South East Coast Ambulance Service NHS
NHS Foundation Trust

Medicines Policy

Contents

1 Statement of Aims and Objectives

1.1. South East Coast Ambulance Service NHS Foundation Trust (the Trust) is committed to providing high quality patient care.

1.2. The Medicines Optimisation Strategy guides the development of medicines optimisation within the South East Coast Ambulance Service NHS Foundation Trust (SECAmb).

1.3. It is a key document that relates to how the principles of medicines optimisation are integrated into the Trust's systems, practices and culture at all levels.

1.4. This Medicines Policy addresses principles and standards for operational systems, processes and procedures for medicines management and governance within SECAmb. This Medicines Policy is the overarching policy for standard operating procedures (SOPs), Patient Group Directions (PGDs), and other policies and protocols pertaining to medicines within SECAmb.

1.5. This policy is applicable to all staff within the Trust involved in any medicines processes and sets out the scope of clinical practice to which they must adhere.

2 Introduction

2.1. Managing medicines safely, effectively and efficiently within SECAmb is a key component for the delivery of good quality patient centred care. Medicines play a significant role in the treatment of patients in urgent healthcare need (111) or in a medical emergency where life is at risk (999) SECAmb policies and procedures support good practice in medicines management, and ensure the correct medication is given, if needed, at the right time and worsening/follow up advice given to enable patients' wellbeing and to help maintain life.

2.2. Good clinical governance demands clear lines of responsibility and accountability and clear policies for managing risk. Systems that ensure the safe and secure handling of medicines are essential elements of good clinical governance.

2.3. This policy reflects the current legislative framework and national good practice for medicines governance within SECAmb. The safe and secure management of medicines within SECAmb is subject to the same principles as any other NHS trusts.

2.4. Medicines within SECAmb are ordered centrally via the SECAmb Medicines Distribution Centre located in Paddock Wood. It is distributed to other geographical areas which include Ambulance Stations and Hub Stores. SECAmb is using Omnicell within some of its operational sites. Omnicell is an automated medicines storage and supply cabinets system. Omnicell allows the Medicines Distribution Centre (MDC) electronic access to determine what medicines stocks are required (see Section 5.19, Medicines Distribution

Centre). Non-Omnicell sites order medicines using the ACESO stock management system. Either way the same medicines management principles should be followed.

3 Aims

3.1. To ensure all SECAmb staff involved with medicines are aware of the medicines management standards expected by SECAmb.

3.2. To ensure that every healthcare professional understands their responsibilities in ensuring safe and secure handling of medicines and work within relevant legislation, national good practice guidance and the code of conduct and standards for their professional regulatory body.

3.3. To ensure Community First Responders (CFRs) and other volunteers/partner services involved with medicines are aware of their responsibilities in relation to medicines.

3.4. To protect patients and staff by managing and minimising risks associated with the use of medicines.

4 Scope

4.1. This policy is applicable to all staff employed by SECAmb including Bank and agency staff who store, prepare, dispense, supply, prescribe, monitor, administer, transport, handle or dispose of medicines. It outlines their responsibilities in relation to medicines. This policy does not cover staff employed by other private or NHS ambulance services working on behalf of SECAmb under mutually agreed contracts/arrangements.

4.2. The scope of this policy is very broad and can therefore not include all details related to medicines management activities in specific areas. However, the principles in this policy are similar in the different settings within SECAmb in terms of medicines management and the professional responsibility of healthcare professionals (e.g., Medical Doctors, Consultant Paramedics, Specialist Paramedics, nurses and pharmacists), other clinicians directly employed by the Trust including those of Community First Responders (CFRs) and other volunteers.

4.3. Clinical elements including administration of medicines are beyond the scope of this policy.

5 Medicines Policy

Accountability of registered and non-registered SECAmb staff

5.1.1. All staff employed by SECAmb are accountable for their own actions.

Registered healthcare professionals

5.1.2. Registered healthcare professionals within SECAmb are expected to work within their own individual scope of practice in the area(s) where they have the

knowledge, skills and experience to practice lawfully, safely, effectively, and that meets their professional regulatory body standards and those of SECAmb.

5.1.3. Registered healthcare professionals are considered as autonomous professionals who are able to make informed, reasoned decisions. They are expected to account for their practice to their professional regulatory body and to SECAmb.

Non-registered SECAmb Staff

5.1.4. SECAmb employs non-registered staff to deliver patient centred care, such as:

- Emergency Care Support Worker - ECSW
- Trainee Associate Ambulance Practitioner – TAAP
- Associate Ambulance Practitioner/Technician – AAP/Tech

5.1.5. Non-registered staff are accountable to SECAmb for their practice and actions. Non-registered staff are not expected to undertake clinical decision making about patients' conditions with a view to administer or supply a Prescriptions Only Medicine (POM) (See Section 5.5, Legal Framework of Medicines).

5.1.6. The only exceptions to this are for

(i) Administration of Schedule 19 parenteral POMs provided non-registered staff have been trained and deemed competent to do so (See Section 5.10, Exemptions to the Human Medicines Regulation (HMRs))

(ii) Situations where the SECAmb Trust Board has approved a protocol allowing non-registered staff to undertake clinical decision making with the view to administering a POM medicine (See Sections 5.13, Medicines administered to patients outside usual recommended legal mechanisms and 5.14, Trust Approved Protocols for Medicines).

SECAmb Volunteer Workers (e.g. Community First Responders)

5.1.7. SECAmb also has a number of workers who are volunteers (e.g., Community First Responders). These workers are non-registered and are accountable to SECAmb for their practice and actions (See Section 6.42, Community First Responders (CFRs), section 6.4 SECAmb Medicines Stored at Home and Supply and Distribution of Medicines to Volunteer Responders SOP)

Legal Framework of Medicines

5.1.8. Medicines are legally classified as General sales list (GSL) medicines, Pharmacy Only (P) medicines and Prescription Only Medicines (POMs). POMs category also covers Controlled Drugs (CDs), where additional controls are in place (see SECAmb Controlled Drugs Policy).

5.1.9. The legal mechanisms available for supply and administration of medicines are Prescribing (See Section 5.6), Patient Specific Directions (see Section

5.7), Patient Group Directions (see Section 5.8), Protocols (see Section 5.9) or exemptions (see Section 5.11).

5.1.10. There are also exemptions to the medicine's legislation i.e. Human Medicines Regulations 2012 (HMR) Schedule 17 Part 3 (see Appendix A) that allow registered paramedics to administer certain parenteral POMs to patients for certain purposes and HMR Schedule 19 (see Appendix B) which allows anyone to administer from a defined list of medicines for the purpose of saving life (see also Section 5.11, Exemptions to the Human Medicine Regulations).

5.1.11. The Clinical Practice Guidelines (JRCALC or SECAmb) are not a legal authorisation that allow ambulance staff to administer the medicines listed in the clinical practice guidelines to patients.

Prescribing

5.1.12. Within the 999 service, prescribing healthcare professionals are not currently utilised nor are prescription pads (FP10 prescriptions) or electronic prescriptions available.

5.1.13. Within the 111 service, medical and non-medical prescribers (NMP) are utilised to provide prescriptions to patients via the Cleric Electronic Prescribing System (EPS) enhancing the services available via 'hear and treat'.

5.1.14. In conjunction to this policy, all prescribers are required to familiarise themselves with the CD policy, Prescribing policy and all relevant EPS documentation and SOPs.

Patient Specific Directions (PSD)

5.1.15. A PSD is a written instruction from an independent prescriber (e.g., doctor, dentist or independent non-medical prescriber) produced after the completion of a patient assessment, to another healthcare professional, to supply and/or administer a medicine directly to a named patient, or to several named patients. In practice, a PSD is commonly referred to as a prescription.

Patient Group Directions (PGDs)

5.1.16. PGDs are defined as written instructions for the supply and/or administration of medicines to groups of patients who may not be individually identified before presentation for treatment. PGDs are not a form of prescribing but provide a legal framework for the supply and/or administration of medicines by a range of registered healthcare professionals (e.g., Paramedics, nurses and pharmacists). SECAmb is responsible for ensuring that all users of PGDs are fully competent and trained in their use.

5.1.17. PGDs within SECAmb are developed, approved and reviewed by the SECAmb PGD Approval Working Group in line with the SOP for Development, Approval, Authorisation, Review, Withdrawal, Management, Use and Audit of Patient Group Directions.

5.1.18. As specified in the regulations, only qualified, registered, health professionals can supply or administer medicines under a PGD upon completion of the required training and assessment. They can only do so as named individuals,

within their professional competence and in accordance with their professional guidance and cannot delegate the supply and administration of a medicine under a PGD.

Trust Specific Medicines Protocols

5.1.19. Within SECAmb, supply of GSL, P and POM medicines to patients is via the legal mechanism of a PGD (Section 5.8, Patient Group Directions) or prescriptions (Section 5.6, Prescribing).

5.1.20. Stock POMs may only be administered to patients by registered clinicians provided they have the legal means to do so and are within their individual scope of practice. However, SECAmb can use protocols for administration of medicines outside of JRCALC which provide an alternative governance framework for authorised staff.

5.1.21. Trust approved protocols provide a robust written governance framework that has been approved and signed off by the Medical Director, Chief Pharmacist and a Consultant Paramedic, which enables authorised staff to administer medicines. The written governance framework should include as a minimum:

- Identify the specific staff group/members this pertains to.
- Justification for why this specific staff group requires access to supply medicines.
- Outline the training and assessment this specific staff group will receive including frequency of repeat training.
- Include each medicine (e.g., name, dose, frequency, indication, side-effects, circumstances for use) and what actions this specific staff group is required to do if patients fall the inclusion criteria.
- Specify how compliance with this protocol will be monitored through audits and who is responsible for auditing this
- These protocols should be approved by the MGG and Trust Board; a review must occur every 3 years or earlier when there are any changes that may affect these protocols (e.g., National guidelines, gaps in service, SPC updates).

5.1.22. Protocols can also be used in exceptional circumstances where SECAmb decides certain staff groups can administer medicines to patients outside the usual legal mechanisms, (e.g., administration of oxygen to patients by Community First Responders). The SECAmb Trust Board must be aware and in agreement when this practice takes place within SECAmb.

