

# Use and Control of Medicines



*Guidelines for the safe prescribing,  
administration, handling, storage and  
custody of medicinal products in the  
Health and Personal Social Services*



Department of

**Health, Social Services  
and Public Safety**

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An Roinn

**Sláinte, Seirbhísí Sóisialta  
agus Sábháilteachta Poiblí**

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## Foreword

Medicines are the single most widely used technology in the HPSS accounting for some £300M of expenditure.

While these therapeutic agents undoubtedly contribute to improving health they also have associated risks, hence their propensity to be highly regulated.

Notwithstanding legislative controls, health care systems across the world are increasingly committed to develop safer systems of work to minimise the risk of adverse incidents due to medicines.

'Use and Control of Medicines' is one such measure designed to ensure that there are proper systems and procedures in place to limit risk to both practitioner and patients as well as setting out statutory obligations.

This new guidance, therefore seeks to take account of important legislative changes and developments in professional practice and accountability as well as integrating and giving consistency to associated guidelines emanating for professional bodies, agencies, reviews etc. In addition, the guidelines extend beyond the secondary care sector in recognition of the medicines control interface across primary, secondary and community care.

In commending these new guidelines to the Service I wish to acknowledge the multidisciplinary input to their development and the extent and quality of the responses to the consultative draft. Such responses give evidence to the critical and important nature of the matter and its impact across the whole of the HPSS family.

The application of these guidelines will, I believe, make a significant contribution to the clinical and social care governance agenda improving the quality of care and minimising medication related risk. Safety needs no justification and where there is good practice patients are advantaged.

**Dr N C Morrow** *Chief Pharmaceutical Officer*

This guidance is directed primarily towards those professionals working in a secondary care setting. However, where appropriate, the principles stated are equally applicable to primary care professionals and local health and social care groups.

Except where stated, the document is not to be regarded as a definitive statement of the law on medicines and has no statutory force. Nevertheless, it does seek to present those principles of known and accepted good practice applicable to its subject. In so doing it is not intended to supersede or conflict with professional standards or codes of practice already in place and it is recognised that more detailed guidance on some of the issues included may form part of existing local policies.

In particular, attention is drawn to the Medicines Management Controls Assurance Standard (which requires HPSS bodies to have in place systems ensuring compliance with legislative requirements and best practice.

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# *Guidelines for the safe handling, administration, storage and custody of medicinal products in the Health and Personal Social Services*

## **1 Objectives**

This document aims to provide practical guidelines for the safe and effective supply, storage, prescribing, administration and documented use of medicines in the health service. This may be achieved by ensuring that:-

- prescriptions are authentic and legible;
- dispensing is accurate;
- storage is adequate and secure;
- administration follows recognised procedures eg NMC Guidelines<sup>1</sup>;
- documentation is appropriate, accurate and complete;
- misuse is prevented;
- staff and patients are safeguarded;
- all appropriate staff are kept informed of all relevant policies, procedures, guidance and instructions.

Care should be taken to ensure that all medicines are prescribed and administered with the consent of the patient and in accordance with Good Practice in Consent<sup>2</sup>.

## **2 Prescribing**

It is essential that prescriptions are unambiguous so that the correct medicine can be administered to the named patient in the correct dose and dosage form, by the route specified, and at the time(s) prescribed.

In order to facilitate this and eliminate errors it is essential that staff become familiar with the documents or process used. Prescription sheets (eg Kardex) are a vital part of a patient's medical records. They must therefore be, and remain, legible and complete. In the secondary sector not more than one main prescription sheet should be in use at any one time for any patient. Where necessary, a continuation sheet should be used and numbered appropriately. In addition to the main prescription sheet, supplementary sheets may be necessary for special prescribing, for example:-

- anticoagulants
- intravenous fluids

- intravenous fluid additives
- insulin
- anaesthetic agents.
- oxygen
- patient controlled analgesia (pca)

Knowledge of the fact that the patient is being treated with these medicines may affect other prescribing and a note of these treatments must always be made on the main prescription sheet. This note should also refer to the existence of any supplementary sheet(s) which would contain details of such medication.

In writing prescriptions the advice given in the British National Formulary (incorporating the Nurse Prescribers' Formulary) (under "General Information" and "Prescription Writing")<sup>3</sup> should be observed.

When completing prescription sheets:-

- each individual prescription must be DATED and PRINTED clearly and entirely in CAPITAL LETTERS
- each prescription sheet must show the PATIENT'S FULL NAME, DATE OF BIRTH, PATIENT REFERENCE NUMBER and/or ADDRESS
- the APPROVED NAME should be used for a medicine wherever possible. Where applicable the proprietary name should also be used, eg for insulins and long acting theophylline preparations where different brands may have varying bioavailability
- the DOSE and dosage FORM must be clearly stated. The dose should be specified in metric units or the number of individual dosage units where appropriate
- the TIME and ROUTE of administration must be indicated and where appropriate the specific site of application eg "left ear", "right ear"
- Where ABBREVIATIONS are used, only those approved by the BNF are appropriate.
- the frequency of administration of "as required" medicines must be indicated by CLEAR AND DEFINITELY STATED MINIMAL INTERVALS AND A MAXIMUM DAILY DOSE.
- when SUPPLEMENTARY SHEETS are used the person initiating the sheet should indicate such action in the appropriate space on the main prescription sheet

- any known DRUG SENSITIVITIES and/or known DRUG ALLERGIES must be clearly indicated on the prescription sheet
- all prescriptions must be SIGNED BY THE PRESCRIBER with a LEGIBLE signature
- prescriptions for medicines must be printed DIRECTLY on to the PRESCRIPTION SHEET. Non-peelable adhesive labels are NOT acceptable.

Under no circumstances should the prescription sheet be defaced. If a prescription requires to be amended in any way, the original entry must be struck out and a new prescription written. In all cases the original entry must remain legible. To DISCONTINUE a prescription (ie to indicate the termination of a specific course of treatment) a single straight line must be drawn through the complete entry, the date inserted in the “discontinued” column and signed. To CANCEL a prescription (ie to delete an erroneous entry) a single straight line must be drawn through the complete entry, which should then be signed and dated, and the word “CANCEL” printed boldly across the “times of administration” column. All prescription sheets are part of the patient’s records and must ultimately be retained as such.

Discharge prescriptions for Controlled Drugs must be written in full by the prescriber who, in addition to completion as above, must specify in words and figures the total amount of the drug or preparation to be supplied.

### 3 Emergency Prescriptions

Only in an emergency may a medicine be administered without a written prescription. IN ALL CASES the administration, alteration or withdrawal of medication must be immediately recorded on the Prescription Sheet and certified by the prescriber within 24 hours. In the event that the prescriber fails to provide appropriate authorisation within 24 hours, further authorisation should be sought before medication is continued.

NMC Guidelines state that instruction by telephone to a practitioner to administer a previously unprescribed substance is not acceptable. In exceptional circumstances, where the 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

methods such as fax or e-mail is the preferred. This should be followed up by a new prescription confirming the changes within 24 hours. In any event, the changes must have been authorised before the new dosage is administered

In the case of the order being received from a prescriber by telephone, the message shall be taken by the practitioner who will:

- acquaint the prescriber with the name and dosages of other medicines currently prescribed for that patient,
- write down the message and read it back to the prescriber checking the patient’s name, the medicine, the dose, the route and time of administration.

In an emergency situation, where a verbal order for administration of a medicine is given by a prescriber who is present, the nurse must check the medicine and measured dose with the prescriber before administration.

The normal procedures for recording the prescription and administration of the medicine must then be followed.

It should be noted that controlled drugs cannot be administered on the basis of a telephoned order.

If in doubt about a prescription or medicine for any reason the nurse must not administer until the Sister/Acting Sister/Nurse in Charge or the prescriber has been consulted.

