Title: Control of methylphenidate (Ritalin) based substances **IA No:** HO0288 **RPC Reference No:** **Lead department or agency:** Home Office **Other departments or agencies:** Department of Health, Department for Business, Energy and Industrial Strategy and The Medicines and Healthcare Products Regulatory Agency	**Impact Assessment (IA)** **Date: 4/5/17** **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** James McLellan, Drugs and Alcohol Unit, 0207 035 1885

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**
£m	£m	£m	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 in relation to a number of methylphenidate (ritalin)-related Novel Psychoactive Substances (NPS) that are currently under a Temporary Class Drug Order (TCDO), which expires on 26 June 2017. The ACMD has considered that the harms associated with these substances are sufficient to constitute a societal problem and therefore recommend these and five further related substances are permanently controlled as Class B drugs under the Misuse of Drugs Act 1971. The ACMD also confirmed on 23 March that they are not aware of any legitimate medicinal, industrial or commercial uses of these substances and as such have recommended that all 12 methylphenidate-related substances be listed as Schedule 1 drugs 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 harm from the misuse of these substances in the UK.
The intended effects are to limit access to the identified compounds, 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: Allow the TCDO to lapse and these substances to be captured under the Psychoactive Substances Act 2016 from 27 June 2017 onwards.

Option 2: Control these as Class B substances under the Misuse of Drugs Act 1971 and its subordinate legislation, as recommended by the ACMD.

Option 2 is the preferred option based on the ACMD's assessment of harms associated with the abuse of these substances. The Misuse of Drugs Act 1971 allows a higher level of control with a posession offence, more strictly defined supply and distribution offences and wider powers for enforcement than the Psychoactive Substances Act 2016.

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

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:** 0	**Non-traded:** 0	

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:** 6th May 2017

Summary: Analysis & Evidence

Policy Option 1

Description:

FULL ECONOMIC ASSESSMENT

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

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	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.

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

Businesses – There should be no further cost to business by controlling these compounds under the Misuse of Drugs Act 1971, as under option 1 their supply would be restricted under the Psychoactive Substances Act 2016.

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 other controlled drugs.

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	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: Higher maximum penalties for supply, production and importation/exportation, a more straight forward regime for control, a consistent regime to control these substances in line with other NPS that have been previously controlled and lower enforcement costs.

Personal/Societal: Given the lower enforcement costs and the clear message sent out by Misuse of Drugs Act control, it provides a stronger, more targeted tool to address the societal harms of 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 in the UK. It is possible that the substances in question are currently being used by UK research bodies. However, most research organisations will already have current licences which will permit access to these drugs for research purposes. Any medicinal use that comes to light will be taken into account as part of ACMD advice on scheduling under the Misuse of Drugs Regulations 2001.

BUSINESS ASSESSMENT (Option 1)

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 several methylphenidate-related NPS as class B drugs under the Misuse of Drugs Act 1971, following the expiry of a TCDO that covers 7 of them up until 26 June 2017.

A.1.1 Methylphenidate-related NPS

Taken from the ACMD's report on Methyphenidate based NPS (unpublished at time of writing):

Methylphenidate

1. Methylphenidate was developed as a CNS stimulant in the 1960s. It acts primarily as a re-uptake inhibitor for dopamine and norepinephrine and has found widespread application in the treatment of Attention Deficit Hyperactivity Disorder (ADHD), as the symptoms of this condition are believed to be linked to depressed levels of these neurotransmitters. Methylphenidate formulations include tablets containing 5, 10 or 20 mg of the active ingredient and slow-release tablets containing up to 40 mg.

2. Methylphenidate is listed within the 1971 UN Convention on Psychotropic Substances as a Schedule II material. In the UK, it is controlled as a Class B material and as a Schedule 2 substance under the Misuse of Drugs Regulations 2001.

Methylphenidate-based NPS

3. Reports from Police Scotland cited ethylphenidate as being a public health issue in Edinburgh. The ACMD also recommended that several other analogues of ethylphenidate be included in the TCDO, to reduce displacement to similar substances:

    - **Ethylphenidate**, is the simple homologue of methylphenidate. It first appeared as a NPS in the UK in 2011 and became one of the most commonly encountered stimulant NPS.
    - **3,4-Dichloromethylphenidate ('3,4-DCMP'),** the halogenated derivative of methylphenidate appeared in the UK as a NPS in 2013. It is claimed to be several times more potent than the parent compound, with a slower onset of action and longer duration.