Private Ambulance Provider (PAP) PGDs

5.1.23. Private Ambulance Providers PGDs must be authorised via the SECAmb PGD authorisation process in order to administer PGD medications to our patients. Their staff are responsible for the development, regular review and any required amendments of their PGDs.

5.1.24. A current memorandum of understanding (MoU) is under development between SECAmb and current PAPs to clearly define the roles and responsibilities of both organisations.

Exemptions to the Human Medicine Regulations (HMRs)

5.1.25. Schedule 17, Part 3 of the Human Medicines Regulations 2012 (Appendix A) allows registered paramedics to administer from a defined list of parenteral POMs for the immediate, necessary treatment of sick or injured persons. This exemption is only applicable to registered paramedics and is not extended to registered nurses or student paramedics even under supervision by a registered paramedic.

5.1.26. Schedule 19 of the Human Medicines Regulations 2012 (Appendix B) allows anyone to administer from a defined list of parenteral emergency POMs for the purpose of saving a life in an emergency provided they are competent to do so and have access to the medicines. SECAmb will agree which practitioner groups can be authorised to administer each schedule 19 medicine and will ensure that all the appropriate protocols, training and competency assessments are in place.

5.1.27. Schedule 17, Part 3 of the Human Medicines Regulations 2012 allows persons (e.g., registered nurses) who hold a current advanced life support provider certificate issued by the Resuscitation Council (UK) to administer parenteral adrenaline 1:10,000 up to 1 mg (intravenously) and parenteral amiodarone but only in an emergency involving cardiac arrest.

Verbal Orders

5.1.28. SECAmb employs different mechanisms to avoid the use of verbal orders (i.e., verbal telephone prescribing by a prescriber) such as the use of Patient Group Directions (See Section 5.8, Patient Group Directions).

5.1.29. The practice of receiving and accepting **verbal/remote orders** for the administration or supply of any Prescription-Only-Medicines by registered clinicians from medical or non-medical prescribers is **not permitted** by SECAmb.

5.1.30. Registered clinicians can obtain advice and support from medical/non-medical prescribers and the clinical operational desk. However, they are expected to act on this advice based on their own professional judgement and only administer or supply medicines to patients if they have the legal means to do so (See Section 5.5, Legal Framework of Medicines). The accountability remains with the clinician administering or supplying medicines and not with the person offering advice.

SECAmb Medicines Formulary

5.1.31. Only medicines on the SECAmb Medicines Formulary can be ordered, stored and used by SECAmb frontline staff (see current Medicines Formulary).

5.1.32. Medicines can only be added to or removed from the SECAmb Medicines Formulary following authorisation from the Medicines Governance Group (MGG) after the receipt of a New Drug Application form (NDA) and documented agreed approval by the MGG. (NDA forms can be accessed on the Trust intranet, also attached to the Medicines Formulary as an appendix).

5.1.33. The NDA form also requires that a written risk assessment and/or quality impact assessment is undertaken by the applicant to determine potential risks

to patients and staff of adding or removing a medicine from Medicines Formulary. This includes assessing the training needs of the relevant SECAmb workforce when introducing a new medicine. This risk assessment and/or quality impact assessment should accompany the Medicines Formulary application form.

5.1.34. The Chief Pharmacist and Medicines Governance Team are responsible for retaining the Medicines Formulary application form, risk assessment, quality impact assessment and the documented outcome of the decisions made by the MGG.

5.1.35. Medicines that are not on the SECAmb Medicines Formulary can only be ordered in exceptional circumstances with prior written agreement from the Chief Pharmacist and Chief Medical Officer provided there is an acceptable documented reason for this variance to standard practice. This must be followed as soon as possible by an NDA form to be considered by the MGG.

5.1.36. The Dictionary of Medicines and Devices (dm+d) is a dictionary of descriptions and codes which represent medicines and devices in use across the NHS. All drugs included in the SECAmb Medicines Formulary must be written according to this dictionary. Anytime a drug is written within any Trust documentation or system, it must match the Formulary for consistency.

Medicines administered to patients outside usual recommended legal mechanisms

5.1.37. In exceptional circumstances SECAmb may decide that certain staff groups can administer medicines outside the normal legal mechanisms that are available to them. It is important that this decision is made at Executive Director level and that the SECAmb Board is aware of this practice. This is because it is not considered good practice to administer medicines to patients outside the usual legal mechanisms available.

5.1.38. For example, where SECAmb staff are expected to administer non-parenteral POMs and there is no legal mechanism for these staff to do so (i.e., staff who are not on the list of approved registered healthcare professionals who can use Patient Group Directions) then one option is to use a SECAmb approved protocol. The same applies if staff who can legally administer parenteral medicine to patients according to Schedule 17 (part 3) or Schedule 19, but where this parenteral medicine is administered via a different route outside its licensed method. This makes this an off-licensed use (off-label) which is not covered by the exemptions in Schedule 17 (Part 3) or Schedule 19 in the Human Medicines Regulations (2012) or through the use of Patient Group Directions (PGDs).

5.1.39. The Executive Management Board (EMB) has delegated authority to the Medicines Governance Group (MGG). The MGG must approve SECAmb protocols where medicines are administered to patients outside the normal legal mechanisms as outlined above.

5.1.40. These must be presented to SECAmb Trust Board for approval where appropriate. The Medical Director and Chief Pharmacist should advise the Trust Board of these practices where they occur within SECAmb.

5.1.41. These protocols must include points 5.14.2 to 5.14.5 above but in addition there should be best evidenced demonstrating as to why SECAmb requires particular staff groups to administer medicines outside usual legal mechanisms. The MGG and Trust Board should determine the review date for these protocols which should not exceed 2 years.

Procurement of Medicines

5.1.42. Medicines are purchased on behalf of SECAmb from approved Wholesale Dealers. The Head of Procurement is responsible for ensuring that procurement of medicines is from providers that have been agreed by the Chief Pharmacist. This is to ensure that these medicines are obtained from a reputable source, are of suitable quality, to minimise the risk of falsification and that the provider has all the appropriate licences in place.

5.1.43. The Medicines and Medical Devices Act 2021 enables the Government to make regulations aimed at preventing falsified medicines from entering the medicine supply chain. No timetable has been set by the Government for consultation, but further details of the government's intentions should be published in 2023.

5.1.44. Only medicines purchased by SECAmb can be administered or supplied to patients by SECAmb staff. The exception to this is patients' own medicines (See Section 6.14, Patients' Own Drugs). Medicines should not be borrowed from local hospitals.

5.1.45. Procured medicines are delivered to the Medicines Distribution Centre (MDC) located at Paddock Wood and onward distribution to Trust sites are governed by internal MDC SOPs.

5.1.46. A system is in place to provide a full audit trail and traceability for medicines; this is accessible by the Medicines Governance Team. This the system oversight includes procurement, ordering, storing, transportation, use or disposal. It can also identify medicines within SECAmb that are subject to any recalls and patient safety alerts (See Section 6.44).

Medicines Distribution Centre (MDC)

5.1.47. Medicines, including Controlled Drugs, are delivered directly to the Medicines Room at MDC Paddock Wood from the medicines provider (Wholesaler). The MDC activity is managed by the Medicines Distribution Centre Manager.

5.1.48. Medicines are entered into the SECAmb stock system ACESO.

5.1.49. The MDC receives medicines orders through ACESO and Omnicell, assemble orders and arranges transportation to the required locations by the logistics staff.

5.1.50. SECAmb's Medicines Distribution Centre is also responsible for assembling different pouches containing medicines used by SECAmb staff (e.g., paramedics).

5.1.51. These assembly processes are undertaken by Pharmacy Support Workers and Senior Pharmacy Support Workers, overseen by registered Senior Pharmacy Technicians who are responsible for the day-to-day management of the MDC.

5.1.52. The use of different pre-packed pouches allows relevant SECAmb staff to have prompt access to the required medicines in an emergency situation. All pre-packed pouches are prepared using a computer-based tracking system (ACESO) to ensure full accountability and management of medicines.

5.1.53. The pre-packed pouches are ordered and distributed via ACESO or Omnicell.

5.1.54. The MDC has local standard operating procedures in place for all activities.

Ordering and Receiving Medicines

5.1.55. Please refer to the Receipt and Distribution of Medicines SOP.

The Master Stock List

5.1.56. The SECAmb Master Stock List includes all the medicines on the approved SECAmb Medicines Formulary (see Section 5.13). This also includes which medicines are stocked at each operational location. Each operational location has an approved site-specific stock list for medicines.

5.1.57. The individual stock list for each operational location should be approved by the Chief Pharmacist. Only Medicines from the approved site-specific stock list can be ordered for that operational location and must be monitored by Medicines leads and Medicines Governance Team during their routine checks.

5.1.58. The master stock list has set medicine quantity levels per station site. This is reviewed and updated regularly by the Medicines Governance Team and Operational Managers. Logistics staff need to be aware when levels are adjusted on non-Omnicell sites so they are topping up to the current operational levels.

Medicine Orders

5.1.59. For Non-Omnicell sites (i.e., operational locations), medicine orders are raised by Operational Team Leaders (OTLs) using the ACESO stock management system for all items except medicines pouches. Logistics staff will visit the operational locations to top-up the various pouches to a standardised level and will leave delivery notes for appropriate record keeping.

5.1.60. For Omnicell sites (i.e., operational locations), the Omnicell system generates medicine orders automatically including orders for pouches assembled by the MDC. This allows an automatic top-up of medicines to ensure the minimum stock level is maintained within the operational locations (e.g., ambulance stations).

5.1.61. All Controlled Drugs are ordered using ACESO and Omnicell.

5.1.62. The medicines ordered via ACESO or Omnicell are picked by MDC staff and booked out to the individual operational sites. The medicines are packed into sealed tamper-proof containers for onward distribution by logistics.

5.1.63. Purchase orders raised for medicines must be authorised and approved according to SECAmb procedures.

5.1.64. All orders for medicines must be authorised by the Chief Pharmacist, who may delegate this to other pharmacy staff but will retain the overall responsibility.

Receipt of Medicines at Station Sites and Hub Stores

5.1.65. Medicines received at operational locations (e.g., ambulance stations), should be checked against the delivery note left by logistics which is then signed and dated to confirm that this check has taken place. These delivery notes should be kept for 2 years for checking and audit purposes by OTLs.

