Title:	Impact Assessment (IA)
Consultation stage impact assessment of proposed consolidation, review and amendments to the Misuse of Drugs Regulations 2001.	**IA No:** HO0046
Lead department or agency: Home Office	**Date: 11/07/2011**
Other departments or agencies:	**Stage:** Consultation
	Source of intervention: Domestic
	Type of measure: Primary legislation
	Contact for enquiries: Des Niimoi (020 7035 3533) Desmond.niimoi@Homeoffice.gsi.gov.uk

Summary: Intervention and Options

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

The Misuse of Drugs Regulations 2001 (as amended) (the 2001 Regulations) authorises acts, in relation to controlled drugs, which are otherwise unlawful under the Misuse of Drugs Act 1971. The 2001 Regulations came into force in February 2002. To date, there have been several amendments to reflect policy changes and clarify provisions under the regulations. This means that the provisions in the 2001 Regulations have become fragmented, complex and can be difficult to follow.

The proposed consolidation will bring all amendments under a single legislative document.

What are the policy objectives and the intended effects?

Objective 1. Consolidating the various statutory instruments containing provisions of the Misue of Drugs Regulations 2001.
Objective 2. Review and amend specific provisions under the 2001 Regulations to ensure the regulations reflect current policy on drugs considered to be dangerous or otherwise harmful.

The intended effects are to ensure that the 2001 Regulations are comprehensive, comprehensible and fit for purpose.

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

Option 1 : No change
Option 2 : Consolidate the Misuse of Drugs Regulations 2001 (as amended) by bringing all legislative provisons under the 2001 Regulations into one document.
Option 3 : Consolidate the 2001 Regulations and review and amend specific provisions to ensure the regulations reflect current policy.

Option 3 is the preferred option. The 2001 Regulations provides access to controlled drugs for legitimate and medical uses, providing an effective framework under which controlled drugs can be possessed, supplied etc. Option 3 ensures that the regulatory framework is effective in order to prevent diversion and misuse of these dangerous drugs .

Will the policy be reviewed? It will not be reviewed. **If applicable, set review date:** Month/Year	
What is the basis for this review? Not applicable. **If applicable, set sunset clause date:** Month/Year	
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	Yes

Ministerial Sign-off For consultation stage Impact Assessments:

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: Angela Browning Date: 27/07/01

Summary: Analysis and Evidence

Policy Option 2

Description:

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

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

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

Costs associated with this option will depend on how many individuals or organisations opt to purchase a copy of the consolidated regulations. A printable copy of the consolidated regulations will be available freely online. There is no obligation to purchase copies of the consolidated regulations. The Home Office assesses that the cost relating to copies purchased at about £6.00 per copy will therefore be negligible.

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

No key non-monetised costs have been identified.

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

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

Key monetised benefits accrue to industry, healthcare proffessionals and healthcare institutions from the clear and comprehensive consolidated regulations and the man hours to be saved by not referring to various statutory instruments. However, we are unable to quantify these benefits as there is no available data on time used to refer to the 2001 Regualtions by either proffessionals or institutions.

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

Key non-monetised benefits relate to the clarity that a consolidated regulations will bring to healthcare proffessionals and industry and the corresponding impact on patient care.

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

Key assumption is that most healthcare proffessionals will refer to and print the online verison of the consolidated regulations.

The risk associated with this potion is that consolidation only will not ensure that the 2001 Regulations are fit for current purpose and will not enable flexibility in healthcare and therefore improved patient care.

Direct impact on business (Equivalent Annual) £m):			In scope of OIOO?	Measure qualifies as
Costs:	**Benefits:**	**Net:**	Yes	IN/OUT

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			Great Britain		
From what date will the policy be implemented?			01/04/2012		
Which organisation(s) will enforce the policy?			Home Office		
What is the annual change in enforcement cost (£m)?			N/A		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** N/A	**Benefits:** N/A	
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	No	
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	
Small firms Small Firms Impact Test guidance	No	
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	
Human rights Human Rights Impact Test guidance	No	
Justice system Justice Impact Test guidance	No	
Rural proofing Rural Proofing Impact Test guidance	No	
Sustainable development Sustainable Development Impact Test guidance	No	

[1] Public bodies including Whitehall departments are required to consider the impact of their policies and measures on race, disability and gender. It is intended to extend this consideration requirement under the Equality Act 2010 to cover age, sexual orientation, religion or belief and gender reassignment from April 2011 (to Great Britain only). The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Summary: Analysis and Evidence

Policy Option 3

Description:

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

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	N/A		£8k	**£8k**

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

same as option 2 plus;
Paramedics: Negligible
Operating Department Practitioners: Nil
Veterinary practitioners: Negligible

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

No key non-monetised costs have been identified.

