EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS (DESIGNATION) (AMENDMENT No. 2) (ENGLAND, WALES AND SCOTLAND) ORDER 2012

2012 No. 1310

AND

THE MISUSE OF DRUGS (AMENDMENT No. 3) (ENGLAND, WALES AND SCOTLAND) REGULATIONS 2012

2012 No. 1311

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 will complement the Misuse of Drugs Act 1971 (Amendment) Order 2012 ("the 2012 Order"), which has already been approved in draft by both Houses of Parliament, upon the 2012 Order being made as anticipated. The 2012 Order classifies for control the following drugs under Schedule 2 to the Misuse of Drugs Act 1971 ("the 1971 Act"):

(i) desoxypipradrol ("2-DPMP"), diphenylprolinol (also known as "D2PM"), 2-diphenylmethylpyrrolidine and other pipradrol-related compounds (by use of a generic definition) in Part 2 of Schedule 2 as Class B drugs;
(ii) any substance which is an ester or ether of Class C pipradrol in Part 3 of Schedule 2 as Class C drugs; and
(iii) 7-bromo-5-(2-chlorophenyl)-1,3-dihydro-2*H*-1,4-benzodiazepin-2-one ("phenazepam") in Part 3 of Schedule 2 as a Class C drug.

2.2 The Misuse of Drugs (Designation) (Amendment No. 2) (England, Wales and Scotland) Order 2012 ("the 2012 Designation Order") amends the Misuse of Drugs (Designation) Order 2001 ("the 2001 Designation Order") by designating 2-DPMP, D2PM, 2-diphenylmethylpyrrolidine and other pipradrol-related compounds as drugs to which section 7(4) of the 1971 Act applies. The Misuse of Drugs (Amendment No. 3) (England, Wales and Scotland) Regulations 2012 (the "2012 Regulations") add 2-DPMP, D2PM, 2-diphenylmethylpyrrolidine and other pipradrol-related compounds to Schedule 1 and phenazepam and any substance which is an ester or ether of pipradrol to Schedule 3 to the Misuse of Drugs Regulations 2001 ("the 2001 Regulations").

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 2012 Order described at paragraph 2.1 above is expected to come into force on 13 June 2012, after consideration by the Privy Council on 30 May 2012. Amendments to the 2001 Designation

Order and the 2001 Regulations are necessary to complement the 2012 Order. As required by the 1971 Act, the ACMD has been consulted on both instruments.

4.2 Section 7(3) of the 1971 Act requires the Secretary of State to make regulations to allow drugs controlled under the 1971 Act to be used for medicinal purposes. 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 2012 Designation Order designates 2-DPMP, D2PM, 2-diphenylmethylpyrrolidine and other pipradrol-related compounds as drugs to which section 7(4) applies.

4.3 The 2012 Regulations add each of the drugs specified in paragraph 2.1 to the appropriate Schedule to the 2001 Regulations. 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 which are designated under the 2012 Designation Order are placed in Schedule 1 to the 2001 Regulations by the 2012 Regulations because they do not have any recognised medicinal uses. They are therefore subject to the strictest level of controls. The particular schedule into which each of the other drugs is added is further explained in section 7 below.

5. Territorial Extent and Application

5.1 These instruments apply to Great Britain.

5.2 Separate instruments will be made by the Northern Ireland Assembly.

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 2012 Order which can be found at http://www.legislation.gov.uk/ukdsi/2012/9780111520857/memorandum/contents sets out the full policy background to the 2012 Order. In summary, the drugs subject to the 2012 Order are sufficiently “dangerous or otherwise harmful” to warrant control under the 1971 Act.

7.2 The 2012 Regulations insert 2-DPMP, D2PM, 2-diphenylmethylpyrrolidine and other pipradrol-related compounds into Schedule 1 to the 2001 Regulations, and these substances are designated under the 2012 Designation Order as drugs to which section 7(4) of the 1971 Act applies. This is because they have no recognised medicinal use beyond potential research use.

