

THE SCOTTISH OFFICE

COMMON SERVICES AGENCY NHS:

MEL(1994)20

16 MAR 1994

ACTION TAKEN St. Andrew's House Edinburgh EH1 3DG

National Health Service in Scotlane.

Management Executive

PARENTERAL ADMINISTRATION OF PRESCRIPTION ONLY MEDICINES (POMs) BY EXTENDED TRAINED AMBULANCE PARAMEDICS/GLUCAGON BY QUALIFIED AMBULANCE STAFF

Summary

Since 18 December 1992 extended trained NHS ambulance paramedics have been able to administer parenterally, on their own initiative, certain Prescription Only Medicines (POMs) for the immediate and necessary treatment of sick and injured persons. This is in addition to their existing powers to administer drugs to patients (see paragraph 3 of Annex A).

The attached document provides full background information and guidance on key areas including:-

- * the Prescription Only Medicines concerned (Annexes B, C, D and F);
- * legal changes;
- * liability;
- * record-keeping and security;
- * Misuse of Drugs Regulations (Annex E).

Action

Chief Area Pharmaceutical Officers (CAPOs) should ensure that:

- * the existing arrangements for the supply of POMs to the Scottish Ambulance Service are reviewed in consultation with the Consultant Medical Director of the Scottish Ambulance Service;
- * guidance on storage, security etc, is provided to ambulance personnel.

General Managers, Chief Executive and CAPOs should note that the Scottish Ambulance Service is maintaining:

* an accurate list of all approved ambulance stations where paramedics may be serving or employed. This is required for compliance with arrangements for Controlled Drugs made under the Misuse of Drugs Regulations.

Addressees:

6 March 1994

For Action:

General Manager Common Services Agency, Chief Area Pharmaceutical Officers

For Information:

General Managers, Health Boards Chief Executives, Chief Executives Designate, NHS Trusts General Manager State Hospital, General Manager Health Education Board for Scotland

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Background

The Medicines Act 1968 controls the supply and administration of medicines. The Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Order 1983(SI 1983 No 1212), made under that Act was amended by the Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Amendment (No 2) Order 1992 (SI 1992 No 2937) with effect from 18 December 1992).

A second Statutory Instrument, The Medicines (Sale or Supply) (Miscellaneous Provisions) Amendment Regulations 1992 (SI 1992 No 2938), also effective on 18 December 1992, adds NHS trusts, established in Great Britain, to the classes of persons who may be sold prescription only medicines or pharmacy medicines by way of wholesale dealing.

These amendments complete a legislative framework by which medicines may be lawfully obtained by those authorities and NHS trusts employing ambulance services and may be administered by paramedics.

Yours sincerely

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GEORGE TUCKER

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ANNEX A

PARENTERAL ADMINISTRATION OF PRESCRIPTION ONLY MEDICINES (POMs) BY EXTENDED TRAINED AMBULANCE PARAMEDICS/GLUCAGON BY QUALIFIED AMBULANCE STAFF

Introduction

1. This Annex sets out the arrangements concerning the parenteral administration of certain Prescription Only Medicines (POMs) by extended trained ambulance paramedics. Information is also provided on the relevant requirements of the Misuse of Drugs Regulations.

2. Parenteral Administration

The POM Order defines parenteral administration as "administration by breach of the skin or mucous membrane".

This would usually mean intramuscular or intravenous administration.

3. Paramedic

The new POM Amendment Order refers to 'persons who hold a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State'.

Currently the accepted certificate of proficiency is the NHS Training Directorate (NHSTD) Certificate in Extended Ambulance Aid.

4. Only a brief summary of the law is provided. In all cases reference should be made to the relevant instruments and to your own legal adviser.

