Medicines Management Policy
A Guide to the Safe and Secure Handling of Medicines

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1 Introduction

Medicines optimisation is the safe and effective use of medicines. It ensures that the right patient gets the right choice of medicine at the right time and encompasses the entire way that medicines are selected, procured, delivered, prescribed, administered and reviewed to optimise outcomes of care. Healthcare providers must have appropriate policies, procedures and quality assurance systems in place to ensure that medicines are used and handled in a safe and secure manner.

Medicines play a crucial role in maintaining health, preventing illness, managing chronic conditions and treating disease. They are integral to the care and treatment provided by Locala each day. Locala is committed to the safe, effective and efficient use of medicines to support the provision of high quality care to patients.

The Medicines Safety and Drug and Therapeutic Committees oversee the management of medicines in Locala, ensuring colleagues and contractors have access to information on the law, best practice and safe systems of working. This policy sets out the minimum standard for the safe management of medicines within Locala and takes into account relevant legal frameworks and guidelines.
2 Purpose

The aim of this policy is to provide standards for all Locala colleagues who order, prescribe, administer, control, store, transport, dispose of or supply medicines as part of their role. The policy provides information on the safe and secure use of medicines and ensures compliance with the law, best practice and Care Quality Commission requirements.

The clinical elements of medicines optimisation and management such as choice of medicine, dose, route of administration and duration of treatment are beyond the scope of this policy, but should be appropriate to the patient’s condition plus take into account allergies, other medication the patient is taking and metabolic limitations. These are covered in relevant disease specific guidelines.

This policy must be read in conjunction with the relevant appendices and following Locala policies:

- Non-medical Prescribing Policy
- Controlled Drug Policy
- Medical Devices Policy
- Incident Reporting and Investigation Policy
- Patient Group Direction Policy
- Insulin Policy
- COSHH Policy
- Code of Business Conduct and Commercial Sponsorship
- Area Specific Standard Operating Procedures
- Guidance on Caring for a Family Member
- Delegation Guidelines
- Guidance on Caring for a Relative or Friend

3 Target Population

This policy is intended for all Locala colleagues, including those on temporary contracts as well as bank colleagues and students. All professionals are required to work within their professional code of practice and terms of service.
4 Explanation of Terms

Administer - To give a medicine by either introduction into the body (e.g. tablet, capsule or injection) or by external application (e.g. cream or ointment).

Controlled Drugs (CD) – Are named in Schedule 1, 2, 3, 4 or 5 of the Misuse of Drugs Regulations 2001 and are subject to special storage and handling requirements.

CD Accountable Officer - The person within a healthcare organisation who takes formal responsibility for all controlled drug handling and governance issues in their organisation. The Locala appointed CD Accountable Officer/Responsible Person has overall responsibility for ensuring the safe, effective use and management of CDs within the organisation.

Dispensing - The assembly and labelling of a medicinal product (including the addition of appropriate cautions, providing information leaflets and necessary counselling for the patient)

General Sales List Medicines (GSL) - A licensed product on the general sales list that can, with reasonable safety, be sold or supplied otherwise than under the supervision of a pharmacist.

Head of Medicines Management - The lead pharmacist within Locala who provides pharmaceutical advice on the management of medicines, including establishing, monitoring and reporting on systems that ensure the safe and secure handling of medicines.

Independent Prescriber – A healthcare professional responsible and accountable for the assessment and clinical management of patients, including prescribing.

Medicine - A substance, which may be administered for the purpose of diagnosis or for preventing or treating disease.

National Health Service Business Services Authority (NHS BSA) - An Arm’s Length Body of the Department of Health which provides a range of critical central services to NHS organisations, NHS contractors, patients and the public.

Non-Medical Prescribing - The term used to describe any prescribing by a healthcare professional other than a doctor or dentist.

Practitioner - A term used to describe a registered medical practitioner, nurse, pharmacist, dentist or other authorised healthcare employee.

Prescribe - To authorise in writing the supply or administration of a medicine.

Prescription Only Medicine (POM) - A medicine that usually requires a prescription, written by an appropriate practitioner (doctor, dentist, non-medical prescriber) before it can be sold or supplied.

Service Centre - A location from which healthcare is provided or which serves as a base for peripatetic practitioners. The term is used to include community clinics, adult training centres, special schools, walk-in centres, GP practices etc.
South West Yorkshire Area Prescribing Committee (SWYAPC) - comprises representatives from local NHS organisations and works to provide evidence based medicines management formularies and prescribing guidance for the population of South West Yorkshire.

Supplementary Prescriber – A healthcare professional responsible for continuing patient care following assessment by an independent prescriber, by working within a clinical management plan agreed with the independent prescriber and the patient.

Supply - To supply a medicine to a professional, patient or carer for administration.
5 Duties and Responsibilities

5.1 Individual colleagues

Each practitioner is accountable for their actions and omissions and must exercise their professional judgement and skill in any given situation. They must take into account Locala policies plus the relevant legislation and guidance from national and professional bodies as appropriate.

All colleagues must understand their scope of practice and work within it.

