Title: Control of Methiopropamine (MPA) **IA No:** HO0291	**Impact Assessment (IA)**
RPC Reference No:	**Date: 17/07/2017**
Lead department or agency: Home Office	**Stage:** Final
Other departments or agencies: Department of Health, Department for Business, Energy and Industrial Strategy and The Medicines and Healthcare Products Regulatory Agency	**Source of intervention:** Domestic
	Type of measure: Secondary legislation
	Contact for enquiries: Sara Soleymani, Drugs and Alcohol Unit, 0207 035 3073

Summary: Intervention and Options

RPC Opinion: Not Applicable

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANDCB in 2014 prices)	**One-In, Three-Out**	**Business Impact Target Status**
N/K	N/K	N/K	Not in scope	Not a regulatory provision

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

The Advisory Council on the Misuse of Drugs (ACMD) has provided further advice regarding Methiopropamine (MPA) which is currently under a Temporary Class Drug Order (TCDO) due to expire on 27 November 2017. In the report dated 16 June 2017, the ACMD concluded that the harms associated with MPA are sufficient to constitute a societal problem and recommended that MPA be permanently controlled as a Class B drug under the Misuse of Drugs Act 1971. The ACMD also confirmed that there are no known legitimate medicinal, industrial or commercial uses of MPA and as such has recommended that MPA be listed as a Schedule 1 drug under the Misuse of Drugs Regulations 2001.

What are the policy objectives and the intended effects?

The policy objective is to reduce the risk of harms associated with misuse of MPA in the UK.

The intended effects are to limit access to MPA, to signal to the public the potential danger from MPA and to enable the police and other authorities to take action against the sale or distribution of MPA including any stereoisomeric forms, any salts of such compounds and any preparation or product containing such compounds.

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

Option 1: Do nothing. This option would mean that the TCDO will lapse and MPA will be captured under the Psychoactive Substances Act 2016 from 27 November 2017 onwards.

Option 2: Control MPA as a Class B drug under the Misuse of Drugs Act 1971 and a Schedule 1 drug under the Misuse of Drugs Regulations 2001, as recommended by the ACMD.

Based on the ACMD's assessment of the harms associated with MPA, option 2 is the preferred option.

Controlling MPA under the Misuse of Drugs Act 1971 would result in a higher level of control which would include a possession offence, more strictly defined supply and distribution offences and wider powers for enforcement than those provided in the Psychoactive Substances Act 2016.

Will the policy be reviewed? It will not be reviewed. **If applicable, set review date:** N/A

Does implementation go beyond minimum EU requirements?		N/A		
Are any of these organisations in scope?	**Micro** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** N/A	**Non-traded:** N/A	

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: Sarah Newton **Date:** 17th July 2017

Summary: Analysis & Evidence

Policy Option 2

Description:

FULL ECONOMIC ASSESSMENT

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

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

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

It is not possible to monetise the costs of this option with the current available data as measures of prevalence and other indicators around the the substance are incomplete.

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

Businesses: There should be no further cost to businesses by controlling MPA under the Misuse of Drugs Act 1971, as under option 1 its supply would remain restricted under the Psychoactive Substances Act 2016.

Public Sector: There may be some costs from enforcement responses, for example enforcing a possession offence under option 2, where none exists under option 1, though it is expected that these will be subsumed into the enforcement and regulatory response to other controlled drugs.

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

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

It is not possible to monetise the benefits of this option with the current available data.

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

Public Sector: Option 1 would allow MPA to be covered by the Psychoactive Substances Act 2016 which would result in lower maximum penalties for the supply, production and importation/ exportation as well as a different regime of control involving different offences. Under Option 2, there will be higher maximum penalties for these offences, including a possession offence under the Misuse of Drugs Act 1971. This would allow for a more straight forward and consistent regime to control MPA in line with other New Psychoactive Substances (NPS) that have been previously controlled. Under Option 2, certain enforcement costs are actually likely to be lower as there are fewer evidential requirements to satisfy when undertaking prosecutions.

