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# REVIEW OF PRESCRIBING, SUPPLY & ADMINISTRATION OF MEDICINES

*Final Report*

*March 1999*

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REVIEW OF PRESCRIBING,  
SUPPLY & ADMINISTRATION  
OF MEDICINES

*Final Report*

*March 1999*



Rt Hon Frank Dobson MP  
Secretary of State for Health  
Room 407, Richmond House  
79 Whitehall  
London SW1A 2NS

Dear Secretary of State

I have pleasure in submitting to you the second Report of the Review of Prescribing, Supply and Administration of Medicines

The Review Team members have considered carefully the extensive evidence that was submitted during the period of consultation. It is inevitable that we could not produce recommendations which would meet all the aspirations expressed to us, while at the same time meeting your requirements for a robust framework for an extension of prescribing which safeguards patient safety.

The team believes, however, that its proposals, if implemented, will provide a secure means of increasing the range of health professionals who are authorized to prescribe. This will improve services to patients, make better use of the skills of professional staff and thus make a significant contribution to the modernization of the Health Service.

I would like to place on record my grateful thanks to the chairs of the Review Team sub-groups and other Team members, all of whom have given generously of their time and energy to this work while maintaining their busy professional responsibilities. Our discussions have been forthright, in considering the complex issues before us, but have always been constructive and good humoured.

The Review Team members join me in expressing our thanks to Donna Sidonio, who led most of the work of the secretariat, and all her colleagues from the Department of Health and the Welsh, Scottish and Northern Ireland Offices. Their knowledge and experience have been invaluable to us in developing our ideas and framing our recommendations.

We hope that the recommendations of this Report will enjoy the confidence of Ministers and of professionals and will play a part in further improving health care in this country.

Yours sincerely

A handwritten signature in black ink that reads "June Crown". The signature is written in a cursive, flowing style.

Dr June Crown



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## Summary and Recommendations

1. This report is submitted to ministers by the Review Team for the Prescribing, Supply and Administration of Medicines chaired by Dr June Crown.
2. It sets out a proposed new framework for the prescribing, supply and administration of medicines inside and outside the NHS in which:
  - ❖ the majority of patients continue to receive medicines on an individual patient-specific basis;
  - ❖ the current prescribing authority of doctors, dentists and certain nurses (in respect of a limited list of medicines) continues;
  - ❖ new groups of professionals would be able to apply for authority to prescribe in specific clinical areas, where this would improve patient care and patient safety could be assured.
3. It recommends introducing a distinction between two new categories of prescribers:
  - (i) independent prescribers - professionals who are responsible for the initial assessment of the patient and for devising the broad treatment plan, with the authority to prescribe the medicines required as part of that plan;
  - (ii) dependent prescribers - professionals who are authorised to prescribe certain medicines for patients whose condition has been diagnosed or assessed by an independent prescriber, within an agreed assessment and treatment plan.
4. The report recommends the establishment of an advisory body to assess applications from organisations seeking authority to prescribe on behalf of specified groups of health professionals. It identifies some of the criteria which might be applied and suggests a number of groups which might be early applicants for this assessment.
5. The report also considers the implications of any extension of prescribing authority on arrangements for the supply and administration of medicines, including supply under group protocols which was the subject of our first report.
6. The recommendations are set out in full in the remainder of this summary. They would apply across the United Kingdom and both inside and outside the NHS, although some details of implementation might differ between England, Wales, Scotland and Northern Ireland. Primary legislation would be needed to implement the key recommendations.

## Recommendations

### *Recommendations to Health Departments*

1. **The legal authority in the United Kingdom to prescribe, including authorising NHS expenditure, should be extended beyond currently authorised prescribers.**

(Para 6.6)
  
2. **Legal authority for new professional groups to prescribe or to authorise NHS expenditure should normally be limited to medicines in specific therapeutic areas related to the particular competence and expertise of the group and may include prescription only medicines within those areas.**

(Para 6.10)
  
3. **Two types of prescriber should be recognised:**
  - i **the *independent prescriber* who is responsible for the assessment of patients with undiagnosed conditions and for decisions about the clinical management required, including prescribing. At present, doctors, dentists and certain nurses in respect of a limited list of medicines are legally authorised prescribers who fulfil the requirements for independent prescribers and this should continue. Certain other health professionals may also become newly legally authorised independent prescribers, subject to the process described below.**
  
  - ii **the *dependent prescriber* who is responsible for the continuing care of patients who have been clinically assessed by an independent prescriber. This continuing care may include prescribing, which will usually be informed by clinical guidelines and will be consistent with individual treatment plans; or continuing established treatments by issuing repeat prescriptions, with the authority to adjust the dose or dosage form according to the patients' needs. There should be provision for regular clinical review by the assessing clinician.**

(Para 6.19)
  
6. **A UK-wide advisory body, provisionally entitled the “New Prescribers Advisory Committee”, should be established under Section 4 of the Medicines Act to assess submissions from professional organisations seeking powers for suitably trained members to become independent or dependent prescribers.**

(Para 6.27)
  
10. **Newly authorised groups of prescribers should not normally be allowed to prescribe medicines in the following categories:**
  - i **controlled drugs (drugs subject to the Misuse of Drugs Act 1971);**
  
  - ii **unlicensed drugs, or drugs used outside their licensed indications;**

- iii “black triangle” drugs;
- iv drugs over which there is continuing professional concern, eg drugs used to treat children and young people with mental health problems;
- v drugs which on public health grounds should be subject to particular safeguards, for instance antibacterial antibiotics.

(Para 6.54)

14. The current arrangements for the administration and self-administration of medicines should continue to apply. Newly authorised prescribers should have the power to administer those parenteral prescription only medicines which they are authorised to prescribe, and to issue directions for the parenteral administration of the same medicines.

(Para 6.62)

17. Repeatable prescriptions should be available on the NHS.

(Para 6.65)

18. Limits should be introduced for the number of times a repeatable prescription can be dispensed and the duration of its validity. These restrictions should apply across all sectors, and not be limited to NHS practice.

(Para 6.65)

19. Where particular extensions to prescribing authority could involve significant cost to the NHS, or where the balance of cost and benefit appears to be uncertain, there should be a thorough evaluation of the likely costs and benefits to the NHS before general adoption is encouraged. This should not be allowed to result in unnecessary delays in improving care.

(Para 7.9)

20. The Government should take general powers in primary legislation, enabling ministers, through regulations, to designate new categories of dependent and independent prescribers for the purpose of the Medicines Act, to authorise them to prescribe medicines for reimbursement by the NHS, and to limit or specify the medicines or classes of medicines which they may prescribe.

(Para 8.7)

25. The new arrangements should be subject to evaluation and monitoring, for which appropriate resources should be made available.

(Para 8.19)

*Recommendations to Health Departments and professional bodies*

4. There should be adequate arrangements for sharing information between independent and dependent prescribers. In particular,

- i both clinicians should have access to a complete medication record, and**
- ii both clinicians should have access to relevant parts of the patient’s medical record.**  
(Para 6.19)

**5. Changes to patterns of clinical care using new models for the prescribing, supply and administration of medicines should be introduced only after full consultation with patient interests, and should wherever possible increase patient choice.**  
(Para 6.23)

**11. Initial prescribing and supply of medicines should normally remain separate functions in order to protect patient safety and provide other safeguards. Where a prescription cannot be furnished, the current arrangements for the emergency sale or supply of medicines should apply.**  
(Para 6.59)

*Recommendation to Health Departments, professional bodies, HAs and employers*

**12. Where exceptionally it is in the interests of patients for the same professional to be responsible for prescription and supply of medicines, this should be subject to clinical audit and probity checks.**  
(Para 6.59)

*Recommendations to professional bodies*

**7. Proposals for new professional groups to be considered as potential prescribers will be expected to come from nationally recognised organisations. They should confirm that the group is formally recognised by the appropriate regulatory body and that that body has seen and is content with the proposed arrangements for training in prescribing and for registration.**  
(Para 6.33)

**13. Professional organisations, in putting forward proposals for extensions to prescribing, should consider whether this could result in members prescribing and supplying POMs to the same patient, and if so what safeguards are required to maintain patient safety and ensure probity. The NPAC, in assessing any proposals from professional groups which could result in members prescribing and supplying POMs to the same patient, should consider the adequacy of the safeguards proposed.**  
(Para 6.59)

**15. Professional organisations, in putting forward proposals for new groups of professionals to have the authority to prescribe certain medicines, should consider the implications for administration of medicines and should ensure that all necessary training aspects are covered in their proposals.**  
(Para 6.62)

21. Professional groups putting forward proposals for extended prescribing should liaise with education providers and bodies responsible for approving training courses to develop suitable training programmes in the required prescribing competencies. All training should include a period of supervised practice, and professional and regulatory bodies should take firm action against supervisors who fail to discharge their responsibilities.
- (Para 8.9)
22. The professional regulatory bodies should draw up clear guidelines on the circumstances in which commercial support or sponsorship for training programmes related to prescribing could be acceptable. Training programmes should not be used to promote particular products.
- (Para 8.12)
23. Professional organisations considering applying for extended prescribing authority should, in conjunction with the appropriate professional regulatory organisations, ensure that adequate arrangements would be established for
- i accrediting training programmes for prescribing;
  - ii maintaining a register of individuals who have acquired and are maintaining competency as prescribers;
  - iii reviewing the results of clinical audit programmes and ensuring that any general lessons are fed back into the content of training;
  - iv keeping the content of the prescribing formulary under review and submitting any proposals for change to the Medicines Control Agency.
- (Para 8.13)

*Recommendations to the GMC/GDC and postgraduate deans*

8. The GMC and postgraduate deans should agree a safe framework within which pre-registration house officers (PRHOs) could prescribe medicines relevant to the duties of their post. Such prescribing should be subject to close monitoring by their clinical supervisor, with due regard to the proper discharge of supervisory responsibility as specified in Recommendation 21.
- (Para 6.51)
9. Overseas doctors given provisional registration by the GMC and required to undertake clinical training similar to that of a PRHO, and overseas dentists, given temporary registration by the GDC to practise in an approved training post in a NHS hospital, should be able to prescribe under similar safeguards to those described in Recommendation 8.
- (Para 6.52)

*Recommendation to employers*

- 16. Employers and managers in all sectors who are responsible for staff who supervise or undertake the administration of any medicines should ensure that those staff have the right training and skills to do so safely and regular opportunities for updating their knowledge.**

(Para 6.62)

*Recommendation to individual practitioners*

- 24. All legally authorised prescribers should take personal responsibility for maintaining and updating their knowledge and practice related to prescribing, including taking part in clinical audit, and should never prescribe in situations beyond their professional competence.**

(Para 8.14)

## Chapter 1: Introduction

### Terms of Reference

- 1.1 The Review of Prescribing, Supply & Administration of Medicines was established in March 1997 with the following terms of reference:-

“Bearing in mind the overriding need to ensure patient safety, the effective use of resources, the skills and competencies of the various health professions, and recent changes in clinical practice and public expectations:

1. to develop a consistent policy framework to guide judgements on the circumstances in which health professionals inside and outside the NHS might undertake new responsibilities with regard to the prescribing, supply and administration of medicines;
2. to advise on the likely impact of any proposed changes on clinical outcomes, the convenience of health service users, professional relationships and costs;
3. to consider the possible implications for legislation, and for professional training and standards;
4. in particular, to advise on the supply or administration of medicines by nurses and other health professionals under “group protocols”, and on any safeguards which should apply;

and to make recommendations to ministers on item 4 within six months and on all other matters within 12 months.”

- 1.2 The Review was Chaired by Dr June Crown CBE, Past-President of the Faculty of Public Health Medicine. The members of the Review Team and the 4 sub-groups set up to support the Review are listed in Annex A. Other experts who advised the Review Team are listed in Annex B.
- 1.3 The first report of the Review, concerned with the supply and administration of medicines by group protocols, was published in April 1998.<sup>1</sup> A summary of the recommendations of the first report is at Annex C. This met the requirement of the fourth of the terms of reference and work is being undertaken to implement the recommendations, including any clarification of the law that may be necessary.
- 1.4 This report addresses the other terms of reference.

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<sup>1</sup> Review of prescribing, supply and administration of medicines: *A report on the supply and administration of medicines under group protocols* (Department of Health, London, April 1998).

## **Aims of this Review**

1.5 The aims of this Review are to:-

- ❖ develop a framework to determine in what circumstances health professionals might undertake new roles with regard to the prescribing, supply and administration of medicines;
- ❖ consider the implications of proposed changes, including those for legislation and for professional training.

1.6 The Review is concerned with the prescribing, supply and administration of medicinal products for human use. The Review does not deal with the dispensing of medicines.<sup>2</sup> It also does not include consideration of medical devices (medical appliances) nor the use of medicines in veterinary practice.

1.7 The overriding principle of the Review is that any changes to existing roles must at the very least maintain, and preferably enhance, patient safety. The changes also need to bring about demonstrable benefits to patient care and be cost-effective. The primary legislation governing the prescribing, supply and administration of medicines is UK-wide and covers all sectors of health care, so the recommendations and their implications will have to be considered in all four countries and will apply to practice inside and outside the NHS. Our recommendations also have implications for the reimbursement of the costs of medicines under the NHS, which is covered by separate legislation (Annex D).

## **Definition of terms**

1.8 During the course of the Review, it became clear to the Review Team that different interpretations are put upon many of the words used in this field. The Team has therefore produced a Glossary which sets out the definitions of terms used by the Team in this report.

## **Acknowledgements**

1.9 Many people contributed to the work of this Review, either by sending in written submissions,<sup>3</sup> by serving on its subgroups (see chapter 4) or by providing technical advice. The Review Team is grateful to all those who helped with this work. The Team members also wish to place on record their thanks and appreciation for the hard work and unfailing support of all the secretariat and officials whose advice was invaluable in reaching our conclusions and forming recommendations.

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<sup>2</sup> There is no legal distinction between “dispense” and “supply” although there are considerable differences in practice. The act of dispensing includes supply and also encompasses a number of other functions (eg checking the validity of the prescription, the appropriateness of the medicine for an individual patient, assembly of the product). In common usage “dispense” is usually reserved to the activity of pharmacists and dispensing doctors.

<sup>3</sup> A list of organisations and individuals who submitted evidence to the Review is at Annex F.

## Chapter 2: The Present situation

### Who can prescribe, supply or administer medicines?

- 2.1 Medicines are made available to the public under rules set out in legislation (the Medicines Act 1968) which are designed to ensure that effective products can be used safely according to the licensed indications (see Glossary) for use.
- 2.2 The terms “prescribe”, “supply” and “administer” are often used imprecisely and with overlap of meaning. The definitions we have used are as follows (see the Glossary for further amplification):

**Prescribe:** in the strict legal sense, as used in the Medicines Act:

- i to order in writing the supply of a prescription only medicine for a named patient;

but commonly used in the extended sense of:

- ii to authorise by means of an NHS prescription the supply of any medicine (not just a prescription only medicine) at public expense;

and occasionally:

- iii to advise a patient on suitable care or medication (including medicine which may be purchased over the counter).

In this report prescribing is usually used in sense (i) and (ii), unless the context makes clear that sense (iii) is intended.

**Supply:** to provide a medicine directly to a patient or carer for administration.<sup>4</sup>

**Administer:** to give a medicine either by introduction into the body, whether by direct contact with the body or not (eg orally or by injection), or by external application (eg application of an impregnated dressing).

- 2.3 Under the Medicines Act, a written prescription is required only for certain medicines called prescription only medicines (POMs - see para 2.7 and Glossary). For many years, the only prescribers of POMs for human use were fully registered doctors and dentists. Dentists normally limit their prescribing to drugs appropriate to dentistry.<sup>5</sup>

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<sup>4</sup> See footnote 2 on page 10.

<sup>5</sup> The General Dental Council (GDC) takes the view that a dentist should only prescribe drugs in connection with *bona fide* treatment (*Maintaining standards*, GDC, November 1997).

- 2.4 In 1989 an advisory group considered the circumstances under which nurses working in the community might prescribe and recommended that certain nurses holding district nurse or health visitor qualifications should be allowed to prescribe from a limited formulary.<sup>6</sup> The necessary legislation came into force in 1994. Pilot schemes were introduced and thoroughly evaluated.<sup>7</sup> The Secretary of State for Health announced in April 1998 plans to implement nationally the current nurse prescribing scheme in England.
- 2.5 The principal route of supply is through pharmacists. As a general principle, only pharmacists may supply POMs and pharmacy medicines (P - see para 2.7 and Glossary). This principle can however be relaxed in order to allow other health professionals to supply medicines in the course of providing health care. The details are complex (see Annex D) but the main exceptions are:
- i medicines legislation allows doctors and dentists to supply or administer any medicine direct to their patients;
  - ii nurses and other health care workers may supply products in the course of the business of a hospital or health centre, in accordance with the directions of a doctor or dentist;
  - iii certain medicines may be sold or supplied by specified health professionals, including chiropodists, optometrists, and midwives, in the course of their professional practice.
- 2.6 There are further restrictions on the administration of POMs by injection (parenteral administration), which must be carried out under the directions of a doctor or dentist except
- i for certain drugs, in an emergency (eg adrenaline, hydrocortisone);
  - ii for some medicines available to certain health professionals, for example ambulance paramedics, who may administer them by injection in the course of their professional practice.

### **POM, P and GSL medicines**

- 2.7 There are 3 legal categories of medicines, grouped according to their potency and risk of adverse side effects and the need for the supply to be professionally supervised. They are:-
- i *POM: prescription only medicines.* These may normally only be sold or supplied against the signed prescription of an “appropriate practitioner”, ie a doctor or dentist or (for certain medicines) a nurse prescriber. (There are various exceptions which allow

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<sup>6</sup> Report of the Advisory Group on Nurse Prescribing (Department of Health, London, 1989). A list of the prescription only medicines which prescribing nurses may prescribe is at Schedule 3 to the Prescription Only Medicines (Human Use) Order 1997. The Nurse Prescribers' Formulary also includes a number of Pand GSL medicines which a prescribing nurse may authorise for NHS reimbursement by issuing an NHS prescription.

<sup>7</sup> Luker K, Austin L, Hogg C et al, *Evaluation of nurse prescribing, final report* (Universities of Liverpool and York, January 1998).

the supply or administration of POMs without a prescription - see paras 2.5-2.6 and Annex D). POMs must be supplied to the patient or carer by a pharmacist or under the supervision of a pharmacist.

- ii *P: Pharmacy medicines.* These must be supplied or sold by a pharmacist or under the supervision of a pharmacist in registered pharmacy premises (for exemptions to these provisions see para 2.5 and Annex D).
- iii *GSL: General Sales List medicines.* These can be supplied direct to the public in an unopened manufacturer's pack at any lockable business premises.

### Payment from public funds

2.8 The arrangements outlined above relate to the legal safeguards that govern prescribing, supply and administration of medicines. They apply to all health care delivery systems in the United Kingdom and to both private and NHS practice. They are found in the Medicines Act 1968 and subordinate legislation made under it.

2.9 There are separate regulations, derived from the National Health Service Act 1977,<sup>8</sup> which govern the payment from public funds for medicines.<sup>9</sup> The key provisions

- i permit reimbursement of pharmacists for the cost of dispensing prescriptions from an authorised prescriber;
- ii place restrictions on the medicines which doctors, dentists and others may prescribe on the NHS;
- iii restrict the powers of doctors in general practice (except for dispensing doctors) to supply medicines from their surgeries;
- iv allow doctors in England and Wales to be reimbursed for the cost of medicines which they personally administer to their patients. In Scotland and Northern Ireland, doctors requisition these medicines from community pharmacists who then claim reimbursement.

2.10 A medicine, irrespective of its legal status, can only be dispensed under NHS arrangements against an NHS prescription, which is required even if the medicine is classified as P or GSL. Thus, an "NHS prescription" serves three purposes:

- i it fulfils the legal requirements authorising the supply of a POM under medicines legislation;

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<sup>8</sup> The Health and Personal Social Services (Northern Ireland) Order 1972 in Northern Ireland.

<sup>9</sup> The main provisions are the NHS (General Medical Services) Regulations 1992, the NHS (General Dental Services) Regulations 1992, the NHS (Pharmaceutical Services) Regulations 1992, and their equivalents for Scotland and Northern Ireland.

- ii it identifies the medicine which is to be supplied to the patient (which need not necessarily be a POM); and
- iii it authorises payment for that medicine from public funds.

As a general rule, NHS prescriptions are specific to individual patients.<sup>10</sup>

- 2.11 In NHS hospitals, medicines for inpatients are generally ordered using a combined prescription, supply and administration record card (or medicine chart). This is not a prescription form but sets out the written directions of an appropriate practitioner, usually a doctor, and includes details such as the patient's name, drug name, dose and frequency. In that sense, it fulfils an equivalent function to the prescription in NHS primary care. Similarly for outpatients, and for inpatients requiring medicines to take away on discharge, the form used to convey the practitioner's directions to the hospital pharmacy contains information similar to that in an NHS prescription. Hospital doctors can also write prescriptions for dispensing in the community, using a modified version of the prescription form used for GP prescribing.

## **Regulatory mechanisms**

### *The Medicines Commission and the Committee on Safety of Medicines*

- 2.12 When making decisions on changes to legislation which affect the supply and administration of medicines, Ministers receive advice from the Medicines Commission and the Committee on Safety of Medicines (CSM). These are independent advisory bodies established under the Medicines Act 1968 whose members are appointed by Ministers.
- 2.13 The Medicines Commission, established under Section 2 of the Medicines Act, has a very broad remit to advise Ministers on any matter relating to human and veterinary medicines within the scope of the Medicines Act. This includes licensing matters, questions relating to the sale and supply of medicines, and the publication of reference works relating to medicines. One specific duty is recommending the establishment of advisory bodies for particular purposes as provided for under Section 4 of the Act (see para 2.14). As part of its wider role it advises Ministers on the risk to public health of particular policy initiatives.
- 2.14 Committees established under Section 4 may be set up for any purpose or combination of purposes connected with the Act. At present, there are four: the CSM, the Veterinary Products Committee, the British Pharmacopoeia Commission, and the Advisory Board on the Registration of Homoeopathic Products. The CSM advises on the safety, quality and efficacy of medicines, both with regard to licensing issues, legal classification and pharmacovigilance and to the powers of health professionals to supply or administer specified medicines.

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<sup>10</sup> There are exceptions - for example, a doctor who is responsible for at least 10 persons residing in a school or other institution may prescribe for them by means of a "bulk prescription".

- 2.15 The impact of any proposed change to secondary legislation affecting the sale and supply of medicines is considered, as appropriate, by the CSM and the Medicines Commission. Ministers are required to take account of their advice. They are also required to consult representatives of interests which are likely to be affected such as professional, trade and consumer bodies.

*Professional self-regulation*

- 2.16 Most health professions have some form of *professional self-regulation* which covers requirements for registration and entry to the profession, specialisation, continuing professional development, and provision for removal or suspension from the professional register in cases of professional misconduct, incompetence or severe health problems.
- 2.17 The arrangements for the medical profession illustrate these essential features in a highly developed form. There are three main components:
- i the *General Medical Council* (GMC) determines the requirements for registration as a doctor and has powers to visit and inspect UK Medical Schools and their qualifying examinations. Following satisfactory completion of further specialist training in hospital specialities, a doctor's name can be included on the relevant specialist register of the GMC. This is now a pre-condition for taking up substantive consultant posts in the NHS. Statutory subcommittees determine allegations of professional misconduct, poor performance, and health problems serious enough to affect performance, through a quasi-judicial process in which the doctor may be legally represented. On the basis of their recommendations the GMC has power to remove doctors from the register, to suspend their registration or to impose conditions on their continued practice;
  - ii the *Specialist Training Authority* was established in 1996. It approves doctors for entry to the GMC's specialist register, either (on advice from the relevant Medical Royal College or Faculty) by award of the Certificate of Completion of Specialist Training (CCST) or by assessing the doctor's training and qualifications as equivalent to CCST standards. Doctors who have been awarded specialist certificates in other EU states may apply directly to the GMC for entry to the specialist register;
  - iii the *Medical Royal Colleges and Faculties* are responsible for the supervision and standards of postgraduate education and training, conducting postgraduate examinations, and arrangements for continuing professional development (CPD) (also know as continuing medical education, CME).
- 2.18 Arrangements for dentistry are broadly similar, with the General Dental Council (GDC) fulfilling the role of the regulatory body and the Faculties of Dental Surgery and General Dental Practitioners of the Royal College of Surgeons advising on educational standards including postgraduate training in the dental specialties. The GDC also fulfils the role of the Specialist Training Authority by approving as well as registering dental specialists.

- 2.19 The General Optical Council is the regulatory body in optometry and the College of Optometrists is responsible for professional and educational standards. Optometric specialties are not yet registered but the College manages a programme of continuing education.
- 2.20 Arrangements for nursing, midwifery and health visiting are similar to those for medicine, though with some significant differences in the roles of the various bodies involved:
- i The *United Kingdom Central Council for Nursing, Midwifery & Health Visiting* is established in statute and is charged with maintaining a professional register of qualified nurses, midwives and health visitors; providing advice on professional standards; setting standards for education, practice and conduct; and dealing with misconduct or unfitness to practice due to ill health;
  - ii Programmes of education leading to registration are approved by the four *National Boards*. Some post basic education courses, such as health visiting and district nursing, are already registrable or recordable with the UKCC. Further specialist practice courses leading to a recordable qualification are being developed;
  - iii *Continuing professional development* is mandatory for all nurses, midwives and health visitors and is linked to three-yearly renewal of their registration.
- 2.21 The Nurses, Midwives and Health Visitors Act, which establishes the UKCC and National Boards and sets out their functions and powers, has recently been reviewed and a report is currently with ministers. The outcome of this review is unlikely to have any fundamental implications for the recommendations of our report.
- 2.22 A single professional body, the Royal Pharmaceutical Society of Great Britain (RPSGB)<sup>11</sup>, is responsible for promoting standards within the pharmacy profession and for professional regulation. The RPSGB
- i approves the standards of university degree courses in pharmacy and the arrangements for the pre-registration year, including the pre-registration examination;
  - ii maintains a register of qualified pharmacists; and
  - iii deals with disciplinary issues through its Statutory Committee, which has the powers to remove practitioners from the register.

A field force of inspectors visit pharmacists to ensure compliance with the law and with professional standards. Participation in continuing professional development is a professional obligation under the Society's Code of Ethics.

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<sup>11</sup> In Northern Ireland, the Pharmaceutical Society of Northern Ireland.

2.23 The Council for the Professions Supplementary to Medicine (CPSM) and its professional Boards were established by the Professions Supplementary to Medicine Act 1960. It regulates the initial training and subsequent professional practice of nine health professions:

- ❖ chiropodists;
- ❖ radiographers;
- ❖ orthoptists;
- ❖ physiotherapists;
- ❖ occupational therapists;
- ❖ dietitians;
- ❖ medical laboratory scientific officers;
- ❖ prosthetists and orthotists;
- ❖ arts therapists (art, drama and music).

The Boards are responsible for promoting high standards of professional education and conduct amongst members, approving training institutions, qualifications and courses, and maintaining registers of those people who have qualified for state registration (the first seven in the list above. State registration, where available, is a requirement for employment in the NHS and in Local Authority social services. Registers for the last two professions are now being assembled.

2.24 The Government has announced its intention to repeal the Professions Supplementary to Medicine (PSM) Act, and to replace it with arrangements based on the recommendations of an independent review published in 1996.

## Chapter 3: Pressures for Change

### Introduction

- 3.1 The historic relationships between doctors, dentists, nurses and pharmacists are long established. The doctor's and dentist's key skills, in the context of this review, are in clinical assessment and diagnosis, and they are responsible for advising on any treatment necessary for the patient's care, including *prescribing* medication when required. Traditionally, the pharmacist prepared medicines and *dispensed*<sup>12</sup> them to the patient. The nurse, as part of the nursing care of the patient, might *administer*, or *supply* to patients for self-administration, medicines prescribed by the doctor.
- 3.2 This traditional description of professional relationships and patterns of care no longer fully reflects the needs of modern clinical practice. Changes in the training and roles of health care professionals from all disciplines, and the widening range, potency and formulation of medicines mean that the arrangements for prescribing, supply and administration of medicines need to be re-examined, with a view to improving the effectiveness and efficiency of health care.<sup>13</sup>
- 3.3 In addition, patients are no longer passive recipients of services, but have increasing expertise in the management of their conditions especially when these are long-standing. Medicines are often self-administered by patients or administered by their carers. Changes in prescribing arrangements should therefore seek to support current efforts to enable patients to be more involved in their treatment and more in control of their own health. Changes should also improve the convenience of services for patients and carers and explicitly value their time, as well as that of health care professionals.

