Title: Control of dienedione under Class C of the Misuse of Drugs Act 1971 **IA No: HO0246** **Lead department or agency:** HOME OFFICE **Other departments or agencies:** DEPARTMENT OF HEALTH, DEPARTMENT FOR BUSINESS INNOVATION AND SKILLS	**Impact Assessment (IA)** **Date:** 19 /7/2016 **Stage:** Final **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries**: James Mclellan 0207 035 1885 james.mclellan@homeoffice.gsi.gov.uk

Summary: Intervention and Options

RPC Opinion: N/A

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**
NK	NK	NK	No	NA

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

The ACMD has made a recommendation to control dienedione as a class C drug. Given the harms associated with this substance the ACMD has concluded that it should be placed under the Misuse of Drugs Act 1971.

Dienedione is an anabolic steroid whose harms the ACMD has assessed as commensurate with other anabolic steroids controlled as Class C drugs. The ACMD therefore recommends that estra-4,9-diene-3,17-dione be controlled under the Misuse of Drugs Act 1971 in Class C and as a Schedule 4 (IV) Part 2 substance under the Misuse of Drugs Regulations 2001, so as not to preclude legitimate use on prescription.

Government intervention is necessary to prevent harm being caused by these substances by restricting their supply using the strict regime provided by control under the Misuse of Drugs Act 1971. Given the reported risks that this substance poses to public health, the ACMD has advised that the 1971 Act remains the preferred option for control.

What are the policy objectives and the intended effects?

The policy objective is to reduce the risk of harms from the misuse of this substance in the UK.

The intended effects are to limit access to the identified substance, to signal to the public the potential danger it poses and to enable the police and other authorities to take action against the sale or distribution of it.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1 - Do nothing. To note: like most anabolic steroids, dienedione is not psychoactive and therefore would not be controlled under the Psychoactive Substances Act 2016 This means its production and supply would be unrestricted.
Option 2 – Control, designation and scheduling of the steroid dienedione under the Misuse of Drugs Act 1971 and its subordinate legislation.

Option 2 is the preferred option on the basis of the current evidence and the ACMD's assessment of evidence on the harms and misuse associated with this compound.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** Within 12 months.

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** 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: Sarah Newton Date: 19 July 2016

Summary: Analysis & Evidence

Policy Option 2

Description: Control of dienedione under Class C of the Misuse of Drugs Act 1971.

FULL ECONOMIC ASSESSMENT

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

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

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

It is not possible to monetise the costs of this option in light of the current available data.

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

Businesses – following consultation with BIS, the MHRA and the chemical and pharmaceutical industry, this compound has been identified as having no legitimate industrial or medicinal use. There is a market in performance/image enhancement, which will incur costs, the restriction of which is the intention of this control. There should be no further cost to business by controlling this compound under the Misuse of Drugs Act 1971.

The **Public sector** may face some costs from enforcement responses, though it is expected that these will be subsumed into the enforcement and regulatory response to similar drugs controlled under the Misuse of Drugs Act 1971.

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

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

It is not possible to monetise the benefits of this option in light of the current available data.

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

Public Sector: Listing it on the face of the Misuse of Drugs Act 1971 provides law enforcement with a consistent regime to control this substance in line with other anabolic steriods that have been previously controlled with similar harms. In practical terms this provides enforcement agencies with a consistent set of powers to restrict the supply of substances thought to be harmful, rather than disparate regimes. This is likely to be easier and more efficient to enforce, saving time of those on the frontline.

Like other anabolic steroids, dienedione is not expected to be psychoactive so would not fall under the controls of the Psychoactive Substances Act if it is not added to the Misuse of Drugs Act 1971. However, the response for permanent control under the Misuse of Drugs Act 1971 is in line with the response law enforcement take on other anabolic steroids which are already controlled.

Personal: It is possible that **personal** benefits arise from the deterrence effect of a clear message sent out that these substances have had a harms assessment and found to pose a risk to public health and safety.

Key assumptions/sensitivities/risks **Discount rate**

To the best of our knowledge, these substances do not have any legitimate industrial or medicinal uses. It is possible that the substances in question are currently being used by UK research bodies, creating the possibility that research will be hampered by the proposed controls. However, most research organisations will already have current licences which will permit access to these drugs for research purposes.

BUSINESS ASSESSMENT (Option 1)

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

Evidence Base (for summary sheets)

A. Strategic Overview

A.1 Background

1.1. This Impact Assessment considers the proposal to control the steroid dienedione in class C, in line with other anabolic steroids.

Dienedione

1.2. Dienedione is an anabolic steroid. Anabolic steroids are synthetic substances which are related to the male sex hormones, particularly testosterone. These substances have a number of physiological effects, most notably anabolic effects (such as growth of skeletal muscle and bone) and androgenic effects (the differentiation, growth and maintenance of the reproductive system and sexual characteristics in males). The sale of dienedione is not currently restricted in the UK.

