

**Professional guidance on the Safe and Secure Handling of Medicines in all Care Settings: an updated draft for consultation February 2018**

**Consultation closes: Friday 20 April 2018**

**Relevant to all care settings where medicines are handled.**

**Contents**

[1. Introduction 4](#_Toc507488880)

[2. Scope of the professional guidance on the safe and secure handling of medicines in all care settings 5](#_Toc507488881)

[3. Developing a governance framework for the safe and secure handling of medicines 7](#_Toc507488882)

[Principle 1: Establish governance arrangements – ‘say what we do and why we do it’ 8](#_Toc507488883)

[Principle 2: Ensure capacity and capability – ‘train people and ensure they have the necessary resources’ 9](#_Toc507488884)

[Principle 3: Undertake assurance – ‘do what we say and prove it’ 9](#_Toc507488885)

[Principle 4: Seek to improve – ‘improve what we do’ 10](#_Toc507488886)

[4. The Medicines Pathway 12](#_Toc507488887)

[Glossary 19](#_Toc507488888)

[Further questions 21](#_Toc507488889)

[Appendix A. Administration of medicines – supplementary guidance 24](#_Toc507488890)

[Appendix B: Investigational medicinal products – supplementary guidance 28](#_Toc507488891)

[Appendix C. Controlled Drugs – supplementary guidance 32](#_Toc507488892)

[Appendix D: Patients’ own medicines – supplementary guidance 36](#_Toc507488893)

[Appendix E: Operating theatres – supplementary guidance 40](#_Toc507488894)

[Appendix F: Storage of medicines – supplementary guidance 44](#_Toc507488895)

**When responding to this consultation please complete the following:**

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| **Are you responding from an organisation or as an individual:** | **Organisation:** | **Individual:** |
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# Introduction

**1.1** The Royal Pharmaceutical Society (RPS) is the body responsible for the leadership and support of the pharmacy profession within England, Scotland and Wales.

**1.2** One of the roles of a professional body is to develop professional standards and guidance that are supportive, enabling and professionally challenging. The importance of professional standards and guidance alongside regulatory standards in supporting patient safety has been repeatedly emphasised. [[1]](#footnote-1) [[2]](#footnote-2) [[3]](#footnote-3)

**1.3** The Safe and Secure Handling of Medicines: a team approach, originally published in 2005, is essential good practice guidance that is widely used in hospitals and across other care settings.

**1.4** The safe and secure handling of medicines is a multidisciplinary responsibility. This guidance, which underpins governance processes in organisations across Great Britain, is therefore of direct relevance to a wide range of health and social care professionals and support staff.

**1.5** The 2005 guidance is significantly out of date and is being updated.

Following a literature review and extensive scrutiny by a multidisciplinary advisory group with lay representation ([click here](https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Support/SSHM/SSHM%20Advisory%20Group%20Feb%202018%20update.pdf) to see who has been involved) the guidance has been drafted. The full process for updating the guidance is outlined in the [RPS process development manual](https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Manuals/How%20the%20RPS%20develops%20standards%20and%20guidance.pdf).

**1.6** This document contains the draft updated guidance which is being posted on the RPS website for an eight week open consultation.

**1.7** This draft is not confidential and may be circulated widely for comment.

* 1. When published, the update to the Safe and Secure Handling of Medicines will be an online resource only.

# Scope of the professional guidance on the safe and secure handling of medicines in all care settings

**2.1** This guidance considers the processes associated with the **physical handling** of medicines. These include obtaining medicines, their transport, receipt, manufacture or manipulation, storage, issuing of medicines, their use or administration, and their removal or disposal.

**2.2** The clinical elements of the prescribing of medicines (such as choice of medicine, treatment duration and method of administration) are beyond the scope of this guidance.[[4]](#footnote-4)

**2.2.1** As the Nursing and Midwifery Council (NMC) are consulting on the withdrawal of their Standards for Medicines Management this guidance has been expanded to cover the administration of medicines (including [transcribing](#Glossary) of medicines) – see [Appendix A: Administration](#App_A).

**2.3** This guidance is relevant to **all** care settings where medicines are handled. Medicines that are obtained and stored by [patients](#Glossary) in their own homes are beyond the scope of this document, however some of the principles are likely to apply and be of use to health and care professionals who work in patients’ homes.

**2.4** This guidance complements the [RPS Professional Standards for Hospital Pharmacy Services](https://www.rpharms.com/resources/professional-standards/professional-standards-for-hospital-pharmacy), for [Homecare Services](https://www.rpharms.com/resources/professional-standards/professional-standards-for-homecare-services) and those for [Optimising Medicines for People in Secure Environments](https://www.rpharms.com/resources/professional-standards/optimising-medicines-in-secure-environments).

**2.5** Application of this guidance is a multidisciplinary responsibility. All staff groups involved in the physical handling of medicines should be involved in developing local procedures and policies. Advice on interpretation of the guidance can be obtained from [pharmacy professionals](#Glossary).

**2.6** In addition to corporate and clinical governance responsibilities, health and care professionals are personally responsible for putting patients first and for a commitment to ethics, values, principles and improvement. They are also responsible for practicing within their own scope and competence, using their acquired knowledge, skills and judgement.

**2.7** This guidance provides the overarching principles needed to control the activities of handling medicines. Accordingly, it should also be used as a basis for the audit and quality improvement of the safe and secure handling of medicines. It is not intended to provide a detailed consideration of all possible circumstances in which medicines are used.

**2.8** The guidance is based on the elements of a structured [medicines pathway](#MP). The pathway covers all activities involving the **physical handling of medicines** and is applicable across a range of different settings and sectors. The guidance is based on the stages shown within the structured medicines pathway with a focus on aspects of governance, responsibility, record keeping and reconciliation.

**2.9** This document does not provide guidance for manufacturers or wholesalers who are subject to relevant good manufacturing or wholesale dealing practice guidance.

**2.10** Unless otherwise stated, the core principles and medicines pathway guidance apply across all areas of practice. However not every stage of the pathway will be applicable in every setting.

**2.11** Whilst the core principles in this guidance apply to all medicines, including radiopharmaceuticals, cytotoxics, biologicals and advanced therapy medicinal products; specific separate guidance also applies to the safe and secure handling of these medicines.[[5]](#footnote-5)

**2.12** Investigational medicinal products (IMPs) are subject to additional safe and secure handling requirements - see [Appendix B – Investigational medicinal products](#App_B).

**2.13** Specific guidance for the safe and secure handling of controlled drugs can be found in [Appendix C – Controlled drugs](#App_C).

**2.14** The guidance essentially deals with medicines however there may be situations where medical devices which incorporate a medicine should also be considered within the same principles.

**2.15** The core principles apply equally to the handling of medical gases. The safe and secure handling of medical gases is also subject to specific separate guidance. [[6]](#footnote-6) [[7]](#footnote-7) [[8]](#footnote-8) [[9]](#footnote-9) [[10]](#footnote-10) [[11]](#footnote-11) [[12]](#footnote-12) [[13]](#footnote-13)

**2.16** Blood and blood components are outside the scope of this guidance.

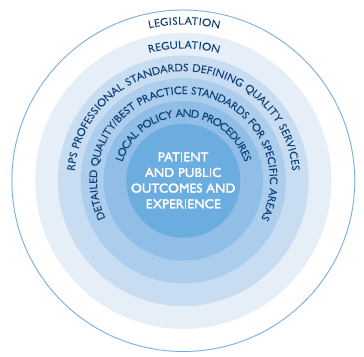
|  |  |
| --- | --- |
| **QUESTION 1:**  **Is the scope of the professional guidance on the safe and secure handling of medicines clear:** | |
| **YES:** | **NO:** |
| **If not, why not?** | |
|  | |

# Developing a governance framework for the safe and secure handling of medicines

**3.1** Figure 1 shows where standards and guidance from professional bodies sit in relation to relevant legal frameworks and core standards that are required by ‘systems’ regulators, the professional regulators and for controlled drugs, the Home Office.

