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AN ROINN

**Sláinte, Seirbhísí Sóisialta  
agus Sábháilteachta Poiblí**

MÄNNYSTRIE O

**Poustie, Resydènter Heisin  
an Fowk Siccar**

# **Safer Management of Controlled Drugs**

*A guide to good practice in secondary care  
(Northern Ireland)*

**August 2009**



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## Foreword

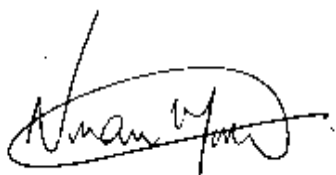


*There have been major advances in the therapeutic use of controlled drugs in the last few years and these are now an essential part of modern clinical care. However, as a result of the actions of Harold Shipman, and the recommendations arising from the Shipman Inquiry, significant changes have been made in both governance and legislation surrounding the use and management of controlled drugs.*

*In implementing better controls which support professionals and encourage good practice we must ensure that patients have appropriate and convenient access to controlled drugs to meet their clinical needs..*

*This document has been developed for secondary care in Northern Ireland and is designed to provide guidance on good practice for the management of controlled drugs. It seeks to take account of the important legislative changes and developments in professional practice and accountability.*

*In commending this guidance to secondary care organisations I wish to acknowledge the multidisciplinary input and the extent and quality of the responses to the consultative draft. The application of this guidance will, I believe, make a significant contribution to improving governance and patient safety.*



Norman C Morrow

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# 1 Executive summary

The purpose of this guidance is to promote the safe and effective use of controlled drugs in healthcare organisations providing secondary care. The new strengthened governance arrangements for controlled drugs and legislative changes that flow from the Government response to the fourth report of the Shipman Inquiry impose significant new responsibilities on healthcare organisations. This guidance sets out how these changes apply to the use and management of controlled drugs in secondary care settings and will support healthcare professionals and organisations in implementing the new arrangements. It has been developed from an original document published by the Department of Health. [*Safer Management of Controlled Drugs A guide to good practice in secondary care*, 17<sup>th</sup> October 2007, [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_079618](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079618)]. That document emerged following widespread consultation with key stakeholders, including representation from Northern Ireland, chaired by the Royal Pharmaceutical Society of Great Britain. The work of the Royal Pharmaceutical Society is acknowledged and appreciation is expressed to the Department of Health for permission to use the original document as the basis for the Northern Ireland version. The document, as revised for Northern Ireland, has been reviewed by professionals here. A list of those who contributed to the design and content of the guidance appears at Appendix 6.

The Northern Ireland response to the Shipman Inquiry's Fourth Report was set out in *Improving Patient Safety – Building Public Confidence*. [27<sup>th</sup> Nov 2006, [http://www.dhsspsni.gov.uk/improving\\_patient\\_safety\\_-\\_building\\_public\\_confidence.pdf](http://www.dhsspsni.gov.uk/improving_patient_safety_-_building_public_confidence.pdf)] The response identified ways for strengthening the current systems for managing controlled drugs to minimise the risks to patient safety of the inappropriate use of controlled drugs. Controlled drugs are subject to special legislative controls because there is a potential for them to be abused or diverted, causing possible harm. However, as the Inquiry recognised, there have been major advances in the therapeutic use of controlled drugs in the last few years. Controlled drugs are now an essential part of modern clinical care. Strengthened controls must be implemented in a way that supports professionals and encourages good practice in the use of these important medicines when clinically required by patients.

*Improving Patient Safety – Building Public Confidence* set out a substantial programme of work to improve the management of controlled drugs. As a result, a number of changes affecting the prescribing, record keeping and destruction of controlled drugs were introduced through amendments to the Misuse of Drugs Regulations (Northern Ireland) 2002 (SR 2002 No. 1) (MDR). The Health Act 2006 provided for regulations to be made relating to strengthened governance and monitoring arrangements for controlled drugs. The Health Act 2006 is primary legislation and applies to the whole of the UK. The Regulations developed under the Health Act may differ to some extent in the different administrations. The Northern Ireland legislation, The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009, comes into operation on 1<sup>st</sup> October 2009.

This document is intended to provide guidance on good practice for the management of controlled drugs in secondary care in Northern Ireland. It aims to set out robust systems for procuring, storing, supplying, transporting, prescribing, administering, recording, and disposing safely of controlled drugs, whilst at the same time helping to

ensure appropriate and convenient access for those patients that require them. It is not designed to provide advice on the clinical choice or use of controlled drugs. However, individual professional organisations provide a range of advisory services to their members (see Appendix 4). Although this guidance is focussed on the safe use and management of controlled drugs in secondary care settings, patients and healthcare professionals will move and work across care sectors. The DHSSPS has published a guide to good practice in the management of controlled drugs in primary care which is available on its website.

This guidance recognises developments that have taken place to modernise working practices in recent years: the changing roles of healthcare professionals, the need to ensure optimal use of skill mix and the key contribution of pharmacy technicians and other healthcare professionals, for example, Operating Department Practitioners, and seeks to clarify how these fit within the existing legal framework for controlled drugs.

Controlled Drugs are those listed in Schedule 2 to the Misuse of Drugs Act 1971. For practical purposes they are classified in Schedules 1 to 5 to the Misuse of Drugs Regulations (Northern Ireland) 2002 according to the controls necessary for their governance. Within this document the emphasis is placed on those contained in Schedule 2 to the MDR, as these are subject to the highest levels of control. On occasions, healthcare organisations choose to manage non-controlled drugs and controlled drugs in other Schedules in the same way as Schedule 2 controlled drugs to ensure a higher level of governance. This is a matter for local decision and does not form part of this guidance.

This guidance is intended to build on and augment the advice provided in two previous documents: *Use and Control of Medicines - Guidelines for safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services* (April 2004, [http://www.dhsspsni.gov.uk/use\\_control\\_of\\_medicines.pdf](http://www.dhsspsni.gov.uk/use_control_of_medicines.pdf)) and *The Safe and secure handling of medicines: A team approach* (the Revised Duthie Report), (March 2005, <http://www.rpsqb.org/pdfs/safsechandmeds.pdf> - commended by the DHSSPS and endorsed by the Pharmaceutical Society of Northern Ireland). Neither of these documents is concerned specifically with controlled drugs and readers are also encouraged to refer them for guidance on more general aspects of medicines management.

This guidance has been organised into chapters dealing with the legislative requirements, governance arrangements and guiding principles. Chapters that deal with the management of controlled drugs in wards, operating theatres and pharmacies follow. A chapter on special situations has been included to accommodate a number of situations that do not obviously fit elsewhere. There is also a brief chapter on training. Separate sections have not been written for each hospital department, because the requirements for the safe management of controlled drugs do not differ between medical and surgical wards or general wards and high-dependency wards. Although the guidance includes most of the commonly-encountered situations, inevitably, as practice continues to develop, users will on occasions find gaps or points which fit uneasily with their situation. In such cases it is hoped that the principles listed in Chapter 3 will provide a basis for policy formulation.

The style of the *Revised Duthie Report* (March 2005) has been adopted. The term “should” has been used for recommendations that relate to good practice and “must” for those governed by legal requirements. Recommendations have also been inserted that “may” be followed as matters of good practice, if they are relevant to local circumstances.



This document has been designed both for those who are involved in management of controlled drugs in secondary care and for those who are responsible for ensuring that controlled drugs are managed appropriately in their organisations or in their part of the organisation. It should be of value in a number of settings where controlled drugs are used including:

- Pharmacies
- Hospital wards and departments including operating theatres
- Midwifery units
- Other health and social care bodies

This guidance should also be of value in a number of settings outside the secondary sector such as hospices, community hospitals, rehabilitation centres and other similar organisations where controlled drugs are used and managed.

Questions relating to the management of controlled drugs may often be resolved by referring to guidance published by professional bodies. Advice may also be sought from the Pharmaceutical Advice and Services Branch of the DHSSPS. Appendix 4 includes professional organisations that provide advice for their members. Regular reference should be made to the following websites to check for up-to-date information:

The Department's website: [www.dhsspsni.gov.uk](http://www.dhsspsni.gov.uk)

The Department of Health website: [www.dh.gov.uk/controlleddrugs](http://www.dh.gov.uk/controlleddrugs)

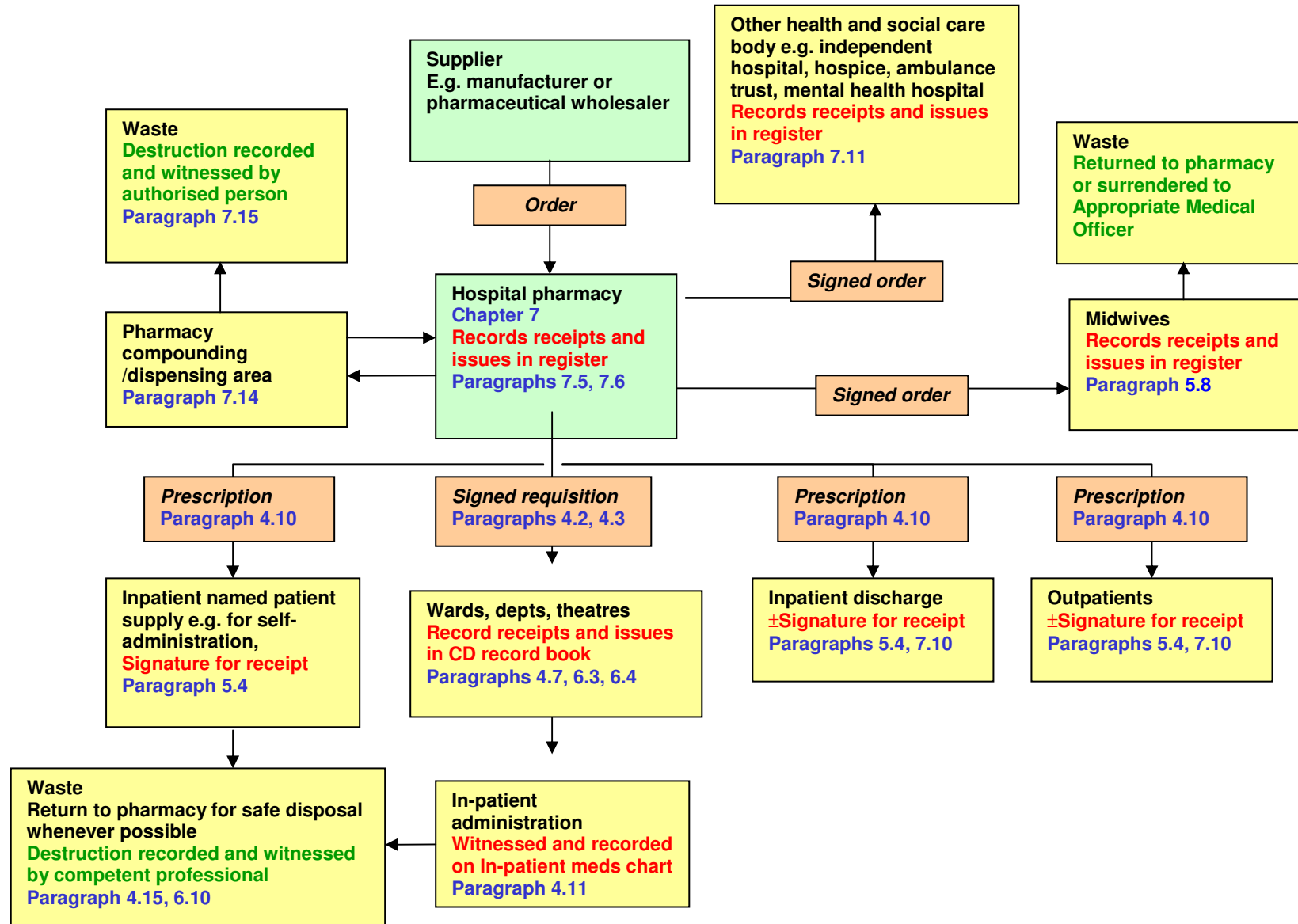
The Home Office websites:

[www.homeoffice.gov.uk](http://www.homeoffice.gov.uk) and [www.drugs.gov.uk/drugslaws](http://www.drugs.gov.uk/drugslaws)

The Pharmaceutical Society of Northern Ireland website: [www.psni.org.uk](http://www.psni.org.uk)

The Royal Pharmaceutical Society of Great Britain website [www.rpsgb.org.uk](http://www.rpsgb.org.uk)

Figure 1 The product journey – CDs in secondary care



# 2 Legislation and governance arrangements

## Legislation

**Legislative framework for controlled drugs**

**Supply and administration of controlled drugs**

## Governance arrangements

**Accountability and responsibility**

**The Accountable Officer**

**Monitoring and Inspection**

**Standard Operating Procedures**

## Legislation

### 2.1 Legislative framework for controlled drugs

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

Additional statutory measures for the management of controlled drugs are laid down in the Health Act (2006) - and its associated Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.

The relevant legislation and guidance is summarised briefly in Appendix 1. Readers are encouraged to refer to the relevant websites for detailed, up-to-date information.

The legal requirements pertaining to the different Schedules of controlled drugs are summarised in Table 1. Schedule 1 drugs have been omitted from the table because drugs in this group have virtually no therapeutic uses.

**Table 1: Summary of legal requirements applying to controlled drugs in Schedules 2, 3, 4 & 5 of the Misuse of Drugs Regulations**

<b>Schedule (refers to schedules of the Misuse of Drugs Regulations)</b>	<b>Schedule 2</b> Includes – Opioids, (e.g. diamorphine, morphine, methadone), major stimulants (eg amphetamines) remifentanil secobarbital	<b>Schedule 3</b> Includes minor stimulants, temazepam, buprenorphine, flunitrazepam, midazolam, barbiturates except secobarbital	<b>Schedule 4 pt I</b> Includes benzo-diazepines	<b>Schedule 4 pt II</b> Includes anabolic steroids, clenbuterol, growth hormones	<b>Schedule 5</b> Includes low strength opioids
Designation	CD	CD No Reg	CD Benz	CD Anab	CD Inv
Safe custody	Yes, except secobarbital	Yes, with certain exemptions (see MEP, details below)	No	No	No
Prescription requirements – apply to OP and discharge prescriptions	Yes	Yes, except temazepam	No	No	No
CD Requisitions necessary?	Yes	Yes	No	No	No
Records to be kept in CD register	Yes	No	No	No	No
Pharmacist must ascertain the identity of the person collecting CD	Yes	No	No	No	No
Emergency supplies allowed	No	No, except phenobarbital for epilepsy*	Yes*	Yes*	Yes*
Validity of prescription	28 days from the appropriate date**	28 days from the appropriate date**	28 days from the appropriate date**	28 days from the appropriate date**	6 mths (if POM)
Maximum duration that may be prescribed	30 days as good practice	30 days as good practice	30 days as good practice	30 days as good practice	

Table adapted from Medicines, Ethics and Practice Guide (MEP) (<http://www.rpsgb.org/pdfs/MEP30s1-2b.pdf>) Further information can be found in the MEP and in the British National Formulary (<http://www.bnf.org/bnf/>)

\* Up to a quantity sufficient for 5 days treatment

\*\* “Appropriate date” means the later of the date on which the prescription was signed by the person issuing it or the date indicated by him as being the date before which it shall not be supplied.

## 2.2 Supply and administration of controlled drugs

There are a number of mechanisms for the supply and administration of controlled drugs in secondary care. Controlled drugs can be

- Prescribed by a doctor, dentist or nurse independent prescriber
- Supplied and administered under Patient Group Directions
- Supplied and administered by a midwife

Certain restrictions apply to each of these routes of supply.

### 2.2.1 Supply and /or administration of controlled drugs under Patient Group Directions

A Patient Group Direction (PGD) allows a range of specified healthcare professionals to supply and /or administer a medicine directly to a patient with an identified clinical condition within an identified set of circumstances without the patient first seeing a prescriber. Individual professionals who are to work within a PGD must be named on it and have received appropriate training for operating the PGD.

Named nurses, paramedics and other specified health professionals can supply and administer certain controlled drugs in restricted circumstances in accordance with a PGD and the additional requirements of the Misuse of Drugs (Amendment) (No.3) Regulations (Northern Ireland) 2003 (SR 2003 No. 420) [http://www.uk-legislation.hmso.gov.uk/sr/sr2003/nisr\\_20030420\\_en.pdf](http://www.uk-legislation.hmso.gov.uk/sr/sr2003/nisr_20030420_en.pdf) (See also the *Home Office Circular 049 / 2003. Controlled Drugs Legislation - Nurse Prescribing And Patient Group Directions*) [<http://www.knowledgenetwork.gov.uk/ho/circular.nsf/79755433dd36a66980256d4f004d1514/248786ae1bb78d6180256dab003b2948?OpenDocument>]

There are currently only limited circumstances in which certain controlled drugs may be administered or supplied under a PGD by certain named health professionals. These are:

- Registered nurses (but no other healthcare practitioners) in accident and emergency departments and coronary care units in hospitals can supply or administer diamorphine for the treatment of cardiac pain in accordance with a PGD.
- Registered nurses, pharmacists, paramedics, midwives, ophthalmic opticians, chiropodists, orthoptists, physiotherapists, radiographers, occupational therapists and orthotists or prosthetists can supply or administer any schedule 4 or 5 controlled drug in accordance with a PGD, except
  - The anabolic steroids in Schedule 4, part 2

- Injectable formulations for the purpose of treating a person who is addicted to a drug

### **2.2.2 Midwife's exemptions**

Registered midwives may administer parenterally, a number of specified controlled drugs in the course of their professional practice. These are:

- Diamorphine
- Morphine
- Pentazocine lactate
- Pethidine hydrochloride

(See - The Prescription Only Medicines (Human Use) Order 1997( SI1997 No. 1830). The Misuse of Drugs Regulations (Northern Ireland) 2002 (SR 2002 No. 1))

(See also paragraph 5.8 Controlled drugs for midwives)

## **Governance arrangements**

### **2.3 Accountability and responsibility**

At local level, all healthcare organisations or designated bodies (see The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009; (SR 2009 No. 225) [available at the website of the Office of Public Sector Information: [www.opsi.gov.uk](http://www.opsi.gov.uk)] are accountable, through the Accountable Officer (AO, see below), for ensuring the safe management of controlled drugs. In Northern Ireland, the following are designated bodies:

- The Regional Health and Social Care Board
- A Health and Social Care Trust
- The Northern Ireland Ambulance Service Trust
- An Independent Hospital

All designated bodies, including HSC Trusts, and independent healthcare organisations, are accountable for the monitoring of all aspects of the use and management of controlled drugs by all healthcare professionals whom they employ, with whom they contract or to whom they grant practice privileges. This will be done through normal governance arrangements such as analysing baseline data and clinical governance visits (for example by clinical governance leads).

