Title: **Impact assessment of proposals to reschedule ketamine under the Misuse of Drugs Regulations 2001** **IA No:** HO0184 **Lead department or agency:** Home Office **Other departments or agencies:** Department of Health	Impact Assessment (IA) **Date:** 13.03.15 **Stage:** FINAL **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** Desmond Niimoi (Desmond.niimoi@homeoffice.gsi.gov.uk) 020 7035 3533
Summary: Intervention and Options	**RPC Opinion: Not in scope**

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, Two-Out?**	**Measure qualifies as**
Not Known (N/K)	N/K	N/K	No	N/K

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

Ketamine is currently listed in Part I of Schedule 4 to the Misuse of Drugs Regulations 2001 (the 2001 Regulations) which means it is lightly regulated. In light of increasing evidence of long term acute harms, the Advisory Council on the Misuse of Drugs (ACMD) has advised the Government to act to reduce the risk of diversion of ketamine from legitimate uses to illicit markets, thereby reducing misuse of ketamine.

Government intervention is necessary to make the legislative changes which implement the ACMD's advice.

What are the policy objectives and the intended effects?

The policy objective is to protect the public from the harms posed by ketamine.

The intended effect is to deter diversion and therefore restrict the misuse of ketamine.

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

Option 1: Do nothing

Option 2: Place ketamine in Schedule 2 to the 2001 Regulations

Option 3: Place ketamine in Schedule 3 to the 2001 Regulations

Option 4: Place ketamine in Schedule 3 to the 2001 Regulations (but exempt it from the safe custody requirements).

In light of the ACMD's advice and consultation responses, Option 2 is the government's preferred option.

Will the policy be reviewed? It will not be reviewed on a set date. **If applicable, set review date:** Month/Year						
Does implementation go beyond minimum EU requirements?			N/A			
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** No	**< 20** No	**Small** No	**Medium** No	**Large** No	
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 Minister for Crime Prevention Lynne Featherstone Date: 20/03/2015

Summary: Analysis & Evidence

Policy Option 2

Description: Place ketamine in Schedule 2 of the Misuse of Drugs Regulations 2001

FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year 2015	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low:	**High:**	**Best Estimate:** N/K

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low				
High				
Best Estimate	N/K		N/K	**N/K**

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

Recording ketamine prescriptions in the controlled drug register is estimated to cost Community pharmacies approximately £3,000 a year.

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

Prescribers of schedule 2 drugs have to provide a wet signature. We assume the time required to provide a signature to be minimal and thus the additional costs to be negligible.
Schedule 2 drugs need to be kept securely, however feedback from the consultation suggests that the majority of NHS and private providers will already have the safes needed to comply with this reform, implying no additional cost.
There may be some additional costs to health and veterinary care providers of recording ketamine distribution on the controlled drugs register. However the majority of hospitals are believed to already treat ketamine as a schedule 2 drug and it is industry guidance for veterinarians to do the same; hence the additional costs are expected to be minimal.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low				
High				
Best Estimate	N/K		N/K	**N/K**

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

There are no monetised benefits associated with this policy.

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

Stricter control of ketamine is expected to reduce the risk of crime and health harms facing the public sector and individuals. We are not able to fully monetise these benefits due to a lack of information on exactly how many hospitals and veterinarians already treat ketamine as a schedule 2 drug and the link between diversion, the price of ketamine and ketamine consumption
In addition, by bringing ketamine regulations in-line with what is currently best practice in the health and veterinary sectors there will be greater clarity and consistency in the regulations surrounding ketamine.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5%

There is a risk that prescribers may be reluctant to prescribe ketamine as a result of the change in legal status. However, this is not expected to have any negative consequences for patients as ketamine can be replaced with other drugs when treating patients. This risk is therefore assessed as low.

There is a risk that our assumptions regarding the additional time taken to issue prescriptions and record ketamine on the controlled drug register are underestimates.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:						In scope of OITO?	Measure qualifies as
Costs:	N/K	**Benefits:**	£0	**Net:**	N/K	No	N/A

Summary: Analysis & Evidence

Policy Option 3

Description: Place ketamine in Schedule 3 of the Misuse of Drugs Regulations 2001

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low:	**High:**	**Best Estimate:** N/K

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low				
High				
Best Estimate	N/K		N/K	**N/K**

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

There are no monetised costs.

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

Prescribers of schedule 3 drugs have to provide a wet signature. We assume the time required to provide a signature to be minimal and thus the additional costs to be negligible.
Schedule 3 drugs need to be kept securely, however feedback from the consultation suggests that the majority of NHS and private providers will already have the safes needed to comply with this reform, implying no additional cost.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low				
High				
Best Estimate	N/K		N/K	**N/K**

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

There are no monetised benefits associated with this policy.