### Changes in professional education and training

- 3.4 The education and clinical practice of many health care professions has changed over the last twenty years. Examples include:
- ❖ an increasing degree of specialisation in many disciplines including medicine, dentistry and nursing, some of which are reflected in regulatory changes:
    - a large number of new medical and dental specialties and subspecialties have become recognised, with training programmes approved by the relevant Royal Colleges and Faculties. Recognised specialties are now registrable with the GMC/GDC on their Specialist Registers.

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<sup>12</sup> For the distinction between dispensing and supply see the Glossary and footnote 2 on page 10. Consideration of issues relating to dispensing are outside the remit of this Review.

<sup>13</sup> See *Responsible self-care, including self-medication*, Joint Statement by the British Medical Association, Royal Pharmaceutical Society of Great Britain, National Proprietary Association, Royal College of General Practitioners and the Royal College of Nurses on the role of inter-professional teamwork in the provision of medicines (January 1998).

- in nursing, new specialties with recognised training programmes include intensive care, practice nursing, community children's nursing, respiratory care, sexual health, diabetes and tissue viability. Some of these specialist qualifications can be recorded with the UKCC.
- ❖ an increasing emphasis on pharmacists' clinical practice including the provision of advice to patients and to other prescribers on the appropriate choice and therapeutic use of medicines. This draws on pharmacists' knowledge of the range, efficacy, safety and cost-effectiveness of drug treatments. It also builds on their understanding of pharmacokinetic principles, drug interactions, side effects and available products.
- ❖ greater opportunities for autonomous practice in many professions, often linked to extensive post-graduate education and specialisation. For example, the role of physiotherapists includes diagnosis in specific areas and extended autonomous practice including manipulation; chiropodists and podiatrists may now undertake foot surgery; and ambulance paramedics administer medicines to patients in their care.
- ❖ the growing professionalisation of primary care, as shown by the introduction of compulsory vocational training for GPs and the development of specialist qualifications for practice nurses, coupled with a greater recognition of the value of preventative health care and of the need to consider the health care needs of entire populations.
- ❖ a growing emphasis on the need for clinical practice to be based as far as possible on rigorous evidence, and the related development of evidence-based aids to clinical practice such as clinical guidelines, protocols, computerised decision support, and associated audit methodologies.

3.5 It is desirable that highly trained health professionals should be able to use their full range of skills in the interests of better patient care, the efficient use of resources and enhanced job satisfaction. It is essential, however, that the extension of professional roles is accompanied by clear arrangements for accountability. One professional should not be expected to take responsibility for clinical decisions that are actually taken by a colleague - for instance, if a district nurse has in fact decided on the appropriate clinical dressing for a particular patient, and the GP has not in any real sense reviewed this decision, it is wrong for the GP to take formal clinical responsibility by signing the prescription. This is not only professionally inappropriate for both parties, but it can lead to confusion which may prejudice patient safety and reduce confidence in the arrangements for care.

### **Changes in patient expectations**

3.6 Patients, especially those with chronic and recurring health problems, and their carers are becoming increasingly expert about the management of their own conditions. They may choose to seek advice from a wider range of health professionals, both in the public and private sector, than has been usual in the past. The process of consultation itself is

increasingly seen as a dialogue between patient and professional, rather than as a one-way process of imparting expert advice.<sup>14</sup>

- 3.7 However, there remain considerable problems about patients' "concordance" with professional advice, and therefore with their adherence to recommended treatments.<sup>15</sup> Where communication between patients and health professionals is inadequate, patients may not always acquire the information they need. Other factors may play a part, such as the patients' own health beliefs, or the influence of family and friends. In some instances, patients may prefer to seek advice from a particular health professional because of ease of access, because a relationship of trust has been built up in the course of a series of consultations, or because of a perception that the particular professional is more appropriate or will have more time available. The patients' social circumstances (eg homelessness, language barriers, or other special needs) may also leave them with limited access to the full range of health services.
- 3.8 There may be unfortunate consequences when, for whatever reason, medicines are not taken as prescribed. The progress of the patients' own conditions may be affected, so that they may need further treatment or even admission to hospital. There may also be important public health implications for others, as for example through the emergence of resistant strains of bacteria when antibiotic treatment is inadequate.<sup>16,17</sup> Medicines may also be wasted or unused,<sup>18</sup> with consequent cost implications.

### Changes in professional relationships

- 3.9 Treatment and care are increasingly provided by multidisciplinary teams of health professionals. Individual team members usually act with a measure of autonomy in relation to their areas of expertise. They make relevant clinical assessments of patients, take decisions on management including the decision to refer to a doctor or other team member when necessary. They are accountable for their clinical interventions and for the maintenance of their professional competence. These team working arrangements have been instituted in the majority of care settings.
- 3.10 In some instances, the decision about whether or not to prescribe a medicine is, for all practical purposes, taken by a team member who is not a doctor. In order to comply with the

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<sup>14</sup> Herxheimer A and Stimpson GV, "The use of medicines for illness" in Blum R, Herxheimer A, Stenzl C, Woodcock J (eds) *Pharmaceuticals and Health Policy* (Holmes and Meier, New York, 1981).

<sup>15</sup> RPSGB Working Party (Chairman Professor Marshall Marinker) *From Compliance to Concordance* (RPSGB, London, 1997).

<sup>16</sup> *The path of least resistance: A report by the Standing Medical Advisory Committee Sub-Group on Antimicrobial Resistance* (Department of Health, London, 1998).

<sup>17</sup> House of Lords Science and Technology Committee, *Resistance to antibiotics and other antimicrobial agents: seventh report from the Science and Technology Committee: Session 1997-98* (London: Stationery Office, 1998 (HL81; Vol 1)).

<sup>18</sup> Woolf M, *Residual medicines: A report on OPCS omnibus survey data produced on behalf of the Department of Health* (London: HMSO, 1995).

law, the doctor is then asked to sign the prescription, even if he or she has not clinically assessed the patient. Increasingly, a team member who is not a doctor will assess a patient's condition and advise a change to the medicine regime. Such decisions currently require a doctor's authorisation in the form of a signed prescription.

### **Changes in the range and complexity of medicines**

3.11 Potent medicines are now available for the treatment of conditions for which until relatively recently there were no effective remedies. The increase in the range and complexity of medicines available and new delivery systems, together with the needs of an ageing population which includes many patients with multiple pathologies, mean that it is increasingly difficult for individual clinicians to claim expertise across the whole range of drug treatments relevant to their practice or to have a detailed understanding of other related fields. The development of clinical guidelines and computerised decision support is one response to this problem.

### **Implications for this review**

3.12 The trends described in this chapter, for health professionals and for patients, have not been fully reflected in changes in the arrangements under which medicines are prescribed, supplied and administered. The task of the Review Team was to consider what changes might be needed to modernise the provision of medicines in the light of changing circumstances.

## Chapter 4: General Principles, Work Programme and Information Gathering

- 4.1 The Review Team met sixteen times between March 1997 and August 1998. Its meetings included a two-day workshop in February 1998, and two meetings, in July 1997 and May 1998, with members of the Review sub-groups. Other experts, listed in Annex B, joined the May 1998 meeting.
- 4.2 The Review Team decided at the outset that its work should be transparent and that every effort would be made to obtain a wide range of views on the issues under discussion. Team members were appointed as individual experts rather than as representatives of organisations or professional groups, but they were expected to consult colleagues about aspects of the work of the Review. Press releases were issued at intervals to provide wider information about the progress of the Review.<sup>19</sup>
- 4.3 In its early meetings, the Review Team agreed on the methodology that it wished to pursue in developing its work, the principles which it considered should underpin the review, and the issues on which it wished to seek wider views.

### **General principles**

- 4.4 The Team established some general principles to inform and guide its work. These principles stood up well to more detailed consideration and helped us in due course to formulate our recommendations, although inevitably some details were subsequently refined. As initially set out, these principles were as follows:

#### **I. Overall Objective**

Any change from current practice should result in improved health outcomes, or else equivalent health outcomes with improved patient convenience or more appropriate professional practice.

#### **II. Criteria**

Any proposed change should be assessed against the following criteria:-

- i health outcomes and patient safety
- ii patient choice

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<sup>19</sup> 13 February 1997 *Announcement of review team*; 20 June 1997 *Requests for submissions of evidence to the Review*; 21 April 1998 *Publication of the Review Team's first report on the supply and administration of medicines under group protocols*.

- iii patient convenience
- iv professional appropriateness
- v effective use of resources

These criteria apply across all health care settings.

### **III. Principles**

- i *Factors contributing to patient safety and improved health outcomes*
  - a. All health professionals authorised to prescribe must be fully qualified and registered with a recognised regulatory body.
  - b. All health professionals authorised to prescribe should have appropriate post qualification training.
  - c. All health professionals authorised to prescribe should undertake continuing professional education relevant to their prescribing role.
  - d. All health professionals authorised to prescribe should be so identified on the register of the relevant regulatory body and this information should be updated at specified intervals.
  - e. Health professionals should only prescribe in circumstances where they are competent to assess all relevant aspects of the patient's clinical condition, to decide on an appropriate programme of clinical management and to take responsibility for prescribing and related decisions.
  - f. No health professional should undertake any aspect of patient care for which they are not trained and which is beyond their professional competence.
  - g. Overall responsibility for the co-ordination of care will normally remain with the general practitioner or, during episodes of hospital care, with a named lead consultant.
  - h. All health professionals authorised to prescribe should have access to the patient's clinical records and schedules of medication. Wherever possible there should be integrated clinical records, with full regard to confidentiality.
  - i. When responsibility for all or part of a patient's care is transferred from one professional to another, there should be transfer of full information on clinical status and medication, and the doctor with overall responsibility for the patient should be informed.

- j. There should normally be a separation of responsibilities for prescribing and for dispensing.
  - k. Arrangements for prescribing should take into account communications and other factors in the relationship between patient and practitioner which might affect the patient's willingness to follow the prescribed treatment.
- ii *Factors contributing to patient choice*
- a. Patients should be informed at all times about the professional background of clinicians responsible for aspects of their care. Wherever possible, patients should be allowed to choose the practitioner they wish to be responsible for their care, including prescribing.
  - b. In assessing the value of changes in prescribing practice, particular attention should be paid to measures of patient satisfaction.
- iii *Factors contributing to patient convenience*
- a. Arrangements for prescribing should, as far as possible, minimise delay between the clinical assessment, including a decision that a medicine is needed, and the patient obtaining the medicine.
  - b. Arrangements for prescribing should minimise journeys by patients or their representatives solely for the purpose of picking up prescription forms.
- iv *Factors contributing to professional appropriateness*
- a. The health professional taking responsibility for clinical decisions and care should also be responsible for related prescribing decisions.
  - b. No professional should be required to write or sign a prescription which relates to clinical care for which he/she is not personally responsible.
- v *Factors contributing to effective use of resources*
- a. Arrangements for prescribing should, as far as possible, avoid duplication of activities between health professionals.
  - b. Arrangements for prescribing should seek to minimise travel time for staff, by reducing journeys made solely to obtain confirmation or signature of prescription forms.

- c. Practitioners with direct clinical responsibility for care should ensure that appropriate medicines are prescribed in appropriate quantities to minimise waste.

4.5 The principles were circulated to all those involved in other stages of the Review.

### **Consultation exercise**

4.6 The Review Team sought opinions on the existing arrangements and ideas for change through a major consultation exercise which took place during the summer of 1997. A consultation letter was sent to a large number of organisations and relevant professional journals. Over 750 submissions were received. The consultation letter is at Annex E and the circulation list and respondents are at Annex F.

4.7 In view of the size of the response to the consultation exercise, the Minister for Health agreed to an extension of the timetable for the Review to allow all submissions to be thoroughly considered.

### **Sub-groups**

4.8 The Review Team set up four sub-groups, each chaired by a Team member, in order to help it assess the submissions and formulate suggestions on possible options for change. The sub-groups were made up of members from a wider range of backgrounds than the Team itself (see Annex A for the list of sub-group members, and terms of reference for the sub-groups). The Review Team members who did not serve on the sub-groups also assessed selected submissions and provided an extra source of advice to sub-group chairs. Every submission was considered by at least one member of the Review Team.

4.9 On receipt, each submission was allocated to the sub-group which reflected most closely the issues covered in the submission. Those submissions which were of a general nature were allocated to the sub-groups so that all had a similar workload. Each submission was analysed in detail by sub-group members against a pro-forma which mirrored the consultation letter. The responses were drawn together to form the basis of reports from the sub-groups to the Review Team.

4.10 Since the Review Team was asked to develop a framework for change which would be robust for the future, it was not considered appropriate to divide the work of the sub-groups according to present organisational structures in the NHS. The Team chose, rather, to relate the work to public and patient needs, which are likely to remain stable and around which new patterns for the provision of care will have to be designed.

4.11 The focus for the work of the four sub-groups was:-

- Sub-group 1.** “Healthy” people, ie those with self-limiting conditions and those capable of advised self-medication.
- Sub-group 2.** People with chronic or progressive illness living in the community.
- Sub-group 3.** People with serious conditions requiring rapid response including those in need of emergency or hospital care.
- Sub-group 4.** People with mental health or behavioural problems, including those in prisons and special hospitals.

4.12 Each sub-group met on a number of occasions between July and November 1997. The Review Team also continued to meet during this period. The sub-groups were reconvened for one meeting in May 1998, with other experts, in order to test the Team’s emerging recommendations.

### **Literature search and other international experience**

4.13 The Review Team commissioned the South East Institute of Public Health to carry out a short search of published information about current practice in the UK and overseas concerning the prescribing, supply and administration of medicines by health professionals other than doctors and dentists. It also wrote to a number of contacts in countries outside the United Kingdom, receiving 7 replies from national regulatory authorities with details of their current prescribing practice.

## Chapter 5: Summary of Evidence

### Sub-Groups

5.1 Each sub-group produced a report for discussion by the full Team based on the responses to the consultation exercise and their own expertise. Although the sub-groups were looking at the needs of different patient groups, their findings showed a wide measure of consistency. In particular, each group recommended that the power to prescribe should be extended in specific circumstances to further groups of health professionals. The sub-group reports also informed the Review Team's first report on the supply and administration of medicines under group protocols, published on 21 April 1998.<sup>20</sup>

#### *Summary of views received*

5.2 The consistent views which emerged from the response to consultation were:

- ❖ many valuable features of current arrangements should be retained, including the clear legal framework, the coordination of care by a single health professional, and the general principle of the separation of the prescribing of medicines from supply and administration;
- ❖ current arrangements fail to make the fullest use of the skills of many professionals;
- ❖ there is overwhelming support for an extension of prescribing to new groups of prescribers, in specific clinical areas related to their expertise and subject to nationally accredited training;
- ❖ in certain circumstances, the precise choice of medicine can be decided by a professional other than the clinician who carries out the initial assessment;
- ❖ the risk of fragmentation of care is recognised, but can be overcome by better team-working, communications and use of information technology;
- ❖ there should be wider use of repeat dispensing or repeat supply arrangements;
- ❖ supply and administration of medicines under group protocol is acceptable in certain limited clinical circumstances.

5.3 A fuller summary is at Annex G.

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<sup>20</sup> Review of prescribing, supply and administration of medicines: *A report on the supply and administration of medicines under group protocols* (Department of Health, London, April 1998) issued under cover of Health Service Circular (HSC)1998/051 in England, Management Executive Letter (MEL) (98)29 in Scotland, Welsh Health Circular (WHC) (98)27 in Wales, and by each Chief Professional Officer to their respective professional groups in Northern Ireland.

*Conclusions from the sub-groups*

5.4 The reports from the sub-groups were all considered by the Review Team as a whole. Final conclusions are set out in later chapters and summarised in the recommendations in chapter 9.

The main issues identified by the sub-groups were:

- i Each sub-group considered that there should be an extension of some prescribing responsibilities to some health professionals. The groups suggested various safeguards to support this recommendation, including:
  - ❖ there should be an agreed framework for the extension of prescribing powers, determined by the core competencies, knowledge and skills of the members of the profession involved;
  - ❖ the training of newly authorised groups of prescribers should match the tasks associated with changed responsibilities;
  - ❖ training should be to a nationally accredited standard, approved and registered by relevant professional organisations;
  - ❖ new prescribers should be required at appropriate intervals to demonstrate continuing competence to prescribe;
  - ❖ there should be clear arrangements to ensure the professional accountability of prescribers;
  - ❖ any new responsibilities for prescribing, supply and administration should be subject to evaluation and clinical audit, linked to mechanisms to improve practice and remedy deficiencies.
- ii Most of these proposed safeguards are equally relevant to existing prescribers and many are already required in current arrangements. Although it is outside the remit of the Review Team to make formal recommendations in this area, we suggest that the relevant medical and dental professional bodies may wish to review arrangements for initial training, continuing professional development and audit in the light of the general principles we recommend for new prescribers.
- iii The sub-groups considered that prescribing should continue to be kept separate from the supply of medicines, except in circumstances where the patient requires immediate treatment.
- iv The sub-group dealing with mental health issues considered that there should be better arrangements for the immediate supply of medicines in the Prison Service.

- v This subgroup also recommended that only doctors should prescribe in the field of child and adolescent psychiatry, because of professional concern about the treatment with drugs of children and young people with mental health problems, and because many medicines in this area are not currently licensed for paediatric use.
- vi Three of the sub-groups considered that it was not always necessary for the same professional to diagnose and to prescribe. The sub-group on patients with serious conditions requiring rapid response considered that, in the special circumstances of emergency care, there should be no separation between the diagnosis and the initial prescribing decision.
- vii Two of the sub-groups developed new models for prescribing in different situations. These included “independent” prescribing, to be extended to certain highly skilled health professionals, and “dependent” prescribing (which could include a variety of models, including initial prescribing by protocol).
- viii All of the sub-groups placed a high priority on safeguarding the interests of patients. Any changes must take into account the need to protect patient safety, ensure good continuity of care, avoid fragmentation and safeguard patient choice and convenience. Changes in the management of care or professional responsibility should as far as possible be subject to patients’ informed agreement.
- ix Each of the sub-groups supported the development of better patient records, accessible to all prescribers, with due regard to the confidentiality of patient-identifiable data.<sup>21</sup> Recommendations included the development of a single, integrated patient record system, and the development of a framework for communication and information systems.

5.5 The consultation raised several issues related to the work of the review which did not form part of the review terms of reference. These matters were, however, identified by the sub-groups and are commended to relevant policy areas in the UK Government Departments. They are described at Annex H.

### **International experience**

5.6 Apart from the United Kingdom itself, the countries with the most experience to date of prescribing by professionals other than doctors and dentists are Sweden and the USA.<sup>22</sup> The majority of evidence relates to nurses and pharmacists. It should not, of course, be assumed that experience in other health care systems would be exactly replicated in the United Kingdom.

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<sup>21</sup> *Report on the review of patient-identifiable information* (“Caldicott” report, Department of Health, December 1997).

<sup>22</sup> See *Report of the Working Group advising on the quality and safety issues associated with extending limited prescribing rights to registered nurses* (New Zealand Ministry of Health, Wellington, November 1997) for a fuller summary.

### *Prescribing by nurses*

- 5.7 District nurses and health visitors in Sweden have been prescribing dressings and appliances for about 20 years. Following a pilot scheme in 1988, a nurse prescribing scheme was introduced in 1994. This allows district nurses with a postgraduate qualification and additional training in pharmacology to prescribe from a list of oral medications for 60 specific indications.
- 5.8 In the USA, nurse prescribing has been closely associated with the development of the concept of “nurse practitioners”, who have undergone postgraduate training in particular specialist areas in either primary or secondary care. Training differs from Sweden or the UK in placing considerable stress on diagnostic skills. Details vary from state to state; most set limits on the setting for prescribing or on the type of drugs that can be prescribed, and in some states nurses may only prescribe within protocols laid down by a supervising physician. In most states nurse prescribers must undergo mandatory continuing education and audit. At the end of 1997, 49 states allowed some form of nurse prescribing.
- 5.9 Australia and New Zealand are also considering introducing some forms of nurse prescribing. New South Wales is considering proposals for nurse prescribing in specialist areas such as neonatal intensive care, and also in primary care in remote rural areas. The New Zealand working party already referred to<sup>23</sup> has recommended a pilot study in one specific area of specialist practice.
- 5.10 Much of the literature is descriptive or presents essentially theoretical arguments for the benefits or risks of extending prescribing; evidence from well-conducted studies is sparse, and much of it comes from the USA and may not be directly applicable to the health care system in the UK. The available evidence suggests:
- i *Acceptability* - where nurse prescribing has been introduced, it has been readily accepted both by patients and by other professionals.<sup>24</sup>
  - ii *Patient/professional relationship* - the UK research suggests that health visitors are considered “more approachable” than GPs and that patients feel more able to discuss areas of concern. Some USA studies reported concern by patients about communication with nurse practitioners,<sup>25</sup> competence to deal with serious medical problems,<sup>26</sup> and

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<sup>23</sup> See footnote 22 on page 29.

<sup>24</sup> Luker K, Austin L, Hogg C et al, *Evaluation of nurse prescribing, final report* (Universities of Liverpool and York, January 1998).

<sup>25</sup> Levine D, Morlock L, Mshlin A et al, “The role of new health practitioners in a prepaid group practice: provider differences in process and outcome of medical care”, *Prev Med* **14**(4) (1976) 326-47.

<sup>26</sup> Kubala S and Clever L, “Acceptance of the nurse practitioner”, *American Journal of Nursing* **74**(3) (1974) 451-2.

readiness to consult physicians about diagnostic and treatment decisions,<sup>27</sup> but these all relate to practice many years ago.

- iii *Access to care* - more recent US literature<sup>28</sup> suggests that prescribing by nurse specialists “has increased access to care for many individuals and families”.
- iv *Timeliness of treatment* - in a survey of nurse practitioners in the USA<sup>29</sup> more than half reported delays in patient treatment resulting from their (then) inability to prescribe, and 11% reported significant delay likely to affect the patient’s health.
- v *Appropriateness of treatment* - the evidence is limited. One study in a UK dermatology ward<sup>30</sup> found that nurses’ choice of topical medication was better correlated with the “gold standard” of their consultants than that of the junior doctors on the ward. A similar study of primary care prescribing in the US<sup>31</sup> found that nurse practitioners scored better than physicians when assessed by a multi-disciplinary panel of experts. Another study in US primary care<sup>32</sup> found that nurse practitioners prescribed medications less frequently than physicians and tended to use a very restricted range of drugs though the study did not comment on appropriateness.
- vi *Use of resources* - evidence from the initial UK pilot study sites<sup>33</sup> showed mixed results. In some practices nurse prescribers identified areas of waste and achieved very significant reductions in prescribing costs, while in others prescribing costs and volume rose, suggesting some previously unmet need. More detailed, recent analysis of prescribing data covering a longer period of time and a wider range of nurse prescribers, suggests that there should be no overall increase in prescribing costs as a result of introducing nurse prescribing, if properly managed (unpublished). The UK research also identified significant savings in the time of nurses and GPs, though it was

<sup>27</sup> Enggist R and Hatcher M, “Factors influencing consumer receptivity to the nurse practitioner” *J Med Syst* **7(6)** (1983) 495-512; Rodeghero J “Perceptions of nurse practitioners among the rural poor” *Nurse Practitioner* **3(5)** (1978) 7.

<sup>28</sup> Talley S and Brooke P, “Prescriptive authority for psychiatric clinical specialists: framing the issues”, *Archives of Psychiatric Nursing* **6(2)** (1992) 71-82.

<sup>29</sup> Biester D and Collins J, “Prescriptive authority for nurse practitioners: a strategy for improving access to child health care”, *Journal of Pediatric Nursing* **6(6)** (1991) 419-420.

<sup>30</sup> Cox N, Walton Y and Bowman J, “Evaluation of nurse prescribing in a dermatology unit”, *British Journal of Dermatology* **133(2)** (1995) 340-1.

<sup>31</sup> Mahoney D, “Appropriateness of geriatric prescribing decisions made by nurse practitioners and physicians”, *Image* **26(1)** (1994) 41-6.

<sup>32</sup> Rosenaur J, Stanford D, Morgan W et al, “Prescribing behaviours of primary care nurse practitioners”, *Am J Public Health* **74** (1984) 10-13.

<sup>33</sup> Luker K, Austin L, Hogg C et al, *Evaluation of nurse prescribing, final report* (Universities of Liverpool and York, January 1998).

not clear how this should be valued. US research suggests that nurse practitioners tend to prescribe less than physicians,<sup>34</sup> and it has been suggested that improved care by nurse practitioners can result in savings on secondary care costs.<sup>35</sup>

### *Prescribing by pharmacists*

- 5.11 In the USA, 17 states, at the time of our literature review, allowed pharmacists to prescribe under protocols from a physician. Here, the pharmacists receive *delegated* authority to prescribe, and share with collaborating physicians the risk and responsibility for the patients' overall outcome, except in Florida, where pharmacists prescribe independently, albeit from a very limited formulary.<sup>36</sup>
- 5.12 There is more extensive experience of pharmacists undertaking *related activities*, such as carrying out medicines reviews, advising doctors on choice of medicines, and counselling patients. Pharmacists also regularly advise patients on the choice of P and GSL medicines (the third sense of "prescribe" in the Glossary). In relation to these activities, the literature (much of it from UK experience) suggests:
- i *Acceptability/access* - pharmacists' involvement in prescribing has been accepted for some time in hospital practice.<sup>37</sup> Similarly, the role of the pharmacist in managing minor ailments in community practice has received acceptance by many prescribers, particularly over the last five years in response to its potential for reducing the NHS prescribing budget.<sup>38</sup>

Studies of *client* acceptability for the management of minor ailments or 'counter-prescribing' have shown that the community pharmacy is recognised as the first port of call for people seeking advice and/or treatment for minor ailments. Convenience, speed, identification of minor symptoms and saving the doctor's time have been cited as

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<sup>34</sup> Avorn J, Everitt D and Baker M, "The neglected medical history and therapeutic choices for abdominal pain", *Archives of Internal Medicine* **151** (1991) 694-698; Sutliff L, "Myth, mystique, and monopoly in the prescription of medicine", *Nurse Practitioner* (March 1996) 153-5.

<sup>35</sup> Campbell S, "The newest gatekeepers: nurses take on the duties of primary care physicians", *Health Care Strategic Management* March 1997 14-15.

<sup>36</sup> Boatwright DE, "Legal aspects of expanded prescribing authority for pharmacists", *Am J Health-Syst Pharm* **55** (1998) 585-594.

<sup>37</sup> Fletcher PJ and Barber ND, "The pharmacist's contribution to clinicians' ward rounds: analysis by the stages in the drug use process", *Int J Pharm Pract* **3** (1995) 241-4.

<sup>38</sup> Erwin J, Britten N and Jones R, "General practitioners' views on over the counter sales by community pharmacists", *BMJ* **312** (1996) 617-8.

common reasons for going to the pharmacy,<sup>39, 40</sup> and there is support for repeat dispensing services at community pharmacies.<sup>41</sup>

ii *Appropriateness of treatment*<sup>42</sup>

*Hospital pharmacy*

In hospital practice, pharmacists have access to the full medication profile prior to dispensing. In one study, interventions were made by the pharmacist on 3.3% of all individual drug prescriptions, corresponding to around 20% of all patients. Of these interventions, 57% were classified as being either moderate (e.g. therapeutic drug monitoring) or major (e.g. total parenteral nutrition calculation).<sup>43</sup> There are also examples of pharmacist involvement in specialist areas of care, such as HIV.<sup>44</sup>

*Primary care pharmacy*

Community pharmacists do not have access to patients' full medication records. Many have therefore established computerised patient medication records (PMRs) which are useful in supplying details that are missing from prescriptions. In one study 17% of repeat prescriptions omitted quantities or dosages that were resolved using the PMR.<sup>45</sup>

Protocols were introduced into community pharmacies in 1996 to improve the service, following criticism by the Consumers' Association. Pharmacy staff now ask relevant questions in accordance with the protocols which determine when to refer the client to the pharmacist.<sup>46</sup>

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<sup>39</sup> McEnlay JC and Dickson FC, "Purchases from community pharmacies of OTC medicines by elderly patients", *Pharm J* **253** (1994) R15.