Where one organisation provides services to another, responsibility for governance arrangements should be specified in the contract (or service level agreement). Reporting should be to the Accountable Officer for the organisation that is receiving the service. (Once the CDs have been received responsibility for them passes to receiving organisation.) In setting up and reviewing these governance arrangements, the AO will want to pay particular

attention to and prioritise key areas of risk which will include the interface with other health and social care providers.

Each designated body may also consider establishing a Controlled Drug Review Group. Such groups may be part of the arrangements that AOs are required to have in place for analysing and responding to adverse incidents involving the management or use of controlled drugs.

## **2.4 The Accountable Officer**

The Accountable Officer is responsible for all aspects of the safe and secure management of CDs in his organisation. This includes ensuring that safe systems are in place for the management and use of CDs, monitoring and auditing the management systems and investigation of concerns and incidents related to CDs.

The regulatory requirements for Accountable Officers are set out in full in the Controlled Drugs (Supervision of Management and Use) Regulations Northern Ireland) 2009; (SR 2009 No.225) and a summary of the main provisions is provided at Appendix 3 of this document. See also 'Safer Management of Controlled Drugs: A Guide to Strengthened Governance Arrangements in Northern Ireland' in the Accountable Officer section of the Department website [www.dhsspsni.gov.uk](http://www.dhsspsni.gov.uk)

## **2.5 Monitoring and inspection**

Regular inspections of hospital pharmacies related to the management of controlled drugs are conducted by inspectors from the DHSSPS. Core activities examined include secure storage facilities, statutory and informal record keeping and the arrangements made for robust audit trails.

## **2.6 Standard operating procedures**

Each of the activities that relate to controlled drugs, regardless of where in the organisation they occur, should be described in a standard operating procedure (SOP). SOPs for controlled drugs become mandatory in Northern Ireland, rather than good practice, with the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009, coming into operation on 1<sup>st</sup> October 2009. SOPs are particularly important if tasks are delegated to others. For example, issue and receipt of stock controlled drugs in the pharmacy may be delegated to a competent pharmacy technician. However, responsibility lies with the pharmacist who authorised the activity.

SOPs must be kept up-to-date, reflecting current legal and good practice requirements for controlled drugs, and each one should be clearly marked with the date of issue and review date. Previous versions should be archived.

All staff who are involved in the prescribing, supplying, administering or disposing of controlled drugs must be familiar with the SOPs.

The standard operating procedures must, in particular, cover the following matters:

- (a) who has access to the controlled drugs;

- (b) where the controlled drugs are stored;
- (c) security in relation to the storage and transportation of controlled drugs as required by misuse of drugs legislation;
- (d) disposal and destruction of controlled drugs;
- (e) who is to be alerted if complications arise; and
- (f) record keeping, including:
  - (i) maintaining relevant controlled drugs registers under misuse of drugs legislation,
  - (ii) maintaining a record of the controlled drugs specified in Schedule 2 to the Misuse of Drugs Regulations 2002 (specified controlled drugs to which certain provisions of the Regulations apply) that have been returned by patients.

SOPs within a health care organisation should be formally approved by the Accountable Officer for that organisation. This task may be delegated to a suitably qualified person, however, the final responsibility lies with the Accountable Officer. .

### Additional Information

A comprehensive list of drugs included within the Schedules to the Misuse of Drug Regulations 2002 can be accessed at:

- [www.opsi.gov.uk](http://www.opsi.gov.uk),
- Home Office [www.homeoffice.gov.uk](http://www.homeoffice.gov.uk)
- Medicines and Healthcare Products Regulatory Agency (MHRA) [www.mhra.gov.uk](http://www.mhra.gov.uk)

Some of the following sites may contain material which may be useful to inform practice in Northern Ireland.

- DHSSPS will also publish guidance for the safer management of controlled drugs in primary care. <http://www.dhsspsni.gov.uk/index/publications/>
- The Care Quality Commission is responsible for overseeing the management of controlled drugs by healthcare organisations in England and a section of the website is dedicated to controlled drugs: [www.cqc.org.uk](http://www.cqc.org.uk)
- Department of Health Controlled Drugs pages: [www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustry/Prescriptions/ControlledDrugs/fs/en](http://www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustry/Prescriptions/ControlledDrugs/fs/en)
- Royal Pharmaceutical Society of Great Britain. *Medicines, Ethics and Practice: A guide for pharmacists.* <http://www.rpsgb.org.uk/pdfs/MEP30s1-2a.pdf>



- Royal Pharmaceutical Society of Great Britain. Patient Group Directions: A resource pack for pharmacists. <http://www.rpsgb.org.uk/pdfs/pgdpack.pdf>.
- Pharmaceutical Services Negotiating Committee (PSNC). *Controlled Drugs – recent changes*. [http://www.psnc.org.uk/index.php?type=more\\_news&id=2056&k=3](http://www.psnc.org.uk/index.php?type=more_news&id=2056&k=3)
- Nursing and Midwifery Council ([www.nmc-uk.org](http://www.nmc-uk.org)). Standards for Medicines Management (February 2008); NMC Circular 25/2005 *Midwives Supply Orders*; NMC Circular 1/2005, *Medicine legislation: what it means for midwives*.

# 3 General principles

There are a number of overarching principles that guide the use of medicines in general and controlled drugs in particular. They underpin and inform the decisions that are made about the safe management of controlled drugs within the current legal framework. The following principles should apply in relation to the management of controlled drugs.

- 3.1 Patients have timely access to the medicines prescribed for them
- 3.2 Organisations and individuals comply with the current legal requirements for controlled drugs
- 3.3 Patients are partners in their treatment and share decision-making with healthcare professionals about their treatment.
- 3.4 Patients are adequately informed about their treatment
- 3.5 Controlled drugs are used and managed safely and securely
- 3.6 There is a clear audit trail for the movement and use of all controlled drugs
- 3.7 The use of controlled drugs is audited and action is taken if necessary
- 3.8 Controlled drugs are prescribed by professionals who are competent to do so and who receive regular training and support on the safe management of controlled drugs
- 3.9 Local procedures and protocols are designed to be as clear and accurate as possible. They should be practical in use and not impose an intolerable administrative burden
- 3.10 The stock levels of controlled drug preparations held in wards and departments match what is routinely used in that clinical area
- 3.11 Healthcare staff have access to up-to-date information about CD legislation and official (Home Office, DHSSPS, professional body and other) guidance
- 3.12 Healthcare staff in the organisation work to standard operating procedures, approved by the Accountable Officer, that are appropriate to their area of work
- 3.13 Healthcare and appropriate ancillary staff receive adequate training and are competent in the management of controlled drugs (appropriate to their sphere of activity and level of responsibility)
- 3.14 Access to controlled drugs is restricted to appropriate, designated and legally authorised personnel

# 4 Management of controlled drugs in wards and departments

This chapter deals with the management of controlled drugs in wards and departments. The management of controlled drugs in operating theatres is covered in Chapter 6.

## Contents of this chapter:

- Accountability and responsibility**
- Controlled drug stocks**
- Requisitioning of controlled drugs**
- Receipt of controlled drugs**
- Storage**
- Key-holding and access to controlled drugs**
- Record-keeping**
- Stock checks**
- Archiving of records**
- Prescribing**
- Prescribing for inpatients/discharge patients**
- Prescribing for outpatients**
- Supplementary prescribers**
- Non-medical independent prescribers**
- Administration of controlled drugs**
- Management of controlled drugs when patients are admitted**
- Management of controlled drugs when patients are transferred to other wards or departments**
- Management of controlled drugs when patients are discharged**
- Return of controlled drugs to pharmacy**

This section deals with measures concerned with the management of controlled drugs that are applicable in most wards and departments, including diagnostic departments. The requirements for pharmacy departments can be found in Chapter 7.

Where additional information can be found in other paragraphs, cross-references are also included.

## **4.1 Accountability and responsibility**

### **4.1.1 Accountable individuals**

The senior registered nurse or registered operating department practitioner (ODP) in charge of a ward or department is responsible for the safe and appropriate management of controlled drugs in that area. The senior registered nurse or ODP in charge can delegate control of access (i.e. key-holding) to the CD cabinet to another, such as a registered nurse or another ODP. However, responsibility remains with the registered nurse or ODP in charge. Whilst the task can be delegated, the responsibility cannot.

### **4.1.2 Standard operating procedures**

There must be standard operating procedures (SOPs) covering each of the activities concerned with controlled drugs such as requisitioning, receipt, administration, record keeping and destruction.

SOPs must be kept up-to-date, reflecting current legal and good practice requirements for controlled drugs, and each one should be clearly marked with the date of issue and review date. Relevant staff should be conversant with the SOPs.

SOPs should be discussed with and approved by the Accountable Officer or by the person to whom he has delegated this task. The Accountable Officer remains finally accountable for all the systems for the safe management of CDs. (See Appendix 3)

## **4.2 Controlled drug stocks**

There should be a list of the controlled drugs to be held in each ward or department as stock items. The contents of the list should reflect current patterns of usage of controlled drugs in the ward or department and should be agreed between the pharmacist or pharmacy technician responsible for stock control of medicines on the ward and the senior registered nurse or registered operating department practitioner in charge.

4.2.1 The list should be modified if practices change and should be subject to regular review at agreed intervals.

## **4.3 Requisitioning of controlled drugs**

The senior registered nurse or registered operating department practitioner (ODP) in charge of a ward, department, operating theatre or theatre suite is responsible for the requisitioning of controlled drugs for use in that area.

4.3.1 The senior registered nurse or ODP in charge can delegate the task of preparing a requisition to another, such as a registered nurse or another ODP (See Chapter 6; The management of controlled drugs in operating theatres and Appendix 2). However, legal responsibility remains with the senior registered nurse or ODP in charge.

4.3.1.1 Orders must be in writing and should be on suitable stationery (e.g. a controlled drug requisition book with duplicate or triplicate pages) and must be signed by an authorised signatory. Stationery should be designed to facilitate a robust audit trail. (See also 4.3.3 Electronic systems)

4.3.1.2 A copy of the signature of each authorised signatory should be available in the pharmacy department for validation. Where electronic systems are in use, there should be a reliable means of validating the identity of individuals who requisition controlled drugs.

4.3.1.3 Requisitions must contain the following:

- Name of hospital
- Name of Ward / Department
- Drug name, form, strength, ampoule size if more than one available
- Total quantity

Signature of senior registered nurse or ODP in charge

The requisition should also contain:

- Date on which it was written
- The printed (as in a legible version) of the name of the senior registered nurse or ODP in charge who signed the requisition

When the drug has been supplied the requisition must:

- Be marked in such a manner to show that it has been complied with.

4.3.1.4 The person making the supply should sign and date the requisition when it has been complied with, if that has not been part of the compliance marking, above.

4.3.1.5 The person who accepts the controlled drugs for transit should sign for receipt. This may be on the duplicate requisition (if space permits) or may be in a separate book kept for this purpose.

4.3.1.6 The person who receives the controlled drugs on the ward should sign the duplicate copy of the requisition.

4.3.1.7 Requisitions must be retained at the dispensary at which the drug was supplied and a copy of the requisition or a note of it must be retained by the recipient (the senior registered nurse or ODP in charge.)

### **4.3.2 CD Top-up schemes**

In some situations pharmacy-led CD top-up schemes for replenishing stocks of controlled drugs on wards and departments are a practical and convenient mechanism of stock control. These are usually carried out by a pharmacy technician or senior assistant technical officer (SATO), but may also be carried out by other suitably-trained, competent members of the pharmacy staff.

4.3.2.1 When a CD top-up scheme is in operation, the responsibility for controlled drugs in a ward or department remains with the senior registered nurse or ODP in charge.

4.3.2.2 In a top-up scheme a member of the pharmacy staff is responsible for checking the stock balances in the ward controlled drug record book against the levels in the agreed stock list and preparing the CD requisition forms in order to replenish the stock. These requisition forms should be signed by the senior registered nurse or ODP in charge.

### **4.3.3 Electronic systems**

Where electronic systems for the requisitioning of controlled drugs are introduced, safeguards in the software should be put in place to ensure that:

- Only individuals who are authorised to requisition controlled drugs from the pharmacy can do so
- The author of each entry is identifiable
- Entries cannot be altered at a later date
- A log of all data entered is kept and can be recalled for audit purposes.

## **4.4 Receipt of controlled drugs**

When controlled drugs are delivered to a ward or department they should be handed to an appropriate individual. On no account should they be left unattended. (See paragraph 5.2 Transfer of controlled drugs). A local procedure should define the appropriate persons who are permitted to receive controlled drugs and the way in which messengers identify them. As a matter of good practice the receiving person should not be the same person who ordered the controlled drugs. The person receiving the supply should sign the duplicate sheet in the requisition book, having checked the items received.

4.4.1 As soon as possible after delivery the senior registered nurse or ODP in charge should:

- Check the controlled drugs against the requisition – including the quantity ordered and received. If this is correct then the duplicate sheet in the controlled drug requisition book should

be countersigned in the “received by” section. If the controlled drugs received do not accord with the requisition then the pharmacy should be contacted immediately. Any tamper-evident seals on packs should be left intact when they are received from pharmacy. (Note, however, that some pharmacies open sealed packs to check for breakage before issue to wards.) Intact seals will simplify and speed up routine checks. A seal should only be broken when the pack is required for administration.

- Place the controlled drugs in the appropriate CD cabinet
- Enter the controlled drugs into the controlled drug record book, update the running balance and check that the balance tallies with quantity that is physically present.
- If, when the tamper evident seal is broken, the contents do not match the expected amount stated on the pack, the senior registered nurse or ODP in charge should contact the pharmacy department as soon as possible.
- Ensure that appropriate records are made in the ward controlled drug record book and all necessary action taken to resolve the discrepancy. See 5.9 Discrepancies and diversion.

4.4.2 Depending on local circumstances, some healthcare organisations may wish to stipulate that receipt of controlled drugs and updating of the controlled drugs record book should be witnessed by a second competent professional.

See also paragraph 6.4 Receipt of controlled drugs in Theatre

## **4.5 Storage of controlled drugs**

The Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973 (SR 1973 No 179) cover the safe custody of controlled drugs in certain specified premises. The Regulations also set out certain standards for safes and cabinets used to store controlled drugs. Apart from specified excepted circumstances the Regulations also require that all controlled drugs to which the Regulations apply, must be in locked storage which can only be opened by a person who can lawfully be in possession of the controlled drugs or a person working under their authority.

4.5.1 Ward CD cupboards should conform to the British Standard reference BS2881:1989 (“Specification for cupboards for the storage of medicines in healthcare premises” ISBN 058017216 3) or be otherwise approved by the pharmacy department. Cupboards should provide a level of security at least comparable to that laid down in the Safe Custody Regulations. 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 further security measures should be introduced.

4.5.2 In certain circumstances, for example when controlled drug discharge medicines are sent to the ward several hours before the patient leaves, the medicines should be stored securely in the CD cupboard. These medicines should be segregated from the ward controlled drug stock. (See paragraph 5.4 Management of CDs that are patients' property)

4.5.3 General measures for the storage of controlled drugs include the following:

- Controlled drugs must be locked away when not in use
- 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 and at any time the key-holder should be readily identifiable
- There must be arrangements for keeping the keys secure. This is particularly important for areas such as day surgery units and five-day wards that are not operational at all times.
- No other medicines or items should normally be stored in the CD cupboard. Occasionally, in response to local circumstances healthcare organisations may decide to allow other drugs that are not controlled drugs to be stored in the CD cupboard. Trusts should carry out a risk assessment and have clear guidelines and SOPs in place to cover this

## 4.6 Key-holding and access to controlled drugs

### 4.6.1 Responsibility for CD keys

The senior registered nurse or ODP in charge is responsible for the CD key.

4.6.1.1 Key-holding (in the sense of giving the key to another for immediate access to the cupboard) may be delegated to other suitably-trained, registered healthcare professionals but the legal responsibility rests with the senior registered nurse or ODP in charge.

4.6.1.2 The controlled drug key should be returned to the senior registered nurse or ODP in charge immediately after use by another registered member of staff.

4.6.1.3 On occasions, for the purpose of stock checking, the CD key may be handed to an authorised member of the pharmacy staff (e.g. the pharmacy technician responsible for stock control of medicines on the ward).

### 4.6.2 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 staff who have just gone off duty.



4.6.2.1 A procedure should be in place to ensure that an appropriate level of nursing/midwifery/theatre management 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 e.g. by issuing a spare key.

4.6.2.2 If the keys cannot be found then the Accountable Officer should be informed. Depending on the circumstances, a decision may be made to contact the police. The DHSSPS Head of Inspection and Investigation should be made aware of the situation. Locks may need to be replaced to prevent unauthorised access to the drugs.

## **4.7 Record-keeping**

Each ward or department that holds stocks of controlled drugs should keep a record of controlled drugs received and administered in a controlled drug record book (CDRB).

The senior registered nurse, or ODP, in charge is responsible for keeping the CDRB up to date and in good order.

### **4.7.1 Controlled drug record books**

4.7.1.1 The controlled drug record book (CDRB) should be bound (not loose-leaf) with sequentially numbered pages and it should have separate pages for each drug and each strength, so that a running balance can be easily maintained. Entries should be made in chronological order, in ink or be otherwise indelible.

4.7.1.2 All entries should be signed by a registered nurse, midwife or ODP and should be witnessed preferably by a second registered nurse, midwife or ODP. If a second registered nurse, midwife or ODP is not available, then the transaction can be witnessed by another registered practitioner (e.g. doctor, pharmacist,) or by a pharmacy technician, or an appropriately trained healthcare assistant, who has been assessed as being competent for the purpose. In defining local policy NMC Medicines Management Standards may be consulted related to witnessing by student nurses or midwives.

4.7.1.3 On reaching the end of a page in the CDRB, the balance should be transferred to another page. The new page number should be added to the bottom of the finished page and the index updated. The finished page number should be indicated at the top of the new follow-on page. As a matter of good practice this transfer should be witnessed.

4.7.1.4 If a mistake is made it should be bracketed in such a way that the original entry is still clearly legible. This should be signed, dated and witnessed by a second registered nurse, midwife, ODP or other registered professional or by an appropriately

trained healthcare assistant. The witness should also sign the correction. An explanation may be made if necessary by a marginal note or footnote.

