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## Nurse and midwife independent prescribing of unlicensed medicines.

### Summary

- The Nursing & Midwifery Council 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.
- On 21 December 2009 legislation<sup>1</sup> was amended to allow nurse and midwife independent prescribers to prescribe unlicensed medicines for those in their care their on the same basis as doctors, dentists and supplementary prescribers.
- This circular takes place with immediate effect.
- It sets out the NMC's requirements for a nurse or midwife prescriber, should they decide to prescribe an unlicensed medicine.
- The information in this circular replaces Practice Standard 17 (17.1) of the *Standards of proficiency for nurse and midwife prescribers* (NMC, 2006).
- This document should be read in conjunction with the NMC documents:
  - *The code: Standards of conduct, performance and ethics for nurses and midwives* (NMC, 2008)
  - *Standards of proficiency for nurse and midwife prescribers* (NMC, 2006)

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### Background

- Unlicensed medicines are medicinal products that are not licensed for any medicines indication or age group. An unlicensed medicine is one that does not have a valid marketing authorisation (licence) in the UK.
- Previously, nurse and midwife prescribers have not been authorised to prescribe unlicensed medicines independently. They could prescribe unlicensed medicines as a supplementary prescriber as part of a clinical management plan.

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<sup>1</sup> The Medicines for Human Use (Miscellaneous Amendments) (no.2) Regulations. SI 2009 3063

- In 2008 the Commission on Human Medicine (CHM) established a Working Group (WG) to discuss “mixing” of medicines.
- During their discussions<sup>2</sup> the WG also considered unlicensed prescribing by nurse and midwife independent prescribers. The WG concluded that a natural extension to their recommendations for mixing of medicines would be to authorise nurse and midwife independent prescribers to order unlicensed medicines.
- The WG recommended that nurse and midwife independent prescribers should be authorised to prescribe unlicensed medicines for people in their care on the same basis as doctors, dentists and supplementary prescribers.
- The CHM endorsed the recommendation.
- On 21 December 2009, The Medicines for Human Use (Miscellaneous Amendments)(No.2) Regulations 2009, authorised nurse and midwife independent prescribers to prescribe unlicensed medicines to meet the individual needs of patients or clients on the same basis as doctors, dentists and supplementary prescribers.

- This circular permits nurse and midwife independent prescribers to prescribe unlicensed medicines.
- Practice Standard 17 (17.1) of the Standards of proficiency for nurse and midwife prescribers (NMC, 2006) should be replaced with the following information;

You may prescribe an unlicensed medication as an independent nurse prescriber providing :

- You are satisfied an alternative, licensed medication would not meet the patient's or client's needs.
- You are satisfied there is a sufficient evidence base and/or experience to demonstrate the medication's safety and efficacy for that particular patient or client.
- You are prepared to take responsibility for prescribing the unlicensed medicine and for overseeing the patient's or client's care, including monitoring and any follow up treatment.
- The patient or client agrees to the prescription in the knowledge that the medicine is unlicensed and understands the implications of this.
- The medication chosen and the reason for choosing it are documented in patient's or client's notes.

<sup>2</sup> Report of the CHM working group on “Mixing Medicine”:  
<http://www.mhra.gov.uk/Howweregulate/Medicines/Availabilityprescribingandsupplyingofmedicines/Frequentlyraisedissues/Palliativecare/index.htm>

- You seek, as necessary, professional advice, for example, from a pharmacist or other authoritative clinical guidance to support your prescribing practice and the specification for the unlicensed medicine.
- You must report suspected adverse drug reactions arising from unlicensed medicines to the Medicines and Healthcare products Regulatory Agency and CHM via the Yellow Card Scheme.

### **Guidance**

Unlicensed medicines are medicinal products that are not licensed for any medicines indication or age group. An unlicensed medicine is one that does not have a valid marketing authorisation (licence) in the UK. The marketing authorisation of a licensed product attests to the quality, safety, and efficacy of a medicinal product. A licensed medicine has been assessed for efficacy, safety, and quality, has been manufactured to appropriate quality standards, and when placed on the market is accompanied by appropriate product information and labelling. Unlicensed medicines do not have the same assurances.

However there are clinical situations when the use of unlicensed medicines may be judged by the nurse or midwife independent prescriber to be in the best interest of the patient on the basis of available evidence. Such practice is particularly common in certain areas of medicine such as paediatrics where difficulties in the development of age-appropriate formulations means that some medicines used in children are unlicensed.

Nurse and midwife independent prescribers should pay particular attention to the risks associated with using unlicensed medicines. These risks may include: adverse reactions, product quality, or discrepant product information or labelling, for example information in a foreign language for unlicensed imports.

We would consider it best practice for nurses and midwives prescribing unlicensed medicines to have in place supporting policies and systems to monitor and manage clinical risks associated with unlicensed medicines.

- All other sections of the Standards of proficiency for nurse and midwife prescribers remain current and valid and must be adhered to.
- Failure to comply these Standards or the Code may bring your fitness to practise into question and endanger your registration.

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This circular has been issued by

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