesty's Court Service and Healthcare Regulatory Bodies.		
What is the annual change in enforcement cost (£m)?			Not known		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:**	**Non-traded:**	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:**	**Benefits:**	
Annual cost (£m) per organisation (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	No	
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	
Small firms Small Firms Impact Test guidance	Yes	
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	Yes	
Human rights Human Rights Impact Test guidance	No	
Justice Justice Impact Test guidance	No	
Rural proofing Rural Proofing Impact Test guidance	No	
Sustainability Sustainable Development Impact Test guidance	No	

[1] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

References

Include the links to relevant legislation and publications, such as public impact assessment of earlier stages (e.g. Consultation, Final, Implementation).

No.	Legislation or publication
1	
2	
3	
4	

+ Add another row

Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the **Annual profile of monetised costs and benefits** (transition and recurring) below over the life of the policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

Annual profile of monetised costs and benefits* - (£m) constant prices

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Transition costs										
Annual recurring cost										
Total annual costs										
Transition benefits										
Annual recurring benefits										
Total annual benefits										

* For non-monetised benefits please see summary pages and main evidence base section



Microsoft Office
Excel Worksheet

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 TAPENTADOL

Background

Tapentadol is a recently developed centrally-acting analgesic (painkiller) which is likely to be marketed in the UK in the near future, following licensing by the Medicines and Healthcare products Regulatory Agency (MHRA).

A tapentadol IR (immediate-release) tablet formulation has been developed for the relief of acute pain and a tapentadol PR (prolonged-release) tablet formulation for the relief of chronic pain in a global development program between Grünenthal GmbH and Johnson & Johnson Pharmaceutical Research & Development.

In line with international guidelines for the Nonclinical Investigation of the Dependence Potential of Medicinal Products (EMEA/CHMP/SWP/94227/2004), a thorough investigation of tapentadol, both in vitro and in vivo, has been undertaken to fully characterize this novel compound with respect to rewarding and reinforcing properties, physical dependence and tolerance development. In addition to the nonclinical program, a human misuse liability trial comparing tapentadol to the opioid hydromorphone was also conducted.

The results of these investigations showed that tapentadol is expected to have dependence potential similar to classic μ-opioid receptor agonists, like morphine and hydromorphone, and therefore a risk of misuse and of diversion from legitimate sources. Tapentadol also presents a risk of addiction, potential illegal diversion and medicinal misuse. The developers have therefore sought to have tapentadol scheduled under UK law prior to marketing in the UK. MHRA is currently awaiting scheduling under UK drug legislation before granting a marketing authorisation for tapentadol.

The Advisory Council on the Misuse of Drugs (ACMD), the Government's statutory advisory body on drug issues, considered the harms associated with the drug and concluded that the potential for misuse of tapentadol is similar to that of other μ-opioid analgesics, including hydromorphone and morphine (both controlled as Class A drugs under the Misuse of Drugs Act 1971). The ACMD also concluded that the misuse liability of tapentadol would be substantial and has the potential to cause social harm through diversion and addiction. The ACMD recommends that tapentadol is controlled under the Misuse of Drugs Act 1971 in Class A – and Schedule 2 of the Misuse of Drugs Regulations 2001 (as amended).

Tapentadol is currently not marketed or available in the UK and therefore no impact is expected on the third sector. In relation to the private sector and small business, no further impact has been identified outside the current requirements of the regulatory framework on all Schedule 2 controlled drugs – recording and safe custody – which are already applicable to businesses dealing in Schedule 2 controlled drugs.

A.2 AMINEPTINE

Background

Amineptine was developed and introduced in France in 1978. It has antidepressant and psychostimulant properties that selectively inhibit the reuptake of dopamine, and to a lesser extent norepinephrine exerting a powerful and fast acting antidepressant effect similar to tricyclic antidepressants. However, amineptine has little cardiovascular, analgesic or anorectic effects. After its release into the European market cases of hepatotoxicity emerged, some serious. This, along

with the potential for misuse, led to the suspension of the French marketing authorisation for Survector (Brand name for amineptine) in 1999.