1.3. The Advisory Council on the Misuse of Drugs (ACMD) has, at the request of UK Anti-Doping (UKAD), and supported by the Home Office, reviewed the World Anti Doping Agency (WADA) Prohibited Lists over the years, to consider those drugs included in the List, where there may also be harms commensurate with the Misuse of Drugs Act 1971.

1.4. UKAD have evidence for the availability of dienedione through detection of the metabolite, 17-hydroxy-estra-4,9-dien-3-one, in urine samples of two athletes. The presence of the metabolite was attributed to the ingestion of a dietary supplement.

1.5. Dienedione was classified in the US as an anabolic steroid under The Anabolic Steroid Control Act 2004, as it was shown by the Drug Enforcement Agency to be chemically and pharmacologically related to testosterone. As such, it became a controlled substance in the US on January 4, 2010, and is classified as a Schedule III anabolic steroid under the United States Controlled Substances Act.

1.6. The ACMD considered the potential physical and social harms of dienedione and advises that these would be commensurate with other anabolic steroids. The ACMD therefore recommended that dienedione be controlled under the Misuse of Drugs Act 1971 in Class C and as a Schedule 4 (IV) Part 2 substance under the Misuse of Drugs Regulations 2001, so as not to preclude theoretical legitimate use on prescription.

Wider uses

1.7. 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, dienedione has been identified as having no legitimate industrial or medicinal use beyond its status as performance/image enhancer and there is therefore a currently legal market in the supply of the substance. It is difficult to assess the size of the market in anabolic steroids given that a number of steroids

have already been controlled as class C drugs. The MHRA also confirmed that there are no marketing authorisations for medicines containing dienedione.

A.2 Groups Affected

1.8. The proposal to control these compounds may affect groups making legitimate use of any of this substance, such as organisations which use and produce chemical standards for research and forensic purposes.

1.9. For dienedione, which does not fall under the controls of the Psychoactive Substances Act 2016, the affected groups will include

- the market in performance/image enhancement,
- UK law enforcement agencies and criminal justice system and
- members of the public, especially young people and young adults.

A.3 Consultation

Within Government

1.10. The Home Office and the ACMD consulted with the MHRA, BIS and the chemical/pharmaceutical industry in deciding its preferred options when the ACMD originally produced its advice for this substance.

Public Consultation

1.11. The Government has considered the recommendations of the Advisory Council on the Misuse of Drugs.

B. Rationale

2.1. The misuse of drugs imposes a cost on society in excess of the individual costs to users. A 2013 Home Office study estimated that the total social and economic costs of illicit drugs in 2010/11 was £10.7bn. In addition, users are not always aware of the costs associated with particular drugs due to the novelty of the substances. However, the ACMD's assessment is that dienedione is a substance with similar properties, effects and risks as those anabolic steroids already controlled under class C.

2.2. Controlling dienedione under the Misuse of Drugs Act 1971, as opposed to taking no action, provides restriction of its supply as follows:

a. Control under the 1971 Act offers strict offences of production and distribution under any circumstances without a licence. Control under the 1971 Act therefore provides a clear legal framework to restrict the supply of particular substances. This is intended to address the open sale and availability of dienedione.

b. The maximum penalty for committing an offence involving a class B or C drug is 14 years imprisonment. These higher tariffs may act as a deterrent to the supply of this substance.
c. There would be no coverage under the Psychoactive Substances Act 2016, as it is probable that most anabolic steroids are not capable of producing psychoactive effects and also have potential uses in medicine.

2.1. Drugs controlled under the 1971 Act have been subjected to a full harms assessment by the ACMD and that they are being or appear to the ACMD likely to be misused and of which the misuse is having or appears to them capable of having harmful effects sufficient to constitute a social problem.

. C. Objectives

3.1. The policy objective is to protect the public from the harms associated with dienedione, in line with the Government's Drug Strategy to restrict the supply of drugs; prevent harmful drug use and build recovery for those dependent on drugs.

3.2. As part of this a key objective will be a reduction in the demand, availability and misuse of these compounds and raised awareness of the harms of these substances.

D. Options

4.1. Two options have been considered in respect of dienedione:

OPTION 1: Do nothing and allow dienedione to remain not controlled under the Misuse of Drugs Act 1971. These means its production and supply in the UK would be unrestricted.

OPTION 2: Control, designation and scheduling under the Misuse of Drugs Act 1971 and its subordinate legislation, as recommended by the ACMD.

Description of controls

- In line with other anabolic steroids, dienedione will be inserted in Class C and will be part of Schedule 4 (IV) Part 2 to the Misuse of Drugs Regulations. As such there will be no possession offence associated with dienedione.
- Under the Misuse of Drugs Act 1971, on indictment the maximum penalties for offences relating to class C drugs are - for supply, production, importation/exportation up to fourteen years' and/or an unlimited fine. On summary conviction, the maximum penalties for offences relating to supply, production or importation/exportation are three months' imprisonment and/or a prescribed fine.

The Government's preferred option is option 2, which is aligned with the ACMD's advice and presents the best means of restricting the availability and reducing the risk of misuse and associated harm to the public.