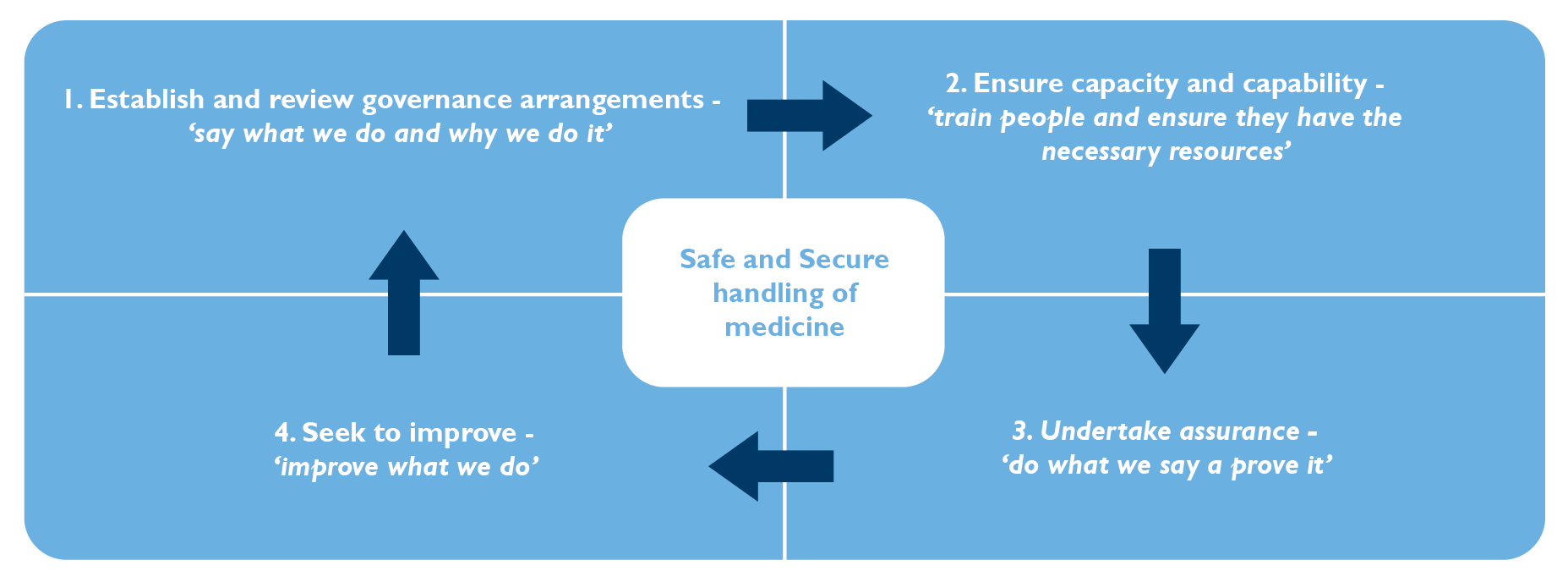
**3.2** This guidance supports the four layers of governance responsibility for the safe and secure handling of medicines: national, professional, organisational, team and individual.

**FIGURE 1: HIERARCHY OF GOVERNANCE**

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**3.3** Leadership within the organisation supports an open and honest safety culture that supports the safe and secure handling of medicines. This is supported by proactive audit and review, and by reporting, sharing, learning and taking action on patient safety incidents.

**3.4** The basic principles described in this document are generic but the way in which they are interpreted and applied are context-specific.

**3.5** The four core principles that underpin the safe and secure handling of medicines are:

**3.6** These four core principles are to be applied to the physical handling processes involved in each stage of the [medicines pathway](#MP).

**3.7** The four core principles take a quality management systems approach to the safe and secure handling of medicines.

# Principle 1: Establish governance arrangements – ‘say what we do and why we do it’

**3.8** A [named individual](#Glossary) who is responsible and accountable at organisational level for the safe and secure handling of medicines is identified. It is the responsibility of the organisation to appoint an individual of sufficient seniority, knowledge and skills to provide leadership (relevant to the type of organisation and with reference to the relevant medicine regulation).

**3.9** The named individual ensures an effective system by which medicines are handled safely and securely is established, documented and maintained, whilst at the same time meeting the clinical needs of patients.

**3.9.1** This system includes formal performance reporting mechanisms to the senior management of the organisation and a commitment to promote awareness of the significance of the system and how it relates to patient and public safety within the organisation.

**3.10** In organisations that have a [pharmacy team](#Glossary), the named individual is an appropriate role for the Chief Pharmacist, Superintendent Pharmacist, or equivalent. Where there is no pharmacy team employed by the organisation, the named individual seeks advice from a [pharmacy professional](#Glossary) with the relevant, knowledge, skills and experience when necessary.

**3.11** [Accountable individuals](#Glossary) ensure that all organisation requirements are reflected in operational frameworks, policies, procedures and plans. These are fit-for-purpose, and take into account all relevant regulations, national standards and guidance, as well as requirements from other stakeholders using the services of the organisation.

**3.12** The named individual ensures that there are sufficient competent accountable individuals relevant for the service.

**3.13** There are potential risks throughout the medicines pathway. Accountable individuals ensure that risk assessments are carried out for all processes that involve the handling of medicines. This is done in accordance with local context specific risk management policies to determine potential risks to medicines, patients and staff. [[14]](#footnote-14)

**3.13.1** Risk assessments are undertaken regularly, documented where appropriate and are used to inform risk mitigation, while also ensuring the management of remaining risks and ongoing improvement.

**3.13.2** Risk assessments are carried out when new medicines or processes are introduced, or if there are changes to a process.

**3.13.3** Risk assessment and mitigation balance requirements for safety and security against the need to ensure that medicines are readily available to patients when needed.

**3.14** Accountable individuals ensure that standard operating procedures (SOPs) are approved by appropriate designated staff as defined in the organisation medicine policy or schedule of delegated authority. SOPs and process descriptions are subject to routine update and review. Records of such reviews are maintained. SOPs are available to any member of staff at the location where they are used. All SOPs are dated and the date of review included.

**3.15** Specific SOPs incorporating references to relevant guidance and appropriate standards exist for each process that supports the safe and secure handling of medicines.

# Principle 2: Ensure capacity and capability – ‘train people and ensure they have the necessary resources’

**3.16** The organisation provides the required resources necessary to support the safe and secure handling of medicines and defines the following:

**3.16.1** The people required, their knowledge, experience and skill mix

**3.16.2** The competencies, performance standards and responsibilities of these people

**3.16.3** The safety and effectiveness of the premises and equipment required

**3.16.4** The environment including a suitable combination of human and physical factors such as social (non-discriminatory, respecting diversity, collaborative), psychological (supported, developed, respected, valued), and physical (temperature, heat, light, hygiene, noise). [[15]](#footnote-15)

**3.17** Training plans specify ongoing training requirements to maintain and update the knowledge, skills and experience of staff. Training records are maintained and updated.

**3.18** The individual accountable for any process and persons who may accept responsibility for any process are defined and recorded.

**3.19** Persons authorised to undertake tasks are accountable and comply with legal and registration frameworks, professional guidance and/or local or relevant national policy requirements. Tasks are only delegated to persons who are legally entitled, authorised, appropriately trained and competent to carry out the task.

**3.20** There are planned maintenance and replacement programmes for facilities and equipment to ensure continuing capability.

**3.21** All materials, including equipment, containers, devices and packaging used for the safe and secure handling of medicines are fit for purpose.

# Principle 3: Undertake assurance – ‘do what we say and prove it’

**3.22** The system for the safe and secure handling of medicines defines local audit and monitoring processes which are used to check the standards of practice that are being delivered.

**3.23** Routine audit is undertaken of all key processes and consequent remedial action taken where necessary.

**3.24** The organisation defines the process for collecting and learning from incidents and complaints.

**3.25** The named individual and accountable individual embed a culture of assurance to ensure that policies, processes and plans are effectively implemented, and that all outputs are consistent with requirements.

**Principle 4: Seek to improve – *‘improve what we do’***

# Principle 4: Seek to improve – ‘improve what we do’

**3.26** The named individual is responsible for the oversight of the quality systems approach to the safe and secure handling of medicines delivered through the accountable individuals.

**3.27** The named individual for the safe and secure handling of medicines embeds a culture of evaluation (both qualitative and quantitative), learning and improvement. This will drive more effective, efficient and agile ways of working to support medicines strategy and the reduction of risk, waste and harm. [[16]](#footnote-16)

**3.28** Systems and processes are in place to ensure incidents are identified, recorded, monitored, appropriately reported, investigated and practice changed and shared to minimise recurrence.

**3.28.1** Relevant incidents are fed into national reporting schemes to support benchmarking, trending and learning on a wider basis.

|  |  |
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| **QUESTION 2:**  **Are the four core principles that underpin the safe and secure handling of medicines clear?** | |
| **YES:** | **NO:** |
| **If not, why not?** | |
|  | |
| **Is anything missing or unnecessary?** | |
|  | |

