Title:	Impact Assessment (IA)
TEMPORARY CONTROL OF **N-methyl-1-(thiophen-2-yl)propan-2-amine (MPA)** **IA No: HO0219** **Lead department or agency:** HOME OFFICE **Other departments or agencies:** DEPARTMENT OF HEALTH, DEPARTMENT FOR BUSINESS INNOVATIONS AND SKILLS AND LAW ENFORCEMENT	**Date:** 16/11/2015 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries**: Des Niimoi (Telephone: 0207 035 3533) (Desmond.niimoi@Homeoffice.gsi.gov.uk Or Jamie Mclellan (Tel: 0207 035 1885)

Summary: Intervention and Options

RPC Opinion: N/A

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, One-Out?**	**Measure qualifies as**
NK	NK	NK	No	NA

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

The compound, N-methyl-1-(thiophen-2-yl)propan-2-amine (also known as MPA) has been assessed by the Advisory Council on the Misuse of Drugs (ACMD) as a harmful drug, posing a serious health threat and warranting control under a temporary class drug order under Section 2A of the Misuse of Drugs Act 1971.
This will prevent this drug from gaining a foothold in the UK and protect the public from its immediate harms. The government will implement a Temporary Class Drug Order (TCDO) while the ACMD undertakes a full assessment of the harm to users and the related societal harm of the compound.
Government intervention is necessary through a TCDO to protect the public from these harms pending further expert advice.

What are the policy objectives and the intended effects?

The policy objective is to reduce the harms created by this substance. The intended effects are to limit access to the identified compound by ending the sale of this substance as a "legal high" in head-shops and online retailers, to signal to the public the potential danger from this substance and to enable the police and other authorities to take action against the sale or distribution of this substance.

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

Option 1 - Do nothing
Option 2 - Make a temporary class drug order under Section 2A to the Misuse of Drugs Act 1971 for the product N-methyl-1-(thiophen-2-yl)propan-2-amine (MPA), including all salts, stereoisomeric forms, preparations and products.

A TCDO is being made due to the ACMD's assessment that the substance presents a risk to public health and safety. The ACMD will gather further evidence into the harms associated with these substances before a decision is made on permanent control.

Option 2 is the preferred option on the basis of the current evidence and the ACMD's initial assessments on the harms and misuse associated with this compound.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** Within 12 months.						
Does implementation go beyond minimum EU requirements?			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:** 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: Mike Penning Date: 23/11/2015

Summary: Analysis & Evidence

Policy Option 2

Description: Make a temporary class drug order under Section 2A to the Misuse of Drugs Act 1971 on the listed Methylphenidate-based compounds.

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		NK	**NK**

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

It is not possible to monetise the costs of this option in light of the current available data, due to a paucity of evidence around the prevalence of MPA and the money invested in its trade. Given the time constraints and public protection issues involved, it would be disproportionate to attempt to collect this data.

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

Businesses – following consultation with BIS, the MHRA and the chemical and pharmaceutical industry, this compound and related substances have been identified as having no legitimate industrial or medicinal use. Businesses currently selling these substances in the 'legal high' market will no longer be able to do so, and face the risk of prosecution if they fail to comply.

The **Public sector** may face some costs from enforcement responses, though it is expected that these will be subsumed into the enforcement and regulatory response to similar drugs permanently controlled under the 1971 Act.

There will also be a personal cost to **individuals** in preventing those who seek pleasure from the consumption of MPA from doing so.

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

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

Public sector benefits arise from a reduction in the number of people seeking medical attention due to the misuse of this substance. There are also benefits from the consistency in law enforcement and regulatory response.

Personal benefits arise to **individuals** from the protection against potential harm from the substance.

Society is protected against the wider harms generated by people who consume this substance.

Key assumptions/sensitivities/risks **Discount rate**

To the best of our knowledge this substance does not have any legitimate industrial or medicinal uses. It is possible that the substance in question is currently being used by UK research bodies, creating the possibility that research will be hampered by the proposed controls. However, most research organisations will already have current licences which will permit access to these drugs for research purposes.

