Title:	Impact Assessment (IA)
Impact Assessment of the control of lisdexamphetamine, zopiclone and zaleplon **IA No:** HO **Lead department or agency:** HOME OFFICE **Other departments or agencies:** DEPARTMENT OF HEALTH, DEPARTMENT FOR BUSINESS INNOVATIONS AND SKILLS AND LAW ENFORCEMENT AGENCIES	**Date: 07/02/2014** **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Primary legislation **Contact for enquiries:** Desmond Niimoi (desmond.niimoi@homeoffice.gsi.gov.uk) 020 7035 3533

Summary: Intervention and Options

RPC Opinion: Not in scope

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, Two-Out?**	**Measure qualifies as**
N/A	N/A	N/A	No	N/A

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

Lisdexamphetamine, zopiclone and zaleplon are considered sufficiently harmful when misused, following advice from the Advisory Council on the Misuse of Drugs (ACMD), to warrant control measures relating to possession, supply, manufacture and import/exportation with associated criminal sanction.

Government intervention is necessary to help protect the public from the potential harms of these substances whilst ensuring their availability for use in healthcare. For lisdexamphetamine, there is no evidence of abuse yet but the risk of this occurring in future is considered sufficient to warrant control.

What are the policy objectives and the intended effects?

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

The intended effect is to restrict the diversion of these substances from legitimate uses and thereby restrict their misuse.

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 : Control lisdexamphetamine as a Class B and a Schedule 2 drug, and zopiclone and zaleplon as Class C and Schedule 4 Part 1 drugs, under the Misuse of Drugs Act 1971, and the Misuse of Drugs Regulations 2001 respectively.

Option 2 is the preferred option. It provides an appropriate level of control with corresponding criminal sanctions for unlawful possession, production and supply, whilst at the same time enabling access to these drugs for use in healthcare under an effective framework that prevents diversion and misuse.

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

Does implementation go beyond minimum EU requirements?			N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** No	**< 20** No	**Small** No	**Medium** No	**Large** No
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** 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: Norman Baker Date: 26 February 2014

Summary: Analysis & Evidence

Policy Option 2

Description:

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:** N/A

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	N/A		N/A	**N/A**

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

There are no monetised costs associated with this policy.

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

This policy is not expected to produce any new costs for businesses, the public sector or individuals, as these drugs are already being controlled to some degree.

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	N/A		N/A	**N/A**

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

There are no monetised benefits associated with this policy.

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

Stricter control of these drugs is expected to reduce the risk of crime and health harms faced by the public sector and individuals. We are not able to monetise this benefit.

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

There is a risk that the control of these substances will lead to new, uncontrolled substances appearing on the market. This risk is mitigated by the ACMD's continual review of the situation regarding both controlled and non-controlled 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

A.1a – Lisdexamphetamine (from 2013 AMCD report[1])

1. Lisdexamphetamine, an inactive pro-drug (a drug which converts to another in its active form) of the Class B and Schedule 2 controlled drug dexamphetamine, was introduced to the UK market in March 2013. It is prescribed by specialists as a second line treatment (when the patient does not respond to basic treatment) for attention deficit hyperactivity disorder (ADHD) in adults. When administered orally, lisdexamphetamine gradually converts to dexamphetamine, the Class B drug. The ACMD's view is that with some basic knowledge, lisdexamphetamine can also be converted into amphetamine prior to administration using very basic techniques.

2. The Home Office and the Advisory Council on the Misuse of Drugs (ACMD), the Government's statutory advisory body on drug issues, became aware of the introduction of lisdexamphetamine immediately prior to the grant of a marketing authorisation by the Medicines and Healthcare products Regulatory Agency (MHRA). Schedule 2 drugs are considered to be very dangerous and are therefore subject to a strict regime around prescribing, storage and destruction. In the absence of control, the Home Office in conjunction with the Royal Pharmaceutical Society issued guidance to pharmacists to treat the drug as a Schedule 2 drug until controlled. The manufacturers, as part of the grant of the marketing authorisation, also undertook to treat the drug as a Schedule 2 drug in the supply chain. These arrangements are currently extant and the drug is being treated as Schedule 2 by both manufacturers and retailers.

3. The ACMD reports that lisdexamphetamine has the potential to exert the physical harms (listed below) and social harms (resulting from drug dependence) associated with amphetamines as a class although there may be some differences. Physical effects can include anorexia, insomnia, dizziness, headaches, tachycardia and hypertension. After chronic and/or high doses convulsions, heart attacks, stroke and death have been reported. The ACMD recommends that lisdexamphetamine should be controlled as a Class B and Schedule 2 drug under the Misuse of Drugs Act 1971 (the 1971 Act) and the Misuse of Drugs Regulations 2001 (as amended) (the 2001 Regulations) respectively.

