EXPLANATORY MEMORANDUM TO

THE MISUSE OF DRUGS (AMENDMENT No. 2) (ENGLAND, WALES AND SCOTLAND) REGULATIONS 2013

2013 No. 625

THE MISUSE OF DRUGS (DESIGNATION) (AMENDMENT No. 2) (ENGLAND, WALES AND SCOTLAND) ORDER 2013

2013 No. 624

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 The Misuse of Drugs (Amendment No. 2) (England, Wales and Scotland) Regulations 2013 ("the 2013 Regulations") place Sativex, a cannabis-based medicine, in Part 1 of Schedule 4 to the Misuse of Drugs Regulations 2001 ("the 2001 Regulations").

2.2 The Misuse of Drugs (Designation) (Amendment No. 2) (England, Wales and Scotland) Order 2013 ("the 2013 Order") places Sativex in Part 2 to the Schedule to the Misuse of Drugs (Designation) Order 2001 ("the 2001 Order").

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

3.1 None.

4. Legislative Context

4.1 The 2001 Regulations regulate legitimate access to drugs considered "dangerous or otherwise harmful" and therefore controlled under Schedule 2 to the Misuse of Drugs Act 1971 ("the 1971 Act"). Drugs controlled under the 1971 Act are scheduled in one of five schedules under the 2001 Regulations, The schedule in which a drug is placed is based on an assessment of its medicinal or therapeutic usefulness, the need for legitimate access as well as its potential for harm when misused. Its schedule determines the regulatory requirements applicable to the possession, supply, and production etc of the drug. By provisions made under the 1971 Act the Secretary of State may by Order designate a drug as one to which section 7(4) of the 1971 Act applies. Once designated, drugs can only be made available for use in research or other special purpose under a Home Office licence.

4.2 As a cannabis-based medicine, Sativex is a Class B drug, currently listed in Schedule 1 to the 2001 Regulations, and designated under the 2001 Order. As a result Sativex is currently available only under a Home Office general licence issued under the 2001 Regulations in 2006.

4.3 The 2013 Regulations and the 2013 Order place Sativex in Part 1 of Schedule 4 to the 2001 Regulations, and in Part 2 of the Schedule to the 2001 Order respectively, with the effect that Sativex now becomes available for use in healthcare without the need for a Home Office licence.

4.4 Section 7 (7) and section 31(3) of the Act provide that the Secretary of State may not make any order under section 7(4) or regulations under the Act except after consultation with the Advisory Council on the Misuse of Drugs (ACMD). The ACMD has been consulted on the above changes.

5. Territorial Extent and Application

5.1 These instruments apply to Great Britain.

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 Sativex (a Class B controlled drug under the 1971 Act and a Schedule 1 drug under the 2001 Regulations) is a cannabis-based medicine which has been approved for use in healthcare. During the development of Sativex in 2006 the Home Office issued a general licence to enable doctors to prescribe at their own risk, pharmacists to dispense and patients to possess Sativex for medicinal use. Sativex continues to be available to healthcare professionals and patients under this licence. In 2010, the Medicines and Healthcare products Regulatory Agency (MHRA) issued a marketing authorisation for Sativex for the add-on treatment for symptom improvement in patients with spasticity due to multiple sclerosis following successful trials to confirm its efficacy.

7.2 The substance Sativex as a cannabis-based medicine continues to be controlled as a Class B drug. However, the Government has accepted the ACMD's recommendation that Sativex should now be placed in Part 1 of Schedule 4 to the 2001 Regulations to provide healthcare access to it under the regulatory framework governing medicines that are also controlled drugs, as opposed to its availability under the Home Office general licence only. This is based on Sativex's low misuse and diversion potential. The ACMD advice is available at http://www.homeoffice.gov.uk/publications/alcohol-drugs/drugs/acmd1/sativex-letter. Regulation 4 of the 2013 Regulations, by inserting a new provision into regulation 22 of the 2001 Regulations, also provides that a person, other than those persons listed in new regulation 22(6), shall make a record of a quantity of Sativex which is possessed or destroyed. Regulation 5 of the 2013 Regulations excepts a person who makes this type of record from the requirements relating to the destruction of drugs controlled under the 1971 Act contained in regulation 27(1) and (3) of the 2001 Regulations.

7.3 Sativex as a cannabis-based drug is also currently designated as a drug to which section 7(4) of the 1971 Act applies. This has the effect of requiring a Home Office licence permitting the possession, production and supply of the drug. As Sativex has been shown to have medicinal benefits and is approved as a medicine it is appropriate to place the drug in Part 2 of the Schedule to the 2001 Order with the effect that Sativex will no longer be a designated drug to which section 7(4) of the 1971 Act applies.

7.4 The scheduling and designation of cannabis (in its raw form) remains unaltered under the 2001 Regulations and the 2001 Order.

- ***Consolidation***

7.4 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 Department of Health and the manufacturers of Sativex extensively. However, a full public consultation is not considered necessary or beneficial in this case. Sativex is already available for use in healthcare under the general Home Office licence issued in 2006. The only effect resulting from the change is that availability will be regulated under the regulatory framework governing availability of medicines that are also controlled drugs – the 2001 Regulations – rather than under a Home Office licence. No further restrictions apply to Sativex as a result of this change and the manufacturers have confirmed that availability to healthcare will continue on a business as usual basis.

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. The Department of Health will also issue guidance to the healthcare sector through their usual communication channels.

10. Impact

10.1 There is no impact on the public sector, business, charities or voluntary bodies as a result of the proposed changes. Sativex continues to be available for use in healthcare under the Home Office general licence. The impact of this change is that the drug will now become available under the regulatory framework rather than under the Home Office licence.

10.2 An Impact Assessment is attached to this memorandum.

11. Regulating small business

11.1 The changes are not expected to impact on small businesses.

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

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 instruments.