### 4 Patient Group Directions

A Patient Group Direction (PGD) is a written instruction for the sale, supply and administration of named medicines in an identified clinical situation. It applies to groups of patients who may not be individually identified before presenting for treatment. The majority of clinical care should continue to be provided on an individual, patient-specific basis and the use of PGDs should be reserved for those limited situations where this offers a distinct advantage for patient care and where it is consistent with appropriate professional relationships and accountability. PGDs are drawn up locally by doctors, pharmacists and other health professionals, signed by a doctor or dentist, as appropriate and a pharmacist and approved by an appropriate body.<sup>4</sup>

## IMPORTANT NOTES:

### Unlicensed medicines

The use of unlicensed medicines is currently excluded from the scope of PGDs

### Controlled Drugs

The Misuse of Drugs (Amendment) (No.3) Regulations (Northern Ireland) 2003 allow the PGD scheme to be extended to the following controlled drugs:

- diamorphine, but only for the treatment of cardiac pain by specialized nurses in accident and emergency departments and coronary care units in hospitals; and
- all controlled drugs listed in Schedule 4 (except the anabolic steroids and any injectable drug which is to be used for the purposes of treating addiction) and Schedule 5 of the 2002 Regulations<sup>5</sup>.

### Details Required for a Valid PGD<sup>6</sup>

The PGD must:

- be signed on behalf of the Department, Trust or Board<sup>7</sup>;
- designate in writing the individual or individuals who may supply medicines under the PGD, who must belong to one of the classes of person specified below;
- relate to medicines that have a marketing authorisation or a homoeopathic certificate of registration;
- be in effect at the time of supply.
- and must contain the following information:
  - The name of the business to which the direction applies;
  - The period during which the PGD shall have effect; (guidance has indicated that the PGD should be reviewed at least every two years)
  - The description or class of POM to which the PGD relates;
  - The class of health professional to which the PGD relates;
  - Whether there are any restrictions on the quantity of medicine which may be supplied on any one occasion, and, if so, what those restrictions are; (This information is not required if the PGD relates to administration only.)
  - The clinical situations which the POM of that description or class may be used to treat;
  - The clinical criteria under which a person shall be eligible for treatment;

- Whether any class of person is excluded from treatment under the PGD and, if so, what class of person;
- Whether there are circumstances when further advice should be sought from a doctor or dentist, and, if so, what circumstances;
- The pharmaceutical form or forms in which the POM of that description or class is to be administered;
- The strength, or maximum strength, at which the POM of that description or class is to be administered;
- The applicable dosage and/or maximum dosage;
- The route of administration;
- The frequency of administration;
- Any minimum or maximum period of administration applicable to the POM of that description or class;
- Whether there are any relevant warnings to note, and, if so, what warnings;
- Whether there is any follow up action to be taken in any circumstances, and, if so, what action and in what circumstances;
- Arrangements for referral for medical advice;
- Details of the records to be kept of the supply and/or the administration of medicines under the PGD

In addition to the above criteria, it is a requirement of the legislation that the PGD is signed by a doctor or dentist as appropriate, and by a senior pharmacist.

### Classes of Persons Permitted to Supply or Administer Medicines under PGDs.

The following is a list of persons who are permitted under the Regulations to supply or administer specified medicines under a PGD:

- State registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by the Secretary of State, or issued with his approval;
- Registered Pharmacists;
- Registered health visitors (live on NMC Register);
- Registered midwives (live on NMC Register);
- Registered nurses (live on NMC Register);
- Registered ophthalmic opticians;
- State registered chiropractors;

- State registered orthoptists;
- State registered physiotherapists;
- State registered radiographers.

It is important to note that the above professionals may only supply or administer medicines under a PGD as named individuals.

## **ADDITIONAL GUIDANCE ON THE DEVELOPMENT, USE AND REVIEW OF PGDs**

1. PGDs should be drawn up by a multi-disciplinary group involving a doctor, a pharmacist and a representative of any professional group expected to supply medicines under the PGD. It is good practice to involve local Drug and Therapeutics Committees, Area Prescribing Committees and similar advisory bodies.
2. A senior person in each profession should be designated with the responsibility to ensure that only fully competent, qualified and trained professionals operate within directions.
3. All professions must act within the scope of their professional practice and according to their appropriate Code of Professional Conduct.
4. Appropriate document(s) should be signed by each member of the multidisciplinary group, the authorising body and the individual health professionals working under the direction. Generally, a direction should be reviewed every two years.
5. There must be comprehensive arrangements for the security, storage and labelling of all medicines. Wherever possible, medicines should be supplied in pre-packs supplied by the Pharmacy Department. In particular there must be a secure system for recording and monitoring medicines use from which it should be possible to reconcile incoming stock and out-goings on a patient by patient basis. Names of the health professionals providing treatment, patient identifiers and the medicine(s) provided should all be recorded.
6. The EC Leaflet and Labelling Directive 92/27 applies to all supplies of medicines, including those supplied under PGDs.

### **Antimicrobials**

Particular caution should be exercised in any decision to draw up PGDs relating to antibiotics. Microbial resistance is

a public health matter of major importance and great care should be taken to ensure that their inclusion in a direction is absolutely necessary and will not jeopardise strategies to combat increasing resistance. A local bacteriologist should be involved in drawing up the PGD. The local Drug and Therapeutics Committee or Area Prescribing Committee should ensure that any such directions are consistent with local policies and subject to regular external audit.

### **Black Triangle Drugs and medicines used outside the terms of the Summary of Product Characteristics**

The use of any medicine should be consistent with the Summary of Product Characteristics (SPC) for the relevant product (save in special circumstances). Black triangle drugs (ie, those recently licensed and subject to special reporting arrangements for adverse reactions) and medicines used outside the terms of the SPCs may be included in PGDs provided such use is supported by best clinical practice. Each PGD should clearly state when the product is being used outside the terms of the SPC and the documentation should include the reasons why, exceptionally, such use is necessary.

## **5 Control of Medicines in Clinical Trials**

Prior to licensing, new medicines are subject to human testing, as are established products for their use in new indications. Unlicensed products may be prescribed by registered medical practitioners for individual patients on a “named-patient” basis. Clinical Trials are within the scope of Research Governance Framework for Health and Social Care<sup>8</sup> which sets out the responsibilities and standards that must be applied to research conducted by or on behalf of the HPSS. In addition, the conduct of clinical trials must be in accordance with published guidelines on Good Clinical Practice (GCP). Under current arrangements, local (Northern Ireland) Ethical Committee approval must be sought prior to trials commencing. The patient/volunteer must be given adequate information about the trial on which to base his/her option to participate or not. All staff directly concerned with the treatment of a patient must be made aware of that patient’s involvement in a clinical trial and its nature; this is particularly relevant to the recognition of side effects. The prescription sheet must be annotated to indicate that the patient is involved in a clinical trial. Administration

and dispensing of trial medicines must be in accordance with locally agreed procedures and records must be kept of dispensing, issue, and administration of all medicines, and their disposal if warranted. Where trials are being conducted in a hospital the pharmacy department should hold a copy of all trial protocols, including codes, and should be involved in the control and audit of the medicines concerned in relation to procurement, storage, documentation and supply. However, local policy must fit in with national guidelines. For example, codes may be held centrally and it may not be possible for the local pharmacy to hold a copy of them. The identity of those staff involved in the trial must be recorded. Separate stocks of trial medicines must not be maintained in wards, clinics or private offices. Clinical Trials involving controlled drugs must be referred to the DHSSPS Misuse of Drugs Inspector to ensure licensing compliance.

It should be noted that from May 2004 the Clinical Trials Directive (2001/20/EC) is effective for all clinical trials conducted in the UK. This requires that clinical trials are conducted in accordance with the principles of GCP which are, for the purposes of the Directive, the current ICH principles<sup>9</sup>.

Where patients involved in a clinical trial attend hospital as out-patients, their continuing supply of clinical trials medicines must be obtained direct from the pharmacy department where the appropriate records will be maintained.

