



Medicines Management Policy

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<p>Linked procedural documents</p>	<ul style="list-style-type: none"> •CSOP 01 SOP Request and Issue of Individual Controlled Drugs Passbook •CSOP 03 Medicines adverse reaction medicines error management protocol (including near miss events) •CSOP04 - Ordering Morphine Sulphate Ketamine and Midazolam ampoules from Hospital Pharmacy •CSOP 05 Disposal of out-of-date drugs and denaturing of controlled drugs •CSOP07 - Waveney Morphine Order and Supply Process v1.3 •CSOP 08 Drugs/key to safe unsecured or found drug protocol •CSOP 09 Medicines or key to the safe to the safe lost/stolen/unaccounted for protocol (including record keeping discrepancies) •CSOP 10 Labelling of medication – Syringes, additives & TTAs •CSOP 11 Out of Date Drugs & Fluids for Training purposes
<p>Dissemination requirements</p>	<p>All managers and Clinicians via email and intranet</p>
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The East of England Ambulance Service NHS Trust has made every effort to ensure this policy does not have the effect of unlawful discrimination on the grounds of the protected characteristics of: age, disability, gender reassignment, race, religion/belief, gender, sexual orientation, marriage/civil partnership, pregnancy/maternity. The Trust will not tolerate unfair

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discrimination on the basis of spent criminal convictions, Trade Union membership or non-membership. In addition, the Trust will have due regard to advancing equality of opportunity between people from different groups and foster good relations between people from different groups. This policy applies to all individuals working at all levels and grades for the Trust, including senior managers, officers, directors, non-executive directors, employees (whether permanent, fixed-term or temporary), consultants, governors, contractors, trainees, seconded staff, homeworkers, casual workers and agency staff, volunteers, interns, agents, sponsors, or any other person associated with the Trust.

All Trust policies can be provided in alternative formats.

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1. Introduction

The Department of Health requires that all health trusts establish, document, and maintain an effective system to ensure that medicines are handled in a safe and secure manner. Clinical governance and risk management are high on EEAST's agenda, so this Medicines Management Policy (MMP) is to be followed for the prescribing, ordering, supplying, storing, administering and disposal of medicines.

This MMP only considers the process associated with the physical handling of medicines. The clinical elements of the management of medicines (such as choice of medicines, dose, route of administration, frequency of administration, etc.) are beyond the scope of this policy.

Application of this MMP is a multi-disciplinary activity. All staff groups undertaking the initiation of treatment and the handling of medicines should be involved.

It is not the intention of this MMP to provide detailed consideration of all possible circumstances that might apply when medicines are used. It provides the principles needed for controlling the activities relating to the handling of medicines. In support of these principles, EEAST has developed a set of Clinical Standard Operating Procedures (CSOPs) that can be found on the intranet.

The MMP in no way countermands professional standards and responsibility or codes of conduct for any groups of health professionals, but rather augments them.

The MMP applies to all staff groups employed by or who work in a sessional capacity for EEAST and including voluntary 'unpaid' work. See appendix 1

This policy applies to all Trust staff including Air Ambulance clinical/medical staff, clinically/medical qualified observers and clinically qualified contractors or co-responders working on behalf of the Trust whilst carrying out their duties.

2. Purpose

This Policy has been developed to provide guidance to promote the safe and effective use of all medicines used by a range of healthcare professionals employed by East of England Ambulance Trust (EEAST).

The document will incorporate guidance published by the Department of Health, Royal Pharmaceutical Society, Health Care Professions Council and Nursing and Midwifery Council including the following documents and other Royal Colleges:

- Medicines Act 1968 and The Human Medicines Regulations 2012 which updates The Medicines Act 1968.
- The Medicinal Products (Prescription by Nurses etc.) Act 1992 and associated Regulations.
- Misuse of Drugs Act 1971.
- Misuse of Drugs Regulations 2001, and subsequent amendments.
- Nice Guidance 46.

It is not the intention of this Policy to inform staff of the clinical indications for use of specific drugs protocols. The standards of clinical quality will be assessed against the JRCALC prehospital clinical guidelines, the Trust's Patient Group Directions and the formulary detailed in the British National Formulary (BNF)

3. Duties

3.1 Chief Executive Officer

The Chief Executive of the East of England Ambulance Service NHS Trust is the officer with overall responsibility for the safe and secure handing of medicines.

The **Trust Board** is responsible for monitoring the effectiveness of this policy and procedures, and for ensuring sufficient resources

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are available to support the implementation within EEAST
Resources will include formal service level agreements for
pharmacy advice and the supply of relevant medicines for the
services that the Trust provides the community.

3.2 Deputy Clinical Director

The Chief Executive has devolved their responsibility for the day-to-day management of medicines to the **Deputy Clinical Director**.

3.3 Medicine Management Team

With specialist advice from the Deputy Clinical Director and the Medicines Management Team and input from the Medicines Management Group will determine the medicines management strategy for the Trust and will determine the standards to be used for the administration of all medicines used by the Trust.

The Medicine Management Team also responsible for:

3.3.1 Ensuring that this policy is reviewed at least once every three years. Any necessary amendments to these documents should reflect and take account of changes in the legal framework relating to medicines management.

3.3.2 Ensuring Patient Group Directions (PGDs) are in place and kept up to date for any formulary medicines to be **administered** that are not listed or approved for Paramedics within schedule 17 of the Medicines Act 1968 (Prescription Only Medicines) and for any medicine to be administered for the purpose of saving life which is not listed under the exemptions provided by Article 19 of the Prescription Only Medicines (Human Use) Order 1997 (the POM Order), or administration not covered under primary legislation and for all circumstances in which medicines are to be **supplied** to patients other than on the directions of an independent prescriber or covered under primary legislation.

3.3.3 To ensure the safe and secure management of Controlled Drugs.

3.3.4 Adequate destruction and disposal arrangements.

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3.3.5 Monitoring and auditing arrangements including declarations and self-assessments.

3.3.6 Ensuring that training needs relating to Controlled Drugs are identified.

3.3.7 Maintenance of records and concerns raised regarding individual practitioners.

3.3.8 Adequate assessment and investigation procedures.

3.3.9 Appropriate systems in place for sharing information.

3.3.10 Attending meetings of appropriate Controlled Drugs Local Intelligence Networks, share intelligence with the network and highlight any issues relevant to the Trust.

3.3.11 Providing quarterly occurrence reports to the appropriate Controlled Drugs Local Intelligence Networks, detailing any concerns that the Trust has regarding its management or use of Controlled Drugs or confirming that the Trust has no concerns to report regarding its management or use of Controlled Drugs.

3.3.12 Ensuring all medicines are stored in compliance with this policy.

3.3.13 Ensuring that medicines management is implemented, monitored, and audited in accordance with this policy and related procedures.

3.3.14 Ensuring the Medical Director is made aware in a timely fashion of any adverse incidents regarding medicines management.

3.3.15 Therefore employees of the Trust are not empowered to use medicinal products acquired by any other means. **THE USE OF TRUST ACQUIRED DRUGS IS PROHIBITED UNLESS FOR EEAST USE.**

3.4 *Controlled Drugs Accountable Office (CDAO)*

The **Controlled Drugs Accountable Officer (CDAO)** responsibilities are set out in the regulations. The CDAO will appoint a deputy CDAO to assist in the role.

3.4.1 Local duties regarding medications are assigned to the respective General Managers (GM). The General Managers are responsible for:

3.4.2 Ensuring that the system for requisitioning and returning of medicines is followed.

3.4.3 Ensuring all medicines issued to any ambulance station or vehicles are stored in compliance with this policy.

3.4.4 Ensuring that only and all appropriate personnel have access to the medicines cupboard and recording the distribution of keys and or access codes.

3.4.5 Making checks to ensure compliance with the Medicines Management Policy at least every three months. Such checks must be recorded and retained for audit purposes.

3.4.6 Ensuring that medicines management is implemented, monitored and audited in accordance with this policy and related procedures.

3.4.7 Ensuring that the Medicines Management team are made aware in a timely fashion of any adverse incidents regarding medicines management. This should be done online using the Trust incident reporting tool.

3.4.8 The Patient Safety and Care Standards Committee will receive reports and policies from the Clinical Quality and Safety Group and ensure that Medicines Management policy and related procedures have been reviewed and are acceptable to all relevant stakeholders, in line with Trust policy.

4. Definitions

See Glossary on page

5. Scope

5.1 This Policy should be read, and the guidance should be followed by all staff who are working for EEAST and who supply and administer and/or prescribe medicines to patients. It intends to encourage good practice in the use of medicines when clinically required by the patient's condition. It aims to set out safe systems for procuring, ordering, prescribing, handling, recording, storing, transporting, administering, and disposing of all medicines used by EEAST whilst at the same time ensuring appropriate and convenient access for those patients whose clinical presentation requires them. By working within the parameters of this Policy all healthcare professionals will be able to provide a safe system of work in a safe environment not only for patients but for their colleagues and any third parties who may be affected by EEAST carrying out its core business.

