Introduction

The Nursing and Midwifery Council (NMC) is the UK regulator for two professions: nursing and midwifery. The primary purpose of the NMC is protection of the public. It does this through maintaining a register of all nurses, midwives and specialist community public health nurses eligible to practice within the UK and by setting standards for their education, training and conduct. One of the most important ways of serving the public interest is through providing advice and guidance to registrants on professional issues. The purpose of this booklet is to set standards for safe practice in the management and administration of medicines by registered nurses, midwives and specialist community public health nurses.

Standards for medicine management replace the Guidelines for the administration of medicines 2004, although many of its principles remain relevant today, for example:

"The administration of medicines is an important aspect of the professional practice of persons whose names are on the Council's register. It is not solely a mechanistic task to be performed in strict compliance with the written prescription of a medical practitioner (now independent/supplementary prescriber). It requires thought and the exercise of professional judgement..."

Many government and other agencies are involved in medicines management from manufacture, licensing, prescribing and dispensing, to administration. As the administration of a medicinal product is only part of the process these Standards reflect the process from prescribing, through to dispensing, storage, administration and disposal. There exists an extensive range of guidance on medicines management from a range of relevant bodies, sources of information are listed on pages 46–47. One of the best sources of advice locally is the pharmacist

As with all NMC standards, this booklet provides the minimum standard by which practice should be conducted and will provide the benchmark by which practice is measured. Due to the complexity, speed and extent of change in contemporary health care, it is not intended to cover every single situation that you may encounter during your career. Instead, it sets out a series of standards that will enable you to think through issues and apply your professional expertise and judgement in the best interests of your patients. It will also be necessary to develop and refer to additional national/local policies or protocols to suit local needs.

Definitions

A Medicinal product is:

"Any substance or combination of substances presented for treating or preventing disease in human beings or in animals. Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or animals is likewise considered a medicinal product." Council Directive 65/65/EEC

Medicines management:

"The clinical, cost effective and safe use of medicines to ensure patients get the maximum benefit from the medicines they need, while at the same time minimising potential harm." (MHRA 2004)

Blood and blood products

Blood is not classified as a medicinal product although some blood components are. Products derived from the plasma component of blood such as blood clotting factors, antibodies and albumin are licensed and classified as considered to be medicinal products. For the purpose of the administration of medicinal products registrants would be expected to apply the standards for medicines management to all medicinal products but should consider additional guidance by the National Patient Safety Agency – guidance launched on 09 November 2006; "Right patient, Right blood" (available at www.npsa.nhs.uk). A key requirement of this guidance is that all staff involved in blood transfusion undergoes formal competency assessment on a three yearly basis.

Use of the word "Patient" throughout the document

Throughout this document where the word "patient" is used this refers to whoever the medication may be administered to e.g. patient, client, user, woman (midwifery).

Use of the word "Registrant" throughout the document

Throughout this document where the word "registrant" is used this refers to nurses, midwives and specialist community public health nurses who are registered on the Nursing and Midwifery Council Register.

Summary of standards

This section provides a summary of the standards, for easy reference. For further detail you should read, follow and adhere to the standards as detailed later in the document. It is essential that you read the full guidance and you must follow the advice.

SECTION 1

Methods of supplying and/or administration of medicines

Standard 1

Registrants must only supply and administer medicinal products in accordance with one or more of the following processes:

- Patient Specific Direction (PSD)
- Patient Medicines Administration Chart (may be called Medicines Administration Record MAR)
- Patient Group Direction (PGD)
- Medicines Act Exemption
- Standing Order
- Homely Remedy Protocol
- Prescription Forms

Standard 2

Registrants must check any direction to administer a medicinal product.

Standard 3

As a registrant you may transcribe medication from one "direction to supply or administer" to another form of "direction to supply or administer".

SECTION 2

Dispensing

Standard 4

Registrants may in exceptional circumstances label from stock and supply a clinically appropriate medicine to a patient, against a written prescription (not PGD), for self-administration or administration by another professional, and to advise on its safe and effective use.

Standard 5
Registrants may use patients' own medicines in accordance with the guidance in this booklet Standards for medicines management.

SECTION 3

Storage and transportation

Standard 6
Registrants must ensure all medicinal products are stored in accordance with the patient information leaflet, summary of product characteristics document found in dispensed UK-licensed medication, and in accordance with any instruction on the label.

Standard 7
Registrants may transport medication to patients including Controlled Drugs, where patients or their carers/representatives are unable to collect them, provided the registrant is conveying the medication to a patient for whom the medicinal product has been prescribed (e.g. from a pharmacy to the patient's home).

SECTION 4

Standards for practice of administration of medicines

Standard 8
As a registrant, in exercising your professional accountability in the best interests of your patients:

- You must be certain of the identity of the patient to whom the medicine is to be administered.
- You must check that the patient is not allergic to the medicine before administering it.
- You must know the therapeutic uses of the medicine to be administered, its normal dosage, side effects, precautions and contra-indications.
- You must be aware of the patient's plan of care (care plan/pathway)
- You must check that the prescription or the label on medicine dispensed is clearly written and unambiguous.
- You must check the expiry date (where it exists) of the medicine to be administered.

- You must have considered the dosage, weight where appropriate, method of administration, route and timing.
- You must administer or withhold in the context of the patient's condition (e.g. digoxin not usually to be given if pulse below 60) and co-existing therapies e.g. physiotherapy.
- You must contact the prescriber or another authorised prescriber without delay where contra-indications to the prescribed medicine are discovered, where the patient develops a reaction to the medicine, or where assessment of the patient indicates that the medicine is no longer suitable (See Standard 25).
- You must make a clear, accurate and immediate record of all medicine administered, intentionally withheld or refused by the patient, ensuring the signature is clear and legible; it is also your responsibility to ensure that a record is made when delegating the task of administering medicine.

In addition:

- Where medication is not given the reason for not doing so must be recorded.
- You may administer with a single signature any Prescription Only Medicine (POM), General Sales List (GSL) or Pharmacy (P) medication.

In respect of Controlled Drugs:

- These should be administered in line with relevant legislation and local standard operating procedures.
- It is recommended that for the administration of Controlled Drugs a secondary signatory is required within secondary care and similar healthcare settings.
- In a patient's home, where a registrant is administering a Controlled Drug that has already been prescribed and dispensed to that patient, obtaining a secondary signatory should be based on local risk assessment.
- Although normally the second signatory should be another registered health care professional (for example doctor, pharmacist, dentist) or student nurse or midwife, in the interest of patient care, where this is not possible a second suitable person who has been assessed as competent may sign. It is good practice that the second signatory witnesses the whole administration process. For Guidance, go to: www.dh.gov.uk and search for Safer Management of Controlled Drugs: Guidance on Standard Operating Procedures.

- In cases of direct patient administration of oral medication from stock in a substance misuse clinic, it must be a registered nurse who administers, signed by a second signatory (assessed as competent), who is then supervised by the registrant as the patient receives and consumes the medication.
- You must clearly countersign the signature of the student when supervising a student in the administration of medicines.

Standard 9
As a registrant you are responsible for the initial and continued assessment of patients who are self-administering and have continuing responsibility for recognising and acting upon changes in a patient's condition with regards to safety of the patient and others.

Standard 10
In the case of children, when arrangements have been made for parents/carers or patients to administer their own medicinal products prior to discharge or rehabilitation, the registrant should ascertain that the medicinal product has been taken as prescribed.

Standard 11
In exceptional circumstances, where medication has been previously prescribed and the prescriber is unable to issue a new prescription, but where changes to the dose are considered necessary, the use of information technology (such as fax, text message or email) may be used but must confirm any change to the original prescription.

Standard 12
As a registrant, you must ensure that there are protocols in place to ensure patient confidentiality and documentation of any text received include: complete text message, telephone number (it was sent from), the time sent, any response given, and the signature and date when received by the registrant.

Standard 13
Where medication has been prescribed within a range of dosages it is acceptable for registrants to titrate dosages according to patient response and symptom control and to administer within the prescribed range.

Standard 14
Registrants must not prepare substances for injection in advance of their immediate use or to administer medication drawn into a syringe or container by another practitioner when not in their presence.

Standard 15
Registrants should never administer any medication that has not been prescribed, or acquired over the internet without a valid prescription.

Standard 16
Registrants must assess the patient's suitability and understanding of how to use an appropriate compliance aid safely.

SECTION 5

Delegation

Standard 17
A registrant is responsible for the delegation of any aspects of the administration of medicinal products and they are accountable to ensure that the patient or carer/care assistant is competent to carry out the task.

Standard 18
Students must never administer/supply medicinal products without direct supervision.

Standard 19
In delegating the administration of medicinal products to unregistered practitioners, it is the registrant who must apply the principles of administration of medicinal products as listed above. They may then delegate an unregistered practitioner to assist the patient in the ingestion or application of the medicinal product.

Standard 20
Wherever possible two registrants should check medication to be administered intravenously, one of whom should also be the registrant who then administers the IV medication.

SECTION 6

Disposal

Standard 21
A registrant must dispose of medicinal products in accordance with legislation.

SECTION 7

Unlicensed medicines

Standard 22
A registrant may administer an unlicensed medicinal product with the patient's informed consent against a patient-specific direction but NOT against a patient group direction.

SECTION 8

Complementary and alternative therapies

Standard 23

Registrants must have successfully undertaken training and be competent to practise the administration of complementary and alternative therapies.

SECTION 9

Management of adverse events

Standard 24

As a registrant, if you make an error you must take any action to prevent any potential harm to the patient and report as soon as possible to the prescriber, your line manager or employer (according to local policy) and document your actions. Midwives should also inform their named Supervisor of Midwives.

Standard 25

As a registrant, if a patient experiences an adverse drug reaction to a medication you must take any action to remedy harm caused by the reaction. You must record this in the patient's notes, notify the prescriber (if you did not prescribe the drug) and notify via the Yellow Card Scheme immediately.

SECTION 10

Controlled Drugs

Standard 26

Registrants should ensure that patients prescribed Controlled Drugs are administered these in a timely fashion in line with the standards for administering medication to patients. Registrants should comply with and follow the legal requirements and approved local Standard Operating Procedures for Controlled Drugs that are appropriate for their area of work.

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Misuse of Drugs (Supply to addicts) Regulations 1997 and Misuse of Drugs (Notification and Supply to Addicts (Northern Ireland) Regulations) 1973

Prescription only medicines (Human Use) Order 1997

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The Standards

Methods of supplying and/or administration of medicines

Methods to enable nurses, midwives and specialist community public health nurses to supply and/or administer may include:

Standard 1

Registrants must only supply and administer medicinal products in accordance with one or more of the following processes:-

- Patient Specific Direction (PSD)
- Patient Medicines Administration Chart (may be called a Medicines Administration Record MAR)
- Patient Group Direction (PGD)
- Medicines Act Exemption (where they apply to nurses)
- Standing Order
- Homely Remedy Protocol
- Prescription Forms

Once a medicinal product has been prescribed and dispensed to an individual the drug is the individual's own property. To use it for someone else is theft. Registrants should refer to DH (2006) Medicines Matters: **A guide to mechanisms for the prescribing, supply and administration of medicines.**

Patient Specific Direction (PSD)

A patient specific direction (PSD) is a written instruction from a qualified and registered prescriber for a medicine including the dose, route and frequency or appliance to be supplied or administered to a named patient. In primary care, this might be a simple instruction in the patient's notes. Examples in secondary care include instructions on a patient's medicines administration chart. The direction would need to be specific as to the route of administration, it cannot simply authorise a course of treatment to several patients. Where a patient specific direction exists, there is no need for a Patient Group Direction.

Each individual patient must be identified on the patient specific direction (PSD). An example of using a PSD is in the administration of routine vaccine where a list of patients

due a vaccine may be identified beforehand. In the case of Controlled Drugs, it is essential to comply with full prescription requirements. Go to www.dh.gov.uk and search: Controlled Drugs.

