National Ambulance Service (NAS)

Policy

Medicines Management

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Table of Contents:

1.0 POLICY STATEMENT

1.1 The Medicines Management Policy describes NAS measures for safe and effective use of medicines.

1.2 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 analyse the data necessary to do this. With an emphasis on a just culture approach, focusing on performance improvement, it is expected that medication error reporting will increase and provide the necessary data.

1.3 Appropriate risk control measures must be added to the Medicines Management Policy when new medication-related risks are identified. The Clinical Director must be informed of medication-related incidents to inform future decisions on safe medicine management.

1.4 The Medicines Management Policy must support clinical governance within the NAS. The Medicines Management Policy also covers the policy and procedures associated with the administration, requisitioning and storage of medicines.

1.5 NAS staff involved with medicines must undertake continuing professional development as required by the NAS Education and Competency Assurance Team (ECAT) and the Pre Hospital Emergency Care Council (PHECC), keeping up to date with changes in medicines management, and updating themselves on this policy.

1.6 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 and formulary as approved by the Pre Hospital Emergency Care Council.

1.7 NAS staff administering medicines to patients must satisfy the following:

- Hold a current PHECC registration at the relevant clinical level.
- Authorisation to practice at the relevant clinical level by the NAS.
- Completion of training in the relevant Clinical Practice Guidelines to the satisfaction of the NAS Education & Competency Assurance Team.
- When practicing on behalf of the NAS.
- In exceptional circumstances when directed by a registered medical practitioner.

2.0 PURPOSE

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

2.2 To describe a safe and secure system for the management of medicines in the NAS within a framework provided by legislation and HSE requirements.

2.3 To foster a just culture approach to the reporting of medication errors in an effort to continuously improve the quality and safety of patient care.

3.0 SCOPE

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

4.0 LEGISLATION/OTHER RELATED POLICIES

A. NASCG006- Management Requisition of Controlled Drugs
B. Medicinal Products (Prescription and Control of Supply) (amendment) Regulations 2008 (SI 512 of 2008)
C. Health Products Regulatory Authority, Group Authority Licence
D. Misuse of Drugs (Amend) Regulations 1993 (SI No. 342 of 1993)
E. Misuse of Drugs (Amend) Regulations 1993 (SI 338 of 1993)
F. Misuse of Drugs Regulations 1988 (SI no. 328 of 1988)
G. Misuse of Drugs (Safe Custody) Regulations 1982 (SI no 321 of 1982)
H. PHECC Clinical Practice Guidelines
I. PHECC Code of Professional Conduct and Ethics
J. National Ambulance Service Management of Medication Shortages - Guidance Document for Managers – Sept 2020
K. Medicinal Product Shortages – A framework for a multi – stakeholder approach to handling shortages of human medicinal products. Health Products Regulatory Authority.
L. Exempt Medicinal Products Health Products Regulatory Authority.
M. Clinical Indemnity Scheme, Use of Unauthorised (Exempt) and Authorised Medicines Prescribed for an Unauthorised Indication (Off-Label), January 2018.
N. HSE Incident Management Framework Guidance document 2020

5.0 GLOSSARY OF TERMS AND DEFINITIONS

5.1 Medicine

A product which contains a substance to treat or prevent disease in humans. Also known as a medicinal product or drug. (HPRA)

5.2 Exempt medicinal product

Unauthorised products which are supplied to the order of registered doctors or dentists for use by their individual patients under their direct personal supervision. (HPRA)

5.3 Controlled Drugs

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 (Amend) Regulations 1993 (SI No. 342 of 1993)
- Misuse of Drugs (Amend) Regulations 1993 (SI 338 of 1993)
- Misuse of Drugs Regulations 1988 (SI no. 328 of 1988)

And also any drugs which it is considered necessary to control for risk management reasons