1. **The Medicines Pathway**

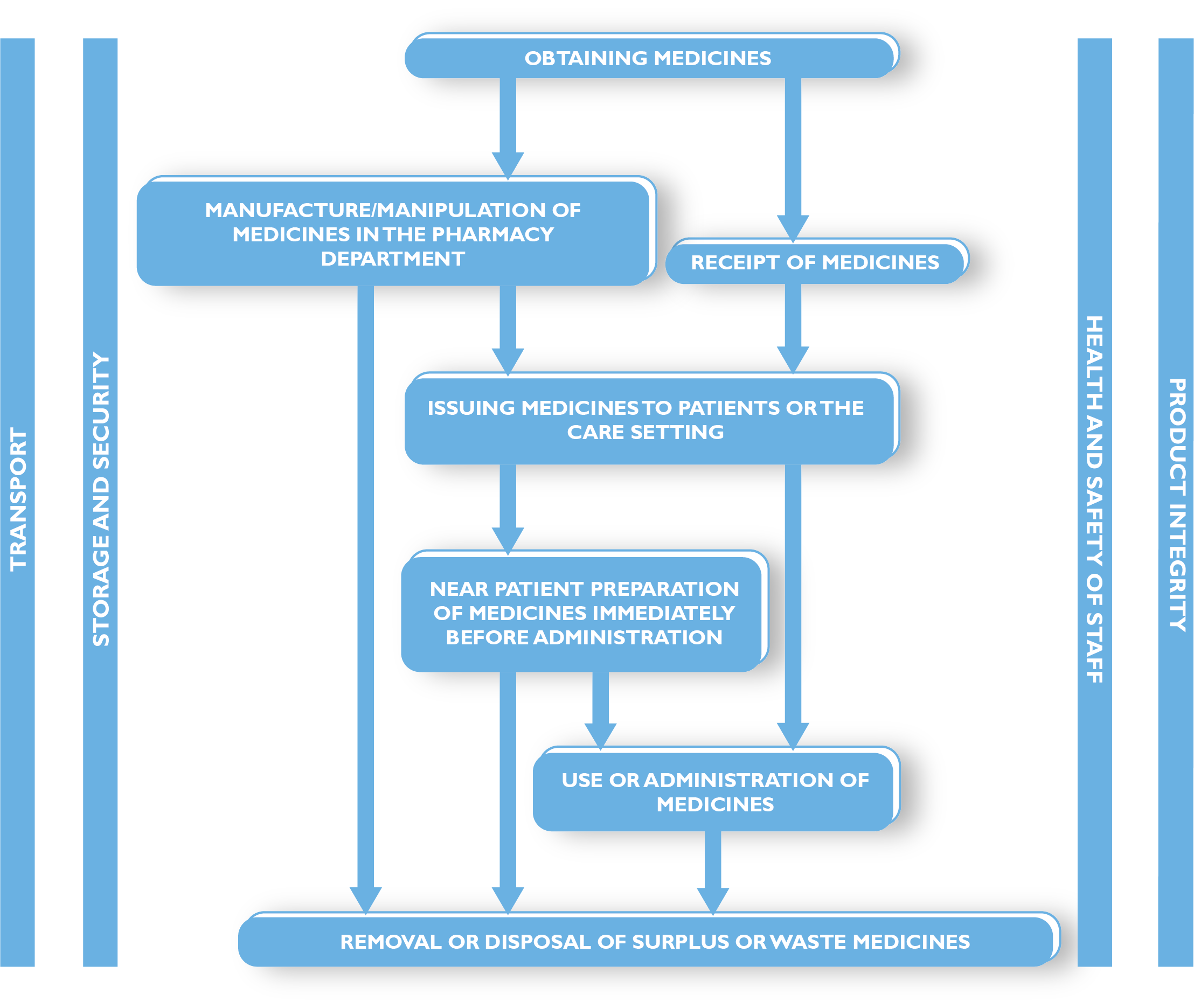
**Introduction to the pathway**

**4.1** The medicines pathway (see Figure 2) covers all potential activities that are associated with the handling of a medicine, from obtaining the medicine through to use or administration, and the disposal of any waste.

**4.2** The four core principles that underpin the safe and secure handling of medicines: 1. Establish governance arrangements; 2. Ensure capacity and capability; 3. Undertake assurance and 4. Seek to improve, are to be applied to processes that involve the physical handling of medicines at each stage of the medicines pathway.

**4.3** The steps in the pathway need to be applied to individual settings. Some of the stages will always be present in the treatment of an individual [patient](#Glossary) whilst others will only occur in specific settings/organisations or when certain medicines are used.

**4.3.1 FIGURE 2: THE MEDICINES PATHWAY**



|  |  |
| --- | --- |
| **QUESTION 3:**  **Given statement 4.3 above, can you apply the steps in the ‘Medicines Pathway’ to your setting?** | |
| **YES:** | **NO:** |
| **If not, why not?** | |
|  | |

**Links between stages of the medicines pathway**

**4.4** The medicines pathway is a multistage process and controlled links are established between the relevant stages.

**4.5** Particular attention is taken to ensure safety and security of medicines when care, and medicines associated with that care are transferred from one setting to another.

**4.6** All information necessary to assure continued safe use and security of those medicines is also securely transferred in compliance with data protection and information governance requirements. [[17]](#footnote-17) [[18]](#footnote-18)

**Obtaining medicines**

**4.7** Medicines are obtained from a reputable source and due diligence applied to ensure quality, their safe onward use and to minimise the risk of falsification. [[19]](#footnote-19)

**4.8** Organisational and legal requirements such as the Falsified Medicines Directive, standing financial instructions and data control are complied with.

**4.9** Potential sources of supply and the specification of the medicine for its intended use are identified.

**4.10** Issues such as availability, lead times and shelf life as well as the method of obtaining are considered.

**4.11** Policies and procedures to reduce risk are available for obtaining medicines, including those that cover specific categories of products such as investigational medicinal products, medicines supplied on a "named patient" basis and imported or repackaged medicines. [[20]](#footnote-20)

**Receipt of medicines**

**4.12** Medicines are received by an organisation within the framework of an effective audit trail from an external source, from the patient, or by transfer from one location to another within the organisation.

**4.13** All medicines received by the organisation are of the quantity and quality specified and are suitable for the purpose for which they are intended. Specific attention is applied to the critical steps of: confirmation of product identity and quantity; confirmation that deterioration through inappropriate storage, such as breakage of cold chain, has not occurred and confirmation of compliance with any legal and/or local requirements.

**4.14** Policies and procedures are in place for managing medicines that patients bring with them into the care setting, including a policy for self-administration see [Appendix D: Patients’ own medicines](#App_D).

**4.15** Once received into the organisation, the physical condition of medicines is protected by controlled storage and inventory records kept. Policies and procedures consider environmental and security aspects of all storage locations, as well as the processes by which records of stock are maintained. See [Appendix F: Storage of medicines](#App_F), for further guidance.

**Manufacture/manipulation of medicines in the pharmacy department**

**4.16** Where medicines are manufactured or manipulated or modified prior to administration to a patient these activities may be carried out in a suitably-equipped pharmacy, or contracted out to NHS or non-NHS operated manufacturers under the appropriate licences.

**4.17** Activities include: manufacturing of medicines from ingredients; repackaging of medicines into small packs from bulk supply; over-labelling; aseptic dispensing of parenteral nutrition solutions; reconstitution of injections, powders and oral suspensions; addition of parenteral medicines to intravenous solutions and the preparation of radiopharmaceuticals. [[21]](#footnote-21)

**4.18** In some cases the point of manipulation may also be the point of dispensing (see also [Near patient preparation of medicines immediately before administration](#near)).

**Issuing medicines to patients or the care setting**

**4.19** Medicines are issued to the place where they will be administered/used, or to the patient directly in response to formal requisitions or orders such as prescriptions, or for supply or administration to patients under [Patient Specific Directions](#Glossary), [Patient Group Directions](#Glossary). These medicines may be supplied as stock, or as dispensed medicines which are labelled to assist the patient or their carer to administer them at the place where they live.

**4.20** Presentation and labelling of the issued medicine is of a consistently acceptable standard. [[22]](#footnote-22)

**4.21** Automated and semi-automated systems are used to reduce risk and error, for example by compliance with [GS1 standards](https://www.gs1.org/standards).

**4.22** Where a care setting holds medicines as stock, a list of stock medicines and quantities to be held is determined by the relevant multidisciplinary team and is subject to regular review at agreed intervals.

**Near patient preparation of medicines immediately before administration**

**4.23** Manipulation of medicines in clinical areas is minimised. Medicines are presented as “ready-to-use” or “ready-to-administer” wherever possible. See also [Appendix E – Operating theatres](#App_E).

**4.24** However, some form of preparation of the medicine may be necessary immediately prior to its administration. For example the withdrawal of volumes from containers, the preparation of injections from vials or ampoules of dry powder and the preparation of mixtures.

**4.25** Injectable medicines are of particular concern as the activities associated with the preparation of these are fundamental to ensuring the correct dose of the correct medicine is administered to the intended patient. The following categories of medicines present the highest level of overall safety risk: parenteral cytotoxic anticancer medicines, parenteral nutrition solutions and additions to them, advanced therapy medicinal products and other locally identified “high-risk” injectable medicines. Their manipulation is as far as possible carried out under pharmaceutical supervision in a suitable controlled environment[[23]](#footnote-23) [[24]](#footnote-24)

**Use or administration of medicines**

**4.26** Due to the potential withdrawal of the Nursing and Midwifery Council Standards for Medicines Management (2007) more detailed guidance on administration is included in [Appendix A - Administration](#App_A).

**Removal and disposal of surplus and waste medicines**

**4.27** National regulations and all legal requirements are met, e.g. Waste Management Regulations [[25]](#footnote-25) [[26]](#footnote-26) and there is full compliance with local policy.

**4.28** Waste medicines are appropriately segregated and stored securely, pending their disposal.

**4.29** Medicines that patients bring in with them into the care setting are removed and/or disposed of only with the agreement of the patient or the patient’s carer.

**4.30** Unused or unwanted stocks of medicines are returned to a pharmacy or a waste management company with appropriate security precautions.

**4.31** Out-of-date medicines, medicines liable to diversion or no longer required medicines, are disposed of or destroyed in a safe and secure manner in accordance with local standard operating procedures (SOPs).

**4.32** Medicines that are no longer suitable for their intended use are removed and disposed of safely.

**4.33** Appropriate records are kept.

**Transport**

**4.34** This covers the transfer of medicines between sites within the same organisation as well as between one organisation and another.

**4.35** Local procedures are compliant with legal requirements and cover situations where staff transport medicines in the course of their duties.

**4.36** Where third party carriers (agents) are used, approved systems and controls are present, including the recording of collections and deliveries.

**4.37** Transfers are managed under a system in which all orders and dispatches are authorised and recorded, and receipt of goods recorded. Staff engaged in the transport of medicines are identified, authorised and appropriately trained.

**4.38** Procedures and equipment used in the transport of medicines are designed to ensure that the integrity and quality of the medicines are not compromised, for example, to minimise temperature excursions within the cold chain (see also [Product integrity](#PI)).

