

Title: Control of Etizolam, related drugs and U-47,700 IA No: HO0274 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: 30/01/2017			
	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 made recommendations to control etizolam, 16 other benzodiazepine compounds and the opioid, U-47,700. Given the harms associated with these substances the ACMD has concluded that their misuse is having/capable of having harmful effects sufficient to constitute a social problem.

Government intervention is necessary to prevent harm being caused by these substances by restricting their supply. Given the reported risks that these substances pose to public health, the ACMD has advised that the Misuse of Drugs Act 1971 Act remains the preferred option for control.

What are the policy objectives and the intended effects?

The policy objective is to reduce the risk of harms 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 – Do nothing and allow these compounds to continue to be dealt with under the Psychoactive Substances Act 2016.

Option 2 - Control, designation and scheduling of Etizolam and related compounds as class C drugs and U-47,700 as a class A drug under the Misuse of Drugs Act 1971 and its subordinate legislation.

Option 2 is the preferred option on the basis of the current evidence and the ACMD's assessment of evidence on the harms and misuse associated with these compounds. The Misuse of Drugs Act 1971 provides a higher level of control with a possession 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:** 13/03/2017

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 – These compounds have been identified as having no legitimate industrial or medicinal use in the UK. 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. 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 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 benzodiazepines and opioids 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, 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:			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 etizolam, 16 other benzodiazepines as class C drugs and the opioid U-47,700 as a class A drug under the Misuse of Drugs Act 1971.

A.1.1 Etizolam and other Benzodiazepines

Taken from ACMD report: 'Designer Benzodiazepines', of 2nd December 2016:

- 1.2. Benzodiazepines refer to a group of drugs which were first synthesised in the 1950s. Originally popular and widely available as sedatives, most notably 'Valium' (Diazepam), it became apparent that this class of drugs caused tolerance and dependence with severe withdrawal symptoms in its users.
- 1.3. Many benzodiazepines are controlled under the Misuse of Drugs Act 1971 as Class C substances. The materials listed are essentially those which are named in the 1971 UN Convention and many are not approved for use in the UK.
- 1.4. There have been increasing reports of 'designer benzodiazepines'- substances are outside the control of the Misuse of Drugs Act 1971 and have no legitimate medicinal use in the UK, being created or imported specifically for the psychoactive effect they induce.

Medicinal Use

- 1.5. The ACMD consulted with the Medicines and Healthcare products Regulatory Agency (MHRA) and found no UK marketing authorisations for the substances as medicines.
- 1.6. Etizolam is not registered as a medicinal product in the UK but is a recognised medicine in Japan, Italy and India. The primary application of Etizolam is for the treatment of generalised anxiety disorder with depressive symptoms. Additional medical applications include treatments for sleep problems and convulsions, as well as replacement therapies for alcohol addiction.
- 1.7. Trade names for Etizolam include: Depas, Etilaam, Etizest, Etizola, Etizolan, Pasaden and Sedekopan.

Misuse and Abuse

- 1.8. Benzodiazepines can be misused in a variety of ways. Their effects are alcohol-like and they can be used instead of alcohol; more commonly they are used with alcohol to potentiate its effects. They can also be used to 'come down' from stimulants, for example by clubbers wishing to sleep after a night out. Large overdoses and overdoses in combination with alcohol are used in suicide attempts.
- 1.9. As well as being self-administered, benzodiazepines have potential for use in drug-facilitated crimes, particularly as some are known to cause amnesia.
- 1.10. Etizolam was first notified as a New Psychoactive Substance (NPS) in 2011 and has reportedly been imported from Europe, the Far East and India as tablets in blister packs.
- 1.11. Street names for Etizolam include: Etiz, Etizzy.
- 1.12. The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) has received reports of seizures of Etizolam in the form of tablets and powders.
- 1.13. Recently, Etizolam has appeared in the form of 'blotters' (similar to LSD paper doses). Its high potency ($\approx 5x$ diazepam) allows an effective dose of a few milligrams to be present on a paper dose.

