Scottish Ambulance Service

MEDICINES MANAGEMENT POLICY

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1 Statement

1.1 Scottish Ambulance Service (the Service) is committed to the safe, secure and effective handling of medicines and medical gases to protect patients, staff, and its financial resources. This Medicines Management policy (the Policy) describes the principles of a safe and secure system for the control and handling of medicines and medical gases within the Service underpinned by the framework provided by medicines and related legislation and official guidance.

2 Scope

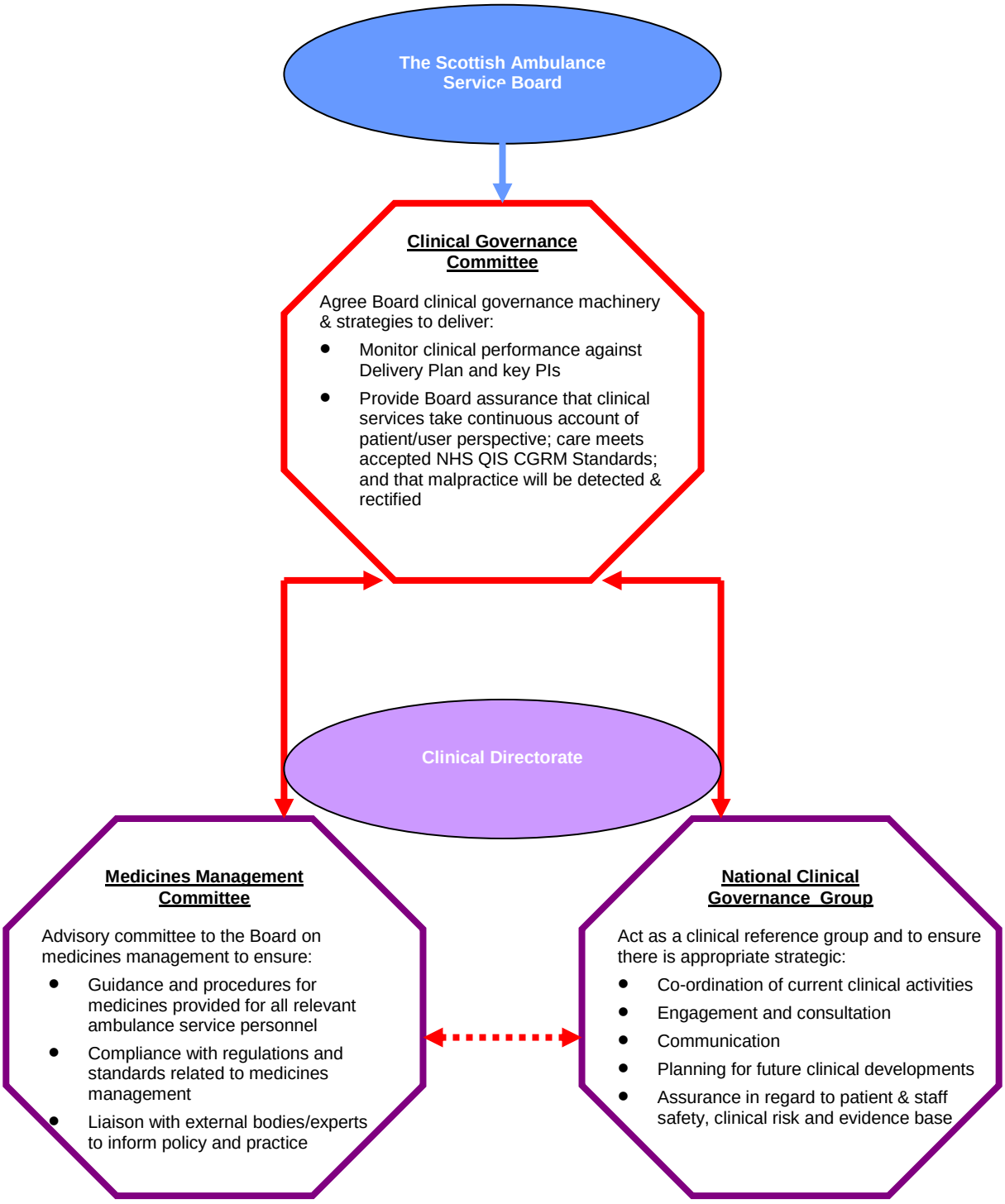
2.1 The Policy covers all aspects associated with the procurement, storage, administration, supply or destruction/disposal of medicines and medical gases.

