EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS (DESIGNATION) (AMENDMENT) (No. 3) (ENGLAND, WALES AND SCOTLAND) ORDER 2014

2014 No. 3276

AND

THE MISUSE OF DRUGS (AMENDMENT No. 3) (ENGLAND, WALES AND SCOTLAND) REGULATIONS 2014

2014 No. 3277

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) (No. 2) Order 2014 ("the 2014 Order"). The 2014 Order extends the generic (group) definition used to control the family of tryptamines under the Misuse of Drugs Act 1971 ("the 1971 Act") to capture additional compounds from this family of drugs for control as Class A drugs under Part 1 of Schedule 2 to the 1971 Act. The Order also classifies the following drugs for control under Part 1 of Schedule 2 to the 1971 Act as Class A drugs:

- (6a*R,*9*R*)-4-acetyl-*N,N*-diethyl-7-methyl-4,6,6a,7,8,9-hexahydroindolo[4,3-*fg*]quinoline-9-carboxamide (ALD-52);
- 3,4-dichloro-*N*-[[1-(dimethylamino)cyclohexyl]methyl]benzamide (AH-7921);
- (6a*R,*9*R*)-*N,N*-diethyl-7-allyl-4,6,6a,7,8,9-hexahydroindolo[4,3-*fg*]quinoline-9-carboxamide (AL-LAD);
- (6a*R,*9*R*)-*N,N*-diethyl-7-ethyl-4,6,6a,7,8,9-hexahydroindolo[4,3-*fg*]quinoline-9-carboxamide (ETH-LAD);
- (6a*R,*9*R*)-*N,N*-diethyl-7-propyl-4,6,6a,7,8,9-hexahydroindolo[4,3-*fg*]quinoline-9-carboxamide (PRO-LAD); and
- 2,4-dimethylazetidinyl{(6a*R,*9*R*)-7-methyl-4,6,6a,7,8,9-hexahydroindolo[4,3- *fg*]quinolin-9-yl}methanone (LSZ)

2.2 The Misuse of Drugs (Designation) (Amendment) (No. 3) (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 compounds listed in paragraph 2.1 above, and those captured by the extended tryptamine generic definition as drugs to which section 7(4) of the 1971 Act applies. The Misuse of Drugs (Amendment No. 3) (England, Wales and Scotland) Regulations 2014 (the "2014 Regulations") adds those drugs to Schedule 1 to the Misuse of Drugs Regulations 2001 ("the 2001 Regulations"). The 2014 Regulations also move 4-Hydroxy-n-butyric acid (GHB) from Schedule 4 to Schedule 2 to the 2001 Regulations.

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

None.

4. Legislative Context

4.1 The 2014 Order comes into force on 7th January 2015. 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 drugs specified in paragraph 2.1 and the compounds captured by the extended tryptamine generic definition as drugs to which section 7(4) applies.

4.3 The 2014 Regulations add the drugs specified in paragraph 2.1 and the compounds captured by the extended tryptamine generic definition to Schedule 1 to the 2001 Regulations and move GHB from Schedule 4 to Schedule 2. 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.

5. Territorial Extent and Application

5.1 These instruments apply to England, Wales and Scotland. The Northern Ireland Department for Health, Social Service and Public Safety (DHSSPS) will make separate legislative arrangements.

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***

Scheduling and Designation of new psychoactive compounds

7.1 The explanatory memorandum to the 2014 Order which can be found at http://www.legislation.gov.uk/ukdsi/2014/9780111123034/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 AH-7921 is a potent synthetic opioid which is being marketed as a 'legal' alternative to morphine, a Class A and a Schedule 2 controlled drug. The LSD-related compounds (ALD-52, ETH-LAD, PRO-LAD, AL-LAD and LSZ), and the compounds captured by the extended generic definition of the tryptamines, such as alpha-methyl-tryptamine (AMT) and 5-MeO-DALT, are potent hallucinogens which are being offered for sale on some specialist websites as 'legal' alternatives to already controlled hallucinogens such as LSD. The 2014 Regulations insert AH-7921, the LSD-related compounds and the compounds captured by the new

tryptamine generic definition into Schedule 1 to the 2001 Regulations. These substances are also 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 which will be enabled under a Home Office licence.

Rescheduling of *4-hydroxy-n-butyric acid* (GHB)

7.3 GHB is a naturally occurring substance found in the human central nervous system, as well as in animals and plants in small amounts. It is used as a sedative medication and an anaesthetic. It is also used as a treatment for narcolepsy and for conditions such as insomnia, clinical depression and alcoholism.

7.4 GHB is also misused, and often referred to as a 'date rape' drug. Its harmful effects when misused include coma, low heart rate and hypothermia. In November 2001 the ACMD recommended that GHB should be controlled as a Class C and a Schedule 4 drug in the same sub-category as the benzodiazepines (currently Schedule 4 Part I) following international control. The ACMD advice was accepted and control measures were put in place in July 2003. GBL (γ-Butyrolactone), a prodrug of GHB, was subsequently brought under the control of the 1971 Act in 2009, but not scheduled, due to its wide use in industry. The ACMD's advice can be found at:
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/246191/ACMD_GHB_Advice.pdf.

7.5 Following a review of its misuse and harms, in June 2013 the United Nations rescheduled GHB under the 1971 UN Convention on Psychotropic Substances. The ACMD considered the available evidence on prescribing, diversion, misuse and harms and recommended that GHB should be rescheduled to Schedule 2 to ensure it is available for use in healthcare under an appropriate level of regulation to prevent diversion and misuse. GHB is rescheduled to Schedule 2 with the effect that it is now subject to the prescription writing, requisition, destruction and safe custody requirements when used in healthcare.

- ***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 outcome

8.1 The Home Office has consulted the ACMD, the Medicines and Healthcare Products Regulatory Agency and the Department for Business, Innovation and Skills (BIS) who have liaised with chemical industry partners to identify any legitimate uses for the new psychoactive compounds being subject to control by the 2014 Order. No legitimate uses were identified through the consultation for these compounds.

9. Guidance

9.1 The changes made by these 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 and forensic providers, while information

about the changes will be made widely available via FRANK (the Government's national drugs awareness service).

9.2 The changes to the Misuse of Drugs Regulations in relation to scheduling of GHB will be communicated to healthcare professionals and the wider public by the Home Office and the Department of Health. The Home Office will issue a circular explaining the changes further and 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 new psychoactive compounds, where there may be research use(s). 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 in respect of the new psychoactive substance relates to enforcement and regulatory agencies. 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 Assessment relevant to the 2014 Regulations and 2014 Designation Order was attached to the explanatory memorandum to the 2014 Order. This can be found at: http://www.legislation.gov.uk/ukia/2014/227/pdfs/ukia_20140227_en.pdf.
10.4 An additional Impact Assessment for the re-scheduling for GBH is attached to this memorandum.

11. Regulating small business

11.1 The legislation relating to new psychoactive substances apply to small business. The harm that can be done through the misuse of these compounds is such that the Home Office 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 Des 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.