5.1.66. OTLs are responsible for all medicines stored and handled at operational locations e.g., ambulance stations. This includes receipt of medicines, and this task can be delegated where appropriate.

5.2.1. For Omnicell sites, the logistics driver loads the medicines (except for controlled drugs) into the Omnicell according to the packing list. It is best practice for these packing lists to be signed and dated and kept for 2 years for checking/audit purposes by the OTLs.

5.2.2. For Controlled Drugs (CDs), a registered practitioner must load the CDs into the Omnicell/ CD cabinet with the logistics driver acting as the witness.

6 Storage and Security of Medicines

Medicines Storage

6.1.1. All medicines (including infusion fluids) should be stored securely in line with the approved Medicines Room Specification, with access restricted to authorised persons only. They should be stored in line with the Health and Safety Control of Substances Harmful to Health (COSHH) Guidelines.

6.1.2. All medicines should be stored in a locked cupboard or other secure container reserved solely for that purpose. Mechanisms should be in place so that no unauthorised staff have access to medicines.

6.1.3. Medicines should always be stored in their original container (i.e., manufacturer’s packaging). Medicines should not be transferred from their original container to another container. They must not be removed from their original container until required for immediate administration to the patient.

6.1.4. Medicines stock must be regularly rotated and checked to ensure medicines have not expired (See SOP for Expiry Date Checking and Rotation of Medicines).

6.1.5. The overall responsibility for the monitoring and storage of medicines lies with OTLs for operational locations (e.g., ambulance stations), Logistics Managers

for the hub-stores and the MDC manager for the Medicines Distribution Centre.

6.1.6. All staff should report any concerns about medicine storage to their line manager and complete an incident report (DIF1).

6.1.7. Parenteral medicines should, where practically possible, be physically segregated from non-parental medicines (e.g., nebuliser solution). This is to minimise risk of accidental administration of a medicine by the wrong route. Clinicians must always check that they are administering the correct medicine by the correct route.

Medicine Pouches and Medicines Bags (or Paramedic bags)

6.1.8. SECAmb uses pre-packed pouches containing medicines (excluding Controlled Drugs) which are assembled by the MDC Pharmacy support workers.

6.1.9. SECAmb uses different coloured tags to seal pouches.

- A green tag indicates the pouch has been packaged and quality checked by the MDC.
- A yellow tag must be used to seal a pouch when more than the minimum stock levels remain.
- A red tag must be used to seal the pouch when the minimum stock level is reached and must be placed in the return bin (See SOP for Pouch Tagging Process).

6.1.10. Pre-packed medicine pouches are loaded back in to the Omnicell at the end of a shift and make ready areas where applicable (Omnicell sites) or returned to an ambulance station for secure storage at the end of a shift (non-Omnicell sites).

6.1.11. The pre-packed pouches are collated and placed in medicines bags by Make Ready Operatives (MROs) as per a standardised load list. These medicines bags are then sealed.

6.1.12. Controlled Drugs (i.e., diazepam injection and morphine injection) are booked out at the beginning of a shift by a registered Paramedic. They should be kept on the Paramedic's person (i.e., personal possession by the paramedic) for the duration of the shift. (See SOP on Controlled Drugs Possession Using Body Worn Pouches).

6.1.13. The CDs must be signed back into the CD cabinet or Omnicell at the end of the shift. This is also the case in situations where the controlled drug has been used or ampoules broken.

6.1.14. In addition, on double crew vehicles Critical Care Paramedics will also carry an individually locked Peli case containing approved extended CD formulary.

This Peli case will be stored in the secure drugs cabinet within the ambulance vehicle.

6.1.15. If a Critical Care Paramedic travels in a single response vehicle, then this locked Peli case and medicines bag (or paramedic bag) must be locked away out of sight. The pouch containing Controlled Drugs (morphine and diazepam) must remain on the Critical Care Paramedic's person at all times.

6.1.16. Vehicles must be locked when unmanned and any medicines stored within them must be kept out of sight wherever possible. Only medicines pouches and medicines bags that have been approved by SECAmb may be used. Pouches and medicines bags must be stored in conditions that ensure the continued quality and stability of enclosed medicines. Medicines must not be kept in vehicles when not in use (e.g., overnight). This includes all infusion fluids and medicine bags.

Storage Temperature for Medicines

6.1.17. Medicines must be stored within the recommended temperature range according to the manufacturers' instructions which is often printed on the packaging. Refrigerated medicines should be stored between +2^{o}C to +8^{o}C and between +15^{o}C to +25^{o}C for medicines stored at room temperature.

6.1.18. Some refrigerated medicines are permitted to be stored outside of the fridge for a limited period (i.e., the expiry date of the product is reduced to a specified amount of time). Only refrigerated medicines which have this included as part of their Marketing Authorisation (product licence), have been agreed by SECAmb for inclusion within the Trust Formulary. There is a clear mechanism in place to ensure that the resultant reduced expiry date is clearly marked and the manufacturers storage requirements adhered to. Examples include Glucagon (18 months expiry) and Rocuronium (12 weeks expiry) when stored outside the fridge.

6.1.19. Medicines refrigerator temperatures and ambient room temperatures must be monitored regularly. If the temperature is outside the required range, then staff must react immediately and seek further advice from Senior Operational leads, the Chief Pharmacist or a senior member of the Medicines Governance Team (see SOP for Manual/Automated Medicines Temperature Monitoring).

6.1.20. Each site/area/operational location must appoint a named OTL who is responsible for ensuring the safety of medicines storage on station sites and any temperature excursions on a day-to-day basis (see SOP for Manual/Automated Medicines Temperature Monitoring).

SECAmb Medicines Stored at Home

6.1.21. Response Capable Managers (RCMs) (i.e., Paramedics who do not have regular paramedic shifts) have paramedic bags containing medicines which are kept in the RCM's home environment. RCMs are responsible for ensuring that their paramedic bag is stored in a cool place away from heat sources (e.g., 15^{o}C to 25^{o}C) within the home, kept securely to limit access as appropriate and that the enclosed medicines are within their expiry dates.

6.1.22. If the RCM suspects a temperature excursion regarding the medicines within their paramedic bag, they are to notify the Medicines Governance Team immediately and submit a Datix.

6.1.23. Community First Responders (CFRs) have medicine pouches which are stored in the CFR's home environment. CFRs are responsible for storing these medicine pouches in a cool place away from heat sources (e.g., 15^{o}C to 25^{o}C), keeping them secure to limit access as appropriate and ensuring that the enclosed medicines are within their expiry dates.

6.1.24. If the CFR suspects a temperature excursion regarding the medicines within their CFR pouch, they are to notify the Medicines Governance Team immediately and submit a Datix.

6.1.25. Expired medicine pouches and RCM paramedic bags should be returned to an operational location (e.g., ambulance station) where a new medicines pouch or paramedic bag can be issued (See SOP for Pouch Tagging Process).

Security of keys and Keypad Access

6.1.26. The responsibility for controlling access to the medicine cupboards and medicine storage areas lies with the OTLs for operational locations (e.g., ambulance stations), and Stores Managers for medicines stores.

6.1.27. They are also responsible for ensuring that a process is in place for the reporting of missing keys promptly and that immediate action is taken to prevent unauthorised access to medicines, including controlled drugs. If a missing key is not found, the lock (or suite of locks if the master key is missing) must be replaced and a Datix must be completed (see SOP on Changing security codes for medicines storage).

Key Checks

6.1.28. All keys must be checked at any shift change.

6.1.29. Any spare second sets of keys must be kept in a secure location and detailed in the local business continuity plan.

6.1.30. Keys for CD cupboards should be kept separate from other keys; the responsibility for the CD keys remains with the duty OTLs or OUMs. If the CD keys cannot be kept separately from other station keys, then a risk assessment should be undertaken, and all keys treated as if they are CD keys.

Keypads

6.1.31. Where access to a medicine's cupboard is controlled by a keypad, only authorised staff may have access to the code. The code should be changed every 3 months (see the SOP for Changing Security Codes for Medicines Storage).

6.1.32. SECAmb staff are forbidden from using any SECAmb equipment or medicines whilst working for a private medical/ambulance service, any of the voluntary

aid societies, charities or voluntary organisations. Should requests for such activity be received, these must be raised to the Chief Pharmacist and Chief Medical Officer.

6.1.33. Staff must not take medicines from stock for personal use.

Transportation of medicines

6.1.34. Transfer of medicines within SECAmb sites (Omnicell and Non-Omnicell sites) should be initiated through a system in which all orders and dispatches are recorded. This includes SECAmb recording receipts of medicines when received.

6.1.35. Procedures and equipment used in transportation of medicines should be designed to ensure that the integrity and quality of the medicines is not compromised. This relates to all vehicles transporting medicines including ambulance vehicles. Medicines must never be stored in a vehicle overnight/when not in use.

6.1.36. Staff engaged in transportation of medicines should be identified, authorised and appropriately trained.

6.1.37. Tamper-evident and, preferably, secured containers should be used when the transportation is under personal control throughout (e.g., by paramedics or logistics staff). Secured containers in secured vehicles should be used when the medicines are not under personal control throughout the transportation.

6.1.38. Controlled Drugs that are delivered to different sites within SECAmb must be received by a Designated Person (i.e., registered healthcare professionals) who should check them against the Controlled Drugs order and record that a check has been made before the CDs are entered into the CD cabinet and filled appropriate register /Omnicell.

6.1.39. Cold chain control, within the limits appropriate to the individual product, should be maintained for items requiring refrigeration (See Section 6.3).

6.1.40. If vehicles are involved in untoward incidents (e.g., road accidents) and taken directly to repair facilities or another location, a manager should attend the scene and remove and secure any medicines within the vehicle.

Mass Casualty Vehicles and Major Incidents

6.1.41. Medicines carried on Mass Casualty Vehicles (MCVs) are provided by the National Ambulance Resilience Unit (NARU) and locally managed by SECAmb following the SECAmb governance system, processes and procedures.

6.1.42. Each MCV will carry medicines to a standard list provided by NARU and the medicines will be exclusively supplied via NARU (not from SECAmb).