Patient Medicines Administration Chart

The patient medicines administration chart is not a prescription but a direction to administer medication. It must be signed by a registered prescriber and authorises the delegation to administer medication on the prescriber's behalf. However, in doing so the registrant is accountable for their actions and for raising any concerns about the direction with the prescriber e.g. in respect to clarity.

Patient Group Direction (PGD)

Patient group directions (PGDs) are specific written instructions for the supply or administration of a licensed named medicine including vaccines to specific groups of patients who may not be individually identified before presenting for treatment. Guidance on the use of PGDs is contained within **Health Service Circular (HSC) 2000/026.**

See Home Office circular 049/2003. Controlled Drugs Legislation – Nurse Prescribing And Patient Group Directions. Go to www.dh.gov.uk and search: Controlled Drugs.

Guidance has also been issued in Wales (WHC 2000/116) and in Scotland and Northern Ireland.

The circular also identifies the legal standing of PGDs plus additional guidance on drawing them up and operating within them. It is vital that anyone involved in the delivery of care within a PGD is aware of the legal requirements. PGDs are not a form of prescribing.

Patient group directions are drawn up locally by doctors, dentists, pharmacists, and other health professionals where relevant. They must be signed by a doctor or dentist and a pharmacist, both of whom should have been involved in developing the direction, and must be approved by the appropriate health care organisation. The NMC would consider it good practice that a lead practitioner from the professional group using the PGD and senior manager where possible, are also involved and sign off a PGD.

PGDs can be used by independent providers for NHS commissioned services. As medicines legislation does not apply outside the United Kingdom a PGD would not be required – for example – on cruise ships, however the NMC would consider it good practice for such bodies to develop protocols using PGD templates that are signed off by a doctor, dentist, pharmacist, other health professionals where relevant and a senior manager where possible.

PGDs should only be used once the registrant has been assessed as competent and whose name is identified within each document. The administration of drugs via a PGD may not be delegated. Students cannot supply or administer under a PGD but would be expected to understand the principles and be involved in the process. Where medication is already subject to Exemption Order legislation there is no requirement for a PGD.

When supplying under PGD, this should be from the manufacturers' original packs or over labelled pre-packs so that the patient details, date and additional instructions can be written on the label at the time of supply. Registrants must not split packs. For more information on labelling see Annexe 2.

See "To PGD or not to PGD" at:
www.portal.nelm.nhs.uk/PGD/viewRecord.aspx?recordID=422

PGDs in the NHS: www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=148

PGDs in the private sector:
www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=147

Medicines Act Exemptions

- Allow certain groups of healthcare professionals including occupational health nurses under occupational health schemes and midwives to sell, supply and administer specific medicines directly to patient/clients.
- Provided the requirements of any conditions attached to those exemptions are met, a Patient Group Direction is not required.
- Registrants must work to locally agreed written protocols/procedures and maintain auditable records.
- Occupational health nurses that offer services e.g. open access travel clinics outside of occupational health schemes must comply with guidance from the appropriate regulator.

(n.b. Registrants may only supply and administer under an Exemption Order where the Order pertains to them. Where nurses are working as Emergency Care Practitioners within an ambulance service they may not supply and administer under Paramedic Exemptions unless they are also registered as a paramedic with the Health Professions Council – to do so would contravene medicine legislation and the employer's vicarious liability would not apply)

Search for NMC Circular 1/2005 "Medicine legislation: what it means for midwives" at
www.nmc-uk.org

Standing Orders

In the past, maternity service providers and occupational health schemes have produced local guidelines, often referred to as "Standing Orders", to supplement the legislation on the medicinal products that practising midwives and occupational health nurses may supply and/or administer. These guidelines are not a prerequisite under any legislation. There is no legal definition for "Standing Orders" and this term does not exist in any medicines legislation. The NMC would consider it good practice where midwives and occupational health nurses are using Standing Orders for medicinal products that are not covered by Medicines Act Exemptions that these should be converted to PGDs.

Homely Remedy Protocols

Homely remedy protocols cannot be used for Prescription Only Medicines including Controlled Drugs. These must be supplied and administered under a PSD, a prescription or a PGD.

Guidance

Homely Remedy Protocols are not prescriptions but protocols to enable administration of general sales list (GSL) and Pharmacy only (P) listed medicines in settings e.g. care homes, children's homes and some educational institutions. Although they have no legal standing they are required for liability purposes. Any registrant using a homely remedy protocol must ensure there is a written instruction that has been drawn up and agreed in consultation with other relevant qualified professionals. (Where possible this should be a medical practitioner or pharmacist). The protocol should clarify what medicinal product may be administered and for what indication it may be administered, the dose, frequency and time limitation before referral to a GP. An example of a homely remedy could be paracetamol for a headache. All registrants using the protocol should be named and they should sign to confirm they are competent to administer the medicinal product, acknowledging they will be accountable for their actions.

The NMC consider it good practice that the employing organisation signs off all protocols.

Prescription forms

NHS prescription forms are classified as secure stationery. Prescription forms are serially numbered and have anti-counterfeiting and anti-forgery features. Within the NHS they are purchased by Primary Care Trusts, Hospital Boards, and hospitals via a secure ordering system and distributed free. The range of prescription forms used by registered prescribers can be found in each UK country government website.

Specific Controlled Drug prescription forms are available from the local health care organisation e.g. PCT, LHB, for use in the private healthcare sector. Specific Controlled Drug prescriptions are used for treatment of addiction and for private prescriptions for Controlled Drugs. Only the designated prescription form should be used. Detailed guidance on how to complete prescription forms, including special requirements when prescribing Controlled Drugs is available from the (Department of Health (DH), Health Care Commission (HCC), Home Office, the Prescription Prices Division of the NHS Business Services Authority website and in the BNF. The Regulation and Quality Improvement Authority is equivalent to the HCC in Northern Ireland. Registrants in Northern Ireland should access their website for up-to-date information on their standards. www.npc.co.uk/controlled_drugs/CDGuide_2ndedition_February_2007.pdf

For the Welsh Health Circular, go to: www.wales.nhs.uk/documents/WHC_2006_018.pdf

Search for the Home Office Circular Controlled Drugs Legislation - Nurse Prescribing and Patient Group Directions at www.knowledgenetwork.gov.uk/HO/circular.nsf

Who may write a prescription?

Any qualified and registered independent prescriber may prescribe all Prescription Only Medicines for all medical conditions. In addition Nurse Independent Prescribers may also prescribe some Controlled Drugs.

Supplementary prescribers may prescribe in accordance with a Clinical Management Plan in a tripartite arrangement with a doctor or dentist, the patient and the supplementary prescriber. A supplementary prescriber when acting under and in accordance with the terms of a clinical management plan (CMP) may administer and/or supply or direct any person to administer Controlled Drugs in Schedules 2, 3, 4 and 5 and can prescribe unlicensed medicinal products. Please see **Section 5** on Delegation.

www.nmc-uk.org/aArticle.aspx?ArticleID=2021

Prescribing by nurses, midwives and specialist community public health nurses

The **Medicinal Products: Prescription by Nurses Act 1992** and subsequent amendments to the pharmaceutical services regulations allow nurses and midwives, who have recorded their qualification on the NMC register, to become nurse or midwife prescribers. There are two levels of nurse and midwife prescribers:

Community practitioner nurse prescribers

These are registrants who have successfully undertaken a programme of preparation to prescribe from Community Practitioner Nurse Prescribers' Formulary. They can prescribe the majority of dressings and appliances, and a limited range of Prescription Only Medicines. The Community Nurse Prescribers' Formulary can be found on the **British National Formulary** website. Go to: www.bnf.org/

Independent/Supplementary Nurse and Midwife Prescribers

These are nurses and midwives who are trained to make a diagnosis and prescribe the appropriate treatment (independent prescribing). They may also, in cases where a doctor has made an initial diagnosis, go on to prescribe or review the medication and change the drug, dosage, timing or frequency or route of administration of any medication as appropriate as part of a clinical management plan. (Supplementary prescribing).

Nurse or Midwife Independent prescribers can prescribe all Prescription Only Medicines including some Controlled Drugs and all medication that can be supplied by a pharmacist or bought over the counter. They must only prescribe drugs that are within their area of expertise, and level of competence and should only prescribe for children if they have the expertise and competence to do so.

Nurse, midwife and specialist community public health nurse prescribers must comply with current prescribing legislation and are accountable for their practice.

For Department of Health guidance go to www.dh.gov.uk and search: nurse independent prescribing.

The Standards

Methods of supplying and/or administration of medicines

Standard 2

Registrants (1st and 2nd level) must check any direction to administer a medicinal product.

As a registrant you are accountable for your actions and omissions. In administering any medication, or assisting or overseeing any self-administration of medication, you must exercise your professional judgement and apply your knowledge and skill in the given situation. As a registrant, before you administer a medicinal product you must always check that the prescription or other direction to administer is:

- not for a substance to which the patient is known to be allergic or otherwise unable to tolerate
- based, whenever possible, on the patient's informed consent and awareness of the purpose of the treatment
- clearly written, typed or computer-generated and indelible
- specifies the substance to be administered, using its generic or brand name where appropriate and its stated form, together with the strength, dosage, timing, frequency of administration, start and finish dates and route of administration
- is signed and dated by the authorised prescriber
- in the case of Controlled Drugs, specifies the dosage and the number of dosage units or total course; and is signed and dated by the prescriber using relevant documentation as introduced e.g. Patient Drug Record Cards

And that you have:

- clearly identified the patient for whom the medication is intended
- recorded the weight of the patient on the prescription sheet for all children, and where the dosage of medication is related to weight or surface area (e.g. cytotoxics) or where clinical condition dictates recorded the patient's weight.

The Standards

Transcribing

Standard 3

As a registrant you may transcribe medication from one "'direction to supply or administer"' to another form of "direction to supply or administer".

Guidance

This should only be undertaken in exceptional circumstances and should not be routine practice. However, in doing so you are accountable for your actions and omissions. Any medication that you have transcribed must be signed off by a registered prescriber. In exceptional circumstances this may be done in the form of an email, text or fax before it can be administered by a registrant.

Any act by which medicinal products are written from one form of direction to administer to another is "transcribing". This includes e.g. discharge letters, transfer letters, copying illegible patient administrations charts onto new charts, whether hand written or computer generated.

When medicine administration records in a care home are hand-written by a registrant, they may be transcribed from the details included on the label attached to the dispensed medicine. However, in doing so the registrant must ensure that the charts are checked by another registrant where possible, and where not, another competent health professional.

The registrant is accountable for what s/he has transcribed.

Managers/employers are responsible for ensuring there is a rigorous policy for transcribing that meets local Clinical Governance requirements.

As care is being increasingly provided in more "closer to home"' settings that are often nurse led, managers/employers should undertake a risk assessment involving registrants, pharmacists and responsible independent prescribers to develop a management process to enable transcribing to be undertaken where necessary. It should not be routine practice. Any transcription must include the patient's full name, date of birth, drug, dosage, strength, timing, frequency and route of administration.

N.B Transposing is the technical term used by pharmacists for transcribing.

Registrants are advised to read the Health Care Commission guidance for the transcribing of prescribed medicines for individuals on admission to children's hospices. The principles apply to all settings. Go to www.healthcarecommission.org.uk/ Registrants in Northern Ireland should refer to the Regulation and Quality Improvement Authority website at www.rqia.org.uk

The Standards

Dispensing

Standard 4

Registrants may in exceptional circumstances label from stock and supply a clinically appropriate medicine to a patient, against a written prescription (not PGD), for self-administration or administration by another professional, and to advise on its safe and effective use.

Guidance

The definition of dispensing is:

"'To label from stock and supply a clinically appropriate medicine to a patient/client/carer, usually against a written prescription, for self-administration or administration by another professional, and to advise on safe and effective use'." (MHRA, 2006)

Dispensing includes such activities as checking the validity of the prescription, the appropriateness of the medicine for an individual patient, assembly of the product, labelling in accordance with legal requirements and providing information leaflets for the patient.

