

**EXPLANATORY MEMORANDUM TO
THE MISUSE OF DRUGS ACT 1971 (AMENDMENT) ORDER 2009**

2009 No.

1. This explanatory memorandum has been prepared by the Home Office and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 The Order in Council classifies the following drugs for control under Schedule 2 to the Misuse of Drugs Act 1971:

- (i) gamma-butyrolactone (GBL) and 1,4-butanediol (1,4-BD) in Part 3 of the Schedule as Class C drugs;
- (ii) 1-benzylpiperazine (BZP) and a group of substituted piperazines in Part 3 of the Schedule as Class C drugs;
- (iii) 15 anabolic steroids and 2 non-steroidal agents (growth promoters) in Part 3 of the Schedule as Class C drugs;
- (iv) synthetic cannabinoid receptor agonists in Part 2 of the Schedule as Class B drugs; and
- (v) oripavine in Part 3 of the Schedule as a Class C drug.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Legislative Context

4.1 The Misuse of Drugs Act 1971 (“the 1971 Act”) controls drugs that are “dangerous or otherwise harmful”. Schedule 2 to the 1971 Act specifies these drugs and groups them in three categories – Part 1 lists drugs known as Class A drugs, Part 2 contains Class B drugs and Part 3 lists Class C drugs. The three-tier system of classification (A, B and C) provides a framework within which criminal penalties are set with reference to the harm a drug has or is capable of having when misused and the type of illegal activity undertaken in regard to that drug.

4.2 Section 2 of the 1971 Act enables amendments to be made to the list of drugs controlled under the Act by means of an Order in Council. Such Orders are subject to the affirmative resolution procedure which requires that they be approved by each House of Parliament. Section 2 also provides that the Secretary of State may not recommend the making of such an Order except after consultation with the Advisory Council on the Misuse of Drugs (ACMD).

4.3 The classification of each of the drugs listed in paragraph 2.1 above is predicated on an assessment of their respective harms and in accordance with recommendations made by the ACMD.

4.4 When ingested GBL and 1,4-BD are rapidly converted to GHB which is already controlled as a Class C drug. However, unlike GHB, GBL and 1,4-BD have a wide range of legitimate industrial uses and therefore we intend, through regulations, to make it lawful to use these substances save where they are intended for human consumption. The control of BZP (and a group of substituted piperazines) is the Government’s response to the European Council decision 2008/206/JHA which requires EU member states to subject BZP to ‘control measures and criminal provisions’. The decision to bring 15 anabolic steroids and 2 non-steroidal substances (growth promoters) under the control of the 1971 Act as Class C drugs will bring UK legislation into line with the World Anti-Doping Agency Prohibited List. Synthetic cannabinoid receptor agonists mimic the effects of the active ingredient of cannabis, which was reclassified as a Class B

drug in January 2009. The synthetic cannabinoids will therefore also be classified as Class B drugs. Control of oripavine under the 1971 Act meets the United Kingdom's obligations following its international control under the UN Single Convention on Narcotic Drugs 1961.

4.5 It is intended to make two further related statutory instruments which will be subject to the negative resolution procedure. The Misuse of Drugs (Designation) (Amendment) Order 2009 will specify those substances which have no statutorily recognised medicinal use. The Misuse of Drugs (Amendment) Regulations 2009 will amend the Misuse of Drugs Regulations 2001 to include these drugs and allow for legitimate use where appropriate and, in particular, to deliver the policy in relation to GBL and 1,4-BD.

5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

6.1 The Parliamentary Under-Secretary of State for the Home Department, Alan Campbell, has made the following statement regarding Human Rights:

In my view the provisions of the Misuse of Drugs Act 1971 (Amendment) Order 2009 are compatible with the Convention rights.

7. Policy background

• *What is being done and why*

7.1 The effects and risks associated with GBL and 1,4-BD are similar to those of GHB whose misuse is associated with unconsciousness, a risk of death by intoxication and a dependence syndrome if used regularly. The risks are increased if combined with alcohol or other depressant substances. Their control as Class C drugs under the 1971 Act, as recommended by the ACMD, brings them in line with GHB which has been a Class C drug since 2003. At the same time we are concerned to ensure that we do not prevent legitimate use of these substances and this will be reflected in the amendments made to the Misuse of Drugs Regulations 2001 which will allow for the possession, supply, manufacture, import and export of these substances save when they are intended for human consumption. The ACMD's advice in respect of GBL and 1,4-BD can be found at <http://drugs.homeoffice.gov.uk/publication-search/acmd/report-on-gbl1?view=Standard&pubID=572970>.

7.2 Control of BZP and a group of substituted piperazines (related compounds) is pursuant to the call for control of BZP contained in the European Council decision 2008/206/JHA of March 2008. BZP is a synthetic drug which stimulates the central nervous system with similar but less potent properties to amphetamine. The ACMD has assessed that the harms associated with BZP range from headaches and increased blood pressure to mood swings, confusion, and association with grand mal seizures. The ACMD's advice in respect of BZP can be found at <http://drugs.homeoffice.gov.uk/publication-search/acmd/ACMD-BZP-Report?view=Binary>.

7.3 BZP is only one of several substituted piperazines which have been found in the UK and which are, or are capable of, being misused with similar harms and risks. The Government accepted the ACMD's recommendation that controls be levied on the group of substituted piperazines, not just BZP, via a generic definition. The wider legislative control obtained by use of a generic definition for piperazine compounds will ensure we deal with both current and foreseeable trends where related compounds start to be used which 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.

7.4 Control of additional anabolic steroids and growth promoters is intended to update the list of substances in this category which are currently controlled. When misused steroids have a range of physical and psychological harms. The original group of in excess of 50 anabolic steroids (as well as 5 growth hormones) which came under the control of the 1971 Act as Class C drugs in 1996 were identified by reference to the International Olympic Commission Prohibited List. It is appropriate for the Government to update the control of such drugs by reference to its successor, the World Anti-Doping Agency Prohibited List. It is also fully in line with the Government's commitment to prevent the misuse of these substances both by the general public and by elite athletes, particularly in the lead up to the 2012 Olympics. The ACMD's advice can be found at <http://drugs.homeoffice.gov.uk/publication-search/acmd/advice-on-steroids1?view=Binary>.

7.5 Synthetic cannabinoid receptor agonists are man-made chemicals that mimic the psychoactive effects of tetrahydrocannabinol (THC), the active ingredient in cannabis. They can be sprayed on herbal smoking products such as 'Spice'. After consideration of the available evidence, the ACMD concluded that the harms of the synthetic cannabinoids are broadly commensurate with those of cannabis and that they should be classified accordingly under the 1971 Act. The ACMD's advice can be found at <http://drugs.homeoffice.gov.uk/publication-search/acmd/acmd-report-agonists?view=Binary>. By using the generic definition provided by the ACMD, our controls will capture a range of agonists and therefore both current and future foreseeable trends. It is also consistent with the UK's legislative approach to other synthetic drugs.

7.6 Control of oripavine as a Class C drug under the 1971 Act is pursuant to the United Kingdom's obligations under the UN Single Convention on Narcotic Drugs 1961. Oripavine is found in poppy straw of the opium poppy which can be converted into thebaine (controlled under the 1971 Act as a Class A drug) and used in the production of semi-synthetic opiates such as hydrocodone and oxycodone. There is presently no evidence of its misuse in the UK. The ACMD recommended that oripavine's potential harm is commensurate with drugs in Class C such as the opioid, buprenorphine. The ACMD's advice can be found at <http://drugs.homeoffice.gov.uk/publication-search/acmd/oripavine?view=Binary>.

- **Consolidation**

7.7 None.

8. Consultation outcome

8.1 A three month consultation on the control options for GBL and 1,4-BD, BZP and substituted piperazines and the additional group of anabolic steroids and growth promoters ran from May to August 2009. Around 50 responses were received in total and summaries of the responses are available at <http://drugs.homeoffice.gov.uk>. The vast majority of responses were supportive of control, citing the harms of the respective drugs. Informed by the 35 responses to the consultation on GBL and 1,4-BD which set out the potential impact on UK industry, regulations will be introduced to ensure that these substances continue to be available for legitimate use in the UK and that controls are confined to situations where GBL and 1,4-BD are intended for human consumption.

9. Guidance

9.1 The law changes and their consequences will be communicated to key stakeholders and the wider public, especially young people, in two main ways. The Home Office will issue a Circular with legislative guidance primarily for the police and the courts, while information about the changes will be made widely available via FRANK – the Government's national drugs awareness campaign.

10. Impact

10.1 The impact on business, charities or voluntary bodies principally relates to additional administrative costs for the pharmaceutical industry in respect of those drugs that have a legitimate use, although this is likely to be small.

10.2 The impact on the public sector relates to certain healthcare sectors, the police and criminal justice system. There are potential additional administrative costs to certain sectors of healthcare in respect of the availability and use of those drugs that have a legitimate use, although these are likely to be small. It is expected that there will be some prosecutions in respect of the drugs to be controlled under this Order.

10.3 An Impact Assessment and Equality Impact Assessment are attached to this memorandum.

11. Regulating small business

11.1 The legislation applies to small business.

11.2 The harm that can be done from misuse and diversion of these drugs is such that we will expect those operating in the pharmaceutical industry and certain sectors of healthcare to comply with the Misuse of Drugs Act 1971 and subordinate legislation made under it, however small the business. However, impact is minimised as these businesses are already likely to be handling controlled drugs, acting under Home Office licence or the Misuse of Drugs Regulations 2001, and guidance is already widely available in this area.

