

**EXPLANATORY MEMORANDUM TO  
THE MEDICINES (SALE OR SUPPLY) (MISCELLANEOUS  
AMENDMENTS) REGULATIONS 2008**

**2008 No. 1162**

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 These Regulations amend the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 (“the Sale or Supply Regulations”) to provide that a health prescription includes a prescription issued by an optometrist independent prescriber and that particulars in pharmacy records must include particulars relating to such a prescriber. They also make amendments to the Medicines (Child Safety) Regulations 2003 (“the Child Safety Regulations”) so that certain requirements under those Regulations do not apply to the sale or supply of a product by a pharmacy in accordance with a prescription given by an optometrist independent prescriber.

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

- 3.1 None.

**4. Legislative Background**

- 4.1 These Regulations make further amendments to the Sale or Supply Regulations which impose various restrictions on the sale and supply of medicines for human use. In particular, pharmacists are required to record the sale or supply of a prescription only medicine except in certain circumstances including where the sale or supply is pursuant to a “health prescription”. The Sale or Supply Regulations are amended so that a health prescription includes a prescription issued by an optometrist independent prescriber.
- 4.2 These Regulations also amend Schedule 2 to the Sale or Supply Regulations so that particulars of optometrist independent prescribers must be included in pharmacy records kept pursuant to regulation 6(1) of the Sale or Supply Regulations.
- 4.3 These Regulations also amend the Child Safety Regulations which in particular impose requirements relating to the packaging of certain medicinal products, so that the requirements do not apply to the retail sale, or supply corresponding to retail sale, of a product by a pharmacy, where that sale or supply is in accordance with a prescription given by 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 best use of professional skills to deliver those improved services. The changes 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](http://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](mailto:anne.thyer@mhra.gsi.gov.uk)) can answer any queries regarding the instrument.