## 6 Medicines Samples

The distribution of samples of medicinal products is not permitted within the hospital. Any samples received from pharmaceutical representatives must be handled through the normal pharmacy stock control system. Local arrangements should ensure that when representatives of pharmaceutical companies are visiting prescribers they should also be referred to the Pharmacy Department.

## 7 Medicines Brought to Hospital by Patients

Hospital in-patients must be made aware of the need to inform hospital staff of their current medicine therapy. Specific enquiries must be made by a doctor, nurse and/or

pharmacist to determine whether the patient is taking any prescribed medicines or any other medicinal preparations and if the patient has brought them to hospital. These medicines are the property of the patient to whom they were supplied and must not be taken without consent. The patient should however be asked to surrender, for examination by a doctor or pharmacist, any such medicines or other preparations brought to the hospital.

Steps should be taken to have such medicines identified and a decision made as to whether it is advisable for them to be continued. Where the patient is to continue on that medication, suitable provision for this should be made in the interests of economy, safety and good practice. On no account must one patient's medicine be given to another patient. Where these medicines are NOT to be continued, the patient, or nearest relative or representative, should be asked to give consent to their destruction. It should be explained to the patient that while in hospital all medicines will be prescribed by authorised prescribers and administered in accordance with their directions.

Where patients do not surrender their own medicines it is possible that they will continue with unapproved self medication. It should be made clear to patients, and their representatives if any, that the taking of these medicines contrary to medical advice may seriously jeopardise current treatment to the extent that it may not be safe to commence or continue it.

Where the patient has surrendered medicines but does not agree to their destruction, he/she should be asked to send them home with a responsible adult. Responsibility for security then passes to that adult. The patient or representative must be advised if the medicines are not safe for use with or without other medication.

Where the patient does not agree to the destruction of his/her surrendered medicines, and they are not taken home, the pharmacist should make arrangements for their secure storage in hospital until the patient's discharge when a decision will be made to return them to the patient or to dispose of them as appropriate. Records of the receipt of such medicines and their eventual disposal should be kept. All medicines brought in with a patient suffering from overdose must be sealed, labelled with the patient's full

name, reference number and date of admission before being stored in the pharmacy. These medicines must not be returned to the patient or disposed of on discharge or otherwise until it is established whether they may be required as evidence in legal proceedings.

Each hospital should include with the notice of admission, or in its admission booklet, advice for patients on the following lines:

“MEDICINES. Whilst you are in hospital the clinical staff may want to prescribe new medicines, or other treatment. Before doing so they will want to know what other medicines, including homoeopathic or herbal remedies, you are already taking, or have with you. It is therefore VERY IMPORTANT that you tell the doctor, nurse or pharmacist about such medicines and bring them with you to hospital if possible. It could be dangerous for you to continue to take your own medicines or to take any medicines brought to you by visitors during your stay in hospital. You should always tell the nurse-in-charge of any medicines brought to you in this way. If you hold a SPECIAL CARD which gives details of any current treatment, for example a steroid or warfarin card, or an allergies alert card or any devices please bring these with you into hospital and show them to the doctor, nurse or pharmacist”.

Where patients are found in possession of unauthorised drugs or other suspicious substances staff should refer to the guidance issued by the Department<sup>10</sup>

## 8 Supply of Patients’ “Take Home” Medicine

Provision must be made for patients on discharge or weekend leave to receive a sufficient quantity of their prescribing medicines from the hospital pharmacy to continue their therapy. This will normally be for up to 72 hours until further supplies can be prescribed (this policy is, currently, under review). This procedure will also apply to cases where ‘one day’ surgery schemes operate. The prescription form used for this purpose should contain a complete and accurate list of the patient’s prescribed medicines on discharge, having been completed (at least in triplicate) and signed by the responsible prescriber. One copy of the form will be retained for use by the pharmacy department for dispensing, one copy for filing in the

patient’s records, and one copy for the patient’s GP where appropriate.

However, suitable provision may be made, where applicable, for patients to continue on the medicines which they brought to hospital with them.

Local arrangements should ensure that, prior to discharge, patients are adequately advised and instructed on the use of their medicines (see section 9). Such advice should also be given to parents, guardians, or relatives where appropriate. Written details of the diagnosis and current medication together with details of any known drug allergies should also be provided for the patient’s General Practitioner (see section 19).

When a patient is discharged outside normal hospital pharmacy hours, special arrangements should be made with the pharmacy to have available at the ward suitable containers, labels and patient information leaflets for the supply of medicines from the ward stock. All such containers, labels and leaflets must be in a locked cupboard and the medicines in question should be checked by a second person. **A record of all medicines so supplied must be made on the relevant prescription sheet and the copy of the prescription sent to the pharmacy.**

Medicines dispensed from ward stock to patients on discharge must bear a printed label showing the date, the name of the patient, the ward number, the name of the medicine, its strength and precise instructions for its administration.

Any medicines brought into hospital by a patient and lodged in the ward/pharmacy may be returned on discharge if the patient so requests (except for illicit drugs or medicines belonging to patients admitted with an overdose) (see section 7). The patient should be advised regarding any risk of using those medicines concurrently with existing treatment.

## 9 Patient Information on Medicines

Studies on the use of medicines have clearly shown that patient compliance with instructions for the self-administration of prescribed medicines is relatively poor.

The reasons for this are diverse and include forgetfulness, misunderstanding of directions, lack of motivation, insufficient information and poor communication by health practitioners and others. In order to optimise the safe, effective, rational and economical use of medicines it is important that patients are given sufficient information and skilled counselling to allow them to use their therapy appropriately and with maximum benefit.

In addition to the printed directions on the medicine container, verbal instructions must be clear and precise, and reinforced in writing as appropriate.

Some situations already exist in Northern Ireland where pharmacists in hospital are, by arrangement with the consultants concerned, directly involved in providing advisory services to selected groups of patients in relation to their prescribed therapy during their hospital stay and prior to their discharge from hospital (eg cardiac and oncology patients).

It is essential that clinicians, in association with other health care professionals as appropriate, take the necessary steps to ensure the provision of adequate information to patients to enable them to use their medication effectively, thus promoting the continuity of care from hospital to the community. It is a legal requirement that patients discharged from hospital should receive a patient information leaflet with each medicine supplied to them.

## 10 Administration

### Nurses

Medicines will normally be administered to a patient by a suitably qualified professional, usually a nurse. If there is any doubt, for example, regarding the legibility of the prescription, the dose of the medicine or the purpose for which the medicine is prescribed, the nurse must seek guidance from the ward manager, prescriber or pharmacist concerned, before administering any medicines. Under no circumstances should guesses be made.

Nurses and midwives whose names are on the first level parts of the Register or second level nurses who have successfully completed approved Pharmacology training should be seen by the employing authority as competent to

administer medicines on their own and responsible for their actions in so doing. The involvement of a second person in the administration of medicines with a first level practitioner need only occur where that practitioner is

- adhering to local policies
- administering a neonatal drug
- administering a Schedule 2 controlled drug
- administering an intravenous solution extemporaneously prepared using potassium chloride concentrate or other strong potassium solutions, or
- administering to a patient whose condition makes it necessary.

Where a student of nursing is administering medicines he/she must be supervised by a first level practitioner.

In hospitals or nursing homes, personnel who are not professionally registered, such as nursing auxiliaries or assistants, should not participate in the administration of medicines unless they have undertaken a course of training endorsed by their employing authority.

In a residential care setting staff involved in the administration of medicines should receive any necessary additional training to enable them to administer medicines to residents who are unable to self-administer.

Second level practitioners should not administer medicines on their own unless the employer:

- has provided additional instruction relevant to the medicines likely to be encountered in a particular setting; and
- has undertaken an assessment and is satisfied as to the individual's knowledge and competence to perform the task; and
- is prepared to accept the responsibility for any errors that are consequential upon using a second level practitioner beyond the role for which they have been trained.

