Title:

Impact assessment of the scheduling of tramadol, and review of exemptions for temazepam prescriptions, under the Misuse of Drugs Regulations 2001

IA No:

Lead department or agency:
HOME OFFICE

Other departments or agencies:
DEPARTMENT OF HEALTH

Impact Assessment (IA)

Date: 05/07/13

Stage: Consultation

Source of intervention: Domestic

Type of measure: Secondary Legislation

Contact for enquiries:

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Summary: Intervention and Options

RPC Opinion: RPC Opinion Status

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, One-Out?**	**Measure qualifies as**
Unknown	£mNegligible	£mNegligible	No	NA

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

Drugs controlled under the Misuse of Drugs Act 1971 (the 1971 Act) are also scheduled under the Misuse of Drugs Regulations 2001 (as amended) (the 2001 Regulations) to provide lawful access for use in healthcare. The Advisory Council on the Misuse of Drugs (ACMD) recommends that tramadol (an opioid analgesic) should be controlled under the 1971 Act and placed in Schedule 3 to the 2001 Regulations.

Government intervention is necessary to ensure an appropriate regulatory framework exists for drugs that are considered dangerous or otherwise harmful, to prevent their diversion and misuse, whilst at the same time enabling legitimate access for use in healthcare.

What are the policy objectives and the intended effects?

The policy objectives are:

1. to place tramadol in Schedule 3 to the 2001 Regulations; and
2. remove the current exemptions applicable to prescriptions for temazepam

The intended effects are to ensure that the 2001 Regulations provide an appropriate level of control for the prescribing and storage of tramadol and temazepam to prevent their diversion and misuse.

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 tramadol in Schedule 3 (and remove temazepam prescription exemptions)

Option 3 : Place tramadol in Schedule 3 (but exempt from safe custody and prescription requirements)

Option 4 : Place tramadol in Schedule 4 Part 1

Option 2 is the preferred option.

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	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes	
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A		

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: ---------- Date: ----------

Summary: Analysis & Evidence

Policy Option 2

Description: Place tramadol in Schedule 3 and remove temazepam prescription exemptions.

FULL ECONOMIC ASSESSMENT

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				
High				
Best Estimate			Negligible	**Negligible**

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

Relevant costs estimated to be negligible.

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

None

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low				
High				
Best Estimate				**Not Known**

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

None

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

- Public sector benefits from savings to be made through a reduction in the number of people seeking medical attention for misuse of these substances.
- Personal benefits from protection against potential harms from the misuse of these drugs.

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

Prescribers may be reluctant to prescribe or reduce the number of prescriptions for tramadol as a result of the change in legal status. However this is not expected to have any negative consequences for patients.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: Negligible	**Benefits: 0**	**Net: Negligible**	No	NA

Summary: Analysis & Evidence

Policy Option 3

Description: Place tramadol in Schedule 3 but with safe custody and prescribing exemptions

FULL ECONOMIC ASSESSMENT

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

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

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

Relevant costs estimated to be negligible.

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

None.

BENEFITS (£m)	**Total Transition** (Constant Price) Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low			
High			
Best Estimate			**Not Known**

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

None.

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

- Public sector benefits from savings to be made through a reduction in the number of people seeking medical attention for misuse of these substances.
- Personal benefits from protection against potential harms from the misuse of these drugs.

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

Given the current trend, the numbers of prescriptions for tramadol may continue to rise. The risk from diversion and misuse and therefore potential harm to the public will increase.

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:			**In scope of OIOO?**	**Measure qualifies as**
Costs: Negligible	**Benefits: 0**	**Net: Negligible**	No	NA

Summary: Analysis & Evidence

Policy Option 4

Description: Place tramadol in Schedule 4 Part 1

FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low:	**High:**	**Best Estimate:** Not Known

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

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

None.

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

None.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low				
High				
Best Estimate	Negligible		Negligible	**Not Known**

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

None.

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

- Public sector benefits from savings to be made through a reduction in the number of people seeking medical attention for misuse of these substances.
- Personal benefits from protection against potential harms from the misuse of these drugs.

