Health Service Circular

NHS Executive

Series Number: **HSC 2000/026**
Issue Date: **09 August 2000**
Review Date: **09 August 2003**
Category: **General Health Service**
Status: **Action**
sets out a specific action on the part of the recipient with a deadline where appropriate

PATIENT GROUP DIRECTIONS [ENGLAND ONLY]

For action by:
Health Authorities (England) - Chief Executive
NHS Trusts (England) - Chief Executives

Cc:
Regional Office Prescribing Leads
Health Authorities (England) – Medical and Pharmaceutical Advisers
Health Authorities (England) – Directors of Public Health
NHS Trusts (England) – Medical Directors
NHS Trusts (England) – Chief Pharmacists
NHS Trusts (England) – Nursing Directors
Primary Care Groups/Trusts – Chief Executives

Further details from: Colin Pearson
6E59 Quarry House
Quarry Hill
0113 2545975
colin.pearson@doh.gsi.gov.uk

Additional copies of this document can be obtained from:

Department of Health
PO Box 777
London
SE1 6XH

Fax 01623 724524

It is also available on the Department of Health web site at
http://www.doh.gov.uk/coinh.htm

PATIENT GROUP DIRECTIONS [ENGLAND ONLY]

Action

1. Chief executives should ensure that any current or new patient group directions comply with new legal requirements and the guidance set out in this circular. Failure to comply with the law could result in a criminal prosecution under the Medicines Act.

Background

2. HSC 1998/051 enclosed copies of a Report on the Supply and Administration of Medicines under Group Protocols (the legal term for which is now Patient Group Directions). These are written instructions for the supply or administration of medicines to groups of patients who may not be individually identified before presentation for treatment. The Report recommended that the legal position should be clarified.

3. The majority of clinical care should be provided on an individual, patient-specific basis. The supply and administration of medicines under patient group directions should be reserved for those limited situations where this offers an advantage for patient care (without compromising patient safety), and where it is consistent with appropriate professional relationships and accountability.

The law

4. The relevant modifications to the provisions in and under the Medicines Act 1968 are contained in the Prescription Only Medicines (Human Use) Amendment Order 2000, the Medicine (Pharmacy and General Sale – Exemption) Amendment Order 2000 and the Medicines (Sale and Supply) (Miscellaneous Provisions) Amendment (No2) Regulations 2000. The changes come into force on 9 August 2000. The legislation applies to the NHS, including private and voluntary sector activity funded by the NHS. Therefore it covers treatment provided by NHS Trusts, Primary Care Trusts, Health Authorities (including SHAs), GP or dentist practices, Walk-in Centres and NHS funded family planning clinics. It does not otherwise apply to the private and voluntary sectors (further legislation is proposed in due course).

5. The patient group direction must be signed by a senior doctor (or, if appropriate, a dentist) and a senior pharmacist, both of whom should have been involved in developing the direction. Additionally the patient group direction must be authorised by the HA, SHA, NHS Trust, Primary Care Trust or Primary Care Group (in its capacity as a sub-committee of the HA). Clinical Governance Leads are probably best placed to do this.

6. The qualified health professionals who may supply or administer medicines under a patient group direction are nurses; midwives; health visitors; optometrists; pharmacists; chiropodists; radiographers; orthoptists; physiotherapists and ambulance paramedics. They can only do so as named individuals.

7. The legislation specifies that each patient group direction must contain the following information:

- the name of the business to which the direction applies;
- the date the direction comes into force and the date it expires;
- a description of the medicine(s) to which the direction applies;
- class of health professional who may supply or administer the medicine;
- signature of a doctor or dentist, as appropriate, and a pharmacist;
- signature by an appropriate health organisation;
- the clinical condition or situation to which the direction applies;
- a description of those patients excluded from treatment under the direction;

- a description of the circumstances in which further advice should be sought from a doctor (or dentist, as appropriate) and arrangements for referral;
- details of appropriate dosage and maximum total dosage, quantity, pharmaceutical form and strength, route and frequency of administration, and minimum or maximum period over which the medicine should be administered;
- relevant warnings, including potential adverse reactions;
- details of any necessary follow-up action and the circumstances;
- a statement of the records to be kept for audit purposes.

