

MEDICINES MANAGEMENT STANDARD (SAFE AND SECURE HANDLING OF MEDICINES)

Standard

The organisation handles medicines safely and securely, in accordance with legislative requirements and best practice.

Overview

The Audit Commission (2001) defined medicines management as encompassing the entire way that medicines are selected, procured, delivered, prescribed, administered and reviewed to optimise the contribution that medicines make to producing informed and desired outcomes of patient care. Medicines governance more specifically focuses upon the safety and risk management issues concerned with medicines and importantly, systems risks that can lead to error and resultant adverse incidents.

This standard, while addressing many of the components identified above is not designed to cover the more specific clinical aspects of medicines management, although there are evidently intrinsic linkages. This is not to minimise the importance of the clinical and cost effective use of medicines and organisations are expected to work to these goals in the provision of optimal patient care.

The safe and secure handling of medicines in both the hospital and primary care settings requires appropriate policies, procedures and quality assurance systems to be in place. It covers processes throughout the organisation, not just in pharmacy.

This standard outlines legislative and best practice relating to the safe handling of medicines, including controlled drugs. The main legislation addressed within this standard includes:

- The Medicines Act 1968, as amended, which regulates the manufacture, distribution, import, export, sale and supply of medicinal products
- The Misuse of Drugs Act 1971, which controls the availability of drugs liable for misuse
- The Misuse of Drugs (Northern Ireland) Regulations 2002, which enables specified health care professionals to possess, supply, prescribe and/or administer controlled drugs in the sphere of their practice.
- The Controlled Drugs (Supervision of Management and Use)(Northern Ireland) Regulations (to be drafted).
- Health Act 2006

Guidance

Each HPSS body (Board, Trust, Agency as it relates to them) needs to ensure the safe and secure handling and storage of medicines. This will require a review of the different locations in which medicines are stored, dispensed and transported and consideration of the various staff groups responsible for these functions.

Within the HPSS body, attention should focus on a review of the risks and control systems covering: procurement, ordering, delivery, storage, distribution, prescribing, dispensing, issue, supply, administration and disposal within and between the various locations (community hospitals, staff working in the community, in GP practices etc). Any such review should also consider continuing professional development as related to pharmacy and medicines management, along with other associated human resource issues (such as COSHH training, skill mix, training in the management of controlled drugs, handling and disposal of drugs in the community, adverse event reporting etc). The HPSS body also needs to ensure that the organisation has effective systems in place for the reporting of adverse events involving medicinal products and can demonstrate a pro-active approach to investigating any incidents locally (as well as responding to DHSSPS or MHRA alerts).

In addition to reviewing its own internal systems in relation to medicines management, the HPSS body should also request evidence from organisations with which the HPSS body holds service level agreements etc. as to the effectiveness of their risk management concerning the handling and storage of medicines (e.g. Ambulance Trusts, Medical Physics Agency, Out-Of-Hours Service Providers) since risks need to be considered across organisational boundaries.

If an organisation undertakes a robust risk assessment against this standard and deems a particular criterion to be non-applicable, it is essential that the rationale for any such decision is documented and evidence is available to support this assessment.

It is also important to consider the linkages between this and other standards (e.g. risk management, governance, purchasing and supply, medical equipment and devices), which seek to ensure that there are controls in place to minimise all risks across the organisation.

Controlled Drugs

The Health Act 2006 introduced three provisions in relation to the Fourth report of the Shipman Inquiry namely,

- the appointment of an Accountable Officer by Designated Bodies with the duties of the Accountable Officer encompassing the development and monitoring of systems to ensure the safe and effective use and

management of controlled within the organisation subject to their oversight.

- a duty to collaborate and share intelligence on controlled drugs by Responsible Bodies. The Duty of Collaboration will place a legal duty on Responsible Bodies to share (within certain constraints) information and intelligence regarding the use of controlled drugs in the health and social care sector.
- A power of entry and inspection for certain Authorised Persons.

The Health Act provides enabling powers for Northern Ireland to take forward it's own subordinate legislation in order to introduce suitable arrangements for the management of controlled drugs. This subordinate legislation is being drafted and there will be guidance and training to support those involved in taking forward these provisions.

Assessment Guidance

HPSS organisations vary significantly in size and in the nature of the services they deliver. It follows that not all controls assurance standards will apply to each organisation. This is implicit in the current Departmental guidance, eg. *The Reference Table on Applicability and Expected Levels of Compliance* which should be referred to before commencing the self-assessment exercise.

Even where a standard is generally applicable to the work of an organisation it is quite possible that not all of the criteria will be materially applicable. Before self-assessing against a standard, therefore, an organisation should consider the relevance of each criterion to its own business and conduct its assessment accordingly. Thus, where a criterion is clearly relevant to an organisation, the score should be based on the **totality of the action taken to address the requirement**. Where there is little or no relevance, the criterion should be considered "not applicable" and ignored for scoring purposes as explained in the guidance on *Reporting Compliance* issued by the Department.

This approach will ensure that the assessment has no unfairly detrimental effect on the organisation's overall score but reflects a proper evaluation of the key areas of risks identified and the actual levels of controls put in place to manage those risks.

Likewise, the *Examples of Verification* set out in the standard are just that – examples, for guidance only. Once again, it is the nature of each organisation's business that determines the type of evidence needed to prove that appropriate controls are in place. In effect, this may mean that only some of the examples listed are relevant to a particular HPSS organisation or, indeed, that there are other more relevant examples which can be adduced as evidence of compliance. It is also the case that some evidence can be deployed to demonstrate compliance with more than one criterion or standard.

KEY REFERENCES

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Circular HSS (PPM) 3/2002 - Corporate Governance: Statement on Internal Control

Circular HSS (PPM) 4/05 AS/NZS 4360:2004 – Risk Management

Circular HSS (PPM) 8/2002 – Risk Management in the Health and Personal Social Services

Circular HSS (PPM) 13/02 Governance in the HPSS: Risk Management

Circular HSSE (OCE) 1/97 - Aseptic Dispensing in HPSS Hospitals

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<http://www.dhsspsni.gov.uk/hss/governance/guidance.asp>

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<http://www.dhsspsni.gov.uk/hss/governance/guidance.asp>

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GMC Guidance *Doctors should not treat themselves or their families*

<http://www.gmc-uk.org/standards/selftreat.htm>

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INDEX OF MEDICINES MANAGEMENT

Criterion 1 (*Accountability*)

Board level responsibility for the safe and secure handling of medicines is clearly defined and there are clear lines of accountability throughout the organisation, leading to the board.

Criterion 2 - 12 (*Processes*)

Suitable controls are in place, which ensure that the principles and the guidelines set out in 'Use and Control of Medicines' are met.

Medicines are procured, stored and handled in an efficient safe and secure manner.

The organisation conforms to the HPSS Charges for Drugs and Appliances (Amendment) Regulations (Northern Ireland) 2003 (as amended)

Unlicensed aseptic dispensing in hospital pharmacies complies with Circular HSSE (OCE) 1/97, and licensable activities are covered by a manufacturing "specials" licence.