#### **4.7.2. Records of controlled drugs received**

A record should be kept of all Schedule 2 controlled drugs that are received or administered.

4.7.2.1 For controlled drugs received, the following details should be recorded on the appropriate page in the CDRB:

- Date on which the controlled drug was received.
- Name of pharmacy making supply and the serial number of requisition
- Quantity received
- Form (name, formulation and strength) in which received
- Name/signature of nurse/authorised person making entry
- Name/signature of witness
- Balance in stock

4.7.2.2 When recording controlled drugs received from pharmacy, the number of units received may be recorded in words not figures (e.g. ten, not 10) to reduce the opportunity for entries to be altered.

4.7.2.3 After every administration, the stock balance of an individual preparation should be confirmed to be correct and the new balance recorded in the CDRB. The entry should be signed and dated.

For records of controlled drugs administered see paragraph 4.11 Administration

### **4.8 Controlled drug stock checks**

The stock balance of all controlled drugs entered in the CDRB should be checked and reconciled with the amounts in the cupboard with sufficient frequency to ensure that discrepancies can be identified in a timely way. The frequency of such checks should be determined locally after a risk assessment has been carried out. If reconciliation is being conducted related to shift change, where possible, a representative from each shift may be involved. In addition, regular documented stock checks should be carried out by pharmacy staff (see paragraph 7.7.2 - Checks of CD stocks held in wards, theatres or departments).

4.8.1 The senior registered nurse or ODP in charge is responsible for ensuring that the regular CD stock check is carried out by staff in the ward or department

4.8.1.1 Two registered nurses, midwives, ODPs or other registered health professionals should perform this check. Both must see the drugs and the records for witnessing to be meaningful.

Where possible, the staff assigned to do this check should be changed periodically. The check should take account of the following points:

- Checking of controlled drugs involves the checking of the balance in the CDRB against the contents of the CD cupboard, not the reverse, to ensure that all balances are checked.
- It is not necessary to open packs with intact tamper-evident seals for stock-checking purposes.
- Stock balances of liquid medicines should generally be checked by visual inspection but periodic volume checks may be helpful. The balance must be confirmed to be correct on completion of a bottle.

4.8.1.2 A record indicating that this reconciliation check has been carried out and confirming the stock is correct may be kept in a separate bound record book or in the CDRB. This record should as a minimum state the date and time of the reconciliation check and include wording such as, “check of stock level” and be signed by the registered nurse, midwife, ODP or other registered health professional and the witness.

4.8.1.3 If a discrepancy is found it should be investigated without delay. (See paragraph 5.9 Discrepancies and diversion) The local investigation and reporting procedures should be followed.

## **4.9 Archiving of controlled drug records**

Healthcare organisations must make arrangements to store records in accordance with legislation and the schedules in *Good Management Good Records*. (<http://www.dhsspsni.gov.uk/dhs-goodmanagement.pdf>) The current guidance that applies to retention of hospital pharmacy CD registers is thirteen years. This retention period also applies to ward CDRBs. The retention period is reckoned from the date when the last entry was made.

All local documents designed to track and/or monitor controlled drug usage should be kept for two years after the last entry/date of use.

See also paragraph 7.9 - Archiving of controlled drug records (and 4.3.1.7 and 5.1.5.2)

## **4.10 Prescribing**

### **4.10.1 Prescribing for inpatients**

For hospital inpatients directions for administration of controlled drugs from ward stocks may be written on the inpatient medicines chart or case sheet (sometimes called the inpatient prescription and

administration chart) or the anaesthetics card in line with local policies and procedures.

4.10.1.1 The written requirements for controlled drugs on these charts are the same as for other medicines and include:

- Start date
- Drug name, form and strength where appropriate
- Route of administration, and where appropriate, the site of application
- Dose
- Time of administration or frequency (if prescribed “when required” e.g. for breakthrough pain, a minimum interval for administration should be specified, e.g. every six hours, and a maximum daily dose)
- Include a finish date where appropriate
- Signature of prescriber

The patient’s name, date of birth, unit number and/or address and any known drug sensitivities or drug allergies should also be written on the chart.

4.10.1.2 If controlled drugs are administered or self-administered from supplies prescribed and dispensed for individual patients (rather than from items ordered as ward stock), then in addition to the requirements of 4.10.1.1, in order to comply with the Misuse of Drugs Regulations (Regulation 15), the total quantities of the controlled drugs prescribed for the individual patients must be present in both words and figures on the patient chart. (See section 5.4.4 Self-administration of controlled drugs.)

#### **4.10.2 Prescribing for discharge patients**

Prescriptions for controlled drugs for patients who are going home (discharge medicines) should be written on locally-approved prescription forms for dispensing by the pharmacy. These prescriptions must conform to all requirements of the Misuse of Drugs Regulations for a controlled drugs prescription (see section 4.10.3).

4.10.2.1 Medical doctors who have not achieved full registration with the GMC are permitted to prescribe controlled drugs (and other POM medicines) on these prescription forms for inpatient use so far as this is necessary for the purposes of their employment as defined in the Medical Act 1983. In line with GMC guidance for general practice, it is recommended that such issues of delegation by supervising practitioners must be clearly documented to avoid any confusion. Further guidance with some explanation of the legislation is available from the GMC at [http://www.gmc-uk.org/education/documents/provisional\\_registration\\_prescribing.pdf](http://www.gmc-uk.org/education/documents/provisional_registration_prescribing.pdf)

4.10.2.2 A clinically appropriate amount, up to a maximum of 30 days supply should be prescribed, as a matter of good practice. There may be circumstances where there is a genuine need to prescribe for more than 30 days. Where the prescriber believes that it is in the clinical interest of the patient to prescribe for more than 30 days and would not pose an unacceptable threat to patient safety, the prescriber should make a record of the reasons in the patient's notes. Pharmacists may legally supply a prescribed quantity of greater than 30 days' supply, if appropriate. (Prescriptions for methadone or buprenorphine for treatment of opiate dependence for instalment dispensing in the community are limited by legislation to a maximum of 14 days supply.)

### **4.10.3. Prescribing for outpatients**

Prescriptions for controlled drugs for outpatients must be written in accordance with the requirements of the Misuse of Drugs Regulations (Regulation 15). Such prescribing must occur within locally agreed frameworks. The prescription document can either be a locally-approved outpatient prescription form for the hospital pharmacy to dispense or, in the case of Substitution Treatment for opiate dependence with methadone or buprenorphine, an SP1 or SP2 form for a community pharmacy to dispense.

4.10.3.1 A prescription for Schedule 2 and 3 controlled drugs (with the exception of temazepam and preparations containing it) must contain the following details, written so as to be indelible, i.e. written by hand, typed or computer-generated

- The patient's full name and address
- The name and form of the drug, even if only one form exists
- The strength of the preparation, where appropriate
- The dose to be taken
- The total quantity of the preparation, or the number of dose units, to be supplied in both words and figures

In addition, it is good practice to include the patient's age and NHS number on the prescription.

4.10.3.2 The prescription must be signed by the prescriber with his usual signature, in his own handwriting (this must be handwritten) and dated (the date does not have to be handwritten).

Amendments to the Misuse of Drugs Regulations 2002, which came into force on 16<sup>th</sup> January 2006, removed the requirement for prescriptions for Schedule 2 and 3 controlled drugs to be written in the prescriber's own handwriting (other than their signature).

CD prescriptions may be computer-generated but **do not have** to be computer-generated. Appropriate prescribers may issue computer-generated prescriptions for all controlled drugs in Schedules 2 and 3. Only the signature has to be in the prescriber's own handwriting. The prescriber should sign any manuscript changes.

4.10.3.3 If the prescription is produced, prior to signature by the prescriber, by someone other than the prescriber then that person should, ideally, be a registered healthcare professional.

4.10.3.4 The use of pre-printed adhesive labels on prescriptions is not recommended. Technically the new legislative requirements for computer generated prescriptions for controlled drugs do not prevent the use of preprinted adhesive labels on prescriptions. If, and where, they are used, such labels should be tamper-evident (i.e. it is obvious if an attempt has been made to remove them). If an adhesive label is used, prescribers should also sign across each label. This is a further safeguard to ensure that such labels are not tampered with or that another label is not placed on top of the one that the prescriber signed for. Relevant procedures should include measures to minimize further risks related to adhesive labels and copies of prescriptions.

4.10.3.5 A clinically appropriate amount up to a maximum of 30 days supply should be prescribed as a matter of good practice. There may be circumstances where there is a genuine need to prescribe a supply for more than 30 days. Where the prescriber believes that it is in the clinical interest of the patient to prescribe a supply for more than 30 days and would not pose an unacceptable threat to public safety, the prescriber should make a record of the reasons in the patient's notes. Pharmacists may legally supply a prescribed quantity of greater than 30 days' supply, if appropriate. (Prescriptions for methadone or buprenorphine for treatment of opiate dependence for instalment dispensing in the community are limited by legislation to a maximum of 14 days supply.)

#### **4.10.4 Supplementary prescribers**

Regulations were amended in 2005 to permit supplementary prescribers, when acting under and in accordance with the terms of an agreed individual clinical management plan (CMP) to prescribe and administer and/or supply or direct any person to administer any controlled drug provided that the controlled drug is included in the CMP.

#### **4.10.5 Non-medical independent prescribers**

##### **Nurse independent prescribers**

Following amendments to the Prescription Only Medicines Order 1997 (SI 1997 No. 1830), the range of drugs that Nurse Independent Prescribers were able to prescribe independently has been extended. From 1st May 2006, the Nurse Prescribers' Extended Formulary was discontinued and qualified Nurse Independent Prescribers are now able to prescribe any licensed medicine for any medical condition within their competence, including some controlled drugs for specific conditions. The Misuse of Drugs Regulations 2002 were amended, with effect from 1<sup>st</sup> June 2006, to reflect the change in terminology relating to Nurse Independent Prescribers. The condition of tonic-clonic seizures was also added as an allowable indication for the prescribing of diazepam, lorazepam and midazolam.

Nurse Independent Prescribers are permitted to prescribe, administer, or direct anyone to administer the following controlled drugs solely for the medical conditions indicated – Table 2 next page. (Regulatory change related to this matter is being considered.)

Table 2: CDs that can be prescribed and administered for specified indications by Nurse Independent Prescribers

Drug	Indication
Buprenorphine	Transdermal use in palliative care
Chlordiazepoxide hydrochloride	Treatment of initial or acute withdrawal symptoms caused by the withdrawal of alcohol from persons habituated to it
Codeine phosphate	Not restricted by the Regulations
Co-phenotrope	Not restricted by the Regulations
Diamorphine hydrochloride	Use in palliative care, pain relief in respect of suspected myocardial infarction or for relief of acute or severe pain after trauma, including in either case postoperative pain relief
Diazepam	Use in palliative care, treatment of initial or acute withdrawal symptoms caused by the withdrawal of alcohol from persons habituated to it, tonic-clonic seizures
Dihydrocodeine tartrate	Not restricted by the Regulations
Fentanyl	Transdermal use in palliative care
Lorazepam	Use in palliative care, tonic-clonic seizures
Midazolam	Use in palliative care, tonic-clonic seizures
Morphine hydrochloride	Use in palliative care, pain relief in respect of suspected myocardial infarction or for relief of acute or severe pain after trauma, including in either case post-operative pain relief
Morphine sulphate	Use in palliative care, pain relief in respect of suspected myocardial infarction or for relief of acute or severe pain after trauma, including in either case post-operative pain relief
Oxycodone hydrochloride	Use in palliative care

#### 4.10.6 Pharmacist independent prescribers

At present Pharmacist Independent Prescribers are not able to prescribe controlled drugs. The outcome of a Home Office consultation will inform any regulatory changes required.

#### 4.11 Administration

See also paragraph 4.7 Record keeping.

The administration of controlled drugs should comply with all local policies and procedures for the administration of medicines.



Nurses and midwives must follow Nursing and Midwifery Council standards and guidance. (<http://www.nmc-uk.org>)

In terms of the Misuse of Drugs Regulations (MDR) any person can administer to a patient any drug specified in Schedule 2, 3 or 4 provided they are acting in accordance with the directions of an appropriately qualified prescriber. (MDR 2002, Regulation 7(3)). Any person can administer to another person any drug specified in Schedule 5 – MDR 2002- Regulation 7 (1)

4.11.1 Healthcare organisations that do not have a system of double checking for administration of controlled drugs should carry out a risk assessment to determine whether the introduction of double checking as an additional risk-reduction measure is necessary, within their organisation.

4.11.1.1 Where two practitioners are involved in the administration of controlled drugs, one of them should be a registered nurse, midwife, doctor or ODP. Both practitioners should be present during the whole of the administration procedure. They should both witness:

- The preparation of the controlled drug to be administered.
- The controlled drug being administered to the patient.
- The destruction of any surplus drug (e.g. part of an ampoule or infusion not required).

A record should be made in the ward or department controlled drug record book (CDRB) when a controlled drug is removed from the CD cupboard.

4.11.1.2 For controlled drugs administered the following details should be recorded:

- Date and time when dose administered (or refused in the case of a controlled drug that was prepared for the patient)
- Name of patient
- Quantity administered and quantity wasted (see 4.11.1.3)
- Form (name, formulation and strength) in which administered
- Name/signature of nurse/authorised person who administered the dose
- Name/signature of witness (where there is a second person witnessing administration)
- Balance in stock

4.11.1.3 If part of a vial is administered to the patient, the registered nurse, midwife or other registered health professional should record the amount given and the amount wasted e.g. if the patient is prescribed 2.5 mg diamorphine and only a 5mg preparation is available, the record should show, "2.5mg

*given and 2.5mg wasted.*" The destruction should be witnessed by a second registered nurse, midwife or other registered health professional who should also sign the record. If a second registered nurse, midwife or other registered health professional is not available, the transaction can be witnessed by another registered practitioner (e.g. doctor, pharmacist) or by an appropriately trained pharmacy technician or healthcare assistant. In defining local policy NMC Medicines Management Standards may be consulted related to witnessing by student nurses or midwives.

4.11.1.4 Individual doses of controlled drugs which have been prepared but not administered should be destroyed by a registered nurse, midwife or other registered health professional on the ward or department in the presence of a witness and the reason documented in the CDRB.

(For appropriate methods of destruction see paragraph 4.16 Disposal and destruction of CDs).

#### **4.12 Management of controlled drugs when patients are admitted**

See paragraph 5.4 Management of Controlled Drugs that are the patient's property

#### **4.13 Management of controlled drugs when patients are transferred to other wards or departments**

See paragraph 5.2 Transfer of controlled drugs

The circumstances are limited where a controlled drug will move with a patient. This is due to the restriction in the Misuse of Drugs Regulations 2002 which prevents controlled drugs being supplied from ward to ward. Patient controlled analgesia will be one of the cases where a controlled drug may need to move with the patient. There should be a local procedure (see section 6.11, Patient Controlled Analgesia, for details) which covers all aspects of the safe management of patient-controlled analgesia. This should include:

- Specification of the entries required in the controlled drug record book in the originating ward or department
- Arrangements for documentation when the patient is moved between theatre and/or wards
- Arrangements for recording administration
- Arrangements for recording unused portions of syringe contents or bags no longer required
- Arrangements for disposal of unused portions
- Arrangements for documenting the destruction of unused portions

#### **4.14 Management of controlled drugs when patients are discharged**

See paragraph 4.10.2 Prescribing for discharge patients and 7.10 Supply to outpatients and discharge patients

#### **4.15 Returning controlled drugs to the pharmacy**

4.15.1 Unused CD stock from wards or departments may be returned to the pharmacy. Such CD stock may be re-issued by the pharmacy provided it was initially issued by that pharmacy, is in good condition and has at all times been under the control of that hospital. The pharmacy department should carry out an assessment of controlled drugs returned to pharmacy to ensure they are fit for re-use.

Controlled Drugs that are time-expired or otherwise unfit for use (e.g. opened liquids) should also be returned to the pharmacy for safe destruction and onward disposal.

Any other controlled drug that is no longer needed on the ward should be returned to pharmacy. This should be done as soon as is practicable. Local policies may define time limits.

##### **4.15.2 Records of controlled drugs returned**

The ward or department should keep a record of drugs returned to pharmacy. This may be in the form of a returns advice book with duplicate pages so that both the pharmacy and the ward have a record of the transaction.

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 the senior registered nurse or ODP in charge

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

In addition, an entry should be made on the relevant page of the ward or department CDRB, showing:

- Date
- Reason for return
- Names and signatures of the senior registered nurse, or ODP responsible and a competent witness
- Quantity removed

- Name, form and strength of drug
- Balance remaining

The drugs should be transferred to the pharmacy in a safe and secure way. (See paragraph 5.2 Transfer of controlled drugs)

#### 4.16 Disposal of controlled drugs in wards and departments

See also paragraph 7.15 Disposal of controlled drugs in pharmacies

In the interests of safety and containment of environmental pollution, controlled drugs should, as far as is practicable, be returned to the pharmacy for safe denaturing and disposal.

**Controlled drugs should be destroyed in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or re-used. Where denaturing is carried out on wards and departments, the methods used should be those currently recommended by the RPSGB [Guidance for Pharmacists on the safe destruction of Controlled Drugs: England, Scotland and Wales.**

[www.rpsgb.org.uk/pdfs/cdsafedestructionguid.pdf](http://www.rpsgb.org.uk/pdfs/cdsafedestructionguid.pdf)

See also the Pharmaceutical Society of Northern Ireland website:

[www.psn.org.uk](http://www.psn.org.uk) where guidance may also be published ]

Some healthcare organisations may wish to provide denaturing kits for use on wards to destroy controlled drugs that have been used for patients. This may be appropriate on wards or departments where large quantities of controlled drugs are used and where the volume of part-used vials, ampoules, syringes and infusion bags may be high. A risk assessment should be carried out before a decision is made whether denaturing kits should be available on wards. Where denaturing kits are provided to wards or departments, an SOP should be developed for this practice.

##### 4.16.1 Disposal of small amounts of CDs

4.16.1.1 In principle, only small amounts of CDs should be destroyed on wards and departments, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used. Policy should be agreed locally regarding denaturing and disposal of larger quantities of controlled drugs, for example, discontinued infusions or patient-controlled analgesia (PCA) syringes. An assessment should be made of risks involved in transport, and of the impact on infection control, prior to establishing any policy that indicates that these items be returned to the pharmacy for safe denaturing and disposal.