If under exceptional circumstances you, as a registrant you are engaged in dispensing, this represents an extension to your professional practice. There is no legal barrier to this practice. However, this must be in the course of the business of a hospital, and in accordance with a registered prescriber's written instructions and covered by a Standard Operating Procedure (SOP). In a dispensing doctor's practice, registrants may supply to patients under a particular doctor's care, when acting under the directions of a doctor from that practice. The patient has the legal right to expect that the dispensing will be carried out with the same reasonable skill and care that would be expected from a pharmacist.

Dispensing

Standard 5

Registrants may use patient's' own medicines in accordance with the guidance in this booklet **Standards for medicines management**.

The NMC welcomes and supports the self-administration of medicinal products and the administration of medication by carers wherever it is appropriate.

The use of patient's' own medicinal products in any setting

Where patients have their own supply of medicinal products, whether prescribed, over the counter (from a pharmacy or supermarket/shop), complementary therapy, herbal preparation or homely remedy such as paracetamol, the registrant has a responsibility to:

- ask to see the medicinal products
- check for suitability of use
- explain how and why they will or won't be used
- establish if they are prescribed
- ascertain if they meet the criteria for use.

These medicinal products including Controlled Drugs remain the patient's property and must not be removed from the patient without their permission and must only be used for that named individual.

The registrant has a responsibility to document in the patient's notes when a patient refuses consent:

- to use their own medicines.
- to dispose of their own medicinal products no longer required.
- to dispose of their own medicinal products not suitable for use.
- when in the hospital or care home setting to send their own medicinal products home with a relative or carer.

Storage of patients' own medicinal products

As a registrant you have the following responsibilities:

- to ensure that suitable facilities are provided to store patients' own medicinal products for their safe storage
- to assess patients on a regular basis using local polices to ensure that the individual patient is still able to self-administer
- to document issues relating to storage in their records.
- that the medicines cabinet/locker is kept locked and that the master key is kept secure.
- that if the patient is self-administering consent is obtained from the patient to keep the individual medicines cabinet/locker locked and the key secure with the patient.
- that if a patient moves to another bed, to another ward/room or is discharged the patient's medicinal products are transferred with the patient.
- In a hospital setting best practice indicates that stock medicines should not be placed in the patient's locked cabinet/locker as they are not labelled for that individual patient.

Administering medicines using the patient's own supply in the hospital/care home setting.

When administering medicines from the patient's own supply the registrant must check the medicines in the locked cabinet/locker with the prescription chart and use only those medicines belonging to that named patient.

If a supply is not available medicines belonging to another patient must not be used.

For further guidance on the use of patients' own medicinal products including discharge and checking medications to take home (TTO's) see Annexe 3. For self-administration of medicines see Standard 9 of this document Self-administration of medicines.

One Stop Dispensing

In some hospitals a system of One Stop Dispensing is in operation and local policies should be developed for this using the guidance for patients' own medicinal products as stated under standard 5 of this document.

Guidance

One-stop dispensing is a system of administering and dispensing medicinal products adopted in hospitals throughout the UK (Audit Commission Report: A Spoonful of Sugar 2002 – The Right Medicine (Scottish Executive 2002). It involves using the patient's own medicinal products during their stay in hospital, either those dispensed by a community pharmacy or by the hospital pharmacy or both, providing they contain a patient information leaflet and are labelled with full instructions for use. Supplies are replenished should the supply run out whilst in hospital or when any new items are prescribed. Patients are discharged with a supply of medicinal products as agreed locally.

In one-stop dispensing medicinal products are dispensed once only on or during admission ready for discharge. Registrants should check that the medication handed to the patient on discharge is as per the discharge prescription, as medicines may be altered/stopped during hospital admission. If a particular medicine has been stopped during admission and is not to be restarted on discharge, the patient must be informed. The ward pharmacist is a useful resource for advice.

The Standards

Storage and transportation

Standard 6

Registrants must ensure all medicinal products are stored in accordance with the patient information leaflet, summary of product characteristics document found in dispensed UK-licensed medication and in accordance with any instruction on the label.

Guidance

The patient information leaflet and/or summary of product characteristics document for UK-licensed medicinal products may be found at www.emc.medicines.org.uk. Policies should be in place to ensure all storage environments meet the required standards and it is the responsibility of the registrant to check such policies are in place and are being adhered to. This is particularly important for medicines requiring storage within a limited temperature range e.g. refrigeration of vaccines when maintenance of the cold chain has to be considered during transfer for school sessions or administration in the patient's home.
Go to www.the-shipman-inquiry.org.uk/4r_page.asp?id=3119

The Standards

Transportation of medication

Standard 7

Registrants may transport medication to patients including CDs, where patients or their carers/representatives are unable to collect them, provided the registrant is conveying the medication to a patient for whom the medicine has been prescribed (e.g. from a pharmacy to the patient's home).

Guidance

However, it is considered good practice that registrants should not routinely transport CDs in the course of their practice. This should only be undertaken in circumstances where there is no other reasonable mechanism available. All drugs should be kept out of sight during transportation.

When collecting Controlled Drugs from a pharmacy the registrant will be asked to sign for them and prove identity in the form of her professional identity badge or pin number (where self-employed). Midwives must be familiar with the use of Midwives Supply Orders. Go to: NMC Circular 25/2005 www.nmc-uk.org/aFrameDisplay.aspx?DocumentID=775 It is anticipated as a recommendation from the Shipman Inquiry Fourth Report that new documentary evidence will be required in the form of a Patient Drug Record Card. Registrants would be expected to be aware of and comply with any new legislation and guidance introduced.

The Standards

Standards for practice of administration of medicines

Having initially checked the "direction to supply or administer" that a medicinal product is appropriate for your patient/client (Standard 2) you may then administer medication.

Standard 8

As a registrant, in exercising your professional accountability in the best interests of your patients:

- You must be certain of the identity of the patient to whom the medicine is to be administered.
- You must check that the patient is not allergic to the medicine before administering it.
- You must know the therapeutic uses of the medicine to be administered, its normal dosage, side effects, precautions and contra-indications.
- You must be aware of the patient's plan of care (care plan/pathway)
- You must check that the prescription or the label on medicine dispensed is clearly written and unambiguous.
- You must check the expiry date (where it exists) of the medicine to be administered.
- You must have considered the dosage, weight where appropriate, method of administration, route and timing.
- You must administer or withhold in the context of the patient's condition (e.g. digoxin not usually to be given if pulse below 60) and co-existing therapies e.g physiotherapy.
- You must contact the prescriber or another authorised prescriber without delay where contra-indications to the prescribed medicine are discovered, where the patient develops a reaction to the medicine, or where assessment of the patient indicates that the medicine is no longer suitable (See Standard 25).
- You must make a clear, accurate and immediate record of all medicine administered, intentionally withheld or refused by the patient, ensuring the signature is clear and legible; it is also your responsibility to ensure that a record is made when delegating the task of administering medicine.

In addition:

- Where medication is not given the reason for not doing so must be recorded.
- You may administer with a single signature any Prescription Only Medicine (POM), general sales List (GSL) or Pharmacy (P) medication.

In respect of Controlled Drugs:

- These should be administered in line with relevant legislation and local Standard Operating Procedures.
- It is recommended that for the administration of Controlled Drugs a secondary signatory is required within secondary care and similar healthcare settings.
- In a patient's home, where a registrant is administering a Controlled Drug that has already been prescribed and dispensed to that patient, obtaining a secondary signatory should be based on local risk assessment.
- Although normally the second signatory should be another registered health care professional (for example doctor, pharmacist, dentist) or student nurse or midwife, in the interest of patient care, where this is not possible a second suitable person who has been assessed as competent may sign. It is good practice that the second signatory witnesses the whole administration process. For Guidance, go to: www.dh.gov.uk and search for Safer Management of Controlled Drugs: Guidance on Standard Operating Procedures.
- In cases of direct patient administration of oral medication e.g. from stock in a substance misuse clinic, it must be a registered nurse who administers, signed by a second signatory (assessed as competent), who is then supervised by the registrant as the patient receives and consumes the medication.
- You must clearly countersign the signature of the student when supervising a student in the administration of medicines.

These standards apply to all medicinal products.

Guidance

Assessing competence to support a patient in taking their medication.

A policy must be in place and adhered to in assessing the competence of an individual to support a patient in taking medication. A record of the individual's training and assessment should be kept and all refresher or continuing education and training should also be routinely kept. The registrant delegating should be satisfied that the individual has an appropriate level of education and training and has been assessed as competent. Where this is not the case the registrant may refuse to delegate, even when requested to do so by another health professional. The registrant is accountable for her own actions including delegation.

Clarifying identity

Where there are difficulties in clarifying an individual's identity e.g. in some areas of learning disabilities, patients with dementia or confusional states, an up-to-date photograph should be attached to the prescription chart/s. For patients with burns where the wearing of a wristband is inappropriate and a photograph would not resemble the patient, local policies should be in place to ensure all staff are familiar with the patients and a system of identification is in place. Registrants are responsible for ensuring the photograph remains up-to-date.

Drug calculations

Some drug administrations can require complex calculations to ensure that the correct volume or quantity of medication is administered. In these situations, it is good practice for a second practitioner (a registered professional) to check the calculation independently in order to minimise the risk of error. The use of calculators to determine the volume or quantity of medication should not act as a substitute for arithmetical knowledge and skill.

The Standards

Standards for practice of administration of medicines

Standard 9

As a registrant you are responsible for the initial and continued assessment of patients who are self-administering and have continuing responsibility for recognising and acting upon changes in a patient's condition with regards to safety of the patient and others.

The NMC welcomes and supports the self-administration of medicinal products and the administration of medication by carers wherever it is appropriate. Registrants may assess the patients as suitable to self-administer medicinal products both in the hospital and primary care settings.

Duty of care relating to using patients' own medicinal products.

Guidance

At all times the registrant jointly with other health care professionals has a duty of care to the patient to ensure that only medicinal products which are prescribed and meet the required criteria are used by the patient.

Where self-administration of medicinal products is taking place, you should ensure that records are maintained appropriate to the environment in which the patient is being cared for. The Mental Capacity Act 2005 requires all those working with potentially incapacitated people to assess the individual's capacity at a particular moment about a particular decision/issue. All patients should be assessed on a regular basis using local policies to ensure that the individual patient is still able to self-administer and this should be documented in their records.

Patients can be assessed for suitability at the following levels:

Level 1
The registrant is responsible for the safe storage of the medicinal products and the supervision of the administration process ensuring the patient understands the medicinal product being administered.

Level 2
The registrant is responsible for the safe storage of the medicinal products. At administration time the patient will ask the registrant to open the cabinet/locker. The patient will then self-administer the medication under the supervision of the registrant.

Level 3
The patient accepts full responsibility for the storage and administration of the medicinal products. The registrant checks the patient's suitability and compliance verbally.

The level should be documented in the patient's notes.

Guidance

Where patients consent to self-administration of their medicines the following points should be considered:

1. Patients share the responsibility for their actions relating to self-administration of their medicines.

2. Patients can withdraw consent at any time.

3. The pharmacy will supply medicines fully labelled, with directions for use, to every patient who is involved in self-administration.

Information given and supervision should be tailored to individual patient need.

The following information should be provided to a patient **before** commencing self-administration:

- the name of the medicine
- why they are taking it
- dose and frequency
- common side effects and what to do if they occur
- any special instructions
- duration of the course or how to obtain further supplies

The registrant must ensure that the patient is able to open the medicine containers or is offered assistance e.g. compliance aid.

Whilst the registrant has a duty of care towards all patients the registrant is not liable if a patient makes a mistake self-administering as long as the assessment was completed as the local policy describes and appropriate actions were taken to prevent re-occurrence of the incident.

