Title:

Control of AH-7921, LSD related compounds and extension of generic definition for the tryptamines

IA No:

Lead department or agency:

Home Office

Other departments or agencies:

DEPARTMENT OF HEALTH, DEPARTMENT FOR BUSINESS, INNOVATION AND SKILLS AND LAW ENFORCEMENT AGENCIES

Impact Assessment (IA)

Date: 07/07/2014

Stage: Final

Source of intervention: Domestic

Type of measure: Secondary legislation

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Summary: Intervention and Options

RPC Opinion: Not Applicable

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/K	N/K	N/K	No	N/A

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

AH-7921, the LSD related compounds – ALD-52, ETH-ALD, PRO-LAD, AL-ALD and LSZ – and the compounds captured by the extended generic definition for the tryptamines are drugs that are used recreationally and used in research. A number of these substances are currently advertised as new psychoactive substances. These compounds have been assessed by the Advisory Council on the Misuse of Drugs (ACMD) as harmful and therefore warranting permanent control. Government intervention is necessary to take immediate action on these compounds, in order to protect the public from their immediate harms.

What are the policy objectives and the intended effects?

The policy objective is to reduce the harms caused by these drugs.

This will be achieved by curbing availability and enabling law enforcement agencies to take appropriate action to tackle the unauthorised activities of production, supply and import/exportation and possession relating to these substances, and to deter 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 – Permanently control, and schedule, AH-7921, the LSD related compounds and extend the generic definition for the tryptamines under the Misuse of Drugs Act 1971.

Option 2 is the preferred option on the basis of the current evidence and the ACMD's advice these compounds.

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

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 Minister for Crime Prevention Lynne Featherstone Date: 6/11/2014

Summary: Analysis & Evidence

Policy Option 2

Description: Control AH-7921, LSD related compounds, and extend tryptamine generic definition.

FULL ECONOMIC ASSESSMENT

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

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

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

We have not been able to monetise any of the costs associated with this policy.

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

This policy is expected to impose costs on those businesses that are no longer able to legitimately sell AH-7921, the LSD related compounds – ALD-52, ETH-ALD, PRO-LAD, AL-ALD and LSZ – and the additional tryptamines, and those individuals who are no longer able to consume these substances.

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

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

We have not been able to monetise any of the benefits associated with this policy.

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

This policy is expected to reduce costs to the public sector resulting from crime and health harms associated with these substances, and will protect individuals from the harms associated with these substances.

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. There is also a risk that an illicit trade in these drugs will arise and bring with it associated costs.

BUSINESS ASSESSMENT (Option 1)

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

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 Background

A.1.a AH-7921 (from 2014 ACMD Report[1])

1. AH-7921 (synonym "doxylam") is a potent synthetic analgesic developed by Allen & Hanburys' pharmaceutical company in the UK more than 40 years ago. The compound was not developed further, presumably because animal studies revealed a high addictive potential. The synthetic drug has recently become available as a legal product; it was first detected in Europe in July 2012 (EMCDDA, 2014). Since then a number drug-related deaths have been reported, detailed in the EMCDDA/Europol report published in 2014[2].

2. The Advisory Council on the Misuse of Drugs (ACMD) reports that AH-7921 has potency similar to morphine and is highly addictive. Harms from AH-7921 misuse are reported as severe pain, difficulty in breathing and risk of death.

3. The ACMD reports that it is not aware of any acute toxicity reports in the UK. However, in 2013 the National Programme on Substance Abuse Deaths reported three deaths involving AH-7921. The EMCDDA/Europol report also confirmed ten deaths linked with AH-7921 across the EU. The ACMD did not find any uses for this compound other than recreational consumption and research.