Additional guidance

8. NHS bodies should already be following the recommendations in the Review Team's Report. In particular

- Patient group directions should be drawn up by a multi-disciplinary group involving a doctor, a pharmacist and a representative of any professional group expected to supply medicines under the PGD. It is good practice to involve local Drug and Therapeutics Committees, Area Prescribing Committees and similar advisory bodies.

- A senior person in each profession should be designated with the responsibility to ensure that only fully competent, qualified and trained professionals operate within directions.

- All professions must act within their appropriate Code of Professional Conduct.

- Appropriate document(s) should be signed by each member of the multi-disciplinary group, the Clinical Governance lead on behalf of the authorising NHS organisation and the individual health professionals working under the direction. Generally, a direction should be reviewed every two years.

9. There must be comprehensive arrangements for the security, storage and labelling of all medicines. Wherever possible, medicines should be supplied in pre-packs made up by a pharmacist. In particular there must be a secure system for recording and monitoring medicines use from which it should be possible to reconcile incoming stock and out-goings on a patient by patient basis. Names of the health professionals providing treatment, patient identifiers and medicine provided should all be recorded. The NHS Executive document *Controls Assurance Standard – Medicines Management (Safe and Secure Handling)* provides guidance on related legislative requirements and best practice.

10. The EC Labelling and Leaflet Directive 92/27 applies to all supplies of medicines, including those supplied under patient group directions.

11. It is important that the use of any medicine is consistent with the Summary of Product Characteristics for the relevant product (save in special circumstances – see paragraph 13) and any relevant guidance from NICE.

Antimicrobials

12. Particular caution should be exercised in any decision to draw up PGDs relating to antibiotics. Microbial resistance is a public health matter of major importance and great care should be taken to ensure that their inclusion in a direction is absolutely necessary and will not jeopardise strategies to combat increasing resistance. A local microbiologist should be involved in drawing up the PGD. The local Drug and Therapeutics Committee or Area Prescribing Committee should ensure that any such directions are consistent with local policies and subject to regular external audit.

Black Triangle Drugs and medicines used outside the terms of the Summary of Product Characteristics

13. Black triangle drugs (ie, those recently licensed and subject to special reporting arrangements for adverse reactions) and medicines used outside the terms of the Summary of Product

Characteristics (eg, as used in some areas of specialist paediatric care) may be included in PGDs provided such use is exceptional, justified by current best clinical practice (eg, NICE guidance) and that a direction clearly describes the status of the product. Black triangle vaccines used in immunisation programmes may be included in PGDs, provided they are used in accordance with the schedules recommended by the Joint Committee on Vaccination and Immunisation. Where the medicine is for children, particular attention will be needed to specify any restrictions on the age, size and maturity of the child. Each PGD should clearly state when the product is being used outside the terms of the SPC and the documentation should include the reasons why, exceptionally, such use is necessary.

Controlled Drugs

14. The use of controlled drugs continues to be regulated under the Misuse of Drugs Act 1971. However, the Medicines Control Agency is initiating discussion with the Home Office about a possible amendment to the Misuse of Drugs Regulations to allow the use of substances on schedules 4 & 5 under PGDs.

Other exemptions and restrictions

15. Ambulance paramedics, midwives and chiropodists are already exempt from certain requirements of the Medicines Act. These exemptions, which allow them to administer or supply certain specified medicines without the directions of a doctor, will continue and are not affected by the new provisions for PGDs. The administration of radiopharmaceuticals continues to be regulated by the Medicines (Administration of Radioactive Substances) Regulations 1978 and should not be included in patient group directions.

Regional Office monitoring

16. Regional Offices have been asked to develop arrangements to monitor and share good practice. A website will be developed to provide examples of model directions. The Joint Colleges Ambulance Liaison Committee is devising a set of model directions for use by ambulance paramedics.

This Circular has been issued by:

Dr Sheila Adam
Deputy Chief Medical Officer/Health Services Director