5.4 Abbreviations

- Manager - Ambulance Officer grade
- Supervisor – (Paramedic/Advanced Paramedic Supervisor/ Clinical Supervisor)
- Practitioner –Healthcare professionals who are registered with the Pre-Hospital Emergency Care Council (PHECC) and authorised to practice at EMT / Paramedic /Advanced Paramedic level.
- NAS Advanced Paramedic – Practitioners registered with the Pre Hospital Emergency Care Council (PHECC) at the level of Advanced Paramedic (AP), and authorised to practice at the level of AP for the National Ambulance Service (NAS) by the NAS Clinical Director.
- NAS Paramedic – Practitioners registered with the Pre Hospital Emergency Care Council (PHECC) at the level of Paramedic and authorised to practice at the level of Paramedic for the National Ambulance Service (NAS) by the NAS Clinical Director.
- NAS Emergency Medical Technician - Practitioners registered with the Pre Hospital Emergency Care Council (PHECC) at the level of EMT, and authorised to practice at the level of EMT for the National Ambulance Service (NAS) by the NAS Clinical Director
- NAS Medical Practitioner – A Physician responding on behalf of the National Ambulance Service.
- ePCR – Electronic Patient Care Report
- CPG – Clinical Practice Guideline
- PHECC – Pre Hospital Emergency Care Council

- CD – Controlled Drug
- ADR – Adverse Drug Reaction

5.5 Designated person in charge

5.5.1 The designated person in charge refers to the designated supervisor or manager who is in charge of an ambulance station or number of ambulance stations.

5.5.2 If a supervisor or manager is not available the designated person in charge will be the Supervisor on duty in NEOC

5.6 Minors (Child/Children)

5.6.1 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.

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

5.6.3 As per PHECC Clinical Practice Guidelines paediatric patients are defined as <16yrs

5.6.4 For the purpose of this policy, a child is any person under theage of 16 years.

5.7 Medication error

5.7.1 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.(HPRA)

6.0 ROLES AND RESPONSIBILITIES

6.1 The NAS Director in his/her role has overall statutory responsibility and accountability for the safe and secure handling of controlled drugs.

6.2 The NAS Clinical Director in the role of chair of the Drugs and Therapeutics Committee has oversight of all NAS processes and procedures described in this document.

6.3 The NAS Corporate Governance Group has responsibility and accountability for ensuring the provision of the appropriate resources required to implement this policy.

6.4 The NAS Drugs and Therapeutics committee are responsible for the revision of this policy.

6.5 The Chief Ambulance Officer in his/her role is responsible for the implementation of this policy within his/her own area.

6.6 The Chief Ambulance Officer in his/her role is responsible for ensuring procedures are in place for safe and effective medicine management. This includes regular audit of the effectiveness of these procedures, this does not include clinical audit aspects outlined in section 6.7.

6.7 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 Clinical Directorate.

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 handling, administering medicines, as specified in this Policy.

6.9 It is the responsibility of the Chief Ambulance Officer or designates to ensure that each Practitioner is aware of and understands this Procedure.

6.10 It is the responsibility of each Practitioner to adhere to this Procedure.

7.0 PROCEDURES

7.1 Administration of medicines

7.1.1 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).

7.1.2 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.

7.1.3 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.

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

7.2 Principles for the administration of medicines

7.2.1 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.

7.2.2 Medicines must only be prepared immediately before administration.

7.2.3 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)

7.2.4 All calculations must be conducted in accordance with the Medication Formulary as contained in PHECC Clinical Practice Guidelines (CPG) and may take the form of utilisation of the approved field guide.

7.2.5 A record must be made contemporaneously after each administration on the Patient Care Report (PCR) including the dose, route and time of any administered medication.

7.2.6 Documenting administration of medications

The responsibility for recording the medication administered lays with the practitioner who is licenced and qualified to administer the medication. e.g Each medication must have the appropriate pin number associated with the medication administration

7.3 Concerns

7.3.1 Concerns in relation to administration of medication: Staff must check appropriateness of any medicine, including its contra-indications, in the Medication Formulary if any concern arises.