5.2 Internal and external audit processes together with proactive exercises by the NHS Counter Fraud Authority will be undertaken to demonstrate that EEAST is operating suitable and adequate management controls to minimise risks to patient safety and to prevent potential harm through the inappropriate use, misuse or abuse of Controlled Drugs and non-controlled drugs.

6. Rationale

Medicines management can be **defined** as a system of processes and behaviours that determines how **medicines** are used by the NHS and patients. Effective **medicines management** places the patient as the primary focus, thus delivering better targeted care and better-informed clinical decisions.

6.1 EEAST recognises changing patient expectations that not only require a responsive service but expect that they will receive

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treatments that will meet the highest standards. It also supports the changing models of patient care so that more patients can be treated efficiently and effectively thereby reducing transfer to A&E. This Policy will support all staff from a range of Healthcare Professions (including Doctors, Nurses, Paramedics, EMT's) to contribute to the level of their competency whilst remaining within the existing legal framework for the use of medicines.

All staff should be aware that any failure to adhere to this policy could result in disciplinary action or in cases where a criminal offence may have been committed referral to the Police or the Counter Fraud & Local Security Management Service (LSMS).

7. Accountabilities

7.1 The Medicines Management Group is accountable to the Quality Governance Committee and operates within the agreed terms of reference. The Trust Medicines Management Operational Group will support the Medical Director to ensure that the Trust complies with Care Quality Commission standards for medicines management. The group will:

7.1.1 Develop, monitor and review policies and procedures to support use of medicines including this Medicines Management Policy, management of medication incidents, Patient Group Directions, Unlicensed/Off label medication, assuring compliance with relevant national guidance on safe practice.

7.1.2 Oversee and audit the implementation of nationally led policies and procedures involving medicines including NICE recommendations and prudent use of antibiotics.

7.1.3 Approve all PGDs prior to implementation and review as required prior to review date.

7.1.4 Regularly review identified medicines related risks on the Trust Risk Register and advice regarding actions to be taken.

7.2 Healthcare Professionals

7.2.1 All healthcare professionals working for EEAST will be trained according to their profession and level of competency on good practice and legislative requirements in the prescribing, supply, administration, storage and disposal of medicines. It is their responsibility to remain up to date and to attend training on an annual basis and maintain full CPD records.

7.2.2 All healthcare professionals working for EEAST will be competent and confident to supply and/or administer medicines under this policy and do so bearing in mind their own professional guidance.

7.2.3 Healthcare professionals must check any direction to administer or supply a medicinal product. In administering or supplying any medication, or assisting or overseeing self-administration of medication, HCPs must exercise professional judgement and apply knowledge and skill in the given situation. Where there is concern regarding a direction to administer or supply a medication the HCP should seek further information and, in some cases, a second opinion from a doctor. Where a healthcare professional is unable to resolve their concern despite seeking further information or a second opinion, they have the right to refuse to administer or supply the medication. In such circumstances the Doctor should be requested to personally attend the patient.

8. Purchasing of Medicines from an External Supplier

8.1 Only those medicines appearing in the EEAST formulary will be purchased by the Trust. Alterations to the stock list may only be made after agreement by the Trust Medicines Management Group.

8.4 Morphine injection will be purchased by the Trust Controlled Drugs Schedule 2, 3 and 4 others than Morphine.

Ketamine, Midazolam and Diazepam may only be obtained by Doctors and Nurse prescribers.

8.6 Samples or clinical trial materials must not be accepted by EEAST staff or left by company representatives in any premises managed by EEAST staff.

9. Storage of Medicine

9.1 Locality stores are held at nominated ambulance stations or within designated EEAST cupboards/stores.

9.2 All medicines and other substances shall be stored in the appropriate cupboard or areas that must be kept locked when not in use, or in EEAST approved drugs bags or pouches.

9.3 Cupboards should conform or be of a standard approved by the manager in consultation with the Medicines Management Team. Drug storage facilities must be sited such that the drugs will be kept within an acceptable temperature range as shown on the packaging.

9.4 Drug Refrigerators are to contain all drugs which require refrigeration. This refrigerator must be used only for the storage of drugs. Refrigerators must be monitored TWICE a day when in use and records kept ensuring temperature remains between 2°-8°C, regularly defrosted, and kept clean and locked. If temperature is outside limits set the AGM & MMT must be notified immediately. Advice should be sought from the Medicines Management Team regarding continued suitability of the stock held in the refrigerator at the time of malfunction. **No other items such as food may be stored in the drugs refrigerator.**

9.5 Drugs bags are to contain medicines and stocks in readiness. Bags must be checked at the beginning and end of each shift and stored under lock and key when in the ambulance station.

9.6 Intravenous fluids should be properly stored off the floor, away from heat, and preferably in wall racking or dispenser units away

from heat in separate containers according to type. They need to be kept in a locked store, with only a running supply available to staff.

9.7 Care must be taken to ensure stocks are rotated and used in date order.

10. Assurance

10.1 The General Manager (GM) of these sites is responsible for those stores and may delegate certain activities to a nominated person's, Medicines Management Local Lead.

10.2 The GM or nominated people will complete an order and ensure an appropriate person is available for signing in the delivery.

10.3 The GM is entirely responsible for the custody of drugs and shall be responsible for the custody of the keys. They may decide to delegate duties, but the responsibility always remains with them.

10.4 No other person's, other than those authorised by the GM should have access to the cupboards.

10.5 All medicine cupboards must be kept locked when not in use. Any incident of tampering with or breach of secure cupboards shall be reported via electronic reporting and investigated by the Local Management team.

10.6 The nominated person must make a check of drugs issued and stock remaining on a regular basis, but at least weekly. Any discrepancies should be reported via the electronic reporting system and identified to the relevant GM who should initiate an investigation.

10.7 The maximum and minimum desirable stock levels of pouches have been set by the MMT and will be reviewed on a quarterly basis.

10.8 Expiry dates of drugs are to be kept under constant review, with short-dated drugs being issued before long-dated, to minimise wastage. Where there are no stock issues, it is good practice to remove the medication a minimum of four weeks prior to expiry.

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This will reduce the chances of expired medication being administered.

10.9 Staff must, wherever possible, ensure that the drugs are kept in an acceptable environment, bearing in mind the labelled storage statement. In some instances, there is a need to document the date of opening a package or container as once open the 'shelf life' is limited or changed, e.g. Glucagon.

10.10 The need to dispose of 'out of date' drugs or those exposed to adverse environmental conditions should be minimal. However, if there is a need the drug/s should be immediately removed from use, clearly identified, and notified to the GM or nominated person who will ensure that the item is disposed of in accordance with Medicines, Disposal of Out-of-Date Drugs and Denaturing of Controlled Drugs. (CSOP).

10.11 The Trust training centres will use out of date drugs for training purposes. The transfer of out-of-date drugs will be from stations located near the training schools and Letchworth. Training centres will store and label these drugs in accordance with the policy for Out of Date Drugs & Fluids for Training purposes (CSOP).

10.12 Controlled Drugs may only be destroyed by authorised persons (except for the disposal of unused portions of ampoules or breakages – see Section 2). Contact the authorised person for CD destruction Disposal of out-of-date drugs and denaturing of controlled drugs (CSOP). All Destructions of Controlled drugs are to take place at Letchworth, unless broken or unused medication on scene

11 Ambulances and Vehicles

11.1 Stock Replenishing

11.1.1 When a vehicle drug bag becomes depleted, it is the responsibility of the Lead Clinician on the vehicle to ensure that the recommended minimum stock levels are maintained. If necessary, the Ambulance Operations Centre (AOC) should

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be contacted to advise that drug stocks are low on the vehicle and to request to proceed to the nearest available store and obtain an issue of drugs.

11.1.2 The restocking of medicine stores, including Specialist Paramedics, should normally be undertaken at any one of the local ambulance's stations or ambulance stock cupboards but could be restocked from any EEAST Ambulance medicines store.

11.1.3 The authorised person drawing stocks keep records using approved documentation with the store location, date, quantity pouch number they are using for restocking. and the drugs bag they are going into. The remaining stock total and including the signature of the authorised person. On receipt of stock, the Technician or Paramedic responsible for the drug bag will record the date, quantity and batch numbers received, and sign the form. The running stock total will be always kept.

11.2 Use of Green/Red 'Patient Own' Medication Bags.

11.2.1 Patients that are being admitted to the hospital through A & E, or any of the hospital wards should have their own medication (in their original containers where possible) transported with them.

11.2.2 All the patients' own medications must be placed in the appropriate bags with the patient's name written on the front of the bag prior to transportation and patient handover. The patient's own medication bag containing the drugs must then be handed over to hospital staff with the patient. This needs to be documented on the PCR when this occurs.

11.3 Storage of Medicines

11.3.1 When the vehicle is operational, the drug bag' will be kept locked away when not in use. When not operational, vehicles will be kept locked. Should the vehicle be off station

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for repair, etc. the drug bag will be removed from the vehicle and kept under lock and key on the ambulance station.