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

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

Same as option 2

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

Same as option 2 plus;
Paramedics, Operating Department Practitioners, Midwives, Senior Registered Nurses - Unquantified benefit as a result of flexibility and access to controlled drugs
Designated bodies - Unquantified flexibillity due to exemption from requirements relating to requisitions.
Prisons and Scotland - Unquantified benefit as a result of clarity of the regulations.

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

The key assumption is that most proffessionals and industry will refer to the freely available online version of the consolidated regulations.

No risks have been identified with this option. This option will ensure that whilst controlled drugs are available for use in healthcare, a rigid regulatory framework exists to prevent their diversion and misuse and therefore protect the public from the harms posed by these potent drugs.

Direct impact on business (Equivalent Annual) £m):			In scope of OIOO?	Measure qualifies as
Costs:	**Benefits:**	**Net:**	Yes	OUT

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			Great Britain		
From what date will the policy be implemented?			01/04/2012		
Which organisation(s) will enforce the policy?			Home Office		
What is the annual change in enforcement cost (£m)?			N/A		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** N/A	**Benefits:** n/A	
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[2] Statutory Equality Duties Impact Test guidance	No	
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	
Small firms Small Firms Impact Test guidance	No	
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	
Human rights Human Rights Impact Test guidance	No	
Justice system Justice Impact Test guidance	No	
Rural proofing Rural Proofing Impact Test guidance	No	
Sustainable development Sustainable Development Impact Test guidance	No	

[2] Public bodies including Whitehall departments are required to consider the impact of their policies and measures on race, disability and gender. It is intended to extend this consideration requirement under the Equality Act 2010 to cover age, sexual orientation, religion or belief and gender reassignment from April 2011 (to Great Britain only). The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

References

Include the links to relevant legislation and publications, such as public impact assessments of earlier stages (e.g. Consultation, Final, Enactment) and those of the matching IN or OUTs measures.

No.	Legislation or publication
1	
2	
3	
4	

+ Add another row

Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the **Annual profile of monetised costs and benefits** (transition and recurring) below over the life of the preferred policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

Annual profile of monetised costs and benefits* - (£m) constant prices

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Transition costs										
Annual recurring cost	£8k	£8k	£8k	£8k	£8k	£8k	£8k	£8k	£8k	£8k
Total annual costs	£8k	£8k	£8k	£8k	£8k	£8k	£8k	£8k	£8k	£8k
Transition benefits										
Annual recurring benefits										
Total annual benefits										

* For non-monetised benefits please see summary pages and main evidence base section

Microsoft Office
Excel Worksheet

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 Background

This is a consultation stage Impact Assessment forming the first step in identifying costs and benefits of the proposals set out in the consultation paper to consolidate and review/amend misuse of drugs legislation. This is a continuous process and respondents are invited to submit any figures, costing or other details of relevance to help refine the final stage impact assessment.

The Misuse of Drugs Regulations 2001 (as amended) (the 2001 Regulations) came into force in February 2002. Since then there have been several amendments to the 2001 Regulations to reflect policy changes and clarify provisions under the regulations. This has led to the provisions in the 2001 Regulations being fragmented, complex and at times difficult to follow. The private sector does provide up-to-date online versions of the 2001 Regulations. However, this comes at a cost to businesses and organisations through subscriptions.

The aim of the consolidation project is to ensure that the 2001 Regulations continue to be comprehensive, comprehensible, fit for current purpose and reflects current policies in relation to drugs controlled under the Misuse of Drugs Act 1971 (the 1971 Act) which are also scheduled under the 2001 Regulations. Consolidating the regulations will also ensure legal certainty for those who need to refer to provisions in their work.

As part of the consolidation process, a targeted review and/or amendment of specific provisions is being considered where a clear and urgent policy or professional need has been identified to ensure the regulations are fit for purpose and reflect current policy on controlled drugs.

These include amendments relating to;

- Requisition exemptions for designated bodies,
- Paramedics and operating department practitioners,
- Midwife ward managers,
- Veterinary practitioners,
- Reference to National Health Service (Scotland) Act 1978, and
- Senior registered nurses in charge of prison health centres.

A.2 Groups Affected

The main groups affected by the policy are healthcare professionals, veterinary practitioners, patients, healthcare institutions and prisons.

A.3 Consultation

Within Government

The Advisory Council on the Misuse of Drugs, Department of Health, Care Quality Commission, Royal Pharmaceutical Society, Veterinary Medicines Directorate and the Medicines and Healthcare products Regulatory Agency.

Public Consultation

Healthcare professionals and regulatory bodies.