BUSINESS ASSESSMENT (Option 1)

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

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 Background

1.1. This Impact Assessment assesses the proposal to make a temporary class drug order for N-methyl-1-(thiophen-2-yl)propan-2-amine (MPA), including stereoisomeric forms, preparations and products under the Misuse of Drugs Act 1971 (Temporary Class Drug) Order 2015.

1.2. On 11 November 2015, the ACMD provided initial advice on the harms and misuse of N-methyl-1-(thiophen-2-yl)propan-2-amine (MPA) pursuant to Section 2B of the 1971 Act (which contains provisions on temporary class drug orders and the role of the ACMD).

N-methyl-1-(thiophen-2-yl)propan-2-amine (MPA) and related substances

1.3. Methiopropamine (MPA) has been visible on the New Psychoactive Substances (NPS) market since 2011; however recent reports suggest an increase in use, particularly by injection, following the Temporary Controlled Drug Order (TCDO) of April 2015 on methylphenidate-based NPS. This proliferation in use and an increasing number of associated deaths and harms related to MPA use has led the Advisory Council on the Misuse of Drugs (ACMD) to consider a TCDO on MPA in line with their statutory duties.

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 and MPA seizures have since been reported throughout Europe. The World Health Organisation has also noted seizures in North America and Canada[1].

1.5. The United Kingdom first issued alerts in 2012 when the national Focal Point reported three cases involving deaths associated with this substance.

1.6. Data from the National Crime Agency shows there have been 45 seizures of MPA between April and June 2015.

1.7. FRANK[8] has received 29 queries in relation to MPA during the period October 2014- September 2015.

1.8. MPA use has been detected in the UK, in pooled anonymous urine samples collected in street urinals in London since 2012. In a more recent study from April 2014[10], MPA was detected in pooled anonymous urine samples collected in London, Newcastle and Birmingham.

1.9. The UK's Forensic Early Warning System's (FEWS) collection plans detected 86 occurrences of MPA in 2013/14 and 65 occurrences in 2014/15, mostly from headshop collection plans.

1.10. An Internet snapshot study performed in June 2013 confirmed that MPA was widely available from Internet sites selling NPS. Of 62 sites identified (of which half could

be located), 45% of suppliers appeared to originate from the UK. 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).

1.11. MPA is reportedly taken orally, by inhalation, snorting, administering rectally, and by injecting, with the dosage ranging between 5-60 mg depending on route of administration[4]. 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.

1.12. In Scotland, MPA injecting has reportedly replaced ethylphenidate injecting as the drug of choice following the TCDO on methylphenidate-based NPS, with reports of associated mental health issues, hospital admissions and public space needle discards.

1.13. MPA has been seen under the following brand names (not exhaustive): Ivory Dove Ultra, China White, Walter White, Quick Silver Ultra, Bullet, Mind Melt, Pink Panthers, Poke, Rush, Snow White[4].

Harms

1.14. MPA has been appropriated 'legal methamphetamine' as it shows similar properties as methamphetamine: stimulation, alertness and an increase of energy and focus. Side effects reported include tachycardia, anxiety, panic attacks, perspiration, headaches, nausea, difficulty breathing, vomiting, difficulty urinating and sexual dysfunction[1].

1.15. The National Programme of Substance Abuse Deaths (npSAD) reported 30 cases where MPA was found in post mortem toxicology, between 2012 and 2015. In 22 of these, MPA was implicated in the cause of death *(see Appendix, Table 1)*.

1.16. Hospital admissions for MPA have been reported in the US and in Europe, with symptoms including anxiety, paranoia and vomiting.

1.17. 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 reported in 2013.

1.18. When MPA is combined with certain other drugs such as the aminoindanes (e.g. MDAI or 5-I-AI), the user is at risk of serotonin toxicity, which can be fatal if not treated quickly and effectively.