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

Stricter control of ketamine is expected to reduce the risk of crime and health harms faced the public sector and individuals. We are not able to fully monetise these benefits, due to a lack of information on exactly how many hospitals and veterinarians currently treat ketamine as a schedule 2 drug and the link between diversion, the price of ketamine and ketamine consumption.
This option does not provide the audit and traceability associated with option 2 and is therefore unlikely to reduce diversion and misuse to the same extent.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5%

Prescribers may be reluctant to prescribe ketamine as a result of the change in legal status. However, this is not expected to have any negative consequences for patients as ketamine can be replaced with other drugs when treating patients. This risk is therefore assessed as low.

There is a risk that our assumption regarding the additional time taken to issue prescriptions is an underestimate.

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:						In scope of OITO?	Measure qualifies as
Costs:	N/K	**Benefits:**	£0	**Net:**	N/K	No	N/A

Summary: Analysis & Evidence

Policy Option 4

Description: Place ketamine in Schedule 3 of the Misuse of Drugs Regulations 2001, but with safe custody exemptions

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low:	**High:**	**Best Estimate:** N/K

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low				
High				
Best Estimate	N/K		N/K	**N/K**

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

There are no significant monetised costs associated with this policy.

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

This option would require prescribers to provide a wet signature with each prescription. We assume the time required to provide a signature to be minimal and thus the additional costs to be negligible.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low				
High				
Best Estimate	N/K		N/K	**N/K**

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

There are no monetised benefits associated with this policy.

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

Stricter control of ketamine is expected to reduce the risk of crime and health harms facing the public sector and individuals. We are not able to fully monetise these benefits, due to a lack of information on exactly how many hospitals and veterinarians already treat ketamine as a schedule 2 drug and the link between diversion, the price of ketamine and ketamine consumption

This option does not provide the audit and traceability associated with option 2 above or the security of storage of ketamine stocks associated with option 3. This option is therefore unlikely to reduce diversion and misuse to the same extent as options 2 and 3 above.

Key assumptions/sensitivities/risks

Discount rate (%) 3.5%

The lack of proper storage to prevent diversion and misuse may have limited negative consequences through a higher risk of diversion and misuse. This risk is therefore assessed as medium.

BUSINESS ASSESSMENT (Option 4)

Direct impact on business (Equivalent Annual) £m:						In scope of OITO?	Measure qualifies as
Costs:	N/K	**Benefits:**	£0	**Net:**	N/K	No	N/A

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 Background

1. Ketamine is a synthetic drug commonly used in medical and veterinary practice as a dissociative anaesthetic and an analgesic (pain reliever). The Advisory Council on the Misuse of Drugs (ACMD) – an advisory non-departmental body tasked with making recommendations to government on the control of dangerous or otherwise harmful drugs – first considered ketamine in 2004 and following its advice ketamine was brought under Class C control and listed in Schedule 4 in 2006 (for a full explanation of the different schedules of controlled drugs, see Annex 1).

2. In 2013, the ACMD completed a review of the harms associated with ketamine misuse following commissioning by the Home Secretary. The Home Secretary's commission was prompted by increasing evidence, and concerns, around chronic toxicity from long term misuse of ketamine. The ACMD's subsequent review of the evidence confirmed that in addition to the harms identified in 2004, regular ketamine use is now also known to be associated with a range of chronic problems including chronic bladder and other urinary tract pathology, gall bladder, gastrointestinal, central nervous system and kidney damage[1]. The ACMD also reports evidence of acute and chronic toxicity associated with ketamine misuse.

3. On 10 December 2013 the ACMD published its report on ketamine[2]. The ACMD advised that ketamine should be reclassified as a class B drug under the 1971 Act, and listed in Schedule 2 to the 2001 Regulations, subject to the outcome of a public consultation to assess the impact of Schedule 2 status on healthcare and veterinary practice. The Minister for Crime Prevention, Norman Baker, accepted the ACMD's advice on reclassification and, following Parliamentary approval, ketamine was subsequently reclassified as a Class B drug under the 1971 Act on 10 June 2014. The Minister also accepted the ACMD advice on rescheduling in principle and approved a public consultation to gather evidence to inform a final decision on the ACMD's rescheduling advice. The twelve week public consultation concluded in November 2014. A summary of the consultation responses and the Government response is published alongside this impact assessment.

A.2 Groups Affected

4. Groups affected by this policy are:

Business – veterinary professionals, private healthcare organisations and professionals, pharmaceutical manufacturers and wholesalers.

Public – healthcare professionals.

Individuals – patients, drug mis-users and wider society.

A.3 Public Consultation

5. The rescheduling of ketamine to Schedule 2 was supported by the majority (61.43%) of respondents to the consultations, including some of the key professional and regulatory bodies . The responses also confirmed that veterinary guidance already required the sector to treat ketamine as a Schedule 2 drug due to the risks of diversion and harms associated with its misuse. Most hospitals also treat ketamine as a Schedule 2 drug for these reasons. As a result the impact from rescheduling to Schedule 2 was assessed to be minimal. Concerns were raised about ketamine's continued availability for use under Patient Group Directions (PGDs) when it is rescheduled. These concerns have been taken on board and regulatory changes are being implemented to ensure ketamine remains available for use under PGDs following rescheduling.