Key assumptions/sensitivities/risks

None.

Discount rate (%)

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	**Benefits:** 0	**Net:** 0	No	NA

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 Background

Tramadol

Tramadol is a synthetic analogue of the phenanthrene alkaloid codeine and is an opioid analgesic of significant medical use for treating moderate to severe pain. It has wide ranging applications, including the treatment of fibromyalgia (chronic widespread pain), cancer pain and moderate to severe musculoskeletal pain.

The ACMD recently completed a review (Advisory Council on the Misuse of Drugs, February 2013)[1] of the harms associated with the non-medicinal use of tramadol. The ACMD's review was prompted by an increasing number of reports within the NHS of tramadol's misuse and harms. The ACMD's subsequent review of the evidence confirmed an increase in Defined Daily Doses (England)[2], from approximately 5.9 million in September 2005 to 11.1 million in September 2012, and an increase in deaths where tramadol is mentioned as a contributory factor (that is, deaths where tramadol is implicated in the death, is mentioned as the sole agent implicated in the death, or where tramadol was implicated but was not prescribed or the route of supply was 'not known'.

On 26th February the ACMD published its advice on tramadol following conclusion of its considerations. The ACMD advises that tramadol should be controlled as a class C substance under the 1971 Act, and listed in Schedule 3 to the 2001 Regulations, which it considers would provide the correct controls to prevent diversion and misuse.

The ACMD report noted "*that in the absence of evidence from clinical practice, the ACMD is unclear whether the prescription requirements associated with Schedule 3 could present further burden for prescribers*." The ACMD therefore recommended that the Home Office should consult with health and social care practitioners on the impact of Schedule 3 (Regulation 15) requirements to ensure any change is proportionate to the harms and risk of diversion outlined in their report. The ACMD report is available at https://www.gov.uk/government/publications/acmd-advice-on-tramadol.

The Minister for Crime Prevention accepted the ACMD advice to control tramadol in principle subject to a public consultation on the impact of Schedule 3 status.

Temazepam

Temazepam is an intermediate-acting psychoactive drug of the benzodiazepine class which is used for its sedative and anxiety-relieving effects. Like many other drugs in the benzodiazepine family, it is also widely misused.

In 1996 Temazepam was rescheduled from Schedule 4 to Schedule 3 under the 2001 Regulations. At the time temazepam was rescheduled, the requirements applicable to the prescription of Schedule 3 drugs had to be hand written. In order to limit the impact on prescribers from rescheduling, National Health Service prescriptions for temazepam were exempted from these requirements. However, private prescriptions for temazepam are still required to be written on a prescription form issued by the relevant PCT (now Commissioning Board) for the purposes of private prescribing.

Subsequent changes to the requirements under Regulation 15 mean that with the exception of a wet signature, all other information on a prescription for temazepam can now be computer generated. In light of the change to computer generated prescriptions and the current ACMD

[1] https://www.gov.uk/government/publications/acmd-advice-on-tramadol

[2] The Defined Daily Doses (DDD) is a measure of prescribing volume maintained by the World Health Organisation (WHO) based upon international prescribing behaviour. It represents the assumed average maintenance dose per day for a drug used for its main indication in adults. The DDD is not a recommended dose but an analytical unit to compare prescribing activity.

advice on tramadol, the Home Office wishes to explore whether the exemption applicable to temazepam prescription is still necessary. The Home Office's assessment is that the exemption is no longer necessary. However, we will like to hear the views of health and social care professionals on the need to maintain or remove the current exemptions.

A.2 Groups Affected

Groups affected by this policy are: healthcare professionals, pharmaceutical manufacturers and wholesalers, and patients.

A.3 Consultation

Within Government

The Home Office has consulted with the Advisory Council on the Misuse of Drugs (ACMD) and the Department of Health.