**4.39** Arrangements are in place to protect staff who are transporting medicines from attack or distractions that could result in their harm or the diversion or theft of medicines.

**4.40** Tamper-evident and, preferably secured containers are used when the transport is under personal control throughout. Secured containers in secured vehicles are used when the medicines are not under personal control throughout transport. Arrangements for transport of controlled drugs, medical gases and radiopharmaceuticals comply with any legal requirements and best practice guidance.

**Storage and security**

**4.41** It is essential to ensure that planning and design of new premises incorporates appropriate facilities and sufficient capacity for safe and secure storage of medicines.

**4.42** Policies and procedures are consistent with the general security arrangements within the organisation and relevant staff such as risk managers, security officers and local crime prevention officers are involved from the design stage for new premises or equipment for storage.

**4.43** From the time of receipt until use or removal, all medicines are kept secure with access only by authorised people. Procedures are in place to ensure that security is maintained in any storage area particularly where it is not continuously staffed. Following risk assessment this may include remote monitoring and alarms.

**4.44** Arrangements are in place to protect from risk of attack, staff who are working in areas where medicines are stored and used.

**4.45** Medicines are stored at a level of security appropriate to their proposed use and at a level appropriate to their risk of diversion or risks in the local environment. They are stored at a level appropriate to the staff present at any time and access is restricted. The level may be different in locations that are staffed continuously compared with those that are staffed intermittently, even when the use of the medicine is the same in each case. See also Appendix F: Storage of medicines.

**4.46** The level of security to be applied and the way in which this is achieved is balanced against the need to ensure timely access to medicines when they are required.

**4.47** At each stage where a medicine changes hands, there are clear policies supported by SOPs explaining where the responsibility for security lies at that stage, the records required and how often reconciliation takes place. The legal requirements related to the category of medicine are considered when developing these policies.

**4.48** The security of medicines storage, including that in clinical areas, is checked periodically by a [pharmacy professional](#Glossary) in accordance with locally agreed procedures.

**4.49** Pharmacy professionals who regularly visit care settings and other clinical areas have a professional responsibility to adhere to this guidance as well as to support clinical staff to do so. Poor practice in relation to medicines security, by any group of staff, is highlighted and challenged wherever and whenever it is identified.

**Product integrity**

**4.50** All medicines obtained for patient use, from whatever source, are subject to appropriate assessment of their fitness for use. Appropriate storage and environmental conditions are specified for all medicines.

**4.51** Processes are in place to ensure that medicines are kept within the specified conditions to the point of use or disposal in all locations where they may be held or during transportation.

**4.52** Equipment or devices associated with storage or transfer (e.g. air tubes, IV lines and cannulae) do not threaten the integrity of the product.

**4.53** Processes specify the required condition of a medicine at the time of use and the checks that are made to ensure it is used according to these conditions.

**4.54** Sufficient data and information about the medicine is available to the staff and/or patient to enable them to identify the medicine and use it correctly. As a minimum this comprises the patient information leaflet.

**4.55** The temperature is controlled and the cold chain is maintained; for items that require refrigeration or freezer conditions, the equipment used conforms to current guidance. [See Appendix F: Storage of medicines](#App_F).

**4.56** When patients assume responsibility for their medicines under self-administration schemes (see [Appendix D – Patient’s own medicines](#App_D)), information and advice about maintaining the security and integrity of the medicine whilst in the clinical area and when at the place where they are living is given.

**4.57** Where conditions relating to product integrity have not been met or cannot be guaranteed, the medicine is not used to treat the patient.

**4.58** The organisation has a policy for dealing with product recalls (e.g. Drug Alerts issued by the Medicines Healthcare products Regulatory Agency).

**Health and safety of staff**

**4.59** The risks associated with the processes of handling or administration of any medicine are assessed for both staff and patients. This includes reference to legislative requirements, where necessary, such as Control of Substances Hazardous to Health and ionising radiation regulations.

**4.60** Processes to minimise risks during transport, receipt, storage, preparation, administration and disposal of medicines are in place.

**4.61** Equipment, devices, protective clothing and decontamination equipment (e.g. for cytotoxics) are available at the point of handling, as specified in the risk minimisation procedure.

**4.62** Training is given to those handling any medicine and, where appropriate, competency checks are carried out at suitable intervals.

**4.63** An SOP covers actions to be taken, including reporting and record keeping, in the event of unplanned incidents such as spillages of hazardous medicines; including recovery processes, record keeping and reporting.

|  |  |
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| **QUESTION 4a:**  **Overall, do these statements support the safe and secure handling of medicines at each stage of the medicines pathway?** | |
| **YES:** | **NO:** |

|  |
| --- |
| **QUESTION 4b:**  **Is anything missing that you feel would demonstrate the delivery of the guidance?** |
| **Please illustrate using examples from your practice:** |
|  |

|  |
| --- |
| **QUESTION 4c:**  **Are there any statements that you feel are unnecessary?** |
| **Please specify:** |
|  |

|  |
| --- |
| **QUESTION 4d:**  **Are there any statements that you feel are unclear?** |
| **Please specify:** |
|  |

# [Glossary](#Glossary)

|  |  |
| --- | --- |
| **ACCOUNTABLE INDIVIDUAL** | For the purposes of this professional guidance these are individuals made ‘accountable’ by the named individual or organisation. Working at an operational level accountable individuals control access to medicines in the care setting ensuring standard operating procedures and similar policies and procedures are fit-for-purpose and take into account all relevant regulations, national standards and guidance.  The accountable individual is a registered healthcare professional with relevant knowledge and skills, or is a person who has undergone training, relevant for the organisation, in the safe and secure handling of medicines. |
| **COVERT ADMINISTRATION** | The defined process whereby a formal decision has been made between healthcare professionals and carers, for medicines to be administered in a disguised format without the knowledge or consent of the patient who lacks capacity. |
| **HOMELY REMEDY PROTOCOL** | A protocol, drawn up and agreed by local healthcare professionals (usually a medical practitioner or a pharmacist) to enable the administration of general sale list (GSL) and pharmacy only (P) medicines in care settings. |
| **MEDICINES ADMINISTRATION RECORD (MAR) CHART** | A written direction to administer medicine signed by a prescriber. The MAR chart authorises the administration of a medicine on the prescriber’s behalf. Also known as ‘patient administration chart’. |
| **NAMED INDIVIDUAL** | For the purposes of this professional guidance this is a senior member of the organisation with the delegated authority for overall responsibility for the safe and secure handling of medicines in the organisation. Where the organisation has a pharmacy team this is a suitable role for a Chief Pharmacist, Director of Pharmacy, or equivalent.  Where there is no pharmacy professional engaged by the organisation, the named individual should be sufficiently senior and seek advice from competent pharmacy professionals when designing, planning and reviewing services, and as necessary following any learning from incidents or adverse events involving medicines. |
| **ONE STOP DISPENSING** | The system whereby medicines are dispensed for individual patients on admission to a care setting with the intention that they are used throughout the episode of care and after discharge. The objective is to avoid delays and waste associated with dispensing separately to meet inpatient and discharge treatment needs. |
| **PATIENT** | The term ‘patient’ includes children and young adults, service users, clients and in the in the case of maternity services, women. The terms also extends to cover next of kin, carers or guardians who have responsibility for decision making on behalf of patients with respect to medicines/consent. |
| **PHARMACY PROFESSIONAL** | Registered professionals with the knowledge and skills in the safe and secure handling of medicines, namely pharmacists and pharmacy technicians. |
| **PHARMACY TEAM** | Pharmacy team encompasses all staff working in the delivery of pharmacy services. |
| **PATIENT GROUP DIRECTION (PGD)** | A written direction that allows the supply and/or administration of a specified medicine or medicines, by named authorised health professionals, to a well-defined group of patients requiring treatment of a specific condition. |
| **PATIENT SPECIFIC DIRECTION (PSD)** | An instruction from a doctor, dentist or other independent prescriber for a medicine to be supplied or administered to a named patient after the prescriber has assessed that patient on an individual basis.  e.g. written direction in patient’s notes or inpatient chart, MAR charts |
| **TRANSCRIBING**  **(also known as TRANSPOSING)** | Transcription is the copying of patient medicine details from one form of ‘direction to administer’ to another. Examples of ‘direction to administer’ include: discharge letters, transfer letters, medicines administration record charts.  Transcription does NOT include the addition of new items or changes. |

# Further questions

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| **QUESTION 5:**  **Have you used ‘Safe and Secure Handling of Medicines: a team approach’ previously in your organisation?** | |
| **YES:** | **NO:** |
| **If yes, please share how you have used the guidance** | |
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| **QUESTION 6:**  **Are there any statements where you feel that a case study would be helpful to illustrate how to apply the guidance in practice?** |
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| **QUESTION 7:**  **Do you have any case studies that you would like to share? Please give details.** |
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| **QUESTION 8:**  **What might be the financial and/or organisational barriers to using this guidance on practice?** |
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| **QUESTION 9:**  **Are there any other comments that you would like to make about the guidance?** |
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| **QUESTION 10:**  **Are there any supporting references or resources that you feel should be highlighted to support implementation of the guidance?** |
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**Note: Additional consultation questions appear at the end of each Appendix.**

# Appendix A. Administration of medicines – supplementary guidance

**This supplementary guidance is issued as an Appendix to the RPS Safe and Secure Handling of Medicines in all care settings and is not intended as a comprehensive stand-alone document. It should be read in conjunction with the core guidance.**

**All the principles in the core guidance regarding the safe and secure handling of medicines apply when administering medicines – this is in addition to the guidance in this Appendix.**

**A1** Healthcare professionals who administer medicines or when appropriate delegate the administration of medicines are accountable for their actions, non-actions and omissions, and exercise professionalism and professional judgement at all times.