A.1b – Zopiclone and Zaleplon (from 2013 ACMD report[2])

4. Zoplicone and zaleplon ('Z-drugs') are sedatives closely related to the benzodiazepine family of drugs and zolpidem, a Class C and Schedule 4 Part 1 drug. The ACMD reports that the number of prescriptions for the Z-drugs has been on the increase as compared to prescriptions for benzodiazepines – controlled as Class C and listed in Schedule 3 or 4 to the 2001 Regulations. The status of the non-controlled Z-drugs is considered an anomaly.

5. The ACMD reports the harms from Z-drug misuse to include a risk of coma, respiratory depression and death associated with use of excess doses of Z-drugs in combination with alcohol or other Central Nervous System (CNS) depressants. Other reported psychosocial effects include depressed mental activity and alertness, memory loss and amnesia and personality and mood changes through drowsiness, lethargy, disinhibition, chronic paranoid behaviour and aggression. Data from the National Program on Substance Abuse Deaths (npSAD) also suggests Z-drugs play a minor role in drug related deaths in the UK, mainly in combination with other CNS depressants, and principally implicated in episodes of intentional poisoning.

[1] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/237035/ACMD_advice_Lisdexamfetamine.pdf

[2] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/237037/ACMD_advice_Z_drugs.pdf

6. The ACMD report concludes that due to the similarities in chemical structure and effects of the Z-drugs and benzodiazepines, the potential social harm from the misuse of zopiclone and zaleplon would be similar to the social harms associated with the misuse of zolpidem and the benzodiazepines. The ACMD therefore recommends that zopiclone and zaleplon should be controlled as Class C and Schedule 4 Part 1 drugs under the 1971 Act and the 2001 Regulations respectively[3].

A.2 Groups Affected

7. Groups affected are healthcare professionals, patients, pharmaceutical manufacturers and wholesalers, misusers of these substances and the health sector.

A.3 Consultation

Within Government

8. The ACMD and the Department of Health have been consulted.

Public Consultation

9. A formal public consultation has not taken place. However, the views of healthcare professionals and the concerns they raised around the availability, likely risk of misuse and the risks associated with misuse of the drugs being controlled were taken into consideration.

B. Rationale

10. The misuse of drugs imposes a high cost on society in terms of crime and health services. Consumption also imposes health costs on the users themselves. The market does not take into account the costs that misuse of these drugs imposes on society. Government intervention is therefore necessary to prevent the listed compounds from being diverted from legitimate use and to protect the public from their harmful effects.

C. Objectives

11. The measure to control lisdexamphetamine, zopiclone and zaleplon is aimed at supporting the overarching aim of UK drugs laws - to protect individuals and society from the harmful effects of dangerous or otherwise harmful drugs. Lisdexamphetamine, zopiclone and zaleplon present a risk of dependence and misuse.

12. Successful outcomes would be a reduction in the risk of diversion of these substances from legitimate users and a reduction in their misuse and associated harms.

D. Options

13. Non-regulatory options have been considered but are not appropriate in this case. The ACMD considerations include whether or not these drugs pose a threat or harm to the public. Their assessment is that these drugs are likely to be misused and that such misuse is causing or likely to cause social harm. This is the statutory threshold for control. Education will be employed alongside control to help prevent the abuse of these drugs.

14. Two options have been considered:

Option 1: to make no changes (do nothing).

[3] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/237037/ACMD_advice_Z_drugs.pdf

15. This option is not acceptable to Government nor was it supported by ACMD advice. The UK Government would not be acting to protect the public from the potential harms associated with the diversion and misuse of these substances if this option is adopted.

<u>Option 2:</u> to control lisdexamphetamine as a Class B drug and a Schedule 2 drug, and zopiclone and zaleplon as Class C and Schedule 4 Part 1 drugs, under the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001 respectively.

16. Option 2 is the Government's preferred option, and is supported by the ACMD's advice. Controlling these drugs in the manner proposed provides the best means to reduce the risk of diversion and misuse, and therefore harm to the public. Unlawful possession, supply and production of the drugs will attract criminal penalties. Their continued availability in appropriate settings (such as medicine and research) will also ensure the safe provision of medicines to patients through an effective regulatory and governance framework.

E. Appraisal (Costs and Benefits)

General assumptions:

- Lisdexamphetamine will be prescribed mainly by National Health Service as a treatment for ADHD.
- The quantities of lisdexamphetamine stored and dispensed or used are very low and can be accommodated in current storage facilities.
- The vast majority of prescriptions, if not all, for lisdexamphetamine will be computer generated.

<u>OPTION 2</u> – to control and schedule lisdexamphetamine, zopiclone and zaleplon

COSTS

<u>Business</u>

17. As a Schedule 2 drug all prescriptions for lisdexamphetamine have to comply with regulation 15 of the Misuse of Drugs Regulations 2001, which sets out the information to be provided on such prescriptions. With the exception of a wet signature, all other requirements on a prescription for lisdexamphetamine can be computer generated. The impact from prescribing is therefore limited to the time used to sign a prescription by the prescriber. Following the issuance of the guidance to treat lisdexamphetamine as a Schedule 2 drug these requirements are already being applied to its prescription. There are therefore no new costs imposed from requiring a signature for lisdexamphetamine prescriptions.