11.3.2 Drugs bags should be secured at the end of every shift

11.3.3 Drugs should not be exposed to extremes of temperature. A drug bag left exposed in hot sunshine for a long period or extreme cold leading to freezing may cause damage to the drugs. All drugs in that box should be replaced as per damaged drugs procedure.

11.4 Control of Medicines

11.4.1 Drugs must always be kept in designated places on Trust vehicles; this will depend upon the type of vehicle operated.

11.4.2 Drugs should not be transported in private cars except when staff are authorised to do so by their senior manager e.g. moving Morphine and then only in accordance with SOPs.

11.4.3 On Station, drug bags must be stored in a locked storage facility.

12. Self Administration and self-prescribing

12.1 All medicines administered or supplied within EEAST are solely for use by patients of the Trust. All medicines supplied and/or administered within EEAST are done so in accordance with this Policy. All medications supplied/administered must be recorded on the PCR and any paperwork within the Drugs Bag and must include the CAD and date.

12.2 Under No circumstances should staff self-administer any Trust medications to themselves. Except for DuoDote.- Auto-injector to be administered by staff who have had adequate training in the recognition and treatment of nerve agent or insecticide intoxication.

12.3 If a member of staff were to administer a medicine to himself or herself or a colleague outside of this policy this may result in formal disciplinary action being taken by EEAST.

13 Verbal Orders (Telephone Prescribing)

13.1 The need for a verbal order for the administration or supply of medicines arises in a variety of settings:

13.2 Verbal orders may only be taken under the following circumstances:

13.2.1 Verbal orders are only permissible within formal contractual arrangements i.e. from independent prescribers who have a formal relationship with the Ambulance Paramedic i.e. employed by an organisation commissioned to provide NHS services and who remain responsible and accountable for the verbal order.

13.2.2 Verbal instructions may be used to authorise the administration of a medicinal product, or the temporary discontinuation of prescribed treatment,

13.2.3 Verbal instructions should be infrequent and can be accepted only in exceptional circumstances.

13.3 Verbal orders are not permissible for Controlled Drugs Schedule 2 or 3. Legally Paramedics are not limited to administering 20mg for Morphine. In circumstances where additional doses are clinically necessary, they may take further clinical advice from a Doctor/Prescriber (Clinical Advice Line), but then take the decision themselves as to whether to administer.

13.4 Only Registered Paramedics, and Nurses are authorised to take verbal orders.

13.5 All verbal orders for medicines should be recorded on the PCR. The ambulance Clinician should note the time of the call in the patient's notes.

13.6 Ambulance Clinicians administering a medicine in accordance with a verbal order should document the verbal order and repeat it back to the prescriber, to check understanding. Where possible a second crew member/colleague should confirm the verbal order.

14. Administration of Medicines

14.1 Medicines can only be administered to a patient within the Trust if they have been purchased by the Trust:

14.2 Medicines shall be administered by:

14.2.1 A suitably qualified Practitioner within their scope of practice following local guidelines and policies, and in accordance with Regulations and JRCALC may administer medications.

14.3 Patient Group Directions- before supplying or administering any medicinal products listed within a PGD, each practitioner must ensure they administer within the terms of the PGD.

14.4 In the absence of a signed prescription, a patient's own containers of medicine, clearly labelled and giving full directions which have been dispensed within the previous 3 months may be administered according to these directions. If there is any doubt the Practitioner must contact the Doctor.

14.5 Where an authorised Practitioner administers any drugs appropriate records shall be kept using the PCR approved system by the Trust.

14.6 Any concerns and details of the action taken must be recorded in the patient electronic report form (PCR) or clinical records for the patient in his/her care. This would also cover situations where a self-medication policy is in operation. The member of staff must be able to justify any action taken in respect of administration and be accountable for any action taken.

14.7 The safe and effective administration of medication requires a partnership between various health professionals. To achieve this,

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the Clinician must have access to senior clinical advice or MMT support.

14.8 In general terms disguising medication in food and drink should not be encouraged as it is potentially dangerous. However, it is recognised that there are exceptional circumstances when it can be justified as in the best interest of the patient. Before pursuing such a course of action, the health professional must ensure that: all other routes of administration have been attempted and all people present are aware of the reasons for disguising.

14.8.1 All staff involved in medicines administration must have access to the Medicines Management Policy and work in accordance with SOPs approved for their service.

14.8.2 Suspected adverse drug reactions must be reported to the Trust via the DATIX Reporting System and after investigations by the Medicines Management Team, be reported using the 'yellow card' system to the Medicines and Healthcare Products Regulatory Agency (MHRA). (www.yellowcard.gov.uk)

15. Issue of Medicines to Patients

Only original manufacturer's packs (GSL or P medicines only) or TTA packs of medicines agreed by the Trust Medicines Management Group may be issued to patients directly.

15.2 All medicines shall be issued to patients by a Practitioner in accordance with a Patient Group Direction or locally agreed protocol in line with legislation.

15.3 Where this is carried out, supply of medication is the responsibility of the Practitioner and they must ensure that the patient receives the medication in the appropriate form, in a suitable container labelled with the patient's details and clear instructions for use, along with the manufacturer's information leaflet.

15.4 Complete courses of medication must be dispensed when an antibiotic is required. Otherwise, the quantity supplied will be in accordance with the Patient Group Direction and/or local guidance.

15.5 A record of all issues shall be made on the patient's electronic record at the time of issue.

16. Errors of Administration

16.1 In the event of errors in the administration of medicines including but not exclusively:

- A medicine given to the wrong patient.
- The wrong medicine given to the patient.
- A patient failing to receive the medicine without good reason.
- The incorrect dose of a medicine given to a patient.
- The wrong route of administration used for a medicine.
- Failure to correctly record the administration of a medicine.

16.2 The trained member of staff must complete the Trusts online incident form DATIX and then inform the GM, Medicines Management Team, The Medical Director as soon as possible. A record of the error must be made in the patient's notes PCR

16.3 It is also extremely important that any 'near misses' are reported through the Trust's incident reporting system, DATIX. The reporting of 'near misses' will assist the organisation in highlighting areas of risk to patients and staff and where further action may be necessary, to address the issue raised. The key to this process is that no actual harm has occurred, but a problem in the system has been identified. It is the best opportunity we have to learn that a process has broken down without anyone coming to any direct harm.

16.4 Most errors or incidents that occur within the NHS are, overall, as a result of a breakdown in the process put in place rather than

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any one individual's skills or competency. The Trust will continue to support the development of a 'culture of no-blame' and will work closely with teams and individuals in assuring this is further supported. For most errors this will be the most appropriate course of action. However, in the event of continual or numerous drug errors, or genuine concerns relating to an individual or individuals' competence to practice, the Trust may wish to liaise with Human Resources and Occupational Health regarding support, training need or appropriate further action.

16.5 Finally, in the event of serious professional conduct, the Trust will carry out a detailed and thorough investigation and may be forced to invoke the disciplinary procedure.

17.0 Disposal of Medicines

17.1 Out of date drugs or those exposed to adverse environmental conditions should be returned for safe storage and eventual disposal in accordance with Waste Regulations and Medicines, Disposal of Out-of-Date Drugs and Denaturing of Controlled Drugs (CSOP). Recording of these should be completed on the Trusts electronic auditing system.

18.0 Traceability

18.1 It is essential that EEAST can trace all medicines from receipt into the Trust to their use or disposal. All staff must complete the necessary paperwork to maintain a full audit trail.

18.2 Audit of stock medicines held in vehicles and in ambulance stations will be carried out on a monthly basis, also in each storage location and recorded on the Trusts electronic audit system.

18.3 Records relating to medicines stock control should be retained for five years from date of last entry.

19.0 Security of Medicines

19.1 NB: Please also refer to Section 2 of the policy for specific guidance on the management of Controlled Drugs.

19.2 It is the responsibility of staff while on duty to maintain adequate security for all medicines They are accountable for both the Drugs bag and Controlled Drugs pouch for the duration of their shift.

19.3 Drug bags must be secured within lockable cabinets or storage devices, where available on all vehicles.

19.4 All stations are required to provide the MMT with a list of all signatures for the purpose of ordering/receipt and refill of Controlled drugs. This list should be updated quarterly. A copy is also held by the stores team.

19.5 While outside the physical confines of the station, all vehicles carrying drugs must be completely locked when left unattended

19.6 If a vehicle's security mechanisms are found to be inoperable, it must be reported to appropriate AOC immediately and the appropriate line manager informed. The appropriate line manager must assess the level of risk and if necessary, make arrangements for an alternative vehicle to be utilised.

20. Loss of Medicines

20.1 When any drug has been lost or cannot be accounted for the loss must be reported to the Local Operational Manager (LOM) as soon as possible by the employee who first discovers in accordance with CSOP

20.2 The GM or other should, with advice from the Medicines Management Lead and the LOM if necessary, assess the risk associated with the nature and quantity of drug involved and determine the appropriate course of action.