**A2** In healthcare settings, the person administering is appropriately trained, competent and meets relevant professional and regulatory standards and guidance.

**A3** Medicines are administered to a [patient](#Glossary) in accordance with a [patient specific direction](#Glossary) (i.e. prescription), [patient group direction](#Glossary) or other relevant exemption specified in the Human Medicines Regulations 2012. (e.g. [medicines administration record chart](#Glossary), [homely remedy protocol](#Glossary)).

**A4** There are local standard operating procedures/protocols in use for the medicines administration process.

**A5** Wherever possible, the actions of prescribing and supply/administration are performed by separate healthcare professionals. Where clinical circumstances define it is in the interests of the patient for the same healthcare professional to be responsible for the prescribing and supply/administration of medicine on the same occasion, an audit trail and documentation is maintained.

**A6** If there are any risks associated with the handling or administration of a medicine, there is a procedure to minimise the risks, and suitable equipment is available. Staff have also undertaken the necessary training (see also [Health and safety of staff](#HS)).

**A7** Sufficient information about the medicine is available to staff and/or the patient to enable identification and correct use of the medicine (see also [Receipt of medicines](#RM)).

**A8** Before administration, the person administering the medicine checks it is clinically appropriate for the patient (e.g. allergies, previous adverse drug reaction, precautions, contraindications, co-morbidities etc.). Seek advice if necessary from a [pharmacy professional](#Glossary).

**A9** The organisation’s administration procedure is followed. This may include, but is not limited to, checking the following:

* the prescription or other direction to administer is unambiguous and includes where appropriate the name, form, strength, and dose of the medicine to be administered
* the identity of the patient
* the directions for administration (e.g. timing and frequency of administration, start and finish dates and route of administration)

**i.** **any** ambiguities or concerns regarding the direction for administration of the medicine are raised with the prescriber or a pharmacy professional without delay

**ii.** **any** calculations needed to provide the right dose are double checked ideally by a second person and uncertainties raised with the prescriber or a pharmacy professional

* the identity of the medicine and its expiry date
* that any specific [storage requirements have been maintained](#PI)
* that the dose has not already been administered by someone else (including patient or carers)
* that issues around consent have been addressed.

**A10** A risk assessment informs local procedures/protocols for second signatories, witness requirements, [transcribing](#Glossary), [one-stop dispensing](#Glossary) and delegating across all stages of the medicines pathway.

**A11** Records are kept of all medicines administered or withheld, as well as those refused by the patient.

**A11.1** Such records are completed immediately (i.e. at the time of the administration/refusal) and are clear, legible and auditable.

**A12.2** Where a medicine is not administered or refused, details of the reason why are included in the record.

**A12** Any adverse drug reaction experienced by the patient is managed in accordance with the organisation policy/SOP. Details of the reaction are documented.

**A13** When patients are discharged, transferred between clinical areas or from one care setting to another, the patient’s medicines or a supply of their medicines (including controlled drugs and fridge items) are transferred with them or obtained appropriately from the pharmacy See also [Appendix E – Operating theatres](#App_E).

**A14** Automated and semi-automated systems are used wherever possible to reduce risk and error in the supply chain, for example by compliance with [GS1 standards](https://www.gs1.org/standards).

**A15** Controlled drugs (CDs) are administered in line with relevant legislation and local standard operating procedures. See also [Appendix C – Controlled drugs](#App_C).

**A16** Where a change to the administration details (e.g. dose) is required for a prescribed medicine (other than a schedule 2 or 3 CD) and the prescriber is unable to issue a new prescription, the changes are communicated by an appropriately secure electronic method.

**A16.1** The patient’s records are updated.

**A16.2** The prescriber requesting the changes provides a prescription containing the new administration details as soon as possible (ideally within 24 hours).

**A17.** Patient self-administration – [see Appendix D – Patients’ own medicines](#App_D).

**Covert administration**

**A18** [Covert administration](#Glossary) is the term used when medicines are administered in a disguised format without the knowledge or consent of the patient. Medicines are administered covertly only in accordance with an agreed management plan.

**A19** Where deemed necessary, covert administration of medicines takes place within the context of existing legal and best practice frameworks – see [further guidance](#FG) below.

**Transcribing**

**A20** [Transcribing](#Glossary) is the copying of patient medicine details from one form of ‘direction to administer’ to another. Examples of ‘direction to administer’ include: discharge letters, transfer letters, medicines administration record charts.

**A21** Transcribing is NOT:

* prescribing
* the issue or addition of new medicines
* altering or changing the original.

**A22** Transcribing is used in the patient’s best interests to ensure the safe and continuous care: ensuring the patient’s medication is administered accurately, without undue delay and is not denied.

**A23** Local standard operating procedures/protocols are in use for transcribing.

**A24** Transcribing occurs with the organisation or manager’s agreement.

**A25** The person transcribing is competent and appropriately trained.

**A26** Transcribing is accurate. Transcribed entries are signed, dated and timed; then checked and witnessed. Particular care is taken in transposing details of high risk medicines such as insulin, anticoagulants, cytotoxics, or controlled drugs.

**A27** Medicines are not transcribed where details on the original document are illegible, unclear, ambiguous or incomplete.

**Further reading**

* Medicines and Healthcare products Regulatory Agency. Drug Safety Update. [Drug-name confusion: reminder to be vigilant for potential errors](https://www.gov.uk/drug-safety-update/drug-name-confusion-reminder-to-be-vigilant-for-potential-errors). 2018.
* National Institute of Clinical Excellence. Guidance. [Managing medicines for adults receiving social care in the community](https://www.nice.org.uk/guidance/ng67). 2017.
* National Institute of Clinical Excellence. Guidance. [Managing medicines in care homes](https://www.nice.org.uk/guidance/sc1). 2014.
* RPS Safe and Secure Handling of Medicines. [Appendix B – Investigational medicinal products](#App_B).
* RPS Safe and Secure Handling of Medicines. [Appendix E – Operating theatres](#App_E).
* Royal Pharmaceutical Society. [Professional Standards for Hospital Pharmacy](https://www.rpharms.com/resources/professional-standards/professional-standards-for-hospital-pharmacy). 2018.
* Royal Pharmaceutical Society. [Optimising medicines for people in secure environments](https://www.rpharms.com/resources/professional-standards/optimising-medicines-in-secure-environments). 2017.

**Further guidance on covert administration**

* Mental Welfare Commission for Scotland. [Covert Medication](http://www.mwcscot.org.uk/media/140485/Covert_Medication_final_feb_2017.pdf). 2017.
* National Institute of Clinical Excellence. [Managing medicines for adults receiving social care in the community](https://www.nice.org.uk/guidance/ng67). 2017.
* National Institute of Clinical Excellence. [Quality Statement 6 Covert Medicines Administration](https://www.nice.org.uk/guidance/qs85/chapter/quality-statement-6-covert-medicines-administration). 2015.
* PrescQIPP. [Best practice guidance in covert administration of medicines](https://www.prescqipp.info/resources/send/216-care-homes-covert-administration/2147-b101-covert-administration). 2015.
* Scottish Executive. [Administration of Medicines in Schools](http://www.gov.scot/Publications/2001/09/10006/File-1). 2006.
* UKMi. [What legal and pharmaceutical issues should be considered when administering medicines covertly?](https://www.sps.nhs.uk/wp-content/uploads/2017/03/Covert-administration-2017.doc) 2017.

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| **QUESTION A1:**  **Does Appendix A support the safe and secure handling of medicines during the administration of medicines?** | |
| **YES:** | **NO:** |
| **If not, why not?** | |
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| **QUESTION A2:**  **Is anything missing that you feel would demonstrate the delivery of the guidance?**  **Please illustrate using examples from your practice:** |
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| **QUESTION A3:**  **Are there any statements that you feel are unnecessary?**  **Please specify:** |
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| **QUESTION A4:**  **Are there any statements that you feel are unclear?**  **Please specify:** |
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# Appendix B: Investigational medicinal products – supplementary guidance

**This supplementary guidance is issued as an Appendix to the RPS Safe and Secure Handling of Medicines in all care settings and is not intended as a comprehensive stand-alone document. It should be read in conjunction with the core guidance.**

**All the principles in the core guidance regarding the safe and secure handling of medicines apply to clinical trials – this is in addition to the guidance in this Appendix.**

**B1** A clinical trial is defined in as ‘*any investigation in human subjects, other than a non-interventional trial, intended*:

* *“to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products,*
* *to identify any adverse reactions to one or more such products, or*
* *to study absorption, distribution, metabolism and excretion of one or more such”*

**B2** This process is regulated in the UK by the Human Medicines Regulations 2012 and The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031 and subsequent amendments).

**B3** The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for its implementation and monitoring and detailed guidance can be found at the MHRA website.[[27]](#footnote-27) More information about practical issues can be found on the Good Clinical Practice forum[[28]](#footnote-28) on the MHRA website and in the Good Clinical Practice Guide first published in 2012[[29]](#footnote-29).