Prescription, supply and administration conform to the requirements of relevant legislation. Prescription, supply and administration of medicines is undertaken only by appropriately qualified, competent staff.

The prescribing, supply, administration, safe custody and destruction of controlled drugs complies with the appropriate legislation.

All medicines no longer required are destroyed or otherwise disposed of in accordance with safety, legal and environmental requirements.

The supply of medicines for clinical trials is undertaken in accordance with relevant legislation and best practice guidelines

The organisation reports adverse incidents involving medicinal products and devices to the relevant agency, and appropriately manages any subsequent required action.

Supervision of pharmaceutical dispensing processes is undertaken in accordance with relevant legislation and current professional standards.

The risk management process contained within the risk management standard is applied to the safe and secure handling of medicines.

Criterion 13-15 (*Capability*)

All healthcare staff involved with medicines undertake continuing professional development to ensure that there are safe and secure handling processes in place.

The organisation, through the Chief Pharmacist, has access to up-to-date legislation and guidance relating to the safe and secure handling of medicines.

Adequate resources support the safe, secure and appropriate use of medicines.

Criterion 16 & 17 (*Monitor, review, learn, improve*)

Key indicators capable of showing improvements in the safe and secure handling of medicines and the management of associated risk are used at all levels of the organisation, including the board, and the efficacy and usefulness of the indicators is reviewed regularly.

The system in place for the safe and secure handling of medicines, including risk management arrangements, is monitored and reviewed by management and the board in order to make improvements to the system.

Criterion 18 (*Independent assurance & Outcomes*)

The board seeks independent assurance that an appropriate and effective system for the safe and secure handling of medicines is in place and that the necessary level of controls and monitoring are being implemented.

CRITERION 1

Board level responsibility for the safe and secure handling of medicines is clearly defined and there are clear lines of accountability throughout the organisation, leading to the board.

Source

- Standards Australia Risk Management AS/NZS 4360:2004
- Best Practice Best Care (2001) - A framework for setting standards, delivering services and improving monitoring and regulation in the HPSS.
- Audit Commission (2001) A Spoonful of Sugar. Medicines management in NHS hospitals. Audit Commission, London.
- Audit Commission (2002) Procurement and Supply. Review of National Findings, Acute Hospital Portfolio, No.5, p.20.

Guidance

The Chief Executive of the organisation has the overall statutory responsibility for the safe and secure handling of medicines. The Chief Pharmacist has responsibility for ensuring that systems are in place to appropriately address all aspects of the safe and secure handling of medicines and reports directly to the Chief Executive for this purpose across the whole of the organisation. The organisation's commitment to the safe and secure handling of medicines should be clearly signalled.

Clear lines of accountability for the Safe and Secure Handling of Medicines throughout the organisation should be established; these should define the relationships between the Board, board sub-committee(s) responsible for overseeing all aspects of risk management and governance Pharmacy Services and other relevant groups. There must be a Medicines Management Committee to review, analyse and monitor medicines use processes.

Examples of Verification

- Accountability arrangements chart
- Minutes of the board sub-committee(s) responsible for overseeing risk management
- Board minutes
- A strategy for medicines use, within the organisation, has been approved by the board, reviewed and reported annually
- Terms of reference for any medicines management committee required.
- Job description of Chief Pharmacist.

Links with other Standards

All standards (generic criterion)

CRITERION 2

Suitable controls are in place, which ensure that the principles and the guidelines set out in 'Use and Control of Medicines' are met.

Source

Use and Control of Medicines: Guidelines for the safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services (2nd edn.2004), DHSSPS.

Other Reading

- Safe and Secure Handling of Medicines - A Team Approach. A revision of the Duthie Report led by the Hospital Pharmacists' Group of the Royal Pharmaceutical Society. RPSGB March 2005

Guidance

The new guidance on the Use and Control of Medicines Guidelines (2004) takes account of important legislative changes and developments in professional practice and accountability as well as integrating and giving consistency to associated guidelines emanating from professional bodies, agencies and reviews. It addresses a wide range of issues but principally:

- Prescribing
- Administration
- Record keeping
- Storage and security
- Supply, delivery and transfer
- Labelling
- Waste
- Practice environments
- Specific practitioners

The revised Duthie report sets out standards for the handling, administration, storage and custody of medicinal products, in hospitals, community clinics, residential and nursing homes, community nursing or midwife units and the ambulance service. While the report itself is under review, the principles at its heart are still of fundamental importance and should continue to provide a basis for local policies and procedures; at each step where a medicine changes hands there should be clear procedures which document:

- Where responsibility lies, whether it may be delegated and how far it extends
- What should be recorded where, by whom and how long records should be kept
- How often stock reconciliation should take place and who should undertake the task

Examples of Verification

- A control system is in place, which meets the principles of the 'Use and Control of Medicines' guidelines
- The organisation audits itself against the principles, and can demonstrate, if necessary, that mechanisms have been put in place to change practice.

Links with other Standards

Health and Safety
Management of Purchasing and Supply
Medical Devices
Records Management
Waste Management

CRITERION 3

Medicines are procured, stored and handled in an efficient, safe and secure manner.

Source

- The Control of Substances Hazardous to Health Regulations (Northern Ireland) 2000. SR No 120
- Medicines Act 1968 (as amended) The Stationery Office, London
- The Misuse of Drugs Regulations (Northern Ireland) 2002 SR No 1 The Stationery Office, London
- The Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973 The Stationery Officer, London
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- The Medicines (Administration of Radioactive Substances) Regulations 1978 SI No 1006 The Stationery Office, London
- The Ionising Radiation (Medical Exposure) Regulations 2000 SI No 1059. The Stationery Office, London

Other Reading

- Self Administration of medicines by hospital inpatients – Audit Commission
- Hospital Pharmacist (2002) One-stop dispensing, use of patients own drugs and self-administration schemes (article March 2002 vol 9)
- The Safe and Secure Handling of Medicines - A Team Approach. A revision of the Duthie Report led by the Hospital Pharmacists' Group of the Royal Pharmaceutical Society. RPSGB March 2005
- The Shipman Inquiry (2004) Fourth Report. The Regulation of Controlled Drugs in the Community (Cm 6249).The Stationery Office, Norwich
- Safer Management of Controlled Drugs A guide to good practice in primary care (Northern Ireland)(draft)
- Safer Management of Controlled Drugs A guide to good practice in secondary care (Northern Ireland)(draft)
- Safer Management of Controlled Drugs Guidance on Standard Operating Procedures (Northern Ireland)(draft)

Guidance

The Medicines Act 1968 applies to all substances, which are used as medicinal products, or as ingredients in medicinal products.

The act divides medicines into three categories:

- Prescription Only Medicine (POM)
- Pharmacy Medicine (P), which is supplied by a pharmacist, but can be dispensed without a prescription
- General Sale List (GSL), which need not be obtained through a pharmacist

Pharmacy staff should be involved in replenishing, monitoring, and adjusting medicines stock control.

Appropriate procedures must be in place for the ordering, stock control, storage, movement and safe handling of medical gases.