Personal/ Societal: Given the lower enforcement costs and the clear message sent out by the Misuse of Drugs control, it provides a stronger, more targeted tool to address the societal harms of MPA.

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

To the best of our knowledge, MPA does not have any legitimicinal, industrial or commericial uses in the UK. In the event that MPA is being used by UK research bodies, most research organisations will already have existing licences which will permit access to these drugs for research purposes.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs:	**Benefits:**	**Net:** 0	

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 Background

1.1. This Impact Assessment considers the proposal to control Methiopropamine (MPA) as a Class B drug under the Misuse of Drugs Act 1971 and as a Schedule 1 drug under the Misuse of Drugs Regulations 2001, following the expiry of a Temporary Class Drugs Order (TCDO) on 27 November 2017.

A.1.1 Methiopropamine (MPA)

Taken from the ACMD's report on MPA, dated 16 June 2017:

1.2. MPA is a thiophene analogue of methamphetamine, originally synthesised in 1942. Its IUPAC name is N-methyl-1-(thiophen-2-yl)propan-2-amine. Other chemical names include methylthienylpropamine, N,α-dimethyl-2-thiopheneethanamine and methedrene. The hydrochloride salt form of MPA is a crystalline powder at room temperature.

1.3. MPA is reportedly taken orally, by inhalation, snorting, administering rectally, and by injecting, with the dosage ranging between 5-60 mg depending on the route of administration. The onset of effects vary depending on the route of administration and generally last between 2-4 hours but can persist for up to 24 hours.

Prevalence

1.4. MPA was first reported to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) following an alert in January 2011 by Finland. MPA seizures have since been reported to the EMCDDA by the UK, Spain, Croatia, Germany, Romania, Italy, Lithuania, Denmark, Poland, Belgium, Hungary, Bulgaria, Slovenia, Norway, Czech Republic, Sweden, France and Finland. The World Health Organization has also noted seizures in North America.

1.5. The National Crime Agency reports 105 seizures of MPA submitted for forensic analysis in 2015-2016, comprising 1.48 kilograms of powder and 1468 tablets.

1.6. MPA use has been detected in the UK, in pooled anonymous urine samples collected in street urinals in London since 2012. In a study from April 2014, MPA was also detected in pooled anonymous urine samples collected in London, Newcastle and Birmingham. MPA was also detected recently in a pooled urine sample at 2016 Creamfields festival.

1.7. The UK's Forensic Early Warning System's (FEWS) head shop collection plans reported 51 occurrences of MPA in 2015/2016, 17 of which were post-implementation of the TCDO. Prior to control, MPA had been widely available from Internet sites selling NPS. The cost of MPA decreased with increasing purchase amount (£19.49 ± 0.15 per gram for 500 mg to £3.54 ± 0.13 per gram for 1 kilogram).

1.8. The National Poisons Information Service (NPIS) reported a total of 677 accesses to the TOXBASE entry for MPA between May 2012 and March 2017 (these peaked in the lead up to the TCDO). There were also 101 telephone enquiries relating to MPA (1 January 2011 to 31 March 2017). Of these, 51 involved exposure to MPA alone and the remaining 50 reported use of other substances in addition. The most common reported products involved were Gogaine, Pink Panther, Purple Bomb and Pikey Dust, which had been identified as containing MPA (WEDINOS data).

1.9. The clinical effects reported by NPIS include predominantly tachycardia, chest tightness, anxiety and nausea, which is consistent with an amphetamine-type substance.

1.10. MPA is manufactured clandestinely with distribution and trafficking facilitated mainly via the Internet. Border Force seizure data reported a number of intercepted packages at Coventry International Postal Hub containing MPA between 2013 and 2015, ranging from 4 grams to 2 kilogram quantities. MPA has been also seen under the following brand names (not exhaustive): Ivory Dove Ultra, China White, Walter White, Quick Silver Ultra, Bullet, Mind Melt, Poke, Rush, Snow White.