2.2 The Policy outlines the means to achieve safe, effective and efficient use of medicines and medical gases within the Service, outlining appropriate governance arrangements.

2.3 This Policy applies to all employees involved in the handling, management or use of medicines within the Service.

3 Accountabilities and Responsibilities

The diagram below outlines the current clinical governance framework and structures within the Scottish Ambulance Service that underpin the provision of safe and effective medicines management. As this policy sets out a framework for the management of medicines and medical gases within the Service, it is therefore the responsibility of **all** Service staff involved in the handling or management of medicines and medical gases to act in accordance with this policy.



The accountabilities and responsibilities of individuals, as well as specific Service groups and committees, regarding the safe and effective management and use of medicines and medical gases are as follows:

3.1 The **Chief Executive Officer** has overall accountability for all aspects of medicines and medical gas use covered by the Policy.

3.2 The **Board** is responsible for monitoring the compliance of the Service with the Policy, ensuring sufficient resources are made available to support the Service in the implementation of the Policy.

3.3 The **Medical Director** is responsible for ensuring medicines and medical gases used by the Service are safe, effective and appropriate for the level of clinical care provided by the Service.

3.3.1 The Medical Director will advise the Head of Education and Professional Development for the Service on aspects of medicines use and medicines management training that are required for clinical staff working within the Service

3.3.2 The Medical Director is the **Accountable Officer for Controlled Drugs** (AOCD) for the Service, and as such is also responsible for ensuring the safe use and management of controlled drugs across the Service. The AOCD is responsible for a range of measures relating to the monitoring of the safe use and management of Controlled Drugs in accordance with the Health Act 2006, Dangerous Drugs, England; Dangerous Drugs, Scotland – The Controlled Drugs (Supervision of Management and Use) Regulations 2013, the Misuse of Drugs Act 1971 and subordinate legislation under that Act and other relevant Controlled Drugs Regulations and guidance.

3.3.2.1 The AOCD must ensure appropriate guidance and standard operating procedures and processes are in place for the procurement, storage, administration, supply and destruction of morphine and controlled drugs (CD) within the Service.

3.3.2.2 The AOCD must ensure the Service is compliant with Controlled Drug standard operating procedures and processes, as evidenced through routine monitoring, review and audit. This will provide assurances around the safe use and management of controlled drugs within the Service.

3.3.2.3 The AOCD will ensure quarterly occurrence reports are provided to the appropriate CD Local Intelligence Network, detailing any concerns that the Service has regarding the management or use of morphine and controlled drugs within the Service, as required by regulation 14 of the Controlled Drugs (Supervision of Management and Use) Regulations 2013 ("the Controlled Drugs Regulations").

3.3.2.4 The AOCD will attend scheduled meetings of the National Accountable Officers Network, and one Controlled Drug Local Intelligence Network to share relevant intelligence and highlight any specific issues to all Networks regarding the Service.

3.3.2.5 The AOCD is able to delegate certain tasks or responsibilities around the safe use and management of controlled drugs to suitable members of staff at his/her discretion, where appropriate. However, accountability around the management of controlled drugs within the Service remains with the AOCD at all times.

3.3.3 The Medical Director will ensure any identified medicines related risks are placed on the Service Risk Register and reviewed by the Clinical Governance Committee

3.3.4 The Medical Director will ensure exception reports are provided to the Board on issues relating to medicines management

3.3.5 The Medical Director will chair the Medicines Management Committee (quarterly meetings) to ensure appropriate governance and management around the use of medicines within the Service

3.3.6 The Medical Director will ensure all issues related to the use of medicines are communicated to the Service through authorised Clinical National Bulletins and other means where appropriate.

3.3.7 The Medical Director will ensure existing medicines are routinely reviewed against available Service data and evidence-based practice, and appropriate recommendations inform future practice.

3.3.8 The Medical Director will ensure the Service has an accurate and up-to-date Medicines Formulary, clearly indicating which medicines are authorised for use within the Service, and by whom.

3.3.9 The Medical Director will provide clinical advice around the use of medicines to the Service as required.

3.4 The **Pharmaceutical Advisor** for the Service will:

3.4.1 Assist the Medical Director in the development and implementation of policy, guidance and related procedures around medicines to ensure the safe and effective management of medicines and medical gases within the Service. The pharmaceutical advisor will also, where requested, assist the Medical Director in executing their responsibilities as defined within this policy.