Individuals are responsible for following the standards described in this policy and must conduct the following in relation to medicines management:

- Identify and escalate risks
- Identify their training needs and make their managers aware of any training deficit
- Maintain personal records of all competency based assessments
- Report all medicines-related ‘near misses’, clinical incidents and serious incidents regarding the prescription, dispensing, storage and administration of medicines in line with the Incident Reporting, Management and Investigation Procedure.
- Act professionally and in line with guidance from their regulator and professional bodies
- Notify the Medicines Management Team of any changes required within Locala policies as a result of changes to practice or learning from incidents

5.2 Managers

Managers must ensure all staff in their areas are aware of and understand the policy and must:

- Investigate failure to comply with the policy
- Ensure medicines-related incidents are investigated, that lessons learned are disseminated and that recommendations are actioned
- Audit clinical practice associated with medicines storage and handling as appropriate
- Identify training needs and ensure staff are appropriately trained in medicines management
- Maintain logs of training and competency based assessment of staff in their sphere of responsibility
- Ensure medicine alerts are disseminated to staff working within their area / department

5.3 Medicines Management Team

The Medicines Management Team provide advice and guidance to colleagues and services on all aspects of safe and secure handling of medicines. This includes ensuring the correct legislative and best practice requirements are in place for colleagues to follow.
5.4 Medicines Safety Officer (MSO)

Locala has a dedicated MSO to fulfil the national requirements of the MSO role, who must:

- Ensure medicines safety principles are continually implemented and embedded throughout Locala
- Provide highly specialist medicines safety advice
- Review medicines safety related incidents and ensure learning is disseminated
- Co-ordinate the work of the Medicines Safety Committee

5.5 Medicines Management Committees

It is the responsibility of the Locala Medicines Safety Committee, Drug and Therapeutics Group and Policy Group to oversee the implementation and adherence to the policy. The terms of reference are available here.

5.6 Responsible Committee

It is the responsibility of the Locala Policy Ratification Group to ratify clinical procedures.

5.7 Chief Executive

The Chief Executive is ultimately accountable of the implementation of these organisation-wide processes.
6 Medicines Management Policy

The standards in this policy and appendices apply to all medicines used within Locala, including oral, inhaled, topical and injectable medicines, medicated dressings, diagnostic agents, and complementary medicines.

The following medicines are governed by this policy:

- Controlled drugs, which are controlled under the provisions of the Misuse of Drugs Act, with stringent requirements for supply, storage, administration and destruction (see also CD policy).
- All other medicines and medicinal products prepared for administration to patients that are controlled by the Medicines Act. This also includes diagnostic agents, X-ray contrast agents and medical gases.
- All complementary medicines e.g. aromatherapy or herbal remedies. These products are used for therapeutic purposes and require the same safeguards as other medicines. This category includes larvae.
- Other pharmaceutical preparations including nutritional products.
- Disinfectants, reagents and other preparations not used directly to treat patients.
- Some substances designated as Medical Devices under Medical Devices Directive (93/42/EEC) and the associated UK regulations implementing the directive (S1 1994 No 3017) but which are administered to patients as part of a medical or surgical procedure.

Where services provide care within shared premises or in conjunction with other providers the service must have a shared agreement in place which stipulates who is responsible for which aspects of the medicines process and which policies to follow in which circumstances.
7 Legal Authorisation of Supply or Administration

Medicines are obtained for most patients by an individual prescription named for the patient. Sometimes medicines may be supplied by other means such as patient group direction (PGD) or patient specific direction (PSD).

Prescription only medicines (POMs) may ONLY be supplied or administered:

- Under the direction of an appropriate practitioner e.g. a prescription or patient specific direction.
- Using a valid patient group direction.
- Under a Medicines Act Exemption (where they apply to health professionals).
- As an ‘emergency supply’ from a community pharmacy.
- When used in an emergency for the purpose of saving life (in accordance with the Human Medicines regulations).

Anyone can administer medication provided they are acting in accordance with the directions of an appropriate prescriber and are assessed as competent. A number of medicines are exempt from this restriction when administered in an emergency for the purpose of saving life (see section 7.4).

Any medicine which is not a prescription-only medicine or a general sale list (GSL) medicine is a pharmacy (P) medicine. Pharmacy medicines must be supplied by or under the supervision of a pharmacist from a registered pharmacy but can be supplied without a prescription.

If a supply of medicines is made to an individual who is not exempt from prescription charges, arrangements must be made to collect the national prescription charge. This also applies to medicines supplied under a patient group direction.

Patients who are not exempt must pay the national prescription fee for any medicine supplied from a Walk-in Centre. Walk-in Centre patients who are exempt from prescription fees must state this on a signed declaration form. Medicines administered at the Walk in Centre (e.g. a once only injection) are exempt from payment charges.

The Department of Health leaflets HC11 and HC12 provide guidance on exemptions and help with health costs. These are available to download from the Department of Health website at:

http://www.nhs.uk/NHSEngland/Healthcosts/Pages/Abouthealthcosts.aspx

7.1 Patient Group Directions (PGDs)

A patient group direction is a written instruction for the supply and/or administration of medicines to groups of patients who may not be individually identified before presentation for treatment.

Only registered healthcare professionals (as specified by the MHRA) and as updated by the Department of Health, may supply and/or administer medicines under the terms and conditions of a valid PGD. This responsibility CANNOT be delegated to others.
The registered healthcare professional must be adequately trained (all PGDs authorised for use indicate the qualifications required to work under them), and be authorised by their manager/clinical lead to work under the PGD.

See Locala Patient Group Direction Policy.

7.2 Patient Specific Directions (PSD)

A patient specific direction is a written direction by an independent prescriber instructing another healthcare professional or appropriately trained person to supply or administer a medicine directly to one or more named patient(s).

This can be a simple request in the patient’s notes or an entry on the patient’s drug chart. It may also be a list of patients’ names and addresses attached to a direction to supply or administer a certain medicine, e.g. patients on a clinic list.

Full responsibility and accountability lies with the independent prescriber who has written the instruction.

The following examples DO NOT meet the requirements of a PSD and are therefore not a legal authority for the administration or supply of medicines:

- A PGD template that has been renamed a “PSD” and used to instruct healthcare staff.
- A generic instruction to be applied to any patient who may be seen by a healthcare professional or who has an appointment on any particular day, for example, an instruction to administer a “flu vaccine” to any patient who fits the criteria attending clinics on a specific day.
- A verbal instruction.

