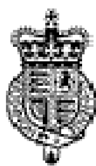


PROPOSED CONTROL UNDER THE MISUSE OF DRUGS ACT 1971 OF (1) 1-BENZYLPIPERAZINE (BZP) AND A GROUP OF SUBSTITUTED PIPERAZINES (RELATED COMPOUNDS) AND (2) AN ADDITIONAL 24 ANABOLIC STEROIDS AND 2 NON-STEROIDAL AGENTS

A consultation paper

21 May 2009

Introduction

1. This consultation seeks your views on the Government's proposals for a number of substances to be controlled under the Misuse of Drugs Act 1971 and its associated subordinate legislation. The proposals have been prepared in consultation with, and on the advice of, the Advisory Council on the Misuse of Drugs, the independent body established to advise the Government on drug misuse issues.

2. Responses should arrive no later than 13 August 2009.

1- BENZYLPIPERAZINE (BZP) AND A GROUP OF SUBSTITUTED PIPERAZINES (RELATED COMPOUNDS)

3. It is proposed that 1-benzylpiperazine (BZP) and a group of substituted piperazines (related compounds) be brought under control of the Misuse of Drugs Act 1971 as Class C drugs and placed in Schedule 1 to the Misuse of Drugs Regulations 2001, having no recognised medicinal use. By use of a generic definition, the substances set out in paragraph 9 below would be subsumed and subject to the same level of controls.

Reasons for the proposal

4. BZP is a synthetic drug which stimulates the central nervous system with similar but less potent properties to amphetamine and is one of the substituted piperazines. BZP is normally manufactured from piperazine, a substance used as an anti-helminthic drug for the treatment of worm infestations. However, BZP itself has no recognised medicinal use, although both BZP and some of the other substituted piperazines can be used as synthetic intermediates and used in the production of pharmaceutical products (see paragraph 11 below). Seizures of BZP and related compounds have steadily increased in the UK since early 2006 and have been found in combination with illegal drugs such as MDMA – "ecstasy" – and amphetamine. Some piperazines appear to mimic or intensify the effects of MDMA.

5. There are risks associated with the use of any stimulant substance. Whilst the data are limited, clinical reports suggest that BZP users suffer a range of adverse reactions such as vomiting, headaches, increased blood pressure, palpitations, poor appetite, stomach pains/ nausea, anxiety, insomnia, mood swings, confusion, irritability and tremors. There is also an indicated association with the occurrence of grand mal seizures.

6. Following a risk assessment by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) - see https://ednd-cma.emcdda.europa.eu/assets/upload/Risk_Assessment_Report_BZP.pdf - the European Council responded to concerns over the misuse of BZP by requiring all EU member states to subject BZP to 'control measures and criminal provisions' pursuant to its decision of March 2008. The European Council decision states that *"......due to its stimulant properties, risk to health, the lack of medical benefits and following the precautionary principle, there is a need to control BZP' through measures 'appropriate to the relatively low risks of the substance".*

7. At the request of the Home Office, the Advisory Council on the Misuse of Drugs undertook an assessment of BZP, reviewing its status through the examination of its use, pharmacology, physical and societal harms. Its report – "Control of 1-benzylpiperazine (BZP) and related compounds" can be found at

http://drugs.homeoffice.gov.uk/drugs-laws/acmd/. Subject to this consultation, the Government has accepted the ACMD's assessment that the harms and misuse of BZP are commensurate to Class C of the 1971 Act. This is the lowest category of control under the 1971 Act and as such attracts a maximum sentence of 2 years imprisonment for possession and 14 years for supply, trafficking and production.

8. As stated above, BZP is only one of several substituted piperazines which have been found in the UK. The ACMD advise that several of the substituted piperazines are, or are capable of, being misused in the UK. The ACMD therefore recommend that controls are levied on the group of substituted piperazines, not just BZP, via a generic definition. The Government supports this recommendation and the reasons behind it. Wider legislative control will enable us to respond to both current and foreseeable trends and to take both full and early action against related compounds that appear to have the same or very similar harms. It will also bring the UK into line with other countries that already control a number of substituted piperazines.

9. Under the generic definition provided by the ACMD the following substituted piperazines would be brought under control as Class C drugs:

1-Benzylpiperazine (BZP)
1-(3-Chlorophenyl)piperazine (mCPP)
1-(4-Chlorophenyl)piperazine (pCPP)
1-(4-Fluorophenyl)piperazine (pFPP)
1-(3-Trifluoromethylphenyl) piperazine (TFMPP)
1-(3-Methylphenyl) piperazine (mMPP)
1-(4-Methylphenyl) piperazine (pMPP)
1-(4-Methoxyphenyl) piperazine (pMeOPP)
1-(3-Chlorophenyl)-4-(3-chloropropyl)piperazine (CPCPP)
1,4-Dibenzylpiperazine (DBZP)
1-Benzyl-4-methylpiperazine (BZMP)

Impact of proposed controls

10. A consultation stage impact assessment has been prepared in line with the proposal (see accompanying Annex). Subject to paragraph 12 below, this proposal is unlikely to have any significant impact on legitimate business. The Government is however interested to hear from any company where any additional direct and indirect costs may arise as a result of this proposal.

11. We are aware that BZP is being sold in the UK as a "legal high". The Medicines and Healthcare products Regulatory Agency (MHRA) has made it clear that BZP fits the definition of a medicinal product, as it has marked pharmacological effects in humans, notwithstanding that it has no recognised medicinal value. Consequently, the sale, supply and advertisement of such products (without a marketing authorisation (product licence) enabling them to be placed on the UK market) contravenes the Medicines Act 1968. Any such unlawful activities are currently enforced by the MHRA, rather than police or customs. The impact of these further proposed controls will not take into account cost on any business or person already undertaking activities in contravention of the Medicines Act in respect of BZP.

12. As identified at paragraph 5.1 of the ACMD's Report, some of the substituted piperazines have legitimate purposes, in particular two substituted piperazines (mCPP and CPCPP) are used in the manufacture of anti-depressants. The Impact Assessment invites respondents to fully set out the scope of these legitimate uses, relevant to the UK. With this information, we will be able to assess the impact (if any)

of control as a Class C, Schedule 1 drug on legitimate industry. We can then look at ways of mitigating the impact on legitimate industry either by accompanying changes to the Misuse of Drugs Regulations 2001 and/or by allowing possession, supply and import/exportation of the relevant substituted piperazines under the current licensing regime implemented by the Home Office Drug Licensing and Compliance Unit.

13. It is not anticipated that controlling BZP and substituted piperazines through drugs legislation will have any significant impact on equality issues in relation to age, disability, gender, race or sexual orientation. However, given there is a need for further information on the use and prevalence of BZP and substituted piperazines, the Government invites comments and views on any equality-related issues that may be associated with a legislative change.

