EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS (DESIGNATION) (AMENDMENT) (ENGLAND, WALES AND SCOTLAND) ORDER 2014

2014 No. 1274

AND

THE MISUSE OF DRUGS AND MISUSE OF DRUGS (SAFE CUSTODY) (AMENDMENT) (ENGLAND, WALES AND SCOTLAND) REGULATIONS 2014

2014 No. 1275

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 (Ketamine etc.) (Amendment) Order 2014 ("the 2014 Order"). The 2014 Order classifies for control the following drugs under Schedule 2 to the Misuse of Drugs Act 1971 ("the 1971 Act"):

(i) groups of NBOMe compounds in Part 1 of Schedule 2 as Class A drugs;
(ii) groups of benzofuran compounds, lisdexamphetamine and ketamine in Part 2 of Schedule 2 as Class B drugs; and
(iii) tramadol, zopiclone and zaleplon in Part 3 of Schedule 2 as Class C drugs.

2.2 The Misuse of Drugs (Designation) (Amendment) (England, Wales and Scotland) Order 2014 ("the 2014 Designation Order") amends the Misuse of Drugs (Designation) Order 2001 ("the 2001 Designation Order") to designate the groups of NBOMe and benzofuran compounds as drugs to which section 7(4) of the 1971 Act applies. The Misuse of Drugs and the Misuse of Drugs (Safe Custody) (Amendment) (England, Wales and Scotland) Regulations 2014 (the "2014 Regulations") add the groups of NBOMe and benzofuran compounds to Schedule 1, lisdexamphetamine to Schedule 2, tramadol to Schedule 3, and zopiclone and zaleplon to Part 1 of Schedule 4 to the Misuse of Drugs Regulations 2001 ("the 2001 Regulations"). The 2014 Regulations also add tramadol to the list of drugs in Schedule 1 to the Misuse of Drugs (Safe Custody) Regulations 1973 as a drug which is exempted from the requirements of the safe custody regulations.

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

3.1 None

4. Legislative Context

4.1 The 2014 Order comes into force on 10 June 2014. Amendments to the 2001 Designation Order and the 2001 Regulations are necessary to complement the 2014 Order. As required by 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 2014 Designation Order designates the groups of NBOMe and benzofuran compounds as drugs to which section 7(4) applies.

4.3 The 2014 Regulations add each of the drugs specified in paragraph 2.1 (with the exception of ketamine) to the appropriate Schedule to the 2001 Regulations. A final decision on the appropriate Schedule in which to place ketamine (in the light of its reclassification to Class B) will be made following a public consultation later this year. Ketamine is currently listed in Schedule 4 Part 1 and will continue to remain in that schedule until the decision on rescheduling is made. 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 2014 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. 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 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 2014 Order which can be found at http://www.legislation.gov.uk/ukdsi/2014/9780111110904/memorandum/contents sets out the full policy background to the 2014 Order. In summary, the drugs subject to the 2014 Order are sufficiently "dangerous or otherwise harmful" to warrant control under the 1971 Act.

7.2 The NBOMe compounds are highly potent hallucinogens which are regarded as alternatives to LSD. They are marketed as new psychoactive substances or legal alternatives to controlled drugs. The benzofuran compounds are related to the family of controlled drugs including ecstasy. These compounds were most commonly sold in samples of the 'legal high' brand name 'Benzo Fury' and marketed as legal alternatives to Class A drugs like cocaine and ecstasy. The 2014 Regulations insert the NBOMe and benzofuran compounds into Schedule 1 to the 2001 Regulations. These substances are designated under the 2014 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 Lisdexamphetamine is closely related to the Class B controlled drug dexamphetamine. When administered orally, lisdexamphetamine slowly converts to dexamphetamine in the body. Lisdexamphetamine is licensed by the Medicines and Healthcare products Regulatory Agency (MHRA) for the specialist treatment of Attention Deficit Hyperactive Disorder in adults where a patient does not respond to other medication. Due to its relative harms, the ACMD recommended that lisdexamphetamine should be subject to the increased regulatory requirements applicable to Schedule 2 drugs which would place it alongside dexamphetamine. As a Schedule 2 drug, it will be subject to regulations 14 (documentation), 15 (prescription writing), 16 (supply on prescription), 18 (marking of containers), 19, 20, 21, 22 and 23 (record-keeping, recording in controlled drug registers 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 Zopiclone and zaleplon are sedatives closely related to the benzodiazepine family of drugs and zolpidem, controlled as Class C drugs. The ACMD recommended that zopiclone and zaleplon should be subject to the lightly regulated controls of Part 1 of Schedule 4. As Schedule 4 Part 1 drugs, zopiclone and zaleplon will be subject to regulations 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.

7.5 Tramadol is a pain reliever of significant medical use for treating moderate to severe pain. It has wide ranging applications, including treatment of chronic widespread cancer and muscle and bone pain. Due to its relative harms, the ACMD recommended that tramadol should be subject to the increased regulatory requirements in Schedule 3. 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. As a Schedule 3 drug tramadol would ordinarily be subject to safe custody requirements. However, due to the large quantities of the various types, forms and strengths prescribed and dispensed, as an exception, tramadol is being exempted from these requirements. Tramadol is therefore added to the listed of drugs in Schedule 1 to the Misuse of Drugs (Safe Custody) Regulations 1973. This avoids any impact from storage requirements on hospitals, pharmacies and businesses etc.

- ***Consolidation***

7.6 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. In respect of tramadol, the Home Office undertook a twelve week public consultation on the scheduling proposals in line with ACMD advice. The majority of respondents to the

public consultation supported Schedule 3 status. However, respondents raised significant concerns around the impact of application of the safe custody requirements. Tramadol is therefore being exempted from the safe custody requirements in line with the consultation outcome. The summary of responses to the consultation and Government's response is published at www.gov.uk/government/uploads/system/uploads/attachment_data/file/288065/TramadolTemazepamConsultationResponses.pdf

9. Guidance

9.1 The changes made by these instruments 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 Medicines and Healthcare products Regulatory Agency to issue guidance to interested healthcare institutions and professionals using their usual communication channels.

10. Impact

10.1 The impact on businesses, charities or voluntary bodies relates to potential additional administrative costs for the UK pharmaceutical and chemical industry in respect of the NBOMe and benzofuran compounds, where there may be research use(s), and the medicines being controlled, although costs are likely to be minimal where existing licensing arrangements are suitable. For those businesses selling 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, and potential additional administrative costs to certain sectors of healthcare in respect of the availability and use of the medicines being controlled, although these are expected to be minimal. Enforcement costs are expected to be subsumed into the enforcement and regulatory arrangements for similar and existing controlled drugs and managed within existing resources.

10.3 The Impact Assessments relevant to the 2014 Regulations and 2014 Designation Order was attached to the explanatory memorandum to the 2014 Order and no separate assessments have therefore 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 Desmond Niimoi at the Home Office, tel: 020 7035 3533 or e-mail: Desmond.niimoi@homeoffice.gsi.gov.uk can answer any queries regarding the instrument.