12. Monitoring & review

12.1 The Government will monitor the control measures as part of the ongoing Drug Strategy.

12.2 In tandem with this, the Government will review its public health messages to ensure that they are appropriately targeted and informative. In particular, there are concerns about the potentially serious consequences of GBL being taken with alcohol.

13. Contact

Richard Mullins at the Home Office, tel: 020 7035 0463 or e-mail: Richard.Mullins1@homeoffice.gsi.gov.uk, can answer any queries regarding the instrument.

Summary: Intervention & Options

Department /Agency: HOME OFFICE	Title: Impact Assessment of NEW DRUG CONTROLS	
Stage: FINAL	Version: FINAL	Date: October 2009
Related Publications: See Annex A		

Available to view or download at: www.drugs.homeoffice.gov.uk

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

The various substances to be controlled – BZP and substituted piperazines, a group of anabolic steroids and 2 growth promoters, oripavine, GBL and 1,4- BD and synthetic cannabinoid receptor agonists – under the Misuse of Drugs Act 1971 are considered sufficiently harmful, following assessment and advice from the Advisory Council on the Misuse of Drugs, to warrant control measures relating to possession, supply, manufacture and import/exportation with associated criminal sanction. Government intervention is necessary to help protect the public from these substances.

What are the policy objectives and the intended effects?

To control substances that are considered “dangerous or otherwise harmful” in accordance with the terms of the 1971 Act. The intended effects are to deter use of these substances, particularly by young people, and reduce their availability via supplier “self-regulation” following implementation of control measures as well as enabling law enforcement agencies to undertake appropriate enforcement action, in particular activity to tackle production and supply.

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

Option 1 : No change

Option 2 : Control under the Misuse of Drugs Act 1971 for each of the substances/groups of substances with alternative options regarding the level of control under the 1971 Act as described below.

Option 2 is the preferred option.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? The control measures will be reviewed as part of the Government’s ongoing Drug Strategy and through the monitoring of Criminal Justice and British Crime Survey statistics to evaluate effects on use and enforcement.

Ministerial Sign-off For final proposal/implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options

Signed by the responsible Minister:

Alan Campbell

.....Date: 19/10/09

Summary: Analysis & Evidence

Policy Option: 2

COSTS	ANNUAL COSTS		Description and scale of key monetised costs by 'main affected groups' It is not possible to monetise the costs of this option either from existing data, or from responses to public consultation (where appropriate).
	One-off (Transition)	Yrs	
	£ UNKNOWN		
	Average Annual Cost (excluding one-off)		
	£ UNKNOWN		Total Cost (PV) £ UNKNOWN
Other key non-monetised costs by 'main affected groups' Potential costs fall to the police and criminal justice system. However, without baseline figures of prevalence, these cannot be quantified at this time. There are also potential additional administrative costs to certain sectors of healthcare in respect of the legitimate use of those drugs identified below.			

BENEFITS	ANNUAL BENEFITS		Description and scale of key monetised benefits by 'main affected groups' It is not possible to monetise the benefits of this option.
	One-off	Yrs	
	£ UNKNOWN		
	Average Annual Benefit (excluding one-off)		
	£ UNKNOWN		Total Benefit (PV) £ UNKNOWN
Other key non-monetised benefits by 'main affected groups' Control measures bringing about the curtailment of availability of these substances will have benefits across government and society as a whole.			

Key Assumptions/Sensitivities/Risks

None

Price Base Year	Time Period Years	Net Benefit Range (NPV) £	NET BENEFIT (NPV Best estimate) £
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What is the geographic coverage of the policy/option?	UK			
On what date will the policy be implemented?	December 2009			
Which organisation(s) will enforce the policy?	Police/HO/CJS			
What is the total annual cost of enforcement for these organisations?	£ UNKNOWN			
Does enforcement comply with Hampton principles?	Yes			
Will implementation go beyond minimum EU requirements?	N/A			
What is the value of the proposed offsetting measure per year?	£ 0			
What is the value of changes in greenhouse gas emissions?	£ 0			
Will the proposal have a significant impact on competition?	No			
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices)			(Increase - Decrease)		
Increase of	£	Decrease of	£	Net Impact £	NEGLIGIBLE

Key:	Annual costs and benefits: Constant Prices	(Net) Present Value
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This Impact Assessment deals with all drugs proposed to be controlled under the Misuse of Drugs Act 1971 by the Misuse of Drugs Act 1971 (Amendment) Order 2009 as follows:

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

Background

BZP is a synthetic drug which stimulates the central nervous system with similar but less potent properties to amphetamine. BZP is normally manufactured from piperazine, a substance used as an anti-helminthic drug for the treatment of worm infestations. It is one of a group of substituted piperazines. It may come as a pill, an off-white powder or a slightly yellow liquid.

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"*.

The Advisory Council on the Misuse of Drugs (ACMD) 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/>. 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.

The ACMD advised that several of the substituted piperazines are or are capable of being misused in the UK. The ACMD therefore recommended that controls are levied on the group of substituted piperazines, not just BZP, via a generic definition. In addition to BZP, the following substituted piperazines would be subsumed by the generic definition proposed by ACMD.

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)

A number of other EU countries control BZP but also mCPP and pFPP. In addition, use of a generic definition is consistent with our approach to drugs control where appropriate. The 1971 Act's classification system contains a number of generic definitions based on substitution patterns eg. the phenethylamines, tryptamines, anabolic steroids etc.

The proposal was subject to public consultation which ran for 3 months, closing on 13 August. A summary of the responses is available at <http://drugs.homeoffice.gov.uk>

As BZP and the associated piperazines are not controlled to date under the 1971 Act there is no population or household survey data collection. It is understood that 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 of BZP and the substituted piperazines have steadily increased in the UK since early 2006, and have been found in combination with illegal drugs such as MDMA – “ecstasy” and amphetamine. Seizures data provided by the Forensic Science Service (FSS) shows that they examine around 400 cases in a quarterly period. The most commonly reported substances have been mCPP, BZP, 1,4-dibenzylpiperazine [DBZP] and 1-(3 trifluoromethylphenyl) piperazine [TFMPP] often in various combinations. Overall FSS data indicates that as the level of MDMA seizures have decreased, BZP and piperazine seizures have increased. Anecdotal police evidence suggests that BZP is frequently mis-sold as MDMA (“ecstasy”) as the appearance of illicit MDMA tablets and BZP tablets are very similar.

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. Those currently prosecuted under medicines legislation face a statutory maximum penalty of 2 years imprisonment and/or unlimited fine. In respect of two recent successful prosecutions undertaken by MHRA under the Medicines Act 1968, the sentences issued were 12 month community order and 2 year conditional discharge.

It is understood that only 2 substituted piperazines, 1-(3-chlorophenyl)piperazine [Mcpp] and 1-(3-chlorophenyl)-4-(3-chloropropyl)piperazine [CPCPP] have legitimate uses. The former is used as a probe of serotonin receptors in experimental neuropharmacology and as the precursor in the synthesis of several anti-depressant drugs (e.g. trazodone). CPCPP is a precursor used in the manufacture of the antidepressant drug nefazodone.

Rationale for intervention

The case for intervention through control measures under the 1971 Act can be examined in relation to potential harms and misuse of the drug as well as the UK's obligations under EU law.

- *Use of BZP (and by association the substituted piperazines) is associated with a range of physical and psychological harms and hazards.* There are risks associated with the use of 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 of grand mal seizures. BZP and some of the related compounds have been found in combination with MDMA and amphetamine. If mixed in this way, these piperazines can intensify the effects of these drugs.
- *To restrict the availability of BZP (and the substituted piperazines) and to deter their use.* Control measures will send a clear message to users, including young people, that these drugs are potentially harmful.
- *The control of BZP is necessary to ensure that the UK is compliant with its obligations as an EU Member State and signatory to the European Union treaties.*

Objective

The measure to control BZP and the substituted piperazines under the Misuse of Drugs Act 1971 (and the Misuse of Drugs Regulations 2001 as amended) 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 and by association the substituted piperazines have been shown to be substances of misuse.

Options and Appraisal

3 options have been considered in respect of BZP and the substituted piperazines.

Option 1- Do nothing

This option is not acceptable to Government nor was it supported by the majority of those responding to the public consultation. The UK Government would not be acting in accordance with its EU obligations.

Option 2- Control BZP under the Misuse of Drugs Act 1971 as a Class C drug (and Schedule 1 under the Misuse of Drugs Regulations 2001 (as amended))

This option is not acceptable to Government nor was it supported by the majority of those responding to the public consultation. Failing to deal with the piperazines could mean that these substances would be misused instead of BZP and we consider it would therefore be sensible to deal with this foreseeable trend now rather than waiting for further evidence of such misuse to become available.

The costs and benefits of this option are subsumed in Option 3 below.

Option 3- Control BZP and a group of substituted piperazines by means of a generic definition under the Misuse of Drugs Act as Class C drugs (and Scheduled under the Misuse of Drugs Regulations 2001 as appropriate)

This option is proposed to Parliament as the preferred option. It is both supported by the ACMD and also by the vast majority of those responding to the public consultation.