Guidance on exclusion criteria for self-administration of medicines can be found in Annexe 4.

Self-administration – children and young people environments

Standard 10

In the case of children, when arrangements have been made for parents/carers or patients to administer their own medicines prior to discharge or rehabilitation, the registrant should ascertain that the medicinal products have been taken as prescribed.

Guidance

This should preferably be done by direct observation but when appropriate also by questioning the patient/parent/carer. The administration record should be initialled and 'patient self-administration' documented.

The administration of medicinal products by parents/carers to their children must be carefully controlled. There is the potential for inadvertent omission of doses or administration of extra doses unless there is clear communication and documentation.

Parents/carers can be encouraged to administer to their children in whatever setting when this is appropriate to the clinical condition of the child and when the registrant has assessed that the parent/carer is competent to do so. In a hospital setting the registrant should provide the medicinal product from the appropriate storage and supervise administration.

Unsupervised administration to children

Some parents/carers may administer to their children unsupervised if this has been agreed with the Registrant in Charge and if the medicinal products are stored in an appropriate secure locker. Responsibilities of the registrant and parent/carer must be specifically agreed and approved by the Registrant in Charge and agreed under local policies. Arrangements must be made for holding keys to the locker and for ensuring their return on discharge and that any medicinal products remaining are supplied for discharge (if appropriately labelled and checked) or returned to the pharmacy.

The employing organisation should ensure appropriate clinical governance structures are in place.

The Standards

Administering medication from a remote prescription/direction to administer

Standard 11

In exceptional circumstances, where medication (NOT including Controlled Drugs) has been previously prescribed and the prescriber is unable to issue a new prescription, but where changes to the dose are considered necessary, the use of information technology (such as fax, text message or email) may be used but must confirm any change to the original prescription.

Guidance

A verbal order is not acceptable on its own. The fax or email prescription/direction to administer must be stapled to the patient's existing medication chart. This should be followed up by a new prescription signed by the prescriber who sent the fax/email confirming the changes within normally a maximum of 24 hours (72 hours maximum – Bank Holidays and weekends). In any event, the changes must have been authorised (via text, email or fax) by a registered prescriber before the new dosage is administered. The registered nurse should request the prescriber to confirm and sign changes on the patient's individual MAR (medicines administration record) chart or care plan.

Where a medication has not been prescribed before, a nurse or midwife independent prescriber may not prescribe remotely if s/he has not assessed the patient, except in life threatening situations. See Standard 20 of the Standards of Proficiency for Nurse Midwife Prescribers at
www.nmc-uk.org/aArticle.aspx?ArticleID=2021

In exceptional circumstances a medical practitioner may need to prescribe remotely for a previously unprescribed medicine e.g. in palliative care or remote and rural areas the use of information technology (such as fax, text message or email) must confirm the prescription before it is administered. This should be followed up by a new prescription signed by the prescriber who sent the fax/email confirming the changes within normally a maximum of 24 hours (72 hours maximum – Bank Holidays and weekends). The registrant is accountable for ensuring all relevant information has been communicated to the prescriber and s/he may refuse to accept a remote

prescription if it compromises care to the patient. In this instance she should document accurately the communication that has taken place. Registrants should note that remote prescribing cannot be undertaken in a care home because they do not have access to a stock of medicines.

nb. A prescription is required when the drug is to be both supplied and administered. For administration only, a direction to administer is sufficient.

It may be helpful to refer to the GMC Good Medical Practice Guide for further information available on the GMC website.

Text messaging

Standard 12

As a registrant, you must ensure that there are protocols in place to ensure patient confidentiality and documentation of any text received include: complete text message, telephone number (it was sent from), the time sent, any response given, and the signature and date when received by the registrant.

Guidance

An order to administer medication by text messaging is an increasing possibility. A second signature – normally another registrant but where this is not possible another person – should sign to confirm the documentation agrees with the text message. It must be regarded as a patient contact and all documentation should be in keeping with the NMC **Guidelines on Record Keeping** (NMC 2005). All received messages should be deleted from the receiving handset after documentation to maintain high standards of confidentiality. Further advice may be helpful including RCN – **Use of text messaging services; Guidance for nurses working with children and young people (March 2006).**

Wherever possible local policies should ensure the use of web-based products for texting that are secure and provide a robust audit trail, clinical governance procedures should be in place to support such practice.

Titration

Standard 13

Where medication has been prescribed within a range of dosages it is acceptable for registrants to titrate dosages according to patient response and symptom control and to administer within the prescribed range.

Guidance

A registrant must be competent to interpret test results e.g. blood results (heparin or glucose levels (insulin)), and assess for example withdrawal symptoms or signs of intoxication in the management of drug or alcohol withdrawal.

Preparing medication in advance

Standard 14

Registrants must not prepare substances for injection in advance of their immediate use or to administer medication drawn into a syringe or container by another practitioner when not in their presence.

Guidance

An exception to this is an already established infusion, which has been instigated by another practitioner following the principles, set out above, or medication prepared under the direction of a pharmacist from a central intravenous additive service and clearly labelled for that patient. Where the specific summary of product characteristic/patient information leaflet indicate it should be prepared in advance e.g. some chemotherapy treatments, it is acceptable to do so.

Where a registrant has delegated to a named individual for a named patient's medication, this may be drawn up in advance to enable the healthcare assistant (HCA) or family to administer the medication. The registrant is accountable for the delegation and a full risk assessment should be documented in the patient's records ensuring the registrant is aware of the risks before agreeing to delegate. The person to whom they are delegating the task is a "named individual" who has been assessed and documented as competent.

Where you may be required to prepare substances for injection by a doctor, e.g. in an emergency situation, you should ensure that the person administering the drug has undertaken the appropriate checks as indicated above.

Medication acquired over the internet

Standard 15

Registrants should never administer any medication that has not been prescribed, or acquired over the internet without a valid prescription.

Guidance

Medication over the internet may not have been stored appropriately, the quality and safety of the medication cannot be verified and there is often no batch number and so no redress from the manufacturer should adverse reactions occur.

nb. Registered pharmacy premises can operate and provide internet pharmacy services. Where medicines are supplied via the internet from a registered pharmacy, the same standards are expected as would be received in a face-to-face situation.

Patient's own medication that has been purchased abroad and does not have a UK product licence.

In this situation a registrant must seek to identify the source of the original prescription to confirm its authenticity. Where this is not possible the registrant should ascertain whether or not the patient would be prepared to have prescribed for them a drug with similar properties that is licensed in the UK. If the patient is in agreement the registrant should request a prescription from a registered prescriber.

In a life threatening situation or where the patient refuses to take anything but the "unlicensed product" and he or she is unable to administer the medication him/herself the registrant may administer the medication in conjunction with locally agreed policies. In all circumstances a clear, accurate and contemporaneous record of all communication and administration of medication should be maintained.

Aids to support compliance

Standard 16

Registrants must assess the patient's suitability and understanding of how to use an appropriate compliance aid safely.

Guidance

Before considering the use of compliance aids the registrant should explore with the patient other possible solutions, for example reminder charts, large print labels, non-childproof tops. Self-administration from the dispensed containers may not always be possible for some patients. If an aid to compliance is considered necessary, careful attention should be given to the assessment of the patient's suitability and understanding of how to use an appropriate aid safely. Ideally a locally recognised assessment tool should be used. However, all patients will need to be regularly assessed for continued appropriateness of the aid. Ideally, any compliance aid, such as a monitored dose container or a daily/weekly dosing aid, should be dispensed, labelled and sealed by a pharmacist. The sealed compliance aids are generally referred to as monitored dosage systems.

Where it is not possible to get a compliance aid filled by a pharmacist, you should ensure that you are able to account for its use. The patient has a right to expect that the same standard of skill and care will be applied by you in dispensing into a compliance aid as would be applied if the patient were receiving the medication from a pharmacist. This includes the same standard of labelling and record keeping. Compliance aids, which can be purchased by patients for their own use, are aids that are filled from containers of dispensed medicines. If you choose to repackage dispensed medicinal products into compliance aids, you should be aware that their use carries a risk of error. You should also be aware the properties of the drug might also change when repackaged and so may not be covered by their product licence. Your employer needs to be aware of this activity and it should be covered by a SOP (Standard Operating Procedure) The NMC would recommend that you confirm the appropriateness of re-packaging dispensed medicinal products with the community pharmacist who dispensed the medicines. You also need to consider how the patient will cope with medicines that cannot be included in compliance aids.

Crushing Medication

The mechanics of crushing medicines may alter their therapeutic properties rendering them ineffective and are not covered by their product licence. Medicinal products should not routinely be crushed unless a pharmacist advises that the medication is not compromised by crushing, and crushing has been determined to be within the patient's best interest.

Disguising Medication

As a general principle, by disguising medication in food or drink, the patient or client is being led to believe they are not receiving medication, when in fact they are. The NMC would not consider this to be good practice. The registrant would need to be sure what they are doing is in the best interests of the patient, and that they are accountable for this decision. See the NMC A–Z of advice for further information at www.nmc-uk.org

The Standards

Delegation

Standard 17

A registrant is responsible for the delegation of any aspects of the administration of medicinal products and they are accountable to ensure that the patient or carer/care assistant is competent to carry out the task.

Guidance

This will require education, training and assessment of the patient or carer/care assistant and further support if necessary. The competence of the person to whom the task has been delegated should be assessed and reviewed periodically. Records of the training received and outcome of any assessment should be clearly made and be available.

See Guidance Section 4, Standard 8.

The Standards

Student nurse and student midwives

Standard 18

Students must never administer/supply medicinal products without direct supervision.

Guidance

In order to achieve the outcomes and standards required for registration, students must be given opportunities to participate in the administration of medication but this must always be under direct supervision. Where this is done, both the student and registrant must sign the patient's/woman's medication chart or document in the notes. The registrant is responsible for delegating to a student and where it is considered the student is not yet ready to undertake administration in whatever form this should be delayed until such time that the student is ready. Equally a student may decline to undertake a task if they do not feel confident enough to do so. The relationship between the registrant and the student is a partnership and the registrant should support the student in gaining competence in order to prepare for registration. As students progress through their training their supervision may become increasingly indirect to reflect their competence level.

Unregistered practitioners

Standard 19

In delegating the administration of medicinal products to unregistered practitioners, it is the registrant who must apply the principles of administration of medicinal products as listed above. They may then delegate an unregistered practitioner to assist the patient in the ingestion or application of the medicinal product.

Guidance

Registrants may only delegate the ingestion or application of a Controlled Drug where the unregistered practitioner remains under the direct supervision of the registrant whether that is in a primary care, secondary care or independent sector setting. In care homes (personal care), health care assistants/support workers/care workers will not be skilled in giving medicines by invasive techniques and appropriate delegation is essential.

In the care of children with complex needs where an individual care plan has been written and signed off by a registrant and the unregistered practitioner has been assessed by a registrant as competent to undertake the specific administration of medicinal products to a specific named patient this may be undertaken e.g. children with complex health needs in community settings, palliative care.

Intravenous medication

Standard 20

Wherever possible two registrants should check medication to be administered intravenously, one of whom should also be the registrant who then administers the IV medication.

Guidance

In the exceptional circumstance where this is not possible, IVs should be checked by one registrant with another competent person who knows the patient. This could be a parent/carer or the patient himself or herself. At a minimum any dose calculation must be independently checked.

Registrants should be aware of the risks identified in the NPSA fourth report from the Patient Safety Observatory **Safety in doses: medication safety incidents in the NHS (2007)**. Search for this report at www.npsa.nhs.uk

In relation to the administration of intravenous medication, throughout the duration of intravenous medication therapy the registered nurse or midwife has a duty of care to the patient to monitor the patient and their response. View the standards for administration of IV therapy on the RCN website at www.rcn.org.uk/

Registrants should also be familiar with the UK Injectable Medicines Guide currently under development at www.ukmi.nhs.uk/

Disposal of medicinal products

Standard 21

A registrant must dispose of medicinal products in accordance with legislation.

