Title:
Control of MT-45 AND 4,4'-DMAR

IA No: HO0172

Lead department or agency:
Home Office

Other departments or agencies:
DEPARTMENT OF HEALTH, DEPARTMENT FOR BUSINESS, INNOVATION AND SKILLS, LAW ENFORCEMENT AND CRIMINAL JUSTICE AGENCIES

Impact Assessment (IA)

Date: 12/12/2014

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?

MT-45 and 4,4'-DMAR are drugs that are used recreationally. They currently have no legitimate medical purpose, although could potentially be used for research.
These new psychoactive substances are currently advertised for sale, mainly online, as legal alternatives to controlled drugs. The potential harms of these substances have been assessed by the Advisory Council on the Misuse of Drugs (ACMD) as sufficient to warrant their permanent (Class A) control under the Misuse of Drugs Act 1971 and listed under Schedule 1 of the Misuse of Drugs Regulations (2001). Government intervention is necessary to take immediate action to protect the public from the potential harms of these drugs.

What are the policy objectives and the intended effects?

The policy objective is to reduce the risk of harms from misuse of these substances in the UK.

This will be achieved by curbing availability and enabling law enforcement agencies to take appropriate action against the unauthorised activities of production, possession, supply, importation and exportation of these substances, and to deter their 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 – Permanent control, designation and scheduling of MT-45 and 4,4'-DMAR under the Misuse of Drugs Act 1971 and its subordinate legislation.

Option 2 is the preferred option on the basis of the ACMD's assessment of evidence on harms and advice to control these substances.

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: 15/12/2014

Summary: Analysis & Evidence

Policy Option 2

Description: Permanent control, designation and scheduling of MT-45 and 4,4'-DMAR under the Misuse of Drugs Act 1971 and its subordinate legislation.

FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	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 economic or financial benefits associated with this policy option, due to a lack of information concerning the current use and availability of either of these drugs.

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

This option is expected to impose costs, through compliance, to (mainly online) UK-based businesses previously advertising either substance for sale as a legal alternative to controlled drugs. These costs cannot be quantified but are expected to be minimal, and limited to 4,4'-DMAR, in the absence of any recognised legitimate uses in the UK and EU beyond the research sector.

In the public sector law enforcement, criminal justice and regulatory agencies may incur minimal costs in the implementation of this option, although these are expected to be minimal and subsumed within existing budgets for drugs subject to similar levels of control. We have not been able to identify any other non-monetised costs associated with this option.

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 benefits associated with this policy option, due to a lack of information concerning the current use and availability of either of these drugs.

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

This policy is expected to reduce any costs to the public sector – including health and emergency services – that would be incurred from the potential health and social harms of these substances if they became more widely available. It will help to support prevention messages, add consistency in the legislative approach to similar drugs and protect the public from the related harms and associated costs.

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

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, as well as UK and international drugs early warning systems to monitor the emergence and prevalence of new psychoactive substances which has informed this policy. There is also a risk that an illicit trade in the two drugs may 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 MT-45 (from 2014 ACMD Report[1])

1. MT-45 is a potent synthetic opioid. Its international (chemical) name is 1-cyclohexyl-4-(1,2-diphenylethyl)piperazine. It was developed by the Japanese company Dainippon Pharmaceutical Co. Ltd in the 1970s. The substance is structurally similar to the controlled Class B drug lefetamine, but its potency is similar to that of Class A drug morphine.

2. Like other opioids, MT-45 has the ability to suppress respiratory function. It has been reported in other EU countries, including as a cause of, or contributory factor in 28 deaths in Sweden in 2013 and 2014, and two in the USA in August 2013. The Advisory Council on the Misuse of Drugs (ACMD) has not seen evidence suggesting that MT-45 is available in the UK. However, it recommends its control as a Class A drug alongside other opioids under the Misuse of Drugs Act 1971 on the basis of its harm potential and to prevent it from being advertised as a legal alternative to banned opioids in the UK.

3. The ACMD advises that the health and social harms associated with opioids like MT-45 include the risks of misuse and addiction, with associated risks of social harms including acquisitive crime, family and social breakdown, respiratory depression and death. In Sweden MT-45 was further linked to 18 non-fatal intoxications requiring hospital treatment for life-threatening symptoms including coma and respiratory depression, as well as loss of hearing. These are also reported in the joint European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)/Europol joint report 2014[2] on MT-45. MT-45 was further subject to a risk assessment by the EMCDDA in 2014[3] in relation to control in the EU.