B. Rationale

Government intervention is necessary to consolidate the 2001 Regulations to ensure an effective legal framework exists to protect the public from the harms posed by these dangerous drugs. An effective regulatory framework will prevent diversion and misuse. Consolidating, reviewing and amending the 2001 Regulations will ensure that the legislation is fit for purpose and reflect current policy on drugs controlled under the Misuse of Drugs Act 1971 which are also scheduled under the 2001 Regulations. Only Government and Parliament can legislate.

C. Objectives

The goal is to consolidate the Misuse of Drugs Regulations 2001 and make clarifying amendments to existing provisions to ensure the regulations are comprehensive, comprehensible and fit for purpose and thereby reflect the current policy on drugs considered to be harmful or otherwise dangerous.

Consolidation will simplify the 2001 Regulations, improving its accessibility to healthcare professionals, industry and to lay readers. This is a significant better regulation initiative consistent with the Government's approach to principles of regulation. A consolidated regulation will provide for legal certainty and the rule of law, contribute to transparency and reduce administrative and compliance burdens. This will make it easier for healthcare professionals and industry to apply the provisions under the 2001 Regulations more easily ultimately benefiting healthcare professionals, patients and industry.

D. Options

The Home Office has consulted informally and has widespread support to consolidate the 2001 Regulations. As a result we have narrowed our available options down to the following;

Option 1: Make no changes (do nothing).

This option will maintain the current position and will mean that the provisions under the 2001 Regulations will remain spread over several legislative instruments.

Option 2: Consolidate the Misuse of Drugs Regulations 2001 (as amended)

This option will bring the provisions under the 2001 Regulations, currently spread over several legislative instruments, into one document. However, no further amendments will be made to clarify the legislation to reflect current policy.

Option 3: Consolidate, review and amend the Misuse of Drugs Regulations 2001 (as amended)

This option will bring the provisions under the 2001 Regulations, currently spread over a number of legislative instruments, into one document as in option 2, and will also include a targeted review and amendment of specific provisions as follows;

1. amendments to exempt designated bodies[3] from requisition requirements, (No costs envisaged as proposal only removes a burden)
2. amendments to include paramedics and operating department practitioners in the list of professions requiring a requisition in order to obtain controlled drugs,
3. amendments to extend of the authorities currently applicable to senior registered nurses in charge of a ward to midwife ward managers, (No costs envisaged as proposal only provides authority)
4. amendments to require veterinary practitioners to include their Royal College of Veterinary Surgeon (RCVS) numbers on prescriptions for Schedule 2 and 3[4] controlled drugs (except temazepam),
5. amendments to remove the reference to National Health Service (Scotland) Act 1978 form the 2001 Regulations, (No costs envisaged as proposal only removes a reference to a repealed Act)
6. Amendments to clarify that the provisions under Regulation 15(3) of the Misuse of Drugs Regulations 2001, which enables hospital prescriptions for controlled drugs to be written on a patient's bed card, is not applicable to prisons (No costs envisaged as proposal only clarifies existing provision), and
7. Amendments to extend authorities to senior registered nurses in charge of prison health centres (No costs envisaged as proposal only provides authority).

E. Appraisal (Costs and Benefits)

GENERAL ASSUMPTIONS & DATA

Paramedics

Number of registered paramedics: 16,930 [Source – Health Protection Council]
Average hourly rate: £17.00 (mid-band: band 5 paramedic) [Source – College of Paramedics]
Percentage affected by proposal: 10% (1,693) [Assumption]

Operating Department Practitioners

Number of registered operating department practitioners (ODPs): 10,333
Average hourly rate: £11 - £20 (NHS pay bands 5-7at £21,176 - £40,157per anum)
Percentage affected by proposal: 60% (6214) [Source – College of Operating Department Practitioners]
Average hourly rate for nurses currently requisitioning on behalf of ODPs: £11 - £20 (NHS pay bands 5-7 at £21,176 - £40,157per anum) [Source – College of Operating Department Practitioners]

Veterinary Surgeons

Number of practicing veterinary surgeons: 17,418 [Source Royal College of Veterinary Surgeons]
Percentage affected by proposal: 95% (16,547) [Source – Veterinary Medicines Directorate]

Requisitions - Assumptions

Time needed to complete a requisition for controlled drugs – 5 to 15 minutes (Average 10)

[3] Organisations, such as hospices, undertaking a regulated activity under the Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2009.

[4] Drugs controlled under the Misuse of Drugs Act 1971 are also scheduled under the Misuse of Drugs Regulations 2001 to enable access for healthcare and industrial purposes. Schedules 2 and 3 contain the most potent drugs that have medicinal uses.