Under the management of Chief Pharmacists, wherever possible, corporate action should be taken to ensure the efficient and effective procurement of all medicines, particularly in the context of the Pharmaceutical Contracting Executive Group, established by Trust Chief Executives and aligned to public procurement policy and strategy.

Particular attention should be paid to all medicine security issues including:

- Storage of medicines, whether in bulk in the pharmacy or in smaller quantities elsewhere
- Methods of ordering medicines
- Means of delivery
- Receipts procedures, including full records
- Methods of distribution both within and between hospitals
- Dispensing of medicines including patients own medicines, dispensing for discharge and self administration
- Administration of medicines
- Disposal of medicines
- Where self-administration schemes are in operation

Physical security measures include:

- Lockable cupboards, freezers and fridges for the storage of medicines, with temperature monitoring as appropriate
- Cabinets which meet the requirements as set out in the revised Duthie report for all medicines
- Lockable medicine trolleys which are immobilised when not in use
- Lockable, bedside medicine storage cupboards, which are not easily portable (where appropriate)

- Lockable, security sealed containers for transporting / moving medicines
- Entrances to pharmacies and other controlled areas should have solid doors, fitted with security locks and intruder alarms
- Stationery including requisition books, order books and blank prescription forms should be kept in a locked cupboard.

COSHH regulations require organisations to ensure that precautions are taken by staff handling medicinal products, which are hazardous to health by any route (inhalation, ingestion, and absorption through the skin or contact with the skin). Contact should either be prevented or, where this is not reasonably practicable, adequately controlled.

Examples of Verification

- There is a local policy in place, which complies with relevant aspects of legislation
- Staff are aware of, and have access to the organisation's policy
- Local procedures comply with the HPSS security manual and the principles of the revised Duthie report
- Pharmacy technician/assistant "top-up" service
- There is a policy in place, which staff are aware of, which states the required action to be taken when there is a breach of security
- COSHH assessments
- Procedures for ordering, stock control, storage, movement and safe handling of medical gases are in place and approved by the quality controller (medical gases)
- There is a policy in place that includes an assessment checklist to support re-use of patient's own drugs (POD's) if applicable
- There is an agreed protocol to assess patients' suitability for self-administration of medicines, which documents informed consent to participate if applicable.
- Compliance with Good Procurement Practice as defined by the Audit Commission (2002)

Links with other Standards

Health and Safety
Management of Purchasing and Supply

CRITERION 4**The organisation conforms to the HPSS Charges for Drugs and Appliances (Amendment) Regulations (Northern Ireland) 2003****Source**

- HPSS Charges for Drugs and Appliances (Amendment) Regulations (Northern Ireland) 2003 (as amended) SR No 153 The Stationary Office, London
- HPSS Management Executive (OP1) 2/92 Supply of Medicines and Other Pharmaceutical Products – Responsibility for Prescribing Between Hospitals and Family Practitioner Services
- 28 Day Dispensing on Discharge from Hospital. Letter Circular HSS SC (804) BP411/01

Guidance

Arrangements should be in place for the collection of prescription charges as specified in the source guidance taking into account permitted exemption and remission from charges.

No charge should be made for medication administered or supplied within hospital premises to HPSS patients. There is also no charge liability for discharge medication.

Medication for the treatment of venereal disease (STDs) is dispensed free of charge.

Examples of Verification

- Policy and procedure

Links with other Standards

Financial Management

CRITERION 5

Unlicensed aseptic dispensing in hospital pharmacies complies with HSSE(OCE)1/97, and licensable activities are covered by a manufacturing "specials" licence.

Source

- Ionising Radiations Regulations 1999. Approved Code of Practice and Guidance. The Stationery Office, London. ISBN 071761-7467 HSE Books
- Medicines Act 1968 (as amended) The Stationery Office, London
- The Medicines (Administration of Radioactive Substances) Regulations 1978 SI No 1006 The Stationery Office, London
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- NHS Executive (2001) The Quality Assurance of Aseptic Preparation Services (3rd Edition) NHS Executive London.
- HC (76) 9 Report of the working party on the additions of drugs to intravenous fluids.
- Chief Pharmaceutical Officer Letter (CPh3/03) Aseptic dispensing in HPSS hospitals. DHSSPS.

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- Notes for Guidance on the Clinical Administration of Radiopharmaceuticals and Use of Sealed Radioactive Sources (December 1998). Administration of Radioactive Substances Advisory Committee (ARSAC)
- Medical and Dental Guidance Notes prepared by the Institute of Physics and Engineering in Medicine. ISBN 1903613 09 4
- Quality Assurance of Radio Pharmaceuticals: The radiopharmacy group and the NHS Quality Control Committee Nuclear Medicine Communications 2001; 22:909-916
- NHS Executive (2000) Manual of Cancer Services Standards
- Chief Pharmaceutical Officer Letter (CPh (1/95) Aseptic Dispensing for NHS Patients Farwell J. Aseptic dispensing for NHS patients [Farwell report]. London: Department of Health; 1995.

- Pharmaceutical Resource for Oncology in Northern Ireland, Report of the RMSC working group (2003)

Guidance

The Medicines Act 1968 allows HPSS hospital pharmacies to carry out aseptic preparation without a manufacturer's licence, if the activity is under the supervision of a pharmacist. HPSS organisations are liable to prosecution, under the Medicines Act 1968, if medicinal products supplied are not of the nature or quality expected.

Unlicensed aseptic dispensing facilities in hospital pharmacies should undergo regular inspections every 24 months. The inspections are carried out by the Regional Pharmaceutical Laboratory Service. The results of the inspections should be made known to the trust Chief Executive and those commissioning health services so that standards are maintained. Licensed activities are subject to regular audit by the Departmental Inspectors. There should also be a programme of regular internal audit.

There should be a programme of capacity planning for equipment and staff.

Aseptic dispensing is an increasing and demanding activity. Extant guidance indicates that it should be carried out under the control of a pharmacist in suitable facilities to avoid the additional risk of microbiological contamination and medication errors sometimes associated with the preparation of parenteral medication at ward level. This is increasingly crucial given the incidence of serious life-threatening infections eg MRSA.

Radiopharmaceutical dispensing activities must take into account the registration of open sources by the Environment Agency, additional training requirements for staff, the radiological implications for staff and a prospective programme for quality assurance of products.

Verification that users of radiopharmaceuticals are authorised to do so must be sought prior to use. Where products are transported to other sites, proper packaging and the services of a safety adviser must be employed. Radiopharmacies should be licensed unless operated under the direct supervision of a pharmacist.

Work is near completion to identify the capacity issues around workforce, workload and workplace in relation to aseptic preparation and organisations will be required to respond to the findings and recommendations.