As Class C drugs under the 1971 Act, it will be unlawful to import/export, manufacture, supply or possess these drugs without lawful authority. Those that are prosecuted for unlawful possession are most likely to be dealt with in the Magistrates Court where the statutory maximum penalties are three months' imprisonment and/or a Level 3 (£1,000) fine. In respect of those cases that are dealt with by the Crown Court, the maximum penalties are two years' imprisonment and/or an unlimited fine. Offences of unlawful supply, production and trafficking of these substances are most likely to be dealt with in the Crown Court, where the maximum penalty is 14 years' imprisonment and/or an unlimited fine.

With control under the 1971 Act, responsibility for enforcement action against these substances will move to the police, with potential cost saving to Medicines Healthcare Regulatory products Agency.

The 1971 Act subjects these substances to the possession offence (which the Medicines Act does not) and maximum sentences available to the Court are generally higher under the 1971 Act.

Costs

The sale and supply of BZP and by association the group of substituted piperazines are unlawful already under the Medicines Act 1968 (without a Marketing Authorisation (Product Licence)). Licensing records indicate that BZP has never been licensed by the MHRA. Consequently, these further proposed controls under the 1971 Act do not take into account the impact on any business or person already undertaking unlawful activities in contravention of the Medicines Act.

Costs in respect of this option are potentially two fold.

- *To the pharmaceutical industry in respect of those substituted piperazines that are considered to have a research or legitimate use.*

BZP and the majority of the substituted piperazines have no recognised legitimate use. In accordance with convention and the ACMD's recommendation these will be placed in Schedule 1 of the 2001 Regulations. Authority to possess and/or supply Schedule 1 drugs can be

granted for research or other “special purpose” if considered in the public interest by the Home Office Drug Licensing and Compliance Unit.

In respect of those substituted piperazines that appear to have a legitimate use, mCPP or CPCPP, there is unlikely to be any impact or additional administration burden at this time. Through public consultation and with consultation with the Association of the British Pharmaceutical Industry (ABPI), we have not identified any UK companies that use these substituted piperazines.

However, their use and availability in the UK will be accommodated by appropriate scheduling under the Misuse of Drugs Regulations 2001 (as amended). In respect of manufacturers, distributors and wholesalers that produce, supply, import or export these substances they will need a licence issued by the Home Office Drug Licensing and Compliance Unit and an import or export licence (for each consignment). Licences are available from the Home Office and applications can be easily 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. There is a potential administration burden on business but would not be considered significant. UK pharmaceutical companies will already be licensed by the Home Office in respect of other controlled drugs they handle; the time taken to complete an import/export licence should be minimal and exporters already have to check for receiving country controls, many of which involve the issue of an import certificate by that country. There will be safe custody and record keeping requirements, although it is anticipated that any company trading in these substances would have storage/safe custody arrangements in place and keeps records for business purposes in any event.

- *To law enforcement and CJS in respect of enforcement against the illicit market.*

Any real costs associated with Option 3 cannot be predicted. Not only is the scale of the availability of these substances unknown, but the impact on the police and consequently the CJS is dependant on the policing response to their control as Class C drugs.

Whilst the Association of Chief Police Officers is considering the policing response with a view to providing practitioner advice on the enforcement approach, training and forensic issues, it is expected in the absence of spare capacity within the CJS, the enforcement response will be managed within existing resources, informed by policy and operational prioritisation. The police and other law enforcement agencies will prioritise resources towards tackling crime, including drugs crime with a focus on those offences which cause the most harm. As such, operational activity may focus on Class A and B drugs. It is also envisaged that enforcement activity will be directed towards supplier and manufacturers of these substances rather than possession for personal use.

Those caught in possession of significant quantities of BZP already face the risk of prosecution under the 1971 Act with some forces pursuing a charge of attempting to possess or intent to supply a Class A drug, if there is any evidence to establish that the person thought they were possessing/ supplying MDMA (“Ecstasy”). Further anecdotal evidence from the police indicates that the majority of the BZP seizures forensically analysed in the UK were originally seized by the police as illicit “ecstasy” and following testing were found to be BZP. This suggests that the forensic analysis costs attributed to BZP are unlikely to increase significantly in respect of this option.

As indicated above, there is no population or household survey data collection. The MHRA have not scoped the UK market to inform their enforcement response as they act following referral to them on a case by case basis. In the absence of any other data, seizure data referred to above provides us with some limited insight in the UK market though it cannot be taken as a direct indication of prevalence and so form a reliable basis for any assessment as to impact. In addition, from anecdotal information from police forces there are considerable variations in the availability of these substances from one force area to another. There is also anecdotal police evidence that following the public statement issued by the MHRA in 2007 advising that it was a

medicinal products and therefore subject to medicines legislation and possibly in anticipation of UK controls following the EU decision, some UK manufacturers and suppliers have “self-regulated” to a degree, particularly internet suppliers, and have withdrawn BZP related products.

Benefits

The overarching benefit of this proposal is that controls should help reduce the supply and use and thus limiting potential harm to individual misuser’s health and also for public health, with associated costs of treatment and care. It will also aid detection and monitoring of the manufacturing and trafficking of these substances.

Control of these drugs under the 1971 Act sends a clear message to users, including young people who may be considering using, as well as to those selling them. Young people in particular may often equate legal with “safe” and do not always understand that these drugs carry real risks. Control will re-enforce our educational messages about the harms of these drugs. There are also potential additional but difficult to measure benefits, for example, improvements in health of a person may enhance an individual’s ability to work, career progression and day to day social activities.

Whilst there is no direct evidence that BZP and the 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.

In respect of the wider control advanced by this proposal, as well as ensuring that the UK is compliant with its EU obligations, it enables the UK to have both current and durable laws. This option will capture piperazines that are, or could be in the future, available in the UK and will keep pace or ahead of a potentially changing market and illicit manufacturers, including those that target the so called “legal highs” market via availability at festivals, in “headshops” and on the internet.

A FURTHER GROUP OF 24 ANABOLIC STEROIDS AND 2 NON-STEROIDAL AGENTS (GROWTH PROMOTERS)

Background

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. Their misuse is associated with negative effects including aggression and violence, an increased risk of infections and in the longer term high blood pressure, liver disease, stroke and heart failure.

Currently 58 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. It is an offence under the Act to produce, supply or possess/import/export with intent to supply these substances without lawful authority. As Class C drugs the maximum sentence for supply, trafficking and production is 14 years. However, it is not an offence to import or export them when in the form of a medicinal product for self-administration nor is it an offence to possess them when in the form of a medicinal product. Anabolic steroids are available under authority of the Misuse of Drugs Regulations 2001 (as amended) enabling those persons authorised by the regulations (e.g. doctors and pharmacists) to prescribe, supply etc them for medicinal purposes.

The ACMD has recommended that a further group of anabolic steroid substances and 2 non-steroidal substances that are not currently subsumed by the generic definition are brought under the same level of control - see <http://drugs.homeoffice.gov.uk/publication-search/acmd/advice-on-steroids1?view=Binary> Following further consultation with the ACMD after responses to public consultation that closed on 13 August 2009, these are:

5 α -Androstane-3,17-diol.
Androst-4-ene-3,17-diol.
1-Androstenediol
1-Androstenedione

5–Androstenedione
Boldione
Danazol.
Desoxymethyltestosterone
Gestrinone.
3–Hydroxy–5 α –androstan–17–one
19–Norandrostenedione
19–Norandrosterone
19–Noretiocholanolone
Prostanozol
Tetrahydrogestrinone
Zeranol
Zilpaterol

Rationale for intervention

The case for bringing these additional anabolic steroids and non-steroidal substances under control can be examined as follows:

- *Misuse of anabolic steroids is associated with a range of physical and psychological harms and hazards as described above.*
- *To update our legislative controls 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.
- *To help 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.

Objective

The measure to control these additional anabolic steroids and non-steroidal substances under the Misuse of Drugs Act 1971 (and the Misuse of Drugs Regulations 2001 as amended) 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. It will also 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.

Options and Appraisal

2 options have been considered in respect of these additional anabolic steroids and non-steroidal substances.

Option 1- Do nothing

This option is not acceptable to Government nor was it supported by the majority of those responding to the public consultation. It would not meet the Government's overarching drugs policy objectives to protect individuals and society. It would leave the UK vulnerable to traffickers avoiding risk of prosecution by supplying otherwise legal steroids.

Option 2- Control of the further group of anabolic steroid substances and 2 non-steroidal substances as a Class C drug (and Schedule 4 Part II drugs under the Misuse of Drugs Regulations 2001 (as amended))

This is the Government's preferred option. Anabolic steroids, including this further group of substances, when in medicinal form are already subject to the provisions of the medicines legislation. Control under the 1971 Act provides specific controls to combat their misuse, with additional controls on the production, supply and importation and exportation in view of their potential misuse.

Costs

- *In relation to legitimate medicinal use*

It is considered that this proposal is unlikely to have any significant impact on the legitimate use of these additional substances in the UK as they are not licensed medicines in the UK. Nor is it understood that any of these substances are manufactured in the UK. No representations were received during public consultation that disputed this.

However, this further group of anabolic steroids and non-steroidal substances will continue to be available as a non-licensed medicine for legitimate medicinal use or if at some time in the future they are UK licensed. They will be scheduled in the Misuse of Drugs Regulations 2001 (as amended) under Schedule 4 Part 11 together with those anabolic steroids already controlled under the 1971 Act. Those persons authorised by the regulations (e.g. doctors and pharmacists) can supply these additional substances for medicinal purposes subject to compliance with regulations. However, regulation 15 (prescription writing requirements) and the statutory safe custody requirements do not apply to Schedule 4 Part 2 drugs.