- **Methylnaphthidate (‘HDMP-28’),** the naphthyl analogue of methylphenidate, became available in the UK as a NPS in late 2014. In addition to acting as a re-uptake inhibitor for dopamine and norepinephrine, it also acts at the serotonin receptor, and is therefore a triple re-uptake inhibitor, reminiscent of cocaine. It is claimed to have several times the potency of methylphenidate, but with a shorter duration of action.
- **Isopropylphenidate (‘IPP’ or ‘IPPD’)** became available in the UK as a NPS in 2015. In 2013, it had been described in the scientific literature as having a greater effect on dopamine levels than norepinephrine when compared with methylphenidate and as being more resistant to metabolism, resulting in a longer-lasting effect.
- **Propylphenidate** has also begun to be advertised in the UK as a NPS in 2015. Little is known of its neurochemical properties, but these can be expected to be similar to isopropylphenidate.
- **4-Methylmethylphenidate,** appeared on online markets following the implementation of the TCDO on the above substances.
- **Ethylnaphthidate (‘HDEP-28’),** the ethyl homologue of Methylnaphthidate, also appeared on online markets following the implementation of the TCDO on the above substances.
- **N-Benzyl-ethylphenidate,**
- **3,4-dichloroethylphenidate,**
- **Methylmorphenate,**
- **4-fluoromethylphenidate and**
- **4-fluoroethylphenidate.**

Prevalence of use

4. Ethylphenidate has been reported to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) by Austria (2016), Greece (2016), the UK (2011, 2013, 2014), Luxembourg (2014), Slovenia (2014), Croatia (2014), Italy (2014), Lithuania (2013), Hungary (2013), France (2013), Denmark (2013), Spain (2013), Finland (2012) and Sweden (2012).

5. Prior to control, ethylphenidate was widely available on NPS websites and had been routinely identified in FEWS surveys since 2011. Ethylphenidate was being sold by internet suppliers as a replacement for cocaine and 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’. The single substance was available as powder, crystals (which commanded a slightly higher price) or ‘pellets’ (tablets) containing up to 50 mg per tablet.

6. Police Scotland had reported overt injecting practises, needle discards and antisocial behaviour in public places related to the injection of Ethylphenidate in Edinburgh. Updates since the implementation of the TCDO report a marked decline in these associated issues.

Polysubstance use

7. Samples taken by Welsh Emerging Drugs and Identification of Novel Substances (WEDINOS) have found the following substances in combination with Ethylphenidate: Methiopropamine, 5-MeO-DALT, Phenacetin, 2-aminoindane, Phenylethylamine, Ephedrine, Caffeine, Lidocaine, Benzocaine and Mannitol.

8. Consumers of ethylphenidate may not be aware that it is often mixed with a variety of other compounds.

Acute harm

9. As might be expected from a stimulant material which boosts dopamine levels, users report a strong urge to re-dose. One branded formulation, 'Burst', has been reported as causing particular problems in the Edinburgh area, including among injecting drug users, who report re-injecting repeatedly. 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.

10. The majority of NPS-related presentations to Accident and Emergency in Edinburgh have been associated with use of 'Burst' (March to September 2014). Ethylphenidate-based products are a growing issue in Edinburgh and their use is associated with bizarre and violent behaviour. The number of presentations at Edinburgh Royal Infirmary related to Ethylphenidate injecting had reportedly reduced from 27 in April 2015 to 3 for the same month the following year.

11. Police Scotland reported that related practices include: communal injecting, users injecting each other due to rapid onset of effects and loss of fine motor control, needle sharing, injecting in unsanitary environments, high-risk injecting (in the neck and groin), and preparation with citric acid to improve water solubility, which additionally increases the corrosive nature of the substance in vivo.

12. These practices are likely to lead to a high risk of bacterial infection and local tissue damage. The injected contents are sometimes not fully solubilised and users will inject without filtering. Police Scotland has seen reports of the

solution partially solidifying on injection. Intravenous drug users in Edinburgh and Lothian were experiencing injuries related to injecting as a consequence of injecting ethylphenidate.

13. Avon and Somerset and Devon and Cornwall Police have had similar reports. Throughout 2014 the market town of Taunton in Somerset has been hit with an epidemic of NPS injecting with all products originating from the one 'Head Shop' located in the main High Street. The injecting was happening in open public places including public toilets and users were abandoning their injecting works on the surrounding ground resulting on one occasion with a local 6-year old receiving a needle-stick injury. In one clear up day in Taunton town centre, over 200 needles were recovered. The injecting and resulting anti-social behaviour reached such a point that the communities set up their own Action Group and worked with the Police and Council to reduce the harms being caused. In December 2014 the Police applied for and achieved the closure of the Head shop under anti-social behaviour legislation. The products most commonly injected were Gogaine, Posh and Ching, all of which are Ethylphenidate-based.

14. The National Programme of Substance Abuse Deaths (NPAD) reported that up to November 2016, ethylphenidate had been found in 28 cases of post mortem toxicology. There have been 17 cases where ethylphenidate was implicated in the cause of death. In the majority of these cases other drugs including NPS were present.

15. The progress report of the UK Early Warning System (EWS) to the EMCDDA (January to June 2014) reported the detection of ethylphenidate.