6.1.43. The MCVs are fitted with controlled drugs cupboards and pharmaceutical fridges. The ordering, storage and monitoring of medicines within MCVs follow a separate SECAmb procedure. This is because SECAmb does not store

medicines or Controlled Drugs in vehicles when not in use. The MCVs are stored in internal locked garages when not in use.

6.1.44. The Hazardous Area Response Team (HART) Operations Manager (HOM) and HART Team Leader (HTL) should follow local operating procedures in accordance with this policy. Contingency, Planning and Resilience (CPR) are responsible for developing and implementing a local standard operating procedure for: Safe and Secure Storage of Medicines including Controlled Drugs within Mass Casualty Vehicles.

Administration of medicines

6.1.45. Administration of medicines to patients can only be carried out by staff who are authorised and competent to do so. This will depend on the clinical grade of the member of staff and training/competency assessment undertaken as appropriate.

6.1.46. When medicines are administered to patients the following details should be recorded in the Patient Clinical Record (paper or electronic):

- Incident number (CAD number)
- Name of patient, date of birth, address
- Diagnosis/ working diagnosis
- Medicine name, form, strength and dose administered (or supplied).
- Route of administration
- Date and time of administration
- Administered via PGD, protocol, exemption…
- Batch number and expiry date of medicines administered
- Information or advice given
- Details of any adverse reactions and action taken
- Name, position and registration number of registered healthcare professionals
- Witness name, position and registration number (if relevant).

6.1.47. Generally, parenteral medicines should not be prepared in advance of their use (i.e., medicines stored in a pre-drawn state). If preparations are required to be prepared in advance, then SECAmb will undertake a risk assessment and wherever possible procure commercially pre-filled syringes. Medicines should generally be prepared immediately before being administered.

6.1.48. Preparation and administration of parenteral medicines should follow the SECAmb Infection Prevention and Control Procedure for Aseptic Non-Touch Technique (see Infection Prevention and Control Policy and Manual).

6.1.49. For general principles of medicines administration refer to SOP Administration of Medicines.

Staff authorised to administer medicines

6.1.50. Registered healthcare professionals are accountable for their own clinical decision making including ensuring they can evidence their competence to

administer medicine(s). They should only work within their own scope of practice. This includes ensuring that the correct medicine is administered to the correct patient via the correct route in the correct form and correct dose at the correct time (See also SOP Administration of Medicines).

6.1.51. Only medicines from the SECAmb medicines formulary can be administered by staff. (See SECAmb Medicines Formulary).

6.1.52. The Clinical Standards Scope of Practice Policy Appendix M: “Medicines Administration Authorised for use, by Clinical Grade” provides a guide to which medicines can be administered or supplied by each staff group and the legal mechanism for administration/supply.

6.1.53. The general staff groups listed in this Appendix M should not be translated into personal authority. This is because individual members of staff may have restrictions or sanctions placed on their scope of practice.

6.1.54. If individual members of staff (registered and non-registered) are unclear what their scope of practice is or what medicines they are authorised to administer, it is their responsibility to raise this with their line manager. Line managers of staff authorised to administer medicines should, through regular one-to-one/supervision, also discuss medicines use/ administration to ensure everyone within SECAmb is clear about their accountabilities and responsibilities related to medicines. This includes identifying any additional training needs of individual members of staff. (See Clinical Supervision Procedure and principles in practice).

6.1.55. Community First Responders (CFRs) and other volunteers can only administer medicines that they have been authorised to administer (see Section 5.9).

6.1.56. Administration of medicines to patients must be documented in the Patient Clinical Record (paper or electronic).

Delegated tasks

6.1.57. Registered healthcare professionals cannot delegate the administration of medicines to other non-registered staff).

6.1.58. However, in practice registered paramedics may find themselves in an emergency situation where their responsibility towards a patient (e.g., maintaining their airway) will require them to delegate the drawing up of a parenteral medicine to a competent ambulance technician. The registered paramedic must be the person administering this parental medicine (i.e., not delegate the administration). The paramedic is responsible for this delegated task and must ensure that the (i) person (e.g., ambulance technician) is competent to draw up this medicine and (ii) correct medicine and dose is being administered to the patient (i.e., checking the original ampoule/vial and reconstitution fluid used).

6.1.59. This process does not apply to Controlled Drugs where it must be the paramedic who draws up the medicines to be administered.

6.1.60. Under no circumstances should a part-used syringe containing medicine be handed over to another clinician taking over the care of a patient.

Controlled Drugs

6.1.61. Controlled Drugs can only be administered to a patient by authorised registered healthcare professionals. All attempts should be made to have a second checker who can witness the whole administration process from the drawing up of the CD to its administration. The name and ID of this witness should also be recorded in the Patient Clinical Record.

6.1.62. The procedure to be followed is included in the SOP for Administration of Controlled Drugs and full governance details can be found in the Trust CD policy.

Patients' Own Drugs (PODs)

6.1.63. Patients can self-administer their own medicines which have been prescribed for them.

6.1.64. Staff can also support patients to administer their own medicine that has been prescribed and labelled, with the patient's consent. Staff must perform the usual medication checks and follow the directions for administration on the medication dispensing label.

6.1.65. Full details of the medication administered with support from staff must be documented on ePCR.

Student Practitioners

6.1.66. Students are non-registered healthcare professionals. Student paramedics can NOT administer paramedic only medicines (see Section 5.5 Legal Framework of Medicines).

6.1.67. However, students should, as part of their training, be involved in the decision making and reasoning behind the administration including considering the indication(s), cautions, contra-indications, interactions and side-effects. A registered healthcare professional is responsible for the final decision making).

6.1.68. Students Paramedics Practitioners are registered healthcare professionals as Paramedics and are allowed to administered Paramedics medicines but until relevant training is achieved, they remain unauthorised to administer medicines stored in PP pouches.

Second check/Witness administration

6.1.69. To ensure the right medicine, at the right dose, is given to the right patient, a second independent check must be obtained from another healthcare professional, family member or able bystander where this is practically possible. This reduces the risk of error administering/supplying medicines to patients.

6.1.70. Extra care should be taken when the medicine is for:

- Children
- Controlled Drugs: It is required by law to obtain the witness signature and explain the reason if not able to obtain. (See SOP CD reconciliation and check).
- Parenteral administration: We have different strengths in our Formulary so it's crucial to second check the right route has been chosen.
- Medicine has potent effects/side-effects requiring close monitoring.
- Calculations involved.

6.1.71. The independent checker/witness should not be influenced by others around them but undertake the check independently.

6.1.72. Accountability for the preparation and administration of the medicines remains with the registered healthcare professional administering the medicines, even with an independent check.

6.1.73. No member of staff should sign/record as a witness/independent checker unless they have actually witnessed the whole process from preparation to administration. Staff are reminded to check they are under the right user when entering data on ePCR relating administration of drugs.

6.1.74. Registered healthcare professionals who are in situations where it is not possible for a second check to be undertaken, will need to follow a process where they double check their own calculations, medicines selection, expiry date before administering this to the patient. This process may involve preparing the medicine for administration, attending to another activity (e.g., documentation), then returning to this process to check again before administering/supplying the medicine.

Staff self-administering medicines

6.1.75. Staff are not allowed to self-administer SECAmb medicines or ask a colleague to administer medicines to them when at work or outside work following a self-diagnosis. However, in an emergency situation where a member of staff requires the services of SECAmb as a patient, then a colleague can treat that member of staff as they would any other patient following an appropriate clinical assessment that is recorded in the Patient Clinical Record.

6.1.76. Staff can purchase their own GSL/P medicines (e.g., from a community pharmacy) for use whilst at work to treat their own minor conditions (e.g., headache). Staff must ensure their own purchased medicines are stored safely away from SECAmb medicines.

6.17.3 Staff who need to carry/store POM medication for personal use at work, following occupational health recommendations and/or authorisation by their line manager (e.g., insulin), are free to do so however this medication cannot be stored in any SECAmb medicines cupboards/refrigerators. All personal medication should be kept in a locker or other secure storage environment under their own risk/responsibility.

Disposal of Medicines

6.1.77. Medicines (pharmaceutical) waste consists of unused, expired and contaminated medicinal products that are no longer required and needs to be disposed of appropriately in accordance with the SECAmb Waste Management Policy.

6.1.78. Records of Controlled Drugs wasted must be entered in ePCR and waste logs held at station. All CD waste must be reconciled by OTLs weekly. (See Disposal of Controlled Drugs SOP for further instructions on the process).

Disposal of Patients' Own Drugs (PODs)

6.1.79. Patient's own medicines should always follow the patient (e.g., use 'Green medicines bag'), as they are the patient's own property and can only be removed from a patient's home with their agreement.

6.1.80. Patients' own medicines that have been left on a vehicle (e.g., in a green medicine's bag) should be re-united with the patient whenever possible (e.g. taking it to the hospital where the patient was admitted). Patients' own medicines should never be brought back to base (i.e., SECAmb operational location).

6.1.81. Patients' own medicines that require disposal (e.g., they cannot be re-united with the patient) should be taken to a community pharmacy at the earliest opportunity for disposal.

6.1.82. In the event of a patient's death, medicines should be handed over to the police, if appropriate. Otherwise, patients' relatives should be told to return these to the community pharmacy for disposal. If SECAmb staff consider there is a risk in the medicines remaining with relatives, then these should be taken to a community pharmacy for disposal at the earliest opportunity. This should be clearly recorded in the Patient Clinical Record.

Pharmaceutical Waste

6.1.83. SECAmb utilises appropriate pharmaceutical waste bins:
blue lidded bins for Pharmaceutical Non-Hazardous (non-cytotoxic and non-cytostatic) waste and purple lidded bins for Pharmaceutical Hazardous (cytotoxic and cytostatic) waste.

6.1.84. The OTLs/Store Manager will ensure that these medicine waste bins are clearly labelled with the required information, with a black permanent marker pen before filling the container.

6.1.85. Once the container is filled to the fill-line it should be securely sealed and the appropriate consignment note completed. They should contact the Medicines Distribution Centre to arrange collection.

6.1.86. Waste containers containing pharmaceuticals must be kept in a locked cupboard (both during fill and when finally full), until just prior to collection by the waste contractor.

6.1.87. The OTL is responsible for ensuring a local waste log is maintained and a new pharmaceutical waste bin is obtained every 3 months even if the existing one is not full.