Polysubstance use

1.11. MPA has been seen in branded packages in combination with ethylphenidate, 5-MeO-DALT, N-methyl-2AI as well as adulterants such as lidocaine, benzocaine and caffeine.

1.12. ‘Synthacaine’ a substance designed to mimic the effects of cocaine and often termed ‘legal cocaine’ has been found to contain MPA amongst varying other substances. This has reportedly been sold on both the surface web and the dark web for prices 3-4 times lower than cocaine.

1.13. A patient admitted to a psychiatry ward reported acute anxiety crisis accompanied by a sense of imminent danger following consumption of ‘Synthacaine’. The patient reported intense fatigue and visual hallucinations as well as self harming related to body dysmorphia. MPA was identified as being present in this ‘Synthacaine’ sample as well as N-methyl-2-amino-indane, 2-amino-indane and lidocaine.

1.14. Other branded combinations include: Charley Sheen (MPA and 2-AI), Go Gain (MPA and ethylphenidate). The brand name and the corresponding contents can vary, with the same branding being used for different drugs/combinations.

Acute harm

1.15. Users report similar effects to other stimulants such as MDMA, amphetamine and cocaine: stimulation, alertness and an increase of energy and focus; with adverse effects reported by users including tachycardia, anxiety, panic attacks, sweating, headaches, nausea, difficulty breathing, vomiting, difficulty urinating and sexual dysfunction.

1.16. The United Kingdom first issued alerts in 2012 when the national Focal Point reported three cases involving deaths associated with this substance. The first alert (January 2012) concerned two cases; the first involved a 'legal high' product known as 'Blow' that was suspected to have been snorted. Chemical analysis of the powder and post-mortem results both confirmed the presence of MPA, methylenedioxyaminoindane (MDAI), lidocaine, and caffeine, with MPA found in greater concentrations; in the second case, both MPA and methoxetamine were detected. The information from this case suggested that a 'legal high' product called 'China White' had been snorted by the deceased. The second alert (September 2012) related to a case where MPA was detected in post-mortem blood along with oxycodone, temazepam, venlafaxine and its metabolite O-desmethylvenlafaxine. The deceased was found collapsed with no other significant post-mortem findings.

1.17. The National Programme of Substance Abuse Deaths (NPSAD) reported 46 cases where MPA was found in post mortem toxicology, between 2012 and April 2017. In all of these occurrences, MPA was found in combination with other substances, mainly NPS.

1.18. MPA was implicated in the cause of death for 33 cases. MPA was found in combination with other substances in most instances. In the cases with only MPA implicated, the blood levels of MPA ranged from 0.74 micrograms per millilitre to 4.6 micrograms per millilitre.

1.19. The EU-MADNESS Project reported that there had been no deaths involving MPA registered in Northern Ireland by the end of December 2015, but during the same period in Scotland, 10 deaths were registered where the substance was recorded in the cause of death, and a further 8 cases where it was found in post mortem toxicology. Provisional data for 2016 death registrations in Scotland do not indicate the presence of MPA as being either implicated in the cause of death or being found in PM toxicology. Similarly, provisional data for Northern Ireland do not indicate the presence of MPA as being implicated in the cause of death.

1.20. Hospital admissions for MPA have been reported in the US and in Europe, with clinical features including anxiety, paranoia and vomiting.