According to the World Health Organisation (WHO) Expert Committee on Drug Dependence (ECDD); *'Amineptine abuse has been reported mainly in Asia and Europe. However, its medical use in developing countries, as well as its abuse continues. The reports of adverse drug reactions collected by the international drug monitoring programme indicated a larger number of case reports of abuse and dependence for amineptine than for other anorectic stimulants currently placed in Schedule IV of the 1971 Convention, such as amfepramone. The responses of governments to the WHO questionnaire also indicated limited diversion and abuse of the drug although some reported hospital admissions have been linked to the use or abuse of amineptine'.*[1]

The WHO ECDD has reported that there had been few animal studies on the potential for dependence or misuse of amineptine. However, some clinical studies have indicated that amineptine has the potential both for dependence and misuse, predominantly in patients with a previous history of substance misuse. The withdrawal symptoms include anxiety, psychomotor agitation and insomnia. Instances of dependence have been reported in Asia and Europe.

On 8th April 2003, the Commission on Narcotic Drugs, on the recommendation of the World Health Organization, decided by 41 votes to none, with 2 abstentions, to include amineptine (7-[(10,11-dihydro-5*H*dibenzo[*a,d*]cyclohepten-5-yl)amino]heptanoic acid) in Schedule II of the Convention on Psychotropic Substances of 1971.[2]

The ACMD have considered the status of amineptine and acknowledge that there is little evidence concerning its licit or illicit use in the United Kingdom as amineptine is currently off-patent and difficult to obtain. However, considering its potential for harms and the UK's obligations under the Convention on Psychotropic Substances of 1971, the UK is obliged to schedule amineptine, under domestic legislation – the Misuse of Drugs Act 1971 – following the decision of the Commission on Narcotic Drugs in 2003. The ACMD recommends that amineptine is controlled under the Misuse of Drugs Act 1971 in Class C – and Schedule 2 of the Misuse of Drugs Regulations 2001 (as amended).

Control of amineptine under UK drug legislation is a result of the UK's obligation as a signatory to the UN Convention on Psychotropic Substances of 1971 and as a precautionary measure based on the assessment of harms and the potential for misuse highlighted by the ACMD.

Amineptine is currently not available in the UK. It has been withdrawn from most western countries and currently available only in the developing world. It is unlikely that this drug will be licensed for use in the UK given its harm potential. No impact is therefore expected on the third sector, private and small business.

1 http://whqlibdoc.who.int/trs/WHO_TRS_915.pdf
2 http://www.unodc.org/documents/commissions/CND-session46/CND-Decision-46-01.pdf

A.3 Groups Affected

B. Rationale

The case for controlling tapentadol and amineptine under the Misuse of Drugs Act 1971 (as amended) can be examined in relation to potential harms when both drugs are misused.

- The effects and risks associated with tapentadol are similar to those of other μ-opioid analgesics, including hydromorphone and morphine (both controlled as Class A drugs under the Misuse of Drugs Act 1971). Tapentadol presents a risk of addiction, potential illegal diversion and medicinal misuse The risks associated with an overdose of tapentadol are constriction of the pupils, vomiting, loss of consciousness, seizures, difficulty in breathing and a risk of serious complications likely to lead to death.

- The effects and risks associated with the use of amineptine are nervousness, irritability, insomnia and suicidal ideation. Amineptine also has the potential both for dependence and misuse, predominantly in patients with a previous history of substance misuse. The withdrawal symptoms include anxiety, psychomotor agitation and insomnia.

- The control measures will ensure compliance with our obligations under the UN Convention on Psychotropic Substances of 1971 (in the case of amineptine), and help prevent the diversion and misuse of tapentadol and amineptine through the regulatory framework for controlled drugs.

C. Objectives

The measure to control tapentadol and amineptine is aimed at supporting the overarching aim of UK drugs laws - to protect individuals and society from the harmful effects of dangerous or otherwise harmful drugs. Tapentadol and amineptine both present a risk of dependence and misuse.

D. Options

2 options have been considered in respect of tapentadol and amineptine.

Option 1: is to make no changes (do nothing).

This option is not acceptable to Government nor was it supported by ACMD advice. The UK Government would not be acting to protect the public from the potential harms associated with the diversion and misuse of these substances if this option is adopted. The UK Government will also not be fulfilling its obligations under the 1971 UN Convention, in the case of amineptine, if it adopted this option.