20.3 An initial report of the loss is also to be made by the GM to the Risk and Patient Safety Manager as soon as possible.

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20.4 The Risk Manager and Patient Safety Manager and the MMT Audit and Compliance Lead will arrange for a senior healthcare professional to investigate the loss, to establish the cause or causes and whether local instructions or procedures have been observed. They must make recommendations to prevent a recurrence. The results of the investigation are to be submitted in writing to the Director of Nursing, Medicines Management Lead and the Pharmaceutical Adviser.

20.5 Where there is any suspicion or an allegation that a loss has been caused by some form of deception (whether by staff or a patient) this must be referred to the Trust's Local Counter Fraud Specialist for investigation as per the Secretary of State's Directions on Counter Fraud Measures, 2004.

20.6 If any Controlled Drug in the possession of any person is stolen or otherwise lost, the LOM or on call manager or other Officer must arrange for a thorough search of the premises and/or vehicles immediately. The loss shall be reported by that person as soon as possible to the Trust CD Accountable Officer, Medicines Management Lead, and the local police. Refer to section 2

21.0 Liability

21.1 EEAST generally accepts responsibility for the negligence of its qualified Nurses, Paramedics and Technicians who, in emergency situations within the United Kingdom, administer Trust approved drugs in the treatment of patients in accordance with their qualifications and this Policy. This applies both during and outside working hours whilst an individual acts in accordance with his or her training but not for any private or voluntary organisation.

21.2 All Doctors must be registered with the General Medical Council (GMC) and will all carry their own medical indemnity insurance and are ultimately accountable for their own prescribing and dispensing practice.

21.3 In addition EEAST will indemnify the salaried Doctors directly employed whilst undertaking EEAST work in the same way as other employees.

21.4 EEAST is not liable for the activities of Nurses, Paramedics or Technicians undertaking work for private or voluntary organisations. In these circumstances, to avoid the imposition of personal liability, individuals are advised to check beforehand that appropriate insurance cover is in place.

22.0 Working with the Pharmaceutical Industry

22.1 Prescribers should act within their professional code of conduct and ensure adherence to the EEAST Commercial Sponsorship Policy and any other guidance on working with the pharmaceutical industry.

22.2 The advertising and promotion of medicines is strictly regulated under the Medicines (Advertising) Regulations 1994, and it is important that independent non-medical prescribers make their choice of medicinal products for their patient based on evidence, clinical suitability and cost effectiveness alone.

22.3 As part of the promotion of a medicine, suppliers may provide inexpensive gifts and benefits, for example pens, diaries, or mouse mats. Personal gifts are prohibited, and it is an offence to solicit or accept a prohibited gift or inducement.

22.4 Companies may also offer hospitality at a professional or scientific meeting. Such hospitality should be reasonable in level and subordinate to the main purpose of the meeting.

23.0 Monitoring and Audit

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23.1 Adherence to this Medicines Management policy will be monitored and audited.

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What	Who	How	Frequency	Evidence	Reporting arrangements	Acting on recommendations	Change in practice and lessons to be shared
Medicines Management Policy	Medicines Management Group	Review of incidents and complaints relating to aspects of the MMP to see if any change could bring greater clarity to the MMP.	Every 3 years	Medicines Management Policy	The OMMG is expected to re-read and interrogate any reports to identify deficiencies in the MMP and act upon them	Required actions will be identified and completed in a specified timeframe.	Required changes to the MMP will be identified and actioned within a specific time frame. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders and staff.
Adverse drug reactions	Operational Medicines Management Group	Reports submitted to OMMG	When applicable	Report to OMMG	The OMMG is expected to read and interrogate any reports to identify	Required actions will be identified and completed in a	Required changes to practice will be identified and actioned within a

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<i>What</i>	<i>Who</i>	<i>How</i>	<i>Frequency</i>	<i>Evidence</i>	<i>Reporting arrangements</i>	<i>Acting on recommendations</i>	<i>Change in practice and lessons to be shared</i>
		as well as to MHRA			any learning that needs action.	specified timeframe.	specific time frame. Medical Safety Officer will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders and staff
Patient Group Directions (PGDs)	Operational Medicines Management Group	Ensure that all clinical staff have signed the PGDs which apply to	When applicable	Database kept by Clinical Directorate administrative assistant.	Report exceptions to the OMMG	Required actions will be identified and completed in a specified timeframe.	Required changes to practice will be identified and actioned within a specific time frame. A lead member of the team will be identified to take

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<i>What</i>	<i>Who</i>	<i>How</i>	<i>Frequency</i>	<i>Evidence</i>	<i>Reporting arrangements</i>	<i>Acting on recommendations</i>	<i>Change in practice and lessons to be shared</i>
		their staff group.					each change forward where appropriate. Lessons will be shared with all the relevant stakeholders and staff.

<i>What</i>	<i>Who</i>	<i>How</i>	<i>Frequency</i>	<i>Evidence</i>	<i>Reporting arrangements</i>	<i>Acting on recommendations</i>	<i>Change in practice and lessons to be shared</i>
Storage of medicines	Area general Manager and Local MM Leads	Quality walks round stations and reports there on by GMs and other members of clinical and	monthly	Database kept by Medicines Management	Report exceptions to the OMMG	Required actions will be identified and completed in a specified timeframe.	Required changes to practice will be identified and actioned within a specific time frame. A lead member of the team will be identified to take each change

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What	Who	How	Frequency	Evidence	Reporting arrangements	Acting on recommendations	Change in practice and lessons to be shared
		quality directorates.					forward where appropriate. Lessons will be shared with all the relevant stakeholders and staff.
Storage of POMs at station and in Drug Bags	Leading Operational Managers	Monthly checks of all stocks against numbers in drug books and if drugs are in date.	Monthly	In drug books. Electronic audit system	Report exceptions to the OMMG	DATIX, if discrepancy	Required changes to practice will be identified and actioned within a specific time frame.
Station storage of CDs in date and Out Of Date stocks	Leading Operational Managers	minimum weekly checks of CDs stocks	weekly	In drug books. Electronic audit system	Report exceptions to the OMMG	DATIX, if discrepancy	Required changes to practice will be identified and actioned within a specific time frame.
Controlled Drugs	Accountable Officer	Complaints, litigations, incidents & PALS enquiries	Quarterly	Report to Local Intelligence Network (LIN).	The OMMG is expected to read and interrogate any reports to the LIN and identify	Required actions will be identified and completed in a specified timeframe.	Required changes to practice will be identified and actioned within a specific time

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What	Who	How	Frequency	Evidence	Reporting arrangements	Acting on recommendations	Change in practice and lessons to be shared
		relating to Controlled Drugs analysis.		Complaints, litigations, incidents & PALS enquiries relating to Controlled Drugs analysis.	deficiencies and thus act upon them		frame. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders.
What	Who	How	Frequency	Evidence	Reporting arrangements	Acting on recommendations	Change in practice and lessons to be shared
Destruction of drugs	Medicines Management Team	Auditing of CD's returned to Letchworth ensuring all appropriate paperwork is attached and completed.	As and when the MMT receive notification of CD's returns.	Controlled Drugs destruction witness statements. Electronic audit system	Report exceptions to the OMMG	Required actions will be identified and completed in a specified timeframe 28 days.	Required changes to practice will be identified and actioned within a specific time frame. A lead member of the team will be identified to take each change forward where

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What	Who	How	Frequency	Evidence	Reporting arrangements	Acting on recommendations	Change in practice and lessons to be shared
							appropriate. Lessons will be shared with all the relevant stakeholders.
Controlled Drugs Record Book ('Red Book')	Clinical Response Leads/ Area General Managers/ HALO in Hospitals/ Individuals	Auditing of Controlled Drugs Record Book to check stocks held in pouch against stocks recorded	Monthly	Electronic audit system	Report to the OMMG	Required actions will be identified and completed in a specified timeframe.	Required changes to practice will be identified and actioned within a specific time frame. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders and staff.
Incidents and complaints relating to medicines	Medicines Management Lead	DATIX reports	Bimonthly	Complaints, litigations, incidents & PALS	Agenda item on every OMMG meeting.	Required actions will be identified and completed in a specified timeframe.	Required changes to practice will be identified and actioned within a

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What	Who	How	Frequency	Evidence	Reporting arrangements	Acting on recommendations	Change in practice and lessons to be shared
				enquiries relating to medicines analysis.			specific time frame. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders and staff.

What	Who	How	Frequency	Evidence	Reporting arrangements	Acting on recommendations	Change in practice and lessons to be shared
Arrangement for the administration of medicines	Area Clinical Leads	Ensure that all clinical staff has signed the PGDs which apply to	Bimonthly	Medicines Management Policy: Section 1	Report exceptions to the OMMG	Required actions will be identified and completed in a specified timeframe	Required changes to practice will be identified and actioned within a specific time frame. A lead member of the

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<i>What</i>	<i>Who</i>	<i>How</i>	<i>Frequency</i>	<i>Evidence</i>	<i>Reporting arrangements</i>	<i>Acting on recommendations</i>	<i>Change in practice and lessons to be shared</i>
		their staff group. DATIX reports					team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders and staff.

