EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS ACT 1971 (KETAMINE ETC.) (AMENDMENT) ORDER 2014

2014 No.

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 instrument

2.1 This Order in Council ("the Order") re classifies Ketamine as a Class B drug under Part 2 Schedule 2 of the Misuse of Drugs Act ("the Act"). The Order also classifies groups of NBOMe compounds as Class A drugs under Part 1 Schedule 2 of the Act. The Order classifies Lisdexamphetamine and groups of benzofuran compounds as Class B drugs under Part 2 Schedule 2 of the Act and the Order classifies Tramadol, Zaleplon and Zopiclone as Class C drugs under Part 3 Schedule 2 of the Act.

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

3.1 None.

4. Legislative Context

4.1 The Misuse of Drugs Act 1971 ("the 1971 Act") controls drugs that are "dangerous or otherwise harmful". Schedule 2 to the 1971 Act specifies these drugs and groups them in three categories – Part 1 lists drugs known as Class A drugs, Part 2 lists Class B drugs and Part 3 lists Class C drugs. The three-tier system of classification (A, B and C) provides a framework within which criminal penalties are set with reference to the harm a drug has or is capable of having when misused and the type of illegal activity undertaken in regard to that drug.

4.2 Section 2 of the 1971 Act enables amendments to be made to the list of drugs controlled under the Act by means of an Order in Council. Section 2 also provides that the Secretary of State may not recommend the making of such an Order except after consultation with the Advisory Council on the Misuse of Drugs (ACMD).

4.3 The classification of each of the drugs listed in paragraph 2.1 is predicated on an assessment of their respective harms and in accordance with recommendations made by the ACMD.

4.4 Lisdexamphetamine is a recently developed inactive pro-drug of the Class B controlled drug dexamphetamine. It is prescribed by specialists as a second line treatment for attention deficit hyperactivity disorder (ADHD) in adults. When administered orally, lisdexamphetamine gradually converts to dexamphetamine, the Class B drug. The ACMD has concluded that lisdexamphetamine presents a risk of misuse, diversion from legitimate sources, addiction and potential medicinal misuse.

4.5 Zopiclone and zaleplon are sedatives closely related to the benzodiazepine family of drugs and zolpidem (Class C drugs). The ACMD reports that the number of prescriptions for zopiclone and zaleplon has been on the increase as compared to prescriptions for benzodiazepines. The ACMD has concluded that due to the similarities in chemical structure and effects of these drugs and benzodiazepines, the potential social harm from the misuse of zopiclone and zaleplon would be similar to the social harms associated with the misuse of zolpidem and the benzodiazepines.

4.6 Tramadol is an analgesic of significant medical use for treating moderate to severe pain. It has wide ranging applications, including treatment of chronic, widespread, cancer and musculoskeletal pain. The ACMD reports that Tramadol presents a risk of misuse and adverse effects, particularly in overdose. There are also potential social harms around the impact that dependence on tramadol can have on those other than the user.

4.7 The NBOMe compounds are highly potent hallucinogens and closely related to Class A phenethylamine substances. With the exception of a single compound being actively developed abroad for use in hospital scanners to produce three-dimensional images or pictures of functional processes in the body and/or in autoradiographic studies, there are no known legitimate uses for these compounds. The ACMD considers that, in the case of the compounds covered by the generic definition, they are drugs that are being, or are likely to be, misused, and that misuse is having, or is capable of having, harmful effects. Some of the NBOMe compounds were made subject to a Temporary Class Drugs Order in June 2013 (S.I. 2013/1294) under section 2A of the 1971 Act and this Order will make them subject to permanent control.

4.8 The Benzofuran compounds are phenethylamine-type materials related to ecstasy (MDMA), a Class A drug under the 1971 Act. There are no known legitimate uses for these compounds. The ACMD reports that the compounds to be covered by the generic definition are drugs that are being, or are likely to be, misused, and that misuse is having, or is capable of having, harmful effects. Some of the benzofuran compounds were made subject to a Temporary Class Drugs Order in June 2013 (S.I. 2013/1294) under section 2A of the 1971 Act and this Order will make them subject to permanent control.

4.9 Ketamine is a synthetic drug commonly used in medical and veterinary practice. It is used as a dissociative anaesthetic and an analgesic (pain reliever). The ACMD first considered ketamine in 2004, and following its advice ketamine was brought under Class C control in 2006. The ACMD reconsidered ketamine following commissioning by the Home Secretary as a result of increasing evidence, and concerns, around chronic toxicity from long term misuse. The ACMD reports evidence of chronic toxicity and long term harms associated with ketamine misuse.