1.21. There is a published case of analytically confirmed acute MPA toxicity in a patient who presented with mild stimulant toxicity: a 27-year-old woman presented to the Emergency Department (ED) 21 hours after oral ingestion of 'Hawaiian baby woodrose seeds' and nasal insufflation of 50 mg of 'Quicksilver' powder. On arrival in the ED she had nausea and dizziness and reported having had difficulty sleeping, intermittent palpitations and chest tightness. On examination she was agitated with dilated pupils but had a normal heart rate, blood pressure and temperature. She received a 5 mg dose of oral diazepam and intravenous fluid replacement. Her symptoms settled and she was discharged with no sequelae 16 hours after ED presentation. Toxicological screening detected MPA at a concentration of 400 ng/mL and two MPA metabolites (N-desmethyl- and hydroxy N-desmethyl-MPA), and ergonovine (concentration <10 ng/mL) a compound present in members of the Hawaiian baby woodrose family. A number of other substances were also detected:

morphine 100 ng/mL; and metabolites of the synthetic cannabinoids JWH-018 and JWH-019 (concentrations <5 ng/mL). As other drugs were present in the body, it was not possible to determine the exact role of MPA in this case; however MPA was found in the greatest concentration and in the opinion of the treating clinicians, was likely to be responsible for the effects seen.

1.22. Another report detailed the case of a 30 year old man who was admitted to a hospital emergency department having ingested 'Synthacaine'. The patient displayed symptoms of paranoid delusion, auditory and visual hallucinations and incoherent speech. Toxicological screening detected only the presence of MPA which was quantified. 13 hours after presentation to the emergency department, the plasma concentration of MPA was found to be 14 ng/mL.

1.23. One fatal case was reported in Sweden, where the concentration of MPA was 1.4 µg/g in femoral blood. Twenty-one non-fatal cases were also reported in Sweden in 2013.

Chronic harm

1.24. As MPA has reportedly only been in use since 2011, there are no data available on any chronic harm. However, the Scottish Drugs Forum suggested that the extended use of MPA similar to other stimulant drugs are likely to result in symptoms including tiredness, weight loss and an increased risk of mental health issues such as paranoia, mood swings and low mood.

International data

1.25. MPA is controlled in Denmark, Estonia, Germany, Hungary, Poland, Portugal, Slovenia, Sweden, Turkey, Republic of Belarus and China. MPA is controlled explicitly in some US states and could be considered under the Analog Act 1986, as an analogue of methamphetamine, a Schedule II substance in the US Controlled Substance Act.

1.26. At its 7th meeting, on 16 March 2017, the Commission on Narcotic Drugs decided to include MPA in Schedule II of the 1971 Convention. This inclusion will require all signatories to the Convention to place appropriate controls on MPA.

Recommendation

1.27. The ACMD has reviewed the evidence and, pursuant to Section 2B(6) of the Misuse of Drugs Act 1971, it considers that, in the case of the N-methyl-1-(thiophen-2-yl)propan-2-amine ('methiopropamine' or MPA), it is a drug that is being, or is likely to be, misused, and that misuse is having, or is capable of having, harmful effects. The ACMD therefore recommends that N-methyl-1-(thiophen-2-yl)propan-2-amine (MPA) be controlled as a Class B substance under the Misuse of Drugs Act 1971 (as amended).

1.28. The control of the compound should extend to include any stereoisomeric forms, any salts of such compounds and any preparation or product containing such compounds.

1.29. The ACMD has found no evidence that N-methyl-1-(thiophen-2-yl)propan-2-amine (MPA) has a recognised medicinal use and therefore advise that it is also controlled as a Schedule 1 substance under the Misuse of Drugs Regulations 2001 (as amended).

A.1.2 Wider uses

1.30. Following consultation with the Medical Research Council, the Department of Health, Public Health England, the Pistoia Alliance, the Office for Life Science, the Department for Business, Energy and Industrial Strategy, the Medicines and Healthcare products Regulatory Agency, the Academy of Medical Sciences, the Association of the British Pharmaceutical Industry, the Health Research Authority, The Royal Society and the British Pharmacological Society, the ACMD confirmed that they are not aware of any legitimate medicinal, industrial or commercial uses of MPA.

A.2 Groups Affected

1.31. The proposal to control MPA may affect groups making legitimate use of this substance, such as organisations which use and produce chemical standards for research and forensic purposes. However as the majority of these are currently controlled under TCDO, certain measures should already have been put in place.