6.1.88. SECAmb non-CD stock medicines that can no longer be used (e.g., expired stock) should be disposed of in pharmaceutical blue lidded waste bins within the operational locations. SECAmb does not allow any members of staff to dispose of medicines into the domestic waste.

6.1.89. When disposing of stock medicines, any outer packaging and Patient Information Leaflets (PIL) may be placed into ordinary paper/cardboard waste containers for recycling. This will help to reduce the volume of pharmaceutical waste.

6.1.90. Community First Responders should return expired medicines to SECAmb for appropriate disposal in accordance with this policy.

6.1.91. The MDC will arrange for the disposal of medicines waste in line with pharmaceutical regulations. SECAmb stock medicines waste cannot be taken to a community pharmacy or local hospital for disposal.

Sharps contaminated with Pharmaceutical Waste

6.1.92. Sharps are items (or parts of items) that could cause cuts or puncture wounds, including needles, the needle part of a syringe, scalpel and other blades, broken glass ampoules, and the patient end of infusion sets.

6.1.93. Pharmaceuticals which are supplied as pre-filled syringes are considered in this category even though they do not require preparation at scene.

6.1.94. Syringes containing pharmaceuticals should not be emptied prior to placing them into a sharps bin (the exception to this is controlled drugs). Syringes containing pharmaceuticals or traces of pharmaceuticals should be disposed of in a receptacle that has been UN approved for liquids.

6.1.95. Sharps waste bins must be available close to the point of preparation of the sharps waste. They should be secure and located away from public areas. They must not be filled above the fill-mark, which indicates that they are full and should be sealed and collection arranged.

6.1.96. It is recommended that sharps containers are exchanged at regular intervals. If the sharps box is seldom used, it should be collected after a maximum of three months, regardless of the filled capacity.

6.1.97. Sharps contaminated with Pharmaceutical Waste can broadly be divided into two categories:

6.1.97.1. Sharps contaminated with Pharmaceutical Non-Hazardous (Non-Cytotoxic and Non-Cytostatic) Waste should be placed in a yellow-lidded sharps bin.

6.1.97.2. Sharps contaminated with Pharmaceutical Hazardous (Cytotoxic and Cytostatic) Waste should be placed in a purple-lidded sharps bin. If staff are

unclear what medicines are cytotoxic or cytostatic, then contact the Medicines Governance Team for advice.

Intravenous Fluids

6.1.98. There are a number of licensed medicinal products that are not pharmaceutically active and possess no hazardous properties (e.g., water for injection).

6.1.99. Where non-pharmaceutically active intravenous fluids occur in small quantities and present no other hazard (e.g., infectious due to contamination with body fluids or the addition of pharmaceutically active substances), these can either be (i) placed in the medicines waste stream or (ii) be discharged to the foul sewer if less than 1 litre and the empty containers placed in the offensive/hygiene waste stream.

6.1.100. Examples include Sodium Chloride 0.9% and glucose solutions. However, where an intravenous fluid contains a pharmaceutically active ingredient (e.g., potassium), they must be placed in the appropriate pharmaceutical waste container.

Vaccines

6.1.101. Pharmaceutical expertise and oversight will be essential to ensure integrity of the vaccines. The Chief Pharmacist will hold the lead responsibility for ensuring the safe handling and use of the vaccines in SECAmb.

6.1.102. All vaccines will enter the Trust via the national vaccine procurement route. Vaccine stocks will be received at the MDC and distributed appropriately throughout the authorised Trust sites.

6.1.103. Medicines Governance and Infection Prevention and Control (IPC) teams will ensure the development of relevant SOPs and training of the staff required for the safe handling of these vaccines.

6.1.104. Pharmacists within the Medicines Governance Team will support the vaccination process where required (e.g. audit visits, training, supervision etc).

Controlled Drugs (CDs)

6.1.105. Controlled Drugs (CDs) are a category of medicines that are subject to additional requirements over and above those that apply to other categories of medicines (such as Pharmacy (P) medicines or Prescription Only Medicines (POMs). Therefore, additional controls are in place for CDs.

6.1.106. The Controlled Drugs Accountable Officer (CDAO) is responsible for the governance of controlled drugs within SECAmb. The SECAmb Chief Medical Officer is the CDAO.

6.1.107. All Controlled Drugs included in SECAmb Formulary are treated under the control level of Schedule 2 controlled drugs irrespective of which schedule they fall under in terms of the law. This will ensure good governance around all CD activities within SECAmb.

6.1.108. SECAmb has a Controlled Drugs Policy and a number of Standard Operating Procedures (SOPs) in place for the management of controlled drugs).

CD Stationery

6.1.109. CD stationery refers to any stationery solely used for the purpose of recording CD use (e.g., CD registers, order books etc.).

6.1.110. CD stationery used within SECAmb are subject to the same rigorous security controls as CDs themselves. This is to ensure a clear audit trail from receipt of CDs to their use or destruction. It is also to prevent illicit use or any manipulation, falsification, or destruction of CD records.

6.1.111. CD registers are only accessible to staff authorised to possess CDs as well as managers and delegated staff responsible for CD stock checks and audits (e.g. MGT, OTLs, Medicines Leads). CD stationery that are in use, should be stored in a locked cupboard; where possible, this should not be the same locked cupboard as controlled drugs. The CD register should be retained locally for a minimum of 2 years from the date of the last entry. (See SOP for CD Record Keeping and Register Entries).

6.1.112. The requisition, use, movement and disposal of CDs should be recorded in the CD Register that pertains to particular operational sites (e.g., ambulance stations). Each type of CD needs a separate CD Register even if the CDs are stored in the same CD safe.

6.1.113. Any member of staff who falsifies an entry or signature in any CD stationery will be subject to investigation under the SECAmb Disciplinary Procedure and may also be reported to the Police. If that member of staff is a registered healthcare professional, they will also be reported to their relevant Regulatory Body.

CD Stock and Reconciliation Checks

6.1.114. The stock balance of Controlled Drugs should be checked each time a controlled drug is signed in/out. Staff must ensure the running balance is accurate prior to taking CDs out of the cabinet.

6.1.115. The OTL is responsible for ensuring that (as a minimum) a weekly stock check takes place.

6.1.116. Once a week, all sections of the CD Registers should be reconciled to ensure the balance recorded in the CD Register actually corresponds with the actual balance in the CD cabinet. Omnicell sites undertake this check by printing the electronic CD Register. This reconciliation also includes checking any controlled drug administered and wasted against patient care records on ePCR.

Disposal of controlled drugs

6.1.117. If a dose of a Controlled Drug is prepared but not required or if part of a dose is administered, the remaining CD should be discharged into a DOOP (Disposal of Old Pharmaceuticals) container which should have a denaturing pad/gel at the bottom (if the pad is not present the DOOP must be returned to

MDC for correct assemble). The amount disposed must be recorded in the electronic Patient Clinical Record and witnessed by another SECAmb employee or family member of the patient.

6.1.118. If an ampoule containing controlled drug is broken, the ampoule and remaining medicine should be placed in a DOOP container, and an incident form completed. A record must be made in the CD Register. (See SOP for Administration of Controlled Drugs and SOP for CD Record Keeping and Register Entries).

6.1.119. Expired CDs should be returned to the MDC. The operational location(s) (e.g., ambulance stations) must at that time, undertake a CD stock check and record the new balance in the CD Register.

6.1.120. Destruction of expired controlled drugs stock must be witnessed by a SECAmb authorised witness (written authorisation provided by the SECAmb Controlled Drugs Accountable Officer and their name listed on the SECAmb Controlled Drugs Home Office licence) or by a Controlled Drugs Liaison Officer (CDLO) with appropriate Home Office Authorisation. See SOP for Disposal of Controlled Drugs.

6.1.121. The CDLO or authorised witness should be contacted to arrange a date for the destruction. The destruction should be arranged with sufficient frequency to avoid excessive accumulation of expired controlled drugs.

6.1.122. All expired controlled drugs should be denatured before being placed in the pharmaceutical waste bin (blue lidded bin). Use of a DOOP container denatures any CDs places inside, rendering them irretrievable.

CD Reconciliation Checks by Medicines governance Team

6.1.123. The security of Controlled Drugs should be checked, by Medicines Governance Team, with audit and reconciliation, at least every six months and when considered appropriate.

Withdrawing and returning CDs (for shifts)

6.1.124. The SOP for Record Keeping and Controlled Drugs Register Entries includes the withdrawing of CDs at the start of a shift. Registered healthcare professionals should only draw controlled drugs for the duration of their shift period. Under no circumstances can CDs be retained whilst being off duty.

6.1.125. Any controlled drug drawn from the CD cabinet/Omnicell must be signed out in the CD Register or electronically from Omnicell sites. CDs must always be signed back into that same CD cabinet and recorded in the appropriate Controlled Drug Register or into the same Omnicell updating the electronic records. The registered healthcare professional who withdrew the individual drug(s) is responsible for signing these back into the safe. CDs that have been used should still be accounted for back at the operational location (e.g., ambulance station).

6.1.126. When controlled drugs are signed out of a controlled drugs safe by paramedics, every effort must be made to obtain a witness to sign in the

Controlled Drug Register. On some occasions, it is accepted that single responders may not be able to obtain a witness signature for the withdrawal or return of CDs. Where this occurs, the solo responder should annotate the witness section as “single response vehicle (SRV) no witness available (NWA)”. The same principles apply to Omnicell sites. The operational leaders or station managers must verify all of these transactions on both Omnicell and non-Omnicell sites with the Medicines Governance Team. If this cannot be verified, or witnesses were available on site, a DIF1 (Datix) must be submitted.

6.1.127. If a paramedic, having administered a controlled drug to a patient, needs to hand that patient over to another paramedic or other appropriately qualified healthcare professional (e.g., pre-hospital doctor); then the practitioner to whom the patient is handed over to must use their own controlled drugs to continue the treatment of the patient. Any unused controlled drugs in the possession of the SECAmb paramedic must be destroyed. Controlled drugs **must not be transferred** between practitioners for any reason including to continue patient care.

Medical Gases

6.1.128. The management and handling of medical gases is covered by the SOP: Compressed Medical Gases Safety.

6.1.129. Medical gases (e.g., oxygen) are legally classified as ‘P medicines ’. These are presented in pressurised gas cylinders.

