Impact Assessment, The Home Office

Title: Control of 20 Substances under the Misuse of Drugs Act 1971	**Date:** 27 November 2023
	Stage: FINAL
IA No: HO0461	**Intervention:** Domestic
RPC Reference No: N/A	**Measure:** Secondary Legislation
Other departments or agencies: N/A	**Enquiries:** lauren.teer@homeoffice.gov.uk
RPC Opinion: Not applicable	**Business Impact Target:** Not a regulatory provision

Cost of Preferred Option (in 2024/25 prices)					
Net Present Social Value NPSV (£m)	0.01	**Business Net Present Value BNPV (£m)**	N/A	**Net cost to business per year EANDCB (£m)**	N/A

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

Following consultation with the Advisory Council on the Misuse of Drugs (ACMD), 20 substances will be controlled under the Misuse of Drugs Act 1971 (MDA 1971), scheduled under the Misuse of Drugs Regulations 2001 (the 2001 Regulations) and, where appropriate, designated under the Misuse of Drugs (Designation) (England, Wales and Scotland) Order 2015 (the 2015 Order). ACMD reports, dated between 18 July 2022 and 6 October 2023, found significant evidence of potential harms to health which in several cases included drug-related deaths (particularly synthetic opioids), resulting in recommendations on appropriate classification and scheduling of these substances. Government intervention is necessary to provide a stronger legal framework, including making possession of these substances an offence and increasing penalties available, including for supply.

What is the strategic objective? What are the main policy objectives and intended effects?

To help deliver the Home Office's priority to cut crime and the harm it causes; and outcomes of the government's 10-year Drug Strategy. The objectives are to reduce harms associated with misuse of these drugs by providing law enforcement with the powers to deal with possession and illicit supply. It ensures the UK, as a signatory, is aligned with its international obligations under the relevant UN Conventions. Placing remimazolam in schedule 4 (Part 1) of the 2001 Regulations ensures availability for use in healthcare, as intended.

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

In line with the statutory requirement under MDA 1971, the government has consulted the ACMD prior to making any changes to drug legislation. Non-regulatory options were not recommended.
Option 1: 'Do nothing'. Substances would only be subject to the Psychoactive Substances Act 2016 (PSA 2016) when taken for psychoactive effect and therefore not unlawful to possess without intent to supply/in a custodial institution. It would be in breach of international obligations for five substances, which have been scheduled under UN Conventions. **Option 2 (preferred - meets strategic/policy objectives)**: Control 20 substances under MDA 1971, amend the 2001 Regulations and where appropriate 2015 Order in line with ACMD recommendations (except cumyl-PeGaClone).

Main assumptions/sensitivities and economic/analytical risks	**Discount rate (%)**	3.5

The main sensitivities and risks of the analysis are the absence of available data to estimate the prevalence of the proposed controlled substances. This in turn prevents estimating the full impact of the intervention. The available data suggests that there is low prevalence of these substances, therefore it is assumed that the impacts on justice and treatment systems will be minimal.

Will the policy be reviewed? It will not be reviewed.

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Minister: Chris Philp Date: 21st November 2023

Summary: Analysis & Evidence

Policy Option 2

Description: Control 20 substances in their relevant Class of the MDA 1971 and schedule of the 2001 Regulations and where appropriate the 2015 order, in line with ACMD recommendations

FULL ECONOMIC ASSESSMENT

Year(s):	Price Base	2024/25	PV Base	2024/25	Appraisal	10	Transition	1
Estimate of Net Present Social Value NPSV (£m)						**Estimate of BNPV (£m)**		
Low:	0.00	**High:**	0.02	**Best:**	**0.01**	**Best BNPV**	**N/A**	

COSTS, £m	Transition Constant Price	Ongoing Present Value	Total Present Value	Average/year Constant Price	To Business Present Value
Low	0.00	N/A	0.00	0.00	**N/A**
High	0.02	N/A	0.02	0.002	**N/A**
Best Estimate	0.01	N/A	**0.01**	**0.001**	**N/A**

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

The only monetised costs are the familiarisation costs of the new legislation to the public sector, estimated to be £7,000 in the first year of the policy only. This is only a partial cost estimate. This IA uses unit costs, for example drug related hospitalisations and custodial sentence costs, where appropriate to illustrate the low expected economic cost of this intervention.

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

The Criminal Justice System (CJS) and treatment services may incur low costs as a result of this intervention. These costs have not been monetised due to an absence of available data. Illustrative examples are used to demonstrate that even in the case of a proportionaly high impact, the cost impact would still be minimal due to the low prevalence of the controlled substances.

BENEFITS, £m	Transition Constant Price	Ongoing Present Value	Total Present Value	Average/year Constant Price	To Business Present Value
Low	N/A	N/A	**N/A**	**N/A**	**N/A**
High	N/A	N/A	**N/A**	**N/A**	**N/A**
Best Estimate	N/A	N/A	**N/A**	**N/A**	**N/A**

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

The benefits for Option 2 could not be monetised due to the difficulty quantifying the policy impact and an absence of available data. This IA instead uses wider evidence on unit costs where appropriate to indicate the potential benefits as a result of this policy intervention.

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

Healthcare services may incur benefits though decreased drug poisoning hospital admissions and fewer drug-related deaths, driven by an increased public awareness surrounding the harms of the controlled substances. One fewer drug-related death would result in a cost saving of **£2.97 million**.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:									
Cost, £m	N/A	**Benefit, £m**	N/A	**Net, £m**	**N/A**				
Score for Business Impact Target (qualifying provisions only) £m:					-				
Is this measure likely to impact on trade and investment?					N/A				
Are any of these organisations in scope?	**Micro**	N	**Small**	N	**Medium**	N	**Large**	N	
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		Traded:	N/A		Non-Traded:	N/A			

PEOPLE AND SPECIFIC IMPACTS ASSESSMENT (Option 2)

Are all relevant Specific Impacts included?	Y	Are there any impacts on particular groups?	N

Evidence Base

A. Strategic objective and overview

A.1 Strategic objective

1. The measures proposed in the policy to place 20 substances under the control of MDA 1971 will contribute to a number of over-arching government strategic objectives, such as:

    - The Home Office's priority to cut crime and the harm it causes[1].
    - The Home Office Outcome Delivery Plan priority outcomes to reduce crime (ODP1)[2].
    - The government's 10-year drug strategy to reduce drug use towards a 30 year low[3].