Guidance

A patient or their representative (who may be a registered nurse or midwife) should return unwanted prescribed medicinal products to a pharmacy for destruction. In primary care unwanted medication should be returned to a community pharmacy where it can be consigned as medicinal waste – classified as "household waste". The definition of ”household waste” is taken from the Controlled Waste Regulations 1992 and includes waste medicines from a patient’s own home and waste medicines from a residential care home. The definition does not extend to stock medicines from other healthcare professionals e.g. midwives, nurses or doctors. There should be local procedures in hospital for the disposal of medicinal waste often overseen by the pharmacy department. If medication is taken to another health care environment it then becomes clinical waste and must be disposed of in accordance with Clinical Waste Regulations. A community pharmacy cannot legally accept prescription medicines for disposal from care homes registered to provide nursing care or from care homes that provide both residential and nursing care. In this situation the care home (nursing) has to make its own arrangements for disposing of medication with a licensed waste management company. When a midwife is in possession of Controlled Drugs (CD) that are no longer required they should be returned to the pharmacist from whom they were obtained, or to an Appropriate Medical Officer. A record of the return should be made in the midwife’s controlled drugs register. When a Schedule 2 CD has been prepared/drawn up but is no longer required, and/or no longer usable, it should be destroyed by the midwife, in accordance with current regulations.

The Standards

Unlicensed medicines

Standard 22

A registrant may administer an unlicensed medicinal product with the patient's informed consent against a patient-specific direction but NOT against a patient group direction.

Guidance

An unlicensed medicine is the term used to refer to a medicine that has no marketing authorisation. If an unlicensed medicine is administered to a patient, the manufacturer may not have liability for any harm that ensues. The person who prescribes and dispenses/supplies the medicine carries the liability. This may have implications for you in obtaining informed consent.

Medicinal products used outside their licence

Medication which is licensed but used outside its licensed indications (commonly known as "off-label") may be administered under a patient group direction only where such use is exceptional, justified by best practice, and the status of the product is clearly described.

As a registrant, you should be satisfied that you have sufficient information to administer a medicine prescribed "off label" safely and, wherever possible, that there is acceptable published evidence for the use of that product for the intended indication.

As a registrant, you should be satisfied that you have sufficient information to administer an unlicensed or "off label" drug safely and, wherever possible, that there is acceptable published evidence for the use of that product for the intended indication. Liability for prescribing an off-label product sits with the prescriber and the dispenser/supplier.

The **British National Formulary** for children provides useful information for the administration of off-label medication for children. More information on unlicensed and off-label drugs can be found in the NMC publication **Standards of Proficiency for Nurse Midwife Prescribers 2006**, which can be viewed at:
www.nmc-uk.org/aArticle.aspx?ArticleID=2021

Complementary and alternative therapies

Standard 23

Registrants must have successfully undertaken training and be competent to practise the administration of complementary and alternative therapies.

Guidance

Registrants are accountable for their practise and must be competent in this area (please refer to **The NMC code of professional conduct: standards for conduct, performance and ethics**.) You must have considered the appropriateness of the therapy to both the condition of the patient and any co-existing treatments. It is essential that the patient is aware of the therapy and gives informed consent.

Complementary and alternative therapies may interact with other types of medicinal products and laboratory tests. All complementary and alternative medicines should be recorded alongside other medicinal products and prescribed on inpatient prescription charts. You need to ensure that your employer has accepted vicarious liability for any complementary/alternative therapy you may undertake or that you have indemnity insurance to cover your practice.

The Standards

Management of adverse events (errors or incidents) in the administration of medicines

Standard 24

As a registrant, if you make an error you must take any action to prevent any potential harm to the patient and report as soon as possible the prescriber, your line manager or employer (according to local policy) and document your actions. Midwives should also inform their named Supervisor of Midwives.

Guidance

The NMC supports the use of a thorough, open and multi-disciplinary approach to investigating adverse events, where improvements to local practice in the administration of medicinal products can be discussed, identified and disseminated.

It is important that an open culture exists in order to encourage the immediate reporting of errors or incidents in the administration of medicines.

The NMC believes that all errors and incidents require a thorough and careful investigation at a local level, taking full account of the context and circumstances and the position of the practitioner involved. Such incidents require sensitive management and a comprehensive assessment of all the circumstances before a professional and managerial decision is reached on the appropriate way to proceed. If a practising midwife makes or identifies a drug error or incident, she should also inform her Supervisor of Midwives as soon as possible after the event. In the NHS all errors (patient safety incidents) and near misses should be reported through local risk management systems. In England and Wales you should then report the incident to the National Patient Safety Agency (NPSA) through the National Reporting and Learning System (NRLS), whereas in Northern Ireland you should report to the Northern Ireland Adverse Incident Centre and in Scotland through the NHS Quality Improvement Scotland (NHSQIS).

When considering allegations of misconduct arising from errors in the administration of medicines, the NMC takes great care to distinguish between those cases where the error was the result of reckless or incompetent practice and/or was concealed, and those that resulted from other causes, such as serious pressure of work, and where there was immediate, honest disclosure in the patient's interest. The NMC recognises

the prerogative of managers to take local disciplinary action where it is considered to be necessary but urges that they also consider each incident in its particular context and similarly discriminate between the two categories described above. Registrants and their managers may find the NPSA's Incident Decision Tree Tool and Being Open Tool (details on www.npsa.nhs.uk and/or www.saferhealthcare.org.uk) useful. Allegations related to midwives would also be investigated by a Supervisor of Midwives as set out in the NMC **Midwives rules and standards: rule 5**.

Reporting adverse reactions

Standard 25

As a registrant, if a patient experiences an adverse drug reaction to a medication you must take any action to remedy harm caused by the reaction. You must record this in the patient's notes, notify the prescriber (if you did not prescribe the drug) and notify via the Yellow Card Scheme immediately.

Guidance

Yellow cards are found in the back of the **British National Formulary** and online on www.yellowcard.gov.uk/ In addition you should report any near misses or adverse events to the National Patient Safety Agency. For further information read the BNF or access the Medicines and Healthcare Products Regulatory Agency website www.mhra.gov.uk/ Adverse drug reactions and patient safety incidents involving medicines, where a side effect (adverse drug reaction) from a medicine was preventable and still occurred, should be reported as a patient safety incident (error) through local risk management systems to the NPSA National Reporting and Learning System (NRLS).

Controlled Drugs

Standard 26

Registrants should ensure that patients prescribed Controlled Drugs are administered these in a timely fashion in line with the standards for administering medication to patients. Registrants should comply with and follow the legal requirements and approved local Standard Operating Procedures for Controlled Drugs that are appropriate for their area of work.

Guidance

Medicines management for Controlled Drugs
Standards for medicines management apply to Controlled Drugs, however, following the government response to the fourth report of the Shipman Inquiry, there has been legislative change and new governance arrangements for Controlled Drugs (CDs), which impact on registrants. Registrants should be familiar with the DH guide **Safer Management of Controlled Drugs 2006** and the DH document **Guidance on the Management of Safe Use and Management of Controlled Drugs in Secondary Care in England Controlled Drugs in Acute Care 2007**.

Go to www.dh.gov.uk and search: Controlled Drugs

Changes affecting the prescribing, record keeping and destruction of Controlled Drugs were introduced as a result of amendments to the Misuse of Drugs Regulations (MDR, 2001), Misuse of Drugs regulations (Northern Ireland), 2002, thereafter referred to as Misuse of Drugs Regulations (MDR), and the Health Act (2006), provided for regulations to be laid relating to governance and monitoring of Controlled Drugs.

The Health Act 2006 is primary legislation and applies to the whole of the UK although the Regulations may differ in each of the devolved administrations. In England the Controlled Drugs (Supervision of Management and Use) Regulations 2006 came into force on 1 January 2007 and in Scotland on 1 March 2007.

Go to www.dh.gov.uk and search: The Controlled Drugs (Supervision of Management and Use) Regulations 2006.

Within the provisions of the Act, Wales and Northern Ireland will make their own regulations in relation to controlled drugs. These will be equivalent to the Controlled Drugs (Supervision of Management and use of) Regulations 2006.

Controlled Drugs are those defined in the MDR (2001) and MDR Regulations, 2002 (NI). See Annexe 1. However, on occasions, health care organisations choose to handle non-CDs in the same way as CDs to ensure a higher level of governance. This is a local decision and does not form part of this guidance, although registrants are reminded they should adhere to local policies where they exist.

At local level, all healthcare organisations are accountable, through the Accountable Officer, (Not applicable to Wales or Northern Ireland until legislation comes into effect until at least 2008) for ensuring the safe management of Controlled Drugs.

The regulatory requirements for Accountable Officers are set out in full in the Controlled Drugs (Supervision and Management of Use) Regulations 2006; www.opsi.gov.uk and a summary of the main provisions is provided at Appendix 2 of the DH **Guidance on the Management of Controlled Drugs in Acute Care 2007**.

Standard Operating Procedures

Each of the activities concerned with CDs, regardless of where in an organisation they occur, must be described in a Standard Operating Procedure (SOP). Registrants should be aware of all SOPs within their organisation.

Requisitioning of Controlled Drugs

1. All stationery which is used to order, return or distribute Controlled Drugs (CD stationery) must be stored securely and access to it should be restricted.
2. CD stationery should be kept in a locked cupboard or drawer.
3. There should be a list of the CDs to be held in each ward or department as stock items. The contents of the list should reflect current patterns of usage of CDs in the ward or department and should be agreed between the senior pharmacist, appropriate medical staff and the Registrant in Charge.
4. Only the CDs listed in the stock list may be routinely requisitioned or topped-up.
5. The Registrant in Charge of a ward, department, operating theatre or theatre suite is responsible for the requisitioning of Controlled Drugs for use in that area.

6. The Registrant in Charge can delegate control of access (i.e. key-holding) to the controlled drugs cabinet to another, such as a registered nurse or operating department practitioner. However, legal responsibility remains with the Registrant in Charge. (In NI it is not possible to delegate key holding to another but they may allow access via the keys which are then returned to the Registrant in Charge. This may change September 2007, post consultation.)
7. Orders must be written on suitable stationery (e.g. a Controlled Drug requisition book) and must be signed by an authorised signatory.
8. A copy of the signature of each authorised signatory should be available in the pharmacy department for validation

Requisitions must contain the following:

- hospital
- ward/department
- drug name, form, strength, ampoule size if more than one available
- quantity
- signature and printed name of nurse
- date
- signature to receive goods for transit
- signature for receipt at ward or department

Receipt of Controlled Drugs

When CDs are delivered to a ward or department they should be handed to a designated person. On no account should they be left unattended. A local procedure should define the persons who are permitted to receive CDs and the way in which messengers identify them.

As soon as possible after delivery the Registrant in Charge should:

- Check the CDs against the requisition – including the number ordered and received. If this is correct then the relevant (usually pink) sheet in the Controlled Drug Requisition Book should be signed in the "received by" section.
- Place the CDs in the CD cupboard

- Enter the CDs into the ward Controlled Drug Record Book, update the running balance and check that the balance tallies with the quantity that is physically present.

Storage

The Misuse of Drugs (Safe Custody) Regulations 1973 cover the safe custody of Controlled Drugs in certain specified premises. The regulations also set down certain standards for safes and cabinets used to store Controlled Drugs.

Ward CD cupboards should conform to the British Standard reference BS2881 or be otherwise approved by the pharmacy department. This is a minimum security standard and may not be sufficient for areas where there are large amounts of drugs in stock at a given time, and/or there is not a 24-hour staff presence, or easy control of access. In this case the advice of security specialists or crime prevention officers should be sought.

All Controlled Drugs should be stored in a locked receptacle which can only be opened by a person who can lawfully be in possession, such as a pharmacist or Registrant in Charge, or a person working under their authority.