3.4.2 Ensure, by liaising with the Head of Training for the Service, that appropriate training around the use of medicines is provided

3.4.3 Act as a national resource for staff for all issues concerning medicines management.

3.5 The **Head of Education and Professional Development (HEPD)** for the Service is responsible for ensuring that medicines management training is safe, effective and underpinned by current evidence-based practice.

3.5.1 The effectiveness of medicines management training must be evaluated at least annually and in response to any changes in medicines management within the Service, with findings reported to the Medicines Management Committee

3.5.2 HEPD is responsible for close liaison with the Clinical Directorate on all matters related to medicines management

3.6 The **Divisional General Managers** are responsible for the following:

3.6.1 Ensuring the appropriate operational arrangements are in place within the Division, and all service staff within the Division are aware of their legal and professional responsibilities around the management of medicines as outlined in this policy and all related guidance/standard operating procedures.

3.6.2 Ensuring that responsibilities, where appropriate, are effectively delegated to relevant people throughout the Division and any additional training and guidance to support them in undertaking their role is provided.

3.6.3 Ensuring staff receive appropriate training in accordance with the Service training needs analysis, and the necessary support and guidance to ensure the safe and effective use of medicines within the Service is provided by the appropriate Department(s).

3.6.4 Ensuring all medicines and medical gases are stored in compliance with this policy, and that storage arrangements are suitably secure with effective stock control procedures in place within each location.

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

3.6.6 It is the Divisional General Manager's responsibility to ensure that security arrangements in each ambulance station within their division meet the minimum legislative requirements outlined in the *Misuse of Drugs (Safe Custody) Regulations 1973* and related amendments. If not, an appropriate exemption certificate must be in place for any premises that don't comply.

3.7 The **Head of Procurement** is responsible for ensuring cost-effective supply, delivery and distribution arrangements for medicines and medical gases is achieved, ensuring sufficient protection of the supply chain and acceptable business continuity:

3.7.1 Ensure the correct medicines (formulation, strength, quantity) are procured, and delivered on time to the correct locations across the Service.

3.7.2 Proactively engage with medicines suppliers to the Service, and users, in order to identify potential medicine shortages and report issues to the Service as soon as possible, outlining alternative arrangements where appropriate.

3.7.3 Ensuring the quality of medicines packaging is of the appropriate quality to withstand normal handling in routine practice.

3.7.4 Ensure all relevant guidance and standard operating procedures for the procurement of medicines and medical gases are in place and up-to-date.

3.8 The Service Security Officer (**Resilience Manager**) has responsibility for

3.8.1 Ensuring appropriate security arrangements regarding the storage of and access to medicines exist within the Service, and are followed.

3.8.2 Inspecting locations where medicines are stored to ensure that Service policies and procedures are complied with, at intervals of not more than 6 months. A record of each inspection will be made and forwarded to the Medical Director.

3.9 The **Area Service Managers** are responsible for the following:

3.9.1 Ensuring guidance and standard operating procedures for requisitioning, receiving, disposing and returning medicines (including controlled drugs) and medicines pouches are followed by staff in their area

3.9.2 Ensuring all medicines and medicines pouches issued to ambulance stations or vehicles are stored in compliance with this policy and related guidance/standard operating procedures, and effective stock control is achieved within stations.

3.9.3 Ensuring all staff are aware of their responsibilities around the security and management of controlled drugs and other medicines, with the Area Service Manager responding to staff-reported problems or issues, escalating where appropriate to the Divisional General Manager (or nominated deputy) or senior clinician on-call as soon as is reasonably practicable.

3.9.4 Ensuring all medicines storage facilities and arrangements prevent unauthorised access, and keys to those vehicles fitted with a CD safe are kept within a supervised area of the station. Spare or unissued swipe cards for CD safes (both station and vehicle) must be kept secure with controlled access and supporting documentation in place.

3.9.5 Agreeing the maximum stock level of controlled drugs to be kept in station safes in consultation with the Chair of the Divisional Patient safety and Quality Group, and witnessing the destruction of controlled drug stock where required.

3.9.6 Ensuring that the routine management of medicines across the area is safe, effective and regularly monitored/audited in accordance with this policy, related guidance and standard operating procedures.

3.10 The **Risk Management Steering Group** (a function of Senior Management Team) is accountable to the Clinical Governance Committee, and must ensure that Medicines Management Policy, guidance and related standard operating procedures have been reviewed, the risks around medicines and medicines management identified, and appropriate mitigation put in place.

