Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Policy
Medicines Management

National Ambulance Service (NAS)

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1.0 POLICY STATEMENT

1.1 The National Ambulance Service (NAS) Medical Directorate are responsible for monitoring compliance with this Medicines Management Policy.

1.2 The Medicines Management Policy describes NAS control measures for reducing medication-related risks.

1.3 A critical success factor for the National Ambulance Service) is to "demonstrate continuous improvement in quality." Reporting of medication errors provides the opportunity to receive and analyze the data necessary to do this. With an emphasis on a non punitive 48 hour approach, focusing on performance improvement, it is expected that medication error reporting will increase and provide the necessary data. All data will be reviewed in a confidential manner.

1.4 Appropriate risk control measures must be added to the Medicines Management Policy when new medication-related risks are identified. The Medical Director must be informed of medication-related incidents to inform future decisions on Clinical Practice Guideline development.

1.5 The Medicines Management Policy must support Clinical Governance (Clinical Practice Guidelines) within the NAS. The Medicines Management Policy also covers the policy and procedures associated with the prescribing, administering, requisitioning and storing of medicines.

1.6 NAS staff involved with medicines must undertake continuing professional development as prescribed by the Pre Hospital Emergency Care Council, keeping up to date with changes in medicines management, and updating themselves on this Policy.

1.7 Medicines used within the NAS must be clinically effective and appropriate for the patient, the condition being treated and in full compliance with Clinical Practice Guidelines as approved by the Pre Hospital Emergency Care Council.

1.8 PHECC Registered staff may initiate treatment only with medicines as per CPGs that have been approved by the Health Service Executive and/or the Pre Hospital Emergency Care Council and following issuance of a letter of authorisation to practice to the individual practitioner.

2.0 PURPOSE

2.1 To ensure safe management of medicines to protect patients and staff and effective use of financial resources.

2.2 To describe the safe and secure system for the management of medicinal products in the NAS within a framework provided by legislation and HSE official guidance.

2.3 To provide a non punitive mechanism for the reporting of medication errors in an effort to continuously improve the medication process and the quality of patient care.

3.0 SCOPE

3.1 Applies to all staff members who are employed by the National Ambulance Service (NAS)

4.1 LEGISLATION/OTHER RELATED POLICIES

A. Medicinal Products (Prescription and Control of Supply) (Amendment) Regulations 2008 (SI 512 of 2008)
B. The Misuse of Drugs (Amendment) Regulations 1993 (SI No. 342 of 1993)
C. Misuse of Drugs (Amendment) Regulations 1993 (SI 338 of 1993)
D. Misuse of Drugs Regulations 1988 (SI no. 328 of 1988)
E. Misuse of Drugs (Safe Custody) Regulations 1982 (SI no 321 of 1982)
F. Non Fatal Offences against the Person Act 1997
G. Mental Health Act 2001
H. Child Care Act 1991
I. Policy – NASCG006 – Management of Controlled Drugs including Morphine Sulphate
J. Policy – OQR006 – Incident Management Procedure
K. Procedure – NASOE014 - Requisition of Drugs

5.1 GLOSSARY OF TERMS AND DEFINITIONS

5.2 Medical Product/Medicine

5.1.1 For the purpose of this policy a `medicinal product' (or a `Medicine') is defined as a substance or article, or an ingredient of either of these, (not being an instrument, apparatus or appliance) supplied for administration to human beings for a medicinal purpose. Medicinal purpose means any one or more of the following:

A. Treating or preventing disease
B. Otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function

5.3 Unlicensed or unauthorised medicinal products

5.2.1 An unauthorised or unlicensed medicine is a medicinal product which is not licensed by the Irish Medicines Board (the regulatory body responsible for the licensing or authorisation of medicinal products for human/veterinary use) or the European Medicines Evaluation Agency (EMEA).

5.3 Controlled Drugs

5.3.1 For the purposes of this Policy, a controlled drug (CD) is a drug named in Schedule 2 (CD2) or schedule 3 (CD3) of the regulations under the Misuse of Drugs Acts 1977, 1984 and 1988 (S.I. No. 328 of 1988), and any amendments, and also any drugs which it is considered necessary to control for risk management reasons. The Misuse of Drugs (Amendment) Regulations 1993 (S.I. No. 342 of 1993) includes Midazolam as a Schedule 4 Drug

5.4 Abbreviations

- Supervisor - Leading EMT (Paramedic/Advanced Paramedic)
- Manager - Ambulance Officer
- EMT - Emergency Medical Technician
- P – Paramedic
- AP – Advanced Paramedic
- PCR – Patient Care Report
- CPG(A) – Clinical Practice Guidelines (Advanced)
- PHECC – Pre Hospital Emergency Care Council
- CD – Controlled Drug
- ADR – Adverse Drug Reaction

5.5 Doctrine of Necessity

5.5.1 This is a common law doctrine, developed through case law in both Irish and other legal systems. In the context of this policy, it applies to an emergency situation where a healthcare professional treats a patient/client, in the absence of consent, in the best interest of the patient/client, where the treatment is necessary to save the life or preserve the health of the patient/client. (Bodily integrity).

5.5.2 Only that treatment which is deemed necessary to save the life of the patient can be initiated.

5.6 Designated Person in Charge

5.6.1 The designated person in charge refers to the designated Supervisor or Manager who may be in charge of an Ambulance Station or number of Ambulance Stations.

5.6.2 The designated person in charge will also be the person to whom the NAS staff in that location report.

5.6.3 The term designated person in charge will therefore be interpreted in each HSE Area/NAS Area in a manner that is consistent with local supervisory/managerial structures.