4.16.1.2 All destruction must be documented in the appropriate section of the CD record book (see below). It should be witnessed by a second competent professional such as

a registered nurse, midwife or ODP. Both persons should sign the CD record book.

#### **4.16.2 Method of disposal**

Small amounts of waste controlled drugs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, should be rendered irretrievable. This may be done by emptying into a burn bin, into the bottom of which some absorbent material (e.g. paper towels) and a little liquid soap has been placed. This bin is used for this purpose and nominated (outwardly anonymously) as the CD waste receptacle. The emptied vial or ampoule should then also be placed in a sharps bin. When the "CD waste receptacle" is sent for destruction, it should be labelled "*contains mixed pharmaceutical waste and sharps – for incineration*".

Where individual hospitals have a formal agreement with Northern Ireland Water (which replaced the Water Service Agency in 2007) small amounts of liquid waste controlled drugs may be disposed of to sewer, so long as the terms of the agreement are complied with.

# 5 Management of controlled drugs – general processes and specific circumstances

## Contents of this chapter:

**Controlled drugs stationery**  
**Transport of controlled drugs**  
**Clinical trials**  
**Management of controlled drugs that are the patient's property**  
**Use of patients' own controlled drugs on the ward**  
**Controlled drug discharge medicines**  
**Receipt of controlled drugs by outpatients**  
**Self-administration of controlled drugs**  
**Out-of-hours supply of controlled drugs**  
**Temporary closure/transfer of wards**  
**Paediatrics**  
**Controlled drugs for midwives**  
**Discrepancies and diversion**  
**Patient Group Directions (PGDs)**

## 5.1 Controlled drug stationery

All stationery which is used to order, return or distribute controlled drugs (CD stationery) should be stored securely and access to it should be restricted. These measures are important to guard against unauthorised use of the stationery to obtain controlled drugs for inappropriate purposes.

### 5.5.1 Definition of CD stationery

CD stationery includes:

- Controlled drug requisition books
- Controlled drug record books
- Local CD documents such as CD returns advice notes, pharmacy distribution documents
- Prescription forms

### **5.1.2 Secure storage of CD stationery**

CD stationery which is kept in wards, theatres or departments should be kept in a locked cupboard or drawer.

Stocks of CD stationery held in pharmacy departments should be kept in a secure area that is locked when there is no one present.

### **5.1.3 Supply of CD stationery**

CD stationery should be issued from the pharmacy against a written requisition signed by an appropriate member of staff. Local policy should define the form of requisition that is required to order such stationery. The local policy should also define the groups of staff who can sign requisitions for CD stationery. It may be appropriate to use the same duplicate book for ordering CD stationery that is used to order controlled drugs. This will ensure that the requisition forms themselves are stored securely.

5.1.3.1 A record should be kept in pharmacy of the supply of CD stationery. It should include:

- Date
- Ward/department
- Name of person ordering the stationery
- Type of stationery issued
- Quantity
- The serial numbers of the stationery
- Signature of the member of pharmacy staff making the supply
- Signature of member of staff receiving the stationery

5.1.3.2 Any unused stationery returned to pharmacy will be recorded as a return, with the details above, in the stationery supply record.

5.1.3.3 Healthcare organisations may wish to number CD requisition books to provide an additional means of tracking.

### **5.1.4 Loss or theft of CD stationery**

Loss or theft of any controlled stationery which may be used to order controlled drugs should be reported immediately to the chief pharmacist and the Accountable Officer. The police should be informed, if appropriate.

### **5.1.5 Use of CD stationery**

Only one CD requisition book per ward or department should normally be in use.

5.1.5.1 When a new CD Record Book is started, the balance of controlled drugs in stock should be written into the new book promptly by ward staff. This transfer should be witnessed by a registered nurse, midwife, ODP or authorised member of staff e.g. pharmacy technician.

5.1.5.2 Completed ward requisition books must be retained for a minimum of two years from the date of the last entry. CD record books should be kept for a period of 13 years from the date of the last entry. (See paragraphs 4.9 and 7.9 Archiving of records)

## **5.2 Transfer of controlled drugs within and outside the hospital**

Transfer of controlled drugs is likely to involve the following situations:

- Collection by ward staff from the pharmacy
- Collection by porters from the pharmacy
- Delivery by pharmacy staff to wards, departments, theatres
- Collection by patient or representative for outpatient items only
- Delivery by Trust porter/driver
- Delivery by commercial courier (e.g. taxi out-of-hours)
- Delivery using (trackable) recorded delivery Postal Service (The use of postal services should not be routine but should be limited to exceptional situations such as when there is an urgent clinical need.)

### **5.2.1 Methods of transfer**

Wherever possible, controlled drugs should be transferred or conveyed in a secure, locked or sealed, tamper-evident container.

5.2.1.1 Depending on local circumstances, some healthcare organisations may choose to use bags with numbered seals for delivery and require a signature for receipt of the bag with the correctly numbered seal. Whichever system is used it must be fully auditable and explicit as to who has custody of the controlled drugs at any point in time.

5.2.1.2 Controlled drugs may not be transported in pneumatic tubes. If consideration is being given to the use of such a system, prior discussion should take place with the Department inspectors.

### **5.2.2 Records of transfer**

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 and the person receiving it.

5.2.2.1 Healthcare organisations may wish to design local distribution/transport documentation as a means of keeping a full audit trail.



### **5.2.3 Messengers**

The person who conveys the controlled drug acts as a messenger, that is to say he/she carries a sealed or locked container and is responsible for delivering the intact container.

5.2.3.1 The person acting as the messenger should:

- Ensure destination is known
- Be aware of safe storage and security, the importance of handing over the item to an authorised person and obtaining a signature for delivery on the delivery document.
- Have valid ID badge

5.2.3.2 Healthcare organisations may wish to stipulate that controlled drugs should only be handed to members of staff who are wearing valid ID badges.

5.2.3.3 Where a commercial courier or taxi driver is responsible for conveying a controlled drug he should be asked to show his valid company ID, as he would for any other medicine.

- Taxi drivers or commercial couriers should not be made aware that controlled drugs are being transported as this may increase the potential for diversion.
- As a matter of good practice the taxi registration or taxi licence number may also be recorded.

5.2.3.4 Healthcare organisations may wish to keep a list of porters who are authorised to transfer controlled drugs. A list of their names with sample signatures may be kept in pharmacy for validation purposes.

### **5.2.4 Transfer from ward to ward or theatre to ward**

In general, the Misuse of Drugs Regulations 2002 prevent controlled drugs being supplied from ward to ward. However, local procedures should define safe, secure and auditable methods to transfer controlled drugs from ward to ward in circumstances where a controlled drug is required to move, for example, when a patient moves to another ward. The three situations in which this is most likely to arise are:

- When a patient is receiving a controlled drug by means of syringe pump (patient controlled analgesia) or infusion or a transdermal patch
- When a patient has his/her own controlled drugs for self-administration
- When a controlled drug has been dispensed on a “named-patient” basis

5.2.4.1 Patients' own controlled drugs should be transferred from ward to ward with the patients in line with local procedures for transferring all other medicines and property belonging to those patients.

5.2.4.2 There should be a local procedure (see section 6.11, Patient Controlled Analgesia, for details) for all aspects of the management of patient controlled analgesia. This should include:

- Specification of the entries required in the controlled drug record book in the originating ward or department
- Arrangements for documentation when the patient is moved from theatre/ward to ward
- Arrangements for recording administration
- Arrangements for recording unused portions of syringe contents or bags no longer required
- Arrangements for disposal of unused portions
- Arrangements for documenting the destruction of unused portions

See also paragraph 5.4 Managing controlled drugs that are the patient's property

### **5.2.5 Transfer from ward to pharmacy**

When controlled drugs have to be returned to the pharmacy they should be placed in a secure container and handed to an authorised messenger. (See paragraph 4.15 Returning controlled drugs to the pharmacy)

## **5.3 Clinical trials**

The procedures for the use of controlled drugs in clinical trials must comply with the Misuse of Drugs Regulations 2002 and with local policies governing the management of clinical trial medicines, in addition to clinical trials legislation and Medicines and Healthcare products Regulatory Agency (MHRA) guidance on clinical trials (<http://www.mhra.gov.uk/home/>).

### **5.3.1 Storage and records**

5.3.1.1 All clinical trial controlled drugs should be stored separately from stock controlled drugs. They do not necessarily need to be stored in a separate CD cupboard. A separate page in the register should be used to record receipt and issues in addition to clinical trial documentation so that a running balance of trial stock can be kept.

5.3.1.2 If a discrepancy is identified then it should be reported on the internal incident reporting system in accordance with local procedures. A note to file should be stored with all the clinical trials documentation. The sponsor and investigator should be

informed and also the chief pharmacist and Accountable Officer. (See also paragraph 5.9 Discrepancies and diversion)

5.3.1.3 For double blind trials in which only one arm involves a controlled drug, pharmacy staff may be unaware which packs contain controlled drugs. In this situation, all supplies should be treated as controlled drugs until the end of trial.

5.3.1.4 For trials that involve the use of Schedule 1 controlled drugs, such as cannabinoids, a licence from the DHSSPS must be obtained before the item is received into stock or supplied. The licence should normally be held by the chief pharmacist. A copy should be kept with the trial protocol.

### **5.3.2. Labelling**

All clinical trial controlled drugs must be labelled and dispensed in accordance with the specific trial protocol in addition to the Misuse of Drugs Regulations 2002 requirements.

### **5.3.3 Disposal**

Clinical trial controlled drugs must be destroyed in the same way as other controlled drugs. (See section 7. 15 Destruction of controlled drugs in pharmacies) However, this destruction may need to be carried out following the monitoring instructions from the trial sponsor. For example, the sponsor may wish to carry out an independent reconciliation (in addition to the check and reconciliation carried out by the pharmacy department) prior to any destruction.

### **5.3.4. Clinical trial controlled drugs returned by patients**

The pharmacy should establish secure arrangements for the storage (and destruction) of CD clinical trial medicines returned by patients. Drug accountability records should be completed promptly when a patient returns the CD clinical trial medicine and opportunities for diversion should be minimised.

### **5.3.5 Arrangements for research departments**

If a hospital pharmacy supplies controlled drugs to a research department, then the same governance arrangements for safe use should apply as for elsewhere in the organisation. All the activities should be covered by SOPs and the processes should be robust and auditable.

## **5.4 Management of controlled drugs that are the patient's property**

A local procedure should be in place for the management of controlled drugs that are the patient's property.

### **5.4.1 Use of a patient's own controlled drugs on the ward**

It may be appropriate to use a patient's own controlled drugs (i.e. controlled drugs brought into the hospital by the patient on admission) whilst they are in hospital, for example, if the patient is self-administering other medicines. On such occasions the drugs should be checked for suitability according to the local procedure for patients' own drugs (PODs) to ensure that they are fit for purpose. (See paragraph 5.4.4 Self-administration of controlled drugs)

5.4.1.1 If patients' own controlled drugs are not required for use in this way then one of the following procedures should be followed and all actions should be recorded:

- If the patient or the patient's agent agrees, medicines may be sent to the pharmacy for safe destruction. Such assent may be recorded with the signature of the patient or their representative if appropriate. The pharmacist should take responsibility for destruction.
- If the patient wishes, the medicines may be returned home via an identified adult. That adult should be given advice regarding the necessity for safe storage of the medicines and that other people must not use them. If the medicines are no longer safe and/or appropriate for future use by the patient, then the patient and/or patient's agent should be advised, and they should be encouraged to allow them to be destroyed in the hospital pharmacy (or to take them to a community pharmacy for safe destruction.)

5.4.1.2 Patients' own controlled drugs that are not to be used for self-administration should not routinely be stored on the ward.

5.4.1.3 Temporary storage of patients' own controlled drugs on the ward may be necessary whilst they are awaiting collection and removal to the pharmacy or to the patient's home. In this situation, they should be placed in the CD cupboard but should be clearly marked and kept separate from ward stock. The presence on, and departure from, the ward of these controlled drugs should be recorded according to local policy.

5.4.1.4 Patient's own controlled drugs must never be used to treat other patients.

### **5.4.2 Controlled drug discharge medicines**

When CD discharge medicines are sent to the ward several hours before the patient leaves, the medicines may be stored in the CD cupboard. These medicines should be segregated from the ward CD stock and clearly marked and should remain in a sealed bag. Healthcare organisations may wish to stipulate that a record of the

receipt and supply of these medicines from the ward should be maintained.

When Schedule 2 controlled drug discharge medicines are collected from the pharmacy, the person collecting them should be asked to sign for receipt as a matter of good practice.

### 5.4.3 Receipt of controlled drugs by outpatients

Patients or their representatives may be asked to provide evidence of identity when collecting controlled drugs.

From July 2006, there has been a requirement for persons asked to supply controlled drugs on prescription to seek to establish whether the person collecting the medicine is the patient, their representative or a healthcare professional acting in his professional capacity on behalf of the patient.

Where the person is the patient or their representative, the supplier:

- **May** request evidence of that person's identity and
- **May** refuse to supply the medicine if he is not satisfied as to the identity of the person
- Where it is a healthcare professional acting in his professional capacity on behalf of the patient, the supplier:
  - **Must** obtain the person's name and address
  - **Must**, unless he is acquainted with that person, request evidence of that person's identity; but
  - **May** supply the medicine even if he is not satisfied as to the identity of the person

Any strengthening of controls has been balanced with ensuring that patients have access to medicines they need and have been prescribed for them. The new requirement placed on the supplier therefore allows them:

- Discretion not to ask patients or patient representatives for proof of identity if, for example, they have concerns that to do so may compromise patient confidentiality or deter patients from having their medicines dispensed.

**From 1<sup>st</sup> February 2008**, it has been a requirement to record the following information in the CD register for Schedule 2 controlled drugs supplied:

- Whether the person who collected the drug was the patient, the patient's representative or a healthcare professional

- If the person who collected the drug was a healthcare professional, that person's name and address [*Guidance* – work address - not home]
- If the person who collected the drug was the patient or their representative, whether evidence of identity was requested (as a matter of good practice a note as to why the supplier did not ask may be included, but this is not mandatory).
- And whether evidence of identity was provided by the person collecting the drug.

Depending on local circumstances, some healthcare organisations may wish to stipulate that outpatients receiving controlled drugs should sign for receipt of a specified number of doses.

#### **5.4.4 Self-administration of controlled drugs**

A local procedure should be in place for wards or departments where patients self-administer their own medicines including controlled drugs.

5.4.4.1 When patients who self-administer controlled drugs require additional supplies, these should be dispensed as for discharge controlled drugs. Prescription details must comply with the requirements of the Misuse of Drugs Regulations 2002. Healthcare organisations may wish to consider whether the administration of these controlled drugs is recorded in the CDRB or in a separate book for recording of controlled drugs that are self-administered.

5.4.4.2 Patients receiving controlled drugs for self-administration should sign for receipt of a specified number of doses.

5.4.4.3 Healthcare organisations may wish to stipulate that these controlled drugs are entered in and out of the ward CDRB so that there is an auditable record of their arrival on the ward. A daily count of the quantity of the controlled drugs in the patient's individual medicines cabinet may be made by the registered nurse, midwife or other healthcare professional and recorded on the medicines chart or in the CDRB.

5.4.4.4 The controlled drugs for patients who self-administer their medicines should be kept in a locked metal receptacle immediately adjacent to their bed, or in their bedside locker. The receptacle should not be easily portable. Healthcare organisations may wish to consider the use of electronic patient medicines lockers accessed by means of programmable transponders. Such systems provide a high level of security and a clear record of who accessed the locker and when.

5.4.4.5 Useful sources of information about controlled drugs for patients are listed at Appendix 5.

## 5.5 Out-of-hours supply

Under the current Regulations, the senior registered nurse in charge of a ward can only supply controlled drugs to a patient on that ward or department, in accordance with the written instructions of an authorised prescriber.

Every effort should be made to ensure that adequate stock levels are maintained to meet likely needs.

Local arrangements for emergency issues of controlled drugs should be discussed with the Accountable Officer and/or chief pharmacist. Where such systems exist, a Standard Operating Procedure should be developed.

## 5.6 Temporary ward closure and transfer of wards

### 5.6.1 Temporary ward closure

There should be a local procedure for the management of controlled drugs during short and long term ward closures. The procedure should ensure the security of the controlled drugs and should be auditable.

5.6.1.1 The procedure should include:

- A provision for a risk assessment to be carried out
- Documented stock reconciliation conducted by senior registered nurse and ward pharmacist
- Arrangements for removal and temporary storage of controlled drugs by the pharmacy, if appropriate
- Arrangements for return of controlled drugs to the pharmacy for re-use, if appropriate
- Specification of the entries required in the CDRB
- Arrangements for secure storage of current (i.e. in use) CD stationery during closure
- Arrangements for return of stocks, including reconciliation with list of controlled drugs removed, if appropriate
- Arrangements for restocking, if appropriate

5.6.1.2 As a matter of good practice, the list of authorised signatories for the ward that is kept in the pharmacy should be annotated by the pharmacist or pharmacy technician responsible for stock control of medicines on the ward so that the pharmacy and audit staff are aware that the ward is temporarily closed. The list will need to be reviewed by the ward pharmacist when the ward reopens, to ensure that signatures are valid and up to date.

### 5.6.2. Transfer of wards

When a ward moves to another location, a decision must be made as to whether its controlled drugs and CDRBs may be transferred or,

where swapping of wards occurs, left on the ward. This will depend upon the appropriateness of the stock list, the periods for which ward premises will be unoccupied and the security of the drugs during this time. (See paragraph 5.6.1 Temporary ward closures).

5.6.2.1 There should be a local procedure for the management of controlled drugs during ward moves. This procedure should ensure the security of the controlled drugs and should be auditable.

5.6.2.2 The procedure, which should have been agreed with the pharmacy department should include:

- A provision for a risk assessment to be carried out
- Arrangements for transfer of controlled drugs and CDRBs, if appropriate
- Arrangements for checking and reconciliation of stocks, in particular when ward staff transfer but controlled drugs and CDRBs are left in place
- Specification of the entries required in the CDRB, in particular when ward staff transfer but controlled drugs and CDRBs are left in place

5.6.2.3 The pharmacist or pharmacy technician responsible for stock control of medicines on the ward should ensure that the ward signatory lists and stock lists are updated to reflect the new ward location/name/number.

## 5.7 Paediatrics

The management of controlled drugs in paediatrics does not differ significantly from the management in adult care and so all the general provisions apply. There are, however, a few specific situations when the management of controlled drugs may require a slightly different approach.