Background

- 5. Until 18 December 1992 the effect of the Medicines Act 1968 and the Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Order 1983 (SI 1983 No 1212), made under that Act (referred to here as the POM Order) was that ambulance personnel were able to administer:
- * all POMs which are not used parenterally;
- * POMs for parenteral use which are specified in Article 5 of the POM Order (see paragraph 6 below and Annex D); and
- * any POM in accordance with the directions of an appropriate practitioner (ie a doctor or dentist).
- 6. To reflect developments in the quality and level of ambulance training, the principal POM Order has been amended. The changes came into force on 18 December 1992. The relevant amendment in the Medicines (Products Other Than Veterinary Drugs) (Prescription Only) Amendment (No 2) Order 1992 (SI 1992 No 2937) (referred to here as the POM Amendment Order) enables a person who holds a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State, to administer parenterally, on their own initiative, certain prescription only medicines for the immediate and necessary

treatment for sick and injured persons. Currently the accepted certificate of proficiency is the NHS Training Directorate (NHSTD) Certificate in Extended Ambulance Aid.

- 7. In certain cases, ambulance and/or paramedical assistance will arrive at the scene of an incident or sudden illness before a doctor. The new powers thus offer considerable potential benefits to the public. It remains for the body employing an ambulance paramedic to decide whether the new powers should be made available and, if so, whether any special safeguards should apply. The Scottish Ambulance Service is establishing these protocols and further information may be obtained from the Service's Consultant Medical Director.
- 8. In addition to the new powers referred to above, the amending Order also adds Glucagon Injection (for the treatment of diabetics) to the list of those medicines specified in an emergency to save life. In particular, this will allow the qualified ambulance personnel who are not paramedic trained to administer Glucagon in a hypoglycaemic emergency.

List of Medicines

- 9. A list of medicines appropriate for use by extended trained ambulance personnel was prepared by the Joint Colleges and Ambulance Liaison Committee (JCALC) in England and Wales and agreed with the Professional Advisory Group to the Scottish Ambulance Service and the Northern Ireland Ambulance Advisory Panel. JCALC, a Department of Health funded body, includes representatives of all the Royal Colleges and Ambulance Services management together with observers from the Department of Health, the Scottish Ambulance Service and the NHS Training Directorate.
- 10. The list of drugs as recommended by JCALC is set out in Annex B. This includes the medicines for parenteral administration which necessitated specific legal authority through amendment of the POM Order, and other medicines which ambulance personnel are already empowered to administer under the Medicines Act. A list, based on the descriptions of the POMs actually specified in the POM Amendment Order, is contained in Annex C. These medicines were approved by Health Ministers on the recommendation of the Medicines Commission and following wide consultation of interested parties and representative organisations. For the present the Professional Advisory Group to the Scottish Ambulance Service has decided to issue only those drugs listed at Annex F and to keep others under review.
- 11. The new arrangements are in addition to the existing powers to administer POMs parenterally under the directions of a doctor, in particular the arrangements under which paramedics have administered certain POMs in accordance with procedures agreed under NHSTD and local Paramedic Steering Committee protocols.

Amendments to the Law

- 12. The POM Amendment Order, was laid before Parliament on 26 November 1992 and came into force on 18 December 1992.
- 13. The amended Order does not limit paramedics' use of the specified POMs to duties carried out in the course of their employment. The

Scottish Ambulance Service has indicated to its staff the circumstances in which when off-duty, an ambulance paramedic may place him/herself on duty to exercise his/her skills, including the administration of drugs, to assist a patient in an emergency in accordance with agreed procedures.

14. A second Statutory Instrument, The Medicines (Sale or Supply) (Miscellaneous Provisions) Amendment Regulations 1992 (SI 1992 No 2938), also effective on 18 December 1992, adds NHS trusts, established in Great Britain, to the classes of persons who may be sold prescription only medicines or pharmacy medicines by way of wholesale dealing.

Liability

- 15. If a paramedic is found negligent in either treating or failing to appropriately treat a patient whilst on duty, the employing health authority or NHS trust may be held vicariously liable.
- 16. Paramedics' terms of employment should make clear whether or not their employing health authority or NHS trust accepts responsibility for paramedics' acts or omissions outside working hours. Staff should be advised, in writing, whether or not they will be indemnified by their employer in respect of any claims arising from their negligent acts or omissions whilst undertaking such work.
- 17. In cases where the employer has indicated that they will not accept responsibility, staff should be advised, in writing, to obtain their own insurance cover or ensure that they are covered by the insurance of those using their services. It is recognised that this may prove difficult to establish where those services are provided in an emergency situation.
- 18. Authorities or NHS trusts employing paramedics should establish clear guidelines concerning the practice of paramedic skills outside working hours (paragraph 11 refers). This is particularly important where paramedics are in possession of or have access to POMs when formally regarded as "off-duty". When formulating local policy, authorities may wish to consider the points made earlier.
- 19. It remains the responsibility of any voluntary aid society, for whom off-duty paramedics may undertake work, to ensure that adequate insurance cover is arranged.