Public Consultation

N/A

B. Rationale

The misuse of harmful drugs is associated with significant social costs. The misuse of tramadol appears to be increasing: current available evidence confirms an increase in Defined Daily Doses (England), from approximately 5.9 million in September 2005 to 11.1 million in September 2012, and an increase in deaths where tramadol is mentioned as a contributory factor (that is, deaths where tramadol is implicated in the death, is mentioned as the sole agent implicated in the death, or where tramadol was implicated but was not prescribed or the route of supply was 'not known'.

Government intervention is necessary in order to make changes to the legislative framework to prevent diversion and misuse and therefore protect the public from the harms associated with tramadol misuse. These changes cannot be effected through market mechanisms (price, exchange, permits, quotas or some other mechanism that does not involve regulation).

C. Objectives

The policy objective is to ensure tramadol and temazepam are available for use in healthcare under an effective regulatory framework which prevents diversion and misuse.

A successful outcome will be a reduction in the harms from diversion and misuse posed by these drugs to the public.

D. Options

Non-regualtory options do not ensure the effective prevention of abuse of tramadol. Four options have been considered:

Option 1: Do nothing

Option 2: Place tramadol in Schedule 3, and remove temazepam prescription exemptions

Option 3: Place tramadol in Schedule 3, but with safe custody and prescribing exemptions

Option 4: Place tramadol in Schedule 4

The Government's preferred option is Option 2. This option is supported by the ACMD's advice. Placing tramadol in Schedule 3 and removing the current exemptions for temazepam prescriptions with the effect that the full requirements under Regulation 15 of the 2001 Regulations apply to prescriptions

for both drugs provides the best means to reduce the risk of diversion and misuse ,and therefore harm to the public.
(Note: See pages 5 and 6 of the consultation document for the implications of full Schedule 3 status)

E. Appraisal (Costs and Benefits)

GENERAL ASSUMPTIONS & DATA

Assumptions:

1. Organisations which need to store tramadol will be able to accommodate in current available storage space without the need to acquire a new safe compliant with the Misuse of Drugs (Safe Custody) Regulations 1973 in order to store tramadol.

2. All prescribers (NHS and private) use computer generated prescriptions.

3. Costs of new prescription writing pads will be offset by savings from old prescription pads that are no longer needed.

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

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

OPTION 1 – Do nothing

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

OPTION 2 - **Place tramadol in Schedule 3 (and remove temazepam prescription exemptions)**

COSTS

Business

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 Schedules 2 and 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 tramadol.

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 of storage will only arise if a business does not currently have a complaint safe for the storage of Schedule 3 drugs. Pharmacies which currently store tramadol for retail to the public and other businesses that store controlled drugs will already have compliant safes for this purpose. Costs attributable to the time taken to generate a prescription are not expected to be different from those applicable to prescribing tramadol as a Prescription only Medicine (POM).

We assume that almost all businesses which deal in tramadol will not need to buy a new safe as a result of the legislative change and will be able to accommodate stocks of tramadol in current safes. We also assume the cost of writing prescriptions compliant with Schedule 3 to be negligible as all prescribers are assumed to be using computer generated prescriptions. Temazepam is already subject to provisions under the 1973 Regulations. **Total costs to the business as a result of the legislative change will therefore be negligible.**

Public Sector

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

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 of storage will only arise if an NHS organisation does not currently have a complaint safe for the storage of Schedule 3 drugs. Costs attributable to the time taken to generate a prescription are not expected to be different from those applicable to prescribing tramadol as a Prescription only Medicine (POM). NHS organisations and pharmacies which currently store tramadol for NHS activity will already have compliant safes for this purpose. It is not expected that the NHS will incur any extra cost in relation to securing extra storage space for tramadol following legislative change. Temazepam is already subject to provisions under the 1973 Regulations.

Total costs to the public sector as a result of the legislative change will therefore be negligible.

Personal and society

No costs are envisaged for individuals who are legitimately prescribed tramadol and temazepam 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.

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.

Total costs to individuals as a result of the legislative change will therefore be negligible.

BENEFITS

Business

No benefits accrue to businesses from this policy.

Public Sector

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. These savings cannot be readily quantified.