7.3.2 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.

7.3.3 Where concerns cannot be allayed, the administration should not proceed

7.4 Consent to treatment

7.4.1 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.

7.4.2 Further considerations apply for:

A. An unconscious patient requiring emergency intervention.
B. A patient who lacks the capacity to consent.
C. Minors, legal parent/guardian consent required (see Section5.7)
D. Life-threatening situations/protecting bodily integrity.
E. Patient incapable of providing expressed consent, e.g. sensory deficit or language barrier.

7.4.3 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 where the treatment is necessary to save the life or preserve the health of the patient in the absence of consent.

7.4.4 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.

7.5 Checking of medicines before administration

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

7.5.2 Where a solo responder is administering medications, extra care must be taken to minimise error.

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

7.5.4 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

7.6 Disposal of individual doses of unused or discarded medicines

7.6.1 No medicine should be removed from its container/packaging except for immediate administration.

7.6.2 Unused or discarded medicines must not be returned to the container but disposed of in an appropriate manner.

7.7 Errors in administration of medicines

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

- Omissions - any required / prescribed dose not administered other than in circumstances where professional judgement has been used.
- Incorrect dose administered
- Unauthorised medicine given - the administration to a patient of any medicine not indicated for the condition
- 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

7.8 Reporting of errors in administration of medicines

7.8.1 NASCG003- Management of Adverse Clinical Events, underpins the principles of just culture and strives to create a safety culture in which NAS clinical staff can self-report clinical / medication error without fear of punishment or disciplinary measures, as long as the practitioner is acting in good faith. HSE Incident Management Framework and associated NAS process must be followed to ensure appropriate tracking and tracing of any incident.

7.8.2 Such a safety culture allows NAS to learn from episodes of clinical adverse events and put measures in place to prevent these adverse events being repeated throughout the organisation.

7.8.3 NAS commits that if a staff member acting in good faith is responsible for an adverse clinical event or medication error and reports the error in a timely manner, the staff member will be dealt with in a sympathetic manner and will not undergo any disciplinary process or punitive measures.

7.8.4 Excluded from this principle are the following:

A. Criminal or deliberately malicious acts

B. Where an incident is deliberately concealed
C. Gross negligence or professional misconduct
D. The wrongful/unlawful consumption/administration of medicines/controlled substances by the employee making the error

7.8.5 If a staff member knowingly fails to report an adverse clinical event / error medication error or attempts to conceal an event/, commits a criminal or deliberately malicious act, or displays gross negligence or professional misconduct, the staff member will face disciplinary proceedings, to include Stage 4 of the Disciplinary Procedure of Dismissal or Action Short of Dismissal, and/or referral to the PHECC Registrar for consideration of Fitness to Practice proceedings.

7.8.6 Excluded from this is the situation whereby a staff member causes an adverse clinical event / medication error but is genuinely unaware that he/she has done so.

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

7.8.8 It is the expectation that any employee who believes a medication error has occurred will report the error. If the error is reported in a timely fashion the principles of just culture will be followed.

7.8.9

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 Medical/Nursing staff at the receiving hospital and the NAS designated person in charge.
C. The designated person in charge ensures that a National Incident Report Form (NIRF) is completed as soon as practicable by the person reporting the error in accordance with the Incident Management Framework and NAS procedures.
D. The designated person in charge forwards all relevant documentation to Education and Competency Assurance Team for audit by the Clinical Directorate within 5 working days

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

A. 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 Clinical Directorate.
B. Discuss the benefits of informing the patient of the error with the Clinical Directorate
C. Where the error is reported, it is the responsibility of the Clinical Directorate to decide on what course of action to take.

D. The Education and Competency Assurance Team must ensure that a National Incident Report Form (NIRF) is completed as soon as practicable in accordance with the Incident Management Framework and NAS procedures or no later than 5 working days.

