Title:	Impact Assessment (IA)
TEMPORARY CONTROL OF DICHLOROMETHYLPHENIDATE ('3,4-DCMP'), ETHYLPHENIDATE, ISOPROPYLPHENIDATE ('IPP' or 'IPPD'), METHYLNAPHTHIDATE ('HDMP-28'), PROPYLPHENIDATE, 4-METHYLMETHYLPHENIDATE and ETHYLNAPHTHIDATE **IA No:** HO0188 **Lead department or agency:** HOME OFFICE **Other departments or agencies:** DEPARTMENT OF HEALTH, DEPARTMENT FOR BUSINESS	**Date:** 31/03/2015 **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

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?

Seven Methylphenidate-based compounds –3,4-Dichloromethylphenidate ('3,4-DCMP'), Ethylphenidate, , Isopropylphenidate ('IPP' or 'IPPD'), Methylnaphthidate ('HDMP-28'), Propylphenidate, 4-methylmethylphenidate and ethylnaphthidate have been assessed by the Advisory Council on the Misuse of Drugs (ACMD) as harmful drugs, 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 these drugs from gaining a foothold in the UK and protect the public from their immediate harms, the government will implement a Temporary Class Drug Order (TCDO) while the ACMD undertakes a full assessment of the compounds to establish their harm. Government intervention is necessary as it is the only body capable of declaring and implementing a Temporary Class Drug Order.

What are the policy objectives and the intended effects?

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

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 listed Methylphenidate-based compounds, including all salts, stereoisomeric forms, preparations and products.

A TCDO is being made due to the ACMD's assessment that the substances present 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 these compounds.

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: 17/06/2015

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.

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

Businesses – following consultation with BIS, the MHRA and the chemical and pharmaceutical industry, these compounds 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.

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 these substances. There are also benefits from the consistency in law enforcement and regulatory response.

Personal benefits arise from the protection against potential harm.

Society is protected against the wider harms generated by people who consume these substances.

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

To the best of our knowledge these substances do not have any legitimate industrial or medicinal uses. It is possible that the substances in question are 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 the listed Methylphenidate-based compounds, including stereoisomeric forms, preparations and products under the Misuse of Drugs Act 1971 (Temporary Class Drug) Order 2015.

1.2. On 31 March 2015, the ACMD provided initial advice on the harms and misuse of the listed Methylphenidate-based compounds pursuant to Section 2B of the 1971 Act (which contains provisions on temporary class drug orders and the role of the ACMD).

Methylphenidate-based compounds and related substances

1.3. Several materials which are very closely related to Methylphenidate but which are uncontrolled are being marketed as NPS (New Psychoactive Substances). Methylphenidate was developed as a central nervous system stimulant in the 1960s; Methylphenidate is controlled in the UK as a Class B drug. Methylphenidate can be used as a recreational stimulant, usually by 'snorting' or injecting ground-up tablets as this produces a more rapid and intense stimulant effect than swallowing tablets. In addition, media reports claim that Methylphenidate is one of the 'smart drugs' which have been adopted by students as a 'study aid', as it is claimed to aid concentration while permitting long hours of work without the need for sleep.

1.4. The ACMD has reviewed the evidence on five methylphenidate-based NPS; these substances are known to have similar psychoactive effects and as a result are believed to be capable of similar harms to Methylphenidate. The ACMD, in its capacity as a statutory independent expert advisory body has therefore advised that a TCDO be enacted while proper evidence on the risks of these substances can be gathered. The substances in question are listed below:

a. **3,4-Dichloromethylphenidate ('3,4-DCMP')**.

b. **Ethylphenidate**, (Ethyl 2-phenyl-2-(piperidin-2-yl)acetate) is one of the most commonly encountered stimulant NPS.

c. **Isopropylphenidate ('IPP' or 'IPPD').**

d. **Methylnaphthidate ('HDMP-28')**.

e. **Propylphenidate.**

f. **4-methylmethylphenidate**

g. **ethylnaphthidate**

Prevalence

1.5. Ethylphenidate first appeared as an NPS in 2011, it is now one of the most commonly encountered stimulant NPS. Ethylphenidate is widely available on NPS websites and has been routinely identified in FEWS surveys since 2011. Ethylphenidate is sold by Internet suppliers as a replacement for cocaine. It is being marketed both as a single substance 'research chemical' and as a component of 'branded' products such as 'Gogaine', 'Nopaine', 'Fake cocaine', 'Banshee Dust' and 'Evoke'.

1.6. The other NPS discussed in this IA are less common than Ethylphenidate. 3,4-Dichloromethylphenidate appeared as an NPS in 2013 and Methylnaphthidate is known to be available in the UK. Both Isopropylphenidate and Propylphenidate became available as NPS in 2015. 4-methyl methylphenidate and ethylnaphthidate have been offered as replacements for the other related compounds listed above.