Wider uses

1.19. Following consultation with the Department for Business Innovation and Skills (BIS), the Medicines and Healthcare products Regulatory Agency (MHRA) and the chemical and pharmaceutical industry, MPA and related substances have been identified as having no legitimate industrial or medicinal use. The MHRA also confirms that there are no marketing authorisations for medicines containing this compound.

ACMD recommendation

1.20. In light of the initial assessment of potential health harms and the risks implied of the compound MPA, the ACMD recommends that MPA and related substances should

be subject to a temporary class drug order. The ACMD's assessment details that this compound 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 will gather further evidence to make an assessment for permanent control.

1.21. In line with its statutory duties and the joint working protocol, the ACMD will continue to gather all available evidence while the temporary class drug order is in force. It will aim to provide a full independent expert assessment of the harms of the listed compound, including societal harms, to recommend whether it should be subject to permanent control under the 1971 Act, all within the timeframe afforded by the TCDO.

Description of controls

1.22. Under the Misuse of Drugs Act 1971, on indictment the maximum penalties for offences relating to drugs which are subject to a temporary class drug order are - for supply, production, importation/exportation up to fourteen years' and/or an unlimited fine. On summary conviction, the maximum penalties for offences relating to supply, production or importation/exportation are six months' imprisonment and/or a prescribed fine (including, for the latter offences, one determined by the value of the drugs if greater than the prescribed amount).

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

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

A.2 Groups Affected

1.24. The proposal to temporarily control MPA and related substances may affect groups making legitimate use of any of these substances, such as organisations which use and produce chemical standards for research and forensic purposes. This is consistent with activities relating to drugs listed in Schedule 1 of the Misuse of Drugs Regulations 2001, which are subject to Home Office licensing by application from a new producer/supplier (as well as for import/export activities).

1.25. The 'legal high' market ('head shops' and internet suppliers) who currently market this substance or 'legal high' branded products containing it will be affected. Members of the public who purchase and use the substance will also be affected. Public sector organisations will be affected by the order. This includes UK enforcement and criminal justice agencies and health services.

A.3 Consultation

Within Government

1.26. The Home Office has consulted with the MHRA, BIS and the chemical/pharmaceutical industry in informing the choice of preferred option. As noted above, the consultees were content because no legitimate uses were identified.

Public Consultation

1.27. The Government has considered the recommendations of the Advisory Council on the Misuse of Drugs, which are summarised in the 'Background' section above. No further public consultation is considered appropriate given the risks of highly discounted sales and stockpiling, should the industry becoming widely aware that control is being considered.

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. The latter includes costs associated with injection, like hepatitis C and HIV treatment costs, and hence is potentially relevant to this substance. The argument is sometimes made that these costs are for drugs already controlled under the 1971 Act and therefore, by driving their use underground, drug control may be contributing to the costs. However, this is balanced against the risk of taking no legislative action, which could give rise to a perception that the substance is somehow safe and therefore potentially lead to increased public consumption over time. The TCDO provides a response, recommended by the ACMD, which balances the risks of control with the harms of allowing the substance to continue to circulate freely.

2.2. In addition, users are not always aware of the harms/costs associated with particular drugs due to the novelty of the substances. As the ACMD report states, while there are indications that MPA is capable of harms akin to controlled drugs, there is a lack of information on exact harms and no data on the long term health impacts. In addition to the lack of information, there is also frequently a lack of consistency in the misuse of NPS products, which often change; further preventing consumers from making informed choices. By placing a drug under temporary control, Government can make it clear that it is unsafe and therefore reduce potential harms/costs to the individual by preventing misuse that would potentially not take place if the consumer had the full facts around a drug's harms.

C. Objectives

3.1. The policy objective is to protect the public from the harms associated with MPA while the ACMD conducts a full independent assessment on whether their harms and effects warrant permanent control under the 1971 Act.

