

**EXPLANATORY MEMORANDUM TO**  
**THE MEDICINES FOR HUMAN USE (ADMINISTRATION AND SALE OR**  
**SUPPLY) (MISCELLANEOUS AMENDMENTS) ORDER 2006**

**2006 No.2807**

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 and the Medicines (Pharmacy and General Sale – Exemption) Order 1980. It makes provision for persons who are operators in nuclear medicine procedures to authorise the administration of radioactive medicinal products (RMPs) or other prescription only medicines. The Order also extends the range of medicines which can be sold, supplied or administered by registered chiropodists. (In this context, the term “chiropodist” also covers podiatrists. The titles are interchangeable and both are legally protected). In addition, it makes provision for certificated members of mountain rescue teams to supply and administer medicines to sick or injured people in mountain rescue emergencies.

**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 sale and supply of medicines -
- 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 exemptions in the Order may only be sold or supplied 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);
  - the Medicines (Pharmacy and General Sale – Exemption) Order 1980 which provides exemptions from the restrictions on sale and supply of medicines under sections 52 and 53 of the Medicines Act 1968. In particular, it provides exemptions from the requirement that POMs 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.

### **Administration of medicines in nuclear medicine procedures**

- 4.2 The amending Order will allow people who are operators in nuclear medicines procedures under the Ionising Radiation (Medical Exposure) Regulations 2000 (the IRME Regulations”) to administer RMPs. The operator must be acting in accordance with the procedures and protocols specified under the IRME Regulations as well as the written guidelines of a doctor or dentist holding a certificate issued by the Administration of Radioactive Substances Advisory Committee (ARSAC).

### **Registered chiropodists**

- 4.3 Under existing exemptions contained in the Orders specified above, registered chiropodists can sell, supply or administer a specified list of medicines provided it is in the course of their professional practice. The amending Order will extend this list.

### **Supply and administration of medicines by members of mountain rescue teams**

- 4.4 The amending Order will allow people who hold a first aid certificate from the Mountain Rescue Council of England and Wales or the Northern Ireland Mountain Rescue Co-ordinating Committee to supply and administer medicines to casualties involved in mountain rescue emergencies.

## **5. Extent**

- 5.1 This instrument applies to all of the United Kingdom.

## **6. European Convention on Human Rights**

- 6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required

## **7. Policy Background**

- 7.1 The changes relating to the administration of medicines in nuclear medicine procedures will be accompanied by amendment of the Medicines (Administration of Radioactive Substances) Regulations 1978. They are intended to reflect existing arrangements in place throughout the NHS and independent healthcare settings for the administration of these medicines and ensure continuity in the provision of patient care.
- 7.2 The changes relating to chiropodists are intended to enhance patient care by offering timely access to treatment. They also update the range of medicines available to chiropodists to reflect modern practice. Allowing members of mountain rescue teams to supply and administer medicines will enable them to offer appropriate treatment to casualties in emergency situations.
- 7.3 All the proposed amendments were subject to public consultation and advice to Ministers by the Commission on Human Medicines.

Detailed analyses of the outcome of the various public consultation exercises have been published on the MHRA website: [www.mhra.gov.uk](http://www.mhra.gov.uk) In each case there general support for the proposals. For example, 24 replies were received in response to the mountain rescue proposals. The majority (15) were supportive and a further seven made no comment or expressed no preference. The remaining two replies opposed the proposal.

7.4 There are no existing plans to consolidate the legislation.

## 8. Impact

8.1 Regulatory Impact Assessments have not been prepared for the proposals because they do not impose a cost compliance 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 0207 084 2392 or e-mail: [anne.ryan@mhra.gsi.gov.uk](mailto:anne.ryan@mhra.gsi.gov.uk) can answer any queries regarding the instrument.