Training

- 20. NHSTD ambulance paramedics are trained in advanced resuscitation techniques to provide sophisticated immediate care to patients suffering from accidents or sudden illness. These techniques include intubation, infusion and defibrillation as well as the administration of POMs and certain other drugs.
- 21. The National Health Service Training Directorate is the current body responsible for the syllabus and training programme for paramedics in the UK leading to the NHSTD Certificate in Extended Ambulance Aid. The programme includes hospital based working under the supervision of Consultants, and is followed by comprehensive, post proficiency training. The Training Directorate is also responsible for the accreditation of regional ambulance training schools.

Paediatric Cases

22. Guidelines on the use of POMs in paediatric cases are already included in the existing ambulance paramedic training package (see Section 8, unit 2 of NHSTD Ambulance Service Paramedic Training Manual).

Record-Keeping

23. Existing procedures for the recording and monitoring of the supply, storage and use of POMs are considered to be adequate at present (see section 8, unit 3 of NHSTD Ambulance Service Paramedic Training Manual). Health authorities, NHS trusts and ambulance services are, however, advised to review their procedures regularly.

Misuse of Drugs Regulations - Controlled Drugs

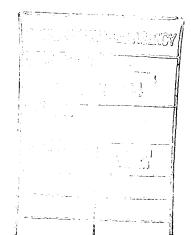
- 24. One of the POMs listed is the controlled drug diazepam. The Home Office have authorised a 'group authority' under the Misuse of Drugs Regulations 1985, enabling NHS paramedics to supply diazepam by way of administration for the immediate and necessary treatment of sick or injured persons. A copy of the authority is at Annex E.
- 25. The 'group authority' refers specifically to NHS paramedics serving or employed at 'approved ambulance stations'. The Scottish Ambulance Service will ensure that a list of approved ambulance stations is maintained for the purpose of this requirement.
- 26. There are 2 conditions attached to the 'group authority'. It is important that these are drawn to the attention of all ambulance paramedics and others who are affected. The conditions are that:
- * any drug in the possession of any person by virtue of the authority shall be produced by that person for inspection when so required by a constable, an inspector of the Home Office Drugs Branch or any person authorised in writing by the Secretary of State for the purpose of regulation 25(1) of the Misuse of Drugs Regulations 1985; and
- * if any drug in the possession of any person by virtue of this authority is stolen or otherwise lost, the loss shall be reported by that person as soon as possible to a constable, and to the Secretary of State by giving notice in writing to that effect to:

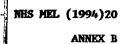
The Chief Inspector Drugs Branch Home Office Queen Anne's Gate LONDON SW1H 9AT

27. The 'group authority' applies to ambulance paramedics serving or employed at an approved ambulance station within the NHS for the purposes of that service or employment. It does not therefore apply to a person employed by an independent ambulance service or a person acting in a voluntary capacity, whether or not on behalf of a voluntary aid society.

Controlled Drugs - Security

- 28. The storage of drugs, controlled or otherwise, must be the subject of a clear written policy. This policy must include a specific reporting procedure for the loss or theft of controlled drugs and must take account of the recommendations of the Duthie Report and the requirements of all relevant Home Office regulations including those referred to in paragraphs 24-26 above.
- 29. Authorities may wish to refer to guidance given in the Ambulance Service Paramedic Training Manual. Advice should also be taken from the local Ambulance Paramedic Steering Committee's pharmacist adviser.