A.2 Background

2. The purpose of this intervention is to control the following substances under MDA 1971 and schedule them under the 2001 Regulations and, where appropriate, designate them under the 2015 Order. Following implementation, the offences under MDA 1971 (including possession, supply, production, import and export), and accompanying enforcement powers will apply. The restrictions on access in healthcare or for research, as outlined in the 2001 Regulations, will also apply:

    - 15 synthetic opioids (14 nitazenes: metonitazene, protonitazene, isotonitazene, butonitazene, flunitazene, metodesnitazene (metazene), etodesnitazene (etazene), *N*-Pyrrolidino-etonitazene (etonitazepyne), *N*-Piperidinyl-etonitazene (etonitazepipne), *N*-Pyrrolidino protonitazene, ethyleneoxynitazene, *N*-Desethyl protonitazene, *N*-Desethylisotonitazene, *N*-Desethyl-etonitazene, and brorphine) as Class A drugs under MDA 1971, schedule 1 under the 2001 Regulations and designated under the 2015 Order;
    - Cumyl-PeGaClone, a synthetic cannabinoid receptor agonist (SCRA), as a Class B drug under MDA 1971, schedule 1 under the 2001 Regulations and designated under the 2015 Order;
    - Three stimulants, diphenidine, ephenidine and methoxyphenidine as Class B drugs under the MDA 1971, schedule 1 under the 2001 Regulations and designated under the 2015 Order, and;
    - Remimazolam, the active ingredient in a medicine given marketing authorisation (a medicines licence) by the Medicines and Healthcare products Regulatory Agency (MHRA), as a Class C drug under MDA 1971 and schedule 4 (Part 1) under the 2001 Regulations.

3. The proposed amendments follow consultation with, and with the exception of cumyl-PeGaClone, follow recommendations from, the ACMD, in line with the statutory requirement under section 2(5) of MDA 1971.

4. Isotonitazene, metonitazene and brorphine have been controlled at an international level under the UN Single Convention on Narcotic Drugs of 1961[4] and cumyl-PeGaClone and diphenadine have been scheduled under the UN Single Convention on Psychotropic Substances 1971[5]. The UK is a signatory to both Conventions, and would therefore look to enact domestic control to ensure alignment with international controls.

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[1] Home Office, About Us. Available here: https://www.gov.uk/government/organisations/home-office/about

[2] Home Office, Home Office Outcome Delivery Plan: 2021 to 2022, July 2021. Available here: https://www.gov.uk/government/publications/home-office-outcome-delivery-plan/home-office-outcome-delivery-plan-2021-to-2022#reduce-crime

[3] From harm to hope: A 10-year drugs plan to cut crime and save lives. Available here: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1079147/From_harm_to_hope_PDF.pdf

[4] UN Single Convention on Narcotic Drugs of 1961. Available here: https://www.unodc.org/pdf/convention_1961_en.pdf

[5] UN Single Convention on Psychotropic Substances 1971. Available here: https://www.unodc.org/unodc/en/treaties/psychotropics.html

5. This legislation is required to ensure that the substances are controlled based on their potential for harm, diversion and misuse. In light of ongoing drug-related deaths and non-fatal overdoses associated with a number of these potent synthetic opioids, including nitazenes, in the UK, this intervention is particularly important to ensure law enforcement is able to deal with the illicit distribution, misuse and harms of these drugs appropriately.

6. The corresponding negative parliamentary procedure Statutory Instrument (SI), which the government intends to lay in early 2024, will place all of the substances, except remimazolam, in schedule 1 of the 2001 Regulations and designate them under the 2015 Order, by virtue of them having no known medicinal or therapeutic value in the UK. This means they will only be available for access under a Home Office controlled drug licence, generally for research purposes. Remimazolam will be placed in schedule 4 (Part 1) of the 2001 Regulations, meaning it can be accessed for use in healthcare subject to the necessary restrictions outlined in the 2001 Regulations.

7. In line with ACMD recommendations, the aforementioned negative SI will also move two substances, etonitazene and clonitazene, from schedule 2 to schedule 1 under the 2001 Regulations and designate them under the 2015 Order. These drugs are already controlled as Class A drugs under MDA 1971 and, following further review, the ACMD have assessed them to have no medicinal or therapeutic value in the UK and therefore recommended they are moved to schedule 1.

A.3 Groups affected

8. The main groups that would be affected by this policy have been identified as follows:

- Criminal Justice Systems (CJS) in the UK which would be affected by a potential increase in the number of offences for the possession of a drug controlled under Class A and B of MDA 1971. This would include HM Prisons and Probation Service (HMPPS) which would face costs in constructing and maintaining new prison places; HM Courts and Tribunals Service (HMCTS) which would face costs in holding Magistrates' and Crown Court trials; the Legal Aid Agency which would fund legal aid for defendants in Magistrates' and Crown Court trials; and the Crown Prosecution Service (CPS) which would prosecute cases.
- Drug treatment services.
- Drugs and Firearms Licensing Unit who are the issuing authority for a Home Office controlled drug licence, which is required to access controlled drugs placed in schedule 1 of the 2001 Regulations.
- Offenders who possess, import, export, produce or supply the controlled drugs without the required licence (where appropriate) or in a medical setting as per the restrictions set out in the 2001 Regulations (for remimazolam only).
- Police, including British Transport Police (BTP) through enforcement of the policy. Border Force and the National Crime Agency who are involved in tacking the supply and trafficking of illicit drugs.
- The Department for Health and Social Care (DHSC).
- The National Health Service (NHS) and private healthcare services.
- Businesses who are authorised to sell and market remimazolam.

A.4 Consultation

Within government

9. The Home Office has engaged with other government departments (OGDs), including the DHSC and the MHRA who were supportive of the interventions. The Home Office has also engaged colleagues in the Department for Health Northern Ireland who have responsibility for the Misuse of Drugs Regulations (Northern Ireland) 2002 and the Misuse of Drugs (Designation) Order (Northern Ireland) 2001, to enable them to make equivalent changes.

Public consultation

10. The amendments follow public consultation, and with the exception of cumyl-PeGaClone, follow recommendations from, the ACMD. Law enforcement partners were also engaged as part of the policy development process for the proposals within this consultation, and were supportive.

B. Rationale for intervention

11. There is a need for government intervention as the UK's treaty obligations require the substances controlled under UN international conventions, to be controlled domestically under MDA 1971. Government is best placed to intervene in such cases as they have the powers to make amendments to the relevant drug legislation to ensure control of the substances as per ACMD recommendations.

B.1 Synthetic Opioids

12. Synthetic opioids give users similar effects to those of morphine and heroin, but some are much more potent. This means that substantially lower doses are needed to achieve the effects desired by users, but there is also a high risk of accidental overdose, and this may cause life-threatening toxicity including loss of consciousness, cardiorespiratory arrest and death.

13. Following the international control of isotonitazene, metonitazene and brorphine, the ACMD have advised controlling 15 synthetic opioids, including 14 nitazenes and brorphine[6]. As of November 2021, nine of these compounds had been reported to the United Nations Office on Drugs and Crime (UNODC) Early Warning Advisory, specifically isotonitazene, 5-aminoisotonitazene, *N*- pyrrolidino-etonitazene, butonitazene, metonitazene, protonitazene, etodesnitazene (etazene), flunitazene and metodesnitazene (metazene)[7].