Option 2: Control tapentadol under the Misuse of Drugs Act 1971 as a Class A drug (and Schedule 2 to the Misuse of Drugs Regulations 2001 (as amended)), and amineptine as a Class C drug (and Schedule 2 to the Misuse of Drugs Regulations 2001 (as amended)).

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

E. Appraisal (Costs and Benefits)

General Assumptions and Data

NONE

Option 2 – Control tapentadol under the Misuse of Drugs Act 1971 as a Class A drug (and Schedule 2 to the Misuse of Drugs Regulations 2001 (as amended)), and amineptine as a Class C drug (and Schedule 2 to the Misuse of Drugs Regulations 2001 (as amended)).

Policy Costs
Tapentadol and amineptine are currently not controlled under the Misuse of Drugs Act 1971 (the 1971 Act). However, these drugs cannot be marketed in the UK as a result of Medicines legislation until a marketing licence has been issued by the MHRA.

Costs in respect of option 2 are as follows;

- *In relation to legitimate medicinal use.*

  It is considered that this proposal is unlikely to have significant impact on the legitimate use of tapentadol and amineptine. Amineptine is currently not licensed for use as a medicine in the UK.

  In respect of the manufacturers, distributors and wholesalers that produce, supply, import or export tapentadol, 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 on-line. The fee for an initial application for a license currently ranges between £3,133.00 and £4,700.00, and between £326.00 and £1371.00 for a replacement license. Licenses are valid for a period of 12 months. The fee for an import or export license is currently £24.00 per transaction. The license fees are necessary to maintain the regulatory framework needed to protect the public from the potential harms posed by these drugs. However, most organisations already dealing in Schedule 2 controlled drugs will have a license in place and will therefore not incur further charges over and above what they will usually require for Schedule 2 controlled drugs. There may also be some relatively small administration costs in relation to time taken to complete an import/export licence application.

  As Schedule 2 drugs under the Misuse of Drugs Regulations 2001 (as amended), tapentadol and amineptine will be subject to safe custody requirements and also record keeping requirements. These statutory requirements are likely to result in minimal additional costs.

  However, the manufacturers have confirmed that they will be using an already established supply chain which handles similar controlled drugs in the UK. This means that they will not be incurring any significant additional costs in relation to safe custody, licensing and recording requirements under the current regulatory framework. It is therefore expected that any impact as a result of these proposals will be minimal.

- *To law enforcement and CJS in respect of enforcement against the illicit market*

Any real costs associated with Option 2 cannot be predicted as both drugs are currently not licensed or prescribed in the UK.

The impact of these proposed controls on the police and consequently the CJS will be subsumed into the enforcement response to similar drugs already controlled under the Misuse of Drugs Act 1971, including morphine and hydromorphone. 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 drugs crime with a focus on those offences which cause the most harm. As such, operational activity may focus on Class A and B drugs.

Administrative Burdens

TOTAL COSTS
Not quantifiable

Policy Benefits

The overarching benefit of this proposal is that controls should reduce, if not eliminate, diversion and misuse and thus limit the potential harm to individual misuser's health, with associated costs of treatment and care. It will also aid detection and monitoring of the manufacturing and supply of these drugs.

In the case of amineptine this proposal will also ensure that we are compliant with our international obligations and support the international community in restricting the availability of this substance. Whilst there is no evidence of licit or illicit use of amineptine in the UK, controlling amineptine under drugs legislation may have some further social benefit in protecting the public.

Administrative Savings
NONE

F. Risks

<u>Option 2 –</u> Control tapentadol and amineptine as Class A and C drugs respectively under the Misuse of Drugs Act 1971 and Schedule 2 to the Misuse of Drugs Regulations 2001 (as amended)

There are no risks attributable to this option. Tapentadol and amineptine are not currently licensed by the MHRA; control under the 1971 Act will prevent the harms associated with the misuse of these drugs.

There is presently no evidence of misuse of tapentadol and amineptine in the UK.