6.1.130. Medical gas cylinders must be stored and secured correctly within designated locked storage areas preventing unauthorised access and with appropriate gas warning notices.

6.1.131. Medical gases on vehicles should be stored securely in designated holding brackets and/or the appropriate response bags. These should be kept out of plain sight. Vehicles containing medical gases should have appropriate warning notices. The exception to this is double crew ambulances where this is not mandatory.

Medicines Training

6.1.132. SECAmb recognises that further work is required to develop and establish a full and comprehensive medicines training programme. SECAmb currently expects the following identified staff groups to complete the following medicines training:

6.1.133. Annual Mandatory Key Skills Training which includes the Medicines Governance Module delivered to all patient facing SECAmb staff.

6.1.134. All registered healthcare professionals using Patient Group Directions must completed the general e-learning for Health (e-LFH) PGD module once every 3 years. This is accessible through ESR.

6.1.135. All new Community First Responders starters undergo a 4-day training course (which includes medicines) delivered by CFR Leads employed by SECAmb. A

'medicines' Discover module is also required before administration of medicines can occur.

6.1.136. Ad hoc internal medicines training may be provided where this is considered appropriate or required.

Antimicrobial Stewardship

6.1.137. SECAmb has a formal arrangement in place to obtain advice from a local Consultant Microbiologist, who for example is involved in the consultation process for PGDs which include antimicrobial medicines.

6.1.138. An annual audit of antimicrobial use is undertaken by the Trust's Clinical Audit Team.

6.1.139. The Chief Pharmacist and the Infection Prevention and Control (IPC) team will ensure that the Medicines Governance Group is informed about any national work on antimicrobials (e.g., antimicrobial stewardship/resistance) and translate this into local actions SECAmb can proactively take to help address these.

Clinical Pathways

6.1.140. SECAmb is involved in providing pre-hospital care. Medicines are used in emergency situations and also in alternative integrated pathways such as "See and Treat" which may involve medicines to avoid transferring the patient to hospital. These changing models of care are evolving.

End of Life Care (EOLC)

6.1.141. Paramedics may be called to attend to patients in their own home who have been prescribed and dispensed with "just in case (JIC)" prescription medicines (anticipatory prescribed medicines). These medicines are in the home in case the patient's condition deteriorates.

6.1.142. Paramedics can only administer these 'JIC' medicines (usually as subcutaneous injections) provided there is a (i) prescription sheet and (ii) medicines administration record sheet.

6.1.143. The paramedic should assess the patient and have a clear understanding of which medicine(s), route and dose to administer. The paramedic should use the 'JIC' medicine that has already been dispensed for the patient. The paramedic should communicate this to the other clinicians caring for the patient such as the community/palliative care team. The paramedic should record the administration of any medicines on the medicines administration record sheet in the home but also record this in ePCR.

6.1.144. If a controlled drug stock sheet or similar paperwork recording the running balance of controlled drugs (e.g., morphine, diamorphine, midazolam) is kept in the patient's home is in place, then this should be completed by the paramedic administering any patient's own controlled drugs within the home.

6.1.145. Paramedics are not expected to set up or replenish subcutaneous syringe drivers, as they have not had the required training to do so.

6.1.146. If a paramedic is in any doubt about treating an end-of-life patient, then they should escalate this by contacting the usual clinician/community/palliative care team caring for the patient or contact the out-of-hours medical provider requesting them to attend. Paramedics should always be working within their own scope of practice and relevant SECAmb EOLC care procedures.

6.1.147. For specialist Paramedics there are four EOL care PGDs authorised.

6.1.148. Verbal orders from prescribers to administer controlled drugs are not permitted.

See and Treat

6.1.149. Medicines can be supplied and/or administered to patients by paramedic practitioners in the "See and Treat" pathway using the legal mechanisms of Patient Group Directions and Trust approved protocols.

6.1.150. All medicines supplied to patients must include the patient's name and date of issue on the label as well as directions for use. A record of the supply must be made in the PCR.

6.1.151. Medicines for supply to patients (e.g., via a Patient Group Direction (PGD)) must be labelled appropriately. These medicines will either be in a pre-pack (i.e., packed down from the original packs by a licenced manufacturing unit to include full directions for use and a patient information leaflet) or be a General Sales List product which must have a SECAmb addressograph label attached. It should be clear from this label that the medicines (pre-packed or GSL product) have been supplied by SECAmb.

6.1.152. The Paramedic must check that the medicines they supply to the patient are the correct medicines (name, dose, frequency and duration) and are within their expiry date. Paramedics will also check the medicines the patient are already taking, allergies/sensitivities and any potential interactions stated in the PGD, or protocol used.

6.1.153. The patient's GP should be contacted with details of medicines administered or supplied to the patient and any follow-up arrangements made as specified in the individual PGD or Protocol used.

New Clinical Care Pathways

6.1.154. When new clinical care pathways are commissioned or developed, then consideration should be given to any medicines involved. This includes medicines that SECAmb is expected to administer or supply and the legal mechanism for doing so. Advice from a Trust Pharmacist must be sought.

6.1.155. New clinical pathways requiring medicines that are not currently on the SECAmb formulary will need to be reviewed and a New Drug Application form (NDA) submitted to the Medicines Governance Group for these medicines to be considered for inclusion within the SECAmb formulary.

Governance Framework Structure

6.1.156. The Medicines Governance Group (MGG) sends a bi-monthly report to the Quality Governance Group which feeds directly into the Executive Management Board.

6.1.157. The Chief Pharmacist will produce an annual Medicines Optimisation Report that will be shared with the SECAmb Executive Management Board.

Clinical Trials

6.1.158. Investigational Medicinal Product (IMP) clinical trials conducted in the Trust must:

- comply with the relevant guidance and regulations.
- safeguard subjects, ambulance staff and the Trust by ensuring that the IMPs are procured, handled and stored correctly.
- be managed correctly ensuring that the IMP is administered to patients in accordance with the trial protocol.

6.1.159. Medicines Governance Team will develop SOPs for the trial with support from the Research Department. The Medicines Governance Team will be responsible for stock management of the IMP (when appropriate) including Good Clinical Practice (GCP) training of the staff involved (e.g. MDC staff, logistics).

Record Keeping

6.1.160. See Patient Data and Health Records Policy.

Reporting Medication Incidents including Near Misses

6.1.161. A near miss is a patient safety incident that is detected before the patient or patient's representative is administered/supplied a medication, preventing any unintended/unexpected harm. This also includes any incident involving processes such as procurement, delivery, storage and not just incidents in front of the patient.

6.1.162. All medication incidents (including near misses) need to be reported using the SECAmb online incident reporting system (Datix). Individual medication incidents will be investigated by the reporter's line manager and any actions and learning will be recorded. Clinicians involved in medication errors may have temporary restrictions placed on their practices in terms of the medicines they can administer/supply as determined by their manager. The SECAmb Medication Safety Officer/Chief Pharmacist is automatically copied in to reported medication incidents.

6.1.163. SECAmb supports an 'honest mistake' culture that encourages reporting and facilitates learning from medication incidents. This does not remove an individual's accountability and responsibilities towards patients in line with SECAmb's policies and procedures or their regulatory body.

6.1.164. Learning from medication incidents will be shared through various internal mediums.

Medicines Related Risks

6.1.165. There are inherent risks associated with medicines themselves and their use. It is therefore important that these risks are considered and mitigated where possible through having a robust governance framework for managing medicines and their use (e.g., provision of training, regular audits, review of medication incidents).

6.1.166. The Medicines Governance Group (MGG) should receive, and review medicines related risks to be added to the risk register. The MGG should review the medicines risks on the SECAmb risk register regularly. This is to ensure that where possible, actions are taken to mitigate these risks.

6.1.167. Risk assessments are required as part of the NDA proforma for any medicine being introduced into the Trust. Where significant changes to a medication or clinical practice are identified, or in response to national requests, ad hoc risk assessments (e.g. quality impact assessments (QIA), Trust-level assessments) will be completed.

Reporting Defect Medicines

6.1.168. A defect is where the product supplied by the manufacturer is not of the expected standard. This may involve, for example, inadequate or incorrect labelling, ineffective packaging or discolouration. When a defect is found or suspected:

- Quarantine the product in question (i.e., retain the product and any associated products or equipment).
- Inform the Medicines Governance Team, and where possible, provide evidence (e.g. pictures).
- The MGT will advise when to contact the supplier of the medicine for advice and implement the necessary reporting, recording or investigation of the defect.
- If the product has been administered to the patient, inform Chief Medical Officer or Deputy Medical Director and report this in the Patient Clinical Record.
- Complete an online incident form (Datix).

Reporting Adverse Drug Reactions (ADRs)

6.1.169. If a patient suffers unwanted or unexpected adverse reactions to a medicine this should be reported to the MHRA (Medicines and Healthcare products Regulatory Agency) using the yellow card scheme. This can be accessed online at http://yellowcard.mhra.gov.uk.

6.1.170. Patients who are triaged/assessed remotely and are deemed well can be encouraged to complete the yellow card report themselves to aid accuracy of reporting and facilitate any additional follow up if required.

6.1.171. Staff should also report this via Datix and where appropriate ensure the medical prescriber responsible for the patient's care and/or GP is informed of this.

6.1.172. The Medicines Governance Team can be contacted for any further advice if required.

Central Alerting System, Medicines Safety and National Patient Safety Alerts

6.1.173. SECAmb aims to ensure that Central Alerting System (CAS) alerts are cascaded and actioned in accordance with national recommended standards.

6.1.174. The SECAmb SOP Handling of Drug Alerts and Recalls outlines the actions taken by the SECAmb Medicines Governance Team and what action to be taken by other staff in the event the Medicines Governance Team is not available.

6.1.175. NHS Improvement Patient Safety Alerts related to medicines will be overseen by the Chief Pharmacist supported by the Medical Director. Information will be disseminated to appropriate staff and action plans will be produced where applicable and presented to the Medicines Governance Group.

Community First Responders (CFRs)

6.1.176. See Community First Responder Policy.

6.1.177. CFRs should only have access to stock medicines that they have been authorised by SECAmb to administer in an emergency situation. CFRs should only carry medicines covered within their scope of practice. CFRs should only administer SECAmb medicines to patients under the care of SECAmb and in no other situations.