7.3 Medicines Act Exemptions

This is an exemption in the legislation which allows a named groups of healthcare professionals to sell, supply or administer patient’s specific named medicinal products within the scope of their clinical practice e.g. midwives and paramedics. Within Locala there are currently no healthcare professionals who use Medicines Act exemptions.

7.4 Medicines Used in an Emergency

Individuals may administer medicines specified in Schedule 19 of the Human Medicines Regulations if this is for the purpose of saving life in an emergency without a written direction. This includes:

- Adrenaline 1:1000 up to 1mg for intramuscular use in anaphylaxis
- Atropine sulphate and obidoxime chloride injection
- Atropine sulphate and pralidoxime chloride injection
- Atropine sulphate injection
• Atropine sulphate, pralidoxime mesilate and avizafone injection
• Chlorphenamine injection
• Dicobalt edetate injection
• Glucagon injection
• Glucose injection
• Hydrocortisone injection
• Naloxone hydrochloride
• Pralidoxime chloride injection
• Pralidoxime mesilate injection
• Promethazine hydrochloride injection
• Snake venom antiserum
• Sodium nitrite injection
• Sodium thiosulphate injection

7.5 Non-Written Instructions to Administer Medicines (“Verbal Orders”)

Instruction by telephone to a practitioner to administer a previously unprescribed substance must NOT be accepted, except where the administration of medicines is to manage an emergency which otherwise endangers life or might result in serious harm.

In exceptional circumstances, if medication (except controlled drugs) has been previously prescribed and the prescriber is unable to issue a new prescription, but where changes to the dose are considered necessary, the use of information technology may be acceptable. This must be followed up by a new prescription signed by the prescriber who sent the fax/email confirming the changes within a maximum of 24 hours (72 hours maximum for bank holidays and weekends). Emails must be sent securely or when faxed this must be to a safe haven machine.

The practitioner receiving a verbal order must take reasonable steps to ensure that it is genuine and that the person sending the message is authorised to do so; the person must either be a prescriber authorised to prescribe the medicine or be following a protocol or similar instruction specified for that patient by an authorised prescriber. Since faxes and emails can be sent several times, the practitioner must ensure that he or she is not duplicating the actions of another in following the directions in the fax or email.

If there is no alternative to following a verbal order, the practitioner must make efforts to avoid any error. This may include repeating back the message, spelling out drug names, etc. The practitioner has the right to refuse a verbal order, after considering the risks of not accepting versus the risks of following it. In all instances the instruction must be fully documented, dated with times, and signed.
7.6 Discretionary Medicines (Homely Remedies)

Selected medicines can be administered by appropriately trained staff as necessary to ensure patients are comfortable until appropriate medical support is available. These are known as discretionary medicines or homely remedies. They must be administered in line with the homely remedy policy.

8 Allergies and Sensitivities

Allergy and sensitivity status must be checked when undertaking reconciliation, prescription, supply or administration of medicines.

An allergy is an immune system response which can result in anaphylaxis. Symptoms include a rash, changes in blood pressure and/or difficulty breathing that can be life-threatening.

A drug sensitivity is an inability to tolerate the adverse effects of a medication. For example, diarrhoea and gastric issues are known side effects of lansoprazole therefore these symptoms would be a sensitivity not an allergy. Sometimes drug sensitivities are tolerated by patients because the benefits of the medication outweigh the side effects.

All staff must be aware of their responsibilities including checking allergy status and allergy documentation, updating the allergy record if a new allergy is identified and reviewing allergy status.

Evidence relating to allergy status should be sought from at least two sources of information. The patient should be one of the information sources wherever possible. If the patient is not competent, information can be sought from a parent/guardian or named carer. This should be verified with at least one other current source e.g. primary care records such as SystmOne.

Where information conflicts exist e.g. differing medicines allergy information, it must be presumed that information from all sources is correct until proven, beyond doubt, to be wrong.

The member of staff must record the item the individual is allergic/sensitive to and the type of reaction which occurs. All paperwork used for prescribing medicines must include a section for allergy documentation (except FP10 prescriptions).
9 Prescribing

Prescribers must:

- be trained and assessed as competent, and have appropriate registration with their professional body as a prescriber before prescribing.

- have been authorised to prescribe within the organisation by the Medicines Management Team and had relevant prescribing rights added to their smartcard by the SystmOne Team.

Any qualified and registered independent prescriber may prescribe prescription only medicines for all medical conditions within their competency. For non-medical prescribers these conditions must be outlined in their intention to prescribe that has been submitted to the Non-medical Prescribing Lead (see Non-medical Prescribing Policy).

Independent prescribers may prescribe some controlled drugs if outlined in their intention to prescribe (see also Non-medical Prescribing Policy and Controlled Drugs Policy).

Supplementary prescribers can only prescribe in accordance with a clinical management plan (CMP) which has been agreed with an independent prescriber, the patient and the supplementary prescriber. The CMP can allow the administration and supply or direct another person to administer controlled drugs in schedules 2, 3, 4 and 5, and unlicensed medicinal products where appropriate.

Community practitioner nurse prescribers can prescribe from the British National Formulary (BNF) Nurse Prescribers’ Formulary for Community Practitioners, which includes the majority of dressings and appliances, and a limited range of prescription only medicines.

NHS dentists can prescribe from the BNF Dental Practitioners’ Formulary.

(See also Appendix 1 – Prescribing)
9.1 Formulary and RAG Status

National or local treatment guidelines and formularies must be followed (where available). These must be approved by Locala Drug and Therapeutics Committee or the South West Yorkshire Area Prescribing Committee as appropriate. All approved formularies are available on the Medicines Management webpages or SWYAPC website.

SWYAPC use a colour coding system to classify which prescribers can prescribe which medication (Red, Amber, Green (RAG) status).