18. Zopiclone and zaleplon are already prescription only medicines and will remain so following control. There are no specific requirements to be added to their prescription following control, and therefore no new costs will be imposed by their control.

19. As a Schedule 2 drug, stocks of lisdexamphetamine have to be stored in safes compliant with the Misuse of Drugs (Safe Custody) Regulations 1973. The low quantities prescribed[4] mean that these stocks can be accommodated in safes currently used by pharmacies. No further costs are envisaged for wholesalers or pharmacies when lisdexamphetamine is controlled. In addition, stocks of lisdexamphetamine are already being kept as Schedule 2 drugs and in compliant safes.

20. Manufacturers require licences to produce, possess and supply scheduled drugs. However, the manufacturers of these drugs will already be in possession of the requisite Home Office licence[5]

[4] The marketing authorisation for lisdexamphetamine is only for second line treatment, meaning that only consultants are able to prescribe it.

[5] Our records confirm that all manufacturers of these drugs already possess Home Office licences.

for the other drugs within these schedules. This measure therefore imposes no new licensing costs.

Public Sector (health sector, enforcement agencies, CJS, regulators)

21. The law enforcement response to this measure would involve using intelligence to tackle supply and trade and disrupting criminal activities relating to these drugs. Since these activities are currently used to tackle other controlled drugs, any costs arising from option 2 will be subsumed into current law enforcement and regulatory activities. The law enforcement response will be managed within existing resources, informed by policy and operational prioritisation. The police and other law enforcement agencies will prioritise resources towards tackling crime, including drug related crime, with a focus on those offences which cause the most harm. As such, operational activity may focus on Class A and B drugs as well as new psychoactive substances.

22. No new costs are expected to be faced by the public sector in relation to prescribing and storing lisdexamphetamine or z-drugs, as outlined under costs to business.

Individuals and society

23. No private costs will be incurred by people who currently use lisdexamphetamine, zopiclone and zaleplon as these drugs are already prescription only medicines and will continue to be available under medical prescription.

BENEFITS

Business

24. No benefits are expected to accrue to business from this policy.

Public Sector (enforcement agencies, CJS, regulators)

25. 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. These savings cannot be quantified due to the novelty of the substances in relation to long-term/chronic use and the novelty of the challenges that they pose to healthcare and treatment services in light of the harms that they can cause.

26. Benefits will also accrue from the improved audit trail applicable to lisdexamphetamine as a Schedule 2 drug. All stocks and supplies of Schedule 2 drugs must be recorded in a controlled drugs register and destruction witnessed. This means the risk of diversion from legitimate uses and therefore misuse is significantly reduced. This will reduce the risk of harm to the public. This reduction in harm cannot be quantified.

Individuals and society

27. Private benefits arise from the protection against potential harms from the misuse of lisdexamphetamine and z-drugs. Society will be protected against possible social harms (including crime and health service costs) resulting from people who misuse these drugs.

ONE-IN-TWO-OUT (OITO)

28. This proposal does not create new regulationI. It is adding new drugs to an existing regulatory framework. This policy is therefore not in scope of one-in-two-out.

F. Risks

OPTION 2 – to control and schedule lisdexamphetamine, zopiclone and zaleplon

29. There is a risk that the control of these substances will lead to new, uncontrolled substances appearing on the market. This risk is mitigated by the ACMD's continual review of the situation regarding both controlled and non-controlled drugs.

G. Enforcement

30. 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	This policy is expected to impose some limited costs on practitioners who will have to sign medical prescriptions and on law enforcement agencies from enforcing these measures. These costs have not been monetised due to a lack of available data.	Stricter control of these drugs is expected to reduce the risk of crime and health harms faced by the public sector and individuals. We are not able to monetise this benefit.

31. The harms associated with the use and misuse of lisdexamphetamine, zopiclone and zaleplon 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. These are thought to outweigh the costs.

32. Therefore Option 2 is recommended as it meets our objectives and has the highest value to society.

I. Implementation

33. The Government plans to implement these changes via an Affirmative Order and a negative instrument in May 2014 subject to Parliamentary approval.

J. Monitoring and Evaluation

34. 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. We will monitor prescribing figures in comparison to those prior to control. 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 will analyse prescribing practices within their area and ensure their areas have processes for establishing an incident panel if serious concerns are raised about overprescribing or diversion of controlled drugs. The ACMD has a statutory duty to continually monitor and review drugs that are controlled under the 1971 Act and new drugs that have the potential to cause harm. A policy review is dependent on the ACMD providing further advice to Government- it is therefore not possible to set a review date.

K. Feedback

35. This will be fed back into future ACMD considerations to inform advice, for instance on rescheduling or reclassification to address any further risks identified.