24. Equality and Diversity

This policy applies to all employees of the Trust regardless of their race, gender, disability, age, class, sexual orientation, religion or belief or the passport they hold.

25. Aim for A Safe Regime

25.1 The overriding consideration of the attending Practitioner is the clinical safety and well-being of the patient.

25.2 The key principles which govern the management of medicines within the Trust are compliance to:

- current prescribing legislation
- management of the risks to patients and staff arising from the physical handling processes involved in the initiation of treatment
- prescribing
- procurement
- acquisition
- storage
- distribution
- dispensing
- preparation
- administration and the safe handling and disposal of any residual medicinal product
- The observance and/or consideration to guidance issued by the Department of Health

26.0 Clinical Standard Operating Procedures

26.1 Clinical Standard Operating Procedures (CSOPs) must be in place to ensure implementation of the medicines policy.

SECTION 2 Controlled Drugs

1.0 Governance Arrangements

The Misuse of drugs (Amendment) regulations 2016 Health Act 2009 introduced a number of strengthened governance arrangements for management of CDs. The key provisions of the Act are:

- All designated bodies such as health care organisations and independent hospitals are required to appoint an Accountable Officer (AO);
- A duty of collaboration placed on responsible bodies, health care organisations and other local and national agencies, including professional regulatory bodies, police forces, (in England Care Quality Commission) to share intelligence on CD issues;
- A power of entry and inspection for the police and other nominated people to enter premises to inspect stocks and records of CDs.

1.1 Controlled Drugs Accountable Officer

As a designated body, EEAST has a duty to appoint an Accountable Officer for Controlled Drugs. EEAST must notify the name of the CD Accountable Officer to the Care Quality Commission and ensure that any changes in personnel are also notified in a timely manner.

The Accountable Officer is responsible for ensuring the safe and effective use and management of CDs within the EEAST. In particular, the Accountable Officer is responsible for ensuring:

- Appropriate arrangements are in place within the organisation to comply with Misuse of Drugs legislation.

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- Adequate and up-to-date Clinical Standard Operating Procedures (CSOPs) are in place in relation to the management and use of CDs;
- Adequate destruction and disposal arrangements for CDs are in place.
- Monitoring and auditing of the management and use of CDs;
- Relevant individuals receive appropriate training.
- Assessing and investigating concerns.
- Appropriate action is taken if there are well-founded concerns.
- Establishing arrangements for sharing information.

1.2 Local Intelligence Networks

The Health Act 2009 places a legal duty on local agencies to share information and intelligence about the use of CDs in the health and social care sector. Local agencies required to share information include healthcare organisations, the police, social service authorities and relevant inspectorates (Care Quality Commission, and the Royal Pharmaceutical Society of Great Britain (GPHC). Information will be shared through a Local Intelligence Network.

Responsibility for establishing Local Intelligence Networks (LINs) lies with NHS England Accountable Officers. LINs enable agencies that have cause for concern about the activities of any health care professional to share them as soon as possible with other local agencies who may be affected or who may have complimentary information.

1.3 Quarterly Reports

All designated bodies must provide the NHS England CD Accountable Officer with a quarterly report regarding the management of Controlled Drugs within their organisations.

The CD Accountable Officer shall provide this report to each NHS England CD Accountable Officer on a quarterly basis, listing all

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Controlled Drugs incidents which have been reported in that quarter. If there have been no incidents, a NIL return must be made.

The CD Accountable Officer will also provide a quarterly report on Controlled Drugs to the EEAST Medicines Management Group and other Committees

Failure to provide information, or providing false information, could lead to investigation and further action.

1.4 Audit

The Trust shall ensure that audit of the management of Controlled Drugs is embedded within the clinical audit work plan. Audits will include both process and clinical audits.

There are three aspects to the routine monitoring of CDs, all running in parallel:

Monitoring of positive indicators:

- Consideration of the special characteristics of the services or Area's population for example; high incidences of cardiac events/disease/requirements for CD use.
- Analysis of incident type information.
- Staff education and training in relation to CDs.
- Audits of CD management and use.
- Review of CD clinical guidelines and CD CSOPs.
- Evidence of compliance with any reporting requirements such as the NRLS or STEIS.
- Involvement in joint training events such that joint care pathways and clinical guidelines are developed across professional groups.
- Participation in Intelligence Networks

Monitoring of negative indicators:

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- Significant event audits (e.g. adverse incidents, patient death, overdose involving CDs), lost or stolen drugs and discrepancies between records.
- Patient or carer complaints involving the use of CDs.
- Concerns expressed by colleagues internally or externally of the Trust.
- Concerns relayed from Police or drugs misuse services about CDs.

Benchmarking:

- Routine monitoring of CD dispensing reports from stores, comparing frequency and quantity of requisition and supply at, sector and area levels.
- Comparison of CD management audits at sector and area levels.
- Comparison of adverse events in relation to CDs at sector and area level.
- Monthly auditing by LOM/AGM of Controlled Drugs Record Book, to check stocks held in the pouch against stocks recorded.

2.0 Authority to Possess and Supply

2.1 Registered Paramedics have 'group authority' to possess and supply Morphine injection at a strength not exceeding 20mg/ml (Schedule 2) and Diazepam –all forms (Schedule 4). Diazepam Solution - PGD

2.2 Registered Paramedics and nurses may also possess Schedule 4 drugs and Midazolam (Schedule 3) which they have been authorised to administer under a Patient Group Direction.

2.3 Nurses have authority to possess morphine if they have been authorised to administer Morphine under a Patient Group Direction.

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2.4 Doctors and Pharmacists have general authority to possess, supply and procure all Controlled Drugs except those in Schedule 1.

2.5 Additional Controlled Drugs like Midazolam and Ketamine (Schedule 2) are carried by EEAST's Specialist/Advanced Paramedics in Critical Care

2.6 Auditing of CDs both stock and pouches is the responsibility of both LOM's and the paramedics/nurses that use them

3.0 Ordering Controlled Drugs

EEAST NHS Trust operates a daily shift management system for Morphine injection requiring individual Paramedics and Nurses to collect from station daily. Except Managers on call, Officers and Critical Care Paramedics

3.1 Morphine injection will be purchased by the Trust from nominated supply chains and supplied to stations from Trust stocks.

3.2 Ambulance Station Locality Stores shall order their Morphine in accordance with CSOP 04.

3.3 The LOM or authorised manager (who must be a Paramedic) shall order Diazepam from stores.

3.4 The LOM or authorised manager will sign for them upon receipt.

3.5 Stocks of Morphine & Diazepam (all forms) will be entered into the Controlled Drugs record book and witnessed by a second person. Both staff involved will sign the CD Record Book to confirm the receipt of the medication and that stocks of CDs being held in total are correct.

3.6 Sample signatures of all Paramedics authorised to hold Morphine or Diazepam will be held at local stations and it is the responsibility of the LOM to ensure that this record is kept updated. This record may be used to verify any signatures in any Morphine records.

3.7 Controlled Drugs Schedule 2, 3 and 4 in addition to Morphine and Diazepam may only be purchased for Trust use by nominated Doctors who then remain totally accountable for safe and secure storage of those Controlled Drugs. In line with the Controlled Drug Licence.

4.0 Storage of Controlled Drugs

4.1 All Schedule 2 drugs are subject to safe custody requirements (under the Misuse of Drugs Safe Custody Regulations 1973). They must be stored in a locked receptacle, such as an appropriate CD cabinet or approved safe, which can only be opened by the person in lawful possession of the CD or a person authorised by them.

4.2 It is Trust policy to store all Controlled Drugs Schedule 3 and Schedule 4 (including Diazepam) in a Controlled Drugs cupboard/safe and to keep full records as per Sch 2 drugs.

4.3 Each locality ambulance station shall have a small, lockable metal cabinet bolted to the floor or wall. Within this cabinet there will be sufficient space to store stocks of Morphine. The master key for the drug cabinet shall be kept within a key safe.

4.4 The stock level in a locality station store shall be maintained at a minimum of 20 ampoules and a maximum of 150 ampoules.

4.5 When not in use the daily pouches are to be kept in the secured lockers at stations and when in use in the drug safe on Trust vehicles which the Paramedic will be responsible for the key.

4.6 Individually held controlled drugs should be returned to a station with a suitable individual safe if the medication will not be used for more than 28 days. (ie not predictably attending work). Paramedics and Nurses, including managers, will need to be authorised to use controlled drugs and to have the need to transport these between locations. All effort should be made to reduce the need to hold medication outside of work time. This includes discussion with your line manager on storing at a station closer to home than your base/administration base. In addition, for staff working at alternative locations additional wall mounted safes

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can be made available. This should be discussed with your line manager.

- Where morphine is approved to be held outside of work then the following applied:
 - It should be secured in a locked Trust approved container
 - Removed from your car at night
 - Stored in a discreet location away from extremes of temperature, children and pets.
 - Not held there for any longer than required and no more than 28 days.

