Title:
Impact assessment of amendments to the Misuse of Drugs Regulations 2001.

IA No: HO0185

Lead department or agency:
Home Office

Other departments or agencies:
Department of Health

Impact Assessment (IA)

Date: 07/10/2013

Stage: Final

Source of intervention: Domestic

Type of measure: Secondary legislation

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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**
-£0.06m	N/A	N/A	No	N/A

Please note: This IA was created in late 2013 based on the data then available, as a result, the costs and benefits may be slightly out of date due to the effect of inflation. The underlying costs and benefits are not believed to be different however.

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. Provisions under the 2001 Regulations need to be reviewed regularly to ensure the regulatory framework on controlled drugs is effective, reflects current policy and keeps pace with an ever changing healthcare landscape, particularly with new healthcare professionals and settings in which care is provided. A public consultation in 2011 highlighted the need for several amendments to the Regulations - these can only be accomplished though government intervention.

What are the policy objectives and the intended effects?

The objective is to ensure the 2001 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 : Amend specific provisions under the 2001 Regulations to ensure the regulations reflect current healthcare policy.

Option 2 is the preferred option. The 2001 Regulations provide access to controlled drugs for legitimate and medicinal uses, providing an effective framework under which controlled drugs can be possessed, supplied, produced and administered. Option 2 ensures that the regulatory framework continues to be effective in order to prevent diversion and misuse of these dangerous drugs whilst at the same time providing healthcare access to these drugs.

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

Does implementation go beyond minimum EU requirements?			Yes / No / N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes/No	**< 20** Yes/No	**Small** Yes/No	**Medium** Yes/No	**Large** Yes/No
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:**	**Non-traded:**	

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs.

Signed by the responsible Minister: Lynne Featherstone Date: 20/03/2015

Summary: Analysis & Evidence

Policy Option 2

Description: Option 2 : Amend specific provisions under the 2001 Regulations to ensure the regulations reflect current healthcare policy.

FULL ECONOMIC ASSESSMENT

Price Base Year 2013	PV Base Year 2013	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	**High:** N/A	**Best Estimate:** -0.06

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A		N/A	**N/A**
High	N/A		N/A	**N/A**
Best Estimate	0		£0.01m	**£0.06m**

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

The largest costs will be felt by paramedics from completing requisition forms. These costs are the monetary value of the time it takes for them to fill out the forms.

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	N/A		N/A	**N/A**
High	N/A		N/A	**N/A**
Best Estimate	Unknown		Unknown	**Unknown**

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

No key monetised benefits have been identified.

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

Key non-monetised benefits accrue to healthcare professionals and healthcare institutions from the clarity and flexibility enabled under the amended regulations, and to patients from the resulting improvements in patient care. However, we are unable to quantify these benefits as there is no available data.

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

The key assumption is that most professionals and industry will use the freely available online version of the mandatory requisition form.

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.

BUSINESS ASSESSMENT (Option 1)

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

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 Background

The Misuse of Drugs Act 1971

1. The Misuse of Drugs Act 1971 controls drugs that are "***dangerous or otherwise harmful***" either to individuals or to society when they are misused. Drugs subject to control are listed in Schedule 2 to the Act and separated into three classes; Classes **A**, **B** and **C**, according to their perceived degree of harm.

Misuse of Drugs Regulations 2001 - Access to controlled drugs in healthcare

2. Access to controlled drugs for legitimate medicinal purpose is permitted but subject to regulation through the Misuse of Drugs Regulations 2001. The Regulations establish a regime of control around prescribing, supplying or administering, safe custody, dispensing, record keeping, destruction and disposal. The single purpose of these restrictions is to prevent the diversion and misuse of controlled drugs for patient and public protection.

3. All controlled drugs are listed in one of five Schedules. Each drug is categorised according to their therapeutic usefulness and potential for misuse and the harms caused by that misuse (to both the individual and society). Schedule 1 controlled drugs are subject to the greatest restrictions and Schedule 5 the least.

Prescribing of controlled drugs in healthcare

4. Practitioners (doctors, dentists and veterinary surgeons), independent prescribers (when acting within their competence) and supplementary prescribers (when acting in accordance with a clinical management plan) are permitted to prescribe all drugs listed in Schedules 2 to 5 of the 2001 Regulations. However the prescription of cocaine, dipipanone and diamorphine for the treatment of addiction is subject to stricter regulations.

5. Prescriptions for Schedules 2 and 3 controlled drugs must meet specific requirements set out in the Misuse of Drugs Regulations 2001.

Production of controlled drugs in healthcare

6. The authority to produce Schedules 2 to 5 controlled drugs, in the healthcare sector, is limited to practitioners, pharmacists and persons lawfully conducting a retail pharmacy.

Supply of controlled drugs in healthcare

7. In the healthcare sector, practitioners, pharmacists, independent prescribers (when acting within their competence) and supplementary prescribers (when acting in accordance with a clinical management plan) are authorised to supply, or offer to supply, all Schedules 2 to 5 controlled drugs.