6.1.178. CFRs can assist patients to self-administer their own medicines which have already been prescribed and dispensed for that patient by a community or hospital pharmacy provided that the CFR feels confident to do so after having assessed the individual patient and situation.

6.1.179. CFRs should fully document the care provided to patients including any medicines administered in the Patient Clinical Record.

6.1.180. CFRs should not have access to Prescription only Medicines (including controlled drugs). Refer to Section 5.5 Legal Framework of Medicines.

6.1.181. SECAmb will only authorise CFRs to carry and administer identified stock medicines following training and assessment by CFR Leads (See Section 6.31, Medicines Training).

6.1.182. SECAmb Director of Operations is responsible for maintaining the list of current CFRs within SECAmb who are competent to hold and administer medicines. This list must be available for scrutiny on request.

6.1.183. CFRs are personally responsible for the security of any stock medicines (including medicine pouches) that are in their possession (see Section 6.4, SECAmb Medicines Stored at Home). OTLs are responsible for monitoring medicine pouches held by CFRs and ensure these are recalled when nearing their expiry.

Working with Other Providers

6.1.184. SECAmb may be working closely in cooperation with other providers both NHS, private (e.g. IC24 within 111) and the third sector (i.e., charities) such as the Helicopter Emergency Medical Services (HEMS). It is important that when

these different providers work together that there are clear lines of responsibilities and accountabilities in terms of medicines in delivering patient care.

6.1.185. SECAmb may subcontract other providers to deliver NHS care on its behalf such as Private Ambulance Providers (PAPs). In these cases there should be clear contracts/agreements in place to ensure the subcontracted provider delivers care that meets the standards of SECAmb.

6.1.186. SECAmb should ensure there are regular monitoring/performance meetings to resolve any issues. These subcontractors are different legal entities. SECAmb should ensure these subcontractors have the required medicines policy in place as well as robust governance processes in place including clarity around the reporting of incidents and handling of complaints related to medicines for SECAmb patients. It should be noted that there are some differences in terms of medicines regulation for an NHS organisation delivering NHS care and private organisations commissioned (i.e., subcontracted) to deliver NHS care.

6.1.187. Patients should always receive safe, seamless quality care regardless of organisational boundaries.

7 Definitions/Glossary

ACESO	Software used by SECAmb to manage stock medicines
Administration	To give a medicine either by introduction into the body e.g., orally, by injection or by external application e.g., impregnated dressing
Adverse Drug Reaction (ADR)	An unwanted or harmful reaction which occurs after administration of a drug or drugs and is suspected or known to be due to the drug(s)
Authorised prescriber	A healthcare professional who is authorised to undertake independent or supplementary prescribing according to current legislation.
British National Formulary (BNF)	A United Kingdom (UK) pharmaceutical reference book containing advice on prescribing and pharmacology, along with specific facts and details about many medicines available on the NHS. Also available electronically as the eBNF.
CDs	See Controlled Drugs
CDLO	Controlled Drug Liaison Officers. CDLOs are members of the police force.
CFR	See Community First Responders
Cold chain	This term is used to describe the cold temperature conditions in which certain medicines products need to be kept during storage and distribution.
Community First Responders (CFRs)	Community First Responders (CFRs) are volunteers who respond to local emergency calls and provide lifesaving first aid before an ambulance arrives.

Community Pharmacy	A retail pharmacy – a private provider delivering some NHS services, e.g. dispensing of FP10 prescriptions.
Controlled Drugs (CDs)	Drugs that are controlled under Misuse of Drugs Act 1971 and the Misuse of Drugs Regulations 2001.
Controlled Drugs Accountable Officer (CDAO)	Member of staff responsible for the governance of controlled drugs within the Trust
Cytotoxic and cytostatic medicines	Cytotoxic and cytostatic medicines are clinical hazardous waste and include any medicine that has one or more of the hazardous properties: Toxic, Carcinogenic, Toxic for Reproduction or Mutagenic. (Note: Toxic for Reproduction should not be confused with Contraindicated for Use in Pregnancy.) This is a wide definition capturing many hormone-based preparations, antimicrobial substances such as chloramphenicol, as well as cancer-treating agents.
Epact (Electronic Prescribing Analysis and Costs)	Electronic analysis of prescribing data obtained from prescription forms such as FP10s.
FP10 prescription	NHS prescription stationery for dispensing and ordering from community pharmacies.
General Sales List (GSL) medicines	A medicine that can be sold in general retail outlets (such as supermarkets) without the supervision of a pharmacist. These medicines must be intact in original packaging and often have restricted pack sizes e.g., Paracetamol packs containing 16 tablets
'Green medicines bag'	A re-sealable green bag which can be used by ambulance staff to collect patients' medicines (enabling them to be kept together) when the patient is transferred to hospital as well as when patients are discharged from hospital. Patient's name must be written on this green medicines bag.
HMR	Human Medicines Regulation
Joint Royal Colleges Ambulance Liaison Committee (JRCALC) Clinical Guidelines	These are established clinical practice guidelines which include medicines commonly used by ambulance services.
JRCALC	See Joint Royal Colleges Ambulance Liaison Committee (JRCALC) Clinical Guidelines.
Licensed Medicine	Medicine with a Marketing Authorisation, formerly known as a Product Licence and granted by the Medicines and Healthcare Products Regulatory Agency (MHRA).

Medicine	Medicinal Products as defined by the Medicines Act 1968 i.e. a substance administered by mouth, applied to or introduced into the body for the purpose of treating or preventing disease, diagnosing disease or ascertaining the existence, degree or extent of a physiological condition, contraception, inducing anaesthesia, or otherwise preventing or interfering with the normal operation of a physiological function.
Medicines Governance Group (MGG)	The formal group within SECAmb that makes decisions and recommendations regarding medicines and their use within SECAmb.
MGG	See Medicines Governance Group.
"Off-label" use of Medicine	Medicine with a Marketing Authorisation but being used outside the terms of the Summary of Product Characteristics (Data Sheet).
Non-medical Prescriber	Nurses, pharmacists, physiotherapists, podiatrists and community practitioners who have undertaken further professional training in prescribing.
Operational Team Leaders (OTLs)	OTLs are registered paramedics with responsibilities for the safe and secure storage, handling and management of medicines including controlled drugs within operational locations (e.g., ambulance stations).
OTLs	See Operational Team Leaders
Registered Paramedic	A person whose name appears on the Paramedic Register maintained by the Health and Care Professions Council.
Parenteral medicines	Medicines which are administered by injecting directly into the body, bypassing the skin and mucous membranes. The common parenteral routes are intramuscular (IM), subcutaneous (SC) and intravenous (IV).
Patient Group Direction (PGD)	A written instruction to enable certain healthcare professionals to supply or administer a medicine to groups of patients that may not be individually identified before presentation for treatment.
Patient Specific Direction (PSD)	A written instruction from an appropriate prescriber for medicines to be supplied or administered to a named patient. This includes instructions on patients' prescription charts.
PGDs	See Patient Group Directions.
Pharmacy (P) Medicines	Any medicinal product other than those designated as GSL or POM products. Pharmacy medicines can be sold or supplied from registered pharmacy by or under the supervision of a pharmacist, subject to certain exceptions.
Preparation of medicines for administration	The activities associated with the preparation of the medicine for use. These include the calculation and selection of doses, the withdrawal of volumes from containers, the preparation of injections from vials/ampoules of dry powder and the preparation of complex admixtures.

Prescription-Only-Medicine (POM)	A medicinal product which may only be sold or supplied against the signed prescription of an appropriate prescriber (e.g., doctor, dentist, independent or supplementary prescriber) and some nurses specified in the Prescriptions Only Medicines (Human Use) Order 1997. The exceptions to this are for emergency medicines used for the purpose of saving a life and exemptions to Medicines Act for podiatrists.
Procurement	The activities through which a medicine is acquired for use in treating a patient.
PSD	See Patient Specific Direction.
Receipt of medicines	The formal activities undertaken when medicines are received by SECAmb from any external source or transferred from one location to another within SECAmb.
Registered doctor	A person whose name appears on the List of Registered Medical Practitioners maintained by the General Medical Council.
Registered nurse	A person whose name appears on the Register maintained by the Nursing and Midwifery Council as a registered nurse.
Standard Operating Procedures (SOP)	A document that describes in detail, step-by-step, how a task should be carried out. It also describes the responsibilities, including audits, necessary to safely manage and accountably manage any set processes. It is a working document detailing current agreed working practices
Summary of Product Characteristics (SPC)	The SPC forms an integral part of the marketing authorisation and is the basis of information for health care professionals. It describes the properties and effects of the medicines as well as warnings about it.
Unlicensed medicine	Medicine without a Marketing Authorisation (or product licence) or use of a medicine for a recognised clinical condition not specified within current market authorisation (also referred to as ‘off label’.

8 Responsibilities

8.1. The **Chief Medical Officer** through delegation by the CEO, has overall responsibility for medicines governance system design and overall assurance. The Chief Medical Officer has responsibility for the implementation, review, and thus revision where required, of this procedure.

8.2. The **Chief Pharmacist** is the professional medicines governance lead for the Trust and is responsible for producing robust systems and processes which comply fully with legislation, national guidance, and regulatory requirements to ensure the safe and effective management and use of medicines throughout the Trust. The Chief Pharmacist supports the Chief Medical Officer and Executive Director of Operations providing pharmaceutical professional advice with regards to all medicines related policies, procedures and practices.

8.3. The **Executive Director of Operations**, through delegation by the CEO, has overall responsibility for the implementation, operation and local assurance of this policy. The Executive Director of Operations has overall responsibility for holding his/her staff to account for any deviations from this policy and is responsible for the operational compliance of this procedure.

8.4. The **Executive Director of Operations**, **Chief Medical Officer** and **Chief Pharmacist** are responsible for escalating unresolved concerns to the Medicines Governance Group (MGG).

8.5. The Executive Director of Operations delegates local responsibilities and accountability for this procedure to the **Associate Directors of Operations**, **Operational Unit Managers, Operational Managers, Specialist Managers** and where relevant the **Head of Fleet and Logistics.**

8.6. The **Associate Directors of Operations, Operational Units Managers**, **Operational Managers, Specialist Managers** and where relevant the **Head of Fleet and Logistics** delegate their local responsibility and accountability for this policy to their staff including the **Operational Team Leaders (OTLs), Logistics Manager**, and others.