4.7 Controlled Drugs requiring secure storage may only be carried in Trust vehicles which are fitted with an approved secure storage box tethered to the vehicle.

4.8 Vehicle storage:

- Ambulance: in a locked compartment
- Car: in a locked compartment, in the locked boot of the car

4.9 Where key codes are in use, Paramedics must not disclose the code to non-authorized personnel and the codes are required to be changed every 3 months (quarterly)

4.10 The majority of Schedule 3 CDs and all Schedule 4 CDs are exempt from safe custody requirements but still require safe storage. However, it is policy within EEAST to store Sch 3 and Sch 4 CDs (including Diazepam) in secure CD storage, along with full record keeping. e.g. Midazolam and Ketamine.

5.0 Carriage

5.1 The security of Controlled Drugs is paramount. Clinicians are not permitted to carry CDs and CD pouches on belt or in pocket this will result in disciplinary action if found.

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5.2 Transfer to a Trust locked store should be undertaken at the earliest opportunity whether it is a drug safe at a station or a drug safe in a Trust vehicle.

5.3 The Paramedic should ensure that the Pouch controlled drug stock is checked against the Pouches drug register and this is witnessed as being correct by a Trust colleague. This will ensure that any discrepancy is noticed at the earliest opportunity. The Red book and pouch should be always kept together.

6.0 Control and Record Keeping

6.1 Morphine Stores on Ambulance Stations.

6.1.1 Only LOMs shall have access to the Morphine store.

6.1.2 LOMs having legitimate access to the key press will be informed verbally of the combination, but they shall not write it down in a manner that could be discovered by unauthorised persons. One set of keys for the cabinet shall be held within a key press bolted to the wall.

6.1.3 The security combination for the key press must be changed at least quarterly by the GM or authorised manager, and authorised managers are informed appropriately. Any requests for obtaining the combination must be documented and referred to the GM.

6.1.4 In the case of a combination lock on the drug cabinet, the combination number is to be made known to the staff that would normally have access.

6.1.5 Each locality station will hold a Controlled Drug Record Book for that station. Stocks shall be replenished only from stores. It is the responsibility of the person in charge of the station at that time to ensure that these are correct.

6.1.6 No cancellation, obliteration, or alteration of any entry in any Controlled drug record shall be made, and a

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correction of an entry shall be made only by way of a note on the page for that purpose. An asterisk is to be marked in any line to which a correction has been made.

- 6.1.7** All entries in the Controlled Drug Record Book are to be witnessed by an appropriate person.
- 6.1.8** Receipts shall be noted on the left-hand page and issues on the right-hand page of the Controlled Drug Record Book, in each case identifying which ampoules have been transferred/ issued, administered, or disposed of, by batch number. This will enable an audit trail for each batch number from issue by the approved supplier, through distribution within the service, to administration to individual patients.
- 6.1.9** Controlled Drug records are to be kept with the drugs to which they always refer. Any discrepancies found in the CD records must be reported to a manager as soon as practicable. That Manager will investigate the matter and decide on any action to be taken.
- 6.1.10** All Controlled Drug stocks, whether in date or waiting for disposal should be audited by an authorised Manager weekly where practical, they should be stored in separate CD cabinets. The check will be recorded on the electronic audit online. Any anomalies shall be immediately notified to an GM, who will instigate investigation and decide on any action to be taken.
- 6.1.11** LOMs shall keep the completed record books of all controlled drug transactions within their area of the service for at least two years from the date of the last entry (NB. legally it is required for be kept for 2 years). If no destruction recorded.
- 6.1.12** The issue of Morphine to pouches shall be recorded in the Controlled Drug Record Book for both the Area Station Store and the pouch, the record of issue

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being made with each individual ampoule being identified by batch number and expiry date.

6.2 Morphine Stores on Vehicles

6.2.1 Where the drugs are stored in a compartment with a digital lock, only Paramedics will have access to the code and/or to the key that is required to set the code.

6.2.2 Each Paramedic will ensure that they hold a minimum of 2 ampoules and a maximum of 5 ampoules of Morphine at the beginning of each shift. Where there are two Paramedics on a vehicle, only one Paramedic shall take the daily shift pouch on the vehicle and shall have sole responsibility for the secure and safe handling of these stocks.

6.2.3 For vehicles with key lock-controlled drug compartments, there are two keys, one (which may be a master key to all the drug in the store) to be kept in the station key press and one (which is individual to the drug) to be held by the Paramedic during the shift. The vehicle key is to be passed to the next Paramedic coming on duty on the vehicle or in the case of there being no Paramedic to pass the key to, the key is to be placed in the station drug store and a note made in the station log.

6.2.4 For vehicles with a digital lock, the Paramedic will set their own code for use during their shift. Codes must not be divulged to non-Paramedic staff.

6.3 Diazepam Stocks on Ambulance Stations and Vehicles.

6.3.1 LOMs will carry out a stock check each time a supply of Diazepam is made to a pouch, in addition to a monthly stock check on the station. LOMs will provide a monthly Drugs report to the Medicines Management team.

6.3.2 Paramedics will check the Diazepam held in the daily shift pouch against the red book. Any anomalies in this are to be reported to a LOM, who will investigate the matter and decide on any action.

7.0 Administration of Controlled Drugs

General Regulations apply where appropriate plus in addition:

7.1 All administration of Controlled Drugs are to be given and administered in accordance with Regulations and primary legislation or a Patient Group Direction.

7.2 Under an exemption from the Medicines Act 1968 Paramedics are authorised to administer injectable Morphine and Diazepam all forms for the immediate, necessary treatment of sick or injured persons without the need for directions from an appropriately qualified prescriber

7.3 All Controlled Drugs must be administered in accordance with Trust policies, JRCALC guidance, Patient Group Directions or in accordance with the directions of an appropriately qualified prescriber.

7.4 Medicines containing Controlled Drugs shall be administered by:

7.4.1 A suitably qualified practitioner e.g. Doctor or Nurse Prescriber or Paramedic.

7.4.2 Self-administration by patients using their own dispensed medications.

7.4.3 A trained member of staff in accordance with a prescription signed by an authorised prescriber or in accordance with a PGD.

7.5 When a clinician administers a controlled drug to a patient, they must record the following:

- Date and time
- Patient's name (Patient Report Form)
- Dosage administered – dosage wasted
- Patient report form or clinical record number
- Name and signature of person that administered the drug (if no witness, document solo worker)

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- Name and signature of the witness
- Stock balance
- Expiry date
- Batch number

7.6 Morphine, Diazemuls, Diazepam Solution, Rectal Diazepam, Ketamine, or Midazolam administered shall be recorded in the Controlled Drug Record Book by the Paramedic who administers the drug, against the replenishment record to identify each ampoule and Rectal tube individually by batch number.

7.7 If a mistake is made when completing the book, then the mistake should be bracketed off across the whole line the correct information should then be recorded in the next row down. Do not tear the page out of the book. There should be NO CROSSING OUT

7.8 All administration of Controlled Drugs should be witnessed. However, it is recognised that with solo responders it may be difficult to have administration of Controlled Drugs witnessed but should make every attempt to obtain a witness. Where there is no witness available the Clinician should record no witness available in the witness column.

7.9 Verbal orders are not permissible for Controlled Drugs Schedule 2 or 3. Legally Paramedics are not limited to administering 20mg for Morphine. In circumstances where additional doses are clinically necessary, they may take further clinical advice from a Doctor, 111 or External End of Life services. But then take the decision themselves as to whether to administer. This must be documented on both Patient care record and red book.

8.0 Destruction of Controlled Drugs

8.1 Expired medicines containing Controlled Drugs Sch 2, Sch 3 and Sch 4 (including Diazepam) must be denatured prior to disposal. CSOP.

9.0 Loss of Controlled Drugs

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9.1 Any apparent loss or discrepancy of Controlled Drugs must be reported to the LOM on duty at the time of the incident as well as the Duty Tactical Commander, Director of Nursing, Deputy Clinical Director, and the CD Accountable Officer as soon as possible in accordance with CSOP. A DATIX form should also be completed.

The following suggested steps should be used to try and resolve the issues,

- Check calculation of previous usage are correct
- Check clinical record to see if doses have been administered and not recorded.
- Check in main station CD stores to ensure error not from re-stocking.

9.2 In the event that drug cannot be accounted for within 24 hours the Police must be notified as well as reporting to the local CD Lin. The police crime number must be added to the Datix.

10.0 Action in the Event of Assault on Crews

10.1 In the event that any member of staff is threatened by a member of the public with a view to them obtaining the Controlled Drugs or any other drug, the member of staff **MUST OFFER NO RESISTENCE**.

10.2 The member of staff must immediately report the loss to the local police. The LOM must also be informed and a datix completed.