24 ANABOLIC STEROIDS AND 2 NON-STEROIDAL AGENTS

14. Further to the ACMD recommendation, it is proposed a further 24 Anabolic Steroids and 2 non-steroidal agents (growth promoters) are brought under the control of the 1971 Act as Class C drugs and placed in Part 2 of Schedule 4 to the Misuse of Drugs Regulations 2001 so as not to preclude legitimate use on prescription. These are as follows:

1-Androstendiol
1-Androstendione
Boldione
Gestrinone
Danazol
Desoexoymethyltestosterone
19-Norandrostenedione
Prostanozol
Tetrahydrogestrinone
Dihydrotestosterone
5α-Androstane-3α,17α-diol
5α-Androstane-3β,17α-diol
Androst-4-ene-3β,17β-diol (‘Androstenediol’)
Androst-4-ene-3α,17α-diol
Androst-4-ene-3α,17β-diol
5-Androstenedione
Epidihydrotestosterone
3α-Hydroxy-5α-androstan-17-one
3β-Hydroxy-5α-androstan-17-one
19-Norandrosterone
19-Noretiocholanolone
Zeranol
Zilpaterol

15. Anabolic steroids are analogues or derivatives of testosterone which have growth promoting properties. Anabolic steroids have been used by sports people in numerous well publicised cases, but there is also increasing concern over the use of anabolic steroids amongst the general public and, in particular, concerns around young people. Although a small number of people misuse anabolic steroids to enhance their physique and strength, steroids can cause serious psychiatric and physical problems. Steroid misuse is associated with negative effects: psychological (e.g. aggression and irritability), cosmetic (e.g. gynaecomastia), cardiovascular (e.g.

hypertension), liver, genitourinary (infertility), musculoskeletal, endocrine, haematological and infection (via the use of needles).

16. Currently, 54 anabolic steroids (as well as 5 growth hormones) are controlled as Class C drugs under the 1971 Act. Further to the ACMD advice and recommendations which can be found at http://drugs.homeoffice.gov.uk/publication-search/acmd/advice-on-steroids1, it is proposed that the group of anabolic steroids and growth promoters is updated in line with our current understanding of the availability of this group of drugs. The original group of steroids were identified by reference to the International Olympic Commission Prohibited List. It is therefore appropriate for us to update our controls by reference to its successor, the World Anti-Doping Agency Prohibited List. It will provide consistency in our approach and is fully in line with the Government's commitment to prevent the misuse of these substances both by the general public but also by elite athletes, particularly in the lead up to the London Olympics in 2012. This will also act as a measure against unintended consequences of control, with traffickers avoiding risk of prosecution by supplying otherwise legal steroids which, on the Advisory Council's advice, are just as harmful.

17. When controls were first introduced for steroids in 1996, the Government accepted the ACMD's advice that there should not be a possession offence when the steroids are in the form of a medicinal product and for personal use. Controls on anabolic steroids continue to be targeted at those illicit suppliers and traffickers who profit from selling these substances. As Class C drugs the maximum sentence for supply, trafficking and production is 14 years.

18. In respect of the legitimate medical use of these additional drugs, by placing them in the same Schedule (Schedule 4 Part 2) to the Misuse of Drugs Regulations 2001 as the other anabolic steroids, those persons authorised by the regulations (e.g. doctors and pharmacists) can supply these additional substances for medicinal purposes. Import and export licences are required for the trade in Schedule 4 Part 2 substances and regulations 22 and 23 (keeping and preservation of records), 26 (furnishing of information) and 27 (destruction - holders of written authorities to produce only) will apply. However, regulation 15 (prescription writing requirements) and the statutory safe custody requirements do not apply to Schedule 4 Part 2 drugs.

Impact of proposed controls

19. A consultation stage impact assessment has been prepared in line with the proposal (see accompanying Annex). It is considered that this proposal is unlikely to have any significant impact on legitimate business and the availability of these substances for legitimate use via prescription. The MHRA has advised that there is only one anabolic steroid licensed for use in the UK (Nandrolone, which is already controlled under the 1971 Act) with associated 2 marketing authorisations. The British National Formulary indicates that it is used for the treatment of plastic anaemia, suggesting that it is prescribed mainly in hospital settings rather than through GPs. The Government is however interested to hear from any company or person where any additional direct and indirect costs may arise as a result of this proposal.

20. It is not anticipated that controlling these further 24 anabolic steroids and 2 non-steroidal agents (growth promoters) through drugs legislation will have any significant impact on equality issues in relation to age, disability, gender, race or sexual orientation. However, the Government invites comments and views on any equality-related issues that may be associated with a legislative change.

GENERAL PROVISIONS

Application of any legislative changes to England, Wales Scotland and Northern Ireland

21. The proposed changes to the Misuse of Drugs Act 1971 would have effect in England, Wales, Scotland and Northern Ireland. The proposed changes to the Misuse of Drugs Regulations 2001 would apply to England, Wales and Scotland only. Northern Ireland has its own Misuse of Drugs Regulations.

Responding to this consultation

22. Implementation of the proposed changes will take place as early as possible subject to any comments received in response to this document, views of Ministers and the timescale for the parliamentary process. We would welcome any comments on the proposed measures and on the partial Impact Assessments in the Annexes accompanying this document.

Circulation of Proposals and Consultation Responses

23. A copy of this letter and attachments is also available at http://www.homeoffice.gov.uk/about-us/haveyoursay/current-consultations/ and www.drugs.gov.uk . You should contact the address given below (in paragraph 24) if you require a copy of this consultation paper in any other format, e.g. braille, large font, audio.

24. The Government would welcome your views on the proposals contained in this document. Please send written comments to:

Drug Legislation Section
Drug Strategy Unit
4th Floor, Peel
Home Office
2 Marsham Street
LONDON SW1P 4DF

or by email to : Drugconsultation2009@homeoffice.gsi.gov.uk .

25. **Comments must be received by 13 August 2009.**

26. A summary of responses will be published before or alongside any further action.

Responses: Confidentiality & Disclaimer

27. The information you send us may be passed to colleagues within the Home Office, the Government or related agencies. Information provided in response to this consultation, including personal information, may be subject to publication or disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 [FOIA], the Data Protection Act 1998 [DPA] and the Environmental Information Regulations 2004).

28. If you want other information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.

29. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

30. The Department will process your personal data in accordance with the DPA and in the majority of circumstances this will mean that your personal data will not be disclosed to third parties.

Government Code of Practice on Consultation

31. The Consultation follows the Government's Code of Practice on Consultation – the criteria for which are set out below:

Criterion 1 – When to consult – Formal consultation should take place at a stage when there is scope to influence the policy outcome.

