EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS (DESIGNATION) (AMENDMENT) (ENGLAND, WALES AND SCOTLAND) ORDER 2009

2009 No. 3135

AND

THE MISUSE OF DRUGS (AMENDMENT) (ENGLAND, WALES AND SCOTLAND) REGULATIONS 2009

2009 No. 3136

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 instruments

2.1 These instruments complement the Misuse of Drugs Act 1971 (Amendment) Order 2009 ("the 2009 Order"). The 2009 Order controls the following drugs under Schedule 2 to the Misuse of Drugs Act 1971 ("the 1971 Act"):

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

2.2 The Misuse of Drugs (Designation) (Amendment) (England, Wales and Scotland) Order 2009 ("the 2009 Designation Order") amends the Misuse of Drugs (Designation) Order 2001 ("the 2001 Order") by specifying those drugs in the above list which have no recognised medicinal use. The Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations 2009 (the "2009 Regulations") amend the Misuse of Drugs Regulations 2001 ("the 2001 Regulations") to enable the continued legitimate use of those drugs specified in paragraph 2.1 above where such uses exist.

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

3.1 None.

4. Legislative Context

4.1 Following consultation with the Advisory Council on the Misuse of Drugs (the "ACMD"), the 2009 Order classifying the drugs listed at paragraph 2.1 above for control under Schedule 2 to the Misuse of Drugs Act 1971 is due to come into effect on 23 December 2009. Complementary amendments to the 2001 Order and the 2001 Regulations are necessary as a result. As required by the 1971 Act, the ACMD has been consulted on both instruments.

4.2. Section 7(3) of the 1971 Act requires regulations to be made to allow for the use for medicinal purposes of drugs controlled under the 1971 Act. Section 7(3) does not apply to any drug designated by order under section 7(4) of the 1971 Act, essentially as a drug with no recognised medicinal use. The 2009 Designation Order designates GBL, 1,4-BD, BZP and a group of substituted piperazines (except two piperazines known as mCPP and CPCPP) and synthetic cannabinoid receptor agonists (excluding nabilone) as such drugs.

4.3 The 2009 Regulations place each of the drugs specified in paragraph 2.1 in the appropriate Schedule to the 2001 Regulations (save for GBL and 1,4-BD). The Schedule into which a drug is placed primarily dictates the extent to which it is lawful to import, export, produce, supply, administer and possess the drug and also imposes requirements around prescription writing, record keeping, labelling, destruction and safe custody. Those drugs (other than GBL and 1,4- BD) which are designated under the 2009 Designation Order are placed in Schedule 1 to the 2001 Regulations by the 2009 Regulations because they do not have any recognised medicinal uses. They are therefore subject to the strictest level of controls. The scheduling of each of the other drugs and approach taken to GBL and 1,4-BD is explained further in section 7 below.

5. Territorial Extent and Application

5.1 These instruments apply to Great Britain.

5.2 Separate instruments containing the same provisions will apply to Northern Ireland.

6. European Convention on Human Rights

6.1 As the instruments are subject to negative resolution procedure and do not amend primary legislation, no statement is required.

7. Policy background

- ***What is being done and why***

7.1 The explanatory memorandum to the 2009 Order which can be found at http://www.opsi.gov.uk/si/si2009/draft/em/ukdsiem_9780111486610_en.pdf sets out the full policy background to the Order. In summary, the drugs subject to the 2009 Order are sufficiently "dangerous or otherwise harmful" to warrant control under the 1971 Act.

7.2 Designation under the 2001 Order and scheduling under the 2001 Regulations have been informed by the ACMD's recommendations, further consultation with relevant parties, including the Medicines Healthcare Regulatory products Agency, and the need for consistency with the scheduling of existing controlled drugs.

7.3 The 2009 Regulations insert the 15 anabolic steroids and 2 non-steroidal agents into Part 2 of Schedule 4 to the 2001 Regulations alongside over 50 other anabolic steroids and growth promoters already controlled. This allows for their medicinal use. In particular, it means that a person is permitted to import or export such drugs without a licence where importation or exportation is for administration to himself and the drug is contained in a medicinal product. A person may also possess such drugs where they are contained in a medicinal product. Regulations 22 and 23 (keeping and preservation of records), 26 (furnishing of information) and 27 (destruction of the drugs only in presence of an authorised person) of the 2001 Regulations will also apply to these drugs.

7.4 Two of the substituted piperazines (mCPP and CPCPP) are used in the manufacture of antidepressant drugs. They have therefore been placed in Part 1 of Schedule 4 to the 2001 Regulations which takes account of their relatively low risk of misuse and allows for their medicinal use. In contrast to the drugs referred to in the preceding paragraph, there is no exception to the possession and import and export offences where the drug is contained in a medicinal product. This means that a licence issued by the Secretary of State will be needed to import or export these drugs. However, regulations 22, 23, 26 and 27 of the 2001 Regulations (referred to above) will apply.

7.5 Nabilone and oripavine have been identified as having recognised medicinal uses and are both inserted into Schedule 2. Nabilone is used for the control of nausea and vomiting caused by chemotherapeutic agents used to treat cancer. It is placed in Schedule 2 to the 2001 Regulations, due to its misuse potential and alongside dronabinol, a synthetic cannabinoid that is already controlled. Oripavine is an alkaloid found in poppy straw of the opium poppy and is used in the production of semi-synthetic opiates. It is placed in Schedule 2 alongside thebaine which is a similar precursor substance and into which oripavine converts. As Schedule 2 drugs, they are subject to the requirements under regulations 14 (documentation), 15 (prescription writing), 16 (supply on prescription), 18 (marking of containers), 19, 20, 21 and 23 (keeping and preservation of registers), 26 (furnishing of information) and 27 (destruction) of the 2001 Regulations. They are also subject to the requirements found in the Misuse of Drugs (Safe Custody) Regulations 1973.

7.6 As discussed in paragraphs 4.2 and 4.3 above, those drugs which have been designated using the 2009 Designation Order have no recognised medicinal use. They have therefore been placed in Schedule 1 to the 2001 Regulations which means that they cannot be lawfully imported, exported, produced, supplied or possessed without a licence issued by the Secretary of State.

7.7 Despite being designated using the 2009 Designation Order, GBL and 1,4-BD are not inserted into any Schedule to the 2001 Regulations because of their widespread legitimate uses (for example, in nail polish, paints and as a food flavouring). Regulation 3 of the 2009 Regulations instead makes it lawful to import, export, produce, supply, offer to supply or possess these substances except where a person does so knowing or believing that they will be used for the purpose of human ingestion other than as a flavouring in food (so that these substances can continue to be used as food flavouring by legitimate producers and available in minute quantities in certain foodstuffs such as dairy products).

- ***Consolidation***

7.8 It is intended that the 2001 Regulations will be consolidated when the final tranche of The Shipman Inquiry related regulatory changes are made.

8. Consultation outcome

8.1 In addition to consulting the ACMD, a three month public 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. The 35 responses to the consultation on GBL and 1,4-BD assisted the Government in understanding the potential impact on UK industry of controlling these substances and helped ensure that the exemptions to the 1971 Act offences

were drafted sufficiently widely to allow for the continued legitimate use of these substances.

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 An Impact Assessment relevant to the 2009 Regulations was prepared in relation to the 2009 Order. It is attached to the explanatory memorandum to the 2009 Order.

10.2 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.

10.3 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 controlled under the 2009 Regulations.

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 the drugs is such that the Home Office expects 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, the impact is minimised as these businesses are already likely to be handling controlled drugs, acting under the 2001 Regulations or Home Office licence, 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.

13. Contact

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