3.11 The **Medicines Management Committee** is accountable to Clinical Governance Committee and operates with agreed terms of reference. The group will:

3.11.1 Seek assurance from the Head of Education and Professional Development on the content and appropriateness of medicines management education and training, and make recommendations for improvement as appropriate.

3.11.2 Take cognisance of the requirements of this policy, and associated guidance/standard operating procedures, and ensure it remains compliant with relevant national guidance on safe and effective medicines management practice.

3.11.3 Review and maintain the Service Medicines Formulary, and provide clinically-focussed recommendations regarding additions/changes/ deletions to the Formulary.

3.11.4 Commission, review and approve Patient Group Directions (PGD) for use within the Service in response to changes in clinical practice within the Service, and in response to requests from clinical staff or partners as appropriate.

3.11.5 Regularly review medicines related risks recorded on the Service Risk Register, updating the level of risk or mitigation on an ongoing basis.

3.11.6 Liaise with Medicines and Healthcare products Regulatory Agency (MHRA), Home Office, Association of Ambulance Chief Executives and other relevant authorities with respect to licensing of medicines for prescription, supply and administration by ambulance staff

3.11.7 In liaison with the National Clinical Governance Group, provide guidance on the therapeutic and pharmaceutical aspects of Service guidelines, care pathways, procedures and standards being developed, and approve/endorse where appropriate.

3.11.8 Advise, and where appropriate seek approval from, the Clinical Governance Committee, and Board where appropriate, on issues relating to medicines management.

3.12 Healthcare Professionals

3.12.1 All healthcare professionals (HCPs) working for the Service must be registered with the appropriate regulatory body, be trained according to their profession, have the necessary level of competence against good practice and legislative requirements in the prescribing, supply, administration, storage and disposal of medicines and medical gases.

3.12.2 It is the responsibility of every healthcare professional working for the Service to remain up to date with medicines management issues and policy, attend training on a regular basis to help maintain full CPD records.

3.12.3 All healthcare professionals working for the Service will be competent and confident in the supply and/or administration of medicines under this policy and related guidance/standard operating procedures, and do so bearing in mind their own professional Code of Conduct and Ethics and Standards of Proficiency.

3.12.4 Healthcare professionals must be fully conversant with the UK Ambulance Services Clinical Practice Guidelines 2013 and any Service Guidance on medicines before they administer or supply a medicine.

3.12.5 All healthcare professionals must adhere to all guidance and standard operating procedures regarding medicines and medical gases referred to under this policy.

4 Procurement of Medicines and Medical Gases

4.1 Procurement of all medicines for use by the Service must be made through the authorised supplier for the Service – Tayside Pharmaceuticals (NHS Tayside, Ninewells Hospital, Dundee). Authorisation must be sought from the Service Head of Procurement and the Medical Director before looking to procure medicines from any other pharmaceutical supplier/ wholesaler.

4.2 The procurement of all medical gases for use by the Service must be through the authorised supplier for the Service – British Oxygen Company (BOC).

4.3 Where controlled drugs are to be ordered by paramedics for vehicle or station stock, a Controlled Drug Requisition Order form must be completed and submitted to Tayside Pharmaceuticals in accordance with the Service controlled drugs guidance and related standard operating procedures.

4.4 Staff must follow Service guidance and all relevant standard operating procedures for obtaining a (re)supply of medicines and medical gases for use in the treatment of patients and members of the public. All Service guidance and standard operating procedures must be up-to-date, and available for reference and use by relevant staff.

5 Storage of Medicines and Medical Gases

5.1 Medicines, medicines pouches and medical gases must be stored in a secure area to restrict unauthorised access.

5.2 Access to medicines and medical gas storage areas must be controlled through the appropriate use of key locks, digital keypads and/or individual staff swipe cards.

5.3 Storage arrangements for controlled drugs must be in accordance with the Service controlled drugs guidance and related standard operating procedures, and meet all relevant legislative requirements and support good governance practice.

5.4 Medicines storage compartments on vehicles should be locked at all times when they contain medicines, except when dispensing/using any of the contents. However, this excludes those medicines kept in emergency kits, intravenous fluids, antiseptics and irrigation solutions.

5.5 Guidance and standard operating procedures that cover all aspects of storage of medicines and medical gases by the Service must be in place, be made available for reference and use by relevant staff, and be up-to-date.

5.6 Medicines and medical gas storage arrangements should be regularly monitored/audited in accordance with this policy, related guidance and standard operating procedures.

