EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS (DESIGNATION) (AMENDMENT) (ENGLAND, WALES AND SCOTLAND) ORDER 2013

2013 No. 177

AND

THE MISUSE OF DRUGS (AMENDMENT) (ENGLAND, WALES AND SCOTLAND) REGULATIONS 2013

2013 No. 176

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 2013 ("the 2013 Order"), a draft of which has been laid before both Houses of Parliament, and which it is anticipated will be made if approved by both Houses. The 2013 Order classifies for control under Part 2 of Schedule 2 to the Misuse of Drugs Act 1971 ("the 1971 Act") as Class B drugs:

(i) Synthetic cannabinoid receptor agonists (synthetic cannabinoids);
(ii) 2-(ethylamino)-2-(3-methoxyphenyl)cyclohexanone (commonly known as methoxetamine) and other compounds related to ketamine (Class C) and phencyclidine (Class A); and
(iii) 2-((dimethylamino)methyl)-1-(3-hydroxyphenyl)cyclohexanol (commonly known as "*O*-desmethyltramadol", a metabolite of the prescription only medicine, tramadol).

2.2 The Misuse of Drugs (Designation) (Amendment) (England, Wales and Scotland) Order 2013 ("the 2013 Designation Order") amends the Misuse of Drugs (Designation) Order 2001 ("the 2001 Designation Order") by designating these compounds as drugs to which section 7(4) of the 1971 Act applies. The Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations 2013 (the "2013 Regulations") amend the Misuse of Drugs Regulations 2001 ("the 2001 Regulations") by replacing and extending generic definitions of synthetic cannabinoids inserted by the Misuse of Drugs (Amendment) (England, Wales and Scotland) Regulations 2009 (SI 2009/3136, article 4(1)(b)), and by inserting the generic definition for methoxetamine and other related compounds, as well as *O*-desmethyltramadol, in Schedule 1 to 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 2013 Order described at paragraph 2.1 above is expected to come into force on 26 February 2013. Amendments to the 2001 Designation Order and the 2001 Regulations are necessary to complement the 2013 Order. As required under 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 which has no recognised medicinal use. The 2013 Designation Order designates *O*-desmethyltramadol, methoxetamine and other compounds related to ketamine and phencyclidine by generic definition, as well as designating by revised generic definition synthetic cannabinoids, as drugs to which section 7(4) applies.

4.3 The 2013 Regulations add each of the drugs specified in paragraph 2.1 to 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. Those drugs which are designated under the 2013 Designation Order are placed in Schedule 1 to the 2001 Regulations by the 2013 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 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 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 2013 Order, which can be found at http://www.legislation.gov.uk/ukdsi/2013/9780111532980/contents, sets out the full policy background to the 2013 Order. In summary, the drugs subject to the 2013 Order are sufficiently "dangerous or otherwise harmful" to warrant control under the 1971 Act.

7.2 The 2013 Regulations substitute existing generic definitions of synthetic cannabinoids inserted by SI 2009/3136 with revised definitions, insert three more generic definitions capturing new families of synthetic cannabinoids, insert a generic definition for methoxetamine and other compounds related to ketamine (Class C) and phencyclidine (Class A), and add *O*-desmethyltramadol by its chemical name into Schedule 1 to the 2001 Regulations. These compounds are designated under the 2013 Designation Order as drugs to which section 7(4) of

the 1971 Act applies because they have no recognised legitimate use beyond potential research use.

7.3 As appropriate, the control, designation and scheduling of these substances are extended to their simple derivatives – salts, stereoisomeric forms, esters or ethers – with the exception of the esters or ethers of *O*-desmethyltramadol being made. The 2013 Regulations amend paragraph 3 of Schedule 1 to the 2001 Regulations to this effect. Similarly, the 2013 Designation Order excepts any ester or ether of *O*-desmethyltramadol from paragraph 3 of Part 1 of the Schedule to the 2001 Designation Order.

- ***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 outcome

8.1 The Home Office has consulted with the Medicines and Healthcare products Regulatory Agency (MHRA) and the Department for Business, Innovation and Skills (BIS), who have liaised with the healthcare sector and chemical industry partners, on any legitimate, medical or chemical use other than potential research use. None has been identified involving the drugs listed in paragraph 2.1.

9. Guidance

9.1 The changes in the law 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 and regulatory partners, the courts and forensic providers, while information about the changes will be made widely available via the Government's national drugs awareness service, FRANK.

10. Impact

10.1 The impact on business, charities or voluntary bodies relates to potential administrative costs where there may be research use(s) of these drugs, although it is likely to be minimal as most organisations licensed to undertake activities involving controlled drugs under the 2001 Regulations are able to undertake activities relating to other drugs of the same schedule for the same purpose(s). The potential impact on the public sector relates to law enforcement and regulatory costs, although any of these are expected to be small and subsumed into arrangements for other Schedule 1 controlled drugs.

10.2 The Impact Assessment relevant to the 2013 Regulations and 2013 Designation Order was attached to the explanatory memorandum for the 2013 Order and no separate assessments have been prepared for these two instruments which complement it.

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 law.

However, the impact is minimised for those businesses already likely to be handling controlled drugs, acting under a Home Office licence or 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 instruments.