

**EXPLANATORY MEMORANDUM TO THE
MEDICINES FOR HUMAN USE (PRESCRIBING ORDER) 2005**

2005 No. 765

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 to extend supplementary prescribing to podiatrists, physiotherapists and radiographers and allow prescribing of unlicensed medicinal products under supplementary prescribing arrangements. The Order also amends the range of medicines which can be sold, supplied or administered by registered ophthalmic opticians. Furthermore, it extends the list of medicines which can be prescribed by Extended Formulary Nurse Prescribers and introduces the use of electronic signatures on prescriptions.
3. **Matters of special interest to the Joint Committee on Statutory Instruments**
 - 3.1 None.
4. **Legislative Background**
 - 4.1 This Order amends the Prescription Only Medicines (Human Use) Order 1997 ("the principal Order"), which specifies the descriptions and classes of medicines ("prescription only medicines" (POMs)) which, subject to exemptions specified in the Order, may be sold or supplied only in accordance with the prescription of an "appropriate practitioner", and may be administered only in accordance with the directions of such a practitioner (see section 58(2) of the Medicines Act 1968).
 - 4.2 Under the Medicines Act, the sale, supply, manufacture and assembly of unlicensed medicines is restricted. However, section 10 of the Act, provides exemptions from these restrictions for a pharmacist (or person acting under the supervision of a pharmacist) in a registered pharmacy, hospital or health centre to prepare or dispense an unlicensed product in accordance with a doctor or dentist's prescription. Section 15(1) of the Medicines Act contains a provision for extending or modifying the exemptions by way of an Order.
 - Supplementary Prescribing**
 - 4.3 The principle Order provides for the prescribing of POM medicines by supplementary prescribers. 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. The amending Order will extend the definition of supplementary prescriber to include podiatrists, physiotherapists and diagnostic and therapeutic radiographers. It will also allow supplementary prescribers to prescribe unlicensed medicines. Finally, the amending Order will make an Order under section 15(1) of the Medicines Act to allow pharmacists or persons acting under their supervision to prepare or dispense an unlicensed product in accordance with the prescription of a supplementary prescriber.

Registered Ophthalmic Opticians

4.4 Under an existing exemption contained in the principal Order, registered ophthalmic opticians can sell, supply or write an order for a specified list of POMs provided it is in the course of their professional practice and in an emergency. The amending Order will update the list for example, by removing medicines which are no longer currently available.

Extended Formulary Nurse Prescribers

4.5 Extended Formulary Nurse Prescribers (EFNPs), who have successfully completed a programme of preparation and training, are able to prescribe from a specific list of POMs, alone or in combination. The list of POMs is set out in Schedule 3A of the principal Order and is known as the Nurse Prescribers' Extended Formulary (NPEF). The amending Order will extend the list and allow EFNPs to prescribe for a wider range of conditions.

Electronic Signatures

4.6 Under section 58(4)(b) of the Medicines Act 1968 a medicine shall not be taken to be sold or supplied in accordance with a prescription given by an appropriate practitioner unless such conditions as are prescribed by the principle Order are fulfilled. Those conditions include a requirement for the prescription to be signed in ink by the appropriate practitioner giving it and to be written ink. This means that prescriptions for POMs are given in paper form. The amending Order will allow the use of advanced electronic signatures thereby enabling electronic transmission of prescriptions. However, prescribers will still be able to sign paper prescriptions by hand in ink as now.

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 changes relating to prescribing and sale and supply of medicines form part of the Government's policy of modernising the NHS. 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. Transmitting prescriptions electronically is expected to introduce significant benefits for patients, prescribers and dispensers. For example, there will be fewer illegible or incomplete prescriptions.

7.2 All the proposed amendments were subject to public consultation and advice to Ministers by the Committee on Safety of Medicines. Detailed analyses of the outcome of the various public consultation exercises have been published on the MHRA website: www.mhra.gov.uk However, in each case, there was general support for the proposals. For example, 50 replies were received in response to the proposals for opticians. The majority (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 the proposals relating to opticians because they do not impose a cost compliance on business, charities or voluntary bodies. Regulatory Impact Assessments for the remaining proposals are attached.

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

9 **Contact**

Anne Ryan at the MHRA tel: 0207 084 2392 or e-mail: anne.ryan@mhra.gsi.gov.uk can answer any queries regarding the instrument.