Criterion 2 – Duration of consultation exercises – Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.

Criterion 3 – Clarity of scope and impact – Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.

Criterion 4 – Accessibility of consultation exercises – Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.

Criterion 5 – The burden of consultation – Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees' buy-in to the process is to be obtained.

Criterion 6 – Responsiveness of consultation exercises – Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.

Criterion 7 – Capacity to consult – Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

32. The full Code of Practice on Consultation is available at: http://www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44420.html

Consultation Co-ordinator

33. If you have a complaint or comment about the Home Office's approach to consultation, you should contact the Home Office Consultation Co-ordinator, Nigel Lawrence. Please DO NOT send your response to this consultation to Nigel Lawrence. The Co-ordinator works to promote best practice standards set by the Government's Code of Practice, advises policy teams on how to conduct consultations and investigates complaints made against the Home Office. He does not process your response to this consultation.

34. The Co-ordinator can be emailed at:
Nigel.Lawrence@homeoffice.gsi.gov.uk or alternatively you can write to him at:

Nigel Lawrence, Consultation Co-ordinator
Home Office
Performance and Delivery Unit
Better Regulation Team
3rd Floor Seacole
2 Marsham Street
London
SW1P 4DF

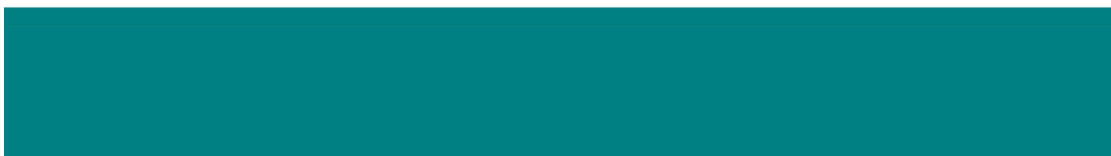
Summary: Intervention & Options

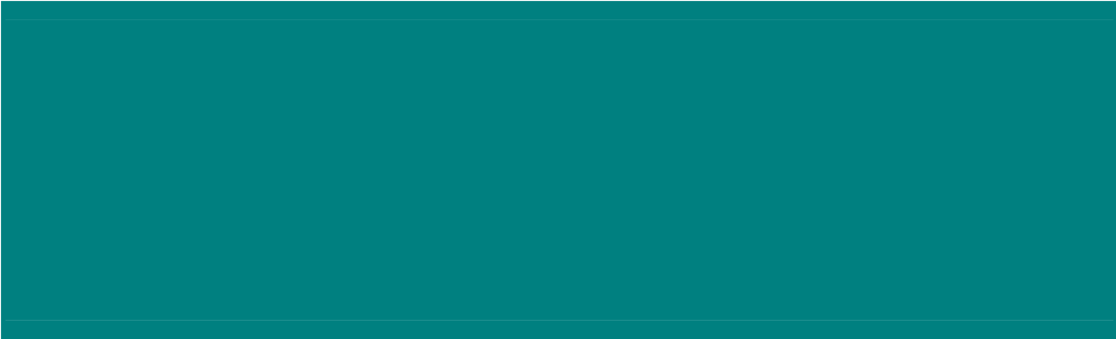
Department /Agency: Home Office	Title: Impact Assessment of proposed changes to the Misuse of Drugs Legislation - BZP	
Stage: **Consultation**	Version:	Date: **21 May 2009**
Related Publications:		

Available to view or download at:

http://www.homeoffice.gov.uk/about-us/haveyoursay/current-consultations/

Contact for enquiries: **Angela Scrutton** Telephone: **020 7035 0458**



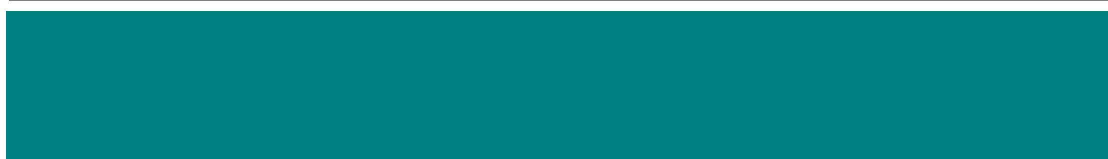


Summary: Analysis & Evidence

Policy Option:	Description:

COSTS	ANNUAL COSTS		Description and scale of **key monetised costs** by 'main affected groups' Costs are unknown at this stage and will be informed by consultation	
	One-off	**Yr**		
	£ Unknown			
	Average Annual Cost			
	£ Unknown		**Total Cost** (PV)	**£ Unknown**
	Other **key non-monetised costs** by 'main affected groups' Costs are unknown at this stage and will be informed by consultation			

BENEFITS	ANNUAL BENEFITS		Description and scale of **key monetised benefits** by 'main affected groups' Costs are unknown at this stage and will be informed by consultation	
	One-off	**Yr**		
	£ Unknown			
	Average Annual Benefit			
	£ Unknown		**Total Benefit** (PV)	**£ Unknown**
	Other **key non-monetised benefits** by 'main affected groups' Costs are unknown at this stage and will be informed by consultation			



Price Base	Time Period	**Net Benefit Range** (NPV) **£ Unknown**	**NET BENEFIT** (NPV Best estimate) **£ Unknown**

What is the total annual cost of enforcement for these			£ Unknown	
What is the value of the proposed offsetting measure per			£ Unknown	
What is the value of changes in greenhouse gas emissions?			£ Unknown	
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large

Evidence Base (for summary sheets)

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

This is a partial Impact Assessment forming the first step in identifying costs and benefits of the proposals set out in the consultation paper to make changes to the Misuse of Drugs legislation. This is a continuous process and respondents are invited to submit any figures, costing or other details of relevance to help refine the final stage regulatory impact assessment.

Background

1-benzylpiperazine (BZP) is a synthetic drug normally manufactured from piperazine; a substance used as an antihelminthic drug for worming. BZP was never developed as a potential antihelminthic drug and has no recognised medicinal use. It is a psychoactive drug belonging to the group of piperazine derivatives. It is not indicated for use in humans nor is it formulated in licensed veterinary products in the UK. It is generally marketed as a recreational stimulant and viewed as a legal alternative to amphetamine.

BZP is a central nervous system stimulant with the ability to modify physiological function and as such comes under the definition of a medicinal product as defined by Article 1 (2) of Directive 2001/83/EC (amended by Directive 2004/27/EC):

"(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or

(b) Any substance or combination of substances which may be used in or administered to human beings wither with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis"

In the UK it is illegal to sell medicinal products without marketing authorisation; those doing so face prosecution under the Medicines Act 1968.

Neither BZP, nor any related substituted piperazine products are currently controlled under the Misuse of Drugs Act 1971 (MDA 1971).

