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Changes to midwives exemptions

Summary

- On 1 July 2011, amending legislation[1] will come into force which enables student midwives to administer medicines on the midwives exemptions list, except controlled drugs, under the direct supervision of a midwife.
- This legislation also updates the range of prescription only medicines that may be sold, supplied or administered by registered midwives in the course of their professional practice.
- This circular takes place with effect from 1 July 2011 and replaces NMC Circular 6/2010.
- This circular should be read in conjunction with the NMC documents:
  - The code: Standards of conduct, performance and ethics for nurses and midwives (NMC, 2008)
  - Midwives rules and standards (NMC, 2004)
  - Standards for medicines management (NMC, 2007).

Background

The Nursing and Midwifery Council (NMC) exists to safeguard the health and well being of the public. We do this by maintaining a register of nurses and midwives and by setting standards for education and practice. This includes setting standards for administration, dispensing and storage of medicines. Midwives may, in the course of their professional practice, supply and administer on their own initiative any of the substances specified in medicines legislation under midwives exemptions.

Under the Medicines Act 1968[2], medicines classified as pharmacy (P) medicines may be sold or supplied only through registered pharmacies by or under the supervision of a pharmacist (section 52).

Prescription only medicines (POM) are subject to an additional requirement: they may only be sold or supplied through pharmacies against a prescription from an appropriate practitioner (section 58).

[1] The Medicines for Human Use (Miscellaneous Amendments) Order 2011. SI 2011/1327.
[2] http://www.opsi.gov.uk/RevisedStatutes/Acts/ukpga/1968/cukpga_19680067_en_1

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General sale list (GSL) medicines may be sold through retail outlets other than pharmacies as they do not need to be sold or supplied under the supervision of a pharmacist (sections 51 and 53).

Midwives exemptions

Exemptions from the general rules are permitted for midwives. These are provided for in the Prescription Only Medicines (Human Use) Order 1997 (SI 1997/1830 the 'POM Order') the Medicines (Pharmacy and General Sale- Exemption) Order 1980 (SI 1980/1924), the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 (SI 1980/1923).

Registered midwives may supply and administer, on their own initiative, any of the substances that are specified in medicines legislation under midwives exemptions, provided it is in the course of their professional practice. They may do so without the need for a prescription or patient-specific direction (PSD) from a medical practitioner. Provided the requirements of any conditions attached to those exemptions are met, a patient group direction (PGD) is not required. If a medicine is not included in the midwives exemptions then a prescription, or a PSD, or a PGD will be required.

Registered midwives must only supply and administer those medicines, including analgesics, in which they have received the appropriate training as to therapeutic use, dosage, side effects, precautions, contra-indications and methods of administration (*Midwives rules and standards*, 2004).

When supplying or administering medicines under midwives exemptions, midwives must ensure their practice is evidence based. Midwives must be familiar with current guidance published in the British National Formulary (BNF) and British National Formulary for Children.

Supply and administration of medicinal products outside of their license

Medicine which is licensed but used outside its licensed indications (commonly known as ‘off label’) may be administered under the midwives exemptions list provided is the following conditions are met:

- There is no appropriately licensed alternative
- There is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy
- Midwives should explain to women and their families, in broad terms, the reasons why the medicine is not licensed for the proposed use.

Administration of medicines on midwives exemptions list by student midwives

Standard 17 of the *Standards for pre-registration midwifery education* (NMC, 2009) states that student midwives must be able at the point of registration to select, acquire and administer safely a range of permitted drugs consistent with legislation, applying

knowledge and skills to the situation which pertains at the time. Methods of administration include: oral, intravenous, intramuscular, topical and inhalational.

Previously, medicines legislation was clear that midwives exemptions relate only to registered midwives and that a registered midwife could not delegate any aspect of these exemptions to a student midwife. This amendment allows student midwives to administer medicines on the midwives exemptions list, except controlled drugs, under the direct supervision of a midwife.

Direct supervision means in direct visual contact during which time the midwife observes the act of administration of medicines by a student midwife.

The Medicines and Healthcare products Regulatory Authority (MHRA) require that the midwife supervising the administration of medicines by a student midwife must have undertaken an approved mentorship programme and be a sign off mentor.

Student midwives may not administer controlled drugs but may participate in the checking and preparation of controlled drugs for administration on the midwives exemption list under the direct supervision of a registered midwife.

On 1 July 2011 medicines legislation will be amended to:

1 Enable student midwives to administer medicines on the exemption list, **except controlled drugs**, under the direct supervision of a midwife

2 Article 3 substitutes the list of medicines in Parts 1 and 3 of Schedule 5 to the POM Order in order to remove and amend substances from the list of the range of prescription only medicines that may be sold, supplied or administered by registered midwives. These substances are:

   2.1 Oral ergometrine and haemacel which are no longer available in the BNF

   2.2 Lidocaine and lidocaine hydrochloride which for topical use are (P) medicines

   2.3 Cyclizine hydrochloride is replaced with cyclizine lactate

No changes were made to legislation that affects pharmacy medicines or general sales list medicines used in the course of a midwife's professional practice.

Amendment of the POM Order
The following is an extract from the Amendments Order 2011[1]:

3.—(1) The POM Order is amended as follows.

(3) in schedule 5 (exemption for certain persons from section 58(2) of the Act):

(a) in Part 1 (exemption from restrictions on sale or supply), in column 2, for item 4 substitute:

"4 Prescription only medicines containing any of the following substances—
Diclofenac
Hydrocortisone acetate
Miconazole
Nystatin
Phytomenadione."

(b) in Part 3 (exemptions from restriction on administration), in column 2, for the substances listed in item 2 substitute—
"Adrenaline
Anti-D immunoglobulin
Carboprost
Cyclizine lactate
Diamorphine
Ergometrine maleate
Gelofusine
Hartmann's solution
Hepatitis B vaccine
Hepatitis immunoglobulin
Lidocaine
Lidocaine hydrochloride
Morphine
Naloxone hydrochloride
Oxytocins, natural and synthetic
Pethidine hydrochloride
Phytomenadione
Prochloperazine
Sodium chloride 0.9%."

The above list will be reviewed by the NMC in collaboration with the MHRA every three years.

Further information and advice

There is no legal definition for standing orders and they do not exist under any medicines legislation (*Standards for medicines management*, 2007). We recommend that the term standing orders is no longer used and is replaced with the term midwives exemptions.

The midwives exemptions list and advice on use and administration of prescription only medicines is attached at annexe 1 and 2. Midwives are reminded that they have access to all (P) and (GSL) medicines providing it is in the course of their professional practice.

This circular may be reproduced by all to whom it is addressed.

This circular has been issued by

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