Cost of requisition form – Free (available online)
Average number of requisitions completed by a paramedic in a year: 5 – 12 (Average 8)
Average number of requisitions completed by ODPs in a year: 20 – 50 per ODP (Average 35)

Veterinary Prescriptions - Assumptions

Time needed to include RCVS number: 5 – 10 seconds
Cost of prescription pad - None (prescription forms already in use so no additional costs)

OPTION 2 – Consolidate the Misuse of Drugs Regulations 2001 (as amended)

COSTS (excluding OIOO)

This proposal simply brings existing provisions of the Misuse of Drugs Regulations 2001 under a single document is unlikely to have any costs implications or impact on the public sector except for those organisations who may want to purchase a copy of the consolidated version of the regulations. A hard copy of the regulations currently cost £6.00. Organisations that subscribe to online services will not incur any additional cost. A copy of the consolidated regulations will also be available free of charge on the Government website at legislation.gov.uk.

COSTS (OIOO)

Any costs associated with this option are ongoing to the degree that an organisation may decide to purchase another copy of the regulations following a further consolidation or amendment to the 2001 Regulations. The costs involved are however minimal and depends on whether an organisation decides to purchase a hard copy. A hard copy of the regulations currently cost £6.00.

TOTAL COSTS

The overall ongoing cost - effect and size - of this option will depend on how many individuals or organisations purchase copies of the consolidated regulations. It is difficult to assess how many organisations will opt to purchase a hard copy given the availability of a free online version which can be printed. The Home Office assesses that very few hard copies will be bought and therefore the corresponding costs will be negligible. There is no obligation to purchase a hard copy of the consolidated regulations.

BENEFITS (excluding OIOO)

This proposal would bring the various statutory instruments which have amended the 2001 Regulations over the past years into one document. This will make it clearer for healthcare professionals in the public service to identify applicable provisions and apply these in their fields.

Other benefits attributable to this option relate to the man hours to be saved by not having to refer to various statutory instruments for provisions under the 2001 Regulations. However, the time involved cannot be quantified as it depends on the number of variables, including provisions that need to be referred to, the source(s) used, how often a reference is made to the 2001 Regulations etc.

BENEFITS (OIOO)

This proposal would bring the various statutory instruments which have amended the 2001 Regulations over the past years into one document. This will make it clearer for healthcare

professionals in the private or third sector and industry to identify applicable provisions and apply these in their fields.

Other benefits attributable to this option relate to the man hours to be saved by not having to refer to various statutory instruments for provisions under the 2001 Regulations. However, the time involved cannot be quantified as it depends on the number of variables, including provisions that need to be referred to, the source(s) used, how often a reference is made to the 2001 Regulations etc.

TOTAL BENEFITS

Total benefits under this option will be ongoing and will relate to the man hours saved by not referring to several documents for provisions under the 2001 Regulations and the clarity that a consolidated regulations will bring to professionals and industry. These benefits cannot be quantified as they are dependent on several variables.

OPTION 3 – Consolidate, review and amend the Misuse of Drugs Regulations 2001 (as amended)

COSTS

Same as option 2 plus

Paramedics:

The Home Office assess that the total costs of the proposal in relation to paramedics as follows;

Number of paramedics affected by proposal: 10,158
Average number of requisitions written by a paramedic in a year: 8
Average time used to complete requisition form: 10 minutes
Average hourly rate: £17.00 (£2.80 for 10 Minutes)

Cost of proposal: (hourly cost for 10 minutes X number of requisitions written in a year) X number of paramedics affected

= (2.80 X 8) X 1,693

= £37,923.00

Paramedics currently order controlled drugs using a non standard form but are encouraged as best practice to use the freely available requisition forms. The amount of time taken to complete these non-standard forms is almost commensurate to the amount of time to be used in completing the requisition form. The Home Office estimates that less than 20 percent of the time to be used in completing requisition forms can be attributed to this proposal. Therefore the overall effect of this proposal is assessed as 20 percent of the total costs calculated above and therefore considered to be negligible.

20% of 37,923.00

= £7,585 per year

Operating Department Practitioners:

The Home Office assess that the total costs of the proposal in relation to as follows;

Number of ODPs affected by proposal: 6214
Average number of requisitions written by an ODP in a year: 35
Average time used to complete requisition form: 10 minutes
Average hourly rate: £15.00 (£2.50 for 10 Minutes)

Cost of proposal: (hourly cost for 10 minutes X number of requisitions written in a year) X number of ODPs affected

= (2.50 X 35) X 6214

= £543,725.00

This role is currently performed by senior registered nurses on similar pay bands to ODPs. As a result there is a corresponding saving of £543,725.00 if ODPs undertake the role themselves. The net effect is a transfer of costs. This proposal therefore has a nil impact.

Veterinary practitioners:

The amendment to require a veterinary surgeon's RCVS registration number to be included on each written prescription for a veterinary controlled drug was subject to a Veterinary Medicine Directorate consultation in 2009. The responses received confirmed that this requirement will not bring additional costs to veterinary practitioners affected by this change. No perceived costs were highlighted in the consultation exercise.