European obligations

Following the risk assessment conducted by the EMCDDA the European Council adopted the decision 2008/206/JHA. This decision finds that due to the stimulant properties, risk to health, a lack of medical benefits and following the precautionary principle, EU member states shall take the necessary measures to submit BZP to control measures proportionate to the risks of the substances and criminal penalties in line with their national laws.

Advisory Council on the Misuse of Drugs advice

Following the decision by the European Council, the Home Office requested the Advisory Council on the Misuse of Drugs (ACMD) - the Government's independent expert body on drug

related issues- to make an assessment of BZP and to consider classification and scheduling under the current legislative framework for controlling drugs. Following an assessment, the ACMD offered two options for control. Both options agree with the European Council decision that BZP be controlled and considers the harms and misuse of BZP and substituted piperazines correspond to Class C under Schedule 2 of the Misuse of Drugs Act 1971 and Schedule 1 of the Misuse of Drugs Regulations 2001 (having no recognised medicinal use).

Rationale for intervention

The case for a change in policy towards BZP and a number of substituted piperazines can be examined in relation to potential harms and misuse of the drug as well as the UK's obligations under EU law.

BZP is an entirely synthetic drug with no legitimate medicinal use or known medical benefits. Overall there is a need for further evidence on the health and social risks associated with BZP. Nevertheless BZP has stimulant properties and the limited data on abuse and dependence potential as well as the effect on the central nervous system shows a similarity to that of amphetamines. This in turn is a significant indication of potential harm associated with the use of BZP.

Both the ACMD report on the control of BZP and the European Monitoring Centre for Drugs and Drugs Addicition's (EMCDDA) risk assessment highlight that there are inherent risks of using any stimulant substance. Whilst the data is limited, clinical reports suggest that BZP users suffer a range of adverse reactions such as vomiting, headaches, increased blood pressure, palpitations, poor appetite, stomach pains/ nausea, anxiety, insomnia, mood swings, confusion, irritability and tremors. There is also an indicated association with the occurrence grand mal seizures. See https://ednd-cma.emcdda.europa.eu/assets/upload/Risk_Assessment_Report_BZP.pdf

BZP is a derivative of piperazine usually available in either tablets or capsules. Piperazine itself has no psychoactive properties but has been used for many years as an antihelmetic drug in the treatment of intestinal round worm infestations. BZP was never developed as a potential antihelmintic drug. It is a recreational stimulant which between1999 -2004 became widespread across Europe as a legal alternative to amphetamine and to some extent MDMA (ecstasy). Owing to the fact that BZP is not currently a controlled drug there is no habitual data collection on the drug through the British Crime Survey.

BZP has some level of popularity in the UK; whilst it is difficult to say whether seizure data is a direct indication of prevalence and use or more reflective of enforcement action, it is a significant indicator in the absence of further information. Seizures data provided by the Forensic Science Service (FSS) shows 304 recordings of BZP between Oct – Dec 2008. Overall FSS data indicates that; as the level of MDMA seizures have decreased, BZP and piperazine seizures have increased; see Annex A.

As referenced by the ACMD in their report on the control of BZP, seizures by the forensic science providers also indicate that several substituted piperazines are also being misused.

Bringing BZP under the control of the Misuse of Drugs Act 1971 is in line the Government's current drug strategy- *Drugs: protecting families and communities. The 2008 drug strategy*. The strategy has the overarching aim of working towards a society free of the problems caused by drugs. This includes actions such as treatment, prevention, enforcement and early education. Controlling BZP protects individuals; particularly young people and families against the risks and potential harms associated with its stimulant properties and the uncertainties around its dependence and potential for abuse. It further ensures that the UK is maintaining robust legislative arrangements for those substances that have potential for abuse and is acting in accordance with its international obligations. The control of BZP is necessary to enable the UK to comply with its duty as an EU Member State and signatory to the European Union treaties. Implementing EC decision 2008/206/JHA into domestic law will in turn comply with the UN drugs conventions.

Objective

The measure to control BZP and related compounds under the Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001 is to support the overarching aim of UK drugs laws - to protect individuals and society from the harmful effects of dangerous or otherwise harmful drugs. BZP has been shown to be a substance of misuse.

BZP first came to the attention of the Advisory Council on the Misuse of Drugs (ACMD) - the independent expert body that advises government on drug related issues in the UK- in April 2006. In 2007 reports of misuse of BZP led the EMCDDA to carry out a risk assessment report; this concluded that there was a European-wide need to control BZP. The ACMD's report and recommendation on the control of BZP are in line with this European decision.

Appraisal

Three options have been considered in the control of BZP. The current Government view, in line with the proposals as set out in the consultation document, and the recommendations of the ACMD, is to control BZP and a group of substituted piperazine (related compounds) (Option 3) -as defined at Annex B of this partial impact assessment - as Class C drugs under the MDA 1971 and Schedule 1 to the Misuse of Drugs Regulations 2001- no recognised therapeutic value.

Option 1- Do nothing

This option would leave the current law unchanged and would not meet the Government's overarching drugs policy objectives to protect individuals and society from the harmful effects of dangerous or otherwise harmful drugs. In addition to this the UK, as a signatory to the EU is bound to implement the EU Council Decision of 3 March 2008 which called on all member states to submit BZP to: control measures proportionate to the risks of the substance and criminal penalties in line with their national laws and through measures appropriate to the relatively low risk of the substance.

Costs

There are no intervention costs but the harms associated with the use of BZP may result in significant economic and social costs, for example to health, to lost output as a result of time off work, and potentially to any related criminal justice costs if the use of BZP causes criminal behaviour - for example associated with anti-social behaviour.

Benefits

A reduction in economic and social costs associated with reductions in the use of BZP represents the potential benefits of intervention to control its use. In addition, there are also potential additional but difficult to measure benefits, for example, improvements in health from a drug-free state may enhance an individual's career progression and day to day social activities.

Option 2- Control BZP under the Misuse of Drugs Act 1971 and associated secondary legislation

Following this option 1-benzylpiperazine would be controlled under the MDA 1971 and its associated legislation. BZP is not currently subject to specific controls of use. As a synthetic

substance it has no recognised medicinal value. Making BZP subject to the provisions of the issues of drugs legislation will provide controls on the production, supply, possession, import and export of the substance in view of its potential for misuse as a psychoactive stimulant.

BZP is a substance that has the ability to modify physiological function through pharmacological action. It is therefore by definition a medicinal product requiring a marketing licence. Given there is no agreed legitimate medicinal use of BZP, vendors and producers of BZP currently face prosecution under the Medicines Act 1968.

Evidence from the ACMD report on the control of BZP suggests that BZP is misused; it is often marketed as a 'legal herbal high'. It is one of several substituted piperazines associated with reports of misuse in the UK and elsewhere in the EU.

