EXPLANATORY MEMORANDUM TO

THE PRESCRIPTION ONLY MEDICINES (HUMAN USE) AMENDMENT ORDER

2008 No. 464

1. This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency (MHRA) part of the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Description

2.1. This Order amends the Prescription Only Medicines (Human Use) Order 1997. It removes the restriction on the prescribing of controlled drugs by Nurse Independent Prescribers and introduces the prescribing of controlled drugs by Pharmacist Independent Prescribers.

2.2 The Order also makes the sale and supply to a person at any one time of products containing more than 720mg of pseudoephedrine salts or 180mg ephedrine base or ephedrine salts subject to prescription.

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

3.1 None.

4. Legislative Background

4.1 This Order amends the Prescription Only Medicines (Human Use) Order 1997 which specifies the description and classes of medicines, which, subject to exemptions in the Order may only be sold or supplied in accordance with the prescription of an appropriate practitioner and may be administered only by or in accordance with the directions of such a practitioner (see section 58(2) of the Medicines Act 1968);

4.2 The amending Order makes Nurse and Pharmacist Independent Prescribers appropriate practitioners for controlled drugs. Until now Nurse Independent Prescribers were only able to prescribe a limited number of controlled drugs and Pharmacist Independent Prescribers were unable to prescribe any.

4.3 This Order also amends the Prescription Only Medicines (Human Use) Order 1997 to impose the restrictions on sale or supply referred to in 2.2. above on products containing pseudoephedrine salts or ephedrine base or salts.

5. Extent

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy Background

Prescribing of controlled drugs by Nurse Independent Prescribers and Pharmacist Independent Prescribers

7.1 Independent prescribing by appropriately qualified nurses was expanded, and pharmacist independent prescribing introduced, in May 2006. This followed public consultations in early 2005. The majority of the responses supported the proposals, although medical organisations were more cautious in their approach. The recommendation of the then Committee on Safety of Medicines (CSM) was that nurse and pharmacist independent prescribers should be able to prescribe or administer (or give directions for administration) any licensed drug within their clinical and professional competence. While CSM's recommendations also in principle included controlled drugs, this could not be implemented at that time as, to achieve the policy intention, a similar recommendation from the Advisory Council on the Misuse of Drugs (ACMD) that there should be corresponding amendments to the Misuse of Drugs Regulations was required. Nurse Independent Prescribers were therefore restricted to prescribing from a list of 13 controlled drugs. Pharmacist Independent Prescribers were unable to prescribe any controlled drugs.

7.2 The Commission on Human Medicines (CHM) subsequently endorsed the recommendation of the former CSM concerning the prescribing of controlled drugs by Nurse and Pharmacist Independent Prescribers and supported amendments to the Misuse of Drugs Regulations 2001 (which concern controlled drugs and are the responsibility of the Home Office).

7.3 The Home Office consulted on the proposals in 2007 and these were generally well supported. For example, the proposals were favoured by 171 of the 200 responses. Both the CHM and the ACMD concluded that the proposals to enable Nurse and Pharmacist Independent Prescribers to prescribe an unrestricted range of controlled drugs, subject to clinical and professional competence, would not lead to an increased risk of diversion or misuse.

7.4 Consequently, the Home Office is amending the Misuse of Drugs Regulations 2001 to mirror the changes being made by this Order to the Prescription Only Medicines (Human Use) Order 1997 so that the previously mentioned policy intention can be achieved.

Making sale and supply of products containing more than 720mg of pseudoephedrine salts and products containing 180mg ephedrine base or ephedrine salts subject to prescription.

7.5 There has been increasing concern that pseudoephedrine and ephedrine can be extracted from over-the-counter (OTC) remedies relatively easily and used in the illegal manufacture of methylamphetamine, which was reclassified as a class A drug on 18 January 2007. The controls to be implemented to prevent misuse of these medicines in the manufacture of methylamphetamine have been subject to public consultation and recommendations from the CHM. The amendments have been generally well received and are recognised to be a proportionate response to the current threat in the UK.

7.6 A public consultation took place in October 2007 on proposals to amend the Prescription Only Medicines (Human Use) Order 1997 to make the sale or supply of products containing more than 720mg pseudoephedrine salts or 180mg ephedrine base or salts subject to prescription. There was unanimous support for the proposals from the Royal Colleges and organisations with an interest in drug misuse. Concerns raised by some companies and the pharmacy profession were subject to further discussions and the proposals were considered by the CHM who took into account new intelligence of methylamphetamine manufacture in the UK. CHM advised that the proposals should be implemented from 1 April 2008 on the grounds that any slippage could pose a risk to public health.

8. Impact

8.1 An Impact Assessment has not been prepared for this instrument as it has no impact on business, charities or voluntary bodies.

8.2 The impact on the public sector is principally to benefit patient care, by providing improved access to the medicines required by patients.

9. Contact

9.1 Anne Thyer at the MHRA (tel: 0207 084 2642, or e-mail: anne.thyer@mhra.gsi.gov.uk) can answer any queries regarding the instrument.