A.1.b 4,4'-DMAR (from 2014 ACMD Report[4])

4. 4,4'-DMAR is a new psychoactive substance with stimulant properties and advertised for sale, often under the name Serotoni, as a legal alternative to banned drugs. Its international (chemical) name is 4-methyl-5-(4-methylphenyl)-4,5-dihydrooxazol-2-amine. The substance is structurally similar to the controlled Class C and A drugs aminorex and (related) 4-MAR, respectively. The ACMD recommends that, due to the risk of serious health harm including death caused by, or partly precipitated by 4,4'-DMAR toxicity, this substance become a controlled Class A drug.

5. 4,4'-DMAR was first reported to the EU by the Netherlands in December 2012. Its availability in tablet and powder form has been detected in a number of EU countries including the UK (in Scotland and Northern Ireland), sometimes alongside other new psychoactive substances including synthetic cannabinoids in smoking mixtures. There have been reports of health harms of 4,4'-DMAR including agitation, convulsions and hyperthermia prior to deaths. In 2013 and 2014 the EU has received 46 reports on fatalities – including from the UK (mainly in Northern Ireland) where 4,4'-DMAR intoxication

[1] ACMD Report on Synthetic Opoid MT-45. www.gov.uk/government/publications/report-summary-synthetic-opioid-mt-45
[2] EMCDDA–Europol Joint Report on a new psychoactive substance: 1-cyclohexyl-4- (1,2-diphenylethyl)piperazine ('MT-45'). www.emcdda.europa.eu/publications/joint-reports/MT-45
[3] Risk Assessment Report of a new psychoactive substance: 1-cyclohexyl-4-(1,2-diphenylethyl)piperazine (MT-45). EMCDDA. www.emcdda.europa.eu/attachements.cfm/att_233323_EN_MT-45%20Risk%20Assessment%20Report.pdf
[4] ACMD report on synthetic stimulant 4,4'-DMAR. www.gov.uk/government/publications/report-summary-synthetic-stimulant-44-dmar

was identified as a direct cause or, in the presence of other drugs, as a contributory factor. There have been not studies on the social harms of this substance.

6. 4,4'-DMAR has also been the subject of a joint EMCDDA/Europol joint report 2014[5] and a formal risk assessment by the EMCDDA in 2014[6] in relation to control in the EU.

A.1.c Medicinal and other legitimate uses

7. 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, MT-45 was identified as having no legitimate industrial or medicinal uses. The EMCDDA reports support this as they have not received any reports indicating use in the manufacture of medicinal products or other legitimate industrial, agrochemical, cosmetic, human or veterinary medical uses in the EU. The same applies to 4,4'-DMAR though there have been research patents with mention of a derivative of this drug for use in the preparation of a range of phospholipase A2 inhibitors.

8. For these reasons, the ACMD recommends that MT-45 and 4,4'-DMAR should also be listed in Schedule 1 to the Misuse of Drugs Regulations 2001 as drugs with no recognised medicinal uses. This will mean that they 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

9. The groups that will be affected are:
    - The 'legal high' market ('head shops' and internet suppliers), if UK-based, selling new psychoactive substances including these substances as legal alternatives to banned drugs or as a component in 'legal high' branded products
    - law enforcement and criminal justice agencies
    - regulatory (drug licensing) authorities
    - members of the public currently using the drugs, most commonly young people and young adults
    - wider members of the public, who will be spared the social costs of these drugs
    - the research sector.

A.3 Consultation

With Government

10. The government has considered the advice and recommendations of the ACMD, who have in turn consulted with the MHRA, BIS and the chemical/pharmaceutical industry. The EMCDDA has produced separate reports including risk assessments[7][8].

