

**EXPLANATORY MEMORANDUM TO THE MEDICINES (PHARMACY
AND GENERAL SALE – EXEMPTION) AMENDMENT ORDER 2005**

2005 No. 766

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 (Pharmacy and General Sale – Exemption) Order 1980 by updating the current arrangements for sale or supply of medicines by registered ophthalmic opticians. It will expand the definition of a supplementary prescriber for the purpose of an existing exemption from the usual Medicines Act restrictions on sale or supply of medicines for products sold or supplied in the course of a business of a hospital. The Order will also allow specified prison staff to supply single doses of general sale list (GSL) medicines to prisoners during periods when qualified healthcare staff are not in attendance at the establishment concerned.

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. General Sale List (GSL) medicines are products which can be sold or supplied with reasonable safety without the need for a prescription or pharmacist supervision. Under section 53 of the Medicines Act 1968, they may not be sold or supplied if the packaging (when it was made up for sale) has been opened. In the prison setting, the effect of section 53 is that the supply of single doses of medicines eg two paracetamol from a pack by custodial staff risks non-compliance with the law.

4.2 Exemptions from the restrictions described at paragraph 4.1 are contained in the Medicines (Pharmacy and General Sale – Exemption) Order 1980. (The “principal” Order)

Registered Ophthalmic Opticians

4.3 The amending Order will update the existing arrangements for registered ophthalmic optician to sell or supply a range of POMs and all P and GSL medicines provided it is in the course of their professional practice and in an

emergency. In particular, it will remove the “emergency” requirement for the sale or supply of P and GSL medicines. This will allow opticians to sell or supply these products direct to the patient for non-emergency ophthalmic conditions. The list of POMs which are available to opticians will also be updated to remove, for example, medicines which are no longer commercially available.

Supplementary prescribers

4.4 The principle Order provides an exemption from sections 52 and 53 of the Medicines Act for medicines which are sold, offered for sale or supplied in the course of the business of a hospital or health centre for the purpose of being administered in accordance with the written directions of a supplementary prescriber. 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, only registered nurses, midwives and pharmacists can act as supplementary prescribers but changes to related legislation (the Prescription Only Medicines (Human Use) Order 1997) will extend the definition to include podiatrists, physiotherapists and diagnostic and therapeutic radiographers. The amending Order will reflect this extension.

Supply of GSL medicines by custodial staff

4.5 The amending Order will create a new exemption from the requirement that GSL medicines must be sold or supplied pre-packed for prison officer grades, operational managers in the prison service and their equivalents in contractually managed prisons.

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 amendments relating to registered ophthalmic opticians are intended to enhance patient care by updating the range of medicines available to the profession and enabling them to sell or supply medicines directly in non-emergency situations. They also reflect developments in practice and training over recent years.

7.2 Extending the definition of supplementary prescriber ensures consistency with other medicines legislation. For prisons, the majority of establishments do not have 24 hour medical or nursing cover and most do not have on site pharmacies. At present, some prisons operate a system whereby non-healthcare qualified staff, the majority of whom are prison/custody officers, supply paracetamol and antacids to prisoners during periods where healthcare

staff are not in attendance at the establishment. Some do this under the auspices of Crown Immunity and where they have managed to come to local agreement for this with their unions. However, dependence on Crown Immunity is not a preferred option. Other prisons do not provide prisoners with access to any medicines out of hours. The lack of adequate arrangements for access to simple medicines leaves prisoners suffering unnecessarily and has the potential to exacerbate the tensions already in existence in a custodial environment. The legislative changes are intended to improve the standard of healthcare in prisons by improving access to medicines and enabling prisoners to take more responsibility for their own health and healthcare.

7.3 The proposals 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 consultation addressed the broad principle of extension to the additional groups of health professional. The vast majority of responses (154 out of 157) supported the proposal. The MHRA received 65 replies in response to the proposals for prisons. The majority (39) supported the proposals and a further 17 made no comment or expressed no preference. The remaining 9 replies either opposed the proposals or had serious reservations about them. 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.

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
- Enable prisoners to access GSL medicines out of hours while making the legal position in relation to the supply of those medicines secure.

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.