### 5.7.1 Part vials of controlled drugs

On many occasions in paediatrics, the dose required for the patient is smaller than that which is contained in a single vial or ampoule. When a dose is given to a child, an amount may be left, which needs to be discarded. In order to minimise the opportunities for diversion, the following steps should be taken:

- When a dose is given, the nearest suitable dose volume should be selected, so that the minimum volume has to be discarded.
- When only part of the contents of a vial or ampoule is used, the entry made in the ward CD record book (CDRB) should clearly show how much was given to the patient and how much was discarded. For example, if the patient is prescribed diamorphine 2.5mg and only a 5mg preparation is available, the record should show, "2.5mg given



and 2.5mg wasted.” This should be witnessed by a second registered health professional who should also sign the record.

- The controlled drug to be discarded should be rendered irretrievable, in the presence of a witness as above, by emptying into a burn bin, into the bottom of which some absorbent material (e.g. paper towels) and a little liquid soap has been placed. This bin is used for this purpose and nominated (outwardly anonymously) as the CD waste receptacle. The emptied vial or ampoule should then also be placed in a sharps bin. When the “CD waste receptacle” is sent for destruction, it should be labelled “contains mixed pharmaceutical waste and sharps – for incineration”. Where individual hospitals have a formal agreement with Northern Ireland Water (which replaced the Water Service Agency in 2007) small amounts of liquid waste controlled drugs may be disposed of to sewer, so long as the terms of the agreement are complied with.
- A risk assessment should be carried out before a decision is made as to whether denaturing kits should be available on the wards. This is particularly relevant within children’s services. Where denaturing kits are provided, an SOP should be developed for this practice.
- The person who administers the dose is responsible for making the entry in the CDRB and this must be done immediately or as soon as is practicable after administration.
- The destruction should be recorded in the CDRB by both the person who undertook the destruction and the witness.

### **5.7.2 Child protection**

Parents who are substance misusers sometimes bring their prescribed controlled drugs on to hospital premises. Healthcare organisations may wish to consider whether, on a parent’s request, they may want to store the controlled drug in the CD cupboard and the parent requests the nurse to supply when a dose is required. These controlled drugs should be clearly labelled and kept separate from other controlled drugs.

Where there are concerns about potential diversion, staff should be alert that this may be a possibility and if appropriate, reference should be made to the appropriate child protection services

## **5.8 Controlled drugs for midwives**

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.

### **5.8.1 Acquisition of controlled drugs by midwives**

Supplies of diamorphine, morphine, pethidine and pentazocine may only be made to a midwife 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.

5.8.1.1 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).

5.8.1.2 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.

5.8.1.3 Supplies of pethidine, pentazocine, morphine and diamorphine may be obtained from a hospital pharmacy if the midwife is engaged in the business of the Trust. (Matters of pharmacy registration or wholesale dealing must be considered if the midwife is not engaged in the business of the Trust.) The pharmacist who makes the supply must ensure that medicines are only supplied on the instruction of an authorised person.

5.8.1.4 The pharmacist must retain the midwife's supply order for two years.

## **5.8.2 Storage and records**

Midwives must 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.

5.8.2.1 Once medicines are received by midwives working in the community or self-employed midwives, they become the responsibility of the midwife, and must be stored safely and securely.

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

5.8.2.3 Administration of controlled drugs by midwives should be in accordance with locally agreed procedures.

5.8.2.4 A record of administration of the controlled drugs should also be kept in the woman's records.

## **5.8.3 Returns and disposal**

When a midwife is in possession of controlled drugs that are no longer required they may be surrendered to the Appropriate Medical Officer, who should make arrangements for safe disposal, or the drugs may

be returned to the pharmacy from which they were obtained. (The Appropriate Medical Officer is a doctor authorised in writing by the Health and Social Care Board who may sign midwives' supply orders, or the person appointed by the Board to exercise supervision over registered midwives.) A record of the return should be made in the midwife's controlled drugs register.

5.8.3.1 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 guidance. Where possible a member of the family should witness the destruction. A record of the destruction should be made in the midwife's register. Some healthcare organisations may wish to provide denaturing kits to midwives to ensure safe destruction.

5.8.3.2 Controlled drugs that have been prescribed for a woman by 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 a community pharmacy for destruction. Where this is not possible, the midwife should obtain the patient's agreement in writing before removing it from the patient's home and returning it to a pharmacy for safe disposal, on behalf of the woman.

## 5.9 Discrepancies and diversion

The balances in the controlled drug record books (CDRBs) should always tally with the amounts of controlled drugs in the cupboard. If they do not, the discrepancy must be reported, investigated and resolved. It is important to remember that a discrepancy can indicate diversion. There should be a procedure for dealing with discrepancies and this should specify the arrangements for reporting and investigation.

In the first instance checks should be carefully made that:

- All requisitions received have been entered into the correct page of the CDRB
- All controlled drugs administered have been entered into the CDRB correctly
- Items have not been accidentally put into the wrong place in the cupboard
- Arithmetic is correct, to ensure that balances have been calculated correctly

If the error or omission is traced, the registered nurse or ODP in charge should make an entry in the CDRB, clearly stating the reason for the entry and the corrected balance. This entry should be witnessed by a second registered health professional. Both persons will sign the CDRB.

If no errors or omissions are detected then the discrepancy should be reported to the chief pharmacist and the Accountable Officer without delay and a local incident form completed in line with the healthcare organisation's policy or procedure for reporting incidents. Depending on the seriousness of the discrepancy and the early investigation findings, the DHSSPS Inspectorate and the police should be informed.

#### 5.10 Illicit substances

DHSSPS has issued guidelines to help in the development of local policy and associated documents with respect to suspected illicit controlled substances recovered from patients. Although the guidance was provided for mental healthcare settings it will be of relevance to any secondary care facility. The DHSSPS Head of Inspection and Investigation should be consulted with respect to destruction of illicit substances. Please refer to *Drug and Substance Misuse in Mental Healthcare Settings – Guidelines for Service Providers*, DHSSPS, September 2004 (Copies are available from the Mental Health Unit at the Department)

# 6 Management of controlled drugs in in-house operating theatres

## Contents of this chapter:

**Accountability and responsibility**

**Controlled drug stocks**

**Ordering and receipt**

**Storage**

**Record-keeping**

**Stock checks**

**Discrepancies**

**Archiving of records**

**Prescribing**

**Administration**

**Patient Controlled Analgesia**

**Returns to pharmacy**

**Disposal/destruction**

This chapter describes measures for management of controlled drugs in in-house operating theatres and departments where controlled drugs are used primarily by anaesthetists.

## 6.1 Accountability and responsibility

### 6.1.1 Accountable individuals

The senior registered nurse or Operating Department Practitioner (ODP) in charge of an operating theatre or theatre suite is responsible for the safe and appropriate management of controlled drugs.

The senior registered nurse, or ODP in charge can delegate control of access (i.e. key-holding) to the CD cupboard to another, such as a registered nurse or another ODP. A nurse or ODP may then only remove controlled drugs from the cupboard and/or return them to the cupboard on the specific authority of either the senior registered nurse or ODP in charge or doctor. Legal responsibility remains with the senior registered nurse or ODP in charge. Whilst the task can be delegated, the responsibility cannot. (The person to whom the task has been delegated is still professionally accountable for his/her actions).

Similar considerations apply to requisitioning and checking of CDs.

### **6.1.2 Standard operating procedures**

Healthcare organisations should ensure that all the procedures for the management of controlled drugs in in-house operating theatres and recovery wards are included in written standard operating procedures and that all staff, including anaesthetists, are aware of these procedures. It is good practice to ensure all staff who have to work in accordance with SOPs have an opportunity to comment on draft versions before the SOPs are finalised to ensure ownership. This is especially important in areas where many different staff are working for, perhaps, only a small part of their working week. Relevant staff must be conversant with the SOPs.

SOPs should be discussed with and approved by the Accountable Officer or by the person to whom he has delegated this task. The Accountable Officer remains accountable for the safe management of controlled drugs

## **6.2 Controlled drug stocks**

There should be a list of controlled drugs to be held in each theatre as stock items. The contents of the list should reflect current patterns of usage of controlled drugs in the theatre and should be agreed between the pharmacy technician or pharmacist responsible for stock control of medicines in the theatre and the Operating Department manager, appropriate medical staff and the senior registered nurse or ODP in charge.

The list should be modified if practices change and should be subject to regular review at agreed intervals.

## **6.3 Requisitioning of controlled drugs**

The senior registered nurse or ODP in charge of an operating theatre or theatre suite is responsible for the requisitioning of controlled drugs for use in the theatre. (See Appendix 2)

The senior registered nurse, or ODP in charge can delegate the task of preparing a requisition to another, such as a registered nurse or another ODP. However, legal responsibility remains with the senior registered nurse, or ODP in charge.

Wherever practicable, different persons should be responsible for requisitioning and receipt of controlled drugs.

Requisitions must comply with the requirements for stationery, authorised signatories and content set out in paragraph 4.3 Requisitioning of controlled drugs

Healthcare organisations may consider the introduction of a pharmacy-led top-up scheme as an efficient way of maintaining adequate stock levels of controlled drugs in theatres

#### **6.4 Receipt of controlled drugs**

When controlled drugs are delivered to a theatre or theatre suite they should be handed to an appropriate individual. On no account should they be left unattended. (See paragraph 5.2 Transfer of CDs). A local procedure should define the persons who are permitted to receive controlled drugs and the way in which messengers identify them. As a matter of good practice the receiving person should not normally be the same person who ordered the controlled drugs.

Receipt of controlled drugs in theatre should follow the provisions set out in section 4.4 Receipt of controlled drugs

#### **6.5 Storage of controlled drugs**

The storage arrangements for controlled drugs in theatres should conform to the general provisions set out in section 4.5 Storage of controlled drugs

It may also be necessary to install separate, secure, CD fridges for aseptically-prepared parenteral doses of controlled drugs.

#### **6.6 Record-keeping**

The records for controlled drugs in theatres should conform to the general provisions set out in section 4.7 Record-keeping

There should be a separate CD record book for each theatre.

In addition to the standard CD record books, some healthcare organisations may wish to stipulate the use of stationery that permits more detailed records of controlled drugs issued, administered and destroyed.

#### **6.7 Controlled drug stock checks**

The stock balance of all controlled drugs entered in the CD Record Book should be checked and reconciled with the amounts in the cupboard with sufficient frequency to ensure that discrepancies can be identified in a timely way. The frequency of such checks should be determined locally after a risk assessment has been carried out.

The senior registered nurse or ODP in charge is responsible for ensuring that stock checks are carried out and recorded. Pharmacy staff should carry out a documented stock check at regular intervals. This should be at least every three months.

Controlled drug stock checks should follow the provisions set out in paragraph 4.8 Controlled drug stock checks

#### **6.8 Archiving of controlled drug records**

The archiving of CD records in theatres should conform to the general provisions set out in paragraph 4.9 Archiving of controlled drug records

## 6.9 Prescribing of controlled drugs

The anaesthetist on duty is usually responsible for prescribing controlled drugs but other prescribers may also be involved. Nurse Independent Prescribers may also be responsible for prescribing or administration of diamorphine and morphine for post-operative pain.

Where separate charts are used e.g. epidural charts, anaesthetic charts, they should be cross-referenced on the patient's main medicines chart.

Prescribing of controlled drugs should follow the general provisions set out in paragraph 4.10 Prescribing of controlled drugs.

## 6.10 Administration

The practice of issuing "active stock" to the anaesthetist and then returning the unused portion to stock, recording both issues and returns in the theatre CD record book, should be avoided. [See *Controlled Drugs in Perioperative Care. January 2006. [www.aagbi.org](http://www.aagbi.org)*] An amount should be issued to the anaesthetist for a specific patient and any surplus drug should be destroyed and witnessed e.g. if the patient is prescribed diamorphine 2.5mg and only a 5mg preparation is available, the record should show, "2.5mg given and 2.5mg wasted"

- Small amounts of waste controlled drugs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, should be rendered irretrievable. This may be done by emptying into a burn bin, into the bottom of which some absorbent material (e.g. paper towels) and a little liquid soap has been placed. This bin is used for this purpose and nominated (outwardly anonymously) as the CD waste receptacle. The emptied vial or ampoule should then also be placed in a sharps bin. When the "CD waste receptacle" is sent for destruction, it should be labelled "*contains mixed pharmaceutical waste and sharps – for incineration*". Where individual hospitals have a formal agreement with Northern Ireland Water (which replaced the Water Service Agency in 2007) small amounts of liquid waste controlled drugs may be disposed of to sewer so long as the terms of the agreement are complied with.
- Injectables should be treated as intended for single use only unless the label specifically indicates that they are licensed and intended for use on more than one occasion or to provide more than a single dose on any one occasion.
- A record of administration should be made on the appropriate chart immediately after administration by the person who administered the controlled drug. This should include the identity of the person, the dose administered and the time of administration.



### 6.11 Patient-controlled analgesia

There should be a local procedure for all aspects of the management of patient controlled analgesia. This should include:

- A description of the CD preparations available and the medical devices (for example, pumps, syringe drivers) used for administration
- Arrangements for requisitioning the appropriate medical devices
- Instructions for prescribing and requisitioning the CD preparations (e.g. pre-loaded syringes, small volume infusion bags)
- Specification of the entries required in the controlled drug record book in the originating ward or department
- Arrangements for documentation when the patient is moved from theatre/ward to ward
- Arrangements for recording administration
- Arrangements for recording unused portions of syringe contents or bags no longer required
- Arrangements for disposal of unused portions
- Arrangements for documenting the destruction of unused portions

### 6.12 Returning controlled drugs to the pharmacy

The arrangements for return of controlled drugs to the pharmacy should conform to the provisions set out in paragraph 4.15 Returning controlled drugs to the pharmacy

In general, date-expired or controlled drugs that are otherwise unfit for use should be returned to pharmacy for safe disposal.

Surplus stock should be returned to the pharmacy as described in section 4.15.

### 6.13 Disposal of controlled drugs

The disposal of controlled drugs in theatres should conform to the general provisions set out in section 4.16 Disposal of controlled drugs in wards and departments.

Unused part-doses should be destroyed promptly and witnessed by a registered nurse or ODP.

- Small amounts of waste controlled drugs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, should be rendered irretrievable. This may be done by emptying into a burn bin, into the bottom of which some absorbent material (e.g. paper towels) and a little liquid soap has been placed. This bin is used for this purpose and nominated (outwardly anonymously) as the CD waste receptacle. The emptied vial or ampoule should then also be placed in

a sharps bin. When the “CD waste receptacle” is sent for destruction, it should be labelled “*contains mixed pharmaceutical waste and sharps – for incineration*”. Where individual hospitals have a formal agreement with Northern Ireland Water (which replaced the Water Service Agency in 2007) small amounts of liquid waste controlled drugs may be disposed of to sewer so long as the terms of the agreement are complied with.

- If large quantities of part used controlled drugs are routinely generated, some healthcare organisations may wish to provide denaturing kits for use in theatres to destroy controlled drugs that have been used for patients. A risk assessment should be carried out before a decision is made as to whether denaturing kits should be available in theatres. Where denaturing kits are provided to theatres, an SOP should be developed for this practice.

# 7 Management of controlled drugs in hospital pharmacies

## Contents of this chapter:

- Accountability and responsibility**
- Security of CDs/Standard operating procedures**
- Ordering and receipt**
- Storage**
- Issuing of CDs to Wards and Departments**
- Record-keeping**
- Stock checks**
- Discrepancies**
- Archiving of CD records**
- Supply to outpatients and discharge patients**
- Supply to external units**
- Transfer of CDs**
- Controlled Drugs returned from Wards**
- Production and Quality Control**
- Disposal/destruction**

This chapter deals with the management of controlled drugs in hospital pharmacies and between pharmacies and other departments or health and/or social care bodies.

## 7.1 Accountability and responsibility

The chief pharmacist is responsible for the safe and appropriate management of controlled drugs in the pharmacy. Day-to-day management of controlled drugs (e.g. receipt into and issue from dispensary stock) in the pharmacy may be delegated to a suitably-trained, competent pharmacy technician or another pharmacist. Where technicians are delegated the management function, legal responsibility for the controlled drugs remains with the delegating pharmacist.

## 7.2 Security of controlled drugs/Standard Operating Procedures

The pharmacy should have standard operating procedures (SOPs – see also page 15) covering each of the aspects of the safe management of controlled drugs including: ordering, receipt, safe custody, record-keeping, auditing, issuing of stock, dispensing prescriptions, transporting of supplies, and destruction of unwanted drugs.

SOPs should be kept up-to-date, reflecting current legal and good practice requirements for controlled drugs, and each one should be clearly marked with the date of issue and review date. Previous versions should be archived.

SOPs should be approved by the Accountable Officer or by the person to whom he has delegated this task. The Accountable Officer remains finally accountable for all the systems for the safe management of CDs. (See Appendix 3)

Relevant staff should be conversant with the SOPs.

## **7.3 Ordering and receipt**

Ordering of controlled drugs from wholesalers and manufacturers and receipt of controlled drugs should follow the principles of good procurement. Local procedures should ensure that there is a robust audit trail and that the opportunities for diversion are minimised.

### **7.3.1 Ordering**

Routine orders to wholesalers and manufacturers for controlled drugs for stock are usually placed electronically. Some healthcare organisations may, for reconciliation and accounting purposes, make a decision to produce paper records.

Stock levels should be determined by need and kept to a minimum, but should not be so low that there is a danger of running out at busy periods. This will normally be calculated by the pharmacy stock management system. It may be necessary to increase stock levels temporarily when it is anticipated that demand may outstrip the normal supply arrangements, for example, during long holiday breaks.

### **7.3.2 Receipt**

There should be a locally agreed procedure for the receipt of controlled drugs into the pharmacy department. The procedure should ensure the security of controlled drugs and should be auditable. It should include:

- Who should sign for receipt (- ideally not the same person who generated the order.)
- How the goods should be checked (e.g. matching of the details on the delivery note to the goods and the original order) and appropriate stock control documentation completed. Any tamper-evident seals on packs should be left intact when they are received from the supplier. This will simplify and speed up routine balance checks.
- What action is to be taken if a tamper evident seal is broken or the contents of a pack do not match the stated amount
- What action is to be taken if the item received is incorrect

- What arrangements are made for storage of incorrect items for return, if appropriate
- The specifications for the record required in the CD register, including who should make the register entry and whether a witness is required

7.3.2.1 It is good practice to record receipt at the first opportunity, and in any event the record must be made no later than the day next following the day of receipt.