14. In October 2021, the National Crime Agency (NCA) reported on 31 suspected heroin overdoses in the UK where isotonitazene had been identified, of which 24 were fatal[8]. The National Programme on Substance Abuse Deaths (NPSAD) data shows that in the UK there have been 25 drug deaths related to nitazenes and 1 drug death related to brorphine in the past 5 years[9].

15. Based on their significant harm and misuse, the ACMD has advised that the following substances should be controlled as Class A drugs under MDA 1971: metonitazene, protonitazene, isotonitazene, butonitazene, flunitazene, metodesnitazene (metazene), etodesnitazene (etazene), *N*-Pyrrolidino-etonitazene (etonitazepyne), *N*-Piperidinyl-etonitazene (etonitazepipne), *N*-Pyrrolidino protonitazene, ethyleneoxynitazene, *N*-Desethyl protonitazene, *N*-Desethylisotonitazene, *N*-Desethyl-etonitazene, and brorphine. Furthermore, as these substances have no known medicinal or therapeutic value in the UK they will also be placed in schedule 1 of the 2001 Regulations and designated under the 2015 Order, meaning they can only be accessed under a Home Office controlled drug licence.

B.2 Synthetic Cannabinoid Receptor Agonist

16. SCRAs, are chemicals that exert psychoactive effects by stimulating the same receptors within the body that are responsible for mediating the pharmacological effects of tetrahydrocannabinol (THC), the major active ingredient of cannabis.

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[6] ACMD synthetic opioids advice. Available here: https://www.gov.uk/government/publications/acmd-advice-on-2-benzyl-benzimidazole-and-piperidine-benzimidazolone-opioids/acmd-advice-on-2-benzyl-benzimidazole-and-piperidine-benzimidazolone-opioids-accessible-version

[7] UNODC Early Warning Advisory on synthetic opioids. Available here: https://www.unodc.org/documents/scientific/NPS_threats_IV_web.pdf

[8] NCA isotonitazene death statistics – Paragraph 10.9. Available here: https://www.gov.uk/government/publications/acmd-advice-on-2-benzyl-benzimidazole-and-piperidine-benzimidazolone-opioids/acmd-advice-on-2-benzyl-benzimidazole-and-piperidine-benzimidazolone-opioids-accessible-version

[9] NPSAD data provided internally by Kings College London. Available here: https://www.kcl.ac.uk/research/the-national-programme-on-substance-abuse-deaths

17. Use of SCRA can produce important adverse health effects including confusion, anxiety, agitation, psychosis, vomiting, reduced level of consciousness with impaired ventilation and loss of airway reflexes, cardiac dysrhythmias, seizures, and liver or kidney failure. These effects may cause hospitalisation and in severe cases death may occur.

18. One of these newer SCRA, cumyl-PeGaClone, has been reviewed by the World Health Organization[10]. Following this, the United Nations Commission on Narcotic Drugs has recommended its addition to schedule 2 of the Convention on Psychotropic Substances 1971. As this requires the UK, as a signatory, to introduce appropriate legal control measures, the ACMD has provided advice on the appropriate domestic controls for cumyl-PeGaClone under MDA 1971[11].

19. The ACMD found that whilst there have been no reports of detection in the UK, due to the harmful effects of cumyl-PeGaClone seen internationally and the fact that is falls outside of the current generic definition for SCRA in MDA 1971, the generic definition should be revised to ensure cumyl-PeGaClone and other similar SCRA are captured. The government has accepted this recommendation but has chosen to control cumyl-PeGaClone individually in the interim as a Class B drug under MDA 1971, in line with controls for other SCRA. This ensures the UK meets its international obligations more quickly and reduces the potential for harm through misuse. These substances have no known medicinal or therapeutic value in the UK and cumyl-PeGaClone will be placed in schedule 1 of the 2001 Regulations and desginated under the 2015 Order, meaning it can only be accessed under a Home Office controlled drug licence.

B.3 Stimulants

20. Diphenidine is a stimulant and was added to the UN Convention on Psychotropic Substances 1971[5] in April 2021 as a schedule 2 substance. The UK's treaty obligations require that it is controlled domestically under MDA 1971. The ACMD was commissioned in January 2022[12] to provide advice on the appropriate classification and scheduling of a number of substances, including diphenidine.

21. The ACMD reports that diphenidine and substances of its type (ephenidine and methoxyphenidine) have dissociative effects (that is, detachment from reality). Adverse health effects include hypertension and tachycardia, hallucinations, sedation/drowsiness, confusion, paranoia and anxiety/agitation and toxicity. These are broadly similar to the effects of ketamine, a Class B drug under MDA 1971. Diphenidine is a derivative of lefetamine, a stimulant also controlled in Class B of MDA 1971.

22. A detailed review was undertaken in late August 2022 by members of the ACMD Novel Psychoactive Substances (NPS) Committee and the ACMD Secretariat. The review identified 48 deaths worldwide between 2014 and 2019 involving diphenidine and/or methoxyphenidine. Of these, 37 occurred in the UK. This review did not identify any deaths in the UK related to ephenidine.

23. As diphenidine has been controlled under the UN Convention on Psychotropic Substances 1971 as a schedule 2 material, the UK would also look to enact domestic control under MDA 1971. The ACMD concluded that as there is evidence that diphenidine, methoxyphenidine and ephenidine have similarities to ketamine from pharmacological studies and/or cases of acute toxicity, they should controlled as Class B drugs under MDA 1971. These drugs have no known medicinal or therapeutic value in the UK and will therefore be placed in schedule 1 of the 2001 Regulations and designated

[10] World Health Organization (2020). Critical Review Report: CUMYL-PEGACLONE. Available here : https://www.who.int/docs/default-source/controlled-substances/43rd-ecdd/cumyl-pegaclone-review-2020.pdf?sfvrsn=959c2bcb_4

[11] ACMD Cumyl-Pegaclone Advice. Available here: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1159142/Cumyl-pegalone_and_other_uncontrolled_SCRA_report-FINAL.pdf

[5] UN Single Convention on Psychotropic Substances 1971. Available here: https://www.unodc.org/unodc/en/treaties/psychotropics.html

[12] ACMD review of Diphenidine, ephenidine and methoxyphenidine. Available here: https://www.gov.uk/government/publications/acmd-review-of-the-evidence-on-the-use-and-harms-of-diphenidine/acmd-review-of-the-evidence-on-the-use-and-harms-of-diphenidine-accessible#uk-prevalence

under the 2015 Order, meaning they can only be accessed under a Home Office controlled drug licence.