The European Council has called for BZP to be subject to control measures and criminal provisions commensurate to risks associated with the substance via national legislation across all member states. Therefore the UK is obliged to implement controls under drugs legislation.

This option would ensure that the UK is conducting its drugs policy in accordance with its EU obligations which in turn are in line with its obligations under the UN conventions on drugs. In addition it will work in line with the UK Government's overarching drugs strategy to protect individuals and society from the harmful effects of 'dangerous or otherwise harmful drugs'. Further benefits of this proposal are that controls on BZP, as emphasised by the EMCDDA risk assessment, would facilitate detection and monitoring of illegal manufacturing and trafficking of BZP, limiting its supply and use and thus limiting potential harm and misuse.

Costs

Actual costs associated with the control of BZP under MDA 1971 are currently unknown but, whilst informed by the consultation process, are thought to be low. As it will be an offence to import and export, manufacture, supply and possess 1-benzylpiperazine under the 1971 Act as a Class C drug, there are likely to be some future costs to the criminal justice system as a result of any criminal sanctions imposed. As BZP has no legitimate industrial or recognised medicinal use and its sale and supply are currently unlawful under medicines legislation, these further proposed controls will not take into account the impact on any business or person already undertaking unlawful activities in contravention of the Medicines Act in respect of BZP.

Benefits

A reduction in economic and social costs associated with reductions in the use of BZP represents the potential benefits of intervention to control its use. In addition, there are also potential additional but difficult to measure benefits, for example, improvements in health from a drug-free state may enhance an individual's career progression and day to day social activities.

Whilst there is no direct evidence that BZP causes any significant social harms such as acquisitive crime and anti-social behaviour, controlling the substances under drugs legislation may have some further social benefit in protecting the public. Controlling the drug through the legislative framework, by giving it a classification, sends a clear message to the public that BZP is potentially harmful.

Option 3- Control BZP and a group of substituted piperazines by means of a generic definition under the Misuse of Drugs Action 1971 and associated secondary legislation

This option seeks to control 1-benzylpiperazine and a group of associated piperazines by means of a generic definition. They would be controlled under the MDA 1971 and its associated legislation.

The proposed definition for the substances to be controlled is as follows:

“1-benzylpiperazine and any compound structurally derived from 1-benzylpiperazines or 1-phenykpiperazine by substitution in the aromatic ring to any extent with alkyl, alkoxy, alkylenedioxy, halide or haloalkyl substituents, whether or not substituted at the nitrogen atom of the piperazine ring with alkyl, benzyl, haloalky, or phenyl substituents”

This definition will cover the compounds as set out in Annex B of this impact assessment.

This option is both compliant with the UK’s obligations as an EU member following the Council decision 2008/206/JHA and in line with the recommendations made by the ACMD. As with option two, making BZP subject to the provisions of the misuse of drugs legislation will provide controls on the production, supply, possession, import and export of the substance in view of its potential for misuse as a psychoactive stimulant. This option gives further consideration to the potential misuse of BZP and associated piperazine substances and will subject these substances to the same controls. In their review of BZP the ACMD found that BZP is one of several substituted piperazines reported in the UK and across the EU in recent years; one of which has been reported as being more widespread than BZP- namely 1(3-chlorophenyl) piperazine (mCPP).

Since 1977, the UK’s classification system has contained a generic type of drug control system. Many examples of generic definitions based on substitution patterns exist in the MDA (phenethylamines, tryptamines, anabolic steroids etc.). The ACMD recommends controlling BZP and a group of substituted piperazines under a generic definition that would include BZP. The generic system is very successful because it legislates for compounds that may otherwise have to be controlled separately.

Under the EU Council decision the UK is only required to implement controls on BZP. However, the ACMD has recommended the wider, generic definition as stated above that would include BZP alongside piperazine derivatives. The Government supports this recommendation in full as it captures a wider definition of piperazines which also have the potential for misuse. Indications from the forensic service providers are that substituted piperazines, as identified by the ACMD, are being misused and appear to mimic the effects of ecstasy; it is further considered that these piperazines if mixed with ecstasy could intensify its effect. This option would have greater regard for the Government’s duty to protect the public against substances of misuse; it would further bring the UK in line with other countries that already control a number of substituted piperazines. Using a wider definition would mitigate the need for further legislation to control other compounds separately. BZP has no legitimate medicinal or commercial use. Two of the substances encompassed by the generic definition do have legitimate use; see the following section on Impact, Cost and Benefits for how this will be considered in the preferred option. It is also worthy of note that the EU risk assessment conducted on BZP did not consider substituted piperazines. This is because some of the substances (namely mCPP) were used in the manufacture of active pharmaceutical ingredients within the EU.

Given there is no recognised medicinal use, BZP and substituted piperazines would be placed in Schedule 1 to the Misuse of Drugs Regulations 2001; this means they can only lawfully be dealt with under a Home Office licence. The legislative framework is as follows:

Controlled drugs that are designated under section 7(4) of the Misuse of Drugs Act 1971 have no statutorily recognised medicinal use. A designation under section 7(4) of the 1971 Act has the effect of preventing section 7(3) of the Misuse of Drugs Act from applying to the controlled drug in question. Therefore the Secretary of State is not required to make regulations permitting certain professionals who usually work with controlled drugs (for example, doctors) to lawfully prescribe, administer, manufacture, compound, supply or possess a designated drug, except for purposes of research or other special purposes under licence or other authority issued by the Secretary of State.

Schedule I drugs are also subject to statutory safe custody requirements; researchers and those licensed to possess these drugs are required to keep them in a complying controlled drug (CD) cabinet.

Notwithstanding the above legal requirements, the only substances subsumed by the proposed generic definition of substituted piperazines that have been found to have legitimate uses are: 1(3-chlorophenyl) piperazines (mCPP), which is used as a probe of serotonin receptors in experimental neuropharmacology and 1-(3-chlorophenyl)-4-(3-chloropropyl)-piperazine, (CPCPP); both are used as precursors in the manufacture of antidepressants.

The preferred option of controlling BZP and the group of substituted piperazines will mean it becomes an offence to import and export, manufacture, supply and possess 1-benzylpiperazine and associated substituted piperazines without lawful authority.

Costs

Actual costs associated with BZP and the group of substituted piperazines being subject to control under MDA 1971 are currently unknown and will be informed by the consultation process. In addition, as it will be an offence to import and export, manufacture, supply and possess these drugs, there are likely to be some future costs to the criminal justice system as a result of any criminal sanctions imposed. As BZP has no legitimate industrial or recognised medicinal use and its sale and supply are currently unlawful under medicines legislation, these further proposed controls will not take into account the impact on any business or person already undertaking unlawful activities in contravention of the Medicines Act in respect of BZP.