[1] 'Ketamine: a review of use and harm', ACMD, 10/12/13, available at www.gov.uk/government/publications/ketamine-report

[2] Ibid

B. Rationale

6. The misuse of ketamine imposes a cost on society in terms of crime and health services. Consumption also imposes health costs on the users themselves. The market does not take into account the costs that the misuse of ketamine imposes on society. Although there is only limited evidence of organised diversion of ketamine from legitimate uses to illicit markets, due to the lack of national data collection, it is the general view that diversion from legitimate sources is a key contributor to the availability of illicit ketamine in the UK. The ACMD also reported that Controlled Drug Local Intelligence Networks have reported evidence of diversion of ketamine from health and veterinary settings into illicit markets, in some localities[3]. Government intervention is therefore necessary to prevent ketamine from being diverted from legitimate use and to protect the public from its harmful effects.

C. Objectives

7. The policy objective is to protect the public from the harms posed by ketamine.

8. The intended effect is to deter and prevent diversion of ketamine from legitimate uses to illicit markets and therefore restrict the misuse of ketamine whilst ensuring continued access for use for veterinary and healthcare purposes.

D. Options

9. Four options have been considered, the first of which is to do nothing and the other three look to utilise the existing regulatory framework:

Option 1: Do nothing

10. Under this option ketamine will continue to remain a Schedule 4 Part 1 drug and will be lightly regulated as in paragraph 7 above. This is the baseline option; the other options will be assessed on their impact relative to this option. As highlighted in the section on costs and benefits below, it is possible that some suppliers of ketamine might already be treating the drug as a schedule 2 or schedule 3 drug, despite its schedule 4 status. Respondents to the consultation also confirmed that the majroity of veterinary practices and hopsitals already treat ketamine as a Schedule 2 drug. The impact of options 2-4 are therefore less than they would be if ketamine was currently always treated as a schedule 4 drug.

Option 2: Place ketamine in Schedule 2

11. This option will subject ketamine to the highest level of regulation for medicines, which includes the application of prescription writing requirements, the need for specific documentation for obtaining stocks; the recording of receipts and supplies in controlled drug registers and the witnessing of the destruction of expired stocks. Ketamine will also be subject to safe custody requirements under this option. This option would ensure that an audit trail is kept for the movement of ketamine within the health and veterinary sectors. This would reduce the risk of diversion of ketamine from legitimate sources and therefore reduce the misuse of ketamine, and the harms associated with such misuse.

Option 3: Place ketamine in Schedule 3

12. This option will subject ketamine to a higher level of regulation compared to its current status, including the application of prescription writing requirements, the need for specific documentation for obtaining stocks and the witnessing of the destruction of expired stocks. Ketamine will be kept in

[3] 'Ketamine: a review of use and harm', ACMD, 10/12/13, available at www.gov.uk/government/publications/ketamine-report

compliant safes under this option but not recorded in a controlled drugs register. This option does not provide the audit and traceability associated with option 2 above and is therefore less likely to reduce diversion and misuse to the same extent as option 2 above.

Option 4: Place ketamine in Schedule 3, but with safe custody exemptions

13. This option will also subject ketamine to a higher level of regulation compared to its current status, including the application of prescription writing requirements, the need for specific documentation for obtaining stocks and the witnessing of the destruction of expired stocks etc. Ketamine will not be kept in compliant safes under this option or recorded in a controlled drugs register. This option does not provide the audit and traceability associated with option 2 or the security of storage of ketamine stocks associated with option 3. This option is therefore unlikely to reduce diversion and misuse to the same extent as options 2 and 3 above, though the costs of this option are may be lower.

E. Appraisal

GENERAL ASSUMPTIONS & DATA

Assumptions (applicable to all options, except assumption 'v' which applies to option 2 only):

i. Organisations which need to store ketamine will be able to accommodate it in currently available storage space without the need to acquire a new safe compliant with the Misuse of Drugs (Safe Custody) Regulations 1973. The veterinary sector is already required to store ketamine in compliant safes as under industry guidance.

ii. The vast majority of prescribers (NHS and private) already use computer generated prescriptions.

iii. The cost in terms of time of a wet signature is assumed to be negligible.

iv. New prescription writing pads are anticipated to cost the same as current prescription writing pads, meaning zero net cost.

v. Electronic prescribing will be replaced by arrangements such as pharmacy pick up of prescriptions from practices.

vi. (We do not anticipate any extra cost on pharmacies picking up prescriptions as this service is already provided for other medicines. Prescriptions for ketamine will form part of the bundle of prescriptions picked up. Patients do not currently pay for this service, and we don't envisage this will change, as the service is offered by pharmacies free of charge to generate business).

