EXPLANATORY MEMORANDUM TO
THE MEDICINES FOR HUMAN USE (MISCELLANEOUS AMENDMENTS) (NO.2) REGULATIONS 2009

2009 No. 3063

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. Purpose of the instrument

2.1 These Regulations amend the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 and the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980. It adds nurse and pharmacist independent prescribers to the list of persons who can order unlicensed medicines for their individual patients. The amending Regulations also allow registered dispensing opticians to obtain wholesale supplies of specified prescription only medicines (POMs) for use by optometrists and doctors attending their practices. It further allows registered dispensing opticians who are additionally registered as contact lens specialists on the register maintained by the General Optical Council to obtain certain POMs for use in the course of their professional practice.

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

3.1 None.

4. Legislative Context

4.1 These Regulations amend two sets of regulations relating to the sale or supply of medicines –

- The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 implement European Community provisions relating to marketing authorisations for medicinal products. In particular, the principal Regulations require all medicinal products which are placed on the market to hold a marketing authorisation granted by the MHRA. There are exemptions from this requirement for medicinal products supplied in response to a bona fide unsolicited order formulated in accordance with the specification of a doctor, dentist or supplementary prescriber for use of their individual patients.

- The Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 (the principal Regulations) impose various restrictions on the sale and supply of medicinal products. In

particular, the Regulations set out restrictions on persons who can be sold POM or P medicines on a wholesale basis.

Nurse and Pharmacist independent Prescribers

4.3 The Regulations will permit the supply of an unlicensed medicine in response to an order by a nurse or pharmacist independent prescriber on the same basis as the existing arrangements for doctors, dentists and supplementary prescribers.

Dispensing Opticians and contact lens specialists

4.4 There are no provisions currently for dispensing opticians to obtain stocks of prescription only medicines. The amending Regulations allow dispensing opticians to obtain wholesale supplies of certain medicines for use by optometrists and doctors who visit the dispensing optician's practice. The Regulations will also allow those dispensing opticians to obtain medicines used in the course of their professional practice in their own right.

Related legislation

4.5 The amending instrument is being laid with a related SI (the Medicines (Exemptions and Miscellaneous Amendments) Order 2009).

5. Territorial Extent and Application

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 amendments which allow nurse and pharmacist independent prescribers to order unlicensed medicines are a result of related work on the mixing of medicines in clinical practice. They recognise that it is a logical step for these independent prescribers to be placed on the same footing as doctors, dentists and supplementary prescribers.

7.2 The amendments relating to dispensing opticians are intended to address the practical problems which arise because only optometrists may order stocks although they may not attend the dispensing optician's premises regularly. Also, these amendments will provide that those dispensing opticians who are registered contact lens specialists and who cannot obtain the medicines used in the course of their practice in their own right are able to do so.

The amending instrument is being laid with a related SI (the Medicines (Exemptions and Miscellaneous Amendments) Order 2009).

8. Consultation outcome

8.1 A three month consultation on the dispensing opticians' proposals ran from 29 August 2008. The MHRA received 86 responses. The vast majority of these (78) expressed support for the proposals.

8.2 The proposals to allow nurse and pharmacist independent prescribers to order unlicensed medicines arose from a consultation exercise aimed at regularising the practice of mixing medicines for administration in palliative care which ran for three months from 5 December 2008. Under medicines legislation, this practice results in a new unlicensed product being produced and, apart from limited circumstances, the person undertaking the mixing would require a manufacturer's licence.

8.3 There were 187 replies to the consultation and 162 of these supported the proposals. However, it was clear from the consultation and work undertaken by a Working Group of the Commission on Human Medicines, that mixing of medicines was undertaken in many other areas of clinical practice and that it would be sensible to allow nurse and pharmacist independent prescribers to order unlicensed medicines for their patients.

8.4 Both consultations were circulated to a range of interested organisations and the outcomes considered by the Commission on Human Medicines.

9. Guidance

9.1 The General Optical Council and professional representative organisations will put guidance in place about the maintenance of skills and the use of the relevant medicines. The Department of Health and the National Prescribing Centre are preparing guidance in relation to the use of unlicensed medicines by nurse and pharmacist independent prescribers.

10. Impact

10.1 Impact assessments have not been prepared for these proposals as they do not impose a cost compliance on business, charities or the voluntary sector.

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

11. Regulating Small Business

11.1 The amending regulations will enable the many dispensing opticians who operate as sole practitioners to directly obtain medicines used in their practices.

12. Monitoring and review

12.1 The changes in this instrument are aimed at benefiting patient care. In line with the Better Regulation Agenda, the instrument will be reviewed in three years time to assess whether it is still fit for purpose.

13. Contact

13.1 Anne Ryan at the MHRA tel: 0207 084 2392 can answer any queries regarding this instrument.