EXPLANATORY MEMORANDUM TO THE

MEDICINES FOR HUMAN USE (PRESCRIBING) (MISCELLANEOUS AMENDMENTS) ORDER 2005

2005 No. 1507

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 Medicines for Human Use (Prescribing) Order 2005, the Prescription Only Medicines (Human Use) Order 1997 and the Medicines (Pharmacy and General Sale – Exemption) Order 1980 to extend supplementary prescribing to registered optometrists. The Order also amends these instruments to allow additional supply optometrists to sell, supply or write an order for a range of medicines. Furthermore, it updates the list of parenteral medicines which can be administered by anyone in an emergency for the purpose of saving life, allows the supply of Water for Injection to drug users in the course of lawful drug treatment services and makes several technical amendments to the list of medicines which can be prescribed by Extended Formulary Nurse Prescribers.

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

3.1 None.

4. **Legislative Background**

4.1 This Order amends several Orders relating to prescribing, sale and supply of medicines. These are:

- the Medicines for Human Use (Prescribing) Order 2005 which made a number of amendments to the Prescription only Medicines (Human Use) Order 1997

- the Prescription only Medicines (Human Use) Order 1997 (the POM Order) which specifies the description and classes of medicines ("prescription only medicines" (POMs)) which, subject to exceptions specified in the Order may only be sold or supplied in accordance with the prescription of an "appropriate practitioner", and may be administered only in accordance with the directions of such a practitioner (see section 58(2) of the Medicines Act 1968). Among other matters it provides for the prescribing of prescription only medicines by supplementary prescribers and Extended Formulary Nurse Prescribers.

- the Medicines (Pharmacy and General Sale – Exemption) Order 1980 which provides exemptions from the Medicines Act restrictions on sale and supply of medicines. In particular, that

POM and medicines classed as pharmacy ("P") medicines may only be sold or supplied on registered pharmacy premises by or under the supervision of a pharmacist (section 52 of the Act).

Supplementary Prescribing

4.2 In brief, supplementary prescribing is an arrangement whereby after a diagnosis by a doctor or dentist (the independent prescriber), the supplementary prescriber can prescribe medicines as part of a Clinical Management Plan agreed with the independent prescriber for an individual patient. Currently, registered nurses, midwives, pharmacists, podiatrists, physiotherapists and diagnostic and therapeutic radiographers can act as supplementary prescribers. The amending Order will extend the definition of supplementary prescriber to include registered optometrists.

Registered Optometrists

4.3 Under existing exemptions contained in the Orders specified above, optometrists can sell, supply or write an order for a specified list of POMs provided it is in the course of their professional practice and in an emergency. The amending order will remove a substance from this list which is no longer commercially available. It will also allow those optometrists who have completed additional training and are accredited by the General Optical Council ("additional supply optometrists") to sell, supply or write an order for an extended range of medicines.

Administration of parenteral medicines to save life in an emergency

4.4 Under the Medicines Act 1968, the administration of parenteral medicines is restricted. Unless self-administered they may only be administered by an appropriate practitioner or a person acting in accordance with the directions of an appropriate practitioner. Article 7 of the POM Order provides an exemption from this restriction to enable the parenteral administration of a list of specified medicines (for example, Adrenaline/Epinephrine) by anyone for the purpose of saving life in an emergency. The amending Order will add Naloxone, which is used as an antidote in opioid overdose, to the list. In line with work to move from the national naming system for medicinal substances, the amending Order will replace the references to certain substances with their International Non-Proprietary Names (rINNs). Finally, the amending Order will update the list by removing substances which are no longer commercially available.

Supply of Water for Injection

4.5 Under the Medicines Act, medicines which are for parenteral administration are classed as POM. Therefore, they can only be sold or supplied against an appropriate practitioner's prescription. An "appropriate practitioner" is a doctor, dentist or, in respect of certain medicines, an Extended Formulary Nurse Prescriber or supplementary prescriber. The amending Order will allow people engaged in the provision of lawful drug treatment services to supply Water for Injection (WFI) to drug misusers.

Extended Formulary Nurse Prescribers

4.6 Extended Formulary Nurse Prescribers (EFNPs), who have successfully completed a programme of preparation and training, are able to prescribe from a specific POMs, alone or in combination. The list is set out in Schedule 3A of the POM Order. The amending Order will make several technical amendments to the list. For example, adding a substance which was inadvertently omitted during the last exercise to extend the list and correcting a typographical error.

5. **Extent**

5.1 This instrument applies to all of the United Kingdom.

6. **European Convention on Human Rights**

6.1 Not applicable.

7. **Policy Background**

7.1 The changes relating to prescribing and sale and supply of medicines form part of the Government's policy of modernising the NHS. They enable appropriately trained healthcare professionals to prescribe, sell or supply medicines in the interests of improving patient care by appropriate use of professional skills. Adding Naloxone to the list of medicines which can be administered by anyone in an emergency and allowing supply of WFI through drug treatment services without the need for a prescription are both measures aimed at reducing harm to drug users.

7.2 All the proposed amendments were subject to public consultation and advice to Ministers by the Committee on Safety of Medicines. Detailed analyses of the outcome of the various public consultation exercises have been published on the MHRA website: www.mhra.gov.uk However, in each case there was general support for the proposals. For example, 57 replies were received in response to the proposals for Naloxone. The majority (47) were supportive and a further 9 made no comment or expressed no preference. The remaining response opposed the proposal.

8. **Impact**

8.1 A Regulatory Impact Assessment is attached for the proposals relating to supplementary prescribing. Regulatory Impact Assessments have not been prepared for the remaining proposals because they do not impose a cost compliance on business, charities or voluntary bodies.

8.2 The impact on the public sector is principally to benefit patient care.

9. **Contact**

9.1 Anne Ryan at the MHRA tel: 0207 084 2392 or e-mail: anne.ryan@mhra.gsi.gov.uk can answer any queries regarding the instrument.