5.6.4 During out of hours, the designated person in charge may be the Supervisor on duty in Ambulance Control

5.7 Minors (Child/Children)

5.7.1 For the purposes of this Policy, the Non Fatal Offences against the Person Act 1997, Section 23, provides that any minor who has attained the age of 16 years can consent to any surgical, medical or dental treatment.

5.7.2 The Mental Health Act 2001 and the Child Care Act 1991 refers to children as those less than 18 years.

5.8 Medication Error

5.8.1 A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labelling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

6.0 ROLES AND RESPONSIBILITIES

6.1 The relevant Director has overall statutory responsibility and accountability for the safe management of medicines.

6.2 The Health Service Executive has responsibility and accountability for ensuring the provision of the appropriate resources required to implement this policy.

6.3 The Education and Competency Assurance Team is responsible for the maintenance of this policy

6.4 Specific responsibilities also lie with a cross section of staff.

6.5 The policy specifies who is responsible for each activity.

6.6 For the purpose of this policy any reference to Advanced Paramedic refers to Registered Advanced Paramedics, registered with the Pre Hospital Emergency Care Council (PHECC).

6.7 A designated Officer will be responsible for the day-to-day safe management of medicines in the NAS and reports directly to the relevant Area Operations Manager or designate for this purpose.

6.8 The Education and Competency Assurance Team is responsible for ensuring that all EMTs/Paramedics/Advanced Paramedics are trained to be competent in all aspects of administering medicines, as specified in this Policy.

6.9 The Education and Competency Assurance Team is responsible for Clinical Audit related to the use of medicines within the NAS including monitoring and reporting of trends of usage to the Medical Directorate.

PROCEDURES

7.1 ADMINISTRATION OF MEDICINES

7.2 Responsibility

7.2.1 NAS staff who administer a medicine are responsible and accountable for their actions.

7.3 Who May Administer Medicines?

7.3.1 The following may administer medicines:

7.3.2 NAS personnel may administer medications within the limitations of the Division of the PHECC Register in which they are currently registered, according to a Clinical Practice Guideline (CPG) or on the direction of a registered medical practitioner, as outlined in the 7th Schedule, Parts 1, 2, 3 (see Appendices II, III, IV).

7.3.3 In addition, an EMT/Paramedic/Advanced Paramedic Trainee or Intern may only administer medications within the additional limitations on Trainees (direct supervision) and Interns (direct or other approved supervision) currently registered within each Division.

7.3.4 The supervising EMT/Paramedic/Advanced Paramedic (who must also be currently registered in the same or higher division) is responsible for ensuring that the medication is correctly administered within the direct or approved supervision arrangements; however, this does not absolve the Trainee or Intern from their individual responsibilities.

7.3.5 All supervising EMTs/Paramedics/Advanced Paramedics should have received appropriate instruction in mentoring techniques.

7.3.6 Registered medical practitioners may have access to NAS medicinal products carried on NAS vehicles for the purpose of immediate administration to patients.

7.4 Principles for the Administration of Medicines

7.4.1 Any authorised person administering a medicine to a patient or checking the administration must be satisfied that she or he knows the therapeutic uses of the medicine, its normal licenced dosage, side effects, precautions and contra-indications.

7.4.2 Medicines must only be prepared immediately before administration.

7.4.3 Checks must incorporate the whole administration process:

A. Indications for use
B. Integrity of packaging
C. Expiry date
D. Free of particulates
E. Product accuracy (dose, strength, volumes, drug name)

7.4.4 All calculations must be conducted in accordance with the Medication Formulary as contained in PHECC Clinical Practice Guidelines (CPG).

7.4.5 A record must be made contemporaneously after each administration on the Patient Care Report (PCR) including the dose and quantity administered.

7.5 Concerns

7.5.1 Concerns in relation to administration of medication: Staff must check appropriateness of any medicine, including its contra-indications, in the Medication Formulary (see Section 7.3.4) if any concern arises.

7.5.2 Concern about a medicine: Any medicine that is potentially defective should not be used and the procedures for Defective Medicines (see Section 10) should be followed.

7.5.3 Where concerns cannot be allayed, the administration should not proceed.

7.6 Consent to Treatment

7.6.1 In general, patients have a right to refuse medicines. It is a basic rule of common law that "INFORMED" consent must be obtained for medical examination, treatment or investigation. Reasons for refusal must be documented on the PCR.

7.6.2 Further considerations apply for:

A. An unconscious patient (implied consent)
B. A patient who is mentally incapable of consent
C. Minors, legal parent/guardian consent required (see Section 5.7)
D. Life-threatening situations/protecting bodily integrity (doctrine of necessity)
E. Patient incapable of providing expressed consent, e.g. sensory deficit or language barrier

7.6.3 In an emergency life-threatening situation where the patient is unable to consent or to appreciate what is required a healthcare professional may administer the necessary medical treatment in the absence of the expressed consent of the patient or the presence of a legal parent/guardian. This is known as the common law doctrine of necessity. This is a common law doctrine developed through case law and is referred to in the Irish legal system in a medical context among others.

7.6.4 It can apply to an emergency situation where a healthcare professional treats a patient, where the treatment is necessary to save the life (maintain bodily integrity (Irish Constitution)) or preserve the health of the patient in the absence of consent.

7.6.5 The actions of the healthcare professional must be taken in the best interests of the patient, where the patient or a legal parent/guardian (in the case of minors) is incapable or unavailable to provide consent.

7.6.6 Where the doctrine of necessity is applied or consent is implied, only that treatment which is required to maintain bodily integrity (save the life) should be administered. Relatives other than a legal parent/guardian cannot override the doctrine of necessity.

7.6.7 A healthcare professional may encounter situations where an advance directive/living will exists, which may be indicative of the patient's wishes/consent. In these situations, the Irish legal system remains unclear on the validity or applicability of such "Advanced Directives/Living Wills".