7.3.2.2 As a matter of good practice the balance in stock should be checked and recorded as correct by the person making the entry.

7.3.2.3 The stock must be put away promptly into the appropriate section of the CD cabinet. Controlled drugs must never be left outside of the cabinet unsupervised.

## **7.4 Storage**

Pharmacy CD cabinets must conform to, or exceed the requirements of the Misuse of Drugs (Safe Custody) Regulations (Northern Ireland) 1973.

The Regulations should be regarded as a minimum security standard and may not be sufficient for areas where there are large amounts of controlled drugs in stock at a given time and/or there is not a 24-hour staff presence or easy control of access. When new hospital pharmacies are being designed, purpose built, compliant strong-rooms should be incorporated in the plans and it is essential to consult in this respect with the DHSSPS Head of Inspection and Investigation.

## **7.5 Issuing of CDs to wards and departments**

There should be a local procedure for the issuing of controlled drugs to wards and departments. The procedure should ensure the security of the controlled drugs and should be auditable. It should include:

- The procedure for checking that the requisition is valid (complete and signed by an authorised signatory)
- The mechanism for correcting an incomplete or inaccurate requisition
- Specifications of the details required on labels (see below)
- Specification of entry required in the register including who should make the register entry
- Whether a witness is required. The decision as to whether a witness is required or not should be made following a risk assessment.
- Arrangements for transfer of the controlled drugs to the ward or department

### **7.5.1 Electronic systems**

Where electronic systems for the requisitioning of controlled drugs are introduced, safeguards in the software should be in place to ensure that:

- Only individuals who are authorised to requisition controlled drugs from the pharmacy can do so
- Entries cannot be altered at a later date
- A log of all data entered is kept and can be recalled for audit purposes

### **7.5.2 Labelling of CDs (Stock)**

There should be a standardised procedure for labelling controlled drugs.

The label should state:

- Drug name, form and strength
- Quantity
- “Store in CD cupboard”
- Department / ward name or number
- Date of issue
- Expiry date if dispensed from bulk. (NB: Certain preparations have a reduced expiry once opened, e.g., Oramorph).
- Manufacturer’s Batch Number if dispensed from bulk
- “Keep out of reach and sight of children”
- Address of pharmacy

Depending on local circumstances, some pharmacies may also wish to add

- The requisition number

Each carton, syringe or bottle must be labelled individually. In addition, labels may also be placed on outer wrappers or containers.

## **7.6 Record-keeping**

### **7.6.1 CD registers**

Pharmacy departments are required to keep registers of receipts and supplies of Schedule 2 controlled drugs.

7.6.1.1 Register entries must be made in consecutive, chronological order. The entry must be made on the day when the drug is received or supplied, or on the next day. Entries must be in ink or be otherwise indelible

7.6.1.2 If a mistake is made the entry should not be crossed out, deleted, obliterated or defaced; liquid paper must not be used. Correction must be made by footnote or marginal note. The note must specify the date on which it was made and should be accompanied by the signature of the person making the

correction. It is acceptable to bracket the incorrect entry. The resulting record in the register must be unambiguous.

7.6.1.3 The following staff may complete the CD register:

- Any registered pharmacist under their own authority
- Any competent member of Pharmacy staff, ideally a regulated healthcare professional, under the authority of the chief pharmacist, provided this is included in the SOP
- Any person who is being trained by a competent member of pharmacy staff such as a trained technician or a pharmacist, under their supervision. The supervisor should countersign the entry

7.6.1.4 The Misuse of Drugs Regulations 2002 were amended in 2007 with changes which came into force **from 1 February 2008**. The "Form of the Register" as specified in Schedule 6 of the 2002 Regulations was removed and replaced with a requirement to maintain, where appropriate, a CD Register with specified headings/ titles by which to capture mandatory fields of information. Additionally in the CD Register or separate part of the CD Register used for each class of drug, separate pages for each strength and form of controlled drug are now required. The name, strength and form of the drug must be entered at the top of each page and the mandatory fields of information recorded under the specified headings. An index should be maintained, together with "carried forward to/from page" details on register pages where appropriate, to enable easy navigation through the register.

7.6.1.5. The fields of information are somewhat expanded from the previous requirements. Entries in respect of drugs supplied and drugs obtained may be made on the same page or separate pages within the CD Register. The fields are as follows:

7.6.1.6 For controlled drugs **supplied** the register entry must include:

- Date supplied
- Name/Address of person or firm supplied
- Details of authority to possess - prescriber or licence holder's details
- Quantity supplied
- Person collecting Schedule 2 controlled drug (patient/patient's rep/healthcare professional) and if healthcare professional, name and address [*Guidance – work address - not home address*]
- Was proof of identity requested of patient/patient's rep (Yes/No)
- Was proof of identity of person collecting provided (Yes/No)

7.6.1.7 For CDs **obtained** the following details must be recorded in the CD Register:

- Date supply received
- Name and address from whom received

- Quantity received

7.6.1.8 The stock balance in the register should be checked against both the quantity in the CD cabinet and the balance shown in the pharmacy stock control system. The frequency of such checks should be determined locally following a risk assessment.

7.6.1.9 The Misuse of Drugs Regulations 2002 were amended in July 2006 to make clear that the details required to be kept in a controlled drug register are a minimum and do not prevent any person required to keep a register from including additional relevant information. This principle is unchanged.

7.6.1.10 The Misuse of Drugs And Misuse of Drugs (Safe Custody) (Amendment) Regulations (Northern Ireland) 2007 can be found at  
[http://www.opsi.gov.uk/Sr/sr2007/nisr\\_20070348\\_en.pdf](http://www.opsi.gov.uk/Sr/sr2007/nisr_20070348_en.pdf)

## **7.6.2 Liquid preparations**

Discrepancies can arise with liquid controlled drugs as a result of manufacturer's overage, the measurement process or spillage. Such overage or losses of liquid preparations should be recorded and the running balance adjusted. In dealing with discrepancies, be alert to the possibility of, or potential for, diversion. 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. It may be appropriate to carry out volume checks at regular intervals. When spillages occur, every effort should be made to find another person who can verify that the spillage has occurred and this should be recorded and initialled by both the person making the spillage and the second person, if there is one. Spilled product should be treated as controlled drug waste; denatured and rendered irretrievable.

## **7.6.3 Computerised registers**

The Misuse of Drugs Regulations 2002 were amended in January 2006 to allow (not require) the CD register to be held on an approved computerised system. The Regulations require that entries in computerised registers must be attributable and auditable.

If the CD register is held in computerised form, the following should be in place:

- Safeguards should be incorporated in the software to ensure the author of each entry is identifiable
- Entries cannot be altered at a later date
- All entries are attributable to an individual making the entry
- A log of all data entered is kept and can be recalled for audit purposes
- Adequate backups are made



- Systems are in place to minimize the risk of unauthorised access to the data
- Systems which permit inspection of the register by authorised persons without disruption to the workflow of the pharmacy.

For further details see The Misuse of Drugs and the Misuse of Drugs (Notification of and Supply to Addicts) (Amendment) Regulations (Northern Ireland) 2005. (SR 2005 No. 564)

[http://www.opsi.gov.uk/Sr/sr2005/nisr\\_20050564\\_en.pdf](http://www.opsi.gov.uk/Sr/sr2005/nisr_20050564_en.pdf)

## 7.7 Checks of CD stocks performed by pharmacy staff

### 7.7.1 Checks of CD stocks held in the pharmacy

All controlled drugs in the pharmacy should be checked periodically e.g. every three months. The frequency of such checks should be determined following a risk assessment by the pharmacist with operational responsibility for managing controlled drugs and this should be included in an SOP.

7.7.1.1 This check may be undertaken by any competent person approved by the pharmacist with operational responsibility for controlled drugs, the store supervisor, or by a trainee working under their direct supervision and this should be included in an SOP.

7.7.1.2 The check should be recorded indelibly in the CD register by means of signature, date and an appropriate entry, e.g., "*Stock checked. Balance correct*".

7.7.1.3 Some healthcare organisations may also wish to stipulate periodic checks of controlled drugs by pharmacy managers who do not routinely work in the dispensary.

### 7.7.2 Checks of CD stocks held in wards, theatres or departments

All stocks of controlled drugs held in wards and departments should be checked by a pharmacist or pharmacy technician at least every three months and at other times when requested by the ward or department manager.

7.7.2.1 The stock check procedure should cover the following:

- A check that the levels of drugs in stock tally with the balances recorded in the CDRB.
- A check of a sample of CD requisition originals (brought from pharmacy) together with sample supply/administration information to ensure that records have been correctly made in the CDRB
- A review of the security and quality of record keeping

- Checking and updating (if required) of the list of authorised signatories for CD requisitions
- A check for exceptional usage or peculiar patterns of usage of controlled drugs
- A check of the physical security arrangement for the storage of controlled drugs, CD stationery and the key-holding policy.

7.7.2.2 The procedure may also include a check of patients' own controlled drugs held on the ward at the time.

7.7.2.3 A record of the stock check should be made clearly and indelibly in the CDRB. The entry should be signed and dated by the person who carried it out.

7.7.2.4 Local documentation may be designed to record all aspects of the CD stock-check procedure (e.g. ward CD inspection report forms) for audit purposes.

## 7.8 Discrepancies

The balance recorded in the hardcopy register and/or, where relevant, the electronic register/pharmacy stock control system, should be reconciled against the stock of every product in the CD cupboard. If one or more of these levels does not tally, the discrepancy must be investigated and resolved without delay. It is important to remember that a discrepancy may indicate diversion. The discrepancy should be reported to a senior pharmacist within one working day.

There should be a careful check of transactions in the register and in the stock control system to trace an error or omission.

If an error is traced then a register entry should be made, clearly stating the reason for the entry, the reference of the error or the omission, the date of the error or omission and the signature of both the person carrying out the amendment and the witness.

If no error or omission can be traced the Chief Pharmacist and the Accountable Officer should be informed. They should decide what action to take.

## 7.9 Archiving of controlled drug records

Every requisition, order or private prescription on which a controlled drug is supplied must be preserved by the Pharmacy department in accordance with legislation **and** the guidance contained in *Good Management Good Records* (GMGR) (<http://www.dhsspsni.gov.uk/dhs-goodmanagement.pdf>). The extensive "Appendix A" to the GMGR document contains detailed information about retention of records, not only in pharmacy, but throughout HPSS. It is important to be aware of the wider content in addition to the section on "Pharmacy". Healthcare organisations should note that even though a short mandatory period of retention may be specified in regulations, cases often come to court at a much later date.

The time periods in GMGR for archiving CD documentation are:

Requisitions	2 years
Registers and CDRBs	13 years from last entry
Extemporaneous preparation worksheets	13 years
Patient Controlled Analgesia worksheets	13 years
Discharge and specialist medicines prescriptions	13 years
Clinical trials	15 years post treatment(may be longer for some trials)

Refer to GMGR for detailed guidance on retention of records relating to children. <http://www.dhsspsni.gov.uk/dhs-goodmanagement.pdf>

Future Regulations may increase the period of time for the storage of records. Readers are advised to refer to the DHSSPS website for up-to-date information.

## 7.10 Supply to outpatients and discharge patients

For outpatient prescriptions being given directly to the patient or their representative:

- Patients or their representatives may be asked to provide evidence of identity when collecting controlled drugs

From July 2006, there has been a requirement for persons asked to supply controlled drugs on prescription to seek to establish whether the person collecting the medicine is the patient, their representative or a healthcare professional acting in his professional capacity on behalf of the patient.

Where the person is the patient or their representative, the supplier:

**May** request evidence of that person's identity and

- **May** refuse to supply the medicine if he is not satisfied as to the identity of the person

Where it is a healthcare professional acting in his professional capacity on behalf of the patient, the supplier:

- **Must** obtain the person's name and address
- **Must**, unless he is acquainted with that person, request evidence of that person's identity; but
- **May** supply the medicine even if he is not satisfied as to the identity of the person

Any strengthening of controls has been balanced with ensuring that patients have access to medicines they need and have been prescribed for them. The requirement placed on the supplier therefore allows them:

- Discretion not to ask patients or patient representatives for proof of identity if for example they have concerns that to do so may compromise patient confidentiality or deter patients from having their medicine dispensed.

**From 1 February 2008**, it has been a requirement to record the following extra information in the CD register for Schedule 2 controlled drugs supplied:

- Whether the person who collected the drug was the patient, the patient's representative or a healthcare professional
- If the person who collected the drug was a healthcare professional, that person's name and address
- If the person who collected the drug was the patient or their representative, whether evidence of identity was requested (as a matter of good practice a note as to why the dispenser did not ask may be included but this is not mandatory).
- And whether evidence of identity was provided by the person collecting the drug.

The patient's date of birth may be used as a second check if necessary.

Depending on local circumstances, some healthcare organisations may wish to stipulate that outpatients and discharge patients should not only sign for receipt of a dispensed item but also for receipt of a specific number of doses.

### 7.11 Supply to external units

A hospital pharmacy can only supply to an external organisation if the pharmacy is registered with the Pharmaceutical Society as a pharmacy within the meaning of the Medicines Act 1968 or holds a Wholesale Dealers licence.

Before making a supply to an external unit the hospital should satisfy itself that it may lawfully supply the controlled drug and that the recipient may lawfully possess controlled drugs. A private hospital that is not maintained by voluntary funds or by a registered charity needs a DHSSPS Licence to hold schedule 2 CD stocks. The supplier should only make the supply if such a licence is held. (For further information see the Home Office Drug Laws and Licensing pages: [www.drugs.gov.uk/drugs-laws/licensing/](http://www.drugs.gov.uk/drugs-laws/licensing/)) The DHSSPS Head of Inspection and Investigation may be consulted regarding local licence holders.

Where the external unit or body is a designated body as defined in the Regulations it will have an Accountable Officer and the AO must ensure that his designated body has up-to-date SOPs for the use and management of CDs. Where the external unit acts on behalf of, or provides services under arrangements made with, the Trust, the Trust's Accountable Officer must ensure that the external unit has established and operates appropriate arrangements for securing safe management and use of controlled drugs. These arrangements include adequate and up-to-date SOPs.

Where a service level agreement (SLA) is drawn up for a service to supply controlled drugs to an external body or unit, the SLA should specify the SOPs that are to be followed (i.e. those of the provider or purchaser).

#### **7.11.1 Supply to external units**

External units include, for example, hospices, prisons and the ambulance trust.

The other unit must comply with the legislation for controlled drugs and should also follow the guidance in this document.

#### **7.11.2 Written agreement (Service Level Agreement [SLA])**

When the hospital pharmacy is providing services to another health and social care body the details should be specified in a written agreement or contract (service level agreement).

In relation to controlled drugs the following points should be included in the written agreement (SLA):

- What is to be supplied; stock controlled drugs and /or patients' own controlled drugs (e.g., for external units where patients are encouraged to self-administer their own medicines including controlled drugs).
- An outline of the ordering and supplying processes and the documentation used.
- The arrangements for obtaining supplies of controlled drugs in emergencies and out of hours.
- Specification of responsibilities and accountability in relation to controlled drugs medicines management including governance arrangements.
- A statement that the pharmacy department and receiving unit produce SOPs for the ordering and issuing processes including transit at their respective facilities. This should include the different ordering processes for stock controlled drugs and patient-specific controlled drugs (see below).
- It is good practice for the other health and social care body to ensure that its SOPs have been reviewed and agreed by a pharmacist. (Note that not all external organisations employ a pharmacist).
- That both parties review each others' SOPs to ensure a consistent, safe and auditable management process for controlled drugs.
- If two different Accountable Officers cover the issuing and receiving units then each Accountable Officer should take responsibility for the SOPs relating to his organisation.
- That the representatives from the issuing pharmacy and the other health and social care body meet on a regular basis to discuss any

problems and agree any remedial action to resolve these and review services.

- That the issuing pharmacy and receiving unit conduct audits across the interface to ensure that process and procedures follow the SOPs and that any gaps in the systems, processes and procedures are identified and rectified. It is good practice to provide the Accountable Officer(s) with the audit reports and action plans.

Further information about the content of service level agreements can be found at <http://www.nelm.nhs.uk/Record%20Viewing/viewRecord.aspx?id=573380>

### **7.11.3 Ordering of stock controlled drugs by another hospital or a nursing home**

Ordering of controlled drugs must comply with the current Misuse of Drugs Regulations.

Where a pharmacist is employed, the purchase of controlled drugs must be under his or her direct supervision and this includes authorising orders to suppliers. Where no pharmacist is employed a doctor or dentist employed by or engaged by the body must countersign orders for controlled drugs raised by the person in charge or acting person in charge of the other hospital or nursing home.

All stock controlled drugs should be ordered as stock items only and contain no patient names.

#### **7.11.3.1. Arrangements when the hospital pharmacy provides a supply service only to another hospital or nursing home**

The person or acting person in charge of a hospital or nursing home, can complete the controlled drugs requisition book and sign this order, which must also be countersigned – see below. The stock controlled drugs order must contain:

- Signature of the person to whom the drug is to be supplied (the recipient),
- The name, address and profession or occupation of the recipient
- Name, formulation, strength and quantity (whole pack sizes) of the controlled drug,
- Purpose for use,
- Countersignature of a doctor (or dentist) who is employed or engaged at the other hospital or nursing home.

The requisition should be dated and should include sufficient information to identify the hospital or nursing home and the ward or department.

The doctor will sign the order as an independent verification that the controlled drugs ordered are to be used within the requesting ward or department within the other hospital or nursing home. Responsibility and accountability should be written into the SLA and be in accordance with the Misuse of Drugs Regulations.

There are circumstances where a doctor may request controlled drugs and is also responsible for the management of the controlled drugs within the department of the other organisation.

## **7.11.4 Ordering of patient specific controlled drugs by external units**

### **7.11.4.1 Ordering from a hospital pharmacy**

Patient specific controlled drugs can be ordered for either use within an inpatient unit (e.g. as part of self-administration scheme) or as discharge medication.

It is acceptable for the external unit to use locally designed and approved prescription forms for prescribing a patient's medication. The hospital pharmacy should manage these prescription forms in the same way as they would internal prescription forms.

A full audit trail should be maintained when transferring the dispensed controlled drugs to the external unit.

The controlled drug prescription on the locally designed prescription forms must comply with all the legal requirements for the prescription of a controlled drug.

### **7.11.4.2 Ordering from a community pharmacy**

A similar arrangement of using locally designed and approved prescription forms can be used when a community pharmacy is supplying patient-specific controlled drugs under a written agreement to an inpatient unit such as a prison or hospice.