1.32. There will be a small impact on the illicit market in drugs (street drug dealers and internet suppliers) as they currently would not be able to sell, produce or import/export MPA under the controls of the TCDO. The stricter regime of control under the Misuse of Drugs Act 1971 is likely to make it even more difficult for them to operate and as such will be of benefit.

A.3 Consultation

Targeted

1.33. The Home Office and the ACMD consulted with the MHRA, BEIS, the chemical/pharmaceutical industry, as well as bodies representing medicine and science, in deciding its preferred option when the ACMD produced its recommendation for MPA.

Public Consultation

1.34. The Government has considered the recommendations of the ACMD, but no public consultation has been pursued.

B. Rationale

2.1. The misuse of drugs imposes a cost on society in excess of the individual costs to users. A 2013 Home Office study estimated that the total social and economic costs of illicit drugs in 2010/11 was £10.7bn, which included £5.8bn in drug-related crime costs and around £2bn in criminal justice system and health service costs. In addition, users are not always aware of the costs to health associated with particular drugs due to the novelty of the substance.

2.2. Controlling MPA under the Misuse of Drugs Act 1971, as opposed to allowing it to be covered under the Psychoactive Substances Act 2016, provides a more effective restriction of its supply as follows:

a. Control under the Misuse of Drugs Act 1971 offers stricter offences of production and distribution under any circumstances without a licence. The offences in the Psychoactive Substances Act 2016 only prohibit the production and distribution of psychoactive substances to be consumed for psychoactive effect. The higher control under the Misuse of Drugs Act 1971 therefore provides a clearer legal framework to restrict the supply of particular substances even more narrowly than the Psychoactive Substances Act 2016.

b. The maximum penalty for committing an offence involving a Class B or C drug is 14 years imprisonment. This contrasts with the 7 year maximum sentence under the Psychoactive Substances Act 2016. These higher tariffs may prove a stronger deterrent to the supply of these drugs.

c. The Psychoactive Substances Act 2016 provides a non-substance specific approach with lighter touch exemptions, most notably with regard to healthcare related activities and research. Where there are no legitimate uses for specified drugs (as in this case), the Misuse of Drugs Act 1971 requires a licence to allow lawful access to these drugs and this will be limited to research or other special purpose.

d. Control under the Misuse of Drugs Act 1971 also involves the imposition of a possession offence, which restricts the scope to be in simple possession of these drugs further and again, only under licence where appropriate.

2.3. These differences reflect that drugs controlled under the Misuse of Drugs Act 1971 have been subjected to a full harms assessment by the ACMD and that they are being or appear to the ACMD likely to be misused and of which the misuse is having or appears to them capable of having harmful effects sufficient to constitute a social problem.

C. Objectives

3.1. The policy objective is to protect the public from the harms associated with MPA, in line with the Government's Drug Strategy to restrict the supply of drugs; prevent harmful drug use and build recovery for those dependent on drugs.

3.2. As part of this a key objective will be a reduction in the demand, availability and misuse of MPA and raised awareness of the harms associated with this substance, building on the message and effects of the current TCDO.

D. Options

Two options have been considered in respect of MPA:

4.1. OPTION 1: **Allow the TCDO to lapse after 27 November 2017 and MPA to be captured under the Psychoactive Substances Act 2016.**

4.2. OPTION 2: **Control MPA as a Class B drug under the Misuse of Drugs Act 1971 and a Schedule 1 drug under the Misuse of Drugs Regulations 2001, as recommended by the ACMD.**

Preferred option

4.3. The Government's preferred option is option 2, which is aligned with the ACMD's advice. It presents the best means of restricting the availability and reducing the risk of misuse and associated harm to the public.

E. Appraisal

5.1. Option 1 is the baseline option, meaning that the costs and benefits of option 2 are assessed relative to option 1 (i.e. additional costs and benefits above the do nothing scenario).