In respect of manufacturers, distributors and wholesalers that produce, supply, import or export these substances they will need a domestic issued by the Home Office Drug Licensing and Compliance Unit and an import or export licence (for each consignment). Licences are available from the Home Office and applications can be made easily 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. There is a potential administration burden on business but would not be considered significant. UK pharmaceutical companies will already be licensed by the Home Office in respect of other controlled drugs they handle; the time taken to complete an import/export licence should be minimal and exporters already have to check for receiving country controls, many of which involve the issue of an import certificate by that country. As Schedule 4 Part II drugs there are no specific record keeping requirements in relation to supply except in respect of importation and exportation. It is anticipated that any company trading in these substances would already keep such records for business purposes. There are no safe custody requirements.

- *To law enforcement and CJS in respect of enforcement against the illicit market*

It is considered unlikely that these further controls will have a significant impact on law enforcement and CJS costs. There are currently 54 anabolic steroids subject to control under the Misuse of Drugs Act 1971 and this option proposes adding an additional 15 anabolic steroids to this list. There is some indicative evidence of the availability of these substances in the UK via website selling pro-hormones and anabolic agents, albeit that the contents of the products are not necessarily what they purport to be. There is no possession offence when contained in a medicinal product, so any enforcement activity will be directed towards suppliers and manufacturers of these substances. Prosecutions in relation to anabolic steroids are rare in comparison to the other drugs controlled under the 1971 Act.

The police and other law enforcement agencies will prioritise resources towards tackling crime, including drugs crime with a focus on those offences which cause the most harm. As such, operational activity may focus on Class A and B drugs with the enforcement response managed within existing resources. However, in preparation for the London 2012 Olympics Government,

the law enforcement agencies are reviewing existing activity to tackle drug-misuse in sport, enhance co-operation between relevant agencies, with the purpose of strengthening the UK's approach to the misuse of drugs in sport.

Benefits

The overarching benefit of this proposal is that controls should help reduce the supply and use of these drugs and thus limiting their potential harm and misuse. The consequent benefits are a reduction in the risk for individual misuser's health and also for public health and the associated costs of treatment and care. It also ensures that the UK's laws reflect the latest knowledge about the harms and availability of these substances, and enables law enforcement to take appropriate enforcement action, and stops traffickers avoiding prosecution by supplying otherwise legal steroids.

ORIPAVINE

Background

Oripavine is an alkaloid found in poppy straw (Class A) of the opium poppy. It can easily be converted into thebaine (controlled under the Misuse of Drugs Act 1971 in Class A and under the Misuse of Drugs Regulations in Schedule 2) and used in the production of semi-synthetic opiates such as hydrocodone and oxycodone.

Oripavine was placed under international control by the UN Commission on Narcotic Drugs and placed in Schedule 1 of the 1961 Single Convention on Narcotic Drugs. It is understood that whilst thebaine has some abuse potential, no actual abuse of thebaine has been reported but that the UN's decision was predicated on the comparative ease with which oripavine can be converted into thebaine (an opiate alkaloid) and subsequently other controlled drugs e.g buprenorphine.

The ACMD has recommended - <http://drugs.homeoffice.gov.uk/publication-search/acmd/oripavine> - that Oripavine is controlled as a Class C drug as the potential harm is more commensurate with drugs in Class C such as the opioid buprenorphine and that it is placed in Schedule 2 of the Misuse of Drugs Regulations 2001 (as amended). The ACMD are unaware of the misuse of oripavine as a substance in its own right (although it has analgesic properties it is also highly toxic, causing seizures). There is presently no evidence of its misuse in the UK and subsequently no known harms to individuals and society. Nor is there any evidence of its illicit conversion, in the UK, to thebaine and other opioids.

Rationale for intervention

- *To ensure compliance with our obligations under UN 1961 Single Convention on Narcotic Drugs.*
- *To help prevent the misuse of this substance, more particularly in the illicit manufacture of any opioid substances.*

Objective

The measure to control Oripavine 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 – and to ensure that the UK is compliant with its international obligations.

Options and Appraisal

2 options have been considered in respect of Oripavine.

Option 1- Do nothing

This option is not acceptable to Government. The UK Government would be in breach of its international obligations, with associated reputational risks.

Option 2- Control Oripavine as a Class C drug (and Schedule 2 drug under the Misuse of Drugs Regulations 2001 (as amended))

This is the preferred option.

Costs

- *In relation to legitimate medicinal use*

In respect of any manufacturers, distributors and wholesalers of oripavine that produce, supply, import or export these substances they will need a “domestic licence” issued by the Home Office Drug Licensing and Compliance Unit and an import or export licence (for each consignment).

The Home Office Drug Compliance and Licensing Unit have advised that, to their knowledge, only one company in the UK imports Oripavine (from Australia) for the production of buprenorphine. This company has been consulted on this proposal. As a Schedule 2 drugs under the Misuse of Drugs Regulations 2001 (as amended)), they will be required to obtain an import licence for each consignment from the Home Office’s Drugs Licensing and Compliance Unit. Licences are currently issued free of charge. There may be some relatively small administration costs in association with time taken to complete an import/export licence. As a Schedule 2 drug, Oripavine will be subject to safe custody requirements and also record keeping requirements. It is understood that the one company in the UK that imports oripavine already keeps this substance under storage/safe custody arrangements and keeps records for business purposes. The statutory requirements are likely to result in minimal additional costs.

- *To the law enforcement and CJS in respect of enforcement against the illicit market*

None. There is presently no evidence of its misuse in the UK.

Benefits

This proposal will ensure that we are compliant with our International obligations and support the international community in restricting the availability of this substance. It will also ensure that as the competent authority the Home Office will be able to support the work of the United Nations International Narcotics Control Board (INCB), as custodian of the UN Drug Conventions, by supplying manufacturing and transaction data for Oripavine. It will also enable the Home Office to ensure that industry complies with the statutory controls which is achieved through a system of vetting and licensing of those companies that manufacture and trade in controlled drugs.

GAMMA-BUTYROLACTONE (GBL) AND 1,4-BUTANEDIOL (1,4-BD)

Background

Gamma-butyrolactone (GBL) and 1,4-butanediol (1,4-BD) are drugs of misuse. They are pro-drugs of gamma-hydroxybutyrate (GHB), meaning that when either substance is ingested it is rapidly converted to GHB. The effects and risks associated with the use of GBL and 1,4-BD are similar to those of GHB whose use is associated with unconsciousness, a risk of death by intoxication and a dependence syndrome if used regularly.

GHB has been controlled as a Class C drug under the Misuse of Drugs Act 1971 since July 2003 but, at present, there are no domestic controls that restrict or impose sanctions on the possession, supply or importation of GBL or 1,4-BD.

There has been concern that users of GHB are switching to GBL and 1,4-BD use as a consequence of GHB control under the 1971 Act. There are no firm baseline figures for GBL and 1,4-BD users. The evidence of use to date in the UK is limited but appears to be generally isolated to the gay communities and clubbing scene rather than the wider community. However, in these communities there has been a

small yet significant increase in presentations for treatment, though it is difficult to isolate from the misuse of GHB. As with GHB, GBL and 1,4-BD has the potential to be used in drug-facilitated sexual assault, but there is no evidence to date to support this.

However, there is evidence that this situation is being exploited by suppliers and users alike and that a market for GBL and 1,4-BD has been established as shown through importation seizure evidence and the promotion of sales via UK and non-UK internet sites. There is also the possibility that there is some diversion from legitimate suppliers who use GBL and 1,4-BD for legitimate purposes.

The ACMD considers that the harms and misuse of GBL and 1,4-BD are commensurate with Class C of the Misuse of Drugs Act 1971. Its report can be found at <http://drugs.homeoffice.gov.uk/publication-search/acmd/report-on-gbl1>. It provisionally recommended that GBL and 1,4-BD be brought under control of the Misuse of Drugs Act and that licensing arrangements are made for their legitimate industrial use. In giving this advice, the ACMD called on the Government to consult in order to allow the Government to ensure that a control option is chosen that minimises the impact on industry.

The options set out below were subject to public consultation which ran for 3 months, closing on 13 August. A summary of the responses is available at <http://drugs.homeoffice.gov.uk>. Whilst the responses from industry representative bodies were very helpful in identifying the impact of controls under the various options, these and others responses provided no or little insight into the scope of the scale of misuse of GBL and 1,4-BD. The ACMD has subsequently provided further advice which can be found at <http://drugs.homeoffice.gov.uk/publication-search/acmd/gbl-consultation-letter>.

Rationale for Intervention

- *The misuse of GBL and 1,4-BD is associated with a range of harms and hazards commensurate with commensurate with drugs in Class C of the Misuse of Drugs Act 1971.*
- *To restrict the human ingestion of GBL and 1,4BD thus limiting potential harms. Control measures will send a clear message to users, including young people, that these drugs are potentially harmful.*

Objective

To restrict the use of GBL and 1,4-BD for human ingestion thereby reducing the personal and social costs of misuse.

Options and Appraisal

4 options have been considered in respect of GBL and 1,4-BD. The Government's preferred option – option 4 – has been informed by the responses to the public consultation and the further advice from the ACMD in support of option 4.

Option 1 - Do Nothing Option

This option is not acceptable to Government nor was it supported by the majority of those responding to the public consultation. It would not meet the Government's overarching drugs policy objectives to protect individuals and society.