Before selecting the medicine to be administered the nurse must:-

- check that there is a valid prescription (see section 2)
- check the NAME of the patient against the details on the prescription and recording sheet and check the drug allergy box which should never be left blank.

- READ the prescription carefully; and make sure that the medicine is to be administered
- ascertain that the DOSE has not already been administered and that the total dose (where stated) will not be exceeded.
- check the DOSE prescribed and the ROUTE of administration
- Check that the dose prescribed is appropriate especially where the dosage of medication is related to body weight (this is particularly important in relation to neonates and children)

Before administering the medicine the nurse must:-

- verify the identity of the patient, by checking, for example, verbally the name, and the name and unique patient registration number on his/her identity bracelet. The date of birth must always be checked
- select the medicine required, check its STRENGTH, and CHECK THAT THE MEDICINE NAME ON THE CONTAINER LABEL MATCHES THAT ON THE PRESCRIPTION SHEET
- check that the medicine is in date and is not obviously defective in any way.

On the medicine round it is the nurse's responsibility to see that the medicines are actually taken.

Because of the more obvious risk of overdosage, particular care should be taken in the administration of all medicines to neonates and children. It is vital to ensure that the prescribed dose is an appropriate paediatric dose, and that any necessary calculations are correct and have been checked by a second person. For oral liquids a 5ml medicines spoon or measuring cup can be used to measure oral doses which are in multiples of 5ml. An appropriate oral syringe should be used for all other doses. IV syringes should not be used to measure and administer oral liquid medicines. Paediatric formulations should be supplied to wards and departments where children receive treatment. Similar care should be taken in the administration of medicines to elderly patients.

## Registered Doctors

The safety of patients comes first at all times. The duties and responsibilities of a registered doctor are outlined in Good Medical Practice<sup>11</sup>. These include responsibilities in respect

of diagnoses, investigation and treatment of patients including those relating to the prescribing and administration of medicines and treatments and the reporting of adverse drug reactions.

Doctors who have special responsibilities for teaching and training must have the skills, attitudes and practices of a competent teacher. They must also ensure that students and junior colleagues are properly supervised. A doctor who delegates treatment or care eg to another doctor, nurse or medical student must ensure that the individual is competent to provide the therapy or carry out the procedure.

## Medical Students and Pre-registration House officers

'Tomorrow's Doctor'<sup>12</sup> sets out the clinical and practical skills which graduates must be able to do safely and effectively. These include skills necessary to the prescribing and administration of medicines including:

- working out the drug dosage and recording the outcome accurately;
- writing safe prescriptions for different types of drugs;
- carrying out the following procedures involving veins:
  - venepuncture
  - inserting a cannula into peripheral veins
  - giving intravenous injections
- giving intramuscular and subcutaneous injections
- using a nebuliser correctly
- administering oxygen therapy

In addition, the Student Logbook for Pre-registration House Officer Workshadowing sets out key tasks and skills which a medical student of Queen's University must achieve under the supervision of a PRHO or other junior staff. This emphasises that no drug or intravenous fluid should be prescribed by a medical student. All such medication must be prescribed by a qualified doctor. The log book sets out key tasks/skills to promote safe prescribing and practical procedures which should be achieved and written up including:

- writing up a fluid balance chart;
- writing a drug prescription chart;
- prescribing anticoagulation based on INR chart;
- prescribing insulin based on diabetic chart;

giving summary of local antibiotic policy  
compiling a list of 10 drugs most commonly used at the Unit, documenting specific details;  
practical procedures, under a named supervising staff member, including IV cannula insertion, erection of IV infusions and SC/IM/IV injections

### **Intravenous Infusions**

Medicines given via any form of intravenous infusion should be administered in accordance with the clearly written directions of the prescriber and as laid down in local procedures established by Boards under Circular HSS(OS3)6/79 “Addition of Drugs to Intravenous Infusion Fluids”. Aseptic dispensing must be carried out in compliance with published standards<sup>13</sup> as advised in circular HSSE (OCE) 1/97

### **Intrathecal Administration**

Due to the serious consequences resulting from maladministered spinal injections, it is essential that the National Guidance on the Safe Administration of Intrathecal Chemotherapy<sup>14</sup> is observed.

### **Potassium Chloride Solutions**

Systems should be in place to avoid incidents where patients accidentally receive an overdose of intravenous potassium. Particular attention should be given to the guidance issued by the National Patient Safety Agency (NPSA) and endorsed by the Department<sup>15</sup>.

### **Cytotoxic Drugs and Radioactive Substances**

By their nature, cytotoxic drugs and radioactive substances constitute a hazard to healthy cells, both in the patient and those who prepare and administer them. Cytotoxic products should, preferably, be prepared in the pharmacy department by trained and experienced pharmacy staff and not at ward level.

Good practice guidelines on the safe handling and administration of cytotoxic<sup>16</sup> and radiopharmaceutical preparations<sup>17</sup> should be observed

### **Prescribing, supply and administration of specialist medicines<sup>18</sup>**

As care for patients becomes more complicated, specialised medicines are increasingly being used. ‘Specialist

medicines’ have been defined by Departmental guidance and have been designated as ‘Red’ or ‘Amber’ List medicines.

It is recommended that the prescribing responsibility for a Red List medicine should remain with the initiating consultant and it should be supplied via a hospital pharmacy. The administration of such medicines may be undertaken by a nurse under the written direction from a doctor/consultant currently registered with the General Medical Council. A formal document should be supplied from the consultant which must state the patient’s name, address, condition being treated, the dose and route of administration of the medicine. It must be signed by the consultant responsible for the treatment of the patient and the nurse once the medicine has been administered. A copy of this document should be sent to the patient’s GP. The authorisation to administer must then be filed in the patient’s notes. Amber List medicines may be prescribed and supplied in primary care. Prescription and supply should be done under a shared care protocol which should be agreed by the hospital and primary care prescriber.

### **Other Health Professionals**

Administration of medicines to patients by other authorised health professionals must be in accordance with the written directions of an appropriate prescriber or in accordance with a PGD. These directions (see sections 2 and 4) must be recorded on the patient’s prescription sheet(s) together with a further record of the administration of the medicine (see section 12) signed by the health professional involved.

## **11 Self-administration of medicines**

Self-administration may be defined as a system which allows persons in health service or private care facilities to have possession of some or all of their prescribed medication and to take responsibility for administering it correctly. It is recognised that various medicines often are self-administered eg glyceryl trinitrate, aerosol bronchodilators, and that these medicines are held by the individual concerned during his stay in such establishments.

There is a case for extending this method of administration to a variety of health care situations. This relates particularly to encouraging people to take greater responsibility for their own treatment and also to improving

the continuity of care from hospital to the community where, in the latter situation, patients almost exclusively administer their own medicines. The difficulties inherent in such a system of medicine administration in hospitals are recognised. It is essential, therefore, that where self-administration is introduced, arrangements are in place for the safe and secure storage of the medication, access to which is limited to the specific patient. In addition, records of such self-administration should be maintained appropriate to the environment in which the patient is being cared for.

Given existing practices and the possibility of the development of self-administration programmes, provision should be made for those who are judged to be competent and confident to administer their own medicines, to have a lockable drawer or cupboard in which to store them. In cases involving self administration of controlled drugs subject to Safe Custody requirements, advice should be sought from the Department's Misuse of Drugs Inspector. In addition, each preparation must be clearly labelled with the name of the patient, the name and strength of the medicine, the directions for use, and date of dispensing and the amount dispensed.

Any developments in the area of self-administration of medicines should be along multidisciplinary lines with agreed written protocols of the procedures to be followed.

