Title:	Impact Assessment (IA)
Impact assessment of the removal of temazepam prescription exemptions under the Misuse of Drugs Regulations 2001 **IA No:** HO0183 **Lead department or agency:** HOME OFFICE **Other departments or agencies:** DEPARTMENT OF HEALTH	**Date: 19th March 2015** **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary Legislation **Contact for enquiries**: Desmond Niimoi (Telephone: 0207 035 3533) (Desmond.niimoi@Homeoffice.gsi.gov.uk)

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, One-Out?**	**Measure qualifies as**
Unknown	Negligible	Negligible	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.

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 objective is to ensure that there are consistent, clear and appropriate regulations regarding access to temazepam, which prevent its diversion and misuse. This would bring the prescribing requirements for temazepam in line with all other Schedule 3 drugs.

The intended effect is a reduction in the harms from diversion and misuse, as well as greater clarity and consistency in drug regulation.

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 : Remove the temazepam prescription exemptions

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: Lynne Featherstone Date: 20/03/2015

Summary: Analysis & Evidence

Policy Option 2

Description: Remove temazepam prescription exemptions

FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	**High:** N/A	**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	Not Known		Negligible	**Negligible**

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

There are no monetised costs.

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

We assume that a majority of prescribers use computer generated prescriptions, meaning there will be no additional costs to them from changing temazepam's prescription requirements by removing the exemptions currently applicable. An additional wet signature will be required; however we assume the cost of this to be negligible.

Some secondary care providers in the public and private sectors do not use computer generated prescriptions. As a result there will be a marginal increase in costs for this small number of organisations.

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

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

There are no monetised benefits.

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 temazepam.
- Personal benefits from protection against potential harms from the misuse of temazepam.

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

There are two key risks for this option:

- Firstly that we have underestimated the number of medical practitioners who do not use computer generated prescriptions. This would result in a small increase in costs, as marginally more time would be required to complete prescriptions.
- Secondly, that the time taken to complete a wet signature is not negligible as assumed. This risk is ameliorated by current proposals to enable Schedule 2 and 3 drugs to be prescribed electronically.

BUSINESS ASSESSMENT (Option 2)

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

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 Background

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

2. In 1996 temazepam was rescheduled from Schedule 4 to Schedule 3 to the Misuse of Drugs Regulations 2001 (the 2001 Regulations[1]) (for a full description of what the different Schedules entail, see Annex 1). In order to limit the impact on prescribers from rescheduling, National Health Service prescriptions for temazepam were exempted from the additional prescription requirements implied by moving the drug to Schedule 3. These additional requirements are:
   - A wet signature in the prescriber's handwriting.
   - That the prescription specifies the address of the person issuing it.
   - That those prescriptions issued by a dentist identify that the drugs are intended for dental purposes only.
   - That the prescription specifies the dose and total quantity of the drug issued.

   The result of this exemption was that, while temazepam continued to function as a Schedule 3 drug, these prescribing requirements were removed solely for NHS prescriptions.
   Private prescriptions for temazepam are still required to be written on a prescription form issued by the relevant Commissioning Board for the purposes of private prescribing.

3. 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 ACMD advice on tramadol, the Home Office explored whether the exemption applicable to temazepam prescription is still necessary. The public consultation on a removal of the exemptions revealed that the cost impact from such change will be minimal and also that bringing temazepam in line with all other Schedule 3 drugs will provide clarity and consistency for professionals involved in prescribing. The Home Office's assessment, in light of these comments, was that the exemption is no longer warranted or necessary and should be removed. This position was supported by Ministers and the Advisory Council on the Misuse of Drugs.

A.2 Groups Affected

4. Groups affected by this policy are: healthcare professionals (which will include those employed by businesses providing contracted services to the NHS) and patients.

A.3 Consultation

Within Government

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

Public Consultation

6. Proposals to remove the current exemption were included in the public consultation on the classification and scheduling of tramadol. The majority of respondents supported the removal of the current exemptions. Respondents also identified a minor impact on secondary care sector where computer generated prescriptions may not be the norm. However, given the lower numbers of prescriptions for temazepam (compared to when the prescribing exemptions were granted), this impact has been assessed as negligible.

[1] http://www.legislation.gov.uk/uksi/2001/3998/contents/made

B. Rationale

7. 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. These changes cannot be effected through market mechanisms (price, exchange, permits, quotas or some other mechanism that does not involve regulation).

C. Objectives

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

9. A successful outcome will be a reduction in the harms from diversion and misuse posed to the public and greater clarity and consistency in drug regulation.

D. Options

10. Two options have been considered:

    Option 1: Do nothing

    Option 2: Remove temazepam NHS prescription exemptions

11. The Government's preferred option is Option 2. This option is supported by the ACMD's advice. Removing the current exemptions for temazepam prescriptions, with the effect that the full requirements under Regulation 15 of the 2001 Regulations apply to prescriptions, provides the best means to reduce the risk of diversion and misuse, and therefore harm to the public.

E. Appraisal (Costs and Benefits)

GENERAL ASSUMPTIONS & DATA

Assumptions:

12. The overall effect of removing temazepam's exemptions are the following additional requirements when a prescription is being issued:
    - a wet signature in the prescriber's handwriting;
    - that the prescription specifies the address of the person issuing it;
    - that those prescriptions issued by a dentist identify that the drugs are intended for dental purposes only; and
    - that the prescription specifies the dose and total quantity of the drug issued.