**B4** As part of its medicines policy, each organisation has a specific policy for management of investigational medicinal products (IMPs). Procedures and systems are also in place for conducting trials and management of IMPs to ensure compliance with UK Regulations, the principles of Good Clinical Practice (GCP) and specific requirements of individual protocols.

**B4.1** The protocol has approval from an ethics committee and authorisation from the Health Research Authority (HRA) and MHRA.

**B4.2** Manufacture and/or assembly (packaging and labelling) of an IMP is undertaken by the holder of an authorisation (licence) for the manufacture of IMP (known as MIA(IMP) licence). All IMPs are manufactured to European Good Manufacturing Practice (GMP) Standards and trial sites are subject to MHRA Good Clinical Practice (GCP) inspection. Manufactured IMPs are labelled in accordance with Annex 13[[30]](#footnote-30) and certified for release by a Qualified Person (QP-IMP).

**B4.2.1** An MIA(IMP) is not needed:

* When the manufacture or assembly is in accordance with the terms and conditions of a marketing authorisation relating to that product.
* ‘The assembly is carried out in a hospital or health centre by a doctor, a pharmacist or a person acting under the supervision of a pharmacist an the IMPs are assembled exclusively for use in that hospital or health centre, or any other hospital or health centre which is a trial site for the clinical trial in which the product is to be used.[[31]](#footnote-31)

**B4.2.2** If manufacture or/and assembly of an IMP occurs outside the European Union or European Economic Area the product is imported by the holder of a manufacturer’s authorisation covering importation of the IMP. The QP(IMP) will release each individual batch and provide a certificate of compliance with European GMP. A copy of the certificate is provided to the end user.

**B5**  The Chief Pharmacist (or equivalent) has overall responsibility for pharmacy support of clinical trials although it is expected that a designated member of pharmacy staff will assume operational responsibility. The Principal Investigator will formally delegate the IMP management responsibility to the Chief Pharmacist and this is evidenced in the delegation log. It is the responsibility of the pharmacy staff involved to ensure that they have the relevant knowledge and skills to meet GCP requirements.

**B5.1** There is a variety of types of clinical trial investigational medicinal products (CTIMPs), including advanced therapy investigational medicinal products (ATIMPs): gene therapy, somatic cell therapy and tissue-engineered products, and radiopharmaceuticals. Specific guidance and regulations may apply to each of these.

**B6** Different types of IMP may have a range of different requirements for safe and secure handling and storage. It is essential to ensure that standard operating procedures are in place and appropriate facilities are available to meet these needs.

**B6.1** IMPs are stored separately from any other pharmacy stock. There are also facilities for segregation of returned and quarantined IMPs.

**B6.2** Where clinical trials take place in a hospital, all IMPs are stored and dispensed by the hospital pharmacy and managed to the same standards as licensed medicines, in accordance with local medicines management policy and the most current version of the study protocol.

**B6.3** When the trial involves a medicine used in an emergency or urgent care setting, sufficient stocks are held in the ward or department clinic for immediate use. When this is not possible, appropriate arrangements are made to ensure timely access to IMPs when clinically required.

**B7** Only qualified and registered healthcare professionals with prescribing rights (including supplementary and independent prescribers) can prescribe IMPs. All prescribers for a clinical trial are named on the delegation log for the study. In-hospital or clinic administration of medicines to trial participants is in accordance with locally agreed policies and procedures.

**B7.1** The patient information sheet (part of the informed consent package) is available to the [patients](#Glossary) when IMPs medicines are dispensed or administered.

**B8** Dispensed IMPs are labelled in accordance with Annex 13[[32]](#footnote-32) and local procedures, including the patient's identification and date of dispensing. If an unused IMP is returned to the sponsor, the patient’s identity must be removed or obscured, to maintain confidentiality.

**B9** Records of receipt, prescribing, dispensing, issue, administration, and disposal of all IMPs are kept to facilitate reconciliation. The identities of all those involved in these activities are also recorded.

**B9.1** Records are regularly monitored and audited by pharmacy against local policies and standard operating procedures. They are also subject to external monitoring and audit by e.g. the MHRA, independent clinical trial monitors and the organisation’s own Research and Development staff.

**B10** As for licensed medicines, local risk assessments of new IMPs are carried out. Potential sources of risk include cost, storage, dispensing, reconstitution, clinical use, blinding and unblinding and treatment allocation and treatment after trial.

**B11** Risk management procedures are in place to minimise identified risks to patients, staff and the organisation.

**B12** The sponsor categorises the IMP according to potential risks to trial subjects:

* Type A: no higher than the risk of standard medical care,
* Type B: somewhat higher than the risk of standard medical care,
* Type C: markedly higher than the risk of standard medical care.

**B12.1** The risk-adapted approach (Medical Research Council/Department of Health/MHRA Joint Project[[33]](#footnote-33)) provides a pragmatic approach to this categorisation by using the marketing authorisation and standard medical care. This risk assessment approach may be used to simplify the process for initiation and conducting some CTIMPs. It covers:

* the need for authorisation by the competent authority
* the content of the Clinical Trials Authorisation (CTA) application
* IMP management
* safety surveillance
* trial documentation
* GCP inspection.

**Further reading**

* Royal Pharmaceutical Society. [Professional Guidance on Pharmacy Services for Clinical Trials Version 1](https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Hospital%20Pharmacy%20Hub/professional-guidance--n-pharmacy-services-for-clinical-trials-141013.pdf). 2013**.**

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| **QUESTION B1:**  **Does Appendix B support the safe and secure handling of medicines of investigational medical products?** | |
| **YES:** | **NO:** |
| **If not, why not?** | |
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| **QUESTION B2:**  **Is anything missing that you feel would demonstrate the delivery of the guidance?**  **Please illustrate using examples from your practice:** |
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| **QUESTION B3:**  **Are there any statements that you feel are unnecessary?**  **Please specify:** |
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| **QUESTION B4:**  **Are there any statements that you feel are unclear?**  **Please specify:** |
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# Appendix C. Controlled Drugs – supplementary guidance

**This supplementary guidance is issued as an Appendix to the RPS Safe and Secure Handling of Medicines in all care settings and is not intended as a comprehensive stand-alone document. It should be read in conjunction with the core guidance.**

**All the principles in the core guidance regarding the safe and secure handling of medicines apply to controlled drugs – this is in addition to the guidance in this Appendix.**

**C1** Controlled drugs (CDs) are defined and governed by the Misuse of Drugs Act (MDA) 1971 and associated Regulations – principally the Misuse of Drugs Regulations (MDR) 2001 which fall within the remit of the Home Office.

**The Misuse of Drugs Act 1971** - the primary purpose of the MDA is to prevent misuse of CDs and makes it unlawful to possess or supply a CD unless an exception or exemption applies.

**The Misuse of Drugs Regulations 2001** enable certain classes of persons to possess, produce, supply, prescribe or administer CDs in the practice of their professions. A list of the most commonly available CDs is published by the [Home Office](https://www.gov.uk/government/publications/controlled-drugs-list--2).

**The Health Act 2006** introduced the concept of an ‘accountable officer’ and requires healthcare organisations, and those providing services to healthcare organisations, to have standard operating procedures in place for using and managing CDs.

**The Controlled Drugs (Supervision of Management and Use) Regulations** require all designated bodies to nominate or appoint a Controlled Drugs Accountable Officer (CDAO) to develop and implement systems for routinely monitoring the management and use of CDs and ensuring they are alerted to any risks, concerns and/or incidents.

**The Misuse of Drugs (Safe Custody) Regulations 1973** control the storage of CDs.

**C2** The NICE guideline (NG46) [Controlled Drugs: safe use and management](https://www.nice.org.uk/guidance/ng46) covers systems and processes for using and managing CDs safely in all care settings in England (except care homes).

Persons using these guidelines should refer to the latest version of relevant legislation and amending regulations and other associated guidelines for up-to date information on the handling of CDs.

**C3** At local level, Controlled Drugs Accountable Officers (CDAO) ensure the safe management and use of CDs within their organisation, and ensure systems are in place for recording concerns and reporting incidents relating to the safe management or use of controlled drugs.

**C4** Arrangements are in place to detect unusual or poor clinical practice, to encourage good practice, and to detect and deter criminality. The arrangements do not interfere with the appropriate use of CDs and good clinical care.

**C5** Controlled Drugs Accountable Officers (CDAOs) ensure relevant individuals receive appropriate training.

**C6** Up-to-date standard operating procedures (SOPs) or policies that comply with current legal framework are in place covering the management and use of CDs in areas such as (but not exclusively) the:

* security, including access to CDs
* receipt
* record-keeping, including transfer between care settings
* prescribing
* administration, including any witness requirements
* supply, including prompt access to ensure [patient](#Glossary) care is not compromised
* disposal, including any witness requirements
* clinical monitoring of patients who have been prescribed controlled drugs.

**C7** A risk assessment, taking into consideration each stage of the [medicines pathway](#MP), evaluates the handling of CDs (Schedules 2, 3, 4 and 5) in the organisation and informs what SOPs or policies are required.

**C8** SOPs or policies are reviewed regularly and after any incident involving CDs.

**C9** The storage of CDs meets the minimum requirements specified in legislation (where applicable) and prevents unauthorised access.

**C10** Each care area, e.g. ward, department, theatre, that holds CD stocks, keeps a record of CDs received and administered in a CD register (paper or electronic).