**Red drugs** are prescribed, maintained and monitored by a hospital specialist.

**Amber drugs** are initiated by a hospital consultant or specialist service who prescribe and monitor the patient until they become stabilised on treatment. After this the patient’s care is transferred to the GP in line with shared care guidance.

**Green with specialist initiation drugs** are initiated by a specialist, but have no requirement for additional monitoring for toxicity over and above the general requirements for all medicines.

**Green drugs** are deemed suitable for initiation, stabilisation and maintenance in a primary, secondary or tertiary care setting.

**Grey drugs / DROP-List medicines** are considered less suitable for prescribing and should only be prescribed in exceptional circumstances.

**Black drugs** are medicines that commissioning organisations across the SWYAPC boundaries have agreed with local trusts and clinicians that they will not commission locally.

Prescribers must be aware of the classification of the medication they intend to prescribe and the necessary monitoring and prescribing requirements before considering issuing the prescription.

Shared care protocols must be followed where joint responsibility for the prescribing and monitoring of medicines is assumed between primary and secondary care. The most recent shared care classification list, together with copies of approved Shared Care Guidelines, are available from the web-formulary.

Prescribers must also be aware of Blacklisted preparations which are not available nationally on NHS prescriptions (published in Part XVIIA of the NHS Drug Tariff denoting medicines and/or specific brands of medicines)

All private CD prescribers MUST be registered with the NHS BSA by the CD Accountable Officer/Responsible Person for Locala to receive a unique prescriber code, and will be required to write CDs on a FP10PCD prescription form.
The patient’s medical record must always be checked before a new item is prescribed and any advance statement / directive must be taken into account.

Prescribing for overseas visitors must be in line with national guidance for NHS treatment.

9.2 Prescribing for Self, Family and Friends

The General Medical Council, Nursing and Midwifery Council, and The General Pharmaceutical Council, recommend that prescribers must not prescribe for themselves, members of their family, friends, or colleagues directly employed or working in the practice, unless the colleague is a registered patient with the relevant Locala service. If this situation arises it is good practice to refer the person to another prescriber or their own GP. (See also Guidance on Caring for a Relative or Family Member)

9.3 Prescription request/task

Occasionally Locala clinicians may need to request a prescription for a new treatment or change of treatment from the patient’s GP. Locala colleagues must make requests in writing for any prescriptions required from an external organisation/agency clearly stating the name of the drug, dose, frequency and quantity required. This written request may be sent via safe electronic means (i.e. SystmOne task) or to a safe haven fax as agreed with the receiving organisation/agency.

9.4 Electronic Prescription Service (EPS)

EPS enables prescribers to send prescriptions electronically to a dispenser (e.g. community pharmacy or dispensing appliance contractor) nominated by the patient. This makes the prescribing and dispensing process more efficient and convenient for patients and staff. Currently this is only available within GP practices not community services.

10 Transcribing

Transcribing involves transferring written medicine details from one form of direction to administer to another. This includes, for example, discharge letters, transfer letters, administrations charts, whether hand-written or computer-generated. It also includes the transfer of information to administration records in a care homes when details are copied from the dispensed medicine’s label (see Appendix 3 – Transcribing).
11 Administration of Medicines

- Medicines must be administered by appropriately qualified and competent individuals in accordance with a relevant authorisation (see section above). This includes the correct use of devices (see also Medical Devices Policy).

- Only medicines of assured quality, efficacy, and safety will be administered (see also Appendix K).

- It is the responsibility of the member of staff undertaking the administration to check the patient’s identity before any drug administration. Staff must always check patient details to be sure they are dealing with the right person using at least 3 identifiers.

- Ensure the 8 rights of medicines administration are followed
  1. Right patient
  2. Right medication
  3. Right dose
  4. Right route
  5. Right time
  6. Right documentation
  7. Right reason
  8. Right response

- All reasonable endeavours will be made to gain the patient’s consent before administration is undertaken in line with Department of Health Reference Guide to Consent to Examination or Treatment, available on ELSIE (see also Appendix 4 Covert Administration of Medicines).

- Each colleague that administers a medicine with the potential to cause anaphylaxis must have ready access to adrenaline (epinephrine) injection of the necessary strength and quantity, and have had appropriate training to be competent in treating anaphylaxis (see Appendix 5 – Medicines for Use in an Emergency).

- The patient record must be completed immediately after a dose is given to the patient. The most appropriate organisational/electronic documentation must be used to record the information. In some instances there may be both electronic and paper records in situ which must be completed.

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

- Staff giving drugs must have access to and be aware of appropriate reference sources to support safe administration, including IV (intravenous) administration guidance (Medusa), the BNF and Regional Medicines Information.

- Medicines must be discussed with patients or their representatives at the time of drug administration where possible.
• The expiry date of medication must be checked prior to administration (see Appendix 6)

• Good practice requirements for administering medication is outlined in Appendix 7

• See also “Patient Self-Administration of Medicines” (Appendix 8).

11.1 Administration of Medicines by Non-registered Professionals

Colleagues other than registered healthcare professionals may be engaged in the handling or administering specific medicines provided that it is specified in their job description. They must have undertaken the required training, be deemed competent to do so by the appropriate manager, and must adhere to a local written and approved protocols. They must not be involved in the administration of medicines that are not defined within their local service procedures.

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

11.2 Administration of Medicines by Practitioners in Training

Practitioners in training must be given every opportunity to become competent in medicines related activities under appropriate supervision. The supervising practitioner has responsibility for medicines procedures at such times.

Student practitioners who are not registered in their own right must not administer medicines without supervision. They must only administer medicines under the direct supervision of a suitable registered practitioner (this includes all medicines administered by any route), and the details of each occasion must be documented in the patient record.
12 Dispensing and Supply of Medicines and Dressings

For most patients medicines are obtained via a prescription, which has been issued by an appropriate practitioner for the medical treatment of that individual. The prescription is then dispensed by or under the supervision of a pharmacist or dispensing doctor, according to national legislation, before being supplied to that patient.