B.4 Remimazolam

24. Remimazolam is an ultra-short acting benzodiazepine which was given marketing authorisation (a medicines licence) in Great Britain on 28 June 2021 by MHRA for use in adults for procedural sedation (a technique to enable medical procedures without preventing the patient breathing by themselves). It is a prescription only medicine, and not currently controlled under MDA 1971. It is also approved for marketing in Europe (including Northern Ireland).

25. The ACMD provided advice on the appropriate classification under MDA 1971 and scheduling under the 2001 Regulations of remimazolam on 2 December 2022[13]. This followed consideration of relevant evidence provided by the MHRA in a written dossier and oral presentation.

26. The safety profile, toxicity, and behavioural effects of remimazolam are consistent with other benzodiazepines in schedule 3 of the 2001 Regulations. The dependence and diversion potential are consistent with other short-acting benzodiazepine drugs and is comparable to midazolam that is used for sedation in several settings and is an existing schedule 3 drug. Midazolam has previously been recognised as a potential 'date rape' drug due to its ability to induce anterograde amnesia and fast-acting sedative effects.

27. Compared to midazolam, remimazolam has a much shorter duration of action and its effects wear off within minutes. Remimazolam has a much lower oral bioavailability than midazolam and bitter taste, hence the ACMD concluded that it is much less likely to be an attractive 'date rape' drug. Furthermore, the requirement for remimazolam to be administered by a clinician in a controlled setting only for procedural sedation meant the availability of remimazolam is less than midazolam.

28. The ACMD recommended that remimazolam should be controlled as a Class C drug under MDA 1971. The ACMD recommended it is placed in schedule 4 (Part 1) of the 2001 Regulations, meaning it is available for use in healthcare but subject to appropriate restrictions.

C. Policy objective

29. The policy objectives are to reduce the harms associated with the misuse of these drugs in the UK, some of which have been associated with drug-related deaths (particularly synthetic opioids), by providing law enforcement with the necessary powers to deal with possession and enforce increased criminal penalties for supply and production. Given five of the 20 substances have also been controlled at an international level, it ensures the UK, as a signatory, is aligned with its international obligations under the United Nations Single Convention on Narcotic Drugs of 1961[4] and the United Nations Single Convention on Psychotropic Substances 1971.

    Placing remimazolam in schedule 4 (Part 1) of the 2001 Regulations ensures availability for use in healthcare, as intended. Placing the remaining 19 substances in schedule 1 ensures they can only be accessed under a Home Office controlled drug licence, as intended by virtue of them having no known medicinal or therapeutic value in the UK.

D. Options considered and implementation

30. In line with the statutory requirement under MDA 1971, the government has consulted the ACMD prior to making any changes to drug legislation. The ACMD did not recommend non-regulatory options.

[13]ACMD advice on Remimazolam. Available here: https://www.gov.uk/government/publications/acmd-advice-on-the-classification-and-schedule-of-remimazolam/acmd-advice-on-the-classification-and-schedule-of-remimazolam

[4] UN Single Convention on Narcotic Drugs of 1961. Available here: https://www.unodc.org/pdf/convention_1961_en.pdf

31. **Option 1**: 'Do nothing'. This would leave the substances subject to PSA 2016 when taken for their psychoactive effect, meaning possession, other than with intent to supply or in a custodial institutions, would not be unlawful. PSA 2016 provides lower criminal penalties and does not include an offence for drug possession.

32. **Option 2**: Control 20 substances in their relevant Class of MDA 1971 (15 in Class A, four in Class B, one in Class C) and schedule of the 2001 Regulations (19 in schedule 1, one in schedule 4 (Part 1), in line with ACMD recommendations. **This is the government's preferred option as it meets the strategic and policy objectives.**

Preferred option and implementation date

33. The preferred option will be given effect via secondary legislation, using existing powers in MDA 1971. There will be no transitional arrangements. Control of the substances is intended in early 2024. Both the instrument controlling the substances and the instrument allowing access for legitimate purposes will enter into force on the same date.

34. This intervention will achieve the policy objectives by providing law enforcement with the necessary powers to deal with illicit supply and possession of these substances, therefore reducing their potential to cause significant harm to individuals and wider society.

E. Appraisal

General assumptions and data

35. The ACMD reports outline the evidence of the harm of the 20 substances in this intervention, as well as the available evidence of their prevalence in the UK. Producing a **monetised** value for the likely impact of the analysis would require evidence regarding:

    - A more comprehensive understanding of the prevalence of these substances in the UK, and how they are used with other controlled substances.
    - The likely change in consumption of the substances following the introduction of greater controls.
    - The substitutability of these substances with other drugs.

36. Without this information it has only been possible to:

    - Provide an informed qualitative judgement of the potential costs and benefits of this legislative change.
    - Use what data is available to demonstrate the potential scale of the economic impact which is likely to be small.

37. The impacts of the preferred option are relative to the counterfactual 'Do-nothing' baseline (Option 1). Due to the lack of available data and evidence, this IA describes the potential impacts of controlling the substances, monetising costs and benefits where appropriate, with a partial Net Present Social Value (NPSV) estimated. Costs presented are in 2024/25 prices.

38. This IA refers to synthetic opioid, SCRA and stimulant users as illegitimate users. Illegitimate users may also be referred to as those who 'misuse' the drug throughout the IA. This IA refers to the production, import, export, supply, offer to supply and possession with intent to supply offences as 'supply and production' offences for simplicity.

39. The only controlled drug with known legitimate use is remimazolam, a medicine used in healthcare services. Following the ACMD's conclusions that there is a low risk of this drug being[14] misused, it is assumed that there will be no illicit use of remimazolam. Businesses will require a Home Office

[14] ACMD remimazolam report. Available here: https://www.gov.uk/government/publications/acmd-advice-on-the-classification-and-schedule-of-remimazolam/acmd-advice-on-the-classification-and-schedule-of-remimazolam

controlled drug licence to possess, supply, produce, import or export remimazolam, unless an exemption, such as in a healthcare setting, applies within the 2001 Regulations. 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 remimazolam or use it for the synthesis of non-controlled pharmaceuticals may become adversely affected by 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 remimazolam once it is controlled under the MDA 1971 and 2001 Regulations. Due to the absence of evidence of legitimate business impact and the negligible costs that would be associated with any impact, the assumption is made that there are no cost implications to business.

Prevalance of Controlled Substances

40. Whilst there is a lack of reliable data on prevalence available for the specific substances being controlled in this intervention, the available data sources illustrate the likely low prevalence, especially relative to overall drug misuse in the UK. The Crime Survey for England and Wales (CSEW)[15] shows that in the year to June 2022, approximately three million adults aged 16-59 reported drug use in the last year, including 881,000 adults reporting Class A drug use. Whilst the prevalence of these drugs is seemingly low in comparison as shown in below sections, they are reported to have high associated harms, particularly synthetic opioids.