7.6.8 Therefore, current best practice suggests that treatment is administered unless consent is withheld by either the patient or the legal parent/guardian.

7.6.9 This position may be contrary to the expressed views of relatives other than a legal parent/guardian who may be present. The healthcare professional should endeavour to assist the relatives understanding of why treatment must be administered. Document if this happens.

7.7 Checking of Medicines before Administration

7.7.1 It is best practice for a second, suitable person i.e. Doctor, Nurse or EMT/Paramedic/Advanced Paramedic, to check all medicines for accuracy before administration, wherever available.

7.7.2 An EMT/Paramedic/Advanced Paramedic Trainee must always have any medicine they wish to administer checked by a qualified EMT/Paramedic/Advanced Paramedic.

7.7.3 Practitioners should ensure the following factors before administration of any medication. Check the Seven Rights:

1. The right patient
2. The right medication
3. The right dose
4. The right route
5. The right time
6. The right to refuse (consent)
7. The right documentation

7.8 Disposal of Individual Doses of Unused or Discarded Medicines

7.8.1 No medicinal product may be removed from its container/packaging except for immediate administration.

7.8.2 Unused or discarded medicines must not be returned to the container but disposed of into a sharps bin.

7.9 Errors in Administration of Medicines

7.9.1 An error is deemed to have been made if one or more of the following circumstances apply:

A. Omissions - any dose not given other than in circumstances where professional judgement has been used.
B. Incorrect dose administered
C. Unauthorised medicine given - the administration to a patient of any medicine not indicated for the condition
D. Incorrect administration from that specified - administration of a medicine by a different route or in a different form from that specified by the Medication Formulary

7.10 Reporting of Errors in Administration of Medicines

7.10.1 Non Punitive Action (See Section 7.13) means that there will be no disciplinary action taken against an employee for a medication error that is reported within 48 hours of being discovered. Under this policy, nothing will be placed in the employee's permanent employment record or used during the performance appraisal process.

7.10.2 Whenever an error in the administration of a medicine is found the following action should be taken, by the person discovering the error:

1. Where the error is discovered whilst the patient is in the care of the NAS:

A. Consider the benefits of informing the patient of the error and seek their consent to continue treatment
B. Immediately report the incident to the Medical/Nursing staff at the receiving hospital and the designated person in charge.
C. The designated person in charge ensures that an Incident/Near Miss Form is completed as soon as practicable by the person reporting the error in accordance with the Incident Management Policy and Procedure.
D. The designated person in charge forwards all relevant documentation to Education and Competency Assurance Team for audit by the Medical Directorate within 5 working days.

2. Where the error is discovered at another time (e.g. during routine checking and auditing of PCRs):

E. Immediately report the incident to a designated person in charge, who in turn must forward all documentation to the Education and Competency Assurance Team, for audit in conjunction with the Medical Directorate.
F. Discuss the benefits of informing the patient of the error with the Medical Directorate
G. Where the error is reported, it is the responsibility of the Medical Directorate to decide on what course of action to take.
H. The Education and Competency Assurance Team must ensure that an Incident/Near Miss Form is completed as soon as practicable in accordance with the Incident Management Policy and Procedure or no later than 5 working days.
I. For the subsequent investigation of the incident see Policy – OQR006 - Incident Management Policy.

7.10 Adverse Events following the Administration of Medicines (Adverse Drug Reaction (ADR))

7.10.1 An adverse event is deemed to have occurred if one or more of the following circumstances apply:

A. The patient has an allergic reaction to the medication.
B. The patient's condition rapidly deteriorates following administration of a medication.

7.11 Reporting of Adverse Events

7.11.1 Whenever an adverse event occurs following the administration of a medicine the following action should be taken, by the person discovering the adverse event:

A. Discuss the event with the patient and seek their consent to continue treatment
B. Immediately report the adverse event to the Medical/Nursing staff at the receiving hospital and the designated person in charge.
C. The designated person in charge ensures that an Incident/Near Miss Form is completed as soon as practicable by the person reporting the adverse event in accordance with the Incident Management Policy.
D. The designated person in charge forwards all relevant documentation to the Education and Competency Assurance Team for audit in conjunction with the Medical Directorate within 5 working days.
E. The reporting member of staff will notify the Irish Medicines Board (IMB) and the relevant Pharmacy.

7.12 Self Administration of Medicines by Patients

7.12.1 Any medicine prescribed for the patient and taken in the presence of NAS staff must be documented on the PCR

7.12.2 The principle of self administration implies that the patient is in control of the rate of administration.

7.12.3 The only medicine offered by the NAS for self-administration by the patient is Entonox for the relief of pain. Self-administration enables the patient to maintain their own level of analgesia.

7.13 Non Punitive Reporting of Medication Errors

7.13.1 Continuing education, remedial training or an individualized action plan is not considered "punitive or disciplinary action" under this policy.

7.13.2 It is the expectation that any employee who believes a medication error has occurred will report the error. If the error is reported within 48 hours of being discovered, the non punitive action steps will be followed.

7.13.3 Exceptions to Non Punitive Action:

1. Information gathered through audits of medical records
2. Intentional acts by the employee in the administration of medications (i.e. not an "error", not the result of "negligence")
3. The wrongful/unlawful consumption of medications/controlled substances by the employee making the error
4. Employees who knowingly fail to report a medication error

7.14 Medicines for Staff

7.14.1 Staff must not take medicines from stock for personal use. The member of staff will see his/her General Practitioner. In an emergency, staff should attend the Emergency Department.

7.15 Retention of Records of Administration

7.15.1 All records of administration must be retained for a period of eight years for adults and twenty-five years for children after the conclusion of treatment as per Policy – NASP023 - Records Management or localised Records Management Policy.