8.7. The **Executive Director of Nursing and Quality** has responsibility for matters relating to regulatory compliance, risk management, health and safety relating to this procedure.

8.8. **Controlled Drug Accountable Officer** is also the **Chief Medical Officer** and is responsible for the safe management and use of Controlled Drugs within the Trust along with co-operating and sharing information relating to concerns about the Trust's use and management under the Controlled Drug (Supervision of Management and Use) Regulations 2013. These responsibilities include keeping records of the investigation of concerns and acting where appropriate.

8.9. The **Medicines Safety Officer (MSO)** is also the **Chief Pharmacist**. The MSO supports local medication error reporting and learning. The MSO acts as the main contact for NHS England and Medicines and Healthcare Products Regulatory Agency (MHRA).

8.10. The **Medicines Governance Group (MGG)** is responsible, for providing strategic direction for the implementation of medicines management and practice within the Trust The primary objective of MGG is to ensure appropriate clinical and cost effective use of medicines, promoting the highest standards of medicines management and safe practice throughout the Trust, by ensuring that senior managers are aware of issues relating to the use of medicines within the organisation as part of the overall clinical and corporate governance structure.

8.11. The role of The **Non-Medical Prescribing (NMP) Group** is to provide overarching multidisciplinary leadership for non-medical prescribing (NMP) within the Trust. In doing so, it manages the process of Trust approval to train as a non-medical prescriber and to prescribe, taking account of service

redesigns and improved patient access to medicines. The NMP Group aims to strengthen and monitor the governance issues associated with non-medical prescribing, to determine potential and support existing non-medical prescribers, advise the MGG on matters relating to non-medical prescribing and will report exceptions relating to non-medical prescribing to the MGG.

8.12. The **Medical Gas Subgroup** provides assurance to MGG that medical gases are effectively monitored and managed within the Trust.

8.13. The **Patient Group Direction (PGD) Approval and Working Group** provides assurance to MGG and ensures the development, review, updates and implementation of PGDs are in line with legislation and national good practice.

8.14. The **Medicines Governance Team (MGT)** are responsible for ensuring the safe and efficient procurement of medicines, including controlled drugs to ensure the quality of the product, safe dispensing/packing into medicines pouches through to safe disposal of pharmaceutical waste. The MGT will support the Chief Pharmacists with drug shortages, drug alerts and relevant information relating to medicines is communicated in a timely manner.

8.15. **All staff** are responsible for their own professional practice. All staff involved in the prescribing, supply, dispensing, handling, storage, administration and disposal of medicines, including controlled drugs, must receive appropriate training and assessment of competence before commencing their roles. All staff who handle medicines are personally accountable for complying with this policy and relevant standard operation procedures, for reporting any concerns and for the safe handling of all medicines.

9 Education and Training

See section 6.31

10 Monitoring Compliance

10.1. Adherence to the Medicines Policy is included in Appendix C: Monitoring Compliance Table.

10.2. In addition, ad-hoc audits will be conducted as and when potential medicines-related problems are identified. Results will be disseminated, and actions taken as appropriate.

10.3. Confirmation that compliance monitoring has taken place will be reported in the Medicines Optimisation Annual Report.

11 Audit and Review (evaluating effectiveness)

11.1. All policies have their effectiveness audited by the responsible Management Group at regular intervals, and initially six months after a new policy is approved and disseminated.

11.2. Effectiveness will be reviewed using the tools set out in the Trust's Policy and Procedure for the Development and Management of Trust Policies and Procedures (also known as the Policy on Policies).

11.3. This document will be reviewed in its entirety every three years or sooner if new legislation, codes of practice or national standards are introduced, or if feedback from employees indicates that the policy is not working effectively.

11.4. All changes made to this policy will go through the governance route for development and approval as set out in the Policy on Policies.

12 References

12.1. Joint Royal Colleges Ambulance Liaison Committee, Association of Ambulance Chief Executives (2019). Cited from: JRCALC Plus (2017) (version 2.2.1) [Mobile application software]. Bridgwater: Class Publishing Ltd. (Accessed 10 Aug 2023)

12.2. National Institute for Health and Care Excellence (NICE). Medicines Optimisation: the safe and effective use of medicines to enable the best possible outcomes – NG5. 4 March 2015. (Link accessed 10 Aug 2023)

12.3. National Institute for Health and Care Excellence (NICE). Controlled drugs: safe use and management – NG64. 12 April 2016. (Link accessed 10 Aug 2023)

12.4. National Institute for Health and Clinical Excellence (NICE). Patient Group Directions - MPG2. Updated 27 March 2017. (Link accessed 10 Aug 2023)

12.5. Royal Pharmaceutical Society. Professional Standards for Hospital Pharmacy Services. For Providers of pharmacy services in or to acute hospital, mental health, private, community service, prison, hospice and ambulance settings. Version 4. November 2022. (Link accessed 10 Aug 2023)

12.6. Royal Pharmaceutical Society. Professional Guidance on the Safe and Secure Handling of Medicines. December 2018. (Link accessed 10 Aug 2023)

12.7. Management of health care waste Management of healthcare waste (hse.gov.uk) (link accessed 31/08/2023)

12.8. Specialist Pharmacy Service. Medicines Use and Safety. Principles on the Disposal of Waste Pharmaceuticals used within Community Health Services. Version 3.1. June 2012. (Link accessed 10 Aug 2023).

12.9. The Controlled Drugs (Supervision of Management and Use) Regulations 2013. Link. (Accessed 10 Aug 2023).

12.10. The Human Medicines Regulations 2012. (Link accessed 10 Aug 2023).

12.11. The Misuse of Drugs Regulation 2001. (Link accessed 10 Aug 2023).

12.12. The National Treatment Agency (Abolition) and the Health and Social Care Act 2012 (Consequential, Transitional and Saving Provisions) Order 2013. (Link accessed 10 Aug 2023)

12.13. Health Service Circular. Patient Group Directions (England Only) 2000/026. August 2000. (Link Accessed 10 Aug 2023).

12.14. Royal Pharmaceutical Society (RPS) and Royal College of Nursing (RCN). Professional guidance on the administration of medicines in healthcare settings. Version 1.0. January 2019. (Link accessed 10 Aug 2023).

13 Financial Checkpoint

13.1. To ensure that any financial implications of changes in policy or procedure are considered in advance of document approval, document authors are required to seek approval from the Finance Team before submitting their document for final approval.

[**EITHER**

13.2. **This document has been confirmed by Finance to have no unbudgeted financial implications.**

OR

13.3. **This document has been confirmed by Finance to have financial implications and the relevant Trust processes have been followed to ensure adequate funds are available.]**

14 Equality Analysis

14.1. The Trust believes in fairness and equality, and values diversity in its role as both a provider of services and as an employer. The Trust aims to provide accessible services that respect the needs of each individual and exclude no-one. It is committed to comply with the Human Rights Act and to meeting the Equality Act 2010, which identifies the following nine protected characteristics: Age, Disability, Race, Religion and Belief, Gender Reassignment, Sexual Orientation, Sex, Marriage and Civil Partnership and Pregnancy and Maternity.

14.2. Compliance with the Public Sector Equality Duty: If a contractor carries out functions of a public nature, then for the duration of the contract, the contractor or supplier would itself be considered a public authority and have the duty to comply with the equalities duties when carrying out those functions.

Appendix A: Human Medicines Regulations 2012 Schedule 17, part 3

Registered paramedics have the following exemptions from the restriction on administration of the following prescription only medicines for parenteral administration.

The administration shall be only for the immediate, necessary treatment of sick or injured persons and in the case of prescription only medicine containing:

- Heparin Sodium shall be only for the purpose of cannula flushing.
- Diazepam 5 mg per ml emulsion for injection,
- Succinylated Modified Fluid Gelatin 4 per cent intravenous infusion,
- medicines containing the substance Ergometrine Maleate 500 microgram per ml with Oxytocin 5 units per ml, but no other active ingredient,
- prescription only medicines containing one or more of the following substances, but no other active ingredient:

    (i) Adrenaline Acid Tartrate,
    (ii) Adrenaline hydrochloride,
    (iii) Amiodarone,
    (iv) Anhydrous glucose,
    (v) Benzlypenicillin,
    (vi) Compound Sodium Lactate Intravenous Infusion (Hartmann's Solution),
    (vii) Ergometrine Maleate,
    (viii) Furosemide,
    (ix) Glucose,
    (x) Heparin Sodium,
    (xi) Lidocaine Hydrochloride,
    (xii) Metoclopramide,
    (xiii) Morphine Sulphate,
    (xiv) Nalbuphine Hydrochloride,
    (xv) Naloxone Hydrochloride,
    (xvi) Ondansetron
    (xvii) Paracetamol,
    (xviii) Reteplase,
    (xix) Sodium Chloride,
    (xx) Streptokinase,
    (xxi) Tenecteplase.

Appendix B: Appendix B: Human Medicines Regulations 2012 Schedule 19

The list of parenteral medicines which anyone can administer for the purpose of saving a life in an emergency:

- 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
- Sterile pralidoxime

Appendix C: Monitoring Compliance Table

Measurable Objective	Monitoring/ Audit Method	Frequency	Person(s) Responsible for Monitoring	Group(s) Monitoring is Reported to
Assurance checks (e.g. security, controlled drugs, temperature monitoring etc)	Monitoring checklist	Quarterly	Medicines Governance Team	Medicines Governance Group.
Annual Medicines Optimisation Report.	Reporting progress with annual medicines optimisation objectives	Yearly	Chief Pharmacist	Medicines Governance Group Executive Management Board
Annual Controlled Drugs Accountable Officer Report	Report on governance related to controlled drugs	Yearly	Controlled Drugs Accountable Officer/ Medical Director	Medicines Governance Group Executive Management Board
RSM (external auditor) Medicines Management audits	Audit method agreed with Chief Pharmacist	Every 2 Years	RSM with agreement from Chief Pharmacist	Medicines Governance Group Executive Management Board
Audit of antimicrobial use	Audit	Yearly	Chief Pharmacist	Medicines Governance Group.