Prevalence of Synthetic Opioid misuse

41. **National Programme on Substance Abuse Deaths (NPSAD) Synthetic Opioids Drug Deaths[16]**: The NPSAD collates reports from coroners in England, Wales, and Northern Ireland pertaining to deaths related to psychoactive drug use. The NPSAD data shows 26 deaths from 2018 to 2022 related to nitazenes and brorphine, and a further 301 deaths related to other synthetic opioids. For these five years, the NPSAD data estimates approximately 65 deaths per year related to all synthetic opiods, of which approximately five deaths per year are related to the synthetic opiods controlled in this intervention.

42. **NCA data[17]**: The ACMD report details that in October 2021 the NCA (Operation ROPERY) reported 31 suspected heroin overdoses in the UK where isotonitazene had been identified, 24 of which were fatal.

43. **Deaths relating to drug poisoning data[18]**: The Office for National Statistics (ONS) published data on the annual numbers of deaths registered related to drug poisoning in England and Wales up to 2021. Those where a new synthetic opioid (NSO) was mentioned on the death certificate were 13 for 2018, 1 for 2019, 1 for 2020 and 3 for 2021. Details on the specific substances involved is not provided and data is not yet available for 2022.

44. **NHS hospital admissions data[19]**: The NHS published data on finished hospital admission episodes with a primary diagnosis of poisoning by drug misuse in England up to 2020. This data set does not provide data on synthetic opioids specifically, but it does provide hospital admissions data for 'Other Opioids' and 'Other Synthetic Narcotics' which are used as a proxy. In the reporting year 2019/20,

[15] CSEW, year ending June 2022. Available here: https://www.ons.gov.uk/peoplepopulationandcommunity/crimeandjustice/articles/drugmisuseinenglandandwales/yearendingjune2022

[16] NPSAD data provided to the Home Office by Kings College London. Available here: https://www.kcl.ac.uk/research/the-national-programme-on-substance-abuse-deaths

[17] NCA Operation Ropery Findings.Available here: https://www.gov.uk/government/publications/acmd-advice-on-2-benzyl-benzimidazole-and-piperidine-benzimidazolone-opioids/acmd-advice-on-2-benzyl-benzimidazole-and-piperidine-benzimidazolone-opioids-accessible-version

[18] Deaths relating to drug poisoning data. Available here: https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/datasets/deathsrelatedtodrugpoisoningbyselectedsubstances

[19] NHS hospital admissions data. Available here: https://digital.nhs.uk/data-and-information/publications/statistical/statistics-on-drug-misuse/2020/drug-admissions-data-tables

there were 9,104 hospital admissions for 'Other Opioids' and 2,149 admissions for 'Other Synthetic Narcotics'.

45. Taking into account the data limitations in this area, based on emerging intelligence it is likely that the prevalence of synthetic opioids is under-estimated.

Prevalence of Synthetic Cannabinoid Receptor Agonist misuse

46. **Deaths relating to drug poisoning data**: The ONS published data on substances involved in annual numbers of deaths related to drug poisoning in England and Wales up to 2021. Those where a new synthetic cannabinoid was mentioned on the death certificate were 60 for 2018, 56 for 2019, 53 for 2020 and 69 for 2021. Details on the specific substances involved is not provided.

47. **NHS hospital admissions data**: The NHS published data on finished hospital admission episodes with a primary diagnosis of poisoning by drug misuse in England up to 2020. 'Cannabis (derivatives)' admissions are used as a proxy for SCRA misuse prevalence. There were 328 admissions in 2017/18, 363 in 2018/19, and 345 in 2019/20 for cannabis derivatives.

48. **Treatment statistics (cannabinoid)[20]**: Drug treatment services in England record presentations of problematic SCRA use referred to in the data as 'predominantly cannabinoid' NPS use. In the reporting year 2020/21 National Drug Treatment Monitoring System (NDTMS) reported 1,148 new treatment presentations citing problematic SCRA use (0.4% of total treatment population).

Prevalence of Stimulants misuse

49. **ACMD Reports Data[21]**: A detailed review was undertaken in late August 2022 by members of the ACMD Novel Psychoactive Substances (NPS) Committee and the ACMD Secretariat. The review identified 48 deaths worldwide between 2014 to 2019 involving diphenidine and/or methoxyphenidine. Of these, 37 occurred in the UK. This review did not identify any deaths in the UK related to ephenidine.

50. **Treatment statistics (stimulants)**: Drug treatment services in England record presentations of problematic sedative use referred to in the data as 'predominantly stimulant' NPS use. In the reporting year 2020/21 National Drug Treatment Monitoring System (NDTMS) reported 177 new treatment presentations citing problematic stimulant use (0.1% of total treatment population).

Prevalence of Remimazolam in medical use

51. **NHS data[22]**: The NHS published Secondary Care Medicines Data (SCMD) which contains processed pharmacy stock control data in standardised format from all NHS Acute, Teaching, Specialist, Mental Health and Community Trusts in England. In the 12 months to July 2023, 524 vials of remimazolam were used.

Appraisal

52. The proposed legislation is expected to have three main impacts:

- **Increased volumes of possession of Class A and B drug offences:** Under PSA 2016 possession of these substances is not illegal, except in the case of simple possession in a custodial institution. Controlling 15 synthetic opioids, 3 stimulants and 1 SCRA under Class A and B respectively of MDA 1971 makes these substances illegal to possess. This could increase the number of possession offences recorded by the police and processed through the CJS. Whilst the volume of possession offences could not be reliably quantified, they are expected to be low. ACMD reports that, in addition to limited prevalence, users of the controlled synthetic opioids are likely to be unaware that they are taking a NSO, and or are already

[20] Drug Treatment Statistics. Available here: https://www.gov.uk/government/statistics/substance-misuse-treatment-for-adults-statistics-2021-to-2022

[21] ACMD review of Diphenidine, ephenidine and methoxyphenidine. Available here: https://www.gov.uk/government/publications/acmd-review-of-the-evidence-on-the-use-and-harms-of-diphenidine/acmd-review-of-the-evidence-on-the-use-and-harms-of-diphenidine-accessible#uk-prevalence

[22] NHS Remimazolam Prevalence data. Available here: https://opendata.nhsbsa.net/dataset/secondary-care-medicines-data-indicative-price

knowingly consuming other controlled drugs, for example heroin or cocaine. Therefore, it is unlikely that an individual will possess one of the synthetic opioids in scope of this IA, and not possess another controlled drug. As a result, these individuals are likely to be committing other drug offences and may be already subject to law enforcement. Therefore, controlling the NSOs under MDA 1971 is not expected to significantly increase the volume of individuals entering the CJS for possession offences.