8.1 SUPPLY AND RETURN OF MEDICINES

8.2 Responsibility

8.2.1 The Area Operations Manager (with delegation as appropriate) is responsible for obtaining all medicinal products, which are required and approved by the NAS, ensuring that they are of a suitable quality and for their issue in line with practitioner authorisations (see Appendices II, III, IV).

8.2.2 The Area Operations Manager is not responsible for the quality of any medicine obtained elsewhere.

8.2.3 The designated person in charge is responsible for ensuring that the system for requisitioning and returning of medicines is followed.

8.2.4 In the absence of a designated person in charge in a particular Station, then the responsibility will rest with a designated Officer.

8.3 Obtaining Medicinal Products

8.3.1 All medicines covered by this Policy, unless the patients' own, must be obtained through the approved Pharmacy.

Note: For requisition of Controlled Drugs (CD) see Procedure – AMBOE002 – Requisition of Controlled Drugs.

Note: For requisition of Drugs see Procedure – NASOE014 – Requisition of Drugs.

8.4 Use of unauthorised or unlicensed medicinal products

8.4.1 *The Medicinal Products (Licensing and Sale) Regulations 1998* provide statutory authority for a registered medical practitioner to treat a patient under her or his care using unlicensed medicinal products.

8.4.2 The PHECC Medical Advisory Group (MAG) may prescribe an unlicensed medicine for use in line with Clinical Practice Guidelines where a licensed medicine is not available, and is satisfied that the effect is the same.

8.4.3 The EMT/Paramedic/Advanced Paramedic who administers the unlicensed medication should be aware of the indications for the drug's intended use (as directed by the Medical Advisory Group and the Pre Hospital Emergency Care Council). Information should also be provided to administer the medicinal product safely.

8.5 Supplies

8.5.1 Supplies of medicines are requisitioned on the appropriate form for each Station as required, by the designated person in charge.

8.5.2 Where Emergency supplies are requested and no designated person in charge is available to sign, then a Manager should be contacted for authorisation.

8.6 Stock Control

8.6.1 Stock levels of all medicinal products must be maintained in line with established requirements for "drug bags" as outlined in the National Equipment List.

8.6.2 Ambulance Stations should hold minimum stock levels as determined locally under the control of a designated person in charge subject to arrangements as per Section 9.0

8.7 Receipt of Medicines

8.7.1 NAS staff collect requisitioned medicines from the relevant Pharmacy. All receipt of medication must be signed and dated by the NAS staff member collecting the requisition.

8.7.2 Following collection at the relevant Pharmacy, the medicines will be secured in the 'drug bag' and the quantities received entered into the Stock Control sheet by the appropriate person and the bag tagged BLUE. (See Section 9.2)

8.8 Unused/Expired/Damaged Medicines

8.8.1 All drug bag tags must be checked at the start of each shift. Tags/medicines which are due to expire should be returned to the relevant Pharmacy as soon as practicable.

8.8.2 Labels on medicine containers must not be altered. If the label is damaged or obliterated the medicine must be disposed of as soon as possible.

8.8.3 The designated person in charge must make appropriate local arrangements for the disposal of these medicines.

9.1 STORAGE OF MEDICINAL PRODUCTS

9.2 Specific Responsibility

9.2.1 All medicines shall be stored under the control of the relevant Area Operations Manager (with delegation as appropriate).
9.2.2 All medicines shall be stored in line with manufacturer's recommendations.
9.2.3 The individual EMT/Paramedic/Advanced Paramedic must safeguard all medications for the duration of the tour of duty.
9.2.4 The designated person in charge must safeguard all medicines issued to any Ambulance Station.
9.2.5 A designated Manager will inspect the requisition and storage process at each Station on a quarterly basis and maintain a log of such inspections.

Note: For storage of Controlled Drugs (CD) see Policy – NASCG006 –Controlled Drugs including Morphine Sulphate.

9.3 Drug Bags/Cupboards/Security Tagging

9.3.1 Medicines issued must be stored in a secured "drugs bag" or other secure receptacle. Each "drug bag" should have a unique identifying number.
9.3.2 Fluids should be stored in a designated "fluids bag".
9.3.3 All "drugs bags" must be security tagged at all times. Where the contents are unused, then the tag should be BLUE.
9.3.4 The designated person in charge must make arrangements for a supply of security tags to be available.
9.3.5 Cupboards for the storage of medicines on vehicles are to be locked at all times when containing medicines except during dispensing of the contents. The following need not be locked:

A. Intravenous fluids
B. Antiseptics and irrigation solutions

9.4 Drugs Bags Contents

9.4.1 Clearly identifiable bags will be issued specifically for use by Paramedics and Advanced Paramedics.
9.4.2 Appendix VII lists the contents of the drug bag to be utilised by Advanced Paramedics
9.4.3 Appendix VIII list the contents of the drug bag to be utilised by Paramedics

9.5 Security on vehicles

9.5.1 "Drugs bags" should only remain on vehicles during operational periods of duty.
9.5.2 The designated person in charge must ensure that all "drugs bags" are removed from vehicles whenever the vehicle is outside of the control of the NAS, e.g. vehicle maintenance.
9.5.3 All "drug bags" must be signed in and out on a Station Medicines Record Book.

9.6 Stock replenishment

9.6.1 Where the contents have been used, then the "drugs bag" must be tagged RED and returned to the Station for replenishment at the earliest opportunity.
9.6.2 The designated person in charge must make arrangements for a supply of security tags to be available.