Examples of Verification

- Policy
- Regular internal and external audit reports and progress on follow-up
- Staff skill mix and competence assessed
- Capacity plan
- Error/near miss reporting in place

- Robust systems in place for high risk procedures e.g. vinca alkaloids and intrathecal injections
- Range of products prepared linked to risk assessment of hospital usage of intravenous products
- Records of appropriate training
- Manufacturer's "specials" licence
- Copies of the Radioactive Substances Act regulations authorisation from the Environment Agency for storage and disposal of radioactive materials
- COSHH assessments
- Certification of clinicians under the Medicines (Administration of Radioactive Substances) Regulations 1978 (Commonly referred to as "ARSAC" certificates)

Links with other Standards

Infection Control
Human Resources
Health and Safety
Medical Devices and Equipment

CRITERION 6

Prescription, supply and administration conform to the requirements of relevant legislation. Prescription, supply and administration of medicines is undertaken only by appropriately qualified, competent staff.

Source

- EC 92/27 Labelling and Leaflet Directive
- Medicines Act 1968 (as amended) The Stationery Office, London
- Prescription Only Medicines (Human Use) Order 1997 (as amended) The Stationery Office, London
- Misuse of Drugs Act 1971 (c. 38) The Stationery Office, London
- The Radioactive Material (Road Transport) Regulations 2002 SI No. 1093 (as amended) The Stationery Office, London
- The Radioactive Material (Road Transport) (Northern Ireland) Order 1992 SI No 234(NI 2). The Stationery Office, London
- Circular HSS (MD) 45/2003 Updated National Guidance on the Safe Administration of Intrathecal Chemotherapy
- Circular HSS 09/2000 Patient group directions
- Circular HSS (MD) 39-02 Safe administration of Intrathecal Chemotherapy.

Other Reading

- Pharmacy in the Future - Implementing the NHS Plan
- NSF Older People Supplement - Medicines for Older People
- MCA Guidance Note 14
- NHS Executive (2000) 2004 update for consultation, Manual of Cancer Services Standards www.doh.gov.uk/cancer/mcss.htm
- Building a safer NHS for patients and implementing OWAM
- Guidance for the Purchase and Supply of Unlicensed Medicinal Products – Notes for prescribers and pharmacists. NHS Pharmaceutical Quality Control Committee 2nd Edition, June 2001
- Department of Health. The prevention of intrathecal medication errors. April 2001
- Department of Health. External inquiry into the adverse incidents that occurred at Queen's Medical Centre, Nottingham, 4th January 2001. 2001
- NHS Executive (2000) Patient group directions HSC 2000/026 20000
- 28 Day Dispensing on Discharge from Hospital. Letter Circular HSS SC (804) BP411/01
- Use and Control of Medicines: Guidelines for the safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services (2nd edn.2004), DHSSPS.
- Medicines legislation – what it means for midwives. [NMC Circular 1/2005 SAT/rc 6 January 2005](#)
- Safer Management of Controlled Drugs A guide to good practice in primary care (Northern Ireland)(draft)

- Safer Management of Controlled Drugs A guide to good practice in secondary care (Northern Ireland)(draft)

Guidance

Prescription Only Medicines (POM) may only be supplied to a patient against the prescription or written direction of an 'appropriate practitioner', as stated in section 52 of the Medicines Act. The principle supply route is through the pharmacist. Comprehensive guidance is available in both the BNF and Ethics and Practice. Doctors, dentists and independent nurse prescribers may prescribe, administer or supply Prescription Only Medicines in areas where they are competent directly to a patient. Supplementary prescribers may only prescribe in accordance with an agreed patient specific clinical management plan and the patient's agreement. Other Nurses and healthcare workers, however, supply medicines under the direction of a doctor. Midwives may administer specified controlled drugs, under a supply order, which is signed by a Doctor or Supervisor of Midwives and any of the substances that are specified in medicines legislation under midwives' exemption, provided it is in the course of their professional midwifery practice.

No-one can administer parenteral POMs otherwise than to himself, unless he is a practitioner or is acting in accordance with the directions of a practitioner. Exceptions to this include:

- Certain life saving drugs used in an emergency
- Medicines available to particular health professionals, for example paramedics, in the course of their professional practice.

Legislation is framed to ensure that the majority of clinical care should be provided on an individual, patient-specific basis. Where the direction of a doctor is not patient specific, the responsible organisation would need to ensure that the appropriate patient group direction meets the criteria (some of which are statutory) set out in Circular HSS 09/2000. In particular such directions should be authorised by a senior doctor and senior pharmacist. Additionally, they should be approved on behalf of the organisation. They should be undertaken by sufficiently competent, trained, experienced personnel, and offer genuine benefit for patients, which cannot be fulfilled by the usual prescription route.

As with other circumstances when medicines are prescribed, supplied and administered, there must be a clear audit trail i.e. a secure system for recording, monitoring and reconciling medicines whether electronic or paper based.

Appropriate protocols should be in place to ensure that arrangements for communication and transfer of patient information relating to medicines, prescribing and medication history support safe practice and confidentiality.

Medicine defects or safety alerts, including those relating to devices, must be implemented as appropriate.

Unlicensed medicines should only be used where a licensed alternative is not available and pharmaceutical quality assurance has been demonstrated for both the procurement and use of such products.

Chemotherapy prescribing, supply, and administration should be in accordance with the policy of the local cancer network. In addition, prescribing, supply and administration of intrathecal chemotherapy must comply with HSS (MD) 45/2003 and HSS (MD) 39-02.

A House Officer, who holds a qualification, which entitles him to be registered, but has yet to complete the relevant period of experience, is entitled to be provisionally registered. The effect is that he may issue prescriptions for POMs or CDs only as part of his required duties in that post. He may not order for private patients or for his own use.

The BNF contains guidance on how to write prescriptions to ensure clarity and safety. These principles should be adopted, and adapted for local use as appropriate. Ward pharmacy services should be in place to ensure that prescriptions are safe, clear, legible etc, and comply with local and national guidance. (See Use and Control of Medicines: Guidelines for the safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services (2nd edn.2004), DHSSPS).

In accordance with the EU directive, patient information leaflets should be supplied each time a medicine is dispensed to a patient.

Examples of Verification

- Staff groups are subject to regular qualification checks:
- Nurses: Nursing and Midwifery Council registration checked
- Doctors GMC/GDC registration or pre-registration checked
- Pharmacists' membership of the Pharmaceutical Society of Northern Ireland
- All patient group directions have been identified, located and reviewed for compliance with Circular HSS 09/2000.
- Dispensing complete with patient information leaflet
- Evidence of the implementation of Medicine defects or safety alerts, including those relating to devices.
- Robust procedures in place for the procurement and use of unlicensed medicines
- Compliance with Manual of Cancer standards
- Register of staff authorised to prescribe, administer and supply intrathecal chemotherapy
- Record of verification of nurse training for drug administration

- Audit of prescriptions and treatment cards (e.g. using ward pharmacist intervention records).

Links with other Standards

Human Resources
Medical Devices and Equipment
Records Management
Risk Management

CRITERION 7

The prescribing, supply, administration, safe custody and destruction of controlled drugs complies with the appropriate legislation.