Harms

1.7. While the exact effects of the listed substances are not yet known, there have already been some indications of the potential harms, particularly for ethylphenidate, the most common of the substances. The National Programme of Substance Abuse Deaths (npSAD) reported 5 cases in 2013-14 where ethylphenidate was found in post mortem toxicology; npSAD also reported 2 cases where ethylphenidate was implicated in the cause of death (2013-14).

1.8. In addition, one branded formulation of NPS: "Burst", which generally contains ethylphenidate, has been reported as causing particular problems in the Edinburgh area. There has recently been a report of an outbreak of *Staphylococcus aureus* and *Streptococcus pyogenes* infections in this area associated with NPS injecting, which is believed to involve ethylphenidate. Ethylphenidate-based products are a growing issue in Edinburgh and their use is associated with anti-social and violent behaviour.

1.9. Due to its boosting of dopamine levels, users report a strong urge to re-dose, including among injecting users. Frequent injecting, together with related unsanitary injecting practices are likely to lead to a high risk of bacterial infection and local tissue damage. The frequent pattern of injecting also increases the risk of HIV or Hepatitis C infection, according to the ACMD.

Wider uses

1.10. 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, the Methylphenidate-based compounds 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 these compounds.

ACMD recommendation

1.11. In light of the initial assessment of potential health harms and the risks implied due to these substances similarity with Methylphenidate (a Class B drug) the ACMD recommends that the listed Methylphenidate-based compounds and related substances should be subject to a temporary class drug order. The ACMD's assessment details that these compounds are drugs that are being, or are 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.

1.12. 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, and will aim to provide a full independent expert assessment of the harms of the listed compounds within 12 months to recommend whether they should be subject to permanent control under the 1971 Act.

Description of controls

1.13. 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).

1.14. 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

1.15. The proposal to temporarily control the listed Methylphenidate-based compounds 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).

1.16. The 'legal high' market ('head shops' and internet suppliers) will no longer be able to lawfully market these substances or 'legal high' branded products containing them. Members of the public will both no longer be able to purchase and consume these

substances and no longer be subject to any negative externalities that may result from their consumption. It is also expected that this change will serve as a signal to the public of the possible harms associated with this drug, discouraging its consumption.

1.17. There may be minimal costs and resource implications for UK law enforcement and criminal justice agencies arising from this option but it is expected that this will be subsumed into the enforcement and regulatory response to similar drugs permanently controlled under the 1971 Act. Finally, there will be some benefits to health services, as they will face reduced demand for services resulting from consumption of these substances.

A.3 Consultation

Within Government

1.18. The Home Office has consulted with the MHRA, BIS and the chemical/pharmaceutical industry in deciding its preferred options.

Public Consultation

1.19. The Government has considered the recommendations of the Advisory Council on the Misuse of Drugs.

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 relevant to these substances. In addition, users are not always aware of the costs associated with particular drugs due to the novelty of the substances. As the ACMD report states, while there are indications that the listed substances may be capable of harm similar to Methylphenidate, 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. Government intervention can therefore reduce potential costs to the individual by preventing misuse that would potentially not take place if the consumer had all the needed information.

C. Objectives

3.1. The policy objective is to protect the public from the harms associated with the listed Methylphenidate-based compounds 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 the listed Methylphenidate-based compounds.

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 the listed Methylphenidate-based compounds, including their 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 amount of these substances sold each year and the profit typically made on each item.

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. 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 the Methylphenidate-based compounds and their related substances. We are unable to monetise these costs due to a lack of information on the current size of the market in these substances.

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. 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; the listed compounds are believed to have a similar level of harm to other substances currently listed under the Misuse of Drugs Act. This includes Methylphenidate, from which the listed substances are chemically related, which is currently a class B drug.

Personal and society

5.8. Personal benefits arise from direct protection against potential harms of the listed substances through reduced availability; this will also benefit society through reduced costs to the NHS. Recent data shows that ethylphenidate was identified in the post mortem toxicology in 5 separate cases and was implicated in the cause of death in 2 cases. 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 Methylphenidate-based compounds and their 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:

- 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 the listed Methylphenidate-based compounds.
- Increased public awareness of the harms associated with the misuse of the listed Methylphenidate-based compounds.

F. Risks

6.1. As referred to by the expert panel on NPS, there are risks associated with this option on the basis of evidence and expert advice that the 'legal high' market will look to synthesise and advertise chemical derivatives of some of these or other controlled drugs, or alternative new psychoactive substances imitating their effects, to circumvent temporary drug control.

6.2. Risks may arise from the impact on law enforcement and criminal justice agencies. 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.

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 license. 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 the listed compounds by gathering data on their 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 substances for consideration for their permanent control under the 1971 Act.