REMEMBER, BLUE SEAL STOCKED, RED SEAL RE-STOCK

9.7 Record of Checks

9.7.1 The Stock Control sheet (see Appendices VII, VIII) for each "drugs bag" must be updated and signed every time medicinal products are removed or added to the contents of the "drugs bag".
9.7.2 This is the responsibility of the staff member concerned.

9.8 Reporting of Losses

9.8.1 The loss or suspected loss of any medicinal product must be reported using the Incident/Near Miss Form to a designated person in charge/ Education and Competency Assurance Team no later than the next working day. The Medical Directorate will determine the appropriate investigation.
9.8.2 The designated person in charge ensures that an Incident/Near Miss Form is completed by the person reporting the loss as soon as practicable in accordance with the Incident Management Policy.
9.8.3 The designated person in charge informs the relevant Manager of the incident as soon as practicable.
9.8.4 Where theft is suspected, the relevant Manager will notify a senior Manager and An Garda Siochana.

9.9 Monitoring of other Medicinal Products

9.9.1 The designated person in charge will make checks to ensure compliance with this Policy at least every three months.

9.9.2 The checks will consist of visible inspections of check lists and stock levels.

10.0 REPORTING DEFECTS IN MEDICINAL PRODUCTS

10.1 When a defect in a medicinal product is discovered or suspected, NAS staff must, as soon as practicable, report the defect to a designated person in charge. All suspect medicine must be labelled so it can be easily identified and inadvertent use prevented then retained in a safe place.

10.2 The staff member who discovers or suspects the defect must complete an Incident/Near Miss Report Form. The report must fully identify the product, the defect, the incident, and the person discovering the defect and any other important information.

10.3 If the designated person in charge feels it appropriate, they must ensure that all medicine of the same batch is withdrawn from use immediately from all vehicles and stored securely, separate from other medicines. The Incident/Near Miss Report Form must be sent by fax or email alert to the Area Headquarters, the issuing Pharmacy and the Quality and Risk Directorate for immediate action as per the Incident Management Policy.

10.4 The reporting member of staff will notify the Irish Medicines Board (IMB) and the relevant Pharmacy.

11.1 MEDICINAL PRODUCT WITHDRAWAL WARNINGS

11.2 Withdrawal Warnings

11.2.1 Withdrawal Warnings relating to defective medicinal products will be notified to the various Hospital Groups' Pharmacy Departments.

11.2.2 Withdrawal warnings about defective products are given categories according to the seriousness of the defect:

A. Serious risk to life
B. Serious product defect
C. Minor product defect
D. For information only

11.2 Pharmacy Action on Receiving a Withdrawal Warning

11.2.1 When a Withdrawal Warning is received in the relevant Pharmacy, the Pharmacist in charge/deputy on duty will determine whether the product in question has entered the NAS supply chain and if so, the issue point(s) to which the product has been supplied and will notify Ambulance Control as appropriate.

11.3 Action on Receiving a Withdrawal Warning

11.3.1 Upon receipt of a Withdrawal Warning from the relevant Pharmacy, Ambulance Control will notify all stations within the Area of the notice by fax. EMTs/Paramedics/Advanced Paramedics will take the appropriate action as determined by the Withdrawal Warning for the identified medicine.

11.3.2 Managers will be notified through the local notification procedure.

11.3.3 The most senior person on duty is responsible for ensuring all staff understand what to do in the event of a warning being received.

12.0 IMPLEMENTATION PLAN

8.1 This Policy will be circulated electronically to all Managers, all Supervisors and Staff

8.2 This Policy will be given to each staff member (electronically where possible), and may also be placed in hardcopy in the Policy Manual in each Ambulance Station and Ambulance Control for ease of retrieval and reference

8.3 Each designated Supervisor/Manager who is responsible for updating the Policy and Procedures Manuals will return the Confirmation Form to Ambulance Headquarters.

13.0 REVISION AND AUDIT

9.1 The Medical Director has the responsibility for ensuring the maintenance, regular review and updating of this policy. Revisions, amendments or alterations to the policy can only be implemented following consultation with the Quality and Risk Directorate and Pharmacy Services.

9.2 This policy and procedure will be reviewed informally on an ongoing basis and formally when necessary following changes in procedures and/or legislation.

9.3 Any Area variations to this Policy must be agreed at a national level by the Director and Medical Director prior to adoption by the relevant NAS Area.

9.4 The NAS Education and Competency Assurance Team are responsible for carrying out an internal audit of this Policy.

14.1 REFERENCES

- PHECC Advanced Clinical Practice Guidelines, (Current Version) incorporating Medications Formulary (copy supplied to each Pharmacy Dept.)
- National Ambulance Equipment List
- Guidance to Nurses and Midwives on Medication Management – An Bord Altranais
- Legal Opinion by Dermot Scanlon and Co. - Advanced Directives and Consent Guidelines.

15.1 APPENDICES

- Appendix I - Policy – Acknowledgement Form
- Appendix II - SI 512 of 2008 Seventh Schedule
- Appendix III - SI 512 of 2008 Seventh Schedule Part 21
- Appendix IV – SI 512 of 2008 Seventh Schedule Part 3
- Appendix V – Glossary of Terms Relating to Medicines Management
- Appendix VI – Useful contact addresses
- Appendix VII - Advanced Paramedic Drugs – Vehicle Bag Stock Control
- Appendix VIII – Paramedic Drugs – Vehicle Bag Stock Control
- Appendix IX - PHECC Medications Formulary

APPENDIX II

Medicinal products that may be supplied to pre-hospital emergency care providers for use by Advanced Paramedics (following successful completion of required training)