## 12 Recording

A record of administration should be made on the medicines recording sheet, at the time the medicine is given to the patient, and initialled by the person (normally the nurse) who administered the medicine. If the medicine has not been taken, this fact should be recorded on the prescription sheet and the prescriber informed. A local system should also be developed whereby any suspected adverse drug reaction is recorded and the appropriate practitioner(s) alerted. Pharmacists could play a useful role in co-ordinating such a scheme. In addition, all suspected adverse drug reactions should be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) using the Yellow Card Scheme. Pre-paid Yellow Cards for reporting such reactions are bound within the inside back cover of the BNF.

## Schedule 2 Controlled Drugs

In addition to the above, the details relating to the administration of Schedule 2 Controlled Drugs shall be entered in the ward controlled drugs register or other separate record kept specifically for that purpose. Such register/record must be signed by a First Level Registered Nurse and a witness who should also be **present at the administration of the drug**. Where two nurses are involved, one of them must always be a First Level Registered Nurse.

There is no legal requirement to keep a register for Schedule 3 Controlled Drugs, for example, temazepam. However, many hospitals, as a matter of good practice, maintain a register for selected Schedule 3 preparations.

Details concerning Controlled Drugs accidentally or deliberately wasted shall be similarly witnessed and recorded in the ward controlled drugs register/record. A documented CD audit should be carried out by the pharmacist at least three-monthly.

## 13 Supply of Medicines to Wards and Departments

It is recognised that a number of different methods are used to effect the supply of medicines to wards. However, pharmacists are responsible for the supervision of the dispensing of medicines and for ensuring that systems are established for the safe, secure, effective and economic supply of medicines.

### Ordering

**Medicines other than Controlled Drugs:** All orders must be made in an approved manner and each requisition must indicate the date, ward, department or other healthcare facility and the name, quantity, strength and form of medicines required. Where a 'topping-up' system of supply is in use the requisition may be in the form of a list prepared by pharmacy staff. The Nurse in Charge is the person with responsibility for approving requisitions. In other departments, eg physiotherapy and podiatry, it is the responsibility of the senior professional to requisition designated medicines.

**Controlled Drugs:** The Misuse of Drugs Regulations (Northern Ireland) 2002 specifies five schedules of medicinal substances which are subject to various forms of control. For most practical purposes hospitals and other healthcare facilities need only be concerned with the specific control requirements of Schedules 2 and 3. However, significant possibilities exist for the illegal diversion of drugs in Schedules 4 and 5 and local procedures should be commensurate with the perceived or actual risk.

- **Schedule 2 Controlled Drugs:** Orders for these medicines, which are mainly opiates, **must** be made on a separate duplicate requisition specifically designated for these preparations and signed by the Sister/Acting Sister in charge of the ward or department or other healthcare facility.
- **Schedule 3 Controlled Drugs:** Schedule 3 drugs include among others dihydrocodeine, temazepam and buprenorphine. They must be ordered on a duplicate requisition signed by the Sister/Acting Sister in charge of the ward or department.

## Delivery

It is the responsibility of the pharmacy department to establish safe systems of delivery, incorporating appropriate documentation so as to allow both the issuing department and the receiving unit to effect proper audit.

Staff involved directly in the transport of medicines should be limited to a minimum practical number of identified people, ensuring, of course, a back up of available staff to maintain continuity of service. Ideally transport and portering staff should be part of the pharmacy establishment. Those transporting medicines shall be responsible for their security until delivered to an authorised person and the delivery acknowledged.

Where, in emergencies, non-Trust transport is employed to transport medicines it is the responsibility of the pharmacy department to ensure that adequate security arrangements are in place.

**Medicines other than Controlled Drugs:** The delivery of medicines to wards, departments etc must be carried out in a manner that ensures that the medicines reach their destination without undue risk of being stolen, damaged or tampered with in any way. Where medicine delivery is

undertaken between hospitals all containers must be locked and/or fitted with tamper-evident seals.

**Controlled Drugs (Schedule 2):** Where Controlled Drugs delivery is undertaken from a pharmacy department within a hospital, delivery (in a sealed package) must be effected in person by a responsible individual. That person must sign for the delivery of the Controlled Drugs before leaving the pharmacy department. At ward level the medicines must be handed to the Sister/Acting Sister who will check the medicines received against the requisition and sign for their receipt.

Where Controlled Drugs have to be delivered between hospitals they must be in a locked container or be fitted with a tamper-evident seal. Where this receptacle contains other medicines the Controlled Drugs must be sealed in a separate package. A signed record of receipt for the Controlled Drugs must be made by the Sister/Acting Sister and returned to the issuing pharmacy department.

## Delivery of Medicines to Patients' Homes

Delivery of medicines to patient's homes should be undertaken in accordance with the guidance articulated in the Code of Ethics issued by the Pharmaceutical Society of Northern Ireland

## 14 Medicines for Staff Personal Use

Medicines for the personal use of staff will not normally be provided from hospital stocks. However, where Boards agree to such provision, where appropriate, charges for the medicines supplied should be made.

## 15 Storage and Custody

Storage of medicines involves both environmental and security factors. Medicines must be stored under optimum environmental conditions (temperature, lighting etc) in accordance with the manufacturers' instructions. Robust systems must be in place to ensure that unauthorised access to medicines is prevented.

Guidance on security matters may be sought from the Department's Pharmaceutical Inspectorate and PSNI Crime Prevention Officers.

Medicines for use in wards should be stored in approved standard modular cupboards conforming to British Standards where applicable. These include the following categories:-

- Controlled Drugs Cabinet
- Internal Medicines Cupboard
- External Medicines Cupboard
- Cupboard for Disinfectants/Antiseptics used in ward cleaning
- All medicines should be stored according to manufacturers' recommendations in respect of temperature. Where products requiring refrigeration are stored the refrigerator used should be equipped with a means of ensuring that the specific temperature range specified for the product has been maintained. A daily record of such monitoring should be made.
- Cupboard for Diagnostic Reagents, including Urine Testing Cabinet
- Dedicated clinical area for Intravenous Fluids and Sterile Topical Fluids.
- Appropriately secured emergency trolley.

Where there is a perceived extra risk of theft, for example due to the nature of certain preparations, their location, or lack of 24 hour staff presence, additional safeguards should be applied as appropriate.

The area in which cupboards are located must be well lighted by day and at night. Medicines in current use, with the exception of Controlled Drugs, may be kept in a locked approved medicine trolley and not returned to the cupboard after each administration. Medicine trolleys must be parked when not in use either in a lockable cupboard or attached by lock and chain to the wall or floor. They must never be left unattended when opened.

Schedule 2 controlled drugs must always be stored in a Controlled Drugs Cabinet providing, in its construction, a level of security at least comparable to that laid down in the Misuse of Drugs (Safe Custody) Regulations 1973. In theatre suites these should be located in each anaesthetic room and/or recovery room which serves one or more theatres.

Areas where controlled drugs are stored which are regularly and routinely unmanned should, where possible, be monitored by alarm systems or CCTV. Locks securing

doors leading to areas where controlled drugs are stored must be adequate to act as a deterrent to theft.

Keys of controlled drugs cabinet must be carried on the person of the Sister/Acting Sister/Nurse in Charge and be handed over personally to the nurse responsible for taking over the custody of the cupboards. Keys to all other medicine cupboards must be held by either the Sister or a First Level Registered Nurse. Loss of keys must be reported immediately for appropriate action by the Nurse in Charge, who will also inform the pharmacy.

In clinical areas where medicines are frequently required for emergency use, local guidelines should ensure maximum security compatible with functional requirements.

In situations where controlled drugs are in daily use the stock balance should be reconciled on each occasion when responsibility for safe custody is transferred. However where controlled drugs are used less often the frequency of this check may be varied for local operational reasons at the discretion of the Sister/Acting Sister/Nurse in Charge, in consultation with the Pharmacist. This check must be carried out by two qualified nurses one of whom should be on the First Level Register, recorded and signed.

The security of ward stocks must be checked by pharmacy staff periodically, normally every three months, in accordance with locally agreed procedures. They must carry out inspections of ward stocks, with reconciliation where necessary.