<sup>40</sup> Williamson VK, Winn S, Livingstone CR and Pugh ALG, "Public views on an extended role for community pharmacy", *Int J Pharm Pract* **1** (1992) 223-9.

<sup>41</sup> Dowell J and Dodd T, "Repeat dispensing by community pharmacists: a popular way to supplement treatment", *Pharm J* **255** (1995) R31.

<sup>42</sup> National Prescribing Centre and NHS Executive. *GP Prescribing Support: a resource document and guide for the New NHS*. September 1998.

<sup>43</sup> Hubbard CN and Alder G, "Interventions during prescription checking on ward rounds" *Pharm J* **248** (1992) 162-3.

<sup>44</sup> Pharmaceutical Care Awards 1997 - Taking the initiative for HIV patients. *The Pharmaceutical Journal* **261** (1998) 28.

<sup>45</sup> Payne M, Thomas J and Allwood MC, "A study of the use of patient medication records in a community pharmacy", *Pharm J* **249** (1992) R39.

<sup>46</sup> Cantrill JA, Weiss MC, Kishida M and Nicolson M, "Pharmacists' perceptions and experiences of pharmacy protocols: a step in the right direction?" *Int J Pharm Pract* **5** (1997) 26-32.

Pharmacists can assist general practitioners to ensure continuing safe and effective treatment. Such collaboration has been shown to reduce inappropriate multiple medication.<sup>47,48</sup> A pilot repeat dispensing project in Tayside showed that 90% of patients preferred the pharmacy-based system and that clinical review was improved.<sup>49</sup>

Pharmacists may also be involved in running specific outpatient clinics. Examples include anti-coagulant clinics,<sup>50</sup> *Helicobacter pylori* eradication,<sup>51</sup> hypertension,<sup>52</sup> asthma,<sup>53</sup> and chronic obstructive pulmonary disease.<sup>54</sup>

- iii *Use of resources* - there is evidence that consultations with pharmacists about OTC medicines reduce referrals to GPs,<sup>55</sup> and that the administrative workload of doctors may be reduced by community pharmacies' repeat dispensing services.<sup>56</sup> Pharmaceutical advisers can help improve budgetary control<sup>57</sup> and cost-effective prescribing in general practice.<sup>58</sup> In the USA, financial savings have been identified through the reduction in inappropriate prescribing following advice from pharmacists.

### *Prescribing by other health professionals*

5.13 There is very little available information about prescribing by other professionals. In Sweden, some other professions including dental hygienists may prescribe from a limited formulary.

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- <sup>47</sup> Hulme H, Wilson J, Burrill, Goldstein R, "Rational repeat prescribing: general practitioners and community pharmacists working together", *Pharm J* **257** (1996) R7.
- <sup>48</sup> Hanlon JT, Samsa GP, Lewis IK, Landsman PB, "Arandomized control trial of a clinical pharmacist intervention to improve inappropriate prescribing in elderly outpatients with polypharmacy" *American J of Medicine* **100** (1996) 428-37.
- <sup>49</sup> Dowell J, Cruikshank J, Bain J and Staines H, "Repeat dispensing by community pharmacists: advantages for patients and practitioners", *British Journal of General Practice* **48** (1998) 1858-1859.
- <sup>50</sup> Radley AS, Hall J, Farrow M and Carey PJ, "Evaluation of anticoagulant control in a pharmacist operated anticoagulant clinic", *BMJ* **48** (1994) 545-7.
- <sup>51</sup> Moorhouse GE, Brown WJD and Edwards C, "Apharmacist managed *H pylori* eradication programme in general practice", *Pharm J* **257** (1996) R5.
- <sup>52</sup> Erickson SR, Slaughter R and Halapy H, "Pharmacists'ability to influence outcomes of hypertension therapy", *Pharmacotherapy* **17**(1)(1997) 140-147.
- <sup>53</sup> Pauley TR, Magee MJ and Cury DC, "Pharmacist-managed, physician-directed asthma management program reduces emergency department visits", *The Annals of Pharmacotherapy* **29** (1995) 5-9.
- <sup>54</sup> Pharmaceutical Care Awards 1997 - A chronic obstructive pulmonary disease clinic. *The Pharmaceutical Journal* **261** (1998) 26.
- <sup>55</sup> Smith FJ, "Referral of clients by community pharmacists in primary care consultations", *Int J Pharm Pract* **2** (1993) 86-9.
- <sup>56</sup> Dowell J and Dodd T, "Repeat dispensing by community pharmacists: a popular way to supplement treatment", *Pharm J* **255** (1995) R31.
- <sup>57</sup> Bradley M, "The role of the practice pharmacist - the new member of the team", *VFM Update* **2** (1996) 27-8.
- <sup>58</sup> Chapman S, "Community pharmacists have positive IMPACT", *VFM Update* **2** (1996) 27-8.

## Chapter 6: Proposed Policy Framework for Extension of Prescribing

### **Introduction**

6.1 This chapter presents the conclusions of the Review in relation to the first part of the terms of reference:

“to develop a consistent policy framework to guide judgements on the circumstances in which health professionals inside and outside the NHS might undertake new responsibilities with regard to the prescribing, supply and administration of medicines”.

6.2 Our first report addressed the question of the circumstances in which supply and administration of medicines under group protocols could safely take place. This chapter is largely concerned with prescribing. However, a later section (paras 6.55-6.62) considers some issues at the interface between prescribing, supply and administration.

6.3 Except where otherwise indicated or implied by the context, we use the term “prescribe” to refer to the ordering of a prescription only medicine (ie sense (i) as defined in our Glossary). However, much of the content of the chapter applies equally to the broader definition (sense (ii)), which is any written order for a medicine and includes authorisation to supply a prescription only medicine and to supply at NHS expense. The detailed implications for medicines and NHS legislation respectively are considered in Chapter 8.

### **Extension of prescribing to new professional groups**

6.4 The Review Team believes that many aspects of the existing arrangements for the treatment of patients should be retained. In particular, it believes that

- i the co-ordination of patient care should normally rest with the general practitioner or, during episodes of hospital care, with a named consultant;
- ii in the great majority of cases, medicines should be prescribed and dispensed on an individual, patient-specific basis;
- iii patient safety should not in any way be compromised;
- iv the provision of medicines to patients should make the best use of professional expertise and the most effective use of resources.

6.5 However, having reviewed all the information available to them in the light of their own professional knowledge and experience, the members of the Review Team unanimously recommend that the legal authority to prescribe in the United Kingdom, or to authorise supply at NHS expense, should be extended beyond currently authorised prescribers.

6.6 The main factors which have led us to this conclusion are

- i growing expertise in advanced clinical roles in many professions (see paras 3.4-3.5), which means that other professional groups have specific skills in particular therapeutic areas;
- ii an increasing tendency for professionals to work together in multi-professional teams in which the precise boundaries of clinical responsibility can vary both over time and with the competencies of the individual professionals involved;
- iii the need for the responsibility and accountability for clinical care to be clear and unambiguous;
- iv a growing expectation from patients that they will experience a “seamless service” with the minimum number of contacts with different health professionals consistent with patient safety;
- v a growing wish on the part of patients to choose the particular pathway through the clinical system which is convenient or appropriate to them, in cases where there are equally safe and effective clinical alternatives.

***Recommendation 1:***

***The legal authority in the United Kingdom to prescribe, including authorising NHS expenditure, should be extended beyond currently authorised prescribers.***

**Limitations on the range of medicines which can be prescribed**

6.7 The Review Team has considered the broad spectrum of opinions which were put forward through the consultation process about the range of medicines which should be available to new prescribers.

6.8 Some respondents argued that any health professionals who have received appropriate training and are authorised to prescribe should be expected to understand the limits of their competence and act within them. On this basis, new prescribers could, like doctors and dentists at present, be legally entitled to prescribe the majority of licensed products, on the understanding that they would in practice prescribe only within the limits of their competence. Any practitioner prescribing outside these limits would be acting unprofessionally, and the relevant regulatory body would be expected to take action. The Review Team considers that such a wide extension of prescribing authority is not necessary to achieve benefits in patient care.

6.9 Others argued that prescription only medicines (POMs) are so designated in order to protect the public, and that only practitioners with broad and extensive training and experience in both diagnostics and therapeutics, such as doctors and dentists, can prescribe them safely. This argument would lead to the conclusion that any new prescribers should be limited to P and GSL medicines. The Review Team considers that such a narrow view is unnecessary for patient

safety, restricts the contribution that skilled professionals could make to improvements in patient care, and fails to build on the experience of modern approaches to the delivery of care.

- 6.10 The Review Team concludes that new prescribers will normally be working within specific therapeutic areas and will need access to a limited range of medicines, which in most cases will include some POMs. One possible exception is for pharmacists continuing treatment initiated by another prescriber, which might relate to a wider range of conditions (see para 6.18). Prescribers will however be expected to be familiar with the implications of multiple pathology and co-morbidity. These should be addressed in their training as important aspects of competence to prescribe.

### **Recommendation 2:**

***Legal authority for new professional groups to prescribe or to authorise NHS expenditure should normally be limited to medicines in specific therapeutic areas related to the particular competence and expertise of the group and may include prescription only medicines within those areas.***

- 6.11 It is possible that some professionals may gain additional qualifications in two or more specialist areas within their profession, all of which confer prescribing authority. This would be acceptable provided the individual is able to fulfil the requirements for updating skills, clinical audit etc for *all* areas of specialisation.

### **Independent and dependent prescribing**

- 6.12 The act of prescribing a medicine is part of a process which starts with the overall clinical assessment of an individual who presents for preventive care or for treatment. In the case of a patient, the assessment should result in a clinical opinion about the management of the condition which may or may not include the establishment of a full diagnosis. The management of the patient may include prescribing medicine. The initiation of care and the development of a treatment plan must take into account all relevant aspects of the patient's condition, and requires knowledge of the implications of any co-existing medical conditions and possible interactions with existing medication.
- 6.13 The Review Team believes that, although assessment and prescribing should form part of a single *process*, it is not always essential that both should be part of a single *consultation* with one professional. The Team therefore proposes that two categories of prescribing should be defined, "independent" and "dependent" prescribing.

#### *Independent prescribing*

- 6.14 The Review Team defines the act of prescribing for a patient presenting for the first time in an episode of care as "**independent prescribing**". This means that the prescriber takes responsibility for the clinical assessment of the patient (usually including establishing a diagnosis) as well as for the appropriateness of any prescription which may be issued at that time.

6.15 The Team believes that doctors and dentists will continue to form the majority of independent prescribers for POMs. Any extensions, beyond district nurses and health visitors who are already legally entitled to prescribe from a limited list of medicines, are likely to be limited to specific therapeutic areas.

#### *Dependent Prescribing*

6.16 Once a diagnosis has been established or a treatment plan prepared for an individual patient, the responsibility for clinical management may be transferred from the assessing clinician (an independent prescriber) to another health professional. In this situation, the prescribing of medicines by the second clinician is defined by the Review Team as “**dependent prescribing**”.<sup>59</sup> This means that the dependent prescriber is not responsible for the initial assessment or diagnosis, which rests with the assessing clinician.

6.17 The *dependent prescriber* is responsible for the appropriateness of any prescription which he or she may issue. This may include an initial prescription for a particular episode of care, if the independent prescriber has not inaugurated pharmaceutical treatment, together with any related clinical assessments. The Team envisages that dependent prescribing will usually be informed by clinical guidelines, and will be consistent with individual treatment plans.

6.18 A particular form of dependent prescribing occurs when a second professional (for instance, a pharmacist or a nurse) continues a course of pharmaceutical treatment after an initial prescription by the assessing clinician (independent prescriber). It differs from repeat dispensing (see para 6.63) in that the dependent prescriber would have the discretion to vary some aspects of the prescription, such as dose, frequency, presentation, or active ingredient group, within the individual treatment plan specified by the assessing clinician. The dependent prescriber would remain responsible for ensuring that a further prescription was both needed and clinically appropriate. There should be provision for regular clinical review by the assessing clinician.

6.19 In any form of dependent prescribing, good communication between the two clinicians is essential. In particular, it is of vital importance that both clinicians have access to a complete medication record, and that the dependent prescriber has access to a summary of the patient’s medical record. This could be secured through the more extensive use of information technology (IT), or, as an interim measure, through the use of hand-held patient records. This is discussed further at para 8.19.

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<sup>59</sup> Note that we are using “dependent prescribing” in a rather different sense from the report of the New Zealand working party cited in footnote 22 on page 29, in which dependent prescribers assess the patient and recommend the course of treatment, but must have any prescription signed by an authorised prescriber.

**Recommendation 3:**

**Two types of prescriber should be recognised:**

- i** *the independent prescriber who is responsible for the assessment of patients with undiagnosed conditions and for decisions about the clinical management required, including prescribing. At present, doctors, dentists and certain nurses in respect of a limited list of medicines are legally authorised prescribers who fulfil the requirements for independent prescribers and this should continue. Certain other health professionals may also become newly legally authorised independent prescribers, subject to the process described below.*
  
- ii** *the dependent prescriber who is responsible for the continuing care of patients who have been clinically assessed by an independent prescriber. This continuing care may include prescribing, which will usually be informed by clinical guidelines and will be consistent with individual treatment plans; or continuing established treatments by issuing repeat prescriptions, with the authority to adjust the dose or dosage form according to the patients' needs. There should be provision for regular clinical review by the assessing clinician.*

**Recommendation 4:**

**There should be adequate arrangements for sharing information between independent and dependent prescribers. In particular,**

- i** *both clinicians should have access to a complete medication record, and*
  
- ii** *both clinicians should have access to relevant parts of the patient's medical record.*

6.20 Examples of the groups of professionals who might reasonably make early application to be given the legal authority to prescribe, and therapeutic areas in which they would have prescribing authority, are given at paras 6.38-6.39.

*Dependent prescribing vs supply and administration under group protocol*

6.21 There are some similarities between the concept of “dependent prescribing”, as we have defined it above, and the concept of supply or administration under group protocol, the subject of our first report. In both cases, a second professional would be required to assess the health care need of the individual patient, and provide appropriate treatment within a general care plan drawn up by another professional (usually a doctor) or team. There are, however, some important distinctions:

- i** *the dependent prescriber would be working within a care plan drawn up for the individual patient, following a full clinical assessment by the assessing clinician; while supply and administration under group protocols is intended mainly to deal with groups*

of patients who may not be individually identified before presentation for treatment, and where either there is an urgent need to initiate treatment, for example in intensive care, or where there is a low risk of interaction with other conditions or medicines;

- ii the dependent prescriber would have much greater discretion over the choice of the treatment regime, including the possible choice of medicines, than the professional supplying medicines under group protocol, whose discretion is likely to be limited to the exact specification of the protocol.

6.22 It is difficult to predict which model is likely to be more appropriate in particular clinical circumstances. Administration or supply within group protocol may be a suitable model where patients' clinical needs are broadly similar and individual prescriptions would be unwieldy or impracticable (as in mass vaccination campaigns), or where there is a need for urgent treatment (as in relief of acute asthma attacks by ambulance paramedics). Dependent or independent prescribing will be preferable where more detailed clinical assessment is needed and the range of treatment options required to meet the clinical needs of the patients is wider (as in family planning clinics). The Review Team does not expect administration or supply under group protocol to be widely adopted in circumstances which do not fully meet the criteria set out in the first report, simply because this appears to be an easier option than applying for authority to prescribe through the mechanisms proposed in this report.

### **Patient choice and patient consent**

6.23 If the recommendations in our two reports are adopted, a number of new models will become available for organising clinical care, including the prescribing and supply of medicines. We think that it is vital that any changes in the pattern of local service delivery should be introduced only after full consultation with patient interests, and wherever possible in such a way as to increase rather than reduce patient choice. Within the NHS Health Authorities,<sup>60</sup> Trusts and Primary Care Groups<sup>61</sup> will need to consider carefully the best way of consulting patients on proposed changes. Community Health Councils<sup>62</sup> are likely to have an important part to play, as may local branches of national patient groups.

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<sup>60</sup> Health Boards in Scotland, Health and Personal Social Services Boards in Northern Ireland.

<sup>61</sup> Local Health Care Co-operatives in Scotland, Local Health Groups in Wales [no equivalent has been established in Northern Ireland as yet].

<sup>62</sup> Health Councils in Scotland.

**Recommendation 5:**

***Changes to patterns of clinical care using new models for the prescribing, supply and administration of medicines should be introduced only after full consultation with patient interests, and should wherever possible increase patient choice.***

**Proposed process for approving new prescribers**

6.24 The Review Team considers that the first stage in any extension of prescribing should be the assessment of the case for a specific professional group. Following approval of the group, individual members of the profession would be entitled to undergo training leading to registration as authorised prescribers. The stages would therefore be:

- i *approval of professional group* - an appropriate professional organisation,<sup>63</sup> acting on behalf of a defined professional group, would put forward an application to ministers<sup>64</sup> for suitably trained professionals within the group to be eligible to apply for the authority to prescribe in a defined therapeutic area;
- ii *approval of individual practitioners* - individual professionals within an approved group would undertake additional training and would then apply to the profession's regulatory body, under criteria to be agreed as part of stage (i), for inclusion in the register of approved prescribers.

The steps involved in the two stages are summarised in Diagrams 1 and 2, on pages 47 and 54.

**Proposed arrangements for the extension of prescribing to new professional groups**

***Advice to Government***

6.25 The Review Team has considered the possible mechanisms for advising Government on applications from professional groups.

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<sup>63</sup> This could be the national regulatory body, or the national body responsible for setting educational standards, or a recognised body representing the interests of a particular group within the profession.

<sup>64</sup> When the devolution acts come into force, responsibility for certain NHS issues will be devolved. Depending on the precise context, "ministers" for the purpose of this report may encompass ministers of the Crown and some or all of ministers of the Scottish Parliament, ministers of the Northern Ireland Assembly, and the executive of the Welsh Assembly.

The main options are:

- i A sub-committee of one of the existing Medicines Act committees, ie either the Medicines Commission or the Committee on Safety of Medicines (see para 2.12 -2.15).*

The benefits of this option are

- ❖ it would in some ways be a logical extension of the advisory functions of the Committee on Safety of Medicines (CSM) or the Medicines Commission;
- ❖ it would make effective use of the expertise in the Medicines Control Agency (MCA) which provides the secretariat for both the CSM and the Medicines Commission;
- ❖ the CSM would in any case need to be consulted on the *specific* medicines which new prescribers could safely prescribe (see below).

There are however some difficulties which, in the view of the Team, would make this option undesirable:

- ❖ one of the major criteria for assessing applications (see below) would be the adequacy of the proposed arrangements for training, updating of skills and audit. None of the existing Medicines Act bodies are, at present, constituted in such a way as to ensure expertise in these areas;
  - ❖ even if a sub-committee with appropriate skills and expertise were assembled, the fact that it was formally answerable to a committee without this expertise might undermine its credibility with those professional groups which would be making applications;
  - ❖ the current role of both the Medicines Commission<sup>65</sup> and of the CSM is in practice largely confined to advising on the issues covered by the Medicines Act itself, ie the safety and efficacy of licensed medicines and the use of medicines whether inside or outside the NHS.
- ii a joint committee of the regulatory and other professional bodies (General Medical Council, General Dental Council, Medical Royal Colleges and Faculties, UKCC, RPSGB etc).*

This option would bring together much of the necessary expertise for the judgements to be made. It has three major drawbacks:

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<sup>65</sup> In law, the Medicines Commission may advise on any aspect of the use of medicines, whether or not covered by the Medicines Act. We understand however that it would be unusual for the Department to seek the advice of the Commission on issues such as whether medicines should be prescribable at NHS expense.

- ❖ it lacks independence. Applications for extended prescribing authority would in most cases be coming from bodies which, directly or indirectly, form the joint committee, so their representatives would be put in the invidious position of “judge and jury”;
  - ❖ arrangements would have to be made for the inclusion of other important groups, such as patient representatives, NHS commissioners, and NHS provider management;
  - ❖ there may be occasions when the interests of one or more of the constituent bodies might be affected by the proposals under consideration, thus undermining the independence and impartiality of the process.
- iii *a new body independent both of existing Medicines Act committees and of the professional bodies.*

This option has several advantages:

- ❖ it would be able to offer independent and impartial advice to ministers;
- ❖ members would be chosen on the basis of their *personal* expertise, and would not represent particular interests or organisations;
- ❖ the terms of reference could make clear that the body was expected to conduct its work and express its opinions openly, without reference to a parent body. It could be required to publish both the general criteria by which applications would be judged and the reasons for particular advice;
- ❖ it would be able to advise ministers on whether prescribing by new groups should be eligible for public funding through the NHS.

6.26 On balance, therefore, the Review Team favours option (iii). The team considers that there could be advantages in setting up such a committee as a statutory committee under Section 4 of the Medicines Act (see para 2.13 and Annex D), although it understands that this would require some amendment to primary legislation if this committee were to advise ministers on cost-effectiveness. Whatever the legislative basis, it would be important to ensure that the new committee could be asked to advise on all aspects of proposals for new groups of prescribers. Although established under the Medicines Act, the new committee would not be directly answerable to the Medicines Commission or the CSM.

6.27 Since medicines legislation applies across the UK, the Team considers that the remit of the new body should similarly be UK-wide.

**Recommendation 6:**

***A UK-wide advisory body, provisionally entitled the “New Prescribers Advisory Committee”, should be established under Section 4 of the Medicines Act to assess submissions from professional organisations seeking powers for suitably trained members to become independent or dependent prescribers.***

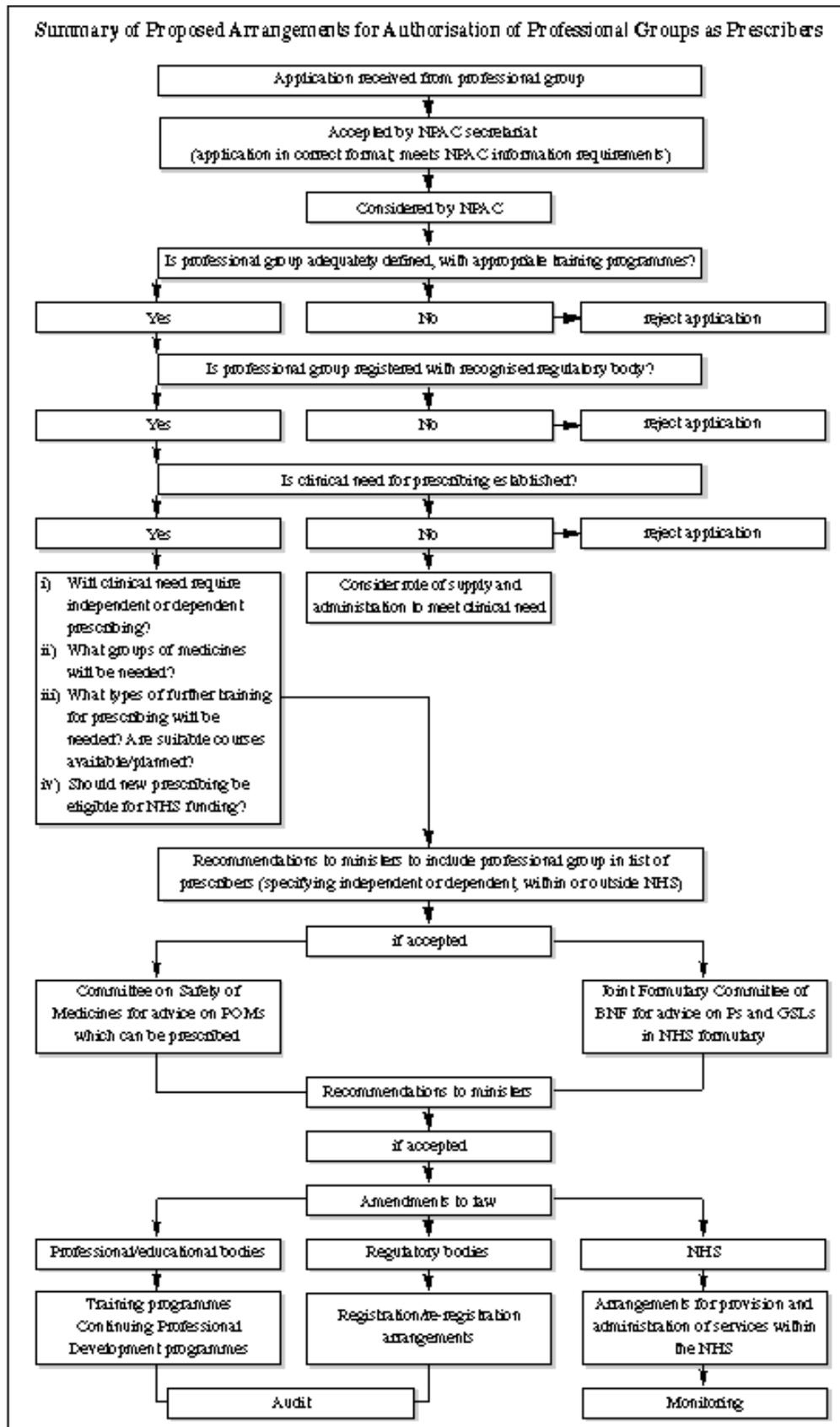
For the remainder of this report, we refer to the proposed new body as the “New Prescribers Advisory Committee” (NPAC). The proposed functions and responsibilities of NPAC are described below and a possible outline process for dealing with submissions is set out in Diagram 1.

6.28 The team proposes that the NPAC should promulgate clear criteria for extensions to prescribing, and should advise on the following aspects of individual applications:

- ❖ the clinical need for the proposed extension of prescribing;
- ❖ the definition and registration arrangements of the professional group concerned, ensuring that there are clear criteria for determining which individuals may be included in the group. This may include consideration of the education and training requirements for the group;
- ❖ the need for additional prescribing to be “independent” or “dependent” in the sense defined above;
- ❖ the broad category(ies) of medicines that might be prescribed;
- ❖ the need for prescribing by the new group to be funded by the NHS.

6.29 If ministers approved a recommendation from NPAC that an application from a particular professional group should be accepted, the proposal would pass to the CSM, for advice on which specific POMs (if any) members of the group could safely prescribe, and to the Joint Formulary Committee of the British National Formulary for advice on which P and GSL medicines could be prescribed at NHS expense. The Medicines Commission might wish to comment on the process as a whole, though it would not necessarily need to advise on each separate application.

Diagram 1



6.30 Possible terms of reference for the NPAC are set out in the box below.

**Suggested terms of reference for the New Prescribers Advisory Committee**

“To advise ministers on the extension of prescribing authority to health professions; and in particular

- i to establish criteria for the inclusion of professional groups on the list of professions whose members may, subject to successful completion of additional training, become authorised independent or dependent prescribers;
- ii to assess applications from professional groups for inclusion in the list of authorised independent or dependent prescribers, taking into account
  - ❖ the clinical need for the proposed extension of prescribing authority;
  - ❖ the definition of the professional group and the arrangements for initial and continuing education and training, assessment and registration;
- iii to form an initial assessment as to the range of medicines which professional groups might prescribe, and the arrangements which would be required for training in prescribing;
- iv to assess any implications for the supply of medicines, and in particular, where the proposals could result in a professional prescribing and supplying POMs to the same patient, to advise on any safeguards needed to maintain patient safety and ensure probity;<sup>66</sup>
- v to advise whether prescribing by the new group should be eligible for public funding through the NHS;
- vi to keep these arrangements under review.”