Medicinal Product	Route of Administration	Conditions of Administration	Authority to Administer
COLUMN 1	COLUMN 2	COLUMN 3	COLUMN 4
Adenosine Solution for Injection	Intravenous	Adults: Supraventricular tachycardias (SVT)	According to CPG or on registered medical practitioner's instructions
Amiodarone injection	Intravenous Intraosseous	Adults and children: Cardiac arrest	According to CPG or on registered medical practitioner's instructions
Aspirin (Various oral dosage forms)	Oral	Adults: Cardiac Chest Pain	According to CPG or on registered medical practitioner's instructions
Atropine injection	Intravenous Endotracheal Intraosseous	Adults and Children: Cardiac arrest Bradycardia Poisoning	According to CPG or on registered medical practitioner's instructions
Benzylpenicillin injection	Intravenous Intraosseous Intramuscular	Adults and children: Suspected or confirmed meningococcal sepsis	According to CPG or on registered medical practitioner's instructions
Cefotaxime Powder for Injection	Intravenous Intramuscular	Adults and children: Suspected or confirmed meningococcal sepsis	According to CPG or on registered medical practitioner's instructions
Ceftriaxone Powder for Injection	Intravenous Intramuscular	Adults and children: Suspected or confirmed meningococcal sepsis	According to CPG or on registered medical practitioner's instructions
Clopidogrel	Oral	Adults: Myocardial Infarction.	According to CPG or on registered medical practitioner's instructions

Cyclizine Injection	Intravenous	Adults and children: To prevent or treat opiate induced nausea and vomiting	According to CPG or on registered medical practitioner's instructions
Dextrose 5% Solution for Injection	Intravenous	Adults and Children: Dilutant for medications	According to CPG or on registered medical practitioners
Dextrose 10% Solution for infusion	Intravenous	Adults and children: Hypoglycaemia Dilutant for medications	According to CPG or on registered medical practitioner's instructions
Diazepam injection	Intravenous Intramuscular	Adults and children: Seizures Sedation	According to CPG or on registered medical practitioner's instructions
Diazepam rectal solution	Per Rectum	Adults and children: Seizures.	According to CPG or on registered medical practitioner's instructions
Enoxaparin Sodium Solution for Injection	Intravenous Subcutaneous	Adults: ST Elevation Myocardial Infarction (STEMI)	According to CPG or on registered medical practitioner's instructions
Epinephrine (Adrenaline) 1mg/1ml (1:1 000) – Injection	Intramuscular	Adults and children: Anaphylaxis Bronchospasm	According to CPG or on registered medical practitioner's instructions
Epinephrine (Adrenaline) 1mg/10ml (1:10 000) -	Intravenous Endotracheal Intraosseous	Adults and children: Cardiac arrest Bradycardia Anaphylaxis	According to CPG or on registered medical practitioner's instructions
Ergometrine Injection 500mcg/ml	Intravenous Intramuscular	Adults: Post partum haemorrhage	According to CPG or on registered medical practitioner's instructions
Furosemide Injection	Intravenous Intramuscular	Adults: Pulmonary Oedema	According to CPG or on registered medical practitioner's instructions
Glucagon for injection	Intramuscular Subcutaneous	Adults and children: Hypoglycaemia	According to CPG or on registered medical practitioner's instructions

Glyceryl Trinitrate Aerosol	Sublingual	Adults: Cardiac chest pain Congestive heart failure	According to CPG or on registered medical practitioner's instructions
Haloperidol Injection 5mg/ml	Intravenous Intramuscular	Adults: Sedation	According to CPG or on registered medical practitioner's instructions
Hartmann's Solution for infusion	Intravenous Intraosseous	Adults and children: Hypovolaemic shock Anaphylaxis Decompression illness, Burns Cardiac arrest Bradycardia Dilutant for medications	According to CPG or on registered medical practitioner's instructions
Hydrocortisone Powder for Solution for Injection	Intravenous Intramuscular	Adults and Children: Bronchospasm	According to CPG or on registered medical practitioner's instructions
Ipratropium Bromide Nebuliser Solution	Inhalation	Adults and Children: Bronchospasm in acute asthma.	According to CPG or on registered medical practitioner's instructions
Ibuprofen (various oral dosage forms)	Oral	Adults and Children: Pain	According to CPG or on registered medical practitioner's instructions
Lidocaine Hydrochloride Injection	Intravenous Endotracheal	Adults: Cardiac arrest	According to CPG or on registered medical practitioner's instructions
Lorazepam Injection	Intravenous Intramuscular	Adults and children: Seizures	According to CPG or on registered medical practitioner's instructions
Lorazepam Tablets	Oral	Adults and children: Sedation	According to CPG or on registered medical practitioner's instructions
Magnesium Sulphate Injection BP	Intravenous	Adults and Children: Cardiac arrest Bronchospasm	According to CPG or on registered medical practitioner's instructions

Meropenem Powder for Injection	Intravenous	Adults and Children: Suspected or confirmed meningococcal sepsis	According to CPG or on registered medical practitioner's instructions
Midazolam Solution for Injection	Intravenous Intramuscular Intranasal	Adults and Children: Seizures Sedation	According to CPG or on registered medical practitioner's instructions
Midazolam Solution (Buccal)	Buccal	Adults and Children: Seizures	According to CPG or on registered medical practitioner's instructions
Morphine Injection	Intravenous Intramuscular	Adults and Children: Moderate to severe pain	According to CPG or on registered medical practitioner's instructions
Morphine Oral Solution	Oral	Children: Pain	According to CPG or on registered medical practitioner's instructions
Naloxone for injection	Intravenous Intramuscular Subcutaneous Intranasal	Adults: Respiratory depression secondary to known or suspected narcotic overdose	According to CPG or on registered medical practitioner's instructions
Nifedipine Capsules	Oral	Adults: Inhibition of labour	According to CPG or on registered medical practitioner's instructions
Nitrous oxide - Oxygen mixture - medical gas	By Inhalation	Adults and children: Pain relief	According to CPG or on registered medical practitioner's instructions
Ondansetron Hydrochloride Injection	Intravenous	Adults and children: To prevent or treat opiate induced nausea and vomiting Anti emetic	According to CPG or on registered medical practitioner's instructions
Oxytocin Solution for Injection	Intravenous Intramuscular	Adults: Post partum haemorrhage	According to CPG or on registered medical practitioner's instructions