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[5] EMCDDA–Europol Joint Report on a new psychoactive substance: 4,4′-DMAR (4-methyl-5-(4-methylphenyl)-4,5-dihydrooxazol-2-amine) http://www.emcdda.europa.eu/publications/joint-reports/4-4-DMAR

[6] Risk Assessment Report of a new psychoactive substance: 4-methyl-5-(4-methylphenyl)-4,5-dihydrooxazol-2-amine (4,4′-dimethylaminorex, 4,4′-DMAR) http://www.emcdda.europa.eu/attachements.cfm/att_233321_EN_4,4'-DMAR%20Risk%20Assessment%20Report.pdf

[7] Risk Assessment Report of a new psychoactive substance: 4-methyl-5-(4-methylphenyl)-4,5-dihydrooxazol-2-amine (4,4′-dimethylaminorex, 4,4′-DMAR) http://www.emcdda.europa.eu/attachements.cfm/att_233321_EN_4,4'-DMAR%20Risk%20Assessment%20Report.pdf

[8] Risk Assessment Report of a new psychoactive substance: 1-cyclohexyl-4-(1,2-diphenylethyl)piperazine (MT-45). EMCDDA. www.emcdda.europa.eu/attachements.cfm/att_233323_EN_MT-45%20Risk%20Assessment%20Report.pdf

B. Rationale

11. The misuse of drugs, including new psychoactive substances or so called “legal highs”, can impose a high cost on society in terms of health and social harms. Consumption also imposes further costs on the users themselves and those around them. The substances being controlled have been assessed as dangerous or otherwise harmful by the ACMD 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

12. The policy objective is to reduce the risk of harms 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.

13. 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.

14. A successful outcome will be a reduction in the harms caused by these compounds and increased awareness of the risk of harms associated with new psychoactive substances (so called “legal highs”).

D. Options

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

    OPTION 1: Do nothing, no controls will be imposed upon MT-45 or 4,4’-DMAR.

    OPTION 2: Permanent control, designation and scheduling of MT-45 and 4,4’-DMAR under the Misuse of Drugs Act 1971 and its subordinate legislation. This is the only option recommended by the ACMD on the basis of available evidence and assessment of harms, which is also supported by EU authorities’ own risk assessments, and consistent with the legislative approach adopted to control the vast majority of new psychoactive substances on a similar basis.

16. The Government’s preferred option is **option 2** and is supported by the ACMD’s advice. The use of the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001 (as well as the Designation Order 2001) to permanently restrict activities related to the listed substances provides the best means to reduce their availability as well as the risks of misuse and associated harms to the public.

E. Appraisal (Costs and Benefits)

OPTION 1 – Do Nothing

<u>No additional costs or benefits, this option forms the baseline for this analysis.</u>

OPTION 2 – Permanent control, designation and scheduling of MT-45 and 4,4'-DMAR under the Misuse of Drugs Act 1971 and its subordinate legislation.

COSTS

Business

17. A ban would impose costs on UK-based businesses by preventing them from profiting from the legitimate trade in these substances. In order to monetise the impact we would need data on the amount of these drugs that is sold and the price at which it is sold if in the UK. However, neither are available as MT-45 has not been seen in the UK and 4,4'-DMAR is mainly available online (on a few websites) and can be found mixed with other products which may or may not be controlled, or sold under brand names, often from outside UK jurisdiction. As such, it is not possible to make a robust estimate of the cost of this measure on businesses. The level of research that would be required to obtain the necessary data is considered disproportionate for this appraisal.

18. There is a possibility that the control of these two drugs will lead to substitutes being developed and appearing on the market, despite the evidence on harms including deaths. This policy may not impose substantial costs on businesses due to substitution if this is the case.

19. Following consultation with BIS, the MHRA and the chemical and pharmaceutical industry, neither substance has been identified as having a legitimate industrial or medicinal use. This is supported by EMCDDA reports on the two drugs.

Public Sector (enforcement agencies, CJS, regulators)

20. The law enforcement response to this measure would involve using intelligence to tackle supply and trade and disrupting criminal activities relating to these drugs as having the potential to cause the highest level of drug harms. Some of these activities can be performed alongside that for other controlled drugs. Any increase in these activities would impose costs on law enforcement as drawing resources away from other areas. There is also the potential for additional demand on the Criminal Justice System, as additional people are arrested for drug related offences.

21. We have not been able to monetise these costs. This is due to a lack of information on the likely future demand for MT-45 and 4,4'-DMAR, how much time the police currently spend on drug related work, how this will change in response to MT-45 and 4,4'-DMAR becoming illegal and how this will affect the number of arrests.