General guidance for the storage of Controlled Drugs should include the following:

- Cupboards must be kept locked when not in use.
- The lock must not be common to any other lock in the hospital.
- Keys must only be available to authorised members of staff.
- The cupboard must be dedicated to the storage of controlled drugs. No other medicines or items may be stored in the controlled drug cupboard. Controlled Drugs must be locked away when not in use.

Key-holding and access to CDs

- The Registrant in Charge is responsible for the CD key and should know its whereabouts at all times.
- Key-holding may be delegated to other suitably trained members of staff but the legal responsibility rests with the Registrant in Charge.
- The Controlled Drug key should be returned to the Registrant in Charge immediately after use by another registered member of staff.

- On occasions, for the purpose of stock checking, the CD key may be handed to an authorised member of the pharmacy staff.

Northern Ireland registrants: see bullet point six "Requisitioning Controlled Drugs" above.

Missing CD keys
If the CD keys cannot be found then urgent efforts should be made to retrieve the keys as speedily as possible e.g. by contacting nursing or midwifery staff who have just gone off duty.

A procedure should be in place to ensure that the Registrant in Charge or duty nurse manager and the duty pharmacist are informed as soon as possible. The procedure should specify the arrangements for preserving the security of CD stocks and for ensuring that patient care is not impeded

Record-keeping – Controlled Drug record books
Each ward or department that hold stocks of CDs should keep a record of CDs received and issued in a CD record book. In primary care the relevant patient drug record card (where used) or CD Record Card for the administration of Controlled Drugs should be used. The Registrant in Charge is responsible for keeping the CD record book up to date and in good order.

The CD record book (acute care) should be bound (not loose-leaf), and it should have separate pages for each preparation. Entries should be made in chronological order, in ink. If a mistake is made it should be crossed out with a single line or bracketed in such a way that the original entry is still clearly legible. This should be signed and dated and witnessed by a second registered nurse or midwife who should also sign the change.

A record should be kept of all (schedule 2) Controlled Drugs that are received or issued.

All entries must be signed by two registrants or one registrant and one student nurse or midwife (for administration only). Exceptionally, the second signature can be by another practitioner (e.g. doctor or pharmacist) provided that they have witnessed the administration of the drug.

For CDs received, the following details should be recorded:

- date on which received

- name of pharmacist making supply/serial number of requisition
- amount received
- form in which received
- balance in stock

For CDs issued the following details should be recorded:

- date on which issue was made
- name of patient
- amount issued
- form in which issued
- name/signature of nurse/authorised person making the issue
- name/signature of witness
- balance in stock

If part of a vial is given to the patient, then the registrant should record the amount given and the amount wasted e.g. if the patient is prescribed a diamorphine 2.5mg and only a 5mg preparation is available, the record should show, **"2.5mg given and 2.5mg wasted"**.

After every administration, the stock balance of an individual preparation MUST be confirmed to be correct and the balance recorded in the Controlled Drug register.

In the community where there may not be two registrants available a second competent person (which may be the carer) may witness the administration and balance of a Controlled Drug.

When recording Controlled Drugs received from pharmacy, the number of units received should be recorded in words not figures (e.g. ten, not 10) to reduce the chance of entries being altered. On reaching the end of a page in the CD record book, the balance must be transferred to another page. The new page number must be added to the bottom of the finished page and the index updated.

Stock Checks
The Registrant in Charge is responsible for ensuring that regular (locally determined protocol) CD stock checks are carried out.

Two registered nurses or midwives, should perform this check (a student nurse or midwife may be the second checker provided they have the necessary knowledge to carry this out).

Checking of Controlled Drugs involves checking of entries in the register against the contents of the Controlled Drug cupboard, not the reverse, to ensure all entries are checked. It is not necessary to open packs with intact tamper-evident seals for stock checking purposes.

A record indicating this check has been carried out and confirming the stock is correct may be kept in a separate record book/sheet or in the Controlled Drug register.

Stock balances of liquid medicines may be checked by visual inspection but the balance must be confirmed to be correct on completion of a bottle. Any discrepancy should be reported to the Registrant in Charge who should inform the pharmacist.

Midwives and Controlled Drugs

A registered midwife may possess diamorphine, morphine, pethidine and pentazocine in her own right so far as is necessary for the practice of her profession. See the Misuse of Drugs Regulations 2001 at www.opsi.gov.uk/si/si2001/20013998.htm

Supplies of diamorphine, morphine, pethidine and pentazocine may only be made to her on the authority of a midwife's supply order signed by the Supervisor of Midwives, or other Appropriate Medical Officer who is a doctor authorised in writing by the local supervising authority.

The Supervisor of Midwives or other Appropriate Medical Officer should be satisfied that locally agreed procedure is being followed before signing the supply order (e.g. that the amount being requested is appropriate etc).

The order must specify the name and occupation of the midwife, the purpose for which the Controlled Drug is required and the total quantity to be obtained. Supplies of pethidine, pentazocine, morphine and diamorphine may be obtained from a hospital pharmacy. However, this is only when classed as within the course of the business of the hospital the midwife works in, or it is a registered hospital pharmacy, or it holds a wholesale dealer's licence. The pharmacist who makes the supply should ensure that medicines are only supplied on the instruction of an authorised person. The pharmacist must retain the midwife's supply order for two years.

Midwives should record full details of supplies of diamorphine, morphine and

pethidine received and administered in their Controlled Drugs Register. This register should be used solely for that purpose and be made available for inspection as required by the Supervisor of Midwives.

Once medicines are received – by midwives working in the community or independent midwives – they become the responsibility of the midwife, and should be stored safely and securely.

Where it is necessary for midwives to keep medicines in their homes, the medicines should be placed in a secure, locked receptacle. If necessary, this should be provided by the employing body.

Administration of Controlled Drugs by midwives should be in accordance with locally agreed procedures. A record of administration of the Controlled Drugs should also be kept in the patient's records.

Returns and disposal

When a midwife is in possession of CDs that are no longer required they should be returned to the pharmacist from whom they were obtained, or to an Appropriate Medical Officer. A record of the return should be made in the midwife's Controlled Drugs Register.

When a Schedule 2 Controlled Drug has been prepared/drawn up but is no longer required, and/or no longer usable, it should be destroyed by the midwife, in accordance with current regulations. A record of the destruction should be made.

Controlled Drugs obtained by a woman by prescription from her doctor, for use in her home confinement are her own property and are not the midwife's responsibility. Even when no longer required, they should not be removed by the midwife, but the woman should be advised to return them to the community pharmacy for destruction.

Returns to pharmacy (all registrants)

The following details should be recorded when controlled drugs are returned to the pharmacy:

- date
- name, form, strength and quantity of drug being returned
- reason for return
- name and signature of pharmacist removing the drugs

- name and signature of nurse witnessing the removal of drugs from the ward

The top copy will be taken from the book and transported with the drugs to pharmacy.

In addition, an entry must be made on the relevant page of the ward Controlled Drug record book, showing:

- date
- reason for return
- names and signatures of both nurse and pharmacist
- quantity removed
- balance remaining

The drugs must be transported to pharmacy in a safe and secure way.

Transport of CDs

At each point where a Controlled Drug moves from the authorised possession of one person to another, a signature for receipt should be obtained by the person handing over the drug.

Wherever possible, CDs must be transported in a secure, lockable or sealed, tamper-evident container.

Registrants working in the community may transport CDs, however, they should present their identity badge to the pharmacist and sign for them on receipt and should ensure they are transported securely to the patient's home. Once in the patient's home, the registrant should sign the Patient Drug Record Card and it should be witnessed that the CD has been received by the patient. Where a second registrant is not available another competent person may witness receipt (this could be a carer).

Disposal/destruction

- Destruction on ward may take place at the same time as a pharmacy stock check.
- CDs should be destroyed in such a way that the drug is denatured or destroyed so that it cannot be retrieved, reconstituted or used.
- Destruction must occur in a timely fashion, so that excessive quantities are not stored awaiting destruction.
- All destruction must be documented in the appropriate section of the register.

- It must be witnessed by a second competent professional authorised under regulation 27 of the MDR. Both persons must sign the register.

For more detail on the methods of destruction for CDs, registrants are advised to access Table 2 of the Guidance on Controlled Drugs in Acute Care (2007), which summarises where CDs may be destroyed and who should carry out the destruction.

For guidance, go to: www.dh.gov.uk and search for Safer Management of Controlled Drugs: Guidance on Standard Operating Procedures.

Annexes

Legislation

Annexe 1

There are a number of pieces of legislation that relate to the prescribing, supply, storage and administration of medicines. It is essential that you comply with them. The following is a summary of those that are of particular relevance.

Medicines Act 1968

This was the first comprehensive legislation on medicines in the United Kingdom. The combination of this primary legislation and the various statutory instruments (secondary legislation) on medicines produced since 1968 provides the legal framework for the manufacture, licensing, prescribing, supply and administration of medicines. Among recent statutory instruments of particular relevance to registered nurses, midwives and specialist community public health nurses is **The Prescription Only Medicines (Human Use) Order 1997, SI No1830**. This consolidates all previous secondary legislation on Prescription Only Medicines and lists all of the medicines in this category. It also sets out who may prescribe them. The sections on exemptions are of particular relevance to midwives, including those in independent practice, and to nurses working in occupational health settings. The Medicines Act 1968 classifies medicines into the following categories:

Prescription Only Medicines (POMs)

These are medicinal products that may only be sold or supplied to a patient on the instruction of an appropriate practitioner. An appropriate practitioner is a doctor, dentist, supplementary prescriber or nurse or pharmacist independent prescriber. For more information on the appropriate use of medicines and the relevant legislation it is advisable to consult with a pharmacist. The RPSGB can also provide more detailed information on medicines legislation.

Pharmacy Only Medicines (Ps)

These can only be purchased from a registered pharmacy. The sale must be by or under the supervision of a pharmacist.

General sales list medicines (GSLs)

These need neither a prescription nor the supervision of a pharmacist and can be obtained from retail outlets.

Controlled Drugs (CDs)

The management of controlled drugs is governed by the Misuse of Drugs Act 1971 and its associated regulations.

Misuse of Drugs Act 1971

The Misuse of Drugs Act (MDA) 1971 and its associated regulations provide the statutory framework for the control and regulation of Controlled Drugs. The primary purpose of the MDA is to prevent misuse of CDs. The MDA 1971 makes it unlawful to possess or supply a Controlled Drug unless an exception or exemption applies. A Controlled Drug is defined as any drug listed in Schedule 2 of the Act.

Additional statutory measures for the management of controlled drugs are laid down in the Health Act 2006 and its associated regulations.

Misuse of Drugs Regulations 2001 (MDR) and Misuse of Drugs Regulations Northern Ireland (NI) 2002

The use of CDs in medicine is permitted by the Misuse of Drug Regulations (MDR). The MDR classify the drugs in five schedules according to the different levels of control required (see below). Schedule 1 CDs are subject to the highest level of control, whereas Schedule 5 CDs are subject to a much lower level of control.

For practical purposes, health care staff need to be aware of the current regulations.

The MDR are periodically amended and revised. The MDR currently in force and its amendments can be found at www.opsi.gov.uk/si/si2001/20013998.htm

Schedule 1 (CD Licence)

Schedule 1 drugs include hallucinogenic drugs such as coca leaf, lysergide and mescaline. Production, possession and supply of drugs in this Schedule are limited, in the public interest, to research or other special purposes. Only certain persons can be licensed by the Home Office to possess them for research purposes. Practitioners (e.g. doctors, dentists and veterinary surgeons) and pharmacists may not lawfully possess Schedule 1 drugs except under licence from the Home Office.

The drugs listed in Schedule 1 have no recognised medicinal use although Sativex© (a cannabis based product) is exempt from the requirements for a specific licence to be held by the pharmacist or prescriber and is currently being supplied on a named-patient basis.