Dispensing is the assembly and labelling of a medicinal product (including the addition of appropriate cautions, providing information leaflets and necessary counselling for the patient). Dispensing must not occur within Locala. This does not apply to pre-labelled packs which may be supplied by registered nurses in accordance with the pre-pack procedures (Appendix 9)

13 Procurement, Ordering, Transport & Storage of Medicines

13.1 Procurement

- All medicines must be sourced from Locala approved supplier and be appropriate and legitimate for their intended use.

- The ABPI Code of Practice for the Pharmaceutical Industry 2014 and Locala Code of Business Conduct must be consulted when procuring medicines.

13.2 Ordering of Medicines for Locala Services

- The contents of service stock lists and formularies, and any variations to these lists, must be agreed by the Head of Medicines Management and/or the Drug and Therapeutics Committee before updating and amending stock lists.

- Only a designated professional or authorised designated person may order medicines for their service. Suppliers will ONLY accept orders from these designated signatories.

- Orders can be sent via email, post, fax or EPROC system depending on the supplier.

- Order books and requisition forms should be treated as controlled stationery and kept in a locked location.

See Appendix 10
13.3 Transport and Receipt of Medicines

- Transport includes the transfer of medicines between sites within Locala’s geographical area e.g. between Locala sites and/or outside locations e.g. a patient’s home.

- Colleagues engaged in transportation of medicines must be identified, authorised, and appropriately trained.

See Appendix 11

13.4 Storage of Medicines

- Medicines must be stored securely in either a lockable cupboard, or a medicine trolley, which can be secured to a wall when not in use.

- The team leader in charge is responsible at all times for the safekeeping and secure storage of medicines in their service, and ensuring that all medicines are stored according to national legislation and local policy.

- Medicines will be stored in an approved, secure location and there will be a reasonable need for the medicine in that location. Access to medicines will only be by authorised personnel.

- This safe and secure storage also applies to prescription pads and stationery used to order medicines (see appendix 12)

- All internal and external medicines, disinfectants and reagents must be stored in locked cupboards, fridges, trolleys or other secure cabinets – all reserved solely for medicinal products. The only exceptions to this requirement are:
  
  o medicines for clinical emergencies which MUST be stored in a tamper evident container, in an easily accessible location (NOT a locked cupboard), when clinical procedures are taking place and must be stored away securely at the end of each clinic day (See appendix 5 – Medicines for Use in an Emergency)

  o intravenous fluids, sterile topical fluids, nutritional products and some bulky medicated dressings, which because of their bulk can be stored in a secure clean area, to which the general public does not have access. Under no circumstances must products be placed on the floor.

- Internal medicines must be stored separately from medicines for external use. Under no circumstances must medicines be transferred from one container to another, nor must they be removed from their original container and left loose. All medicines in transit must be stored in a sealed tamper evident container.

- Cupboards or refrigerators for the storage of medicines must be sited where they are convenient for colleagues, allow adequate space to permit surveillance and afford maximum security against unauthorised entry. Medicine cupboards
should generally be sited in a clean utility room to which unauthorised persons do not have access. Cupboards must not be sited where they may be subject to higher than average humidity or temperature. Reagent cupboards must be sited in areas where testing is carried out.

- Medicines and vaccines that require refrigeration MUST be stored in an approved dedicated medicines fridge that is temperature monitored to maintain the stability of the medicines (Refer to Locala Cold Chain policy).

- Controlled drugs must be kept in a locked cupboard, solely for the storage of CDs, which must be secured to the wall. Refer to Locala CD Policy.

- Flammable liquids, gases and aerosols must be stored in line with Health and Safety policies.

- See also Appendix 13

14 Medicines in Patients’ Homes

- Patients or their carers are responsible for storage of patient drugs in their homes.

- Patients should be encouraged to store drugs in a safe place and out of the reach of children.

- If a practitioner has concerns about medicine storage in a patient’s home they must undertake a risk assessment, which must be recorded in the patient’s notes.

- Medicines prescribed for a patient are legally the property of the patient and consent must be sought prior to removal for safe disposal. There is an exemption if the medicines pose an immediate risk to patients or the public. When medicines are removed this must be clearly documented and signed by the patient. The relevant form and procedure can be accessed via Elsie.

- Drugs must be stored under appropriate conditions e.g. appropriate temperature. Storage should not be near a radiator nor in warm, damp places e.g. kitchen or bathroom, and away from direct sunlight. Medicines should be kept in the original container that they were dispensed in.

- Patients/carers must be advised to take any unwanted medicines back to a community pharmacy for safe disposal.

- See also appendix 14
15 Discharge or Transfer of Patients from one Service to Another

- Healthcare professionals transferring a patient must ensure that all necessary information about the patient's medicines is accurately recorded and transferred with the patient, and that responsibility for on-going prescribing is clear.

- The healthcare professional responsible for taking over the care of a patient, must check that information about the patient's medicines has been accurately received, recorded and reconciled. See appendix 15 – Medicines Reconciliation

- Information about patient’s medicines must be communicated in a way which is timely, clear, unambiguous and legible; ideally generated and / or transferred electronically.

- Communications with GPs, patients, carers and community pharmacists about discharge medication should be timely and comprehensive.

- Giving a medication to a patient to take home is classed as supplying medicines. The same checks as administering must be used to ensure safety i.e. right patient, right drug, right dose, right time, duration of treatment.

- It is also the practitioner’s responsibility to ensure the patient and/or his/her carer is aware of why, when and how the medicines should be taken, what side effects may occur and what action to take should this happen.

- A discharge or transfer checklist should be used.