G. Enforcement

Enforcement of the proposed legislation will be undertaken by the Police Service, the UK Border Agency, Health Regulatory Bodies, Accountable Officers and other relevant Agencies responsible for enforcing criminal legislation in the UK. Police enforcement will form part of their wider approach to tackling controlled drugs. The UK Border Agency 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	£x/year	£x/year
	Cost to (not quantified)	Benefits to (not quantified)
3	£x/year	£x/year
	Cost to (not quantified)	Benefits to (not quantified)

Source:

I. Implementation

Subject to Parliamentary approval, the Government plans to implement the Misuse of Drugs Act (Amendment) Order 2011 on 28 March 2011.

J. Monitoring and Evaluation

The Government will monitor the control measures through the regulatory framework governing medicines and controlled drugs, and also through the oversight of Accountable Officers and the healthcare regulatory bodies in England and the Devolved Administrations.

K. Feedback

Feedback will be sought from suppliers and medical prescribers of these drugs.

Annexes

Annex 1 should be used to set out the Post Implementation Review Plan as detailed below. Further annexes may be added to provide further information about non-monetary costs and benefits from Specific Impact Tests, if relevant to an overall understanding of policy options.

Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their actual costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

Basis of the review: [The basis of the review could be statutory (forming part of the legislation), it could be to review existing policy or there could be a political commitment to review];

The basis of a review of this proposal would be on policy grounds.

Review objective: [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?]

The review objective will be to identify if practitioners and those who handle these drugs are working within the regulatory framework in order to prevent diversion and misuse of the drugs.

Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach]

The approach of the review will involve a yearly in depth evaluation of prescribing trends by the healthcare regulatory bodies in the UK, using data from the National Health Service prescribing agency as well as information from Local Intelligence Networks for controlled drugs.

The information gathered through submission of prescription data to the National Health Service agency in addition to those received from Local Intelligence Networks will be evaluated by the health regulatory bodies to identify trends of diversion and misuse as well as prescribing trends.

Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured]

The baseline for measuring changes is the non availability and therefore the non-prescribing of these drugs in addition to a comparism with prescriptions for similar drugs.

Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives]

The success criteria will be a position where these drugs are not over prescribed and where the prescription and dispensing of the drugs are conducted under the regulatory framework, especially in the case of private prescribing.

Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection systematic collection of monitoring information for future policy review]

The monitoring arrangements for this proposal are already provided for under the provisions of the Misuse of the 2001 Regulations, and currently apply to all Schedule 2 controlled drugs. The 2001 Regulations places requirements on organisations and individuals in relation to the prescribing, dispensing, requisitioning, recording, import/export and destruction of Schedule 2 controlled drugs.

In addition, the Misuse of Drugs (Safe Custody) Regulations 1973 places safe custody requirements on organisations and individuals dealing with Schedule 2 controlled drugs. The Health Act 2006 also established the role of Accountable Officers with responsibility to establish and ensure appropriate arrangements to comply with Misuse of Drugs legislation. Accountable officers have a duty to establish Local Intelligence Networks to analyse prescribing practices within their area and ensure their areas have processes for establishing an incident panel if serious concerns are raised about controlled drugs.

Reasons for not planning a PIR: [If there is no plan to do a PIR please provide reasons here]

N/A

Annex 2. Specific Impact Tests

Statutory Equality Duties
Equality Impact Assessment

EQUALITY IMPACT ASSESSMENT
Group: Crime and Policing Group
Directorate: Drugs, Alcohol and Partnerships Directorate
Unit: Drug Strategy Unit

PRELIMINARY SCREENING

Date of Screening	2010
Name of Policy Writer	Des Niimoi
Director General	**Stephen Rimmer**

Name of Policy	**x**	This is a **new** policy
		This is a **change** to an existing policy
		This is an **existing** policy

Policy Aims, Objectives & Projected Outcomes
To control tapentadol and amineptine which are considered “dangerous or otherwise harmful”, when misused, in accordance with the terms of the Misuse of Drugs Act 1971. Tapentadol is a recently developed centrally-acting analgesic (painkiller) which is likely to be marketed in the UK in the near future, following licensing by the Medicines and Healthcare products Regulatory Agency (MHRA). Tapentadol is expected to have dependence potential similar to classic mu-opioid receptor agonists, like morphine and hydromorphone, and therefore a risk of misuse and of diversion from legitimate sources. Tapentadol also presents a risk of addiction and medicinal misuse. Amineptine was developed and introduced in France in 1978. It has antidepressant and psychostimulant properties that selectively inhibit the reuptake of dopamine, and to a lesser extent norepinephrine exerting a powerful and fast acting antidepressant effect similar to tricyclic antidepressants. Amineptine has the potential both for dependence and misuse, predominantly in patients with a previous history of substance misuse.