7.3 Phenazepam is a part of the family of benzodiazepines which are currently listed in Schedule 3 and Part 1 of Schedule 4 to the 2001 Regulations. It is produced and prescribed in Russia and some Commonwealth of Independent State countries. It is not licensed by the Medicines and Healthcare products Regulatory Agency (MHRA) nor is there any evidence that it is prescribed in the UK. Due to its relative harms, the ACMD recommended that phenazepam should be subject to the increased regulatory requirements in Schedule 3 which would place it alongside a number of benzodiazepines, such as flunitrazepam. As a Schedule 3 drug, it will be

subject to regulations 14 (documentation), 15 (prescription writing), 16 (supply on prescription), 18 (marking of containers), 22 and 23 (record-keeping and preservation of registers), 26 (furnishing of information) and 27 (destruction of the drugs only in presence of an authorised person) of the 2001 Regulations.

7.4 Any ester or ether of pipradrol has been included within a new paragraph 3 in Schedule 3 to the 2001 Regulations in line with the recommendation made by the ACMD on the control and scheduling of 2-DPMP and its pipradrol-related compounds, and the numbering of existing paragraphs 2 to 4 of the 2001 Regulations, before amendment by the 2012 Regulations, has been amended to take this into account.

- ***Consolidation***

7.5 The Government intends to consolidate the 2001 Regulations at the earliest suitable opportunity. Proposals to consolidate the 2001 Regulations have been the subject of a public consultation.

8. Consultation

8.1 The Home Office has consulted with the MHRA and the Department for Business, Innovation and Skills (BIS) who have liaised with chemical industry partners. The MHRA and BIS have commented on the appropriate classification of 2-DPMP, D2PM, 2-diphenylmethylpyrrolidine and phenazepam.

9. Guidance

9.1 The law changes and their consequences will be communicated to key stakeholders and the wider public, especially young people. The Home Office will issue a circular with legislative guidance primarily for law enforcement authorities, the courts and forensic providers, while information about the changes will be made widely available via FRANK – the Government's national drugs awareness service. The Home Office will liaise with the Department of Health and the MHRA to issue guidance to interested healthcare institutions and professionals using their usual communication channels.

10. Impact

10.1 The impact on business, charities or voluntary bodies relates to potential additional administrative costs for the UK pharmaceutical and chemical industry in respect of 2-DPMP and pipradrol-related compounds where there may be research use(s), although costs are likely to be minimal where existing licensing arrangements are suitable. For those businesses selling these substances in the "legal highs" market, the potential harm is such that those trading in this market are expected to comply with the new legislative requirements or face the risk of prosecution.

10.2 The potential impact on the public sector relates to enforcement and regulatory agencies although it is expected to be small and subsumed into the enforcement and regulatory arrangements for similar and existing controlled drugs, managed within existing resources. In term of healthcare provision, there is no evidence of availability of the two anabolic steroids or phenazepam in the UK but appropriate provisions in the Misuse of Drugs Regulations 2001 (as amended) will facilitate their availability in the UK if required, in keeping with the existing regulatory framework.

10.3 The Impact Assessment relevant to the 2012 Regulations and 2012 Designation Order was attached to the explanatory memorandum to the 2012 Order and no separate assessments have been prepared for these instruments.

11. Regulating small business

11.1 The legislation applies to small business. The harm that can be done through misuse and diversion of these drugs is such that we will expect all businesses to comply with the new legislative requirements. However, the impact is minimised for those businesses already likely to be handling controlled drugs, acting in accordance with a Home Office licence or within 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 through the regulatory framework governing medicines and controlled drugs, and also through the oversight of Accountable Officers and the healthcare regulatory bodies in England and the Devolved Administrations.

13. Contact

13.1 Cyrille Marcel at the Home Office, tel: 020 7035 0618 or e-mail: Cyrille.Marcel2@homeoffice.gsi.gov.uk can answer any queries regarding the instrument.