E. Appraisal

OPTION 1: This is the baseline option, meaning that the costs and benefits of option 2 are assessed relative option 1 (i.e. additional costs and benefits above the do nothing scenario).

OPTION 2:

COSTS

Business

5.1. There will be a cost to those businesses that supply dienedione as a performance/image enhancer. It is difficult to estimate the costs to this market, which, in the evidence provided to the ACMD is used primarily to enhance performance in sport.

5.2. Excepting the performance/image enhancing market mentioned above, these compounds have been identified as having no legitimate industrial or medicinal use therefore no wider business costs are expected.

Public Sector (enforcement agencies, CJS, regulators)

5.3. Any real and opportunity costs associated with option 2 cannot be predicted in light of limited data on the prevalence and use of dienedione. It is expected that minimal costs arising from option 2 will be subsumed into the law enforcement and regulatory response to the control of other drugs under the 1971 Act. As such the law enforcement response can reasonably 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.

Personal and society

5.4. The main personal cost would be to those who use the substance being unable to obtain it legally. Those uses are generally illicit in some way, for there is evidence it has been used in sport, where dienedione is included on the WADA prohibited substances list. We are unable to monetise these costs due to a lack of information on the current size of the market in this substance. The possession of dienedione will not be an offence, so this would not contribute to those costs.

BENEFITS

Business

5.5. No benefits accrue to businesses from this policy.

Public Sector (enforcement agencies, CJS, regulators)

5.6. Benefits are expected to arise from consistency in enforcement and regulatory response to harmful substances; dienedione is believed to have a similar level of harm to other substances currently listed under the Misuse of Drugs Act. This includes currently controlled anabolic steroids (class C), from which the current substance is chemically related. In practical terms this provides enforcement agencies with a consistent set of

powers to restrict the supply of substances assessed to be harmful, rather than disparate regimes. This is likely to be more efficient to enforce, saving time and costs.

Personal

5.7. Personal benefits to individuals arise from the protection against potential harms. The ACMD previously reported a range of potential harms associated with the use of anabolic steroids; these include acne, cardiovascular symptoms, psychological (e.g. aggression, violence and hypomania) and hepatic dysfunction. In particular, harms to young people from the use of anabolic steroids can lead to virilisation and potentially disrupt the normal pattern of growth and behavioural maturation.

NET EFFECT

5.8. Overall it is considered likely that the benefits from the proposals will outweigh the costs, although it has not been possible to quantify these benefits and costs. The main benefits to arise from the proposals are to provide enforcement agencies with powers and offences surrounding the trafficking in this substance with the aim of reducing the associated harms.

5.9. Additionally, given that the ACMD did not report any psychoactive properties associated with this substance it would not be expected to be captured under the Psychoactive Substances Act 2016.

5.10. While the permanent control of dienedione will impose costs on businesses seeking to sell it, restricting their misuse is expected to protect society from the harmful effects that they may have on health.

F. Risks

6.1. There is also a limited risk that voluntary, charity or private sector research organisations or institutions: manufacturers, distributors and wholesalers that produce, supply, import or export dienedione for the synthesis of non-controlled pharmaceuticals may become adversely affected due to the potential costs of updating or applying for a license. However, organisations dealing with permanently controlled scheduled drugs will already possess a licence to undertake activities involving dienedione. Due to the absence of evidence of legitimate business use beyond the performance/image enhancing market, and the costs that would be associated with this use, the assumption is made that there are minimal cost implications to business.

G. Enforcement

7.1. 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. 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. There will be no interference with the regulatory framework and processes implementing temporary control measures in law enforcement and regulatory agencies as part of their routine activities.

H. Summary and Recommendations

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

Table H.1 Costs and Benefits

Option	Costs	Benefits
2	£NK	£NK
	- Personal costs to those who use dienedione to enhance performance/image. - Minimal costs to law enforcement. - Costs to businesses that currently sell dienedione.	- Control under the 1971 Act provides offences and powers which will have a restrictive effect on supply. - Reinforcement of public awareness of the harms of the substance by making clear it is of concern, by classifying it according to harm and providing stricter penalties for offences.

8.2. Taking option 1 (do nothing) would mean dienedione would remain out of scope of the Misuse of Drugs Act 1971.

8.3. Option 1 is the least preferred option. It would provide no restriction on the supply of dienedione, thus allowing a substance which has been assessed as being harmful enough to warrant control under the 1971 Act to remain available.

8.4. Option 2 is the preferred option and is aligned with the ACMD's advice. The use of the 1971 Act and its Regulations to control the substance provides the best means to reduce availability and potential harm to the public. The resultant clear message to the public that this compound has harms commensurate with current class C controlled drugs may also assist in dissuading the use, as alluded to in the ACMD's evidence.

I. Implementation

9.1. The Government plans to implement these changes via an affirmative resolution Order, subject to Parliament's approval.

J. Monitoring and Evaluation

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

11.1. Information gathered from the monitoring and evaluation process will inform future ACMD advice on the (re)classification, designation and scheduling of these drugs.