EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS ACT 1971 (AMENDMENT) ORDER 2013

2013 No. 239

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") controls the following as Class B drugs under Part 2 of Schedule 2 of the Misuse of Drugs Act 1971 (the "1971 Act):
 - (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).

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 contains 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 causing 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. Such Orders are subject to the affirmative resolution procedure which requires that they be approved by each House of Parliament. 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 control and classification of the drugs as listed in paragraph 2 above are predicated on the assessments of their respective harms and in accordance with recommendations made by the ACMD.
- 4.4 Synthetic cannabinoids mimic the effects of the main active ingredient of cannabis and their harms are similar to those of cannabis, a Class B drug. In excess of 140 synthetic cannabinoids were classified as Class B drugs by virtue of the Misuse of Drugs Act 1971 (Amendment) Order 2009 (SI 2009/3209). The new definitions introduced by virtue of article 4 of the Order replace and extend the definitions used in SI 2009/3209 to capture further synthetic cannabinoids seen in the UK and in Europe. Methoxetamine and other

compounds to be brought under control as Class B drugs are related to ketamine (Class C) and phencyclidine (Class A). *O*-Desmethyltramadol is the active metabolite of tramadol, a prescription only medicine, identified as an active ingredient in 'legal high' branded products in other European countries. Tramadol itself is not a controlled drug. The ACMD concludes that the harms of these drugs are significant enough to warrant Class B control and the Government accepts this advice.

- 4.5 As appropriate, controls on the substances listed at paragraph 2 are extended to their simple derivatives salts, stereoisomeric forms, esters or ethers. The esters or ethers of *O*-desmethyltramadol are not subject to control.
- 4.6 It is intended to make two further related statutory instruments which will be subject to the negative resolution procedure amending the Misuse of Drugs Regulations 2001 (as amended) to include the compounds captured by the generic definitions of synthetic cannabinoids and methoxetamine and other compounds as well as *O*-desmethyltramadol in Schedule 1 to those Regulations. The Misuse of Drugs (Designation) Order 2001 (as amended) will be amended to designate these drugs which have no recognised legitimate use.

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 of State for Crime Prevention has made the following statement regarding Human Rights:

In my view the provisions of the Misuse of Drugs Act 1971 (Amendment) Order 2013 are compatible with the Convention rights.

7. Policy background

- What is being done and why
- 7.1 A range of synthetic cannabinoids were first brought under control in December 2009. It was acknowledged at the time that generic control for these compounds would likely require updating as the market developed. The ACMD has continued to monitor the situation and found uncontrolled cannabinoids available in the UK and across Europe, with many of the mixtures available under different brand names such as "Black Mamba" and "Annihilation". The ACMD has assessed the harms of these new compounds as broadly similar to those controlled in 2009. They include cardiovascular symptoms (tachycardia), convulsions, nausea, severe agitation and hallucinations. It also found indications of a trend towards increased availability and use of these new synthetic cannabinoids. The ACMD's further advice in respect of synthetic cannabinoids can be found at http://www.homeoffice.gov.uk/publications/agencies-public-bodies/acmd1/synthetic-cannabinoids-2012. The 2009 generic definitions, of which there were five, are replaced and added to, with the five synthetic cannabinoids listed by name under SI 2009/3209, including "nabilone", unchanged.
- 7.2 Methoxetamine (and its simple derivatives) became subject to a temporary class drug order on 5 April 2012 (SI 2012/980) under section 2A of the 1971 Act, pending the ACMD's advice in relation to permanent control. The ACMD now confirms that the harms

of methoxetamine include significant hypertension and dissociative effects, as seen with ketamine toxicity, as well as additional toxicity including agitation and cerebellar functions. The ACMD has also identified other closely related analogues to ketamine (Class C) and phencyclidine (Class A), which are sold by 'legal high' suppliers and whose effects and potential harms are similar to those of Class B drugs. The ACMD has therefore provided a generic definition to capture methoxetamine and these other compounds for control as Class B drugs. Its advice on methoxetamine and other closely related analogues of ketamine and phencyclidine can be found at http://www.homeoffice.gov.uk/publications/agencies-public-

bodies/acmd1/methoxetamine2012. Methoxetamine will cease to be subject to SI 2012/980 upon the coming into force of this Order when it is added to the list of controlled Class B drugs in Part 2 of Schedule 2 to the 1971 Act. This is because, while it was specified under its chemical name in article 2(a) of SI 2012/980, it is captured by the generic definition set out in the new paragraph 1(d) being inserted by article 4 of this Order. Simple derivatives of methoxetamine specified in SI 2012/980 are subject to temporary control and will, also on the coming into force of this Order, be specified as controlled drugs and by virtue of section 2A(6)(b) of the 1971 Act will cease to be subject to such temporary control.