Schedule 2 (CD POM)

Schedule 2 includes more than 100 drugs such as the opioids, the major stimulants, secobarbital and amphetamine.

Safe custody – Schedule 2 CDs (except secobarbital) are subject to safe custody requirements (under the Misuse of Drugs Safe Custody Regulations 1973 – see below). They must be stored in a locked receptacle, such as an appropriate CD cabinet or approved safe, which can only be opened by the person in lawful possession of the CD or a

person authorised by them.

A licence is required to import or export drugs in Schedule 2.

Schedule 2 CDs may be administered to a patient by a doctor or dentist, or by any person acting in accordance with the directions of an appropriately qualified prescriber who is authorised to prescribe Schedule 2 CDs.

Nurse Independent Prescribers are currently permitted to prescribe, administer, or direct anyone to administer some CDs for specific conditions and routes of administration (under review).

Schedule 3 (CD No Register)
Schedule 3 includes a small number of minor stimulant drugs and other drugs, which are less likely to be misused than drugs in Schedule 2, or are less harmful if misused.

Safe custody – Schedule 3 CDs are exempt from safe custody requirements. Exceptions are flunitrazepam, temazepam, buprenorphine and diethylpropion, which must be stored in a locked CD receptacle within a secure environment.

Schedule 4 (CD Benzodiazepines and CD Anabolic steroids)
Schedule 4 is split into two parts.

Part 1 (CD Benzodiazepines) contains most of the benzodiazepines, plus eight other substances including zolpidem, fencamfamin and mesocarb.

Part 2 (CD Anabolic steroids) contains most of the anabolic and androgenic steroids such as testosterone, together with clenbuterol (adrenoreceptor stimulant) and growth hormones (5 polypeptide hormones).

There is no restriction on the possession of a Schedule 4 Part 2 (CD Anabolic steroids) drug when it is part of a medicinal product. However, possession of a drug from Schedule 4 Part 1 (CD Benzodiazepines) is an offence without the authority of a prescription in the required form. Possession by practitioners and pharmacists acting in their professional capacities is authorised.

Schedule 5 (CD Invoice)
Schedule 5 contains preparations of certain CDs (e.g. codeine, pholcodine, morphine), which are exempt from full control when present in medicinal products of low strengths, as their risk of misuse is reduced.

There is no restriction on the import, export, possession, administration or destruction of these preparations and safe custody regulations do not apply.

Invoices must be retained for a minimum of two years.

Misuse of Drugs (Safe Custody) Regulations 1973 Misuse of Drugs (Safe Custody) Regulations Northern Ireland 1973
The Safe Custody Regulations impose controls on the storage of Controlled Drugs. The degree of control depends on the premises within which the drugs are being stored.

All Schedule 2 and some Schedule 3 CDs should be stored securely in accordance with the MDR Regulations. These regulations state that such CDs must be stored in a cabinet or safe, locked with a key. It should be made of metal, with suitable hinges and fixed to a wall or the floor with rag bolts that are not accessible from outside the cabinet

Misuse of Drugs (Supply to Addicts) Regulations 1997 and Misuse of Drugs (Notification and Supply to Addicts (Northern Ireland) Regulations 1973
These regulations prohibit doctors from prescribing, administering or supplying diamorphine, cocaine or dipipanone for the treatment of addiction or suspected addiction except under Home Office licence. A licence is not required with such drugs for the treatment of organic disease or injury.

Prescription Only Medicines (Human Use) Order 1997
This Order sets out the requirements for a valid prescription. It also allows midwives to possess and administer diamorphine, morphine, pethidine or pentazocine in the course of their professional practice.

A number of health care professionals are permitted to supply or administer medicines generally in accordance with a patient group direction (PGD) under Medicines Act legislation. Registered nurses are permitted to supply or administer some CDs in accordance with a PGD under Misuse of Drugs legislation.
www.opsi.gov.uk/si/si2001/20013998.htm

Health Act 2006
The key provisions of the act are:

- All designated bodies such as healthcare organisations and independent hospitals are required to appoint an accountable officer.
- A duty of collaboration placed on responsible bodies, healthcare organisations and other local and national agencies including professional regulatory bodies, police forces, the Healthcare Commission and the Commission for Social Care inspection to share intelligence on Controlled Drug issues.
- A power of entry and inspection for the police and other nominated people to enter premises to inspect stocks and records of Controlled Drugs.

Controlled Drugs (Supervision of Management and Use) Regulations 2006

The Controlled Drug (supervision of management and use) regulations 2006 came into effect in England on the 1 January 2007. These regulations set out the requirements for certain NHS bodies and independent healthcare bodies to appoint an accountable officer and describe the duties and responsibilities of Accountable Officers to improve the management and use of Controlled Drugs.

The regulations also require specified bodies to co-operate with each other, including with regard to sharing of information, concerns about the use and management of Controlled Drugs, and the setting out arrangements relating to powers of entry and inspection.

Guidance on labelling/over-labelling of medicines

Annexe 2

There may be occasions when registrants are required to dispense medicinal products and it is important that they understand the requirements for labelling correctly.

General sale list medicines (GSL) are sold over the counter in containers showing the product in the box. Each medicinal product includes patient information either as a leaflet or on the packet or both.

Medicines dispensed to a patient-specific prescription must be labelled with all the required information.

Standard labelling requirements for all dispensed items:

- the name of the person to whom the medicine is to be administered
- the name and address of the person who sells or supplies the medicinal product
- the date of dispensing
- directions for use
- the words "Keep out of the reach of children" or words of direction bearing a similar meaning (e.g. Keep out of the reach and sight of children)

Medicines supplied for use under a patient group direction (PGD) are already labelled. These labels include all the standard labelling requirements apart from the patient's name and date of supply. On supplying these medicines to the patient the patient's name and date of supply must be completed. This is sometimes known as over-labelling.

Registrants are advised to access the Medicines Ethics and Practice Guide at www.rpsgb.org.uk/informationresources/downloadsocietypublications

Suitability of patient's own medicinal products for use

Annexe 3

Additional guidance to Standard 5 of this document

The registrant must check that the medicinal products are suitable for use by ensuring:

- correct packaging and labelling
- dispensing date
- expiry date
- instructions for use
- dose
- the medicinal product matches what is on the label
- the patient Information leaflet is enclosed
- correct patient name/ownership

If the registrant is in any doubt as to the suitability of any of the medicinal products they must discuss this with their line manager or the pharmacy department. The registrant must seek consent to dispose of any unwanted medicinal product or they must be returned to the patient. Every effort must be made to ensure the patient understands the correct use of medications and the consequences of taking unprescribed medicines.

Where the prescription is changed the registrant has a responsibility to ensure that the medicinal products are re-dispensed as soon as possible.

Where a medicinal product is discontinued it must be removed and with the patient's permission disposed of in the appropriate manner.

Administering medicines using the patient's own supply in the hospital/care home setting

When administering medicines from the patient's own supply the registrant must check the medicines in the locked cabinet/locker with the prescription chart and use only those medicines belonging to that named patient.

If a supply is not available medicines belonging to another patient must not be used.

Discharge of patients from hospital who have used their own supply and/or when checking medications to take home (TTOs/TTAs)

Guidance

On discharge, the registrant is responsible for ensuring the:

- The medicinal products have been clinically checked by the pharmacist.
- The medicinal products are over-labelled for the patient.
- The patient has the correct medicines, prescription or discharge summary and the supply is checked by a pharmacist/registered nurse or by two registrants if out of hours or according to local policy.
- The patient has had sufficient medicinal products prescribed, dispensed and supplied to cover a period of time to enable them to access further supplies from their usual practitioner.
- The patient is aware of any changes to their medication i.e. new medicine, dose, brand, route.
- The patient has been educated and given patient information leaflets relating to all medication whether current or new.
- The patient takes all their medicinal products home with them or has given permission to dispose of the medicines no longer prescribed.
- Where the patient wishes to retain their discontinued medicines the risk of confusion and possible under or overdose needs to be pointed out to him/her.
- In the hospital setting, if the patient has been self-administering the key is returned to the Registrant in Charge of the ward/unit before the patient is discharged or care transferred.
- If the bedside cabinet/locker key is lost the appropriate hospital policy must be followed.

Exclusion criteria for self-administration of medicines

Annexe 4

When assessing a patient's suitability for self-administration of medicines, if the assessing registrant, in his or her professional judgement, is at all unhappy to let the patient self-administer, then the patient should be excluded and reassessed at another point.

If the patient does not give consent to self-administer and other arrangements are made, information about their medicines and what to do after discharge must still be given.

Patients who may be confused must not be given custody of their medicines but may administer on levels one and two only (see Standard 9 of this document)
In the hospital setting, this includes patients who are "nil by mouth", immediately post-op and under the influence of anaesthetic agents, acutely ill patients or confused patients. The assessment should be carried out at an appropriate time in the course of the patient's admission to determine if they should be able to self-administer at a later stage i.e. when the anaesthetic agents have worn off or the acute stage of their illness is over.

Patients with a past history of drug or alcohol abuse do not have to be excluded from self-administration of their medicines but the need for extra supervision and reinforcement of education should be highlighted and documented. These patients should spend more time on levels one and two to ensure they receive adequate supervision and education. These patients may never get to administer at level 3 but they can still be educated at levels 1 and 2.

Any change in the patient's condition would necessitate a review of their self-administration status.

Local policies should be developed for this using the guidance for self-administration of medicinal products stated under Standard 9 of this document.

Registrants should be aware that the Mental Capacity Act 2005 requires all those working with potentially incapacitated people to assess the individual's capacity at a particular moment about a particular decision/issue. This would be predominantly older people and people with learning difficulties.

Administering medicinal products in research clinical trials

Annexe 5

Registrants involved in the supply or administration of a treatment or a placebo as part of a clinical trial would not need to consent to the trial itself, however, patients are required to do so. They would, however, need to know that the trial was taking place, and be willing to take part to the extent that they would be supplying/administering the medicine/placebo. The registrant's employer would need to discuss the trial with the registrant and provide an information sheet in order to ensure that they had all the information available and confirmation that ethical approval had been sought and approved.

The purpose of the trial would be to establish whether the treatment is effective. Therefore, patients taking the placebo are not being deprived of a medicine that is known to be effective. There should be no reason for a registrant to object to taking part in that they are not depriving a patient of effective treatment but rather contributing to the evidence base for effective treatment in the future.

Also see Midwives rules and Standards Rule 8 – Clinical trials, at:

www.nmc-uk.org/aArticle.aspx?ArticleID=1658

Information and advice

Annexe 6

Royal Pharmaceutical Society of Great Britain
1 Lambeth High Street
London SE1 7JN
Telephone 020 7735 9141

The Pharmaceutical Society of Northern Ireland
73 University Street
Belfast BT7 1HL
Telephone 028 90 326 927

Scottish Pharmaceutical General Council
42 Queen Street
Edinburgh EH2 3NH
Telephone 0131 467 7766

Office of the Chief Pharmacist
Department of Health
Richmond House
79 Whitehall
London SW1A 2NS
Telephone 020 7210 5761

Home Office
50 Queen Anne's Gate
London SW1H 9AP
Telephone 020 7273 3474
www.homeoffice.gov.uk

Medicines and Healthcare Products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ
Telephone 020 7084 2000
www.mhra.gov.uk

NMC Professional Advice Service
23 Portland Place
London W1B 1PZ
Telephone 020 7333 6541/6550/6553
Fax 020 7333 6538
Email advice@nmc-uk.org
Web site www.nmc-uk.org

The Association of the British Pharmaceutical Industry
12 Whitehall
London SW1A 2DY
0870 8904333

The Association of the British Pharmaceutical Industry (Scotland)
Third Floor East
Crichton House
4 Crichton's Close
Canongate
Edinburgh EH8 8DT

European Council for Classical Homeopathy at www.homeopathy-ecch.org/

Prince of Wales Foundation for Integrated Health at www.fih.org.uk/

Publications

Royal Pharmaceutical Society of Great Britain. **Medicines, Ethics and Practice: A guide for pharmacists** is published annually and is available from www.rpsgb.org.uk

National Prescribing Centre (NPC). (2004) **A guide to good practice in the management of Controlled Drugs in primary care (England)**. www.npc.co.uk

The **British National Formulary** and the **British National Formulary for Children** are published jointly by the British Medical Association and the Royal Pharmaceutical Society of Great Britain. Copies are available from the Pharmaceutical Press, PO Box 151, Wallingford, Oxfordshire OX10 8QU.