Option 2 - Control of GBL and 1,4-BD under the Misuse of Drugs Act 1971 as a Class C drug (Schedule 1 as having no medicinal purpose) prohibiting possession, supply, production and importation/exportation with no concession for legitimate use by industry.

This option is effectively a complete ban on the possession and supply of GBL and 1,4-BD and related products.

Costs

- *To industry and retail*

The estimated annual worldwide production capacity for GBL is 200,000 tonnes, with the European Union accounting for 50,000 tonnes. The estimated annual worldwide production capacity for 1,4-BD is 1,900,000 tonnes with 3 European producers manufacturing 500,000 tonnes. Government is advised that there is no economically viable way in which these chemicals could be easily substituted by other chemicals. If the UK banned these chemicals, the probable outcome would be a shift of some manufacturing processes to other countries where the chemicals would still be available and available for illicit import into the UK.

It is difficult to calculate a monetary value from all the potential losses that a ban would impose. Based on the best information available to Government, provided by the representative bodies of industry which the Government has no reason to dispute, it is estimated that a ban could result in a cost to the UK industry and society of tens of millions of pounds per annum, more particularly if production facilities had to be closed with employment and financial consequences.

Products in which GBL and 1,4-BD are sold in pure form or where they form part of the end product for the public would also be withdrawn from the UK market at significant cost. Option 3 below refers.

- *To law enforcement and CJS in respect of enforcement against the illicit market*

There would be costs associated with enforcing a UK domestic and importation/exportation ban on GBL and 1,4-BD. The costs have not been quantified and would be dependent how industry and suppliers responded and complied with the ban, and the ongoing scale of GBL and 1,4-BD misuse. The scale of misuse is unknown as no population or household survey data is collected and the consultation did not provide any better understanding of this.

Benefits

The benefit of this proposal is that an outright ban of GBL and 1,4-BD would be the strongest level of control to help reduce the supply of these substances for human ingestion and thus limit potential harm from this misuse to the individual misusers' health and also for public health, with associated costs of treatment and care and associated social and economic benefits.

Summary

Option 2 is not considered to be a viable option. It would cause significant financial hardship to the UK chemical industry and would put UK industry at a competitive disadvantage in EU and wider world markets. There is no readily available alternative for either chemical; GBL has a more favourable environmental toxicity rating compared with other solvent materials. This option cannot be justified as a proportionate response to the misuse of GBL and 1,4-BD, more so when the scale of misuse is unknown and there is no clear evidence of diversion from the UK chemical supply chain.

Option 3 – Control of GBL and 1,4-BD under the Misuse of Drugs Act 1971 as a Class C drug (Schedule 1 as having no medicinal purpose) prohibiting possession, supply, production and importation/exportation BUT subject to licensing regime for industrial use.

Option 3 is the same as Option 2 but with the addition of a licensing system to allow some legitimate uses of GBL and 1,4-BD to continue.

Companies that need to possess and/or supply GBL and 1,4-BD for legitimate use would require a licence issued by the Home Office Drug Licensing and Compliance Unit. Similarly, those needing to import or export GBL and 1,4-BD would require an import or export licence (for every consignment). Applications can easily be made to the Home Office and applications can be made on-line. The 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.

Companies will be under an obligation to advise on any changes to the business or adverse or suspicious incidents. The licences issued by the Home Office could also set out additional safe custody and record keeping requirements to help to minimise diversion

Costs

- *To industry and retail*

By enabling the continued use of GBL and 1,4-BD for legitimate industrial use under licensing arrangements the costs of this option could be expected to be less than Option 1.

Compliance and administration costs would be incurred by industry, particularly the licensing costs both for domestic manufacture/distribution and import/export. There would also be costs on regulators, to ensure that industry complies with the statutory controls which are achieved through a system of vetting and licensing of those companies that import and trade in GBL and 1,4-BD in the UK. These costs have not been able to be quantified on information made available to the Home Office but could be significant in view of the scale of legitimate use in the UK. However, there are valid issues as to whether the current drug licensing system which deals with pharmaceutical products lends itself easily to industrial accounting process which deals with large tonne quantities.

Notwithstanding that legitimate industrial trade in GBL and 1,4-BD would continue under this option, there could still be an adverse impact on UK industry and sales revenues with the UK being a less attractive place of business than other countries because of additional regulator requirements, with the risk of a shift away from the UK. If so, similar if not full costs to industry of Option 2 may be incurred.

Products in which GBL and 1,4-BD are sold in pure form or where they form part of the end product would most likely have to be withdrawn from UK market/shop shelf. Representations were received from the public consultation exercise from a number of trade associations whose members supply products containing GBL and 1,4-BD. It was the view of these associations – including the Printing Industry Confederation and Cosmetic, Toiletry and Perfumery Association (CTPA) – that the impact of controls could result in a significant loss to industry in terms of sales revenues and disposal of products already in the distribution chain. Based on the assessment of CTPA, the UK cosmetic industry alone – where GBL is used as both a fragrance and flavour ingredient and is a vital ingredient in nail enamel remover pads, wipes and sponges – could incur lost sales of £2 million plus per year.

- *To law enforcement and CJS in respect of enforcement against the illicit market*

There would be costs associated with enforcing a UK domestic and import/export ban on GBL and 1,4-BD. There would be costs associated with operating and enforcing the licensing arrangements to regulators who would operate the system of vetting and licensing/registration of those companies and individuals that trade in GBL and 1,4-BD, as well as ensuring that licensees comply with the statutory controls and terms of the licence. Law enforcement costs associated with enforcing control and pursuing suppliers/users acting outside of the licensing arrangements have not been quantified and would be dependent on the ongoing scale of GBL and 1,4-BD misuse. The scale of misuse is unknown as no population or household survey data is collected.

Benefits

The benefits of this option would be the reduced availability of GBL and 1,4-BD for misuse purposes, leading to limiting the potential harm to the individual misusers' health and also for public health, with associated costs of treatment and care as well as associated social and economic benefits. As distinct from option 2, the scale of these benefits is dependent on the effectiveness of the licensing regime and compliance with it as well as the risk associated with siphoning off legitimate imports and supply for personal use.

Summary

Option 3 is not considered to be a viable option at this time. To the extent that the UK's drug licensing system is an appropriate system to license GBL and 1,4-BD, this option cannot be justified as a proportionate response to the misuse of GBL and 1,4-BD, more so when the scale of misuse is unknown and there is no clear evidence of diversion from the UK chemical supply chain. As well as administration and compliance costs on legitimate industry, the most tangible impact would be the withdrawal of any number of retail products currently available in pure form or where they form part of the end product.

Option 4 - Control of GBL and 1,4-BD under the Misuse of Drugs Act 1971 as a Class C drug prohibiting possession, supply, production and importation/exportation where they are intended for human ingestion only

This option removes any onus from industry and simply makes it illegal to possess, supply, produce and import/export GBL and 1,4-BD for purposes of personal ingestion.

Costs

- *To industry and retail*

This option avoids the costs to industry that could be expected to be imposed under Options 2 and 3 because products and sales would be completely unaffected, with the exception of sales etc that buyers intend for personal consumption. Those cosmetic and personal care products that contain GBL - e.g. nail enamel remover pads, wipes and sponges – will not be caught by the control measures via proposed amendments to the Misuse of Drugs Regulations 2001 (as amended) – and would still be available for to the public.

The only cost therefore might be the voluntary use of labelling or other warning devices to ensure products, especially those made available to the public are not used for personal ingestion but this will not be a statutory requirement under the 1971 Act. Suppliers and retailers of GBL and 1,4-BD may also wish to raise awareness amongst their staff with training etc.

It has not been possible to estimate the volume of UK sales for human ingestion only. There is no population or household survey prevalence data collection on use which might be an indicator. Whilst there are any number of websites – UK (and non) UK ISPs – offering to sell GBL this is most often under the guise of legitimate use.

- *To law enforcement and CJS in respect of enforcement against the illicit market*

Policing GBL and 1,4- BD that are legally available and importable raises policy and operational issues for law enforcement. Whilst the Association of Chief Police Officers is considering the policing response with a view to providing practitioner advice on the enforcement approach, in the absence of spare capacity within the CJS, the enforcement response will be managed within existing resources, informed by policy and operational prioritisation along side all other controlled drugs. Enforcement will need to distinguish between legitimate and illegitimate possession and distribution. This may be problematic and lead to additional costs in pursuing prosecutions.

Benefits

The benefits of Option 4 are likely to be less than for Options 2 and 3 due to the continuing possibility of divergence from legitimate products and the continued availability of pure GBL and 1,4-BD products to the public. However, control as a Class drug will support the message that GBL and 1,4-BD are harmful drugs and not safe, and should help deter use as well as the overt sale and promotion of these substances for human use. Class C controls will complement the Government's education messages. There is also an expectation that legitimate sellers of GBL and 1,4-BD will "self-regulate" and be more circumspect with their sales and use labelling or other warning devices on their products to inform the public that these products are not for human ingestion. This option retains the benefits through deterring use to reduce the potential harm to the individual misusers' health and also for public health, with associated costs of treatment and care as well as with associated social and economic benefits.

Summary

Option 4 is considered the only viable option under the 1971 Act at this time. Class C control sends a clear message to users and suppliers that these drugs are harmful. It creates an offence where possession and/or supply etc are intended for human ingestion but does not unduly impact on legitimate business in the way contemplated by options 2 and 3.

