

EXPLANATORY MEMORANDUM TO
THE MEDICINES FOR HUMAN USE (MISCELLANEOUS AMENDMENTS)
ORDER 2010

2010 No. 1136

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 Medicine (Human Use) Order 1997. It adds Dental Hygienists and Dental Therapists to the list of health professionals who can sell, supply and administer prescription only medicines (POMs) to patients in accordance with a Patient Group Direction (PGD). The Order also amends the range of POMs which can be sold, supplied or administered by registered midwives in the course of their professional practice. The Order further amends the Medicines (Pharmacy and General Sale – Exemption) order 1980 to allow Dental Hygienists and Therapists to sell or supply pharmacy (P) and general sale list (GSL) medicines.

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, supply and administration of medicines –

- the Prescription Only Medicines (Human Use) Order 1997 (the POM Order) which specifies the description and classes of medicines, 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. The Order also provides exemptions from the requirement that medicines classed as general sale list (GSL medicines) may only be sold from non-pharmacy

premises provided they are lockable and the products are pre-packed.

Changes relating to Dental Hygienists and Dental Therapists

- 4.2 Under existing exemptions contained in the Orders, specified groups of health professional can sell, supply or administer medicines under PGDs. A PGD is a written instruction for the supply or administration of POMs to persons generally. The amending Order will extend the use of PGDs to Dental Hygienists and Dental Therapists.

Registered midwives

- 4.3 There are also existing exemptions for registered midwives which allow them to sell, or supply specified POM medicines in the course of their professional practice. In addition, midwives are allowed to administer certain parenteral medicines in the course of their professional practice. The amending Order will allow midwives to access an extended range of medicines

5. Territorial Extent and Application

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

6. European Convention on Human Rights

- 6.1 Not applicable.

7. Policy Background

- *What is being done and why*

- 7.1 The amendments allowing Dental Hygienists and Dental Therapists to use PGDs will enable them to administer medicines and sell or supply preventative therapies (such as fluoride supplements for children) without the need to refer the patient back to the dentist. This avoids unnecessary delays to the delivery of patient care. It also enables a better use of dental skill mix.
- 7.2 The amendments relating to midwives aim to ensure equal access to the same range of medicinal products for women choosing to have their babies in hospital or at home. They will also improve quality of care and provide improved access to services for patients while maintaining patient safety.

8. Consultation Outcome

- 8.1 A three month consultation on the Dental Hygienist/ Therapist proposals ran from 28 August 2009. The MHRA received 110 replies. The majority of these originated from Dental Therapists and

Hygienists who expressed support for the proposals but made no further comment. Others - for example the Independent Healthcare Advisory Services and several training providers - either supported or had no comments on the proposals.

8.2 A three month consultation was also undertaken on the midwives proposals running from 30 November 2007. The MHRA received 87 responses. The majority of these (58) expressed support for the proposals. Twenty nine (29) made no comment on the proposals or expressed no preference. None of the responses expressed opposition to the general principle of extending the midwives' list.

8.3 Both consultations were circulated to a range of interested organisations and the outcomes considered by the Commission on Human Medicines.

9. Guidance

9.1 The General Dental Council and the Nursing and Midwifery Council who are the relevant regulatory bodies, will put guidance in place about the maintenance of skills and use of the medicines concerned.

10. Impact

10.1 Impact assessments have not been prepared for these proposals as they do not impose a cost compliance on business, charities or the voluntary sector.

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

11. Regulating Small Business

11.1 There are no adverse implications for 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 can answer any queries about this instrument.