Where there has been unauthorised access to, or theft of, ward medicine stock this must be reported immediately to the Nurse in Charge who will conduct an initial investigation and subsequently inform the pharmacy department. It then becomes the responsibility of the pharmacy department to investigate the matter, enlisting the support of other disciplines and liaising with the police as appropriate.

## 16 Labels

Medicines dispensed from pharmacy must be clearly labelled in accordance with legal requirements. If any of the details on the label on any container are defaced or obliterated, eg name, expiry date or strength, the container must be returned to the pharmacy for replacement.

Alterations to labels must not be made under any circumstances except to indicate the addition of a prescribed drug to a container of intravenous or irrigation fluid, or to indicate when any particular pack (eg eye drops) was first used.

## **17 Transfer of Medicines between Containers**

The transfer of any medicine from one container to another, other than by pharmacy staff, is forbidden. Any loose medicines present on a ward must not be used or returned to the container but sent to the pharmacy for disposal.

## **18 Transfer of Medicines between Wards**

Only in exceptional circumstances should medicines supplied from ward stock be used on another ward. In such cases, the smallest original pack should be supplied. Local arrangements should ensure that such transfers are fully documented. The Misuse of Drugs Regulations do not permit the transfer of controlled drugs between wards.

## **19 Transfer of Patients**

Occasionally when a patient is transferred between hospitals insufficient information regarding treatment is given to the hospital to which the patient is transferred. It is appreciated that in some instances hospitals prefer to retain their own records and that an abbreviated summary is often more convenient for the receiving hospital, but the lack of sufficient information could have an adverse effect on the patient's treatment.

A written record of the patient's diagnosis and current treatment, including medication regimen together with any information on known drug allergies and, where appropriate, a 24 hour supply of medication, should accompany the patient on transfer to another hospital. The time when the patient received the last medication must also be given.

These principles should also be applied for the information of the appropriate General Practitioner when a patient is discharged to the Community (see also section 8) and for the information of the nursing home when a patient is discharged to a home.

## **20 “Out of Hours” Pharmacy Arrangements**

Local arrangements for HPSS establishments should ensure the provision of a pharmacy “out of hours” service. Consideration should be given to the provision of an emergency medicines cupboard, the contents of which should be decided by the Pharmacy Department in consultation with senior medical and nursing staff. Access should be restricted to named individuals and records kept of any stock used.

## **21 Hospital Pharmacy Security Responsibility**

Each pharmacy department must have a pharmacist with delegated responsibility for all aspects of the safe and secure handling of medicines. The pharmacist will define suitable systems of work and storage within the department, taking account of statutory requirements and professional guidance.

### **Access**

Access to the pharmacy stocks must be restricted to personnel authorised by the pharmacist in charge. Medicines can only be supplied in accordance with written procedures approved by the pharmacist in charge.

Emergency pharmaceutical cover should be available for occasions when access to the pharmacy is necessary when the department is closed. Hospital emergency cupboards may provide a source of emergency “out of hours” medicines (see section 20).

### **Physical Security**

Security precautions in general should comply with recommendations made by local Health and Safety Officers, PSNI Crime Prevention Officers and Departmental Officers. There should be a suitable intruder alarm installed in each Department linked to the hospital switchboard or local police station. Such alarms should be regularly tested. Staff must be well informed of the procedures to be followed in the event of a breach of security. Additional security measures including appropriate use of CCTV, panic buttons, toughened glass and restricted access areas are now recommended for all hospital pharmacies.

## Storage of Controlled Drugs

Controlled Drugs must be stored in cabinets, safes, or rooms which must at least conform to the standards laid down in the Misuse of Drugs (Safe Custody) Regulations 1973. Stock levels should be kept to a minimum compatible with hospital demand and the logistics of replenishment.

## Stock Control/Recording and Reconciliation

The purchase and receipt of medicines by the pharmacy should be conducted, and recorded, according to written and approved standard operating procedures (SOPs). These must include a means of identifying the member of pharmacy staff involved at each stage of the transaction.

There must be a clear method whereby medicines being received into the pharmacy store from a supplier are correlated with an official order. The person initiating the order should not, as far as possible, be the person verifying its receipt.

Permanent records of medicines purchased must be maintained and records kept of all medicines coming into and out of the pharmacy. The date of each transaction and the identities of those involved must be recorded.

SOPs should include provision for checks enabling the tracing of medicines, for example, where defects/hazards are reported. Regular stock reconciliation spot checks should be carried out and any discrepancies investigated.

All medicines dispensed from the pharmacy must have been ordered in writing by an appropriate person and a record of the transaction must be maintained together with the signature of the authorised member of the pharmacy staff or other means of his/her identification.

## Controlled Stationery

Controlled stationery is any stationery which, in the wrong hands, could be used to obtain medicines fraudulently. Stocks of controlled stationery must be received, held secure and distributed by the pharmacy department.

In normal circumstances only one book/pad of forms should be held by each ward/unit/department at any given time and replacement stationery should only be issued on the evidence that existing forms have been used. Loss or theft of any controlled stationery must be reported immediately to the person in charge of the ward/unit/department and to the pharmacy for investigation.

## Inspection

The rights of access and inspection by the Department's Pharmaceutical Inspectorate apply to all health service facilities.

## 22 Pharmaceutical Waste

The disposal of medicines and controlled drugs should be carried out in accordance with local policies based on *Guidance on the Handling and Disposal of Pharmaceutical Clinical Waste* (Health Estates 2002)<sup>19</sup>.

## 23 Residential and Nursing Homes

The principles relating to prescribing, administration and storage of medicines given in previous paragraphs should also apply to the handling of medicines in residential homes and private nursing homes. In a residential home setting, it is the responsibility of the owner/employing authority to ensure that medicines management is, as far as possible, in line with the standards and guidance given in this document. Boards should establish detailed procedures to be followed in all such homes subject to their control and inspection. The procedures should take into account the specific guidance given in the following paragraphs.

With the exception of approved "household" remedies, all medicines must be prescribed on an individual "named person" basis. Medicines must also be dispensed on an individual "named person" basis and therefore must be administered only to that person.

All prescriptions must clearly indicate the dosage, frequency and route of administration of the medicine. General instructions such as "as directed" are not acceptable.

Each facility should employ a prescription sheet that fulfils all the requirements listed in section 2 whereon a complete record of each resident's prescription(s), administration of medicine(s) etc is maintained. General Practitioners should be encouraged to verify and sign the prescription record sheet as a matter of good professional practice so as to ensure that the residents' prescribing records are at all times up to date and accurate.

Procedures should include instructions, drawn up in consultation with pharmacy, medical, nursing and social services staff as appropriate, for the Manager in relation to approved home remedies for minor ailments and the

recording of their use. Such procedures should conform to published Regional Guidelines.

Where a resident needs a supply of medicine during a temporary absence from the Home, or on discharge, provision must be made for an adequate, suitably labelled supply to be given to the resident, or responsible adult/relative, for administration as prescribed.

All medicines which are unused and/or unfit for use should be returned to a community pharmacy for disposal.

In specialist units eg Hospice care, where specific arrangements for the procurement of medicines have been agreed with the Department of Health, Social Services and Public Safety, their control and use in those units should follow the guidelines laid down in this document for hospital wards.

## 24 Community Nurses and Health Visitors

Community Nurses and Health Visitors should not normally carry medicines. It is, however, acknowledged that Community Nurses may carry some medicines for emergency use eg adrenaline injection.

Except when carried on the person of the authorised nurse, medicines must be kept out of sight in the nurse's locked vehicle during domiciliary visits. When they are kept overnight in the nurse's own home, they must be securely locked away. Nurses who carry medicines must also carry an identification document, signed by a Senior Nurse, stating their authority to do so.

Each medicine carried must be related to the written prescription of a registered prescriber.