- 7.3 The ACMD has identified O-desmethyltramadol – a more potent opiate than tramadol its parent drug and a prescription only medicine – as sufficiently harmful to warrant control under the 1971 Act as a Class B drug. It found that O-desmethyltramadol has been an undeclared active ingredient in samples of the 'legal high' branded product 'Krypton' which has been linked to a number of deaths in Sweden. The ACMD has reviewed the drug specifically, within the context of its use as a new psychoactive substance, and concluded that its harms include confusion, respiratory depression, seizures The ACMD's advice can at http://www.homeoffice.gov.uk/publications/agencies-public-bodies/acmd1/ACMD-Odesmethyltramadol.
- 7.4 The Government has accepted the ACMD's assessments that the harms associated with synthetic cannabinoids, methoxetamine and other closely related analogues of ketamine and phencyclidine as well as *O*-desmethyltramadol are commensurate to those of Class B drugs. The maximum penalties for offences relating to a Class B drug are on indictment, for possession, five years' imprisonment and/or a fine, and for supply, production or importation/exportation fourteen years' imprisonment and/or an unlimited fine; the maximum penalties on summary conviction for Class B drugs on possession are three months' imprisonment and/or a fine of £2,500 and for supply, production or importation/exportation, are six months' imprisonment and/or a prescribed fine.

• Consolidation

7.5 None

8. Consultation outcome

8.1 The Home Office has consulted the Medicines and Healthcare products Regulatory Agency (MHRA) and the Department for Business, Innovation and Skills (BIS), who have liaised with chemical industry partners, on any legitimate medical or chemical use beyond potential research. Through this consultation, none of the new substances subject to this Order has been identified as having any legitimate medical or chemical use beyond potential research use.

9. Guidance

9.1 The changes in the law made by this Order 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, 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 harms of the drugs subject to this Order are such that the Government must legislate to control them, to protect the public, and those businesses selling them in the "legal high" market are expected to comply with the law or face the risk of prosecution. There is no evidence of legitimate or medicinal use of the non-controlled substances subject of this Order, or of any change in the last assessments of methoxetamine and synthetic cannabinoids which are already subject to a form of control. The potential impact on business, charities or voluntary bodies relates to administrative costs where there may be research use(s), although these are likely to be minimal as most organisations licensed to undertake activities involving controlled drugs under the Misuse of Drugs Regulations 2001 are able to undertake activities relating to other drugs of the same schedule for the same purpose(s).
- 10.2 The potential impact on the public sector relates to law enforcement and regulatory agencies although any associated costs are expected to be small and subsumed into arrangements for similar controlled drugs and managed within existing resources. Benefits are also expected to arise from added consistency in the agencies' implementation of control of similar drugs since methoxetamine is already subject to temporary control and a range of synthetic cannabinoids are already Class B drugs, while raised awareness and reduced availability of the harms of these drugs are expected to reduce the risk of medical costs associated with their misuse.
- 10.3 An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on www.legislation.gov.uk.

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 Order. However, the impact is minimised for those businesses already likely to be handling controlled drugs, acting under a 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 as part of its drug strategy. In tandem with this, the Government will review its public health messages to ensure that they are appropriately targeted and informative.

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.



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POLICY EQUALITY STATEMENT (PES)

Name of Policy/Guidance/Operational Activity

To control substances considered "dangerous or otherwise harmful" in accordance with the terms of the 1971 Act as a public health and protection measure. The intended objectives are to deter use and misuse of these substances amongst the general population and to curb their availability through suppliers withdrawing them from sale to comply with control measures as well as enabling law enforcement to take appropriate action to tackle illicit production, supply and import/exportation while the undertaking of activities relating to one or more of the substances to be controlled is enabled under the Misuse of Drugs Regulations 2001.

Summary of the evidence considered in demonstrating due regard to the Public Sector Equality Duty.

The Advisory Council on the Misuse of Drugs' (ACMD) advice to Government on 'novel psychoactive substances or NPS (http://www.homeoffice.gov.uk/publications/agencies-public-bodies/acmd1/acmdnps2011): the ACMD highlights in its considerations evidence that 'Users, particularly young people, who are in possession of what they think are "legal highs may well be in possession of controlled substances and could face the prospect of being subject to prosecution and a potential criminal record if found in possession of them by the Police.' Its advice also points at the increase in access to and availability of harmful substance through modern technologies which are appealing to young people.