PRESCRIPTION ONLY MEDICINES FOR USE BY AMBULANCE PARAMEDICS - JCALC

Drug	Indications	Route	Individual Dose	Maximm Dose
Adrenaline	Cardiac Arrest	IV or ET bolus	10ml of 1:10,000 IV (10ml of 100 micrograms/ml) IV 20ml of 1:10,000 ET (20ml of 100 micrograms/ml) ET Repeat at 5 minute intervals up to the maximum dose	40ml of 1:10,000 IV (40ml of 100 micrograms/ml) IV 80ml of 1:10,000 ET (80ml of 100 micrograms/ml) E
Adrenaline	Anaphylactic shock	IV	2ml of 1:10,000 (2ml of 100 micrograms/ml)	4m1 of 1:10,000 (4m1 of 100 micrograms/m1)
	child	SC or	Under age 7 - 0.5ml of 1:1,000 (0.5ml of 1mg/ml)	0.5ml of 1:1,000 (0.5ml of 1mg/ml)
	adult	IM	lml of 1:1,000 (lml of lmg/ml)	<pre>lm1 of 1:1,000 (lml of lmg/m1)</pre>
Atropine	Cardiac arrest (Asystole)	IV or ET bolus	2mg IV 4mg ET	2mg IV 4mg ET
Atropine	Bradycardia - heart rate less than 50 beats per minute, with clinical evidence of shock and a BP of 90mmHg or less		250mcg over 10 seconds. After 2 minutes, if the response is inadequate, give another 250mcg dose over 10 seconds. If the response remains inadequate give 500mcg over 10 seconds.	1mg
Sodium Bicarbonate	Prolonged cardiac arrest (15 minutes or longer)	IV bolus	50mmo1 (50ml of 8.4%)	50mmo1 (50ml of 8.4%)
Lignocaine Yydrochloride	Ventricular Tachycardia Rates above 140bpm	IV bolus	100mg IV Repeat after 15 minutes	200mg
Lignocaine Hydrochloride	Ventricular fibrillation pulseless ventricular tachycardia refractory to 4DC shocks and ADRENALINE	IV or ET bolus	100mg IV 200mg ET	200mg 400mg
Lignocaine Hydrochloride	Following successful defibrillation	IV or ET	100mg given IV or 200mg given ET	100mg given IV or 200mg given ET
Nalbuphine Hydrochloride (Nubain)	Pain not controlled by ENTONOX	IV	10mg over 5 minutes, repeated after 10 minutes if pain is not controlled	20mg
Diazepam - As Diazemuls	Adult Prolonged convulsions,	IV	10mg repeated once if necessary	20mg
for IV administration	Status epilepticus Eclampsia	Rectal tube	10mg repeated once if necessary	20mg
only, or by rectal tube (Adult dose is the same for bot	Child h)	Rectal tube	5mg repeated once if necessary	10mg

Drug	Indications	Route	Individual Dose	Maximum Dose
Dextrose 50%	Acute or suspected Hypoglycaemia or in unconscious diabetic patients	IV	50ml of 50%	50ml of 50%
0.9% Normal Saline	Hypovolaemia in Adults	IV	1 litre	2 litres
Haemacce1	Hypovolaemia in Adults	IV	2 x 500mls	2 litres - only to be exceeded on the direct advice of a doctor
Gelofusine	Hypovolaemia in Adults	IV	2 x 500mls	2 litres - only to be exceeded on the direct advice of a doctor
7% Dextrose	To keep a vein open	IV		500mls
Ergometrine	Emergency control of post partum haemorrhage and/or severe haemorrhage due to abortion	IA	250mcg	250mcg
Heplok/Hepsal	Flush cannula through	IV	lml	5m1
Naloxone	Opiate overdose	IV	400mcg repeat after 3 minutes if the response is unsatisfactory	800mcg



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ANNEX C

LIST OF POMS FOR PARENTERAL USE BY EXTENDED TRAINED AMBULANCE PARAMEDICS: SCHEDULE TO SI 1992 No 2937

Adrenaline Injection, 1 in 1,000 (1mg/ml) & 1 in 10,000 (100 micrograms/ml)

Diazemuls (PL 10183/0001)
For use in adults only

Ergometrine Injection
Use already covered in ambulance paramedics training package

Gelofusine (PL 00183/5025R)

Glucose Intravenous Infusion

Heparin Sodium in Sodium Chloride Injection For cannula flushing

Lignocaine Injection

Nalbuphine Hydrochloride Injection

Naloxone Hydrochloride Injection

Polygeline Intravenous Infusion (Haemaccel)

Sodium Bicarbonate Intravenous Infusion Given as IV bolus - not drip administration