- Patient medicines lockers (also known as patient own drug (POD) lockers) must be emptied at the time of discharge or transfer.

- Any patient own controlled drugs stored in central CD cupboards and any items held in the medicines fridge must also be returned to the patient.

- Medication which the patient is routinely prescribed by other organisations eg the hospital, should be documented in the 'other medication' section of SystmOne.

- See also Admission and Discharge Policy.

16 Disposal of Medicines and Sharps

For general guidance on disposal of Waste Medicines and Sharps see Locala Waste Management Guidelines

For the disposal of controlled drugs see controlled drugs policy.
17 Managing Medicines Risk

17.1 Managing Errors or Incidents relating to Medicines

All medicines incidents must be reported and handled in line with the Locala Incident Reporting, Management and Investigation Procedure and Duty of Candour Guidance. All medicines incident reports received through Datix will be reviewed by the Medicines Management Team.

External incidents received will be sent to the medication safety officer within the relevant organisation on a quarterly basis, unless the incident is deemed to have the potential to cause moderate or significant harm or involves a controlled drug, in which case it will be reported immediately.

See also controlled drugs policy.

17.2 Adverse Drug Reaction Reporting

- Any drug may produce unwanted or unexpected adverse reactions. Detection and recording of these is important to identify any trends and themes. Prompt reporting must be carried out for any suspected adverse reactions to new drugs and vaccines under intense surveillance. Drugs under intense surveillance are given the symbol of an inverted black triangle (▼).

- Reporting must also be undertaken for unlicensed drugs and for any serious or unusual reactions to established products. Reporting must be carried out for both prescribed drugs and those medicines obtained by patients over the counter and herbal medicines.

- If a severe or unexpected reaction to a prescribed medicine occurs, the prescriber should report this to the Medicines and Healthcare Products Regulatory Authority (MHRA) as appropriate.

- All colleagues must also report any adverse drug reactions through the Datix.

- The patient’s GP must be informed of any adverse reaction to a drug or dressing prescribed by a non-medical prescriber.

17.3 Medicine Defect Reporting

A defect is present if a product supplied by the manufacturer is not of the expected standard. Defects may involve inadequate or incorrect labelling, ineffective packaging, contamination, discoloration, breakage, or incorrect contents.

When a defect is found or suspected in a medicine:

- If the medicine is a stock item in a service centre inform the relevant supplier. Otherwise inform the community pharmacy from which the medicines were obtained.
They will advise and implement any necessary reporting, recording and investigation of the defect.

- Report the defect to Locala Head of Medicines Management.
- Retain and quarantine any remaining product and associated products or equipment.
- Record the details of the product and the defect.
- If the product has been administered to a patient, inform the doctor responsible for the patient and record the defects in the patient’s notes.
- Report the incident using the Datix Incident Reporting System.
- Adverse incidents arising from the use of a medicinal product or medical device thought to be defective must also be reported to the Medicines and Healthcare Regulatory Agency (MHRA).

17.4 Healthcare Safety Alerts, Drug/Device Recalls and other communications

When defects represent a significant hazard to health, the Medicines and Healthcare Products Regulatory Authority (MHRA) may issue a drug alert, which provides 4 categories of urgency for recall or caution in use. These alerts/recalls will be actioned in line with the Locala alert process.

A number of other communications are routinely received by the Medicines Management Team. These include letters to healthcare professionals, patient safety notices involving medicines and vaccine updates. All communications received are logged on the Medicines Management Team Communication Log including any relevant action taken to provide assurance to the Medicines Safety Committee that communications are being actioned.

17.5 Control of Substances Hazardous to Health Regulations (COSHH)

The Control of Substances Hazardous to Health Regulations, known as COSHH, is the UK legislation on chemical hazards at work. Some medicines, by their nature, are hazardous. Assessment of medicines which come under COSHH should be assessed in line with the Locala COSHH Policy.
18 Unlicensed Medicines

A drug company must have a licence to market a medicine. The licence states:

• which condition(s) the medicine can be used for
• what dose(s) can be used, and how long for
• how the medicine should be stored and given (e.g. by mouth, by injection)
• which group of patients it can be used for
• warnings about possible side effects and interactions with other medicines

The above details can be found in a licenced product’s Summary of Product Characteristics (SPC). Using a medicine in a way other than as described in its licence is called off-label use, and renders the product unlicensed.

Practitioners who prescribe unlicensed products take complete responsibility and liability for any adverse reactions which may occur, and may be called upon to justify their actions.

All unlicensed medicines initiated by hospital prescribers are classified as ‘red drugs’ and must be prescribed by a hospital specialist only.

Generally Locala employed practitioners must not prescribe unlicensed medicines. However on occasions, an unlicensed product in the UK may be substituted for a licensed product with the sanction of the Department of Health or Public Health England.

Such products may be prescribed and administered either using a prescription, under a Patient Specific Direction or an agreed protocol. This will have been authorised by Locala Drug and Therapeutics Committee.

The Locala Non-medical Prescribing Policy provides further information for colleagues on unlicensed and off-label prescribing.

Refer to MHRA Off-label or unlicensed use of medicines: prescribers' responsibilities for further information on the prescribing of unlicensed and off-label drugs.

19 Complementary and Alternative Medicines

The use of complementary or alternative medicines within Locala must be authorised through the Drug and Therapeutics Committee. The APC website provides commissioning statements regarding the restrictions on the prescribing of herbal and homeopathic preparations.
20 Clinical Trials

All clinical trials in the UK are governed by the Medicines for Human Use (Clinical Trials) Regulations 2004.

If you wish to participate in any clinical trials involving medicines or research regarding any aspect of medicines management please contact a member of the Medicines Management Team.

21 Relations with the Pharmaceutical Industry and Commercial Sponsorship

Sponsorship must not be accepted for activities that will place pressure on prescribers to compromise patient safety, efficacy, or cost-effectiveness in the prescribing of medicines.