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<sup>66</sup> See paras 6.56-6.59 for further discussion of this aspect.

### **Composition of the New Prescribers Advisory Committee**

6.31 The members of the NPAC should be chosen for their personal expertise, and not as representatives of any particular interest or body. Nevertheless, a wide range of perspectives will be needed. These include:

- i current prescribers
- ii other relevant health care professions
- iii professional regulatory bodies
- iv education and training accrediting bodies (currently the National Boards for Nursing, Midwifery and Health Visiting; the Medical Royal Colleges and Faculties; the Royal Pharmaceutical Society of Great Britain; and the professional Boards of the Council for Professions Supplementary to Medicine)
- v NHS commissioners and provider units
- vi patient groups

with perhaps an observer from the Medicines Commission. The composition of the body would need to reflect its UK-wide responsibilities. In order to maintain its independence, members should be appointed by health ministers, after consultation with relevant organisations.

6.32 The Review Team recognises that ministers will wish to consider further whether the new advisory committee should be established on a statutory or non-statutory basis. Whatever its status, the Team would expect its recommendations to be communicated clearly to the public and to the professions concerned, and to be in the public domain.

### **Arrangements for applications**

#### **Source of Applications**

6.33 Applications for prescribing authority would be made on behalf of health professions or specific groups within major professions, such as nurses specialising in asthma care or family planning, or pharmacists specialising in advising patients on discharge medication or in anti-coagulation treatment. Submissions could be made *either* by a national body representing the interests of the profession as a whole, or by a specialty association. In the latter case the association should indicate whether or not the proposal is supported by the main national body(ies). In every case, the professional organisation putting forward the submission will need to confirm that the group is defined by completion of an accredited training programme leading to a specialist qualification which is formally recognised by the appropriate regulatory body. In addition, evidence will be required that the regulatory body has been consulted and

is content with the proposals for assessing and registering or recording any further training required for prescribers.

**Recommendation 7:**

***Proposals for new professional groups to be considered as potential prescribers will be expected to come from nationally recognised organisations. They should confirm that the group is formally recognised by the appropriate regulatory body and that that body has seen and is content with the proposed arrangements for training in prescribing and for registration.***

**Criteria for applications**

6.34 It would be for the new body to determine the precise criteria for assessing applications from professional groups to become independent or dependent prescribers. The Review Team suggests that the criteria might be based on the following questions:

- i What clinical benefits are expected to be derived from the proposed extension of the authority to prescribe? Could these benefits be secured in a different way, for example through use of supply or administration under group protocol, or through amendments to the POM Order, by removing the prescription only status of particular medicines?<sup>67</sup>
- ii What impact would the change have on patient convenience and patient choice?
- iii Does the proposed process ensure that only professionals with appropriate specialist qualifications, recorded or registered with the appropriate professional regulatory body, would be allowed to apply for prescribing authority?
- iv Are there adequate arrangements for ensuring that all new prescribers will:
  - ❖ undergo satisfactory training in all relevant aspects of prescribing?
  - ❖ undertake regular continuing professional development related to their prescribing, approved by the appropriate professional body?
  - ❖ participate in professional audit or other quality assurance activities?
- v What would be the benefits from allowing prescribing at public expense, and are these sufficient to justify any additional costs which might be incurred?

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<sup>67</sup> Amendments to the POM Order are made on the advice of the CSM. The initiative in seeking amendments usually comes from pharmaceutical companies, but there is no reason why proposals should not also be put forward by professional groups.

### ***Content of applications***

- 6.35 The Review Team would therefore expect each professional group to demonstrate to the new body that:
- ❖ patient care and/or patient convenience would be improved if all or some of its members were to become authorised prescribers;
  - ❖ its members are fully qualified professionals registered with a recognised regulatory body;
  - ❖ successful completion of any additional training required to practice in the specialist area relevant to the proposed prescribing would be accredited and registered or recorded with a recognised regulatory body;
  - ❖ its members would have access to approved training programmes for prescribing, and for any additional clinical skills required to ensure safe and appropriate prescribing;
  - ❖ there would be adequate arrangements for assessing the competence of members who had completed training; and for ensuring that all members (including where relevant those intending to work outside the NHS) participate in clinical audit and in continuing professional development relevant to prescribing skills.

Submissions should clearly indicate whether the proposal is for *independent* or *dependent* prescribing authority, and (in broad terms) what medicines or groups of medicines might be prescribed.

### ***Monitoring and updating the new arrangements***

- 6.36 As clinical practice develops, the conditions which applied when the NPAC first considered the application for a particular professional group may change. In general, the responsibility will lie with professional organisations and professional regulatory bodies to keep under review the training requirements and other safeguards for new prescribers, to exploit new opportunities to improve services and to ensure that patient safety is at all times preserved (see Chapter 8). However, the NPAC may itself need on occasion to take the initiative by requiring professional groups to submit evidence to show that prescribing by a particular group is still safe and effective.
- 6.37 The Review Team also expects that the range of medicines available to the newly authorised groups of prescribers will need to be reviewed regularly to ensure that up-to-date clinical practice can be maintained. Proposals for changes relating to NHS prescription of P or GSL medicines could be considered by an appropriate sub-committee of the British National Formulary's Joint Formulary Committee (see para 6.29). Proposals to vary the range of POMs which a particular group could prescribe would need to go to the CSM, which is responsible for advising ministers on any changes to the POM Order (see para 2.14).

### **Possible early candidates for prescribing authority**

6.38 The Team was asked to develop a *general* framework for any possible extension of prescribing authority, rather than to recommend extension to any *particular* professional groups. Nevertheless, in the course of our work we considered a variety of circumstances in which extended prescribing might, subject to proper safeguards, lead to better patient care. Those with the strongest support are where:

- i prescribing is limited to the choice between a relatively small range of medicines in which the prescriber can be expected to develop a considerable degree of expertise;
- ii clinical assessment is within a fairly narrow range of possibilities, either because patients are seeking specific care or because they have already been assessed by another clinician. Prescribers must, however, be aware of unusual presentations or possible contraindications which would require referral back to the clinician with overall responsibility for the patient's care.

6.39 The following illustrative examples suggest a number of professional groups which may wish to consider applying at an early stage for the authority to prescribe medicines (including where appropriate prescribing POMs and incurring NHS expenditure). This list is not exclusive.

#### *Independent prescribers*

- i **Family planning nurses.** Nurses in family planning clinics are very often patients' first contact with the health care system, and the relative ease and informality of access is an important strength in this service. This is a typical example of prescribing in a specialised area, from a relatively limited list of products, by highly trained practitioners.
- ii **Tissue viability nurses.** Nurses with special expertise are often asked to assess the viability of a patient's skin, typically in the patient's own home. A diagnosis is established and treatment started immediately. As independent prescribers, tissue viability nurses would be able not only to prescribe themselves, but also to develop a care plan for a dependent prescriber to follow.
- iii **Chiropodists and podiatrists.** Specialist podiatrists undertake some forms of foot surgery. Although they are currently able to supply a limited range of medicines, a small expansion of the list, and the ability to prescribe as well as supply, would enhance significantly the care they could give to patients.
- iv **Specialist physiotherapists** (also known as extended scope practitioners). Specialist physiotherapists now work independently in outpatient clinics assessing, diagnosing, and taking sole management responsibility for patients. They can already order investigations, and refer on to other specialists. Prescribing would entail the use of a small range of medicines including analgesics and non-steroidal anti-inflammatory medication, for both oral use and for injection.

- v **Optometrists.** Optometrists' expertise relating to the eye and visual system, coupled with the use of specialised diagnostic instruments, is the basis of the care they provide in the community, including domiciliary visits. Having established a diagnosis, prescribing would allow them to provide effective treatment for emergency eye conditions and non-sight-threatening eye conditions.

*Dependent prescribers*

- vi **Specialist diabetes nurses.** Diabetes nurses are already skilled in advising patients with diabetes, training them in the use of insulin or other therapies, and assessing and changing the dose required. Typically, a newly presenting patient is seen in the first instance by a hospital specialist who establishes a diagnosis of diabetes mellitus. If diabetes nurses were approved as dependant prescribers they could take over clinical responsibility at this point, assess the precise requirement for insulin or other medicines, prescribe as needed, and supervise continuing treatment, referring back to the doctor as necessary.
- vii **Specialist asthma nurses.** Patients who have been diagnosed as suffering from asthma by a doctor could be followed up by an asthma nurse. The nurse would undertake a clinical review, including an assessment of the patient's respiratory function. Within the framework of the patient's care plan the nurse would be able to vary the treatment and prescribe further medication as required.
- viii **Specialist palliative care nurses.** Palliative care nurses work closely with medical and nursing colleagues in hospitals and in the community, and have particular expertise in symptom control and the management of pain. Typically, a patient would be seen by a hospital specialist or GP (the independent prescriber). Responsibility would then pass to the palliative care nurse who would, if a dependent prescriber, be able to review and revise medication, within the overall care plan.
- ix **Pharmacists in specialist areas,** such as oncology, asthma or diabetes clinics. Pharmacists would bring wide experience and knowledge of clinical pharmacy and pharmacology, including potential drug and food interactions, as well as specialist knowledge of the particular clinical area. Pharmacists already interpret the results of drug monitoring, undertake assessments, titrate therapy and counsel patients, but currently require any prescriptions to be signed by a doctor.
- x **Pharmacists carrying out reviews of patients' medication,** eg patients on multiple therapy. Pharmacists in primary care already have extensive experience of medication reviews,<sup>68</sup> where they are able to alert the GP prescriber to possible drug interactions or to changes in the patient's condition. This often leads to a proposal for alternative and more appropriate drug choices. As dependent prescribers, pharmacists could be given

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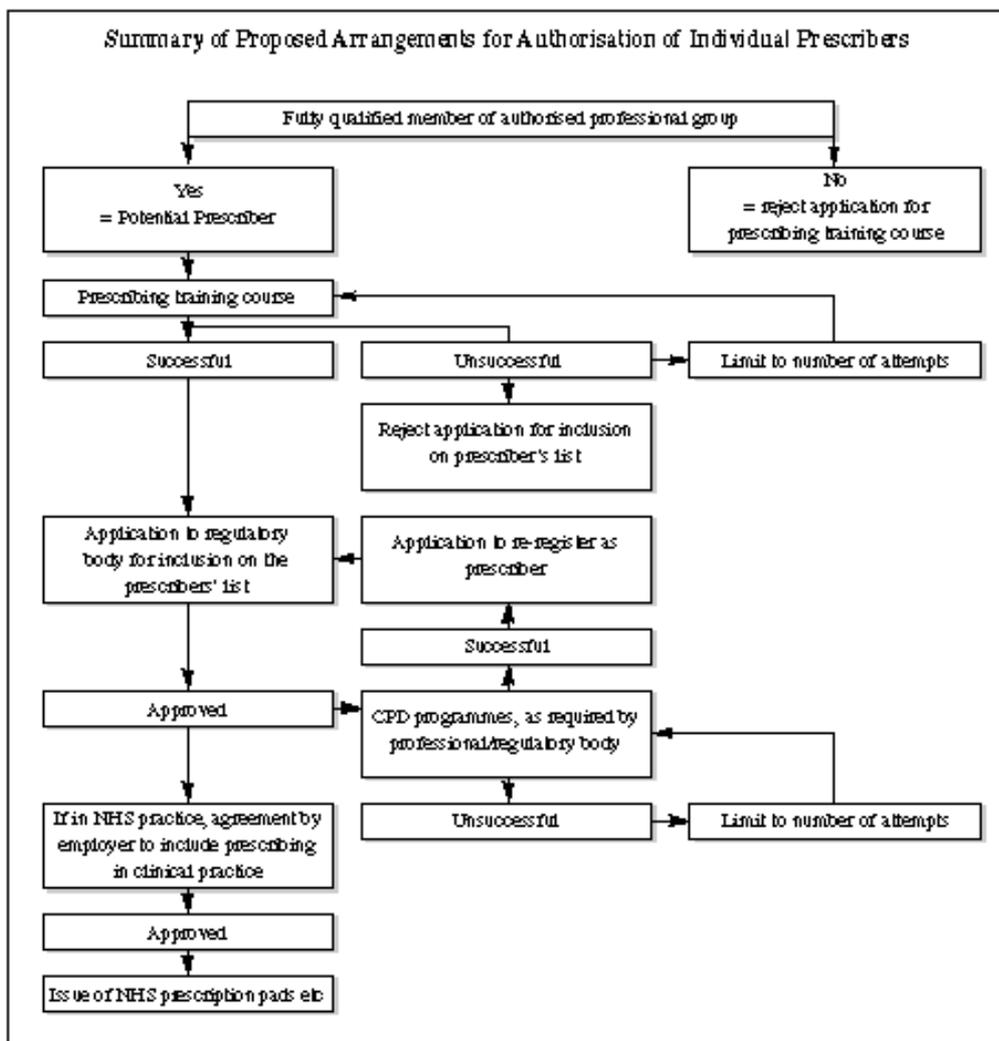
<sup>8</sup> National Prescribing Centre and NHS Executive. *GP Prescribing Support: a resource document and guide for the New NHS.* September 1998.

limited discretion to vary treatment on their own initiative, within limits agreed with the independent prescriber. Clear arrangements for such joint working would need to be developed, and should include mechanisms to ensure that the GP is informed as soon as practicable of any change in treatment and that the patient is given clear advice and written information about any variations in treatment.

**Proposed arrangements for the authorisation of individual practitioners as prescribers**

6.40 The Review Team envisages that individual practitioners who are fully qualified members of professional groups which have been approved for prescribing would become authorised prescribers by a process which is outlined in Diagram 2.

*Diagram 2*



- 6.41 At the present time, such practitioners will have to undertake an approved training programme for prescribing. In the future, training for prescribing may be incorporated into other professional training programmes. If this occurs, these arrangements would have to be suitably modified.
- 6.42 The Review Team considers that there would be advantages in developing training programmes for prescribing which consist of a core of topics which would be required by candidates from all professional backgrounds, together with specific modules related to the clinical specialities and medicinal products relevant to individual groups. Such arrangements would foster multidisciplinary learning and make best use of the educational resources available for prescribing training. All training programmes should include a period of supervised practice.
- 6.43 An individual who wished to become an authorised prescriber would be required to demonstrate to the body responsible for the approved training programme that s/he was a fully qualified and registered member of a professional group which had been approved to prescribe. Anyone not able to provide such evidence would not be accepted on a course.
- 6.44 On completion of the course and following assessment of the skills attained, successful candidates would be able to apply to the relevant regulatory body for inclusion on the list of authorised prescribers. Unsuccessful candidates would be required to retake all or part of the course. The relevant professional bodies should give consideration to the number of resits that should be allowed.
- 6.45 When duly registered, prescribers should be required to complete an approved continuing professional development programme relevant to their prescribing responsibilities. The professional and regulatory bodies should determine the frequency of re-registration as a prescriber, the criteria for successful completion of continuing professional development programmes and the number of attempts allowed, subject to approval by NPAC.
- 6.46 The arrangements proposed above would apply to professional practice in any sector. For those professionals working in the NHS, in groups which have been recommended by NPAC and approved by Government as authorised NHS prescribers, an additional step is required.
- 6.47 Within the NHS, changes in the content of jobs to include undertaking prescribing responsibilities must be approved by the employer<sup>69</sup> within locally agreed patterns of health care provision. The authority to prescribe may be a requirement in the job description for some posts in the future. Arrangements will be required for approved NHS prescribers to be issued with NHS prescription pads and for other administrative procedures to be established.

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<sup>69</sup> Or, in the case of a PMS pilot scheme (see Annex D) led by the professionals seeking to prescribe, by the health authority in contract with the pilot practice.

## **Particular prescribing issues**

### *Pre-registration house officers in general practice placements*

- 6.48 Pre-registration house officers (PRHOs) are doctors who have successfully completed undergraduate medical training and are provisionally registered with the GMC. They undergo a further year of supervised general clinical training (the “PRHO year”), usually in a hospital setting, before they can be fully registered. PRHOs are not currently expected to issue prescriptions, although in the hospital setting they will be expected to make entries on medicine charts either under the supervision of a fully registered doctor or, exceptionally, on their own initiative.
- 6.49 PRHOs may now spend part of their 12-month training on a clinical placement in general practice. It has been suggested that PRHOs in general practice might be given the authority to prescribe not only under direct supervision but, when their supervisor considers they are ready to do so, on their own responsibility, as a stepping-stone towards the further responsibilities they will have as fully registered doctors.
- 6.50 In considering these issues, the Team has had regard to three factors:
- i the need to expose PRHOs to an increasing level of responsibility;
  - ii the need to preserve the principle that PRHOs, whilst making a service contribution, are progressively developing their skills under supervision as part of their educative process;
  - iii the overriding need to protect patient safety.
- 6.51 We believe that PRHOs have sufficient education in clinical diagnosis and in clinical pharmacology and therapeutics, both theoretical and practical, to be able to develop their experience and training by prescribing within the supervised environment of the pre-registration year. We therefore recommend that the GMC agrees with postgraduate deans a safe framework within which this could take place. This framework, which should apply equally to approved PRHO placements in all clinical sectors, would allow PRHOs at the discretion of their supervising clinician to prescribe all appropriate medicines relevant to the duties of their post. This prescribing should be subject to close monitoring by their supervisor, with due regard to the proper discharge of supervisory responsibility as specified in para 8.8 and Recommendation 21.

**Recommendation 8:**

***The GMC and postgraduate deans should agree a safe framework within which pre-registration house officers (PRHOs) could prescribe medicines relevant to the duties of their post. Such prescribing should be subject to close monitoring by their clinical supervisor, with due regard to the proper discharge of supervisory responsibility as specified in Recommendation 21.***

*Newly-arrived overseas doctors and dentists*

6.52 Most overseas doctors and dentists come to the UK for postgraduate medical education with sufficient clinical experience to be accepted from the outset as authorised prescribers. In some cases, overseas doctors need to requalify via the primary qualifying diplomas of the United Examining Board. In these circumstances, they would be given provisional registration and would need to undertake a clinical placement analogous to a UK PRHO. The considerations in such cases are exactly parallel to those discussed in the previous section.

**Recommendation 9:**

***Overseas doctors given provisional registration by the GMC and required to undertake clinical training similar to that of a PRHO, and overseas dentists, given temporary registration by the GDC to practice in an approved training post in a NHS hospital, should be able to prescribe under similar safeguards to those described in Recommendation 8.***

**Medicines which should not normally be available to new groups of prescribers**

6.53 A number of groups of medicines should, for a variety of reasons, not normally be available to new groups of prescribers. Examples include:

- i *controlled drugs* which are subject to the special provisions of the Misuse of Drugs Act 1971 (see Annex D paras 23-27);
- ii *unlicensed drugs or drugs used outside their licensed indications*, including drugs undergoing pre-licensing clinical trials, and certain medicines which are commonly used for children but have never been licensed for paediatric use;
- iii *“black triangle” drugs*, which are newly-introduced drugs, still subject to special monitoring for potential side-effects by the MCA (so called because they are identified by a black triangle symbol in the British National Formulary);
- iv *drugs over which there is continuing professional concern*, for instance drugs used to treat children and young people with mental health problems;
- v *drugs which on public health grounds should be subject to particular care*, for instance antibacterial antibiotics.

6.54 Where, exceptionally, a group of new prescribers can demonstrate a good clinical case for prescribing antibacterials or other antibiotics, it is expected that this would be for a very limited range of drugs and for very clearly defined clinical indications, and subject to the safeguards advocated in the recent reports from the Standing Medical Advisory Committee<sup>70</sup> and the House of Lords Science and Technology Committee.<sup>71</sup>

***Recommendation 10:***

***Newly authorised groups of prescribers should not normally be allowed to prescribe medicines in the following categories:***

- i controlled drugs (drugs subject to the Misuse of Drugs Act 1971);*
- ii unlicensed drugs or drugs used outside their licensed indications;*
- iii “black triangle” drugs;*
- iv drugs over which there is continuing professional concern, eg drugs used to treat children and young people with mental health problems;*
- v drugs which on public health grounds should be subject to particular safeguards, for instance antibacterial antibiotics.*

**Implications for the sale, supply and administration of medicines**

6.55 This section considers the relationship between the recommendations in this report for possible extension of the authority to prescribe, and arrangements for the sale, supply and administration of medicines. It is concerned with the supply of medicines to individual patients, as opposed to groups of patients, which was the subject of this Review’s first report (see para 1.3 and Annex C).

***Sale and supply of medicines***

6.56 Many of the submissions to the Review Team supported, as a general rule, the continued separation of the prescribing and supply of medicines in respect of the same patient.

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<sup>70</sup> *The path of least resistance: A report by the Standing Medical Advisory Committee Sub-Group on Antimicrobial Resistance* (Department of Health, London, 1998).

<sup>71</sup> House of Lords Science and Technology Committee. *Resistance to antibiotics and other antimicrobial agents: seventh report from the Science and Technology Committee: Session 1997-98* (London: Stationery Office, 1998 (HL81; Vol 1)).

6.57 The separation of these actions provides two important safeguards:

- i it provides a check on the accuracy of the prescribing decision. It enables a second health professional (usually a pharmacist) to apply further professional skills and knowledge before the medicine is supplied. It also gives the patient or carer a further opportunity to discuss the medication and its use;
- ii in the context of NHS reimbursement, it provides a safeguard against fraud and abuse.

6.58 The Review Team considered whether these reasons for the separation of prescribing and supply continue to be valid, in particular in the case of *dependent* prescribing where a second professional is already involved. On balance, we concluded that

- i separation of prescribing and supply should in the case of initial prescribing still be regarded as the ideal, both for reasons of patient safety and for probity;
- ii there might however be circumstances in which the traditional separation might not be in the patient's best interest. Each case would need to be considered on its merits, on a prudent assessment of the risks and benefits of any relaxation. Such cases might for instance include, in addition to the long-standing arrangements for dispensing by doctors in rural areas and by dentists where immediately continuing treatment is necessary, the following:
  - ❖ the need for emergency supply of medicines, to the extent that this is not already covered by the current provision for the emergency sale or supply of medicines by pharmacists;<sup>72</sup>
  - ❖ instances in which a pharmacist authorised as a dependent prescriber amends a prescription by correcting obvious errors in dosage, nomenclature etc as part of the dispensing process;<sup>73</sup>
  - ❖ sale of P and GSL medicines, where it is already lawful and common practice for pharmacists to advise patients on the possible choice of medicines ("prescribe" in sense (iii) of the Glossary) before supplying the chosen product;
- iii any exceptions to the general principle, in particular for POM medicines and for medicines supplied at NHS expense, should be subject to clinical and probity audit, to minimise any risks to patient safety or scope for abuse.

The Team also expects that pharmacists will continue to supply the vast majority of medicines.

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<sup>72</sup> Article 8 of the POM Order 1997.

<sup>73</sup> As a matter of good professional practice the dependent prescriber would be expected either to consult the independent prescriber in advance, or to notify the changes made as soon as possible afterwards.

6.59 The Team recognises that some professional groups which currently have the authority to sell or supply certain medicines in the course of treatment may apply for new powers to prescribe those medicines. If their applications are successful, individual members of those professions could be put in the position where they could have the legal power to sell or supply POMs which they themselves have prescribed. We recommend that professional organisations, in putting forward proposals for extensions to prescribing, should consider whether these proposals could put their members in the position of both prescribing and supplying POM medicines to the same patient and if so what safeguards are required to maintain patient safety and ensure probity.

**Recommendation 11:**

***Initial prescribing and supply of medicines should normally remain separate functions in order to protect patient safety and provide other safeguards. Where a prescription cannot be furnished, the current arrangements for the emergency sale or supply of medicines should apply.***

**Recommendation 12:**

***Where exceptionally it is in the interests of patients for the same professional to be responsible for prescription and supply of medicines, this should be subject to clinical audit and probity checks.***

**Recommendation 13:**

***Professional organisations, in putting forward proposals for extensions to prescribing, should consider whether this could result in members prescribing and supplying POMs to the same patient, and if so what safeguards are required to maintain patient safety and ensure probity. The NPAC, in assessing any proposals from professional groups which could result in members prescribing and supplying POMs to the same patient, should consider the adequacy of the safeguards proposed.***

**Administration of Medicines**

6.60 The “administration” of a medicine is the term used to describe the act of putting into effect a medicine either by introduction into the body, whether by direct contact with the body or not, or by external application (see Glossary). The administration of a medicine is preceded by its supply. Chapter 2 describes the restrictions on the supply of medicines which provide safeguards to patients. There are no additional restrictions on any medicine which is self-administered by the patient, or on the administration of any P or GSL product or POM administered orally. The only additional restrictions relate to parenteral (injectable) POMs which can only be administered:

- i by an “appropriate practitioner” (ie a doctor or dentist and certain nurses in respect of a limited list of medicines); or
- ii in accordance with the directions of an “appropriate practitioner”.

6.61 The Review Team proposes that newly authorised prescribers should be legally defined as “appropriate practitioners” in respect of designated medicines. This means that they would have the power to (i) administer POMs which they are authorised to prescribe, and (ii) give directions concerning the parenteral administration of POMs. In our view, this would be a natural extension of their prescribing responsibilities.

6.62 In making this recommendation, the Review Team is assuming that all staff who administer POMs under the direction of new prescribers are or will be suitably trained. This has two consequences:

- i in putting forward proposals for extended prescribing, professional groups should consider any implications for the administration of medicines and should be able to give assurances that all training aspects have been covered;
- ii employers and managers in all sectors who are responsible for staff who administer or who supervise the administration of medicines should ensure that they have adequate and up-to-date knowledge and skills. The Review Team has been made aware of suggestions that this may be a particular issue in sectors outside the NHS where staff other than qualified health professionals need to administer medicines, eg schools, prisons, and local authority residential homes (see Annex H).

***Recommendation 14:***

***The current arrangements for the administration and self-administration of medicines should continue to apply. Newly authorised prescribers should have the power to administer those parenteral prescription only medicines which they are authorised to prescribe, and to issue directions for the parenteral administration of the same medicines.***

***Recommendation 15:***

***Professional organisations, in putting forward proposals for new groups of professionals to have the authority to prescribe certain medicines, should consider the implications for administration of medicines and should ensure that all necessary training aspects are covered in their proposals.***

**Recommendation 16:**

***Employers and managers in all sectors who are responsible for staff who supervise or undertake the administration of any medicines should ensure that those staff have the right training and skills to do so safely and regular opportunities for updating their knowledge.***

**Repeatable Prescriptions**

6.63 Medicines legislation<sup>74</sup> authorises prescribers to indicate on the prescription that it may be dispensed more than once. It is not at present possible for a medicine to be dispensed and reimbursed more than once against the same NHS prescription,<sup>75</sup> so repeatable prescriptions are only used in the private sector. This means that when a patient requires long-term medication in the NHS, the patient has to apply to the prescriber for another prescription, known as a “repeat prescription”. The Review Team considers that this arrangement is inconvenient to patients and could result in poor adherence to treatment.

6.64 The Medicines Act also provides that no prescription can be dispensed more than six months after the date on which it was signed. However, for repeatable prescriptions, only the first dispensing must be within six months. There is no time limit for subsequent dispensing, unless specified by the prescriber, and no limit on the number of times the prescriber can direct the product to be dispensed. This means that a medicine can be dispensed long after the need for treatment has been established and possibly even when treatment may no longer be appropriate. This is wasteful and potentially dangerous.

6.65 The Review Team therefore recommends that repeatable prescriptions should be available within the NHS, and that in all health care sectors they should be subject to restrictions on the number of times they can be dispensed and on the duration of their validity.

**Recommendation 17:**

***Repeatable prescriptions should be available on the NHS.***

**Recommendation 18:**

***Limits should be introduced for the number of times a repeatable prescription can be dispensed and the duration of its validity. These restrictions should apply across all sectors, and not be limited to NHS practice.***

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<sup>74</sup> The Prescription Only Medicines (Human Use) Order 1997.

<sup>75</sup> There are exceptions, for instance certain controlled drugs may be ordered on a special form to be dispensed in regular (typically daily) instalments.