The Home office assesses that for those prescriptions that are printed there will be a one off amendment to software packages to include the RCVS number on prescriptions when printed. Following this all prescriptions generated will automatically include the RCVS number. The costs associated with this are assessed as one off and negligible.

For those prescriptions that are handwritten an average of 10 seconds will be required to add the RCVS number to the prescription. No other information over and above what is already included on veterinary prescriptions will be required as a result of the proposed change. Any costs attributable to the extra seconds needed are again assessed as negligible.

TOTAL COSTS

Total costs associated with this option is ongoing and will result from the cost of purchasing copies of the consolidated regulations and the cost (time) spent completing requisitions for controlled drugs by paramedics and ODPs. The overall cost - effect and size - of this option will depend on how many individuals or organisations purchase copies of the consolidated regulations and how many organisations, paramedics or ODPs choose to avail themselves of the authorities under the 2001 Regulations. There are no additional training costs involved with this proposal.

The Home Office assesses the total costs of this option excluding costs attributable to obtaining copies of the consolidated regulations as;

Paramedics: Negligible
ODPs: Nil
Veterinary practitioners: Negligible

Total cost of proposals: *Negligible*

BENEFITS

The benefits associated with this option are ongoing and are as follows;

1. Benefits accrue as a result of the consolidation of the regulations from the reduction in time spent by healthcare professionals and industry referring to the various statutory instruments which contain provisions of the 2001 Regulations. However, these benefits are not quantifiable as there is no data available on the amount of time spent referring to the 2001 Regulations by healthcare professional or healthcare institution.

2. Flexibility accruing to healthcare professionals in the private sector as a result of the proposed change. Current provisions under the 2001 Regulations place restrictions on healthcare professionals able to perform certain task in relation to controlled drugs. The proposed changes will expand the number of healthcare professionals and provide flexibility to healthcare professionals and institutions which will improve the care provided to patients. However, it is not possible to quantify the benefits resulting from such flexibility as this will depend on the number of institutions that decide to avail themselves of the new provisions.

3. Benefits also accrue as a result of the clarity and certainty that consolidated and reviewed regulations will bring to healthcare professionals and institutions. Some healthcare professionals currently perform roles that are not covered with the requisite authority under the 2001 Regulations. The proposed changes will bring parity to this sector in relation to controlled drugs and remove any risk of prosecution for the affected healthcare professionals. These benefits cannot be quantified as there is no data on the number of professionals currently operating at risk as a result of the lack of authority.

4. There are also benefits that accrue in relation to data gathering and monitoring arrangements. The 2001 Regulations enable the use of drugs that are considered dangerous or otherwise harmful when misused. The risk of diversion attributed to these drugs is significant. By setting a minimum framework that enables the acquisition, prescribing and dispensing of these drugs to be monitored, the 2001 Regulations ensure that the public are protected from the harms associated with these drugs. The benefits arising form the protection of the public cannot be quantified.

Other benefits accruing from the specific amendments are as follows;

5. Extension of Senior Registered Nurse Authorities:

This proposal will ensure that the authorities available to senior registered nurses in charge of wards in the public sector under the 2001 Regulations are extended to senior registered nurses in charge of prison health centres and midwives in the public sector.

Under current provisions senior registered nurses in charge of prison health centre are unable to take responsibility for the controlled drugs used in the health centre. This situation is not ideal as the doctors who sign for these drugs and therefore have responsibility are most times not on site. This makes the governance arrangements less than ideal. The proposed change will ensure that a senior registered nurse in charge of a prison health centre can take responsibility for controlled drugs within the health centre to minimise the risk of diversion and misuse and therefore improve the governance arrangement on controlled drugs within a prison health centre. The benefits accruing form the improved governance arrangement cannot be quantified.

Midwife ward managers, not necessarily senior registered nurses, currently manage maternity wards and require the use of controlled drugs. However, the authorities afforded to senior registered nurses in charge of hospital wards under current provisions under the 2001 Regulations do not extend to midwife ward managers. This means that in performing their duties some of these managers will be acting outside the 2001 Regulations and therefore open themselves up to the risk of prosecution. The proposed change will place midwife ward managers on a level footing with senior registered nurses in relation to controlled drugs and remove the risk of prosecution. This risk cannot be quantified.

6. Requisitions

The benefits accruing to this proposal relate to the improved regulatory framework on controlled drugs acquired by the relevant healthcare professionals which ensures that the public are protected form these dangerous or otherwise harmful drugs. One of the key recommendations of the Shipman enquiry is to ensure that the requisition activity of individual healthcare professionals are recorded and monitored to prevent the diversion and thus misuse of the potent drugs involved. This proposal will ensure the movement of these drugs are effectively monitored to support the control regime and therefore protect the public. This benefit cannot be quantified.