Personal and society

Personal benefits may arise from protection from the potential harms identified with the misuse of these drugs. Society will be protected against possible externalities resulting from people who misuse these. The regulatory framework is expected to reduce the risk from diversion, misuse and therefore harms to the public.

Net Effect

The costs are assumed to be negligible and the benefits are not quantified. However, expert opinion from the ACMD has indicated that there will be an identifiable benefit to the public sector, individuals and society. Therefore, it is assumed that the net effect of this option is positive although the scale of this net benefit cannot be estimated.

ONE-IN-TWO-OUT (OITO)

COSTS (INs)

Business costs are assumed to be negligible.

BENEFITS (OUTs)

No benefits accrue to businesses

NET

The net cost to business is assumed to be negligible.

OPTION 3 - Place tramadol in Schedule 3, but with safe custody and prescribing exemptions

COSTS

Business

Costs to business under this option will arise from application of limited requirements under Regulation 15 of the Misuse of Drugs Regulations 2001. The specific costs relate to the use of a specific form for the private prescribing of tramadol. The costs of the forms to be used will be offset by the saving from those forms replaced.

Public Sector

Potential costs to the public sector will arise from application of provisions under Regulation 15. However, under this option NHS prescriptions for tramadol will be exempt from the requirement to use a specific form for the prescribing of tramadol.

The specific costs under this option will therefore be attributed to the time used to generate and sign a prescription under this option. These costs are envisaged to be minimal and the same as those applicable if tramadol were to be prescribed as a POM.

Personal and society

No costs are envisaged for individuals who are legitimately prescribed tramadol and temazepam 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.

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

No benefits accrue to businesses under this option

Public Sector

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. These savings cannot be readily quantified.

Personal and society

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

Net Effect

The costs are assumed to be negligible and the benefits are not quantified. However, expert opinion from the ACMD has indicated that there will be an identifiable benefit to the public sector, individuals and society. Therefore, it is assumed that the net effect of this option is positive although the scale of this net benefit cannot be estimated.

Whilst Option 3 provides some control to minimise diversion and misuse, controls under Option 2 provide a much better framework for drugs that are considered dangerous or otherwise harmful when misused. Therefore the net benefit of Option 3 is ranked below that of Option 2.

ONE-IN-TWO-OUT (OITO)

COSTS (INs)

None.

BENEFITS (OUTs)

No benefits accrue to businesses under this option.

NET

The net effect for business will be nil.

OPTION 4 - Place tramadol in Schedule 4 Part 1

COSTS

Business

There will be no costs to businesses under this option. Schedule 4 Part 1 status does not attract specific prescription writing or safe storage requirements.

Public Sector

There will be no costs to the public sector under this option. Schedule 4 Part 1 status does not attract specific prescription writing requirements or safe storage.

Personal and society

No costs are envisaged for individuals who are legitimately prescribed tramadol and temazepam for medicinal use. 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

No benefits accrue to businesses under this option.

Public Sector

Benefits accruing to the public sector 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. These savings cannot be readily quantified.

Personal and society

Personal benefits arise from protection from the potential harms identified with the misuse of these drugs. Society will be protected against possible externalities resulting from people who misuse these. The regulatory framework is expected to reduce the risk from diversion, misuse and therefore harms to the public.

Net Effect

The costs are assumed to be negligible and the benefits are not quantified. However, expert opinion from the ACMD has indicated that there will be an identifiable benefit to the public sector, individuals and society. Therefore, it is assumed that the net effect of this option is positive although the scale of this net benefit cannot be estimated.

Whilst Option 4 provides a framework to minimise diversion and misuse, controls under Option 2 provide a much better framework for drugs that are considered dangerous or otherwise harmful when misused. Therefore the net benefit of Option 4 is ranked below that of Option 2.

ONE-IN-TWO-OUT (OITO)

COSTS (INs)

No costs are envisaged for businesses under this option.

BENEFITS (OUTs)

No benefits accrue to businesses under this option

NET

The net effect on businesses is nil.