Source

- Medicines Act 1968 (as amended) The Stationery Office, London
- Misuse of Drugs Act 1971 (c. 38) The Stationery Office, London
- The Misuse of Drugs Regulations (Northern Ireland) 2002 SR No 1 The Stationery Office, London
- The Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973 The Stationery Office, London
- Use and Control of Medicines: Guidelines for the safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services (2nd edn.2004), DHSSPS.
- The Prescription Only Medicines (Human Use) Order 1997 as amended . The Stationery Office, London
- Health Act 2006
- The Controlled Drugs (Supervision of Management and Use)(Northern Ireland) Regulations (to be drafted).
- Safer Management of Controlled Drugs A guide to good practice in primary care (Northern Ireland)(draft)
- Safer Management of Controlled Drugs A guide to good practice in secondary care (Northern Ireland)(draft)
- Safer Management of Controlled Drugs Guidance on Standard Operating Procedures (Northern Ireland)(draft)

Other Reading

- RPSGB Fitness to Practise and Legal Affairs Directorate Fact Sheet: One, Controlled Drugs and Community Pharmacy, September 2007
- RPSGB Fitness to Practise and Legal Affairs Directorate Fact Sheet: Two, Controlled Drugs and Hospital Pharmacy, Currently being revised.
- The Handling of Medicines in Social Care (2007)
- Guidelines for the Control and Administration of Medicines in Residential Care Homes and Nursing Homes. NHSSB Nov 2003 (The same or similar policy exists in all HSS Board Areas)
- Safe and Secure Handling of Medicines - A Team Approach. A revision of the Duthie Report led by the Hospital Pharmacists' Group of the Royal Pharmaceutical Society. RPSGB March 2005
- The Freedom of Information Act 2000

Guidance

- Possession, supply, storage and record keeping of controlled drugs must meet the requirements of both the Medicines Act and the Misuse of Drugs Act and regulations made under the legislation. Comprehensive guidance is available in the BNF, Ethics and Practice, Safer Management of Controlled Drugs A guide to good practice in primary care (Northern Ireland)(draft) and Safer Management of Controlled Drugs A guide to good practice in secondary care (Northern Ireland)(draft),

Legal requirements include:

The pharmacy must keep a register in the form set out in Regulations 19 and 20 of the Misuse of Drugs Regulations (Northern Ireland) 2002.

Requisitions must be in writing and contain the information detailed in Regulation 14 of the Misuse of Drugs Regulations (Northern Ireland) 2002.

In addition, a midwife authorised by Regulation 11(1) to have any Schedule 2 controlled drug in their possession, is also required to keep a record of supplies received and drugs administered, in a book solely for that purpose.

There must be documented systems and procedures in place for the destruction of all Controlled Drugs, including patients' own drugs, which adhere to regulations where these apply.

A number of recommendations from the Shipman Inquiry have been introduced through the Health Act 2006 and will be implemented in Northern Ireland under the Controlled Drugs (Supervision of Management and Use)(Northern Ireland) Regulations (to be drafted). The legislation will require a Designated Body to appoint the CEO as Accountable Officer (AO). The AO will be responsible for ensuring the Designated Body, and any body or person providing services on behalf of, or providing services under arrangements made with the Designated Body, develops and monitors safe and effective systems relating to the use and management of controlled drugs. Standard Operating Procedures (SOPs) will be mandatory under this legislation. The legislation will also place a duty to collaborate and share intelligence by Responsible Bodies and will establish a Centre of Investigative Excellence. In addition, the legislation will provide a power of entry and inspection for certain authorised persons.

Examples of Verification

- There is an internal audit process in place, including regular and periodic checks by pharmacy and nursing staff, which evaluates and documents compliance to controlled drug, prescription writing and record keeping legislation where appropriate
- Prescription audit
- Self-assessments and standard declarations (when implemented)
- SOPs
- There is a suitable policy in place for dealing with discrepancies in reconciliation:

The policy should include when to involve

- external organisations
- pharmacy destruction records where appropriate

Links with other Standards

Records Management

Health and Safety

Human Resources

Waste Management

CRITERION 8

All medicines no longer required are destroyed or otherwise disposed of in accordance with safety, legal and environmental requirements.

Source

- Environmental Protection Act 1990 (c. 43) The Stationery Office, London
- Environmental Protection (Prescribed Processes and Substances) Regulations 1991 SI No 472 The Stationery Office, London
- The Misuse of Drugs Regulations (Northern Ireland) 2002 SR No 1 The Stationery Office, London
- Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973 The Stationery Office, London
- The Special Waste Regulations (Northern Ireland) 1998 SR No 289
- The Controlled Drugs (Supervision of Management and Use)(Northern Ireland) Regulations (to be drafted).
- Use and Control of Medicines: Guidelines for the safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services (2nd edn.2004), DHSSPS).
- Pharmaceutical Society of Northern Ireland (1997), Ethics, and Practice: A Guide for Pharmacists in Northern Ireland.
- A guide to pharmaceutical clinical waste (2002), DHSSPS

Other Reading

- The Safe and Secure Handling of Medicines - A Team Approach. A revision of the Duthie Report led by the Hospital Pharmacists' Group of the Royal Pharmaceutical Society. RPSGB March 2005
- Guidelines for Drug Donations (WHO)
- Guidelines for the Handling and Disposal of Pharmacy Wastes - NHS QC Committee
- Guidelines on the Handling and Disposal of Pharmacy Wastes NHS Pharmaceutical Quality Assurance Committee (September 2002, under review)
- Safer Management of Controlled Drugs A guide to good practice in primary care (Northern Ireland)(draft)
- Safer Management of Controlled Drugs A guide to good practice in secondary care (Northern Ireland)(draft)

Guidance

A number of principles should be adopted when disposing of medicines:

- Witnessed accountability
- Secure transit
- Adequate documentation

- Legally authorised persons to carry out and, where necessary, witness the destruction
- Adherence to legislation

Some clinical waste is also classified as 'special waste' and is subject to controls under the Special Waste Regulations 1998 Prescription-only medicines ('Medicinal Product' is the term used in the SI) are classed as special waste. The regulations require all movements to be tracked using consignment notes, with adequate records being kept for three years.

Any person required by the Misuse of Drugs Regulations (Northern Ireland) 2002 to keep records of Controlled Drugs in Schedule 1, 2, 3 or 4 may only destroy them in the presence of an authorised person (update as per Criterion 7).

Examples of Verification

- There is a written policy relating to the safe disposal of medicines
- Staff are aware of, and have access to the organisation's policy
- Methods of destruction follow locally agreed procedures but they must take into account national guidance when appropriate

Links with other Standards

Environment Management
Health and Safety
Records Management
Waste Management

CRITERION 9

The supply of medicines for clinical trials is undertaken in accordance with relevant legislation and best practice guidelines

Source

- The Medicines for Human Use (Clinical Trials) Regulations 2004 SI No 1031
- Research Governance Framework for Health and Social Care R&D Office DHSSPS Nov 2002
- Guidance on Good Clinical Practice and Clinical Trials (1999), Department of Health, London
- Good Clinical Practice in Clinical Trials Directive 2001/20/EC
- Medicines Act 1968 (as amended) The Stationery Office, London
- Use and Control of Medicines: Guidelines for the safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services (2nd edn.2004), DHSSPS).