vii. Average time taken to record a receipt or supply of ketamine in the controlled drug register is 2 minutes. 2 minutes is selected because the data requirements are minimal. Only the date of supply, name and address of supplier and quantity received must be recorded for receipts of Schedule 2 drugs. For supplies, date of supply, name and address of person or firm supplied to, details of authority to possess (i.e prescriber or supplier licence number) and quantity supplied need to be recorded, and it is envisaged that it should not take more than 2 minutes to complete this information. This assumption was tested through the consultation process.

viii. There are approximately 3,000 prescriptions for ketamine issued by the NHS in England each year.[4] Uplifting this by population figures for England, Scotland and Wales[5] gives a figure of approximately 3,500 prescriptions for ketamine dispensed in the community (rather than in hospitals) each year.

ix. No transitional costs are envisaged for the implementation of rescheduling, including for information dissemination. Controlled drug registers are already in use for other drugs and

[4] Data provided by NHS Business Services Authority on 'National Data for Ketamine presentations' show that there were 3,091 ketamine presentations in January-December 2011, 3,197 in 2012 and 2,693 in 2013, an average of 2,994 per year.

[5] Office for National Statistics, Population Estimates for UK, England and Wales, Scotland and Northern Ireland, Mid-2013, avaialble at http://www.ons.gov.uk/ons/taxonomy/index.html?nscl=Population#tab-data-tables

professionals will be familiar with recording. Information on changes will be included in general communication to health and veterinary care professionals.

x. No additional enforcement costs are envisaged following implementation of rescheduling. Enforcement costs generally relate to classification and the criminal penalties associated with the class of a drug, although there may be professional sanctions if the regulations applicable following rescheduling are breached.

xi. No additional prosecutions are envisaged following implementation of this policy, because of the reasons stated for assumption viii. Breach of the 2001 regulations can however lead to professional sanctions (see assumption viii above).

Note: Assumptions i to iv were tested during the tramadol consultation[6]. With the exception of assumption i, none of the other assumptions were challenged. Assumption i holds in the case of the options presented here, because ketamine is used on a significantly much smaller scale to tramadol. Respondents to the consultation agreed with this assumption.

COSTS AND BENEFITS

OPTION 1 – Do nothing

14. There are no additional costs and benefits identified with the option.

OPTION 2 – **Place ketamine in Schedule 2**

COSTS

Business

15. This reform may affect veterinary professionals, private healthcare organisations and professionals and pharmaceutical manufacturers and wholesalers. The potential impacts can be summarised as:

1) Increased costs due to more time being taken to complete prescriptions in compliance with Regulation 15 of the Misuse of Drugs Regulations.
2) Costs resulting from new safes which may be required in order to store the ketamine in compliance with safe custardy regulations (Misuse of Drugs (Safe Custody) Regulations 1973).
3) Additional costs due to the additional time taken to maintain a controlled drug register (Regulation 19) as well as complete order forms for ketamine (Regulation 14).

These costs are considered below.

16. The costs of writing a prescription relate to the time used in completing a prescription and the wet signature required to make a prescription compliant under Regulation 15. Costs attributable to the time taken to generate a prescription are not expected to be different from those applicable to prescribing ketamine as a Schedule 4 Part 1 controlled drug as both can be computer generated. We assume the cost of a wet signature to be negligible; as a result, there should be not additional costs for medical professionals as a result of this change. In the case of the veterinary sector, ketamine will be supplied directly to pet owners by the veterinary practitioner and therefore a very limited amount of time is likely to be spent prescribing for dispensing from a pharmacy.

17. Respondents to the public consultation agreed that businesses dealing in, or using, ketamine will not need to buy a new safe as a result of the legislative change and will be able to accommodate stocks of ketamine in current safes. The veterinary sector already store ketamine in compliant safes under their current guidance. Costs of storage will only arise if a business does not currently have a compliant safe for the storage of Schedule 3 drugs. Pharmacies which

[6] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/224564/TramadolTemazepamSchedulingIA.PDF

currently store ketamine for retail to the public and other businesses that store controlled drugs will already have compliant safes for the storing of other drugs

18. Potential costs may also arise from the time used to record receipts and supplies of ketamine in the controlled drug register. The Misuse of Drugs Regulations 2001 specifies information that must be recorded in the controlled drug register. The average time for recording is estimated at two minutes (see assumption v), which is an assumption that was tested during the consultation. In the event that all of the approximately 3,500 NHS prescriptions dispensed in the community would require a private pharmacy to make a record on the controlled drug register, this could result in a total additional cost to business of approximately 110 hours per year across England, Scotland and Wales. This would be a cost for these businesses, equal to their labour-related costs of employee time. Data from the Office of National Statistics[7] suggests that the mean gross hourly wage for a pharmacist is £19.90. The Department for Business Innovation and Skills recommend applying a 17.8% uplift to take account of non-wage labour costs[8], which would result in an approximate hourly cost of £23.50. The total annual cost to these businesses is therefore estimated to be around £3,000. We do not have figures for the number of prescriptions issued by private healthcare organisations, though these are expected to be far fewer than those issued by the NHS.