7.10 Reporting of Adverse Drug Reaction

7.10.1 An Adverse Drug Reaction is deemed to have occurred if one or more of the following circumstances apply:

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

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

C. Discuss the event with the patient and seek their consent to continue treatment
D. Immediately report the adverse event to the Medical/Nursing staff at the receiving hospital and the designated person in charge.
E. The designated person in charge ensures that a National Incident Report Form (NIRF) is completed as soon as practicable by the person reporting the adverse event in accordance with the Incident Management Framework and National Ambulance Service Policy Management of Adverse Clinical Events
F. 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.
G. The designated person in charge will, after discussion with the Clinical Director notify the HPRA and relevant Pharmacy where applicable.

7.11 Self- administration of medicines by patients

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

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

7.11.3 The only medicines offered by the NAS for self-administration by the patient are Methoxyflurane and Entonox for the relief of pain. Self- administration enables the patient to maintain their own level of analgesia.

7.12 Medicines for staff

7.12.1 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.

7.13 Retention of records of administration

7.13.1 All records of administration must be retained as per Policy – NASP023 - Records Management or localised Records Management Policy.

- All records of an adult – eight years after last treatment or death.
- Children and young people – until the patient's 25th birthday, or 26th if the young person was 17 at the conclusion of treatment, or eight years after the patient's death.

8.0 SUPPLY AND RETURN OF MEDICINES

8.1 Responsibility

8.1.1 The Chief Ambulance (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).

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

8.2 Obtaining Medicinal Products

8.2.1 All medicines covered by this policy, unless the patients' own, must be obtained through the approved pharmacy or medicine wholesaler.

8.3 Use of unauthorised or unlicensed medicinal products

- The management of medication shortages and unlicensed medications is outlined in the National Ambulance Service Management of Medication Shortages - Guidance Document for Managers – Sept 2020

- Medicinal Product Shortages – A framework for a multi – stakeholder approach to handling shortages of human medicinal products. Health Products Regulatory Authority.

- Exempt Medicinal Products Health Products Regulatory Authority.

- Clinical Indemnity Scheme, Use of Unauthorised (Exempt) and Authorised Medicines Prescribed for an Unauthorised Indication (Off-Label), January 2018.

8.4 The EMT/Paramedic/Advanced Paramedic who administers the unlicensed medication should be aware of the indications for the drugs intended use (as directed by the Medical Advisory Committee of 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. The NAS staff member must be in uniform and have identification to hand.

8.7.2 Following collection at the relevant Pharmacy, the medicines should be checked to ensure that they correspond to the medicines requisitioned. Medicines will be secured and stored appropriately and the quantities received entered into the stock control sheet by the appropriate person.

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.

9.0 STORAGE OF MEDICINAL PRODUCTS

9.1 Specific Responsibility

9.1.1 All medicines shall be stored under the control of the relevant Chief Ambulance Officer (with delegation as appropriate)

9.1.2 All medicines shall be stored in line with manufacturer's recommendations.

9.1.3 The individual EMT/Paramedic/Advanced Paramedic / Medical Practitioner must safeguard all medications for the duration of the shift.

9.1.4 The designated person in charge must safeguard all medicines issued to any Ambulance Station.

9.1.5 A designated Manager will inspect the requisition and storage process at each Station on a quarterly basis and maintain a log of such inspections.

9.2 Drug Bags/Cupboards/Security Tagging

9.2.1 Medicines issued must be stored in a secured "drugs bag" or other secure receptacle. Each "drug bag" should have a unique identifying number.

9.2.2 Fluids should be stored in a designated "fluids bag".

9.2.3 All "drugs bags" must be security tagged at all times.

- Where the contents are unused, then the tag should be BLUE.
- Where the contents are used but do not exceed minimum stock levels, then the tag should be GREEN.
- Where the contents are used and exceed minimum stock levels then the tag should be RED.

9.2.4 The designated person in charge must make arrangements for a supply of security tags to be available.

9.2.5 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

9.3 Drugs Bags Contents

9.3.1 Clearly identifiable bags will be issued specifically for use by Paramedics and Advanced

Paramedics.