In respect of businesses that legitimately use substituted piperazines as synthetic intermediates in the production of pharmaceutical products as identified by the ACMD Report, these businesses would likely be required to have a licence (or their activities could be regulated under the Misuse of Drugs Regulations 2001). The costs associated with licensing will need to be included, but are thought to be minimal. Companies that need to possess and/or supply any substituted piperazines for legitimate use would require a “domestic licence” issued by the Home Office Drug Licensing and Compliance Unit. Similarly, those needing to import or export substituted piperazines would require an import or export licence (for each consignment).

Licences are easily available from the Home Office and applications can be made on-line. The Home Office Drug Licensing and Compliance Unit will undertake a “verification process” with the purpose of ensuring that the business of the Company is legitimate and that the Company is equipped to self-regulate with Standard Operating procedures (SOPs) in place and an understanding of the security issues.

Benefits

A reduction in economic and social costs associated with reductions in the use of BZP and the group of substituted piperazines represents the potential benefits of intervention to control the use of these drugs. In addition, there are also potential additional but difficult to measure benefits, for example, improvements in health from a drug-free state may enhance an individual’s career progression and day to day social activities.

Whilst there is no direct evidence that BZP and substituted piperazines cause any significant social harms such as acquisitive crime and anti-social behaviour, controlling the substances under drugs legislation may have some further social benefit in protecting the public. Controlling the drug through the legislative framework, by giving it a classification, sends a clear message to the public that BZP and associated piperazine substances are potentially harmful.

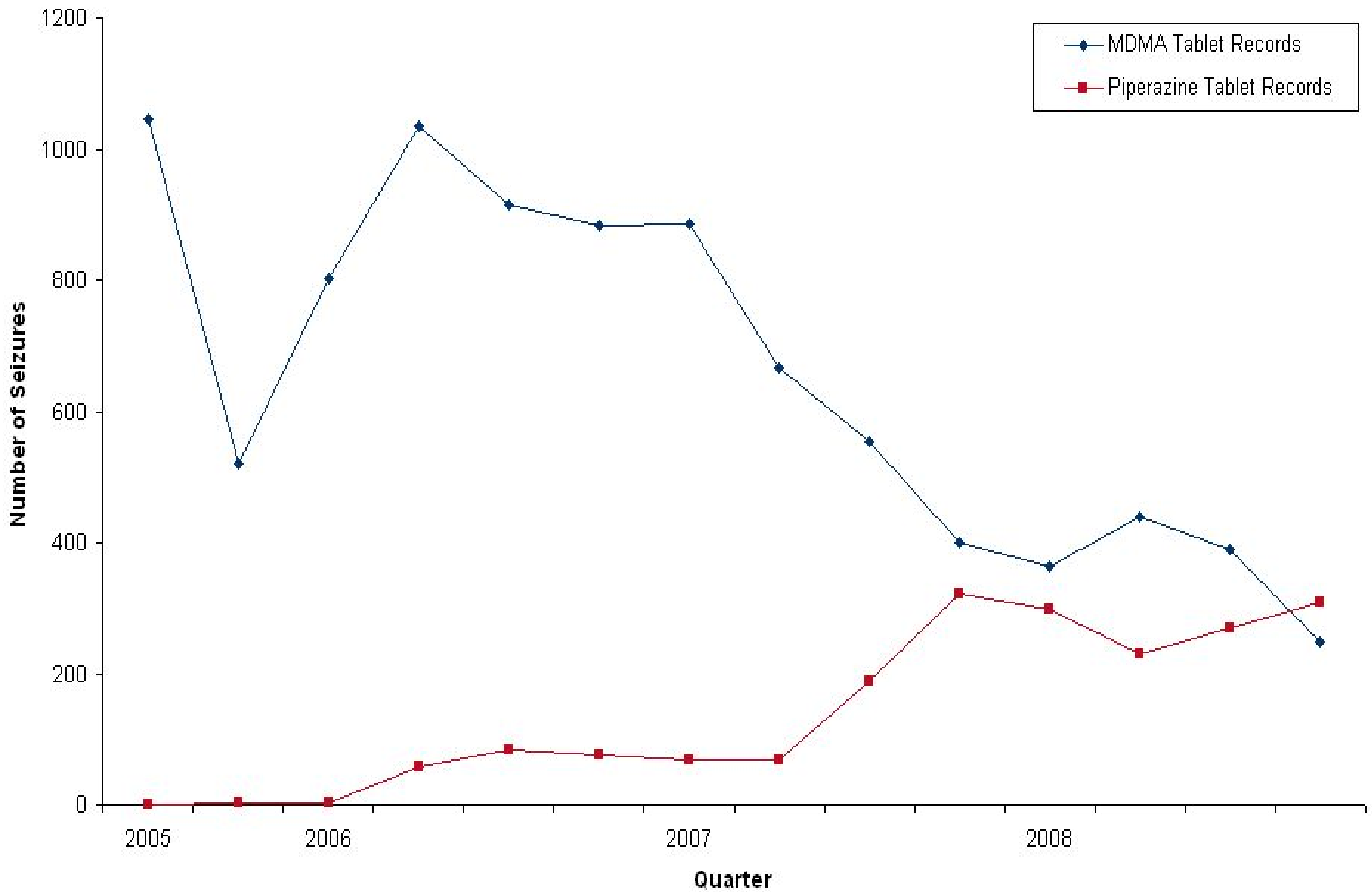
Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Annexes

Annex A:



Data provided by the FSS*

*** The data provided by the FSS is based on drug submissions to the FSS only by Police and HMRC that have an entry on the drugs database.**

ANNEX B

Substituted piperazines (1-pheny and 1-benzyl) that would be subsumed under the proposed generic definition:

Phenylpiperazines

Name (acronym)	R^1	R^2	R^3
1-(3-Chlorophenyl)piperazine (mCPP)	H	Cl	H
1-(4-Chlorophenyl)piperazine (pCPP)	Cl	H	H
1-(4-Fluorophenyl)piperazine (pFPP)	F	H	H
1-(3-Trifluoromethylphenyl) piperazine (TFMPP)	H	CF_3	H
1-(3-Methylphenyl) piperazine (mMPP)	H	CH_3	H
1-(4-Methylphenyl) piperazine (pMPP)	CH_3	H	H
1-(4-Methoxyphenyl) piperazine (pMeOPP)	CH_3O	H	H
1-(3-Chlorophenyl)-4-(3-chloropropyl)piperazine (CPCPP)	H	Cl	CH_2CH_2-CH_2Cl

Benzylpiperazines

Name (acronym)	R^4
1-Benzylpiperazine (BZP)	H
1,4-Dibenzylpiperazine (DBZP)	C_6H_5-CH_2
1-Benzyl-4-methylpiperazine (BZMP)	CH_3

