

**EXPLANATORY MEMORANDUM TO THE MEDICINES (SALE OR
SUPPLY) (MISCELLANEOUS PROVISIONS) AMENDMENT
REGULATIONS 2005**

2005 No. 764

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 by expanding the definition of a supplementary prescriber for the purpose of an existing provision relating to records which must be maintained by pharmacists. It updates the list of prescription only medicines which can be sold to registered ophthalmic opticians on a wholesale basis. The Regulations also increase the maximum pack size of Bisacodyl tablets on general sale.

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

3.1 None.

4. Legislative Background

4.1 The Medicines Act 1968 sets out the legal controls on the retail sale or supply of medicines. Under section 52 of the Act, prescription only (POM) and pharmacy (P) medicines may only be sold or supplied on registered pharmacy premises by or under the supervision of a pharmacist. Section 53 of the Act allows the sale of general sale list (GSL) medicines from ordinary retail outlets provided the premises are lockable and the products are pre-packed. The Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 (the principal Regulations) impose various restrictions on the sale and supply of medicinal products.

4.2 In particular, the principal Regulations require pharmacists to record the sale or supply of POMs. The requirement does not apply to medicines supplied against NHS prescriptions and other specified transactions. The effect is on medicines supplied against private prescriptions written by doctors, dentists, district nurse/health visitor prescribers and extended formulary nurse or supplementary prescribers. Currently, only registered nurses, midwives and pharmacists can act as supplementary prescribers but amendments to related legislation (the Prescription Only Medicines (Human Use) Order 1997) will extend the definition to include podiatrists, physiotherapists and diagnostic and therapeutic radiographers. These amending Regulations will reflect the extended definition.

4.3 The principle Regulations set out restrictions on the classes of person who can be sold POM or P medicines on a wholesale basis. There are exemptions from these restrictions for the sale of specified POMs to registered ophthalmic opticians. The amending Regulations will update the list by removing, for example, substances which are now of limited clinical value.

4.4 Finally, the principle Regulations set out conditions relating to the quantity of certain GSL medicines that can be sold or supplied in any one container or pack. Under the Regulations, the maximum pack size of Bisacodyl tablets available from non-pharmacy retail outlets is 20 tablets. The amending Regulations will increase this to 50 tablets.

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 Extending the definition of supplementary prescriber ensures consistency with other medicines legislation. The amendments relating to registered ophthalmic opticians are intended to enhance patient care by updating the range of medicines available to the profession. Bisacodyl tablets are indicated for the relief of constipation. They have been available for many years as a GSL product in pack sizes of up to 20 tablets. Other similar laxative products have been available as GSL in larger quantities over a comparable period and the safe use of these products by the general public has been established during that time.

7.2 The principals of extending supplementary prescribing and updating the range of medicines available to opticians were subject to public consultation and advice to Ministers by the Committee on Safety of Medicines. Detailed analyses of the outcome of the public consultations have been published on the MHRA website: www.mhra.gov.uk For supplementary prescribing, the vast majority of responses (154 out of 157) were supportive. For the opticians' proposals, 50 replies were received. Most (35) were supportive and a further 12 made no comment or expressed no preference. The remaining 2 replies opposed the proposals.

7.3 The response to the consultation on increasing the pack size of Bisacodyl tablets available for general sale was mixed. However, the proposal was considered by the Committee on Safety of Medicines who advised

8. Impact

8.1 A Regulatory 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 to benefit patients

9. **Contact**

9.1 Anne Ryan at the MHRA, tel: 020 7084 2392] or e-mail:
anne.ryan@mhra.gsi.gov.uk can answer any queries regarding the instrument.