Will the policy have an impact on national or local people/staff?	YES
Are particular communities or groups likely to have different needs, experiences and/or attitudes in relation to the policy	NO
Are there any aspects of the policy that could contribute to equality	NO

or inequality?	
Could the aims of the policy be in conflict with equal opportunity, elimination of discrimination, promotion of good relations?	NO
If this is an amendment of an existing policy, was the original policy impact assessed?	N/A

If your answer to any of these questions is **YES**, go on to the full EIA.

If you have answered **NO** to all of these questions then please attach the following statement to all future submissions and within your regulatory impact assessment and ensure it is signed off by senior management.

“This policy was screened for impact on equalities on [insert date]. The following evidence [Evidence] has been considered. No full equality impact assessment is required. “

Remember that all policies that are likely to have a significant impact on individuals and the public as a whole are likely to require a full EIA.

FULL IMPACT ASSESSMENT

STATISTICS & RESEARCH

What relevant quantitative & qualitative data do you have in relation to this policy?

Equality Target Areas	**How does the data identify potential or known positive impacts?** **How does the data identify any potential or known adverse impacts?**
Race (consider e.g. nationalities, Gypsies, Travellers, languages)	None at present. To our knowledge, no data is available on race in relation to the use of these substances. It is not anticipated that the change in policy will have any disproportionate impact on race.
Disability (consider social access and physical access)	None at present. To our knowledge, no data is available on disability in relation to the use of these substances. It is not anticipated that the change in policy will have any disproportionate impact on disability.
Gender	None at present. It is not anticipated that this policy will have any disproportionate impact on gender.
Gender Identity	None at present. To our knowledge, no data is available on gender identity in relation to the use of these substances. It is not anticipated that the change in policy will have any disproportionate impact on gender identity.
Religion and Belief	None at present. To our knowledge, no data is available on religion and belief in relation to the use of these substances. It is not anticipated that the change in policy will have any disproportionate impact on religion and belief.
Sexual Orientation	None at present. To our knowledge, no data is available on sexual orientation in relation to the use of these substances. It is not anticipated that the change in policy will have any disproportionate impact on sexual orientation.
Age	None at present. To our knowledge, no data is available on sexual orientation in relation to the use of these substances. It is not anticipated that the change in policy will have any disproportionate impact on sexual orientation.

What research have you considered commissioning to fill any data gaps?

Who are the stakeholders, community groups, staff or customers for this policy area?
• Drug users, their children, their families and all members of communities impacted by illegal drug use. • Practitioners working in drug treatment services. • Advisory Council on the Misuse of Drugs (ACMD). • The National Treatment Agency for Substance Misuse (NTA). • Primary Care Trusts (PCTs). • Inter-agency drug action teams and local partnerships, including Drug Action Teams (DATs), Drug and Alcohol Action Teams (DAATs) and Crime and Disorder Reduction Partnerships (CDRPs). • Enforcement agencies and all parts of the Criminal Justice System**.** • Educational institutions. • Local Authorities. • The Home Office. • Department of Health. • Department for Children, Schools and Families, • Ministry of Justice. • Department for Work and Pensions. • Department for Communities and Local Government. • Other UK governments – Wales, Scotland and Northern Ireland. • Charity and voluntary groups.