Prevalence

- 1.14. The EMCDDA has received notifications that Etizolam has been detected in several European countries including Cyprus, Denmark, Finland, France, Germany, Hungary, Norway, Lithuania, Luxembourg, Spain, Sweden and the United Kingdom often in transit from China.
- 1.15. Intelligence from Police Scotland shows a general decrease in the prominence of Diazepam, an exponential increase in Etizolam and a more gradual increase in Diclazepam. Current trends, as identified by forensic services in Scotland, suggest that Etizolam has become the predominant benzodiazepine abused within the illicit drug market across Scotland.
- 1.16. The ACMD is concerned with Police Scotland's report that a number of benzodiazepines are being sold as "street valium". When analysed, tablets with the appearance of diazepam tablets were found to contain diclazepam, diazepam, a mixture of etizolam and the synthetic opiate U-47,700 or U-47,700 on its own.

1.17. The Forensic Early Warning System (FEWS) project detected Etizolam in its prison collection plan in 2015 to 2016 and Diclazepam in its head shop collection plan for the same period.

1.18. Information from the National Poisons Information Service (NPIS) recorded a total of 1257 accesses to the *Toxbase* database regarding Etizolam (from 18 June 2013 until 13 July 2016). There were an additional 93 telephone enquiries during the same time period.

Acute Harms

1.19. Etizolam has been detected regularly in post-mortem cases since October 2013. Drug-related deaths evidence from Police Scotland indicates that there has been a spike in the presence of Etizolam in post-mortem toxicology results since the end of 2015, with projection data suggesting this could increase to 50 drug-related deaths per month in Scotland.

1.20. There has also been a 113% increase in Section 4 Road Traffic Act 1988 cases, as tested by Scottish Police Authority Forensic Services and an 800% increase in those involving Etizolam.

1.21. In Glasgow, one NHS hospital has reported that the number of presentations of patients presenting at Accident and Emergency with benzodiazepine overdoses hit a peak of six patients per day.

1.22. The EU-MADNESS project collates drug-related deaths data from Scotland and Northern Ireland. There have been 46 deaths in 2016 registered in Scotland during the first six months of 2016 where Etizolam has been implicated and 22 deaths involving Diclazepam.

Chronic Harms

1.23. Prolonged use of benzodiazepines can lead to tolerance and dependence which can be difficult to resolve.

Polysubstance Use

1.24. The misuse of benzodiazepines by high-risk opioid users is common and associated with morbidity and mortality among this group.

1.25. Data from the National Programme on Substance Abuse Deaths (NPSAD) indicated that in 2015 there were a total of 25 instances where an uncontrolled benzodiazepine was implicated in the cause of death. In all cases, these substances were found in combination with other drugs, and over half were

combined with other NPS. Heroin or morphine was found in twelve cases and methadone in two.

- 1.26. NPSAD data showed 32 instances where a non-controlled benzodiazepine was found in post-mortem toxicology. These uncontrolled benzodiazepines were implicated with other drugs in 21 cases (11 of which were other NPS).

International Control

- 1.27. Etizolam is controlled in several European countries including Denmark, Estonia, Finland, Germany, Italy, Sweden and Turkey.

Conclusion

- 1.28. The risks associated with the designer benzodiazepines are very similar to those of the currently controlled benzodiazepines, and some are highly potent. Etizolam has been implicated in drug related deaths in the UK this year and reports from different sources also indicate harms and death. There has also been a report of Etizolam being mixed with a potent opiate. There is therefore an imminent case for control.
- 1.29. There is a risk that controlling one benzodiazepine could lead to displacement to other benzodiazepines which have the potential to cause harms. Therefore ACMD consider that control should apply to a group of listed benzodiazepines.
- 1.30. There is also the potential that other designer variants could emerge in the future as the structures can be easily modified.

Recommendation

- 1.31. 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 Etizolam, this is a drug that is being, or is likely to be, misused, and that misuse is having, or is capable of having, harmful effects.