It should be remembered that medicines supplied on prescription to persons in the community are the property of the person for whom they are prescribed.

Nurses have a responsibility for assisting in the education of the public regarding the safe custody and administration of their medicines. Patients should also be warned that medicines require careful storage and that prescribed medicines must not be made available to, or given to, persons other than the patient for whom they were prescribed.

In the administration and recording of medicines by community nurses, the principles of good practice as set out in section 10 must be applied. In addition to the nurse's own records, a record of each administration must be completed for retention by the patient.

Nurses should advise patients and/or their relative(s) and representative(s) that any medicine no longer required should be returned to a pharmacy for disposal.

If at any time the availability of medicine(s) in a patient's home gives cause for concern in relation to the safety of the patient or the custody of the medicine(s), the nurse must exercise his/her professional judgement regarding the removal of medicines. A record of the action taken must be made (including reasons as appropriate) and the patient's doctor fully informed.

## 25 Midwives

Midwives must observe the rules set out in the Midwives Rules (NMC) and Code of Practice and follow relevant legislation and any local policy and/or procedures specified by the Supervisor of Midwives.

### In the Community

#### Supply and Administration of Controlled Drugs

The Misuse of Drugs Act 1971 provides for the supply of pethidine and pentazocine to midwives using a 'supply order' in accordance with Regulation 11 of the Misuse of Drugs Regulations (Northern Ireland) 2002. In these circumstances full records must be maintained for pethidine in a Controlled Drugs Register which must be made available for inspection, if required, by the Department's Misuse of Drugs inspector. Any controlled drugs prescribed by a general practitioner remain the property of the woman and midwives should ensure that they are stored securely in the woman's home.

Possession and administration of Controlled Drugs by midwives must be in accordance with locally agreed procedures and Regulation 11 of the Misuse of Drugs Regulations 2002. Midwives must record full details of the administration of pethidine or other drugs in the patient's records. All records must be made available for inspection as required by the Supervisor of Midwives.

#### Supply and Administration of Other Medicines

A list of prescription only medicines which may be supplied to, and used, by midwives is included in the Prescription

Only Medicines (Human Use) Order 1997. The medicines which are to be used by midwives must be decided by the Supervisor of Midwives in accordance with local policy. Supplies should be arranged as above.

Midwives must keep a record of supply, administration and disposal of all prescription-only medicines issued to them.

When in the custody of the midwife, the security of medicines is the midwife's responsibility.

### **Return/Disposal of Medicines**

As indicated above, Controlled Drugs obtained by a woman on prescription from her doctor, for use in her home confinement, are her own property. Even when no longer required they should not be removed by the midwife, but the woman should be encouraged to return the drugs to the pharmacy from which they were supplied so that they may be safely destroyed.

Where a midwife is in possession of medicines, other than Controlled Drugs, which are no longer required, but are still usable, they may be returned to the pharmacy from which they were supplied. In the case of prescription only medicines, a receipt should be obtained and a record of their return made in the midwife's records. A record must also be made of all prescription only medicines disposed of by the midwife.

### **Audit of Records**

Supervisors of Midwives must, as part of their duties, periodically audit the records of medicines kept by each midwife. Any discrepancies must be investigated.

## **In Hospitals**

### **Midwives Working in Hospitals**

Administration of Controlled Drugs and other medicines by midwives working in hospitals must be in accordance with relevant legislation, locally agreed policies and the guidance given in section 10.

## **26 Primary Care including GP Practices, Health Centres and Community Clinics**

**Security and storage of prescriptions:** There should be an appropriate prescription security system in place to ensure the safe ordering, receipt and storage of prescriptions. It is recommended that practices should

have a written policy and documented procedure. Unused prescriptions should be stored in a locked cabinet. It is advised that a register should be kept which should include the following information as a minimum:

- The date and procedure for ordering;
- The date of receipt of prescriptions from courier;
- The prescription serial numbers, the date and to whom prescriptions were issued from the central supply;
- The register should also record the quantity and date of supply to locums, and record the date of return of unused scripts

Prescriptions pads should not be left unattended at any time. It is recommended that a minimum number of prescriptions should be carried when working outside the practice environment. The responsibility for security of prescription pads rests solely with the prescriber to whom the pads were issued.

It is recommended that stock order forms should be used in accordance with Departmental guidance. The principles of security and storage, as outlined above, should also apply to stock order forms.

Blank computerised prescription sheets should be kept secure and the written policy on prescription security should also incorporate best practice on the issuing and use of computerised prescriptions. Detailed advice has been produced by Health and Social Services Boards and further advice may be obtained from the HSS Family Practitioner Units.

**Medicines stored and used under the personal control of a doctor:** In most cases supplies of medicines are carried personally by doctors. Responsibility for the safe custody of such medicines, including professional samples, rests solely with the doctor concerned and must not be delegated. There should be a practice policy and procedure in place for regularly checking the expiry date and replacement of essential medicines and consequent disposal in accordance with Special Waste Regulations..

**Essential medicines (excluding Controlled Drugs) stored in treatment rooms or other clinical areas for daily use by nursing or other professional staff eg for immunisation, podiatry, dentistry, physiotherapy and family planning:** The amount stored should be kept to a minimum and need not be under the direct

control of the General Practitioner. Emergency packs of medicines should be clearly marked “For Emergency Use” and be easily accessible to staff during the hours when patients attend. All medicines should be stored according to manufacturers’ recommendations in respect of temperature. Where products requiring refrigeration are stored the refrigerator used should be equipped with a means of ensuring that the specific temperature range specified for the product has been maintained. A daily record of such monitoring should be made.

**Controlled Drugs:** General Practitioners are obliged to store their controlled drugs in accordance with the Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973 which requires the use of a locked receptacle. General Practitioners are advised to use a custom made Controlled Drugs cabinet which is affixed properly in an appropriate area in the practice.

Doctors may carry their personal stock in a locked bag but are advised to ensure personal control of this at all times and should avoid storage in an unattended vehicle where it would be susceptible to theft.

It should be noted that the use of the Controlled Drugs Register is mandatory. An appropriate Register may be obtained from the Central Services Agency and guidance on good practice in respect of prescription, supply, administration and destruction of controlled drugs, which has been approved by the Department, is contained in the Register.

**Prescription Pads:** The importance of safe storage and custody of prescription pads (HS21 Rev) is emphasised. Responsibility for the security of these pads rests solely with the prescriber.

### **Out of Hours (OOH) GP Services**

Providers of OOH services should note and follow the principles outlined above for the safe prescription and use of medicines. It is recommended that OOH services **should not** maintain a central supply of controlled drugs but rather ensure that doctors carry a small supply for clinical use.

In certain circumstances small amounts of immediately necessary treatment is issued by practitioners via OOH services. It is essential that these are appropriately labelled with the names of the patient and of the

medicine, the quantity supplied and clear instructions for use. The law also requires that a patient information leaflet be supplied to patients.

### **GP Dispensing Practices**

Dispensing GP practices should operate to the same standards as community pharmacy practice.

### **Medicine Administration**

Medicines must not be administered by nursing staff in health centres/GP practices without the written prescription of a registered prescriber or under the authority of an approved PGD.

### **Supply of Medicines to Community Clinics**

Medicines for use in community clinics are normally supplied via Trust hospital pharmacies. The range of medicines for use in these facilities must be agreed by the practitioners involved and the hospital Trust pharmacist.

Orders for medicines must be in writing and on a supply form provided by the pharmacy. Each order must bear the signature of the person authorised to have possession of the medicines.

### **Primary Care Dental Practitioners**

Primary care dental practitioners should familiarise themselves and put into practice those sections of the guidance which are relevant to their own clinical situation.

## **27 Ambulance Service**

The Medicines Act 1968 restricts the administration of parenteral medicines. All medicines for parenteral administration are prescription only and unless self administered, they may be administered only by or under the directions of a doctor or dentist. Under the Prescription Only Medicines (Human Use) Order 1997 (the POM Order), exemptions from these restrictions are provided for specified persons in respect of specified medicines.