F. Risks

OPTION 2 – Place tramadol in Schedule 3 and remove temazepam prescription exemptions

1. Prescribers may be reluctant to prescribe or reduce the number of prescriptions for tramadol as a result of the change in legal status. However, this is not expected to have any negative consequences for patients. This risk is therefore assessed as low.

OPTION 3 - Place tramadol in Schedule 3 but with exemptions from safe custody and prescribing requirements

1. Current data shows an increasing trend in tramadol prescriptions (from approximately 5.9 million Defined Daily Doses in September 2005 to 11.1 million in September 2012[3] in England). The numbers of prescriptions for tramadol may continue to rise under this option with the consequence that the risk from diversion and misuse and therefore potential harm to the public will increase.

OPTION 4 – Place tramadol in Schedule 4 Part 1

1. This option will provide the lowest level of regulatory control amongst all three options and there is a risk that under this option prescription numbers for tramadol will continue to rise, again increasing the risk of diversion and misuse and therefore potential harm to the public.

G. Enforcement

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

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

Table H.1 Costs and Benefits		
Option	**Costs**	**Benefits**
2	Negligible	Not quantified
3	Negligible	Not quantified
4	None	Not quantified
Source:		

Option 2 is the preferred option.

The harms associated with the use and misuse of tramadol and temazepam requires government to act through effective legislation to prevent their diversion and misuse, in order to protect the public, whilst enabling legitimate access for use in healthcare. There are benefits to be derived from implementing the proposal through a reduction in the harms and medical needs associated with misuse of these drugs.

Whilst Option 3 provides some control to minimise diversion and misuse, controls under Option 2 provide a much better framework for drugs that are considered dangerous or otherwise harmful when misused.

I. Implementation

The Government plans to implement these changes via a negative resolution in [**January 2014**]

[3] NHS Business Services Authority (NHSBSA)

J. Monitoring and Evaluation

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.

K. Feedback

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

L. Specific Impact Tests

None

Glossary

UK Law: The Schedules

The 2001 Regulations determine in what circumstances it is lawful to possess, supply, produce, export and import controlled drugs. The authorised scope of activity will depend on the schedule to which the controlled drug is assigned. There are five schedules. Schedule 1 contains those drugs that are considered to have little or no therapeutic value and are subjected to the most restrictive control. Schedule 5 contains drugs that are considered to have therapeutic value and are commonly available as over the counter medicines.

Schedule 1

Drugs belonging to this schedule are thought to have no therapeutic value and therefore cannot be lawfully possessed or prescribed. These include LSD, MDMA (ecstasy) and cannabis. Schedule 1 drugs may be used for the purposes of research but a Home Office licence is required.

Schedule 2 & 3

The drugs in these schedules can be prescribed and therefore legally possessed and supplied by pharmacists and doctors. They can also be possessed lawfully by anyone who has a prescription. It is an offence contrary to the 1971 Act to possess any drug belonging to Schedule 2 or 3 without prescription or lawful authority. Examples of schedule 2 drugs are methadone and diamorphine (heroin). Schedule 3 drugs include subutex and most of the barbiturate family.

The difference between Schedule 2 and Schedule 3 drugs is limited to the application of the 2001 Regulations concerning record keeping and storage requirements in respect of schedule 2 drugs.

Schedule 4 (i) & (ii)

Schedule 4 was divided into two parts by the 2001 Regulations [as amended by the Misuse of Drugs (Amendment No. 2) Regulations 2012.

Schedule 4(i) controls most of the benzodiazepines. Schedule 4(i) drugs can only be lawfully possessed under prescription. Otherwise, possession is an offence under the 1971 Act.

Schedule 4(ii) drugs can be possessed as long as they are clearly for personal use. Drugs in this schedule can also be imported or exported for personal use where a person himself carries out that importation or exportation. The most common example of a schedule 4(ii) drug is steroids.

Schedule 5

Schedule 5 drugs are sold over the counter and can be legally possessed without a prescription.

Source: http://www.release.org.uk/drugs-law/uk-law/the-schedules