Paracetamol suppositories	Per Rectum	Children : Pyrexia	According to CPG or on registered medical practitioner's instructions
Paracetamol (Various oral forms)	Oral	Adults and Children: Pain Pyrexia	According to CPG or on registered medical practitioner's instructions
Salbutamol for nebulisation	Inhalation	Adults and children: Bronchospasm in anaphylaxis and acute asthma	According to CPG or on registered medical practitioner's instructions
Salbutamol inhaled aerosol	Inhalation	Adults and children: Bronchospasm in Anaphylaxis and acute asthma	According to CPG or on registered medical practitioner's instructions
Sodium Bicarbonate Injection BP	Intravenous	Adults and Children: Crush Injury Poisoning	According to CPG or on registered medical practitioner's instructions
Sodium Chloride 0.9% for infusion	Intravenous	Adults and Children: Hyperglycaemia Dehydration Cardiac arrest Crush injury hypothermia To keep vein open Cannula flush Dilutant for medications	According to CPG or on registered medical practitioner's instructions
Tenecteplase	Intravenous	Adults: ST Elevation myocardial infarction (STEMI)	According to CPG or on registered medical practitioner's instructions
Tetracaine Gel 4%	Topical	Adults and children: Anaesthesia prior to Venepuncture	According to CPG or on registered medical practitioner's instructions

APPENDIX III

Medicinal products that may be supplied to pre-hospital emergency care providers for use by Paramedics (following successful completion of required training)

Medicinal Product	Route of Administration	Conditions of Administration	Authority to Administer
Column 1	Column 2	Column 3	Column 4
Aspirin (various oral dosage forms)	Oral	Adults: Cardiac chest pain	According to CPG or on registered medical practitioner's instructions
Cyclizine injection	Intramuscular	Adults and children: To prevent or treat opiate induced nausea and vomiting	On registered medical practitioner's instructions
Dextrose 10% Solution for Infusion	Intravenous	Adults and Children: Hypoglycaemia	According to CPG or on registered medical practitioner's instructions
Diazepam rectal solution	Per Rectum	Adults and children: Seizures	On registered medical practitioner's instructions
Epinephrine (Adrenaline) 1mg/1ml (1:1 000)	Intramuscular	Adults and children: Anaphylaxis	According to CPG or on registered medical practitioner's instructions
Glucagon for injection	Intramuscular Subcutaneous	Adults and children: Hypoglycaemia	According to CPG or on registered medical practitioner's instructions
Glyceryl Trinitrate aerosol	Sublingual	Adults: Cardiac chest pain, Congestive heart failure	According to CPG or on registered medical practitioner's instructions
Hartmann's Solution for infusion	Intravenous	Adults and children: Hypovolaemic shock Anaphylaxis Decompression illness Burns Cardiac arrest Bradycardia Medication Dilutant	According to CPG or on registered medical practitioner's instructions

Ibuprofen (various oral dosage forms)	Oral	Adults and Children: Pain	According to CPG or on registered medical practitioner's instructions
Midazolam Solution for Injection	Intranasal	Adults and Children: Seizures	According to CPG or on registered medical practitioner's instructions
Midazolam Solution (Buccal)	Buccal	Adults and Children: Seizures	According to CPG or on registered medical practitioner's instructions
Morphine Injection	Intravenous Intramuscular	Adults and Children: Moderate to severe pain	On registered medical practitioner's instructions
Naloxone for injection	Intramuscular Subcutaneous Intranasal	Adults: Respiratory depression secondary to known or suspected narcotic overdose	According to CPG or on registered medical practitioner's instructions
Nitrous oxide - Oxygen mixture - medical gas	By Inhalation	Adults and children: Pain relief for medical, surgical or trauma conditions	According to CPG or on registered medical practitioner's instructions
Paracetamol suppositories	Per Rectum	Children: Pyrexia	On registered medical practitioner's instructions
Paracetamol (various oral forms)	Oral	Adults and Children: Pain Pyrexia	According to CPG or on registered medical practitioner's instructions
Salbutamol for Nebulisation	Inhalation	Adults and children: Bronchospasm in Anaphylaxis and acute asthma	According to CPG or on registered medical practitioner's instructions
Salbutamol inhaled aerosol	Inhalation	Adults and children: Bronchospasm in Anaphylaxis and acute asthma	According to CPG or on registered medical practitioner's instructions
Sodium Chloride 0.9% for infusion	Intravenous	Adults: Hyperglycaemia Adults and children: To keep vein open Cannula flush	On registered medical practitioner's instructions

Tetracaine Gel 4%	Topical	Adults and children: Anaesthesia prior to Venepuncture	On registered medical practitioner's instructions

APPENDIX IV

Medicinal products that may be supplied to pre-hospital emergency care providers for use by Emergency Medical Technicians (following successful completion of required training)