Practitioners must not give samples or materials received from pharmaceutical companies to patients/clients unless pre-approved at the Drug and Therapeutics Committee. This includes dressings, nutritional supplements, medicines, devices, etc. This is to prevent issues relating to probity and transparency in the selection of products and to ensure in line with local formulary and guidance.

Refer to Locala Business Conduct and Commercial Sponsorship Policy.

22 Availability of Medicines Out Of Hours

Medicines required by patients out of hours can be obtained via a number of routes depending upon the circumstances. Further information is available via the NHS Choices website.

In the event that an urgent prescription is needed out of hours and cannot wait until the next day, Local Care Direct should be contacted by ringing 111. Where it is not possible for the patient to access the medicine via the available pharmaceutical services, Local Care Direct will issue, (if stocked), the complete course of the medicine to the patient.
23 Training and Education

All colleagues involved in the storage and handling of medicines must be appropriately trained and competence assessed. They must also have knowledge of the risks related to products and procedures within their area of work.

23.1 Continuing Professional Development (CPD)

The requirements for the 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) in line with organisational and professional body requirements.

24 Equality Impact Assessment

Locala Community Partnerships aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. The Equality Impact Assessment Tool (Appendix A) provides evidence of analysis undertook to establish whether its policies and practices would further, or had furthered, the aims set out in the section 149 (1) of the [Equality Act 2010].

25 Consultation Process

This policy has been widely circulated within the organisation. See Appendix B for full details.

26 Dissemination and Implementation

26.1 Dissemination

The ratified document will be uploaded onto the Medicines Management Policies section of Elsie and the previous version removed and archived. To inform colleagues of the new policy, a supporting article will be circulated within Locala Live, placed in the Business Unit Report and discussed at relevant forums. The Medicines Management Team will undertake and number of re-launch communications and activities. A reminder and refresher article will be included in the next Medicines Newsletter.

26.2 Training

No specific training is required for the implementation of the updated policy however a number of re-launch activities will be undertaken – see above.
27 Monitoring Compliance with the Document.

27.1 Process for Monitoring Compliance

The Medicines Management team and services will monitor compliance by conducting audit, routine inspections of services and by routinely reviewing incidents to identify learning and trends as part of a rolling process (See appendix 17).

All Locala premises (community clinics, team bases and other service centres), will be inspected by a member of the Medicines Management Team on an annual basis.

The purposes of these inspections are to:

- Ensure the safety of patients & colleagues.
- Provide information on the standards required for satisfactory performance and compliance with legislation relating to the control and use of medicines.
- Establish safe and efficient systems for medicines control and use within Locala.
- Reduce risks in the day-to-day operation of the components of medicines control and use.
- Ensure that the quality of prescribing, recording, administration, storage, disposal and monitoring of medicines is of the required standards.
- Support medical, nursing, pharmacy, dental and other colleagues dealing with all aspects of medicines whilst delivering safe, appropriate care with medicines for patients.
- Achieve continual improvement in the use of medicines in Locala by promoting effective risk management.
- To ensure that the standards laid out by the Care Quality Commission are met.

Specific medicines management audits are compiled and approved through the Audit and Effectiveness Committee and relevant medicines committee to provide assurance to the organisation, teams, colleagues and our patients that the use of medicines in the community setting closely follows the correct legislative requirements and best clinical practice (see Audit Policy).

Monitoring and findings will be reviewed at the Medicines Safety Committee.

Failure to adhere to the content of the policy may also be a breach of an individual's relevant professional body's registration requirements and the law.

27.2 Key Performance Indicators

Annual inspection of each service
Action plan for each service
Number of completed actions
Number of incidents
28 References / Bibliography

- The Code for nurses and midwives (2015)
- The Medicines Act 1968
- The Misuse of Drugs Act 1971
- The Misuse of Drugs Regulations 2001
- The Controlled Drugs (Supervision and Management of Use) Regulations 2013
- The Safe and Secure Handling of Medicines (Revision of Duthie Report 1988) 2005
- The Health Act 2006
- Control of Substances Hazardous to Health (COSHH) Regulations 2002
- Environment and sustainability Health Technical Memorandum 07-01: Safe management of healthcare waste
- The Human Medicines Regulations 2012 (SI 2012 /1916
- The Human Medicines (Amendment) Regulations 2013
- The Human Medicines (Amendment) (No. 2) Regulations 2013
- The Human Medicines (Amendment) Regulations 2014
- The Human Medicines (Amendment) (No. 2) Regulations 2014
- The Human Medicines (Amendment) Regulations 2015
- The Human Medicines (Amendment) (No. 2) Regulations 2015
- The Human Medicines (Amendment) (No. 3) Regulations 2015
- http://www.mhra.gov.uk/
- Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes

29 Associated Policy Documentation

Mental Capacity Act and Deprivation of Liberty Safeguards (DoLS) Policy and Guidance 2016


Controlled Drugs (CD) Policy

Policy on the Storage and Handling of Vaccines and Other Medicines Requiring Cold Storage ‘Cold Chain Policy’

Non-medical Prescribing Policy
Policy For The Development, Approval And Implementation Of Patient Group Directions (PGDs)

Waste Management Guideline
Risk Management (Health & Safety Policy)

Code of Business Conduct and Commercial Sponsorship

‘Risk Management (Incident Reporting and Investigation) Policy and Guidance.'
# Appendix A – Equality Impact Assessment