SYNTHETIC CANNABINOIDS

Background

Synthetic cannabinoid receptor agonists ('synthetic cannabinoids') are man-made chemicals that mimic the psychoactive effects of tetrahydrocannabinol (THC), the active ingredient in cannabis. They can be sprayed on herbal smoking products such as 'Spice' which act on the body in a similar way to cannabis but can be far more potent. 'Spice' is a common brand name for a range of inert herbal mixes that are tobacco and cannabis-free but are often sprayed with synthetic cannabinoids.

In March 2009 the Advisory Council on Misuse of Drugs (ACMD) was commissioned by the Government to look at the harms and availability of so called 'legal highs'. As the first output of this work the ACMD undertook an assessment of synthetic cannabinoids, reviewing its status through the examination of its use, pharmacology, physical and societal harms. Its report – "ACMD report on the major cannabinoid agonists" can be found at <http://drugs.homeoffice.gov.uk/drugs-laws/acmd/>. The Government has accepted the ACMD's assessment that the harms and misuse of synthetic cannabinoids are broadly commensurate with those of cannabis and that they should be classified accordingly as Class B drugs under the Misuse of Drugs Act 1971 Act. The maximum penalties for offences relating to a Class B drug set by the legislative framework are - for possession, the maximum penalty on indictment is five years imprisonment and supply, production and trafficking; the maximum penalties on summary conviction are six months imprisonment and/or a Level 5/£5,000 fine. The maximum penalties on indictment are fourteen years imprisonment and/or an unlimited fine.

The ACMD advised that a wide range of synthetic cannabinoids are, or are capable of, being misused in the UK. Following ACMD recommendations the majority of the synthetic cannabinoids will be brought under control largely by means of generic definitions.

Currently Austria, Germany and France in the EU have controlled a number of synthetic cannabinoids identified in Spice and a number of other EU countries have legislation pending. In addition, use of a generic definition is consistent with our approach to anticipating future trends as well as existing harms. The 1971 Act's classification system contains a number of generic definitions based on substitution patterns e.g. the phenethylamines, tryptamines, anabolic steroids etc.

As synthetic cannabinoids are not controlled to date under the 1971 Act there is no population or household survey data collection. Data on prevalence is limited in the UK, as in most other member states, as synthetic cannabinoids are not controlled and as such material is unlikely to be submitted for forensic analysis. It is understood that Spice and other synthetic cannabinoids have some level of popularity in the UK; they are sold through the internet or in specialised 'head shops' and are therefore commonly available. The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) briefing paper – *Understanding the "Spice" phenomenon* – states the extent to which Spice products are used in Europe is unknown and the users appear to be a varied group.

The Medicines and Healthcare products Regulatory Agency (MHRA) view is that Spice Gold 3g is a medicinal product for which a marketing authorisation has to be granted before it can be sold or supplied in the UK. 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.

It is understood that only one synthetic cannabinoid, nabilone, has a legitimate use and is used to reduce nausea and vomiting for neuropathic pain.

Rationale for intervention

The case for intervention through control measures under the 1971 Act can be examined in relation to potential harms and misuse of the drug. Generic control will enable the Government, as far as possible, to future proof legislation and to keep one step ahead of the illicit manufacturers who have been shown to move to similar but 'non-controlled' compounds when individual synthetic cannabinoids have been controlled in other EU member states.

- *Use of synthetic cannabinoids are associated with a range of physical and psychological harms and hazards.* Recent case-reports and pharmacological studies on the respective synthetic cannabinoids suggest that the addictive potency may be at least as high as that of cannabis. However, the effect of the synthetic cannabinoids is many times stronger than that of THC, the active ingredient of cannabis. These synthetic substances will produce comparable intoxicating effects to those of cannabis with only a fractional amount of that used for cannabis. The inevitably uneven distribution of the highly active substances in the herbal mix may lead to over dosage and poisoning following the smoking of Spice and similar products.
- *To restrict the availability of synthetic cannabinoids and to deter their use.* Control measures will send a clear message to users, including young people, that these drugs are potentially harmful. It will also reduce the availability of these compounds by supporting enforcement activity in respect of suppliers and manufacturers of synthetic cannabinoids.

Objective

The measure to control synthetic cannabinoids under the Misuse of Drugs Act 1971 (and the Misuse of Drugs Regulations 2001 as amended) 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. The ACMD advise that the potential harms of synthetic cannabinoids are broadly commensurate with those of cannabis which was reclassified as a Class B drug under the 1971 Act in January 2009.

Options and Appraisal

2 options have been considered in respect of synthetic cannabinoids.

Option 1- Do nothing

This option is not acceptable to Government in light of the potential health and social harms caused by these compounds.

Option 2- Control synthetic cannabinoids by means of a generic definition under the Misuse of Drugs Act as Class B drugs (and Scheduled under the Misuse of Drugs Regulations 2001 as appropriate)

This option is proposed to Parliament as the preferred option. It is supported by the ACMD and reflects control measures being taken in other EU member states to tackle the market in these products.

Costs

The sale and supply of synthetic cannabinoids are unlawful already under the Medicines Act 1968 (without a Marketing Authorisation (Product Licence)). Licensing records indicate that synthetic cannabinoids have never been licensed by the MHRA. Consequently, these further proposed controls under the 1971 Act do not take into account the impact on any business or person already undertaking unlawful activities in contravention of the Medicines Act.

Costs in respect of this option are potentially two fold.

- *To the pharmaceutical industry in respect of those synthetic cannabinoids that are considered to have a research or legitimate use.*

Synthetic cannabinoids (with the exception of nabilone) have no recognised legitimate use. In accordance with convention and the ACMD's recommendation these will be placed in Schedule 1 of the 2001 Regulations. Authority to possess and/or supply Schedule 1 drugs can be granted for research or other "special purpose" if considered in the public interest by the Home Office Drug Licensing and Compliance Unit.

In respect of nabilone, its use and availability in the UK will be accommodated by amendments to the Misuse of Drugs Regulations 2001. In respect of manufacturers, distributors and wholesalers that produce, supply, import or export nabilone they will need a "domestic licence" issued by the Home Office Drug Licensing and Compliance Unit and an import or export licence (for each consignment). Licences are 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. There is a potential administration burden on business but would not be considered significant. UK pharmaceutical companies will already be licensed by the Home Office in respect of other controlled drugs they handle; the time taken to complete an import/export licence should be minimal and exporters already have to check for receiving country controls, many of which involve the issue of an import certificate by that country. There will be safe custody and record keeping requirements, although it is anticipated that any company trading in these substances would have storage/safe custody arrangements in place and keeps records for business purposes in any event.

- *To law enforcement and CJS.*

Those currently prosecuted under medicines legislation face a statutory maximum penalty of 2 years imprisonment and/or unlimited fine.

The 1971 Act introduces the offence of possession as well as increased maximum sentences available to the Court. As Class B drugs under the 1971 Act, it will be unlawful to import/export, manufacture, supply or possess these drugs without lawful authority. Those that are prosecuted for unlawful possession are most likely to be dealt with in the Magistrates Court where the statutory maximum penalties are three months' imprisonment and/or a Level 4 (£2,500) fine. In respect of those cases dealt with by the Crown Court, the maximum penalties are five years' imprisonment and/or an unlimited fine. Offences of unlawful supply, production and trafficking of these substances are most likely to be dealt with in the Crown Court, where the maximum penalty is 14 years' imprisonment and/or an unlimited fine.

The cost impact to the police and CJS will be dictated by the scale of the availability of these substances and the policing response to their control as Class B drugs.

As indicated above, there is no population or household survey data collection. The MHRA have not scoped the UK market to inform their enforcement response as they respond following referral to them on a case by case basis. Spice and other herbal smoking mixes are often marketed as room odourisers or incense and are widely available on the internet and in specialised 'head shops' across the UK. Forensic analysis is required to establish whether these products contain identified synthetic cannabinoids and as the compounds are not currently subject to control seizure and forensic data is limited. In the absence of any other data, seizure data provides us with some limited insight in the UK market though it cannot be taken as a direct indication of prevalence and so form a reliable basis on which an assessment as to costs can be made. In addition, from anecdotal information from police forces there are considerable variations in the availability of these substances from one force area to another.

Whilst the Association of Chief Police Officers is considering the policing response with a view to providing practitioner advice on the enforcement approach; training and forensic issues, it is expected in the absence of spare capacity within the CJS, the enforcement response will be managed within existing resources, informed by policy and operational prioritisation. The police and other law enforcement agencies will prioritise resources towards tackling crime, including drugs crime with a focus on those offences which cause the most harm. As such, operational activity may focus on more harmful Class A drugs. It is also envisaged that enforcement activity

will be directed towards supplier and manufacturers of these substances rather than possession for personal use.

Benefits

The overarching benefit of this proposal is that controls should help reduce the supply and use and thus limiting potential harm to individual misuser's health and also for public health, with associated costs of treatment and care. It will also aid detection and monitoring of the manufacturing and trafficking of these substances.

Control of these drugs under the 1971 Act sends a clear message to users, including young people who may be considering using, as well as to those selling them. Young people in particular may often equate legal with "safe" and do not always understand that these drugs carry real risks. Control will re-enforce our educational messages about the harms of these drugs. There are also potential additional but difficult to measure benefits, for example, improvements in health of a person may enhance an individual's ability to work, career progression and day to day social activities

Whilst there is no direct evidence that synthetic cannabinoids 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.

In respect of the wider control advanced by this proposal it enables the UK to have both current and durable laws. This option will capture synthetic cannabinoids that are, or could be in the future, available in the UK and will keep pace or ahead of a potentially changing market and illicit manufacturers, including those that target the so called "legal highs" market via availability at festivals, in "head shops" and on the internet.