Other Reading

- The International Committee on Harmonisation (ICH) Harmonised Tripartite Guidelines for Good Clinical Practice
- Pharmaceutical Society of Northern Ireland (1997) Ethics and Practice: A Guide for Pharmacists in Northern Ireland
- The Safe and Secure Handling of Medicines - A Team Approach. A revision of the Duthie Report led by the Hospital Pharmacists' Group of the Royal Pharmaceutical Society. RPSGB March 2005
- Clinical Trials Toolkit - a comprehensive resource for practical help in meeting requirements of the UK Medicines for Human Use (Clinical Trials) Regulations 2004 and the EU Clinical Trial Directive.
- Department of Health (2001) *Research Governance Framework for Health and Social Care*. Department of Health: London. Second edition in draft, 2003
- Clinical Trials Toolkit. <http://www.ct-toolkit.ac.uk/>

Guidance

The Medicines for Human Use (Clinical Trials) Regulations 2004 SI No 1031 requires trials that are sponsored by a drug company hold a clinical trial authorisation (CTA). To obtain a trial certificate an application must be made to the Medicines and Healthcare products Regulatory Agency (MHRA).

All clinical trials involving medicines must comply with the Medicines for Human Use (Clinical Trials) Regulations 2004. The regulations can be found at <http://www.mhra.gov.uk>

All trials must identify a sponsor which takes responsibility for the initiation, management and/or financing of a clinical trial

All trials must be authorised by the Licensing Authority (LA) prior to commencement, there are no exemptions e.g. DDX, CTX

All trials conducted with a DDX granted before the latest regulations came into force must notify the Licensing Authority (LA) of intention to continue after 1st May 2004, and provide details of the current study sponsor so as to be considered as having the necessary authorisation. (confirm the source that obviates the need for application).

Clinical trials must be carried out in accordance with the conditions and principles of good clinical practice as set out in The Medicines for Human Use (Clinical Trials) Regulations 2004.

The manufacture of investigational medicinal products (including placebos and active comparators) should be undertaken only at licensed manufacturing sites with an additional specific IMP license under GMP conditions. Manufacture or importation from outside EU will require prior authorisation by LA.

Procedures must be in place for dealing with untoward events.

The wider aspects of for example, Good Clinical Practice are referred to in "Good Clinical Practice for Trials on Medicinal Products, Guidance on Good Clinical Practice and Clinical Trials."

All medicines, or constituent ingredients, for clinical trials should be ordered, stored and dispensed by the hospital pharmacy.

Key points relating to clinical trials in hospital include:

- A suitably trained and competent pharmacist designated as responsible for clinical trials supplies
- Responsibility of the pharmacist to ensure that the authorisation certificate is in place before the trial starts
- Pharmaceutical input to the trial protocol
- Pharmaceutical input to the local research ethics committee
- Ordering, storage and dispensing in accordance with the requirements of 'Good Clinical Practice for Trials on Medical Products in the European Community' and the guidelines provided in the revised Duthie Report.
- Stock accountability
- Access to trial protocols
- Reimbursement of pharmacy costs

Examples of Verification

- Designated, competent staff trained in GCP
- Drug trial policy
- Appropriately validated Ethics Committee approval, CTA and Trust R&D committee approval.
- Records of receipt, dispensing and study administration and waste disposal to GCP standard

- Job description for the designated pharmacist
- Appropriate records of receipt, dispensing and stock reconciliation
- Evidence of Pharmacist involvement in:
 - Protocol development
 - Documentation and designing of Standard operating procedures
 - Patient information
 - Secure Database of all the studies managed by the pharmacy department.

Links with other Standards

Health and Safety
Human Resources
Records Management
Risk Management
Waste Management

CRITERION 10

The organisation reports adverse incidents involving medicinal products and devices to the relevant agency, and appropriately manages any subsequent required action.

Source

- Guidance to Trusts on reporting defective medicinal products (2001), DHSSPS
- NIAIC Safety Notice MDEA (NI) 2004/01 Reporting Adverse Incidents and Disseminating Medical Device / Equipment Alerts. Health Estates, Northern Ireland Adverse Incident Centre (NIAIC).
- The Controlled Drugs (Supervision of Management and Use)(Northern Ireland) Regulations (draft).
- Health Act 2006

Other Reading

- NHS Executive (1993) Reporting Adverse Incidents and Reactions, and Defective Products Relating to Medical and Non- Medical Equipment and Supplies, Food, Buildings and Plant and Medicinal Products HSG (93) 13 1993
- Department of Health 2000, An Organisation With A Memory. Report of An Expert Group on Learning From Adverse Events in the NHS. The Stationery Office, London.
- Department of Health 2001, Building a Safer NHS for Patients. Implementing An Organisation With A Memory, Department of Health, London
- MCA (1999) Guidance on Reporting Accidents with, and defects in, medicinal products
- Circular HSS (PPM) 06/04 – Reporting and follow-up on serious adverse incidents: Interim Guidance

Guidance

Organisations must identify and learn from all patient safety incidents and demonstrate improvements in practice, based on local and national experience and from the information derived from analysis of incidents.

Adverse Drug Reactions

HPSS organisations should encourage the prompt reporting to the Medicines and Healthcare products Regulatory Agency (MHRA) of *any* suspected adverse reactions due to “black triangle” drugs and any serious or unusual suspected reactions to established products. The ‘yellow card’ should be used for reporting adverse drug reactions to the agency.

Defective Medical Products

Adverse incidents arising from any medicinal product, thought to be defective, as opposed to incidents due to error, should be reported to the Pharmaceutical Branch, DHSSPS in accordance with Guidance to Trusts on reporting defective medicinal products (2001), DHSSPS. Any necessary recall of products is the responsibility of the licence holder. However, when defects present a significant hazard to health, the MHRA may issue a 'drug alert' letter, which provides 4 categories of urgency for recall or caution in use.

A pharmacist should be nominated to co-ordinate the reporting of such incidents and also the necessary action resulting from a 'drug alert' letter. Regular reviews should be undertaken to ensure that the procedures are effective and are being followed.

Defective medical devices

Procedures should be established and maintained to ensure the prompt reporting of adverse incidents relating to medical devices to the Northern Ireland Adverse Incident Centre (NIAIC) to conform with the Safety Notice "Reporting Adverse Incidents and Disseminating Medical Device / Equipment Alerts" [MDEA (NI) 2004/01].

A Liaison Officer should be nominated to co-ordinate the reporting of incidents and the local dissemination of NIAIC safety warnings. Regular reviews should be undertaken to ensure that the procedures are effective and are being followed.

Medication Incidents

The organisation should also have a local, multidisciplinary, medication incident (prescribing, dispensing, and administration) reporting and monitoring system as part of the risk management system. Medication incidents should be reported on existing clinical incident report forms or on separate medication incident form such as the Medicines Governance Team form. Trusts should consider facilitating online reporting of medication incidents. Medication incident reports should be monitored by a multi-professional management committee.

The organisation should contribute to the regional analysis of medication incidents undertaken by the Northern Ireland Medicines Governance Team.