19. Current Veterinary Medicines Directorate guidance requires veterinary practitioners to record ketamine in the controlled drug register. No additional impact is therefore expected on the veterinary sector from the recording requirements. Additionally, some private hospitals and healthcare providers already record receipts and supplies of ketamine in the controlled drug register. The total cost impact on the private sector from the recording requirements is therefore expected to be small.

20. Private prescribers are required to complete specific forms for both schedule 2 and 4 drugs; the forms are different but similar. We assume that no additional time is required to complete the schedule 2 form in comparison to the schedule 4 form, meaning no additional costs. The forms are also identical in cost, meaning there will be no change in overall costs.

Public Sector

21. Potential costs to the public sector will again arise from the application of Regulations 14, 15, 19 and the safe custody requirements as stated above.

22. As discussed above, Schedule 2 drugs require a wet signature when being prescribed. As the time taken to complete a wet signature is believed to be negligible, costs are not expected to be different from those applicable to prescribing ketamine as a Schedule 4 Part 1 controlled drug.

23. NHS organisations and pharmacies which currently store ketamine for NHS activity will already have compliant safes for storing other controlled drugs. It is not expected that the NHS will incur any extra cost in relation to securing extra storage space for ketamine following legislative change.

24. Potential costs may also arise from the time used to record receipts and supplies of ketamine in the controlled drug register. The Misuse of Drugs Regulations 2001 specifies information that must be recorded in the controlled drug register. The average time for recording is estimated at two minutes. We do not have information on the number of NHS pharmacists who will be dispensing ketamine within hospitals, and so we have been unable to perform a similar calculation to that in paragraph 23. However, the public consultation revealed that a large number

[7] Annual Survey of Hours and Earnings, 2013 Provisional Results, http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcm%3A77-328216

[8] Based on Eurostat figures at: http://epp.eurostat.ec.europa.eu/statistics_explained/index.php?title=File:Labour_costs_per_hour_in_EUR,_2008-2012_whole_economy_excluding_agriculture_and_public_administration.png&filetimestamp=20130411095404 and the calculation 0.151/(1-0.151) =17.8%

of hospitals and healthcare providers in the public sector already record receipts and supplies of ketamine in the controlled drug register, so for them there will be no additional impact. The cost impact on the public sector from the recording requirements is therefore expected to be small. Regarding inspection costs, we do not expect the recording of ketamine in the controlled drug register to lead to extra inspection costs. Inspection of controlled drugs registers are most likely to occur during visits by regulatory bodies such as the Care Quality Commission or by Home Office compliance officers where the organisation operates under a Home Office licence. These visits are comprehensive and a review of the register forms a minor part of the checks made. Ketamine will be one of a number of drugs recorded in the register and any review will relate to records in the controlled drug register as a whole and not only to ketamine.

Individuals and society

25. No costs are envisaged for individuals who are legitimately prescribed ketamine for medicinal use. The primary use of ketamine is for anaesthesia and so take home prescriptions for the treatment of pain are limited. Where ketamine is prescribed as a take home drug, there may be some inconvenience for those who rely on electronic prescriptions in that they will need to physically take the prescription to a pharmacy for dispensing. However, the expectation is that patients will take advantage of current arrangements which enable pharmacies to pick up prescriptions on behalf of a patient prior to dispensing. Proposals are also underway to enable the electronic prescribing of Schedules 2 and 3 drugs. When in place patients will be able to avail themselves of the benefits of having their prescriptions for ketamine to be electronically sent to their preferred pharmacy for collection.

26. There may be some costs to those who currently obtain these drugs for the sole purpose of misuse but benefits from illegally obtained drugs (and corresponding costs from reduced availability) are not considered in scope for appraisal.

BENEFITS

Business

27. No benefits accrue to businesses from this policy.

Public Sector

28. Benefits accruing to the public sector may arise from savings to be made through a reduction in the number of people seeking medical assistance due to the misuse of these substances. Drug Statistics from the National Drug Treatment Monitoring System (NDTMS) show that 868 people presented for treatment citing ketamine misuse in 2012/13. [9] The average over the last 8 years was 555, but this has risen quite significantly over the period, such that the average over the last 3 years was 821. In terms of the potential savings, the Drug Treatment Outcomes Research study (DTORS) gives an estimated average cost of drug treatment services[10] of £6,064 per person, though this is not specifically for ketamine.[11] The figures presented here are indicative of the scope for potential savings from reducing the misuse of ketamine. However, we have not attempted to fully estimate the savings associated with each option, as we are unable to confidently assess the likely reduction in ketamine misuse as a result of implementing measures to prevent diversion of the drug. Given that the majority of Hospitals and Veterinarians already treat ketamine as a schedule 2 drug, impacts on diversion are likely to be limited. Although there will be a benefit from greater clarity and consistency in drug regulation.