    Of these requirements we assume that the time requirement of a wet signature is negligible and that the other requirements can all be easily added using computer generated prescriptions. The assumptions below were tested during the public consultation and were not disputed:
    1. The vast majority of prescribers (NHS and private) use computer generated prescriptions.
    2. New prescription writing pads are anticipated to cost the same as current prescription writing pads, meaning zero net cost.
    3. Electronic prescribing will be replaced by arrangements such as pharmacy pick up of prescriptions from practices.
    4. We assume that the time-requirement of a wet signature is negligible.

(We do not anticipate any extra cost on pharmacies picking up prescriptions as this service is already provided for other medicines. 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

13. There are no additional costs and benefits identified with the option. Temazepam will continue to be prescribed as a Schedule 3 drug with prescribing exemptions for NHS prescriptions. There is the continued elevated risk of diversion due to the less restrictive prescribing requirements in comparison with other Schedule 3 drugs. Additionally, there is the continuing potential for confusion due to temazepam being out of step in terms of regulation with all other Schedule 3 drugs.

OPTION 2 - Remove temazepam NHS prescription exemptions

COSTS

Business

14. 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. As discussed above, the actual effect of this change would be a wet signature and some additional information on the prescription. As the exemption from Schedule 3 requirements for prescribing was only provided for NHS prescriptions, additional costs as a result of this change will only be for NHS prescriptions issued by businesses.

15. The specific costs relating to this reform are as a result of the additional time used in completing a prescription and producing a wet signature. The vast majority of prescribers currently use computer generated prescriptions for both Schedule 3 and temazepam prescriptions in their current format. This means that no additional time will be required to complete prescriptions for these prescribers. The only additional requirement in terms of time for these prescribers will be a wet signature. We assume that the time requirement of a wet signature is negligible; as a result this option has negligible additional costs for businesses.

16. Feedback from the consultation suggests that a minority of secondary care establishments, issuing a relatively small number of temazepam prescriptions, do not use computer generated prescriptions. Given the small number of prescriptions these organisations issue, and the relatively minor difference in time, we assume the impact of this change will be negligible.

17. **Total costs to the business as a result of the legislative change will therefore be negligible.**

Public Sector

18. Potential costs to the public sector will again arise from the application of Regulation 15, which will affect medical practitioners prescribing temazepam.

19. The specific costs as a result of this reform relate to the time used in completing a prescription and the wet signature required to make a prescription compliant under Regulation 15. As discussed above, we do not believe there will be any additional cost in generating a prescription for temazepam once the exemptions are removed as prescriptions will continue to be computer generated. Schedule 3 drug prescriptions do require a wet signature; however we assume the additional cost of this in terms of time to be negligible.

20. Similarly to the costs to businesses, there are also a small number non-computer generated temazepam prescriptions issued by public sector secondary care establishments. The additional cost in completing the prescription is believed to be minor, hence the costs for these establishments are likely to be negligible.

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

Personal and society

22. No costs are envisaged for individuals who are legitimately prescribed 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.

23. 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.

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

BENEFITS

Business

25. No benefits accrue to businesses from this policy.

Public Sector

26. 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 misuse of temazepam. These savings cannot be readily quantified due to a lack of clarity on the difference prescription writing requirements will make to rates of diversion and the link between diversion and the total level of temazepam misuse.

27. Some prescribers may reconsider making temazepam prescriptions in light of the more consistent message on the harm of the drug provided by ending the exemption. This may both reduce the harms of temazepam being mis-prescribed and potentially reduce NHS costs if the alternative medication is cheaper. No attempt has been made to monetise these costs due to uncertainty around how doctors will respond to this change.

Personal and society

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

Net Effect

29. 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 a benefit to the public sector, individuals and society. Therefore, it is believed that the net effect of this option should be positive although the scale of this net benefit cannot be estimated.

ONE-IN-TWO-OUT (OITO)

COSTS (INs)

30. Business costs are assumed to be negligible.

BENEFITS (OUTs)

31. No benefits accrue to businesses

NET

32. The net cost to business is assumed to be negligible.

F. Risks

OPTION 2 – Remove temazepam prescription exemptions

33. There are two key risks for this option:
    - Firstly that we have underestimated the number of medical practitioners who do not use computer generated prescriptions. This would result in a small increase in costs, as marginally more time would be required to complete prescriptions.
    - Secondly, that the time taken to complete a wet signature is not negligible as assumed. This risk is mitigated by current proposals to enable Schedule 2 and 3 drugs to be prescribed electronically.

G. Enforcement

34. 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 continue to enforce import controls by seizing suspected substances at the ports, also as part of their wider import control role.

H. Summary and Recommendations

35. The costs of Option 2 are believed to be negligible, the benefits are believed to be small but have not been quantified. The overall net benefit is therefore believed to be positive.

Option 2 is the preferred option.

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

I. Implementation

37. The Government plans to implement these changes via a negative resolution in **March 2015**.

J. Monitoring and Evaluation

38. 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

39. 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.

Annex 1: UK Law: The Schedules

40. 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

41. 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

42. 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.

43. 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)

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

45. 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.

46. 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

47. 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