The Northern Ireland Medicines Governance Team has been established to support organisations in their actions to prevent and protect patients from medicine related adverse events through:

- development of the risk management process itself, including the identification, analysis, evaluation and treatment of medicines-related risk.
- development of 'good practice' policies exemplified through education and training, ward and pharmacy procedures and protocols.

Organisations should ensure that:

Adverse Drug Reactions

- Staff are aware of the process for reporting an adverse drug reaction and report suspected adverse reactions via the yellow card system

Defective medicinal products and devices

- Defective medicinal products are reported to the relevant agency
- Products are kept and, if necessary quarantined, until the option of investigating the incident has been dismissed.
- Staff are aware of the mechanisms for reporting a defect with a medicinal product
- An auditable procedure is in place in primary and secondary care relating to the management of drug recalls.

Medication Incidents

Staff are aware of the process for reporting medication incidents and the reported incidents are investigated locally. These incidents should also be analysed for regional trends, to inform the priorities of the Medicines Governance Team.

The best practice policies, safety memos and learning bulletins issued by the Northern Ireland Medicines Governance Team should be evaluated and implemented.

Organisations are expected to comply with implementation requests as designated in DHSSPS guidance

Duty of Collaboration (controlled drugs)

- Under The Controlled Drugs (Supervision of Management and Use)(Northern Ireland) Regulations (to be drafted) there will be a legal duty placed on Responsible Bodies to share information and intelligence (within certain constraints), about controlled drugs in the healthcare sector. Those bodies required to share information will include DHSSPS Inspectorate, RQIA, healthcare organisations, Police Service for Northern Ireland, Social Service Authorities, other relevant inspectorates and professional bodies. It is proposed to establish a single Local Intelligence Network where concerns about the activities of any healthcare professional or organisation could be shared. While joint action may be agreed, each Agency would retain responsibility for taking appropriate action where required.

Examples of Verification

- There are policies that outline:
 - a. required action to be taken in the event of a suspected defect with a medicinal product or device and staff are aware of the policies;

- b. response to drug alerts, including out of hours, with a named lead professional and annual audit of results from the system;
- c. reporting and analysis of adverse medication incidents.
- Regular reviews are undertaken to ensure the procedures are effective and are being followed.
- Implementation of best practice policies/safety memos/learning bulletins/guidance from the Medicines Governance Team and DHSSPS e.g. Circular HSS(MD)22/2005; Circular HSS(SQSD)07/08.
- Medication incident report file or database.
- Minutes from the organisation's multi-professional management committee for medication incidents.
- Induction/training schedule and content

Links with other Standards

Health and Safety
Human Resources
Medical Devices and Equipment
Risk Management

CRITERION 11

Supervision of pharmaceutical dispensing processes is undertaken in accordance with relevant legislation and current professional standards.

Source

- Medicines Act 1968 (as amended) The Stationery Office, London
- Pharmaceutical Society of Northern Ireland (1997) Ethics and Practice: A Guide for Pharmacists in Northern Ireland

Guidance

Pharmacists have a legal and professional duty to ensure the safe, accurate and clinically appropriate dispensing of medicines, including those that are extemporaneously prepared.

For inpatient medication, where pharmaceutical oversight may commence with the clinical check at ward level with subsequent delegation of dispensing tasks, the accountable pharmacist must ensure that the staff involved in carrying out the delegated tasks are suitably trained and competent to undertake the tasks required

Similarly, good practice dictates that such controls should be in place for the dispensing of medicines for patients to take home, for one stop dispensing for discharge and for inpatient use. Appropriate clinical pharmacy input should also be provided.

The accountable pharmacist, must at all times, be satisfied that suitable systems are in place to discharge their legal and professional duties of supervision. These systems must be fully documented in suitable standard operating procedures (SOPs), which adequately cover all the processes by which dispensing, and its associated activities are undertaken. The SOPs should be reviewed at least annually.

The SOPs should include a suitable system for reporting, recording and prompt review of known dispensing errors.

Pharmacists are also reminded of their responsibility under the Code of Ethics & Standards with regard to extemporaneous preparation.

Examples of Verification

- Staffing schedules are in place to ensure adequate cover
- SOPs are present, suitable and recently reviewed
- Maintenance records
- COSHH records
- Relevant post-basic training schemes (e.g. accredited technician checking) are suitable and are appropriately accredited
- Documentation of training present

- Procedures for dealing with errors present
- Relationship with Risk Management

Links with other Standards

Health and Safety
Human Resources
Records Management
Risk Management

CRITERION 12

The risk management process contained within the risk management standard is applied to the safe and secure handling of medicines.

Source

- Standards Australia Risk Management AS/NZS 4360:2004

Guidance

Risks should be systematically identified and recorded on a continuous basis. Risks associated with the safe and secure handling of medicines can be systematically identified using a number of approaches including:

- Control self assessment workshops
- Use of checklists
- Judgements based on experience and records
- Flow charts
- Systems analysis
- Scenario analysis
- And systems engineering techniques

Historic data, including adverse event data, medication incident reports, complaint and claim information, staff sickness/absence details can also be a valuable source of information to identify risk.

The following risk management elements should be in place:

- All identified risks should be documented as part of a 'risk register' and systematically assessed and prioritised.
- Risk treatment plans should be developed and implemented (in order of priority and alongside other risk treatments which are necessary to deal with wider risks faced by the organisation, where appropriate) in order to minimise risk.
- Risks and the effectiveness of implemented risk treatments should be monitored and reviewed on a continuous basis.
- Senior management and the Board should be informed of any significant risks and associated risk treatment plans.
- Upon induction all medical, nursing and pharmacy staff including those on fixed term contracts, and other relevant stakeholders should receive information and training on systems in place to minimise risks associated with the safe and secure handling of medicines.
- Ongoing staff training in the safe and secure handling of medicines should be undertaken.

Examples of Verification

- Risk Register
- Risk treatment plans
- Staff training/information log

- Induction schedule and content
- Correspondence with stakeholders
- Reporting mechanisms that inform risk management process

Links with other Standards

Human Resources
Records Management
Risk management

CRITERION 13

All healthcare staff involved with medicines undertake continuing professional development to ensure that there are safe and secure handling processes in place.

Source

- Best Practice Best Care (2001) - A framework for setting standards, delivering services and improving monitoring and regulation in the HPSS.
- Standards Australia Risk Management AS/NZS 4360:2004.

Guidance

All staff involved with medicines have a duty to ensure safe and secure handling of medicines through compliance with relevant legislation, DHSSPS guidance and local Trust policies.

Staff must be aware of and apply these requirements at all times.

The requirements for safe and secure handling of medicines may change over time. It is therefore **essential** that all practitioners keep up to date with current practice. This involves continuing learning i.e. continuing professional development (CPD). CPD is an essential element in improving service quality.

Examples of Verification

- CPD policy
- Training and development plans for all staff
- Staff CPD log books
- Training records
- Audit of adherence to local medicines policies

Links with other Standards

Human Resources

CRITERION 14

The organisation, through the Chief Pharmacist, has access to up-to-date legislation and guidance relating to the safe and secure handling of medicines.

Source

- Use and Control of Medicines: Guidelines for the safe prescribing, administration, handling, storage and custody of medicinal products in the Health and Personal Social Services (2nd edn.2004), DHSSPS).