4. Following consultation with the Department for Business, Innovation and Skills (BIS), the Medicines and Healthcare products Regulatory Agency (MHRA) and the chemical and pharmaceutical industry, AH-7921 was identified as having no legitimate industrial or medicinal use. The MHRA also confirmed that there are no marketing authorisations for medicines containing these compounds. The drugs are mainly sold for consumption online and in some headshops. They are usually mixed with other products and sold using brand names, so it is difficult to estimate the size of the market,

5. For these reasons, the ACMD recommends that AH-7921 should be brought under the control of the 1971 Act as a Class A drug and listed in Schedule 1 to the Misuse of Drugs Regulations 2001 as a drug with no recognised medicinal uses. This will mean it will be illegal to produce, possess, supply import or export unless under a Home Office licence for research or other special purpose.

A.1.b Tryptamines and LSD related compounds (from 2014 ACMD Report[3])

6. The tryptamines are hallucinogens, a large number of which are currently controlled under the 1971 Act as Class A drugs via generic (group) definition. The ACMD reports that in recent years there has been significant interest in hallucinogens of this type. A number of these substances which fall outside of the current generic definition are offered for sale as new psychoactive substances. Two in particular, alpha-methyl tryptamine (AMT) and 5-methoxy daillyltryptamine (5-MeO DALT) have been routinely encountered through the Home Office's Forensic Early Warning System.

7. The named LSD related compounds which are currently not controlled under the 1971 Act have similar effects to LSD. These substances are also hallucinogenic and have been offered for sale on specialist websites devoted to hallucinogens.

8. The physical effects of these substances are reported as visual illusion, hallucination and euphoria amongst others. The ACMD also reports a small number of confirmed post mortem toxicology

[1] https://www.gov.uk/government/publications/nps-report-ah-7921

[2] http://www.emcdda.europa.eu/publications/joint-report/AH-7921

[3] https://www.gov.uk/government/publications/nps-reports-on-tryptamines-and-ah-7921

reports rising from 1 in 2009 to 4 in 2013[4], with AMT being the most frequently linked to reported tryptamine deaths.

9. Following consultation with the Department for Business, Innovation and Skills (BIS), the Medicines and Healthcare products Regulatory Agency (MHRA) and the chemical and pharmaceutical industry, the additional tryptamines and listed LSD related compounds were identified as having no legitimate industrial or medicinal uses. The MHRA also confirmed that there are no marketing authorisations for medicines containing these compounds. The drugs are mainly sold for consumption online and in some headshops. They are usually mixed with other products and sold using brand names, so it is difficult to estimate the size of the market.

10. For these reasons the ACMD recommends that the tryptamine generic definition under the 1971 Act should be extended to capture compounds that currently evade control. The ACMD recommends that these compounds, and the named LSD related compounds, should be brought under the control of the 1971 Act as Class A drugs and listed in Schedule 1 to the Misuse of Drugs Regulations 2001 as a drug with no recognised medicinal uses. This will mean it will be illegal to produce, possess, supply import or export unless under a Home Office licence for research or other special purpose.

A.2 Groups Affected

11. The 'legal high' market ('head shops' and internet suppliers) selling these substances as 'legal high' branded products, UK law enforcement agencies and criminal justice system and members of the public, especially young people and young adults.

A.3 Consultation

Within Government

12. The Home Office has consulted with the MHRA, BIS and the chemical/pharmaceutical industry.

Public Consultation

13. The Government has considered the recommendations of the ACMD.

B. Rationale

14. The misuse of drugs, including new psychoactive substances or so called "legal highs", imposes a high cost on society in terms of crime and health services. Consumption also imposes health costs on the users themselves. The substances being controlled have been assessed as dangerous or otherwise harmful and are not known to be used other than in recreational consumption and research. 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 taking a foothold in the UK and to protect the public from their harmful effects.

C. Objectives

15. The policy objective is to reduce the risk of harm from new psychoactive substances in support of the Government's commitments. This is in line with the Government's overarching Drug Strategy to take a preventative, enforcement and recovery-based approach to drug-related issues supported by the available evidence and expert advice of the ACMD.

16. The measure is also an essential intervention to deliver the objectives of the cross government NPS Action Plan, published on 17 May 2012, which combines legislative measures alongside public health, prevention and international policy approaches to tackle new psychoactive substances.