Individuals and society

22. Private costs will be incurred by people who can no longer derive benefits from legitimate uses of MT-45 and 4,4'-DMAR. We are unable to monetise these costs.

BENEFITS

Business

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

Public Sector (enforcement agencies, CJS, regulators)

24. The ACMD has concluded 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 health and related support services, 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[9]. In addition, the Drug Treatment Outcomes Research study (DTORS) gives an estimated average cost of drug treatment services[10] of £6,064 per person[11]. 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. Control further supports public health messaging on the potential harms of the two drugs as well as being consistent with wider public health messaging on similar drugs. MT-45 also has addictive potential, with addiction to synthetic opioids being associated with social harms including acquisitive crime and loss of social functioning.

Individuals and society

25. Benefits to individuals arise from the protection against potential harms of the listed substances, including the risk of death, especially 4,4'-DMAR which has been associated with a number of deaths in the UK, either as a cause or a contributory factor. It has previously been estimated that the average cost of a death due to drug misuse is £1.6m[12]. This makes use of the Department for Transport estimate of the value of a prevented road casualty, which comprises of 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.

NET EFFECT

26. 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 may impose costs on businesses seeking to sell them before they are controlled, restricting their misuse is expected to protect society from the harmful effects that they may have on health and society. This will result in benefits to public health and in public sector savings from reduced healthcare costs (and social costs due to MT-45).

27. The total net benefits cannot be quantified due to a lack of robust data but are believed to outweigh the costs.

ONE-IN-TWO-OUT (OITO)

28. 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.

[9] Understanding organised crime: estimating the scale and the social and economic costs. Research Report 73. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/246390/horr73.pdf

[10] Including inpatient treatment, specialist prescribing, GP prescribing, counselling, structured day care, residential rehabilitation, aftercare, structured alcohol care and other structured care.

[11] The Drug Treatment Outcomes Research study (DTORS):Cost-effectiveness analysis. Home Office Research Report 25, http://www.dtors.org.uk/reports/DTORS_CostEffect_Main.pdf

[12] Understanding organised crime: estimating the scale and the social and economic costs. Research Report 73, page 74. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/246390/horr73.pdf

F. Risks

29. 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.

30. 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.

31. There is a risk that current users of DMAR may substitute for a currently illegal or legal drug in response to the banning of DMAR, or revert to previous illegal drug use behaviour. Depending on the substitute substance selected this may imply higher or lower costs, as different substances imply different costs for the police, health services and society.

32. 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[13]. 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.

33. 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 licence. However, organisations dealing with similar drugs are assumed to already possess a licence in order to undertake activities involving controlled drugs.

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

G. Enforcement

35. Enforcement of the proposed legislation will be undertaken by police forces, Border Force, the Home Office Drug Licensing Unit and other relevant agencies responsible for enforcing the legislative and regulatory framework for controlled drugs in the UK. As discussed above, it is expected that the enforcement of the proposed legislation can be conducted alongside that for other controlled drugs. However it is possible that there may be additional costs, both for law enforcement and the Criminal Justice System.

36. Police enforcement will form part of their wider approach to tackling new psychoactive substances as well as other drug controlled under the 1971 Act. Border Force will enforce import controls by seizing suspected substances at the ports, also as part of their wider customs role.

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

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 if UK-based except for research purposes.	Non-monetised benefits to the public sector from reduced health and social costs associated with these substances.

37. 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 health and social costs associated with the misuse of these drugs.

I. Implementation

38. The Government plans to implement these changes via an affirmative resolution Order, requiring Parliament's approval, in winter 2014/15.

J. Monitoring and Evaluation

39. As part of its statutory duties under the 1971 Act the ACMD keeps the situation relating to drugs under review. Together with the Government, it will continue to monitor the two drugs 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 related activities (predominantly research). The Home Office, as the regulatory authority on licensing of activities relating to all controlled drugs and as the 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

40. Information gathered from the monitoring and evaluation process will inform future ACMD advice on classification/reclassification, designation and rescheduling as well as further 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, designate and schedule MT-45 and 4,4'-DMAR under the Misuse of Drugs Act 1971 and its subordinate legislation.

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[14].

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.

[14] 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