Guidance

Access to legislation and guidance is essential for the organisation to carry out the statutory duties imposed upon it by law and mandatory duties imposed by the DHSSPS.

As a minimum, the organisation should have access to the key references listed on the front page of this standard.

There should be appropriate mechanisms in place for the dissemination of information.

There are many sources of information on legislation and guidance on the safe and secure handling of medicines, including books and, through subscriptions to specialist information providers, CD-ROMs containing the full text. Up-to-date DHSSPS guidance can be accessed on the Internet on the DHSSPS website (<http://www.dhsspsni.gov.uk>). Equivalent NHS documents can be accessed via the Department of Health COIN database (<http://www.doh.gov.uk>). The Medicines and Healthcare products Regulatory Agency (<http://www.mhra.gov.uk>) contains some information. Full text copies of all legislation issued from 1 January 1997 can be downloaded from <http://www.official-documents.co.uk>, which contains information on UK official documents.

Wherever possible, the DHSSPS Governance website www.dhsspsni.gov.uk/hss/governance/index.asp contains the relevant information pertaining to the development of controls assurance standards for Northern Ireland. Further useful guidance can be obtained from the Health Care Standards (formerly CASU) website (<http://www.hcsu.org.uk>).

Examples of Verification

- Library
- CD-ROMs
- Internet access
- Cascade process chart

Links with other Standards

All standards (generic criterion)

CRITERION 15

Adequate resources support the safe, secure and appropriate use of medicines.

Source

- Circular HSS (PPM) 10/2002 – Governance in the HPSS: Clinical and Social Care Governance - Guidance on Implementation.
- Circular HSS (PPM) 3/2002 – Corporate Governance: Statement of Internal Control
- Circular HSS (PPM) 8/2002 - Risk Management in the Health and Personal Social Services
- Circular HSS(PPM) 5/2003 – Governance in the HPSS – Risk Management and Controls Assurance

Guidance

A fundamental element of the safe and secure handling of medicines is the need for all parts of the system to be adequately resourced with competent personnel and suitable facilities and equipment. In addition it is vitally important that there is strong collaboration across Primary and Secondary Care relative to the use of medicines. In this regard the establishment of joint Drug and Therapeutics Committees to agree, implement and monitor adherence to prescribing guidelines across these sectors should be undertaken.

Consideration should be given to the development of these in line with HPSS modernisation plans.

Examples of Verification

- Baseline data for services against standards
- Benchmarking
- CPD – Training budgets/staffing budget
- Audit – Critical incidents, facilities
- Capacity Planning
- Business Plan
- Review monitoring process to ensure that pharmacy remains adequately resourced
- Minutes of meeting of Area Drug and Therapeutics Committee
- Document joint initiatives, policies etc.,

Links with other Standards

Financial management
Medical Devices and Equipment
Risk Management

CRITERION 16

Key indicators capable of showing improvements in the safe and secure handling of medicines and the management of associated risk are used at all levels of the organisation, including the board, and the efficacy and usefulness of the indicators is reviewed regularly.

Source

- Standards Australia Risk Management AS/NZS 4360:2004.

Guidance

The organisation should develop indicators, which demonstrate that medicines are being safely and securely handled and risks are minimised. One indicator is degree of compliance with this standard. Ideally the indicators should be designed to demonstrate improvement in the performance of pharmacy services and staff prescribing and handling medicines over time. The number of indicators devised should be sufficient to monitor all aspects of the process, including risk management. It is not necessarily the case that the board will use all the indicators. The board should select those, which are useful for ensuring that the internal controls are working satisfactorily and medicines are being safely and securely handled.

Examples of Verification

- Indicators
- Evidence of usage at all levels

Links with other Standards

All standards (generic criterion)

CRITERION 17

The system in place for the safe and secure handling of medicines, including risk management arrangements, is monitored and reviewed by management and the Board in order to make improvements to the system.

Source

- Standards Australia Risk Management AS/NZS 4360:2004.
- The Controlled Drugs (Supervision of Management and Use)(Northern Ireland) Regulations (to be drafted).
- Health Act 2006

Guidance

It is the responsibility of management and the board to monitor and review all aspects of the system for the safe and secure handling of medicines, including:

- Accountability arrangements
- Processes, including risk management arrangements
- Capability
- Outcomes
- Internal audit findings

The review should be carried out by individuals with the relevant knowledge and expertise of the safe and secure handling of medicines and should include review of any adverse incidents.

The committee with responsibility for risk management will play a significant role in monitoring and reviewing all aspects of the system as a basis for establishing significant information that should be presented to, and dealt with by the board. The Audit Committee should review internal audit findings.

Controlled drugs

- Under The Controlled Drugs (Supervision of Management and Use)(Northern Ireland) Regulations (draft) it is proposed that the duties of the Accountable Officer will encompass the developing and monitoring of systems to ensure the safe and effective use and management of controlled drugs subject to their oversight.

Examples of Verification

- Internal audit report(s)
- Audit Committee minutes

- Minutes of the board sub-committee(s) responsible for overseeing risk management and governance
- Self assessments/self-declarations(proposed)

Links with other Standards

All standards (generic criterion)

CRITERION 18

The board seeks independent assurance that an appropriate and effective system for the safe and secure handling of medicines is in place and that the necessary level of controls and monitoring are being implemented.

Source

- Standards Australia Risk Management AS/NZS 4360:2004.
- Circular HSS (PPM) 10/2002 – Governance in the HPSS: Clinical and Social Care Governance - Guidance on Implementation.
- Circular HSS (PPM) 3/2002 - Corporate Governance: Statement on Internal Control
- Circular HSS (PPM) 8/2002 – Risk Management in the Health and Personal Social Services
- Circular HSS(PPM) 5/2003 – Governance in the HPSS – Risk Management and Controls Assurance

Guidance

Management should consider the range of independent internal and external assurance available, and avoid duplication and omission.

The adequacy of the independent assurance will depend upon the scope and depth of the work performed, bearing in mind its timeliness and the competency of the staff performing it. The level of reliance that can be placed upon such assurances should consider, among other things, the professional standing of the assurer, their level of independence, and whether they could reasonably expect to provide an objective opinion. It is important that any review that takes place results in a report, recommendations for action where necessary, and the retention of sufficient evidence to enable other potential reviewers to rely upon the work already undertaken. The reports should be made to the appropriate sub-committee of the board.

Management arrangements will include an internal audit function, as well as other quality control and assurance functions such as clinical audit. The internal audit function is required to give an opinion to the board on the adequacy and effectiveness of the overall system of internal control. In doing so, they will seek to work with, and rely on the work of other bodies for example the HPSS Regulation and Improvement, Authority.

In addition, the HPSS organisation will be subject to independent inspection by the DHSSPS Medicines Inspectorate on those areas subject to statutory authority.

Examples of Verification

- Schedule of planned reviews
- Copy of reports

- Committee minutes
- Action plans
- Notes of follow up of actions
- Evidence file
- Details of staff involved in the review

Links with other Standards

All Standards (generic criterion)