- **Increased sentence lengths for the supply and production of Class A and B drug offences and increased barriers to availability:** The sentencing guidelines under MDA 1971 indicate a longer sentence length than under PSA 2016. For Class A substances, the maximum sentence under PSA 2016 is seven years, compared with life imprisonment under MDA 1971. For Class B substances the maximum sentence length is seven years under PSA 2016 compared to 14 years under MDA 1971. This may have an impact on the prison system. Increased setences for supply and production offences could increase the barriers to availability of the controlled sunstances for suppliers, producers and misusers.
- **Reduction in the harms associated with the controlled substances:** By controlling these substances under MDA 1971 it is expected that there will be an increased public awareness of the harms of these substances, particularly the synthetic opioids.This may have an impact on treatment services and potentially an impact on healthcare services, whereby more people participate in treatment and fewer people get admitted to hospital.

COSTS

Monetised Costs

Set-up costs: Familiarisation costs

53. It is assumed that police officers, employees of DHSC and senior medical practitioners in the NHS will need to familiarise themselves with the new legislation. The familiarisation cost to medical practitioners only working in private healthcare services is not estimated due to a lack of data.

54. Documentation associated with this legislative change is expected to be between 250 and 350 words, with a central estimate of 300 words[23]. The median hourly wage for the professionals that would be required to read and comprehend the legislation is used[24]. This is then uplifted to 2024/25 prices[25] and adjusted to account for non-wage labour costs, estimated to be 22 per cent for public sector workers[26].

55. The Readingsoft calculator[27] was used to calculate low, central, and high estimates for the time required to read and comprehend the changes. The formula used to estimate familiarisation costs are as follows:

time taken to read x median wage of professional reading the guidance x number of professionals reading the guidance x (1 + (non-wage uplift))

56. Total familiarisation costs are estimated to be between **£1,600 and £21,000 with a central estimate of £7,000** (2024/25)**.** These costs are only incurred in Year 1 of the appraisal period.

Non-Monetised Costs

[23] The length of the document is an assumption, based on the average length of Home Office circulars. A range is taken around the estimates to reflect uncertainty.
[24] ONS, 2022, *Earnings and hours worked, occupation by four-digit SOC: ASHE Table 14*. Available here: https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/occupation4digitsoc2010ashetable14
[25] HMT, 2023, *GDP Deflators at market prices and money GDP June 2023*. Available here: https://www.gov.uk/government/collections/gdp-deflators-at-market-prices-and-money-gdp
[26] ONS, 2020, *Index of Labour Costs per Hour, seasonally adjusted*. Available here: https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/indexoflabourcostsperhourilchseasonallyadjusted
[27] Readingsoft, 2023, *Speed Reading Guide*. Available here: https://readingsoft.com/speed-reading-guide/

Cost 1: Law Enforcement and CJS Costs

57. Due to an absence of reliable data on prevalence, the volume of additional drug offence cases that could be recorded by law enforcement and progress through the CJS could not be monetised. However this impact is expected to be small.

58. In the year ending June 2022, four per cent of Class A possession offences and two per cent of Class B possession offences were sentenced to immediate custody[28]. If an increase in recorded possession offences occurs, it is expected that it will be proportionally small[29]. For example, a 0.5 per cent increase in the current levels of possession offences would result in an additional 38 Class A possession offences and 63 Class B possession offences per year. Using the four per cent and two per cent split for the proportion of offences that receive total immediate custody, a 0.5 per cent increase in these offences would lead to two additional Class A and one additional Class B custodial sentences for possession. Applying this to the average custodial sentence length (ACSL) for a possession offence (4.8 months for Class A and 1.4 months for Class B substances[30]) one additional Class A possession offence would cost a maximum of **£26,200** (2024/25 prices), and one additional Class B possession offence would cost a maximum of **£10,500** (2024/25 prices)[31]. This is a purely illustrative example to show the small proportions of possession of Class A and Clas B drugs which progress through the CJS to immediate custody, which represents the most costly outcome. Applying these small proportions to the expected low prevalence of the drugs in scope of this legislative change, the overall impact on law enforcement and the CJS is expected to be negligible.

59. In the year ending June 2022, 78 per cent of Class A production and supply offences and 42 per cent of Class B production and supply offences received total immediate custody[32]. The supply and production of the controlled synthetic opioids, cum-PeGaClone and stimulants for their psychoactive effects is already a crime under PSA 2016. Controlling these substances under MDA 1971 will only increase the maximum custodial sentence given to offenders.

Cost 2: Treatment Cost

60. An increased understanding surrounding the risk of using the controlled drugs may lead to an uptake in misusers utilising drug treatment services.This combined with enforcement agencies being encouraged to refer individuals to treatment through programmes such as Project ADDER[33] could result in increased costs to drug treatment services. Given that in the year to March 2022, those in treatment for 'predomintantly cannabinoid', 'predominantly stimulant' and 'predominantly

[28] CJS Outcome by Offence data. Available here: https://www.gov.uk/government/statistics/criminal-justice-system-statistics-quarterly-june-2022

[29] The CSEW reported that in the year ending June 2022, there were approximately three million adults aged 16-59 that had reported drug use, including 881,000 adults who had reported taking a Class A drug within the last year. Taking the NSPAD prevalence of all synthetic opioids (see paragraph 42), there are approximately 100 deaths per year. This would represent 0.01 per cent of the reported Class A users from the CSEW. The NPSAD estimates that 5 deaths annually relate to the specific synthetic opioids being controlled in this intervention. This would account for 0.0006 per cent of the reported Class A users. Although internal MI data suggests that the prevalence of synthetic opioids may be higher than the publicly available data sources indicate, the known prevalence of these drugs compared to total misuse is still very low. CSEW, Available here: https://www.ons.gov.uk/peoplepopulationandcommunity/crimeandjustice/articles/drugmisuseinenglandandwales/yearendingjune2022

[30] CJS Outcome by Offence data. Available here: https://www.gov.uk/government/statistics/criminal-justice-system-statistics-quarterly-june-2022

[31] This is the maximum cost that assumes the uptake of police station legal aid, crown court legal aid, a crown court trial and a custodial sentence of 4.8 months and 1.4 months for Class A and Class B possession offences respectively. This cost is an overestimation as it takes the maximum possible cost scenarios.

[32] CJS Outcome by Offence data. Available here: https://www.gov.uk/government/statistics/criminal-justice-system-statistics-quarterly-june-2022. The data is from the following offence codes: 92A.01: Unlawful Importation – Class A, 92A.05: Unlawful Exportation – Class A, 92A.09: Production, supply and possession with intent to supply a controlled drug – Class A, 92A.02: Unlawful Importation – Class B, 92A.06: Unlawful Exportation – Class B and 92A.10: Production, supply and possession with intent to supply a controlled drug – Class B

[33] About Project ADDER. Available here: https://www.gov.uk/government/publications/project-adder/about-project-adder

sedative/opioid' only accounted for 0.5 per cent of the total adult population of all people in treatment[34], the expected economic impact on treatment services is low.