The **Monthly Index of Medical Specialities** (MIMS) is available from MIMS Subscriptions, PO Box 43, Ruislip, Middlesex HA4 0YT, telephone 020 8845 8545 or fax 020 8845 7696.

The **Review of Prescribing, Supply and Administration of Medicines: A Report on the Supply and Administration of Medicines under Group Protocols**, (Crown I) (Department of Health, London, April 1998) was published under cover of Health Service Circular (HSC) 1998/051 in England; Management Executive letter (MEL) (98)29 in Scotland; Welsh Health Circular (WHC) (98)27 in Wales, and by each Chief Professional Officer to their respective professional groups in Northern Ireland. Copies are available from the NHS response line on 0541 555 455. The **Review of Prescribing, Supply and Administration of Medicines: Final Report** (Crown II) (Department of Health, London 1999) is available from the same source.

Non medical prescribing in Wales: a guide for implementation, July 2007, Welsh Assembly Government

Drug Information at www.druginfozone.nhs.uk/ and includes a centrally maintained archive of approved PGDs.

Medicines for Older People: Implementing medicines-related aspects of the NSF for Older People. DH March 2001 Can be searched for, and downloaded at, www.dh.gov.uk

Medicines Partnership Programme at www.npc.co.uk/med_partnership/

National Electronic Library of Medicines www.nelm.nhs.uk

National Health Service Quality Improvement www.nhshealthquality.org/

National Institute for Clinical Excellence www.nice.org.uk

National Patient Safety Agency (2007) **Safety in doses: medication safety incidents in the NHS**. The fourth report from the Patients' Safety Observatory.

PRODIGY www.prodigy.nhs.uk

Royal Pharmaceutical Society Great Britain (March 2005) **The Safe and Secure handling of medicines: a team approach**. A revision of the Duthie Report (1988)

Great Britain (1977) National Health Services Act 1977, The Stationery Office

Great Britain (1984) Misuse of Drugs Act 1971, the Stationery Office

Great Britain (2001) Misuse of Drugs Regulations2001 SI No 3938, The Stationery Office

Great Britain (1977) Misuse of Drugs (Safe Custody) Regulations 1973, The Stationery Office [SI1973 No 798]

Great Britain (1972) Medicines Act 1968 (as amended), The Stationary Office, London

Great Britain (1983) POM Order 1983 (as amended), The Stationary Office, London

Great Britain (1992) Prescription by Nurses Act 1992, The Stationery Office, London

NHS Executive (2000) The Prescriptions Only Medicines (Human Use) Amendment (No2) Order 2000 SI No 22899 The Stationery Office, London

NMS Executive (2000) Patient group directions HSC 2000/026 200000

Royal Pharmaceutical Society of Great Britain (2004) Factsheet on Patient Group directions www.rpsgb.org.uk/pdfs/factsheet10.pdf

MHRA Patient Group Directions in the NHS. Search for at www.mhra.gov.uk

MHRA Patient Group Directions in the Private Sector. Search for at www.mhra.gov.uk
EC 92/27 Labelling and Leaflet Directive

Self-administration of medicines by hospital inpatients
www.audit-commission.gov.uk/itc/doc/selfadmin.doc

Care Standards Act 2000

The Regulation of Care (Scotland) Act 2001

The Health and Social Care (Community Health and Standards) Act 2003

The Private and Voluntary Health Care (England) Regulations 2001

Department of Health National Minimum Standards for social care services
www.csci.org.uk/choose_and_find_care/your_rights/national_minimum_standards.aspx

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For a list of current NMC publications go to www.nmc-uk.org and go to the Publications link.

Glossary

Annexe 7

Clinical governance	Quality assurance activities which ensure that pre-determined clinical standards that have been set, are seen to be maintained by practitioners, and are evident within health care settings.
Clinical Management Plan (CMP)	The CMP is the foundation stone of supplementary prescribing. Before supplementary prescribing can take place, it is obligatory for an agreed CMP to be in place (written or electronic) relating to a named patient/client and to that patient/client's specific condition(s) to be managed by the supplementary prescriber. The CMP is required to include details of the illness or conditions that may be treated, the class or description of medical products that can be prescribed or administered, and the circumstances in which the supplementary prescriber should refer to, or seek advice from, the doctor/dentist. Supplementary prescribers must have access to the same patient/client health records as the doctor/dentist. Since April 2005, nurse supplementary prescribers can prescribe Controlled Drugs, provided the doctor/dentist has agreed to this within the clinical management plan.
Competence	Relates to the need for the student to demonstrate their "capability" in certain skill areas to a required standard at a point in time.
Competencies	Component skills which contribute to being competent and achieving the standards of proficiency for registration. Competencies might include skills arising from learning outcomes or other requirements.
Dispensing	To label from stock and supply a clinically appropriate medicine to a patient/client/carer, usually against a written prescription, for self-administration or administration by another professional, and to advise on safe and effective use.

Health Care Commission

Is the health watchdog in England. It has a statutory duty to assess performance of health care organisations, award annual performance ratings for NHS and co-ordinate the review of health care by others

Independent prescribing

A prescriber who is legally permitted and qualified to prescribe and takes the responsibility for the clinical assessment of the patient/client, establishing a diagnosis and the clinical management required, as well as the responsibility for prescribing, and the appropriateness of any prescribing.

Licensed medication

The Medicines and Healthcare products Regulatory Agency (MHRA) operates a system of licensing before medicines are marketed (see **Marketing authorisation**). However, the Medicines Act allows certain exemptions from licensing which include:

- the manufacture and supply of unlicensed relevant medicinal products for individual patients/clients (commonly known as ”specials”)
- the importation and supply of unlicensed relevant medicinal products for individual patients/clients
- herbal remedies exemption

Marketing authorisation

Previously known as a "product licence". This normally has to be granted by the MHRA before a medicine can be prescribed or sold. This authorisation, which confirms that medicines have met standards for safety, quality and efficacy, considers all of the activities associated with marketing medicinal products.

Medicines Act Exemptions

Allow certain groups of healthcare professionals including occupational health schemes and midwives to sell, supply and administer particular medicines directly to patient/clients. Provided the requirements of any conditions attached to those exemptions are met, a Patient Group Direction is not required.

Medicines Administration Record

Also known as Patient Administration Chart, the record by which medicinal products administered to a patient are recorded.

Medicines Healthcare Products Regulatory Agency	Is a government agency responsible for ensuring that medicines and medical devices work and are acceptably safe.
National Patient Safety Agency	A special health authority created to co-ordinate all the efforts of all those involved n health care to learn from patient safety incidents occurring in the NHS.
Nurse Independent Prescribers	Nurses and midwives who are on the relevant parts of the Nursing and Midwifery Council (NMC) register may train to prescribe any medicine for any medical condition within their competence with the exception of s.
Nurse Prescribers Formulary for Community Practitioners (CPF)	The formulary from which nurses who have successfully completed the integrated prescribing component of the SPQ/SCPHN programme may prescribe independently.
One-stop dispensing	One-stop dispensing is a system of administering and dispensing medicinal products. It involves using the patient's own medicinal products during their stay in hospital, either those dispensed by a community pharmacy or by the hospital pharmacy or both, providing they contain a patient information leaflet and are labelled with full instructions for use.
Parts of the register	The NMC register, which opened on 1 August 2004, has three parts: nurses, midwives and specialist community public health nurses. A record of prescribing qualifications on the register identifies the registrant as competent to prescribe as Community Practitioner Nurse Prescriber or a Nurse Independent/Supplementary Prescriber.

Patient Group Direction (PGD)	Are written instructions for the supply or administration of named medicines to specific groups of patients who may not be individually identified before presenting for treatment. Guidance on the use of PGDs is contained within **Health Service Circular (HSC) 2000/026**. (Note: In Wales WHC 2000/116. Separate guidance has also been issued in Scotland and NI). The circular also identifies the legal standing of PGDs plus additional guidance on drawing them up and operating within them. It is vital that anyone involved in the delivery of care within a PGD is aware of the legal requirements. It is not a form of prescribing. See also guidance at www.npc.co.uk
Patient information leaflet	Data sheets found in all dispensed medicinal products which should be brought to the patient's attention on administering the medicinal product.
Patient specific direction	Are written instructions from a doctor, dentist or nurse prescriber for a medicine to be supplied and/or administered to a named person. This could be demonstrated by a simple request in the patient/client's notes or an entry on the patient/client's drug chart.
Prescription Pricing Division (PPD)	Is a division of the NHS Business Services Authority in England responsible for processing all prescription items.
Registrants	Nurses, midwives and specialist community public health nurses currently entered in the NMC register.
Repeat prescribing	A partnership between patient/client and prescriber that allows the prescriber to authorise a prescription so it can be repeatedly issued at agreed intervals, without the patient/client having to consult the prescriber at each issue.
Regulation and Quality Improvement Authority (RQIA)	Is an Independent health and social care regulatory body for Northern Ireland which encourages continued improvement in quality of services through a programme of inspections and reviews.

Rules	Rules are established through legislation and they provide the legal strategic framework from which the NMC develops standards, e.g. Education, Registration and Registration Appeals Rules 2004 (SI 2004/1767). "Standards" support the rules. Standards are mandatory and gain their authority from the legislation, in this case the Order and the Rules.
Specialist Community Public Health Nurse	A nurse who aims to reduce health inequalities by working with individuals, families, and communities, promoting health, preventing ill health and in the protection of health. The emphasis is on partnership working that cuts across disciplinary, professional and organisational boundaries that impact on organised social and political policy to influence the determinants of health and promote the health of whole populations
Stakeholders	Those who have a major interest in ensuring an effective programme outcome, including programme providers, placement providers, students, mentors, practice teachers, external examiners, external agencies, service users and carers.
Standards	The NMC is required by the Nursing and Midwifery Order 2001 to establish standards of proficiency to be met by applicants to different parts of the register. The standards are considered to be necessary for safe and effective practice [Article 5(2)(a)]. These are set out within the **Standards of proficiency** for each of the three parts of the register, and for the recorded qualification of nurse or midwife prescriber.
Summary of Product Characteristics	Information on medicinal products dispensed may be found at the Electronic Medicines Compendium
Supplementary prescribing	A voluntary partnership between an independent prescriber (doctor/dentist) and a supplementary prescriber, to implement an agreed patient/client-specific clinical management plan with the patient/client's agreement.

Transcribing (Transposing)

Any act by which medicinal products are written from one form of direction to administer to another is "transcribing". Including discharge letters, transfer letters, copying illegible patient administrations chart onto new charts, (whether hand written or computer generated).

Unlicensed medicines

This term refers to medicines that are not licensed for any indication or age group. Reasons why a drug may not be licensed include:

- the drug is undergoing a clinical trial, has been imported, has been prepared extemporaneously or prepared under a special manufacturing licence
- the product is not a medicine but is being used to treat a rare condition.

Unregistered practitioners

Practitioners providing care who are neither registered or licensed by a regulatory body and have no legally defined scope of practice

Yellow Card Scheme

If a patient/client experiences an adverse drug reaction to a medication the nurse/midwife should record this in the patient/clients notes, notify the prescriber (if they did not prescribe the drug) and notify via the Yellow Card Scheme immediately. Yellow cards are found in the back of the **British National Formulary** and online on www.yellowcard.gov.uk/ For further information read the BNF or access the MHRA website www.mhra.gov.uk/

Annexes

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