COSTS

Business

5.2. Whilst the open trade in psychoactive substances to be consumed for their psychoactive effect would be restricted by the Psychoactive Substances Act 2016 (option 1), this leaves open a theoretical market for other uses. Control under the Misuse of Drugs Act 1971 restricts supply for any purpose, which could mean that businesses conducting research incur further costs. However, as these businesses are likely to be in possession of a Home Office Licence since they would have been operating under the conditions of a TCDO, the cost is likely to be minimal.

Public Sector (enforcement agencies, CJS, regulators)

5.3. Any real and opportunity costs associated with option 2 cannot be predicted in light of limited data on the prevalence and use of MPA to be controlled in the UK. It is expected that minimal costs arising from option 2 will be subsumed into the law enforcement and regulatory response to the control of other drugs under the Misuse of Drugs Act 1971. As such the law enforcement response can reasonably 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.

Personal and society

5.4. It is unlikely that personal costs will differ significantly between options 1 and 2, which both have a restrictive effect on the supply of MPA. We are unable to monetise these costs due to a lack of information on the current size of the market in MPA.

BENEFITS

Public Sector (enforcement agencies, CJS, regulators)

5.5. Whilst it is difficult to compare the costs under the Misuse of Drugs Act 1971 and under the Psychoactive Substances Act 2016, the greater evidential burden under that Psychoactive Substances Act 2016 means that further forensic testing and expert evidence are required to discharge the evidential burden since there will be the requirement to prove that MPA is capable of producing a psychoactive effect and used for human consumption. These costs are difficult to monetise, but are likely to make prosecutions more expensive under the Psychoactive Substance Act 2016. As such the costs of enforcement of offences under the Misuse of Drugs Act 1971 are likely to be lower for enforcement agencies. Furthermore, it is expected that minimal costs arising from restricting supply using the stricter regime provided by the Misuse of Drugs Act 1971 will be subsumed into the law enforcement and regulatory response to the control of other drugs under the Misuse of Drugs Act 1971. As such the law enforcement response can be reasonably 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 can cause the most harm. As such, operational activity may focus around Class A and Class B drugs.

Benefits are expected to arise from consistency in enforcement and regulatory response to harmful substances; MPA is believed to have a similar level of harm to other substances currently listed under the Misuse of Drugs Act 1971. In practical terms this provides enforcement agencies with a consistent set of powers to restrict the supply of substances assessed to be harmful, rather than disparate regimes. This is likely to be easier and more efficient to enforce, potentially saving time and costs.

Personal and society

5.6. The effect of options 1 and 2 may not be significantly different. Although the control under the Misuse of Drugs Act 1971 may restrict the supply of MPA even further than the Psychoactive Substances Act 2016, the supply would remain restricted under both options, as is currently the position since the implementation of the TCDO. Personal benefits arise from this direct protection against potential harms of MPA through their reduced availability. Under Option 2, possession of MPA would also constitute a criminal offence with the penalties for MPA being akin to other drugs currently classified as Class B drugs. As a result, is expected that controlling MPA fully under the Misuse of Drugs Act 1971 will also reinforce to the public its potential harms by underlining that its harms have been assessed as commensurate with other Class B drugs. This specific targeting may reduce the harms caused by MPA. The Psychoactive Substances

Act 2016 contains no such harms assessment and therefore does not differentiate between the harms of specific drugs.

Benefits to Business

5.7. There are no known legitimate medicinal, industrial or commercial uses of MPA so there is no benefit to business under option 1 or option 2.

NET EFFECT

5.8. Overall it is considered likely that the benefits from the proposals will outweigh the costs, although it has not been possible to quantify these benefits and costs. The main benefits to arise from the proposals are that they reduce the prevalence and harms produced by MPA by providing enforcement agencies with wider powers, stricter offences and higher penalties surrounding the trafficking in this substance. This in turn is likely to make it easier for them to restrict the supply of this substance than under option 1. Additionally this option makes possession without a licence unlawful and therefore control and availability even tighter than would be imposed under the Psychoactive Substances Act 2016. This in turn reinforces that MPA is harmful and encourages targeted action by law enforcement to tackle the trade.