7. Scotland

The proposal will provide clarity in the 2001 Regulations by removing the current reference to a repealed Act. It will ensure that those who need to operate under the Regulations are clearly informed of the designated person to provide the requisite authority for controlled drug requisitions.

ONE-IN-ONE-OUT

IN:

Paramedics: *£8k per year- Negligible*
ODPs: *Nil*
Veterinary practitioners: *Negligible*

OUT:

All the benefits above apply to both the private and voluntary sectors.

In addition, a specific benefit also accrues to the private and voluntary sectors in relation to Designated Bodies. Under current provisions of the 2001 Regulations designated bodies are required to present a requisition in order to obtain controlled drugs. The requisition data is then collated by the National Health Service Business Services Agency to inform the monitoring systems for controlled drugs. This requirement is being removed. However, designated bodies will revert to using duplicate ordering pads which were used before requisitions were introduced. The removal of this requirement will reduce the administrative burden on these organisations though some the benefit of the proposal will be offset by reverting to the use of ordering pads.

TOTAL BENEFITS

Total benefits are ongoing and relate to the clarity and certainty of provisions and the relatively shorter time it will take healthcare professionals to refer to the consolidated Regulations. Benefits also accrue from the flexibility and access provided to controlled

drugs which supports healthcare professionals in their delivery of patient care. The overall benefit is improved access to controlled drugs and patient care within an effective regulatory framework and the removal of the risk of prosecution. These benefits cannot be quantified as there is currently no data to underpin any calculation of the benefits.

F. Risks

OPTION 1 – Do nothing

There are risks involved with this option. The current provisions are spread over several statutory instruments and online copies of the 2001 Regulations, unless accessed from a subscription, are provided in the original version which came into force in 2002. This means that in some cases healthcare professionals refer to the wrong provisions. This can present difficulties for those who need to use these provisions in their work with the consequence that the risks involved with these dangerous drugs – diversion and misuse – increase. Consolidating the 2001 Regulations into one single legislative document will remove this risk.

OPTION 2 – Consolidate the Misuse of Drugs Regulations 2001 (as amended)

There are some risks involved with this option. Consolidation will simply bring into one document current provisions under the 2001 Regulations. However, no amendments will be made to reflect current policy on controlled drugs. This will mean that the regulatory framework on controlled drugs will continue to be less rigid, with a corresponding increase in the risk of diversion and misuse of drugs considered dangerous or otherwise harmful to the public. Reviewing and amending provisions as part of the consolidation exercise, where a clear and urgent policy or professional need exists, will mitigate this risk.

OPTION 3 – Consolidate, review and amend the Misuse of Drugs Regulations 2001 (as amended)

There are no risks involved with this option. Consolidating, reviewing and amending the current provisions under the 2001 Regulations will ensure that the regulatory framework on controlled drugs is comprehensive, comprehensible, reflects current policy and therefore fit for purpose. This will allow for the safe management and use of controlled drugs in communities and industry, preventing diversion and therefore misuse of these potent drugs.

G. Enforcement

The proposed option involves no changes to the way the legislation is currently enforced.

H. Summary and Recommendations

The table below outlines the costs and benefits of the proposed changes.

Table H.1 Costs and Benefits

Option	Costs	Benefits
2	Unknown	Unknown

	Cost to industry, healthcare institutions and professionals (not quantified)	Benefits to industry, healthcare institutions and professionals (not quantified)
3	Negligible per year	Unknown
	Cost to healthcare professionals and institutions (not quantified)	Benefits to healthcare institutions, healthcare professionals, patients and the public (not quantified)
Source:		

Option 3 is the preferred option.

Whilst option 2 consolidates the 2001 Regulations to make it comprehensive and comprehensible, it does not respond to the specific needs of healthcare professionals as a result of changes in the healthcare sector to improve flexibility and thus patient care.

Option 3 will ensure that the 2001 Regulations are comprehensive, comprehensible and fit for current purpose. This option will ensure that whilst these potent medicines are available for used in healthcare, a corresponding regulatory framework exists to prevent diversion and misuse and therefore protect the public from the harms posed by these drugs. The costs associated with this option are negligible and any minimum requirements placed on those who are given access to these dangerous drugs does not place a burden over and above what is currently in force, and in most cases is offset by the savings from the flexibility being introduced, the improved patient care and the protection afforded to the public under the regulatory framework.

I. Implementation

The Government plans to implement these changes on 1st April 2012

J. Monitoring and Evaluation

The effectiveness of the new regime would continue to 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.

K. Feedback

Feedback on the proposed changes will be sought from identified key stakeholders and healthcare profession representative bodies and also from the Care Quality Commission through its annual reports.