(It should be noted that these prescriptions are not private prescriptions but part of a system for supplying patients/prisoners with appropriate dispensed and labelled medicines including controlled drugs on discharge from that unit or as part of a patient self-administration scheme).

The controlled drug prescription on the locally designed prescription forms must comply with all the legal requirements for the prescription of a controlled drug.

## **7.12 Transfer of controlled drugs**

At each point where a controlled drug moves from the authorised possession of one person to another, the transfer should be recorded by means of the signatures of both parties.

Wherever possible, the drug must be transported in a secure, lockable container and a suitable delivery document completed to provide a full audit trail.

See paragraph 5.2 - Transfer of controlled drugs



### 7.13 Controlled drugs returned from wards

There should be a local procedure and auditable documentation for the management of controlled drugs returned from wards.

See also paragraph 4.15 – Returns to Pharmacy

### 7.14 Production and Quality Control

Where pharmacy production or aseptic units are preparing products that contain controlled drugs, then the same governance arrangements for safe use should apply as for elsewhere in the organisation. All the activities should be covered by SOPs and the processes should be robust and auditable.

### 7.15 Disposal/destruction

See also section 4.16 disposal of controlled drugs in wards and departments

Unwanted controlled drugs should be denatured in a pharmacy, and when required by legislation, in the presence of an authorised witness. Treated waste should be placed in appropriate containers for eventual incineration and should not be allowed to enter the sewerage system. [See *Handling and Disposal of Pharmaceutical and Clinical Waste* (Health Estates 2002) <http://www.dhsspsni.gov.uk/pharmaceutical-waste-guidance.pdf>] Reference has previously been made (e.g. section 4.16.2) to circumstances whereby small quantities of waste liquid controlled drugs at ward or department level may be disposed of to sewer. Note that this pertains where hospitals have individual agreements with Northern Ireland Water, and act within the parameters of those agreements.

Controlled drugs should be disposed of in such a way that the drug is denatured or rendered irretrievable so that it cannot be reconstituted or used again.

There should be a local policy for disposal of controlled drugs and this policy must be in accordance with current Home Office guidance, Waste Management Regulations and Environment and Heritage Service guidance. The methods used for denaturing should be in accordance with RPSGB guidance. [See *Guidance for Pharmacists on the safe destruction of Controlled Drugs: England, Scotland and Wales*. [www.rpsgb.org.uk/pdfs/cdsafedestructionguid.pdf](http://www.rpsgb.org.uk/pdfs/cdsafedestructionguid.pdf) Check also the PSNI website for further guidance that may be published.]

The Environment Agency (EA), which covers England and Wales, has decided that it is not in the public interest to expect pharmacies to obtain a waste management licence for denaturing CDs as this is seen by the EA as a 'low risk' activity. The Environment and Heritage Service in Northern Ireland has taken the following position: "EHS have considered the risks posed by the destruction of controlled drugs in a pharmacy and have concluded that it will not normally take enforcement action against persons carrying out this activity providing the subsequent movement and disposal of the denatured drugs is in compliance with all relevant waste legislation... Pharmacies must ensure that the activities they undertake to denature controlled drugs protect the environment, workers and others within the pharmacy." The EHS may take

appropriate action where it considers that there is a risk to human health and/or the environment. It may also amend its position if there are regulatory changes, future government guidance or in the light of experience of this type of activity. It is therefore essential that local policies and procedures for destruction of CDs not only ensure effective destruction but also protect the environment and people in the pharmacy.

### **7.15.1 Destruction of stock controlled drugs**

Any pharmacy-held stock of obsolete, expired or unwanted Schedule 2 controlled drugs not returned by patients, that requires destruction can only be destroyed in the presence of a person authorised by the DHSSPS.

7.15.1.1 Authorised witnesses currently include pharmacy inspectors, and other named persons employed by Trusts, who have been authorised and trained by DHSSPS.

7.15.1.2 Until they can be destroyed, obsolete, expired and unwanted stock controlled drugs requiring safe custody, according to arrangements appropriate to their schedule, must be kept segregated from other controlled drugs in the CD cupboard. Stock controlled drugs awaiting destruction should be clearly marked in order to minimise the risk of errors and inadvertent supply.

7.15.1.3 When stock Schedule 2 controlled drugs are destroyed, the following details must be entered into the CD register:

- Drug name
- Drug form
- Drug strength
- Quantity of drug being destroyed
- Date of destruction
- Signature of the authorised person in whose presence the drug was destroyed

7.15.1.4 It is good practice for the person carrying out the destruction to also sign against this record.

### **7.15.2 Destruction of controlled drugs returned by patients**

These are controlled drugs that have been prescribed for, and dispensed to, a named patient and then returned unused or part-used by the patient or their representative to the pharmacy.

Controlled drugs that have been returned by patients do not form part of the pharmacy stock and can be destroyed without the presence of an Authorised Person.

7.15.2.1 Although recording of patient-returned controlled drugs is not a current legal requirement in relation to the Misuse of Drugs Regulations 2002 it is good practice to keep a record.

7.15.2.2 A record of controlled drugs returned by patients should be kept as above and a record of their destruction should be made. As a matter of good practice, destruction should be witnessed, preferably by a pharmacist or pharmacy technician.

7.15.2.3 The record of these destructions should be made somewhere other than the CD register – for example in a separate “Destruction Book” designated for that purpose. It is recommended that the following details are recorded:

- Date of return of the controlled drugs
- Name, quantity, strength and form of the controlled drugs
- Role of the person who returned the controlled drugs (if known)
- Name and signature of the person who received the controlled drugs
- Patient’s name and address (if known)
- Names, positions and signatures of the person destroying the controlled drugs and the witness
- Date of destruction
- Any other comments relevant to the receipt or destruction of that particular dispensed medicine

A suggested recording form is available at <http://www.rpsgb.org.uk/pdfs/restooldestrcd.pdf>

7.15.2.4 Controlled drugs requiring safe custody awaiting destruction should be stored in the CD cabinet separately from pharmacy stock controlled drugs.

7.15.2.5 Destruction of controlled drugs should occur regularly and with sufficient frequency to ensure that excessive quantities are not stored awaiting destruction. The frequency should be determined locally following a risk assessment.

### **7.15.3 Methods of disposal for CDs**

Denatured controlled drugs for disposal should be placed in suitable waste containers which are then sent for incineration and should not be disposed of in the sewerage system. The containers of waste should be labelled, “*contains pharmaceutical waste – for incineration*”.

The Home Office has advised that Schedule 2, 3 and 4 Part 1 controlled drugs must be denatured before being placed into waste containers.

7.15.3.1 Wherever practicable, CD denaturing kits should be used to denature controlled drugs. Where this is not possible or practical other methods of denaturing may be used. Used denaturing kits should be placed in pharmaceutical waste bins that are destined for incineration. Regardless of the methods

used, measures should be taken to ensure safety of personnel and non-contamination of the environment.

7.15.3.2 Details of suitable methods for destruction of CDs in different dosage forms can be found in *Guidance for Pharmacists on the safe destruction of Controlled Drugs: England, Scotland and Wales*. ([www.rpsgb.org.uk/pdfs/cdsafedestructionguid.pdf](http://www.rpsgb.org.uk/pdfs/cdsafedestructionguid.pdf)) and it is strongly recommended that these methods are used.

7.15.3.3 Small amounts of waste controlled drugs, for example, the surplus when a dose smaller than the total quantity in an ampoule or vial is drawn up or when a dose is drawn up but not used, should be rendered irretrievable. This may be done by emptying into a burn bin, into the bottom of which some absorbent material (e.g. paper towels) and a little liquid soap has been placed. This bin is used for this purpose and nominated (outwardly anonymously) as the CD waste receptacle. The emptied vial or ampoule should then also be placed in a sharps bin. When the “CD waste receptacle” is sent for destruction, it should be labelled “*contains mixed pharmaceutical waste and sharps – for incineration*”.

Where denaturing kits are used, their use should be included in an SOP.

Small unrequired excesses are most likely to arise when products are being prepared. In these circumstances, the controlled drug has already been issued to the extemporaneous preparation area or aseptic preparation area and is no longer part of the pharmacy CD stock. A full audit trail should be maintained. The worksheet should show the amount used and the amount wasted, for example: “2.5ml used 0.5ml wasted”.

As a matter of good practice, the disposal of the part dose should be witnessed and recorded on the worksheet. Both people should sign the worksheet.

## 8 Staff training for management of controlled drugs

The Accountable Officer is responsible for ensuring that members of staff who are involved in prescribing, supplying, administering or disposing of controlled drugs receive appropriate training to enable them carry out their duties.

Staff should receive appropriate training on local standard operating procedures for controlled drugs when they first become involved in prescribing, supplying, administering or disposing of controlled drugs and then regularly thereafter. The frequency of training should be determined locally.

Staff should be informed and, if necessary, receive additional training when SOPs are revised or amended and when new CD products or systems are introduced.

# Glossary of terms

Administer	<p>To give a medicine either by introduction into the body, whether by direct contact with the body or not, (eg orally or by injection) or by external application (eg application of an impregnated dressing). There are specific definitions in medicines legislation as follows:</p> <p>“external use” means application to the skin, hair, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina or anal canal when a local action only is intended and extensive systemic absorption is unlikely to occur; and references to medicinal products for external use shall be read accordingly except that such references shall not include throat sprays, throat pastilles, throat lozenges, throat tablets, nasal drops, nasal sprays, nasal inhalations or teething preparations;</p> <p>"parenteral administration" means administration by breach of the skin or mucous membrane.</p>
Chief Pharmacist	<p>In the context of this document the term is used to describe the pharmacist with overall responsibility for the hospital pharmacy. In some circumstances consultation may be necessary with a higher level of pharmacy management.</p>
Controlled Drugs (CDs)	<p>The drugs listed in Schedule 2 to the Misuse of Drugs Act 1971. These drugs are categorised in schedules 1-5 of the Misuse of Drugs Regulations (Northern Ireland) 2002 (as amended). Drugs listed in the different MDR schedules are subject to differing levels of control but all are controlled drugs.</p>
CD record book (CDRB)	<p>Bound book in which records are made of controlled drugs received and supplied in wards, theatres and departments.</p>
CD register	<p>A “register” as specified in the Misuse of Drugs Regulations 2002 (as amended) means either a bound book, which does not include any form of loose leaf register or card index, or an approved computerised system which is in accordance with best practice guidance endorsed by the Secretary of State under section 2 of the National Health Service Act 1977.</p>
Discrepancy	<p>Difference between the amount shown in the register or record book and the amount that is physically present.</p>
Designated body/bodies	<p>Health care organisations - the Board, HSC Trusts, the Northern Ireland Ambulance Service, Independent Hospitals – as defined in Regulation 3 of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009.</p>
Dispense, dispensing	<p>Dispensing of controlled drugs: preparation (including compounding, dissolving, diluting, packing and labelling.) In some contexts it may include the transfer (supply) of medicines to individual patients</p>

Diversion	Removal of controlled drugs for unauthorised use; theft
Duty Pharmacist	Senior pharmacist on duty for the time being
Healthcare organisations	Organisations responsible for the delivery of healthcare. Includes Trust hospitals and independent hospitals.
Local Intelligence Network	A network established by the Department for sharing information regarding the management and use of controlled drugs
“may”	Used in this document in connection with recommendations concerned with good practice if they are relevant to local circumstances
MDR	Misuse of Drugs Regulations – Regulations made under the Misuse of Drugs Act (1971)
“must”	Used in this document in connection with legal requirements e.g. “records of schedule 2 controlled drugs received and supplied by a pharmacy must be kept in a CD register.”
Operating Department Practitioner (- Registered Operating Department Practitioner)	Operating Department Practitioner whose name is on the register of the Health Professions Council and should be a member of the College of Operating Department Practitioners – see Appendix 2
Order	In the context of controlled drugs: To make a formal order for controlled drugs. Can only be done by someone who is entitled to be in possession of controlled drugs (as defined in current MDR). Must be addressed to a suitable pharmaceutical supplier.
Patient Group Directions (PGD).	Written directions from a senior doctor (or dentist) and a senior pharmacist and a representative of the appropriate organisation giving specified registered nurses, pharmacists and other specified health professionals a general authority to supply and administer specified medicines to patients, who are not individually identifiable, in specified clinical situations.
PCA	Patient-controlled analgesia
Pharmacist (– Registered Pharmacist)	Person registered in the register of pharmacists maintained by the Pharmaceutical Society of Northern Ireland
Pharmacy technician	Pharmacy technicians in Northern Ireland are not currently registered with the Pharmaceutical Society of Northern Ireland and are not, therefore, regulated professionals. Their activities related to controlled drugs should be circumscribed by standard operating procedures and must be carried out under the authority of a pharmacist.
PODs	Patient’s own drugs. In this context - controlled drugs brought into the hospital by the patient on admission
Prescribe	Prescribing is the ordering of a medicine for an individual patient. In medicines legislation, certain medicines may be supplied only in accordance with a prescription by a doctor, dentist or other appropriate practitioner, and which meets the conditions specified in the Prescription Only Medicines (Human Use) Order 1997. The term has however become commonly used to describe authorising - by means of an NHS

	prescription - the supply of any medicine (Prescription Only Medicine, Pharmacy or General Sales List medicine) at public expense to a named patient;
Registered nurse in charge	The registered nurse who is in charge for the time being (senior registered nurse on duty) and is therefore responsible for management of controlled drugs.
Relevant persons	People who <ul style="list-style-type: none"> <li>• are directly or indirectly concerned with the provision of health care and/or</li> <li>• carry on activities that involve or may involve the supply or administration of controlled drugs</li> <li>• work for a designated body</li> </ul>
Requisition	In the context of controlled drugs: To make a formal, written request, compliant with Regulation 14(6) of the Misuse of Drugs Regs (NI) 2002, for a supply of a Controlled Drug for use in a ward or department. The requisition must be signed by an authorised signatory. Requisitions are usually made in stationery designed specifically for that purpose. Confusingly these books are often called “Controlled Drug Order Books”.
Responsible body	Bodies listed in regulation 22 of the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009. Includes: Designated bodies, the Department, the Regulation and Quality Improvement Authority, the Regional Business Services Organisation, the Police Service, Regulatory Bodies.
Senior Assistant Technical Officer	In this context, a member of the pharmacy staff who has received in-house training for specific duties. Not a pharmacy technician.
Service Level Agreement (SLA)	Written agreement between two parties that specifies the service to be provided
“should”	Used in this document in connection with recommendations concerned with good practice
Standard Operating Procedure (SOP)	A standard operating procedure specifies in writing what should be done, when, where and by whom in order to manage safely and accountably any set of processes, in this case around the total management of controlled drugs.
Supervisor of midwives	A person appointed by the local supervising authority to exercise supervision over midwives in its area in accordance with rule 11(1) of the Nursing and Midwifery Council (Midwives) Rules 2004 (SI 2004/1764) <a href="http://www.hmsa.gov.uk">www.hmsa.gov.uk</a>
Supply	In the context of legal supply of controlled drugs: making a supply against a signed order, requisition, Patient Group Direction or a prescription.
Transcribe	To copy the details of one document on to another.



# Appendix 1: Legislation for the management of CDs

## Misuse of Drugs Act 1971

The Misuse of Drugs Act (MDA) 1971 and its Regulations provide the statutory framework for the control and regulation of controlled drugs. The primary purpose of the MDA is to prevent misuse of controlled drugs. 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 to the Act.

## Misuse of Drugs Regulations (Northern Ireland) 2002 (MDR)

The use of controlled drugs 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 controlled drugs are subject to the highest level of control, whereas Schedule 5 controlled drugs are subject to a much lower level of control.

The MDR are periodically amended and revised. The MDR currently in force and its amendments can be found at the website of the Office of Public Sector Information ([www.opsi.gov.uk](http://www.opsi.gov.uk))

## 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. In Northern Ireland only certain persons can be licensed by the DHSSPS 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 DHSSPS.

The drugs listed in Schedule 1 have no recognised medicinal use although Sativex<sup>®</sup> (a cannabis based product), for which there is an open general licence, 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 controlled drugs (except secobarbital) are subject to safe custody requirements (under the Misuse of Drugs (Safe Custody) (Northern Ireland) 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.

Schedule 2 controlled drugs may be manufactured or compounded by a licence holder, a practitioner, a pharmacist or a person lawfully conducting a retail pharmacy business acting in their capacity as such.

A pharmacist may supply schedule 2 controlled drugs to a patient only on the authority of a prescription in the required form issued by an appropriate prescriber.

Schedule 2 controlled drugs 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 controlled drugs. Not all prescribers can prescribe controlled drugs and some prescribers are limited to certain controlled drugs for use in specified circumstances.

Nurse Independent Prescribers are permitted to prescribe, administer, or direct anyone to administer some controlled drugs for specific conditions and routes of administration.

### **Record-keeping**

There is a statutory requirement for pharmacy departments to keep a register for Schedule 2 controlled drugs and this register must comply with the requirements of the Misuse of Drugs Regulations 2002. Wards and departments should also keep a Controlled Drugs Record Book (often loosely referred to as a register) for Schedule 2 controlled drugs.

Midwives must keep a register for the Schedule 2 controlled drugs that they are permitted to possess and administer.

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

### **Destruction**

The destruction of Schedule 2 CD stock must only take place in the presence of an appropriately authorised person.

### **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**

Some Schedule 3 controlled drugs are exempt from safe custody requirements and may be stored on the open dispensary shelf. Non-exempt examples include flunitrazepam, temazepam, buprenorphine and diethylpropion, which must be stored in a locked CD receptacle within a secure environment.

### **Record keeping**

There is no legal requirement to record transactions involving Schedule 3 controlled drugs in a CD register. Some organisations keep a non-statutory register as a matter of good practice.

Invoices must be retained for a minimum of two years.

Schedule 3 controlled drugs are subject to full import and export control.

## **Destruction**

The requirements for destruction do not apply unless the controlled drugs are manufactured by the entity in legal possession.

## **Schedule 4 (CD Benz and CD Anab)**

Schedule 4 is split into two parts.

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

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

Unauthorised possession or supply of a drug in Schedule 4 Part 1 (CD Benz) is an offence. Possession and supply by practitioners and pharmacists acting in their professional capacities is authorised.

There is no restriction on the possession of a Schedule 4 Part 2 (CD Anab) drug when it is in the form of a medicinal product. Unauthorised supply to a third party is unlawful.