IMPLEMENTATION

Subject to Parliamentary agreement, the drug controls described above will be implemented on the commencement date cited in the Misuse of Drugs Act (Amendment) Order 2009.

MONITORING & EVALUATION

The Government will monitor the control measures as part of the ongoing Drug Strategy.

FEEDBACK

Information for the purposes of evaluation will be gathered from Criminal Justice and British Crime Survey statistics to evaluate effects on use and enforcement; further consideration and advice from the ACMD.

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.

Type of testing undertaken	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
Competition Assessment	No	No
Small Firms Impact Test	No	No
Legal Aid	No	No
Sustainable Development	No	No
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	No	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	No
Rural Proofing	No	No

Annexes

List of References

1. Advisory Council on the Misuse of Drugs report on Control of 1-benzylpiperazine (BZP) and related compounds
<http://drugs.homeoffice.gov.uk/publication-search/acmd/ACMD-BZP-Report?view=Binary>
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
5. Home Office Consultation Paper, "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 and summary responses. <http://drugs.homeoffice.gov.uk>
6. Advisory Council on the Misuse of Drugs advice on the classification of 24 steroidal and 2 non-steroidal substances - <http://drugs.homeoffice.gov.uk/publication-search/acmd/advice-on-steroids1?view=Binary>
7. Advisory Council on the Misuse of Drugs advice on Oripavine
<http://drugs.homeoffice.gov.uk/publication-search/acmd/oripavine>
8. Advisory Council on the Misuse of Drugs' report on GBL and 1,4-BD
<http://drugs.homeoffice.gov.uk/publication-search/acmd/report-on-gbl1> and its further advice following public consultation <http://drugs.homeoffice.gov.uk/publication-search/acmd/gbl-consultation-letter>
9. Home Office Consultation Paper, "Proposed Control Under The Misuse Of Drugs Act 1971 of Gamma-butyrolactone (GBL) and 1,4-butanediol (1,4-BD) and summary responses <http://drugs.homeoffice.gov.uk>
10. Advisory Council on the Misuse of Drugs' advice on synthetic cannabinoid receptor agonists <http://drugs.homeoffice.gov.uk/publication-search/acmd/acmd-report-agonists>

11. EMCDDA Briefing Paper, "Understanding the Spice phenomenon"
[http://www.emcdda.europa.eu/attachements.cfm/att_80086_EN EMCDDA Understanding%20the%20%E2%80%98Spice%E2%80%99%20phenomenon 4Update%200090813.pdf](http://www.emcdda.europa.eu/attachements.cfm/att_80086_EN EMCDDA Understanding%20the%20%E2%80%98Spice%E2%80%99%20phenomenon%204Update%200090813.pdf)



Equality Impact Assessment

Preliminary Screening

Statistics & Research

Gathering Evidence through Community Engagement

Assessment & Analysis

Action Plan

The EIA Report



EQUALITY IMPACT ASSESSMENT
Group: Crime and Policing Group
Directorate: Drugs, Alcohol and Partnerships Directorate
Unit: Drug Strategy Unit

PRELIMINARY SCREENING

Date of Screening	2009
Name of Policy Writer	Angela Scrutton
Director General	Stephen Rimmer

Name of Policy	<input checked="" type="checkbox"/>	This is a new policy
	<input type="checkbox"/>	This is a change to an existing policy
	<input type="checkbox"/>	This is an existing policy

Policy Aims, Objectives & Projected Outcomes

To control substances that are considered “dangerous or otherwise harmful” in accordance with the terms of the Misuse of Drugs Act 1971. These substances are BZP and substituted piperazines, a group of anabolic steroids and 2 growth promoters, oripavine, GBL and 1,4-BD and synthetic cannabinoid receptor agonists. The intended objectives are to deter use of these substances, particularly by young people, and to reduce their availability via supplier “self-regulation” following implementation of control measures as well as enabling law enforcement agencies to undertake appropriate enforcement action, in particular activity to tackle production and supply.

Will the policy have an impact on national or local people/staff?	YES
Are particular communities or groups likely to have different needs, experiences and/or attitudes in relation to the policy	Unknown
Are there any aspects of the policy that could contribute to equality or inequality?	Unknown
Could the aims of the policy be in conflict with equal opportunity, elimination of discrimination, promotion of good relations?	NO
If this is an amendment of an existing policy, was the original policy impact assessed?	N/A

If your answer to any of these questions is **YES**, go on to the full EIA.

If you have answered **NO** to all of these questions then please attach the following statement to all future submissions and within your regulatory impact assessment and ensure it is signed off by senior management.

“This policy was screened for impact on equalities on [insert date]. The following evidence [Evidence] has been considered. No full equality impact assessment is required. “

Remember that all policies that are likely to have a significant impact on individuals and the public as a whole are likely to require a full EIA.

FULL IMPACT ASSESSMENT

STATISTICS & RESEARCH

What relevant quantitative & qualitative data do you have in relation to this policy?

Equality Target Areas	How does the data identify potential or known positive impacts? How does the data identify any potential or known adverse impacts?
Race (consider e.g. nationalities, Gypsies, Travellers, languages)	None at present. To our knowledge, no data is available on race in relation to the use of these substances. It is not anticipated that the change in policy will have any disproportionate impact on race.
Disability (consider social access and physical access)	None at present. To our knowledge, no data is available on disability in relation to the use of these substances. It is not anticipated that the change in policy will have any disproportionate impact on disability. In respect of legitimate medical use of certain substances, for example nabilone and steroids, access to these will be made available via healthcare professionals.
Gender	No systematic data is available in this area. However, the ACMD in their report, "GBL & 1,4 BC: Assessment of Risk to the Individual and Communities in the UK", reference a study cited in an oral presentation by Wood and Dargan which looked at patients presenting to the A & E Department at St Thomas' Hospital in 2006. This study identified that almost all presenting were male (94%).
Gender Identity	None at present. To our knowledge, no data is available on gender identity in relation to the use of these substances. It is not anticipated that the change in policy will have any disproportionate impact on gender identity.
Religion and Belief	None at present. To our knowledge, no data is available on religion and belief in relation to the use of these substances. It is not anticipated that the change in policy will have any disproportionate impact on religion and belief.

<p>Sexual Orientation</p>	<p>The evidence of use of GBL to date is limited but appears to be generally isolated to the gay communities and clubbing communities. The ACMD in their report, “GBL & 1,4 BD: Assessment of Risk to the Individual and Communities in the UK”, reference a study cited in an oral presentation by Wood and Dargan which looked at patients presenting to the A & E Department at St Thomas’ Hospital in 2006. The study identified significant numbers of people presenting for treatment following GBL ingestion in Vauxhall’s gay clubs.</p>
<p>Age</p>	<p>The ACMD in their report, “GBL & 1,4 BD: Assessment of Risk to the Individual and Communities in the UK”, reference a study cited in an oral presentation by Wood and Dargan which looked at patients presenting to the A & E Department at St Thomas’ Hospital in 2006. The study identified that “the majority of those presenting were in the 20-34 year old age group.”</p> <p>Further, the EMCDDA in its briefing paper, “Understanding the ‘Spice’ phenomenon”, comment that “Spice products are reported to be generally used by teenagers and young people.”</p>

What research have you considered commissioning to fill any data gaps?

The gathering of quantitative data on use amongst the population is needed to inform this area. As part of our 2008 national drug strategy, *“Drugs: protecting families and communities”*, the Government agreed to consider conducting a qualitative analysis of the sources of data and information relating to diversity that are available at a national and local level.

To ensure Drug Strategy expectations that the needs of all members of the community should be properly understood and met, we have put in place a consultative framework to ensure equality issues can be addressed coherently. We therefore re-launched in 2009 the Drug Strategy Equality Forum with a membership that can better reflect the full range of key equality groups than ever before. Key priorities for the Forum are to look across the Drug Strategy and drive delivery of our equality commitments, which include the development of a Drug Strategy Equality toolkit; review of ongoing equality research needs and identification of effective communications and case studies of effective practice.

Who are the stakeholders, community groups, staff or customers for this policy area?

- Drug users, their children, their families and all members of communities impacted by illegal drug use.
- Practitioners working in drug treatment services.
- Advisory Council on the Misuse of Drugs (ACMD).
- The National Treatment Agency for Substance Misuse (NTA).
- Primary Care Trusts (PCTs).
- Inter-agency drug action teams and local partnerships, including Drug Action Teams (DATs), Drug and Alcohol Action Teams (DAATs) and Crime and Disorder Reduction Partnerships (CDRPs).
- Enforcement agencies and all parts of the Criminal Justice System.
- Educational institutions.
- Local Authorities.
- The Home Office.
- Department of Health.
- Department for Children, Schools and Families,
- Ministry of Justice.
- Department for Work and Pensions.
- Department for Communities and Local Government.
- Other UK governments – Wales, Scotland and Northern Ireland.
- Charity and voluntary groups.

What are the overall trends and patterns in this qualitative & quantitative data?

As these substances are not controlled to date under the Misuse of Drugs Act 1971, there no robust available evidence to evaluate the overall trends and patterns.

Please list the specific equality issues that may need to be addressed through consultation (and further research)?

Consultation took place with the public and other stakeholders in the form of Government consultation papers, "Proposed control of Gamma-Butyrolactone (GBL) and 1,4-Butanediol (1,4-BD)" and "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", both of which were published 21 May 2009. No representations were received raising any specific equality issues arising from these proposed control measures.