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<tr>
<th></th>
<th>Yes/No</th>
<th>Comments</th>
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<tbody>
<tr>
<td><strong>1.</strong> Does the document/guidance affect one group less or more favourably than another on the basis of:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Race</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>• Ethnic origins (including gypsies and travellers)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>• Nationality</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>• Gender (including gender reassignment)</td>
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<td></td>
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<tr>
<td>• Culture</td>
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<td></td>
</tr>
<tr>
<td>• Religion or belief</td>
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<td></td>
</tr>
<tr>
<td>• Sexual orientation</td>
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<td>• Age</td>
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<td></td>
</tr>
<tr>
<td>• Disability - learning disabilities, physical disability, sensory impairment and mental health problems</td>
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<td></td>
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<tr>
<td><strong>2.</strong> Is there any evidence that some groups are affected differently?</td>
<td>No</td>
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<tr>
<td><strong>3.</strong> If you have identified potential discrimination, are there any valid exceptions, legal and/or justifiable?</td>
<td>N/A</td>
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<tr>
<td><strong>4.</strong> Is the impact of the document/guidance likely to be negative?</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td><strong>5.</strong> If so, can the impact be avoided?</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td><strong>6.</strong> What alternative is there to achieving the document/guidance without the impact?</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td><strong>7.</strong> Can we reduce the impact by taking different action?</td>
<td>N/A</td>
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If you have identified a potential discriminatory impact of this procedural document, please provide suggestions as the action required to avoid/reduce this impact.
Appendix B – Consultation Process with Key Stakeholders

Stakeholders are usually people with specialist knowledge of the subject or who potentially will be affected by it. Stakeholders you should consider are:

- A member of Medicines Management Team (Rachel Urban / Basia Engiert)
- Infection Control (Sheena Kelly)
- Safeguarding
- Training (Liz Clough)
- Business Unit Group

<table>
<thead>
<tr>
<th>Stakeholder name and designation</th>
<th>Date feedback requested</th>
<th>Date feedback received</th>
<th>Details of feedback received</th>
<th>Action taken</th>
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<tr>
<td>Damian Conway, Walk in Centre</td>
<td>17/7/17</td>
<td></td>
<td>Include responsibilities where services use medicines of other organisations</td>
<td>Added: Where services provide care within shared premises or in conjunction with other providers the service must have a shared agreement in place which stipulates who is responsible for which aspects of the medicines process and which policies to follow in which circumstances.</td>
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<td>Claire McKay</td>
<td>17/7/17</td>
<td></td>
<td>Add how to interpret expiry dates</td>
<td>Table added</td>
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<td>Elizabeth Ruane</td>
<td>17/7/17</td>
<td></td>
<td>Transport of Medicines when admitting into the bed bases from the community is not included nor are sealed medicines bags used</td>
<td>Included sentence to exclude transportation by ambulance</td>
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<td>Sheena Kelly, Infection Control</td>
<td>17/7/17</td>
<td></td>
<td>No Response</td>
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<tr>
<td>Tammie Drake, Community Matron</td>
<td>17/7/17</td>
<td></td>
<td>Nothing to add</td>
<td></td>
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<tr>
<td>Wendy Edmondson, Substance Misuse Service</td>
<td>17/7/17</td>
<td></td>
<td>Could SMS be included in the Medicines Reconciliation Appendix</td>
<td>Made policy generic so that it can be used</td>
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<tr>
<td>Judith Stones</td>
<td>17/7/17</td>
<td></td>
<td>Suggested a number of additions</td>
<td>All included</td>
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<td>Date</td>
<td>Comments</td>
<td>Notes</td>
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<tr>
<td>Safeguarding</td>
<td>17/7/17</td>
<td>Sent Covert Medicines Administration.</td>
<td>Happy with content</td>
<td></td>
</tr>
<tr>
<td>Gemma Fowler</td>
<td>17/7/17</td>
<td>Various comments on overarching document.</td>
<td>All included/ clarified</td>
<td></td>
</tr>
<tr>
<td>Medicines Safety Committee</td>
<td>25/7/17</td>
<td>No comments other than above</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The Policy Ratification Group are mandatory stakeholders for ALL clinical guidance, organisational policy and strategy documents, however the administrator will process this element of the consultation. Comments will go back to the author to consider.
### Appendix C – Checklist for the Review and Ratification of Procedural Documents (to be used at the Quality & Safety Business Unit Meeting)

*This should be the very last Appendix following all the others in the document*

<table>
<thead>
<tr>
<th>Title of document being reviewed:</th>
<th>Yes/No</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Title</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the title clear and unambiguous?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Is it clear whether the document is a guideline, policy or protocol?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td><strong>2. Rationale</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are reasons for development of the document stated?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td><strong>3. Development Process</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the method described in brief?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Are individuals involved in the development identified?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Is there evidence of consultation with appropriate stakeholders and users?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td><strong>4. Content</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the objective of the document clear?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Is the target population clear and unambiguous?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Are the intended outcomes described?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Are the statements clear and unambiguous?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td><strong>5. Evidence Base</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the type of evidence to support the document identified explicitly?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Are key references cited?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Are the references cited in full?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are local/organisational supporting documents referenced?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Title of document being reviewed:</td>
<td>Yes/No</td>
<td>Comments</td>
</tr>
<tr>
<td>----------------------------------</td>
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<tr>
<td>6. Ratification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the document identify which committee/group will ratify it?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>If appropriate, have the Staff Side committee been consulted about the document?</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>7. Dissemination and Implementation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there an outline/plan to identify how this will be done?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Does the plan include the necessary training/support to ensure compliance?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>8. Document Control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the document identify where it will be held?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Have archiving arrangements for superseded documents been addressed?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>9. Process for Monitoring Compliance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are there measurable standards or KPIs to support monitoring compliance of the document?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Is there a plan to review or audit compliance with the document?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>10. Review Date</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the review date identified?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Is the frequency of review identified? If so, is it acceptable?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>11. Overall Responsibility for the Document</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is it clear who will be responsible for coordinating the dissemination, implementation and review of the documentation?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>12. Policy Overview Group Date</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>