6 Administration or Supply of Medicines and Medical Gases

The supply and administration of medicines and medical gases by Service staff must be in accordance with current legislation, the UK Ambulance Services Clinical Practice Guidelines 2013 and any approved Service guidance such as the Scottish Ambulance Service Medicines Formulary and approved patient group directions.

6.1 Staff authorised to administer/supply medicines and medical gases

A number of staff groups are permitted to administer and/or supply medicines and medical gases in the course of their work, although the range of medicines/medical gases that can be legally administered or supplied depends on their level of qualification, registration status and their clinical experience and competence.

6.1.1 Under medicines legislation, paramedics who hold current registration with the Health Professionals Council and are deemed proficient by the Service, are authorised to administer a range of parenteral medicines on their own initiative for the immediate, necessary treatment of sick or injured persons without the usual requirement for a prescription or directions of a prescriber. Paramedics are also authorised to administer/ supply specific medicines under Patient Group Direction or Patient Specific Direction where appropriate (see section 6.2). The list of authorised medicines (parenteral and non-parenteral) for use by registered paramedics is detailed within the Scottish Ambulance Service Medicines Formulary.

6.1.2 Provision 7 of the Prescription Only Medicines (Human Use) Order 1997 lists those POMs that can be administered parenterally by anyone for the purpose of saving life, this includes ambulance technicians, assistant practitioners, student paramedics, first aiders and members of the public, Ambulance Technicians and supervised students who have successfully completed an approved training programme, and are deemed proficient by the Service to administer this limited range of medicines can do so on their own initiative. These medicines are clearly marked within the Scottish Ambulance Service Medicines Formulary.

6.1.3 Students must be supervised when working in the clinical practice setting, and are only authorised to administer a limited range of medicines/ medical gases (see 6.1.2 above). Paramedics do not have prescriber status and as such cannot direct students (or others) to administer prescription only medicines (POMs) on their behalf..In all cases of student supervision, the qualified paramedic who is supervising a student's clinical practice must take full responsibility for all aspects of drug administration.

6.1.4 Healthcare professionals registered with the General Medical Council are authorised to administer/supply any medicine or medical gas where appropriate in the treatment of patients requiring medical care.

6.2 Patient Group Directions

The use of Patient Group Directions (PGD) by registered paramedics to administer/supply medicines is permitted within the Service, provided the PGD has been approved and authorised by the Medical Director, Pharmaceutical Advisor and the Service Medicines Management Committee.

6.2.1 The Service will ensure a PGD is in place where required for those medicines approved by the Service which are not listed or approved within schedule 5 of the Medicines Act 1968 (Prescription Only Medicines). This will also apply for any medicine to be administered for the purpose of saving life which is not listed under the exemptions provided by Article 7 of the Prescription Only Medicines (Human Use) Order 1997 (the POM Order) and for all medicines supplied to patients other than on the directions of an independent prescriber. The list of approved medicines for use by Service paramedics under

a PGD is detailed within the Scottish Ambulance Service Medicines Formulary.

6.2.2 Each Service PGD must comply with *NHS MEL 2001 (7) Patient Group Directions and* , and be developed and maintained in line with The Human Medicines Regulations 2012 (Schedule 16), *'NHS Quality Improvement Scotland Patient Group Directions Best Practice Statement 2006'* and NICE guidance on Patient Group Directions 2013.

6.2.3 Before using a PGD, each individual paramedic must have undertaken any additional training/education required and signed the relevant declaration of competence. A signed copy of this declaration must be held by the Service, and the paramedic's own line manager must be satisfied of their competence to work safely and appropriately under the PGD concerned.

6.3 Patient Specific Directions (PSD)

A patient specific direction (PSD) is a written instruction from a qualified and registered prescriber for a medicine including the dose, route and frequency or appliance to be supplied or administered to a named patient. (Ref: NMC Medicines Management Standards 2007).

6.3.1 The use of a PSD within the Service is permitted, provided it has been approved and authorised by the Medical Director, Pharmaceutical Advisor and the Service Medicines Management Committee.

6.3.2 The Service is responsible for ensuring all relevant staff are made aware of all current PSDs, and ensure the appropriate training, support and advice is available for staff expected to operate under a PSD where necessary.

6.4 Principles for administration or supply of medicines and medical gases

Any authorised individual deciding to administer or supply a medicine or medical gas to a patient, or being asked to check the administration or supply, must be familiar with and competent in the use of that medicine or medical gas.