4.10 The ACMD has been consulted, as required by statute, on the above changes.

5. Territorial Extent and Application

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

6.1 The Minister for Crime Prevention, Norman Baker MP, has made the following statement regarding Human Rights:

> "In my view, the provisions of the Misuse of Drugs Act 1971 (Ketamine etc.) (Amendment) Order 2014 are compatible with the Convention rights."

7. Policy background

- ***What is being done and why***

7.1 The effects and risks associated with lisdexamphetamine are similar to those of other amphetamine type drugs (controlled as Class B drugs under the Misuse of Drugs Act 1971). Harms associated with the use of amphetamines result, in the main, from their stimulatory effects brought about by inhibition of the re-uptake of monoamine neurotransmitters. Physical effects can include anorexia, insomnia, dizziness, headaches, tachycardia and hypertension. After chronic and/or high doses, convulsions, heart attacks, stroke and death have been reported. Psychologically amphetamines can improve alertness and concentration but can also give rise to anxiety or agitation. These periods of stimulation are frequently followed by rebound periods of depression and fatigue due, in part, to sleep deprivation.

7.2 The effects and risks associated with zaleplon and zopiclone are similar to those of zolpidem and the benzodiazepine family of drugs (controlled as Class C drugs under the Misuse of Drugs Act 1971). The ACMD also reports the harms from zaleplon and zopiclone misuse to include a risk of coma, respiratory depression and death associated with use of excess doses of these drugs in combination with alcohol or other Central Nervous System (CNS) depressants. Other reported psychosocial effects include depressed mental activity and alertness, memory loss and amnesia and personality and mood changes through drowsiness, lethargy, disinhibition, chronic paranoid behaviour and aggression. Data from the National Program on Substance Abuse Deaths (npSAD) also suggests zolpidem, zaleplon and zopiclone play a minor role in drug related deaths in the UK, mainly in combination with other CNS depressants, and principally implicated in episodes of intentional poisoning.

7.3 Lisdexamphetamine's control as a Class B drug, and zaleplon and zopiclone's control as Class C drugs, under the 1971 Act, as recommended by the ACMD not only acts as a protective and precautionary measure but also brings the drugs in line with drugs of similar structure and harms, including the amphetamines and benzodiazepines. At the same time we are concerned to ensure that we do not prevent legitimate use of zaleplon, zopiclone or lisdexamphetamine, and this will be reflected in the amendments made to the Misuse of Drugs Regulations 2001 (S.I. 2001/3998) which will allow for the possession, supply, manufacture, import and export of lisdexamphetamine, zaleplon and zopiclone for legitimate use. The ACMD's advice in respect of lisdexamphetamine, zaleplon and zopiclone is available at; https://www.gov.uk/government/publications/acmd-advice-on-lisdexamfetamine-and-z-drugs

7.4 The ACMD reports that tramadol overdose results in drowsiness, constricted (small) pupils, agitation, tachycardia (rapid heartbeat), hypertension (high blood pressure), and nausea, vomiting and sweating. Seizures are more common with tramadol overdose than with other opioids and occur in up to 15% of cases. In severe poisoning coma, seizures and hypotension (low blood pressure) can occur. Tramadol's unique dual-action pharmacological profile also increases the risk of adverse effects seen in overdose. Prescribing data from the NHS Business Services Authority indicates an increase in prescribing, with the number of Daily Defined Doses (England) increasing from approximately 5.9 million in September 2005 to 11.1 million in September 2012. Data from the Office of National Statistics for 2011 shows 154 deaths where tramadol had been mentioned on the death certificate, as compared to 87 in 2009, and 83 in 2008. Tramadol is being controlled as a Class C drug, as recommended by the ACMD, in order to protect the public from the harms associated with its misuse, particularly in overdose. The ACMD's advice in respect of tramadol is available at https://www.gov.uk/government/publications/acmd-advice-on-tramadol.