A.1.2 U-47,700

Taken from the ACMD report, 'U-47,700', of 2 December 2016:

- 1.32. U-47,700 is a synthetic opioid, originally developed as a research chemical but with no legitimate use. Reportedly 7.5 times more potent than morphine it is a structural analogue of AH-7921. AH-7921 was controlled as a Class A drug in January 2015 following ACMD advice, particularly regarding its high addiction potential.

- 1.33. The ACMD is concerned that abuse of U-47,700 has the potential for severe harms, particularly following reports from the USA of more than 80 deaths attributed to this substance and that the patterns of abuse are mirroring those of heroin.
- 1.34. The US Drug Enforcement Administration has consequently subjected U-47,700 to temporary emergency scheduling under the Controlled Substances Act.

Misuse and Abuse

- 1.35. U-47,700 was first notified as an NPS in Europe to the EMCDDA in 2015, following a seizure by Swedish customs. It has since been identified in Austria, Belgium, Denmark, Estonia, Finland, France, Germany, Lithuania, Poland, Slovenia, Spain and the United Kingdom.
- 1.36. U-47,700 can be inhaled, insufflated, taken orally as tablets and injected.
- 1.37. In the US, the patterns of abuse of U-47,700 mimic those of heroin and other opioids: the clandestine forms of distribution include 'deals' contained in knotted plastic and stamped with logos.
- 1.38. This substance is therefore likely to be sought as a legal substitute by users of illicit opioids such as heroin and/or prescription opioids.
- 1.39. U-47,700 is being obtained as a 'research substance' from unregulated sources, particularly online. Therefore the purity, identity and quality are inconsistent.
- 1.40. The Drug Enforcement Administration (DEA) reports that U-47,700 may act as a precursor to opioid use and dependence.

Acute Harms

- 1.41. Users of U-47,700, particularly those who are using it for the first time, are likely to be at risk of developing substance use disorders, overdose and death.
- 1.42. The EMCDDA reported three deaths in Europe in 2016 where U-47,700 has contributed or been the cause (Belgium, Sweden and the United Kingdom).
- 1.43. With regards to the death in the UK, there was no information or evidence of prior opioid use in the individual involved.
- 1.44. The public health risks posed by U-47,700 are therefore the same as heroin, fentanyl and other opioid analgesics.

1.45. In the US, the DEA have received reports of at least 46 confirmed deaths related to U-47,700.

Prevalence

1.46. The EMCDDA reported an increase in detection of U-47,700 since the end of 2015.

1.47. The EMCDDA reported several notable seizures of U-47,700 in Europe including over 1 kg in powder form and 260 ml of liquid. The largest single seizure of U-47,700 in powder form was 1.054 kg, which was seized in Spain, en route from China to Barcelona in January 2016.

1.48. In the US, seizures of U-47,700 have been encountered in the form of counterfeit tablets that mimic pharmaceutical opioids.

1.49. Information from the NPIS recorded a total of four accesses to the *Toxbase* database regarding U-47,700 (from 17 November 2015 until 13 July 2016).

1.50. Police Scotland made a total of six seizures of tablets containing U-47,700 which had the appearance of Diazepam tablets. Three of these seizures amounted to a total of 2,626 tablets between January and March 2016.

1.51. On the 1st June 2016, Police Scotland reported one further seizure in Lanarkshire, found to contain three bags of 50 tablets (150 tablets in total).

International Data

1.52. U-47,700 is controlled in several European countries including Czech Republic, Denmark, Estonia, Finland, Germany, Hungary, Latvia, Sweden and Turkey.

1.53. The US DEA published its intention to temporarily control U-47,700 as a Schedule 1 substance under the Controlled Substances Act, with effect from November 2016, citing "U-47,700 poses an imminent hazard to public safety".

Social Harms

1.54. It is too early to document any social harms associated with the use of U-47,700. However, extensive knowledge of the dangers of other opioids suggests the potential for social harm. Opioid use can lead to addiction, acquisitive crime, family disruption and loss of employment and these could be predicted as possible consequences if U-47,700 were to gain widespread use.

Polysubstance Use

1.55. In the USA there is association between the presence of U-47,700 and fentanyl/ fentanyl derivatives in post-mortem tests.