6.4.1 The Consent Policy applies to the administration or supply of medicines and medical gases. Consent should always be sought if possible before any medicine or medical gas is given to a patient, and should be documented in the Patient Report Form (ePRF). Further considerations apply for:

- Children
- Adult with incapacity
- Life-threatening situations

In these situations, consultation with relatives may also be appropriate, and should also be documented.

6.4.2 Medication for administration must only be prepared immediately prior to administration to the patient. No medicinal product may be removed from its container/packaging except for immediate administration.

6.4.3 The person administering or supplying the medicine should ensure the correct medicine has been selected, the correct route of administration has been selected, and the correct dose to be given has been identified prior to any administration or supply. Wherever possible, a second suitable person i.e. Doctor, Nurse or Ambulance personnel, must be asked to check all medicines/doses for accuracy before administration or supply. This is deemed best practice.

6.4.4 Where students are required to administer a medicine, they must always have every aspect of the administration of that medicine checked by the supervising paramedic or technician beforehand (see 6.1.3) and have gained consent to administer it to the patient.

6.4.5 Staff authorised to administer medical gases (oxygen, Entonox) must ensure the patient is receiving the appropriate oxygen flow rate for their condition. The Scottish Ambulance Service Medicines Formulary indicates those staff authorised to administer medical gases.

6.4.6 Medicines specially packed for supply to a patient to take away with them must only be supplied by authorised paramedics under a current PGD previously authorised for use by the Service. See 6.2.3.

6.4.7 A record must be made immediately after each administration or supply of a medicine or medical gas on the Service Patient Report Form (ePRF). The identity of the person administering/supplying a medicine or medical gas must be clearly documented, and all relevant information on the medicine and the administration of that medicine recorded in the ePRF in line with current guidance and related standard operating procedures.

6.4.8 There may be occasions where an individual decides it is appropriate to seek advice, support and/or authority from another health care professional in the treatment of a patient in their care.

- Doubts about the appropriateness of a specific medicine: Staff must consider the appropriateness of any medicine selected for administration, including contra-indications, and seek further advice from an appropriate health care professional where necessary. Where an individual is unable to resolve a concern, despite having discussed the care of the patient with another health care professional first, they must ensure the patient is transferred without unnecessary delay into the care of a clinician or facility capable of delivering the required level of care. However, the overall responsibility for the care of the patient will remain with the attending clinician prior to any handover.

- Doubts about integrity of a medicine: Any medicine that is found or thought to be defective (faulty or degraded) should not be used and should be handled/reported in accordance with current guidance and related standard operating procedures for Defective Medicines.

6.4.9 All relevant clinical information around the administration of a medicine(s) must be passed on by appropriate Service staff as part of any clinical handover to receiving staff.

6.5 Self administration of medicines and medical gases by patients

Wherever a patient is permitted to self administer a medicine or medical gas e.g. Entonox whilst under the care of a Service clinician, the clinician must ensure the patient is given clear instructions on how to safely and effectively administer the medicine or medical gas.

6.5.1 Any self-administered medicines (previously prescribed by a Medical Practitioner or other qualified prescriber) currently in possession of the patient which are taken whilst in the presence of ambulance personnel must be recorded in the ePRF.

6.5.2 Details of any medicine supplied to a patient by an authorised paramedic under a PGD, for the patient to take away and self-administer, must be fully documented on the ePRF along with the instructions and advice given.

6.6 Medicines for staff

6.6.1 Personal use by staff of Service medicines stock is not permitted. If a member of staff is unwell, they should consult the most appropriate health care professional for access to treatment and advice. In an emergency, staff should attend the nearest hospital Emergency Department or be treated on scene by a suitably trained colleague or clinician.

6.6.2 First Aid boxes held on ambulance stations or Service workplaces should not contain any medicines.

6.7 Errors in administration of medicines and medical gases

Wherever an error or near miss in the administration of a medicine or medical gas has occurred (or been detected), all efforts must be made to minimise the risk of harm to the patient.

6.7.1 Where the error is discovered whilst the patient is still under the care of the Service, or subsequently found, all details of the incident must be immediately reported by the person discovering the error to the Medical/Nursing staff at the appropriate receiving unit and their first line Supervisor.

6.7.2 Where the error is discovered at another time e.g. during routine checking and auditing of ePRFs, the incident must be reported immediately to a first line Supervisor.

6.7.3 For every error and near miss that is detected, the person discovering the error must complete an Adverse Incident/Near Miss Report Form in full in DATIX as soon as is practicable in accordance with the Service Risk Management policy.