7.5 The ACMD reports the harms associated with the NBOMe compounds as confusion, shaking, nausea, insomnia, paranoia and unwanted feelings. "*There is a high risk of overdose owing to the extremely high potency of these materials, even at microgram amounts of powder, and they are regarded as probable alternatives to LSD*." A number of fatalities have also been reported as associated with the NBOMe compounds, both in the UK and internationally. The ACMD reports that the "*limited evidence available to date, indicates that the NBOMe compounds will carry the same risks of personal and social harm as LSD. Because of their extremely high potency there is a high risk of overdose – particularly when the compounds are handled in liquid or powder form."* The NBOMe compounds are being controlled as Class A drugs, as recommended by the ACMD, in recognition of the lack of legitimate uses and to protect the public from the harms associated with their misuse. The generic definition being used to permanently control these drugs is wider, and therefore captures more drugs, than that used under the temporary class order. The aim is to future-proof the legislation, by reducing the likelihood of further modifications to the chemical structures of these drugs to evade control. The ACMD's advice in respect of the NBOMe compounds is available at https://www.gov.uk/government/publications/nbome-compounds-a-review-of-the-evidence-of-use-and-harm.

7.6 The ACMD reports the harms from the misuse of benzofuran compounds as hyper-pyrexia (elevated body temperatures). Research suggests that there is a potential risk of cardiac toxicity associated with long term use of these compounds. Anecdotal user reports also suggest consumption of these substances can cause insomnia, increased heart rate and anxiety, with some users reporting ecstasy-like symptoms. The ACMD reports that the limited evidence available to date indicates that the Benzofuran compounds have the potential to carry similar risks of personal and social harm as Ecstasy. The Benzofuran compounds are being controlled as Class B drugs, as recommended by the ACMD, in recognition of their lack of legitimate uses and to protect the public from the harms associated with their misuse. The generic definition being used to permanently control these drugs is wider, and therefore captures more drugs, than that used under the temporary class order. The aim is to future-proof the legislation, by reducing the likelihood of further

modifications to the chemical structures of these drugs to evade control. The ACMD's advice in respect of the benzofuran compounds is available at https://www.gov.uk/government/publications/benzofurans-a-review-of-the-evidence-of-use-and-harm

7.7 The ACMD reports the harms associated with ketamine misuse as increased heart rate and cardiac output, high blood pressure – with potentially dangerous effects for people with diseases of the cardiovascular system including those with coronary artery disease, irregularities of heart rhythm, and in individuals at risk of stroke – and hallucinations and experiences of alternate realities similar to those found in schizophrenia associated with long term ketamine misuse. In addition, regular ketamine use is now also known to be associated with a range of chronic problems including chronic bladder and other urinary tract pathology, gall bladder, gastrointestinal, central nervous system and kidney damage. The ACMD also reports evidence of acute and chronic toxicity associated with ketamine misuse.

7.8 The ACMD also reports that there is less data available on social harms associated with ketamine use as compared with drugs such as heroin or cocaine. However, it identifies its social harms as negative impact on families, social skills and participation in social activities. Large doses of ketamine are also known to induce dissociation – intense detachment that can be unpleasant and frightening and can put the user in a position of vulnerability to robbery, assault or rape. The number of deaths where ketamine is mentioned as present has also seen a rise in the past two years (11 on 2011 and 12 in 2012) following a drop from 15 in 2009 to 6 in 2010. Ketamine is being reclassified to Class B, as recommended by the ACMD, based on the evidence of harms due to acute toxicity from long term use, more particularly irreversible bladder and kidney damage. The ACMD's advice in respect of ketamine is available at https://www.gov.uk/government/publications/ketamine-report.

- ***Consolidation***

7.9 None.

8. Consultation outcome

8.1 The Government has consulted its independent experts, the Advisory Council on the Misuse of Drugs. The ACMD has recommended control of the drugs being controlled and reclassified following a review of their harms.

9. Guidance

9.1 The law changes and their consequences will be communicated to key stakeholders and the wider public. The Home Office will issue a Circular with legislative guidance primarily for the police and the courts.

10. Impact

10.1 The impact on business, charities or voluntary bodies principally relates to additional administrative costs for the pharmaceutical industry in respect of the drugs proposed for control which have legitimate uses, although this is likely to be small.

10.2 The impact on the public sector relates to certain healthcare sectors. There are potential additional administrative costs to certain sectors of healthcare in respect of the availability and use of these drugs, although these are likely to be small.

10.3 Impact Assessments are attached to this memorandum.

11. Regulating small business

11.1 The legislation applies to small business.

11.2 The harm that can be done from misuse and diversion of these drugs is such that we will expect those operating in the pharmaceutical industry and certain sectors of healthcare to comply with the Misuse of Drugs Act 1971 and subordinate legislation made under it, however small the business. However, impact is minimised as these businesses are already likely to be handling controlled drugs, acting under Home Office licence or 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 the healthcare regulatory bodies in England and the Devolved Administrations.

13. Contact

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.