[9] Drug Statistics from the National Drug Treatment Monitoring System (NDTMS): 2012-2013, Public Health England, http://www.population-health.manchester.ac.uk/epidemiology/NDEC/factsandfigures/statisticsfromndtms201213.pdf

[10] Including inpatient treatment, specialist prescribing, GP prescribing, counselling, structured day care, residential rehabilitation, aftercare, structured alcohol care and other structured care.

[11] The Drug Treatment Outcomes Research study (DTORS):Cost-effectiveness analysis. Home Office Research Report 25, http://www.dtors.org.uk/reports/DTORS_CostEffect_Main.pdf

Individuals and society

29. Personal benefits may arise from protection from the potential harms identified with the misuse of ketamine. Society is likely to be protected against possible externalities resulting from people who misuse ketamine, though we are unsure of the scale of such benefits. The regulatory framework is expected to reduce the risk from diversion, misuse and therefore harms to the public.

Net Effect

30. The costs are expected to be small. Neither the costs nor the benefits have been fully quantified due to a lack of available data. The ACMD's report has indicated that there will be some benefit to the public sector, individuals and society. However, due to the fact that the majority of Hospitals and Veterinarians already treat ketamine as a schedule 2 drug, and the fact that relatively little ketamine is dispersed by pharmacies; any impact on diversion is likely to be modest. Despite this, the harmful nature of this drug and the small costs involved mean that we expect that there will be a net benefit from this option.

OPTION 3 – **Place ketamine in Schedule 3**

COSTS

Business

31. Potential costs to business under this option may arise from application of requirements under Regulation 15 of the Misuse of Drugs Regulations, which sets out how prescriptions for drugs in Schedule 3 to the 2001 Regulations should be written and, where relevant, the forms to be used for prescribing these drugs. There could also be costs relating to safe storage under the minimum conditions set out in the Misuse of Drugs (Safe Custody) Regulations 1973 (the 1973 Regulations) if new safes are required to store ketamine.

32. The specific costs relate to the time used in completing a prescription and the wet signature required to make a prescription compliant under Regulation 15. Costs attributable to the time taken to generate a prescription are not expected to be different from those applicable to prescribing ketamine as a Schedule 4 Part 1 drug, as both can make use of computer generated prescriptions. We assume the cost of a wet signature to be negligible; as a result, there should not be additional costs for medical professionals as a result of this change.

33. We assume that almost all businesses which deal in ketamine will not need to buy a new safe as a result of the legislative change and will be able to accommodate stocks of ketamine in current safes. Costs of storage will only arise if a business does not currently have a compliant safe for the storage of Schedule 3 drugs. Pharmacies which currently store ketamine for retail to the public and other businesses that store controlled drugs will already have compliant safes storing other schedule 2 and 3 drugs. The veterinary sector is already required to store ketamine in compliant safes under current industry guidance. We assume the vast majority of the veterinary sector already complies with this guidance and thus will incur no additional cost.

34. Private prescribers are required to complete specific forms for both schedule 3 and 4 drugs; the forms are different but similar. We assume that no additional time is required to complete the schedule 3 form in comparison to the schedule 4 form, meaning no additional costs. The forms are also identical in cost, meaning there will be no change in overall costs.

Public Sector

35. Potential costs to the public sector will again arise from the application of Regulation 15 and the safe custody requirements as stated above.

36. The specific costs relate to the time used in completing a prescription and the wet signature required to make a prescription compliant with Regulation 15. Costs attributable to the time taken to generate a prescription are not expected to be different from those applicable to prescribing ketamine as a Schedule 4 Part 1 drug as all information required can be programmed into software and computer generated. As discussed above, the cost of a wet signature is assumed to be negligible.

37. Costs of storage will only arise if an NHS organisation does not currently have a compliant safe for the storage of Schedule 3 drugs. NHS organisations and pharmacies which currently store ketamine for NHS activity will already have compliant safes for other schedule 2 and 3 drugs. It is not expected that the NHS will incur any extra cost in relation to securing extra storage space for ketamine following legislative change.

Individuals and society

38. No costs are envisaged for individuals who are legitimately prescribed ketamine for medicinal use. There may be some inconvenience for those who rely on electronic prescriptions in that they will need to physically take the prescription to a pharmacy for dispensing. However, the expectation is that patients will take advantage of current arrangements which enable pharmacies to pick up prescriptions on behalf of a patient prior to dispensing.

39. There may be some costs to those who currently obtain these drugs for the sole purpose of misuse but benefits from illegally obtained drugs (and corresponding costs from reduced availability) are not considered in scope for this appraisal.