The key research issue is prevalence of use; once this has been established through gathering of quantitative data it can be established whether any further research is needed.

GATHERING EVIDENCE THROUGH COMMUNITY ENGAGEMENT

INTERNAL STAKEHOLDER ENGAGEMENT: Consulting & involving Other Government Departments, Staff, Agencies & NDPBs

Does this policy affect the experiences of staff? How? What are their concerns?	
Staff	Bringing these substances under the control of the Misuse of Drugs Act 1971 could affect staff in treatment services, in enforcement agencies, in education and children’s services, staff throughout the criminal justice system and those concerned with benefits and needs assessment and provision.
Staff Networks & Associations	-----
Trade Unions	-----

How have you consulted, engaged and involved internal stakeholders in considering the impact of this proposal on other public policies and services?
The control measures to be introduced are in line with ACMD advice, following consultation with them. The ACMD did not raise any concerns about adverse impact on equality. The ACMD’s advice is available at http://drugs.homeoffice.gov.uk/drugs-laws/acmd/reports-research/ . Officials at other Government departments have been present at discussions which formulated the ACMD advice.

What positive and adverse impacts were identified by your internal consultees? Did they provide any examples?
No positive or adverse impacts have been identified.

EXTERNAL CONSULTATION & INVOLVEMENT

How did your engagement exercise highlight positive and negative impacts on different communities?	
Voluntary Organisations	<ul style="list-style-type: none">• No concern expressed in response to the public consultation over the impact of controlling these drugs on local communities and voluntary organisations through raised awareness of these substances.
Race	<ul style="list-style-type: none">• No concern expressed in response to the public consultation over the impact of controlling these drugs on race.
Faith	<ul style="list-style-type: none">• No concern expressed in response to the public consultation over the impact of controlling these drugs on faith.
Disability Rights	<ul style="list-style-type: none">• No concern expressed in response to the public consultation over the impact of controlling these drugs on disability rights.
Gender	<ul style="list-style-type: none">• No concern expressed in response to the public consultation over the impact of controlling these drugs on gender.
Gender Identity	<ul style="list-style-type: none">• No concern expressed in response to the public consultation over the impact of controlling these drugs on gender identity.
Sexual Orientation	<ul style="list-style-type: none">• No concern expressed in response to the public consultation over the impact of controlling these drugs on gender identity.
Age	<ul style="list-style-type: none">• No concern expressed in response to the public consultation over the impact of controlling these drugs on age.

ASSESSMENT & ANALYSIS

Does the EIA show a potential for differential impact on any group(s) if this proposal is introduced? If Yes, state briefly whether impact is adverse or positive and in what equality areas.

EIA highlights the absence of robust data and refers to the potential for greater impact on the gay and clubbing communities and young people.

What were the main findings of the engagement exercise and what weight should they carry?

The engagement exercise showed support for control measures for these drugs, but did not raise any findings associated with equality issues.

Does this policy have the potential to cause unlawful direct or indirect discrimination? Does this policy have the potential to exclude certain group of people from obtaining services, or limit their participation in any aspect of public life?

Bringing these substances under control of the Misuse of Drugs Act 1971 will not cause unlawful discrimination. The Parliamentary Under-Secretary of State for the Home Department, Alan Campbell, has made the following statement regarding Human Rights: "In my view the provisions of the Misuse of Drugs Act 1971 (Amendment) Order 2009 are compatible with the Convention rights."

How does the policy promote equality of opportunity?

Control will help to deter use, improving an individual's health and should therefore enhance an individual's ability to work, career progression and day to day social activities.

How does your policy promote good relations? How does this policy make it possible for different groups to work together, build bridges between parallel communities, or remove barriers that isolate groups and individuals from engaging in civic society more generally?

The Government's decision to classify these substances under the Misuse of Drugs Act 1971, subject to parliamentary approval, is necessary to help protect the public from these substances.

How can the policy be revised, or additional measures taken, in order for the policy to achieve its aims without risking any adverse impact?

See Action Plan.

Are there any concerns from data gathering, consultation and analysis that have not been taken on board?

No.

ENSURING ACCESS TO INFORMATION

How can you ensure that information used for this EIA is readily available in the future?

(N.B. You will need to include this in your action plan)

- The full report on the equality impact assessment will be made available for those reviewing the policy at different stages.

How will you ensure your stakeholders continue to be involved/ engaged in shaping the development/ delivery of this policy?

(N.B. You will need to include this in your action plan)

- There is continual liaison with both internal and external stakeholders. This engagement will continue.

How will you monitor this policy to ensure that the policy delivers the equality commitments required?

(N.B. You will need to include this in your action plan)

- The control measures will be reviewed as part of the Government's ongoing Drug Strategy and through the monitoring of Criminal Justice and British Crime Survey statistics to evaluate on use and enforcement.

Now submit your EIA and related evidence for clearance.

ACTION PLAN

Recommendations	Responsibility	Actions required	Success Indicators	Target Date	What progress has been made?
Data Collection	Home Office (Home Office Statistics Crime	Testing new questions in British Crime Survey to develop potential future monitoring of prevalence. Monitor through British Crime Survey and Criminal Justice System statistics	Up to date and routine data on drugs usage available	Ongoing	
Publication Arrangements	Home Office Drug Strategy Unit	Publish summary of EIA along with final strategy	EIA on Home Office website	October 2009	
Monitoring & Review Arrangements	Local partnerships, commissioners and service providers	Local providers to establish monitoring systems across diversity strands	Improved baseline and continuing data	Ongoing	
Monitoring & Review Arrangements	Home Office Drug Strategy Unit	Engage with Drug Strategy Equality Forum Panel to raise new drugs controls as an issue for Equality toolkit due March 2010	New drug controls discussed at both forums and covered within the toolkit	March 2010	
Equality	Home Office Drug Strategy Unit	Engage with the Drug Strategy Forum to raise awareness of new controlled drugs	Drug Strategy Forum raises awareness of new controlled drugs	Autumn 2009	

Research	Home Office Drug Strategy Unit	Ensure new drugs controls are considered as part of wider equality research plans of Drug Strategy Equality Forum and Cross-Government Research Programme on Drugs	New drugs controls are considered as part of the forum and programme	March 2010	
Consideration by Cross Government Research Programme on Drugs (CGRPD)	Home Office (RAU)	Consideration of future prevalence data by the CGRPD Strategic Board	Appropriate research issues identified	2011/2012	
Research	ACMD	Continuing consideration of so called "legal highs" with overarching advice on a number of areas including public health issues/messages, analytical challenges and availability.	Improved understanding of drug harms	Ongoing	

THE EQUALITY IMPACT ASSESSMENT REPORT

Background:

On 25 August 2009, the Government announced its intention to classify various substances— BZP and substituted piperazines, a group of anabolic steroids and 2 growth promoters, oripavine, GBL and 1,4-BD and synthetic cannabinoid receptor agonists – under the Misuse of Drugs Act 1971. This decision reflects the fact that these substances are considered sufficiently harmful, following assessment and advice from the Advisory Council on the Misuse of Drugs, to warrant control measures relating to possession, supply, manufacture and import/exportation with associated criminal sanction. Government intervention is necessary to help protect the public from these substances.

The Government is tackling drug use through a comprehensive package of measures as part of our national drug strategy, *“Drugs: protecting families and communities”*, including prevention, education, early intervention, enforcement, treatment and reintegration.

Methodology:

The Equality Impact Assessment was informed by the advice from the Advisory Council on the Misuse of Drugs’ reports on the various substances - BZP and substituted piperazines, a group of anabolic steroids and 2 growth promoters, oripavine, GBL and 1,4-BD and synthetic cannabinoid receptor agonists – as well as the responses to public consultation. See Annex A for a full list of document references that have informed this Equality Impact Assessment.

Consultation & Involvement:

The Government published two consultation papers in May 2009. During these consultations, specific questions were asked in relation to the control measures for these drugs. Summaries of the responses is available at <http://drugs.homeoffice.gov.uk>

Assessment & analysis

None at this time.

Recommendations

See Action Plan.

Annex A

List of References

1. Advisory Council on the Misuse of Drugs report on Control of 1-benzylpiperazine (BZP) and related compounds <http://drugs.homeoffice.gov.uk/publication-search/acmd/ACMD-BZP-Report?view=Binary>
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
5. Home Office Consultation Paper, "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 and summary responses.
<http://drugs.homeoffice.gov.uk>
6. Advisory Council on the Misuse of Drugs advice on the classification of 24 steroidal and 2 non-steroidal substances - <http://drugs.homeoffice.gov.uk/publication-search/acmd/advice-on-steroids1?view=Binary>
7. Advisory Council on the Misuse of Drugs advice on Oripavine
<http://drugs.homeoffice.gov.uk/publication-search/acmd/oripavine>
8. Advisory Council on the Misuse of Drugs' report on GBL and 1,4-BD
<http://drugs.homeoffice.gov.uk/publication-search/acmd/report-on-gbl1> and its further advice following public consultation <http://drugs.homeoffice.gov.uk/publication-search/acmd/gbl-consultation-letter>
9. Home Office Consultation Paper, "Proposed Control Under The Misuse Of Drugs Act 1971 of Gamma-butyrolactone (GBL) and 1,4-butanediol (1,4-BD) and summary responses
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11. EMCDDA Briefing Paper, "Understanding the Spice phenomenon
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