What are the overall trends and patterns in this qualitative & quantitative data?
As these substances are not controlled to date under the Misuse of Drugs Act 1971, there is no robust available evidence to evaluate the overall trends and patterns. The MHRA have confirmed that there are no licences for both drugs and that there are no records of amineptine being imported as a constituent of another drug into the UK

Please list the specific equality issues that may need to be addressed through consultation (and further research)?
None

GATHERING EVIDENCE THROUGH COMMUNITY ENGAGEMENT

INTERNAL STAKEHOLDER ENGAGEMENT: Consulting & involving Other Government Departments, Staff, Agencies & NDPBs

Does this policy affect the experiences of staff? How? What are their concerns?	
Staff	Bringing these substances under the control of the Misuse of Drugs Act 1971 could affect staff in treatment services, in enforcement agencies, in education and children's services, staff throughout the criminal justice system and those concerned with benefits and needs assessment and provision.
Staff Networks & Associations	----------
Trade Unions	----------

How have you consulted, engaged and involved internal stakeholders in considering the impact of this proposal on other public policies and services?
The control measures to be introduced are in line with ACMD advice, following consultation with them. The ACMD did not raise any concerns about adverse impact on equality.

What positive and adverse impacts were identified by your internal consultees? Did they provide any examples?
No positive or adverse impacts have been identified.

EXTERNAL CONSULTATION & INVOLVEMENT

How did your engagement exercise highlight positive and negative impacts on different communities?	
Voluntary Organisations	•
Race	•
Faith	•
Disability Rights	•
Gender	•
Gender Identity	•
Sexual Orientation	•
Age	•

ASSESSMENT & ANALYSIS

Does the EIA show a potential for differential impact on any group(s) if this proposal is introduced? If Yes, state briefly whether impact is adverse or positive and in what equality areas.
EIA highlights the absence of robust data but does not highlight any potential for greater impact on a specific group.

What were the main findings of the engagement exercise and what weight should they carry?

Does this policy have the potential to cause unlawful direct or indirect discrimination? Does this policy have the potential to exclude certain group of people from obtaining services, or limit their participation in any aspect of public life?
Bringing these substances under control of the Misuse of Drugs Act 1971 will not cause unlawful discrimination. The Minister for Crime Prevention, James Brokenshire, has made the following statement regarding Human Rights: "In my view the provisions of the Misuse of Drugs Act 1971 (Amendment) Order 2010 are compatible with the Convention rights."

How does the policy promote equality of opportunity?
Control will help to deter misuse, improving an individual's health and should therefore enhance an individual's ability to work, career progression and day to day social activities.

How does your policy promote good relations? How does this policy make it possible for different groups to work together, build bridges between parallel communities, or remove barriers that isolate groups and individuals from engaging in civic society more generally?
The Government's decision to classify these substances under the Misuse of Drugs Act 1971, subject to parliamentary approval, is necessary to protect the public from these substances.

How can the policy be revised, or additional measures taken, in order for the policy to achieve its aims without risking any adverse impact?

Are there any concerns from data gathering, consultation and analysis that have not been taken on board?
No.

ENSURING ACCESS TO INFORMATION

How can you ensure that information used for this EIA is readily available in the future? (N.B. You will need to include this in your action plan)
• The full report on the equality impact assessment will be made available for those reviewing the policy at different stages.

How will you ensure your stakeholders continue to be involved/ engaged in shaping the development/ delivery of this policy? (N.B. You will need to include this in your action plan)
• There is continual liaison with both internal and external stakeholders. This engagement will continue.

How will you monitor this policy to ensure that the policy delivers the equality commitments required? (N.B. You will need to include this in your action plan)
• The control measures will be reviewed as part of the Coalition Government's new Drug Strategy to be published in December.

Economic Impacts

Small Firms Impact Test

Tapentadol, when licensed, will be supplied to patients via the usual route of prescription by a practitioner and dispensing through a pharmacy. This proposal will ensure that the necessary regulatory framework under the Misuse of Drugs Regulations 2001 is in place to govern those who deal with the drug – subjecting them to recording and safe custody requirements. Given the fact that pharmacies already deal with drugs in the same schedule any impact as a result of these proposals would be negligible.

Amineptine is currently not licensed in the UK and therefore no impact is expected on small business as a result of these proposals.

Environmental Impacts

NONE

Social Impacts

Health and Well-being

It is expected that the proposed changes will have a positive impact on the health and well being of users by ensuring that an effective regulatory framework is in place to prevent the diversion and misuse of the drugs.

Justice

[Insert Text] (NB Delete if there is not going to be an impact)

Sustainability

NONE