EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS ACT 1971 (AMENDMENT) ORDER 2011

2011 No. Draft

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 The Order in Council classifies the following drugs for control under Schedule 2 to the Misuse of Drugs Act 1971:

(i) tapentadol; and
(ii) amineptine

2.2 The Order in Council makes clarifying amendments to paragraph 1(a) of Part 2 of Schedule 2 to the Misuse of Drugs Act 1971 in respect of "4-methylmethcathinone" (also known as mephedrone).

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. Recommendations to make such Orders are not made unless a draft of such an order has been approved by resolution of both Houses of Parliament and section 2(5) also provides that the Secretary of State shall not lay a draft 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 above is predicated on an assessment of their respective harms and in accordance with recommendations made by the ACMD, pursuant to the statutory duty to consult under section 2(5) of the 1971 Act.

4.4 Tapentadol is a recently developed centrally-acting analgesic (painkiller), with effects similar to opioids like morphine, likely to be marketed in the UK in the near future. The ACMD has concluded that tapentadol presents a risk of misuse, diversion from legitimate sources, addiction and potential medicinal misuse. Amineptine is a powerful and fast acting antidepressant, misuse of which has been reported mainly in Asia and Europe. In 2003, the Commission on Narcotic Drugs, on the recommendation of the World Health Organisation, decided to include amineptine in Schedule II of the Convention on Psychotropic Substances of 1971. The UK is a signatory to the 1971 UN Convention. The ACMD recommends that tapentadol and amineptine are controlled under the Misuse of Drugs Act 1971 in Class A and Class C respectively and Schedule 2 to the Misuse of Drugs Regulations 2001 (as amended) (the 2001 Regulations).

4.5 When 4-methylmethcathinone (mephedrone) was controlled in April 2010, the policy intention was to make it clear to the public that the substance was controlled by specifying this on the face of the 2010 Order. This amendment further clarifies the legislation on mephedrone and means mephedrone will now be captured by the generic definition in paragraph 1(aa) of Part 2 of Schedule 2 to the 1971 Act which controls related cathinone derivatives. The control of mephedrone – as a Class B drug under the 1971 Act – is not affected by this clarification.

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, James Brokenshire, has made the following statement regarding Human Rights:

> In my view the provisions of the Misuse of Drugs Act 1971 (Amendment) Order 2011 are compatible with the Convention rights.

7. Policy background

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

7.1 The effects and risks associated with tapentadol are similar to those of other μ-opioid analgesics, including hydromorphone and morphine (both controlled as Class A drugs under the Misuse of Drugs Act 1971). Tapentadol presents a risk of addiction, and potential medicinal misuse. The risks associated with an overdose of tapentadol are constriction of the pupils, vomiting, loss of consciousness, seizures, difficulty in breathing and a risk of serious complications likely to lead to death. Tapentadol's control as a Class A drug under the 1971 Act, as recommended by the ACMD, not only acts as a precautionary measure but also brings the drug in line with similar μ-opioid analgesics, including hydromorphone and morphine. The ACMD's advice in respect of tapentadol can be found at

http://www.homeoffice.gov.uk/publications/drugs/acmd1/acmd-letter-tapentadol.

7.2 Amineptine was included in Schedule II of the Convention on Psychotropic Substances of 1971, by the Commission on Narcotic Drugs, on the recommendation of the World Health Organisation. The UK is a signatory to the 1971 Convention. The ACMD, the statutory body which advises Government on drug issues, has considered amineptine in the light of its potential harms and advises control as a Class C drug under the 1971 Act. The ACMD's advice in respect of amineptine can be found at; http://www.homeoffice.gov.uk/publications/drugs/acmd1/acmd-letter-amineptine.

7.3 It is intended to make a further related statutory instrument amending the Misuse of Drugs Regulations 2001 (as amended), to insert tapentadol and amineptine in Schedule 2 to the 2001 Regulations, with the effect that the requirements of Regulations 14, 15, 16, 18, 19, 20, 21, 23, 26, and 27 would apply to these drugs.

7.4 When mephedrone was controlled in April 2010, the policy intention was to make it clear to the public that the substance was controlled by specifying this on the face of the 2010 Order. The Order controlling mephedrone specifically carved out mephedrone from the generic definition used to control other related cathinone derivatives to highlight its control. This amendment further clarifies the legislation on mephedrone, subsuming mephedrone within the generic definition created by paragraph 1(aa) of Part 2 of Schedule 2 to the 1971 Act which controls related cathinone derivatives. The control of mephedrone – as a Class B drug under the 1971 Act – is not affected by this clarification.

- ***Consolidation***

7.5 None.

8. Consultation outcome

8.1 Consultation is not necessary or beneficial in the control of tapentadol and amineptine. Tapentadol is currently not licensed by the Medicines and Healthcare products Regulatory Agency and no evidence on UK prescribing either by the National Health Service or privately is available. Amineptine is also currently off-patent and not licensed for use in the UK.

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 potential 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 potential 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 An Impact Assessment and Equality Impact Assessment are attached to this memorandum.

11. Regulating small business

11.1 The legislation applies to small business.

11.2 The harm from misuse and diversion of these drugs is such that the pharmaceutical industry and certain sectors of healthcare will be expected to comply with the 1971 Act (as amended) and subordinate legislation made under it, however small the business. However, the potential impact is minimal as these businesses are already likely to be handling controlled drugs, acting under Home Office licence or the 2001 Regulations (as amended), 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.