EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS (DESIGNATION) (AMENDMENT) (ENGLAND, WALES AND SCOTLAND) ORDER 2015

2015 No. 232

AND

THE MISUSE OF DRUGS (AMENDMENT) (ENGLAND, WALES AND SCOTLAND) REGULATIONS 2015

2015 No. 231

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 2015 ("the 2015 Order"). The 2015 Order classifies for control under Part 1 of Schedule 2 to the Misuse of Drugs Act 1971 ("the 1971 Act") as Class A drugs:

- 1-cyclohexyl-4-(1,2-diphenylethyl)piperazine (MT-45)
  and
- 4-methyl-5-(4-methylphenyl)-4,5-dihydrooxazol-2-amine (4,4'-DMAR).

2.2 The Misuse of Drugs (Designation) (Amendment) (England, Wales and Scotland) Order 2015 ("the 2015 Designation Order") amends the Misuse of Drugs (Designation) Order 2001 ("the 2001 Designation Order") to designate MT-45 and 4,4'-DMAR as drugs to which section 7(4) of the 1971 Act applies. The Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations 2015 (the "2015 Regulations") inserts the same two drugs into Schedule 1 to the Misuse of Drugs Regulations 2001 ("the 2001 Regulations").

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

None.

4. Legislative Context

4.1 The 2015 Order comes into force on 11 March 2015. Amendments to the 2001 Designation Order and the 2001 Regulations are necessary to complement the 2015 Order. As required under the 1971 Act, the Advisory Council on the Misuse of Drugs ("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 2015 Designation Order designates MT-45 and 4,4'-DMAR as drugs to which section 7(4) applies.

4.3 The 2015 Regulations inserts MT-45 and 4,4'-DMAR into Schedule 1 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. Drugs which are designated under the 2015 Designation Order are placed in Schedule 1 to the 2001 Regulations because they do not have any recognised medicinal uses. They are therefore subject to the strictest level of controls.

5. Territorial Extent and Application

5.1 Both instruments apply in England, Wales and Scotland.

5.2 The Department for Health, Social Service and Public Safety will make separate legislative instruments to apply in Northern Ireland.

6. European Convention on Human Rights

6.1 As the instruments are subject to the 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 2015 Order which can be found at www.legislation.gov.uk/ukdsi/2015/9780111125861/memorandum/contents sets out the full policy background. In summary, the drugs subject to the 2015 Order are sufficiently "dangerous or otherwise harmful" to warrant control under the 1971 Act. The ACMD advises that MT-45, a synthetic opioid, and 4,4'-DMAR, a new psychoactive substance with stimulant properties, have been linked to serious adverse effects including a number of deaths.

7.2 The 2015 Regulations insert MT-45 and 4,4'-DMAR into Schedule 1 to the 2001 Regulations. MT-45 and 4,4'-DMAR are also designated under the 2015 Designation Order as drugs to which section 7(4) of the 1971 Act applies. This is because they have no recognised medicinal uses beyond potential research use which is enabled under a Home Office licence.

7.3 As appropriate, the control, designation and scheduling of MT-45 and 4,4'-DMAR are extended to their simple derivatives – salts, stereoisomeric forms, esters or ethers as applicable.

- ***Consolidation***

7.4 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 the ACMD for advice following consultation with the Medicines and Healthcare Products Regulatory Agency and the Department for Business, Innovation and Skills (BIS) who have liaised with relevant partners to identify any legitimate uses for MT-45 and 4,4'-DMAR. No legitimate uses were identified through the consultation on these compounds beyond use in the research sector.

9. Guidance

9.1 The changes made by the negative instruments and their consequences, as they relate to new psychoactive substances, 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, forensic providers and regulatory partners, while information about the changes will be made widely available via FRANK (the Government's national drugs awareness service).

10. Impact

10.1 The impact of legislation on businesses, charities or voluntary bodies relates to the potential additional administrative costs for the UK pharmaceutical and chemical industry where there may be research use(s) in respect of new psychoactive substances. For those businesses advertising, distributing and selling new psychoactive substances in the "legal highs" market, the potential harm of MT-45 and 4,4'-DMAR is such that these businesses are expected to comply with the new legislative requirements or face the risk of prosecution.

10.2 The potential impact of legislation on the public sector in respect of new psychoactive substances relates to enforcement and regulatory agencies. Enforcement costs are expected to be subsumed into the enforcement and regulatory arrangements for similar controlled drugs and managed within existing resources.

10.3 The Impact Assessment relevant to the 2015 Regulations and 2015 Designation Order was attached to the explanatory memorandum to the 2015 Order. This can be found at www.legislation.gov.uk/ukdsi/2015/9780111125861/impacts.

11. Regulating small business

11.1 Legislation relating to new psychoactive substances applies to small business. The harm that can be done through the misuse of MT-45 and 4,4'-DMAR is such that the Home Office will expect all businesses to comply with new legislative requirements. However, the impact is minimised for those businesses already likely to be handling controlled drugs in accordance with a Home Office licence or within the 2001 Regulations, 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 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.