F. Risks

6.1. There is a limited risk that voluntary, charity or private sector research organisations or institutions: manufacturers, distributors and wholesalers that produce, supply, import or export MPA or use it for the synthesis of non-controlled pharmaceuticals may become adversely affected due to the potential costs of updating or applying for a licence. As these organisations will have been operating under the conditions of the TCDO, they should already have taken steps to obtain a suitable licence to undertake activities in relation to this substance. Due to the absence of evidence of legitimate business use and the negligible costs that would be associated with any use, the assumption is made that there are no cost implications to business.

G. Enforcement

7.1. Enforcement of the proposed legislation will be undertaken by Police Forces, Border Force, the Home Office Drug Licensing Unit and other relevant agencies responsible for enforcing the legislative and regulatory framework for controlled drugs in the UK. Police enforcement will form part of their wider approach to tackling new psychoactive substances as well as other drug controlled under the Misuse of Drugs Act 1971. Border Force will enforce import controls by seizing suspected substances at the ports, also as part of their wider customs role. There will be no interference with the regulatory framework and processes implementing temporary control measures in law enforcement and regulatory agencies as part of their routine activities.

H. Summary and Recommendations

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

Costs and Benefits		
Option	**Costs**	**Benefits**
2	£NK	£NK
	- There are no significant costs to the preferred option. There may be costs to law enforcement but these are assumed to be absorbed by current budgets.	- Control under the Misuse of Drugs Act 1971 is likely to be less resource-intensive to enforce than the Psychoactive Substances Act 2016 and provides wider powers, producing a more restrictive effect on supply. - It will also reinforce public awareness of the harms of MPA by making clear that this substance is of concern, by classifying it according to harm and providing stricter penalties for offences.

8.2. Taking option 1 (do nothing and allow the TCDO to lapse) would mean that MPA will be covered by the Psychoactive Substances Act 2016.

8.3. Option 1 is the least preferred option. As outlined above, the Psychoactive Substances Act 2016 is a very different regime of control, aimed at those substances which have not had their harms assessed. It contains lower penalties, more narrowly defined offences and a higher evidential burden for prosecuting agencies. To allow MPA to lapse to coverage under the Psychoactive Substances Act 2016 would not be commensurate with the assessment of harm that the ACMD have already made. Forensic testing and expert advice will be required to determine whether MPA is capable of having a psychoactive effect (the evidential requirement under the Act). The costs of testing, and length of time it will take, are difficult to monetise, and will depend on operational requirements, but will make prosecutions more expensive under the Psychoactive Substances Act 2016. The lower penalties, specific *mens rea* (proof of intention, recklessness or knowledge of the offender to supply a psychoactive substance for human consumption), civil penalties and no possession offence are a weaker signal to the public. In addition, allowing a TCDO to lapse would give out mixed messages for substances which have already been classified as harmful.

8.4. Option 2 is the preferred option and is aligned with the ACMD's advice. The use of the Misuse of Drugs Act 1971 and its Regulations to control MPA provides the best means to reduce availability and potential harm to the public. The resultant clear message to the public that MPA has harms commensurate with current class B controlled drugs may also assist in dissuading the use, as alluded to in the ACMD's evidence.

I. Implementation

9.1. The Government plans to implement these changes via an affirmative resolution Order, subject to Parliament's approval.

J. Monitoring and Evaluation

10.1. As part of its statutory duties under the Misuse of Drugs Act 1971 the ACMD keeps the situation relating to the misuse of drugs under review. Together with the Government, they will continue to monitor MPA by gathering data on its prevalence and misuse (particularly whilst under temporary drug control) through UK and EU drugs early warning systems, the health sector and the regulatory framework governing legitimate activities (predominately research) in relation to MPA. 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

11.1. Information gathered from the monitoring and evaluation process will inform future ACMD advice on the classification, designation and scheduling of MPA, including any future legitimate uses of this compound.