

EXPLANATORY MEMORANDUM TO
THE MEDICINES FOR HUMAN USE (PRESCRIBING)
(MISCELLANEOUS AMENDMENTS) (NO.2) ORDER 2005

2005 No. 3324

1. This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency (MHRA), an executive agency 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 (the “POM Order”) by extending the list of medicines which can be prescribed by Extended Formulary Nurse Prescribers. It also amends the POM Order and the Medicines (Pharmacy and General Sale – Exemption) Order 1980 to add a further medicine to the list of medicines which additional supply optometrists can sell, supply or write an order for.

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

3.1 None.

4. **Legislative Background**

4.1 This Order amends two Orders relating to the prescribing, sale and supply of medicines. These are:

- the Prescription Only Medicines (Human Use) Order 1997 (the POM Order) which specifies the description and classes of medicines (“prescription only medicines” (POMs)) which, subject to exceptions specified in the Order may only be sold or supplied in accordance with the prescription of an “appropriate practitioner”. Among other matters it provides for the prescribing of medicines by Extended Formulary Nurse Prescribers (EFNPs) and the sale or supply of medicines by additional trained optometrists.
- the Medicines (Pharmacy and General Sale – Exemption) Order 1980 which provides exemptions from the Medicines Act 1968 restrictions on sale and supply of medicines. In particular, that POM and medicines classed as pharmacy (P) medicines may only be sold or supplied on registered pharmacy premises by or under the supervision of a pharmacist (section 52 of the Act).

Additional Supply Optometrists

4.2 Under existing exemptions in the Orders specified above, optometrists who have completed additional training and are accredited by the General Optical Council (“additional supply optometrists”) may 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 add a substance to this list.

Extended Formulary Nurse Prescribers

4.3 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 is set out in Schedule 3A of the POM Order and is known as the Nurse Prescribers' Extended Formulary (NPEF). The amending Order will extend the list of controlled drugs that EFNPs can prescribe for a wider range of conditions.

5. Extent

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

6.1 No statement is required..

7. Policy background

7.1 The amendment to the additional supply optometrists' list is a technical one. The substance was inadvertently omitted during an earlier exercise which introduced arrangements for sale and supply of medicines by additional supply optometrists. The changes relating to prescribing by Extended Formulary Nurse Prescribers form part of the Government's policy of modernising the NHS. They enable appropriately trained nurses to prescribe medicines in the interests of improving patient care by appropriate use of professional skills.

7.3 The proposals were subject to public consultation and advice to Ministers from the Committee on Safety of Medicines. These additions to the NPEF were part of an earlier, wider consultation on extending the formulary. However, they are controlled drugs which are also regulated by the Misuse of Drugs Act 1971. As such, the proposals also needed to be considered by the Home Office's Advisory Council on the Misuse of Drugs. There was general support for all the proposals and the relevant amendment to the Misuse of Drugs Regulations came into force on 14 November 2005. .

8. **Impact**

8.1 A Regulatory Impact Assessment has not been prepared for this instrument because it does not impose a cost compliance on business, charities or voluntary bodies.

8.2 The impact on the public sector is to benefit patients by underpinning improvements in patient care and making the best use of professional skills.

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.