Total Costs

61. Total costs are estimated to be between **£0.00 million and £0.02 million (PV)**, with a central estimate of **£0.01 million (PV)** over the 10-year appraisal period. This is a partial cost estimate, based on familiraisation costs only.

BENEFITS

Monetised Benefits

62. There are no monetised benefits for Option 2 due to the data and evidence gaps, primarily on prevalence of use.

Non-Monetised Benefits

Benefit 1: Improved public awareness and reduced harms

63. By controlling these substances under MDA 1971, it is assumed that there will be an increased public awareness of their harms. Improved knowledge on the potential risk surrounding these substances, in particular synthetic opioids, may lead to improved local government and public health responses. The ACMD has advised that it would be useful to make those who may use drugs better aware of these compounds and the risks they carry, especially users of heroin and cocaine[35].

64. Changes to the law to control the 20 substances under MDA 1971 will be communicated to key stakeholders, including healthcare professionals, and the wider public by the Home Office and DHSC. The Home Office will issue a circular with legislative guidance, primarily for the police and the courts. The DHSC will issue guidance to the healthcare sector regarding remimazolam.

65. The government will continue to update its messaging on the harms of these substances, including through its FRANK information and advisory service online[36], which is aimed at young people and adults to inform them of drug related risks and harms.The Office for Health Improvements and Disparities (OHID) has the ability to issue national patient safety alerts for high risk substances. Making the general public, including drug users and drug treatment services aware of the harms may lead to improved responses to drug poisoning incidents. As a result, there may be fewer hospital admissions for drug poisoning incidents.

Benefit 2: Reduced hospitalisations and drug deaths

66. If there was one fewer hospital admission for drug related overdoses and poisonings as a result of improved knowledge of the harms of these substances, there would be a cost saving of **£881**[37] (2024/25). If there was one fewer drug related death, there would be a cost saving of **£2.97 million**[38] (2024/25).

Total benefits

67. Total monetised benefits are estimated to be zero due to the lack of data which would enable any benefits to be monetised.

NPSV, BNPV and net cost to business

[34] Drug Treatment Statistics – New Psychoactive Substances breakdown of all people in treatment. Available here: https://www.gov.uk/government/statistics/substance-misuse-treatment-for-adults-statistics-2021-to-2022

[35] ACMD advice on drug users understanding the risk surrounding synthetic opioids. Available here: https://www.gov.uk/government/publications/acmd-advice-on-2-benzyl-benzimidazole-and-piperidine-benzimidazolone-opioids/acmd-advice-on-2-benzyl-benzimidazole-and-piperidine-benzimidazolone-opioids-accessible-version#uk-prevalence

[36] FRANK: Available here: https://www.talktofrank.com/

[37] This has been calculated using the National Schedule of NHS Costs for 'acute drug intoxication'.

[38] The Economic and Social Cost of Crime. Available here: https://assets.publishing.service.gov.uk/media/5b684f22e5274a14f45342c9/the-economic-and-social-costs-of-crime-horr99.pdf

68. The NPSV is estimated to be between **-£0.00 to -£0.02 million (PV),** with a central estimate of **-£0.01 million (PV)** over the 10 year appraisal period.

69. As there is no cost to business, both the Business Net Present Value (BNPV) and the net cost (EANDCB[39]) to business is zero.

F. Proportionality

70. The analysis in this IA contains the best estimates for the cost and benefits of the proposed policy. Every effort has been made to ensure the analysis presents the best possible estimate of the likely impact of the options, given the time, resource and data available. These have been quantified where data is available, with risks highlighted in Section G. A NSPV has not been fully estimated due to insufficient data and evidence.

G. Risks

Analytical Risk 1: Quality of available data

71. There is a lack of data to estimate the overall prevalence of each of these substances in the UK. Proxy data for similar drugs, or data on treatment and deaths, have been used instead to give context to the potential scale of drug use, which appears to be low. This limitation means it is difficult to estimate the full costs and benefits of intervention.

Data used to estimate Class A and B misuse prevalence:

72. The fatalities data sources associated with the controlled substances are likely to underestimate the use of these substances as not all drug-related deaths are investigated using methods sufficiently sensitive to detect the involvement of these compounds. Additionally, drug-deaths data sources do not provide an understanding of the bigger picture of misuse, and are not a sufficient indicator of possession, or supply and production prevalence.

73. NHS data for drug poisoning admissions is not granular enough to record the specific controlled drugs, and the data set only includes drugs that are currently controlled under MDA 1971. This makes it difficult to get a clear understanding of drug poisoning related to the controlled substances and their wider misuse. The involvement of the controlled substances will not be recognised in most non-fatal cases of drug-related toxicity because detailed sample analysis is not a component of usual clinical care. Therefore, there is a significant risk that the available data sources underestimate the prevalence of these substances, particularly synthetic opioids in the UK.

74. Treatment statistics used are not specific to the controlled drugs.

Data used to estimate the legitimate prevalence of remimazolam:

75. The data used is provisional NHS data so subject to change and is based on stock records rather than patient records. The prevalence data may include vials of remimazolam that have been wasted, expired, or used for reasons other than being administered to a patient.

76. The data set only includes the year to July 2023 so does not give a long term picture of how widely remimazolam is used. Furthermore, the data only includes data from NHS Acute, Teaching, Specialist, Mental Health and Community Trusts in England, so likely underestimates the prevalence as it does not include data from NHS Wales, Scotland or Northern Ireland, or private healthcare.

Analytical Risk 2: A possible sustained increase in prevalence

[39] The net direct cost to business is defined as the Equivalent Annual Net Direct Cost to Business (EANDCB) and is a measure used by the Regulatory Policy Committee (RPC) to assess the regulatory burden on business.

77. There is evidence on the recent emergence of several NSOs into illicit drug markets internationally[40]. It is likely that the current data on NSO provides an underestimate of the potential NSO use and fatalities in the UK . As some of these substances are not yet controlled, it is difficult to make a reliable assumption about prevalence. There is the risk that the prevalence may continue rise, meaning this IA may underestimate the impacts of the intervention. If there is a sustained increase in the prevalence of synthetic opioids there could be an impact on the CJS and healthcare services which are not captured by this IA.

Analytical Risk 3: Unable to monetise costs

78. The majority of costs in this IA are non-monetised due to an absence of available data and evidence. Therefore, an NPV has not been modelled. In place of this, the IA describes potential impacts to demonstrate the possible impact of the intervention. The risk is that the IA underestimates the impact and the costs of controlling the substances.