Requisitioning of controlled drugs in healthcare

8. A practitioner, a nurse or pharmacist independent prescriber, a supplementary prescriber, an operating department practitioner, and a senior registered nurse in charge of a ward or theatre are all authorised to requisition stocks of controlled drugs.

Administration of Schedules 2 to 5 controlled drugs in healthcare

9. A doctor or a dentist, and any person acting in accordance with their directions, is permitted to administer any drug specified in Schedules 2 to 4. Nurse and pharmacist independent prescribers, and persons acting in accordance with their directions, also have authority to administer any drug in Schedules 2 to 5 when acting within their competency.

A.2 Groups Affected

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

A.3 Consultation

Within Government

11. 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 have all been involved in consultations.

Public Consultation

12. The proposals set out in this impact assessment were the subject of a full public consultation in 2011. Further consultation with key stakeholders was also undertaken on some specific proposals in light of responses to the public consultation.

B. Rationale

13. The Government is committed to preventing diversion and misuse of dangerous drugs whilst at the same time providing healthcare access to these drugs. As such, the Government wishes to amend the 2001 Misuse of Drugs Regulations in order to keep the regulatory framework up to date with changes that have occurred in the healthcare sector.

14. The proposals were the subject of a full public consultation in 2011, in which respondents overwhelmingly supported the proposal to consolidate and review specific proposals under the 2001 Regulations.

15. Only Government and Parliament can amend the existing legislation.

C. Objectives

16. The objective is to ensure the regulations are comprehensive, comprehensible and fit for purpose thereby reflecting the current policy on drugs considered to be harmful or otherwise dangerous.

D. Options

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

Option 1: Make no changes (do nothing).

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

18. This option will ensure that provisions under the 2001 Regulations meet with current changes in policy and practice in the healthcare sector. These will include a targeted amendment of specific provisions to:

i. exempt designated bodies[1] from requisition requirements, (no costs envisaged as proposal only removes a burden);

ii. include paramedics and operating department practitioners in the list of professions requiring a requisition in order to obtain controlled drugs;

iii. extend the authorities currently applicable to senior registered nurses in charge of a ward to midwife ward managers, (no costs envisaged as proposal only provides enabling authority and midwife ward managers already have the relevant training);

iv. require veterinary practitioners to include their Royal College of Veterinary Surgeon (RCVS) numbers on prescriptions for Schedule 2 and 3 controlled drugs (except temazepam);

v. remove the reference to National Health Service (Scotland) Act 1978 from the 2001 Regulations, (no costs envisaged as proposal only removes a reference to a repealed Act);

vi. extend authorities to senior registered nurses in charge of prison health centres (no costs envisaged as proposal only provides authority and senior nurses already have the relevant training);

vii. make the use of a specific form for the requisition of controlled drugs mandatory (no costs are envisaged as this replaces other forms currently used by healthcare professionals);

viii. provide authority to NHS Ambulance Trusts to possess and supply controlled drugs to employees (no costs envisaged as proposal provides enabling authority); and

ix. make Midwife Supply Orders patient specific (no costs envisaged as these are clarifying changes to existing mechanism).

E. Appraisal (Costs and Benefits)

GENERAL ASSUMPTIONS & DATA

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

19. *Paramedics*

Number of registered paramedics: 16,930[2]
Average hourly rate: £17 (mid-band: band 5 paramedic)[3]

Percentage assumed to be affected by proposal: 10% (1,693)

20. *Operating Department Practitioners (ODPs)*

Average hourly rate: £11 - £20 (NHS pay bands 5-7 at £21,176 - £40,157 per year)

Average hourly rate for nurses currently requisitioning on behalf of ODPs: £11 - £20 (NHS pay bands 5-7 at £21,176 - £40,157 per year)[4]

21. *Veterinary Surgeons*

Number of practicing veterinary surgeons: 17,418[5]
Percentage affected by proposal: 95% (16,547)[6]

22. *Requisitions (assumptions)*

Time needed to complete a requisition for controlled drugs: 5 to 15 minutes (Average 10)
Cost of requisition form: free (will be made 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)

23. *Veterinary Prescriptions (assumptions)*

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

OPTION 2: Amend the Misuse of Drugs Regulations 2001 (as amended)

COSTS

There are no additional costs associated with provisions i, iii, v, vi, vii, viii and ix.

Provision ii:

24. *Cost to paramedics:*

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

Number of paramedics affected by proposal: 1,693
Average number of requisitions written by a paramedic in a year: 8
Average time used to complete requisition form: 10 minutes

[2] Health Protection Council
[3] College of Paramedics
[4] College of Operating Department Practitioners
[5] Royal College of Veterinary Surgeons
[6] Veterinary Medicines Directorate

Average hourly rate: £17.00 (£2.80 for 10 Minutes)

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

= £38,000[7]

Paramedics currently order controlled drugs using a nonstandard form but are encouraged as best practice to use the freely available requisition forms. The amount of time taken to complete these nonstandard forms is almost equal to the amount of time to be used in completing the new requisition form. The additional cost imposed by the proposal is therefore estimated at only 20% of £38,000, since paramedics are already completing a similar form anyway.