BENEFITS

Business

40. No benefits accrue to businesses from this policy.

Public Sector

41. Benefits accruing to the public sector may arise from savings to be made through a reduction in the number of people seeking medical assistance due to the misuse of ketamine. The likely savings under this option cannot be readily quantified (see paragraph 31 above).

Individuals and society

42. Personal benefits may arise from protection from the potential harms identified with the misuse of ketamine. Society is likely to be protected against possible externalities resulting from people who misuse ketamine, though we are unsure of the scale of such benefits. The regulatory framework is expected to reduce the risk from diversion, misuse and therefore harms to the public.

Net Effect

43. The costs are expected to be small and lower than those associated with option 2 as regulatory requirements under this option are less stringent. However, it is difficult to assess the difference in net effect. Neither the costs nor the benefits have been fully quantified due to a lack of available data. Any impact on diversion is likely to be limited, as the majority of Hospitals and veterinarians already treat ketamine as a schedule 2 drug, and relatively small amounts of

ketamine are distributed by pharmacies. Despite this, the harmful nature of this drug, as explained by the ACMD report, means that even a relatively small reduction in diversion is likely to lead to a net benefit from this option.

OPTION 4 – Place ketamine in Schedule 3, but exempt from safe custody

COSTS

Business

44. Private prescribers are required to complete specific forms for both schedule 3 and 4 drugs; the forms are different but similar. We assume that no additional time is required to complete the schedule 3 form in comparison to the schedule 4 form, meaning no additional costs. The forms are also identical in cost, meaning there will be no change in overall costs.

Public Sector

45. Potential costs to the public sector will arise from application of provisions under Regulation 15, as a schedule 3 prescription as well as a wet signature will be required. The cost of generating a prescription is believed to be the same as the cost of generating a Schedule 4 Part 1 drug, all information required can be entered electronically, and the prescription computer generated. We assume the cost of a wet signature to be negligible; as a result, there should not be additional costs for medical professionals as a result of this change.

Personal and society

46. No costs are envisaged for individuals who are legitimately prescribed ketamine for medicinal use. There may be some inconvenience for those who rely on electronic prescriptions in that they will need to physically take the prescription to a pharmacy for dispensing. However, the expectation is that patients will take advantage of current arrangements which enable pharmacies to pick up prescriptions on behalf of a patient prior to dispensing.

47. There may be some costs to those who currently obtain these drugs for the sole purpose of misuse but illegally obtained benefits (and corresponding costs from reduced availability) are not considered in scope for this appraisal.

BENEFITS

Business

48. No benefits accrue to businesses from this policy.

Public Sector

49. Benefits accruing to the public sector may arise from savings to be made through a reduction in the number of people seeking medical assistance due to the misuse of these substances. There may also be savings accruing as a result of a reduction in prescribing following a change in legal status. The likely savings under this option cannot be readily quantified (see paragraph 31 above).

Personal and society

50. Personal benefits should arise from protection from the potential harms identified with the misuse of these drugs. Society may be protected against possible externalities resulting from people who misuse ketamine, though we are unsure of the scale of such benefits. The regulatory

framework is expected to reduce the risk from diversion, misuse and therefore harms to the public.

Net Effect

51. The costs are expected to be small. Neither the costs nor the benefits have been fully quantified due to a lack of available data. Any impact on diversion is likely to be limited, as the majority of hospitals and veterinarians already treat ketamine as a schedule 2 drug, and relatively small amounts of ketamine are distributed by pharmacies. Despite this, the harmful nature of this drug, as explained by the ACMD report, means that even a relatively small reduction in diversion is likely to lead to a net benefit from this option.

ONE-IN-TWO-OUT (OITO)

52. This proposal moves a controlled drug within a regulatory framework that already exists. This policy is therefore not in scope of one-in-two-out.

F. Risks

Option 2 – Place ketamine in Schedule 2

- Prescribers may be reluctant to prescribe ketamine as a result of the change in legal status. However, this is not expected to have any negative consequences for patients as ketamine can be replaced with other drugs when treating patients. This risk is therefore assessed as low.
- There is a risk that our assumptions regarding the additional time taken to issue prescriptions and record ketamine on the controlled drug register are underestimates.

Option 3 – Place ketamine in Schedule 3

- Prescribers may be reluctant to prescribe ketamine as a result of the change in legal status. However, this is not expected to have any negative consequences for patients as ketamine can be replaced with other drugs when treating patients. This risk is therefore assessed as low.
- There is a risk that our assumption regarding the additional time taken to issue prescriptions is an underestimate.

Option 4 – Place ketamine in Schedule 3 but exempt from safe custody

- The lack of proper storage to prevent diversion and misuse may have limited negative consequences through a higher risk of diversion and misuse. This risk is therefore assessed as medium.