9.4 Security on vehicles

9.4.1 Drugs bags should only remain on vehicles during operational periods of duty.

A. In circumstances where drugs bags/controlled drugs are stored in a response vehicle by an officer / practitioner / medical practitioner responding on behalf of the NAS it is the responsibility of that officer / practitioner / medical practitioner to ensure medications are all in date and/or returned in line with local drug bag rotation procedures
B. In circumstances where drugs bags/controlled drugs are stored in a response vehicle by an officer / practitioner / medical practitioner responding on behalf of the NAS it is the responsibility of that officer / practitioner / medical practitioner to ensure medications are securely stored in the vehicle during all on-call periods

9.4.2 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.

9.4.3 All drug bags must be signed in and out on a station medicines record book.

9.5 Stock replenishment

9.5.1 Where the contents have been used, then the drugs bag should be tagged RED/GREEN and returned to the Station for replenishment at the end of the shift or earliest opportunity.

9.5.2 The designated person in charge must make arrangements fora supply of security tags to be available.

9.6 Record of checks

9.6.1 The Stock Control sheet for each drugs bag must be updated and signed every time medicinal products are removed or added to the contents of the drugs bag.

9.6.2 This is the responsibility of the staff member concerned.

9.7 Reporting of losses

9.7.1 The loss or suspected loss of any medicinal product must be reported using the Incident Management Framework to a designated person in charge.

9.7.2 A senior manager will determine the appropriate investigation.

9.7.3 The designated person in charge ensures that all appropriate documentation is completed by the person reporting the loss as soon as practicable in accordance with

the Incident Management Framework.

9.7.4 The designated person in charge informs the relevant manager of the incident as soon as practicable.

9.7.5 Where theft is suspected, the relevant manager will notify a senior Manager and An Garda Síochána.

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 in accordance with the Incident Management Framework. 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. In these circumstances the incident must be reported through the Incident Management Framework and to the Area Headquarters and the Quality and Risk Directorate.

10.4 The designated person in charge will notify the relevant Pharmacy or wholesaler and the Health Products Regulatory Authority (HPRA) where applicable.

11.0 MEDICINAL PRODUCT WITHDRAWAL WARNINGS

11.1 Withdrawal Warnings

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

11.1.2 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/Wholesaler Action on Receiving a Withdrawal Warning*

11.2.1 When a withdrawal warning is received in the relevant pharmacy or wholesaler, 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 the Chief Ambulance Officer (with delegation as appropriate)

11.3 Action on receiving a withdrawal / warning

11.3.1 Upon receipt of a withdrawal warning from the relevant Pharmacy/wholesaler, The Chief Ambulance Officer (with delegation as appropriate) will notify all stations. 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

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

12.2 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 NEOC for ease of retrieval and reference

12.3 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

13.1 The Drugs and Therapeutics Committee has the responsibility for ensuring the maintenance, regular review and updating of this policy.

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

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

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

14.1 REFERENCE

- NASCG006- Management Requisition of Controlled Drugs
- Medicinal Products (Prescription and Control of Supply) (amendment) Regulations 2008 (SI 512 of 2008)
- Health Products Regulatory Authority, Group Authority Licence
- Misuse of Drugs (Amend) Regulations 1993 (SI No. 342 of 1993)
- Misuse of Drugs (Amend) Regulations 1993 (SI 338 of 1993)
- Misuse of Drugs Regulations 1988 (SI no. 328 of 1988)
- Misuse of Drugs (Safe Custody) Regulations 1982 (SI no 321 of 1982)
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- HSE Incident Management Framework Guidance document 2020

15.1 APPENDICES

PHECC Medication Formulary

MEDICINAL PRODUCTS (PRESCRIPTION AND CONTROL OF SUPPLY) (AMENDMENT) (NO. 2) REGULATIONS 2020