In relation to harms, the ACMD considered that 'The use of NPS can also result in young people and young adults putting themselves in situations where they may be vulnerable or at risk of other harms (e.g. through collapse, intoxication, etc) including accidents and being victims of crime (e.g. sexual or physical assault)'. It also gave due consideration to the impact of legislation in relation to 'Police enforcement and the criminalisation of Young People' outweighed by the need for Government intervention to protect young people from harmful drug use in light of the assessment that they 'have made it clear that the belief that these substances are "legal and therefore safe—is the main driver for trying them.' Government considerations on these issues have resulted in the introduction of legislative provisions to temporarily control a potentially harmful NPS without introducing a simple possession offence in relation to a temporary class drug until a decision is made on whether to control it permanently under the Misuse of Drugs Act 1971. Methoxetamine has been a temporary class drug since 5 April pending full ACMD advice and will continue to be until it becomes a controlled Class B drug.

As part of its advice on NPS, and with reference to such considerations in the 2010 Drug Strategy (http://www.homeoffice.gov.uk/publications/alcohol-drugs/drugs/drug-strategy/), the ACMD has also considered the impact of drug education and considered targeted prevention, treatment and social approaches. On 17 May 2012 the Government published, as an Annex to the first annual review of the Drug Strategy and informed by the ACMD's advice on NPS, a cross-government NPS Action Plan setting out ongoing and future policy objectives ranging from legislative measures to public health and prevention approaches – particularly in relation to harmful NPS use amongst young people – in line with the approaches taken in the drug Strategy. On the drugs to be controlled specifically,

the ACMD included further considerations in its advice to Government on the drugs to be controlled:

- Further advice on synthetic cannabinoids (2012) extending the range of these substances subject to Class B control under the 1971 Act, at http://www.homeoffice.gov.uk/publications/agencies-public-bodies/acmd1/synthetic-cannabinoids-2012: referring to clusters of hospitalisations involving young people linked to their use of branded products associated with harmful new synthetic cannabinoids to be controlled;
- Methoxetamine and related compounds, recommending temporary class drug
 methoxetamine be subject to Class B control and associated penalties, along with
 related harmful compounds that are sold as 'legal high' alternatives:
 http://www.homeoffice.gov.uk/publications/agencies-public-bodies/acmd1/statement-methoxetamine): the ACMD highlights anecdotal
 evidence of the popularity of methoxetamine in although targeted LGBT
 venues, in particular higher prevalence amongst gay male clubbers and young
 adults; and
- O-desmethyltramadol to become a controlled Class B drug, at http://www.homeoffice.gov.uk/publications/agencies-public-bodies/acmd1/ACMD-O-desmethyltramadol: the ACMD has considered evidence that it was being sold as an NPS although a harmful drug with opiate properties, sometimes identified but undeclared as an active ingredient in smoking mixtures like synthetic cannabinoids and linked to casualties in Sweden.

While other protected characteristics were considered but deemed not disproportionately affected, the main policy objective remains public protection, indiscriminately.

Government research and publications - Data collection and statistical bulletins -

- Home Office: Crime Survey for England & Wales and Drug Misuse Declared (England & Wales), at http://www.homeoffice.gov.uk/publications/science-research-statistics/research-statistics/crime-research/drugs-misuse-dec-1112/, looking at prevalence of use amongst age groups and informing ongoing work to target specific higher-risk groups of users. Annual Drug Misuse Declared statistical bulletins have highlighted higher levels of stimulant drug use amongst young adults aged 16 to 24, including NPS now subject to 1971 control such as mephedrone and trends since their control. The data help to inform social interventions i.e. public health (FRANK) targeted at specific user groups.
- National Treatment Agency for Substance Misuse: NTDMS data identifying drug
 use, harm and treatment trends, including diversity and equality data, as well as
 stock-take and future challenges to treatment in building recovery, at
 http://www.nta.nhs.uk/uploads/commentaryfinal[0].pdf and
 http://www.nta.nhs.uk/uploads/six-yearstudy.pdf. This is further complemented by
 Schools Drink and Drugs surveys.

SCS sign off	Daniel Greaves	Name/Title	Head of Unit
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I have read the available evidence and I am satisfied that this demonstrates compliance, where relevant, with Section 149 of the Equality Act and that <u>due regard</u> has been made to the need to: eliminate unlawful discrimination; advance equality of opportunity; and foster good relations.

Directorate/Unit	Crime Directorate Drugs and Alcohol	Lead contact	Cyrille Marcel
Date	6 December 2012	Review Date	N/A