G. Enforcement

53. No enforcement costs relate to the rescheduling of ketamine as enforcement activity usually applies to breaches related to classification and criminal penalties, rather than the schedule. Enforcement of the proposed legislation will be undertaken by Police Forces, the UK Border Force, the Home Office Drug Licensing Unit and other relevant Agencies responsible for enforcing the legislative and regulatory framework in the UK. Police enforcement will form part of their wider approach to tackling new psychoactive substances as well as existing drug controlled under the 1971 Act. UK Border Force will enforce import controls by seizing suspected substances at the ports, also as part of their wider import control role.

H. Summary and Recommendations

54. Whilst Options 3 and 4 provide some control to minimise diversion and misuse, controls under Option 2 provide a much better framework for a drug that is considered dangerous or otherwise harmful when misused. Option 2 provides an audit trail of movement of ketamine in health and veterinary care which enables discrepancies to be dealt with immediately and reduces the risk of diversion from legitimate use or sources. Due to the fact that most health and veterinary prescribers currently treat ketamine as a schedule 2 drug, additional costs from all of these changes are expected to be minimal. Therefore the net benefit of Options 3 and 4 is expected to be below that of Option 2.

55. Whilst Options 3 and 4 provide some control to minimise diversion and misuse, controls under Option 2 provide a better framework for a drug that is considered dangerous or otherwise harmful and which can have severe and long lasting impact on an individual when misused.

I. Implementation

56. The Government plans to implement these changes via a negative resolution in April 2015.

J. Monitoring and Evaluation

57. The effectiveness of the new regime 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 Misuse of Drugs legislation. Accountable officers have a duty to establish Local Intelligence Networks to analyse prescribing practices within their area and ensure their areas have processes for establishing an incident panel if serious concerns are raised about controlled drugs.

58. In addition, the ACMD is currently undertaking a review of diversion; attempting to understand the scale and significance of the problem as well as possible solutions.

K. Specific Impact Assessments

Health impact assessment

59. Ketamine is used both in community and secondary healthcare settings. Prescribing data for England in 2013 show that there were 500 prescription items for ketamine injection, and 2,300 prescription items for oral liquid specials that were dispensed in the community.

60. Registered paramedics can administer ketamine which may be restricted to senior or specialist paramedics. NHS Ambulance Trusts may also increasingly be taking over the running of out of hours emergency services where other practitioners such as specialist nurses and doctors are dispatched to assess and treat patients.

61. NHS Ambulance Trusts generally will have already established operational policies and procedures covering controlled drugs. These will deal with ordering, storing, using and destroying controlled drugs as well as other matters such as record-keeping and dealing with incidents. For example, the London Ambulance Services NHS Trust already treats ketamine as a Schedule 2 controlled drug. Other Ambulance Trusts may pursue a similar policy, in which case the preferred option of rescheduling ketamine as Schedule 2 is likely to impose little, if any, additional burden.

Annex 1 : REQUIREMENTS ATTACHED TO THE SCHEDULES OF THE MISUSE OF DRUGS REGULATIONS 2001

62. Schedule 1 – covers drugs such as ecstasy, LSD and cannabis that have no currently recognised medicinal uses. For this reason, they may not be prescribed by doctors and may only be possessed under Home Office licence for research and other special purposes.

63. Schedule 2 – drugs in this schedule are subject to prescription writing requirements, including handwritten signatures by prescribers; specific documentation for obtaining stocks; recording of receipts and supplies in controlled drug registers and witnessing of destruction of expired stocks amongst others. Most Schedule 2 drugs are also subject to the statutory safe custody requirements which mean they must be kept in a safe that is compliant with specified requirements under the Misuse of Drugs (Safe Custody) Regulations 1973.

64. Schedule 3 – drugs in this schedule are subject to prescription writing requirements, including handwritten signatures by prescribers; specific documentation for obtaining stocks and witnessing of destruction of expired stocks amongst others. Schedule 3 drugs do not have to be recorded in the controlled drug register. In addition, some Schedule 3 drugs are subject to the statutory safe custody requirements.

65. Schedule 4 Part I – drugs in this schedule are lightly regulated. The prescription writing requirements, specific documentation for obtaining stocks witnessing of the destruction of expired stocks do not generally apply to these drugs. Schedule 4 Part I drugs are also not subject to the safe custody requirements.

66. Schedule 4 Part II – drugs in this schedule are treated in a similar way to drugs in Schedule 4 Part I. The prescription writing requirements, specific documentation for obtaining stocks witnessing of the destruction of expired stocks do not generally apply to these drugs. Schedule 4 Part II drugs are also not subject to the safe custody requirements. Drugs in Schedule 4 Part II are exempt from the simple possession offence (though are still subject to the offence of possession with intent to supply), whereas those in Schedule 4 Part I are not exempt from this offence.

67. Schedule 5 - drugs in this schedule are very lightly regulated and can be sold over the counter. They do not necessarily require a prescription and the prescription writing requirements do not apply to these drugs. The requirements in relation to specific documentation for obtaining stocks witnessing of the destruction of expired stocks do not generally apply to these drugs. Schedule 5 drugs are also not subject to the safe custody requirements.