Analytical Risk 4: Unable to consider the deterrence effect

79. The analysis does not consider any deterrence effect in which individuals stop misusing the controlled drugs as a result of the intervention. This is not included due to a lack of evidence on the likelihood of a deterrence following drug control, both across all controlled drugs and the specific drugs controlled in this legislation.

Analytical Risk 5: Unable to quantify impact on businesses who legitimately use remimazolam

80. The analysis assumes there is no impact on legitimate businsess from controlling remimazolam. It is likely that any businesses dealing with permanently controlled scheduled drugs will already possess a licence that would enable them to undertake activities involving remimazolam, and therefore there will no additional burdens. It is unknown if there are any businesses legitimately using remimazolam who do not currently have the necessary licence, but it is expected to be a small number to no busineses. If businesses did require a licence, this would impose a direct cost from both familiarisation of the changes and applying for a Home Office controlled drug licence.

H. Direct costs and benefits to business calculations

81. There are no expected direct costs and benefits to businesses as part of this intervention. The only substance with a known legitimate use is remimazolam. Businesses will require a Home Office controlled drug licence to possess, supply, produce, import or export remimazolam, unless an exemption, such as in a healthcare setting, applies within the 2001 Regulations. Organisations currently dealing with permanently controlled scheduled drugs will already possess a licence to undertake activities involving remimazolam once it is controlled under the MDA 1971 and 2001 Regulations. Whilst it was not possible to estimate the number of businesses that legitimately use remimazolam without currently holding the necessary licence, the number is expected to be a small number to no businesses.

I. Wider impacts

Improved international relations

82. Option 2 has been designed to ensure that, as a signatory, the UK remains aligned with international drug control under the United Nations Single Convention on Narcotic Drugs of 1961[4] and the

[40] ACMD conclusions on synthetic opioids. Available here: https://www.gov.uk/government/publications/acmd-advice-on-2-benzyl-benzimidazole-and-piperidine-benzimidazolone-opioids/acmd-advice-on-2-benzyl-benzimidazole-and-piperidine-benzimidazolone-opioids-accessible-version#uk-prevalence

[4] UN Single Convention on Narcotic Drugs of 1961. Available here: https://www.unodc.org/pdf/convention_1961_en.pdf

Convention on Psychotropic Substances of 1971[5]. By controlling the 20 substances under MDA 1971, the UK continues to maintain international relations by upholding its international obligations.

83. In addition, the increased threat posed by synthetic drugs, globally has resulted in formation of a US-led Global Coalition to Address Synthetic Drug Threats to bring global attention and action to address the public health and security threats posed by synthetic drugs. The UK is a part of this. Controlling the 20 substances, including 15 synthetic opioids, one SCRA and three synthetic stimulants, could help further strengthen international relations with the US, and more widely, as the UK remains proactive in its control of harmful substances that have led to numerous drug-related deaths worldwide.

J. Trade Impact

84. There is no expected trade impact as a result of this intervention.

K. Monitoring and evaluation plan

85. As part of its statutory duties under MDA 1971, the ACMD monitors the misuse of drugs through horizon scanning. Together with the government, the ACMD will continue to monitor the 20 substances by reviewing data on their prevalence and misuse. The government has also accepted recommendations from the ACMD to consult with stakeholders, including academia and the chemical and pharmaceutical industries on: the introduction of a generic control on 2-benzyl benzimadole variants (nitazenes) as new examples may be encountered and; an updated generic control for SCRA (that would capture Cumyl-PeGaClone and other similar SCRA). This process will involve further monitoring and consideration of substances similar to those proposed for control in this intervention.

86. The effectiveness of the new regime in respect of remimazolam, as a medicine, would be monitored by the Care Quality Commission for England and the healthcare regulatory bodies for Wales and Scotland. The Health Act 2006 also established the role of Accountable Officers with responsibility to establish and ensure appropriate arrangements to comply with the 2001 Regulations. Accountable Officers have a duty to establish local intelligence networks to analyse prescribing practices in their area and ensure that their areas have processes for establishing an incident panel if serious concerns are raised about controlled drugs. All other substances, except remimazolam, are proposed for scheduling in schedule 1 of the 2001 Regulations and designation under the 2015 Order, and will therefore be accessed under a Home Office controlled drug licence only, generally for research purposes. The Drugs and Firearms Licensing Unit (DFLU) collect data on licences issued which can assist monitoring of any legitimate use of these controlled drugs in research, for example.

87. The impacts of Option 2 will be monitored using existing data sources:

- A reduction in registered deaths involving the controlled substances. This can be measured using existing ONS and NPSAD data.
- A reduction in drug overdose or poisoning hospital admissions. This can be measured using existing NHS data.

[5] UN Single Convention on Psychotropic Substances 1971. Available here: https://www.unodc.org/unodc/en/treaties/psychotropics.html

Impact Assessment Checklist

Mandatory specific impact test - Statutory Equalities Duties	Complete
Statutory Equalities Duties The public sector equality duty requires public bodies to have due regard to the need to eliminate discrimination, advance equality of opportunity, and foster good relations in the course of developing policies and delivering services.The Home Office are satisfied that the Equalities IA demonstrates compliance with section 149 of the Equality Act 2010 and that due regard has been made to the need to: eliminate unlawful discrimination; advance equality of opportunity; and foster good relations. All of the protected characteristics have the potential for positive or negative impact, however, further information is needed to determine this for the following characteristics: Disability, Gender Reassignment and Pregnancy and Maternity. Some of the key findings include: 16 to 24 year olds are most likely to use drugs, including Class A drugs, so are likely be disproportionally affected by restrictions on their use but there is no data on use of these specific substances or substance groups (for example, synthetic opioids) by age group; 16 per cent of people who are single reported using a drug in the last year, compared with three per cent of people who were married or in a civil partnership; black people are stopped and searched for drugs at a rate six times higher than white people; the prevalence of drug use is higher for men than women aged 16 to 59 overall in every year of available CSEW data but prevalence of Class A drug use is higher for women than men aged 16 to 24 in the year ending June 2022; from October 2021 to June 2022, eight per cent of heterosexual adults reported using a drug in the last year, this compares with 30 per cent of gay/lesbian adults, and 31 per cent of bisexual adults. Any disproportionate impact is expected to be objectively justified on health, safety and welfare grounds owing to the risk of health harms related to the misuse of these substances. For the age, disability, race, religion or belief, sex and sexual orientation characteristics, any impact may have a positive effect by reducing drug use and thereby health and social harms. Action to address the potential negative impacts include education through FRANK, and public communication of the law change which is sufficiently accessible and targeted at all groups. **The SRO has agreed these summary findings.**	**Yes**