L. Specific Impact Tests

Annexes

Annex 1 should be used to set out the Post Implementation Review Plan as detailed below. Further annexes may be added where the Specific Impact Tests yield information relevant to an overall understanding of policy options.

Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. If the policy is subject to a sunset clause, the review should be carried out sufficiently early that any renewal or amendment to legislation can be enacted before the expiry date. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

Basis of the review: [The basis of the review could be statutory (forming part of the legislation), i.e. a sunset clause or a duty to review , or there could be a political commitment to review (PIR)]; The basis for review of this proposal would be on policy grounds.
Review objective: [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?] The review objective will be to identify if the legislative framework provides the necessary regulatory framewrok needed to prevent the diversion and misuse of drugs considered dangerous or otherwise harmful to the public.
Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach] the review approach will focus on stakeholder views and the oversight of the CQC and Acountable officer networks
Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured] The baseline for measurement is the non-consolidated and reviewed regulations and the effect this has on proffessionals through the associated lack of flexibility and certainty .
Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives] An effective regulatory framework to reduce the risk of diversion and therefore misuse of drugs considered to be dangerous or otherwise harmful.
Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection systematic collection of monitoring information for future policy review] There will be a continious monitoring of the effectiveness of the new regime 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.
Reasons for not planning a review: [If there is no plan to do a PIR please provide reasons here]

Annex 2. Specific Impact Tests

Statutory Equality Duties

Equality Impact Assessment

EQUALITY IMPACT ASSESSMENT
Group: Crime and Policing Group
Directorate: Drugs, Alcohol and Partnerships Directorate
Unit: Drug Strategy Unit

PRELIMINARY SCREENING

Date of Screening	2011
Name of Policy Writer	Des Niimoi
Director General	**Stephen Rimmer**

Name of Policy		This is a **new** policy
	x	This is a **change** to an existing policy
		This is an **existing** policy

Policy Aims, Objectives & Projected Outcomes
To consolidate the Misuse of Drugs Regulations 2001 (as amended) and review and amend specific provisions to reflect current policy, where a clear and urgent policy and/or professional need exists. This proposal will ensure that the Misuse of Drugs Regulations 2001 are comprehensible, comprehensive and effective in regulating the availability of drugs that are considered dangerous or otherwise harmful when misused. The projected outcomes are access to controlled drugs and flexibility for healthcare professionals and thus improved patient care.

Will the policy have an impact on national or local people/staff?	YES
Are particular communities or groups likely to have different needs, experiences and/or attitudes in relation to the policy	NO
Are there any aspects of the policy that could contribute to equality or inequality?	NO
Could the aims of the policy be in conflict with equal opportunity, elimination of discrimination, promotion of good relations?	NO
If this is an amendment of an existing policy, was the original policy impact assessed?	YES

If your answer to any of these questions is **YES**, go on to the full EIA.

If you have answered **NO** to all of these questions then please attach the following statement to all future submissions and within your regulatory impact assessment and ensure it is signed off by senior management.

“This policy was screened for impact on equalities on [insert date]. The following evidence [Evidence] has been considered. No full equality impact assessment is required. “

Remember that all policies that are likely to have a significant impact on individuals and the public as a whole are likely to require a full EIA.

FULL IMPACT ASSESSMENT

STATISTICS & RESEARCH

What relevant quantitative & qualitative data do you have in relation to this policy?

Equality Target Areas	**How does the data identify potential or known positive impacts?** **How does the data identify any potential or known adverse impacts?**
Race (consider e.g. nationalities, Gypsies, Travellers, languages)	None at present. To our knowledge, no data is available on race in relation to provisions under the 2001 Regulations. It is not anticipated that consolidating the 2001 Regulations will have any disproportionate impact on race.
Disability (consider social access and physical access)	None at present. To our knowledge, no data is available on disability in relation to provisions under the 2001 Regulations. It is not anticipated that consolidating the 2001 Regulations will have any disproportionate impact on disability.
Gender	None at present. To our knowledge, no data is available on gender in relation to provisions under the 2001 Regulations. It is not anticipated that consolidating the 2001 Regulations will have any disproportionate impact on gender.
Gender Identity	None at present. To our knowledge, no data is available on gender identity in relation to provisions under the 2001 Regulations. It is not anticipated that consolidating the 2001 Regulations will have any disproportionate impact on gender identity.
Religion and Belief	None at present. To our knowledge, no data is available on religion and belief in relation to provisions under the 2001 Regulations. It is not anticipated that consolidating the 2001 Regulations will have any disproportionate impact on religion and belief.
Sexual Orientation	None at present. To our knowledge, no data is available on sexual orientation in relation to provisions under the 2001 Regulations. It is not anticipated that consolidating the 2001 Regulations will have any disproportionate impact on sexual orientation.