List of References

Home Office documents

1. Advisory Council on the Misuse of Drugs report on Control of 1-benzylpiperazine (BZP) and related compounds

EU documents

2.Risk Assessment Report of a new psychoactive substance: 1-benzylpiperazine (BZP) in accordance with Article 6 of Council Decision 2005/387/JHA on information exchange, risk assessment and control of new psychoactive substances;

https://ednd-cma.emcdda.europa.eu/assets/upload/Risk_Assessment_Report_BZP.pdf

3. **Council Decision 2008/206/JHA** 3 March 2008 on defining 1-benzylpiperazine as a new psychoactive substance which is to be made subject to control measures and criminal provisions:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:063:0045:0046:EN:PDF

4. **Council Decision 2005/387/JHA** 10 May 2005 on the information exchange, risk assessment and control of new psychoactive substances:

https://ednd-cma.emcdda.europa.eu/assets/upload/Risk_Assessment_Report_BZP.pdf

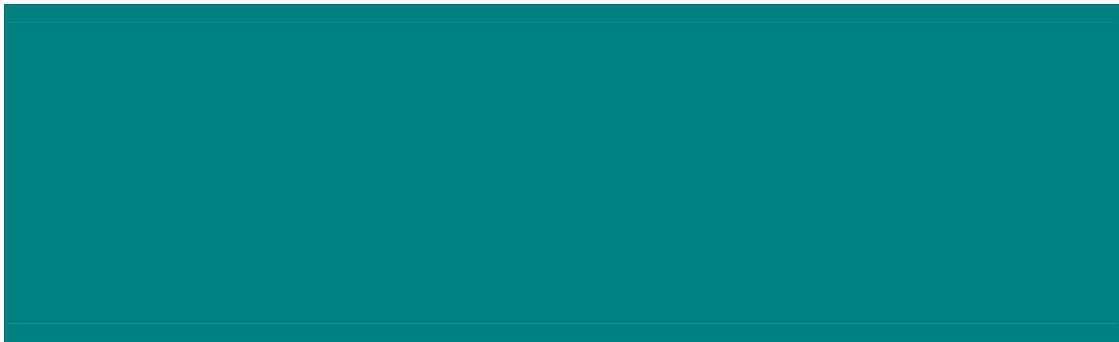
Summary: Intervention & Options		
Department /Agency: Home Office	**Title:** Impact Assessment of Proposed changes to the Misuse of Drugs Legislation- Anabolic Steroids and 2 non- steroidal agents	
Stage: **Consultation**	Version:	Date: **21** May 2009
Related Publications:		

Available to view or download at:

http://www.homeoffice.gov.uk/about-us/haveyoursay/current-consultations/

Contact for enquiries: **Angela Scrutton** Telephone: **020 7035 0458**

What policy options have been considered? Please justify any preferred option.

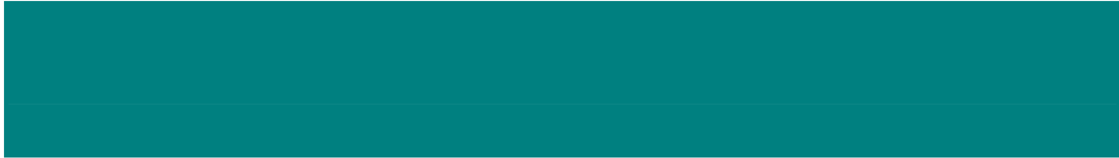


Summary: Analysis & Evidence

Policy Option:	**Description:**

COSTS	ANNUAL COSTS	Description and scale of **key monetised costs** by 'main affected groups' Will be informed by consultation
	One-off Yr	
	£ Unknown	
	Average Annual Cost	
	£ Unknown	Total Cost (PV) £ Unknown
	Other **key non-monetised costs** by 'main affected groups' Will be informed by consultation	

BENEFITS	ANNUAL BENEFITS	Description and scale of **key monetised benefits** by 'main affected groups' Will be informed by consultation
	One-off Yr	
	£ Unknown	
	Average Annual Benefit	
	£ Unknown	Total Benefit (PV) £ Unknown
	Other **key non-monetised benefits** by 'main affected groups' Will be informed by consultation	



Price Base	Time Period	**Net Benefit Range** (NPV) **£ Unknown**	**NET BENEFIT** (NPV Best estimate) **£ Unknown**

What is the total annual cost of enforcement for these	£ Unknown

What is the value of the proposed offsetting measure per	£ Unknown
What is the value of changes in greenhouse gas emissions?	£ Unknown

Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large

Evidence Base (for summary sheets)

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

This is a partial Impact Assessment forming the first step in identifying costs and benefits of the proposals set out in the consultation paper to make changes to the Misuse of Drugs legislation. This is a continuous process and respondents are invited to submit any figures, costing or other details of relevance to help refine the final stage regulatory impact assessment.

Background

In 1993, the Advisory Council on the Misuse of Drugs (ACMD) - the Government's independent expert body on drug related issues- considered the misuse of anabolic steroids concluding that the misuse of steroids (and other related substances) constituted a social problem – a key criterion under the Misuse of Drugs Act 1971 which needs to be satisfied before a particular subject can be controlled. It was recommended that legislative controls be introduced aimed at the activities of illicit suppliers and traffickers who fed anabolic steroid misuse.

It was not recommended that an offence of simple possession be introduced as that would unnecessarily criminalise a group of people. It is therefore not an offence to simply possess anabolic steroids when in the form of a medicinal product for personal use. In the absence of a simple possession offence, it was considered anomalous and contrary to EU restrictions to make the importation or exportation of the substances for personal use an offence i.e. to have a stricter regime of controls at ports. Permitting importation for personal use was consistent with permitting simple possession inland. However, in all other circumstances importation and exportation would require a Home Office licence; such activity without a licence is an offence. The Government accepted this advice and anabolic steroids were brought under the legislative framework.

In 1995, the ACMD gave further consideration to the drugs that should be included in the legislative measure. As well as anabolic steroids, beta-2-agonists and growth hormones were considered for control. The ACMD acknowledged that people involved in sporting activities took a wide range of substances; the most common reasons cited included legitimate therapeutic purposes, performance continuation, performance enhancement and recreational use. The ACMD also took into account at this time the anabolic substances and androgenic (or

masculinising) substances which are banned in sports and on the International Olympic Commission (IOC) list- (now known as the World Anti-Doping Agency (WADA) prohibited list).

Currently 54 anabolic steroid substances, as well as 5 growth hormones, are controlled as Class C drugs under the Misuse of Drugs Act 1971 by a generic definition. They were made subject to Schedule 4 Part 2 of the Misuse of Drugs Regulations 2001 with additional import/ export restrictions. It is an offence under the Act to produce, supply or possess/import/export with intent to supply without a licence. The current regulations for Schedule 4 Part 2 require a Home Office licence to be issued for those importing/ exporting anabolic steroids unless the substance is in the form of medicinal product being imported for personal use only.