Drugs in Part 1 (CD Benz) are subject to full import and export control and a DHSSPS licence is also required for the importation and exportation of substances in Part 2 (CD Anab) unless the substance is in the form of a medicinal product and is for administration by a person to himself.

All substances in Schedule 4 are exempt from safe custody requirements, with destruction requirements only applying to importers, exporters and manufacturers. It is good practice to store securely excess stock of Schedule 4 controlled drugs.

Prescription-writing requirements for these controlled drugs do not apply, except those requirements laid out in the Medicines Act 1968. CD registers do not need to be kept for Schedule 4 drugs, although records should be kept if such controlled drugs are compounded, or if a licensed person imports or exports such drugs (see Regulation 22 of the Misuse of Drugs Regulations 2002).

## **Schedule 5 (CD Invoice)**

Schedule 5 contains preparations of certain controlled drugs (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.

Preparations containing not more than 0.1% cocaine are no longer exempt from prohibitions on import, export and possession.

A practitioner or pharmacist acting in his capacity as such, or a person holding an appropriate licence, may manufacture or compound any controlled drug in Schedule 5.

Invoices must be retained for a minimum of two years.

### **Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973**

The Safe Custody Regulations 1973 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 certain non-exempted Schedule 3 controlled drugs should be stored securely in accordance with the Misuse of Drugs (Safe Custody) Regulations. These Regulations state that such controlled drugs 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 (Notification of 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 DHSSPS licence. A licence is not required with such drugs for the treatment of organic disease or injury. Doctors must notify the DHSSPS of patients whom they consider to be addicted to specified controlled drugs.

### **Medicines Act 1968**

This Act, and Regulations made under the Act, set out the requirements for the legal sale, supply and administration of medicines. It also allows certain exemptions from the general restrictions on the sale, supply and administration of medicines which, for example, enable midwives to supply and/or administer diamorphine, morphine, pethidine or pentazocine. A number of healthcare professionals are permitted to supply and/or administer medicines generally in accordance with a Patient Group Direction (PGD). Some of these professional groups, but not all, are permitted to possess, supply or administer controlled drugs in accordance with a PGD under Misuse of Drugs legislation

### **Health Act 2006**

The key provisions of the Act are:

- Designated bodies (as prescribed by regulations) are required to appoint an Accountable Officer with responsibilities (prescribed by regulations) in connection with the safe and effective management of controlled drugs
- A duty of collaboration is placed on responsible bodies (as prescribed by regulations) to share intelligence on controlled drug issues
- A power of entry and inspection is granted for the police and other nominated people to enter premises to inspect stocks and records of controlled drugs

### **The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009**

These regulations, made under the Health Act 2006, set out the requirements for certain healthcare organisations and independent hospitals to appoint an Accountable Officer and describe the duties and responsibilities of Accountable Officers related to 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 about concerns related to the use and management of controlled drugs, and set out further arrangements relating to powers of entry and inspection.

### **Misuse of Drugs and Misuse of Drugs (Safe Custody) (Amendment) Regulations (Northern Ireland) 2007**

This Regulation amends the Misuse of Drugs Regulations (Northern Ireland) 2002 and the Misuse of Drugs (Safe Custody) Regulations (Northern Ireland) 1973 to (among other matters):

Update the references to premises covered by the Safe Custody Regulations

Update references to “sister” to “senior registered nurse”

Replace the prescribed form of the CD register with prescribed headings for entries in the register

Permit ODPs to possess and supply CDs in accordance with prescriber directions

## Appendix 2: Operating Department Practitioners

Operating Department Practitioner (ODP) is defined in the Misuse of Drugs Regulations 2002 (as amended by SR 2007/348) as a person who is registered under the Health Professions Order 2001 (SI 2001/254 as amended by SI 2004/2033) as an operating department practitioner. The amendment to the Misuse of Drugs Regulations afforded to this group of registered professionals similar (but not identical) authority to that already granted to the “senior register nurse (formerly ‘sister’) or acting senior registered nurse for the time being in charge of a ward, theatre or other department...” The ODP was granted authority to possess and supply controlled drugs supplied to him by the person responsible for dispensing and supply of medicines at the hospital. The ODP may supply to a patient in a ward, theatre or other department only in accordance with the directions of an appropriate prescriber who may legally prescribe that drug. The amendment to the Misuse of Drugs Regulations did not specify that the ODP had to produce the same requisition as required of the senior registered nurse in charge. Because the ODP’s authority to “possess and supply” implies the ability to obtain the drugs, the Home Office has stated that the ODP’s authority is sufficient to “order” controlled drugs from the hospital pharmacy. Until such time as the Misuse of Drugs Regulations are further amended to require the same requisition from the ODP as the nurse in charge of a ward, hospitals should ensure that, as a matter of good practice and/or in order to comply with SOPs, supply of controlled drugs to ODPs should still be dependant upon the receipt by the hospital pharmacy of a requisition of exactly the same nature that a nurse in charge of a ward would present. Furthermore hospitals should specify in policy and SOPs which registered professional (senior nurse in charge or ODP) is responsible for the stock of controlled drugs in the particular ward, theatre or other department. Whereas the legislation grants authority to the senior (or acting senior) registered nurse in charge, **any** ODP is permitted to possess and supply controlled drugs under certain conditions. This guidance document has followed the position of the Department of Health document in referring to the senior registered nurse in charge or **ODP in charge** although it is recognised that this goes beyond the actual wording of the legislation. The intention is to indicate that it should be crystal clear in policy and procedures who is responsible for the controlled drug stock held in any theatre, ward or other department.

# Appendix 3: The Accountable Officer

The regulatory requirements for Accountable Officers are set out in full in the Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 SR2009/225 ; [www.opsi.gov.uk](http://www.opsi.gov.uk). Further detail is also given in 'Safer Management of Controlled Drugs: A Guide to Strengthened Governance Arrangements in Northern Ireland' in the Accountable Officer section of the Department website [www.dhsspsni.gov.uk](http://www.dhsspsni.gov.uk)

The following paragraphs provide a summary of the main provisions.

## **Persons who may be appointed as Accountable Officers**

Each HSC Trust and other designated bodies must appoint an Accountable Officer. This should be a senior executive officer of the organisation (i.e. an Executive Director or someone who reports directly to an Executive Director). Where designated bodies are large organisations, the Accountable Officer may consider appointing Designated Officers to assist in the day-to-day discharge of responsibilities.

The Accountable Officer should not be personally involved in the routine prescribing, supply, administration or disposal of controlled drugs. An organisation can have an Accountable Officer who has occasional need to handle CDs (for example, in emergencies), but if this is the case, their use of CDs should be open to the scrutiny of another senior member of the organisation or Accountable Officer of another body. Individuals such as Chief Nurses, Medical Directors and Chief Pharmacists can be appointed as Accountable Officers if they meet these criteria. Accountable Officers should call on other Accountable Officers if a conflict of interest arises.

The organisation's controlled drugs policy should specify the person whom staff should approach if they have concerns about the practice of their Accountable Officer.

The Accountable Officer for an HSC Trust should liaise with the Chair of the Local Intelligence Network.

## **Responsibilities of the Accountable Officer**

In discharging his responsibilities, an Accountable Officer must have regard to best practice in relation to the management and use of controlled drugs.

The Accountable Officer must:

- Secure the safe and effective use and management of controlled drugs within local organisations subject to his oversight (i.e. the organisation and those with which it contracts).

*(For some of the following duties and responsibilities the regulations frequently use the form of words, "The Accountable Officer must ensure/establish ..., or ensure that his designated body ensures/establishes ...")*

- Establish, operate and periodically review appropriate systems for the safe management of controlled drugs
- Ensure that all arrangements comply with relevant statutory requirements
- Ensure that adequate and up-to-date standard operating procedures are in place for the management and use of controlled drugs
- Establish and operate appropriate arrangements for securing the safe destruction and disposal of controlled drugs
- Ensure monitoring and auditing of the management and use of controlled drugs within the organisation and take action where necessary. The following must be in place:
  - Systems to alert the Accountable Officer to complaints or concerns involving the management of controlled drugs
  - An incident reporting system to capture untoward incidents involving the management or use of controlled drugs
- Establish and operate arrangements for analysing and responding to untoward incidents involving the management or use of controlled drugs
- Ensure that individuals involved in prescribing, supplying, administering or disposing of controlled drugs receive appropriate training. Arrangements must be in place for relevant individuals:
  - to receive information and, where appropriate, training on local standard operating procedures for controlled drugs when they first become involved in prescribing, supplying, administering or disposing of controlled drugs
  - to be informed when any local standard operating procedures for controlled drugs are subsequently reviewed or amended
- Monitor and audit the management and use of controlled drugs by relevant individuals, and to monitor and assess their performance. The Accountable Officer must, where appropriate, provide for the following:
  - Recording concerns raised in relation to the management or use of controlled drugs by a relevant individual
  - Assessing and investigating concerns raised regarding the management or use of controlled drugs by a relevant individual
  - Determining whether there are concerns in relation to the management or use of controlled drugs by a relevant individual which the designated body reasonably considers should be shared with a responsible body.

The Accountable Officer should be aware that unusually high usage of some CDs or unusually high numbers of breakages could indicate misuse.



The Accountable Officer in Acute Care should also monitor prescriptions that are written in hospital but dispensed in the community.

- Maintain a record of concerns regarding relevant individuals. Such records may be paper-based or electronic. The Accountable officer must:
  - Establish and operate appropriate arrangements for recording concerns expressed about incidents that involved, or may have involved, improper management or use of controlled drugs by a relevant individual. This must include a system to ensure that access to such records is limited to the Accountable Officer, his staff and others who need to have access for the purposes of ensuring the safe management or use of controlled drugs.
  - Ensure that adequate records are compiled, which must include (but not be limited to), as appropriate:
    - the date on which the concern was made known to the accountable officer;
    - dates on which the matters that led to the concern took place;
    - details regarding the nature of the concern;
    - details of the relevant individual in relation to whom the concern was expressed;
    - details of the person who, or body which, made known the concern;
    - details of any action taken by the designated body in relation to the concern;
    - the assessment of whether information in relation to the concern should be disclosed to another responsible body
    - if information regarding the concern is disclosed to another responsible body, the details of any such disclosure, including the name of the responsible body to which the disclosure was made and the nature of the information disclosed to the body.
  
- Assess and investigate concerns. The accountable officer must:
  - Establish and operate appropriate arrangements for assessing and investigating concerns about incidents that involved, or may have involved, improper management or use of controlled drugs by a person who is, as regards his designated body, a relevant individual
  - Take appropriate action if there are well-founded concerns

- Establish and operate appropriate arrangements for ensuring that appropriate action is taken for the purposes of protecting patients or members of the public in cases where concerns in relation to the management or use of controlled drugs by a person who is, as regards designated body, a relevant individual, appear to be well-founded.
- Establish arrangements for sharing information. The accountable officer must:
  - Establish and operate appropriate arrangements for ensuring the proper sharing of information, by his designated body with other responsible bodies regarding the management and use of controlled drugs
  - Provide a quarterly report to the Chair of the Local Intelligence Network
  - Cooperate with other organisations including the Department, the RQIA, the Business Services Organisation and the police as circumstances require.
  
- Participate in the Local Intelligence Network

# Appendix 4: Useful contacts

## British Medical Association

BMA House  
Tavistock Square  
London  
WC1H 9JP

Tel: 0207 387 4499  
Fax: 0207 383 6400  
Website: [www.bma.org.uk](http://www.bma.org.uk)

## Community Practitioners' and Health Visitors Association

33-37 Moreland Street  
London  
EC1V 8HA

Tel: 0207 505 3000  
Website: [www.amicustheunion.org/cphva/](http://www.amicustheunion.org/cphva/)

## Council for Healthcare Regulatory Excellence

1st Floor, Kierran Cross  
11 Strand  
London  
WC2N 5HR

Tel: 0207 389 8030  
Fax: 0207 389 8040  
Website: [www.chre.org.uk](http://www.chre.org.uk)

## Department of Health

Richmond House  
79 Whitehall  
London  
SW1A 2NS

Tel: 0207 210 4850  
Website: [www.dh.gov.uk](http://www.dh.gov.uk)

## Department of Health, Social Services and Public Safety

Pharmaceutical Advice and Services  
Room D4.5,  
Castle Buildings  
Stormont  
Belfast  
BT4 3SQ

Tel: 028 9052 8688  
Fax: 028 9052 2335  
Website: [www.dhsspsni.gov.uk](http://www.dhsspsni.gov.uk)

## Dispensing Doctors' Association

Low Hagg Farm  
Starfitts Lane  
Kirbymoorside  
North Yorkshire  
YO62 7JF

Tel: 01751 430835  
Fax: 01751 430836  
Website: [www.dispensingdoctor.org](http://www.dispensingdoctor.org)

## General Medical Council

Regent's Place  
350 Euston Road  
London  
NW1 3JN

Tel: 0845 357 3456  
Website: [www.gmc-uk.org](http://www.gmc-uk.org)

## Home Office Drugs Licensing Branch

2 Marsham Street  
London  
SW1P 4DF

Tel: 0207 035 0483  
Website: [www.drugs.gov.uk](http://www.drugs.gov.uk)

### **Home Office Drugs Legislation and Enforcement Unit**

2 Marsham Street  
London  
SW1P 4DF

Tel: 0207 035 0464  
Website: [www.homeoffice.gov.uk](http://www.homeoffice.gov.uk)

### **Medicines and Healthcare products Regulatory Agency**

Market Towers  
1 Nine Elms Lane  
London  
SW8 5NQ

Tel: 0207 084 2000  
Fax: 0207 084 2353  
Website: [www.mhra.gov.uk](http://www.mhra.gov.uk)

### **National Clinical Assessment Service (part of the National Patient Safety Agency)**

Market Towers  
1 Nine Elms Lane  
London  
SW8 5NQ

Tel: 0207 062 1620  
Fax: 0207 084 3851  
Website: [www.ncas.npsa.nhs.uk](http://www.ncas.npsa.nhs.uk)

### **National Patient Safety Agency**

4-8 Maple Street  
London  
W1T 5HD

Tel: 0207 927 9500  
Website: [www.npsa.nhs.uk](http://www.npsa.nhs.uk)

### **National Pharmacy Association**

Mallinson House  
38-42 St Peter's Street  
St Albans  
Hertfordshire  
AL1 3NP

Tel: 01727 832161  
Fax: 01727 840858  
Website: [www.npa.co.uk](http://www.npa.co.uk)

### **National Prescribing Centre**

The Infirmary  
70 Pembroke Place  
Liverpool  
L69 3GF

Tel: 0151 794 8134  
Fax: 0151 794 8139  
Website: [www.npc.co.uk](http://www.npc.co.uk) (Internet)  
[www.npc.nhs.uk](http://www.npc.nhs.uk) (NHSNet)

### **National Treatment Agency**

8th Floor, Hercules House  
Hercules Road  
London  
SE1 7DU

Tel: 020 7261 8801  
Fax: 020 7261 8883  
Website: [www.nta.nhs.uk](http://www.nta.nhs.uk)

### **NHS Clinical Governance Support Team**

1st Floor  
St. Johns House  
30 East Street  
Leicester  
LE1 6NB

Tel: 0116 295 2000  
Fax: 0116 295 2001  
Website: [www.cgsupport.nhs.uk](http://www.cgsupport.nhs.uk)

**Nursing and Midwifery Council**

23 Portland Place  
London  
W1B 1PZ

Tel: 020 7637 7181  
Fax: 020 7436 2924  
Website: [www.nmc-uk.org](http://www.nmc-uk.org)

**Pharmaceutical Society of Northern Ireland**

73 University Street  
Belfast  
BT7 1HL

Tel: 028 9032 6927  
Fax: 028 9043 9919  
Website: [www.psni.org.uk](http://www.psni.org.uk)

**Prescribing Support Unit**

The Health and Social Care  
Information Centre  
1 Trevelyan Square  
Boar Lane  
Leeds  
LS1 6AE

Tel: 0113 254 7041  
Fax: 0113 254 7097  
Website: [www.psu.nhs.uk](http://www.psu.nhs.uk)

**Regional Business Services Organisation**

2 Franklin Street  
Belfast  
BT2 8DQ

Tel: 028 9032 4431  
Website:  
[www.centralservicesagency.n-i.nhs.uk/](http://www.centralservicesagency.n-i.nhs.uk/)

**The Regulation and Quality Improvement Authority**

9th Floor Riverside Tower  
5 Lanyon Place  
Belfast  
BT1 3BT

Tel: 028 9051 7500  
Website: [www.rqia.org.uk](http://www.rqia.org.uk)

**Royal Pharmaceutical Society of Great Britain**

1, Lambeth High Street  
London  
SE1 7JN

Tel: 020 7735 9141  
Fax: 020 7735 7629  
Website: [www.rpsgb.org](http://www.rpsgb.org)

# Appendix 5: Patient Information

## **NHS Direct**

The NHS Direct website has developed a Common Health Question about CDs specifically to inform the public. It is entitled 'What is a controlled drug (medicine)?' and is available at [www.nhsdirect.nhs.uk/articles/article.aspx?articleid=1391](http://www.nhsdirect.nhs.uk/articles/article.aspx?articleid=1391). The text defines a controlled drug in legal terms, how the Regulations apply to them and directs patients to information about requirements for traveling abroad.

## **HOME OFFICE**

Useful advice for patients travelling with controlled drugs can be accessed at <http://drugs.homeoffice.gov.uk/drugs-laws/licensing/personal/>.

## **Medicines Guides**

Medicine Guides provide a source of information for members of the public who are looking for information about individual medicines that is up-to-date, reliable and easy to understand. Medicine Guides are being developed as part of the Medicines Information Project which aims to provide people with information about medicines, conditions and the different treatment options available.

The Medicine Guides on controlled drugs can be found on the [www.medicines.org.uk](http://www.medicines.org.uk) website which is published by Datapharm Communications. There is a link to the NHS Direct Common Health Question within each Guide. Guides for the controlled drugs that have been published to date can be accessed at <http://medguides.medicines.org.uk/cd>.

# Appendix 6: Contributors

The following individuals and organisations are among those who contributed to the design and content of this guidance and/or the original Department of Health document:

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# Appendix 7

## Suggestions for Future Revisions

Name:	
Organisation:	
<b>Section number</b> Indicate <b>page/section heading</b> or ' <b>general</b> ' if your comment relates to the whole document	<b>Comments</b>  <b>Please insert each new comment in a new row.</b>
<i>P.24, Record keeping</i>	<i>In our hospital we refer to...</i>