Conclusion

1.56. Given the serious adverse effects and deaths already reported in the short period U-47,700 has been available in the UK and given our knowledge of the abuse characteristics of other potent opioid drugs, the ACMD believes that U-47,700 should be subject to control in the UK.

A.1.3 Wider uses

1.57. Etizolam is recognised as a medicine in Italy, Japan and Turkey. However, the ACMD has identified no legitimate medical uses of etizolam, the other named benzodiazepines or U-47,700 in the UK.

1.58. Following consultation with the Department for Business Energy and Industrial Strategy (BEIS), the Medicines and Healthcare products Regulatory Agency (MHRA) and the chemical and pharmaceutical industry, these compounds have been identified as having no legitimate industrial or medicinal use in the UK outside of research.

A.2 Groups Affected

1.59. 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.

1.60. There will be minimal impact on the illicit market in drugs ('head shops' and internet suppliers) as they currently would not be able to sell, produce or import/export these substances to be consumed for psychoactive effect under the controls of the Psychoactive Substances Act 2016. 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

1.61. The Home Office and the ACMD consulted with the MHRA, BEIS and the chemical/pharmaceutical industry in deciding its preferred options when the ACMD originally produced its recommendation for these substances.

Public Consultation

1.62. 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. As the ACMD report states, there are strong indications that the listed benzodiazepines are capable of harm similar to benzodiazepines already controlled under the Misuse of Drugs Act 1971 (currently Class C) and that U-47,700 is capable of similar harms to Opioids controlled under Class A..
- 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.

- 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.

D. Options

Two options have been considered in respect of these benzodiazepines:

- 4.1. OPTION 1: Do nothing and allow these compounds to be covered by the Psychoactive Substances Act 2016.
- 4.2. OPTION 2: Control, designation and scheduling under the Misuse of Drugs Act 1971 and its subordinate legislation, as recommended by the ACMD.

Description of controls

- 4.3. Under the Misuse of Drugs Act 1971, on indictment the maximum penalties for offences relating to class C drugs 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). For equivalent class A offences, the maximum is life imprisonment on indictment and 6 months on summary conviction.
- 4.4. Possession of a class C drug carries a maximum penalty of 3 months imprisonment and a £1,000 fine on summary conviction and a maximum of 2 years imprisonment on indictment. Possession of a class A drug carries a maximum sentence of 7 years and/or a fine on indictment and 6 months/ a fine on summary conviction.

Preferred option

- 4.5. 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. Following consultation with BEIS, the MHRA and the chemical and pharmaceutical industry, the benzodiazepines recommended for control by the ACMD have been identified as having no legitimate industrial or medicinal use. As a result, no wide impacts/costs on legitimate business are expected.
- 5.3. 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 business conducting research incur further costs. However, as these businesses are likely to be in possession of a Home Office Licence anyway, the cost is likely to be minimal.

Public Sector (enforcement agencies, CJS, regulators)

- 5.4. 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

- 5.5. 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)

- 5.6. 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 PS Act 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 Substances 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.
- 5.7. 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 1971. This includes currently controlled benzodiazepines (class C) and currently controlled opioids (class A). 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

- 5.8. 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.
- 5.9. In contrast to the blanket ban on supply of option 1, it is expected that controlling these substances will also reinforce to the public their potential harms by underlining that their harms have been assessed as commensurate with other class C and class A 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

- 5.10. 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 that they reduce the prevalence and harms produced by designer benzodiazepines 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 that U-47,700 and the benzodiazepines 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. However, organisations dealing with permanently controlled scheduled drugs will already possess a licence to undertake activities involving those substances inserted into Schedule 1 of the Misuse of Drugs Regulations. 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

	<ul style="list-style-type: none"> - 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. 	<ul style="list-style-type: none"> - 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.
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8.2. Taking option 1 (do nothing) would mean these substances will be covered by the Psychoactive Substances Act.

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 Psychoactive Substances Act 2016). 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.

8.4. Option 2 is the preferred option and is aligned with the ACMD's advice. The use of the 1971 Act 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 (re)classification, designation and scheduling of these drugs, including any future legitimate uses of the named compounds.