3.2. A successful outcome will be a reduction in the demand, availability and misuse of these compounds and raised awareness of the harms of these new psychoactive substances.

D. Options

4.1. Two options have been considered in respect of these substances:

OPTION 1: Do nothing.

OPTION 2: Make a temporary class drug order under Section 2A to the Misuse of Drugs Act 1971 of **N-methyl-1-(thiophen-2-yl)propan-2-amine (MPA)**.

It should be noted that a third option, of immediate permanent control under the Misuse of Drugs Act 1971 has not been considered at this time. Based on its initial assessment of individual harms, the ACMD considers there to be a case for immediate control only through temporary control at this stage. A further assessment will allow for more evidence to be gathered on the social harms to assess the case for permanent control. The government must consult the ACMD before altering the list of drugs permanently controlled by the 1971 Act.

4.2. The Government's preferred option is option 2, which is aligned with the ACMD's initial advice. The use of the 1971 Act and its Regulations to temporarily control the listed substances provides the best means to reduce availability and potential harm to the public.

E. Appraisal

OPTION 1: There are no additional costs and benefits associated with this option.

OPTION 2: Make a temporary class drug order under Section 2A to the Misuse of Drugs Act 1971 of t **N-methyl-1-(thiophen-2-yl)propan-2-amine (MPA)** , including its preparations and products.

COSTS

Business

5.1. Option 2 will impose some costs to businesses currently selling these substances in the "legal high" market. Businesses trading in this market would need to comply with the order or face the risk of prosecution. As a result they will be deprived of the profit generated through the sale of the targeted substances. It is not possible to estimate this cost due to a lack of information on the volume of this specific substance sold each year and the profit typically made on each item. Data is not collected on the sales of this substance specifically, and given the time constraints and public protection issues involved in a TCDO it would be disproportionate to collect this data.

5.2. Following consultation with BIS, the MHRA and the chemical and pharmaceutical industry, these compounds have been identified as having no legitimate industrial or medicinal use. As a result, no wider impacts on business are expected.

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 the listed substances to be controlled in the UK. There is evidence that the market for "legal highs" self regulates in response to temporary control, withdrawing from sale banned NPS subject to legal sanction. This is supported by the experience of previous TCDOs for Methoxetamine and Methylphenidate-based compounds. With the methylphenidate compounds in particular, usage and supply (as noted in the background) has displaced to legal NPS, such as MPA. 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 1971 Act. The law enforcement response will be managed within existing resources, informed by policy and operational prioritisation. The police and other law enforcement agencies will prioritise resources towards tackling crime, including drug related crime, with a focus on those offences which cause the most harm. As such, operational activity may focus on Class A and B drugs as well as new psychoactive substances.

Personal and society

5.4. Personal costs will be incurred by people who can no longer purchase MPA and its related substances. As supply is restricted, users will be unable to obtain the substance and thereby will no longer derive the pleasure associated with its consumption. We are unable to monetise these costs due to a lack of information on the current size of the market in this substance.

BENEFITS

Business

5.5. No benefits accrue to businesses from this policy.

Public Sector (enforcement agencies, CJS, regulators)

5.6. Benefits accruing to the public sector arise from savings to be made through a reduction in the number of people seeking medical assistance due to the misuse of these substances. Whilst hospital admissions data is not available for MPA at the current time, recent data shows that MPA was identified in the post mortem toxicology in 30 separate cases and was implicated in the cause of death in 22 cases. These savings cannot be quantified due to the novelty of the substances in relation to long-term/chronic use and the novelty of the challenges that they pose to healthcare and treatment services in light of the harms that they can cause.

5.7. 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. This includes methamphetamine, from which the listed substances are chemically related, which is currently a class A drug.

Personal and society

5.8. Personal benefits arise from direct protection against potential harms of MPA through reduced availability. It is expected that initiating a Temporary Class Drug Order for these substances will also hopefully signal to the public their potential harms, reducing misuse.