6.8 Adverse drug reactions

Wherever an adverse drug reaction in response to the administration of a medicine or medical gas has occurred (or been detected), all efforts must be made to minimise the risk of harm to the patient.

6.8.1 Clinical staff involved in the administration of a medicine or medical gas must be familiar with it's use in clinical practice, and the relevant section of the UK Ambulance Services Clinical Practice Guidelines 2013 or PGD on adverse effects.

6.8.2 Clinical staff should always be vigilant for possible adverse drug effects arising in a patient given a medicine, and know what action to take in the event of one occurring, including the immediate treatment of the patient and referral for additional medical assistance where appropriate.

6.8.3 Where an adverse drug reaction is suspected or confirmed, all details of the incident must be immediately reported by the person treating the patient to the Medical/Nursing staff at the appropriate receiving unit, and their first line Supervisor.

6.8.4 For every adverse drug reaction that is suspected/confirmed, the person who treated the patient must complete an Adverse Incident/Near Miss Report Form in full in DATIX as soon as is practicable in accordance with current Service guidance and related standard operating procedures.

6.8.5 For every adverse drug reaction that is suspected/confirmed, an online YellowCard report must also be completed (https://yellowcard.mhra.gov.uk/). The BNF also contains standard YellowCard scheme report forms where online access is not possible or practical. YellowCard is part of the UK Medicines and Healthcare products Regulatory Agency surveillance and reporting mechanism.

6.9 Records of medicine administration

The Patient Report Form (ePRF) is the document in which the administration of all medicines and medical gases to patients must be routinely recorded. All forms must be retained within the Service for a period of 7 years from the date they were created in all cases.

7 Destruction and Disposal of Medicines and Medical Gases

7.1 After treating a patient, any surplus medicine that is unusable i.e. waste medicine, must not be returned to the original container but disposed of as clinical waste into the sharps bin. However, disposal of morphine and other controlled drugs must be in accordance with separate guidance for controlled drugs and related standard operating procedures.

7.2 All unwanted or unusable medicines and medical gas stock must be clearly marked with the reason for destruction or disposal e.g. out of date, recall, withdrawal from use, etc., and be stored in a designated area of the ambulance station as soon as is practicable. However, unwanted or unusable morphine and other controlled drugs should be treated differently, and in accordance with separate guidance for controlled drugs and related standard operating procedures.

7.3 Area Service Managers must ensure appropriate arrangements are in place in every ambulance station to enable the safe and effective return/disposal of unwanted or unusable medicines by Service staff. They must also ensure compliance with relevant Health and Safety and Environmental legislation and guidance as appropriate.

7.4 It is not permissible to use any time-expired medicine or medical gas for training purposes. In-date drugs or placebos must always be used in the training environment.

8 Defective medicines and medical gases

8.1 When a defective medicine or medical gas product is discovered (or suspected), staff must report the defect in line with Service guidance and related standard operating procedures. It must also be labelled so that it can be easily identified and it's inadvertent use prevented. An accompanying report must be completed that fully identifies the product, the defect, the incident, the person discovering the defect and any other relevant information.

8.2 There must be systems in place to ensure that where a defective medicine or medical gas product is identified, products with the same batch number are withdrawn from use immediately from all vehicles, stored securely in a designated area within the ambulance station and stored separately from other medicines.

8.3 Issues around defective medicines and medical gases should be raised with Service procurement in the first instance, who can then take any issue up with relevant suppliers. In most cases, Tayside Pharmaceuticals will do this on behalf of the Service and they also have procedures in place for investigating and reviewing defective medicines, reporting relevant issues to the MHRA where appropriate.

9 Controlled Drugs

Registered Paramedics are allowed to have possession of and use morphine sulphate and diazepam without direct reference to a medical practitioner, in line with a specific Group Authority under the Misuse of Drugs Regulations 2001. No other Service staff, employees or volunteers are permitted to have morphine or diazepam in their possession at any time unless appropriately authorised by the Accountable Officer for Controlled Drugs.

9.1 It is permissible for staff authorised by the Accountable Officer for Controlled Drugs (AOCD) to take receipt of or transport morphine and other controlled drugs across the service where appropriate.

9.2 Service guidance for the Management of Controlled Drugs and related standard operating procedures exist covering the ordering, receipt, storage, administration, disposal and record keeping requirements for controlled drugs. This guidance and related standard operating procedures applies to all individuals working within the Scottish Ambulance authorised to deal with controlled drugs as part of their job role within the service, and must be followed.