[4] https://www.gov.uk/government/publications/nps-reports-on-tryptamines-and-ah-7921

17. A successful outcome will be a reduction in the harms caused by these compounds and increased awareness of the harms of new psychoactive substances or so called “legal highs”.

D. Options

18. Two options have been considered in respect of these substances:

    OPTION 1: Do nothing

    OPTION 2: Control and schedule AH-7921, the named LSD related compounds and extend the generic definition for the tryptamines under the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001.

19. The Government’s preferred option is **option 2** and is supported by the ACMD’s further advice. The use of the 1971 Act and its Regulations to permanently control the listed substances provides the best means to reduce availability and potential harm to the public.

E. Appraisal (Costs and Benefits)

OPTION 2 – To control and schedule AH-7921, the named LSD related compounds and extend the generic definition for the tryptamines.

COSTS

Business

20. A ban would impose costs on businesses by preventing them from profiting from legitimate trade in these substances. In order to monetise the impact we would need an idea of the amount of these drugs that is sold and the price at which it is sold. However, neither are available as the substances that are being controlled are usually mixed with other products and sold using brand names, often from outside UK jurisdiction. As such, it is not possible to make a robust estimate of the cost this measure will impose on businesses. The level of research that would be required to obtain the necessary data is considered disproportionate for this appraisal.

21. There is a possibility that the control of these substances will lead to substitutes being developed and appearing on the market. If this is the case, this measure may not impose substantial costs on businesses due to substitution.

22. Following consultation with BIS, the MHRA and the chemical and pharmaceutical industry, these compounds and related substances have been identified as having no legitimate industrial or medicinal use.

Public Sector (enforcement agencies, CJS, regulators)

23. The law enforcement response to this measure would involve using intelligence to tackle supply and trade and disrupting criminal activities relating to these drugs. Some of these activities can be performed alongside that for other controlled drugs. Any increase in these activities would impose costs on law enforcement, drawing resources away from other areas.

Individuals and society

24. Private costs will be incurred by people who can no longer derive benefits from legitimate use of AH-7921, the LSD related compounds and additional tryptamine compounds and their related substances. We are unable to monetise these costs.

BENEFITS

Business

25. No benefits are expected to accrue to businesses from this policy.

Public Sector (enforcement agencies, CJS, regulators)

26. The ACMD regards that the misuse of these substances is having, or is capable of having, harmful effects. As such, we assume that their misuse would impose costs on the health service and that controlling their consumption would result in savings. It has previously been estimated that the average cost to the NHS of an inpatient bed day due is £321 for drug-related mental and behavioural disorders and £723 for drug overdoses[5]. However, these savings cannot be fully monetised as we are not able to estimate the extent to which control of these substances would reduce the number of incidences of misuse.

Individuals and society

27. Benefits to individuals arise from the protection against potential harms of the listed substances, including the risk of death. In 2013 the National Programme on Substance Abuse Deaths reported three deaths involving AH-7921. The ACMD reported four deaths in 2013 where tryptamines were named in post mortem toxicology reports. It has previously been estimated that the average cost of a death due to drug misuse is £1.6m[6]. This comprises the reduction in quality-adjusted life years and the output lost, along with some health costs. However, these benefits cannot be fully monetised as we are not able to estimate the extent to which control of these substances would reduce the number of associated deaths.

28. Any reduction in crime that the ban causes will also reduce the costs of crime to society.

NET EFFECT

29. Overall it is considered that the benefits from the proposals will outweigh the costs, although it has not been possible to quantify the net effect. While the permanent control of these substances will impose costs on businesses seeking to sell them, restricting their misuse is expected to protect society from the harmful effects that they may have on health. This will result in benefits to public health and in public sector savings from reduced healthcare costs.

30. The total net benefits cannot be quantified due to a lack of robust data but are believed to outweigh the costs. The Home Office will be seeking more evidence in general on the costs and benefits of new psychoactive substances during an upcoming review.

ONE-IN-TWO-OUT (OITO)

31. This proposal does not create new regulation - rather, it is adding new drugs to an existing regulatory framework. This policy is therefore not in scope of one-in-two-out.