Sodium Chloride Intravenous Infusion

ANNEX D

THE MEDICINES (PRODUCTS OTHER THAN VETERINARY DRUGS) (PRESCRIPTION ONLY) ORDER 1983 SI 9183 No 1212

Article 5 of this Order includes the following list of medical products for parenteral administration:

Adrenaline Injection BP

Atropine Sulphate Injection

Chlorpheniramine Injection

Cobalt Edetate Injection

Dextrose Injection Strong B.P.C

Diphenhydramine Injection

Glucagon Injection (POM Order 1992/2937)

Hydrocortisone Injection

Mepyramine Injection

Promethazine Hydrochloride Injection

Snake Venom Antiserum

Sodium Nitrite Injection

Sodium Thiosulphate Injection

Sterile Pralidoxime

ANNEX E

MISUSE OF DRUGS REGULATIONS, 1985: GROUP AUTHORITY TO NATIONAL HEALTH SERVICE AMBULANCE PARAMEDICS

In pursuance of Regulations 9(4) and 10(4) (c) of the Misuse of Drugs Regulations, 1985 the Secretary of State hereby authorises:

- 1. Ambulance paramedics, serving or employed at any approved ambulance station, to supply or offer to supply diazepam to any person who may lawfully have this drug in his possession; and
- 2. Ambulance paramedics, serving or employed at any approved ambulance station to possess diazepam

for the purposes of that service or employment, subject to and in accordance with the following terms:

- a. paragraph 1 does not extend to the supply of any drug, or an offer to supply it, otherwise than as required for the purpose of its administration for the immediate necessary treatment of sick or injured persons
- b. paragraph 2 does not extend to the possession of any drug, otherwise than as required for the purpose of its administration for the immediate necessary treatment of sick or injured persons,

and subject to the following conditions:

- i. any drug in the possession of any person by virtue of this authority shall be produced by that person for inspection when so required by a constable, an inspector of the Home Office Drugs Branch or any person authorised in writing by the Secretary of State for the purpose of regulation 25(1) of those Regulations; and
- ii. if any drug in the possession of any person by virtue of this authority is stolen or otherwise lost, the loss shall be reported by that person as soon as possible to a constable, and to the Secretary of State by giving notice in writing to that effect to the Chief Inspector, Drugs Branch, Home Office, Queen Anne's Gate, London SW1H 9AT.

In this authority:

i. "Ambulance paramedic" means any person who holds a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State for Health.

ii. "Approved ambulance station" means any ambulance station approved for this purpose in England and Wales by an authority or trust constituted for the purposes of the National Health Service and in Scotland by the Common Services Agency of the Scottish National Health Service.

An Assistant Under-Secretary of State

Home Office Queen Anne's Gate London SW1H 9AT

6 January 1993

Notes

1. Under Section 30 of the Misuse of Drugs Act 1971, the Secretary of State may modify or revoke this authority at any time.

ANNEX F

MEDICINES FOR USE IN THE SCOTTISH AMBULANCE SERVICE

Qualified Accident & Emergency Staff

Glucagon - 1mg Injection Kit

Salbutamol - 2.5mg nebules

Paramedics

Glucagon - 1mg Injection Kit

Salbutamol - 2.5mg nebules

Adrenaline - 10ml minijet (1:10,000)

1ml minijet (1: 1,000)

Lignocaine Hydrochloride - 100mg in 5ml minijet

0.9% Saline - 2ml ampoule

Atropine Sulphate - 1mg in 10ml minijet

Diazepam (Rectal Solution) - 10mg

Glyceryl Trinitrate

"Suscard Buccal" - 2mg Tablets

Aspirin - 300mg (as "Solmin")

Naloxone Hydrochloride - 800 micrograms/2ml minijet

Gelofusine - 500ml)

Polygeline "Haemacel" - 500ml)

Polygeline "Haemacel" - 500ml) Issued locally in accordance) with the wishes of the Sodium Chloride infusion - 500ml) Local Paramedic Steering

5% Dextrose - 500ml) Committee: but to National Guidelines

Ringer's Lactate - 500ml

List as approved by Scottish Ambulance Service Professional Advisory Group 1993.