

**EXPLANATORY MEMORANDUM TO**  
**THE MEDICINES (MISCELLANEOUS AMENDMENTS) ORDER 2011**

**2011 No. 1327**

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. Purpose of the Instrument**

2.1 This Order updates the chiropodist exemptions in the Medicines (Pharmacy and General Sale Exemption) Order 1980 (“the P and GSL Order”) and ensures that those exemptions apply to podiatrists also. This Order makes similar amendments to the Prescription Only Medicines (Human Use) Order 1997 (“the POM Order”) in relation medicines that may be sold, supplied or administered by chiropodists and podiatrists. The POM Order is also amended to allow student midwives to administer certain parenteral (injectable) medicines under the supervision of a registered midwife.

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

3.1 None.

**4. Legislative Context**

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

- the P and GSL Order which provides exemptions from the requirement that prescription only medicines (POMs) and medicines classed as pharmacy medicines may only be sold or supplied on registered pharmacy premises by or under the supervision of a pharmacist;
- the POM Order which specifies the description and classes of prescription only medicines which, subject to exemptions in the Order, may only be sold or supplied in accordance with the prescription of an appropriate practitioner or, may only be administered in accordance with the directions of such a practitioner.

**Registered Podiatrists**

4.2 Under existing exemptions contained in the P and GSL Order and the POM Order, registered chiropodists can sell, supply or administer a specified list of medicines provided it is in the course of their professional practice. This Order will extend the exemptions to podiatrists and update the list of medicines to which the exemption applies. The amendments in this Order will also ensure that pharmacists may sell or supply medicines on the chiropodists/ podiatrists list if they are presented with an order signed by a registered chiropodist/ podiatrist for any of those medicines.

## **Student Midwives**

4.3 Exemptions in the POM Order permit registered midwives to administer certain parenteral (injectable) medicines in the course of their professional practice. The amendments in this Order will permit student midwives to administer these medicines under the direct supervision of a registered midwife. The amendments also make some technical amendments to the list of medicines covered under this exemption.

## **5. Territorial Extent and Application**

5.1 The instrument applies to all of the United Kingdom.

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

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 term “chiropodist” also covers podiatrists and both are regulated by the Health Professions Council. Medicines legislation currently only refers to chiropodists. Extending the exemptions to podiatrists ensures that there is no doubt that they are able to access the medicines subject to exemption on the same footing as chiropodists. The remaining amendments relating to chiropodist exemptions are aimed at benefitting patient care. They will:

- remove pack size restrictions on certain medicines included on the list of medicines to which the exemptions apply to ensure that chiropodists and podiatrists are able to supply such medicines in pack-sizes that are commercially available;
- enable chiropodists and podiatrists to sell or supply a wider range of analgesics in accordance with local NHS arrangements and allow them to administer commercially available combinations of injectable medicines on their list. This means the patient does not have to have several injections;
- allow medicines to be sold or supplied by a pharmacist against an order signed by the chiropodist or podiatrist. This will enable patients to access treatment when the chiropodist or podiatrist does not have stocks available to sell or supply themselves.

7.2 In the past it was customary for student midwives to administer the parenteral medicines on the midwives’ list under the supervision of a registered midwife. Medicines legislation is clear that the exemptions for the parenteral administration of medicines relate only to registered midwives and the exemptions cannot be delegated to a student. The amendments extend the midwives exemptions to student midwives. This will allow student midwives to reach the required levels of competency in administration of parenteral medicines required by the Nursing and Midwifery Council at the point of registration. The amendments also include

several technical amendments to the midwives' list of medicines that will be made to remove, for example, medicines which are no longer available.

## **8. Consultation Outcome**

8.1 The MHRA undertook two three month consultations. In relation to podiatrists, 14 responses in total were received and eight of those expressed broad support for the proposals. Of the remainder, two were partially supportive and four gave no specific comment or preference relating to the proposals.

8.2 There were 158 replies to the student midwives' consultation. One hundred and thirty five of the replies expressed broad support for the proposals. Twenty-two responses made no comments specifically relating to the proposals or expressed no preference. One anonymous reply opposed the proposal to allow student midwives to administer medicines.

## **9. Guidance**

9.1 The Nursing and Midwifery Council and the Society of Chiropractors and Podiatrists will issue guidance on the legislative changes and good practice to midwives, students and podiatrists as appropriate.

## **10. Impact**

10.1 Initial Impact Assessments were prepared for these proposals. As the proposals are minor and do not create any burdens for the public or private sector, we considered it would be disproportionate to undertake full impact assessments.

## **11. Regulating small business**

11.1 The legislation does not impact adversely on small business.

## **12. Monitoring and Review**

12.1 The changes in this instrument are aimed at benefiting patient care. In line with the Better Regulation Agenda, the instrument will be reviewed in three years time to assess whether it is still fit for purpose.

## **13. Contact**

13.1 Anne Ryan at the MHRA (tel 0203 0806392, e-mail [anne.ryan@mhra.gsi.gov.uk](mailto:anne.ryan@mhra.gsi.gov.uk)) can answer any queries regarding the instrument.