## Chapter 7: Likely Impact of the Proposed Changes

7.1 This chapter fulfils the second part of our terms of reference:

“to advise on the likely impact of proposed changes on clinical outcomes, the convenience of health care users, professional relationships, and costs”.

Inevitably, our predictions are somewhat speculative. We do not know how our recommendations, if they are accepted by Government and the professions, will be implemented, nor do we know which professional groups will put forward a sufficiently convincing case for extended prescribing authority. However, we are confident that our recommendations will lead to benefits in the following broad areas.

### Clinical Outcomes

7.2 We believe that our recommendations will bring clear benefits to patients in three main areas:

- i Our proposals will *make more effective use of the skills and experience of groups of professionals who are not at present authorised to prescribe*. In particular:
  - ❖ in many clinical situations, we foresee an end to the artificial separation of the prescribing decision from other aspects of the patient’s clinical management, creating clearer accountability and increasing the patient’s confidence in the consultation;
  - ❖ the prescribing choice can be made by the professional with particular specialist skills and experience, resulting on occasions in more clinically appropriate and sympathetic prescribing and reducing the potential for wasteful use of resources;
  - ❖ dependent prescribing, in particular, opens up the possibility of making more effective use of the expert knowledge of a wider range of professionals, allowing the clinician responsible for the initial assessment to concentrate on the broad clinical management of the patient.
- ii We expect in some important instances to see an improvement in *patients’ access to advice and treatment*, resulting in better uptake of services and better concordance between the perceptions of patients and professionals:
  - ❖ in some situations, improved access to the prescriber will result in more timely initiation of treatment with, in some cases, reduced duration of illness, better control of chronic disease, and fewer complications;
  - ❖ some vulnerable groups of people who find it difficult to access care at present may be more easily contacted by prescribers who will be able to initiate treatment immediately, reducing the risk of loss of contact with care services;

- ❖ some new prescribers may in the course of their duties already be spending significant time with patients, resulting in better communication and thus improved adherence to treatment programmes.
- iii Our proposals should on some occasions lead to *better clinical oversight* of patients' medication. In particular, we think that the facility for repeatable prescriptions will encourage general practitioners to set a realistic interval for full review of patients' overall clinical management, allowing pharmacists in the intervening period to assess any obvious changes in patients' condition or continuing need for medication.
- iv Our recommendations should ensure that all newly authorised prescribers will undertake continuing education and clinical audit related to their prescribing responsibilities, encouraging the more rapid dissemination of up-to-date practice informed by evidence on clinical and cost effectiveness. We expect that the professional bodies responsible for standards of practice for existing prescribers will wish to take account of our recommendations in the context of their arrangements for continuing professional development.

### **Convenience of Users**

- 7.3 Our proposals will lead to *a more convenient, "seamless" service*. For example,
- i in the community setting, patients will be able to receive prescriptions more simply at the time of a home visit, or visit to an appropriate specialist, without the need to go to the surgery solely to pick up a prescription. One example would be treatment of patients in their own homes by tissue viability nurses;
  - ii in the hospital setting, delays in discharge experienced by patients waiting for medicines to take home can be reduced;
  - iii repeatable prescriptions will allow patients on long-term medication to renew their supplies of medicines more simply, without any reduction in the level of clinical oversight of their continuing need for the medication;
  - iv in certain circumstances, patients will be able to choose which health professional will be responsible for aspects of their care, including prescribing.

### **Professional Relationships**

- 7.4 Relationships between professionals will be enhanced, both in primary and secondary care, through
- i more effective teamwork, with the improved use of the full range of skills and experience of all team members;

- ii improved mutual recognition and respect for the contribution which other professions can make;
- iii greater clarity of roles and responsibilities across professions.

## Use of resources

### *Prescribing costs*

- 7.5 The Review Team has worked on the assumption that most patients are receiving adequate care under the NHS at present and an extension of the authority to prescribe will not result in significant increases in the volume of prescribing. Any potential increase in volume should be offset by more appropriate, timely and cost-effective prescribing, improved quality of care, less waste, and reduced costs to other parts of the public sector or to informal carers.
- 7.6 However, a widespread extension of the authority to prescribe has not yet been tested, and generalised conclusions for all possible groups of new prescribers cannot be drawn from the nurse prescribing pilots evaluated to date. Some financial savings can be expected from improved patient adherence to treatment and better management of repeat prescriptions. New prescribers may, however, meet demands for medicines which were previously unmet, with consequent increase in drugs expenditure.

### *Other costs*

- .7 Any extension of prescribing to new groups of practitioners will involve training costs. These costs will include:
- i specialist training in prescribing for new prescribers who are already fully professionally qualified;
  - ii continuing education of new prescribers as required by professional and/or regulatory bodies;
  - iii incorporation of prescribing training into existing training programmes.
- 7.8 There will also be administrative costs:
- i for professional and regulatory bodies in establishing and maintaining registers of legally authorised prescribers;
  - ii for the NHS in establishing and maintaining procedures for the issue and processing of NHS prescriptions;

- iii for the Prescription Pricing Authority and other UK prescription pricing bodies<sup>76</sup> in collecting and analysing prescribing information on new prescribers;
- iv for Health Departments in setting up and servicing the new advisory body.

Some of these costs could be considerably reduced if and when electronic data interchange is used as part of the prescribing process (see para 8.18).

*Further work*

- 7.9 In assessing applications for new prescribing involving NHS reimbursement, the NPAC will need to form a judgement on whether the benefits would justify any net costs to the NHS. Where these costs could be significant or there appears to be a large degree of uncertainty these judgements should be tested through piloting and evaluation, before individual extensions to prescribing authority are rolled out on a national scale. Piloting may also be valuable for particularly innovative extensions to prescribing, so that practical issues of implementation can be assessed and resolved before general adoption is encouraged. Every effort should be made to ensure that such pilot studies do not lead to unnecessary delays in the wider introduction of improved services for patients.

***Recommendation 19:***

***Where particular extensions to prescribing authority could involve significant cost to the NHS, or where the balance of cost and benefit appears to be uncertain, there should be a thorough evaluation of the likely costs and benefits to the NHS before general adoption is encouraged. This should not be allowed to result in unnecessary delays in improving care.***

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<sup>76</sup> The Prescription Pricing Service in Wales, The Pharmacy Practice Division in Scotland, The Central Services Agency in Northern Ireland.

## Chapter 8: Implications for Legislation, Professional Training and Standards

8.1 This chapter deals with the third part of our terms of reference:

“To consider the possible implications for legislation, and for professional training and standards”.

### **Legislation**

#### *The Medicines Act*

- 8.2 Implementation of the Review Team’s recommendations to extend prescribing authority will require changes in primary legislation (the Medicines Act 1968) and in subordinate legislation. We recommend that this should be done by taking general powers in primary legislation to allow the designation of new categories of dependent and independent prescribers through secondary legislation. Consequential amendments may be needed to other legislation to allow all the relevant statutory bodies to maintain registers of approved prescribers.
- 8.3 Changes to secondary legislation will also be needed to implement our recommendation to introduce limits on the number of times a repeatable prescription can be dispensed and the duration of its validity (paras 6.63-6.65, Recommendations 17&18). Further thought will be needed on the precise limits and whether they could vary between classes of pharmaceuticals.
- 8.4 Legislation might also be necessary to set up the new prescribing advisory body depending on decisions about its status.
- 8.5 Any changes will have to comply with relevant European Union requirements. This is not expected to be a problem, as long as the required qualifications of any proposed new groups of prescribers are clearly defined.

#### *NHS legislation*

- 8.6 Some changes to primary legislation (the NHS Act 1977 and equivalents for Scotland and Northern Ireland) would probably be required in order to extend the categories of professionals who may use NHS prescriptions, and, as in the case of existing nurse prescribers, the categories of medicines they may prescribe. The aim should be to create a broad primary power which would enable ministers to designate through secondary legislation new categories of prescribers whose prescriptions could be dispensed at NHS expense, and to impose limitations on the medicines which they could specify as NHS prescriptions (analogous to the Selected List Scheme for GPs described at para 33 of Annex D).
- 8.7 The remaining changes can be secured through changes to secondary legislation, in particular

the regulations governing reimbursement of pharmacy contractors.

**Recommendation 20:**

***The Government should take general powers in primary legislation, enabling ministers, through regulations, to designate new categories of dependent and independent prescribers for the purpose of the Medicines Act, to authorise them to prescribe medicines for reimbursement by the NHS, and to limit or specify the medicines or classes of medicines which they may prescribe.***

**Professional training**

8.8 Our recommendations have profound implications for professional training. Training programmes for prescribing would need to be set up in the first instance for those health professionals who have already obtained the necessary specialist clinical qualifications. In due course, such training may be incorporated into the relevant specialist training course. It would be for the professional bodies<sup>77</sup> to decide whether in future *all* members undergoing such training should be trained as potential prescribers, or whether this would be an option within the specialism. Either way, the regulatory body for the profession will need to set up arrangements to ensure that an up-to-date register of legally authorised prescribers is maintained.

8.9 In addition, we have made clear (para 6.42) that all training should include a period of supervised practice. Particular care should be taken with training relating to the use of drugs listed at para 6.53. Professional and regulatory bodies will be expected to take firm action against supervisors who fail to discharge their responsibilities.

**Recommendation 21:**

***Professional groups putting forward proposals for extended prescribing should liaise with education providers and bodies responsible for approving training courses to develop suitable training programmes in the required prescribing competencies. All training should include a period of supervised practice, and professional and regulatory bodies should take firm action against supervisors who fail to discharge their responsibilities.***

8.10 Similarly, all professional groups which propose to take on new prescribing powers will be required to show how they will provide and assess continuing education programmes for authorised prescribers.

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<sup>77</sup> The precise division of responsibilities between the professional body responsible for promoting professional practice and the professional regulatory body varies between professions.

- 8.11 In the first year or two, there may be some difficulties in finding trainers with the right combination of skills to provide training for all potential new prescribers. Professional groups putting forward proposals for new prescribing should give particular attention to the way in which this problem could be overcome.
- 8.12 All training programmes established to meet the requirements for gaining or maintaining the right to prescribe should be independently accredited by the profession's regulatory body(ies). Training programmes, whether part of initial training or of continuing professional development, should not be used to promote particular products. We recommend that the regulatory bodies should draw up clear guidelines on the acceptance of any commercial support or sponsorship for such training programmes.

**Recommendation 22:**

***The professional regulatory bodies should draw up clear guidelines on the circumstances in which commercial support or sponsorship for training programmes related to prescribing could be acceptable. Training programmes should not be used to promote particular products.***

**Professional standards**

- 8.13 The Review Team expects that the examination of potential prescribers will be supervised by the relevant professional regulatory bodies. These bodies would be responsible for
- i ensuring that health professionals seeking prescribing authority for the first time are properly assessed, with the involvement of independent assessors;
  - ii ensuring that authorised prescribers take part in satisfactory programmes of continuing professional development related to prescribing;
  - iii ensuring that the content of professional training programmes takes account of changing needs, and that any such changes are appropriately monitored;
  - iv ensuring the review of clinical audit on a sample basis to ensure that any points of general application are fed back into the content of training, and if necessary reported to the MCA and the NPAC if there are implications for the prescribing formulary;
  - v keeping the adequacy of the prescribing formulary under review and for submitting to the MCA any proposals for changes that may be needed to meet changing clinical requirements.

**Recommendation 23:**

***Professional organisations considering applying for extended prescribing authority should, in conjunction with the appropriate professional regulatory organisations, ensure that adequate arrangements would be established for***

- i accrediting training programmes for prescribing;*
- ii maintaining a register of individuals who have acquired and are maintaining competency as prescribers;*
- iii reviewing the results of clinical audit programmes and ensuring that any general lessons are fed back into the content of training;*
- iv keeping the content of the prescribing formulary under review and submitting any proposals for change to the Medicines Control Agency.*

8.14 The maintenance of professional standards of practice cannot however be assured by the requirements of professional and regulatory bodies. Modern professional education in all disciplines seeks to establish a culture and expectation of life-long learning and to impress on all those who qualify the need to take personal responsibility for maintaining and updating their knowledge and practice and for taking part in externally validated clinical audit. The Review Team strongly endorses this attitude and therefore includes a formal recommendation aimed at individual practitioners, as a reminder that they are the prime custodians of safe and effective clinical practice, including prescribing.

**Recommendation 24:**

***All legally authorised prescribers should take personal responsibility for maintaining and updating their knowledge and practice related to prescribing, including taking part in clinical audit, and should never prescribe in situations beyond their professional competence.***

**Organisational and administrative aspects**

8.15 The regulatory body for each profession will need to set up arrangements

- i to identify and register or record all those members who satisfactorily complete training as authorised prescribers;*
- ii to ensure that this information is kept up to date, and is readily accessible to legitimate enquirers, such as health authorities, employers and pharmacists;*

- iii to ensure that prescribers provide evidence of continuing education and participation in audit at regular intervals, as a condition of remaining on the prescribers register;
  - iv to deal with any allegations against their members of serious deficiencies in their prescribing practice.
- 8.16 Health authorities<sup>78</sup> and primary care groups<sup>79</sup> will need to take account of the presence of additional prescribers in setting budgets, in arrangements for funding professional education and training, and in monitoring prescribing patterns. Central government, through the prescription pricing bodies, will need to ensure that information on prescribing by new prescribers can be analysed and fed back to practitioners and to their employing authorities in ways which are helpful and encourage better prescribing.
- 8.17 The introduction of independent and dependent categories of prescriber will necessitate the provision of new administrative arrangements, including prescription forms. At present, separate identifiable NHS prescription pads are issued to nurse prescribers. Similar pads could be used by other independent prescribers. Prescription forms for use by dependent prescribers should state the name of the clinician who is responsible for initial clinical assessment of the patient (usually the patient's general practitioner).
- 8.18 New arrangements would also be needed to introduce repeatable prescriptions into the NHS (see paras 6.63-6.65, and Recommendations 17&18). These are likely to include amendments to the existing prescription form system, for example to allow details of the number and timing of instalments to be set out in a safe and auditable way; corresponding changes to prescription pricing bodies' computer systems; and some adaptation of patient medication record systems in community pharmacies.
- 8.19 These practical arrangements could be greatly simplified by the effective use of information technology (IT), and in particular by the electronic exchange of information on medication and on other aspects of patients' treatment. We have noted in para 6.19 the particular need for good communications between independent and dependent prescribers. The Review Team therefore warmly welcomes the proposals set out in the recently published NHS IT strategy<sup>80</sup> for the introduction of electronic health records (lifelong summary records of patients' health and health care) and electronic patient records (more detailed records of particular aspects of care). When implemented, these systems will provide a mechanism for the transfer of clinical and medication information between professionals which is essential for safe and effective prescribing.

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<sup>78</sup> Health Boards in Scotland, Health and Personal Social Services Boards in Northern Ireland.

<sup>79</sup> Local Health Care Co-operatives in Scotland, Local Health Groups in Wales [no equivalent has been established in Northern Ireland as yet].

<sup>80</sup> NHS Executive *Information for health: an information strategy for the modern NHS* (NHS Executive, September 1998).

## **Evaluation and monitoring**

- 8.20 The new arrangements should be subject to evaluation and monitoring, for which appropriate resources should be made available. This needs to take place at various levels, for a number of complementary purposes:
- i professional and regulatory bodies, especially in the early years of prescribing by any new group, need to monitor carefully the clinical practice of individual prescribers and to draw out as quickly as possible any general lessons which could affect the training and assessment of future prescribers (para 8.13);
  - ii health authorities, Trusts and primary care groups<sup>81</sup> need to monitor prescribing patterns as part of their clinical governance arrangements, and to take action as needed to improve the appropriateness of prescribing by individual prescribers (para 8.14);
  - iii central government should establish pilot studies of some aspects of extended prescribing, where necessary, within time frames that provide satisfactory information for decisions on the extension of such services, but which do not unduly delay the wider introduction of improved services to patients (para 7.9).

### ***Recommendation 25:***

***The new arrangements should be subject to evaluation and monitoring, for which appropriate resources should be made available.***

- 8.21 There are particular issues over monitoring and evaluation in the private sector, where the information systems for routine analysis of prescribing data may not be as well-developed as in the NHS. Private primary health care may be particularly problematic. Pharmacists are required to keep records of private prescriptions, but this information is not routinely available for clinical audit. These issues go beyond our terms of reference, but should be considered further by the Health Departments (see Annex H).

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<sup>81</sup> See footnotes 60-62 for the equivalents in Wales, Scotland and Northern Ireland.

## Chapter 9: Summary of Conclusions and Recommendations

### **Conclusions**

- 9.1 Professional practice is changing in response to changing patterns of clinical care, professional education and patient expectations. These trends have not been fully reflected in the arrangements for the prescribing, supply and administration of medicines. (Chapter 3)
- 9.2. Our consultation exercise revealed considerable support for an extension of the groups of professionals who may prescribe, which would be expected to improve multidisciplinary team-work and to make the fullest use of professional skills. (Chapter 5)
- 9.3 The literature and international experience both support further moves in this direction. (Chapter 5)
- 9.4 The general practitioner should continue to be responsible in most circumstances for the co-ordination of the patient's care. (Chapter 6)
- 9.5 The majority of patients should continue to receive medicines on an individual, patient-specific basis. Exceptionally, it may be in patients' interests to supply or administer medicines under group protocols. In either case, the provision of medicines to patients should ensure that patient safety is not compromised or put at risk. It should make the best use of professional expertise and the most effective use of resources. (Chapter 6)
- 9.6 The extension of prescribing to new professional groups, subject to safeguards which would be established by the professional regulatory bodies, would yield benefits to patient care, improved patient convenience and better team-working between professionals. (Chapter 7)
- 9.7 The available evidence is insufficient to enable us to determine whether specific extensions to NHS prescribing would increase or reduce total NHS running costs. Some initial costs for training new prescribers are inevitable. Each proposal will need to be scrutinised to assess whether extended prescribing at NHS expense would represent a good use of NHS resources. (Chapter 7)
- 9.8 Legislation, both primary and secondary, would be required to implement our recommendations. (Chapter 8)

## Recommendations

### *Recommendations to Health Departments*

1. **The legal authority in the United Kingdom to prescribe, including authorising NHS expenditure, should be extended beyond currently authorised prescribers.**

(Para 6.6)
  
2. **Legal authority for new professional groups to prescribe or to authorise NHS expenditure should normally be limited to medicines in specific therapeutic areas related to the particular competence and expertise of the group and may include prescription only medicines within those areas.**

(Para 6.10)
  
3. **Two types of prescriber should be recognised:**
  - i **the *independent prescriber* who is responsible for the assessment of patients with undiagnosed conditions and for decisions about the clinical management required, including prescribing. At present, doctors, dentists and certain nurses in respect of a limited list of medicines are legally authorised prescribers who fulfil the requirements for independent prescribers and this should continue. Certain other health professionals may also become newly legally authorised independent prescribers, subject to the process described below.**
  
  - ii **the *dependent prescriber* who is responsible for the continuing care of patients who have been clinically assessed by an independent prescriber. This continuing care may include prescribing, which will usually be informed by clinical guidelines and will be consistent with individual treatment plans; or continuing established treatments by issuing repeat prescriptions, with the authority to adjust the dose or dosage form according to the patients' needs. There should be provision for regular clinical review by the assessing clinician.**

(Para 6.19)
  
6. **A UK-wide advisory body, provisionally entitled the “New Prescribers Advisory Committee”, should be established under Section 4 of the Medicines Act to assess submissions from professional organisations seeking powers for suitably trained members to become independent or dependent prescribers.**

(Para 6.27)
  
10. **Newly authorised groups of prescribers should not normally be allowed to prescribe medicines in the following categories:**
  - i **controlled drugs (drugs subject to the Misuse of Drugs Act 1971);**
  
  - ii **unlicensed drugs, or drugs used outside their licensed indications;**

- iii “black triangle” drugs;
- iv drugs over which there is continuing professional concern, eg drugs used to treat children and young people with mental health problems;
- v drugs which on public health grounds should be subject to particular safeguards, for instance antibacterial antibiotics.

(Para 6.54)

14. The current arrangements for the administration and self-administration of medicines should continue to apply. Newly authorised prescribers should have the power to administer those parenteral prescription only medicines which they are authorised to prescribe, and to issue directions for the parenteral administration of the same medicines.

(Para 6.62)

17. Repeatable prescriptions should be available on the NHS.

(Para 6.65)

18. Limits should be introduced for the number of times a repeatable prescription can be dispensed and the duration of its validity. These restrictions should apply across all sectors, and not be limited to NHS practice.

(Para 6.65)

19. Where particular extensions to prescribing authority could involve significant cost to the NHS, or where the balance of cost and benefit appears to be uncertain, there should be a thorough evaluation of the likely costs and benefits to the NHS before general adoption is encouraged. This should not be allowed to result in unnecessary delays in improving care.

(Para 7.9)

20. The Government should take general powers in primary legislation, enabling ministers, through regulations, to designate new categories of dependent and independent prescribers for the purpose of the Medicines Act, to authorise them to prescribe medicines for reimbursement by the NHS, and to limit or specify the medicines or classes of medicines which they may prescribe.

(Para 8.7)

25. The new arrangements should be subject to evaluation and monitoring, for which appropriate resources should be made available.

(Para 8.19)

*Recommendations to Health Departments and professional bodies*

4. There should be adequate arrangements for sharing information between independent and dependent prescribers. In particular,

- i both clinicians should have access to a complete medication record, and**
- ii both clinicians should have access to relevant parts of the patient’s medical record.**  
(Para 6.19)

**5. Changes to patterns of clinical care using new models for the prescribing, supply and administration of medicines should be introduced only after full consultation with patient interests, and should wherever possible increase patient choice.**  
(Para 6.23)

**11. Initial prescribing and supply of medicines should normally remain separate functions in order to protect patient safety and provide other safeguards. Where a prescription cannot be furnished, the current arrangements for the emergency sale or supply of medicines should apply.**  
(Para 6.59)

*Recommendation to Health Departments, professional bodies, HAs and employers*

**12. Where exceptionally it is in the interests of patients for the same professional to be responsible for prescription and supply of medicines, this should be subject to clinical audit and probity checks.**  
(Para 6.59)

*Recommendations to professional bodies*

**7. Proposals for new professional groups to be considered as potential prescribers will be expected to come from nationally recognised organisations. They should confirm that the group is formally recognised by the appropriate regulatory body and that that body has seen and is content with the proposed arrangements for training in prescribing and for registration.**  
(Para 6.33)

**13. Professional organisations, in putting forward proposals for extensions to prescribing, should consider whether this could result in members prescribing and supplying POMs to the same patient, and if so what safeguards are required to maintain patient safety and ensure probity. The NPAC, in assessing any proposals from professional groups which could result in members prescribing and supplying POMs to the same patient, should consider the adequacy of the safeguards proposed.**  
(Para 6.59)

**15. Professional organisations, in putting forward proposals for new groups of professionals to have the authority to prescribe certain medicines, should consider the implications for administration of medicines and should ensure that all necessary training aspects are covered in their proposals.**  
(Para 6.62)

**21. Professional groups putting forward proposals for extended prescribing should liaise with education providers and bodies responsible for approving training courses to develop suitable training programmes in the required prescribing competencies. All training should include a period of supervised practice, and professional and regulatory bodies should take firm action against supervisors who fail to discharge their responsibilities.**

(Para 8.9)

**22. The professional regulatory bodies should draw up clear guidelines on the circumstances in which commercial support or sponsorship for training programmes related to prescribing could be acceptable. Training programmes should not be used to promote particular products.**

(Para 8.12)

**23. Professional organisations considering applying for extended prescribing authority should, in conjunction with the appropriate professional regulatory organisations, ensure that adequate arrangements would be established for**

- i accrediting training programmes for prescribing;**
- ii maintaining a register of individuals who have acquired and are maintaining competency as prescribers;**
- iii reviewing the results of clinical audit programmes and ensuring that any general lessons are fed back into the content of training;**
- iv keeping the content of the prescribing formulary under review and submitting any proposals for change to the Medicines Control Agency.**

(Para 8.13)

*Recommendations to the GMC/GDC and postgraduate deans*

**8. The GMC and postgraduate deans should agree a safe framework within which pre-registration house officers (PRHOs) could prescribe medicines relevant to the duties of their post. Such prescribing should be subject to close monitoring by their clinical supervisor, with due regard to the proper discharge of supervisory responsibility as specified in Recommendation 21.**

(Para 6.51)

**9. Overseas doctors given provisional registration by the GMC and required to undertake clinical training similar to that of a PRHO, and overseas dentists, given temporary registration by the GDC to practice in an approved training post in a NHS hospital, should be able to prescribe under similar safeguards to those described in Recommendation 8.**

(Para 6.52)

*Recommendation to employers*

- 16. Employers and managers in all sectors who are responsible for staff who supervise or undertake the administration of any medicines should ensure that those staff have the right training and skills to do so safely and regular opportunities for updating their knowledge.**

(Para 6.62)

*Recommendation to individual practitioners*

- 24. All legally authorised prescribers should take personal responsibility for maintaining and updating their knowledge and practice related to prescribing, including taking part in clinical audit, and should never prescribe in situations beyond their professional competence.**

(Para 8.14)

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## Glossary

<b>Adherence</b>	A more modern term for “compliance” (qv).
<b>Administer</b>	To give a medicine either by introduction into the body, whether by direct contact with the body or not, (eg orally or by injection) or by external application (eg application of an impregnated dressing) [qv “administer” in section 130 Medicines Act 1968].
<b>Appropriate prescribing</b>	Prescribing the right medicine in the right dose for the right duration.
<b>Appropriate practitioner</b>	Technical term used in Medicines Act for an authorised prescriber (ie a doctor, dentist or nurse prescriber).
<b>Assessing clinician</b>	The clinician (an independent prescriber) who is responsible for the initial assessment of a patient’s condition and for broad decisions about the clinical management required. Responsibility for continuing care and for prescribing specific medicines may then pass to a dependent prescriber (qv). See paras 6.14-6.15.
<b>Black triangle drugs</b>	Newly-introduced drugs, still subject to special monitoring for potential side-effects by the Medicines Control Agency (so called because they are identified by a black triangle symbol in the British National Formulary).
<b>Care Programme Approach</b>	Multi-professional approach to care for patients being treated in the community, involving a “Care Programme” for the patient which is agreed by the full clinical team and overseen by a lead professional within the team.
<b>Clinical assessment</b>	Assessment of a patient’s condition leading, in consultation with the patient, to a decision on treatment and/or on further diagnostic tests and/or on referral to another clinician.
<b>Clinical guideline</b>	A summary of best clinical practice for a particular condition or disease area, usually covering all aspects of diagnosis and management, and identifying the strength of the evidence for each element.
<b>Clinical responsibility</b>	Accountability for a particular aspect of the clinical assessment or management of a patient’s condition.
<b>Clinician</b>	A health care professional who is engaged in the direct examination, treatment and care of patients.

<b>Compliance</b>	Action by a patient that accords with and follows advice given by a qualified health professional which may include a schedule of prescribed medication.
<b>Concordance</b>	A model of consultation in which the prescriber and patient negotiate a therapeutic alliance based on both sets of health beliefs. The key to this alliance is that the most important determinants are those that are made by the patient. The resulting agreement may be an agreement to differ. The ultimate aim of concordance is to optimise the health gain from the use of medicines, compatible with what the patient desires and is capable of achieving.
<b>Controlled drugs</b>	Narcotic drugs or other drugs liable to misuse which are subject to special controls under the Misuse of Drugs Act 1971 (see Annex D).
<b>CPD</b>	Continuing professional development.
<b>CSM</b>	Committee on Safety of Medicines.
<b>Dependent prescriber</b>	A clinician who takes over the continuing care of a patient, which may include prescribing, after initial assessment by an independent prescriber (qv). See paras 6.16-6.19.
<b>Diagnosis</b>	A determination of the nature or identity of a disease, typically based on the patient's medical history, an analysis of signs elicited by physical examination and, as required, the results of laboratory tests, imaging or other investigations.
<b>Dispense</b>	To make up or give out a clinically appropriate medicine to a patient for self-administration or administration by another, usually another professional. In the case of prescription only (POM) medicines, dispensing must be in response to a legally-valid prescription (qv). The act of dispensing is combined with advice on safe and effective use. <sup>82</sup>
<b>General Sales List (GSL) Medicine</b>	A medicinal product which can be sold or supplied direct to the public in an unopened manufacturer's pack from any lockable business premises. Such products are listed in the Medicines (Products Other than Veterinary Drugs) (General Sales List) Order 1984.
<b>GDC</b>	General Dental Council.
<b>GMC</b>	General Medical Council.