**C11** The balance of all entries in the CD register are checked and reconciled with the stock amounts in the cupboard.

**C.11.1** The frequency of such checks is determined locally after a risk assessment has been carried out to ensure that discrepancies can be identified in a timely way.

**C.11.2** Any discrepancies are investigated without delay and a local incident form completed. Unresolved discrepancies are reported to the CDAO.

**C12** Where part of an injectable CD is administered to the patient, the CD register details the amount given and the amount discarded.

**C13** Individual doses of CDs which have been prepared but not administered are destroyed and witnessed (in accordance with local risk assessment/SOP) and the reason documented.

The RPS is planning to issue more detailed guidance on CDs in secondary care in the future. The management of CDs in other settings is covered in details by the NICE guideline (NG46) [Controlled Drugs: safe use and management](https://www.nice.org.uk/guidance/ng46).

Please bear this in mind when considering your response to the questions below.

**Further reading:**

* Association of Anaesthetists of Great Britain and Ireland. [Controlled Drugs in Perioperative Care](https://www.aagbi.org/publications/guidelines/controlled-drugs-perioperative-care) 2006.
* Association of Anaesthetists of Great Britain and Ireland. [Position statement on administration of controlled drugs ay anaesthetists for patient use](https://www.aagbi.org/sites/default/files/AAGBI%20Position%20Statement%20on%20administration%20of%20controlled%20drugs%20by%20anaesthetists%20for%20patient%20use_0.pdf). 2015.
* Royal Pharmaceutical Society. [Medicines, Ethics and Practice – the Professional Guide for Pharmacists](https://www.rpharms.com/resources/publications/medicines-ethics-and-practice-mep).   
  (accessed online 31/01/18).

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| **QUESTION C1:**  **Does Appendix C support the safe and secure handling of medicines of controlled drugs?** | |
| **YES:** | **NO:** |
| **If not, why not?** | |
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| **QUESTION C2:**  **Is anything missing that you feel would demonstrate the delivery of the guidance?**  **Please illustrate using examples from your practice:** |
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| **QUESTION C3:**  **Are there any statements that you feel are unnecessary?**  **Please specify:** |
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| **QUESTION C4:**  **Are there any statements that you feel are unclear?**  **Please specify:** |
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# Appendix D: Patients’ own medicines – supplementary guidance

**This supplementary guidance is issued as an Appendix to the RPS Safe and Secure Handling of Medicines in all care settings and is not intended as a comprehensive stand-alone document. It should be read in conjunction with the core guidance.**

**All the principles in the core guidance regarding the safe and secure handling of medicines apply to patient’s own medicines – this is in addition to the guidance in this Appendix.**

**Medicines brought into the care setting by patients**

**D1** Organisations have a local policy in place and procedures for managing medicines that [patients](#Glossary) bring with them into the care setting, including that the medicines are assessed as fit for administration. These are drawn up in consultation with an appropriate [pharmacy professional](#Glossary).

**D2** Policies and procedures take into account current guidance on consent[[34]](#footnote-34) [[35]](#footnote-35) [[36]](#footnote-36) [[37]](#footnote-37) [[38]](#footnote-38) [[39]](#footnote-39) [[40]](#footnote-40) [[41]](#footnote-41) [[42]](#footnote-42) [[43]](#footnote-43)

**D3** Where medicines are brought into the care setting by a patient one of the following processes is followed and all actions recorded:

**D3.1** The medicines are retained in the care setting for the sole use of the patient during their stay. These are assessed and approved for use by appropriately-trained staff following positive identification and assessment against defined quality criteria (including appropriate labelling). Responsibility and arrangements for security are the same as with all stocks of medicines.

**D3.2** The medicines are securely stored by the organisation until they are returned to the patient prior to or upon discharge.

**D4** If no longer required and the patient or the patient’s carer agrees, the medicines are disposed of at ward level or sent to a pharmacy or waste management company for destruction, as appropriate (see also ‘Removal and disposal of surplus and waste medicines’. If the patient requests, the medicines may be returned to the place where the patient lives via an identified adult. Responsibility for security is given to that adult. The patient and/or patient’s carer is advised if the medicines are not safe and/or appropriate for use.

**Self-administration of medicines**

**D5** The organisation has a policy for self-administration of medicines. This sets out any exclusion criteria for self-administration and the responsibilities and accountabilities of the staff for the care of the patient who has assumed responsibility for the self-administration of their medicines.[[44]](#footnote-44)

**D6** Patients may retain or assume responsibility for some or all of their own medicines during their stay in the care setting, including any items provided as part of a [‘one-stop’ dispensing](#Glossary) process.

**D6.1** Systems and processes for this transfer of responsibility incorporate an assessment stage to determine whether:

**D6.1.1** the storage and administration of the patients’ medicines remain under the supervision of a heathcare professional

**D6.1.2** the patients’ medicines are stored under the supervision of a heathcare professional and the patient self-administers under supervision

**D6.1.3** the patient assumes full responsibility for the storage and self-administration of the medicine.

**D7** Transfer of responsibility occurs on the basis of an assessment of the patient’s ability to manage the tasks involved in self-administration of medicines and with the patient’s agreement.

**D8** Records are kept of any assessment undertaken and the outcome. The record includes details, including the time and date, of the patient’s agreement to assume responsibility of the self-administration of their medicines, where appropriate.

**D9** Processes are in place to ensure that the patient has controlled access to an adequate supply of the correct medicines. These are appropriately stored so that they are fit for use, and so that the medicines cannot be subject to unauthorised removal e.g. by other patients.

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| **QUESTION D1:**  **Does Appendix D support the safe and secure handling of medicines of patients’ own medicines?** | |
| **YES:** | **NO:** |
| **If not, why not?** | |
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| **QUESTION D2:**  **Is anything missing that you feel would demonstrate the delivery of the guidance?**  **Please illustrate using examples from your practice:** |
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| **QUESTION D3:**  **Are there any statements that you feel are unnecessary?**  **Please specify:** |
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| **QUESTION D4:**  **Are there any statements that you feel are unclear?**  **Please specify:** |
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# Appendix E: Operating theatres – supplementary guidance

**Includes some interventional areas such as radiology and cardiac catheterisation laboratories**

**This supplementary guidance is issued as an Appendix to the RPS Safe and Secure Handling of Medicines in all care settings and is not intended as a comprehensive stand-alone document. It should be read in conjunction with the core guidance.**

**All the principles in the core guidance regarding the safe and secure handling of medicines apply to operating theatres including some interventional areas in hospital settings such as radiology and cardiac catheterisation labs – this is in addition to the guidance in this Appendix.**

**E1** As outlined in the [core guidance](#near), manipulation of medicines in clinical areas is minimised and medicines are presented as “ready-to-use” or “ready-to-administer” wherever possible.[[45]](#footnote-45) [[46]](#footnote-46) [[47]](#footnote-47)

**E2**  All medicine-containing infusions and syringes are clearly labelled.3 [[48]](#footnote-48)

**E3**  If medicines are drawn up and labelled in a theatre setting this is done by the person who will administer them.[[49]](#footnote-49) [[50]](#footnote-50)

**E3.1** The exception to this is when a practitioner requires that a medicine is drawn up on their behalf because it would be unsafe or inappropriate for them to do so, e.g. when working in a sterile field. Where this is the case, these medicines are:

**E3.1.1** Checked with the requesting practitioner before they are opened

**E3.1.2** Drawn up in the presence of the requesting practitioner – and checked (medicine, diluent, dose, and expiry dateprior to administration.

**E4** Open systems (including gallipots and other types of open container such as moulded plastic procedure trays) are never used as containers for injectable medicines – with the exception only of embolisation procedures involving embolic agents that need to prepared openly.[[51]](#footnote-51) [[52]](#footnote-52) [[53]](#footnote-53) [[54]](#footnote-54) [[55]](#footnote-55)

**E5**  Medicines for epidural infusion or for continuous regional infusion are always supplied as ready-to-administer presentations and clearly identifiable (such as different coloured lines, bags and labels).[[56]](#footnote-56)

**E6** Infusion pumps for epidural or regional nerve block infusions are permanently dedicated for a single purpose, and appropriately coloured and labelled. They have appropriate security and safety features, such as locks and pass codes.10

**E7**  All local anaesthetic infusions are stored separately from intravenous infusion solutions10 and other segregation processes are applied where relevant, for example paediatric IV fluids.[[57]](#footnote-57)

**E8**  The Royal College of Anaesthetists (RCoA) and the Association of Anaesthetists of Great Britain and Ireland (AAGBI) have published guidance on the storage of drugs in anaesthetic rooms which form an ‘annexe’ to the main operating theatre and may sometimes be temporarily unoccupied.11 The following points incorporate elements of the pragmatic advice from these two organisations that are specific to this scenario and not already covered in the RPS core guidance.[[58]](#footnote-58)

**E8.1** Decisions about medicines security in anaesthetic rooms reflect a balance between patient safety, staff protection and security – the RCoA and AAGBI advise that they understand that this may mean, in defined circumstances, that medicines cupboards (excluding those that contain controlled drugs or medicines designated as controlled by a local Controlled Drugs Accountable Officer following risk assessment) will remain unlocked when the anaesthetic room is temporarily unoccupied and the operating theatre is in use. See also Appendix F – Storage of medicines for clinical emergency.

**E8.2** Patient safety is paramount and immediate access to a variety of medicines may be essential. Even short delays to access of medicines can make a difference to patient outcomes.