SECTION 3 LEGAL FRAMEWORK

1.0 Medicines

For the purpose of this policy, medicines (drugs) are defined as those substances included in the 1968 Medicines Act as medicinal products. The MHRA defines a medicinal product under Article 1 of Directive 2001/83/EC as:

(a) "Any substance or combination of substances presented as having properties for treating or preventing disease in human beings;

(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting, or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis."

2.0 Exemptions to Medicines Act

There are several exemptions from POM control of administration. The exemption may specify a particular form of a medicine and the exemption does not apply to any other form of the medicine.

2.1 Non-Parenteral Prescription Only Medicines (POM)

The Prescription Only Medicines (Human use) Order 1997 ([Statutory Instrument 1997 No. 1830](#)) states:

Exemption for non-parenteral administration to human beings.

The restriction imposed by section 58(2)(b) (*of the Medicines Act*) (restriction on administration) shall not apply to the administration to human beings of a prescription only medicine which is not for parenteral administration.

This means that **any** person, including lay people, is legally allowed to **administer** any POM that is not given parenterally. Parenteral administration is defined as breaching the skin or mucous

membrane and so nebulisation and rectal administration of drugs are **not** parenteral administration.

Administer does not include making a supply of medication for the patient to take away.

All administration should be supported by protocols or policies. EEAST has formally adopted the JRCALC guidelines to provide governance around administration of non-parenteral POMs in addition to locally agreed guidelines.

The control for non-parenteral POMs lies in the restrictions around purchasing POMs.

2.2 Emergency Administration of Parenteral POMs

The Prescription Only Medicines (Human use) Order 1997 ([Statutory Instrument 1997 No. 1830](#) and its amendment [Statutory Instrument 2005 No.1507](#)) states that:

The restriction imposed by section 58(2)(b) (restriction on administration) (*of the Medicines Act*) shall not apply to the administration to human beings of any of listed medicinal products for parenteral administration including:

- Adrenaline injection 1-1000
- Atropine sulphate injection
- Chlorphenamine injection
- Glucagon injection
- Hydrocortisone injection
- Naloxone injection

where the administration is for the purpose of saving life in an emergency.

This means that **any** person, including lay people, may administer these drugs parenterally in an emergency. Ambulance Technicians and lay pre-hospital care providers may administer defined parenteral medicines under this exemption.

2.3 Exemption for Paramedics

Paramedics are exempt from certain requirements of the Medicines Act. These exemptions allow them to administer or supply certain specified medicines without the directions of a Doctor.

The Prescription Only Medicines (Human use) Order 1997 Schedule 5n ([Statutory Instrument 1997 No. 1830](#)) lists the POM drugs that **Paramedics** may administer parenterally under an exemption. The administration shall only be for the immediate, necessary treatment of sick or injured persons. The following drugs may be administered by Paramedics under this exemption:

- Diazepam 5mg per ml emulsion for injection;
- Succinylated modified gelatine 4% IV infusion;
- Medicines containing the substances ergometrine maleate 500mcg per ml with oxytocin 5 i.u. per ml, but no other active ingredient;

Prescription-only medicines for parenteral administration containing one or more of the following substances but no other active ingredients:

- Adrenaline acid tartrate
- Amiodarone
- Anhydrous glucose
- Benzylpenicillin
- Bretylium tosylate
- Compound sodium lactate IV infusion (Hartmann's solution)
- Ergometrine maleate
- Frusemide
- Glucose
- Heparin sodium (cannula flushing only)
- Lignocaine hydrochloride

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- Metoclopramide
- Morphine sulphate
- Naloxone
- Ondansetron
- Paracetamol
- Polygeline
- Reteplase
- Tenecteplase
- Sodium bicarbonate
- Sodium chloride

This exemption only applies to Paramedics not Nurses. Nurses may only administer in accordance with the directions of an independent prescriber or a Patient Group Direction.

The Joint Royal Colleges Ambulance Liaison Committee (JRCALC) Guidelines provide advice to assist healthcare professionals to make decisions about the management of the patient's health, including treatments. The guidelines cover the full range of Paramedic treatments but also provide a tool for ambulance Technicians and other pre-hospital care providers. JRCALC guidance is **advisory**; it is not a legal document, but it may be used to support treatment decisions made by the organisation.

2.4 Access to Medicines by Patients

Patients access medicines in the following ways:

2.4.1 Self-Purchased from any retail outlet (GSL medicines) or from pharmacies (P and GSL medicines)

2.4.2 Patient **Specific** Direction i.e. individually prescribed by authorised prescriber using prescription form and dispensed to a named patient, or simple written instruction in the patient notes authorising administration. Prescribing is the preferred way for

patients to receive medicines. The Trust recognised both medical and non-medical prescribers-e.g. Nurses.

2.4.3 Patient Group Direction-medicines administered or supplied by an authorised healthcare professional to a patient not previously identified.

2.5 Misuse of Drugs Act 1971

The management of CDs is governed by the Misuse of Drugs Act (1971) and its associated Regulations (in England and Wales). There are additional statutory measures for the management of Controlled Drugs laid down in the Health Act (2006) and its associated Regulations. The primary purpose of the Misuse of Drugs Act is to prevent misuse and makes it unlawful to possess or supply a controlled drug unless an exception or exemption applies.

As Controlled Drugs are an essential part of modern clinical care and can be used to treat a range of clinical conditions in the community and the prehospital environment, EEAST is mindful that there is a potential for them to be misused causing harm. A separate section of this Policy addresses the safe management of Controlled Drugs.

There are several mechanisms for the supply and administration of Controlled Drugs.

Controlled Drugs can be:

(a) Prescribed by a Doctor or Nurse or Pharmacist independent prescriber - The Medicines and Human Use (Prescribing) (Miscellaneous Amendments) Order of May 2006 and subsequent updates.

(b) Supplied and administered by a Paramedic.

Paramedics are authorised under Group Authority to possess and supply to another person authorised to possess Controlled Drugs, Morphine and Diazepam.

Under an exemption to the POM Order (paragraph 9 of Part III to schedule 5) State Registered Paramedics are authorised to administer a range of **parenteral** medicines **for the immediate and**

necessary treatment of the sick or injured persons, including Controlled Drugs, Diazepam and Morphine.

(c) Supplementary prescribing Physiotherapists, Radiographers, Chiropodists/Podiatrists and Optometrists can prescribe any medicine, including some Controlled Drugs and unlicensed medicines providing they are listed in an agreed Clinical Management Plan for the patient concerned. All supplementary prescribers may prescribe for any medical condition, if they do so under the terms of a patient-specific Clinical Management Plan (CMP) agreed with the Doctor.

(d) Supplied and administered under Patient Group Directions-limited according to healthcare professional and specific Controlled Drugs in particular circumstances.

2.6 Misuse of Drugs Regulations 2001 (MDR)

The use of Controlled Drugs is permitted by the Misuse of Drug Regulations 2001(MDR).

The MDR classify the drugs in five schedules according to the different levels of control required. Schedule 1 CDs are subject to the highest level of control, whereas Schedule 5 CDs are subject to a much lower level of control. All Staff employed by EEAST who use medicines need to be aware of the current Regulations, these are periodically amended and revised so staff should keep up to date to any legislative changes.

2.7 The Misuse of Drugs (Safe Custody) Regulations 1973

The Misuse of Drugs (Safe Custody) Regulations 1973 (SI 1973 No 798) cover the safe custody of Controlled Drugs in certain specified premises. The Regulations also set out certain standards for safes and cabinets used to store Controlled Drugs.

2.8 Misuse of Drugs (Supply to Addicts) Regulations 1997

These Regulations prohibit Doctors from prescribing, administering or supplying Diamorphine, Cocaine or Dipipanone for the treatment of addiction or suspected addiction except under Home

Office licence. A licence is not required with such drugs for the treatment of organic disease or injury.

2.9 Health Act 2009

This Policy is further underpinned by The Health Act 2009 and The Controlled Drugs (Supervision of Management and Use) Regulations 2009. The Health Act 2009 supports local agencies to share information and intelligence within certain parameters about the use of Controlled Drugs in the health and social care sectors. Local agencies include the police, social services, the GPHC and inspectorates such as the Healthcare Commission. In carrying out this duty, EEAST will ensure that it complies with the GDPR and the policies of practice on patient confidentiality, taking into account the Caldecott principles.

The Health Act 2009 has placed a duty of collaboration on healthcare organisations and others, including professional regulatory bodies, police forces and the Care Quality Commission (CQC). **This duty of collaboration requires each organisation to share intelligence about possible CD issues and take appropriate action within their sphere of responsibility.** These new arrangements give a clear local responsibility for action and should lead to the coordination of local monitoring and inspection activities. It also has the provision for power of entry and inspection for the police and other nominated people to enter premises to inspect stocks and records of Controlled Drugs. This includes the Care Quality Commission (CQC) when conducting their annual assessments or inspections or reviews for registered bodies.

2.10 Patient Group Directions - The Law

The use of PGDs allows named healthcare professionals, other than medical practitioners, to supply and/or administer (but not prescribe) medication without having to call upon a Doctor to prescribe medication in each individual case.