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<sup>82</sup> See footnote 2 on page 10.

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<b>General Medical Services (GMS)</b>	Services to patients of the kind provided by general practitioners.
<b>GP</b>	General practitioner.
<b>Group protocol</b>	A specific written instruction for the supply or administration of named medicines in an identified clinical situation. It is drawn up locally by doctors, pharmacists and other appropriate professionals, and approved by the employer, advised by the relevant professional advisory committees. It applies to groups of patients or other service users who may not be individually identified before presentation for treatment.
<b>Health [care] professional</b>	Statutorily registered practitioner in an occupation which requires specialist education and training in practical skills in health care. The professions concerned are self-regulating and practitioners are expected to satisfy the profession's accepted standards of practice and conduct.
<b>Independent prescriber</b>	A clinician who is responsible for the assessment of patients with undiagnosed conditions and for decisions about the clinical management required, including prescribing. See paras 6.14-6.15.
<b>Licensed indication</b>	Treatment purpose for which a product may be used under the terms of the marketing authorisation granted by the Licensing Authority.
<b>Licensed medicine</b>	A medicine which falls within the definition of a medicinal product and which is granted a marketing authorisation by the Licensing Authority when the safety, quality and efficacy of the product have been satisfactorily demonstrated by the Licence Holder (holder of marketing authorisation) in accordance with EC Directive 65/65.
<b>Licensing Authority</b>	The ministers collectively responsible under the Medicines Act for determining which medicines may be licensed for use in the UK.
<b>MCA</b>	Medicines Control Agency.
<b>Medicinal product</b>	Any substance or combination of substances presented for treating or preventing disease in human beings or animals. Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product (Article 1.2 EC Directive 65/65).
<b>Medicines Commission</b>	The statutory body set up to advise ministers on all aspects of the Medicines Act and the use of medicines (see Annex D).

<b>NPAC</b>	New Prescribers Advisory Committee.
<b>Over the counter (OTC) medicines</b>	Medicines legally classified as P (Pharmacy) or GSL (General Sales List).
<b>Parenteral medication</b>	Medication administered by injection.
<b>Patient organisation</b>	A body, often a voluntary organisation or registered charity, representing the interests of patients and working to meet their needs. Some patient organisations are concerned with specific medical conditions, others act as an umbrella body or represent a wider constituency.
<b>Patient-specific protocol</b>	A written statement defining the management of a named patient which has been agreed by the clinician responsible for the patient, and by other appropriate health professionals.
<b>Personal Medical Services (PMS)</b>	Medical services, similar to General Medical Services (qv), provided by a general practitioner contracted with a Health Authority under the special arrangements set out in the NHS (Primary Care) Act 1997. See Annex D para 29.
<b>Pharmacy (P) medicine</b>	Any medicinal product other than those designated as GSL or POM products. Pharmacy medicines can be sold or supplied only from a registered pharmacy by or under the supervision of a pharmacist, subject to certain exceptions (eg where the sale or supply is in the course of business of a hospital as defined in the Medicines Act 1968 or health centre as defined in the NHS Act 1977 and related legislation).
<b>Prescribe</b>	<p>The term “prescribe”, as used in the Medicines Act, means</p> <p>i to order in writing the supply of a POM for a named patient;</p> <p>The term is also commonly used in the extended sense:</p> <p>ii to authorise by means of an NHS prescription (qv) the supply of any medicine (POM, P or GSL) at public expense;</p> <p>and occasionally:</p> <p>iii to advise a patient on suitable care or medication (including medicine which may be purchased “over the counter”, ie without a written order).</p>

“Prescribing” in senses (i) or (ii) is the preserve of authorised prescribers (qv - ie currently doctors, dentists and some nurses) but pharmacists and other health professionals can “prescribe” in sense (iii).

In this report, prescribing is usually used in sense (i) and (ii) unless the context makes clear that sense (iii) is intended.

<b>Prescriber</b>	A health professional who is legally authorised to prescribe a prescription only medicine (ie sense (i) of “prescribe”, qv). Currently the only authorised prescribers are doctors, dentists and certain nurses in respect of a limited list of medicines.
<b>Prescription</b>	An order for dispensation of a medicine made to a professional who is legally authorised to dispense. For prescription only medicines, the order must be in writing in legally prescribed format and signed by the person qualified by law to prescribe.
<i>NHS prescription</i>	An order for the supply of a medicine (not necessarily a prescription only medicine) under NHS legislation for a named individual at public expense.
<i>Repeat prescription</i>	A further prescription for the same medication issued by a prescriber on request from the patient.
<i>Repeatable prescription</i>	An instruction from a prescriber that the same medication is to be dispensed on successive occasions at the patient’s request, subject to the judgement of the dispenser that the medication is still appropriate.
<b>Prescription only medicine (POM)</b>	A medicinal product which may only be sold or supplied against the signed prescription of an appropriate practitioner ie doctors, dentists and certain nurses (in respect of a specified list of POMs) specified in the Prescription Only Medicines (Human Use) Order 1997.
<b>PRHO</b>	Pre-registration house officer.
<b>Protocol</b>	A set of instructions, usually written, on the management of a patient or group of patients. See group protocol; patient-specific protocol.
<b>RPSGB</b>	Royal Pharmaceutical Society of Great Britain.
<b>Self-administration</b>	The process of patients administering their own medicines.

<b>Supply</b>	To provide a medicine directly to a patient or carer for administration <sup>83</sup> . The term, described as “retail sale or supply in circumstances corresponding to retail sale” under the Medicines Act does not include supply to a health professional who is going to supply the product to the patient or carer as part of professional practice eg. supply from a pharmacy or wholesaler to a chiropodist. This activity constitutes “wholesale dealing” under section 131 of the Medicines Act and is outside the terms of the Review.
<b>Treatment</b>	Broadly, the management and care of a patient to prevent or cure disease or ameliorate suffering and disability; or, a substance or method used in treating a patient.
<b>UKCC</b>	United Kingdom Central Council for Nursing, Midwifery and Health Visiting.

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<sup>83</sup> See footnote 2 on page 10.

## Annex A: Membership of the Review Team and Sub-Groups

### **Review Team**

Dr June Crown CBE (Chairman), Past-President, Faculty of Public Health Medicine. Chairman of the Advisory Group on Nurse Prescribing 1988-1989.

Ms Jennifer Brown, Therapy Services Manager, St George's Hospital, Tooting.

Dr Peter Carter, Chief Executive, North West London Mental Health Trust.

Ms Sally Gooch, Assistant Director of Nursing, Tower Hamlets Healthcare Trust.

Professor Dame Rosalinde Hurley DBE, Emeritus Professor of Microbiology at the University of London Imperial College of Medicine. Chairman of the Medicines Commission 1982-1993.

Professor Clare Mackie, Head of Pharmacy, Robert Gordon University, Aberdeen.

Ms Helen Remington, Chief Pharmacist, Addenbrookes Hospital, Cambridge.

Ms Grethe Ridgway, Director of Nursing, Southampton Community Health Services NHS Trust.

Ms Frances Sheldon, Member North and Mid Hampshire Health Authority.

Dr Nuala Sterling CBE\*, Consultant Physician in Geriatric Medicine, Southampton General Hospital

Dr Ross Taylor GP, Foresterhill Health Centre, Aberdeen, and Senior Lecturer, Department of General Practice and Primary Care, Aberdeen University.

Ms Judy Wilson, Director, Long-Term Medical Conditions Alliance (LMCA).

\* Dr Sterling joined the Team in October 1997 following the resignation of Professor Ray Tallis, Professor of Geriatrics at Salford University.

### **Secretariat**

(Department of Health (DH), Scottish Office (SO), Welsh Office (WO))

Ms Catherine Dewsbury, DH.

Mr Charles Dobson, DH.

Miss Angela Field, DH.

Mr Bryan Hartley, DH.

Dr Philip Leech, DH.

Ms Joanna Nicholson, DH [until August 1998]; Ms Gill Aitken, DH [from September 1998].  
Ms Alison Pickford, DH [until August 1998]; Ms Michelle Hanchard, DH [from September 1998].  
Ms Thelma Sackman, DH [from March 1998].  
Dr Nick Salfield, DH.  
Ms Donna Sidonio, DH [until July 1998].  
Mr John Thompson, DH [until June 1998].  
Mr Bill Scott, SO [until September 1997]; Ms Pamela Warrington, SO [from September 1997].  
Ms Carwen Wynne Howells, WO.  
Ms Sonya Yates, DH [until December 1997]; Ms Ginny Storey, DH [from May 1998].

## **Review Sub-Groups**

### **Group (i) “Healthy” people (ie those with self-limiting conditions)**

#### **Chair: Professor Clare Mackie**

Ms Pippa Bagnall, Queens Nursing Institute [until September 1997].  
Ms Meredyth Bell, General Dental Practitioner, Cumbria.  
Ms Helen Bristow, Physiotherapist, South Thames Region.  
Dr Derek Browne, GP, Hampshire.  
Dr Terry Maguire, School of Pharmacy, Queens University of Belfast.  
Dr Peter Marks, Director of Public Health, Nottinghamshire HA.  
Ms Shelley Mehigan, Family Planning Nurse, Slough.  
Ms Kathy Picton, Consumers Association.  
Ms Chris Ruby, Senior Lecturer in Midwifery and Health Studies, Worcester College of FE.

Secretariat: Dr Philip Leech, DH; Ms Mary Waugh, SO.

### **Group (ii) People with chronic/progressive illness living in the community**

#### **Chair:- Ms Grethe Ridgway**

Ms Jean Ashcroft, Arthritis Care [until September 1997].  
Dr John Axford, Consultant Rheumatologist, St George’s Hospital, Tooting.  
Ms Heather Ballard, Community Nursing and District Nursing Association.  
Mr Mike Chapman, Community Pharmacist, Taunton.  
Ms Maggie Cherry, Continence Specialist Nurse, Central Health Clinic, Avon.  
Dr James Dunbar, GP Fundholder, Dundee.  
Ms Anne Felton, British Diabetic Association [from September 1997].  
Ms Chris Fines, Assistant Director of Quality and Clinical Services, Rotherham NHS Trust.  
Mr David Milns, Chiropodist, Lifespan NHS Trust, Cambridge.  
Ms Mary Tompkins, Director of Pharmacy, North Essex HA.

Secretariat: Ms Nicky Cogan, DH; Dr Fran Collins, WO.

### **Group (iii) People with serious conditions requiring rapid response**

#### **Chair:- Ms Helen Remington**

Mr Jim Butcher, Chief Executive, West Wales Ambulance Trust [until August 1997].

Dr Jim Cox, GP, Caldbeck, Cumbria.

Mr Michael Cross, Chief Pharmacist, Kings College Hospital.

Ms Deborah Dawson, Head of Nursing (Critical Care), Royal Sussex County Hospital.

Mr Stan Dobrzanski, Pharmacist, Bradford Royal Infirmary.

Dr Dilip Kapur, Anaesthetist, Perth Royal Infirmary.

Ms Ann O'Doherty, A&E Triage Nurse, Royal Victoria Hospital, Belfast .

Professor Philip Routledge, Professor of Clinical Pharmacology, University of Wales.

Ms Shirlene Rudder, Chair, Sickle Cell Society [until August 1997].

Secretariat: Ms Catherine Dewsbury, DH; Ms Sonya Yates, DH.

### **Group (iv) People with mental health/behavioural problems**

#### **Chair: Ms Frances Sheldon**

Mr John Atkinson, Psychiatric Nurse, HMP Barlinnie, Glasgow [until September 1997].

Mr Stephen Bazire, Pharmacy Services Director, Hellsdon Hospital, Norwich.

Ms Alison Cobb, MIND.

Ms Carole Davies, District Occupational Therapist, Carmarthen.

Mr Ian Ferris, Head of Community Nursing, Hensol Hospital, Pontyclun.

Dr Philip Harrison-Read, Consultant Psychiatrist, NW London Mental Health Trust.

Ms Anita Ram, Nursing Home owner, Cambridge.

Dr Simon Ramsden, GP, London.

Ms Barbara Swyer, Forensic Services Manager, Hampshire Social Services.

Secretariat: Ms Carwen Wynne-Howells, WO; Ms Alison Pickford, DH.

### **Terms of Reference for the Sub-Groups**

Bearing in mind the overall terms of reference for the Review of Prescribing, Supply and Administration of Medicines, and any guidance from the Review Team:

- ❖ to assess the evidence, including written evidence submitted to the review in relation to selected clinical scenarios relevant to healthy patients ie patients with self-limiting conditions;
- ❖ to seek any supplementary written or oral evidence that may be required;

- ❖ to review the principles which should apply to clinical practice in the areas selected for detailed study, and the extent to which these could be extrapolated to other clinical areas within the remit of the sub-group;
- ❖ to submit a report on findings to the Review Team within 4 months.

## Annex B: Further Experts Consulted on Emerging Proposals

Dr Michael Brindle CBE, President, Royal College of Radiologists.  
Dr Howard Baderman OBE, Consultant in Accident and Emergency Medicine.  
Dr Adrian Bull, PPP Healthcare.  
Dr Frances Charlesworth, Association of the British Pharmaceutical Industry.  
Ms Ann Grant, Depression Alliance.  
Dr Robert Hangartner, Chief Medical Officer, Guardian Health Ltd.  
Dr Peter Mitford, Director, Primary Care, Northumberland Health Authority.  
Dr George Rae, BMA, General Medical Services Committee.  
Dr Stewart Sanders, GP in private practice.

## Annex C: Summary of the Recommendations from the Report on Supply and Administration under Group Protocol<sup>84</sup>

1. The term “group protocol” is defined by the Review Team as follows:

*A group protocol* is a specific written instruction for the supply or administration of named medicines in an identified clinical situation. It is drawn up locally by doctors, pharmacists and other appropriate professionals, and approved by the employer, advised by the relevant professional advisory committees. It applies to groups of patients or other service users who may not be individually identified before presentation for treatment.

2. Group protocols or guidelines, corresponding more or less closely to this definition, are already in widespread use in the NHS. However, the legality of such arrangements has been called into question; and some current arrangements fall short of the standards required to ensure safe clinical practice. The Review Team were therefore asked to submit an interim report specifically on this aspect of their terms of reference.
3. The Team’s conclusions and recommendations were as follows:

### “Conclusions

- ❖ The Review Team considers that the majority of clinical care should be provided on an individual, patient-specific basis. The supply and administration of medicines by group protocols should be reserved for those limited situations where this offers an advantage for patient care, and where it is consistent with appropriate professional relationships and accountability. Group protocols should comply with the general principles for the supply and administration of medicines in other circumstances.
- ❖ The Review Team believes that, even if the authority to prescribe is extended more widely in the future to health professionals other than existing prescribers, there will still be a need for supply and administration of medicines under group protocols in certain limited situations as a component of comprehensive health care.
- ❖ Patient safety can only be protected if group protocols for the supply and administration of medicines are clear and comprehensive. The Review Team proposes that group protocols should comply with the guidance framework in Appendix A [not attached to this summary].

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<sup>84</sup> Review of prescribing, supply and administration of medicines: *A report on the supply and administration of medicines under group protocols* (Department of Health, London, April 1998).

**We recommend that:**

- 1. The majority of patients should continue to receive medicines on an individual basis. However, there is likely to be a continuing need for supply and administration under group protocols in certain limited situations as part of a comprehensive health service.**
- 2. Current safe and effective practice using group protocols which are consistent with the criteria at Appendix A should continue (see also Recommendation 5).**
- 3. The law should be clarified to ensure that health professionals who supply or administer medicines under approved group protocols are acting within the law.**
- 4. All group protocols should comply with the criteria specified in Appendix A.**
- 5. Current protocols should be reviewed in the light of those criteria.**
- 6. The criteria for group protocols should be widely disseminated by the Health Departments in association with relevant professional bodies.**
- 7. Consideration should be given to commissioning an evaluation study of the use of group protocols including health outcomes.**
- 8. These recommendations should apply to all sectors of health care including the private and charitable sectors.**

## Annex D: Current Arrangements for the Prescription, Supply and Administration of Medicines<sup>85</sup>

### Background

1. Under UK law, the legislative requirements relating to the prescribing, supply and administration of medicines are set out in the Medicines Act 1968, and in secondary legislation made under the Act, certain parts of which are implemented by EU legislation (Directive 92/26/EEC). Legislation on the reimbursement of medicines under the NHS is derived from the NHS Act 1977.

### Definitions

2. “*Prescribe*”. Neither “prescribe” nor “prescription” are defined in the Medicines Act. In principle, anyone can write a prescription, but medicines can only be sold or supplied against them in specified circumstances. Subordinate legislation (the Prescription Only Medicines (Human Use) Order 1997 - the “POM” Order 1997) sets out some of the practical requirements for prescribing, for instance a prescription must be signed by the practitioner giving it, written in ink, and satisfy other specified requirements.
3. “*Supply and Administer*”. Part III of the Medicines Act includes the sections which deal with the sale and supply of medicines for human and for veterinary use. In the Medicines Act, “administer” means to give a medicine to a human being (or an animal) orally, by injection or by introduction into the body in any other way, or by external application, whether by direct contact with the body or not. Certain provisions, such as section 58 of the Act, make a clear distinction between the controls on supplying and on administering, whereas others refer only to selling or supplying, where it seems that administration could be incorporated into the latter.

### Categories of Medicines

4. Medicines are divided into three categories (their legal status), depending mainly on the dangers they pose and the risk of misuse:-
  - i Prescription Only Medicine (POM);
  - ii Pharmacy Medicine (P); and
  - iii General Sale List (GSL).

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<sup>85</sup> This annex sets out a guide to key relevant legislation for the purposes of this report. It is not a legal document and is not intended to be definitive.

A medicinal product will be a P medicine unless specific legal provision has been made to make it either a GSL or POM. The substances which are GSL are listed in the Medicines (Products Other than Veterinary Drugs) (General Sales List) Order 1984 as amended [“the GSL Order”]; those which are POM are listed in the POM Order 1997.

## **Sale, supply and administration of Medicines**

### *General principles*

5. GSL medicines may be sold or supplied from any lockable business premises (section 53 Medicines Act). P and POM medicines may only be sold or supplied by or under the supervision of a pharmacist from registered premises (section 52 Medicines Act), although there are some exemptions.
6. POMs have an additional restriction in that they may only be supplied by a pharmacist against the prescription of an “appropriate practitioner” - ie doctors, dentists and certain nurses (in respect of a specified list of POMs) who have been specified in an order made under section 58 of the Medicines Act.
7. In addition, POMs may only be administered by or in accordance with directions from an appropriate practitioner.
8. The nurses who are “appropriate practitioners” are either:-
  - i registered in Part 1 or 12 of the Register maintained by the UKCC under section 10 of the Nurses, Midwives and Health Visitors Act 1979 and holding a district nursing qualification recorded in the professional register under rule 11 of the Nurses, Midwives and Health Visitors Rules 1983; or
  - ii registered as a qualified health visitor in Part 11 of the professional register,and in either case, with an entry against the nurse’s name in the relevant register signifying that s/he is qualified to order drugs, medicines and appliances for patients.
9. Such nurses were able to become appropriate practitioners as a result of the Medicinal Products: Prescription by Nurses Act 1992 and SI 1994/3050 (which amended an earlier POM Order, the POM Order 1983). This legislation followed the work of the Advisory Group on Nurse Prescribing, chaired by Dr June Crown, which led to the 1989 Report on Nurse Prescribing and Supply.
10. There is a specific and limited list of products which such nurses may prescribe. These are set out in a Schedule to the POM Order.

### ***Exemptions for the sale and supply of Ps and POMs***

11. The exemptions from the general requirement that Ps and POMs can only be sold or supplied by a pharmacist are set out in both primary and secondary legislation. With regard to both Ps and POMs, section 55(1) of the Medicines Act specifies that:-
  - i doctors and dentists may sell or supply medicines to their patients or to a person under whose care the patient is. Within the NHS this power is modified to restrict these activities - eg only doctors in designated rural areas may dispense any medicine to their patients. Non-dispensing doctors may administer medicines personally to their patients and may provide small quantities for immediate treatment.
  - ii medicines may be sold or supplied in the course of the business of a “hospital or health centre”, for the purpose of being administered (whether in the hospital or health centre or elsewhere) in accordance with the directions of a doctor or dentist.

Secondary legislation: exemptions for supply and administration of POMs

12. *The POM Order* sets out further exemptions to the requirement that POMs can only be *sold* or *supplied* by a pharmacist against a lawful prescription, or *administered* under the directions of an appropriate practitioner. These allow:
  - i specified drugs for parenteral *administration* (injection) to be administered by anyone for the purpose of saving life in an emergency;
  - ii the *administration* of all POMs except those which are administered parenterally;
  - iii a POM to be *sold* or *supplied* in the course of the business of a hospital provided the POM is sold or supplied in accordance with the written directions of a doctor or dentist notwithstanding that those directions do not fulfil the usual conditions which apply to writing prescriptions (eg the giving of addresses, dates, signing in ink etc);
  - iv the *sale* or *supply* only or *parenteral administration* by specified categories of persons, of specified products under certain conditions. These detailed exemptions are set out in schedules to the POM Order. They apply to people such as state registered chiropodists who hold a certificate of competence in the use of analgesics, registered midwives, the owner or master of a ship which does not carry a doctor on board, or ambulance paramedics, who may administer medicines in their list, provided they comply with specified conditions;
  - v certain drugs to be *supplied* in an emergency by community pharmacists.
13. *The Medicines (Pharmacy and General Sale - Exemption) Order 1980* exempts certain categories of persons, including professional groups, from the restrictions which apply to selling or supplying specified P and GSL medicines. These include midwives and chiropodists.

## **Statutory Medicines Act committees**

14. The Medicines Act creates a framework for statutory committees and establishes the Medicines Commission as an expert body to advise ministers on matters arising under the Act.
15. The Medicines Commission is established by section 2 which sets out minimum membership criteria and specifies the disciplines which must be represented on the Commission. The disciplines which must be represented include human medicine, veterinary medicine, pharmacy, chemistry (other than pharmaceutical chemistry) and the pharmaceutical industry. Appointments are made by ministers and one of the members is appointed as Chairman.
16. The Commission's role is to provide advice to ministers on matters relating to the execution of the Act or the exercise of any power conferred by it. They also advise on matters relating to medicinal products (whether or not in relation to the Act) and are expressly authorised by section 3(1) to provide advice to Ministers either at their request or in circumstances where the Commission considers it expedient.
17. The Commission also has the function of making recommendations to ministers with regard to the functions of other committees established under the Act. There is however no requirement that the Commission oversee the work of any such committees.
18. By section 4, ministers may establish committees ("section 4 committees") for any purpose connected with the execution of the Act and the exercise of any power conferred by it, whether generally or in relation to any particular class of medicines. Before establishing the committee ministers must consult with appropriate organisations and this would always include the Medicines Commission. Nevertheless section 4 committees are not sub-committees of the Medicines Commission. Rather they are independent bodies established to advise ministers. The best known of these committees is the Committee on Safety of Medicines (CSM) but other section 4 Committees established each have their own character and do not necessarily operate in the same way as the CSM. In some areas practices have grown up so that decisions made on the advice of the CSM are appealed or reviewed by the Commission. There is however now no statutory requirement that this should happen as a matter of course<sup>86</sup> and the practice does not affect all aspects of decision making under the Act.
19. The creation of a further section 4 committee with a remit to consider matters arising out of this Review might require some amendment to primary legislation if the committee were to advise ministers on cost-effectiveness. If it were not, its creation would be reasonably straightforward. The public consultation on the changes envisaged by the Review would, subject to ministers' views, specifically include a consultation on the remit of the new proposed committee and on the criteria for appointments. The committee would be established by an order without any Parliamentary procedure and this would govern (if

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<sup>86</sup> Except for a few products which are not available elsewhere in the European Community and for which an authorisation or renewal application was made between 1 January 1995 and 31 December 1997 and is pending.

inclusion of these features were considered desirable) the disciplines to be represented in the membership. Members would then be appointed by ministers and would perform the functions set out in the establishment order.

### **European Community Law**

20. Until comparatively recently, little attention has been given at EC level to the classification of medicinal products so Member States have developed different systems. However, the Community is now seeking to harmonize the classification arrangements.
21. The Legal Status Directive (92/26/EEC) provides that, when Member States authorise a product, they must categorise it as either to be subject to medical prescription or not to be subject to medical prescription. The Directive also sets out the criteria which are used to determine whether a product should be available on prescription only. These criteria are set out in section 58A of the UK Medicines Act. “Medical prescription” is “any prescription issued by a professional person qualified to prescribe medicinal products”. There is no definition of “prescription”, and there is no distinction between prescribing and supplying as is set out in the UK Medicines Act. The classification is considered in terms of the status of the product rather than of the person prescribing or supplying it.

### **Other relevant public health legislation**

22. Although the Medicines Act 1968 and related provisions under the Act apply to the prescribing, supply and administration of all medicines, the Misuse of Drugs Regulations 1985 apply further safeguards to those activities in relation to drugs which are controlled under the Misuse of Drugs Act 1971 but which also have therapeutic uses and are used as medicines.

### ***The Misuse of Drugs Act 1971***

23. The Misuse of Drugs Act 1971 controls the availability of drugs liable to misuse. The drugs which are subject to the Act’s controls are termed “Controlled Drugs” (CDs). They are listed in Schedule 2 of the Act and separated into three Classes - Class A, Class B or Class C, depending on the level of control under which the drugs have been placed by the United Nations Convention on Narcotic Drugs.
24. The Act contains provisions relating to the import, export, supply and possession of controlled drugs; the safe custody of controlled drugs; offences and penalties relating to unlawful possession and trafficking.
25. Where a medicinal product contains a controlled drug it will be subject to the Medicines Act 1968, but with the Misuse of Drugs legislation providing an additional level of control. Medicinal products containing controlled drugs are all POMs.

### ***The Misuse of Drugs Regulations 1985***

26. The use of controlled drugs as medicines is permitted by the Misuse of Drugs Regulations 1985. These regulations enable the manufacture on a commercial scale and wholesaling of controlled drugs to be undertaken under licence obtained from the Home Office, and they confer authority on doctors, dentists, veterinary surgeons and practitioners, pharmacists and certain other persons (eg police constables and registered midwives) to possess, supply, prescribe and/or administer controlled drugs in the practice of their professions. The regulations and schedules set out which drugs may be used, by which persons, and in what circumstances.

### ***Other legislation relating to Controlled Drugs***

27. Further conditions relating to Controlled Drugs are set out in The Misuse of Drugs (Notification of and Supply to Addicts) Regulations 1973, The Misuse of Drugs (Supply to Addicts) Regulations 1997, and the Misuse of Drugs (Safe Custody) Regulations 1973.

### **NHS Legislation<sup>87</sup>**

#### ***The basic structure***

28. The NHS Act 1977 consists of two parts, which describe different systems. Part I of the Act is primarily concerned with the provision of health care in hospitals and the provision of community health services. Part II of the Act is concerned with the provision of family health services (general medical, general dental, general ophthalmic and pharmaceutical services) which are provided in the community. In general, health professionals working under Part I arrangements are salaried employees of an NHS body, whereas health professionals under Part II are self-employed, or employees of an individual, a partnership or a private corporate body who have made arrangements with an NHS Health Authority for the provision of services.
29. The NHS Act has been significantly amended and in particular by
- i the NHS and Community Care Act 1990 which introduced the distinction between “purchasers” (health authorities and GP fundholders) and “providers” (NHS hospital or community trusts);
  - ii the Medicinal Products Prescription by Nurses [etc] Act 1992, which allowed certain nurses to prescribe some medicines as part of NHS services;
  - iii the Health Authorities Act 1995 which was concerned with the functions and funding of the Health Authorities; and

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<sup>87</sup> The description below is for England and Wales. There are some significant differences in Scotland and Northern Ireland, though the basic structure is the same.