Age	None at present. To our knowledge, no data is available on age in relation to provisions under the 2001 Regulations. It is not anticipated that consolidating the 2001 Regulations will have any disproportionate impact on rage.

What research have you considered commissioning to fill any data gaps?
None

Who are the stakeholders, community groups, staff or customers for this policy area?
• Drug users, their children, their families and all members of communities impacted by illegal drug use. • Practitioners working in drug treatment services. • Advisory Council on the Misuse of Drugs (ACMD). • The National Treatment Agency for Substance Misuse (NTA). • Primary Care Trusts (PCTs). • Inter-agency drug action teams and local partnerships, including Drug Action Teams (DATs), Drug and Alcohol Action Teams (DAATs) and Crime and Disorder Reduction Partnerships (CDRPs). • Enforcement agencies and all parts of the Criminal Justice System**.** • Educational institutions. • Local Authorities. • The Home Office. • Department of Health. • Department for Children, Schools and Families, • Ministry of Justice. • Department for Work and Pensions. • Department for Communities and Local Government. • Other UK governments – Wales, Scotland and Northern Ireland. • Charity and voluntary groups.

What are the overall trends and patterns in this qualitative & quantitative data?
None

Please list the specific equality issues that may need to be addressed through consultation (and further research)?
None

GATHERING EVIDENCE THROUGH COMMUNITY ENGAGEMENT

INTERNAL STAKEHOLDER ENGAGEMENT: Consulting & involving Other Government Departments, Staff, Agencies & NDPBs

Does this policy affect the experiences of staff? How? What are their concerns?	
Staff	Consolidating provisions under the 2001 Regulations is not expected to have any impact on staff
Staff Networks & Associations	----------
Trade Unions	----------

How have you consulted, engaged and involved internal stakeholders in considering the impact of this proposal on other public policies and services?
The consolidation of the 2001 Regulations is in line with ACMD advice, following consultation with them. The ACMD did not raise any concerns about adverse impact on equality.

What positive and adverse impacts were identified by your internal consultees? Did they provide any examples?
No adverse impacts have been identified. However, the proposed changes are assessed as having a positive impact on patient care.

EXTERNAL CONSULTATION & INVOLVEMENT

How did your engagement exercise highlight positive and negative impacts on different communities?	
Voluntary Organisations	• No impact was identified
Race	• No impact was identified
Faith	• No impact was identified
Disability Rights	• No impact was identified
Gender	• No impact was identified
Gender Identity	• No impact was identified
Sexual Orientation	• No impact was identified
Age	• No impact was identified

ASSESSMENT & ANALYSIS

Does the EIA show a potential for differential impact on any group(s) if this proposal is introduced? If Yes, state briefly whether impact is adverse or positive and in what equality areas.
EIA does not highlight any potential for greater impact on a specific group.

What were the main findings of the engagement exercise and what weight should they carry?
The main finding of the engagement with the ACMD is that no equalities impact arises out of the proposed consolidation and review of the Misuse of Drugs Regulations 2001. the ACMD is the statutory body which advises Government on controlled drug issues.

Does this policy have the potential to cause unlawful direct or indirect discrimination? Does this policy have the potential to exclude certain group of people from obtaining services, or limit their participation in any aspect of public life?
No

How does the policy promote equality of opportunity?
Consolidating and amending the Misuse of Drugs Regulations will enable healthcare professionals to have access to controlled drugs providing flexibility in healthcare and therefore improving care for all patients.

How does your policy promote good relations? How does this policy make it possible for different groups to work together, build bridges between parallel communities, or remove barriers that isolate groups and individuals from engaging in civic society more generally?
The proposal to consolidate and review the Misuse of Drugs Regulations 2001 does not have any impact on good relations.

How can the policy be revised, or additional measures taken, in order for the policy to achieve its aims without risking any adverse impact?
No adverse impact is attributed to the proposal

Are there any concerns from data gathering, consultation and analysis that have not been taken on board?
No.

ENSURING ACCESS TO INFORMATION

How can you ensure that information used for this EIA is readily available in the future? (N.B. You will need to include this in your action plan)
• The full report on the equality impact assessment will be made available for those reviewing the policy at different stages.

How will you ensure your stakeholders continue to be involved/ engaged in shaping the development/ delivery of this policy? (N.B. You will need to include this in your action plan)
• There is continual liaison with both internal and external stakeholders. This engagement will continue.

How will you monitor this policy to ensure that the policy delivers the equality commitments required? (N.B. You will need to include this in your action plan)
• The consolidation and review of the Misuse of Drugs Regulations 2001 will be reviewed as part of the Coalition Government's new Drug Strategy.