16. There is one published case report of analytically confirmed acute ethylphenidate toxicity. This was a 26-year-old male who presented with anxiety, paranoia, visual disturbance, and chest pain following use of 500 mg ethylphenidate. On presentation to the Emergency Department (ED), he was restless, tachycardic and hypertensive.

Chronic harm

17. There is currently no data available on the potential for chronic harm associated with ethylphenidate or related analogues. However, with this frequent pattern of injecting, it is likely to lead to an increased risk of hepatitis C or HIV.

International data

18. Ethylphenidate is controlled in China, Denmark, Estonia, Germany, Hungary, Italy, Poland, Portugal, Slovenia, Sweden and Turkey. It is also classified under analogue scheduling in the US and Australia.

19. At the 38th Expert Committee on Drug Dependence in November 2016, Ethylphenidate was recommended to be controlled under Schedule 2 of the United Nations Single Convention on Narcotic Drugs 1971.

Recommendation

20. As such, the ACMD recommended that the group of novel psychoactive substances listed below, are controlled as class B drugs under the Misuse of Drugs Act 1971:

- Ethylphenidate,
- 3,4-Dichloromethylphenidate,
- Methylnaphthidate,
- Isopropylphenidate,
- Propylphenidate,
- 4-Methylmethylphenidate,
- Ethylnaphthidate,
- N-Benzyl-ethylphenidate,
- 3,4-dichloroethylphenidate,
- Methylmorphenate,
- 4-fluoromethylphenidate and
- 4-fluoroethylphenidate.

21. In separate advice, published on 23 March 2017, the ACMD also recommended that these substances be placed in Schedule 1 of the Misuse of Drugs Regulations 2001.

A.1.2 Wider uses

1.2. 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 Pharmalogical Society, the substances listed above have been identified as having no legitimate industrial or medical use.

A.2 Groups Affected

1.3. The proposal to control these compounds 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. However as the majority of these are currently controlled under TCDO, certain measures should already have been put in place.

1.4. 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 these substances 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

1.5. 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 options when the ACMD originally produced its recommendation for these substances.

Public Consultation

1.6. 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 substances.

2.2. Controlling these substances under the Misuse of Drugs Act 1971, as opposed to allowing the substances to be covered under the Psychoactive Substances Act 2016, provides a more effective restriction of their 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 substances.
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 licence to be issued to allow exemptions to offences and this would only be for 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 compounds 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 these substances, 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 these compounds and raised awareness of the harms of these substances, building on the message and effects of the current TCDO.

D. Options

Two options have been considered in respect of these methylphenidate-related NPS:

4.1. OPTION 1: **Allow the TCDO to lapse after 26 June 2017 and these substances to be captured under the Psychoactive Substances Act 2016.**

4.2. OPTION 2: **Control these Class B substances under the Misuse of Drugs Act 1971 and its subordinate legislation, 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 theoretically mean that businesses conducting research incur further costs. However, as these businesses are likely to be in possession of a Home Office Licence and considering they will have been operating under the conditions of a TCDO for the past two years, 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 the listed substances 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 these 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

Public Sector (enforcement agencies, CJS, regulators)

5.5. Whilst it is difficult to compare the costs under the Misuse of Drugs Act 1971 to 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. These costs are difficult to monetise, particularly because the legislation has only been recently been introduced, 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.

5.6. 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 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

5.7. The effect of options 1 and 2 will be similar in this regard. As noted above though, control under the Misuse of Drugs Act 1971 may restrict the supply of the compounds even further than the Psychoactive Substances Act 2016. Personal benefits arise from this direct protection against potential harms of the listed substances through their reduced availability.

5.8. In contrast to the blanket ban on supply of option 1, it is expected that controlling these substances fully under the Misuse of Drugs Act 1971 will also reinforce to the public their potential harms by underlining that their harms have been assessed as commensurate with other Class B drugs. This specific targeting may reduce the harms caused by the substances. The Psychoactive Substances Act 2016 contains no such harms assessment and therefore does not differentiate between the harms of specific drugs.

NET EFFECT

5.9. 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 methylphenidate-related NPS by providing enforcement agencies with wider powers, stricter offences and higher penalties surrounding the trafficking in these substances. This in turn is likely to make it easier for them to restrict the supply of these substances 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 methylphenidate-related NPS are 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 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. As these organisations will have been operating under the conditions of the TCDO for the past two years, they should already have taken steps to obtain a suitable licence to undertake activities in relation to these substances. 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 the substances by making clear they are of concern, by classifying them according to harm and providing stricter penalties for offences.

8.2. Taking option 1 (do nothing and allow the TCDO to lapse) would mean these substances 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 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 the substances 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 the substances are 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 the listed substances provides the best means to reduce availability and potential harm to the public. The resultant clear message to the public that these compounds have 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 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. Information gathered from the monitoring and evaluation process will inform future ACMD advice on the classification, designation and scheduling of these drugs, including any future legitimate uses of the named compounds.