The ACMD has advised the Home Secretary that 24 steroidal and 2 non-steroidal substances should be brought under classification. Their recommendation also addresses the need to ensure the UK has a consistent approach in the policy towards anabolic steroids that reflects its position in relation to the WADA list and to work in line with the Government commitment to preventing the use of prohibited drugs and doping in sport particularly in the run up to the London Olympics 2012.

Rationale for intervention

The case for bringing the additional 26 anabolic steroids and non-steroidal substances under control can be examined in relation to the general principles of control around anabolic steroids, the need to have a consistent UK policy towards anabolic steroids and growth hormones as well as current trends in anabolic steroid use amongst the general public.

The ACMD, as the Government's independent advisory body on drugs, has given careful consideration to the issues surrounding anabolic steroids. Their recommendation to control these substances recognises their legitimate use but also their potential for harm The ACMD considers the misuse potential of this type of drug alongside increasing trends of use amongst the general public, particularly young people. Their recommendation for control and classification of these 26 additional substances associated with sport, body building and image enhancement is based on demand reduction, harm minimisation and reduction of supply.

Objective

The measure to control 24 additional anabolic steroid substances and 2 non-steroidal products under the Misuse of Drugs Act 1971 will support the Government's commitment to strengthening the mechanisms to tackle doping in sport, targeting those facilitating doping and tackle trafficking, supply and manufacture of doping substances and those involved in such activities. In addition it protects the integrity of UK athletes in preparation for the 2012 Olympics and ensures consistency in UK policy towards anabolic steroids. This action is in line with the Government's overarching drug strategy to take a wider, preventative view on all substances and risk factors. Evidence suggests an increase in use of these substances amongst the general public and in particular young people. Controls on these substances work towards protecting individuals from potential harms related to the misuse of these substances.

Appraisal

Option 1- Do nothing

This option would leave the current law unchanged and would not meet the Government's overarching drugs policy objectives to protect individuals and society, particularly UK athletes by taking wider preventative action not just on illegal drugs but from the harmful effects of all substances and associated risk factors.

Costs

As there is no intervention there are no direct intervention costs. However, by doing nothing account should be taken of any likely economic and social costs that are incurred by the misuse of anabolic steroids, for example, any costs associated with poor health, lost output as a result of time off work, or any associated criminal justice costs – for example from anti-social behaviour.

Benefits

Generally, any reduction in the use of anabolic steroids from an intervention can be quantified by any reduction in the economic and social costs that are associated with the use of the drug.

Option 2- Control an additional 24 anabolic steroids and 2 non steroidal products under the Misuse of Drugs Act 1971 and associated secondary legislation

This is the Government's preferred option.

Following this option, the 26 substances outlined in Annex A would be controlled as Class C drugs under the MDA 1971 and its associated legislation. This option will ensure that the UK's drug controls are up to date with the latest evidence of harms and availability of these groups of drugs. The 26 additional substances have recently been added to the WADA list and are not subsumed by the generic definition for anabolic steroids as set out in the MDA 1971. Whilst there is little evidence of misuse by the general public of these specific additional substances, the principle of controlling anabolic steroids as Class C drugs is well established since 1996.

Anabolic steroids by definition are a group of synthetic hormones that promote the storage of protein and the growth of tissue. They are often misused by athletes to increase muscle size and strength. There is current evidence of increased used amongst the general public, particularly young people. It is the role of the Government to ensure a consistent policy towards drug types; anabolic steroids not only jeopardise the integrity of sport but pose serious health risks to those who misuse them; controlling these further substances under the MDA and associated legislation protects the public from the risks and harms associated with their use.

Costs

At this stage the costs associated with additional control of anabolic steroids and the 2 non-steroidal substances are unknown but are thought to be minimal. Whilst these substances for legitimate use can be made available via prescription, the MHRA has advised that there is only one anabolic steroid licensed for use in the UK (Nandrolone, which is already controlled under the 1971 Act) with two associated marketing authorisations. The British National Formulary indicates that it is use for the treatment of plastic anaemia, suggesting that it is prescribed mainly in hospital settings rather than through GPs. The Government is however interested to hear from any company or person where any additional direct and indirect costs may arise as a result of this proposal. There will also be potential criminal justice costs in that 24 anabolic steroids and 2 non-steroidal products will become Class C controlled drugs. Those not entitled

to possess, supply, import and export these drugs will be liable to prosecution under Misuse of Drugs legislation.

Benefits

More generally any reduction in the harms associated with reductions in the use of anabolic steroids as a result of government interventions can be quantified as the benefits.

Whilst there is no direct evidence that the 24 anabolic steroids and 2 non-steroidal products cause any significant social harms, such as acquisitive crime and anti-social behaviour, controlling the substances under drugs legislation may have some further social benefit in protecting the public. Controlling the drugs through the legislative framework, by giving them a classification, sends a clear message to the public that misusing anabolic steroid substances are potentially harmful.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Annexes

Annex A:

Anabolic Steroids and 2 non-steroidal agents recommended by the ACMD for classification in Class C (Misuse of Drugs Act 1971) and scheduled as Schedule 4 (IV) (Misuse of Drugs Regulations) on the 2007 WADA list - but not presently controlled by the Misuse of Drugs Act 1971.

All 26 substances are **not** subsumed by the MDA 1996 generic definition; neither are they listed explicitly by SI 1243:2003 or SI 1300:1996. Zeranol & Zilpaterol are not steroids but the WADA sub-category includes Clenbuterol, which **is** MDA controlled.

Chemical Name
1-Androstendiol
1-Androstendione
Boldione
Gestrinone
Danazol
Desoexoymethyltestosterone
19-Norandrostenedione

Prostanozol
Tetrahydrogestrinone
Dihydrotestosterone
5α-Androstane-3α,17α-diol
5α-Androstane-3α,17β-diol
5α-Androstane-3β,17α-diol
5α-Androstane-3β,17β-diol
Androst-4-ene-3β,17β-diol (‘Androstenediol’)
Androst-4-ene-3α,17α-diol
Androst-4-ene-3α,17β-diol
Androst-4-ene-3β,17α-diol
5-Androstenedione
Epidihydrotestosterone
3α-Hydroxy-5α-androstan-17-one
3β-Hydroxy-5α-androstan-17-one
19-Norandrosterone
19-Noretiocholanolone
Zeranol
Zilpaterol

List of References

Home Office documents

HM Government; *Drugs: protecting families and communities. The 2008 Drug Strategy,* COI on behalf of HM Government, February 2008.