5.9. Society will be protected against possible externalities resulting from people who have taken MPA and its related substances.

NET EFFECT

5.10. 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:

- The protection of individuals from the harms of this substance by preventing them from consuming it.
- A reduction in the number of people seeking medical help and therefore a reduction in costs to the public purse.
- Public protection from the externalities created by misuse of MPA.
- Increased public awareness of the harms associated with the misuse of MPA.

F. Risks

6.1. As referred to by the expert panel on NPS, there are risks associated with this option. The 'legal high' market is likely to produce further (uncontrolled) new psychoactive substances which imitate the effects of MPA or other controlled substances, to circumvent this temporary drug control. Users in turn may then be displaced to new substances in a similar way that has happened with the rise in prevalence of MPA since 2011. It is anticipated that this will be mitigated by the implementation of the Psychoactive Substances Bill, which will create a blanket ban on the production, supply and importation/exportation of any psychoactive substance to prevent this displacement.

6.2. Risks may arise from the impact on law enforcement and criminal justice agencies, namely that the cost of enforcing the offences in this TCDO will draw resources away from other priorities, or conversely that they will be unable to sufficiently enforce this Order. However, Government intervention is needed to enable law enforcement to protect the public from the harms of these drugs under option 2, of which these may become insufficient over a period of time as the emergence of new related compounds cannot be excluded. This risk is usually mitigated by the ACMD, which has a duty to review the situation in relation to both controlled and non-controlled drugs (including new psychoactive substances), and temporary class drugs. Additionally the framework for enforcing against these substances is familiar to agencies, so it is considered that any additional burden will be subsumed into existing drug enforcement work, as evidenced by previous TCDOs.

6.3. There is also a limited risk that voluntary, charity or private sector research organisations or institutions: manufacturers, distributors and wholesalers that produce, supply, import or export these substances or use them for the synthesis of non-controlled

pharmaceuticals may become adversely affected due to the potential costs of updating or applying for a licence for research or other special purpose. However, organisations dealing with permanently controlled scheduled drugs will already possess a licence to undertake activities involving temporary class drugs which are treated as those listed under Schedule 1 to the Misuse of Drugs Regulations 2001. Due to the absence of evidence of legitimate business use and the negligible costs that would be associated with any 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, the UK Border Force (UKBF), 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 1971 Act. The UKBF 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.

Table H.1 Costs and Benefits

Option	Costs	Benefits
2	£NK	£NK
	- There will be a loss of profit to those businesses currently selling these substances, or they face the risk of prosecution for failure to comply. - Law enforcement agencies and regulatory response to the control of drugs. - Personal costs to people that can no longer legitimately buy these substances.	- Public sector savings from reduction in people seeking medical assistance. - Consistency in enforcement and regulatory response. - Personal benefits from protection against potential harms. - Society is protected against externalities resulting from people who have taken these substances.

8.2. Option 2 is the preferred option. The harms associated with the misuse of these listed compounds require Government to act swiftly through effective legislation to protect the public. There are benefits to be derived from implementing the proposal through a reduction in medical costs associated with the misuse of these drugs.

8.3. There are no additional costs associated with Option 1, but there are also no additional benefits. Additionally, there is the potential for the costs of the current regime to increase if the prevalence of these substances increases.

I. Implementation

9.1. The Government plans to implement these changes via the made affirmative resolution, subject to debates in both Houses of Parliament within 40 sitting Parliamentary days from which the temporary class drug order is laid, to seek approval of the Misuse of Drugs Act 1971 (Temporary Class Drug) Order 2015.

J. Monitoring and Evaluation

10.1. As part of its statutory duties under the 1971 Act the ACMD keeps the situation relating to drugs under review. Together with the Government, they will continue to monitor 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 these drugs. The Home Office, as the regulatory authority on licensing of activities relating to all controlled drugs and as lead department working with other Government departments to deliver the Drug Strategy, will continue to monitor the situation in relation to compliance with the regulatory framework.

K. Feedback

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