EXPLANATORY MEMORANDUM TO THE MEDICINES FOR HUMAN USE (PRESCRIBING) (MISCELLANEOUS AMENDMENTS) ORDER 2008

2008 No. 1161

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 and the Medicines (Pharmacy and General Sale - Exemption) Order 1980 to introduce independent prescribing by optometrists and to enable hospitals and health centres to sell, offer for sale or supply medicines in accordance with the written directions of an optometrist independent prescriber.

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

3.1 None.

4. Legislative Background

4.1 This Order makes further amendments to 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 exemptions specified 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 (section 58(2) of the Medicines Act 1968). The amendments to the POM Order make optometrist independent prescribers (optometrists who have successfully completed a programme of preparation and training) appropriate practitioners in relation to any licensed medicine except for controlled drugs or medicines for parenteral (injected) administration.

4.2 The Order also makes further amendments to the Medicines (Pharmacy and General Sale - Exemption) Order 1980 which specifies exemptions from the requirements for the sale or supply of POM and Pharmacy (P) medicines (normally only from pharmacies by or under the supervision of a pharmacist) and General Sale List (GSL) medicines (from lockable premises and in original manufacturer packs). The amendments provide an exemption from these requirements where the sale, offer for sale or supply of medicines is by a hospital or a health centre in the course of its business and is in accordance with the written directions of an optometrist independent prescriber.

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

7.1 The changes relating to prescribing and sale and supply of medicines form part of the Government's policy of improving patient services, including timely access to medicines, and making the bet use of professional skills to deliver those improved services. 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.

7.2 The proposed amendments to introduce independent prescribing by optometrists were subject to public consultation and advice to Ministers by the Commission on Human Medicines (CHM). There was general support, although doctors' organisations were more cautious, for the proposals which were first considered by a working group of the CHM and external advisers before consideration by the Commission. CHM's recommendation was that suitably qualified optometrists should be able to prescribe any licensed medicines (except for controlled drugs or medicines for parenteral (injected) administration) for ocular conditions affecting the eye, and the tissues surrounding the eye, within their recognised area of expertise and competence. In making the recommendation, the Commission made clear that the extent of independent prescribing for optometrists would be controlled in detail through guidelines. Therefore, while these amendments to medicines legislation enable an optometrist independent prescriber to prescribe any licensed medicine, except for controlled drugs or medicines for parenteral administration, the College of Optometrists will provide clinical guidelines, and the General Optical Council (GOC) will amend its rules, to ensure that optometrist independent prescribers only prescribe licensed medicines for ocular conditions affecting the eye, and the tissues surrounding the eye, within their recognised areas of expertise and competence.

7.3 Optometrists who wish to undertake independent prescribing responsibilities must successfully undertake training provided by a Higher Education Institution and accredited by the GOC. In addition practitioners will need to register their independent prescribing specialty with the GOC before they can exercise prescribing responsibilities. Copies of the replies to the public consultation exercise have been published on the MHRA website: www.mhra.gov.uk

8. Impact

8.1 An Impact Assessment has not been prepared for these proposals because they do not impose significant cost compliance 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.