Medicinal Product	Route of Administration	Conditions of Administration	Authority to Administer
Column 1	Column 2	Column 3	Column 4
Aspirin (various oral dosage forms)	Oral	Adults: Cardiac chest pain	According to CPG or on registered medical practitioner's instructions
Cyclizine injection	Intramuscular	Adults and children: To prevent or treat opiate induced nausea and vomiting	On registered medical practitioner's instructions
Epinephrine (Adrenaline) Injection 1mg/1ml (1:1,000)	Intramuscular	Adults and children: Anaphylaxis	According to CPG or on registered medical practitioner's instructions
Glucagon for Injection	Intramuscular Subcutaneous	Adults and Children: Hypoglycaemia	According to CPG or on registered medical practitioner's instructions
Glyceryl trinitrate aerosol	Sublingual	Adults: Cardiac chest pain	According to CPG or on registered medical practitioner's instructions
Morphine Injection	Intravenous Intramuscular	Adults and Children: Moderate to severe pain	On registered medical practitioner's instructions
Naloxone for injection	Intramuscular Subcutaneous Intranasal	Adults: Respiratory depression secondary to known or suspected narcotic overdose	On registered medical practitioner's instructions
Nitrous oxide - Oxygen mixture - medical gas	By Inhalation	Adults and children: Pain relief	According to CPG or on registered medical practitioner's instructions

Paracetamol (various oral dosage forms)	Oral	Adults and Children: Pain Pyrexia	According to CPG or on registered medical practitioner's instructions
Salbutamol inhaled aerosol	Inhalation	Adults and children: Bronchospasm in Anaphylaxis and Acute asthma	According to CPG or on registered medical practitioner's instructions

APPENDIX V

Glossary of Terms Relating to Medicines Management

Accountability the fulfillment of a formal obligation to disclose to referent others the purposes, principles, procedures, relationships, results, income and expenditures for which one has authority (Lewis and Batey, 1982).

Adverse drug reaction is a response to a drug that is noxious and unintended and occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function (EEC Directive of 2001, [2001/83/EC]).

Administration to give an individual dose of a medicinal product to a patient/client via direct contact (e.g. orally, by injection) or by indirect contact (e.g. application of a medicated dressing) and ensuring the completion of this activity.

Competence the ability of the registered EMT/Paramedic/Advanced Paramedic to practice safely and effectively fulfilling her/his professional responsibility within her/his scope of practice

Decision-making the process of evaluating all the accessible information regarding a patient/client and arriving at a judgment or conclusion based on that information about the therapeutic plan for a patient/client

External use application to the skin, hair, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina, or anal canal when a local action is intended and extensive systemic absorption is unlikely to occur (shall not include transdermal delivery systems, throat sprays, throat pastilles, throat lozenges, throat tablets, nasal drops, nasal sprays, nasal inhalations, or teething products *(Medicinal Products (Prescription and Control of Supply) Regulations, 1996).*

Health prescription issued in connection with arrangements made under section 59 or section 67 of the *Health Act (No. 1 of 1970)* on a form supplied by or on behalf of a health board *(Medicinal Products (Prescription and Control of Supply) Regulations, 1996).*

Health service provider any setting where health care is provided, this includes residential facilities, schools and colleges.

Hospital includes a clinic, nursing home or similar institutions *(Medicinal Products [Prescription and Control of Supply] Regulations, 1996).*

Institution a hospital or a nursing home, which is wholly or mainly maintained by a public authority out of public funds or by a charity or by voluntary subscriptions (Article 8 (1) (a) of the *Misuse of Drugs Regulations, 1988).*

Medication error any preventable event that may cause or lead to inappropriate medication use or patient/client harm while the medication is in the control of the health care professional, patient/client encounter or consumer. These events may be associated with professional practice, health care products, procedures and systems. This includes prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration: education; monitoring and use (National Coordinating Council for Medication Error Reporting and Prevention, 1998). In the Irish health care context the activity of supply should be included in this definition.

Medication is the facilitation of safe and effective use of prescription

Medicinal product any substance or combination of substances presented for treating or preventing disease in human beings. Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product *(EEC directive of 2001 [2001/83/EC]).*

Parenteral administration by breach of the skin or mucous membrane *(Medicinal Products (Prescription and Control of Supply) Regulations, 1996).*

Pharmacist a person keeping open shop for the dispensing or compounding of medical preparations or for the sale of poisons under the *Pharmacy Acts, 1875-1977*. It also includes a registered pharmaceutical chemist, a registered dispensing chemist and druggist, and a registered druggist *(Misuse of Drugs Act, 1977)*.

Practice of medicine includes practice of surgery, midwifery and other disciplines of medicine and "medical practitioner" should be construed accordingly *(Medical Practitioners Act, 1978).*

Practitioner registered medical practitioner, registered dentist and registered veterinary surgeon *(Misuse of Drugs Regulations, 1988).*

Practice Guidelines written guidelines (developed by multidisciplinary collaboration amongst health care professionals) under which specific medicinal products are administered by registered EMT/Paramedic/Advanced Paramedic's to patients/clients in a defined clinical situation.

Register bound book and does not include any form of loose-leaf register or card index *(Misuse of Drugs Regulations, 1988).*

Supply distribute, sell, or offer a medicinal product to a patient or client under the directions of a registered medical practitioner as noted in an individual prescription or written instructions *(Medicinal Products (Prescription and Control of Supply) Regulations, 1996).*

APPENDIX VI

Useful contact addresses

Department of Health and Children
Hawkins House
Dublin 2
01 - 635 4000
www.doh.ie

Irish Medicines Board
The Earlsfort Centre
Earlsfort Terrace
Dublin 2
01 - 676 4971
www.imb.ie

The Pharmaceutical Society of Ireland
18 Shrewsbury Road
Dublin 4
01 - 283 7294
www.pharmaceuticalsociety.ie

National Medicines Information Centre
St. James Hospital
James's Street
Dublin 8
01 - 410 3000
www.stjames.ie/clinicalservices/nationalmedicinesinformationcentre

National Poisons Information Centre
Beaumont Hospital
Dublin 9
01 - 809 3000