- iv the NHS (Primary Care) Act 1997 which introduced changes applying primarily to doctors and dentists which enabled what were previously Part II services to be delivered under a more flexible system (“Personal Medical Services” or “Personal Dental Services”) within Part I of the Act.
30. In hospitals and the community health services, medicines are usually provided as an integral part of clinical care under Part I of the Act. In certain circumstances (eg in some outpatient clinics) hospital doctors and dentists and community trust nurse prescribers write prescriptions that are subsequently dispensed in the community, as Part II pharmaceutical services.
31. The legal basis for the provision of “pharmaceutical services” in the community, including the dispensing of NHS prescriptions, is set out in sections 41 and 43 of Part II of the Act, and in the NHS (Pharmaceutical Services) Regulations 1992. These regulations require Health Authorities to provide pharmaceutical services, mainly by arrangements with pharmacists, and to set out the terms of service within which such pharmacists must operate.
32. The Pharmaceutical Services Regulations also contain provisions which
- i enable certain doctors in specified rural areas to dispense to specified patients;
  - ii require all doctors to provide drugs needed for the immediate treatment of their patients;
  - iii enable all doctors to provide drugs which are personally administered by them to their patients.

### ***Restrictions***

33. There are some restrictions on the range of medicines which may be provided and publicly funded through NHS prescriptions. Dentists providing general dental services may only prescribe those medicines listed on the Secretary of State’s dental list and nurse prescribers may only prescribe in accordance with the Secretary of State’s nurse prescribing formulary. GPs who are providing general medical services are required to prescribe in accordance with their terms of service set out in the NHS (General Medical Services) Regulations 1992 (paras 43-46 of Schedule 2). These prohibit them from prescribing at NHS expense any medicines listed in Schedule 10, and place conditions on the prescribing of medicines in Schedule 11. A non-statutory committee, the Advisory Committee on NHS Drugs (the ACD), advises ministers on the medicines to be included in Schedule 10, although ministers may act on their own initiative without seeking the ACD’s advice provided that the criteria for their decisions are verifiable and objective.<sup>88</sup>

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<sup>88</sup> The “Transparency” directive, Council Directive 89/105/EEC.

### ***Funding***

34. Sections 97-97A of Part II of the Act contain the legal basis for reimbursing the costs of pharmaceuticals. Section 97(1) provides for payment by the Secretary of State to Health Authorities sums equal to their “general Part II expenditure”, ie the actual cost of payments to those providing family health services excluding any elements which have been brought within HA cash limits. At present, the reimbursement of pharmacists for the costs of the medicines they dispense forms part of the non-cash limited “general Part II expenditure”. It is envisaged that from April 1999 they will become part of cash-limited expenditure under section 97(3A).
35. The Pharmaceutical Services Regulations require the Secretary of State to compile and publish a statement, referred to as the Drug Tariff, which gives details of the prices at which medicines will be reimbursed and the rates of remuneration for pharmacists. Payments for the supply of drugs by doctors under the Pharmaceutical Services Regulations are contained in the Secretary of State’s Statement of Fees and Allowances.
36. The changes introduced in the NHS (Primary Care) Act 1997 will have relatively little impact on the arrangements for reimbursement of the costs of medicines. In particular, doctors and dentists providing personal medical services (PMS) or personal dental services will still have their prescriptions dispensed as pharmaceutical services under Part II of the Act.

### ***Designation of new NHS prescribers***

37. In order to enable additional professional groups to prescribe at NHS expense, it would be necessary to make further amendments to the definition of “pharmaceutical services” in section 41 of the NHS Act. As suggested in the main report, it would probably be most convenient to take a broad power through primary legislation, enabling ministers to nominate specific groups of new prescribers, and to define or vary the range of medicines they are authorised to prescribe at NHS expense, through secondary legislation.

## Annex E: Copy of Consultation Letter

**19 June 1997**

Dear Colleague

### **REVIEW OF PRESCRIBING, SUPPLY AND ADMINISTRATION OF MEDICINES**

1. I am writing to invite you to submit evidence to the review currently taking place into the arrangements for the prescribing, supply and administration of medicines.
2. The Review was set up in March following the publication by the Department of Health last December of its White Paper “Primary Care: Delivering the Future”, which announced proposals to review the current arrangements for the prescribing, supply and administration of medicines, and to consider whether any changes should be made to those arrangements. The Review is not intended to look at the current arrangements for the dispensing of medicines.

The Review Team has members from a wide range of backgrounds, who are listed in Annex A. The Terms of Reference of the review are at Annex B.

3. The Review Team would welcome your advice on:
  - i the extent of perceived problems (if any) with current arrangements;
  - ii the options for change;
  - iii examples of specific clinical circumstances which could be used by the review team to test the adequacy of existing arrangements and the advantages and disadvantages of possible changes.

I would be grateful if, in replying, you would address the attached list of questions as well as any other relevant issues you would like to bring to the team’s attention. It would be extremely helpful if all general comments could, as far as possible, be illustrated by reference to specific clinical examples. We would also appreciate copies of any relevant reports or other material which we might not otherwise have picked up through a standard literature search.

4. Replies to the questions will be considered in the first instance by 4 sub-groups which are currently being set up to support the Review Team, covering the needs of patients in the following broad areas (i) “healthy” patients (ie those with self-limiting illness/those capable of advised self-medication); (ii) people with chronic/progressive illness living in the community; (iii) people with serious conditions requiring rapid response; (iv) people with mental health and behavioural problems, including those in prisons and special hospitals.

5. The sub-groups or the Review Team may wish to seek supplementary written or oral evidence from some respondents. Individual replies will be treated as strictly confidential to the Review Team and its secretariat, although a list of parties giving evidence and a non-attributable summary of the main findings is likely to appear in the final report.
6. I attach a list of the organisations to whom this letter is being sent. I should be grateful if you would copy this letter to any other organisations or individuals who you think might wish to submit comments.
7. If on reflection you do not feel that you have any contribution to make to the review it would be very helpful if you could drop me a short note to say so.

Please send replies to me, Dr June Crown,

c/o  
Review Secretariat  
Room 6E64,  
Quarry House  
Quarry Hill  
LEEDS  
LS2 7UE

to arrive by 21 July 1997.

Yours sincerely

Dr June Crown  
Chairman, Review Team

## **ISSUES TO BE ADDRESSED**

Please illustrate all replies as far as you can with reference to specific clinical circumstances. Examples of innovation, whether successful or unsuccessful, would be particularly helpful. Definitions of some of the terms used are given at the end of the list of questions.

### **A. General**

1. Bearing in mind the criteria of patient safety, clinical effectiveness, effective use of resources, access to services and patient convenience
  - a. what features of the current arrangements for the prescribing, supply and administration of medicines do you believe are particularly valuable and need to be retained in some form?
  - b. what features could be improved?
  - c. what features are now obsolete and should be discarded?
  - d. what inconsistencies and anomalies are there in current arrangements and how could these be removed?
2. To the extent that you see change as desirable, what steps would be needed to encourage successful change to take place (eg changes to legislation, professional roles, training etc)?

### **B. Specific**

- (i) Prescribing
  3. At present, it is usual for one health professional to assess/diagnose the patient's condition, choose the broad treatment strategy and also to take the detailed prescribing decision. Is this essential? Would a separation of diagnosis/assessment from the treatment decision (and/or separation of the choice of the broad treatment strategy from the detailed prescribing decision) raise any unusual issues of clinical, legal and financial accountability?
  4. Is it always necessary to establish a full a priori diagnosis and assessment of the patient's condition, or are there circumstances in which a more limited assessment, within a relatively limited range of alternatives, would be sufficient without compromising patient safety?
  5. How far would it be desirable/practicable to extend education and training of particular professional groups to enable them to prescribe for specific conditions from a restricted formulary? What professional groups should be considered for this kind of limited prescribing role? In each case, how far would this build on existing skills and competencies and how far would additional training be needed?

6. Is it in principle acceptable for continuation of prescribing (with or without subsequent adjustment of the details of treatment) to be carried out by a different professional from the original prescriber? How far in practice would this differ from current experiments in repeat dispensing (see Q11)? What are the implications for professional roles, responsibilities and accountability?
7. Are there any circumstances in which the professional status of the prescriber could influence the patient's readiness
  - a. to seek clinical advice,
  - b. to accept that advice as authoritative?

What are the implications for this review?

8. Is there any danger that an extension of the role of other health professionals in prescribing could lead to fragmentation of patient care? What could be done to ensure that the GP or other responsible doctor is still able to maintain an overview of the care of the patient?
  - (ii) Supply of medicines
9. It is usual practice for one professional (eg a doctor or dentist) to write a prescription, and for another (eg a pharmacist) to supply it or administer it (eg a nurse). How important is this traditional separation of roles, eg in relation to patient safety? With reference to specific examples, how far does this derive from
  - a. the complementary skills of the two professionals concerned,
  - b. the wish to improve safety in the administration of medicines (eg double checking of the prescribed dosage)?
10. Under what circumstances might it be (i) desirable, or (ii) essential for the patient to be given a (possibly small) supply of the medicine prescribed at or immediately following the consultation (eg where there is a need for early treatment or for patient convenience)? What are the implications for professional roles and responsibilities?
11. Would you wish to see a wider use of repeat dispensing (ie multiple dispensing under the professional oversight of a pharmacist following an assessment and prescription by a doctor)?
  - (iii) Supply or administration of medicines under protocol
12. Are there any circumstances in which supply or administration of medicines under group protocols (ie non-patient specific) could be clinically justified?

13. How precise do the doctors' and dentists' instructions need to be, eg on
- (i) clinical assessment of individuals?
  - (ii) contra-indications and interactions?
  - (iii) doses?
  - (iv) referral for further opinion?
  - (v) discharge procedures?
14. What (a) understanding of principles of clinical assessment, (b) other core competencies, (c) special training should professionals have before they can accept responsibility for the supply and administration of medicines? Does administration under group protocols raise any fundamentally new issues of clinical responsibility?

## Annex F: Circulation List and List of Respondents

### **Distribution of Consultation Letter**

Academy of Medical Royal Colleges  
Ambulance Service Association  
Ambulance Service Institute  
Association for Quality in Healthcare  
Association of British Pharmaceutical Industries  
Association of Chief Chiropody Officers  
Association of Community Health Councils of England and Wales  
Association of National Specialists in Scotland  
Association of Nurse Prescribing  
Association of Optometrists  
Association of Private Hospital Pharmacists  
Association of Professional Ambulance Personnel  
British Association for Immediate Care  
British Dental Association  
British Dental Association Community Dental Services Group (Wales)  
British Dental Association Hospital Group (Wales)  
British Dental Association University Teachers Group (Wales)  
British Diabetic Association  
British Dietetics Association  
British Health Care Association  
British Medical Association  
British Oncology Pharmacy Association  
British Orthoptic Society  
British Psychological Society  
British Society of Clinical Pharmacologists  
Carers National Association  
Central Consultants and Specialists Committee of the British Medical Association  
Chartered Society of Physiotherapists  
Chief Pharmacists of NHS Trusts in England & Wales  
College of Occupational Therapists

College of Optometrists  
College of Pharmacy Practice  
College of Radiographers  
Community & District Nursing Association  
Community Care Liaison Group  
Company Chemists Association  
Community Services Pharmacists Group  
Consumers Association  
Council for the Professions Supplementary to Medicine  
Council of Europe Committee of Experts on Pharmaceutical Questions  
Department for Education and Employment  
Directors of Pharmaceutical Public Health (Wales)  
Directors of Pharmaceutical Services of Boards (NI)  
Directors of Pharmaceutical Services of Trust Hospitals (NI)  
Dispensing Doctors Association  
English National Board of Nursing, Midwifery & Health Visiting  
Faculty of Accident & Emergency Medicine  
Faculty of Dental Surgery (Royal College of Surgeons of England)  
Faculty of General Dental Practitioners - North Wales  
Faculty of General Dental Practitioners - South Wales  
Faculty of Occupational Medicine  
Faculty of Pharmaceutical Medicine  
Faculty of Pre-Hospital Care  
Faculty of Public Health Medicine  
General Dental Council  
General Dental Practitioners Association  
General Dental Services Committee of the British Dental Association  
General Medical Council  
General Medical Services Committee of the British Medical Association (now General Practitioners Committee)  
General Optical Council  
Genetic Interest Group  
Guild of Hospital Pharmacists  
Heads of Therapy Schools (Wales)  
Health Authorities in England & Wales  
Health Boards in Scotland & Northern Ireland  
Health Visitors Association  
Home Office  
Hospice Pharmacists Association  
Institute of Health Services Management  
Joint Consultants Committee of the British Medical Association / Academy of Medical Royal Colleges  
Joint Royal Colleges Ambulance Service Liaison Committee  
Junior Doctors Committee of the British Medical Association  
Liaison Committee of Royal Colleges in Wales

Local Medical Committees  
Local Pharmaceutical Committees  
Long Term Medical Conditions Alliance  
Medical Defence Union  
Medical Ethics and Law  
Medical Protection Society  
Medical Schools  
Medicines Control Agency  
National Association of Commissioning GPs  
National Association of Fundholding Practices  
National Association of Health Authorities and Trusts now the NHS Confederation  
National Association of Senior Pharmacy Managers  
National Board of Nursing, Midwifery and Health Visiting, Northern Ireland  
National Board for Nursing, Midwifery and Health Visiting, Scotland  
National Consumer Council  
National Council for Hospice and Specialist Palliative Care  
National Nursing, Midwifery and Health Visiting Advisory Committee (Scotland)  
National Pharmaceutical Advisory Committee  
National Pharmaceutical Advisers Group  
National Pharmaceutical Association  
National Pharmacy Advisors Group  
National Prescribing Centre  
Neurological Alliance  
NHS Trusts in England, Wales, Scotland & Northern Ireland  
Northern Ireland Post-Graduate Education & Training Committee  
Orthoptists Board  
Patients' Association  
Patients' Forum  
Pharmaceutical Contractors Committee [Northern Ireland]  
Pharmaceutical Services Negotiating Committee  
Prescription Pricing Authority  
Prescription Pricing Services (Wales)  
Podiatry Association  
Post-Qualification Education Board for Pharmacists in Scotland  
Public Health Laboratory Service  
Queens Nursing Institute  
Royal College of Anaesthetists  
Royal College of General Practitioners  
Royal College of Nursing of the UK  
Royal College of Midwives  
Royal College of Obstetricians and Gynaecologists  
Royal College of Ophthalmologists  
Royal College of Paediatrics and Child Health  
Royal College of Pathologists  
Royal College of Physicians and Surgeons of Glasgow

Royal College of Physicians of Edinburgh  
Royal College of Physicians of Ireland  
Royal College of Physicians of London  
Royal College of Psychiatrists  
Royal College of Radiologists  
Royal College of Speech and Language Therapists  
Royal College of Surgeons of Edinburgh  
Royal College of Surgeons of England  
Royal College of Surgeons of Ireland  
Royal Pharmaceutical Society of Great Britain  
Royal Pharmaceutical Society of GB (Scottish Department)  
Royal Pharmaceutical Society of GB (Welsh Executive)  
Royal Pharmaceutical Society of Northern Ireland  
Scottish Association of Health Councils  
Scottish Cancer Care Group  
Scottish Chief Pharmaceutical Officers Group  
Scottish Committee of Optometrists  
Scottish Neonatal and Paediatric Pharmacist's Group  
Scottish Pharmaceutical General Council  
Scottish Pharmaceutical Federation  
Scottish Pharmaceutical Prescribing Advisors Group  
Scottish Pharmacists in Mental Health  
Scottish Trust Chief Pharmacists' Group  
Society and College of Radiographers  
Society of Apothecaries of London  
Society of Chiropodists and Podiatrists  
Standing Committee on Pharmacy Education  
Standing Pharmaceutical Advisory Committee  
United Kingdom Central Council for Nursing, Midwifery and Health Visiting  
UK Neonatal and Paediatric Pharmacist Group  
UK Drug Information Pharmacists' Group  
UK Psychiatric Pharmacy Group  
Ulster Chemists Association  
UNISON Health Care  
United Kingdom Clinical Pharmacy Association  
University College of Medicine (Wales)  
Welsh Board Royal College of Midwives  
Wales Committee for Health Care Professionals  
Welsh Central Pharmaceutical Committee  
Welsh Committee Community Practitioners and Health Visitors Association  
Welsh Committee for Postgraduate Pharmaceutical Education  
Welsh Council for Postgraduate Medical and Dental Education  
Welsh Dental Committee  
Welsh Medical Committee  
Welsh Medical Resources Centre (WeMeReC)

Welsh Nursing and Midwifery Committee  
Welsh National Board for Nursing, Midwifery and Health Visiting  
Welsh Optical Committee  
Welsh Pharmaceutical Committee  
Welsh Post-Graduate Education Committee  
Welsh School of Pharmacy  
Welsh Scientific Advisory Committee

## **Respondents to Consultation Letter**

*Health Authorities (HAs) including Local Medical Committees (LMCs), Pharmaceutical Advisory Committees (PACs) etc*

Argyll & Clyde Health  
Argyll & Clyde Health Board  
Avon HA  
Ayrshire & Arran Health Board  
Ayrshire & Arran Area Pharmaceutical Committee  
Bath Lodge Practice (comments for LMC Hants)  
Barking & Havering and Redbridge & Waltham Forest LPCs  
Barnet HA  
Barnsley HA  
Bedfordshire Health  
Bexley & Greenwich HA  
Birmingham HA  
Blackburn, Hyndburn & Ribble HA  
Bradford HA  
Brent & Harrow HA  
Bromley HA  
Bro Taf HA  
Bro Taf LPC  
Bro Taf LMC  
Buckinghamshire HA  
Calderdale & Kirklees HA  
Cambridge & Huntingdon HA  
Cornwall & Isles of Scilly HA  
Coventry HA  
Croydon HA  
Doncaster HA  
Dorset HA  
Dudley HA  
Durham HA  
Durham LPC  
Dyfed Powys LPC

Dyfed/Powys Nursing & Midwifery Advisory Committee  
Ealing, Hammersmith & Hounslow HA  
East Lancashire HA  
East Norfolk HA  
East & North Herts LMC  
East & North Hertfordshire HA  
East Surrey HA  
East Sussex, Brighton & Hove HA  
Enfield & Haringey HA  
Fife Health Board (Public Health)  
Forth Valley Health Board  
Forth Valley Local Health Council  
Gateshead & South Tyneside HA  
Gloucester HA  
Grampian Health Board  
Gwent HA  
Gwent HA - District Pharm Comm  
Gwent Local Optical Committee  
Hampshire LMC  
Herefordshire HA  
Hillingdon HA  
Iechyd Morgannwg HA  
Iechyd Morgannwg District Pharm Committee  
Iechyd Morgannwg Local Nursing & Midwifery Committee  
Kensington, Chelsea & Westminster HA  
Kingston & Richmond HA  
Lambeth, Southwark & Lewisham HA  
Lambeth, Southwark & Lewisham LPC  
Lanarkshire Health Board  
Leeds HA  
Leicestershire Health  
Lincolnshire HA  
Liverpool HA  
Lothian Health Board  
Merton, Sutton & Wandsworth HA  
Newcastle & North Tyneside HA  
Northamptonshire HA  
North Notts HA  
North Cheshire HA  
North Cumbria HA  
North Cumbria LMC  
North Derbyshire HA  
North Staffs HA  
Northumberland HA  
North Wales HA

North Wales LPC  
North West Lancs HA (LMC comments)  
Nottingham LMC  
North West Anglia HA  
North West Anglia Local Dental Committee  
North West Lancs HA  
Nottingham HA  
North West Anglia HA  
Oxfordshire HA  
Pharmaceutical Directors of Health & Social Services Boards in NI  
Portsmouth & SE Hants HA  
Rampton Hospital Authority  
Redbridge & Waltham Forest HA  
Redbridge & Waltham Forest LPC  
Rotherham HA  
Salford & Trafford HA  
Sandwell HA - prescribing committee  
Sefton HA  
Shetland Health Board  
Shropshire HA  
Shropshire Health (HA) Director of Quality  
Solihull HA  
Solihull LPC  
Somerset HA  
Southampton & South West Hants HA  
South Cheshire HA  
Southern Derbyshire HA  
Southern H & SS Board  
South Essex LMC  
South Humber HA  
South Staffs HA  
South & West Devon HA  
St Helens & Knowsley HA  
Sunderland HA  
Tees HA  
Wakefield HA  
Walsall HA  
Warwickshire HA  
Western Area Board  
Western Isles Health Board  
Western Isles Health Unit  
West Herts HA  
West Hertfordshire LPC  
West Kent HA  
West Midlands Chief Pharmacists (Birmingham & Solihull)

West Pennine HA  
West Sussex HA  
Wigan & Bolton HA  
Wiltshire HA  
Wolverhampton HA  
Worcester HA

***NHS Trusts***

Aberdeen Royal Hospitals Trust  
Addenbrooke's Trust  
Airedale Trust - pharmacy  
Altnagelvin Hospitals Health & Social Services Trust  
Antrim Hospital  
Anglian Harbours Trust  
Ashworth Hospital Authority  
Avon Ambulance Trust  
Aylesbury Vale Healthcare  
Ayrshire & Arran Community Health Care Trust  
Barnsley Community & Priority Services Trust  
Basildon & Thurrock Hospitals/ Thameside Community Trust  
Basildon & Thurrock Trust  
Bath & West Community Trust  
Bedford & Shires Health & Care Trust  
Belfast City Hospital  
Bethlem & Maudsley Trust  
Birmingham Heartlands & Solihull Trust  
Bishop Auckland Hospitals Trust  
Blackpool, Wyre & Fylde Community Trust  
Borders General Hospital  
Bradford Royal Infirmary  
Bridgend & District Trust  
Brighton Health Care Trust  
Burnley Health Care Trust  
Burton Hospitals Trust  
Bury Health Care, Mrs Abbott  
Camden & Islington Community Trust  
Canterbury & Thanet Community Health Care Trust  
Cardiff Community Health Care  
Cardiff Royal Infirmary Emergency Nurse Practitioners  
Cardiothoracic Centre, Liverpool Trust

Carlisle Hospitals  
Causeway Health & Social Services Trust  
Central Manchester HC Trust  
Central Scotland Healthcare Trust nursing  
Central Sheffield University Hospitals Trust  
Ceredigion & Mid Wales Trust  
Ceredigion & Mid Wales Trust  
Chase Farm Hospital Trust  
Chelsea & Westminster Health Care Trust  
Cheshire Community Health Care Trust  
Cheshire Health Care Community Trust  
Chesterfield & North Derbyshire Royal Hospital Trust  
Chorley & South Ribble Trust  
Christie Hospital Trust Holt Radium Institute  
Christie Hospital Trust  
City & Hackney Community Services Trust  
City Hospitals Sunderland Trust  
Clatterbridge Centre of Oncology  
Community Health Sheffield  
Community Health Services Trust  
Community Health Care Bolton Trust  
Coventry Healthcare Trust  
Craigavon & Banbridge Community Health and Social Services Trust  
Croydon Community Health Trust  
Darlington Memorial Hospitals Trust  
Dartford & Gravesham Trust  
Derbyshire Ambulance Service Trust  
Derbyshire Royal Infirmary  
Derrifield Hospital, Plymouth  
Doncaster Healthcare Trust  
Doncaster Royal & Montagu Hospital Trust  
Dorset Community Trust  
Dorset Healthcare Trust  
Down Lisburn Trust  
Dudley Group of Hospitals Trust  
Dumfries & Galloway Community Trust  
Dumfries & Galloway Trust  
East Berkshire Community Health Trust  
Eastbourne & County Healthcare Trust  
Eastbourne Hospitals Trust  
East Cheshire Trust  
East Glamorgan Trust  
East Hertfordshire Trust  
East & Midlothian Trust  
East & North Herts Trust

East Somerset NHS Trust  
East Yorks Community Trust  
Edinburgh Health Care Trust  
Edinburgh Sick Children's Trust  
Enfield Community Care Trust  
Enfield Community Care Trust  
Epsom Health Care Trust  
Essex Rivers NHS Trust  
Falkirk & District Royal Infirmary Trust  
Fife Health Care Trust  
Forth Valley Hospital Pharmaceutical Services (Stirling Royal Inf)  
Fosse HealthTrust  
Foyle Health & Social Service Trust  
Freeman Group of Hospital  
Frenchay Healthcare Trust  
Frenchay Trust  
Frimley Park Hospital Trust  
Gateshead Hospitals Trust  
George Eliot Hospital Trust  
Glan Clywd Trust  
Glan Hafren Trust  
Glan-y-Mor Trust Midwifery & Nursing Committee  
Glan -y- Mor Medical Director  
Glasgow Dental Hospital & School  
Glasgow Royal Infirmary  
Glasgow Royal Infirmary Univ Trust  
Glenfield Hospital Trust  
Gloucestershire NHS Trust  
Good Hope Hospital Trust  
Grantham & District Trust  
Greater Glasgow Community & Mental Health Trust  
Great Ormond Street Trust  
Green Park Healthcare Trust  
Greenwich Health Care Springfield University Hospital  
Guild Community Health Care Trust  
Guy's & St Thomas' Trust  
Gwynedd Hospitals Trust  
Grampian Healthcare Trust  
Halton General Hospital  
Hammersmith Hospitals Trust  
Harefield Hospital  
Harrogate Health Care NHS Trust  
Hartlepool & East Durham Trust  
Hastings & Rother Trust  
Havering Hospitals

Heatherwood & Wexham Park Trust  
Hereford Hospitals Trust  
Highland Communities Trust  
Hillingdon Hospital Trust  
Hinchingsbrooke HC Trust  
Homerton Hospital Trust  
Hope Hospital  
Horizon Trust  
Hounslow & Spelthorne Community & Mental Health NHS Trust  
Huddersfield Trust  
Inverclyde Royal NHS Trust  
Inverclyde Royal Trust  
John Radcliffe Hospital  
Keith Farrar Wirral Hospital  
Kent & Sussex Weald Trust  
King's Healthcare Trust  
Kingston & District Community Trust  
Lancaster Acute Hospitals Trust  
Lambeth Health Care Trust - Drug & Therapeutics Committee  
Lanarkshire Health Care Trust  
Law Hospital Trust  
Leeds Community & Mental Health Services Trust  
Leicester General Hospitals Trust  
Lifecare Trust  
Lifespan HC Trust  
Lincoln District Trust  
Lincoln & Louth Trust  
Liverpool Women's Hospital Trust  
Llanelli/Dinefwr Trust  
Lomond Health Care Trust  
Mancunian Community Health Trust  
Mater Hospital, Belfast  
Mid Cheshire Hospitals Trust  
Mid Glamorgan Ambulance Trust-Dr Lewis  
Mid-Kent Health Care Trust  
Milton Keynes Community Trust  
Monklands & Bellshill Trust  
Moray Health Services Trust  
Morrison Hospital Trust  
Mount Vernon & Watford Hospitals Trust  
Northern Birmingham Community NHS Trust  
New Cross Hospital Trust  
Newham Community HS Trust  
Newham Healthcare Trust  
North Ayrshire & Arran Trust

North Down & Ards Community Trust  
Northern Birmingham Community Trust  
North Derbyshire Community Trust  
North Durham Acute Hospitals Trust  
North Durham Community HC Trust  
North East Lincolnshire Trust (Grimsby Drug & Therapeutics Committee)  
Northern General Hospital Trust  
Northgate & Prudhoe Trust  
North Hants Hospitals Trust  
North Lakeland Health Care Trust  
North Manchester Health Care Trust  
North Middlesex Hospital  
North Staffs Combined Health Care Trust  
North Staffordshire Hospital  
North Tees Health Trust  
North Tyneside Health Care Trust  
Northumberland Community Health Trust  
Northwick Park & St Marks Hospitals  
Nottinghamshire Ambulance Service Trust  
Nottingham City Hospital Trust  
Nottingham HC Trust  
Nuffield Orthopaedic Centre Trust  
NW Anglia Health Care Trust  
Oldham Trust  
Optimum Health Services NHS Trust  
Oxford Radcliffe Hospital Trust  
Oxfordshire Community Health Trust  
Papworth Hospital Trust  
Parkside Health Trust  
Pathfinder Mental Health Services Trust Drugs Advisory Committee  
Pembrokeshire & Derwen Trust  
Perth & Kinross Trust  
Perth & Kinross Health Care Trust  
Peterborough Hospitals Trust  
Pinderfields Trust  
Poole Hospital Trust  
Portsmouth Healthcare Trust  
Preston Acute Hospitals Trust  
Queen Margaret Hospital Trust Dumfermline  
Queen Mary's Sidcup Trust  
Queen's Medical Centre, Nottingham  
Queen Victoria Hospitals Trust  
Redbridge Health Care Trust  
Richmond, Twickenham & Roehampton Health Care Trust  
Riverside Community Health Care Trust