9.3 It is the responsibility of Area Service Manager to ensure that day to day security of controlled drugs within ambulance station premises and Service vehicles is maintained, ensuring restriction of access to authorised staff only and that controlled drug safes are locked with spare swipe cards stored securely.

9.4 Each individual paramedic in charge of a vehicle fitted with a controlled drug safe or on-station is responsible for ensuring controlled drugs are managed in accordance with the Service guidance for the Management of Controlled Drugs and related standard operating procedures.

10 Control of Substances Hazardous to Health (CoSHH)

All medicines have the potential to cause side effects or drug reactions in some patients, and can be hazardous if misused. However, certain medicines and medical gases have additional inherent risks to any staff handling them and therefore compliance with the Control of Substances Hazardous to Health (CoSHH) Regulations 2002 (as amended) is required.

10.1 CoSHH assessments should be carried out for hazardous substances (including medical gases) used in the area. All staff should ensure that they are familiar with Service guidance and related standard operating procedures for such substances.

10.2 Staff should use appropriate protective measures to avoid inhalation or absorption of hazardous substances e.g. when applying creams or ointments.

10.3 Those medicinal products most likely to be affected more generally include the following: Antibiotics and Hormones (these can cause problems when handling uncoated tablets or powders. Care should be taken to avoid the risk of contact with or absorbing these medicines through the skin or by inhalation of dust).

10.5 Mercury: no mercury based equipment may be used within the Service

11 Drug and Health Alerts

Recent notices for medicines and medical gases can be viewed on the Medicines and Healthcare products Regulatory Agency internet site www.mhra.gov.uk , although many of them will be cascaded through the Service Medical Director and implementation co-ordinated by Tayside Pharmaceuticals.

11.1 All Drug and Health Alerts received by the Service should be acted upon promptly, and within the requested timeframe (where given). All Area Service Managers must be informed, and relevant information cascaded to all appropriate staff in accordance with Service guidance and related standard operating procedures.

11.2 Area Service Managers must ensure appropriate arrangements are in place in every ambulance station for the collection/handling/disposal/return of medicines or medical gas products affected by a Drug or Health Alert.

12 Medicines Risk Assessment

12.1 Formal risk assessments should be undertaken within the Service to identify those risks related to the use and management of medicines and medical gases across the Service.

12.2 Identified risks for the use and management of medicines and medical gases must be included within the appropriate Service Risk Register(s), detailing the level of risk and mitigating action(s) in line with Service policy on risk management.

12.3 The management of risk around the use and management of medicines and medical gases across the Service should be monitored by the Service Clinical Governance Committee.

13 Audit

13.1 A regular programme of audit (internal and external) must be in place to ensure compliance with this policy, Service guidance and related standard operating procedures.

13.2 Actions identified through audit activity must be clear and specific, listing those individuals responsible for ensuring individual actions for improvement are completed, and by when.

13.3 The outcomes of audit (and re-audit) activity should be monitored by the Service Clinical Governance Committee.

14 Working with the Pharmaceutical Industry

14.1 Health care professionals working for the Service should act within their own professional code of conduct and ensure they adhere to both Service policy and 'A Common Understanding 2012 Working Together for Patients' guidance issued by the Scottish Government. Adherence to any other relevant guidance on working with the pharmaceutical industry and getting involved with clinical trials work is also expected.

14.2 The advertising and promotion of medicines is strictly regulated under the Medicines (Advertising) Regulations 1994, and staff must ensure the selection of a medicine to treat a patient is on the basis of evidence, clinical suitability and cost effectiveness alone.

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

14.4 Companies may also offer hospitality at a professional or scientific meeting. Such hospitality should be reasonable in level and subordinate to the main purpose of the meeting, and all hospitality must be sanctioned by the Service Medical Director in the first instance, and be in accordance with the current Association of the British Pharmaceutical Industry (ABPI) Code of Practice. All staff must act in accordance with the 'Acceptance, Financial Assistance, Gifts & Hospitality and Declaration of Interests' Policy for the Service.

15 Review of the Policy

15.1 The Board will review this policy one year from the date of approval Policy, and every 2 years thereafter.

16 Liability

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

16.2 All doctors must be registered with the General Medical Council (GMC) and are ultimately accountable for their own prescribing and dispensing practice

16.3 In addition, the Service will indemnify the salaried doctors directly employed whilst undertaking Service work in the same way as other employees.

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

List of Standard Operating Procedures

To be added once complete