The relevant modifications to the provisions in and under the Medicines Act 1968 are contained in the Prescription Only Medicines (Human Use) Amendment Order 2000, the Medicine (Pharmacy and

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General Sale - Exemption) Amendment Order 2000 and the Medicines (Sale and Supply) (Miscellaneous Provisions) Amendment (No 2) Regulations 2000 and subsequent extensions in 2002 and 2003. The legislation applies to the NHS, including the private and voluntary sector activity funded by the NHS.

Any PGDs drawn up for the care and treatment of patients must meet the requirements set out in the Health Services Circular 026/2000. They should also ensure that the signatory requirements specified in section 9(b)(iv) of the Prescription Only Medicines (Human Use) Amendment Order 2003 are met as outlined above.

Controlled drugs

The use of Controlled Drugs continues to be regulated under the Misuse of Drugs Act 1971 and associated regulations made under that Act. Legislation permits the supply and administration of Midazolam (Schedule 3) and substances on Schedule 4 (with the exclusion of anabolic steroids) and all substances on schedule 5 to be included in PGDs. Also the use of Morphine and Diamorphine (Schedule 2) under PGDs by Nurses in any care setting when used **for the immediate and necessary treatment of the sick or injured persons**. See EEAST PGD policy.

2.11 Discretionary Medicines

EEAST operates a discretionary medicines list containing only P and GSL medicines. Discretionary medicines may be **administered** in accordance with the Discretionary medicines protocol or JRCALC. Discretionary medicines must be recorded on the computer /record card and must be clearly marked "Discretionary" to distinguish them from medication administered or supplied in accordance with a Patient Group Direction or directions of a prescriber.

- 2.0 Prescription Only Medicines (Human Use) Order 1997 (POM Order)
- Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980

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- Medicines (Products other than Veterinary Drugs) (General Sales List) Order 1984 (GSL Order)
- The Medicinal Products (Prescription by Nurses etc.) Act 1992 and associated Regulations.
- Misuse of Drugs Act 1971
- Misuse of Drugs Regulations 2001, and subsequent amendments
- Guidance on Strengthened Governance Arrangements for Controlled Drugs January 2007
- A Guide to Good Practice in the management of Controlled Drugs in Primary Care Feb 2007
- Safer Management of Controlled Drugs in Secondary Care May 2007
- Security standards and guidance for management and control of controlled drugs in the ambulance sector April 2013
- Guidance for Pharmacists on the Safe Destruction of Controlled Drugs (RPSGB 2007)
- Drug Misuse and Dependence: UK Guidelines on Clinical Management (DH 2007)
- Patient Group Directions HSC 2000/02 and subsequent HSCs
- Hazardous Waste (England and Wales) Regulations 2005
- Providing Medicines Out of Hours Achieving Safe Practice July 2005.
- Medicine Matters July 2006
- The Safe and Secure Handling of Medicines: A Team Approach (the revised Duthie report) March 2005
- Standards for the Administration of Medicines February 2008 (NMC)
- UK Ambulance Service Clinical Practice Guidelines (2006) and updates (JRCALC and ASA)

Glossary

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Drugs that state 'USE BY' e.g. April 2015 must be used or returned as 'out of date' stock by end of April 2015. Drugs which give an 'EXPIRY' date e.g. April 2015 can be used up until 30th April 2015. Drugs that state USE BEFORE e.g. April 2015 can be used up until 31st March 2015.

3.0 Definitions

3.1 Personnel Definitions

3.1.1 Trained Member of Staff: a Paramedic, Nurse, Dentist, Pharmacist or Doctor.

3.1.2 Within this policy a Health Care Practitioner (HCP) is:

3.1.2.1 A Paramedic who is registered with the Health Professions Council

3.1.2.2 A Nurse who is registered as a Level 1 Nurse with the Nursing and Midwifery Council.

3.1.2.3 A Doctor who holds full General Medical Council registration and the appropriate right to work visa, who has appropriate qualifications, training and experience

3.1.2.4 Authorised Member of Staff: any registered Nurse/Paramedic who satisfies the criteria to enable him/her to administer medicines without supervision i.e. who has been authorised by EEAST to administer or supply medicines

3.1.2.5 Pharmaceutical Adviser: the Pharmacist responsible for the provision of pharmaceutical advice to EEAST

3.1.2.6 Pharmacist: a person whose name appears on the register of the General Pharmaceutical Council.

3.1.2.7 Prescriber: a Doctor or Nurse who has satisfied the requirements to be an independent prescriber and is registered as such with their professional body.

3.2 Process Definitions

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3.2.1 Any substance or combination of substances presented for treating or preventing disease. Any substance or combination of substances which may be administered with a view to making a medical diagnosis or restoring, correcting, or modifying physiological or psychological functions.

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

3.2.3 Dispense - To prepare a clinically appropriate medicine for a patient for self- administration or administration by another. The act of dispensing includes supply and also encompasses a number of other cognitive functions (e.g. checking the validity of the prescription, the appropriateness of the medicine for an individual patient, assembly of the product).

3.2.4 Supply-To supply a medicine to a patient/carer for administration. This would include the supply of pre-pack medicines.

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

3.2.6 Patient Group Direction- A specific written instruction for the supply and/or administration of named medicines in an identified clinical situation in the absence of a written prescription. It applies to groups of patients or other service users who may not be individually identified before presentation for treatment.

3.2.7 Patient Specific Direction- A Patient Specific Direction is a written instruction from a Doctor or dentist or non-medical prescriber for a medicine or appliance to be supplied or administered to a named patient. For example, a simple instruction in the patient's notes. Where a patient specific direction exists, there is no need for a Patient Group Direction.

Appendix

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- 1) Sessional work includes all agency, bank and includes any voluntary work completed by EEAST staff for Nars, Bears, Sars and Basic Air Ambulance services. This list is not exhaustive and can be amended.

Appendix A – Equality Impact Assessment

EIA Cover Sheet	
Name of process/policy	Medicines Management Policy
Is the process new or existing? If existing, state policy reference number	Existing policy
Person responsible for process/policy	Senior Pharmacy Technician Manager
Directorate and department/section	Clinical Directorate
Name of assessment lead or EIA assessment team members	N/A
Has consultation taken place? Was consultation internal or external? (please state below):	Yes with Operational Medicines Management Group, and Trust Medicine Management Group. These include a wide range of people that use our medicines

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The assessment is being made	Guidelines	
	Written policy involving staff and patients	x
	Strategy	
	Changes in practice	
	Department changes	
	Project plan	
	Action plan	
	Other (please state) Training programme.	

Equality Analysis

What is the aim of the policy/procedure/practice/event?

The aim of this policy is to provide guidance to promote the safe and effective use of all Medicines used across the Trust.

Who does the policy/procedure/practice/event impact on?

Race	<input type="checkbox"/>	Religion/belief	<input type="checkbox"/>	Marriage/Civil Partnership	<input type="checkbox"/>
Gender	<input type="checkbox"/>	Disability	<input type="checkbox"/>	Sexual orientation	<input type="checkbox"/>
Age	<input type="checkbox"/>	Gender re-assignment	<input type="checkbox"/>	Pregnancy/maternity	<input type="checkbox"/>

Who is responsible for monitoring the policy/procedure/practice/event?

Medicines Management Team

What information is currently available on the impact of this policy/procedure/practice/event?

No evidence to suggest that there is any potential differential impact for any of the protected characteristics.

Do you need more guidance before you can make an assessment about this policy/procedure/ practice/event? No

Do you have any examples that show that this policy/procedure/practice/event is having a positive impact on any of the following protected characteristics? Yes/No, If yes please provide evidence/examples: N/A

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Race	<input type="checkbox"/>	Religion/belief	<input type="checkbox"/>	Marriage/Civil Partnership	<input type="checkbox"/>
Gender	<input type="checkbox"/>	Disability	<input type="checkbox"/>	Sexual orientation	<input type="checkbox"/>
Age	<input type="checkbox"/>	Gender re-assignment	<input type="checkbox"/>	Pregnancy/maternity	<input type="checkbox"/>

Please provide evidence:

Are there any concerns that this policy/procedure/practice/event could have a negative impact on any of the following characteristics? Yes/No, if so please provide evidence/examples:

Race	<input type="checkbox"/>	Religion/belief	<input type="checkbox"/>	Marriage/Civil Partnership	<input type="checkbox"/>
Gender	<input type="checkbox"/>	Disability	<input type="checkbox"/>	Sexual orientation	<input type="checkbox"/>
Age	<input type="checkbox"/>	Gender re-assignment	<input type="checkbox"/>	Pregnancy/maternity	<input type="checkbox"/>

Please provide evidence:

No evidence to suggest that there is any potential differential impact for any of the protected characteristics.

Action Plan/Plans - SMART

Specific

Measurable

Achievable

Relevant

Time Limited

Evaluation Monitoring Plan/how will this be monitored?

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Who- Medicines Management Team

How- Audits

By Senior Pharmacy Technician Manager

Reported to- MMG