F. Risks

32. There are risks associated with option 2 on the basis of evidence and expert advice that the 'legal high' market will look to synthesise and advertise chemical derivatives of some of these or other controlled drugs, or alternative new psychoactive substances imitating their effects, to circumvent the control measures being implemented.

33. This risk is mitigated by the ACMD, which has a duty to review the situation in relation to both controlled and non-controlled drugs (including new psychoactive substances) and temporary class drugs.

[5] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/246390/horr73.pdf

[6] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/246390/horr73.pdf

34. There is a risk that there may be costs to the research sector. However, most relevant research organisations are likely to already possess a Schedule 1 licence. The cost of a licence is between £3,000 and £4,700[7]. In the unlikely event that a licence would be required for research into these drugs, the maximum cost imposed on any research organisation would be £4,700.

35. There is a limited risk that voluntary, charity or private sector research organisations or institutions (manufacturers, distributors and wholesalers that produce, supply, import or export these substances or use them for the synthesis of non-controlled pharmaceuticals) may face the costs of updating or applying for a license. However, organisations dealing with permanently controlled scheduled drugs are assumed to already possess a licence in order to undertake activities involving controlled drugs.

36. There is also a risk that an illicit trade in these drugs will arise and bring with it the associated harms.

G. Enforcement

37. Enforcement of the proposed legislation will be undertaken by police forces, the UK Border Force (UKBF), the Home Office Drug Licensing Unit and other relevant agencies responsible for enforcing the legislative and regulatory framework for controlled drugs in the UK. Police enforcement will form part of their wider approach to tackling new psychoactive substances as well as other drug controlled under the 1971 Act. The UKBF will enforce import controls by seizing suspected substances at the ports, also as part of their wider customs 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	Non-monetised costs to businesses and individuals who are no longer able to legitimately sell or purchase these substances.	Non-monetised benefits to the public sector from reduced health and crime costs associated with the use of these substances.

38. Option 2 is the preferred option. The harms associated with the use or misuse of these compounds require Government to act swiftly through effective legislation to protect the public. There are benefits to be derived from implementing the proposal through a reduction in medical costs associated with the misuse of these drugs.

I. Implementation

39. The Government plans to implement these changes via an affirmative resolution Order, and subject to Parliamentary approval in winter 2014.

J. Monitoring and Evaluation

40. As part of its statutory duties under the 1971 Act the ACMD keeps the situation relating to drugs under review. Together with the Government, they will continue to monitor the compounds being controlled by gathering data on their prevalence and misuse through UK and EU drugs early warning systems, the health sector and the regulatory framework governing legitimate activities (predominantly research) in relation to these drugs. The Home Office, as the regulatory authority on licensing of activities relating to

[7] https://www.gov.uk/controlled-drugs-licences-fees-and-returns#licence-fees

all controlled drugs and as lead department working with other Government departments to deliver the Drug Strategy, will continue to monitor the situation in relation to compliance with the regulatory framework.

K. Feedback

41. Information gathered from the monitoring and evaluation process will inform future ACMD advice on classification/reclassification and rescheduling as well as health advice on these drugs.

Appendix 1: Specific Impact Tests

Preferred option 2: Small and Micro Business Assessment

1. The preferred option is to permanently control, and schedule, AH-7921, the LSD related compounds and extend the generic definition for the tryptamines under the Misuse of Drugs Act 1971.

2. The majority head shops and internet suppliers selling these substances are expected to have less than ten employees. While there are no robust estimates of the number of these shops, it is likely to be under 1,000[8].

3. It is not known how many head shops are small or micro, but it is considered that the proportion would be high. We do not propose to exempt small or micro-businesses from these controls. This is because any variation of regulatory controls to different sizes of businesses would be counter productive, undermining the objectives of this policy and the credibility of the regulatory regime.

[8] One estimate put the total at 250, though this is likely to be an underestimate: http://www.prnewswire.co.uk/news-releases/over-250-headshops-in-uk-are-selling-legal-highs-says-angelus-foundation-232476221.html