Rockingham Forest Trust  
Rotherham General Hospitals Trust  
Rotherham NHS Trust  
Royal Alexandra Hospital, Renfrewshire  
Royal Brompton Hospital  
Royal Cornwall/Cornwall Healthcare Trust  
Royal Group of Hospitals, Belfast  
Royal Group of Hospitals & Dental Hospital Health and Social Services Trust  
Royal Hospitals Trust  
Royal Hull Hospitals Trust  
Royal Infirmary of Edinburgh Trust  
Royal Marsden Trust & Senior Pharmacy Managers in North Thames  
Royal United Hospital, Bath  
Royal Victoria Infirmary  
Rugby NHS Trust  
Salford Royal Hospitals Trust  
Salford Community Trust  
Salford Royal Hospitals  
Salisbury Health Care Trust  
Sandwell Healthcare Trust  
Scarborough & North East Yorks Trust  
Scottish Ambulance Service NHS Trust  
Shropshire's Mental Health Trust  
Singleton Hospital - Swansea Trust  
Solihull Healthcare Trust  
Southampton Community Health Services Trust  
Southampton University Hospitals Trust  
South & East Wales Ambulance Trust  
South Ayrshire Hospitals Trust  
South Beds Community Trust  
South Birmingham Mental Health Trust  
South Devon Health Care Trust  
South Durham Trust  
Southend HC Trust  
South Kent Hospitals Trust  
South Lincolnshire Community & Mental Health Services Trust  
South Manchester University Hospitals Trust  
Southmead Health Services Trust  
Southport & Formby Trust  
South Tees Community Mental Health Trust  
South Tees Acute Hospital Trust  
South Tyneside Health Care Trust  
South Yorks Metropolitan & Paramedic Service Trust  
South Warwickshire Trust  
Sperrin Lakeland Trust

St George's Health Care Trust  
St Mary's NHS Trust  
St Richard's Hospital Trust  
St Stephen's Centre, Chelsea & Westminster Hospital  
Stirling Royal Infirmary Trust  
Stockport Acute Services Trust  
Tameside & Glossop Community & Priority Services Trust  
Tayside Trust Pharmacy Managers  
Thameside Community Trust  
The Victoria Infirmary Trust, Belfast  
Tower Hamlets Health Care Trust  
Ulster, North Down & Ards Trust  
United Bristol HC Trust (Bristol Oncology Centre)  
United Leeds Teaching Hospitals - Leeds General Infirmary  
University Hospital Birmingham Trust  
Victoria Infirmary Trust, Glasgow  
Wakefield & Pontefract Community Health Trust  
Walsall Community Health Trust  
Walsall Hospitals Trust  
Walton Centre Trust  
Warrington Community HC Trust  
Warrington Hospital Trust  
Warwickshire Ambulance Trust  
Westcountry Ambulance Services Trust  
West Cumbria Trust  
West Lothian Trust  
West Middlesex University Hospital Trust  
Weston Area Health Trust  
Weston General Hospital  
Weston Park Hospital Trust  
Whittington Hospital  
Wigan & Leigh Health Services Trust  
Wiltshire HC Trust  
Winchester & Eastleigh Health Care Trust  
Wirral Hospital  
Worcestershire Community Health Care Trust  
Worthing Community & Mental Healthcare  
Worthing Priority Trust  
York Health Services Trust  
Yorkhill NHS Trust, Glasgow

## **Professional Bodies**

Ambulance Service Association  
Association of Anaesthetists  
Assoc. Welsh Nurse Practitioners  
Association of the British Pharmaceutical Industry  
Association of Chief Chiropractic Officers  
Association of Anaesthetists  
Association for Palliative Medicine of GB & Ireland  
Association of Pharmacy Technicians UK  
Association of Primary Care Medical Advisers  
Association of Optometrists  
Assoc of Chartered Physiotherapists in Management  
British Medical Association  
British Association for Antimicrobial Chemotherapy  
British Association of Applied Chiropractic  
British Association of Operating Department Assistants  
British Association of Medical Managers  
British Dental Association  
British Diabetic Association  
British Dietetic Association  
British Epilepsy Association  
British Medical Acupuncture Society  
BMA Scottish Office  
British Nuclear Medicine Society  
British Orthoptic Society  
British Pharmacological Society (clinical section - Wolfson Unit )  
British Pharmaceutical Students' Association  
British Psychological Society  
Cambridge College Nurses Association  
Chartered Society of Physiotherapy  
College of Optometrists  
College of Pharmacy Practice  
College of Occupational Therapists  
Community Practitioners and Health Visitors Association  
Community Psychiatric Nurses' Association  
Committee of Regional Advisers in General Practice in England  
Community Care Liaison Group  
Community Services Pharmacists  
Community Services Pharmaceutical Sub-committee - Welsh Pharm Committee  
Dispensing Doctors Association  
English National Board for Nursing, Midwifery & Health Visiting  
Faculty of Family Planning & Reproductive Health Care  
Faculty of Homeopathy  
Faculty of Public Health Medicine

Family Planning Association  
Family Planning Nurses Forum, RCN  
General Chiropractic Council  
General Dental Council  
General Medical Council  
General Medical Services Committee (BMA)  
General Osteopathic Council  
Guild of Hospital Pharmacists  
Institute for Complementary Medicine  
Joint Consultants Committee (BMA)  
National Association of Nurses for Contraception & Sexual Health  
National Association of Fundholding Practices  
National Association of Senior Pharmacy Managers  
National Board of Nursing, Midwifery & Health Visiting for NI  
National Board for Nursing, Midwifery & Health Visiting for Scotland  
National Pharmaceutical Association  
NHS Wales: Heads of Chiropody/Podiatry Group  
Pharmacists Association  
Royal College of General Practitioners  
Royal College of Midwives  
Royal College of Nursing  
Royal College of Nursing, Scottish Board  
Royal College of Obstetricians & Gynaecologists  
Royal College of Ophthalmologists  
Royal College of Paediatrics & Child Health  
Royal College of Physicians of London  
Royal College of Physicians of Edinburgh  
Royal College of Physicians & Surgeons of Glasgow  
Royal College of Radiologists  
Royal College of Surgeons of Edinburgh  
Royal College of Surgeons of England  
Royal Pharmaceutical Society of GB  
Royal Pharm Soc of GB: Scottish Dep  
Royal Pharm Soc of GB: Welsh Exec  
Scottish Association of Health Councils  
Scottish Association of Medical Prescribing Advisers  
Scottish Association for Mental Health  
Scottish Cancer Care Pharmacists' Group  
Scottish Joint Consultants Committee  
Scottish Pharmacists in Mental Health  
Scottish Pharmaceutical Federation  
Scottish Pharmaceutical General Council  
Scottish Pharmaceutical Presc Advisers Gp  
Scottish Practice Nurse Association  
Scottish Centre for Post-Qualification Pharmaceutical Education

Society of Apothecaries  
Society of Apothecaries of London  
Society of Chiropodists & Podiatrists  
Society of Orthoptists  
United Kingdom Central Council for Nursing, Midwifery & Health Visiting

***Professional Organisations***

Hospice & Palliative Care  
Independent Federation of Nursing in Scotland  
Intensive Care Society  
Intensive Care Society via Dr Kapur  
Joint Royal Colleges Ambulance Service Liaison Committee  
National Blood Service  
National Council for Hospice & Specialist Palliative Care Services  
Neonatal & Paediatric Pharmacists Group  
Northern Ireland Prescribing Advisers' Group  
North Wales Dental Committee  
Pharmaceutical Advisers Group  
Pharmaceutical Contractors' Committee of Northern Ireland  
Pharmaceutical Society of Northern Ireland  
Pharmaceutical Services Negotiating Committee  
Queen's Nursing Institute  
UK Radiopharmacy Group  
UK Psychiatric Pharmacy Group  
Welsh Comm for PG Pharm Education  
Welsh National Board for Nursing, Midwifery & Health Visiting

***Other Organisations***

Anaphylaxis Campaign  
Anonymous (Univ Hospital, Birmingham)  
Associated Chemists (Wicker) Ltd  
Association of CHCs for E & W  
Aston University  
Bayer plc  
British Association of Cancer United Patients  
Boots Pharmacists' Association  
Boots the Chemists  
British Airways Travel Clinics  
Brook Advisory Centres  
City University  
City University - St Barts School of Nursing & Midwifery

Company Chemists Association  
Co-operative Pharmacy Technical Panel  
Crossroads Caring for Carers  
Cystic Fibrosis Trust  
Dental Protection  
Depression Alliance  
Dixon & Spearman Ltd  
Drug Utilization Research Unit Queens University Belfast  
Edge Hill University College  
European Parkinson's Disease Association  
Genetic Interest Group  
Glaxo Wellcome  
Health & Care Professions Education Forum HM Prison Service - health care  
Home Office - Action against Drugs Unit  
Keele Dept of Medicines Management  
King Alfred's College of Higher Education, Winchester  
Long-Term Medical Conditions Alliance  
Margaret Pyke Family Planning Centre  
Marie Curie Cancer Care  
Medical Defence Union (Nursing)  
Medical & Dental Union of Scotland  
MENCAP  
Middlesex Pharmaceutical Group  
MIND  
MSF - Guild of Hospital Pharmacists  
National Consumer Council  
National Deaf, Blind Association  
National Prescribing Centre  
National Schizophrenia Fellowship  
National Schizophrenia Society  
Pain Society  
Patients Association  
Pharmaceutical Support Services (hospital pharmacy managers in SW (East) region)  
Pharmacy Practice Division, Common Services Agency, Scotland  
Pharmacy Practice Group(Kings College)  
Pharmacy Support Group  
Prescription Pricing Authority  
Proprietary Association of Great Britain  
Public Health Laboratory Service  
Public Health Laboratory Service Communicable Disease Surveillance Centre  
Queen's University, Belfast  
Queens Univ, Belfast - Pharmacy Practice Research Group  
Resource & Service Development Centre  
Resuscitation Council (UK)  
Royal National Institute for the Blind

SCOPE for People with Cerebral Palsy  
Skin Care Campaign  
St Anthony's Medical Group  
St Catherine's Hospice  
St Luke's Hospice, Sheffield  
Solihull Metropolitan Borough Council  
South & West Regional Office of NHS Executive  
Sussex Pharmacy Academic Practice Unit  
Tesco  
Thames Valley University  
UKAN - Narcolepsy Association  
UNISON  
University of Bradford (nursing)  
University of Brighton - Nursing & Midwifery  
University of Bristol, Faculty of Health Care  
University of Central Lancashire  
University College London Hospitals  
University College of St Martin Lancaster  
University of Dundee School of Nursing & Midwifery  
University of East Anglia School of Nursing & Midwifery  
University Hospital of Wales  
University of Huddersfield - School of Human & Health Sciences  
University of Liverpool  
University of North London (School of Health Studies)  
University of Portsmouth  
University of Sheffield - ScHARR  
University of Southampton School of Nursing & Midwifery  
University of Wales, Cardiff Dept of Optometry & Vision Sciences  
University of Wales Dept of Psychological Medicine  
University of Wales Institute Faculty of Community Health Sciences  
University Hospital of Wales Pharmacy Department  
Univ of Wales College of Medicines  
Welton & District Patients and Doctors Assoc  
Western Consortium: Local Supervising Authorities  
Young Pharmacists Group

***Practices and Surgeries***

Ailsa Surgery  
Ashgrove Surgery, Mid Glamorgan  
Barrowbygate Pharmacy  
Brynteg Surgery  
Downfield Surgery, Dundee  
Gorbals Health Centre

Midlock Medical Centre  
Northgate Medical Centre  
Parkhead Health Centre  
Possilpark Health Centre  
Turret Medical Centre  
Winterton Medical Practice

### ***Individuals***

Martin Anderson, Pharmacist Chelmsford  
Dr Moses Apiliga, Glasgow GP  
Mr Surinder Bassan, Pharmacist Atherstone  
Dr Trevor Bayley, PG Dean, Mersey  
Cath Boury, Community Pharmacist Hull  
Dr J Bryson, GP Millport  
Mary Cooksley, Nurse Practitioner, Cardiff  
Judith Cope, Pharmacist, Harrow  
Prof Cromarty, National Specialist in Clinical Pharmacy, Aberdeen  
Stan Dobrzanski, Pharmacist, Bradford Royal Infirmary  
Mrs Duncan & Mr Richards, Pharmacists, Dundee  
Dr Durham, Consultant, London  
Dr R Fitzpatrick/Miss H Boardman; Dept of Medicines Management Keele  
Dr Steven Ford, GP, Haydon Bridge  
Marian Garner Patel / Dr Geoffrey Waterman, Pharmacists, Harrow  
Mr M I Grace, Pharmacist, Huddersfield  
Dr GI Graham, Cwmbran  
Dr T Greenhalgh, GP, London  
Wendy Harris, Community Pharmacy Adviser, Derby  
Mrs M Hartley, College Nurse, Cambridge  
Paul Hughes, Homeopath, London  
P Kirkpatrick, Pharmacist,  
East Grinstead  
Mr A MacLaren, Pharmacist, Glasgow  
Dr Maddock, Pharmacist, Padstowe  
Dr Malone, GP, Glasgow  
Prof Marshall Marinker, London  
Dr R J Moffatt, GP, Woodbridge  
Shaun O'Connell, GP, Tadcaster  
Mr Pillai, Pharmacist Frimley  
Mr H Purves, Pharmacist, Fife  
Jenny Rainsbury, School Nurse, Wrexham  
Sally Rees, Director of Primary Care  
Dr Rosen, London

Martin Schweiger, Consultant, Leeds  
Dr Selley, GP, Crediton  
Kevin Smith, Pharmacist, Wales  
Andrea Thomas, Health Visitor, Wales  
Dr C Tyrie, Consultant Psychiatrist  
Fiona Winstanley, Nurse, Woodbridge

## Annex G: Summary of Main Points Raised in Response to Consultation

There was a wealth of detail in the response to consultation, and it is impossible to do justice to it in reasonable length. This annex seeks merely to convey the main weight of opinion on each of the questions posed in the consultation letter.

### General issues

*Q1 What valuable features of the current arrangements [for prescription, supply and administration of medicines] need to be retained? What features could be improved? What features are obsolete and should be discarded? What inconsistencies and anomalies are there, and how could these be removed?*

Valuable features of the current system which should be retained or enhanced included:

- ❖ the clear legal framework, including the separation of medicines into POM, P and GSL categories;
- ❖ the separation of prescribing from supply and administration (strongly supported in the areas covered by all 4 sub-groups);
- ❖ the coordination of care by a single professional, usually the GP;
- ❖ the pharmacist's role in providing information and advice both to patients and to other professionals.

Features which needed to be improved included:

- ❖ patient choice and patient access;
- ❖ communication between professionals, including better use of IT (strongly supported);
- ❖ communications with patients.

Features which respondents thought obsolete or in need of radical revision included:

- ❖ repeat prescribing/medicine review arrangements (strongly supported);
- ❖ the failure to use fully the skills of all professionals, eg in advising on appropriate medication, and the need for written endorsement of their prescribing advice by a second clinician (very strongly supported).

*Q2 If change is desirable, what steps are needed to encourage successful change?*

Responses to this question reflected the overwhelming support for allowing some extensions to prescribing by new professionals (see Q5 below), and for clarification of the role of supply and administration under group protocol. Steps needed to encourage change included:

- ❖ review of the legislation;
- ❖ nationally accredited education and training (strongly supported);
- ❖ pilot schemes;
- ❖ use of integrated IT to ensure safe communication within the professional team.

## Specific issues

### *(i) Prescribing*

*Q3 At present, it is usual for one health professional to assess/diagnose the patient's condition, choose the broad treatment strategy **and** also take the detailed prescribing decision. Is this essential? Would a separate of diagnosis/assessment from the treatment decision (and/or a separation of the choice of the broad treatment strategy from the detailed prescribing decision) raise any unusual issues of clinical, legal and financial accountability?*

Responders were split on this issue. A minority felt that the traditional model was more “holistic” and preferable (for some respondents essential) on grounds of patient safety, clear legal and financial accountability, and patient convenience. The majority however felt that models in which detailed prescribing was carried out by a second professional, after an initial assessment and broad choice of treatment by a first, were acceptable. Possible advantages mentioned included the use of specialist skills (eg pharmacology) in the prescribing decision, and greater time for the second professional to discuss the prescribing choice with the patient, resulting in better concordance.

*Q4 Is it always necessary to establish a full **a priori** diagnosis and assessment of the patient's condition, or are there circumstances in which a more limited assessment, within a relatively limited range of alternatives, would be sufficient without compromising patient safety?*

Again responders were split. A minority felt that a full diagnosis was necessary before prescribing, but the majority view was that this was not always practicable (especially in emergency situations) and that prescribing on the basis of a more limited, symptomatic assessment was acceptable given various safeguards including:

- ❖ working within clear protocols;
- ❖ recognition of limits of competence;

- ❖ sharing of information by appropriate use of IT.

*Q5 How far would it be desirable/practicable to extend education and training of particular professional groups to enable them to prescribe for **specific** conditions from a **restricted** formulary? What professional groups should be considered for this kind of limited prescribing role? In each case, how far would this build on existing skills and competencies and how far would additional training be needed?*

There was overwhelming support for this proposal, in the responses seen by all 4 subgroups. Possible professional groups to be considered for prescribing included:

- ❖ specialist nurses (eg nurses in diabetic and dermatology clinics, palliative care nurses, stoma nurses, tissue viability nurses, community psychiatric nurses, anaesthetic assistants, nurse practitioners);
- ❖ midwives;
- ❖ pharmacists (eg pharmacists in secondary care, acute care, clinics for lithium and anticoagulants);
- ❖ dieticians, chiropodists and podiatrists, physiotherapists, occupational therapists, optometrists, ambulance paramedics, radiographers.

Many respondents emphasised the need for prescribing to be related to core clinical competencies and for additional, nationally accredited training in prescribing issues, including pharmacology, monitoring and review, prescribing systems, and appraisal skills.

Responses to sub-group D suggested that in some clinical situations in the mental health field, particularly those relating to compulsory treatment, it might not be desirable for non-medical members of the multiprofessional team to prescribe because of the potential effect on relationships with the patient.

*Q6 Is it in principle acceptable for **continuation of prescribing** (with or without subsequent adjustment of the details of treatment) to be carried out by a different professional from the original prescriber? How far in practice would this differ from current experiments in repeat dispensing (see Q11)? What are the implications for professional roles, responsibilities and accountability?*

Generally, respondents agreed that continuation prescribing could be safely carried out by a second professional, subject to safeguards such as:

- ❖ adjusting medication within agreed protocols;
- ❖ access to full records of the reason for the original prescribing decision;

- ❖ occasional full review by the original prescriber.

Some respondents felt that continuation prescribing of this kind could lead to an *improvement* in medicines management as compared to the actual practice of repeat prescribing in many busy GP practices. A few respondents, however, felt that repeat prescribing should wherever possible be carried out by the original prescriber.

*Q7 Are there any circumstances in which the professional status of the prescriber could influence the patient's readiness*

- a. to seek **clinical advice**,*
- b. to accept that advice as **authoritative**?*

*What are the implications for this review?*

Many respondents did not have strong views on this question, but a number commented that at present prescribing advice from doctors was more likely to be regarded as authoritative, though patients might be more ready to explain their health concerns to other professionals who were perceived as having more time available. Any extension of prescribing to other professionals would need to be supported by public information in order to establish their authority in the public's eyes.

There are again special factors in the mental health field - see answer to Q5.

*Q8 Is there any danger that an extension of the role of other health professionals in prescribing could lead to fragmentation of patient care? What could be done to ensure that the GP or other responsible doctor is still able to maintain an overview of the care of the patient?*

The dominant view that this was a potential problem but could be overcome by some or all of:

- ❖ continued overview of patients by a lead professional (usually but not always identified as the GP);
- ❖ better communication within the team, using IT solutions and/or patient-held records;
- ❖ use of district-wide protocols so that (eg) district nurses were not expected to operate to different clinical standards in different practices.

A few respondents thought that there was already considerable fragmentation, and that extended roles for other professionals might positively help. Respondents in the mental health area thought that communications between professionals in primary and secondary care could also be problematic, and saw the single patient record as the key to overcoming it.

**(ii) Supply of medicines**

*Q9 It is usual practice for one professional (eg a doctor or dentist) to write a prescription, and for another (eg a pharmacist) to supply it or administer it (eg a nurse). How important is this traditional separation of roles, eg in relation to patient safety? With reference to specific examples, how far does this derive from*

- a. the complementary skills of the two professionals concerned,*
- b. the wish to improve safety in the administration of medicines (eg double checking of the prescribed dosage)?*

There was strong support on safety grounds for the traditional separation of functions, with almost equal numbers referring to the complementary skills of the two professions and to the need for double checking. Some respondents mentioned probity as an added reason for the separation. Only a few respondents felt that separation of functions was unnecessary or ineffective, or that it was not always practicable.

*Q10 Under what circumstances might it be (i) desirable, or (ii) essential for the patient to be given a (possibly small) supply of the medicine prescribed at or immediately following the consultation (eg where there is a need for early treatment or for patient convenience)? What are the implications for professional roles and responsibilities?*

The general view was that there were a limited range of circumstances in primary care in which the initial prescriber (doctor or nurse) might need to give a small initial supply so that treatment could start without delay. Examples given included:

- ❖ emergency contraception;
- ❖ soft tissue and other minor injuries;
- ❖ infectious outbreaks;
- ❖ pain relief;
- ❖ asthma therapy including nebulisers;
- ❖ psychiatric treatment when the patient was hesitant about starting treatment.

Respondents agreed that safety, not patient convenience, should be the overriding consideration. Some respondents mentioned the need for clear local protocols on what medicines should be supplied and how, and for suitable supplies of “starter packs” purchased by the HA (on the Scottish model) rather than supplied for promotional reasons by the manufacturer.

A minority felt that any extension of emergency supply by the original prescriber should be resisted, and that it would be better to seek to improve access to out-of-hours pharmacy services.

Some respondents mentioned the particular problems of supply and/or administration of emergency medicine at institutions like schools or residential homes.

*Q11 Would you wish to see a wider use of **repeat dispensing** (ie multiple dispensing under the professional oversight of a pharmacist following an assessment and prescription by a doctor)?*

The majority view was that wider use of repeat dispensing by pharmacists (or repeat supply by nurses) would be convenient to patients and result in fewer medication errors and less waste, provided that:

- ❖ the process was supported by good IT links, and/or patients registered with a single pharmacist;
- ❖ there were regular reviews by the original prescriber.

Areas where this model might be useful included:

- ❖ use of strong analgesics;
- ❖ chronic conditions;
- ❖ community nurse supply of dressing packs, catheters and enemas;
- ❖ dispensing in residential or nursing homes;
- ❖ dispensing to patients at risk of overdosing themselves.

A minority were not in favour, arguing that repeat dispensing could increase the risk of wastage or polypharmacy, or that GPs needed to have control since they were responsible for their drug budgets.

Some respondents, while generally sympathetic, suggested that repeat *prescribing* by pharmacists under agreed protocol might be a better model; others felt that remuneration for pharmacists would need to be reviewed to avoid incentives to abuse.

*(iii) Supply or administration of medicines under protocol*

*Q12 Are there any circumstances in which supply or administration of medicines under **group** protocols (ie non-patient specific) could be clinically justified?*

Analysing the response to this question was made more difficult because some respondents did not appear to distinguish clearly between limited *prescribing* and *supply/administration under group protocol*. However, the dominant view was that supply/administration under group protocol could be a useful and acceptable model in certain limited circumstances, generally:

- i when treatment needed to be initiated very quickly, eg
  - ❖ pain relief (eg administration of pethidine by midwives);
  - ❖ acute asthma attacks (eg administration of salbutamol by paramedics);
  - ❖ in intensive care;
  - ❖ in A&E, eg treatment for injury, shock or anaphylaxis;

or

- ii when prescribing for individual patients was unwieldy or impracticable (or could reduce effective access), eg
  - ❖ oral contraception;
  - ❖ immunisation and vaccination;
  - ❖ travel vaccines;
  - ❖ treatment of headlice;
  - ❖ healthcare for homeless people;
  - ❖ dressings, catheters, enemas;
  - ❖ care in nursing or residential homes.

Advocates of the use of group protocols stressed the need for those working within them to have appropriate training, in particular to be able to recognise when to refer for help in circumstances outside the scope of the protocol.

A number of respondents were not convinced that group protocols were clinically safe or necessary. Some felt that, in primary care settings, prescribing (possibly “dependent prescribing” as defined in our main report) was a better model than supply under group protocol.

*Q13 How precise do the doctors' and dentists' instructions need to be, eg on*

- (i) clinical assessment of individuals?*
- (ii) contra-indications and interactions?*
- (iii) doses?*
- (iv) referral for further opinion?*
- (v) discharge procedures?*

The majority view was that protocols should be very specific and clear. A minority felt that the protocol should leave some room to the clinical judgement of the health professional concerned. Some respondents pointed out that pharmacists already manage discharge medication prescribing in many hospitals.

*Q14 What (a) understanding of principles of clinical assessment, (b) other core competencies, (c) special training should professionals have before they can accept responsibility for the supply and administration of medicines? Does administration under group protocols raise any fundamentally new issues of clinical responsibility?*

Respondents agreed that training course would need to be agreed and accredited nationally. Core elements would include:

- ❖ clinical examination and assessment;
- ❖ pharmacology;
- ❖ prescribing and therapeutics;
- ❖ evaluation and review;
- ❖ legislation.

Some respondents suggested that training should be interdisciplinary, to promote team-working.

## Annex H: Related Issues for Consideration by Other Groups

Among the helpful comments received in response to the consultation undertaken by the Review Team, a number raised issues which are broadly related to the prescribing, supply and administration of medicines but which fell outside the Review's terms of reference. A number of these seemed to the Team to be particularly significant. These are listed below and **are commended to the relevant parts of government for further consideration.**

### **Issues for the Health Departments**

- i Continuing Professional Development should as far as possible be multidisciplinary, and fragmented funding arrangements which inhibit this should be reviewed.
- ii The processes for determining which new medicines, dressing and appliances are prescribable on the NHS should be reviewed to make them more consistent, responsive and transparent. Arrangements for introduction of new treatments should take account of evidence on cost-effectiveness as well as the traditional criteria of safety, efficacy and quality.
- iii Remuneration for pharmacists and dispensing doctors should be reviewed in order to remove anomalies and perverse incentives.
- iv Health Departments should review the arrangements in the private sector for routine monitoring of prescribing data and clinical audit of prescribing practice, and should consider what further safeguards may be needed to ensure the safety of patients.

### **Issue for the Health Departments and the Home Office**

- v The Care Programme Approach (see Glossary) should be introduced into non-NHS establishments, including prisons, and should be further promoted throughout all aspects of mental health care.

### **Issues for the Health Departments, the Home Office and the Department for Education and Employment**

- vi Arrangements for the administration of medicines by staff other than qualified health professionals, for instance in non-NHS establishments such as schools, prisons, or Local Authority residential homes, should be reviewed.

**Issues for the Home Office**

- vii Arrangements for the immediate supply of medicines in prisons should be reviewed.
- viii Arrangements for the transfer of clinical information (including medicines regimes) when individuals are transferred between prison medical services and other care agencies should be improved.