**E8.3** It is not possible to provide a national list of medicines that should be available at all times as these vary depending on patient condition and the surgical procedure being performed. There are few medicines stored in anaesthetic room medicine cupboards that will not be needed urgently on occasion. A core list of medicines that need to be immediately available in a specific setting may be developed at a local level.

**E8.4** Even if in the interests of patient safety medicines cupboards in anaesthetic rooms cannot be locked during surgical procedures, practices are followed that are aimed to minimise medicines security risks.

**E8.4.1** The roles as responsibilities within the theatre team with respect to the safe and secure handling of medicines are defined explicitly with respect to unlocked cupboards as a variance to the core guidance on Security and storage.

**E8.5** Measures to maintain security in anaesthetic rooms, such as viewing windows, CCTV, swipe card access are assessed for suitability at local level and maximised where appropriate.

**E8.6** Anaesthetic room medicine cupboards are locked when there is no patient care taking place in the operating theatre.

**E8.7** Medicines that are prepared for immediate availability in emergency during the course of an anaesthetic procedure and cannot accompany the patient from the anaesthetic room into the operating theatre are stored in the anaesthetic room securely, but in a manner that also maintains their immediate availability and integrity.

**E8.8** Medicines are adequately labelled and disposed of appropriately immediately following the anaesthetic procedure if they are not used for that patient.

**E8.9** Local standard operating procedures cover storage of and access to rarely-used emergency medicines that are stored in a central location, serving the entire theatre suite. The location of these medicines is clearly signposted.

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| **QUESTION E1:**  **Does Appendix E support the safe and secure handling of medicines in operating theatres (and other interventional areas in hospital settings such as radiology and cardiac catheterisation laboratories)?** | |
| **YES:** | **NO:** |
| **If not, why not?** | |
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| **QUESTION E2:**  **Is anything missing that you feel would demonstrate the delivery of the guidance?**  **Please illustrate using examples from your practice:** |
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| **QUESTION E3:**  **Are there any statements that you feel are unnecessary?**  **Please specify:** |
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| **QUESTION E4:**  **Are there any statements that you feel are unclear?**  **Please specify:** |
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# Appendix F: Storage of medicines – supplementary guidance

**This supplementary guidance is issued as an Appendix to the RPS Safe and Secure Handling of Medicines in all care settings and is not intended as a comprehensive stand-alone document. It should be read in conjunction with the core guidance.**

**All the principles in the core guidance regarding the safe and secure handling of medicines apply when storing medicines – this is in addition to the guidance in this Appendix.**

**F1** Medicine storage should be in line with national guidance and regulatory requirements. Audit trails and governance processes are in place to underpin the storage of medicines.

**F2** Controlled drugs (CD) storage complies, as a minimum, with current legislation and CDs are stored separately from other medicines. For further information on CDs - [see Appendix B – Controlled drugs](#App_B).

**F3** The following categories of medicines are stored separately in designated areas:

* medical gases
* flammable solutions (indicated by flammable pictogram)
* cytotoxics
* investigational medicinal products (see also [Appendix B – Investigational medicinal products](#App_B)).

**F4** Storage of different types of medicines is segregated as much as reasonably possible, to minimise patient safety risks from selection errors as below:

* intravenous fluids and sterile topical fluids
* epidural and intrathecal infusions and other designated “high risk” medicines
* injectable medicines
* oral solid medicines
* oral liquid medicines
* high dose opioids
* rectal medicines
* inhalers
* external medicines and medicated dressings
* medicines requiring refrigerated storage
* medicines requiring freezer storage
* medicines to take home
* patients’ own medicines.

Further segregation within groups will follow latest safety guidance including, but not limited to, adult and paediatric intravenous fluids, high dose opioids, sound alike/look alike drugs (SALADs).

**F5** Medical gases in cylinders are stored safely and securely to mitigate the following health and safety and diversion risks:

* cylinders can be heavy and can cause severe injuries if mishandled
* cylinders contain compressed gas at high pressure and can cause severe injury or death if damage leads to sudden escape of gas
* oxygen supports combustion and increases the risk of fire.
* other gases may cause suffocation if used inappropriately or be subject to theft, diversion and abuse.

**F5.1** Medical gas cylinders are stored in a cage, on a purpose designed trolley or secured to a wall by a safety chain, at all times. When transported in vehicles such as ambulances, cylinders are secured appropriately so they cannot move in transit.[[59]](#footnote-59)

**F6** Non-medicines and chemicals such as diagnostic reagents, including those for urine testing, non-medicated dressings and dietary supplements that may be accessed by people who would not otherwise have access to medicines are stored separately from medicines.

**F7** All medicines, including intravenous fluids and frequently used small volume injections in ampoules (such as sodium chloride 0.9% and water for injection) are stored in their original containers and not loose. Where this is not possible, enhanced risk assessments are undertaken and reviewed regularly.

**F8** Outside the pharmacy and pharmacy department, cupboards for the storage of medicines comply with the current British Standard(s). Cupboards are made of metal to ensure compliance with BS 2881(the current British Standard at time of writing).

**F8.1** Locks for metal cupboards (except patients’ medicine cabinets) comply with the current British Standard as a minimum. The current British Standard is BS 3621.

**F9** Cupboards and closed storage units in which medicines are stored and the rooms that accommodate these are lockable and locked when not being accessed.

**F10** Bulk flammable solutions are stored in lockable metal cupboards. A risk assessment is undertaken to determine whether a fire resistant cabinet is required - this may not be required for limited ready-use stocks in clinical areas.

**F11** A designated person is responsible for controlling access (by key or other means) to cupboards, trollies and rooms where medicines are stored.

**F11.1** A risk assessment is undertaken to determine the number of key copies and safe custody arrangements for these that are appropriate for the care setting at all times.

**F11.2** Electronic locking systems that secure areas used to store medicines use electronic keys, swipe cards or fingerprint and other technology that open the lock and lock immediately on closing the door. These systems allows cards or keys to be allocated to individual authorised persons, enabling audit of access to take place. Standard keypads where a number is shared with multiple users are not suitable for medicine cupboards, although may be suitable for clinical room doors.

**F12** Requirements for electronic medicines storage and issuing systems are agreed locally and include consideration of those for access to power and IT connectivity.

**F13** Medicine trolleys are lockable and secured at an anchor point (i.e. a point at which trolleys can be secured to the floor or wall). Alternatively, medicines trolleys may be stored securely in a locked room when not in use if access to the room is restricted to authorised persons.

**Storage of medicines for clinical emergency[[60]](#footnote-60)**

**F14** Storage arrangements in all care settings allow for immediate access to critical medicines in the event of a clinical emergency, e.g. cardiac arrest. For further information on theatre setting see [Appendix E: Operating theatres](#App_E).

**F15** These are held in containers that are clearly marked "for emergency use" and the locations of containers are clearly signposted.

**F16** These containers are tamper-evident and are not held in locked trolleys, locked cupboards or locked rooms, but at strategic and accessible sites.

**F17** Procedures are in place to ensure that as soon as possible after a box has been opened, a replacement is provided.

**F18** Policies and procedures are in place to manage the risks of theft of and tampering with these medicines.

**Temperature control**

**F19** Medicines are stored under conditions that assure their quality until they are used or administered.

**F20** Any decision to store a medicine or use a medicine which has been stored outside the recommended temperature range for a period of time is informed by a robust risk management approach to safeguard patient and public health.

**F21** A risk management approach is taken to determine suitable storage arrangements depending on patients’ needs, the type and range of medicines stored, the length of time that medicines will be stored and local environmental factors.

**F22** Temperature monitoring of all storage facilities for medicines is undertaken (whether for those at room temperature or other controlled conditions) to give assurance that medicines are stored appropriately.

**F23** There is a policy in place and procedures that outline the actions to be taken in the event of temperature excursions outside the range specified for the medicines being stored and assurance processes ensure that the procedure is followed.

**F24** For items that require refrigeration or freezing, the equipment used conforms to current guidance.[[61]](#footnote-61) [[62]](#footnote-62) [[63]](#footnote-63) [[64]](#footnote-64)

**F24.1** The temperature of the refrigerator or freezer is monitored on each working day using a calibrated maximum-minimum thermometer or other approved monitoring device and a recording system is in place. This may be a fully automated system, or a manual reading which is recorded by the person who monitors the temperature.

**F24.2** Staff reading the temperature are trained to ensure correct readings are recorded and that they understand how to reset thermometers where relevant.

**F25** Refrigerators and freezers are not overloaded to allow air circulation and medicines are not stored in contact with the sides of the refrigerator.

**F26** Refrigerators and freezers are locked when not in use.

**F27** Steps are taken to ensure that refrigerators and freezers are not accidently switched off.

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| **QUESTION F1:**  **Does Appendix F support the safe and secure handling of medicines in relation to the storage of medicines?** | |
| **YES:** | **NO:** |
| **If not, why not?** | |
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| **QUESTION F2:**  **Is anything missing that you feel would demonstrate the delivery of the guidance?**  **Please illustrate using examples from your practice:** |
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| **QUESTION F3:**  **Are there any statements that you feel are unnecessary?**  **Please specify:** |
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| **QUESTION F4:**  **Are there any statements that you feel are unclear?**  **Please specify:** |
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**Thank you for taking the time to respond to this consultation.**

**Consultation closes: Friday 20 April 2018**

**Please return this document to** [**support@rpharms.com**](mailto:support@rpharms.com)



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