### **Arrangements for ambulance paramedics**

Paramedics holding a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State or persons who are state registered paramedics are authorised to administer a range of parenteral medicines<sup>20</sup> for the immediate, necessary treatment of sick or injured persons.

## Glossary

**Medicinal Product** Article 1 of Directive 2001/83 EC defines a medicinal product as 'any substance or combination of substances presented for treating or preventing disease in human beings or animals. Any substance or combination of substances which may be administered to human beings or animals with a view to making a diagnosis or to restoring, correcting or modifying physiological functions in human beings or animals is likewise considered a medicinal product'.

**Administer** means administer to a human being or an animal whether orally, by injection or by introduction into the body in any other way, or by external application, a substance or article either in its existing state or after it has been dissolved or dispensed in, or diluted or mixed with, some other substance used as a vehicle (Medicines Act 1968).

**Medicine** is used in this guidance to refer to all medicinal products.

**Controlled Drugs (CD)** are substances which are subject to the Misuse of Drugs Act 1971 and Regulations made under that Act. As medicinal products they are also subject to the Medicines Act and its Regulations. Attention is drawn to the Misuse of Drugs Regulations (Northern Ireland) 2002 (No 1) specifying 5 schedules of Controlled Drugs, to which separate controls apply.

**Register** means the Single Professional register kept by the Nursing and Midwifery Council (NMC).

### Parts of the Register

**Part 1** First Level nurses trained in general nursing.

**Part 2** Second level nurses trained in general nursing (England and Wales).

**Part 3** First level nurses trained in the nursing of persons suffering from mental illness.

**Part 4** Second level nurses trained in the nursing of persons suffering from mental illness (England and Wales).

**Part 5** First level nurses trained in the nursing of persons with learning disabilities.

**Part 6** Second level nurses trained in the nursing of persons with learning disabilities (England and Wales).

**Part 7** Second level nurses (Scotland and Northern Ireland)

**Part 8** Nurses trained in the nursing of sick children.

**Part 9** Nurses trained in the nursing of persons suffering from fever.

**Part 10** Midwives.

**Part 11** Health visitors.

**Part 12** First level nurses trained in adult nursing (Project 2000)

**Part 13** First level nurses trained in mental health nursing (Project 2000)

**Part 14** First level nurses trained in learning disabilities nursing (Project 2000)

**Part 15** First level nurses trained in children's nursing (Project 2000)

**Nursing and Midwifery students** are persons who are undergoing pre-registration training for admission to the appropriate parts of the Register.

**Sister/Acting Sister/Ward Manager** is a nurse for the time being in charge of a ward, theatre or other department in a hospital or nursing home or, a caseload holder in a community setting. It includes any male nurse occupying a similar position. Authorised Medical Officer is a doctor who is for the time being authorised in writing by the local Board's Chief Administrative Medical Officer for the purposes of Regulation 11 - Exemption for Midwives - of the Misuse of Drugs (Northern Ireland) Regulations 2002 or (for signing Midwives' Supply Orders only) a Supervisor of Midwives who is so authorised for the purposes of Regulation 11(2) of those Regulations.

**Prescriber** is a person authorised under the Medicines Act 1968 to order in writing the supply of a prescription only medicine for a named patient

**Authorised person** is a person authorised by the Department for the purposes of Regulation 27 of the Misuse of Drugs Regulations (Northern Ireland) 2002 (destruction of controlled drugs).

**Approved name** of a medicine is its designated generic name devised and selected by the British Pharmacopoeia Commission and published in accordance with the Medicines Act 1968.

In this guidance all references to staff and patients should be taken as including either sex.

## References

- <sup>1</sup> *Guidelines for the administration of medicines*, Nursing and Midwifery Council, 2002
- <sup>2</sup> *Good Practice in Consent*, issued under cover of HSS(MD)7/2003 on 13th March 2003
- <sup>3</sup> *British National Formulary*, incorporating the Nurse Prescribers' Formulary, BMA and RPSGB
- <sup>4</sup> A helpful flowchart for determining the appropriateness or otherwise of a PGD is provided at <http://www.groupprotocols.org.uk>
- <sup>5</sup> *Misuse of Drugs Regulations (Northern Ireland) 2002*
- <sup>6</sup> The relevant provisions are contained in *The Prescription Only Medicines (Human Use) Amendment Order 2000* (SI 2000 No 1917)
- <sup>7</sup> By virtue of *The Prescription Only Medicines (Human Use) Amendment Order 2003* (SI 2003 No 696) the use of PGDs has been extended to the private sector.
- <sup>8</sup> *Research Governance Framework for Health and Social Care*, DHSS&PS, November 2002
- <sup>9</sup> <http://www.emea.eu.int/pdfs/human/ich/013595en.pdf>
- <sup>10</sup> *Guidance Procedures when a Patient in a Hospital or Clinic Setting is found in possession of Unauthorised Drugs or other Suspicious Substances*, issued under cover of HSS(MD)11/95 on 14th August 1995.
- <sup>11</sup> *Good Medical Practice*, General Medical Council, 2001
- <sup>12</sup> *Tomorrow's doctors; Recommendations on undergraduate medical education*, General Medical Council, July 2002
- <sup>13</sup> *Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2002*, The Stationery Office, 2002
- <sup>14</sup> *National Guidance on the Safe Administration of Intrathecal Chemotherapy*, Department of Health, London, 2001 (<http://www.doh.gov.uk/intrathecalchemotherapy/guidance.pdf>); issued in Northern Ireland under cover of HSS(MD)31/01 on 16th November 2001. See also letter on Frequently Asked Questions issued 3rd May 2002 and HSS(MD)2/2003 issued on 9th January 2003.
- <sup>15</sup> *Patient Safety Alert - Potassium Chloride*, National Patient Safety Agency (NPSA), 2002 (<http://www.npsa.org.uk/admin/publications/docs/riskalertpsa01.pdf>); issued under cover of letter CPh2/02 on 23rd July 2002
- <sup>16</sup> *Recommendations on Facilities, Staffing and Procedures related to Chemotherapy Administration within the Northern Ireland Cancer Treatment Service*, Regional Advisory Committee on Cancer (RACC), 1999
- <sup>17</sup> *Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources*, Administration of Radioactive Substances Advisory Committee (ARSAC) 1998
- <sup>18</sup> *The Regional Group on Specialist Drugs - Implementation of Red/Amber Lists* issued under cover of HSS(MD)16/2003 on 2nd April 2003
- <sup>19</sup> *Pharmaceutical Clinical Waste - A Guide*, Health Estates, 2002; issued under cover of Health Estates Circular PEL (02) 10
- <sup>20</sup> Diazepam 5 mg per ml emulsion for injection;  
Succinylated Modified Fluid Gelatin 4 per cent intravenous infusion;  
Medicines containing the substances ergometrine maleate 500mcg/ml with oxytocin 5iu/ml but no other active ingredient;  
Prescription Only Medicines containing one or more of the following substances but no other active ingredient-

Adrenaline Acid Tartrate	Lignocaine Hydrochloride
Anhydrous Glucose	Metoclopramide
Benzylpenicillin	Morphine Sulphate
Bretylium Tosylate	Nalbuphine Hydrochloride
Compound Sodium Lactate Intravenous Infusion (Hartmann's Solution)	Naloxone Hydrochloride
Ergometrine Maleate	Polygeline
Fruzemide	Sodium Bicarbonate
Glucose	Sodium Chloride
Heparin Sodium	Streptokinase
	Syntometrine

In addition, ambulance paramedics are included within the classes of persons permitted to supply or administer medicines under Patient Group Directions (see under section 4 above).





Department of  
**Health, Social Services  
and Public Safety**

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An Roinn  
**Sláinte, Seirbhísí Sóisialta  
agus Sábháilteachta Poiblí**

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