The additional cost is therefore estimated at £7,600 per year.

25. *Cost to operating department practitioners:*

The role of completing requisitions for controlled drugs is currently performed by senior registered nurses (on similar pay bands to ODPs) on behalf of the ODPs. As a result there is a net transfer of costs, and this provision imposes no additional costs.

Provision iv:

26. *Cost to 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.

TOTAL COST:

27. There are no costs expected to be imposed by any of the other provisions. We therefore estimate the total cost of this option as;

Paramedics: £7,600 per year
ODPs: Nil
Veterinary practitioners: Nil

Total cost of option 2: £7,600 per year, giving a net present value of £63,200.

BENEFITS

Non-monetised benefits associated with this option are ongoing and are as follows;

28. The proposed changes (provisions i, iii, vi and viii) will expand the number of healthcare professionals able to perform certain tasks in relation to controlled drugs under the 2001 Regulations, providing greater flexibility to practitioners and healthcare institutions, which will improve the quality of patient care.

[7] (2.80*8)*1,693 = 37923

29. There are also benefits that accrue in relation to data gathering and monitoring arrangements. By setting a minimum framework that enables the acquisition, prescribing and dispensing of these drugs to be monitored, the amendments (provisions ii, iv and vii) to the 2001 Regulations ensure that the public are protected from the harms associated with these drugs. It was perceived by respondents to the public consultation in 2011 that the current lack of provision mandating paramedics and operating department practitioners to provide a requisition when ordering controlled drugs is a barrier to better data collection and therefore effective audits of requisition activity by these professionals.

30. The extension of senior registered nurse authorities in prisons (provision vi) 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. The current situation is not ideal as the doctors who sign for these drugs, and therefore have responsibility, are frequently off site. 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.

31. Imposing stricter requisition requirements (provisions ii and vii) will ensure that the public are protected form dangerous or otherwise harmful drugs. One of the key recommendations of the Shipman enquiry is to ensure that the requisition activities of individual healthcare professionals are recorded and monitored to prevent the diversion, and thus misuse, of the potent drugs involved. This proposal will ensure that the movement of these drugs is effectively monitored to support the control regime and therefore protect the public.

32. Making Midwife Supply Orders patient specific is supported by the Nursing and Midwifery Council (NMC), the professional body which represents midwives. The NMC strongly recommended the proposed change, citing the view that making Midwife Supply Orders patient specific rather than midwife specific "*will allow improved access to pain relieving medicines during labour and for medicines to be in the possession of the "patient" rather than the midwife*".

NET EFFECT

33. Net benefits are ongoing and relate to the clarity and certainty of provisions. Benefits also accrue from the flexibility and access provided relating to controlled drugs which support healthcare professionals in their delivery of patient care. The overall benefit is from improved access to controlled drugs and patient care, within an effective regulatory framework. While the benefit to each patient is expected to be relatively small, the net benefit when accounting for the impact on many thousands of patients over an ongoing period of time could be large. These benefits cannot be quantified as there is currently no data to underpin any calculations. Given the relatively small expected average impact and the complex nature of the data involved, our judgement is that it would not be proportionate to attempt to quantify the impact further. However, costs are also expected to be small and are expected to be outweighed by benefits.

ONE-IN-TWO-OUT (OITO)

34. There are no effects on the private or voluntary sectors associated with this policy. The policy is therefore not in scope of OITO.

F. Risks

OPTION 1: Do nothing

35. There are risks involved with this option. The current provisions under the 2001 Regulations do not provide clarity on certain professionals and the authorities under which they operate when using controlled drugs. The provisions have also fallen behind changes made in the healthcare sector. This can present difficulties for those who need to use provisions under the 2001 Regulations in their work. As a consequence, the risks involved with these dangerous drugs - diversion and misuse - have increased. Amending specific provisions under the 2001 Regulations will provide clarity to professionals and reduce this risk.

OPTION 2: Amend the Misuse of Drugs Regulations 2001 (as amended)

36. There are no risks involved with this option. Amending the current provisions under the 2001 Regulations will ensure that the regulatory framework on controlled drugs is comprehensive, comprehensible, reflects current policy and is 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

37. 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	***Monetised***	***Monetised***
	£0.06m cost to paramedics from completing mandatory requisition forms	N/A
	Non-monetised	***Non-monetised***
	None	Benefits to healthcare institutions and professionals arising from increased flexibility and clarity regarding access to controlled drugs

Option 2 is the preferred option.

38. Option 2 responds to the specific needs of healthcare professionals as a result of changes in the healthcare sector to improve flexibility and thus patient care.

39. The changes under option 2 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 use 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 impose a significant burden over and above what is already in force.

I. Implementation

40. The Government plans to implement these changes in **November 2013**.

J. Monitoring and Evaluation

41. 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. They must also ensure that each area has a process for establishing an incident panel if serious concerns are raised about controlled drugs.

K. Feedback

42. 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

43. None.